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PHYSICIAN'S CLINICAL GUIDE

new 2.0 doublo™

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HIRONIC

Physician's Clinical Guide

Effect

SD (Synergy Dotting) Cartridge with Enhanced RF Energy
FL (Focused Linear) Advance Cartridge for Further Concentrated MFU Energy

Precision

RM Handpiece's Multi-Pulse: Adjustable in 1ms Increments
RM Handpiece's Multi-Frequency: Options of 0.5, 1.0, 2.0MHz

Diversity

FL(Focused Linear) Handpiece Eight Dedicated Cartridges
SD(Synergy Dotting) Handpiece Six Exclusive Cartridges

Speed

Unified LINE & DOT Mode Capability

new 2.0 doublo™
DOUBLE EFFECT DOUBLE SAFETY

DISCLAIMER
(Additional Explanation)

The treatment guidelines suggested in this Physician's Clinical Guide are based on various clinical studies, academic papers, and a range of cases. The parameters for the intended procedure must be adjusted according to individual cases. The manufacturer is not responsible for issues arising from improper use of the equipment or excessive treatment.

Before using the equipment, the practitioner must check the user manual, understand the accurate operation and handling of the equipment, and then proceed with the treatment.

The treatment protocol includes patient history assessment and lesion diagnosis during pre-treatment consultation, treatment process, number of sessions, expected treatment outcomes, potential side effects, pre- and post-treatment precautions for both practitioners and patients, patient disclosure, selection of appropriate treatment variables according to the treatment purpose, post-treatment care, medication prescriptions, and scheduling follow-up visits.

The indications and parameters introduced in this booklet may be updated based on various clinical cases and treatment experiences. Practitioners are advised to refer to the latest insights for clinical application.

MFU+RF Synergy Device:

New Doublo 2.0

This clinical protocol includes guidelines, parameters, and various case studies for using energy-based devices that leverage the synergistic effects between MFU and RF. This content is based on the opinions of medical professionals with extensive clinical experience and is recommended as a reference for practitioners during procedures. To improve proficiency in equipment operation, a fundamental understanding of and training in MFU and RF, along with the accumulation of practical experience, are necessary.

This booklet presents basic parameters according to the treatment purpose. These parameters may need to be adjusted based on individual patient factors such as gender, age, skin thickness of the treatment area, physique, and differences in sensitivity, pain, and response to MFU and RF treatments. Additionally, the selection of appropriate parameters is necessary based on the characteristics and location of each individual lesion. When treating areas with deeper skin layers, applying relatively higher energy can be expected to yield more improved effects.

Conversely, for areas with shallower skin layers, it is recommended to apply lower energy during the procedure. To maximize the results of the procedure and minimize side effects, it is important to identify factors that may negatively affect the patient's wound healing process after treatment, prior to the procedure.

While MFU and RF treatments are safe with minimal to no downtime required, when combined with other procedures like Laser or Micro-needle RF, appropriate pre and post-treatment care should be administered to reduce side effects and downtime. In cases where higher parameters are applied, the use of air coolers or icepack cooling should be employed to alleviate any discomfort or side effects for the patients.

Chapter. 01

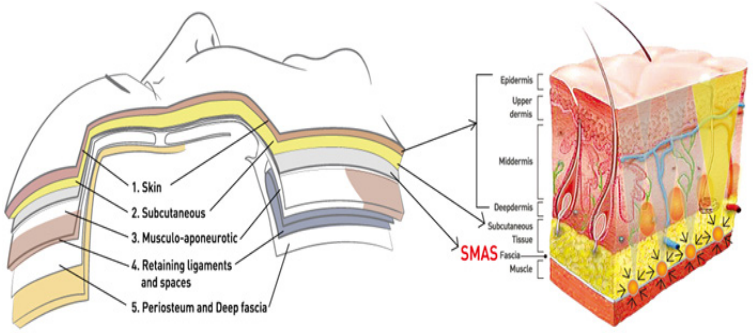
Overview

01
Introduction

[1] Introduction

As we age, the skin and its underlying tissues undergo continuous aging. Notably, in the skin, the number of fibroblasts decreases, leading to reduced collagen synthesis, and the number and function of various skin appendages also diminish. Aging of the subcutaneous tissues that maintain the face contouring results in decreased skin elasticity and sagging skin.

The aging of subcutaneous tissues leading to decreased skin elasticity and sagging causes the overall facial structures to droop in the direction of gravity. This phenomenon of wrinkles and reduced elasticity in the face is primarily related to gravity, and the process of counteracting this skin sagging in the opposite direction of gravity is referred to as face lifting.



1. Skin
2. Subcutaneous Layer
3. Musculoaponeurotic Layer
(SMAS: Superficial Musculoaponeurotic System)
4. Loose Areolar Tissue
W(Spaces and Retaining Ligaments)
5. Fixed Periosteum and Deep Fascia

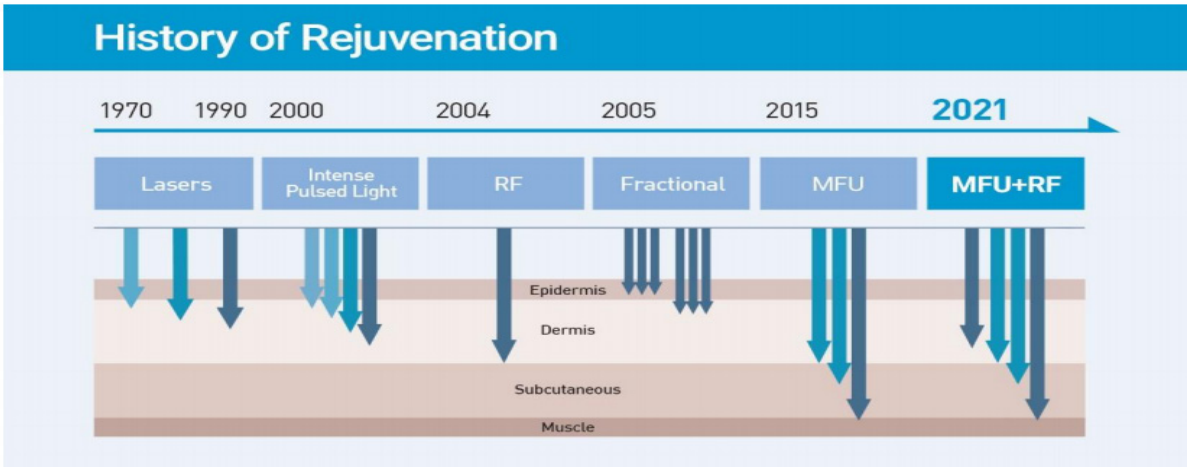
Before delving into face lifting using 'Micro Focused Ultrasound (MFU)' and 'Radio Frequency (RF)', it's essential to understand facial anatomy. The face and scalp are composed of five basic layers. Traditional dermatological laser treatments focused on areas such as the epidermis and dermal collagen remodeling. While collagen remodeling in the dermis can improve skin elasticity to some extent, fundamentally enhancing face contouring itself is known to be challenging.

