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CLATUU™

OPERATION MANUAL

Ver. 1.0



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CLATUU_(CL2-M360)

The “CLATUU” is intended for use only by properly trained physicians and properly trained persons under the supervision of such a trained physician (Henceforth “the User”).

Prior to operating the system, the user must thoroughly read and understand this manual. Improper use of the system may cause personal injury and/or damage to the system that may invalidate the warranty agreement.

Note: This user manual describes the operation of the “CLATUU” only. It is not a substitute for the required clinical training on the procedure that utilizes the system.

CLATUUTM

OPERATION MANUAL (Ver. 1.0)

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1. Introduction to Manual

1-1. Purpose

This User’s Manual provides a description of the System components, its controls and displays, instructions for its operation, and other equipment information important to the user.

Warning: Do not operate the “**CLATUU**” before reading this manual thoroughly and being trained on the clinical procedure by an authorized Classsys Inc. representative. This manual is not a substitute for clinical treatment guidelines and training provided by the Company.

1-2. Conventions




Caution: Cautions alert the user to precautionary steps necessary to properly operate the system. Failure to observe these cautions 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.

All procedures are broken down by numbered steps. Steps must be completed in the sequence they are presented.

Bulleted lists indicate general information about a particular function or procedure. They do not imply a sequential procedure.

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2. Medical Safety

2-1. Indications for Use

The **“CLATUU”** is indicated for:

This device is cooling therapeutic equipment. This device is indicated for minimize pain, thermal injury and prevention of edema during laser and dermatological treatments.

2-2. Contraindications


The **“CLATUU”** is contraindicated for use in patients with vulnerable wounds and Cryoglobulinemia and Paroxysmal Cold Hemoglobinuria.

2-3. Precaution

When not in use by trained personnel, the **“CLATUU”** User Key should be removed from the system to help prevent unauthorized use. Keep the **“CLATUU”** User Key in a designated place accessible only to authorized and trained personnel.

The **“CLATUU”** has not been evaluated for use in the following patient populations:

- Pregnant or breast feeding women
- Experienced microdermabrasion
- Heart disease
- Bleeding disorders treatment

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2-4. Patient Safety



Warning: Use this system only if you are trained and qualified to do so.



Warning: If any problems occur during system operation, take immediate action(s):

Press the Emergency Switch, or turn off the key switch whit anti-clock wise.

2-5. Potential Side Effects


Side effects reported in the clinical evaluation of the “**CLATUU**” were mild and transient in nature. These were limited to:

- Mild pain would be felt in the treatment area during the procedure.
- Bruising could be occur at the treated area after the procedure. (Bruises disappear within four days after the procedure)
- Affected area may feel itch temporarily.
- Blunt senses can be felt at the affected area temporarily.
- Stiffness can be felt in the affected area temporarily.
- Please requires attention because patient may experience transiently pain, frostbite, scab and minor nerve after the operation.

2-6. Complaints and Adverse Events

No serious adverse events were observed at the “**CLATUU**”.

Classsys Inc. follows MDR (Medical Device Reporting) rules for handling complaints and adverse events. Should an adverse event be suspected or reported, contact Classsys Inc. at the number on the cover page of this document: for those outside the Rep. of Korea, contact your local Classsys Inc. representative.

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3. System Overview

3-1. System Description

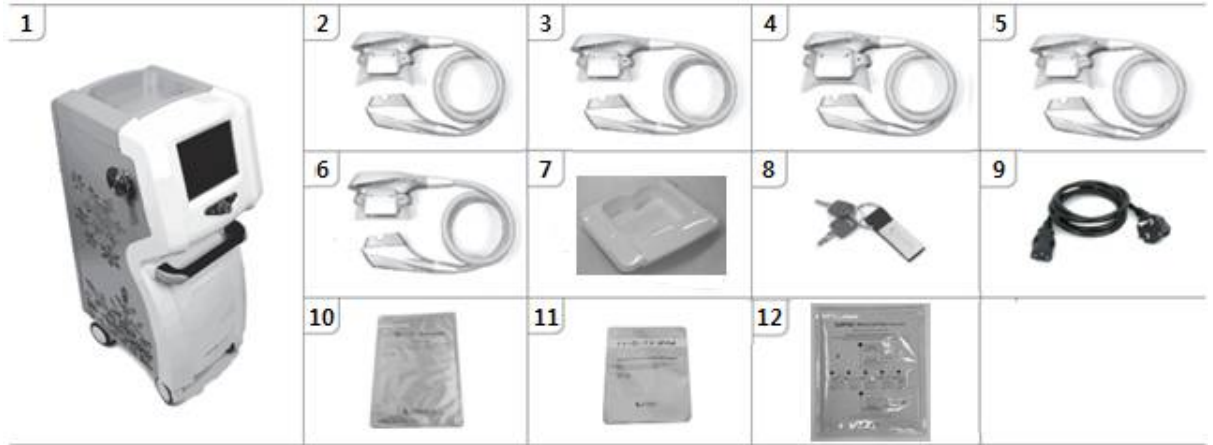
The “CLATUU” is cooling therapeutic equipment. This device is indicated for minimize pain, thermal injury and prevention of edema during laser and dermatological treatments.

The optional function is used to reduce the fat and cellulite for chronic obesity using non-invasive cold-assisted lipolysis of the body.

Precisely controlled energy extraction(cold) from the treatment area. This cooling of the body surface treats pain and non-invasive lipolysis of the body without damage to other tissue types.


3-2. System Components and Features

The “CLATUU” is consisted of primary components as shown in the *Figure 3.1*: the main body unit with integrated touchscreen, the hand-piece with cable, Matrix Gel Pad, and OP Pad (see *Figure 3.1*).



