Reform Your Youth





2020.05.07

Micro and Macro Focused Ultrasound Non-surgical Lifting, Tightening & Contouring System

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TREATMENT

The following guidelines and precautions are intended for conducting proper procedural methods on the patient with the ULTRAFORMER III Main Body and System.

Refer to these instructions for safe and successful treatments with the ULTRAFORMER III.



Introduction

ULTRAFORMER III System



The ULTRAFORMER III is a completely non-invasive, face lifting and tightening, body tightening and contouring device that provides customized treatment procedures for the entire face, neck, and body. Utilizing HIFU technology with Micro and Macro Focused Cartridges, the ULTRAFORMER III focuses uniform ultrasound energy that induces thermal coagulation in the face and contractions in the body.

Precautions for Treatment

Contraindications

The ULTRAFORMER III is contraindicated for use in patients with:

- Pregnancy or when breastfeeding
- Open wounds or lesions on the treatment area
- Severe or cystic acne on the treatment area
- Metal stents/electrical implants in the treatment area
- Bio-absorbable mechanical implants
- Skin infections of any type
- Hemorrhagic disorders or dysfunctions

Preferred Patient Selection

Patients who comply with the following requirements are preferred for yielding greater results:

- Patients with a sufficient amount of stubborn fat cells in the treatment area
- No large scars or redundant skin folds in the treatment area
- Mild-to-moderate skin with soft tissue laxity
- Crepey and wrinkled skin
- Patients with lowered brow lines, sagging skin, fine lines, or wrinkles

Potential Side Effects

Patients receiving the ULTRAFORMER III may react to responses which are mild and temporary as follows:

- Edema (swelling)
- Erythema (redness)
- Tenderness
- Bruising
- Scarring
- Transient numbness or tingling

*The local doctor or practitioner should consult with the patient for any history of severe pain or mild discomfort undergoing topical, non-invasive treatments including the ULTRAFORMER III.

Precautions for Patient

Determine whether treatment is appropriate for patients with the following conditions:

- Anticoagulant therapy
- Skin conditions caused by autoimmune diseases, skin cancer, and Herpes Simplex
- Diabetes or epilepsy
- Severe skin diseases
- Decortication or heart disease
- Hypersensitiveness or hypertrophic scars
- Hemostatic dysfunctions

Precautions for Procedure

To avoid safety hazards from occurring during treatment with the ULTRAFORMER III:

- Do not use the ULTRAFORMER III without completion of training by an authorized CLASSYS representative.
- To prevent unauthorized use of the device, ensure access is limited strictly to trained and certified personnel only.
- To avoid possible injury during treatment, do not apply the ULTRAFORMER III hand-pieces near the patient's eyes.
- Avoid applying treatment on the thyroid gland, thyroid cartilage, and trachea.
- Avoid applying treatment directly on the breast tissue and major vessels.
- If any malfunctions or adverse events occur, immediately stop the treatment procedure.
- Always apply ultrasound gel on target areas before proceeding with the ULTRAFORMER III treatment.
- Before conducting shots, check that the Cartridge attached on the transducer is applied on the skin properly.

Precautions for Treatment

Precautions for System Safety

To ensure safety of the System and proper maintenance of the ULTRAFORMER III:

- To avoid risk of electric shock, always inspect the Cartridge, Hand-piece, and Cable before use.
- Do not use a Cable or Cartridge that has been damaged or is leaking fluid.
- Do not remove the covers of the ULTRAFORMER III Main Body or Hand-pieces as modification of this equipment is not allowed.
- The ULTRAFORMER III contains no user serviceable components. Contact a local distributor or CLASSYS representative if the System requires service.
- Do not lean over the equipment obliquely and do not give physical external shock to the equipment as it may cause permanent System damage.
- Do not use the equipment with anesthetic gases or flammable materials in the surrounding areas.
 - *For additional information, refer to the ULTRAFORMER III Maintenance Guide.

Patient Consultation

For accurate assessment and treatment plan of the patient:

- Check the patient's medical history.
- Check for past surgical procedures performed on the proposed treatment areas.
- Assess patient concerns on each individual facial and body preference.
- Consult with patients about their pain tolerance levels to determine if administration of pain medication is appropriate.
- Coordinate custom treatments with the patient.

Pain Management

For patients who report higher pain sensitivity levels, recommend the following during procedure:

- Local or topical anesthetics
- Oral pain medication
- Topical numbing cream
 - *No further pain medication is necessary following treatment.

