

ULTRAFORMER® III

General User Guidelines



Contents

1. Introduction	Page
A) What is MMFU.....	3
B) What is ULTRAFORMER III.....	4
2. Before ULTRAFORMER III treatment	
A) Good candidates for ULTRAFORMER treatment.....	5
B) How to consult with patients.....	5
C) Pain management.....	5
D) Contraindication.....	5
E) Precautions.....	6
F) FAQs.....	6
G) Avoiding superficial nerves during treatment.....	7
3. How to treat	
A) Preparation.....	7
B) How to operate the touch screen.....	8
4. Post treatment	
A) Recommendations for post-treatment care.....	11
B) Planning for ULTRAFORMER treatment.....	11
C) How to maximise treatment benefits.....	12
D) Normal response vs. side effects.....	12

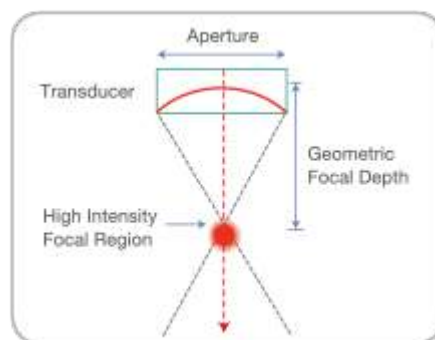
1. Introduction

A) What is MMFU?

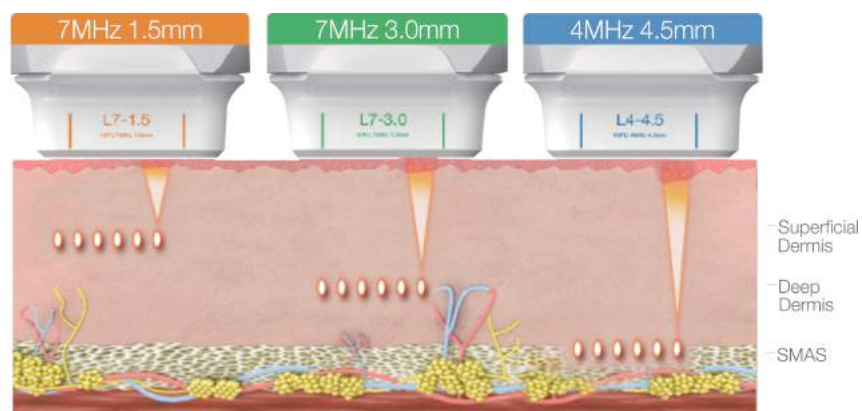
Micro & Macro Focused Ultrasound (MMFU) is the focusing of high intensity sound waves to create heat at a specific point. When MMFU energy is delivered to a specific location within the body, the tissue temperature at the focal point is elevated, while the tissue around the focal point remains unharmed.

Recently MMFU has been used for skin tightening and face lifting. Non-invasive ultrasound energy generates low levels of heat in the targeted skin.

Its transducer creates coagulation (micro parcels of heat) in the focal zone, as shown below.



The transducer generates heating points of up to 60-70°C (depending on the set energy level) of micro or macro focused ultrasound (MMFU) energy, then creates thermal coagulation in the target layers of skin tissue, with no damage on the skin surface at all. Following the initial treatment, the skin starts to undergo a wound healing process, which stimulates collagen synthesis and regeneration. The formation of new collagen provides longer-term tightening of the skin. Patients' facial contours and fine wrinkles show peak improvement after 8-12 weeks of treatment. Additional skin firming and tightening or at least maintenance of the results can last from 12-24 months post treatment.



B) What is ULTRAFORMER III

ULTRAFORMER III treatment is a non-invasive method of treating skin laxity of the face and neck by lifting and strengthening the skin. It is not a surgical, injectable or laser treatment. Instead, It creates thermal coagulation in the targeted area of skin, causing contraction of the deep tissues. ULTRAFORMER III energy works in the deeper layers of the skin, not on the surface of the skin, so you can see immediate and long-lasting results with little or no down time.



2. Before ULTRAFORMER III treatment

A) Good candidates for Ultraformer III treatment

- Mild to moderate skin and soft tissue laxity, where the skin begins to feel and look less firm.
- Patients between age 40 and 70 are usually good candidates.
- Lax, crepey skin throughout the face that occurs with ageing and photo damage.
- Younger patients are more likely to have good outcomes with MMFU treatment.
- People who are interested in non-surgical treatment options.
- Patients with a lowered eyebrow line, loose skin on the neck, sagging under the chin, and lines or wrinkles on the face.