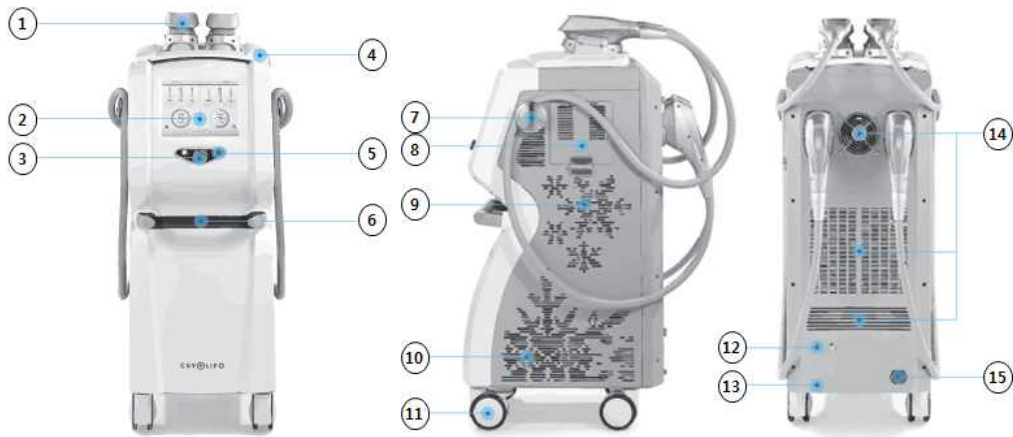
No.	Item	No.	Item	No.	Item
1	Main body	2	Hand-piece(Wing type)	3	Hand-piece(Flat type)
4	Hand-piece (Wide type-Option)	5	Hand-piece (New Wing type-Option)	6	Hand-piece (New Flat type-Option)
7	Hand-piece Holder	8	Power Key	9	AC Power Cord
10	CLATUU Matrix Gel Pad	11	CLATUU OP Pad	12	CLATUU Matrix Gel Pad (Tray version-Option)

Figure 3.1 Main components of the “CLATUU”

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3-2-1. Main body

The Main Body is the information center for the “CLATUU”. It houses the touchscreen monitor (10.4inch LCD) and Graphical User Interface (GUI) that allows the user to interact with the device. This screen sets and displays the operating conditions, including equipment activation status, treatment parameters, system messages and prompts. *Figure 3.2* illustrates the physical features of the Main body, such as the connector ports and power controls.




No.	Item	No.	Item	No.	Item
1	Hand-piece (with 4.3inch LCD)	2	10.4inch LCD (GUI)	3	Emergency Switch
4	Hand-piece Holder	5	ON/OFF Key Switch	6	Knob
7	Hand-piece Cable Holder	8	Oil Drain Cover	9	Vents
10	Fan / Vents	11	Caster	12	Water Inlet
13	Water Outlet	14	Fan / Vents	15	Power Inlet

Figure 3.2 Main body front, side and rear view.

On the rear of the main body is a Hand-piece connector receptacle that interfaces with the Hand-piece cable. Below the monitor, on the front panel is an **ON/OFF** Key switch.

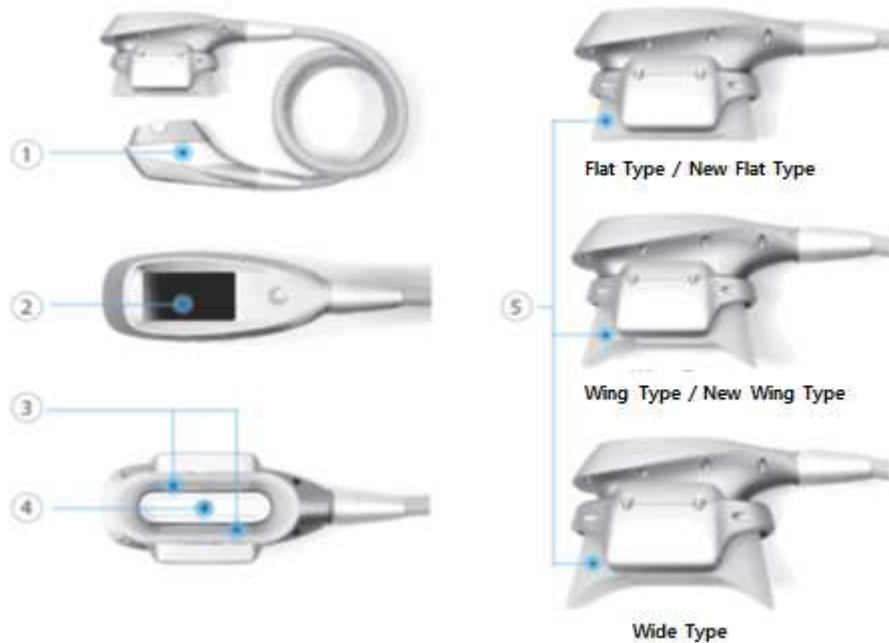


Warning: When not in use by trained personnel, the “CLATUU” User Key of key switch should be removed from the system to help prevent unauthorized use. Keep the “CLATUU” User Key of key switch in a designated place accessible only to authorized and trained personnel

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3-2-2. Hand-piece

The Hand-piece is a 4.3inch LCD touch screen with “STANDBY / PROGRESS” button on one end and an electrical cable for attachment to the control system on the other end. The Hand-piece has 4.3inch LCD touch screen: deliver therapy. *Figure 3.3* provides two views of the Hand-piece.



No.	Item	No	Item	No	Item
1	Hand-piece Connector	2	4.3inch LCD touch screen	3	Cooling Plate
4	Suction Inlet	5	Probe		


Figure 3.3 Hand-piece top, bottom, and side views.

3-2-3. Essential Accessories

Make sure to use “Matrix Gel Pad” during treatment.

Make sure to use “OP Pad” to prevent the gel to be absolved to the Hand-piece during treatment.

Other essential components provided for operation of the “**CLATUU**” are the power cord that connects the “**CLATUU**” to an AC power outlet, and the Power Key of switch

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4. System Safety

The following precaution and warnings must be reviewed and observed:

4-1. Electrical and Fire Safety



Warning: To avoid risk of electric shock, always inspect Hand-piece and cable before use. Do not use a damaged cable that has been damaged or is leaking fluid.

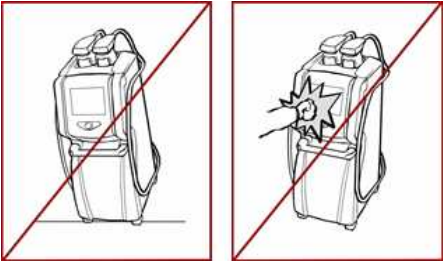
Power supply must be AC 200 – 240VAC, 50/60Hz to operate the system safely.