Avoiding Nerves

Nerve areas to avoid during treatment:

- Navel
- Posterior superior iliac spine (PSIS)
- Pelvic nerves
- Ulnar nerves
- Sciatic nerves
- Marginal mandibular nerve
- Temporal facial nerves
- Supraorbital facial nerves

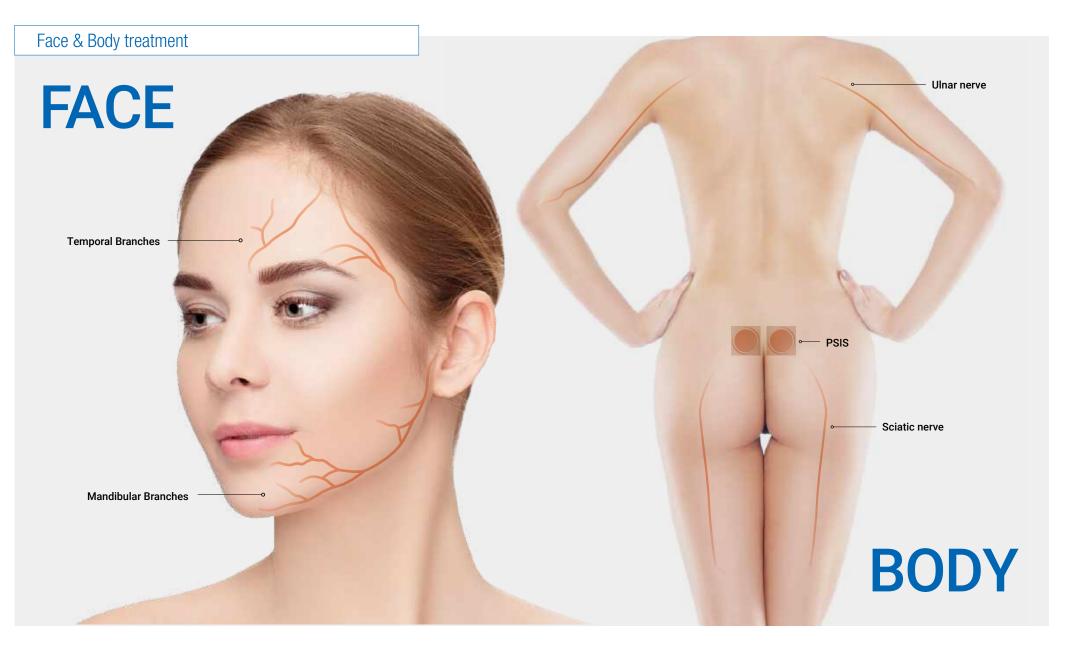
*If the patient experiences undue pain or tingling sensations in a specific target area, stop the procedure and proceed to the next treatment site.

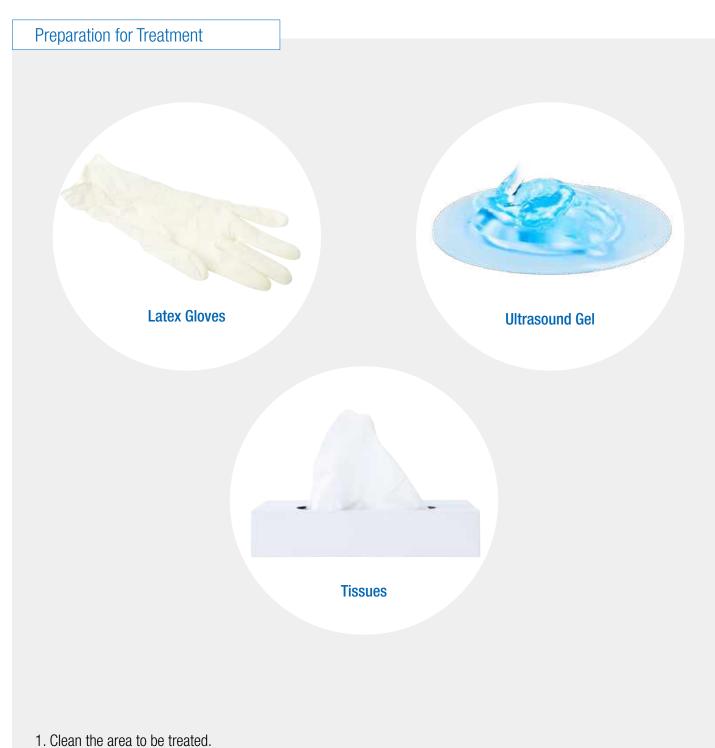
*Customize parameters based on the sensitivity and tolerance levels of the patient.



DO NOT apply shots without making proper contact between the Cartridge and skin.

DO NOT press the shot button of the Hand-piece without applying ultrasound gel onto treatment area.





- 2. Outline target areas according to the intended treatment plan.
- 3. Inspect the condition of the Cartridges.
- 4. Ensure to apply a sufficient amount of ultrasound gel on target areas before proceeding with treatment.

ULTRAFORMER III TREATMENT GUIDE

Treatment

Precautions for Face & Body Procedures

OPrecautions for Face & Décolleté Procedures

- Do not apply treatment on the bony areas and nerve regions.
- Do not apply treatment directly on the breast region, clavicle, supraorbital, temporal, or marginal mandibular nerves.
- When treating facial areas, apply treatment one side at a time before proceeding to the other.
- Do not apply shots on the same treatment site consecutively.
- Avoid applying treatment on specific points which may trigger tingling sensations in the patient.

