SCIZER™

OPERATION MANUAL

Ver. 1.2

CLASSYS
Technology for better life

SCIZER™

(Model name SC1-M400)

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.

Note: This manual describes the operation of the SCIZER only. It is not a substitute for the required clinical training to use the system. Contact a Classys representative or distributor to acquire other SCIZER Manuals or Guides to assist in effective operation of the SCIZER.

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1. Introduction to Manual

1-1. Purpose

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

WARNING: Do not operate the SCIZER prior to reading this manual thoroughly and being trained by an authorized Classys representative.
This manual is not a substitute for clinical treatment guidelines and training provided by Classys 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 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.

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 SCIZER is:

- A non-invasive therapeutic device for the treatment of lipomas using the principle of coagulation and necrosis in the body. This device is a Focused Ultrasound Therapeutic System to provide a non-invasive approach that it can deliver focused ultrasound energy which achieves disruption of mature adipose tissue located in the subcutaneous tissues.

2-2. Contraindications

The SCIZER is not recommended for patients with the following:

- Hernia in the area to be treated
- Pregnant or suspected to be pregnant
- Implants or foreign bodies of any type in treatment area

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

2-3. Precautions

Do not use the equipment if you have not been trained and qualified to operate the SCIZER. For the following conditions of patients consult with experts to decide whether treatment is appropriate.

- Use of medications which include anticoagulants or to treat platelet aggregation
- Use of chronic steroid or immunosuppressive therapy
- Use of non-steroidal anti-inflammatory drugs
  (NSAIDs for analgesia and daily low dose aspirin are permissible)
- Prior liposuction, injection lipolysis, abdominoplasty, surgery
- Laser, RF and Cryolipolysis within the past 90 days
- Sensory loss or localized skin disease, or abscesses in treatment area
- Swollen, infected, or inflamed area

The SCIZER has not been evaluated for use in the following patient populations:

- Large scars in treatment area
- Wounds within the area
- Skin that does not lie flat or folds during treatment
- Redundant skin folds

2-4. Potential Side Effects

This equipment is a high intensity ultrasound therapeutic device which is applied to the skin. This device had no serious adverse events or major side effects occurring during clinical research. The following may occur post procedure:

- Erythema (Redness): The treated area may exhibit erythema after treatment and generally resolves within 48 hours of treatment.
- Edema (Swelling): The treated area may exhibit mild edema following treatment and generally resolves within 48 hours of treatment.
- Pain: Whilst undergoing treatment minor discomfort may be experienced.
- Bruising: Mild bruising caused by damage to soft tissue blood vessels may occur occasionally. This symptom generally resolves within 48-72 hours of treatment.
- Scarring: The possibility for scar formation may exist if incorrect treatment technique is used.

2-5. Complaints and Adverse Events

No serious or adverse observations were made from the use of the SCIZER, 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 SCIZER is designed to produce and control the delivery of high heat to the body using ultrasonic energy for treatment of lipomas using the principle of coagulation and necrosis in the body.

It is computer-controlled and is capable of producing localized heat within the tissues or organs. Energy delivered to the patient is via an externally-mounted transducer. It is a safe and effective device to assist in treatment of dermatologic diseases.

It is recommended to use an ultrasound imaging system to visualize the sub-dermal regions of interest prior to treatment. It allows the physician to compile a precise view of the target treatment area.

The SCIZER's lifecycle is 5 years.

3-2. System Components and Features

The SCIZER consists of the following primary components as shown in *Figure 3.1*: the Main Body with an integrated 10.4 inch touchscreen, Hand-piece cable, AC Power cable and interchangeable cartridge.

No.	Item	No	Item	No	Item
1	Main Body	2	Hand-piece cable (2ea)	3	Treatment Cartridge (C3, C5, C6, C9, C13)
4	AC Power cable	5	User Key	6	Grid Template & Spray

Figure 3.1 Main components of the SCIZER

3-2-1. Main Body

The Main Body is the information center for the SCIZER. It houses the 10.4 inch touch screen monitor (LCD) and the 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* shows the physical features of the Main Body.