The “**CLATUU**” is intended for indoor, dry location use. Avoid liquid spills and splashes. Do not place the system in the condition of direct sun light, high humidity and nearby heater.

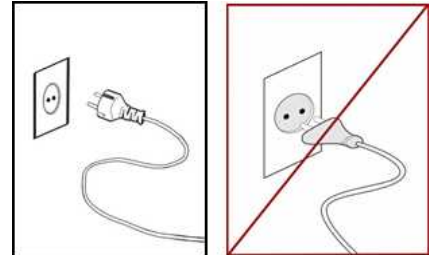


Do not lean over the system obliquely. And do not give to external shocks to the system.



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The “**CLATUU**” comes with a three-conductor AC power cord and plug. Use a properly grounded outlet and always plug the “**CLATUU**” directly into the outlet. Never remove the ground conductor or compromise the ground conductor via any AC adapter plugs or extension cords.



Disconnect the power cord from the outlet by pulling on the plug not the cord.

Do not touch the power cord with wet hand.

Turn off the AC power switch and disconnect the AC power supply before cleaning the main body.


Do not remove the covers on the main body or Hand-piece; the main body contains hazardous voltages. The “**CLATUU**” contains no user-serviceable components. If the system requires service, contact Classsys Inc..

No modification of this equipment is allowed.



The “**CLATUU**” should not be used near flammable gases or anesthetics. Fire or explosion can result. The “**CLATUU**” is not AP or APG rated.

Avoid restricting ventilation under and behind the main body. Maintain an open space of at least 20cm around the main body. If ventilation holes are obstructed, the system could overheat.

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The Hand-piece 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.

To avoid a burn hazard, remove the Hand-piece from the patient before performing HF electrosurgical procedure.



Warning: Please follow the direction below if the system does not turn on.

- Ensure the key switch is in the ON position.
- If the problem still occurred, unplug the power cord.
- Pull the fuse holder below the power Inlet.
- Replace the fuse(250V 10A).
- If the problem still occurred, please contact the Classys Inc. support.

4-2. Equipment Use and Care




Caution: Failure to observe these precautions may void the warranty.

The Hand-piece connectors must be kept clean and dry. Do not use the Hand-piece connector if the connectors have been immersed in liquid. See the instructions for cleaning the Hand-piece.

Every effort has been made to make the Hand-pieces as rugged as possible; however, they may be permanently damaged if dropped onto a hard surface or if the membrane is punctured. Hand-pieces damaged in this manner are not covered by the warranty.

The “**CLATUU**” has no user-serviceable components except the fuse. Do not attempt to open the main body enclosure or Hand-pieces. Contact Classys Inc. if service is required.

When not in use by trained personnel, the “**CLATUU**” User Key should be removed from the system to help prevent unauthorized use. Keep the “**CLATUU**” User Key in a designated place accessible only to authorized and trained personnel.

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4-3. Electromagnetic Compatibility and Immunity

The RF of “**CLATUU**” emissions are very low and are not likely to cause interference in nearby electronic equipment.

The “**CLATUU**” is suitable for use in all establishments other than domestic and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.

Mains (AC) power quality should be that of a typical commercial or hospital environments.

Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30% to avoid excessive static electricity.



Warning: The “**CLATUU**” should not be situated adjacent to, or stacked with, other electronic equipment. If the system must be installed in close proximity to other equipment, both the “**CLATUU**” and the nearby equipment should be observed to verify normal operation in that configuration.


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



















Caution: The “**CLATUU**” has been designed to meet the standards of IEC60601-1-2 for electromagnetic compatibility; however some computer equipment unintentionally emits strong interfering RF signals. Portable RF communication devices may also affect “**CLATUU**”.


4-4. Disposal

Depleted “Matrix Gel Pad” and “OP Pad” should be disposed of in accordance with federal, state, and local regulations.

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4-5. Safety Symbols


No	Symbol	Meaning
1		Type BF Applied Part
2		CE marking indicating manufacturer's declaration of compliance with appropriate EU product directives
3		Date of Manufacture
4		Serial Number
5		Manufacturer
6		Authorized Representative in The European Community
7		Alternate Current
8		Refer to instruction manual
9		Pushing prohibited
10		Sitting prohibited
11		Stepping prohibited
12		Crossed out wheeled bin
13		Caution
14		General warning sign
15	STOP	Emergency Switch
16		Protective Earth
17		Do not re-use



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4-6. Labeling







Cooling Therapeutic Equipment

Model: CL2-M360
Rating: 200-240V ~ 50/60Hz
1250VA
Weight: 92kg



0470





Please read user's manual carefully before use.



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5. Setting Up for First-Time Use

5-1. Unpacking

The main body and Hand-pieces are shipped together in one container.


5-2. Physical Environment

5-2-1. System Base

The entire area for the device is shown in *Figure 5.1*. To maintain optional efficiency, space should be allocated in accordance with the indicated installation space as *Figure 5.1*. System weight and dimensions are listed in 9. Specifications.



Figure 5.1 The entire area for the “CLATUU”

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5-2-2. Electromagnetic Environment

The System is not likely to cause interference in nearby electronic equipment; however, other electronic equipment should not be stacked or placed immediately adjacent to the System.

Flooring should be wood, concrete or ceramic tile. If covered with synthetic material, the relative humidity should be at least 30%.



Warning: The **“CLATUU”** should not be situated adjacent to, or stacked with, other electronic equipment. If the system must be installed in close proximity to other equipment, both the **“CLATUU”** and the nearby equipment should be observed to verify normal operation in that configuration.



Caution: The **“CLATUU”** has been designed to meet the standards of IEC60601-1-2 for electromagnetic compatibility; however, some computer equipment unintentionally emits strong interfering RF signals. Portable RF communication devices may also affect the **“CLATUU”**.

5-3. Electrical Requirements

The **“CLATUU”** has an international power supply and may be used with 200-230 VAC, 50/60 Hz power systems. See Section 4-1. Electrical and Fire Safety for additional information.

5-4. Connecting Components

5-4-1. Connecting the Hand-piece

The Hand-piece connector receptacle is located on the rear of the main body as shown in *Figure 5.2*.