OPrecautions for Body Procedures

- Do not apply treatment on the bony areas and nerve regions.
- Do not apply treatment directly on the navel, posterior superior iliac spine (PSIS), pelvic, ulnar, or sciatic nerves.
- When treating areas of the body, apply treatment one side at a time before proceeding to the other.
- Avoid applying treatment on specific points which may trigger tingling sensations in the patient.

- After applying a few shots check for skin reactions and the sensitivity level of the patient. Proceed to treat or reduce parameters depending on the tolerance level of the patient.
- Ensure to always apply an even distribution of shots onto the marked treatment area.
- When treating multiple layers, treat from deep to shallow in sequential order as follows:

Ex: 4.5mm ► 3.0mm ► 1.5mm

- After applying a few shots check for skin reactions and the sensitivity level of the patient. Proceed to treat or reduce parameters depending on the tolerance level of the patient.
- Ensure to always apply an even distribution of shots onto the marked treatment area.
- Patients must comply with standards of each Body Cartridge based on the pinch test and treatment area being targeted:

MF6: 6.0mm MF9: 9.0mm MF13: 13.0mm

*Take note that the '/' symbol in the parameters indicates shots for each side.

When treating with both Face and Body Cartridges on Repeat Shot Mode, ensure to always keep the Cartridge moving.
When treating with both Face and Body Cartridges on Single Shot Mode, ensure to keep the Cartridge stationary when applying shots.

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Treatment Steps for Face & Décolleté

1. Turning the System ON

Press the 'I' symbol on the AC Power Switch at the rear of the Main Body and proceed to turn the key clockwise to turn the System ON.

2. Selecting Cartridges

Select the Face Cartridge based on patient assessment and treatment area targeted:

L7-1.5: 1.5mm L7-3.0: 3.0mm L4-4.5: 4.5mm

MF2: 2.0mm cartridges are available with the Ultraformer (full version).

3. Inspecting the Cartridge

Always inspect the physical condition of the Cartridge and that there are no remaining residues of ultrasound gel or dust particles before proceeding with treatment.

4. Applying Ultrasound Gel

Apply a sufficient amount of ultrasound gel on the treatment area as a lubricating agent between the Hand-piece and skin during procedure. Ensure to always reapply a sufficient amount of gel when necessary.

5. Loading the Hand-piece Interface

Remove the Hand-piece from its Hand-piece Holder in which the Hand-piece Automatic Recognition function will load the Graphical User Interface (GUI) to its respective Hand-piece Interface.

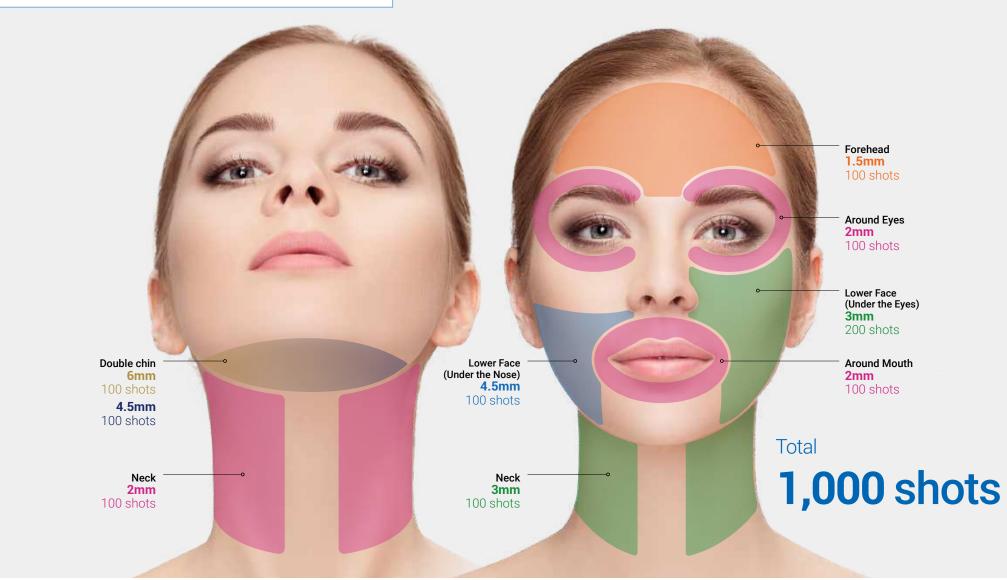
6. Setting Parameters and Preferences

Set the parameters and preferences on the Graphical User Interface (GUI) and press READY. The following settings are available to be customized:

- Energy Fluence
- Pitch
- Single/Repeat Shot Mode
- Alarm
- Timer
- Volume

*For additional information, refer to the ULTRAFORMER III Maintenance Guide.

Full face + Double chin + Neck Treatment



Treatment Steps for Body

1. Turning the System ON

Press the 'I' symbol on the AC Power Switch at the rear of the Main Body and proceed to turn the key clockwise to turn the System ON.

