

OPERATION MANUAL Ver. 1.2



CLATUU ALPHA (Model Name: CL5-M500)

The CLATUU ALPHA is intended for use only by properly trained physicians and properly trained persons under the supervision of such a trained physician.

Users must thoroughly read and understand this manual prior to operating the device. Improper use of the system may cause injury to parties and/or may cause damage to the system that may void the warranty agreement.

Note1: This user manual describes the operation of the CLATUU ALPHA only. It is not a substitute for the required clinical training to use the system.

Note2: Classys Inc. provides this manual in English by default. Classys Inc. also translates the manuals into the language of each country sold in Europe only.

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1. Introduction to Manual

1-1. Purpose

This manual provides a description of the CLATUU ALPHA system components, displays, operational instructions and other related information vital to the functions of the system.

WARNING: Do not operate the CLATUU ALPHA prior to reading this manual thoroughly and being trained by an authorized Classys Inc. representative.

This manual is not a substitute for clinical treatment guidelines and training provided by the company or its distributors.

1-2. Conventions



Caution: This signal alerts the user to precautionary steps necessary to effectively operate the system. Failure to observe these precautions may void the warranty.



Warning: Warnings alert the user to information that is of the highest importance and vital to the safety of the patient and user.

Numbered sections are presented in steps and must be completed in sequence.

Bulleted lists indicate general information about a particular function or procedure. It does not imply a sequential procedure.

2. Safety Information

2-1. Indications for Use

The CLATUU ALPHA is:

- A non-invasive cooling therapeutic equipment for treatment of pseudogynecomastia by reduction of excess subcutaneous adipose tissue
- Target patient
 - 1) Patient populations: 18-67 years old male
 - 2) Those who have excess adipose tissue around and under the nipples.
 - 3) Those who have Grade I, IIa, IIb, III grade of Simon's Gynecomastia Classification

2-2. Contraindications

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

- Cryoglobulinemia
- Paroxysmal Cold Hemoglobinuria
- Those who have gynecomastia by endocrinologic disease
- Cold agglutinin disease
- Those who had surgical or body contouring procedures done on the area of intended treatment
- Those who have BMI (Body Mass Index) exceeding 35kg/cm²
- Those who have a personal history of previous breast malignancy

2-3. Warning

Do not use the equipment without prior training and qualifications to operate the CLATUU ALPHA. For the following conditions of patients, consult with experts to decide whether treatment is appropriate.

- 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

^{*}For other conditions refer to your local doctor or practitioner for consultation.

- 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

2-4. Potential Side Effects

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

- Mild pain or tenderness, mild pinching in the treatment area during the procedure.
- Tingling or stinging during the procedure
- Mild Bruising (purpura, petechiae) which may occur in the treated area after the procedure.
- Itching, Skin sensitivity or numbness in the affected area temporarily.
- Redness(erythema) or stiffness may occur in the affected area temporarily.
- Mild edema(swelling) and light scratches
- · Cramping and aching

Please pay extra attention because patients may experience mild pains, scabs and temporary numbness to the nerves after the procedure.

2-5. Rare Side Effects

- Paradoxical adipose hyperplasia(PAH): Visibly enlarged tissue volume within the treatment area, which may develop two to five months after treatment. Surgical intervention may be required.
- Freeze burn(frostbite): First and second degree freeze burn may occur during treatment. It typically resolves without sequelae with proper care.

2-6. 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.

3. System Overview

3-1. System Description

The CLATUU ALPHA is a cooling therapeutic device. Cold-assisted lipolysis is a non-invasive treatment used to reduce adipose cell volume through freezing. The principle behind this technology exploits the premise that adipocytes are more susceptible to cooling than other skin cells. The life cycle of CLATUU ALPHA is 5 years.

3-2. System Components and Features

3-2-1. System Components

The CLATUU ALPHA consists of the following components including accessories as shown in Figure 3.1.