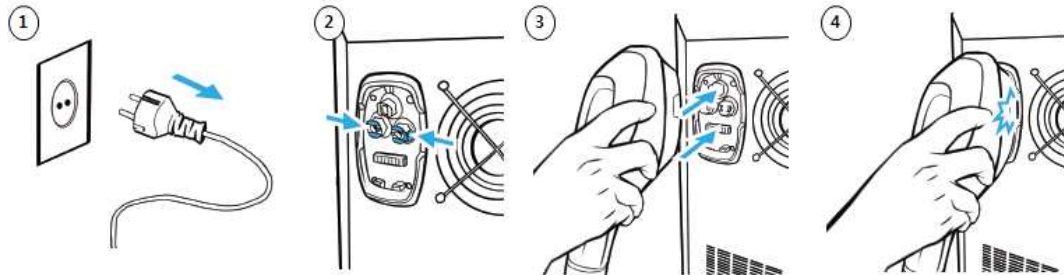
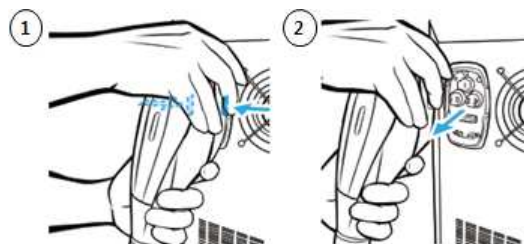


Figure 5.2 Hand-piece Connector Receptacle and Hand-piece

- ① Pull out a Power cord.
- ② Release a connector and coupling at the original position as shown in *Figure 5.2*.
- ③ To attach the Hand-piece connector, align it with the Hand-piece cable facing down and push it into the receptacle.
- ④ It will latch when seated properly.

※ Disconnect the Hand-piece



- ① Press the connector switch on both sides.
- ② Take out the Hand-piece.

5-4-2. Water injection

Coolant is injected through the water inlet in the rear of the main body.



Caution: Working with the power cord removed.

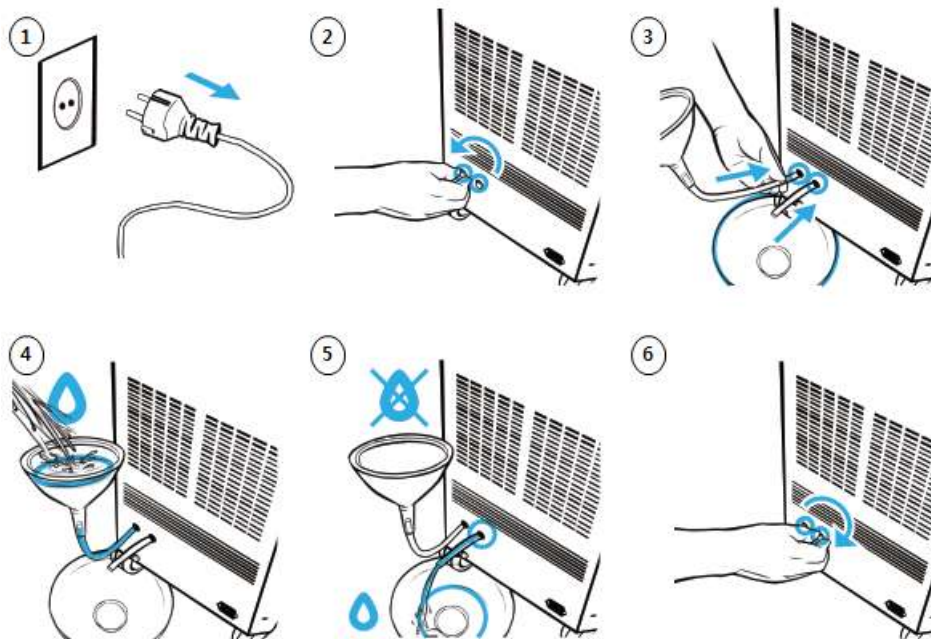



Figure 5.3 Method of water injection

- ① Pull out a Power cord.
- ② Turn the two of water inlets on rear main body around anticlockwise to open it.
- ③ Insert a water funnel to one of water inlet holes.
- ④ Fill up water using funnel.
- ⑤ Stop filling water up when water flows out the other water inlet hole.
- ⑥ Lock the water inlets. (Turn it around clockwise)

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5-4-3. Connect the power cord

Insert the main power cord to the system until the power supply is secured.




5-4-4. Trial Test

Turn the key switch clockwise to “ON” and after about 10 seconds anticlockwise to “OFF”. Repeat 2~3 times this procedure to remove the water flow error message on the display.



Fill up the water into the water tank. (Refer to 5-4-2. Water injection)

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6. System Operation

6-1. Overview of System Functions

6-1-1. Operating Graphical User Interface (GUI) – Main body

The Settings function allows you to change general system settings and to recall parameters setting value of save existing.

An overview of this screen is seen in *Figure 6.1*.

