

# Ulfite

New Industry Standard of  
Face Lifting & Body Contouring System



Ultimately Slim  
Beyond Limits

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# Ulfite

## TREATMENT

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

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



## ULFIT System



The ULFIT is a completely non-invasive, face lifting and tightening, body tightening and contouring device that provides customized treatment procedures applicable to the face, neck, and multiple areas of the body. Utilizing HIFU technology with Micro Focused and Macro Focused Circular Cartridges, the ULFIT focuses both uniform and perpetual ultrasound energy that induces thermal coagulation in the face and contraction in the body, excluding direct contact with or damage to the epidermis.

## ULFIT Cartridges

### Face & Body Cartridges

Micro Focused Ultrasound-powered Cartridges are designed to target more shallow regions for lifting and tightening multiple layers during treatment.

Macro Focused Circular Ultrasound-powered Cartridges are engineered to treat the thicker regions of the body for fat reduction and contouring.



**F7-1.5 : 1.5mm**



**F7-3.0 : 3.0mm**



**F4-4.5 : 4.5mm**



**B2-13.0 : 13.0mm**

# Precautions for Treatment

## Contraindications

The ULFIT 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 ULFIT 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 ULFIT.

## 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 ULFIT:

- Do not use the ULFIT without completion of training by an authorized CLUEDERM representative.
- To prevent unauthorized use of the device, ensure access is limited strictly to trained and certified personnel only.
- Avoid applying treatment on bony areas or nerve regions.
- Avoid applying treatment directly on 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 ULFIT treatment.
- Before conducting shots, check that the Cartridge attached on the transducer is applied on the skin properly.
- If the Cartridge has applied more than 1,000 consecutive shots, switch Cartridges or allow the Cartridge to cool down before proceeding with additional treatment.
- Avoid applying treatment on the thyroid gland, thyroid cartilage, and trachea.
- Avoid applying treatment directly on the breast tissue and major vessels.

# Precautions for Treatment

## Precautions for System Safety

To ensure safety of the System and proper maintenance of the ULFIT:

- 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 ULFIT Main Body or Hand-pieces as modification of this equipment is not allowed.
- The ULFIT contains no user serviceable components. Contact a local distributor or CLUEDERM 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 ULFIT 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.

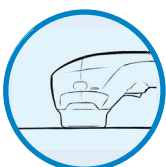
## Avoiding Nerves

Nerve areas to avoid during treatment:

- Navel
- Posterior superior iliac spine (PSIS)
- Popliteal fossa
- Pelvic nerves
- Ulnar nerves
- Sciatic nerves
- Marginal mandibular nerves
- 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.



DO NOT apply an excess amount of ultrasound gel to avoid buildup of liquids from entering the rear of the Body Hand-piece and causing short circuits from occurring.

## Preparation for Treatment



**Latex Gloves**



**Ultrasound Gel**



**Tissues**

1. Clean the area to be treated.
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.



# Treatment

## Precautions for Face & Body Procedures

### ○ Precautions for Face & Décolleté Procedures

- Do not apply treatment on the bony areas and nerve regions.
- Do not apply treatment directly on or near 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.
- 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

### ○ Precautions for Body Procedures

- Do not apply treatment on the bony areas and nerve regions.
- Do not apply treatment directly on or near 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.
- When treating with the Body Cartridge, treat in a slow to moderately fast pace.
- 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.
- Change Cartridges of the Body Hand-pieces based on the pinch test and treatment area:  
B2-13.0: depth of at least 2.5cm

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

- ⚠ 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.

## Treatment Steps for Face & Décolleté

### 1. Turning the System ON

Press the 'I' symbol on the AC Power Switch and press the Power Switch in front of the Main Body to turn the System ON.

### 2. Selecting Cartridges

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

F7-1.5: 1.5mm

F7-3.0: 3.0mm

F4-4.5: 4.5mm

### 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 Face 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 ULFIT Maintenance Guide.