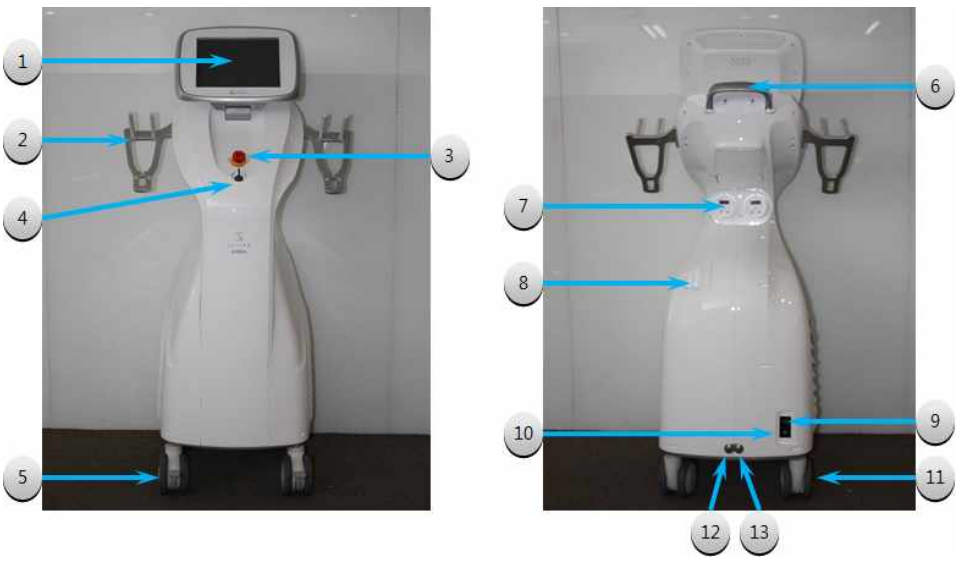
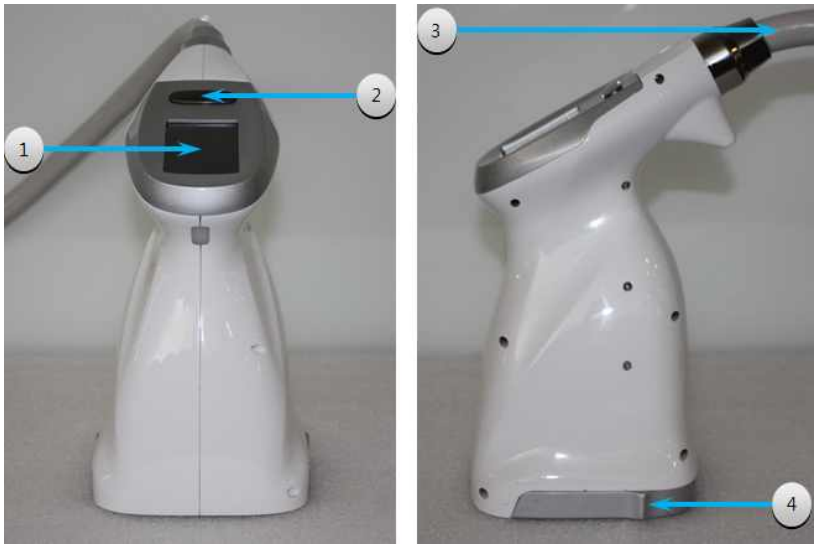


Figure 3.2 Main body front view (left) and rear view (right)

No	Item	Description
1	10.4” LCD Touch Screen	Screen for user can interface with device
2	Hand-piece Holder	Hand-piece holder
3	Emergency Switch	Emergency stop switch
4	ON/OFF Key Switch	Turn ON/OFF Key switch
5	Locking Caster	Wheel lock
6	Knob	Holder for ease in moving device
7	Hand-piece Connector Receptacle	Socket for plugging in Hand-piece Cable
8	Water Inlet	Hole to fill water
9	AC Power Switch	AC Power ON/OFF Switch
10	Power Cord Receptacle	AC Power cable connection
11	Caster	Wheels for ease in moving device
12	Water Outlet	Outlet to drain water from the System
13	Water Level Check	Outlet to determine water level

3-2-2. Hand-pieces

On one end of the Hand-piece is a connection output to attach the Cartridge. The other end of the Hand-piece is connected to the insertion on the rear of the Main Body. The Hand-piece images are shown below in Figure 3.3. The Hand-piece Output button is utilized to apply the ultrasound shot.



No	Item	Description
1	2.2” LCD Screen	Displays reference for the user
2	Ultrasound Output Button	Button for ultrasound output
3	Strain Relief / Cable	Cable for connecting Main Body and Hand-piece
4	Latch	Locks Cartridge into Hand-piece

Figure 3.3 Hand-piece without cartridge, top and side views.

3-2-3. Cartridge

Figure 3.4 shows an image of the Cartridge. The Cartridge can treat a region of tissue up to 46mm long and 46mm wide. Per application of the Cartridge, a maximum of 25 lines in length and width is applied.

