

Freeze ON Fat OFF



CLATUU O

No Limitations

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CLATUU O

TREATMENT

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

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



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CLATUU Alpha System



CLATUU Alpha is the most advanced device for freezing fat away. The process involves the non-invasive cooling of fat cells to induce lipolysis, without damage to other tissue types. The purpose of CLATUU Alpha treatment is to remodel the shape of the body, but in a completely non-invasive way compared to liposuction.

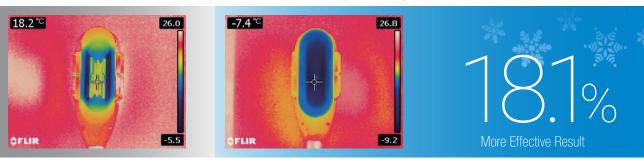
CLATUU Alpha Advanced Technology

Upgraded 360° Surround Cooling

360° Surround Cooling Technology unlike the conventional two-side cooling methods, increases efficiency by up to 18.1%. Allowing delivery of cooling to the entire cup and in result removes fat cells more effectively.

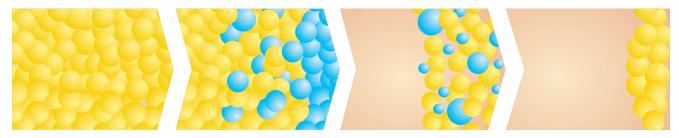
Previous Methods

360° Surround Cooling Technology



Science Behind CLATUU Alpha

Each cooling applicator is engineered to target the patient's subcutaneous fat layer without damaging surrounding tissues or nerve regions, It is through this advanced cooling technology that we are able to welcome you to the Innovative Age of CLATUU Alpha.



Al Applicator

The CLATUU Alpha automatically computes recommended parameters for each cup upon connection of each respective cooling applicator and in result effectively disposes of unwanted fat.

Faster to Target Point

The cooling system of the CLATUU Alpha is engineered to reach its target temperature faster than previous models, reducing the inconveniences of waiting and maximizing time efficiency for both patients and physicians.

Adjustable Levels

Not only is the CLATUU Alpha capable of 20% stronger suction, it also provides medical practitioners with the ability to adjust both cooling and suction levels to confidently provide customized treatments for patients.

CLATUU Alpha Applicator

7 Types of Applicator

The CLATUU Alpha is wide range of cooling cups are designed to perfection within our R&D labs and are suitable to conform to a large variety of body shapes and patients. Each individual cup helps to achieve a variety of customized treatment plans to effectively reduce fat cells for the ultimate body contouring experience.

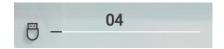
NAME		TYPES OF APPLICATOR	AREAS
	WING	- For Large Fat Pockets - Extending Applicator - For Broad & Curving Contours	Upper Abdomen Lower Abdomen Other Large Areas
	WING PLUS	For Small Fat PocketsBlunt-end ApplicatorFor Flat Contours	Bra Line Love Handles Back
	FLAT	For Small Fat PocketsFlat-end ApplicatorFor Flat Contours	Abdomen Inner Thighs
	FLAT MINI	For Small Fat PocketsFlat-end ApplicatorFor Flat Contours	Double Chin (Side) Knees (Side) Other Local Regions
	WING MINI	For Large Fat PocketsApplicable for Local RegionsFor Broad & Curving Contours	Axilla (Front & Back) Above the Knees
	ARC-T	- For Thigh Regions - Wide Area at Once	Around the Thighs Flat and Wide Areas
	WING MAX	- For Large Fat Pockets - Wide Abdomen Area at Once	Upper Abdomen Lower Abdomen

SAT (System Access Token)

SAT Cards are provided with Shield Pads manufactured specifically for use with the CLATUU Alpha. Required for the proper and safe operation of the CLATUU Alpha.

