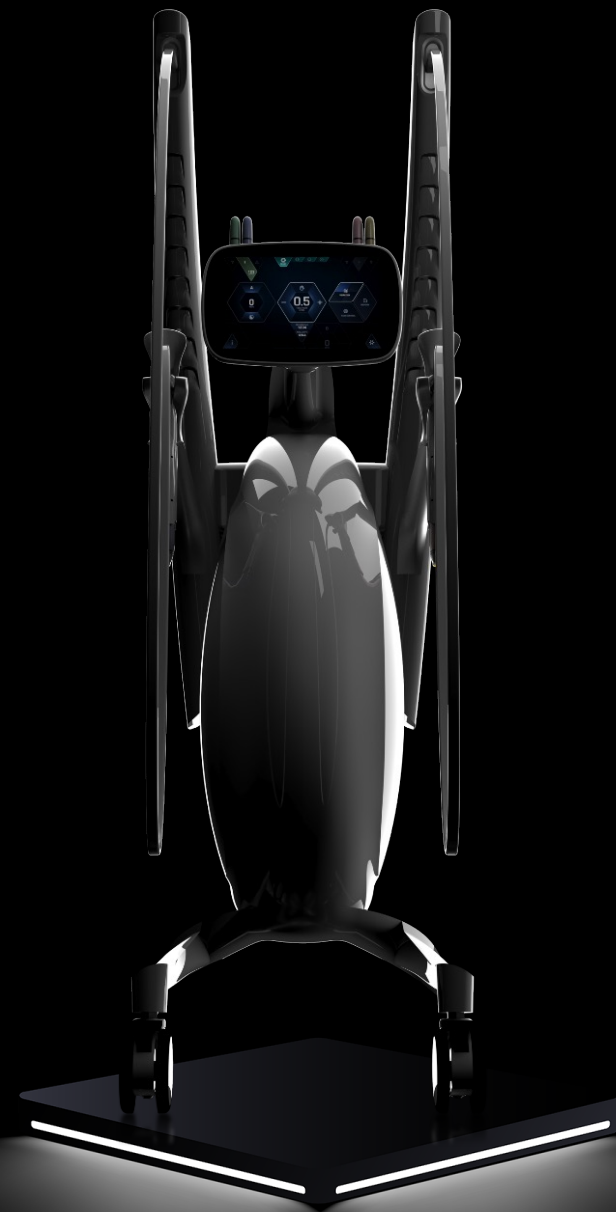


VOLNEWMER®

 **CLASSYS**
Technology for better life



VOLNEWMER System Overview

1

VOLNEWMER

- ✓ 6.78Mhz
- ✓ Non- Invasive
- ✓ 2 Hand-pieces Usability
and 4 Interchangeable

2

Gold RF Technology

- ✓ Hidden Edge
- ✓ Curved Surface & Flexible Head
- ✓ Continuous Water Cooling System
- ✓ No Time Lock
- ✓ Even RF Energy delivery

3

Safety

- ✓ Impedance Level Checking
- ✓ Shot Stop Technology
- ✓ Pain Control, No downtime



VOLNEWMER System Overview

2 Hand-pieces Usability and 4 Interchangeable

| | | | | |
|-----------------|-----------------------------------------------------------------------------------|------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| Types |  |  |  |  |
| Tip Size | 0.25cm ² | 3.0cm ² | 4.0cm ² | 16.0cm ² |
| Applicable Area | Periorbital and perioral areas, eyebrow | Full face | Full face and body | Body |

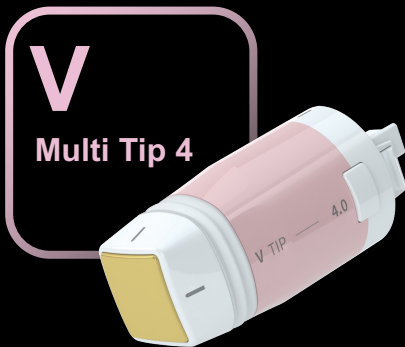


Treatment Setting

Energy Delivery for each level



| Area(cm ²) | Units of energy | 0.5 | 1.0 | 1.5 | 2.0 | 2.5 | 3.0 | 3.5 | 4.0 | 4.5 | 5.0 | 5.5 | 6.0 | 6.5 |
|------------------------|-------------------|-----|-----|------|------|------|------|------|------|------|------|------|------|------|
| 3 | J/cm ² | 6.7 | 9.0 | 11.7 | 14.0 | 16.7 | 19.0 | 21.7 | 24.3 | 27.0 | 29.7 | 32.3 | 35.0 | 37.7 |



| Area(cm ²) | Units of energy | 0.5 | 1.0 | 1.5 | 2.0 | 2.5 | 3.0 | 3.5 | 4.0 | 4.5 | 5.0 |
|------------------------|-------------------|-----|-----|------|------|------|------|------|------|------|------|
| 4 | J/cm ² | 6.3 | 8.8 | 11.3 | 13.8 | 16.3 | 18.8 | 21.3 | 23.8 | 26.3 | 28.8 |

Treatment Setting

Energy Delivery for each level

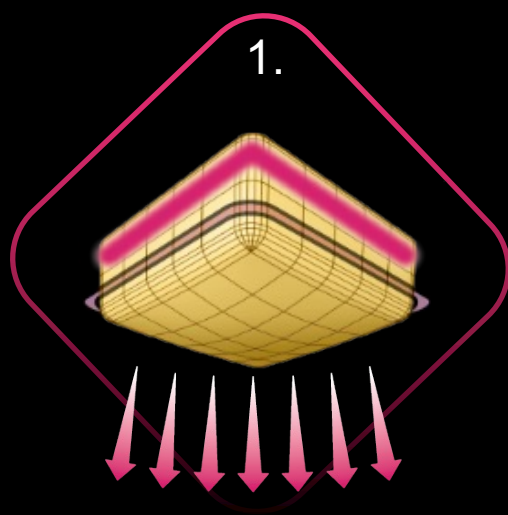


| Area(cm ²) | Units of energy | 0.5 | 1.0 | 1.5 | 2.0 | 2.5 | 3.0 | 3.5 | 4.0 | 4.5 | 5.0 |
|------------------------|-------------------|------|------|------|------|------|------|------|------|------|------|
| 0.25 | J/cm ² | 12.1 | 15.9 | 20.1 | 24.0 | 27.9 | 32.1 | 36.0 | 39.9 | 44.1 | 48.0 |

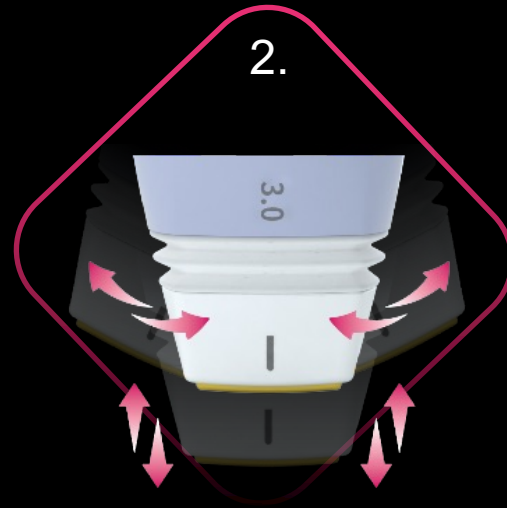


| Area (cm ²) | Units of energy | 0.5 | 1.0 | 1.5 | 2.0 | 2.5 | 3.0 | 3.5 | 4.0 | 4.5 | 5.0 | 5.5 | 6.0 | 6.5 | 7.0 | 7.5 | 8.0 | 8.5 | 9.0 | 9.5 |
|-------------------------|-------------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|------|------|------|------|------|------|------|------|------|------|
| 16 | J/cm ² | 3.8 | 4.5 | 5.3 | 6.0 | 6.8 | 7.5 | 8.3 | 9.0 | 9.8 | 10.5 | 11.3 | 12.0 | 12.8 | 13.5 | 14.3 | 15.0 | 15.8 | 16.5 | 17.3 |