No	Item	Description
1	Water Fitting	Connect to the Hand-piece for water flow
2	Hand-piece Magnetic Connection Parts	Parts that are magnetic for efficient connection purposes
3	Cartridge window	Surface to apply to the skin

Figure 3.4 Cartridge, separated from Hand-piece, top and side views

The types of Cartridge reflect variations in treatment depths as shown in Table 3.1

No	Cartridge Type	Function
1	C3	Frequency: 2MHz, Depth: 3.0mm
2	C5	Frequency: 2MHz, Depth: 4.5mm
3	C6	Frequency: 2MHz, Depth: 6.0mm
4	C9	Frequency: 2MHz, Depth: 9.0mm
5	C13	Frequency: 2MHz, Depth: 13.0mm

3-2-4. Essential Accessories

The essential accessories are an ultrasound imaging system and water. Water must be used at all times when treating. The Ultrasound imaging system is recommended for use, to analyze depth during assessment of treatment.

Other essential components provided for operation of the SCIZER include the AC Power cord and the key switch.

3-3. Precautions for use

3-3-1. Warnings 

- To prevent unauthorized use of the SCIZER, store in a controlled environment only accessible by authorized and trained personnel.
- To avoid risk of electric shock, always inspect the Cartridge, Hand-piece and cable before use.
- Do not use a cable or Cartridge that has been damaged or is leaking fluid.
- Power supply must be 220-240V~, 50/60Hz to operate the system safely.
- The SCIZER is intended for indoor use and in a dry location. Avoid liquid spills and splashes.
- Do not place the System in vicinity of direct sun light, high humidity or nearby heating devices.
- Ensure that the surface of the Cartridge and the treatment area is wiped clean after attending to all treatment sites.
- Do not lean over the equipment obliquely and do not give physical external shock to the equipment as it may cause permanent System damage.
- The SCIZER comes with a three-conductor AC Power cable and plug. Use a properly grounded outlet and always plug the SCIZER directly into the outlet.
- 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 AC Power switch and disconnect the AC Power cable prior to cleaning the Main Body.
- Do not remove the covers on the Main Body or Hand-piece. The SCIZER contains no user-serviceable components. If the System requires service, contact local distributors or

Classys Inc. No modification of this equipment is allowed.

- The SCIZER is not be used with anesthetic gases or flammable materials in the surrounding areas. Fires or explosions can result. The SCIZER is not AP or APG rated.
- Maintain an open space of at least 20cm around the Main Body. If ventilation holes are obstructed, the System could overheat.
- The Hand-piece may provide a connection between the patient and a protective earth. This may present a hazard if the patient becomes connected to other equipment with excessive electrical current leakage.
- Use of accessories other than those specified, may result in increased emissions, or inconsistencies with the device.
- Use the Cartridge provided by Classys Inc. only. Operating with any other Cartridges may cause patient injury or malfunction of the device.
- Do not suddenly remove the Hand-piece from the Main Body. It may malfunction or cause damage if separated by force.

3-3-2. Cautions 

- Do not turn on and activate the device without applying water to the Cartridge. This may cause damage to the Cartridge.
- Do not apply the Cartridge to the skin without using water as an agent.
- Before proceeding with treatment, check if the Cartridge is properly attached.
- The Hand-piece connectors must be kept clean and dry. Do not use the Cartridge if the connectors have been immersed in liquid. Refer to sub-section 7.1 of this manual.
- Do not apply force to the latching cantilever without the Cartridge being properly installed into the Hand-piece.
- The Hand-piece has been designed to be robust, however it may be damaged if dropped onto a hard surface or if the membrane is punctured. If physical damage is incurred it will not be covered by warranty.
- The SCIZER has been designed to meet the standards of electromagnetic compatibility; however some computer equipment unintentionally emits strong interfering RF signals. Portable RF communication devices may also affect the SCIZER.

- Operators are advised to check the remaining shots of the Cartridge prior to treatment, in order for the user to replace the Cartridge before depletion of the Cartridge. If additional Cartridges are required, contact local distributors or Classys Inc.
- Used up Cartridge should be disposed of in accordance with local regulations.

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

- Ensure the Main Power switch and key switch is in the ON position.
- If the problem still occurs, unplug the Power cable.
- Pull the fuse holder below the AC Power switch.
- Replace the fuse (T10AH250V).
- If the problem still occurs, please contact the local distributor or Classys Inc.

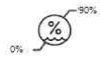
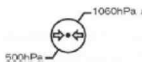
3-3-3. Electromagnetic Compatibility and Immunity

The SCIZER has been designed to meet the standards of electromagnetic compatibility. The System is not likely to be affected or the source of interference to surrounding electronic equipment.

3-3-4. Environment

- Main Power sources should be of a typical commercial or hospital environment standard.
- 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 does not generate.

