Treatment Guide



Reduce Your Size





Non-surgical Body Contouring System

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TREATMENT

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

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



Introduction

SCIZER System



The SCIZER is a completely non-invasive, body tightening and contouring device that provides customized treatment procedures to reduce stubborn fat cells from multiple areas of the body. Utilizing HIFU technology equipped with Macro Focused Scanning Ultrasound Cartridges, the SCIZER covers wide regions and transfers both uniform and stable ultrasound energy without making any direct contact with the epidermis or damaging tissues surrounding subcutaneous fat layers.

Introduction

SCIZER Cartridges

Body Cartridges

Macro Focused Scanning Ultrasound-powered Cartridges are engineered to treat the subcutaneous layers of the body for fat reduction and contouring.



D9: 9.0mm



D13: 13.0mm

Precautions for Treatment

Contraindications

The SCIZER is contraindicated for use in patients with:

- Pregnancy or when breastfeeding
- Open wounds or lesions on the treatment area
- Severe or cystic acne on the treatment area
- Metal stents/electrical implants in the treatment area
- Bio-absorbable mechanical implants
- Skin infections of any type
- Hemorrhagic disorders or dysfunctions
- Hernias
- Large scars
- Redundant skin folds

Preferred Patient Selection

Patients who comply with the following requirements are preferred for yielding greater results:

- Patients with a sufficient amount of stubborn fat cells in the treatment area
- No large scars or redundant skin folds in the treatment area
- Patients who satisfy a Body Mass Index (BMI) between 25 and 30

Potential Side Effects

Patients receiving the SCIZER may react to responses which are mild and temporary as follows:

- Hypersensitivity due to topical application of a local anesthetic
- Edema (swelling)
- Erythema (redness)
- Tenderness
- Bruising
- Scarring
- Transient numbness or tingling
 - *The local doctor or practitioner should consult with the patient for any history of severe pain or mild discomfort undergoing topical, non-invasive treatments including the SCIZER.

Precautions for Patient

Determine whether treatment is appropriate for patients with the following conditions:

- Anticoagulant therapy
- Skin conditions caused by autoimmune diseases, skin cancer, and Herpes Simplex
- Diabetes or epilepsy
- Severe skin diseases
- Decortication or heart disease
- Hypersensitiveness or hypertrophic scars
- Hemostatic dysfunctions

Precautions for Procedure

To avoid safety hazards from occurring during treatment with the SCIZER:

- Do not use the SCIZER without completion of training by an authorized CLASSYS representative.
- To prevent unauthorized use of the device, ensure access is limited strictly to trained and certified personnel only.
- Avoid applying treatment on nerve regions and major vessels.
- If any malfunctions or adverse events occur, immediately stop the treatment procedure.
- Always apply water on target areas before proceeding with the SCIZER treatment.
- Before conducting shots, check that the Cartridge attached on the transducer is applied on the skin properly.

Precautions for Treatment

Precautions for System Safety

To ensure safety of the System and proper maintenance of the SCIZER:

- 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.
- Do not remove the covers of the SCIZER Main Body or Hand-pieces as modification of this equipment is not allowed.
- The SCIZER contains no user serviceable components. Contact a local distributor or CLASSYS representative if the System requires service.
- Do not lean over the equipment obliquely and do not give physical external shock to the equipment as it may cause permanent System damage.
- Do not use the equipment with anesthetic gases or flammable materials in the surrounding areas.
 - *For additional information, refer to the SCIZER Maintenance Guide.

Patient Consultation

For accurate assessment and treatment plan of the patient:

- Check the patient's medical history.
- Check for past surgical procedures performed on the proposed treatment areas.
- Assess patient concerns on each individual facial and body preference.
- Consult with patients about their pain tolerance levels to determine if administration of pain medication is appropriate.
- Coordinate custom treatments with the patient.

Pain Management

For patients who report higher pain sensitivity levels, recommend the following during procedure:

- Local or topical anesthetics
- Oral pain medication
- Topical numbing cream
 - *No further pain medication is necessary following treatment.