[2] History of Face Lifting & Tightening

'Rejuvenation' is a compound word derived from the Latin 'Re (again)' and 'Juvenile (child)', which can be interpreted as 'returning to youth' or 'becoming young again.' Rejuvenation has influenced the development of cosmetic medical procedures, and advancements in LASER (Light Amplification by Stimulated Emission of Radiation) and cosmetic medical devices are primarily of six types:

The Development History of Facial Rejuvenation Procedures

- Ablative Resurfacing with Lasers: Skin surface improvement through laser incision
- Photo-Rejuvenation with IPL: Photorejuvenation using IPL
- Rejuvenation with Electrical Current(RF): Rejuvenation treatments using electricity
- Rejuvenation with Fractional Laser: Rejuvenation treatments using fractional lasers
- Rejuvenation with HIFU: Rejuvenation treatments using HIFU
- Synergy Effect from the Combination of HIFU & RF: Synergistic effects of combining HIFU & RF



Before the advancement of laser technology, face lifting using Ablative Lasers or Chemical Peeling often resulted in severe side effects. However, these early procedures significantly influenced the subsequent development of laser technology. The introduction of IPL (Intense Pulsed Light) brought attention to photo rejuvenation, but its limited rejuvenation effects soon led to its decline in popularity. Nevertheless, IPL proved to be highly effective in treatments for pigmentation, vascular lesions, and hair removal, and it continues to be widely used to this day.

The most longstanding item in rejuvenation has been the use of electrical energy through RF (Radio Frequency), which can be either mono-polar or bi-polar. RF has been applied alone or in hybrid forms with other technologies like diode lasers, NIR (Near Infra-Red), and IPL. In South Korea, the combination of RF and needles to deliver fractional electrical currents is a prevalent approach. Fractional Lasers have also been a long-standing technology in rejuvenation. Various wavelengths of light, such as 1,550nm Er: glass fiber, 10,600nm CO2, 2,940nm Er: YAG, have been developed as fractional lasers for therapeutic applications.

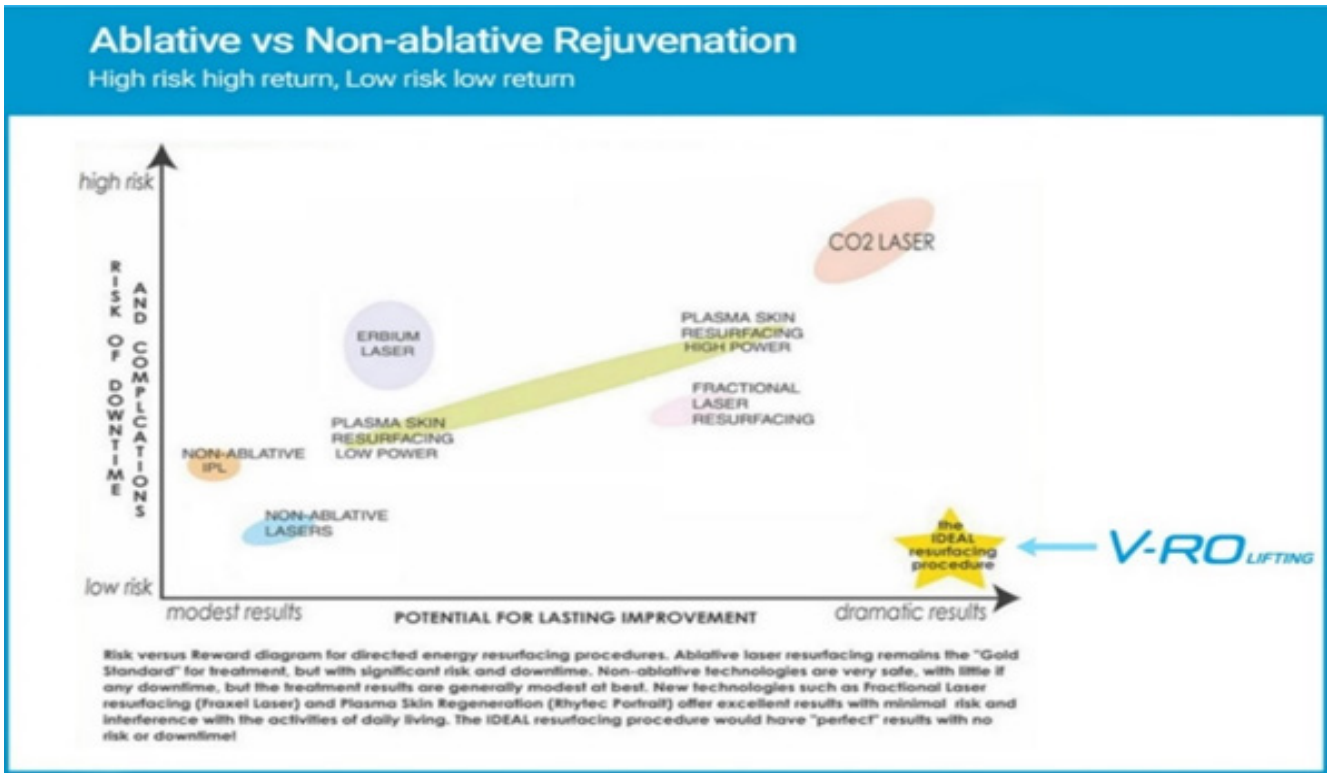
HIFU (High Intensity Focused Ultrasound) improves skin aging by creating selective thermal coagulative zones, smaller than $1mm^3$, in subcutaneous tissues or the SMAS layer without damaging surrounding tissues. HIFU delivers intensely focused ultrasound energy fractionally to a depth of a few millimeters under the skin, causing thermal damage in the deep structures such as the lower dermis, dermo-subcutaneous fat boundary layer, fibrous tissue in the fat layer, SMAS layer, and fascia.

Through the wound healing process, it achieves a gradual face lifting effect over several months. In addition to inducing tissue response through heat, HIFU, with its high energy, is also used for tumor treatment and fat removal, as it can create cavitation and cause cell necrosis through a thermomechanical process. Conversely, in the recent field of skin aesthetics, equipment like MFU, which only induces thermal reactions using milder energy to raise the tissue temperature to a specific level, is increasingly utilized.

[3] Ideal Conditions for Rejuvenation Equipment

The most crucial condition for rejuvenation equipment is to maximize effectiveness while minimizing side effects. Full face resurfacing rejuvenation using Ablative Lasers or chemical peeling, while effective, carries a high risk of side effects. When developing rejuvenation equipment, the most critical aspect is to maximize effectiveness while minimizing side effects, and HIFU (High Intensity Focused Ultrasound) equipment best aligns with this objective.