Displays Remaining Count (Default: 50)

Remaining Count decreases by one for each hand-piece used in treatment





SAT Card Chart

If Remaining Count value is 1	Only one hand-piece will be functionable
If the SAT Card is disconnected during the procedure	Active hand-pieces will be stopped immediately
If the SAT Card has a green light	Able to proceed with treatment
If the SAT Card has a flashing green light	No remaining count or in progress of loading
If the SAT Card has a red light	Error recognized

Precautions

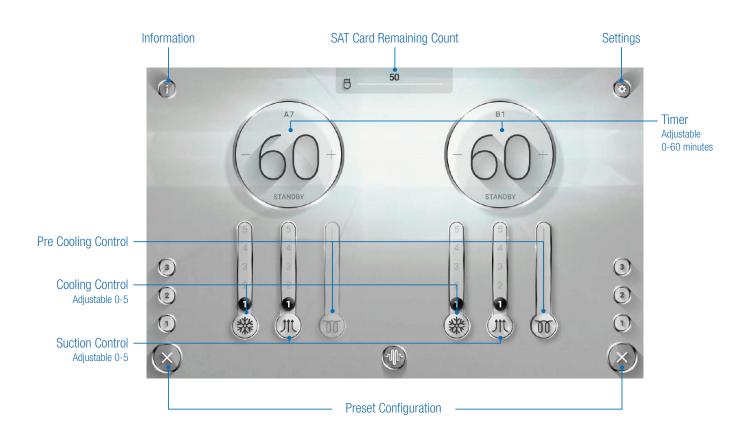
- Count deductions are applied two minutes after the start of the procedure.
- In the case a Shield Pad is not attached properly, re-application of the Shield Pad should be performed using a new Shield Pad within two minutes.
- If any error of application is discovered after the two minute period, the procedure should be terminated for safety reasons.
- Ensure that the Remaining Count is sufficient before proceeding to treatment.
- If the Remaining Count reaches 0, a new SAT Card with sufficient Remaining Counts must be inserted to perform treatment.

Warning!

- Inserting the SAT Card to any other device or inserting any other USB cable into the SAT Card USB port may cause malfunctions to occur.



Graphical User Interface





SIGNAL	INDICATION	
Still white light	Standby	
Flashing white light	Treatment complete, suction on	
Still blue light	Suction on, cooling in progress	
Flashing blue light	Suction incomplete	
Still yellow light	Cup change mode	

MODE	ACTION
STANDBY > PROGRESS	Press one button for two seconds
PROGRESS > STANDBY	Press one button for two seconds
Cup Change Mode	Press both buttons for two seconds

Before the Treatment

Appropriate Patients for Treatment

- A person who is in relatively good shape, but who has some modest deposits of unwanted fat.
- A person seeking spot reduction of specific areas of fat.
- The CLATUU Alpha procedure is not for weight loss or obesity.
- If the target area is thin, treatment may not be appropriate and clinical results may greatly vary
- Common applications are shown below: double chin, upper arms, abdomen, flank, thigh, back, bra bulge, love handles, and hips.



Double Chin
Axilla
Arms
Bra Line
Abdomen
Flanks
Love Handles
Below Buttocks
Outer Thighs
Inner Thighs
Knees

Contraindications

The CLATUU Alpha is not recommended for patients with the following:

- Cryoglobulinemia
- Paroxysmal Cold Hemoglobinuria
- Pregnant or breast feeding woman
- A sensitivity to cold urticaria or Raynaud's disease
- Peripheral circulatory failure of treatment area
- Neuropathy such as diabetic neuropathy or postherpetic neuralgia
- Cutaneous dysesthesia
- Open or infected wounds
- A bleeding disorder or a combination of anticoagulant
- Recent surgery or scar tissue in the treatment area
- Hernia of treatment area
- Skin diseases such as eczema, dermatitis or rash
- * For other conditions refer to your local doctor or practitioner for consultation.

How to Consult with Patients

Document the patient's medical history

- Current medical conditions and medications
- Previous surgeries
- Drug allergies
- Past medical diagnoses and treatments

Assessment of the target treatment areas

- Consult with your patient on where to treat
- Two applicators can work simultaneously, for example, lower belly right and left, etc.
- Patient selection is the single most important aspect in success of treatments. Ensure proper assessment is made before treating any area, and explain to the patient why some areas are not ideal to treat.
- Stress the time-saving aspect of the treatment to your patient.

Applicator selection

- Wing type applicator: for large fat pockets, such as on the upper abdomen, flanks.
- Flat type applicator: for large for pockets such as inner thighs, abdomen and upper arms.