2. Selecting Cartridges and Hand-pieces

Patients must comply with standards of each Body Cartridge based on the pinch test and treatment area being targeted:

MF6: 6.0mm MF9: 9.0mm MF13: 13.0mm

3. Inspecting the Cartridge

Always inspect the physical condition of the Cartridge and that there are no remaining residues of ultrasound gel or dust particles before proceeding with treatment.

4. Applying Ultrasound Gel

Apply a sufficient amount of ultrasound gel on the treatment area as a lubricating agent between the Hand-piece and skin during procedure. Ensure to always reapply a sufficient amount of gel when necessary.

5. Loading the Hand-piece Interface

Remove the Hand-piece from its Hand-piece Holder in which the Hand-piece Automatic Recognition function will load the Graphical User Interface (GUI) to its respective Hand-piece Interface.

6. Setting Parameters and Preferences

Set the parameters and preferences on the Graphical User Interface (GUI) and press READY. The following settings are available to be customized:

- Energy Fluence
- Pitch
- Single/Repeat Shot Mode
- Alarms
- Timer
- Volume

*For additional information, refer to the ULTRAFORMER III Maintenance Guide.

7. Applying the Hand-piece

Apply the Hand-piece flat onto the treatment area and press the Shot Button to emit ultrasound energy.

*For additional details on avoiding bony areas and nerve regions when applying the ULTRAFORMER III Hand-piece during treatment, refer to specific precautions below each treatment section and 'Precautions for Body Procedures' of this Treatment Guide.

Single Shot Mode

- Single Shot Mode requires pressing the Shot Button for each shot to be applied.
- ▲ Ultrasound energy should not be applied on the same treatment site consecutively.

8. Pausing or Stopping Procedures

To pause or to stop use of the Body Cartridge, press STANDBY on the Graphical User Interface (GUI).

▲ When treating with the Body Cartridge on Single Shot Mode, ensure to keep the Cartridge stationary when applying shots.

Repeat Shot Mode

- Repeat Shot Mode requires holding down the Shot Button for continuous application.

8. Pausing or Stopping Procedures

To pause or to stop use of the Body Cartridge while on Repeat Shot Mode, release your finger from the Shot Button to stop continuous shot application and proceed to press STANDBY on the Graphical User Interface (GUI).

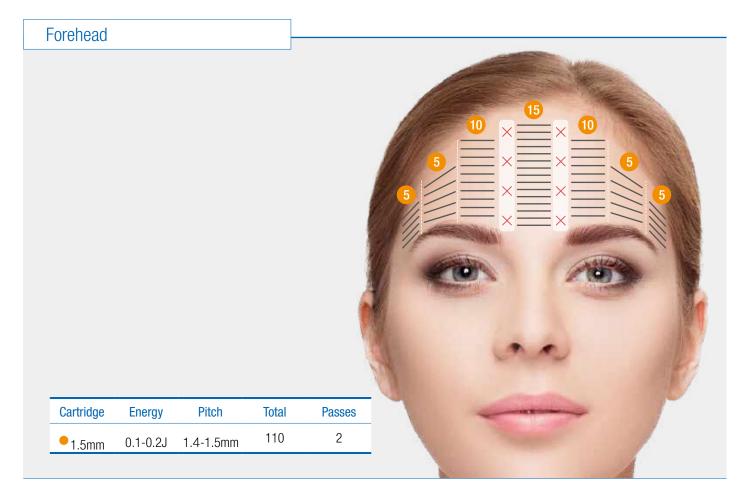
△ When treating with the Body Cartridge on Repeat Shot Mode, ensure to always keep the Cartridge constantly moving.

9. Cleaning the Cartridge and Hand-piece

Wipe the Cartridge with a standard 50-70% isopropyl alcohol prep pad before placing it into its Hand-piece Holder.

10. Cleaning the Treatment Area

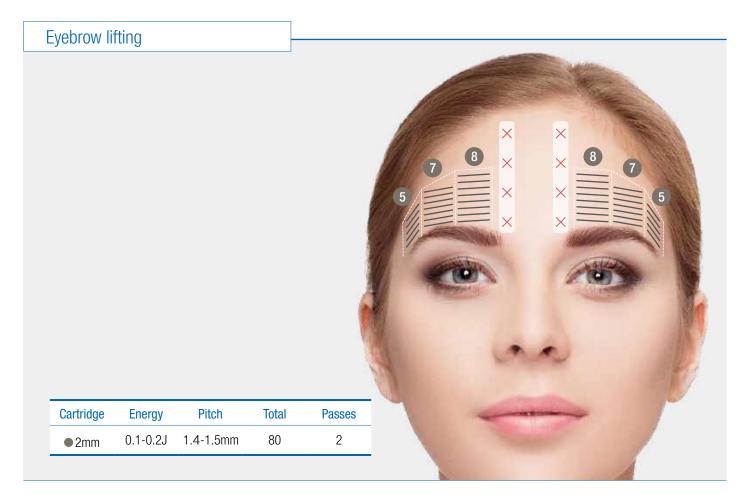
Wipe down the treatment area for any remaining ultrasound gel with wet tissues or cotton pads.