Correlation Between the Effectiveness and Side Effect Risks of Different Rejuvenation Equipment

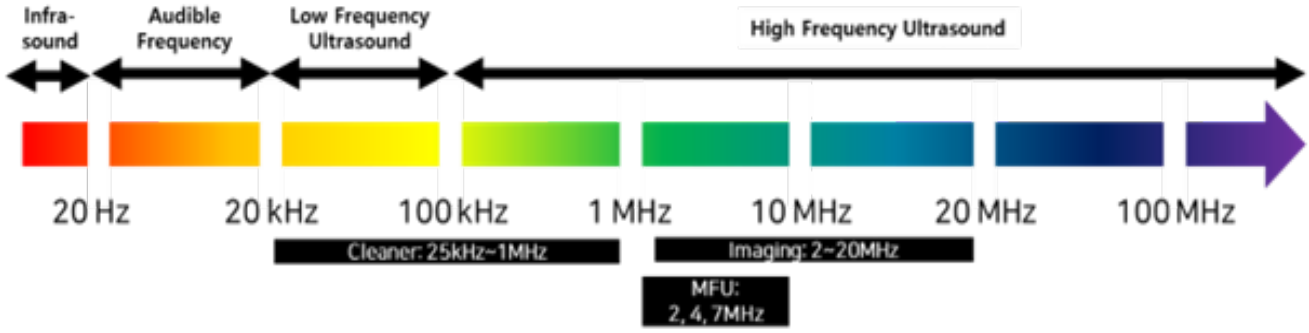


02
What is HIFU

[1] Definition of HIFU

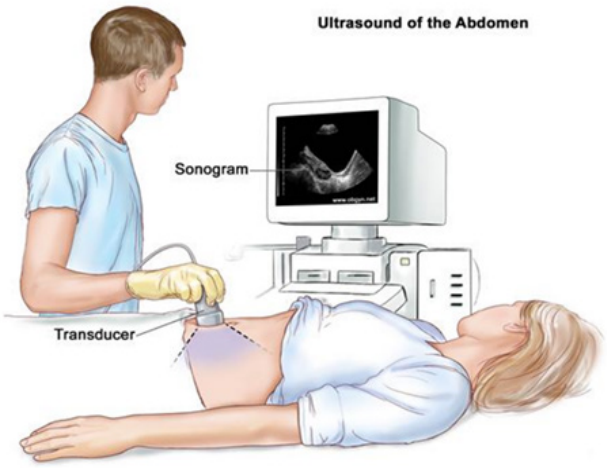
HIFU (High Intensity Focused Ultrasound) is a novel type of treatment equipment that uses 'sound waves' instead of 'light' like traditional lasers. To understand HIFU, one must first understand ultrasound. The frequency range of sounds audible to the human ear averages from '16Hz to 20kHz', and sound waves with frequencies above 20kHz are referred to as 'Ultrasonic Waves.'

Classification of Sound Waves by Frequency Range



Ultrasound with frequencies above 100kHz is classified as 'High Frequency Ultrasound.' Ultrasound, known for its ability to penetrate water, has been used for a long time in medical diagnostics, and more recently, it has been widely utilized in physiotherapy devices.

Ultrasound Used for Diagnostic Purposes, Observing Images by Detecting Reflected Ultrasound Waves

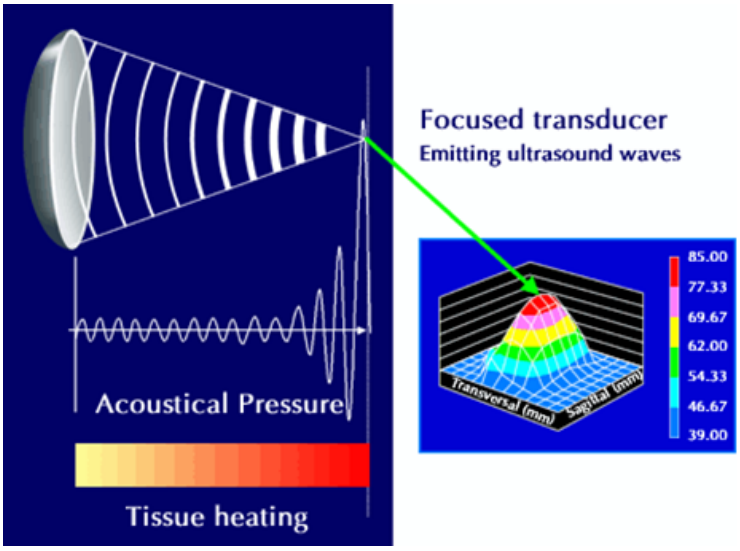


The Three Physical Effects of Ultrasound in Detail

- Mechanical Effect
- Cavitational Effect
- Thermal Effect

The principle behind the use of HIFU in skin aesthetics is based on the thermal effect. When ultrasound is applied to the skin, some of it is absorbed and some is scattered. The absorbed ultrasound generates heat, causing denaturation of proteins within the tissues, which leads to the desired effects. Since its adoption in the field of skin aesthetics, HIFU technology has made significant advancements.

The Treatment Principle of HIFU



High-Intensity Focused Ultrasound Emission

▼

Induces molecular vibration in targeted tissue

▼

Generates heat through molecular friction

▼

Denaturation(60~70°C)

When ultrasound is emitted from a transducer, it induces vibration of molecules at the focused tissue site. This maximizes molecular friction, which is then converted into thermal energy, Cau sing denaturation of the tissue.

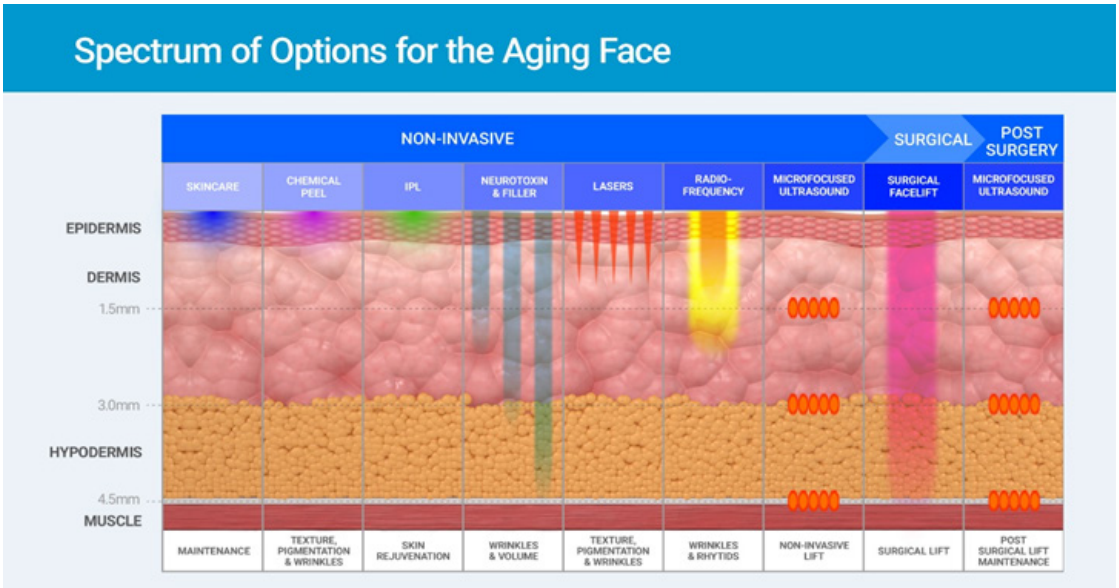
[2] History of Using Ultrasound in Treatment

HIFU utilizes ultrasound generated from a transducer, focusing it on the target layer to leverage the thermal effects at the focus point. Initially, it was used in treating solid tumors such as liver, uterine, and breast cancer. Later, it gained attention as a non-invasive treatment modality and was adopted in skin aesthetics.