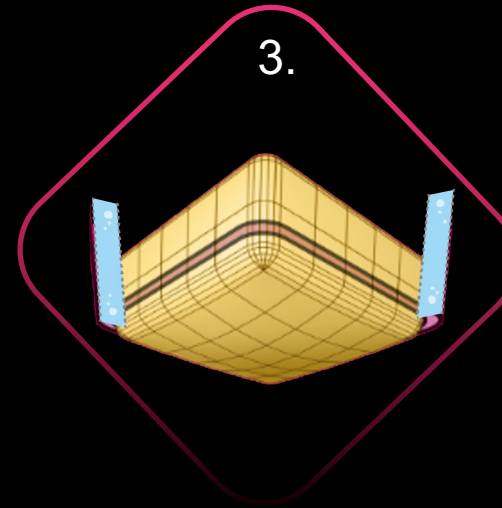
VOLNEWMER System Overview



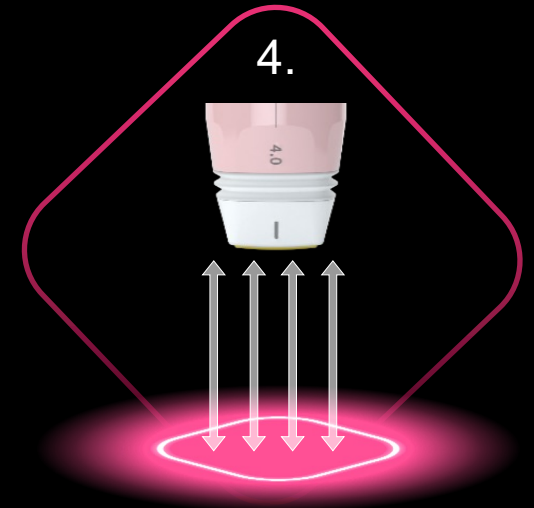
**Curved Surface &
Hidden Edge**



Flexible & Tilting Head



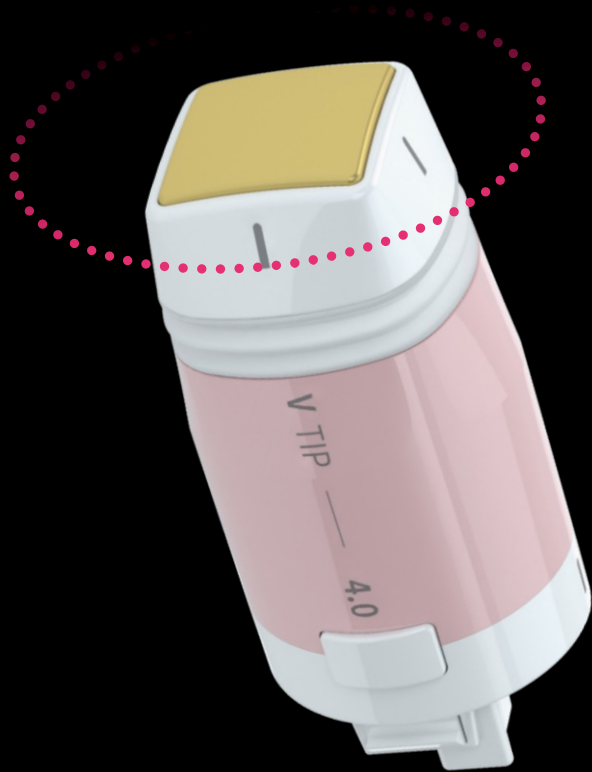
**Continuous
Water Cooling System**



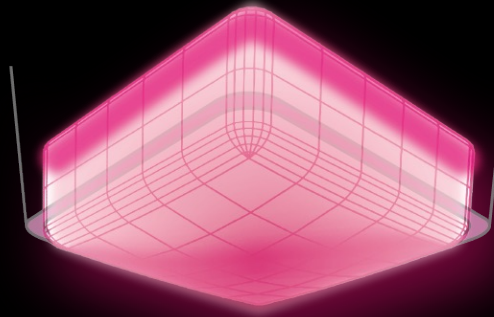
**Automatic Impedance
Detecting**

VOLNEWMER's

1) Combination of Hidden Edge and Curved Surface Tip Design



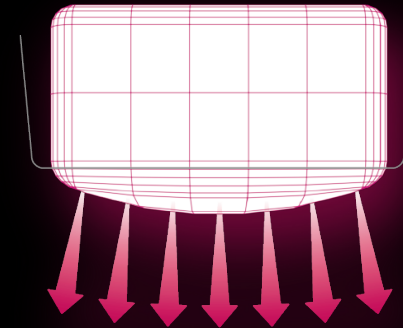
Hidden Edge Design



Built-in (concealed inside) tip design

Tip is designed inward to minimize side effects due to overheating

Curved Surface Design



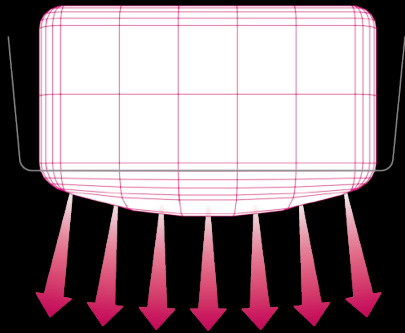
Convex shape tip design

As the tip is curved, RF energy is delivered into the dermis evenly

VOLNEWMER's

1) Combination of Hidden Edge and Curved Surface Tip Design

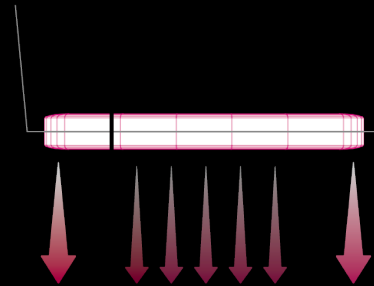
Curved Tip



Ergonomics curved tips for perfect contact with the skin to optimize the RF energy delivery



