

# High Intensity Focused Ultrasound (8D HIFU)

## User Manual

### FG 660D+



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# Chapter 1 Installation

## I. Installation Conditions

### Specification:

Input voltage range: 95-120VAC, 220-250VAC

Rated current: 1.8A

Rated power: 400VA

Cartridge: standard is 2 for each handle (the others are for option)

Temperature: 18-35°C

Storage temperature: 0-40°C

Noise level: 45dB

Electric shock protection: I Class, BF Type

Anti-corrosive liquid: Normal

## II. Installation & Notes

### 1. Packaging



## 2. Accessory



Handles



Power Plug



USB Key



Pedal

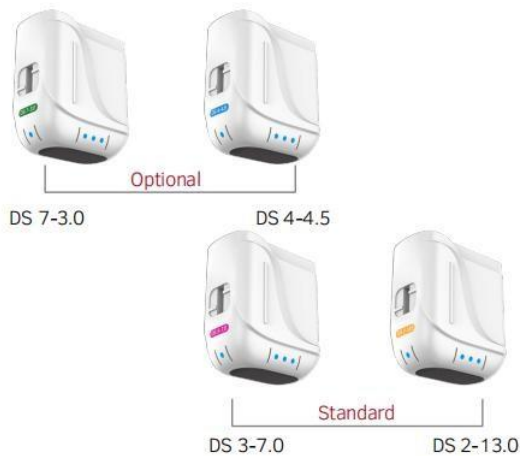
### For facial treatment



### For body slimming



One line handle 4.5mm cartridge & 3.0mm cartridge are standard, the others are optional



Multi-lines handle 7mm cartridge & 13mm cartridge are standard, the others are optional

### 3. Machine



- ① USB entrance
- ② Start button

- ③ Emergency button
- ④ Handle connectors

- ⑤ Power plug

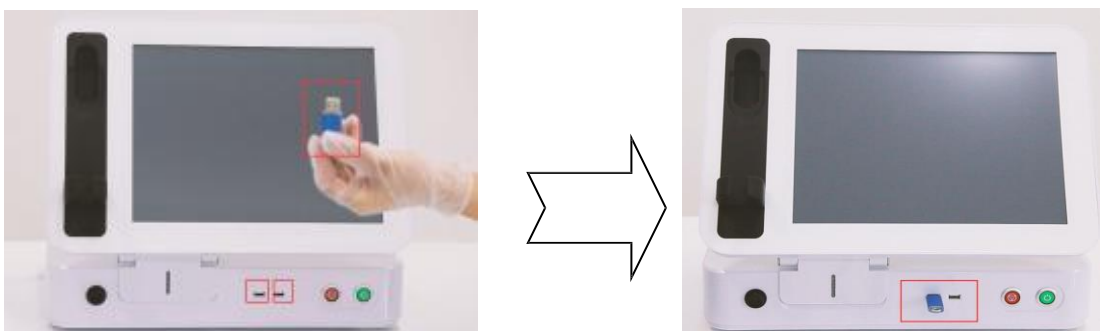
### 4. Installation

Please place the machine on level ground, make sure a clean room environment is about 22~28°C and humidity more than 20%.

#### 1) Connect the handles



#### 2) Insert the USB KEY (two ports are all available)

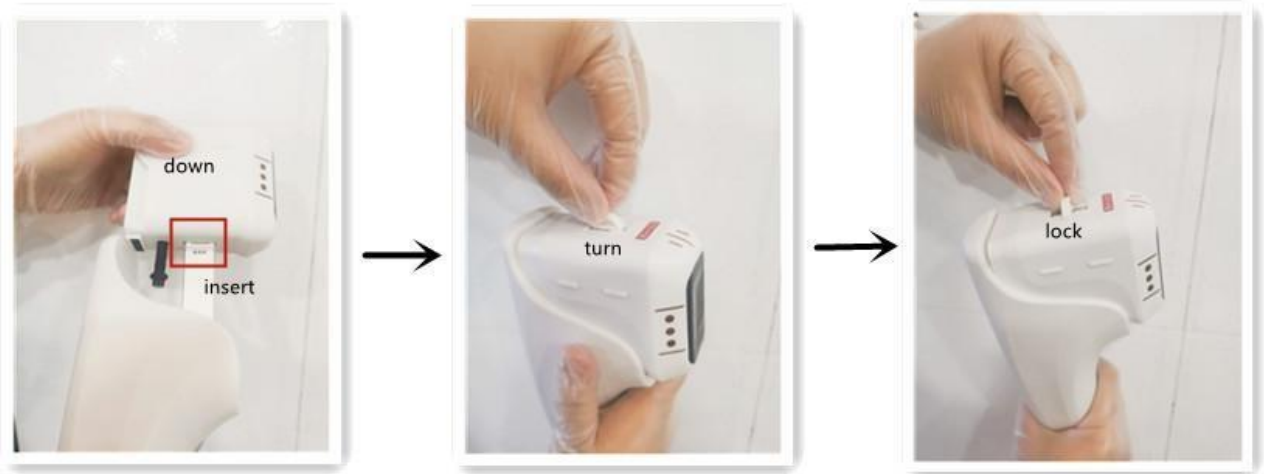


### 3) Assemble the Cartridges

\* One line handle cartridge assemble



\* Multi lines handle cartridge assemble



Instructions:

1 line handle cartridge assemble

- 1) Connect the metal green end to the handle as the picture shows.
- 2) Follow the track to insert the cartridge.
- 3) Push into end until it reaches the buckle. Make sure the buckle lock the cartridge as well.