[3] History of Using Ultrasound in Skin Rejuvenation

HIFU selectively induces thermal coagulative changes in the subcutaneous layer or SMAS layer without damaging surrounding tissues. While other light-based and RF devices struggle to stimulate deeper dermal layers without affecting the epidermis or upper dermis, HIFU minimally impacts the skin and subcutaneous layers. It specifically forms Thermal Coagulative Zones in deeper areas, effectively targeting the desired points

Differences in Treatment Areas Among Various Rejuvenation Equipment



Traditional rejuvenation equipment like Fractional Lasers, RF, and IPL target the epidermis or upper dermis, whereas HIFU can target the deep dermis or deeper structures without affecting the epidermis or upper dermis. The first use of HIFU in skin rejuvenation was by Gliklich et al. in 2007, and it gained significant attention following the publication of research data using cadaver tissues by the Harvard Wellman Center in 2008. Additionally, the 2010s saw a focus on research in eyebrow-lifting and facial skin tightening.

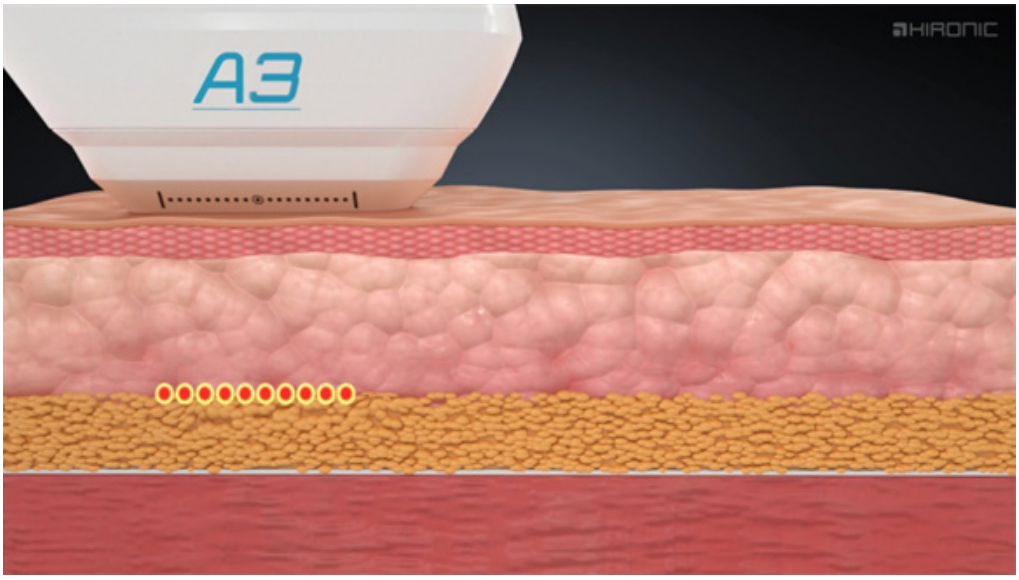
[4] Why Choose MFU (Micro Focused Ultrasound)?

In recent skin aesthetics, MFU (Micro Focused Ultrasound) is gaining popularity for its ability to maximize effects while minimizing side effects using relatively low energy. MFU is a HIFU technology that selectively uses lower energy. It minimizes pain and swelling associated with HIFU treatments and overcomes some of HIFU's drawbacks. Traditional HIFU uses ultrasound at 2MHz with energy levels of 47-59J/cm² or even exceeding 100J/cm², which can cause tissue reaction from heat and create cavitation leading to cell necrosis. On the other hand, MFU operates at 4-10MHz with mild energy levels of about 0.2-1.5J/mm², inducing only thermal reactions in tissues, thus minimizing side effects

[5] The Principle of 'Face Lifting' Using MFU (Micro Focused Ultrasound)

When electrical energy is transmitted to the ceramic inside the MFU generator, it is converted into ultrasound. When this generated ultrasound is focused, heat is produced at the center of the focus point.

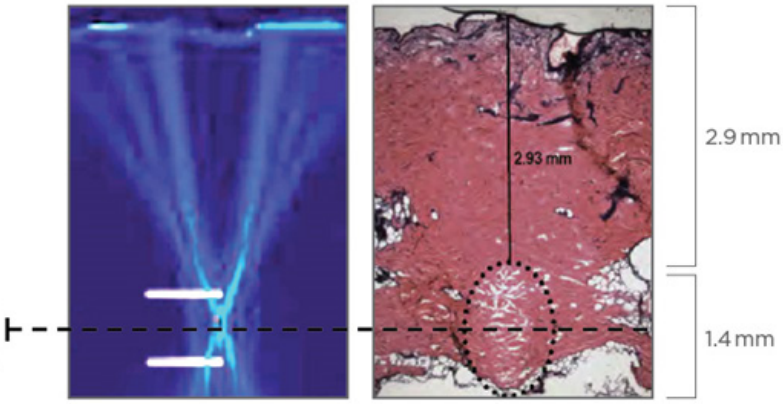
Treatment Principle of MFU: A Diagram Showing the Formation of a Thermal Coagulative Zone in the Actual SMAS Layer by Emitting MFU from the FL Cartridge



Observing the thermal effect of ultrasound within the tissue, heat is generated only at the center of the focus, creating a Selective Thermal Coagulative Zone at the desired target layer or depth without damaging the epidermis. This selective thermal transmission results in a high thermal reaction above 55°C at the target site. Consequently, the sagging skin tissues contract, and the skin is lifted, which is the principle behind the lifting procedure using MFU.

The Principle of Creating Hot Spots through Focusing in MFU

Focusing heat at a specific depth without affecting intermediate tissues



A. An image showing the focus of 7.5MHz MFU using the Schlieren technique.
B. An image demonstrating the formation of coagulative zones when MFU is applied to actual tissue.

MFU delivers intensely focused ultrasound energy fractionally to a few millimeters depth in the skin, causing thermal damage to the deep structures such as the lower dermis, dermo-subcutaneous fat boundary layer, fibrous tissue in the fat layer, SMAS layer, and fascia. This triggers a wound healing process, resulting in gradual face lifting effects.

The frequency unit of MFU is Hz (vibrations per second). As the Exposure Time (a kind of Pulse Duration) increases, a thermal zone forms along the axial direction on the skin surface. However, prolonged exposure can damage the epidermis, so in clinical practice, a short exposure time is crucial to preserve the epidermis and dermis while effectively targeting the treatment area.