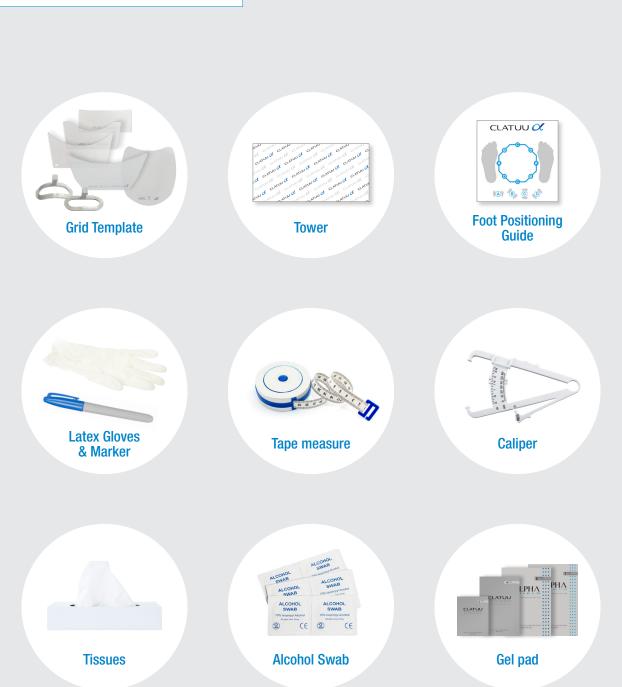
Patient communication regarding CLATUU Alpha treatment

- How it works
- Potential levels of discomfort
- Possible side effects
- Answers to any specific patient questions.

Pain Management

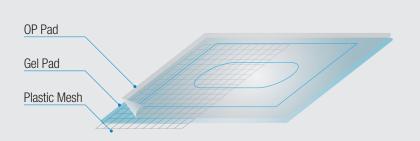
CLATUU Alpha procedures do not require anesthesia. During the procedure, the patient will feel a moderate amount of discomfort for the first ten minutes, but this will steadily diminish as the tissue becomes numb from the cold applicator. When the applicator is first applied, the feeling is that of the skin being pulled strongly into a vacuum. When the cooling process begins, there may be a stinging or cold sensation for the first ten minutes. The patient should then feel quite comfortable for the remainder of the treatment.

Preparation for Treatment



CLATUU Shield 360 Gel Pad - A Type

- The Gel pad from Classys is an essential component of the CLATUU Alpha procedure as it has been approved by CE and KFDA.
- The gel pads are disposable. Reusing them is not recommended. This may cause problems both for the device and for the patient being treated.
- It is critical that the original Gel pad from Classys be used as per instructions.





A Type



Tear the CLATUU Shield Pad A-Type open from the top of the packaging.



Remove the CLATUU Shield Pad A-Type from the packaging with care.



Open up the CLATUU Shield Pad A-Type and ensure all of the layers are firmly intact.



Apply the CLATUU Shield Pad A-Type at the center of the marked treatment area.



Remove the bottom layer of plastic mesh from the rest of the CLATUU Shield Pad A-Type.



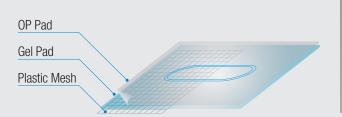
Smooth out any air bubbles and wrinkles before applying the Hand-piece on the outlined center of the CLATUU Shield Pad A-Type.

CLATUU Shield 360 Gel Pad - C Type

- The Gel pad from Classys is an essential component of the CLATUU Alpha procedure as it has been approved by CE and KFDA.
- The gel pads are disposable. Reusing them is not recommended. This may cause problems both for the device and for the patient being treated.
- It is critical that the original Gel pad from Classys be used as per instructions.



Tear the CLATUU Shield Pad C-Type open from the top of the packaging.



C Type

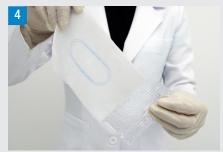
CLATUU



Remove the CLATUU Shield Pad C-Type from Open up the CLATUU Shield Pad C-Type and the packaging with care.



ensure all of the layers are firmly intact.



Remove the bottom layer of plastic mesh from the rest of the CLATUU Shield Pad C-Type.



Apply the outlined center of the CLATUU Shield Pad C-Type on the marked treatment area. Smooth out any air bubbles and wrinkles before applying the Hand-piece.



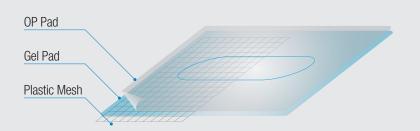
Apply the Hand-piece on the marked treatment area.