Flat Tip

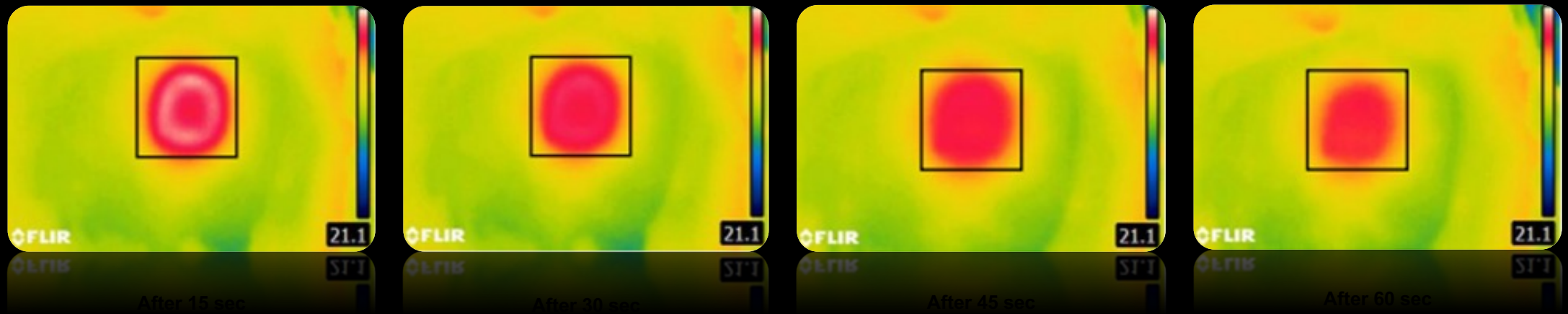


Increased clinical efficacy



VOLNEWMER's

RF Thermal Energy Delivered to the Dermal Layer

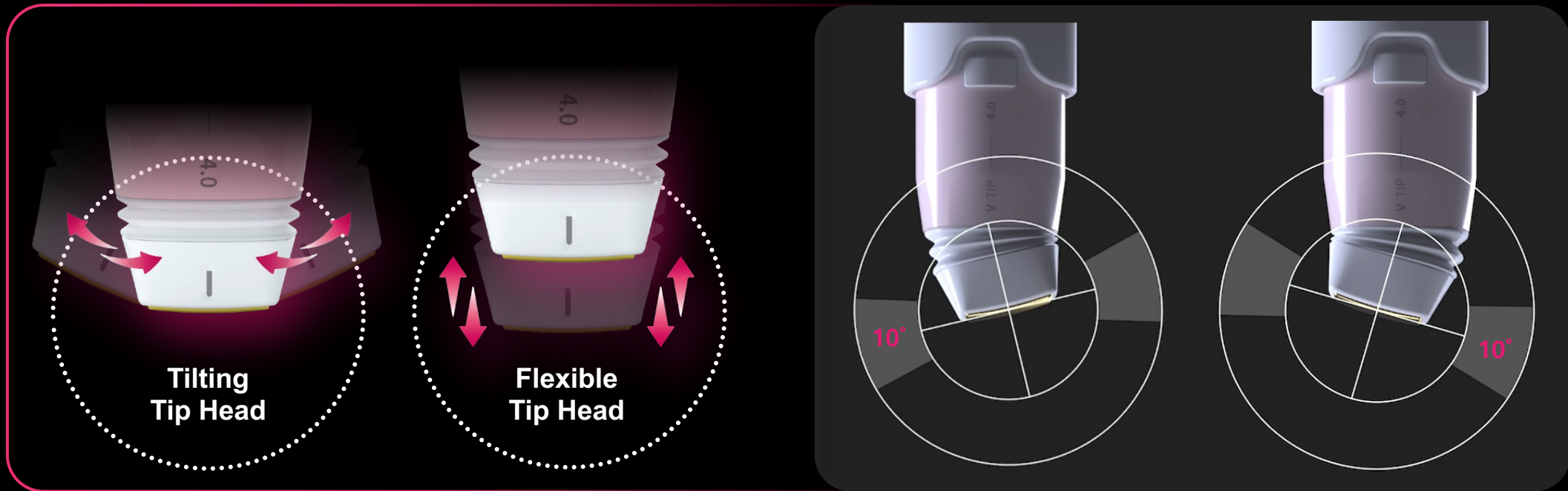


Evenly Maintaining RF Thermal Energy

VOLNEWMER's

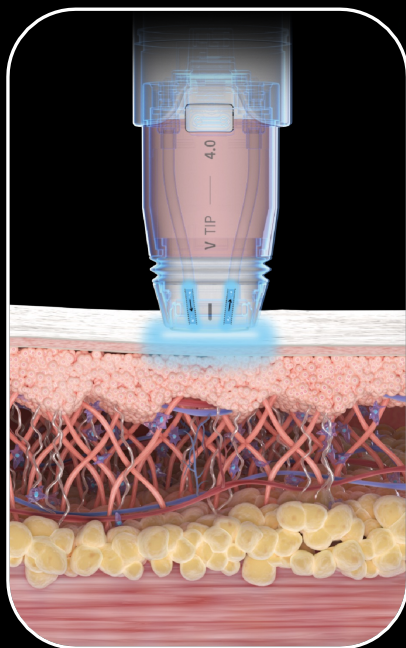
2) Tilting Head of Tip : Flexible & Easily Movable Head Hand-piece

- ✓ Comfortable treatment at any angle
- ✓ Less pain



VOLNEWMER's GOLD RF TECHNOLOGY

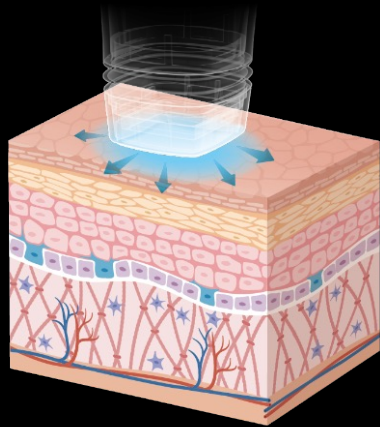
4) Safe Energy Delivery : Pain Reducing Cooling & Vibration



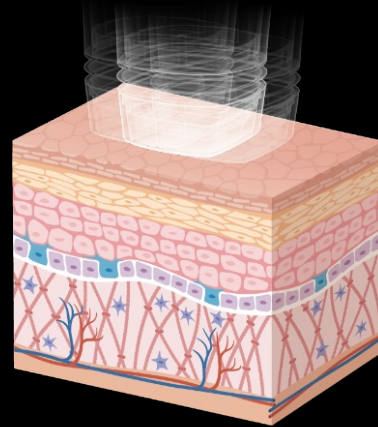
**Continuous
Water Cooling System**

VOLNEWMER's GOLD RF TECHNOLOGY

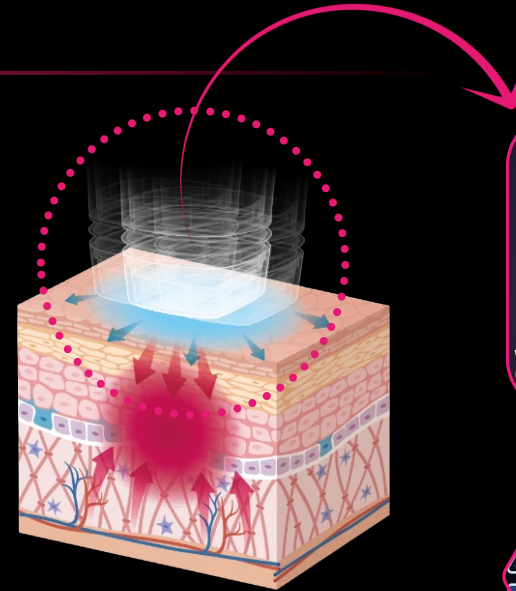
4) Safe Energy Delivery : Pain Reducing Cooling & Vibration



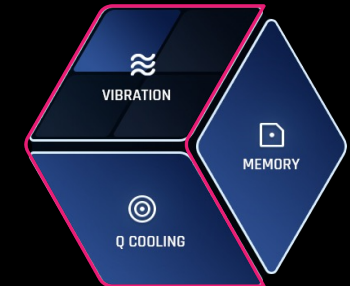
LuxIR Handpiece approaching surface of the skin



VLN maximizes the cooling efficiency of the epidermis by adopting a continuous water cooling system at all times -> The effective cooling provides deep penetration of RF energy to the dermis



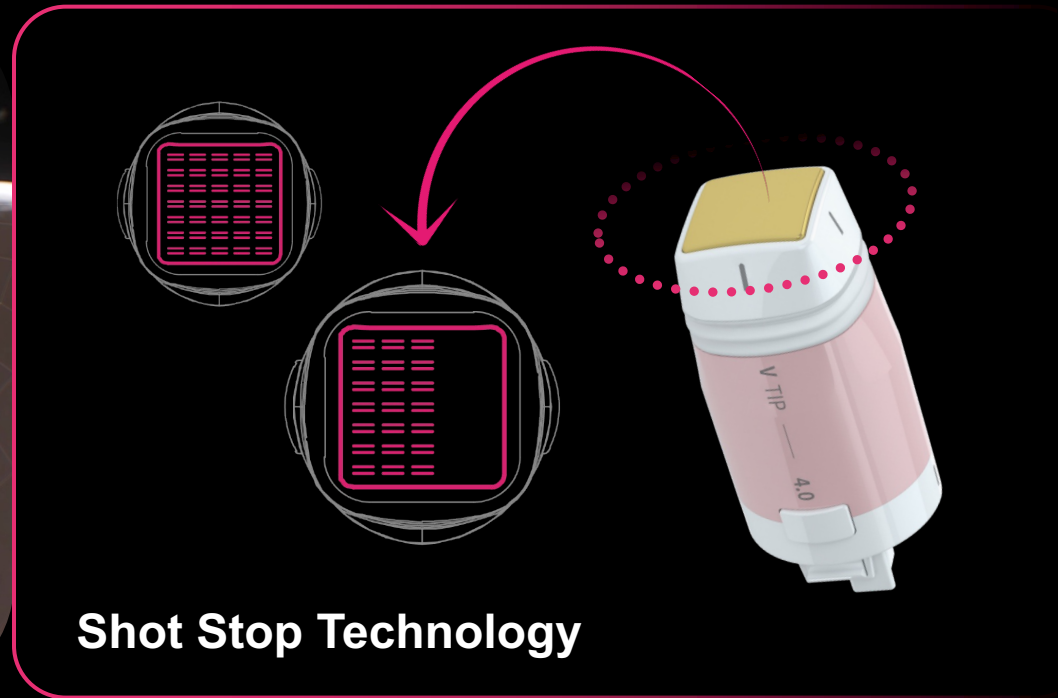
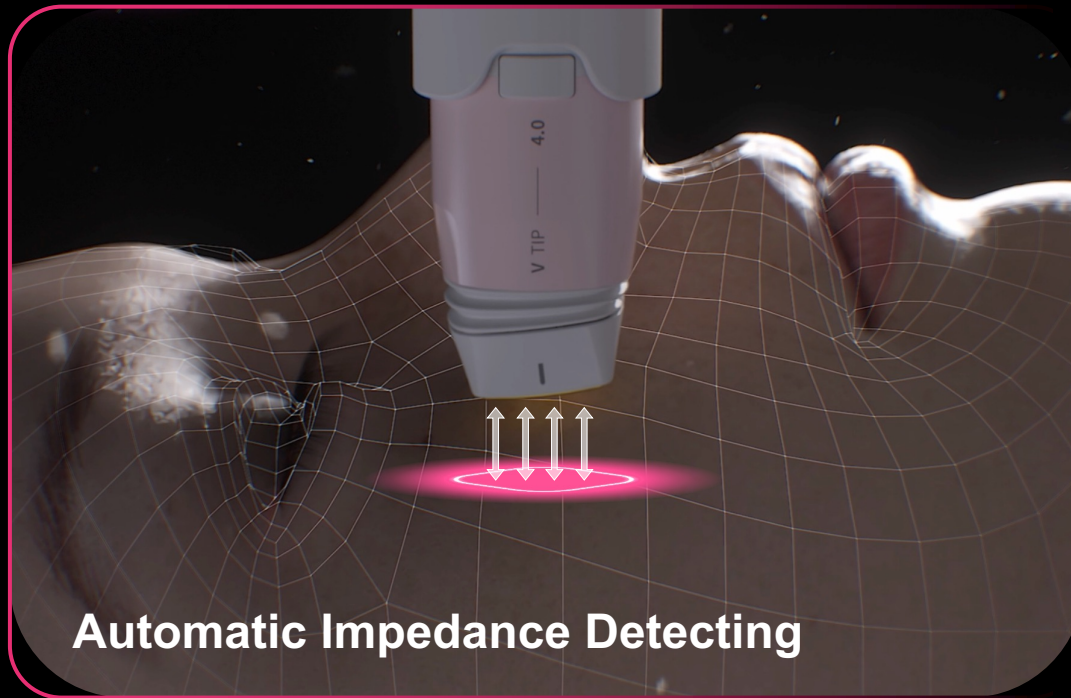
Efficient cooling provides maintenance of the treatment level when the thermal energy overlaps