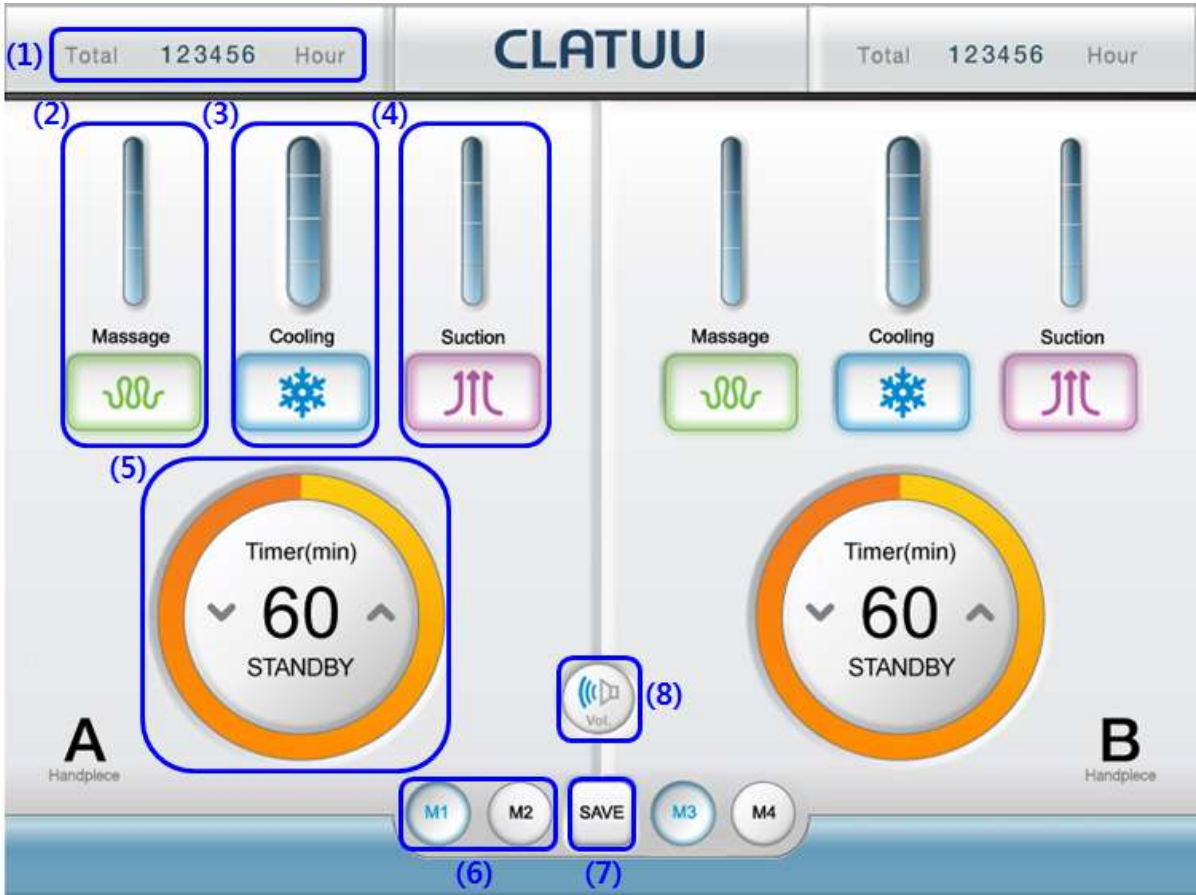


Figure 6.1 Main body screen in “STANDBY” state (See Table 6.1 for description)






























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Table 6.1 Main body screen Description

No	Sign			Description
1				Total accumulated time
2		ON		Massage time Step 1
				Massage time Step 2
		OFF		Massage time Step 3
3		ON		Cooling Step 1
				Cooling Step 2
		OFF		Cooling Step 3
				Cooling Step 4
4		ON		Vacuum Pressure Step 1
				Vacuum Pressure Step 2
		OFF		Vacuum Pressure Step 3
				Vacuum Pressure Step 4

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5		STANDBY		Down in one-minute decrements
		PROGRESS		Up in one-minute increments
6				Hand-piece A : Recalling the pre-set
				Hand-piece B : Recalling the pre-set
7				Save user setting value
8				Sound value setting Mute / Vol. 1 / Vol. 2 / Vol. 3

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6-1-2. Operating Graphical User Interface (GUI) – Hand-piece

Display screens that are set on the Main screen. This interface can't select the mode. This interface can only select "STANDBY" or "PROGRESS".

An overview of this screen is seen in *Figure 6.2*.

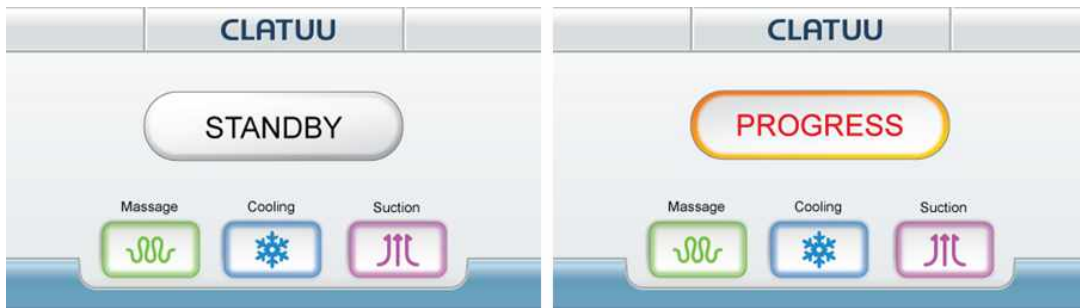











Figure 6.2 Hand-piece screen in "STANDBY" state (See Table 6.2 for description)

Table 6.2 Hand-piece screen Description

No	SIGN		Description
1		ON	Massage setting display
		OFF	
2		ON	Cooling setting display
		OFF	
3		ON	Suction setting display
		OFF	
4			Ready for operation status
			Press and hold this button for 3 sec to operate
			Operating status
			Press and hold this button for 3 sec to stop

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6-2. Activating the Main Body

6-2-1. Ensure the power cord on the back of the system is plugged into wall socket.

For the safety of patients, operators and electrical safety, you should connect the external ground terminal of the device to the separate ground terminal in the room.

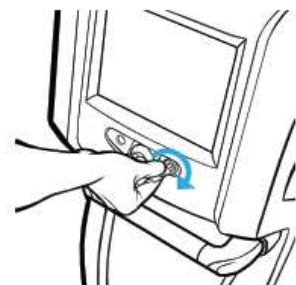



Warning: While running, this switch should not be used to shut down the system.

6-2-2. Insert the “**CLATUU**” User Key into the Key switch on the front of the main body.

The “**CLATUU**” must be used only with the authorized “**CLATUU**” User Key.

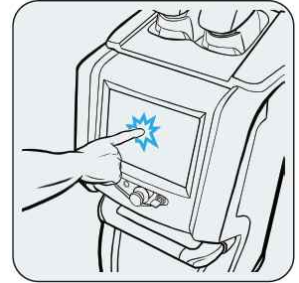
6-2-3. Turn the key switch provided from Classys Inc. clock wise to “ON”.



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6-3. Treatment Steps

6-3-1. Set the parameter.



6-3-2. Ensure the treatment area have been cleansed thoroughly.