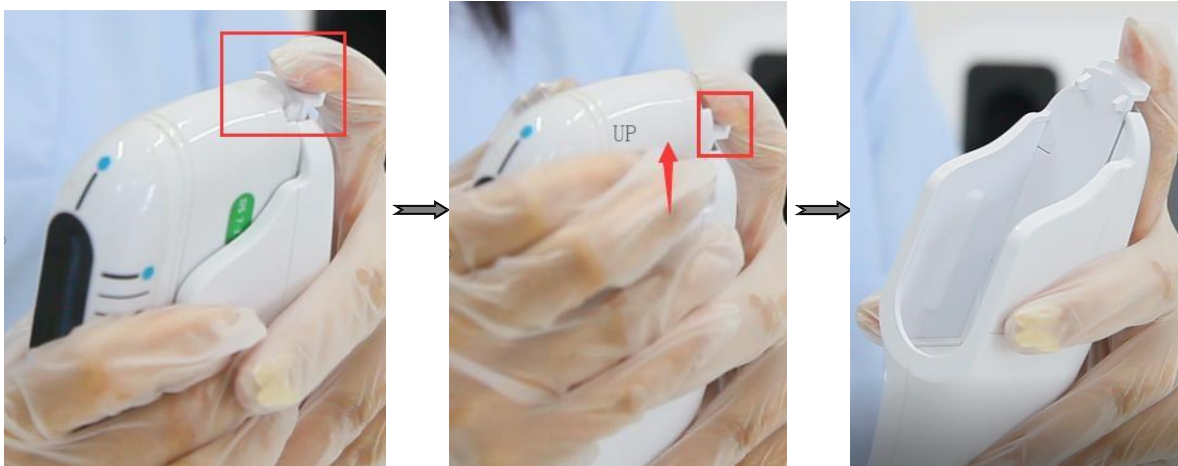
Multi lines handle cartridge assemble

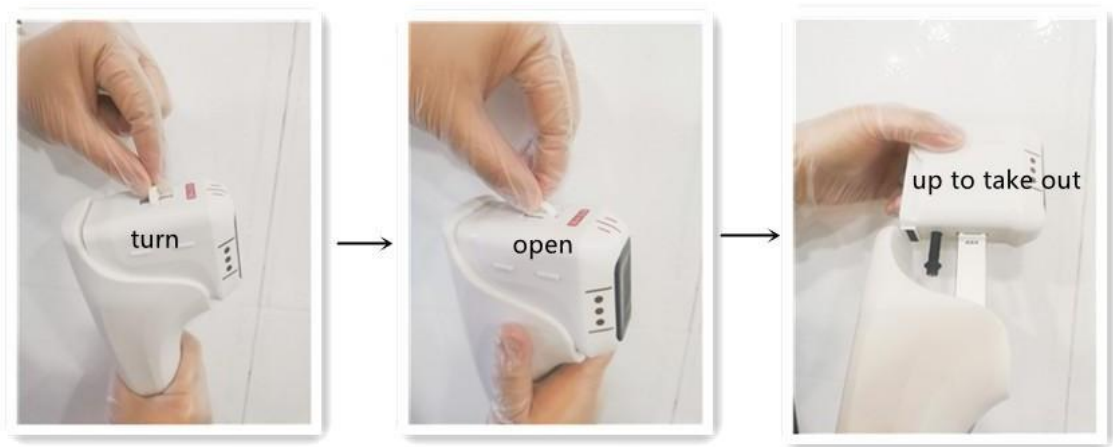
- 1) Insert handle connector into cartridge.
- 2) Put the cartridge into socket.
- 3) Lock the cartridge as picture shows.

**Attentions:**

**Please assemble the cartridge before turning on the machine!**

4) Remove cartridges





Instructions:

Take out 1 line handle cartridge

Lift the buckle with one finger gently (no need very strong strength, or it may be broken) with one hand, another hand pulls out the cartridge. This can be allowed when machine is turned off only. Otherwise the cartridge may be burned.

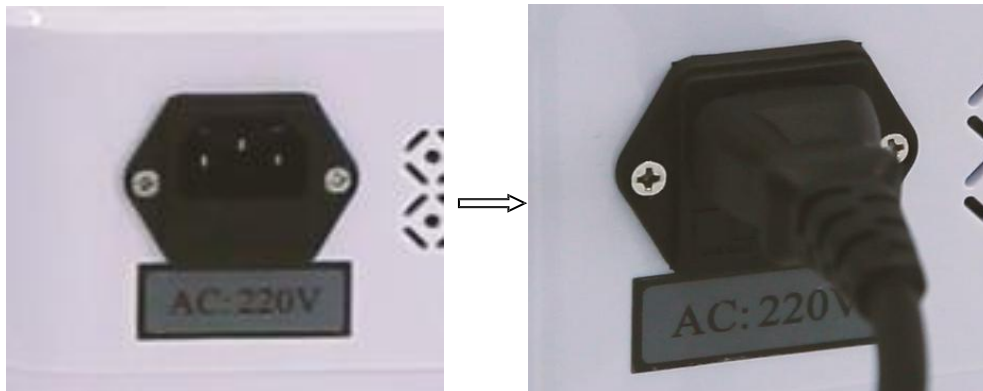
Take out multi lines handle cartridge

Turn to unlock the cartridges, lift then take out.