B) How to consult with patients

- ① Check the patient's medical history
- ② Check the patient's experience of previous surgeries, whether major or minor.
- ③ Assess the patient's concerns regarding the appearance of his/her face.
- ④ Assess the patient's pain tolerance to determine whether you need to use pain control medicine.
- ⑤ Design the appropriate treatment plan with ULTRAFORMER.
- ⑥ Check if patients are on blood thinners, if so advise there could be post-treatment bruising.

C) Pain management

Pain tolerance varies from patient to patient.

Most patients are able to tolerate the ULTRAFORMER procedure without significant pain; however, they can certainly feel the procedure. How intense this sensation feels varies significantly from patient to patient.

When you consult the patient prior to the ULTRAFORMER procedure, you should check their level of sensitivity to pain.

If you determine that the patient needs pain control, you can choose between oral medication, local anaesthesia cream applied 45 minutes before treatment, or sedation. When using numbing cream; however, lidocaine cream penetrates only to the epidermal and the dermis layer, not to the SMAS layer. This means that it cannot remove all discomfort of the ULTRAFORMER treatment.

You can also use a contact cooling or cool air system for pain control.

The treatment does have a level of discomfort; but this is, for the most part, fleeting, and pain medication is not required after the procedure.

D) Contraindication

Ultraformer is contraindicated for use in patients with:

- | Open facial wounds or lesions
- | Severe or cystic acne on the face or neck
- | Metal stents/implants in the face or neck

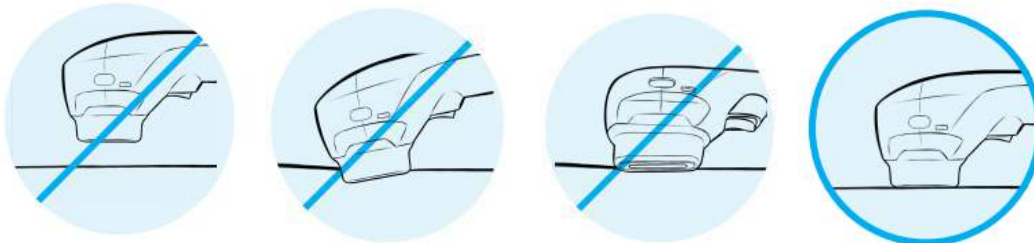
E) Precautions

Patients with the following conditions are recommended to consult with a medical professional prior to the procedure.

- | Pregnant or breast feeding women
- | Patients under the age of 18 (Require parent or guardian supervision)
- | Patients on anticoagulant therapy
- | Patients with herpes virus infections
- | Patients with autoimmune diseases
- | Patients with haemorrhagic disorders or other haemostatic dysfunction

Precautions for the procedure:

- ① When not in use by trained personnel, the Ultraformer System Access Key should be removed from the system to help prevent unauthorised use. Keep this system in a designated place only accessible by authorised and trained personnel.
- ② Do not use on or directed to the patient's eyes to avoid the risk ultrasound energy possibly causing severe discomfort or affecting the patient's vision.
- ③ It is recommended that the thyroid gland, thyroid cartilage and trachea areas should be avoided during the treatment.
- ④ Please do not apply the shot head to the skin without first applying ultrasound transmission gel.
- ⑤ Before activating the shot, check that the cartridge is correctly placed on the skin.



F) FAQ

| **Ultraformer and dermal fillers**

Ultraformer treatment may speed up degradation of dermal fillers.

We recommend that Ultraformer treatment is performed before injectable filler procedures.

| **Ultraformer, botulinum toxin, fillers, laser treatment. In which order should these treatments be administered?**

Ultraformer is recommended to be performed before botulinum toxin, fillers or laser treatment.

Botulinum toxin and filler injections can be done straight after an Ultraformer treatment.

If botulinum toxin injection is done prior to Ultraformer treatment, we recommend to wait 72 hours before treating. If fillers are done prior, we recommend to wait 1 month before treating with Ultraformer.

| **Side effects**

You may see redness and/or swelling at first, and the patient might feel some tingling. Most will disappear within hours but on occasion this can remain for some weeks (there is no need for alarm and it will eventually resolve). It signals that the beneficial process of collagen regeneration has begun. MMFU skin tightening is clinically proven to be very safe, with natural rejuvenation effects.

| **Importance of SMAS layer**

SMAS (Superficial Musculo-Aponeurotic System) is the same layer of tissue that plastic surgeons pull tight in a facelift.

As Ultraformer thermal energy safely heats this tissue, it contracts, resulting in an immediate tightening of the skin. Over time, this results in a noticeable lift. This is because Ultraformer treatment stimulates ongoing growth of new collagen protein, which tightens up the skin structure.

Safety of Ultraformer

Registered with the Therapeutic Goods Administration of Australia, Korean FDA and European CE, this Micro and Macro Focused Ultrasound (MMFU) device achieves excellent aesthetic outcomes in jowl lifting, nasolabial fold reduction, periorbital wrinkle reduction, overall skin tightening and rejuvenation in targeted areas with low risk for side effects.