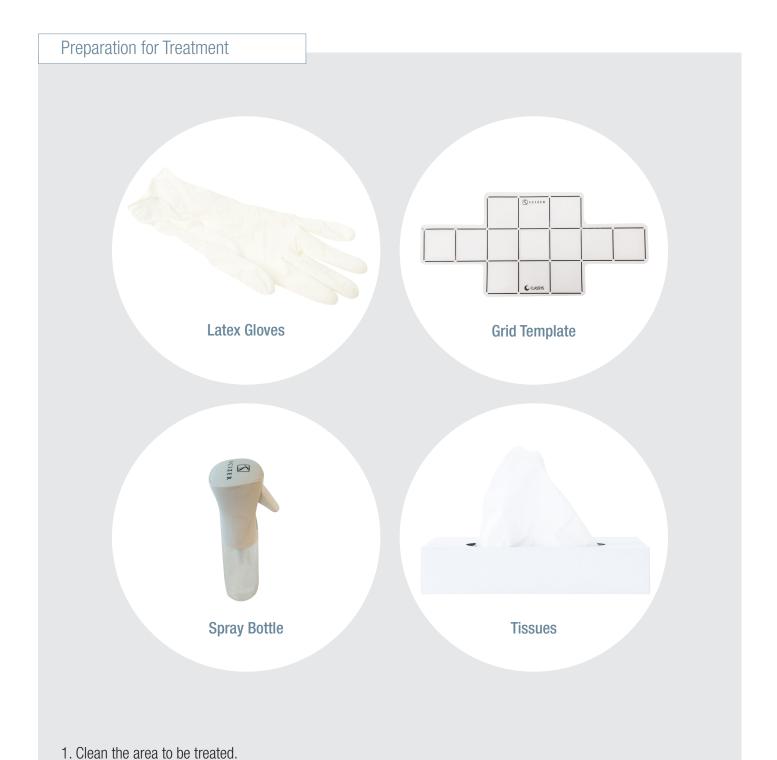
Avoiding Nerves

Nerve areas to avoid during treatment:

- Navel
- Posterior superior iliac spine (PSIS)
- Pelvic nerves
- Sciatic nerves
 - *If the patient experiences undue pain or tingling sensations in a specific target area, stop the procedure and proceed to the next treatment site.
 - *Customize parameters based on the sensitivity and tolerance levels of the patient.



DO NOT commence treatment without conducting a test shot at 0 J/cm² to ensure the transducer is moving according to the set pattern.



4. Ensure to apply a sufficient amount of water on target areas before proceeding with treatment.

2. Using a Grid Template, outline target areas according to the intended treatment plan.

3. Inspect the condition of the Cartridges and conduct a test shot.

Precautions for Midsection & Around the Thigh Procedures

O Precautions for Midsection Procedures

- Do not apply treatment on the bony areas and nerve regions.
- Do not apply treatment directly on the navel, posterior superior iliac spine (PSIS), or pelvic nerves.
- Treating the Midsection with a total energy fluence range between 140-180 J/cm² per site is applicable.
- When treating the Midsection, apply treatment one side at a time before proceeding to the other.
- After applying a few shots check for skin reactions and the sensitivity level of the patient. Proceed to treat or reduce parameters depending on the tolerance level of the patient.
- Ensure to always apply an even distribution of energy onto the marked treatment area.
- Change Cartridges of the Hand-pieces based on the pinch test and treatment area:

D9: depth of at least 1.8cm D13: depth of at least 2.5cm

O Precautions for Around the Thigh Procedures

- Do not apply treatment on the bony areas and nerve regions.
- Do not apply treatment directly on the sciatic nerves.
- Treating Around the Thighs with a total energy fluence range between 90-140 J/cm² per site is applicable.
- When treating Around the Thighs, apply treatment one side at a time before proceeding to the other.
- After applying a few shots check for skin reactions and the sensitivity level of the patient. Proceed to treat or reduce parameters depending on the tolerance level of the patient.
- Ensure to always apply an even distribution of energy onto the marked treatment area.
- Change Cartridges of the Hand-pieces based on the pinch test and treatment area:

D9: depth of at least 1.8cm

- *Take note that the '/' symbol in the parameters indicates optional levels of shot energy based on the number of passes for each treatment site.
- ⚠ When treating with a Cartridge, ensure to keep the Cartridge stationary until the treatment pattern and delivery of shot energy are complete.