Start the procedure.

ALPHA Shield Gel Pad - B Type

- The Gel pad from Classys is an essential component of the CLATUU Alpha procedure as it has been approved by CE and KFDA.
- The gel pads are disposable. Reusing them is not recommended. This may cause problems both for the device and for the patient being treated.
- It is critical that the original Gel pad from Classys be used as per instructions.





B Type



Tear the ALPHA Shield Pad B-Type open from the top of the packaging.



Remove the ALPHA Shield Pad B-Type from the packaging with care.



Open up the ALPHA Shield Pad B-Type and ensure all of the layers are firmly intact.



Remove the bottom layer of plastic mesh from the rest of the ALPHA Shield Pad B-Type.



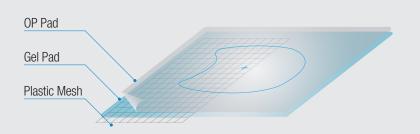
Smooth out any air bubbles and wrinkles before applying the Hand-piece on the outlined center of the ALPHA Shield Pad B-Type.



Start the procedure.

ALPHA Shield Gel Pad - T Type

- The Gel pad from Classys is an essential component of the CLATUU Alpha procedure as it has been approved by CE and KFDA.
- The gel pads are disposable. Reusing them is not recommended. This may cause problems both for the device and for the patient being treated.
- It is critical that the original \mbox{Gel} pad from Classys be used as per instructions.





T Type



Tear the ALPHA Shield Pad T-Type open from the top of the packaging.



Remove the ALPHA Shield Pad T-Type from the packaging with care.



Open up the ALPHA Shield Pad T-Type and ensure all of the layers are firmly intact.



Remove the bottom layer of plastic mesh from the rest of the ALPHA Shield Pad T-Type.



Smooth out any air bubbles and wrinkles before applying the Hand-piece on the outlined center of the ALPHA Shield Pad T-Type.



Start the procedure.

Treatment process - Abdomen



Talk to your doctor about the area you want treated.



Measure for fat thickness in the target area using a caliper. Measure for abdominal circumference.



Take pre-treatment photos using the foot positioning guide.



Use the grid template to mark the target area based on cooling cup.



Connect the selected cooling cup to the handpiece. (Press down firmly until a clicking sound occurs.)



Set the parameters according to the target area. (Time, Cooling, Suction)

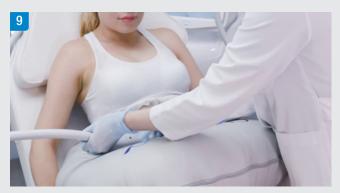
Treatment process - Abdomen



After removing the plastic mesh from the shield pad, apply at the center of the marked treatment area.



After the cooling cup has been applied on the target area, commence with suctioning the skin.



Ensure that sufficient fat tissue is drawn into the cup. Verify that the gel pad remains outside of the cooling cup. Use a cushion to support the cooling cups and to improve patient comfort.



Adjust the lighting of the room for a comfortable treatment environment. Apply a blanket over the patient to help maintain normal body temperature.



After completion of treatment, press and hold down the button on the hand-piece for 2 seconds to deactivate the suction. Remove the hand-piece and shield pad.



Gently massage the target area for 2 minutes. Remove any gel residues with a warm towel.

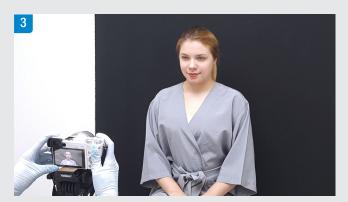
Treatment process - Double chin



Talk to your doctor about the area you want treated.



Measure for fat thickness in the target area using a caliper.



Take pre-treatment photos using the foot positioning guide. (Face front, 45° & 90°)



Use the grid template to mark the target area based on cooling cup.



Have the patient sit on a chair facing at a 45° angle.



Connect the selected cooling cup to the handpiece. (Press down firmly until a clicking sound occurs.)

Treatment process - Double chin



Set the parameters according to the target area. (Time, Cooling, Suction)



Apply the C-type shield pad at the center of the marked treatment area. (Smooth out any air bubbles and wrinkles from the shield pad.)



Adjust a pillow around the patient's neck. After the cooling cup has been applied on the target area, commence with suctioning the skin. Verify that the gel pad remains outside of the cooling cup.