## 7. Applying the Hand-piece

Apply the Face 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 ULFIT Face Hand-piece during treatment, refer to specific precautions below each treatment section and 'Precautions for Face & Décolleté 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 Face Cartridge, press STANDBY on the Graphical User Interface (GUI).

⚠ When treating with the Face 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 Face 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 Face 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.

## Treatment Steps for Body

### 1. Turning the System ON

Press the 'I' symbol on the AC Power Switch and press the Power Switch in front of the Main Body 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:

B2-13.0: depth of at least 2.5cm

### 3. Inspecting the Body Cartridge

Always inspect Cartridge conditions prior to proceeding with treatment.

\*Refer to 'Inspecting the Body Cartridge' of this Treatment Guide.

### 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.

⚠ DO NOT apply an excess amount of ultrasound gel to avoid buildup of liquids from entering the rear of the Hand-piece and short circuits from occurring.

### 5. Loading the Hand-piece Interface

Remove the Body 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
- Pain Control/Normal Mode
- Alarms
- Timer
- Volume

\*For additional information, refer to the ULFIT Maintenance Guide.

## 7. Applying the Hand-piece

Apply the Body 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 ULFIT Body 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 does not require pressing the Shot Button after each shot.

\*Cartridges should be moved in a slow to moderately fast pace.

## 8. Pausing Procedures

To pause use of the Body Cartridge, press the Shot Button to stop emission of ultrasound energy.

### Stopping Procedures

To stop use of the Body Cartridge while on Repeat Shot Mode, press 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.

## Inspecting the Body Cartridge

There are occasions where the Body Cartridge may be exposed to positive or negative air pressure which will cause improper rotation of the transducer during treatment.

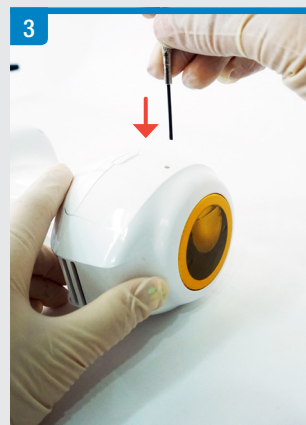
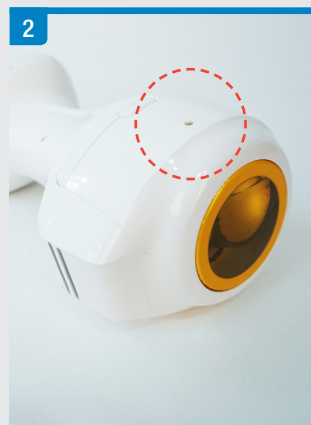
If in the case the transducer is not making a complete or successful rotation during a test shot, perform the following precautionary measures:

- Observe whether the surface window is visibly bulging outward or pushing inwards as the transducer may be in direct contact with the surface window.
- Place the Hand-piece with the pin hole of the Cartridge facing upwards and insert a metal pin into the hole to release or insert air pressure out of or into the Cartridge.

Conduct another test shot to observe whether the transducer is rotating properly.

Inspect the Body Cartridge on a frequent basis to ensure safe and effective treatments with the ULFIT.

⚠ If the metal pin is inserted into the opening when the pin hole is NOT facing upwards, water may leak out of the Cartridge and enter the cooling fan causing it to short-circuit.



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

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

For further enquiries contact:

**[info@cluederm.com](mailto:info@cluederm.com)**

## TREATMENT GUIDE

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**Manufacturer** CLASSYS Inc.  
2F, Baekyoung Bldg., 546, Samseong-ro Gangnam-gu, Seoul, Rep. of Korea

**Tel** +82-2-517-2114      **Fax** +82-2-6008-3457

**Website** [www.cluederm.com](http://www.cluederm.com) **E-mail** [info@cluederm.com](mailto:info@cluederm.com)