3-4. Safety Symbols

No	Symbol	Meaning
1		Type B applied Part
2		Alternate Current
3		Serial Number
4		Date of Manufacture
5		Manufacturer
6		Authorized Representative in The European Community
7		Storage Range
8		Relative Humidity
9		Atmospheric Pressure Limits
10		Caution
11		General Warning or Risk of danger
12		Mind instruction for use
13		Pushing prohibited
14		Sitting prohibited
15		Stepping prohibited
16		Crossed out wheeled bin
17	STOP	Emergency Switch
18		Protective Earth
19		Dangerous Voltage

3-5. Information of Applied Standards

EN 60601-1: 2006/A1:2013	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
EN 60601-1-2: 2007/AC:2010	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-6: 2010	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
EN 62366:2008	Medical devices. Application of usability engineering to medical devices
EN 60601-2-62:2015	Medical electrical equipment - Part 2-62: Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment
EN 62304: 2006	Medical device software. Software life-cycle processes
EN ISO 15223-1: 2012	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
EN ISO10993-1: 2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-5: 2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-10: 2010	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization

4. Setting Up for First-Time Use

4-1. Unpacking

The Main Body, Hand-piece and Cartridges are shipped together in one container.

4-2. Physical Environment

4-2-1. System 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 parameters shown in Figure 4.1. It is a general condition 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 manual.

Figure 4.1. The required storage area for the SCIZER

4-2-2. Electromagnetic Environment

- The System is not likely to be affected or the source of interference to surrounding electronic equipment. As a safety measure, it is recommended to keep the System clear of other devices.
- Flooring of the surrounding environment is recommended to be wood, concrete or ceramic tiles. In the case of a synthetic material floor cover, the humidity levels should be of at least 30%.

4-3. Connecting Components

4-3-1. Connecting the Hand-piece

The Hand-piece connector receptacle is located on the rear of the Main Body.

① Ensure the AC Power cable is pulled out from the wall socket.

② Detach the connector cover of the Hand-piece.

③ Insert the Hand-piece connector to its socket.

④ Turn the Hand-piece connector clockwise until it is firmly connected.

4-3-2. Inserting water in the System

① Ensure the AC Power cable is pulled out from the wall socket.

② Remove the cover of the Water Inlet on the rear body to open it.

③ Turn the Water Level Outlet tab anti-clockwise.

④ Insert a water funnel to the Water Inlet hole and pour water into the hole.

⑤ Fill up approximately 3L of water until water flows out of the Water Level Outlet hole.

⑥ Remove the water funnel and lock the Water Level Outlet with the cover by turning the screw clockwise.

4-3-3. Connecting the Cartridge

To connect the Cartridge, align both the Hand-piece and the Cartridge and attach them together. Proceed to pull the latch towards the inside of the Hand-piece until the latch is secured as shown in *Figure 4.4.* Ensure the latch is properly sealed.

Figure 4.4 Connecting a Cartridge to the Hand-piece

4-3-4. Separating the Cartridge

To disconnect the Cartridge, press the button on either side of the Hand-piece and dismount the Cartridge in reverse order of the assembly as shown in Figure 4.5. Draw the latch towards the outside of the Hand-piece and disconnect the Cartridge from the Hand-piece.

Figure 4.5 Separating the Cartridge from the Hand-piece

When the Cartridge is inserted, the Graphical User Interface will automatically recognize which Cartridge has been inserted and the remaining shot count of the particular Cartridge.

4-3-5. Connecting the Power cable

Ensure the AC Power cable connected from the rear of the device is plugged into the wall socket. For electrical safety, connect the external ground terminal of the device to a separate ground terminal.

5. System Operation

5-1. Overview of System Functions

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

The Graphical User Interface displays a combination of functions necessary for effective operation of the SCIZER. An overview of this screen is shown in *Figure 5.1*.