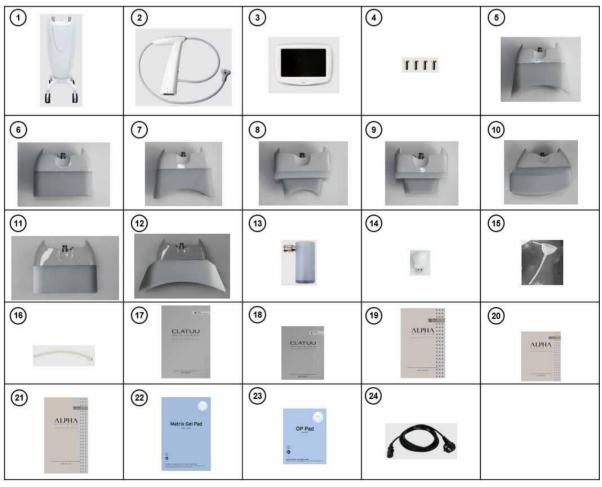


Figure 3.1 Main components of the CLATUU ALPHA

No.	ltem	No.	Item	No.	Item
1	Main Body	2	Arm Stand with Hand-piece (2EA)	3	Monitor
4	Screws	5	Cup "WING" type (Option)	6	Cup "FLAT" type (Option)
7	Cup "WING PLUS" type (Option)	8	Cup "WING MINI" type (Option)	9	Cup "FLAT MINI" type (Option)
10	Cup "ARC-T" type (Option)	11	Cup "ARC-A" type (Option)	12	Cup "WING MAX" type (Option)
13	Oil Receiver	14	SAT Card	15	Funnel
16	Plastic tube	17	CLATUU SHIELD 360 (Type A)	18	CLATUU SHIELD 360 (Type C)
19	ALPHA SHIELD (Type B)	20	ALPHA SHIELD (Type C)	21	ALPHA SHIELD (Type T)
22	Matrix Gel Pad (Option)	23	OP Pad (Option)	24	AC Power cable

3-2-2. System Features

The Main Body is the information center for the CLATUU ALPHA. The Graphic User Interface (GUI) allows the user to interact with the device. This screen sets and displays the operating conditions including equipment activation status, treatment parameters and system messages. Figure 3.2 illustrates the physical features of the System.

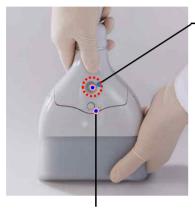


Figure 3.2 Main body front, and rear view

No.	Item	No.	Item	No.	Item
1	Arm Stand with Hand-piece	2	10.1 inch LCD (GUI)	3	Power Button
4	Button for adjusting the length of the Hand- piece cable	5	Hand-piece cable	6	Caster
7	Oil Drain	8	Knob	9	SAT Card
10	Water Inlet	11	Power Inlet	12	Vent outlet
13	Water Drain				

3-2-3. Hand-piece

The Hand-piece has buttons on both side of Hand-piece. It is used to operate the modes, and also the operation status, both of which are indicated by LED as shown in the Figure 3.3. The Hand-piece latch is used to replace the Cooling Cup.



Latch for replacement of Cooling Cups

Mode	Action
STANDBY > PROGRESS	Press one button for 2 seconds
PROGRESS > STANDBY	Press one button for 2 seconds
Cup Exchange Mode	Press two buttons for 2 seconds

LED 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

Figure 3.3 Hand-piece side view

3-2-4. Cups Figure 3.4 illustrates the exterior of Cups.



Figure 3.4 Appearance of Cups

The type of cup to be sold by the customer's request is determined and packaged. In addition, eight cups may not be sold together.

3-2-5. CLATUU SHIELD 360 Pads / ALPHA SHIELD Pads

CLATUU SHIELD 360 Pads (A, C type) / ALPHA SHIELD Pads (C, B, T type) have the same ingredients, but differ in size. The composition of each Pad is as shown in Figure 3.5.

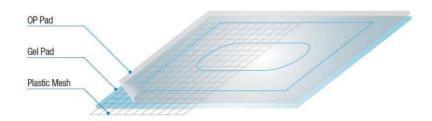


Figure 3.5 Composition of Pad

How to use gel pad is as follows:

- 1 Tear the Pad open from the top of the packaging.
- 2 Remove the Pad from the packaging with care.
- (3) Unfold the Pad and ensure all of the layers are firmly intact.
- (4) Apply the Pad by aligning the center design with the marked treatment area.
- (5) Remove the bottom layer of plastic mesh from the rest of the Pad.
- (6) Smooth out any air bubbles and wrinkles before applying the Hand-piece on the outlined center of the Pad.

3-2-6. Matrix Gel Pad and OP Pad

In case of Matrix Gel Pad and OP Pad, use them in the following order. The Matrix Gel pad should be used with OP Pad.

- (1) Carefully and securely apply the Matrix Gel Pad to the allocated area.
- ② Stick the OP Pad on the Matrix Gel Pad. (Make sure the position of the Matrix Gel Pad aligns with the lines of the OP Pad correctly)
- ③ Evenly apply any remaining gel from the package of the Matrix Gel Pad to the OP Pad.
- (4) Stick another OP Pad on the first OP Pad.
- (5) Evenly apply gel from the package of the Matrix Gel Pad to the OP Pad.
- (6) Hand-piece parts of silicone are attached so that they are perpendicular to the center of the OP Pad.

3-3. Precautions for Use

3-3-1. Warnings

- To prevent unauthorized use of the CLATUU ALAPHA, store in a controlled environment only accessible by authorized and trained personnel.
- To avoid risk of electric shock, always inspect the Hand-piece, Cups and cable before
 use.
- Do not use a cable that has been damaged or is leaking fluid.
- If the hand-piece is damaged or torn, do not use or replace with another hand-piece to operate the system.
- Power supply must be 220-240V~, 50/60Hz to operate the system safely.
- The CLATUU ALPHA is intended for use in and indoor dry location. Avoid liquid spills and splashes.
- Do not place the system in the vicinity of direct sun light, high humidity or nearby heating devices.
- To avoid system damage, do not tile the equipment and avoid collisions with other electrical devices.
- The CLATUU ALPHA comes with a three-conductor AC power cord and plug. Use a
 properly grounded outlet and always plug the CLATUU ALPHA directly into the outlet.
 Never remove the ground conductor via any AC adaptor plugs or extension cables.
- Disconnect the AC Power cable from the outlet by pulling on the plug and not the cord.
- Do not touch the AC Power cable with wet hands.
- Turn off the Main Power Switch and disconnect the AC Power Cable from the outlet prior to cleaning the Main Body.
- Do not remove the covers on the Main Body, Hand-pieces or Cooling Cups. The CLATUU
 ALPHA contains no user-serviceable components. If the System requires service,
 contact local distributors or Classys Inc.
- No modification of this equipment is allowed.
- The CLATUU ALPHA should not be used near flammable gases or anesthetics. Fire or explosions may occur. The CLATUU ALPHA is not AP or APG rated.