Traditional rejuvenation equipment inevitably stimulated epidermal melanocytes as they delivered energy through the epidermis to the dermis. In contrast, MFU delivers energy only to the dermis without affecting the epidermal melanocytes. Unlike light-based treatments like lasers, MFU's effects are independent of skin color or chromophores, a characteristic often referred to as 'Color Blind.' This feature allows effective treatment in ethnic groups or individuals with darker skin, where light-based treatments carry a higher risk of side effects. As a color-blind and effective rejuvenation device, MFU represents a new concept in truly non-invasive rejuvenation equipment. Schlieren Technique: A method that visualizes sound by using light refracted dueto changes in density caused by sound waves.

03
What is RF

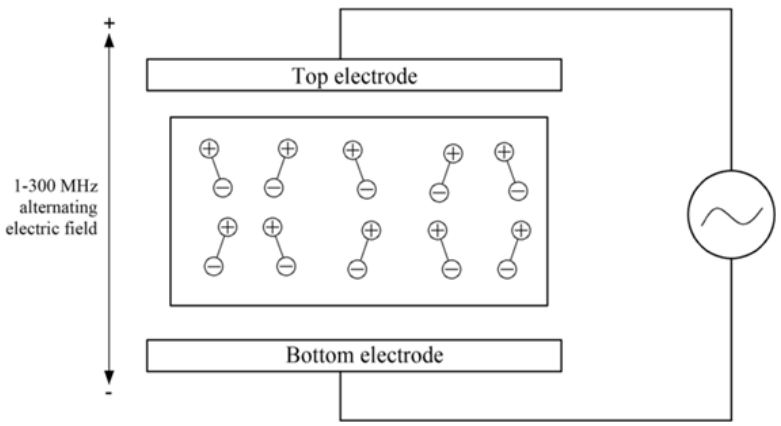
[1] Definition of RF

Radio Frequency is a form of electromagnetic wave, similar to radio waves, microwaves, infrared, visible light, ultraviolet, X-rays, and gamma rays. They all are electromagnetic waves differing only in wavelength and frequency. The principles that allow Radio Frequency to be used in medical devices are as follows:

① When Radio Frequency current flows through human tissue, the vibration amplitude is very short, causing almost no ion movement. Therefore, there are no electrochemical or electrolytic reactions. The pulse duration required to stimulate normal muscles is about 1ms, but the pulse duration of RF current is only about 0.001ms. Unlike other current forms, it does not stimulate sensory or motor nerves, hence causing no discomfort or muscle contraction. This allows specific areas within the tissue to be heated without discomfort.

② As the RF current flows, ions like Na+ and K+, and polar molecules like H2O, rotate, causing friction and collision with adjacent molecules. The energy expended in the twisting of non-polar molecules like fats is converted into heat energy, known as conversive heat. This process of transferring energy to specific tissue areas to generate heat is also referred to as volume heating. Ultimately, the generation of heat is due to the molecular motion within the tissue. Because the heat penetrates the skin, it's also called deep diathermy or deep heating.

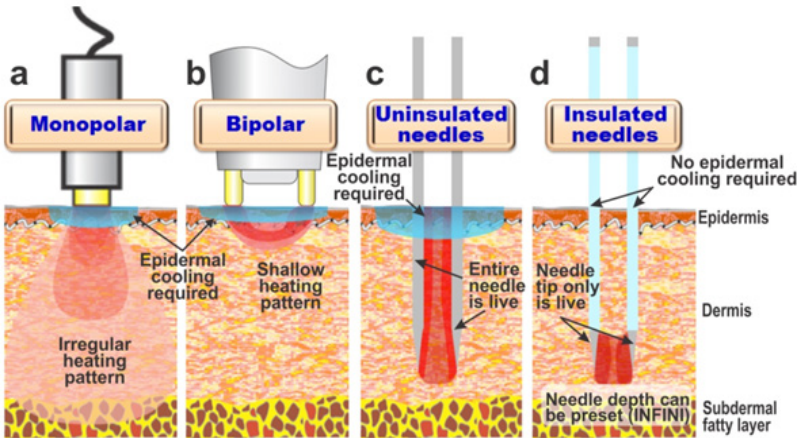
Methods of Generating Heat Energy in Tissues Using Radio Frequency



[2] The Principle of 'Face Lifting' Using RF

The principle of lifting and tightening using Radio Frequency involves flowing current through the skin and utilizing the heat generated by the body's impedance (electrical resistance) during the electrification of the treatment area. The vibrational, rotational, and collisional movements of the water molecules in the tissue due to impedance generate frictional heat, also known as bioheat. This bioheat causes contraction of the target layer, resulting in a tightening effect. Additionally, it stimulates fibroblasts in the dermis to promote collagen regeneration, thereby achieving a rejuvenation effect.

Methods of Generating Heat Energy in Tissues Using Resistive Heating with Radio Frequency