Treatment Steps

1. Turning the System ON

Press the "I" symbol on the AC Power Switch at the rear of the Main Body and proceed to turn the key right to turn the System ON.

2. Selecting Cartridges

Select the Cartridge based on patient assessment and treatment area targeted. Patients must comply with standards of each Cartridge based on the pinch test and treatment area being targeted:

D9: depth of at least 1.8cm D13: depth of at least 2.5cm

3. Inspecting the Cartridge

Always inspect the physical condition of the Cartridge and ensure that there are no remaining water residues or dust particles before proceeding with treatment.

*Refer to 'Conducting a Test Shot' of this Treatment Guide.

4. Outlining the Target Region

Have the patient lie on the treatment bed and mark the areas to be treated using the Grid Template.

5. Applying Water

Apply a sufficient amount of water on the treatment area as a lubricating agent between the Hand-piece and skin during procedure. Ensure to always reapply a sufficient amount of water when necessary.

6. Setting Parameters and Preferences

Set the parameters and preferences on the Graphical User Interface (GUI) and press READY.

The following settings are available to be customized:

- Energy Fluence
- Shot Pattern
- Contact Cooling Control
- Alarm
- Timer
- Volume
- Single/Sequential Shot Mode

*For details on Preset Mode, refer to the 'Preset Configuration' of this Treatment Guide.

*For detailed information of the Graphical User Interface (GUI), refer to the SCIZER Maintenance Guide.

7. Applying the Hand-piece

Apply the Hand-piece flat onto the treatment area outlined by the Grid Template and press the Shot Button to emit ultrasound energy.

*For additional details on avoiding bony areas and nerve regions when applying the SCIZER Hand-piece during treatment, refer to specific precautions below each treatment section and 'Precautions for Midsection & Around the Thigh Procedures' of this Treatment Guide.

8. Pausing or Stopping Procedures

To pause or to stop use of the Cartridge during treatment, hold down the Shot Button to stop emission of ultrasound energy.

⚠ When treating with a Cartridge, ensure to keep the Cartridge stationary until the pass and delivery of shot energy are complete.

9. Cleaning the Cartridge and Hand-piece

Wipe the Cartridge with a standard 50-70% isopropyl alcohol prep pad before placing it into its Hand-piece Holder.

10. Cleaning the Treatment Area

Wipe down the treatment area for any remaining water residues with a dry cloth.

Preset Configuration

The SCIZER allows for the user to apply single or consecutive passes under Presets 1 and 2.

Select between Single Shot or Sequential Shot Mode by tapping either Preset once or twice.

Below are four different modes of treatment that the user can customize for each Hand-piece:

Preset 1 Single Shot Mode

With the Shot Button pressed for each pass, the shot energy will remain the same as the original parameter setting for a total of 3 passes.

PRESET 1

| Pass 1 | Pass 2 | Pass 3 |
|--------------------------|----------------------|----------|
| Ex: 60 J/cm ² | 60 J/cm ² | 60 J/cm² |

Preset 2 Single Shot Mode

With the Shot Button pressed for each pass, the shot energy will decrease by 5 J/cm² from its original parameter setting for a total of 3 passes.

PRESET 2

| Pass 1 | Pass 2 | Pass 3 |
|--------------------------|----------------------|----------------------|
| Ex: 60 J/cm ² | 55 J/cm ² | 50 J/cm ² |

Preset 1 Sequential Shot Mode

With the Shot Button pressed only once, the shot energy will remain the same as the original parameter setting for a total of 3 consecutive passes.



| Pass 1 | Pass 2 | Pass 3 |
|--------------------------|----------------------|----------------------|
| Ex: 60 J/cm ² | 60 J/cm ² | 60 J/cm ² |

Preset 2 Sequential Shot Mode

With the Shot Button pressed only once, the shot energy will decrease by 5 J/cm² from its original parameter setting for a total of 3 consecutive passes.



| Pass 1 | Pass 2 | Pass 3 |
|--------------------------|----------------------|----------------------|
| Ex: 60 J/cm ² | 55 J/cm ² | 50 J/cm ² |

^{*}The minimum shot energy value is 30 J/cm². If the first of three passes starts at 30-35 J/cm² using Preset 2, the energy value per pass will decrease or remain at the minimum of 30 J/cm².