Continuous water cooling system provides higher RF energy delivery without the pain

VOLNEWMER's GOLD RF TECHNOLOGY

4) Safe Energy Delivery : Automatic Impedance Detecting



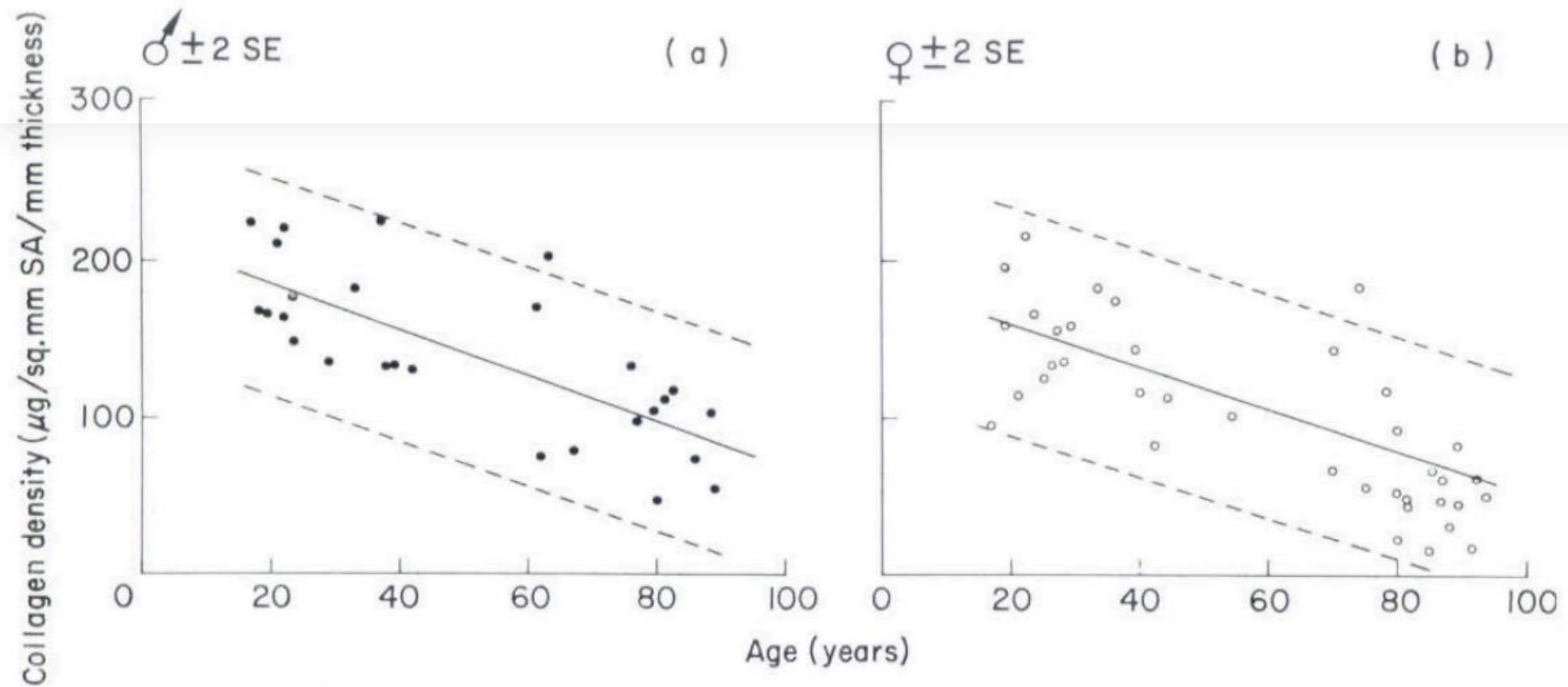
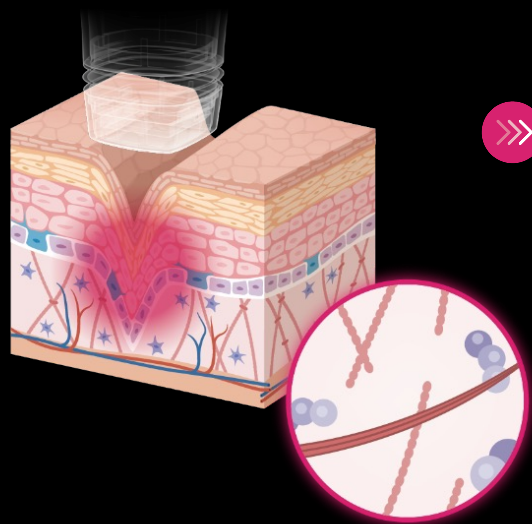
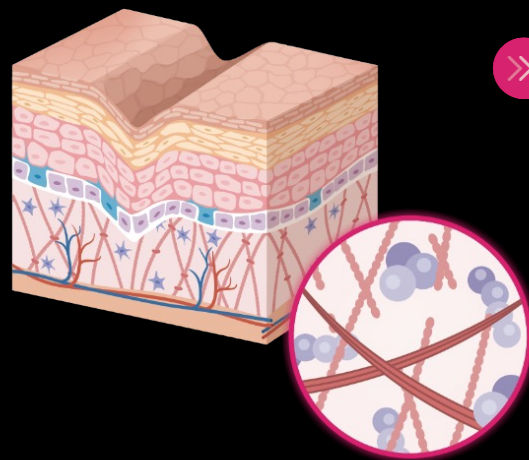


FIGURE 4. The relationship of skin collagen and density to age in males (a) and females (b).