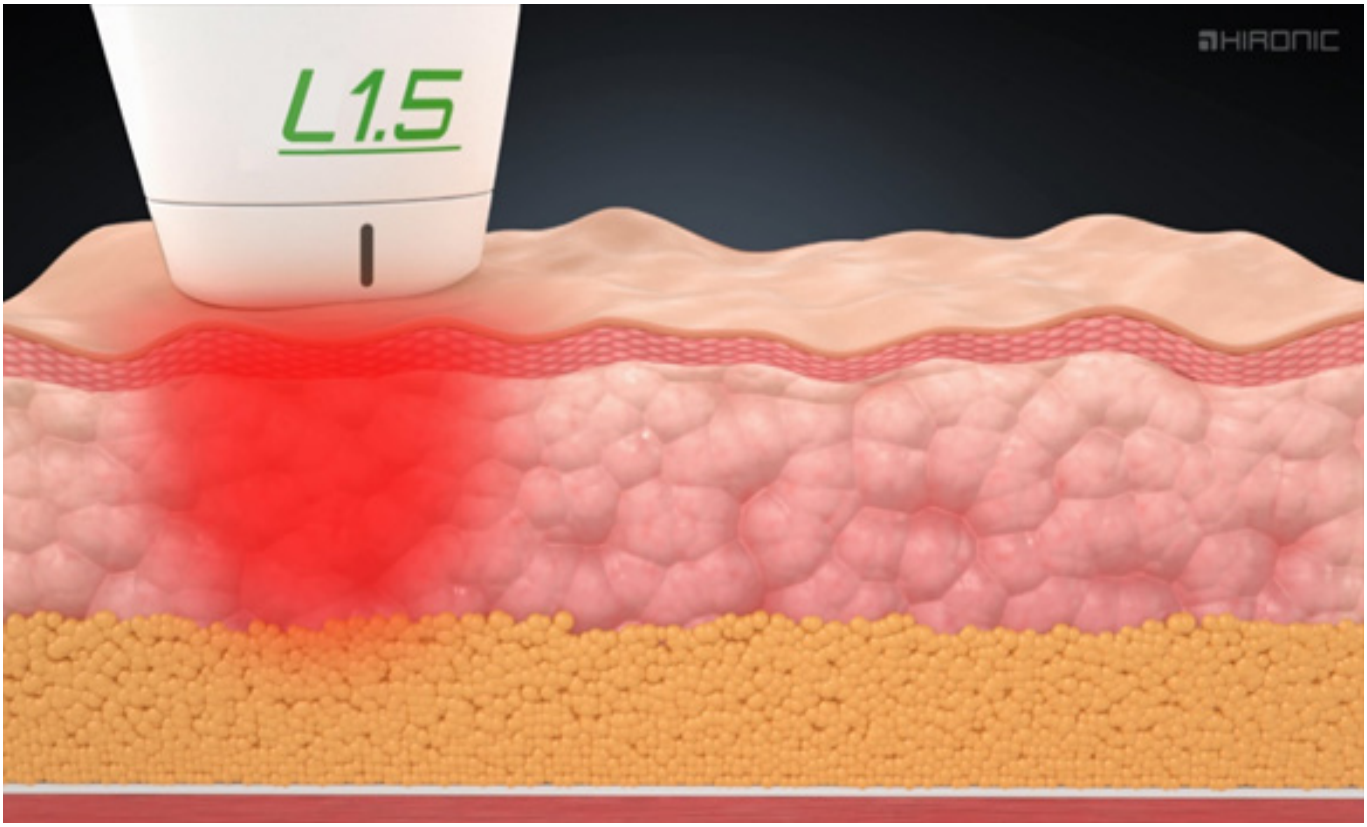


a. Monopolar (Single-pole)
b. Bipolar (Dual-pole)
c. Uninsulated (Non-Insulated)
d. Insulated

Radio Frequency (RF) devices are primarily categorized into monopolar (single-pole) and bipolar (dual-pole) based on the number of poles used. Monopolar devices use a single electrode, with a return patch attached to the body for completing the circuit, allowing them to deliver a significant amount of energy to deeper locations. In contrast, bipolar devices, which do not require attaching a patch, are more convenient but deliver limited energy and have a shallower penetration depth compared to monopolar devices. While monopolar focuses on lifting and tightening, bipolar is more oriented towards rejuvenation and improving skin texture and elasticity. Additionally, there are techniques involving the insertion of needles into the treatment area and passing current through them for scar and pore improvement. These can be divided into insulated and non-insulated methods.

In the insulated method, part of the needle is metal-coated, so energy is only delivered from the tip, concentrating the heat energy in the target layer. This allows for the transmission of a significant amount of energy to deeper areas, effectively treating scars and pores. The non-insulated method, where the current flows through the entire needle, allows the energy to be distributed more broadly, making it suitable for overall rejuvenation, skin texture, and tone improvement.

RF Treatment Principle: A Diagram Showing the Emission of RF Energy from the SD Cartridge and its Transmission of Heat Sensation to the Epidermis and Dermis

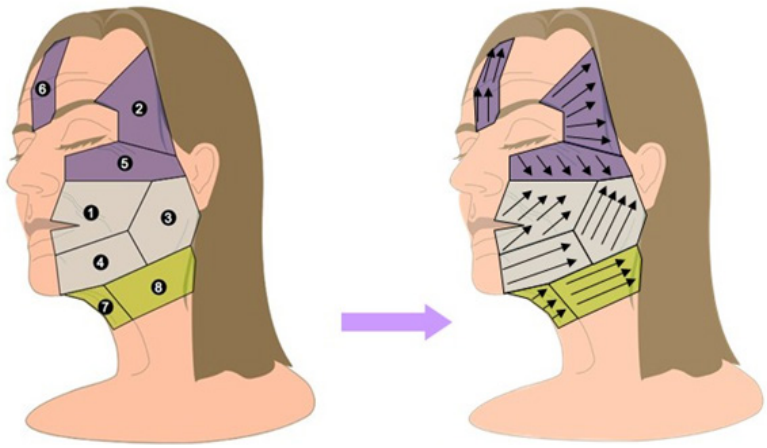


04

Clinical Considerations for MFU & RF Treatment

[1] Facial Muscles and Direction of Treatment in MFU Procedures

Guidance on Treatment Direction According to Area

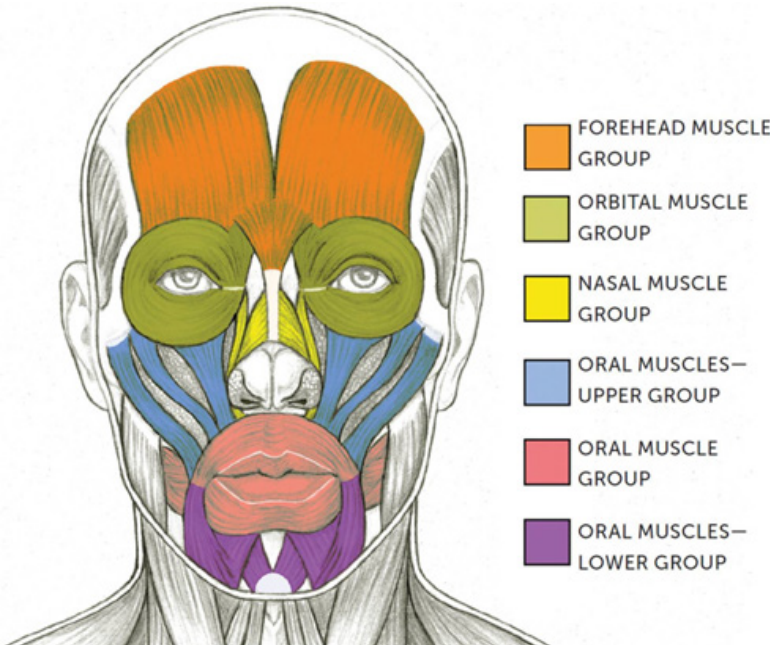


The reasons for facial lines sagging due to aging include:

① Atrophy of subcutaneous facial fat
② Volume reduction due to decreased elasticity in facial dermis
③ Relaxation of the fascial fibrous layer connecting the skin to the bone

The fascial fibrous layer is a net-like tissue similar to the reticular layer of the skin's dermis. It is divided into supporting ligaments that directly connect the bone to the skin, fascial tendons that attach the bone to muscles, and fascial fibers that connect muscles to the skin. For effective lifting, the most crucial aspect is accurately understanding the muscle's vector direction and the focus depth.

Facial Muscle Groups



[2] Pain

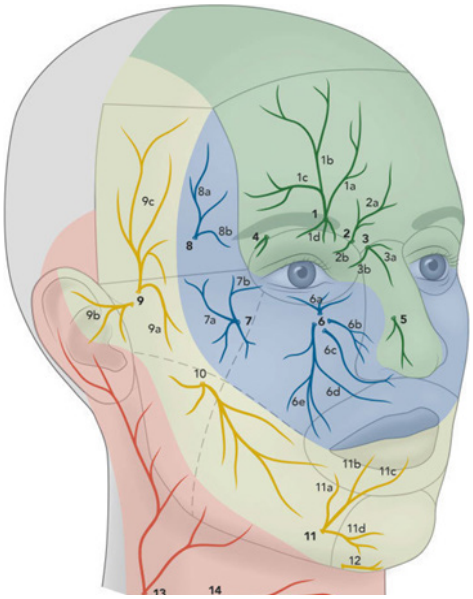
Strictly speaking, HIFU (High Intensity Focused Ultrasound) is a 'shockwave' created by 'sound waves', which generates heat through secondary actions and can cause pain, sometimes requiring anesthesia. In the past, when HIFU was predominantly used, topical anesthesia with anesthetic creams was recommended. However, the recent trend in treatments has shifted to using MFU with milder energy levels, often eliminating the need for anesthesia. Additionally, in MFU+RF Synergy treatments, the heat sensation from RF can alleviate pain, allowing the procedure to be more comfortable.e risk of side effects.