Conducting a Test Shot

To ensure that Cartridges & Hand-pieces function properly during treatments, refer to the following:

- 1. Set the following parameters on the Graphical User Interface (GUI):
- Energy Setting: 0 J/cm²

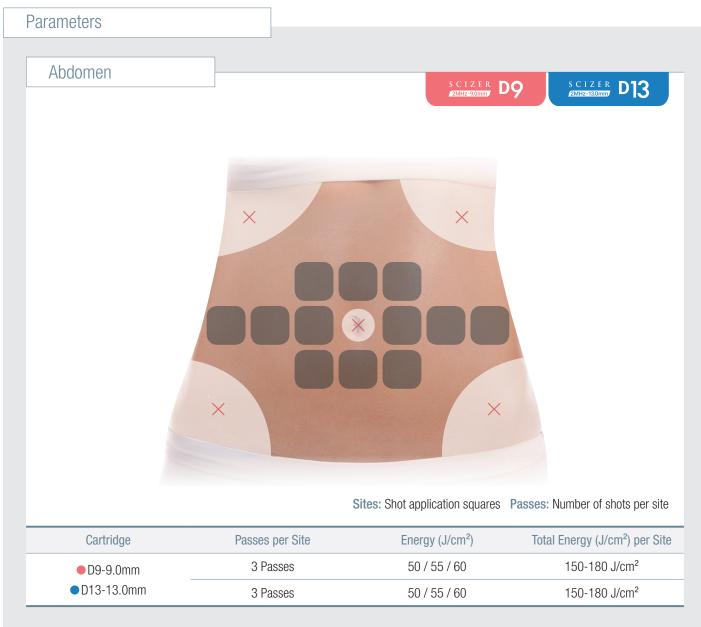


- Shot Pattern: 8x8



- 2. Press 'READY' on the Graphical User Interface (GUI) to activate the Hand-piece.
- 3. Remove the Hand-piece from its respective Hand-piece Holder and proceed to hold down the Shot Button located on top of the Hand-piece until the treatment pattern is completed.
- 4. Check through the window surface and the Graphical User Interface (GUI) that each transducer is moving according to the treatment pattern selected.
- 5. If an error occurs, restart the System and conduct another test shot. If the problem persists please contact the CLASSYS service team.
- *Ensure to check both Hand-pieces before use on a regular basis.

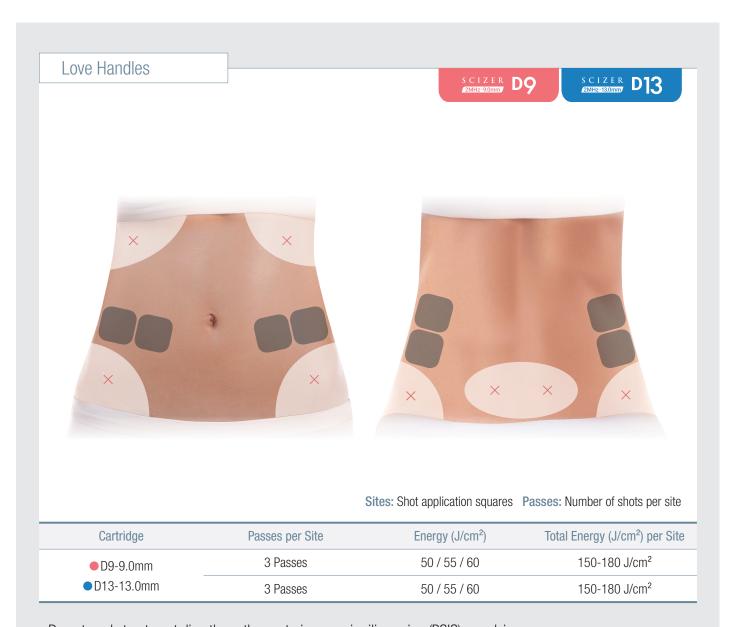




- Do not apply treatment directly on the navel, ribs, or pelvis.
- When treating the abdomen, apply treatment on one side at a time before proceeding to the other.
- Take note that the '/' symbol in the parameters indicates optional levels of shot energy based on the number of passes for each treatment site.
- Setting the Cooling Control
 Set between 3-5 depending on pain