**Attention:**

**This can only be done when machine is turned off. Otherwise the cartridge may be**

5) Insert the power plug (On the back of machine)



The HIFU system can be used in hospital or beauty salon.

Attentions for Installation:

- ◆ Open package, place machine on flat ground.
- ◆ Check up machine and accessories, make sure no damage, no loss.
- ◆ Make sure good condition of power supply, including the ground wire.
- ◆ The cartridge should connect very well, and all the wires.
- ◆ Note: input voltage must be consistent with the machine voltage.
- ◆ Function test.

# Chapter 2 Operation

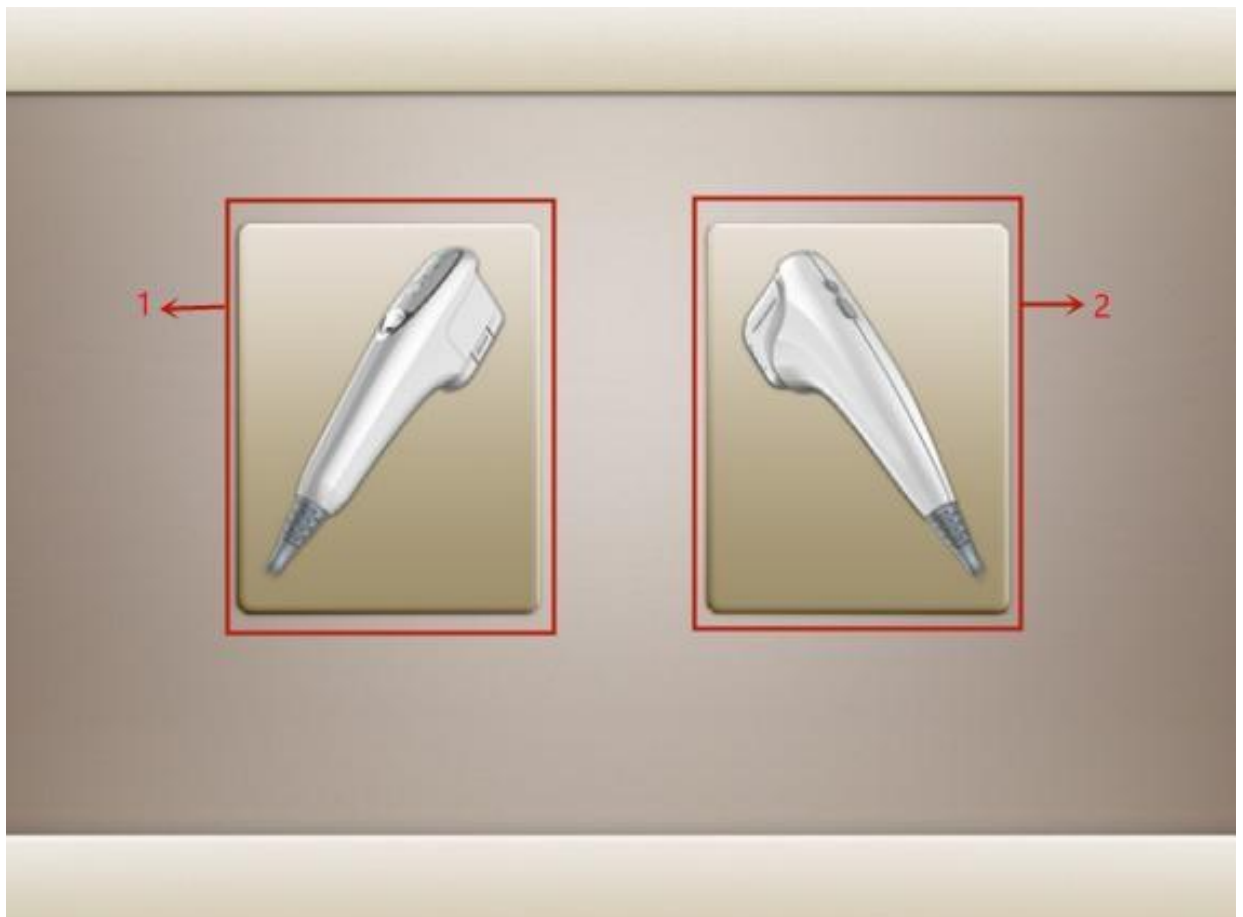
## I. Prepared Materials

Test Board, Cartridge, Cooling Gel, Pencil, Wet Papers, Paper Towels, Gloves.