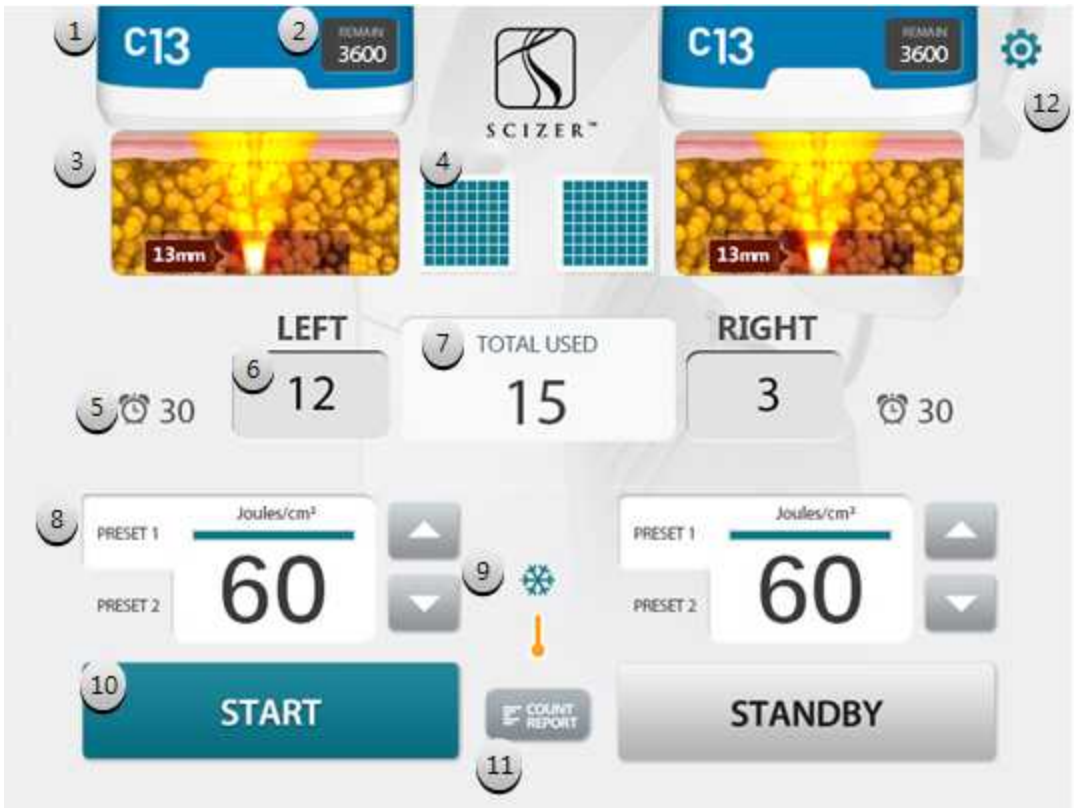
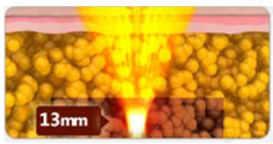
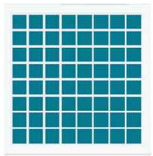
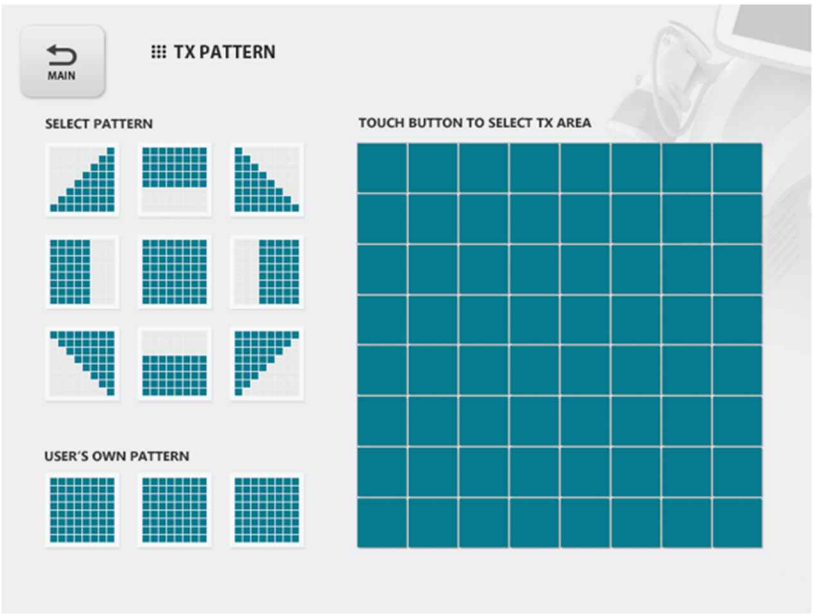
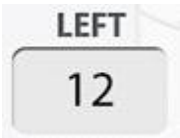
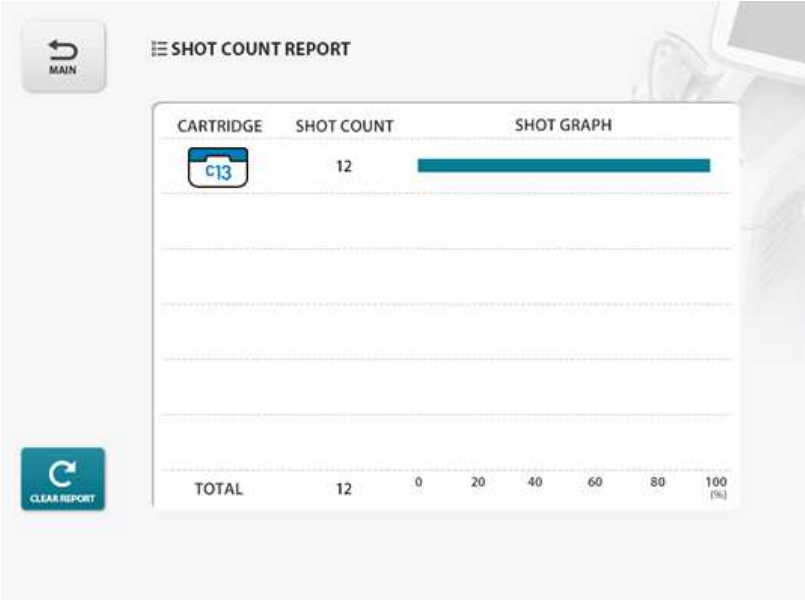
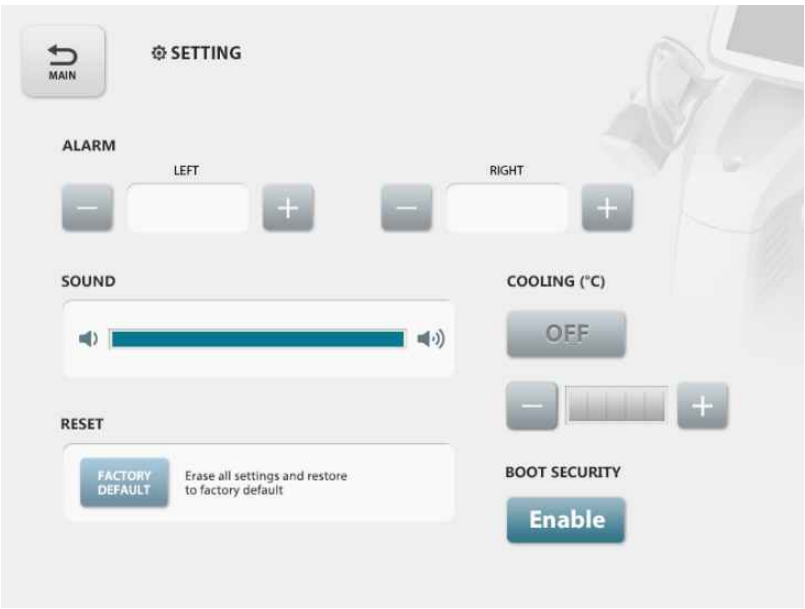