Adjust the lighting of the room for a comfortable treatment environment. Apply a blanket over the patient to help maintain normal body temperature.



After completion of treatment, press and hold down the button on the hand-piece for 2 seconds to deactivate the suction. Remove the hand-piece and shield pad.



Gently massage the target area for 2 minutes. Remove any gel residues with a warm towel.

Treatment Posture

Cup

Treatment Posture

Wing



Upper or lower abdomen

Wing Plus



Bra-line Back Love-handles

Flat





Upper abdomen

Inner thighs

Treatment Posture

Cup

Treatment Posture

Flat Mini





Double chin (side)

Knees side





Above the Knees

Wing Mini



Axilla (front)

Axilla (back)

Treatment Posture

Cup

Treatment Posture



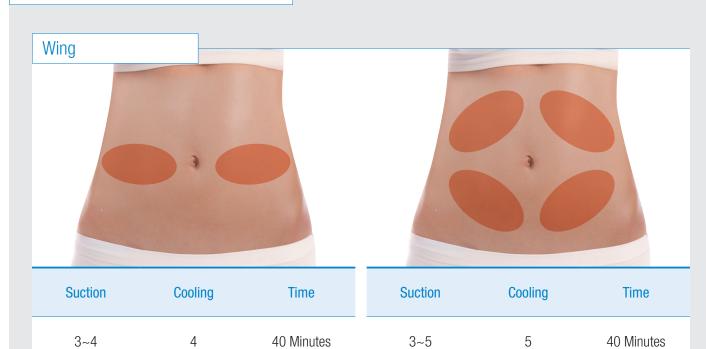
Wing Max

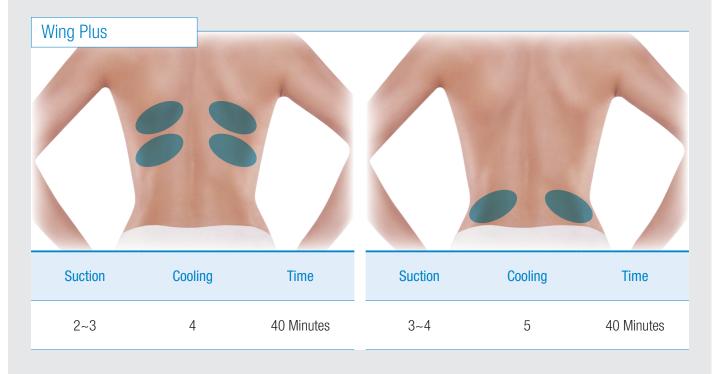


Safe & Comfortable Posture for Mini Cooling Cups



Parameters

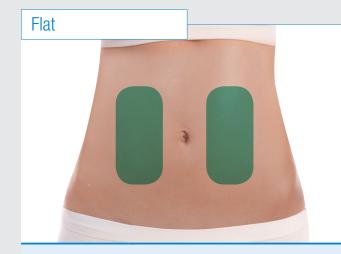




Parameters

Suction

3~4

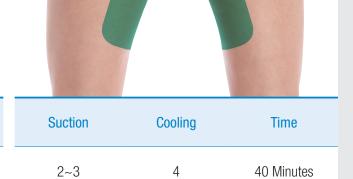


Cooling

4

Time

40 Minutes

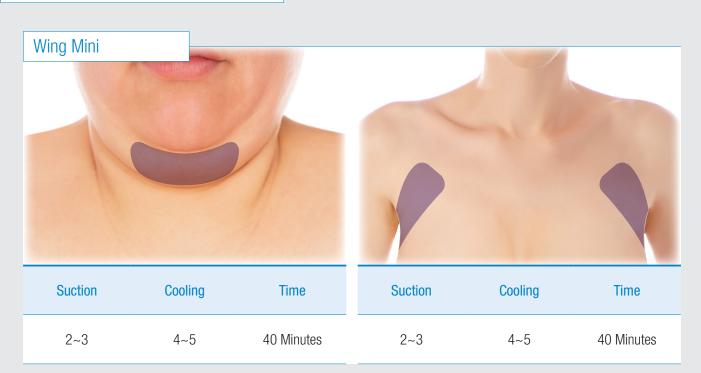






Suction	Cooling	Time	Suction	Cooling	Time
2~3	4~5	40 Minutes	2~3	4~5	40 Minutes

Parameters





Suction	Cooling	Time	Suction	Cooling	Time
3~4	4	40-50 Minutes	3~4	4	40-50 Minutes