Areas to be cautious about during treatment include bony prominences. These areas, with relatively thinner tissues, are susceptible to unintended deep penetration of MFU, potentially reaching the periosteum. Such areas on the face include the cheekbones, jawline, and forehead. Forehead treatments, in particular, are frequently accompanied by pain, which can lead to complications. Toothache-like complaints sometimes occur, mainly when prosthetics, orthodontic devices, or dental implants are near the treatment area. In such cases, reducing the intensity of the treatment and employing techniques like inflating the cheeks or using gauze to create space can mitigate pain and minimize side effects.

[3] Nerve Injury

Since MFU (Micro Focused Ultrasound) targets relatively deep layers like the SMAS layer, there is a potential risk of nerve injury. If nerve damage occurs, conditions like neurapraxia (physiological nerve block) or axonotmesis (axon cutting) can recover over time, but neurotmesis (nerve severance) can result in permanent disability. Therefore, careful attention must be paid to the treatment area and energy selection. The pain or facial nerve reactions reported by patients during the procedure serve as important indicators for the treatment process. As mentioned earlier, this is why nerve blocks are generally not recommended. A critical consideration is the area where facial sensory nerves become superficial near the skin. Excessive pressure during the procedure can transmit energy to the nerves, so caution is necessary to avoid nerve damage.

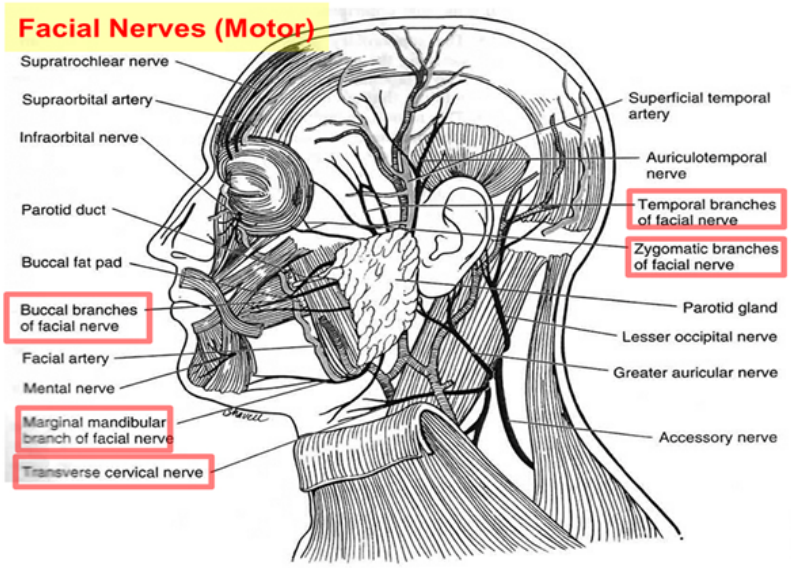
Dangerous Zones to be Cautious of During MFU Treatment



Areas requiring particular caution are around the eyes and mouth, where facial sensory nerves are superficially distributed. Additionally, caution is needed when treating near the thyroid, as its safety has not been fully verified. Around the mouth, care must be taken with the branches of the infraorbital nerve (orbit nerve) and the mental nerve (chin nerve). Special attention is required in areas of bony prominence, as they are more prone to complications. Avoid aggressive treatment around the lips, and ensure the patient is thoroughly informed and understands the procedure. Around the eyes, be cautious of the supratrochlear nerve and infraorbital nerve.

Theoretically, motor nerves can also be damaged by MFU treatment. Major motor nerves distributed in the face include the temporal branch, zygomatic branch, buccal branch, marginal mandibular branch, and cervical branch, as shown in the illustration.

Branches of Facial Nerves to Be Cautious of During MFU Treatment

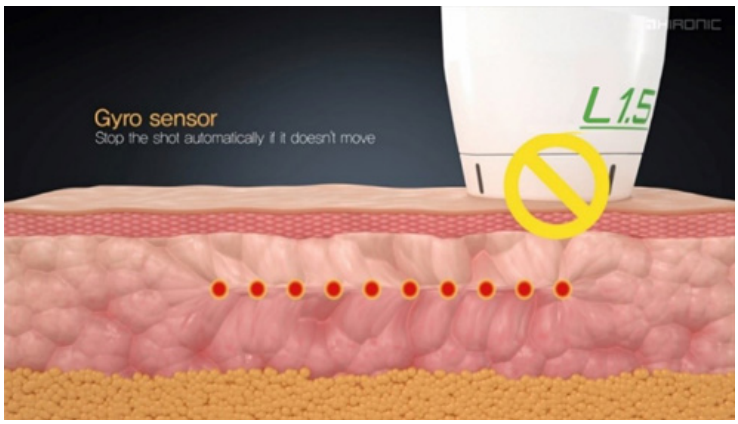


All branches of the facial nerve are susceptible to damage from MFU. Particularly, the marginal mandibular branch, which wraps around the mandible, is one of the nerves most commonly affected. When treating motor nerves, facial muscle twitching can be observed. Therefore, if abnormal muscle movements are noticed on the face, it's advisable to avoid treating that area or to lower the energy value.

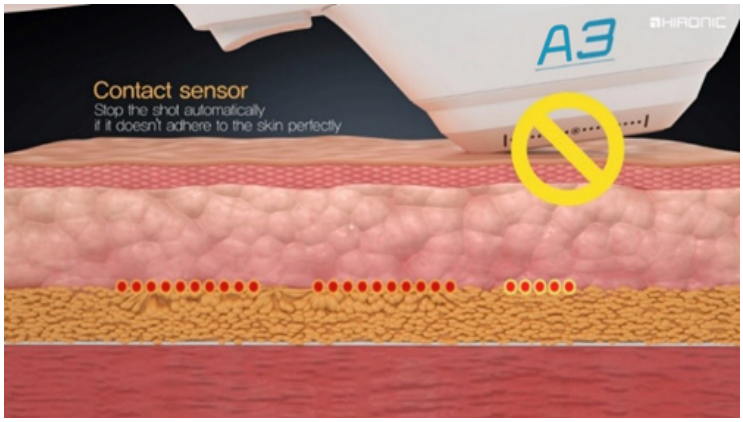
[4] Thermal Injury (Burn)

Burns are much less common with MFU compared to IPL or fractional laser treatments. There are two main scenarios where skin burns might occur with MFU treatment: Firstly, if the energy is too high, the area of thermal damage can become extensive, resulting in burns on the skin surface. This phenomenon occurs when the energy increases, causing the column forming the Thermal Coagulation Zone to expand axially towards the skin surface. The causes of thermal injury can include 1) emitting very strong energy, 2) continuously applying energy to the same area, or 3) setting the spacing too narrow in relation to the energy level. The second cause of burns is poor contact between the cartridge and the skin, leading to misaligned focus. This type of heat generation at the interface, when ultrasound penetration is not smooth, results in burns similar to typical skin burns. This can occur if the ultrasound gel is not adequately applied or if the device is used without proper skin contact.