Before

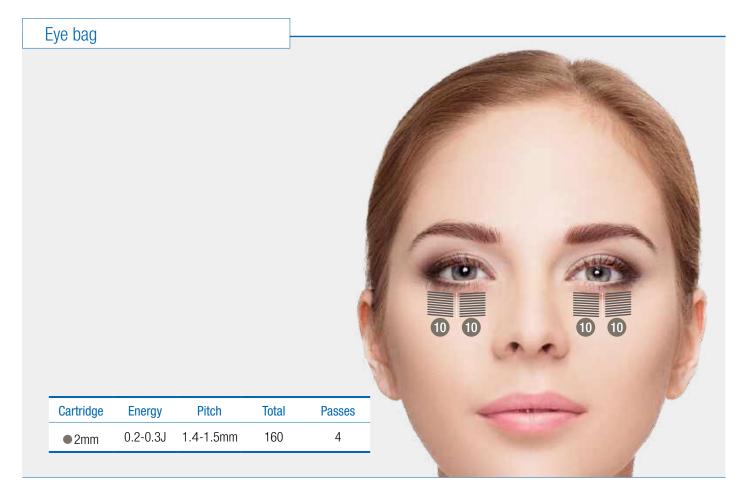
After





<u>ower eye</u>	lid wrinkl	es			
Cartridge	Energy	Pitch	Total	Passes	
	0.1-0.2J	1.4-1.5mm	200	4	