- Avoid restricting ventilation under or behind the main body of the system. Maintain an open space of at least 50cm around the Main Body. If ventilation holes are obstructed, the System may overheat.
- The Cup is rated as a Type BF patient applied part. It may provide a connection between the patient and protective earth. This may present a hazard if the patient becomes connected to other equipment with excessive electrical current leakage.
- Use the Cup provided by Classys Inc. only. Operating with any other Cups may cause patient injury or malfunctions.
- Do not suddenly remove the Hand-piece or Cup. It may malfunction or cause damage if separated by force.
- Please refer to section "3-3-3" for warnings of Electromagnetic Compatibility and Immunity".

3-3-2. Cautions 1

- Before proceeding with treatment, check if the Hand-pieces and Cups are properly attached.
- The Hand-piece and Cup connectors must be kept clean and dry. Do not use the Hand-piece and Cup connectors if the connectors have been immersed in liquid. See the instructions for cleaning the Hand-piece and Cup.
- Every effort has been made to make the Hand-piece and Cup robust; however, it may
 be damaged if dropped onto a hard surface. Physically damaged Hand-pieces or Cups
 are not covered by warranty.
- For replacements or additional Cups contact your local distributor or Classys Inc.
- No other cleansing methods are allowed. Do not use acetone or other solvents as this
 can damage the Main Body, Hand-piece and Cup.
- Use DI (Deionized) water or distilled water to prevent shortening of filter lifetime.
- Always turn the system off and unplug the power cord before performing maintenance procedures. The interior of the system or its components may be serviced only by your local distributor or Classys Inc.
- 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.

- Before the treatment, ensure that breast enlargement was due to idiopathic pseudogynecomastia, rather than true gynecomastia.
- If you touch the LCD with your hand with water(gel) after removing the LCD protective film, it may cause monitor failure due to the inflow of foreign substances.
- Please refer to section "3-3-3" for cautions of Electromagnetic Compatibility and Immunity".

Please follow the directions below if the system does not turn on:

- Ensure the Main Power Switch is in the ON position and press the power button to turn the System ON.
- If the problem persists, unplug the AC Power Cable.
- Pull the fuse holder below the Main Power Switch.
- Replace the fuse (250V 10A).
- If the problem persists, please contact local distributors or Classys Inc.

3-3-3. Electromagnetic Compatibility and Immunity

The RF emission of the "CLATUU ALPHA" meets the requirements of the safety standard for medical equipment. Therefore, it causes almost no interference.

Its energy requirement is mainly commercial. However, a hospital installation is required except for near active HF surgical equipment and the RF shielded room for a system of magnetic resonance imaging, where the intensity of EM precautions is high.



Warning: Use of "CLATUU ALPHA" adjacent to, or stacked with, other equipment should be avoided because it could result in improper operation. If such use is necessary, "CLATUU ALPHA" and the other equipment should be monitored to verify that they are operating normally.



Warning: Use of accessories other than those specified, may result in increased emissions or decreased immunity of this system.



Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12

inches) from any part of the CLATUU ALPHA, including cables specified by Classys Inc. Otherwise, degradation of the performance of CLATUU ALPHA could result.



Caution: The EMISSIONS characteristics of CLATUU ALPHA make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the equipment.



Caution: The "CLATUU ALPHA" has been designed to meet the standards of IEC60601-1-2 for electromagnetic compatibility; however, output can be lost or degraded due to EM disturbances.

3-3-4. Environment

- Main (AC) power quality should be that of typical commercial or hospital environments.
- Flooring should be wood, concrete or ceramic tile. If covered with synthetic material, the relative humidity should be at least 30% to ensure that strong static electricity is not generated.
- Service personnel trained by an authorized Classys Inc. provide regular service during
 the life cycle of equipment to check the environment in terms of EM disturbance and
 to maintain the safe use of the device.

3-3-5. Alert on Environmental Considerations



- Discard the Gel Pad after use to prevent the Gel component from entering the surface or groundwater.
- Recyclable packaging can be recycled.



 Excess amounts of isopropyl alcohol may cause soil, surface or groundwater contamination.