6-3-3. **“CLATUU”** exclusive CLATUU Matrix Gel Pad fitted well to the affected area.




6-3-4. Please stick to CLATUU OP Pad on the CLATUU Matrix Gel Pad as a below figure. (Make sure the position of the CLATUU Matrix Gel Pad should be matched with the line of the CLATUU OP Pad correctly)



6-3-5. Please apply a gel from a package of the CLATUU Matrix Gel Pad to the CLATUU OP Pad evenly.



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6-3-6. Please stick to other CLATUU OP Pad on the CLATUU OP Pad as a side figure.

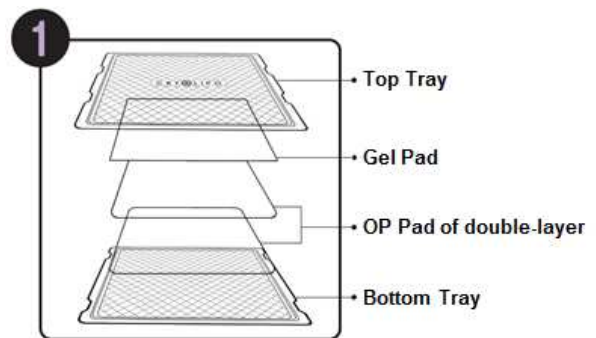


6-3-7. Please apply a gel from a package of the CLATUU Matrix Gel Pad to the CLATUU OP Pad evenly.

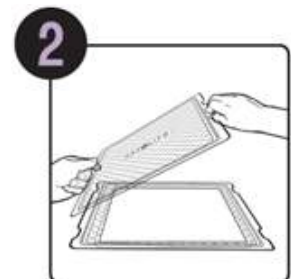



※ When use the CLATUU Matrix Gel Pad(Tray version), please refer to the following sequence. (6-3-3. ~ 6-3-7)

6-3-3. The contents of the CLATUU Matrix Gel Pad (Tray version) is like this picture.

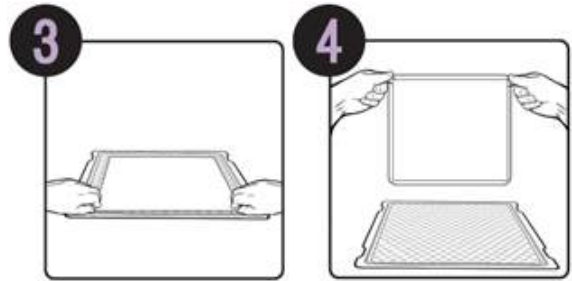


6-3-4. Check the contents by opening the plastic tray cover.



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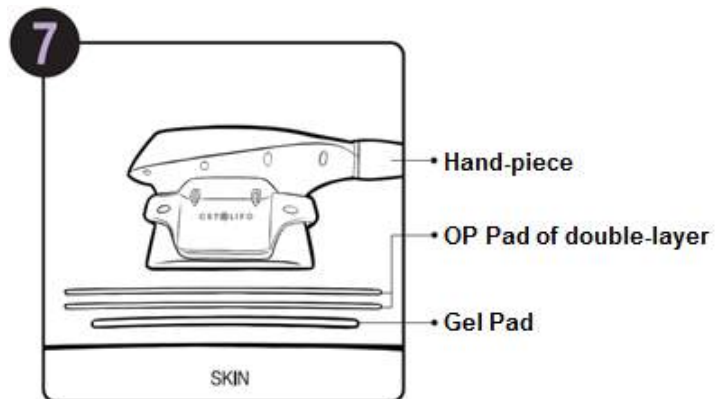
6-3-5. Hold the CLATUU Matrix Gel Pad and CLATUU OP Pad together. And take out contents inside plastic tray container.




6-3-6. Place it by attaching the CLATUU Matrix Gel Pad on the skin.

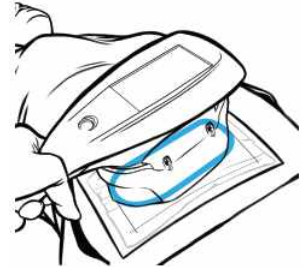


6-3-7. Be sure to place CLATUU Matrix Gel Pad bottom and CLATUU OP Pad on the top position.



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6-3-8. Hand-piece parts of silicone are attached so that it is perpendicular to the center of CLATUU OP Pad.



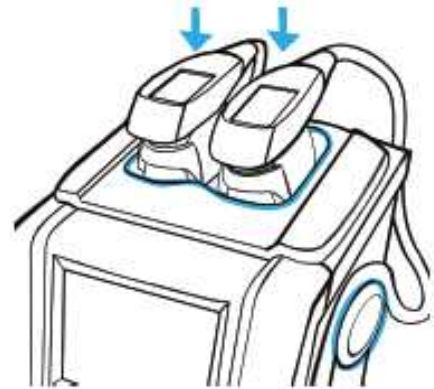
6-3-9. "STANDBY" button of Hand-piece LCD screen press for 3 seconds.



- ※ The behavior stops and automatically switched to "STANDBY" from "PROGRESS", when the procedure is complete. Also, USER can stop the operation from Emergency switch when any error occurs. (When you stop a while "PROGRESS" button of Hand-piece LCD screen press for 3 seconds)

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6-3-10. After the treatment the Hand-piece mounted on the Hand-piece holder as below figure.




6-4. Shutting Down the System

6-4-1. Turn off the key switch with anti-clock wise and remove the “**CLATUU**” User Key to prevent unauthorized usage.





6-4-2. Follow cleaning and maintenance instructions in Section 8.

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7. System Messages

The “**CLATUU**” is designed with internal checks to ensure that all aspects of the device are functioning appropriately. Please follow the instructions refer to the information listed below.


7-1. Is filled with oil

Symptom	Icon
 Is filled with oil <small>Please refer to troubleshooting guide in the operation manual</small>	 OIL



⇒ Oil is full - Remove the oil from the oil tank

<p>① Pull out a Power cord.</p>	<p>② Open the oil cover at right side. (Turn anticlockwise)</p>
<p>③ Open the oil valve. (Push it down)</p>	<p>④ Lock the oil valve. (Pull it up)</p>
<p>⑤ Pull out the oil tank and empty it.</p>	<p>⑥ Close the oil cover. (Turn clockwise)</p>

⑦ If the problem persists please see the User’s Manual for further information or contact Classsys Inc. Support.