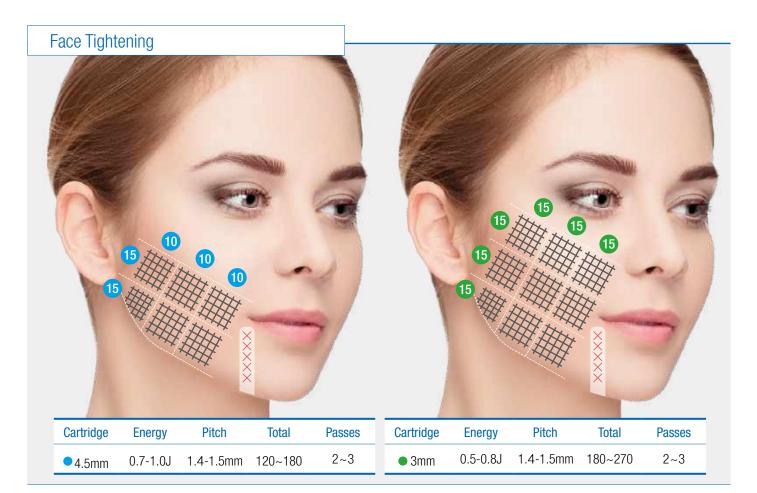
Before

After

Nasolabial fold









Before

After

Plumping & Tightening

For thin faces or compromised dermis





Before

After

Facial Volumising

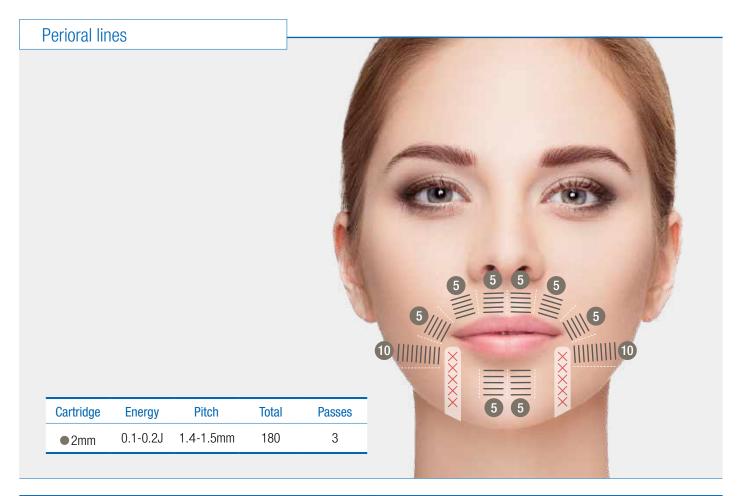
For patients with facial hollowing



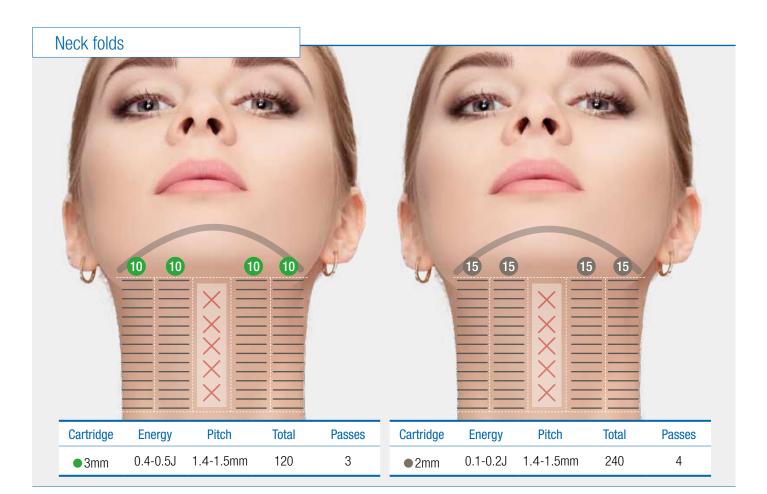


Before

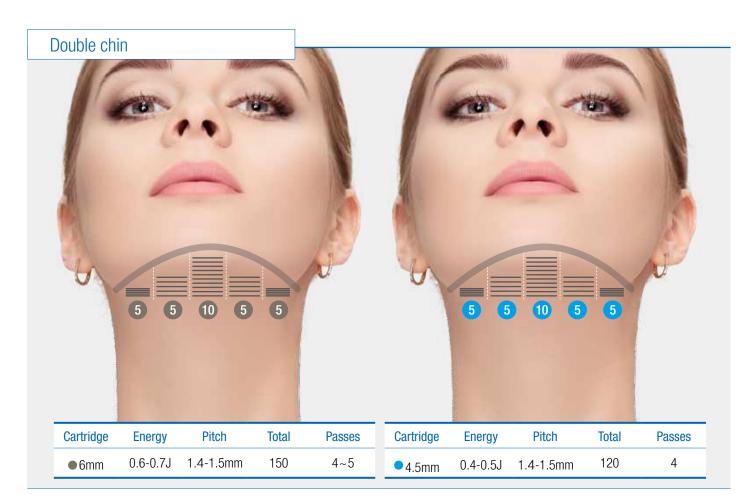
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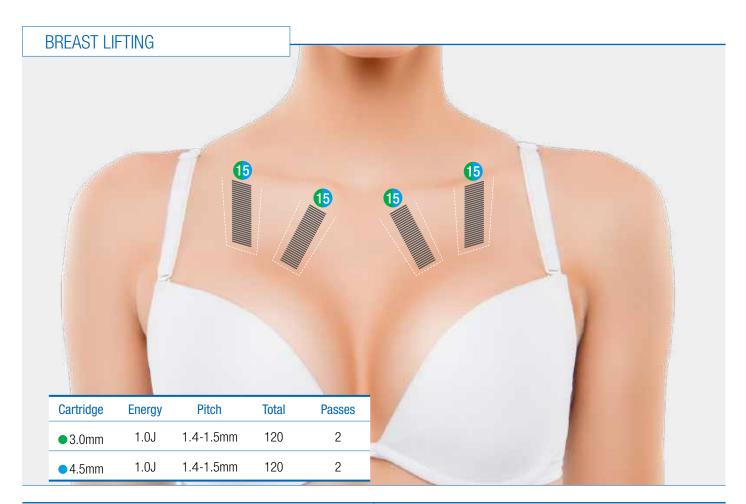


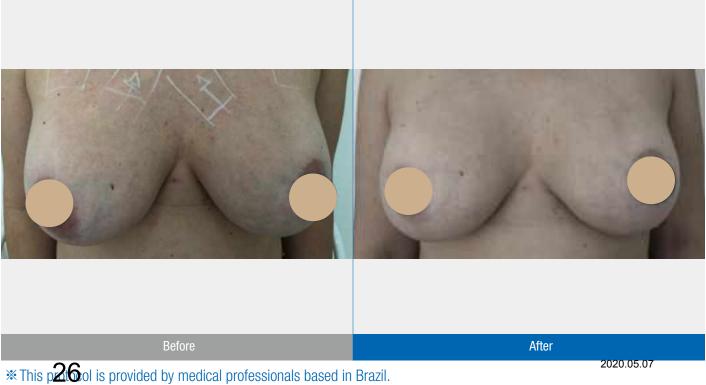






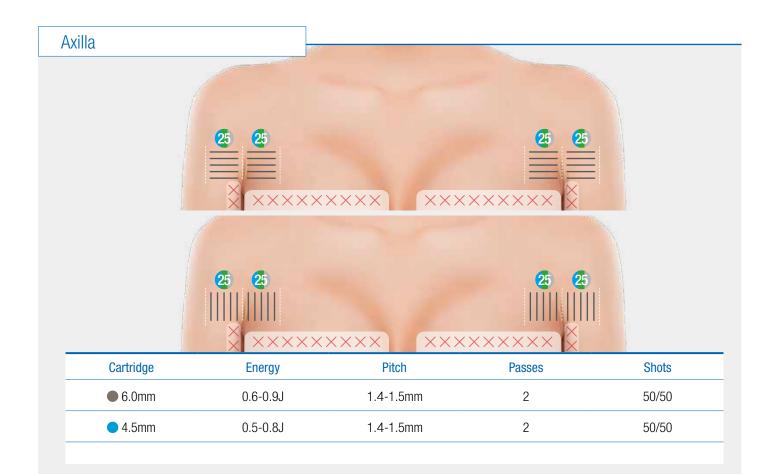
Décolleté									
							20 20		
22			10 2				30 30	20 10	
Cartridge	Energy	Pitch	Total	Passes	Cartridge	Energy	Pitch	Total	Passes
4 .5mm	0.4-0.8J	1.4-1.5mm	100-150	2-3	4 .5mm	0.2-0.4J	1.4-1.5mm	120	1
●3mm	0.4-0.8J	1.4-1.5mm	100-150	2-3	•3mm	0.2-0.4J	1.4-1.5mm	120	1
1 .5mm	0.1-0.2J	1.4-1.5mm	30-50	1	● 1.5mm	0.1-0.2J	1.4-1.5mm	40	1