## II. Open the machine

1. Turn on machine and enter operation interface

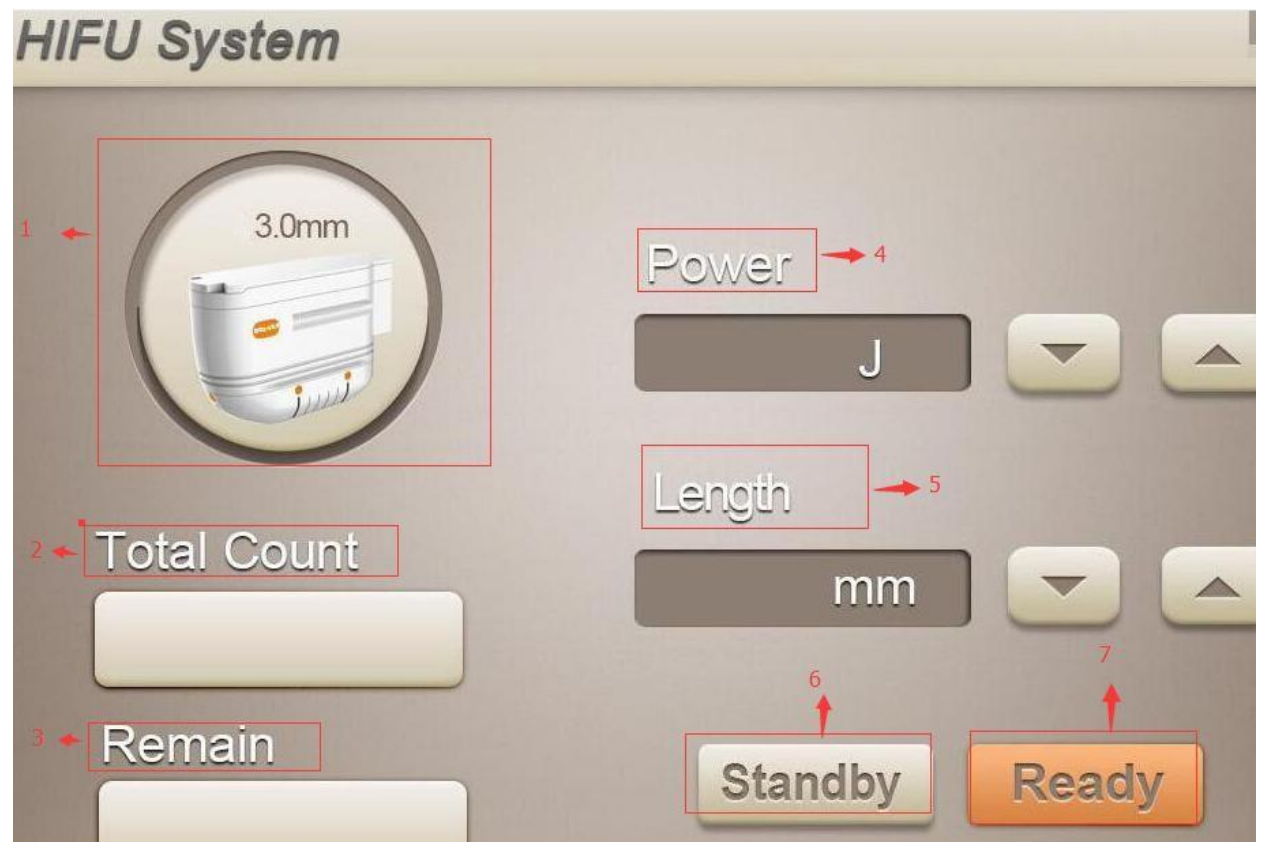
2. System choosing Interface



1) Press to choose one line system

2) Press to choose multi lines system

### 3. One line system Parameter Settings Interface



1) Cartridge: If the machine fails to read the cartridge, this symbol reminds you to load the cartridge.

2) Total Count: 10000 shots. Each cartridge has maximum 10,000 shots.

3) Remain: The remaining shots of the cartridge.

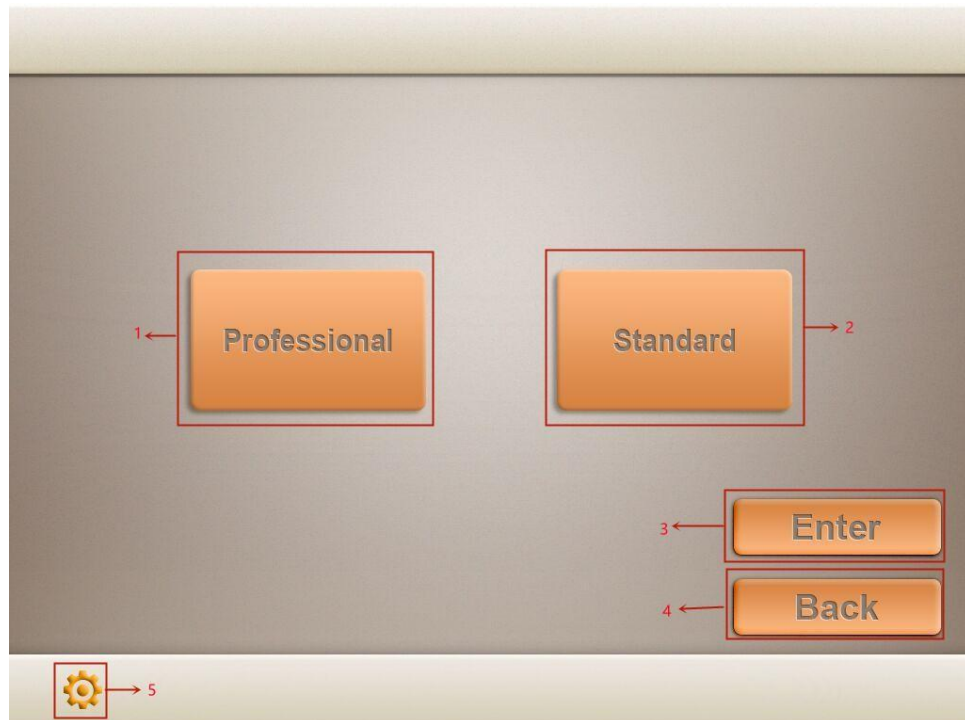
4) Power: Energy adjustment, the energy can be adjusted by up and down keys. ( Range 0.1-2.0 J, step by 0.1 J ). Recommendation for cartridge 3.0mm is 0.2 j - 0.6 j, cartridge 4.5mm is 0.1 j - 0.8 j.