The applications of Ultraformertreatment

Blurred jawline, nasolabial folds, sagging eyelids, loose neck fold, fine lines and wrinkles, uneven skin tone or texture, and large pores.

Ultraformer face system has five types of cartridges, which can treat various problem locations around the eyes, cheeks, jowl and neck.

G) Avoiding superficial nerves during treatment

There have been no permanent problems with nerves reported by the manufacturer to date. Overall, Ultraformer treatment has proven its safety via the numbers of procedures done over 1,000,000 to date.

Even temporary nerve damage is extremely rare but does happen. If there is a temporary stunning of the nerve that normally lowers the corner of your mouth, you should be careful when you treat the area.

Treating directly over the mandible or facial nerves may possibly cause severe discomfort and other temporary side effects.

You should keep in mind the location of the following nerves when you treat with ULTRAFORMER III:

- **Supraorbital and temporal facial nerves**
- **Marginal mandibular nerve**

If the patient is experiencing undue pain or a tingling sensation while delivering the energy, the energy setting should be reduced.

3. How to treat

A) Preparation

- ① Clean the patient's face with soft cleanser (EG: baby wipes).
- ② Agree on a plan for the Ultraformer treatment, and check the area to be treated.
- ③ It is highly recommended that the entire face be treated, but patients might prefer to have treatment on a specific area of the face in which case you may advise them that for best results full face treatments are done to achieve a cumulative cosmetic effect.
- ④ Turn on the Ultraformer power and set the energy level for the treatment.
- ⑤ Apply the ultrasound transmission gel to the procedure area.
- ⑥ Begin treatment with the deeper layers of the skin first.
- ⑦ Determine the energy by shooting one or two lines. Check the patient's reaction.

B) How to operate the touch screen

The Settings function allows you to change general system settings and to save existing parameter values and settings for later recall.

An overview of this screen is seen in Figure 6.1.

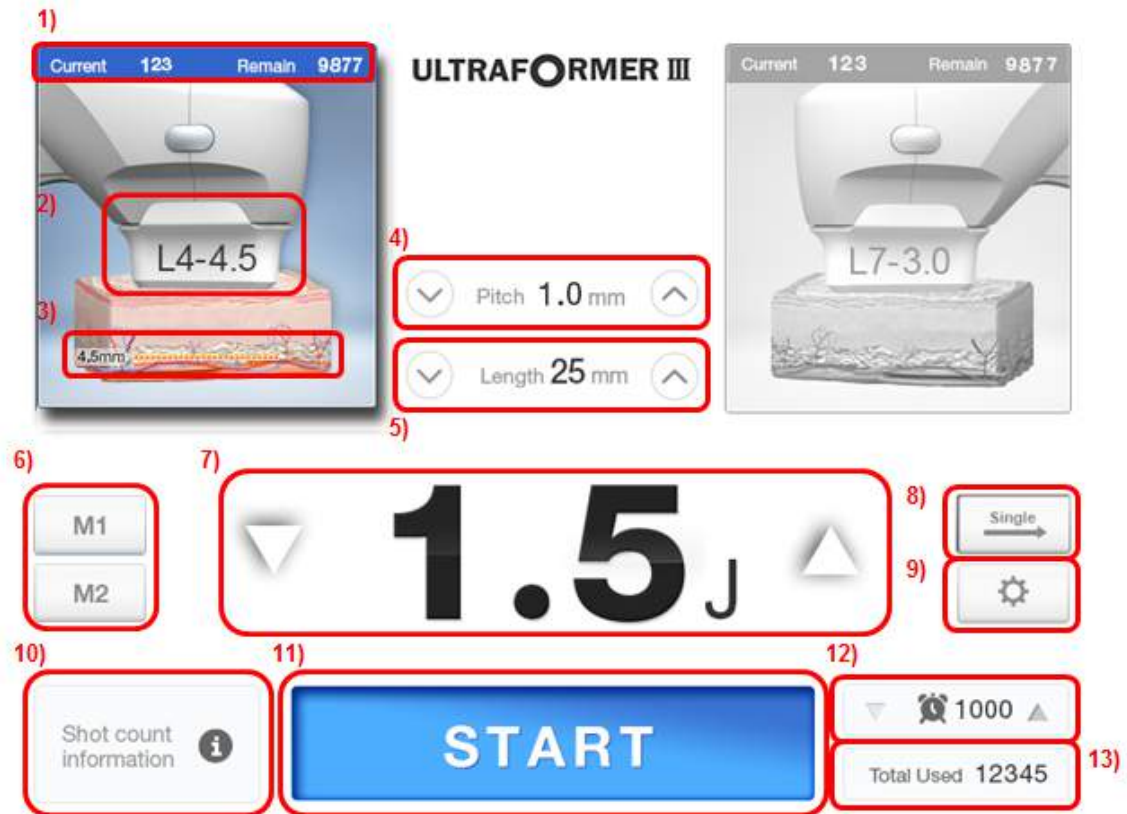








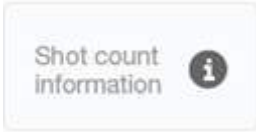





Figure 6.1 Screen in "START" state (See Table 6.1 for description)