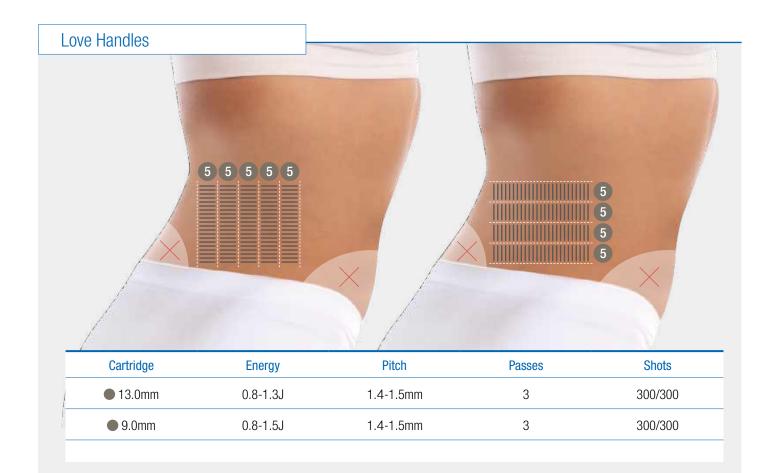






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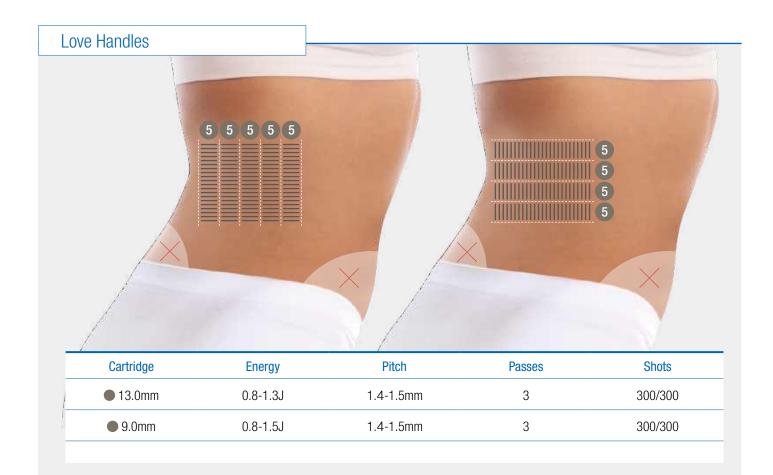
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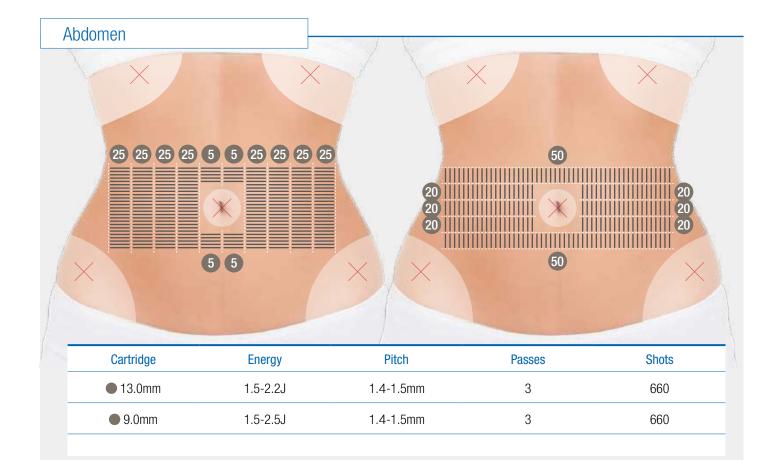
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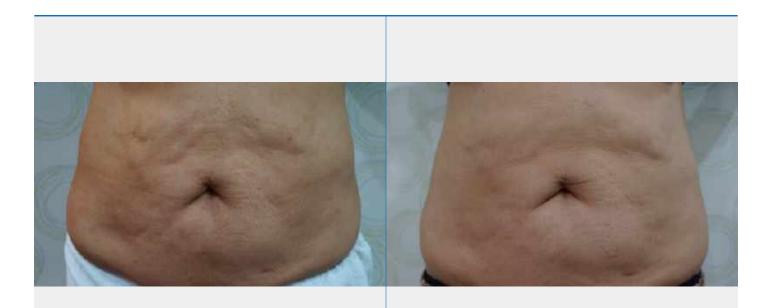