3-4. Safety Symbols

No.	Symbol	Meaning
1	济	Type BF Applied Part
2	~~	Alternate Current
3	SN	Serial Number
4	w	Date of Manufacture
5	***	Manufacturer
6	EC REP	Authorized Representative In The European Community
7	*C 60° Storage Range	Storage Range
8	90%	Relative Humidity
9	1060hPa	Atmospheric Pressure Limits
10	\triangle	Caution
11	<u>^</u>	General warning, caution and risk of danger
12	(3)	Mind instructions for use
13		Pushing prohibited

14		Sitting prohibited
15		Stepping prohibited
16	Ž	Crossed out wheeled bin
17		Protective Earth
18	②	Do not reuse
19	<u>ce</u>	CE marking indicating manufacturer's declaration of compliance with appropriate EU product directives

4. Setting Up for First-Time Use

4-1. Unpacking

The Main Body, Hand-pieces and Cups are shipped in one container.

4-2. Physical Environment

4-2-1. Main Body

The device dimensions are shown in Figure 4.1. To maintain optional efficiency, sufficient space should be allocated in accordance with the indicated installation space shown in Figure 4.1. It is a general expectation that external temperatures of the device will rise when the device is used continuously and should be accounted for. System weight and dimensions are additionally listed in "Specifications" (Refer to Section 8) of this Operation Manual.



Figure 4.1. The required storage area for the CLATUU ALPHA

4-3. Connecting Components

4-3-1. Installing the Monitor

The CLATUU ALPHA Monitor connects on top of the Main Body facing outwards as shown in *Figure 4.2*.

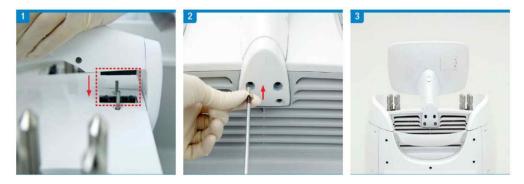


Figure 4.2 Monitor connects to the Main Body

- 1) Align the connectors of both components and press down on the Monitor.
- (2) Insert the four screws with sockets at the base of the Monitor outlet.
- 3 Check that the Monitor is firmly connected as seen from the rear of the Main Body.

4-3-2. Connecting Arm Stands

The CLATUU ALPHA Arm Stands connect to outlets located on opposite ends on top of the Main Body. Each Arm Stand should be facing outwards from the Main Body forming a "V" shape following successful connection as shown in *Figure 4.3*.



Figure 4.3 Arm Stands connect to the Main Body

- 1) The Hand-piece Cable connects from within the base of the Arm Stand.
- 2 Align connectors of both components and press down firmly until a clicking sound occurs.
- ③ Press the button on top of each Arm Stand to adjust the length of the Hand-piece Cable.

4-3-3. Connecting Cups

The Hand-piece is designed for easy exchange of Cups for applying treatments to the skin as shown in *Figure 4.4*.

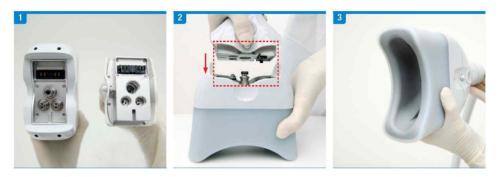


Figure 4.4 Cup connect to the Hand-piece

- 1) The Hand-piece Cable connects from within the base of the Arm Stand.
- ② Align connectors of both components and press down firmly until clicking sound occurs.
- ③ Check that the Cup is firmly connected to ensure that it does not disconnect or malfunction during treatments.

4-3-4. Inserting Water

VENT (top) & 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 as shown in *Figure 4.5*.



Figure 4.5 Inserting Water into the container of the Main Body

- 1 Insert Tube into the VENT outlet opening and place the opposite end in a container.
- ② Pour approximately 1.5 Liters of water into the filter (located on top of Main Body) until water exits from the VENT outlet and into the container.
- (3) Press down on the release button located next to the VENT outlet and remove the Tube.

4-3-5. Connecting the SAT (System Access Token) Card

The SAT Card connects to the Main Body, providing memory to the System that enables all treatment functions of the CLATUU ALPHA. See *Figure 4.6*.

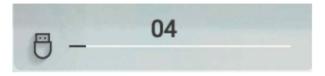


Figure 4.6 SAT Card connects into the USB port

SAT Cards are provided with Pads manufactured specifically for use with the CLATUU ALPHA.

Required for the proper and safe operation of the CLATUU ALPHA.

Remaining Count: 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 functional
If the SAT Card is disconnected during the procedure	Active hand-pieces will stop 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 loading in progress
If the SAT Card has a red light	Error recognized



Caution

- Count deductions are applied two minutes after the start of the procedure.
- In the case Pad is not attached properly, re-application of the Pad should be performed using a new 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.

4-3-6. Turning the System ON

The AC Power Switch is located at the lower rear of the Main Body with the power button located below the Monitor

How to turn the System ON is as follows:

- ① After connecting the AC Power Cable to the Main Body and grounded power source, press the 'I' symbol on the AC Power Switch.
- 2) Press the power button to turn the System ON.
- ③ Wait approx. 5 seconds for the System to load to the Main Graphic User Interface (GUI).

5. System Operation

5-1. Overview of System Functions

5-1-1. Operating Graphical User Interface (GUI)

An overview of this screen is seen in Figure 5.1.