Table 6.1 Screen Description

No	SIGN	Description
1	Current 123 Remain 9877	Used & Remaining shots in the cartridge (Ex: 123 used shots, 9877 remaining shots)
2		Installed cartridge information display (Ex: 4MHz 4.5mm Cartridge)

3		Current settings display (Depth, Pitch, Length) for each cartridge (Only display)
4		Sets the distance between thermal coagulation points, we generally recommend 1.4mm distance between each energy dot (From 1.0 to 2.0mm, in 0.1mm steps)
5		Sets the length of the treatment line (mostly used at 25mm) (From 5 to 25mm, in 5mm steps)
6		Establish the preset value "M1", "M2" Save Parameter value (Press and hold for 3 sec to save)
7		Sets energy level
8		One shot by one click of Single treat pushbutton Continuous shot by clicking the Repeat pushbutton
9		Configuration of volume control, factory default setting
10		Shot count information gives you a summary of the number of lines used per individual cartridge on a treatment. This number remains recorded in the system until the device is turned off or the reset button is pressed for 5 seconds to reset back to zero.
11		System Status "STANDBY" or "START"
12		Sets the shot limitation (Beep sound occurs when the number of shots exceeds this limit.)
13		Total used shots (The same as Total shots of Shot count information)

4. Post treatment

A) Recommendations for post-treatment care

- Moisturiser
- LED treatments
- Vitamin C treatment

B) Planning for ULTRAFORMER treatment

Ultraformer + IPL

This program can further reduce face laxity, improve collagenesis and overall rejuvenation.
IPL treatment 1 month after Ultraformer treatment.

Ultraformer + Botulinum toxin

We recommend to wait 72 hours post neurotoxin injection for an Ultraformer treatment.
Botulinum toxin can be administered immediately after an Ultraformer treatment.

Ultraformer + Fillers

Wait at least 1 month after filler injection before Ultraformer treatment.
Fillers can be administered immediately after an Ultraformer treatment.

Ultraformer treatment only

One treatment typically delivers noticeable results for your patient.
If necessary to do multiple treatments, we recommend a maximum of 3 Ultraformer treatments in total per year spaced at least 3-6 months apart.

C) How to maximise treatment benefits

Most people can return to their regular activities immediately following the treatment.

Wash your skin with water (avoid hot water).

You should avoid exposing your skin to extremes of heat and cold, and you should protect your skin with a sun block cream. Your normal makeup regime can be followed immediately.

Please do NOT have any other form of facial treatment or therapy. (If you want to have another facial treatment or therapy, you should discuss with your practitioner which treatment you wish to receive and when you can have it.)

Following Ultraformer treatment, your skin should feel tighter, smoother and more youthful. Over time you may notice additional tightening.

D) Normal response vs. side effects

Ultraformer treatment is an entirely non-invasive procedure, which has no downtime. Patients are able to return to their normal activities right after the procedure. Normal responses are mild and temporary in nature. They are as below. A small percentage of patients may have slight swelling, tingling or tenderness to touch.

- 1 **Edema (swelling):** The treated area may exhibit mild edema following Ultraformer treatment. This typically resolves within a week.
- 1 **Erythema (redness):** the treated area may exhibit erythema immediately following treatment. This typically resolves within a few hours of treatment.
- 1 **Tenderness:** Tenderness to the touch may be experienced following the procedure. This typically resolves within 2 weeks of treatment.
- 1 **Bruising:** mild bruising, which is caused by damage to soft tissue blood vessels, may occur occasionally, and typically resolves within 1~3 weeks of treatment.
- 1 **Lump:** A mild lump, if it occurs, is caused by the strong energy, and typically resolves within 2 weeks of treatment.
- 1 **Pain:** Momentary discomfort may be experienced during the procedure while the Ultrasound energy is being delivered. If patients have post-procedure discomfort, this typically resolves within 2 days.
- 1 **Scarring:** If incorrect treatment technique is used, scar formation is possible.
- 1 No permanent nerve injuries have been reported.

You should review or consult with any patient who experiences more severe pain than a mild discomfort, or if it persists.