Suction	Cooling	Time
3~4	4	40-50 Minutes

After the Treatment

Safety Information

Potential Side Effects

This equipment is a non-invasive cooling therapeutic equipment which is to be applied to the skin. This device has no serious adverse events or major side effects occurring during clinical research. The following occurred during clinical trials:

- Mild pain in the treatment area during the procedure.
- Bruising which may occur in the treated area after procedure. (Bruises disappear within four days after the procedure)
- An itch in the affected area temporarily.
- Stiffness may occur in the affected area temporarily.
- Please pay extra attention because patients may experience mild pains, frostbite, scabs and temporary numbness to the nerves after the operation.
- A feeling of fullness in the throat after treatments involving the neck or chin region.

Complaints and Adverse Events

 No serious or adverse observations were made from the use of the preceding equivalent devices in reference to the clinical study. Classys Inc. follows MDR (Medical Device Reporting) rules for handling complaints and adverse events. Should an adverse event be suspected or reported, please contact Classys Inc.

FAQ

What is a normal response after the CLATUU Alpha procedure?

 After the treatment finishes, the area may feel tender or stiff. Some patients can observe redness in the treated area, but this typically fades in a few hours. Patients are free to engage in normal activities immediately after the treatment.

What results should be expected from CLATUU Alpha treatment?

 Patients should normally see a noticeable improvement in the treated area after 6 weeks. Remaining fat cells continue to be gradually eliminated from the body, resulting in further fat reduction. The full benefit of the treatment should be seen after 90 days, at which point the practitioner can determine whether another treatment is needed.

What is Apoptosis?

 Apoptosis is the process of programmed cell death (PCD) that may occur in multicellular organisms. Biochemical events lead to characteristic cell changes (morphology) and death; other cells clean away the dead cells, leaving no trace of them in the body.

How much is the size of the treated area likely to reduce?

- Studies indicate that one session (applying one applicator) can reduce the size by 1 centimeter. Given that CLATUU Alpha has 2 applicators, it is possible to reduce the size by 2 centimeters at a time.

How long does a CLATUU Alpha treatment take?

 CLATUU Alpha treatment takes 40-60 minutes. The practitioner should determine the time and level of CLATUU Alpha procedure according to the targeted area. The patient can relax, sleep, read or listen to music in a comfortable position during the treatment. It is important not to exceed the recommended treatment time.

How many treatments are needed?

- It depends on the thickness of the fat. CLATUU Alpha treatment can be repeated on the same area at 30-day intervals.

What can the patient expect during the procedure?

The initial sensation is that the skin is being pulled into a vacuum.
 For the first 10 minutes, the cooling process may sting or feel uncomfortable. Thereafter, the area simply feels cold and numb.
 When the applicator is removed, the treated area feels cold and hard.
 Massage after the treatment assists in optimising the results.

How safe is the CLATUU Alpha procedure?

CLATUU Alpha has been subjected to thousands of hours of testing.
 Controlled cooling has been proven to damage fat cells only. CLATUU
 Alpha requires the use of a gel pad provided by Classys, as this is essential to protect the surface layers of the skin.

How long will it take to recover from CLATUU Alpha treatment?

 CLATUU Alpha treatment is completely non-invasive and non-surgical, so, in most cases, patients can return to their normal routine after treatment.

After the Treatment

Post Treatment

1. Recommendations for post-treatment care

- When the applicator is removed, the treated area will feel cold.
- Massage: after 40-60 minutes, the treatment is completed and the handpiece is removed. The treated area will be firm immediately after the procedure. Massage can optimise the treatment results. It also helps remove stiffness, reduce the cold sensation and redness.
- Compared to liposuction surgery, the CLATUU Alpha procedure is non-invasive, and anaesthesia or pain medication is not generally required. Downtime or scarring are extremely unlikely.
- No difference in fat deposits can be seen immediately after the treatment. About a month after treatment, the patient will see a visible reduction of fat in the treated area.

2. Planning further CLATUU Alpha treatments

Additional treatments can help achieve the desired outcome. After 30 days, the same area can be treated again. When planning a second treatment on the same area, it is recommended that you customise the plan, changing applicators, and varying the location slightly.