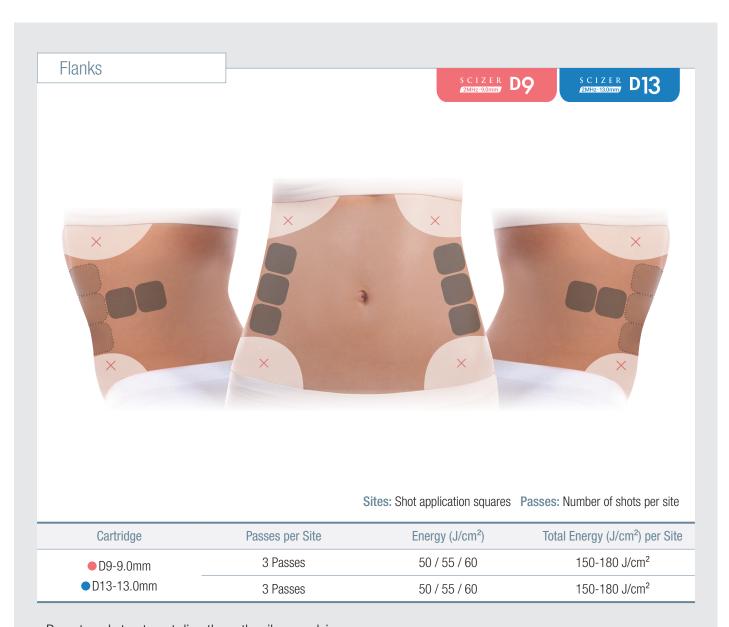
^{*}The following are recommendations for treating the target areas of the body.



- Do not apply treatment directly on the posterior superior iliac spine (PSIS) or pelvis.
- When treating the love handles, apply treatment on one side at a time before proceeding to the other.
- Take note that the '/' symbol in the parameters indicates optional levels of shot energy based on the number of passes for each treatment site.
- Setting the Cooling Control
 Set between 3-5 depending on pain



^{*}The following are recommendations for treating the target areas of the body.



- Do not apply treatment directly on the ribs or pelvis.
- When treating the flanks, apply treatment on one side at a time before proceeding to the other.
- Take note that the '/' symbol in the parameters indicates optional levels of shot energy based on the number of passes for each treatment site.
- Setting the Cooling Control
 Set between 3-5 depending on pain



^{*}The following are recommendations for treating the target areas of the body.



- Do not apply treatment directly on the sciatic nerve.
- When treating below the buttocks, apply treatment on one side at a time before proceeding to the other.
- Take note that the '/' symbol in the parameters indicates optional levels of shot energy based on the number of passes for each treatment site.
- Setting the Cooling Control
 Set between 3-5 depending on pain



^{*}The following are recommendations for treating the target areas of the body.



- Do not apply treatment directly on the sciatic nerve.
- When treating the inner thighs, apply treatment on one side at a time before proceeding to the other.
- Take note that the '/' symbol in the parameters indicates optional levels of shot energy based on the number of passes for each treatment site.
- Setting the Cooling Control
 Set between 3-5 depending on pain



^{*}The following are recommendations for treating the target areas of the body.



- Do not apply treatment directly on the sciatic nerve.
- When treating the outer thighs, apply treatment on one side at a time before proceeding to the other.
- Take note that the '/' symbol in the parameters indicates optional levels of shot energy based on the number of passes for each treatment site.
- Setting the Cooling Control
 Set between 3-5 depending on pain



^{*}The following are recommendations for treating the target areas of the body.

For further guidelines and enquiries on the SCIZER System, refer to additional training materials for the proper and professional use of the SCIZER. -Maintenance Guide -Installation Guide -Quick Operation Guide -Operation Manual

For further enquiries contact: info@classys.com

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TREATMENT GUIDE

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