5) Length: The length of line, length can be adjusted by the up and down keys. ( Range 5.0-25.0 mm, step by 1 mm). Recommendation: don't change it. Make it fixed at 25mm.

6) Standby: Click to enter standby status. If you don't operate for long time, please click standby.

7) Ready: Click to enter the ready status, parameters setting can't be changed under ready mode.

#### 4. Multi lines system parameter setting interface



- 1) Professional working mode
- 2) Standard working mode
- 3) Enter selected working mode
- 4) Back to last page
- 5) Setting: after insert password, can choose language and logo on or off.



## Professional working mode



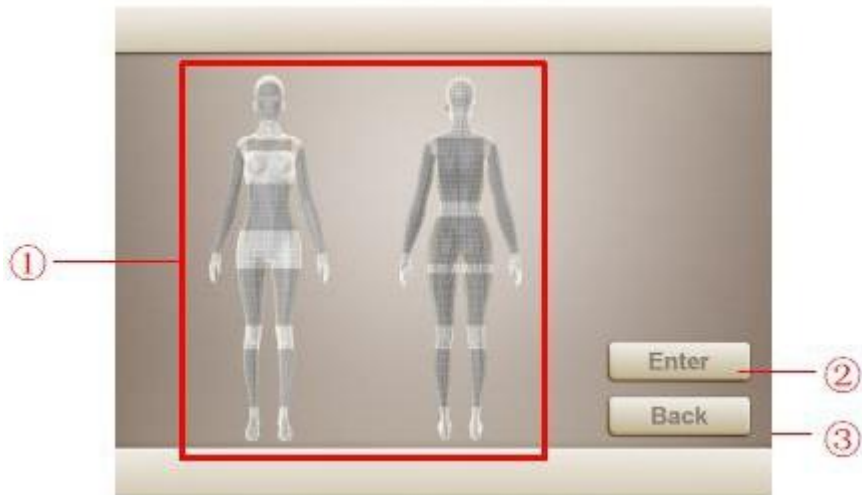
- ① Cartridge: If the machine fails to read the cartridge, this symbol reminds you to load the cartridge.
- ② Multi lines treatment area setting: Here shows multi lines treatment area length and distance between each dot setting: **Width** shows treatment area width, range: 1-12mm, step 1mm; **Dot pitch** shows distance between each dot in horizontal, range: 1.0-2.0mm, step 0.1mm; **Length** shows treatment area length, range: 8-25mm, step 1mm; **Row pitch** shows treatment area distance between each dot in row, range: 1.0-2.5mm, step 0.1mm (when energy >0.8J, row pitch minimize 2.0mm). All data adjustment by up and down arrows according to treatment situation. During treatment, the dots will changed to red color after shots, and pause must after one line shots finished.
- ③ Total Count: 10000 shots. Each cartridge has maximum 10,000 shots.
- ④ Remain: The remaining shots of the cartridge.
- ⑤ Single count, counting for one treatment.
- ⑥ Energy adjustment buttons, range 0.1-2.0J, one step 0.1J.
- ⑦ Save: press to save parameters, can save 6 sets data.
- ⑧ Save 6 sets of data, no need reset parameters, convenient to use.
- ⑨ Standby: Click to enter standby status. If you don't operate for long time, please click standby.

⑩ Ready: Click to enter the ready status, parameters setting can't be changed under ready mode.

④ Return: Back to last page.

\* We can switch ready and standby with handle button too.

### Standard working mode



① Treatment area chosen: here can shows chosen treatment area, press to choose.

② Enter chosen area treatment system.

③ Back: back to laser page.

Press “Enter” into treatment system:



(1) Cartridge: If the machine fails to read the cartridge, this symbol reminds you to

load the cartridge.

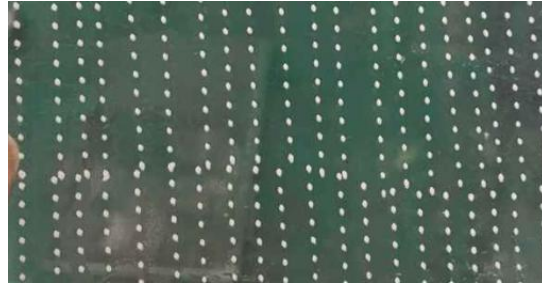
- (2) Multi lines treatment area setting: Here shows multi lines treatment area length and distance between each dot setting: **Width** shows treatment area width, range: 1-12mm, step 1mm; **Dot pitch** shows distance between each dot in horizontal, range: 1.0-2.0mm, step 0.1mm; **Length** shows treatment area length, range: 8-25mm, step 1mm; **Row pitch** shows treatment area distance between each dot in row, range: 1.0-2.5mm, step 0.1mm (when energy >0.8J, row pitch minimize 2.0mm). All data adjustment by up and down arrows according to treatment situation. During treatment, the dots will changed to red color after shots, and pause must after one line shots finished.
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- (6) Energy adjustment buttons, range 0.1-2.0J, one step 0.1J.
- (7) Save: press to save parameters, can save 6 sets data.
- (8) Standby: Click to enter standby status. If you don't operate for long time, please click standby.
- (9) Ready: Click to enter the ready status, parameters setting can't be changed under ready mode.
- (10) Back: Back to last page.