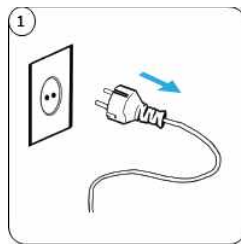
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7-2. Water Level Sensor Error

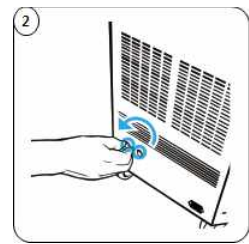
Symptom	Icon
	

⇒ Lack of water - Refill water into a water tank.

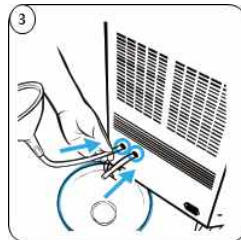
- ① Pull out a Power cord.



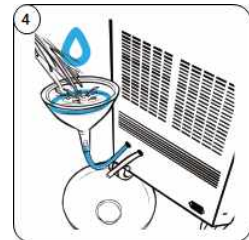
- ② Turn the two of water inlets on rear main body around anticlockwise.



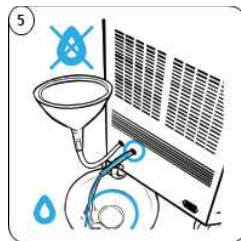
- ③ Insert a water funnel to one of water inlet holes.



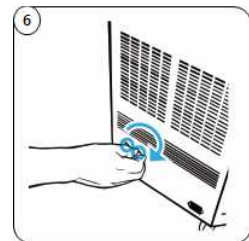
- ④ Fill up water using funnel.




- ⑤ Stop filling water when water flows in the other water inlet hole.





- ⑥ Lock the water inlets. (Turn it around clockwise)



- ⑦ If the problem persists please see the User's Manual for further information or contact Classsys Inc. Support.

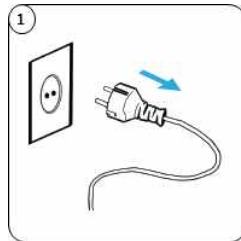
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7-3. Communication Error

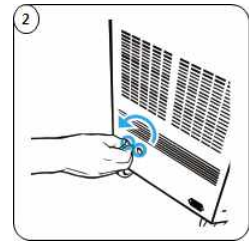
Symptom	Icon
 <p>Communication Error</p> <p><small>Please refer to troubleshooting guide in the operation manual.</small></p>	

⇒ Bad connection of Hand-piece – Reconnection of Hand-piece.

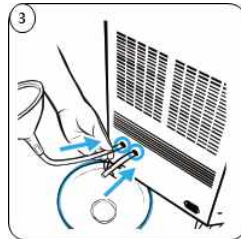
① Pull out a Power cord.



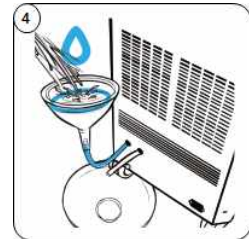
② Press the connector switch on both sides on a Hand-piece.



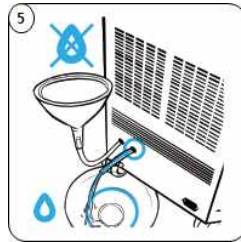
③ Pull out a Hand-piece.



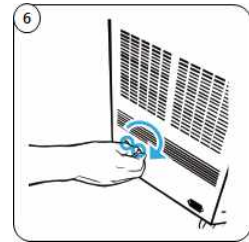
④ Release a connector and coupling at the original position.




⑤ Push a connector to its coupling.





⑥ Push a Hand-piece until you hear “click” sound.



⑦ If the problem persists please see the User’s Manual for further information or contact Classsys Inc. Support.


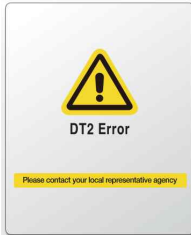


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7-4. Communication Error


Symptom	Icon
	

- ① Restart (1~3 times) system to remove air from the water line.
- ② Release the Hand-piece cable rightly.
- ③ If the problem persists please see the User's Manual for further information or contact Classsys Inc. Support.

7-5. DT Error

Symptom			Icon
			

Temperature sensor is defective.
Please see the User's Manual for further information or contact Classsys Inc. Support.

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8. Cleaning and Care

8-1. Cleaning the System and the Hand-piece

8-1-1. Main Body

The outer surface of the system may be wiped clean with a soft dry cotton cloth once every 10days.

Be careful not for water flowing in the inside of the system.

8-1-2. Hand-piece

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


Because the Hand-pieces will come in contact with the skin of a patient, the standard practice for cleaning and low level disinfection of Hand-piece between patients is to gently but thoroughly wipe the Hand-pieces with a standard 90% isopropyl alcohol prep pad. One may also use a standard 90% isopropyl alcohol prep pad to gently wipe the Hand-piece cable.



Warning: Use only this procedure for cleaning. Do not use acetone or other solvents as this can damage the main body and the Hand-piece.




Warning: Always turn the system off and unplug the power cable before performing maintenance procedures. And interior of the system or its components may be serviced only by local authorized technical personnel.

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8-2. General Care of the System


To get the best possible performance, treat the equipment carefully by adhering to the following guidelines:

1. Inspect the Hand-piece and connectors regularly for any problems.
2. Do not drop the Hand-piece on the floor or other hard surfaces. This can cause permanent damage.
3. Do not twist or pull the Hand-piece cables. This could cause damage to internal wires and connections.
4. The **“CLATUU”** must be used only with the authorized “Matrix Gel Pad” and “OP Pad”. Other pad or lubricants or lotions, particularly mineral oil, could eventually damage the main body or the Hand-piece.
5. Apply Matrix Gel Pad and OP Pad only to the probe of the Hand-piece and wipe it from the Hand-piece after completing a treatment. Avoid getting the gel on the Hand-piece or main body.
8. Probe of Hand-piece should be cleaned between procedures. See cleaning procedure information immediately preceding this subsection.