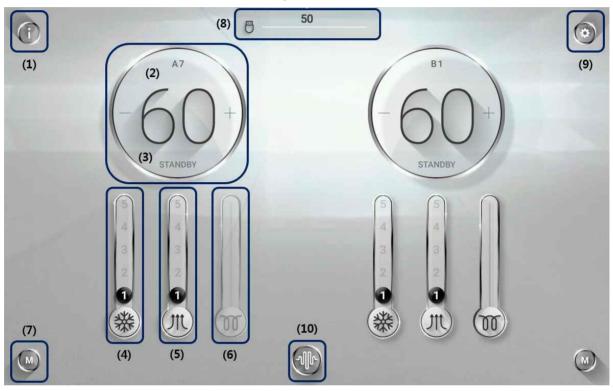


Figure 5.1 Main Body screen in "STANDBY" mode

No.	Sign	Description
(1)	1	Configuration of information of SAT card, CUP ID etc. For details, refer to 5-1-2.
(2)	(60 +)	It displays the ID of the Cup connected to the Hand-piece. (A: Hand-piece A, 7: ID of Cooling Cup)
(2)	A7 - 60 +	The timer is adjustable from 0- 60 minutes using the '-' and '+'buttons on both sides of the timer.

No.	Sign	Description
(3)	A7 C C C C C C C C C C C C C C C C C C C	Display "STANDBY" when not in use
	PROGRESS +	Display "Progress" when in use
		Briefly press the "Cooling" icon to set the steps. Cooling Control from 1 to 5
(4)		Press and hold to disable or enable the "Cooling" function.
	5 4 3 2	Briefly press the "Suction" icon to set the steps. Suction Control from 1 to 5
(5)	(a) (b) (b)	Press and hold to disable or enable the "Suction" function.
		Pre-cooling is used to lower the Cup temperature before the treatment, and the gauge will raise during the pre-cooling operation to reach the target temperature.
(6)		Press and hold to disable or enable the "Pre-cooling" function.

No.	Sign	Description	
(7)	M	When pressing the 'M' button, memory buttons display on the screen as shown below. Save parameter value (Press and hold for 3 seconds to save) Press 1 or 2 or 3 to recall	
(8)	50	Displays Remaining Count (Default: 50) Remaining Count decreases by one for each hand-piece used in treatment. For details, refer to 4-3-5.	
(9)		Configuration of volume control and factory default etc. For details, refer to 5-1-3.	
(10)		Not applicable	

5-1-2. Information Graphical User Interface (GUI)
Information for this screen is seen in *Figure 5.2*.

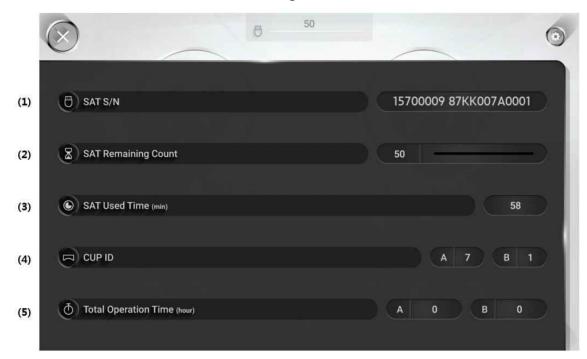


Figure 5.2 Information screen

No.	Sign	Description
(1)	(d) SAT S/N	Displays the information about the serial number of the SAT Card
(2)	SAT Remaining Count	Displays the remaining count number of the SAT Card (Default: 50) Remaining Count decreases by one for each hand-piece used in treatment
(3)	SAT Used Time (min)	Displays the used time of SAT Card
(4)	CUP ID	Displays the ID of each Cup connected on the Hand-pieces.
(5)	(f) Total Operation Time (hour)	Displays the total operation time for each Hand-piece

5-1-3. Settings Graphical User Interface (GUI)
An image of this screen is seen in *Figure 5.3*.

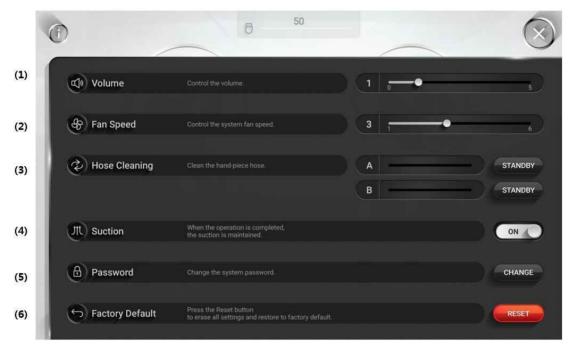


Figure 5.3 Settings screen

No.	Sign	Description		
(1)	(1) Volume	Control the volume from 1 to 5		
(2)	Fan Speed	Control the system fan speed from 1 to 6		
(3)	We describe Hose Cleaning	Cleaning function of each Hand-piece hose		
(4)	JIL Suction	Button to set whether or not to maintain suction function even after timer has finished.		
(5)	Password	Change the system password		
(6)	Sectory Default	Factory default function		

5-2. Treatment Steps

- 5.2.1 Check the list of components required for the procedure.
- 5-2-2. Choose a Cooling Cup and attach the Cup to the Hand-piece.