*\* We can switch ready and standby with handle button too.*

### **III. Operation procedure**

1. Take pictures before treatment ( front, left 45 degree, left, right 45 degree, right).
2. Clean the application part and dry the water-drop before operation.
3. Draw line.
4. Apply 3mm cooling gel on plastic board (there are 2 plastic board with machine, one 4.5mm thickness for 4.5mm cartridge, other 3mm thickness for 3.0mm

cartridge), making shots on plastic board to check energy. The shots should be same size, same distance and in straight line as below.



5. Setting parameters, replace the treating head needed before operating, and the power should be optimally within client's feelings range from low to high.

6. Apply about 3mm cooling gel evenly on the treatment area.

7. Place probe vertically on skin and start treatment. Keep the treating head flattening the skin during operation and the operating distance should be tight. Inquiry the client for comfort degree and adjust the power during operation so as to keep client delighted during the operation.

8. A whole face & neck needs about 500-800 lines to finish, interval distance of each is around 2-3mm.

## IV. Face & Neck Pre-treatment and Treatment

### 1. Face & Neck Pre-treatment

We need to draw white lines to divide the treatment area, steps as follows.

1) Draw the first 3 lines.

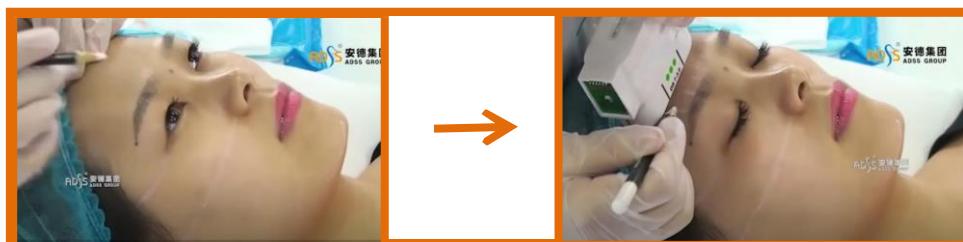
1<sup>st</sup> line: From the middle chin along the contour to the ear. Touch the bone there, the line should be above the bone.

2<sup>nd</sup> line: From the alae of the nose to the middle of ear.

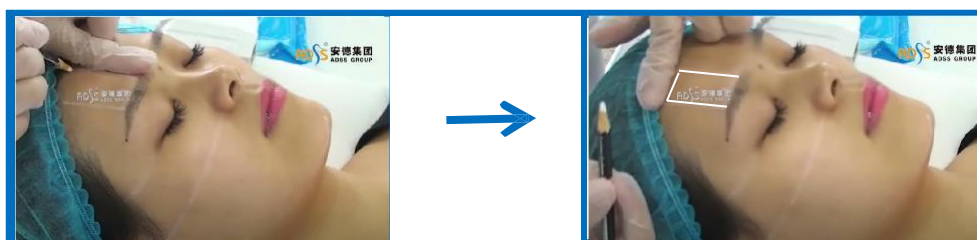
3<sup>rd</sup> line: From the canthus to the hairlines. Do as the photo shows.



2) Fourth line: please let the client open the eyes, focused on the pupil of eyes, operator click a point above the eyebrows. Centered on the origin point, measure this area into 3 parts.



Draw vertical lines to the hairline. These lines are parallel. Leave one finger width from the hairline. The forehead is operated only in the lined part.



3) Leave one finger width from the mouth corner and draw line, use cartridge to measure the width, mark 3 points on jawline and the 2<sup>nd</sup> line ( Step 1 ), connect the corresponding points, as the photo shows.



4) Confirm the position of the eyelid bone and draw a line under the bone. Mark the points on this line and the 2<sup>nd</sup> line ( Step 1 ), then connect them.



5) Touch the Adam's Apple. Leave one finger width above it and draw a line. Then centered on the middle part of chin, measure by the cartridge, draw 2 lines, totally 5 lines for the neck.



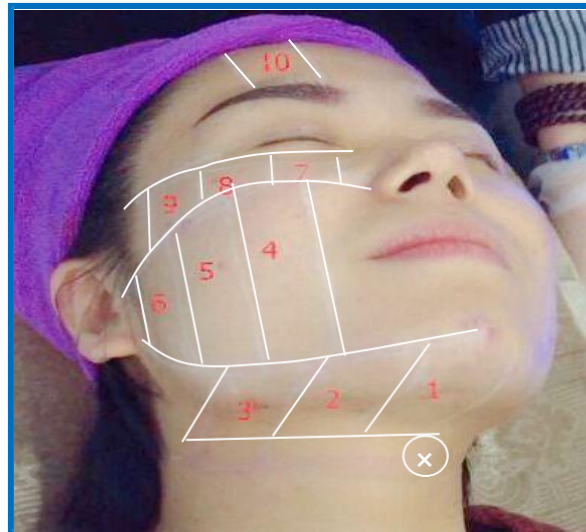
Draw line above Adam's Apple

Measure by cartridge

Totally 5 lines for the neck

## 2. Face & Neck treatment

We suggest you use both Cartridges (4.5mm & 3.0mm) do the treatment separately, do left part and right part separately.



1) Firstly, use 4.5mm cartridge make lines on 1-6 areas once.