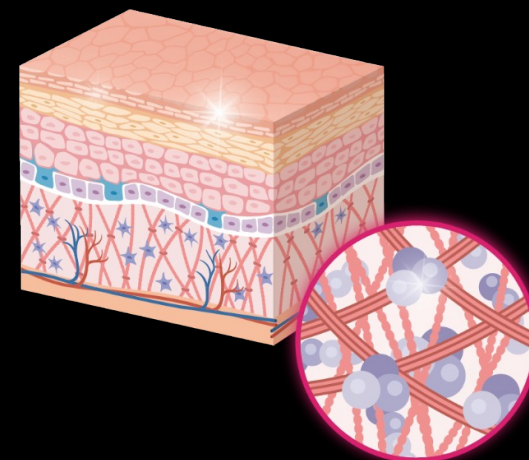
VOLNEWMER System Overview



RF energy is transmitted to the dermis of the skin



Stimulate the production of large amount of collagen



Gold RF technology renew the collagen, promote skin barrier, improve elasticity and tighten the skin

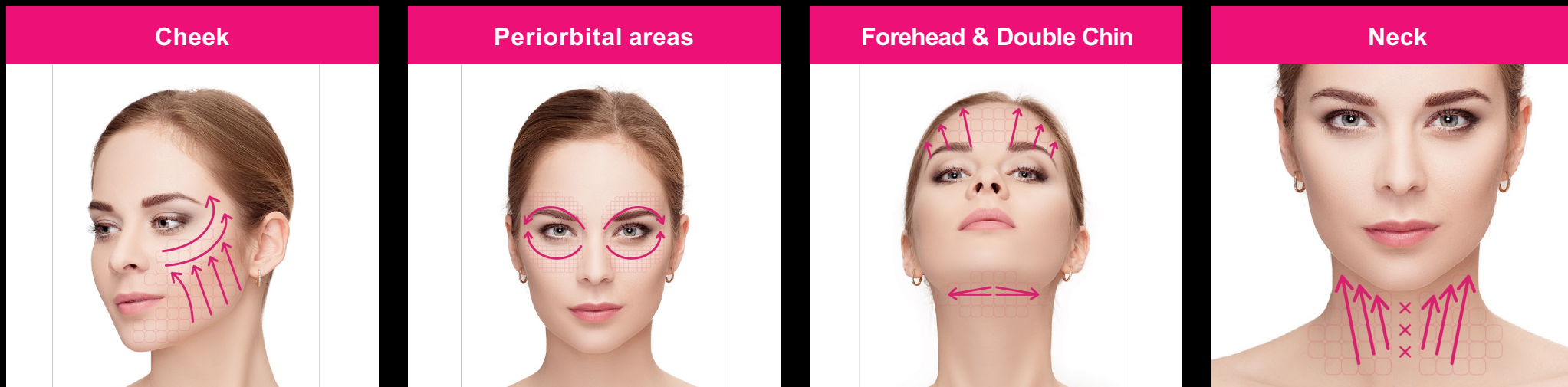


When RF energy is applied to the underlying skin and soft tissue, it generates contraction by 2 mechanisms: (1) immediate cleavage of hydrogen bonds in the collagen triple helix causing shortening and thickening of the collagen fibrils and (2) initiation of a wound healing cascade to trigger neoangiogenesis, neocollagenesis, and elastin reorganization over the following 3–4 months.

[The Use of Radiofrequency in Aesthetic Surgery - PMC \(nih.gov\)](#)

Treatment Guideline

Parameters for Face



| I TIP / F3 TIP / V4 TIP PARAMETERS | | | | | | | |
|------------------------------------|---------------------------------|-----|-------------------|------------------------|-----|---------------------------------|-----|
| Treatment Area | Periorbital areas | | Periorbital areas | Forehead & Double Chin | | Neck | |
| TIP | F | V | I | F | V | F | V |
| Starting LEVEL | 3.0 | 3.0 | 2.0 | 2.0 | 2.0 | 1.0 | 1.0 |
| PASS | 3-4 passes 5-6 vector passes | | 3-4 passes - | 3-4 passes - | | 2-3 passes 2-3 vector passes | |
| REPs | 500 | | 300 | 100 | | 200 | |

Before the Treatment

Preparation



STEP 1

- Check contraindications & precautions.
- Consent Form
- Post treatment Record Forms
- (treatment areas, shots, energy)

STEP 2

- Remove make up and oil residue.
- Remove all the metallic items and accessories.

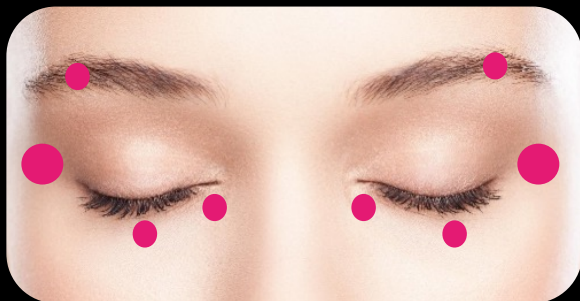
STEP 3

- Disinfect the treatment area.
- Take photo before the treatment.
- Apply the return pad. * System error occurs when the return pad is not properly attached
- Apply the return pad on the upper back to the side area.
- Attach the return pad cable. *Please refer to the treatment guide page 17
- Wear gloves and mark the treatment the area.
- Apply the coupling gel. * There is a risk of the burn when you don't apply the VOLNEWMER coupling gel
- Inspect the tip before the treatment.

Treatment Guideline

Step 1. Assessment

1. Medical and surgical history
2. Remove all metallic items and accessories.
3. Patient's Concerns (Identify problem areas)
4. Skin Analysis: wrinkles, volume, deflated areas, skin laxity
5. Skin Thickness (pinch test)



Common Area of Pain

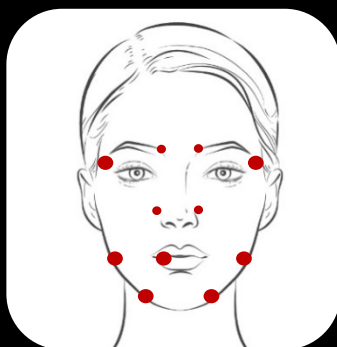
Contraindications

Patients with the following conditions are contraindicated:

- Patient with an artificial pacemaker, implanted defibrillator, or an automatic implantable cardioverter defibrillator(AICD) or any other electrical device for implantation
- Patients with pre-injected permanent fillers or facial implants in the treatment area
- Patients with a pathological abnormality or open wound at the treatment site
- Patients with any type of infection at the treatment site
- Patients currently with ongoing cancer or malignant disease
- Pregnant women and breastfeeding women

Treatment Guideline

Step 2. Check Impedance Level



Common areas of pain

Around the mouth: especially patient with dental treatment(Implant, crown). To prevent discomfort, place the gauze between the dental treatment area and the gums.

1. **Coupling Gel** : Apply the sufficient VOLNEWMER coupling gel (about 30ml for 500shots).

2. **Impedance Level Check** : Complete tuning process.

3. **Treatment Level Check** :

Testing Shot: 5~10 shots

Recommended treatment level is 3.0, but it depends on the pain tolerance level of each patient.

※ **“Hot but tolerable” level is recommended**

(Please refer to the Temperature Scale 0~4.)

0

No Sensation

1

Warm
Comfortable
heat sensation

2

Hot
Hot but tolerable

3

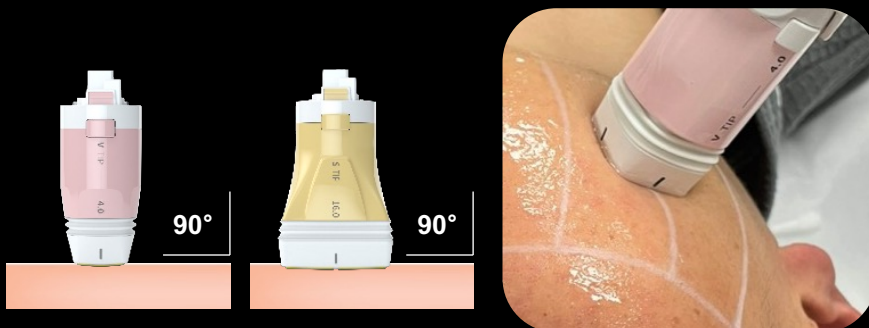
Very Hot
Tolerable only
for a short time

4

Intolerable
Stop the treatment
immediately.

Treatment Guideline

Applying shots



- Make sure the tip is fully contacted and perpendicular to the skin.
- Make a firm contact to the skin with an appropriate pressure.
- Proceed with the vector treatment per marked treatment area.

(*For more information of the Vector treatment, please refer to The Treatment Guideline on Page 17)

Treatment Tips

- Choose the suitable tips based on the treatment areas and skin thickness.
- Avoid the bony area when applying the shots and choose the appropriate energy level.

Coupling Gel

- Apply the sufficient amount of the coupling gel.
(The risk of burn is possible with insufficient VOLNEWMER coupling gel.)
- Use around 30ml for 500 shots.