- 5-2-3. Ensure the AC Power cable on the back of the system is plugged into the wall socket.

 For the safety of patients, operators and electrical safety, you should connect the external ground terminal of the device to a separate ground terminal in the room.
- 5-2-4. Press the 'I' symbol on the AC Power Switch. Then, press the power button to turn the System ON.



- 5-2-5. Ensure that the Remaining Count of the SAT Card is sufficient before proceeding to treatment. For details, refer to the 4-3-5 'Connecting the SAT (System Access Token) Card'.
- 5-2-6. Disinfect the operator's disposable gloves, cups and areas to be treated with alcohol.

 Ensure the treatment area has been cleansed thoroughly.
- 5-2-7. Apply the CLATUU SHIELD 360 Pads or ALPHA SHIELD Pads or Matrix Gel Pad to be aligned with the marked treatment area. (Refer to 3-2-5, 3-2-6)

5-2-8. Cooling Cup is attached so that it is perpendicular to the center of Pads. Avoid contact with bones prevent freeze burn.

Check the patient's comfort and support the treatment area with a cushion to secure the cup.



- 5-2-9. Set parameters manually for treatment by adjusting the buttons on the GUI.
- 5-2-10. Press one button on the Hand-piece for 2 seconds to operate the device.

When the procedure is performed, the screen changes from 'STANDBY' to 'PROGRESS', and an animation is displayed on the background screen displaying the timer.

To prevent freeze burn, make sure that the Pad occupies a larger area than the cooling cup.

When the time has elapsed, the icon will change to OPERATION COMPLETE as shown below.



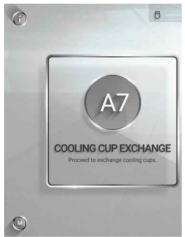




5-2-11. In order to change the Cup, press both buttons on the Hand-pieces in STANDBY mode as shown in the steps below.



(1) Simultaneously press the two buttons on both sides of the Hand-piece for 2 seconds. LED signal displays a yellow light.



(2) The LCD screen will indicate 'COOLING CUP EXCHANGE'.



(3) Press the latch to detach the Cup from the Handpiece.



(4) The LCD screen will indicate 'COOLING CUP DETACHED'.



(5) When the Cooling Cup is reconnected to the Handpiece the LCD screen will indicate 'COOLING CUP ATTACHED'.

5-2-12. After the treatment, remove the Cup and ensure the Hand-piece is mounted on the holder.



5-2-13. Remove the Pads attached to the treatment area.

Use a towel soaked in warm water to remove any gel on the skin.



Warning

Side effects such as erythema and numbness may occur after treatment of pseudogynecomastia. Therefore, applying a massage to the treatment area at least 2 minutes after completion of treatment to alleviate those side effects.

5-3. Shutting Down the System

- 5-3-1. Turn off the equipment by pushing the power button located on the monitor.
- 5-3-2. The AC Power Switch on the rear of the Main Body should be facing down in the ON position; however, it may be switched OFF when moving the equipment between rooms or for storage or cleaning.
- 5-3-3. Follow cleaning and storage guidelines in Section 7.

** The treatment progress stops and automatically switches to "STANDBY" from "PROGRESS", when the procedure is complete. When pausing the treatment, press one button on the Hand-piece for 2 seconds.



Gel Pads are for single use only, disposable and non-sterile.



Warning

Please use genuine products provided by Classys Inc.

Do not alter Gel Pads by cutting or forcibly stretching.

6. System Messages

The CLATUU ALPHA is designed with an internal checking system to ensure that all aspects of the device are functioning properly. Please follow the instructions and refer to the information listed below when errors occur.



Info Code	Message Displayed	Description & Corrective action
HP System Error - HC	E-HC:0000001 Turn the system OFF and ensure the hand-pieces are connected properly.	HP Communication Error Turn the system OFF and ensure the hand- pieces are connected properly.
HP System Error - FS	E-FS:0000001 Turn the system OFF and ensure the hand-pieces are connected properly.	Flow Sensor Error Turn the system OFF and ensure the hand- pieces are connected properly.

Info Code	Message Displayed	Description & Corrective action	
HP System Error - DT	E-DT:0000003 Restart the system. If the error persists, contact your local distributor or manufacturer.	TEC Error 1. Restart the system. 2. If the problem persists please contact your local distributor or Classys Inc.	
Cooling System Error - WL	E-WL:0000001 The cooling water level is not suffice. Refer to proper instructions in the manual and insert additional water to the system.	Cooling Water Level Error 1. The cooling water level is not sufficient. 2. Add more water.	
Cooling System Error - WP	E-WP:0000001 Restart the system. If the error persists, contact your local distributor or manufacturer.	Water Pump Error 1. Restart the system. 2. If the problem persists please contact your local distributor or Classys Inc.	
Cooling System Error - CF E-CF:000000C4 Restart the system. If the error persists, contact your local distributor or manufacturer.		Cooling Fan Error 1. Restart the system. 2. If the problem persists please contact your local distributor or Classys Inc.	
Main System Error - DO	E-DO:00000002 Restart the system. If the error persists, contact your local distributor or manufacturer.	SMPS Dc Output Error 1. Restart the system. 2. If the problem persists please contact your local distributor or Classys Inc.	