Apply gel                                      10-20 shorts for 1-2-3 per area                                      30-40 shorts for 4-5-6 per area

**【Warm Tips】**

- Thickness of gel is same as a coin.
- Use 4.5mm cartridge, energy adjust form 0.2J-0.8J, from low to high level according to client's feeling.
- After one shooting, slide up for 1mm and press Start again.
- In treatment area, slide form bottom to top for operation.
- If gel is unevenly, stop and apply the gel again.

2) Secondly, use 3.0mm cartridge make lines on whole treatment areas. The operation should avoid temples.



Change 3.0mm cartridge                                      10-15 shorts for 7-8-9 per area                                      5-10 shorts for area 10

**【Warm Tips】**

- Thickness of gel is same as a coin.
- Use 3.0mm cartridge, energy adjust form 0.1J-0.6J, from low to high level according to client's feeling.
- After one shooting, slide up for 1mm and press Start again.
- In treatment area, slide form bottom to top for operation.
- If gel is unevenly, stop and apply the gel again.
- After treatment, wipe the gel and clean right face. Take the After photo, the same way as the Before photo.
- Analysis the difference between right face and left face, the instant result after treatment is about 10%-12%. Make a plan for left face.
- Do the left face, the same way as the right face.
- The operation should avoid temples.

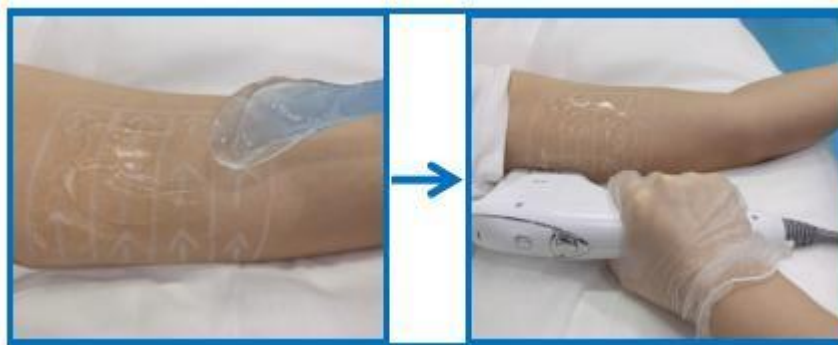
## V. Body Pre-treatment and Treatment

### 1. Arm Pre-treatment and Treatment

- 1) Mark the arm treatment area and measure by cartridge, connect the correspond points and mark the arrow as the operation way.



- 2) Apply gel evenly on the treatment area and do the treatment.



#### **【Warm Tips】**

- Thickness of gel is same as a coin.
- Use 7.0mm cartridge for twice. The first time, the energy 0.4J, adjust higher energy from low to high level according to client's feeling. The second time, the energy 0.6J, adjust higher energy from low to high level according to the client's feeling. Use the cartridge in horizontal way as the picture shows, from bottom to top. Do it step by step according to the marked arrow.
- After 7.0mm cartridge finished, use 4.5mm cartridge for twice. The first time, the energy 0.4J, from low to high level according to client's feeling. The second time, the energy 0.6J, adjust higher energy according to the client's feeling. Use the cartridge in horizontal way as the picture shows, from bottom to top. Do it step

by step according to the marked arrow.

## 2. Leg Pre-treatment and Treatment

- 1) Mark the arm treatment area and measure by cartridge, connect the correspond points and mark the arrow as the operation way.



- 2) Apply gel evenly on the treatment area and do the treatment.



### **【Warm Tips】**

- Thickness of gel is same as a coin.
- Use 13mm cartridge for twice. The first time, the energy 0.6J, adjust higher energy from low to high level according to the client's feeling. The second time, the energy 0.8J, adjust higher energy from low to high level according to client's feeling. Use the cartridge in horizontal way as the picture shows, from bottom to top. Do it step by step according to the marked arrow.
- Use 7.0mm cartridge for twice. The first time, the energy 0.6J, adjust higher energy from low to high level according to the client's feeling. The second time, the energy 0.8J, adjust higher energy from low to high level according to the client's feeling. Use the cartridge in horizontal way as the picture shows, from

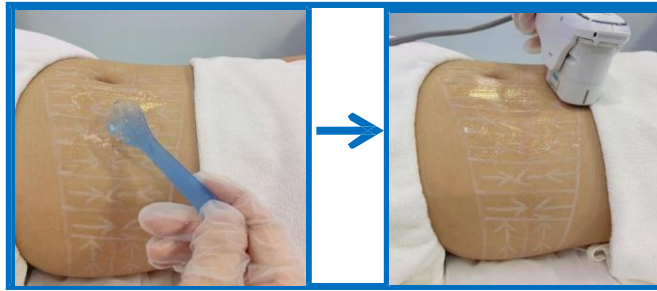
bottom to top. Do it step by step according to the marked arrow.

### 3. Belly Pre-treatment and Treatment

- 1) Mark the arm treatment area and measure by cartridge, connect the correspond points and mark the arrow as the operation way as follows. Avoid the belly button.



- 2) Apply gel evenly on the treatment area and do the treatment.