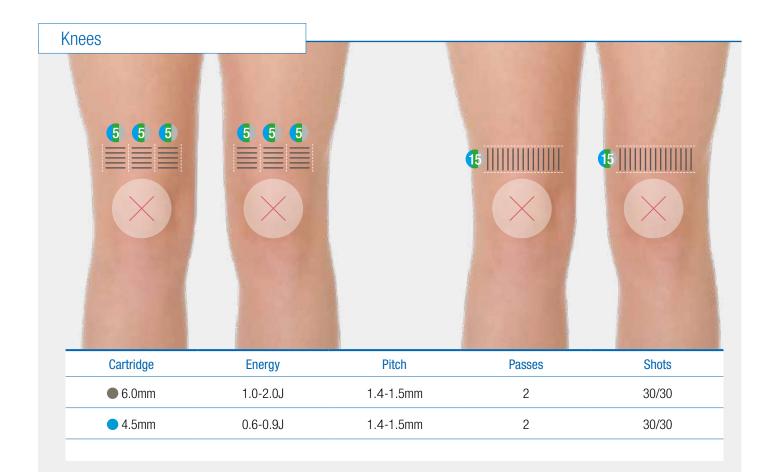


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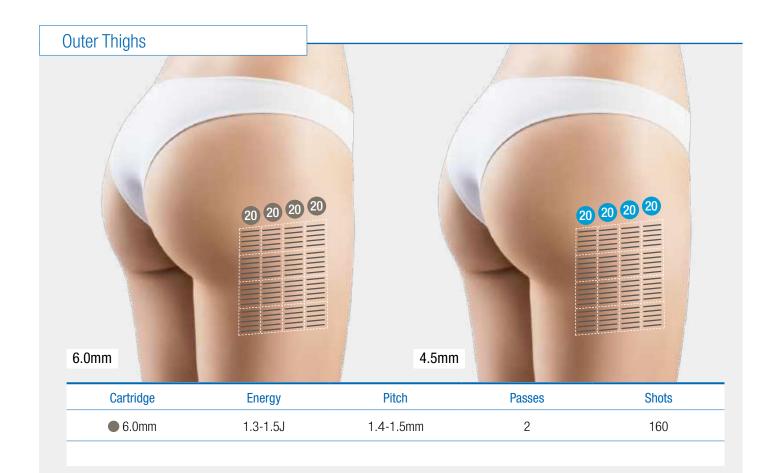


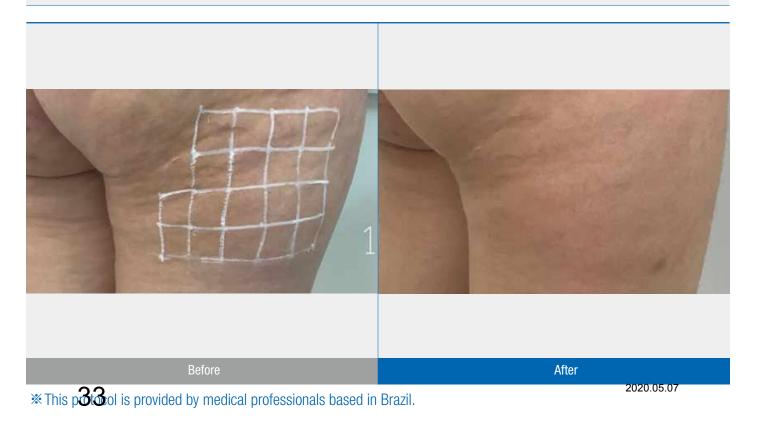


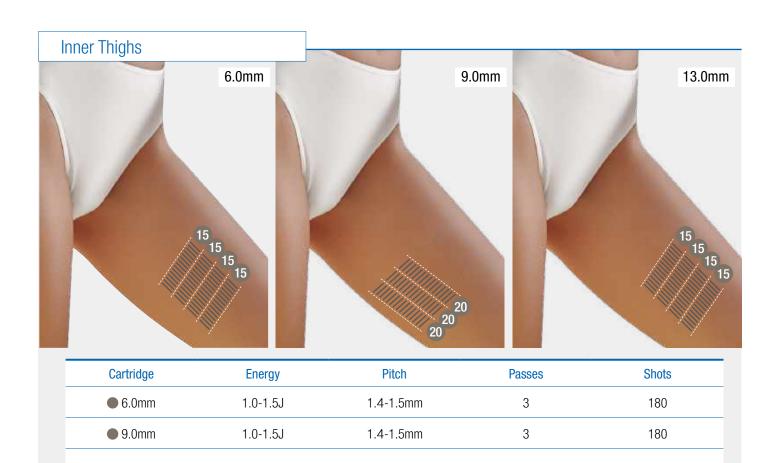


efore

After









Refer to additional training material for the proper and professional use of the ULTRAFORMER III.

-Maintenance Guide -Installation Guide -Quick Operation Guide -Operation Manual

For further enquiries contact: info@classys.com

TREATMENT GUIDE

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