Info Code	Message Displayed	Description & Corrective action	
Main System Error - RD	E-RD:0000001 Restart the system. If the error persists, contact your local distributor or manufacturer.	Relay board Detect Error 1. Restart the system. 2. If the problem persists please contact local distributor or Classys Inc.	
Main System Error - BC	E-BC:0000001 Restart the system. If the error persists, contact your local distributor or manufacturer.	Base board Communication Error 1. Restart the system. 2. If the problem persists please contact local distributor or Classys Inc.	
HP system Caution - OL	E-OL:0000001 The oil tank is full. Please empty the conents before proceeding.	Oil Level Caution 1. The oil tank is full. 2. Please empty the contents before proceeding.	
Cooling system Caution - WT	E-WT:0000002 The cooling system temperature is unstable. Keep the system ON and wait for the temperature to stabilize.	Cooling Water Temperature Caution 1. The cooling system temperature is unstable. 2. Keep the system ON and wait for the temperature to stabilize.	
Cooling system Caution - CT E-CT:00000001 The cooling system temperature is unstable. Keep the system ON and wait for the temperature to stabilize.		Chiller Radiator Temperature Caution 1. The cooling system temperature is unstable. 2. Keep the system ON and wait for the temperature to stabilize.	
Cooling system Caution	& W & W DT3	Cooling Water Filter Caution Replace the Cooling Water Filter.	

Info Code	Message Displayed	Description & Corrective action	
NO SAT	SAT ERROR The System Access Token is not inserted. Insert a token to operate the system.	The System Access Token is not inserted. Insert a token to operate the system.	
OUT OF SAT	SAT ERROR The current System Access Token has expired, insert a loaded token to operate the system.	The current System Access Token has expired. Insert a loaded token to operate the system.	
INVALID SAT SAT ERROR The System Access Token is invalid. Insert a valid token to operate the system.		The System Access Token is invalid. Insert a valid token to operate the system.	

7. Cleaning and Storage

7-1. Cleaning the Main Body, Hand-pieces and Cooling Cups

7-1-1. Main Body

Turn OFF the AC Power Switch on the rear of the Main Body when not in use.

After use, apply 50-70% isopropyl alcohol on a soft cloth and proceed to clean, wipe the smudges and dirt from the exterior body. Be careful not to let liquids seep inside the equipment.

After the treatment, remove the oil even if the oil caution level alert is not on. It is recommended to remove oil as soon as possible.

7-1-2. Hand-pieces and Cups

Hand-pieces and Cups are packaged and shipped non-sterile and ready to use.

Due to the fact that the Cups come in contact with the patient's skin, the standard practice for low level disinfection and cleaning of Cups between usages is to gently but thoroughly wipe the Hand-pieces and Cups with a standard 50-70% isopropyl alcohol prep pad. Clean the Hand-piece cable using alcohol.



Warning

Be careful not to let the isopropyl alcohol get into the drain hole due to careless handling of the isopropyl alcohol container. Excess amounts of isopropyl alcohol may cause contamination of soil, surface or groundwater.

7-2. General Care of the System

To accomplish the highest performance of the device, treat the equipment carefully by adhering to the following guidelines:

- 1. Regularly inspect the Hand-piece, connectors and Cups for any problems.
- 2. Do not drop the Hand-pieces and Cups on the floor or other hard surfaces.
- 3. Do not twist or pull the Hand-piece cables. This could cause damage to internal wires and connections.
- 4. The CLATUU ALPHA must be used only with the authorized "CLATUU SHIELD 360 Pads" or "ALPHA SHIELD Pads" or "Matrix Gel Pads". Other pads, lubricants or lotions, particularly mineral oil could eventually damage the Main Body, Hand-pieces or Cups.
- 5. Apply the Cups to the Gel Pads and wipe any remaining gel from the Cups after completing a treatment. Avoid getting the gel on the Cups, Hand-pieces or the Main Body.
- 6. Cups should be cleaned between procedures. See cleaning procedure information in subsection 7-1.

7-3. Draining Oil

Proceed when error message is displayed as shown.

Ensure the System turned OFF and the Main Body casters are in the locked position before proceeding.

Please wait 10 - 15 min. for approximately 200 ml of oil to drain completely from the System as shown in Figure 7.1.