Treatment Guideline

Treatment Tip

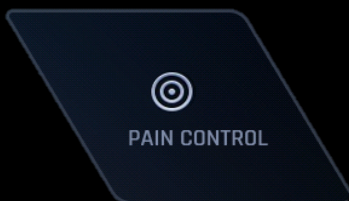
- Main Shot : Criss-cross 3 Passes (horizontal-vertical-horizontal) to heat up the dermal layer evenly
- 1 Pass : 50% overlapping
- 2-3 Pass : 50% overlapping, Turn on the <Pain control> mode when the patient complains of the pain.
- Main Shot : Additional shots are required for the area with uneven heat distribution.

Vibration



- Vibration Level from 1 to 4
- Adjust the vibration level based on patient's feedback.
- Level 1 to 2 vibration mode is recommended for the patient with thin skin.

Pain Control

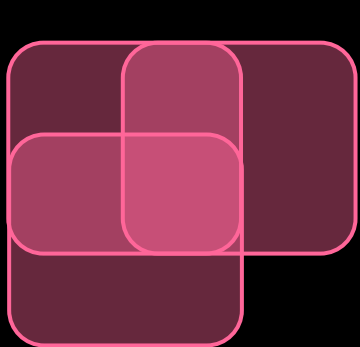


- Water Cooling System: adjusted from Level 1 to 4 (1: 20°C, 2: 18 °C, 3: 16 °C, 4:14°C)
- PAIN CONTROL : temperature of the tip reaching up to 12°C
- PAIN CONTROL mode is recommended after 1 pass of Main shot.

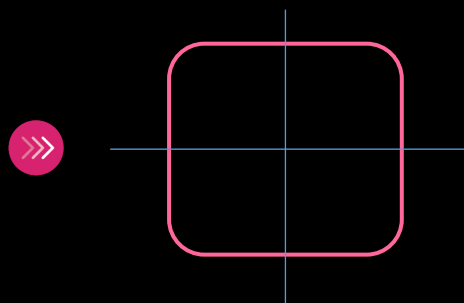
Treatment Guideline

Overlapping

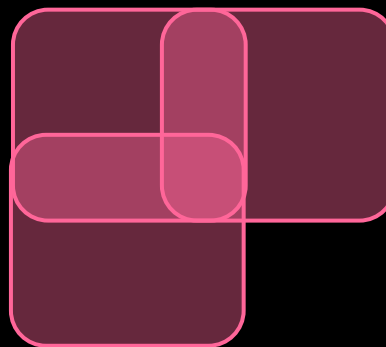
- Each pass should be overlapped 50% in the beginning.
- Turn on the Pain Control mode when the patient complains of pain.
- When pain is severe, make the wide spacing between each shot as per shown below.
(50% overlapping → 30% overlapping → 20% overlapping)



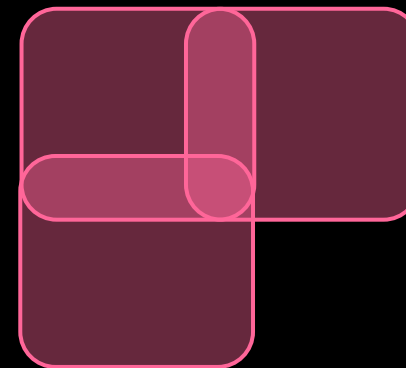
<50% vertical & horizontal overlapping>



50% overlapping is most effective method to heat up the epidermis



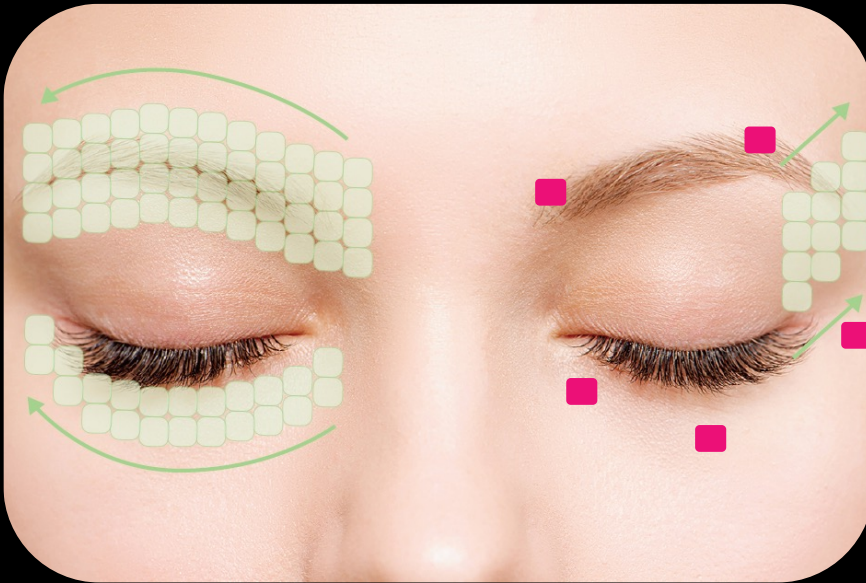
<30% example of overlapping>



<20% example of overlapping>

Treatment Guideline

I Tip Treatment Areas



Eyes : From the inner area to the outer area

(Eyebrow) : 4 Line / 3 Passes

(Eye bag) : 2 Line / 3 Passes

(Crow's feet) : 4 Line / 3 Passes

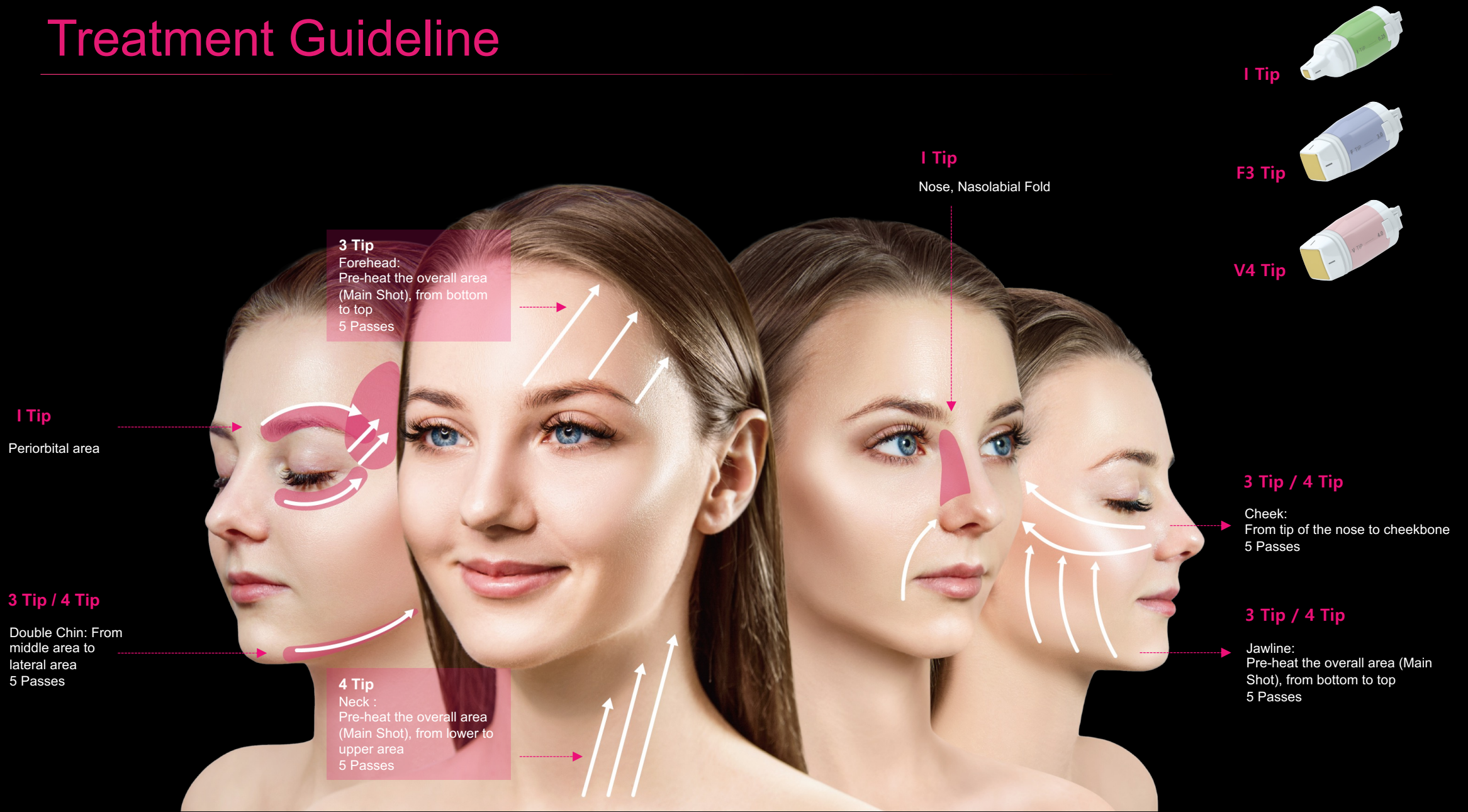


- Do not deliver the shot right on the eyeballs
- To protect the eyeball, use a gauze during the eye procedure