Figure 5.1 Screen in "START" state

No	SIGN	Description
1	C13	Displays the installed cartridge information
2	REMAIN 3600	Remaining shots of Cartridge (Example : 3600 remaining shots)

3		Displays the treatment position by Cartridge and shot animation when undergoing treatment
4		A choice of buttons to select one of the TX patterns or allow users to optimize custom patterns. The variable treatment patterns are designated by touching buttons to select TX area from the grid, boxes one to sixty four. 
5		Setting an alarm (Beep sound occurs when set counter reached)
6		Used shots of Cartridge on a particular side
7		Total used shots
8		“PRESET 1”, “PRESET 2” are parameter memory slots. Save Parameter value (Press and hold for 3 seconds to save) Press Preset 1 or Preset 2 to recall.
9		The fluence is displayed in joules per square centimeters (J/cm^2). The fluence is adjustable using the up and down buttons on the right hand side.

10		Displays “STANDBY” when not in use Displays “START” when in use
11		Shot count information is saved and stored for reference. 
12		Configuration of volume control, factory default setting, alarms for individual Hand-pieces, cooling, boot security. 

5-1-2. Hand-piece Graphical User Interface (GUI)

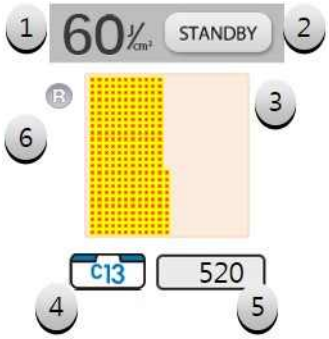
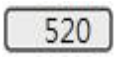


Figure 5.2 Screen in "START" state

No	SIGN	Description
1		The fluence is displayed in joules per square centimeter (J/cm^2).
2		Displays "STANDBY" when not in use Displays "START" when in use
3		Displays shot animation when undergoing treatment.
4		Displays the installed Cartridge information
5		Remaining shots of Cartridge (Example: 520 remaining shots)
6		Displays Hand-piece side (R: Right Hand-piece) (L: Left Hand-piece)

5-2. Activating the Main Body

5-2-1. 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, connect the external ground terminal of the device to a separate ground terminal in the room.

5-2-2. Ensure the Main Power Switch is in the ON position.

5-2-3. Insert the SCIZER User Key into the Key Switch on the front of the Main Body. The SCIZER must be used only with the authorized SCIZER User Key.