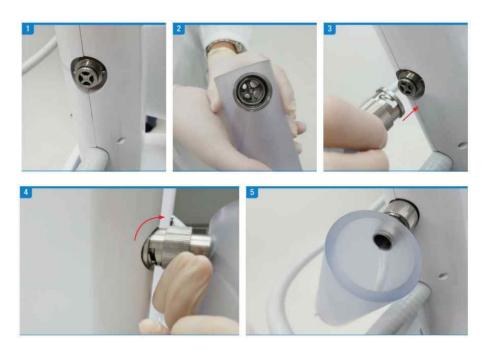


Figure 7.1 Draining Oil

- 1 Check the outlet of the Oil Receiver located behind the Arm Stand.
- (2) Prepare to connect the Oil Receiver to the outlet.
- (3) Align and insert the input of the Oil Receiver into the outlet.
- 4 After the input of the Oil Receiver is inserted into the outlet, turn the input right to ensure a firm connection.
- (5) 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 successful drainage, remove the Oil Receiver from the Arm Stand in reverse sequence.

7-4. Movement, Storage and Disposal

7-4-1. Movement

- Handle the CLATUU ALPHA with caution at all times.
- Unlock the Main Body casters and use the knob to move the equipment to the desired site.
- It is required to have more than one person to move the system.

7-4-2. Storage

Please store the CLATUU ALPHA in an environment where the conditions are as follows:

• Temperature: 5°C - 60°C

• Relative Humidity: 0% - 90%

• Air Pressure: 500hpa - 1060hPa

7-4-3. Disposal

- Electric and electronic equipment must not be disposed of together with household waste.
- The user is obligated to dispose of a broken redundant electrical or electronic device at a dedicated collection location and put it in a special container.



The details are set forth based on the relevant national laws. The obligation is indicated on the product label or in the manual in the form of a crossed-out waste bin. By sorting waste for recycling, you help to protect the national environment.

8. Specifications

8-1. Specifications table

No.	Performance	Specifications
1	Product Name	Cooling Therapeutic Equipment
2	Trade Name	CLATUU ALPHA
3	Model Name	CL5-M500
4	Electrical Requirement	220-240V~, 50/60Hz
5	Classification of Applied Parts	Type BF
6	Electric Power consumption	1600VA
7	Display	10.1" LCD Touch Screen
8	Dimension	705(D) X 500(W) X 1520(H) mm
9	Weight	90kg
10	Cups (Optional)	WING, FLAT, WING PLUS, WING MINI, FLAT MINI, WING MAX ARC-T, ARC-A
		[Operating Environment] - Temperature: 10°C - 35°C - Relative Humidity: 0% - 90%
11	Environmental	- Air Pressure: 700hpa - 1060hPa
		[Shipping and Storage] - Temperature: 5°C - 60°C
		- Relative Humidity: 0% - 90% - Air Pressure: 500hpa - 1060hPa

Appendix A. Electromagnetic Emissions and Immunity

Manufacturer's declaration - electromagnetic emission

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Manufacturer's declaration - electromagnetic immunity

The CLATUU ALPHA is intended for use in the electromagnetic environment specified below. The User or Licensee of the CLATUU ALPHA should assure that it is used in such an environment.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic Environment -guidance
Electrostatic discharge (ESD) IEC 61000-4-2	8 kV Contact 15 kV Air	8 kV Contact 15 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %
Electrical fast Transient / burst IEC 61000-4-4	2kV for power supply lines 1kV for input/output lines	2kV for power supply lines 1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	1 kV differential mode 2 kV common mode	1 kV differential mode 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60Hz) Magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

The CLATUU ALPHA is intended for use in the electromagnetic environment specified below. The User or Licensee of the CLATUU ALPHA should assure that it is used in such an environment.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic
		•	Environment -guidance
Voltage dips, short Interruptions and Voltage variations on power supply input lines IEC 61000-4-11	0% <i>U</i> τ (100% dip in <i>U</i> τ) for 0.5cycle (at 0, 45, 90, 135, 180, 225, 270 and 315) 0% <i>U</i> τ (100% dip in <i>U</i> τ) for 1cycle 70% <i>U</i> τ (30% dip in <i>U</i> τ) for 25 cycle (at 0)	0% <i>U</i> T (100% dip in <i>U</i> T) for 0.5cycle (at 0, 45, 90, 135, 180, 225, 270 and 315) 0% <i>U</i> T (100% dip in <i>U</i> T) for 1cycle 70% <i>U</i> T (30% dip in <i>U</i> T) for 25 cycle (at 0)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the CLATUU ALPHA requires continued operation during power mains interruptions, it is recommended that the CLATUU ALPHA be powered from an uninterruptible power supply or a battery
	0% <i>U</i> т (100% dip in <i>U</i> т) for 250 Cycle	0% <i>U</i> т (100% dip in <i>U</i> т) for 250 Cycle	
Conducted RF IEC 61000-4-6	3 V 150 kHz to 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz	3 V 150 kHz to 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz	-
Radiated RF IEC 61000-4-3	3 V/m 80.0 MHz to 2.7 GHz	3 V/m 80.0 MHz to 2.7 GHz	Recommended separation distance $E = \frac{6}{d} \sqrt{P}$ Where P is the maximum power in W , d is the minimum separation distance in m , and E is the IMMUNITY TEST LEVEL IN V/m .

Note 1) U_T is the A.C. mains voltage prior to application of the test level.

Note 2) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the EUT is used exceeds the applicable RF compliance level above, the EUT should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the EUT.



OPERATION MANUAL (Ver. 1.2, April. 2021)



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