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9. Specifications

No	Performance	Specification
1	Item	Cooling Therapeutic Equipment
2	Classification	Class IIa
3	Model Name	CL2-M360
4	Intended Use	This device is indicated for minimize pain, thermal injury and prevention of edema during laser and dermatological treatments.
8	GUI	10.4 Inch LCD touch screen (Main body) 4.3 Inch LCD touch screen (Hand-piece)
9	Input power, Frequency	AC 200-240V, 50/60Hz
10	Power consumption	1250VA
11	Protection by electric shock	1grade, Type BF Applied part
12	Dimension	490(D) X 715(W) X 1140(H) mm
13	Weight	92kg
14	Hand-piece	Flat Type : 169(D) X 104(W) X 138(H) mm Wing Type : 172(D) X 104(W) X 146(H) mm Wide Type : 222(D) X 117(W) X 167(H) mm New Flat Type : 169(D) X 104(W) X 138(H) mm New Wing Type: 172(D) X 104(W) X 146(H) mm
15	Environmental	Operating Environment - Temperature: 10℃ ~ 35℃ - Relative Humidity: 0% ~ 90% - Air Pressure: 700hpa ~ 1060hPa
		Shipping and Storage, System - Temperature: 5℃ ~ 60℃ - Relative Humidity: 0% ~ 90% - Air Pressure: 500hpa ~ 1060hPa

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Appendix A.


Electromagnetic Emissions and Immunity

Manufacturer's declaration - electromagnetic emission

The "CLATUU" is intended for use in the electromagnetic environment specified below. The customer or the user of "CLATUU" should assure that it is used in such an environment		
Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The "CLATUU" uses RF energy only for its internal function. Therefore. Its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
RF emissions CISPR 11	Class A	The "CLATUU" is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supplies buildings used for domestic purposes.
Harmonics emission IEC 61000-3-2	A	
Voltage fluctuation IEC 61000-3-3	Complies	


Manufacturer's declaration - electromagnetic immunity


The "CLATUU" is intended for use in the electromagnetic environment specified below. The customer or the user of the "CLATUU" 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	6 kV Contact 8 kV Air	6 kV Contact 8 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.

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Power frequency (50/60Hz) Magnetic field IEC 61000-4-8	3.0 A/m	3.0 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short Interruptions and Voltage variations on power supply input lines IEC 61000-4-11	<p><5% U_T (>95% dip in U_T) for 0.5cycle</p> <p>40% U_T (60% dip in U_T) for 5 cycle</p> <p>70% U_T (30% dip in U_T) for 25 cycle</p> <p><5% U_T (<95% dip in U_T) for 5 s</p>	<p><5% U_T (>95% dip in U_T) for 0.5cycle</p> <p>40% U_T (60% dip in U_T) for 5 cycle</p> <p>70% U_T (30% dip in U_T) for 25 cycle</p> <p><5% U_T (<95% dip in U_T) for 5 s</p>	Mains power quality should be that of a typical commercial or hospital environment. If the user of the "CLATUU" requires continued operation during power mains interruptions, it is recommended that the "CLATUU" be powered from an uninterruptible power supply or a battery
Note: U_T is the a.c. mains voltage prior to application of the test level.			

<p>The "CLATUU" is intended for use in the electromagnetic environment specified below.</p> <p>The customer or the user of the "CLATUU" should assure that it is used in such an environment</p>			
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	<p>Portable and mobile RF communications equipment should be used no closer to any part of the CardioTouch-3000 system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$

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Radiated RF IEC 61000-4-3	3 V/m 80.0 MHz to 2.5 GHz	3 V/m 80.0 MHz to 2.5 GHz	Recommended separation distance $d = \left[\frac{3,5}{E_1} \right] \sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1} \right] \sqrt{P}$ 800 MHz to 2,5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, (a) Should be less than the compliance level in each frequency range (b). Interference may occur in the vicinity of equipment marked with the following symbol: 
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Note 1) U_T is the A.C. mains voltage prior to application of the test level.

Note 2) At 80 MHz and 800 MHz, the higher frequency range applies.

Note 3) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a 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.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V / m.

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Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the “CLATUU”.

The “CLATUU” is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the CardioTouch-3000system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the “CLATUU” as recommended below, according to the maximum output power of the communications equipment.


Rated maximum output power (W) of transmitter	Separation distance (m) according to frequency of transmitter		
	150 kHz to 80 MHz z	80 MHz to 800 MHz	800 MHz to 2.5 GHz z
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies


Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Immunity and Compliance Level			
Immunity test	IEC 60601 Test Level	Actual Immunity Level	Compliance Level
Conducted RF IEC 61000-4-6	3 Vrms, 150 kHz to 80 MHz	3 Vrms, 150 kHz to 80 MHz	3 Vrms, 150 kHz to 80 MHz
Radiated RF IEC 61000-4-3	3 V/m, 80 MHz to 2.5 GHz	3 V/m, 80 MHz to 2.5 GHz	3 V/m, 80 MHz to 2.5 GHz

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Guidance and manufacturer's declaration - electromagnetic immunity

The "CLATUU" is intended for use in the electromagnetic environment specified below. The customer or the user of the "CLATUU" should assure that it is used in such an environment


Immunity test	IEC 60601 Test level	Compliance level	E l e c t r o m a g n e t i c environment -guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80MHz	3 Vrms 150 kHz to 80 MHz	"CLATUU" must be used only in a shielded location with a minimum RF shielding effectiveness and, for each cable that enters the shielded location with a minimum RF shielding effectiveness and, for each cable that enters the shielded location
Radiated RF IEC 61000-4-3	3 V/m 80.0 MHz to 2.5 GHz	3 V/m 80.0 MHz to 2.5 GHz	Field strengths outside the shielded location from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than 3V/m. ^a Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Note 2) It is essential that the actual shielding effectiveness and filter attenuation of the shielded location be verified to assure that they meet the minimum specification.

a- 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 outside the shielded location in which the EUT is used exceeds 3V/m, the EUT should be observed to verify normal operation.

If abnormal performance is observed, additional measures may be necessary, such as relocating the EUT or using a shielded location with a higher RF shielding effectiveness and filter attenuation.

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CLATUU™

OPERATION MANUAL (Ver. 1.0)

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