#### **【Warm Tips】**

- Thickness of gel is same as a coin.
- Use 13mm cartridge for twice. The first time, the energy 0.6J, adjust higher energy from low to high level according to the client's feeling. The second time, the energy 0.8J, adjust higher energy from low to high level according to client's feeling. Use the cartridge in horizontal way as the picture shows, from bottom to top. Do it step by step according to the marked arrow.
- Use 7.0mm cartridge for twice. The first time, the energy 0.6J, adjust higher energy from low to high level according to the client's feeling. The second time, the energy 0.8J, adjust higher energy from low to high level according to the client's feeling. Use the cartridge in horizontal way as the picture shows, from bottom to top. Do it step by step according to the marked arrow.

- The treatment should avoid the belly button.

## **VI. Recovery**

- Some minor redness may be present for an hour or so after treatment; however, there is no downtime and clients are able to immediately return to their normal routine. Other temporary side effects may include mild swelling, tingling or tenderness.
- After treatment, collagen refresh, need to hydrate skin, the clients can use moisturizing mask.
- Don't rub the treatment area within 7 days, avoid cold compresses and hot compresses, avoid high-heat exercises, such as hot springs and saunas.

## **VII. Sessions**

One session required, further treatments must be after 3 to 6 months accordingly. The obvious result is after one month and some patients report continued improvement for up to six months or even longer as new collagen forms.

## **VIII. Taboos**

This machine shall be used with enough caution in the following cases, suggestions from doctors or professionals are necessary prior to use, some details are listed as follows:

- 1) In the following situations, you should use this machine with caution, and you must consult a doctor or professional before using it. Some details are listed below:
- 2) When using this equipment, keep the probe away from the eyes and prohibit it from passing through the eyeball;
- 3) Pregnant women and patients with severe heart disease;
- 4) Patients with malignant tumors, hemophilia or severe bleeding;
- 5) Patients with the severe disease, skin disease or infectious disease shall be cautious enough;
- 6) Be enough cautious when the treatment area is near the heart, forehead, neck

nerve centre, spine;

7) Patients with the hyperthyroidism, asthma and hypertension;

8) HIFU treatment is not allowed within 15 days after injection of hyaluronic acid;

9) Please do not wash your face with hot water and don't massage in one week, please apply mask every day during the first week, please pay attention to sun protection, please don't accept other treatment in the same area within one month, such as RF /Vacuum / ultrasound / mechanical roller etc.

## HIFU maintenance card

**Equipment name: HIFU**

**Equipment maintenance:**

1. Must use the plug with a ground wire.
2. Clean the machine with a damp cotton cloth (no alcohol product).
3. After using the machine, it is best to cover it with dust-free cloth.
4. The cartridge must be handled with care, not scratching.
5. The machine can not be exposed.
6. Place the machine in a clean room, temperature is about 22-28°C and humidity is more than 20%.
7. The regulator should be equipped with standard voltage under normal use.
8. Prohibit the handle shooting energy upward in the process of installation and treatment.
9. Carefully protect the cartridge and prevent falling on the ground, otherwise it will cause leakage.
10. Unload handle when moving to prevent the handle line is damaged.
11. When the cartridge has less ultrasonic superconductor fluid, the test plate does not have a complete energy output when testing, the machine cannot continue to operate. The plate test energy: 0.6-0.8J.
12. The handle wire cannot be twisted, bent, folded when in use.
13. The USB key must be properly stored, if it is lost, the equipment cannot be used.
14. Turn off the machine when replacing the cartridge.
15. In Winter, the equipment needs to be moved into the room for three hours before using.
16. Except professional operators, it is forbidden to use by others.
17. Only under the guidance of professionals, the machine can be disassembled and checked internal.
18. If there is any change without notice, the final interpretation right belongs to the company.

## HIFU operation consent form

User name: \_\_\_\_\_ ID card: \_\_\_\_\_

After treatment with HIFU, there are following things to note:

1. After the treatment with HIFU, the treatment area may show redness and swelling. These are normal reactions after operation. They are only temporary and generally disappear within 48 hours.
2. If there is a grand occasion soon after, guests should decide whether to accept the HIFU treatment.
3. Don't rub the treatment area within 7 days. When swelling and redness fade, avoid cold compresses and hot compresses, avoid high-heat exercises, such as hot springs and saunas.
4. Alcohol should be avoided within 48 hours, as alcohol can dilate blood vessels and increase swelling.
5. Regular drinking ( 6-8 cups of water per day is recommended ).
6. Apply a daily moisturizer mask within 10–14 days after treatment. Do not use Glycolic Acid or AHA peels or other irritating masks or do laser treatment.
7. If you are taking aspirin or other similar drugs, these drugs may increase the bruising on the treated area.
8. After the HIFU treatment is finished, it is forbidden to eat spicy or stimulating food ( such as mutton, pork, fish, shrimps, etc). Use warm water to wash your face. If you need to apply a mask, warm the mask in warm water and apply it.

Understand that following things:

1. I understand the course of treatment and understand that everyone has different reaction to treatment.
2. I understand that I cannot rub the treatment area within 7 days after treatment.
3. If I have any treatment records and changes must be detailed to the doctor.
4. I have read the above related documents carefully and have raised relevant questions.
5. I hereby agree and are willing to accept the HIFU treatment.

The clinician has explained to me in detail and answered my questions. I am aware that the effect of the treatment depends on the treatment area, skin type and personal lifestyle, and will follow the instructions of the clinician for nursing after treatment and return visits on time.

Patient: \_\_\_\_\_ Clinician: \_\_\_\_\_ Observer: \_\_\_\_\_

Date: \_\_\_\_\_ Date: \_\_\_\_\_ Date: \_\_\_\_\_