5-2-4. Turn the Key Switch in a clockwise direction.

5-3. Treatment Steps

5-3-1. Set the parameters for treatment by using the buttons of the LCD screen.

5-3-2. Ensure the treatment area has been cleansed thoroughly.

5-3-3. Proceed to spray water to the treatment area to act as an agent between the cartridge and the skin. Other lubricants or lotions may damage the Cartridges and Hand-pieces.

5-3-4. Press the “STANDBY” button on the GUI. Once selected it will change to “START”.

5-3-5. A specific number of shots on the selected areas will be delivered.

5-3-6. Users must wait until the shots have been completely irradiated and can check the progress of treatment procedures via the LCD monitor on the Hand-piece or GUI.

5-3-7. Between applications of the Cartridge, conduct visual checks of the Cartridge window and surface of the skin, to check if water needs to be reapplied.

5-3-8. Continue in this pattern until the recommended number of treatment lines for the region has been delivered. The beeping sound will occur when the set number of treatment lines is delivered.

5-3-9. When all targeted regions have been treated, press the “START” button to change to “STANDBY” mode.

5-3-10. Please place the Hand-piece on the Hand-piece holder.

5-4. Shutting Down the System

5-4-1. Turn off the key switch in an anti-clockwise direction and remove the SCIZER User Key to prevent unauthorized usage.

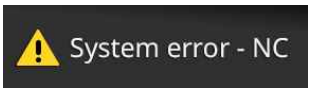
5-4-2. The Main Power switch on the rear of the Main Body should be facing down in the ON position. The System may be switched OFF when moving the equipment between rooms or for storage or cleaning purposes.

5-4-3. Follow maintenance and storage instructions shown in Section 7 of this manual.

6. System Messages

The SCIZER is designed with internal checks to ensure that all aspects of the equipment are functioning accordingly. Please follow the instructions and refer to the information listed below when errors occur.

Info Code	Message Displayed	Description & Corrective action
1-A	Check HP-CF	Cartridge motions malfunction 1. Ensure that the Cartridge is properly mounted to the Hand-piece. 2. Remove and re-insert the Cartridge. 3. If the problem persists please contact local distributors or Classys Inc.
1-B	Check HP-MS	Hand-piece motor malfunction. 1. Inspect the Hand-piece. 2. Ensure that the Cartridge is properly mounted and latched into the Hand-piece. 3. If the problem persists please contact local distributors or Classys Inc.
1-C	System error - F1	Hardware (Cooling FAN) was halted due to an event detected in the Main body. 1. Turn the System “OFF” and restart. 2. If the problem persists please contact local distributor or Classys Inc.
1-D	System error - EC	Hardware (Power Driver) was halted due to an event detected in the Main body. 1. System “OFF” and restart. 2. If the problem persists please contact local distributor or Classys Inc.

1-E		Base board malfunction. 1. Turn the System “OFF” and restart. 2. If the problem persists please contact local distributor or Classys Inc.
2-A		Water level caution Level 1 (Cooling will halt shortly) 1. Pull out the AC Power from the wall socket. 2. Insert water into the System. 3. Turn the System on. If the problem persists please contact local distributor or Classys Inc.
2-B		Water level caution Level 2 (Cooling halted) 1. Pull out the AC Power from the wall socket. 2. Insert water into the System. 3. Turn the System on. If the problem persists please contact local distributor or Classys Inc.
2-C		In case of failure to temperature hardware. 1. Turn the System “OFF” and restart. 2. If the problem persists please contact local distributor or Classys Inc.
2-D		Hand-piece Detect Error 1. Turn the System “OFF” and restart. 2. If the problem persists please contact local distributor or Classys Inc.
2-E		Flow Sensor Error 1. Restart (1-3 times) system to remove air from the water hose. (The flow sensor circulates through the water hose) 2. Straighten the Hand-piece cable. 3. If the problem persists please contact local distributor or Classys Inc.
3		Cooling water circulation is below standard After turning the device ON, it may display this symbol on the Graphical User Interface. This issue resolves within 2-3 minutes and the symbol will disappear once stabilized.

7. Cleaning and Storage

7-1. Cleaning the Main Body, Hand-piece and Cartridge

7-1-1. Main Body

Turn OFF Main Power button of 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 of the exterior. Do not allow any liquid to seep inside the equipment. Cleaning is recommended once every 10-15 days.

7-1-2. Hand-piece and Cartridge

Cartridges are packaged and shipped non-sterile and ready to use.