3. Maximising treatment benefits

Patients should expect slight discomfort after the procedure.

Patients may resume their normal activities immediately after the procedure.

Patients should be encouraged to maintain a healthy regimen of diet and exercise after treatment.

Patients should avoid the use of anti-inflammatory medications such as ibuprofen, naproxen for 6 weeks after the treatment. Patients should schedule a follow-up medical assessment to review your clinical results and discuss the opinion.

4. Normal response vs. side effects

Chilling: During the CLATUU Alpha procedure, the patient will feel a moderate amount of discomfort for the first 10 minutes. This will steadily decrease as the tissue becomes numb from the cold applicator.

Erythema (redness): The treated area may exhibit erythema immediately following the treatment. This typically resolves within a day of treatment.

Bruising: Mild bruising, which is caused by strong suction to soft tissue blood vessels, may occasionally occur and typically resolves within 2-3 weeks of treatment.

Discomfort: Initial discomfort may be experienced during the first 10 minutes of the procedure.

Numbness: The patient could experience a temporary dulling of sensation in the treated area. This can occur up to 2-4 weeks after the procedure.

Itchy feeling: A mild itchiness may occur in the treated area that may last 2-4 weeks after the procedure.

Stiffness: The patient's skin may feel sensitive to touch following the procedure. This is a normal and temporary response.

Maintenance

Cleaning the Hose

It is recommended to clean the Hose once a day after using the CLATUU Alpha System.

- It takes approximately 5 minutes to clean each Hose (stop cleaning when the Hose is completely clear of oil and other residues).
- If cleaning the Hose is not frequently carried out, the oil in the component may harden preventing the Hand-piece suction from functioning properly.
- After cleaning the Hose, use the Oil Receiver to drain the oil from the Arm Stand when necessary.



Press the Settings button located on the far upper right corner of the interface.



When Arm Stands A and B are displayed as options beside Hose Cleaning under Settings, press STANDBY for each to clean the Hose in separate or simultaneous sequence (approx. duration: 5 min.).



To clean the pipe, please pour 100ml of warm water (around 40° Celsius) into to the cup.

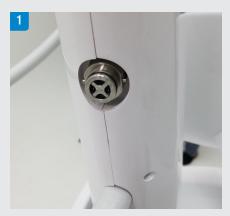
- Hose Cleansing: Once a day
- Warm Water Cleansing: Once a week (In case of frequent usage, it's advised to clean it more than recommended.)

Maintenance

Draining Oil

- Proceed when error message is displayed as shown.
- Ensure to turn the System OFF before proceeding.
- Please wait 10 15 min. for approximately 200ml of oil to drain completely from the System.





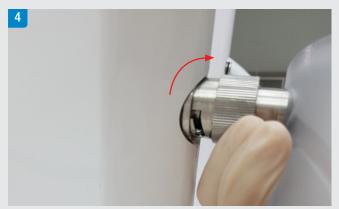
Check the outlet of the Oil Receiver located behind the Arm Stand.



Prepare to connect the Oil Receiver to the outlet.



Align and insert the input of the Oil Receiver into the outlet.



After the input of the Oil Receiver is inserted into the outlet, turn the input right to ensure a firm connection.



Check that the oil is draining properly through the input of the Oil Receiver.

Keep the Oil Receiver connected until oil is completely drained from the System. After a successful drainage, remove the Oil Receiver from the Arm Stand in reverse sequence.

Maintenance

Inserting Water

VENT (top) and DRAIN (bottom) outlets are located at the lower rear of the Main Body. The lid to the filter for inserting water is located at the top of the Main Body.



Insert the Plastic Tube into the VENT outlet with the opening at the opposite end placed in a container.



Pour approximately 2 Liters of water into the filter until water exits from the VENT outlet and into the container.



Press down the release button located next to the VENT outlet and remove the Plastic Tube.

For further guidelines and enquiries on the CLATUU Alpha System, refer to additional training materials for the proper and professional use of the CLATUU Alpha.

-Installation Guide

-Quick Operation Guide

-Operation Manual

-Treatment Guide

For further enquiries contact: info@cryomed.com.au

TREATMENT GUIDE Supported in Australia & New Zealand by Cryomed Tel 1300 346 448 Website cryomed.com.au E-mail info@cryomed.com Alpha_Treatment_Guide_201911