Treatment Video

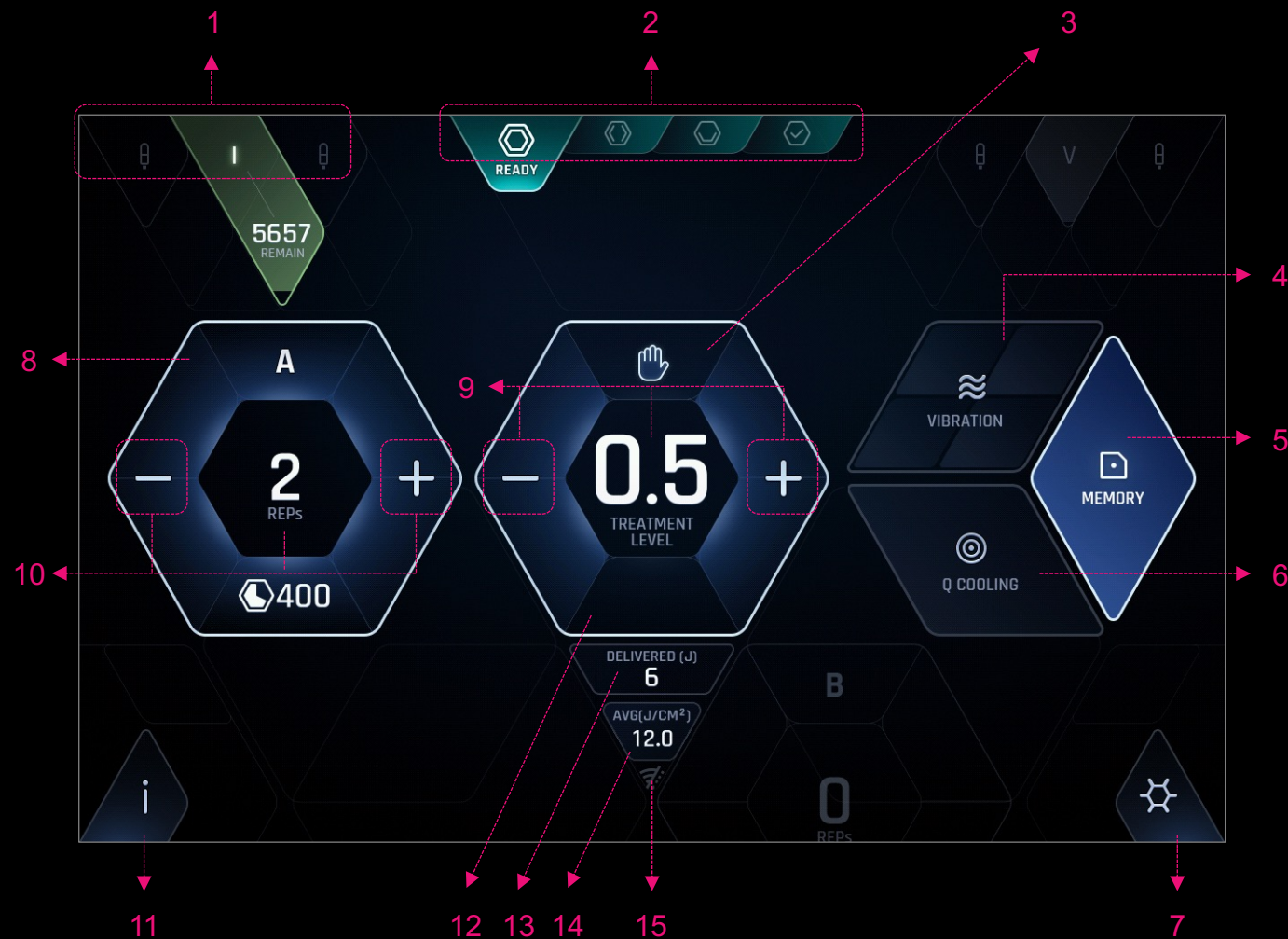


Treatment Guideline



G.U.I Display

Main Menu



| NO. | G.U.I |
|-----|-----------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1 | SAT activation for the Tip connected to A H/P |
| 2 | Treatment Process: READY / ARMED / ACTIVE / COMPLETE |
| 3 | Current Mode of Trigger Source (Hand/Foot) |
| 4 | Vibration Intensity: Switch by Touch (from one to four squares in sequence) |
| 5 | Short Key (Press shortly for Memory Selection Mode, and press longer for Memory Saving Mode) Information to save: Power/Vibration/ Pain Control/Alarm) |
| 6 | Pain Control : To Reduce Temperature |
| 7 | To Setup Screen |
| 8 | Activated Hand-piece Information (A) |
| 9 | Power Level Selection (0.5 Step each) [(+) UP; (-) DOWN] |
| 10 | Alarm On/Off (Set to On Mode) Frequency Increase (+)/Decrease(-) by Long Key |
| 11 | To Information Screen |
| 12 | Training Mode (For tutorial purpose, no delivery of shot) |
| 13 | Total Power Delivered(J) |
| 14 | Average Power Delivered Per Shot(J/cm²) |
| 15 | Wi-Fi Connection |
| 16 | Long Key: Press Longer To Reset the Shot Number |