As the Cartridge directly contacts the skin, the standard practice for cleaning and low level disinfection of Cartridges between treatments or patients is to gently but thoroughly wipe the Cartridge with a standard 50-70% isopropyl alcohol prep pad. Use alcohol as a cleaning agent. Neither the Cartridges nor the Hand-piece should be submerged in liquid. Place the Cartridge back into its original packaging or Cartridge storage of the trolley if not in use. Cleaning is recommended once every 10-15 days.

7-2. General Care of the System

To achieve a longer lifetime and use of the SCIZER, treat the equipment carefully by adhering to the following guidelines:

1. Inspect the Hand-piece and Cartridges regularly for any issues.
2. Turn the device off before changing Cartridges to ensure proper identification of Cartridges and to prolong the life of the system.
3. Do not drop the Hand-piece or Cartridges on the floor or other hard surfaces. This may cause permanent damage.
4. Do not twist or pull the Hand-piece cables. This could cause damage to internal wires and connections.
5. Use water only. Other lubricants or lotions, particularly mineral oil, may damage Cartridges or Hand-piece.

6. Do not use acoustic standoff pads or any objects between the Cartridge and the patient.
7. Apply water only to the window of the Cartridge and wipe it from the Cartridge after completing a session of treatment.
8. Cartridges should be cleaned between procedures. Refer to cleaning procedure information allocated in subsection 7-1.

7-3. Movement and Storage

7-3-1. Movement

- Unlock the Main Body casters.
- Use the Knob at the rear of the Main Body for extra stability and support when moving the device.
- Handle the SCIZER with caution at all times.

7-3-2. Storage

Store the SCIZER in an environment where the conditions are as follows:

- Temperature: 5℃ - 60℃
- Relative Humidity: 0% - 90%
- Air Pressure: 500 - 1060hPa

8. Specifications

Item	Content
1. Electrical Requirement	220-240V~, 50/60Hz
2. Classification of Applied Parts	Type B
3. Electric power consumption	1200VA
4. Fluence	0-60J/cm^2
5. Display	10.4” LCD Touch Screen
6. Treatment site zone	Max. 46 x 46mm
7. Dimension	601(W) X 463(D) X 1,207(H) mm
8. Weight	55kg
9. Cartridge	C3: Frequency: 2MHz, Depth: 3.0mm
	C5: Frequency: 2MHz, Depth: 4.5mm
	C6: Frequency: 2MHz, Depth: 6.0mm
	C9: Frequency: 2MHz, Depth: 9.0mm
	C13: Frequency: 2MHz, Depth: 13.0mm
10. Environmental	[Operating Environment] - Temperature: 10℃ - 35℃ - Relative Humidity: 0% - 90% - Air Pressure: 700hpa - 1060hPa
	[Shipping and Storage] - Temperature: 5℃ - 60℃ - Relative Humidity: 0% - 90% - Air Pressure: 500hpa - 1060hPa

Appendix A.

Electromagnetic Emissions and Immunity

Manufacturer's declaration - electromagnetic emission

The "***SCIZER***" **is intended for use in the electromagnetic environment specified below. The customer or the user of "*SCIZER*" should assure that it is used in such an environment**		
Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The "***SCIZER"*** 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 "***SCIZER***" 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 "*SCIZER*" is intended for use in the electromagnetic environment specified below. The customer or the user of the "*SCIZER*" 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.
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	<5% U_T (>95% dip in U_T) for 0.5cycle 40% U_T (60% dip in U_T) for 5 cycle 70% U_T (30% dip in U_T) for 25 cycle <5% U_T (<95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5cycle 40% U_T (60% dip in U_T) for 5 cycle 70% U_T (30% dip in U_T) for 25 cycle <5% U_T (<95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the "***SCIZER***" requires continue d operation during power mains interruptions, it is recommended that the "***SCIZER***" 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.			

The "*SCIZER*" is intended for use in the electromagnetic environment specified below. The customer or the user of the "*SCIZER*" should assure that it is used in such an environment			
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	Portable and mobile RF communications equipment should be used no closer to any part of the SCIZER, including cables, than th e recommended separation distance calculate d from the equation applicable to the frequ ency of the transmitter. **Recommended separation distance** $d = [\frac{3,5}{V_1}]\sqrt{P}$

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 $d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 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 deter-mined 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: 

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.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the "*SCIZER*".			
The "***SCIZER***" is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the SCIZER can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the "***SCIZER***" 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	80 MHz to 800 MHz	800 MHz to 2.5 GHz
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

Guidance and manufacturer's declaration - electromagnetic immunity

The "*SCIZER*" is intended for use in the electromagnetic environment specified below. The customer or the user of the "*SCIZER*" should assure that it is used in such an environment			
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80MHz	3 Vrms 150 kHz to 80 MHz	"*SCIZER*" 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.

SCIZER™

CE 0476

OPERATION MANUAL (Ver. 1.2, 2016-12)

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