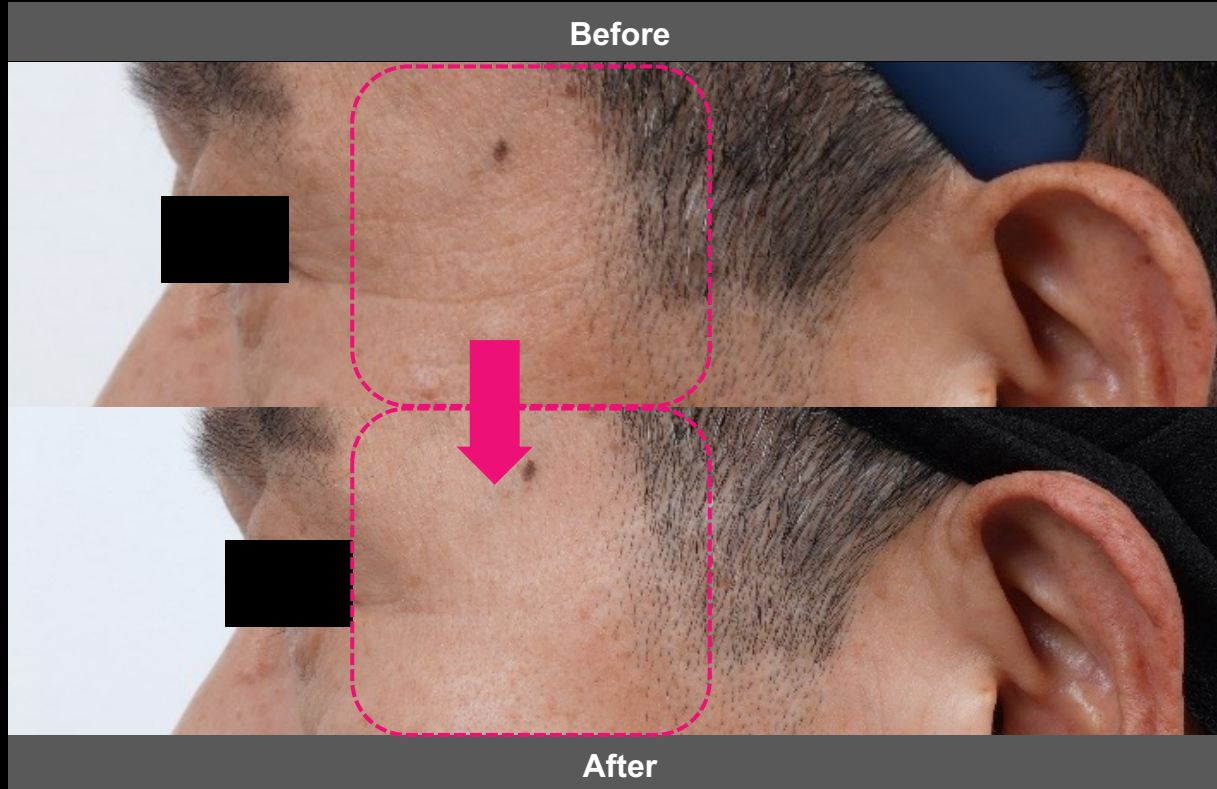
G.U.I Display

Setup



| NO. | G.U.I |
|-----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1 | Sound Selection |
| 2 | Volume Selection (Level 0-5) |
| 3 | ARM Rod Color Selection (COLOR1: White COLOR2: Activated Hand-piece Color on COLOR3: Both Hand-piece Color on) |
| 4 | Hand-piece Auto-recognition mode (On/Off) |
| 5 | Trigger Source Selection (Hand / Foot) |
| 6 | Auto Tuning Selection On / Off |
| 7 | Tip Replacing Mode for changing the tip |
| 8 | Cooling Level Selection (Level 1-4) |
| 9 | Shot Mode Selection Basic: Pressing the button for each shot Easy: Pressing the button while the shot is delivered Moving: Used for moving shot treatment |
| 10 | Training Mode (On / Off): No delivery of RF energy |
| 11 | Password Change |
| 12 | License Status (Update): |
| 13 | Factory Default |
| 14 | Information Display Switch |
| 15 | To the Main Screen |

Before & After

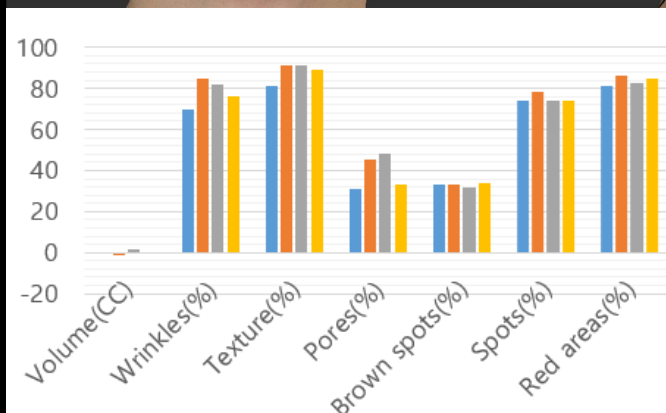
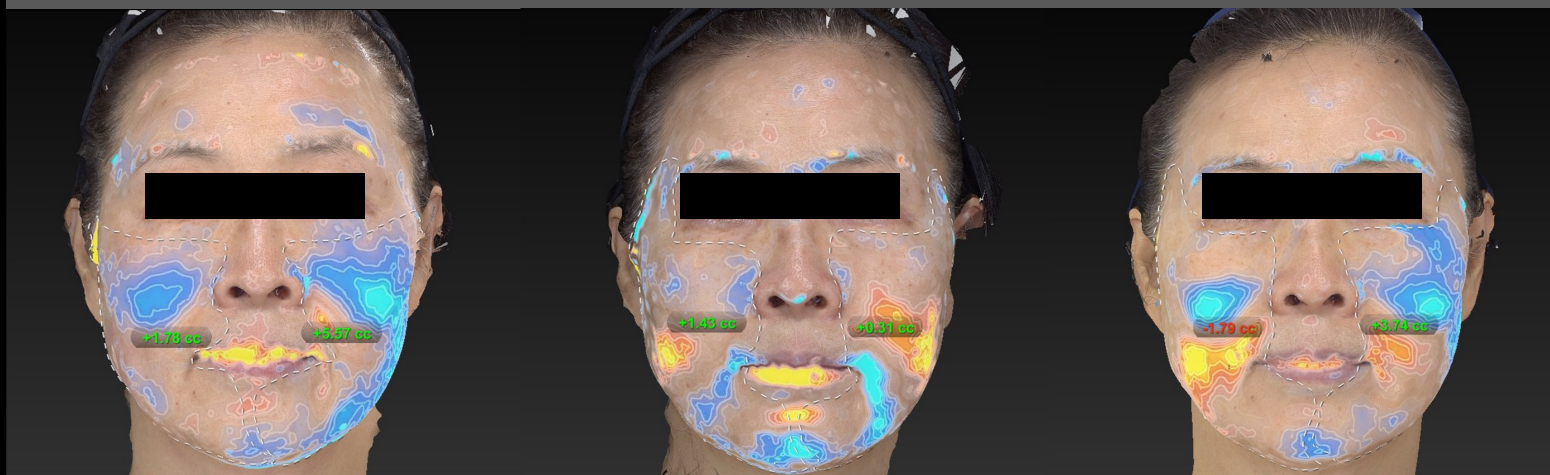


Before & After



Before & After

Volume Change by measurement: Increase in 2.00cc



VECTRA 3D Report



3D Rotating

Before & After



Before & After

Before



After



The Efficacy and Safety of Mono-Polar Radiofrequency for Mid-Face Volume Augmentation and Face Tightening

BACKGROUND Over several years, cosmetic surgeons have sought out rejuvenating effects while minimizing recovery time and the risks of postoperative infection, leading to the subsequent development of non-invasive modalities for facial rejuvenation. Non-invasive, aesthetic technologies share a common method of inducing thermal, dermal injury, and immediate, heat-induced changes in collagen structure are believed to induce tissue tightening in several clinical studies. Many studies have reported that monopolar RF is best suited for patients with early signs of aging, it is one of the most widely used noninvasive procedures for treating skin wrinkle and laxity.

OBJECTIVE The purpose of this study was to evaluate the safety and efficacy of pre and post-mono-polar radiofrequency treatment for mid-face volume augmentation and lower face tightening.

METHOD Twenty-five Asian patients with mild to moderate laxity of the middle and lower face were to receive two treatments at 4-week treatment intervals. They were shown before and after treatment photographs of participants treated with a radiofrequency (RF) device. Two RF treatments were performed. The first session of the RF treatment protocol consisted of a V Tip (Treat 4.0cm²) with 600 shots applied over the full face. The second treatment session after 4-week intervals consisted of a V Tip (4.0cm²) 300shots applied mid-face, a total of two treatments. Acute clinical response and pain scores were assessed after each session. Standardized photographs, 3D Vectra photos, and reports were taken at baseline, at 4 weeks, and at 8 weeks after the second treatment. At the 4-week and 8-week post-treatment follow-up visits, a post-treatment photo was taken and assessed by both the participants and the physician. Participants also completed a self-assessment questionnaire.

RESULT After each treatment session, temporary anticipated adverse effects were reported. The RF treatment was well tolerated by most of the participants. The participants responded with higher scores for treatment results in all categories of the photographic analysis. The physician's photographic and 3D Vectra photo assessment demonstrated continued improvement.

CONCLUSION Two RF treatments yielded significantly better improvement than a single treatment in the tightening of the marionette line and nasolabial folds. Significant improvement in laxity, tightening, and volume after treatment was seen between the 4-week and 8-week follow-up visits. Skin tightening effects in the treatment areas continued to occur between 4 and 8 weeks post-procedure with extremely low adverse effects and minimal downtime.

Figure 1. Adverse Effects Report

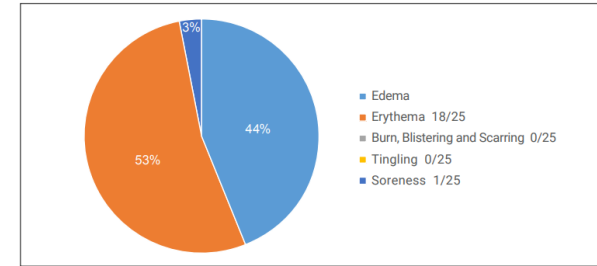


Figure 2. First Treatment: 4.05 Second Treatment: 3.75 out of 10

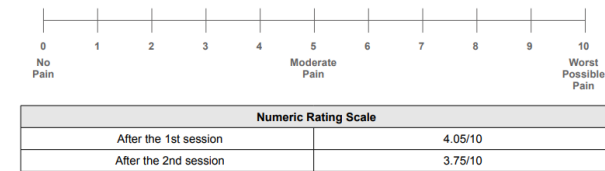


Figure 3. Self-Assessment Questionnaire