New Doublo 2.0 movement detection sensor
to prevent continuous energy irradiation to the same area



New Doublo 2.0 safety sensor
to prevent energy irradiation in case of poor contact



To prevent thermal injury, New Doublo 2.0 has two patented safety features. The contact sensor prevents energy emission if there is poor skin contact, and the motion detection sensor automatically stops energy emission if no movement of the handpiece is detected. These features help prevent side effects caused by thermal damage.

Regarding treatment areas, the cheeks have a very low frequency of side effects, while the neck and forehead areas have relatively higher frequencies. Swelling that occurs post-treatment is usually temporary and tends to resolve without scarring within a week.

Clinical Aspects of Side Effects by Treatment Area: Swelling of the Cheeks

This is a temporary phenomenon, typically resolving within a week without any special treatment or scarring. In the neck area, blisters or scabs can occur even at relatively low energy levels.

Clinical Aspects of Side Effects by Treatment Area: Blisters on the Neck

Cases where tiny vesicles on the neck area developed into crusts have improved without scarring after applying a topical steroid for a week. The reason for such side effects occurring more commonly on the neck compared to the face is believed to be because the neck has 1) less dermal microvascular blood flow, leading to poor heat dissipation, and 2) a thinner subcutaneous layer, increasing the likelihood of side effects. In areas like the forehead and jawline, which are bony prominences, improper contact of the cartridge surface with the skin can lead to the formation of coagulative zones at shallower depths than intended.

[5] Fat Atrophy

MFU creates coagulative zones in the SMAS layer, which is deep within the dermis, to achieve a tightening effect. While the MFU device forms consistent coagulative zones, the skin doesn't always have uniform structures at consistent depths. This varies from one area to another and from one patient to another, leading to a variety of variables in each situation. It's common for coagulative zones to be formed not only in the SMAS layer but also in the subcutaneous fat layer. In such cases, the treatment may result not only in tissue tightening but also in a debulking effect due to volume reduction. When performing MFU treatments, it's essential to consider both the aspects of tightening and lipolysis. While a moderate degree of lipolysis (fat breakdown) can induce tissue volume reduction, thereby slimming the face, excessive lipolysis can lead to undesirable cosmetic outcomes due to excessive atrophy of subcutaneous fat.
Fat atrophy due to lipolysis is more likely to occur in older patients, especially when treated with relatively high energy levels. For patients over 60 years old, it is advisable to lower expectations slightly and use about 30% less energy than usual for treatments.

[6] Split Face Trial

In cases of rejuvenation treatments aimed at overall skin elasticity and wrinkle improvement, the effects often become apparent over time. The principle is to first assess the degree of facial asymmetry before treatment and start with the areas requiring improvement. After treating one side of the patient's face, let them objectively compare the improvements before proceeding to the other side. After all treatments are completed, patients can also be encouraged to feel the elasticity of their skin by touching it with their palms.

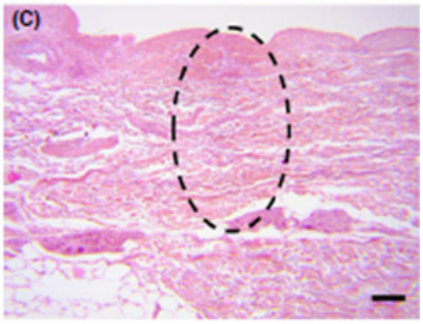
05
MFU+RF Synergy Effect

[1] Various Test Results on the Synergy Effect of MFU & RF

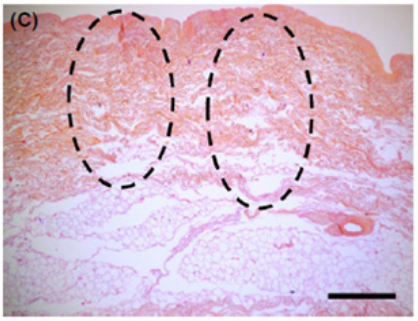
1. MFU & RF Synergy Effect in Pre-Clinical Trial

The synergy effect of MFU and RF has been demonstrated in tests conducted in South Korea on cadaver skin. When combining 7MHz focused ultrasound (MFU) with 1MHz and 6MHz Radio Frequency (RF), the resultant thermal coagulation response in tissues was more extensive and pronounced compared to RF treatment alone.

Non-invasive RF only Treatment

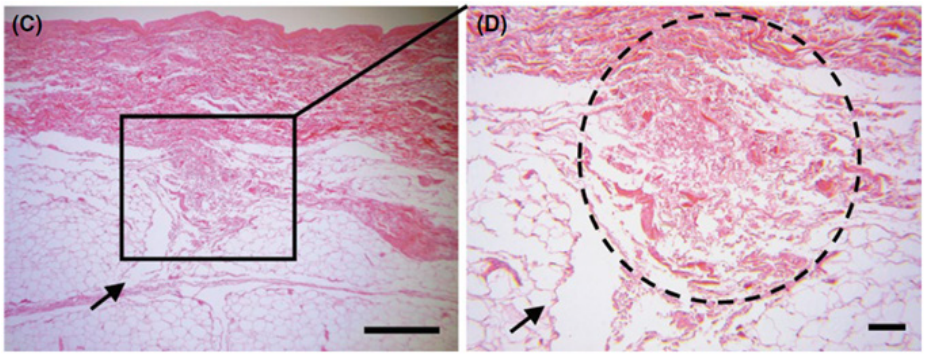


MFU followed by Non-invasive RF



When non-invasive RF was applied after MFU exposure and compared with non-invasive RF only treatment, a broader extent of maximum thermal tissue damage was observed in the mid to lower dermis. The combination treatment using MFU and non-invasive RF induced a significant coagulation response from the mid-dermis to the upper subcutaneous fat, showcasing a mixed pattern of thermal tissue reactions.

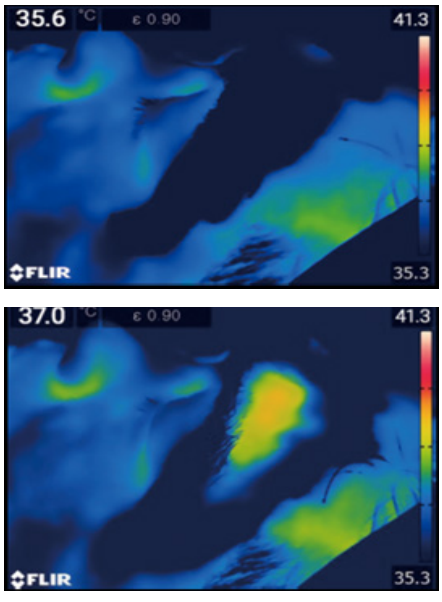
Non-invasive RF followed by MFU



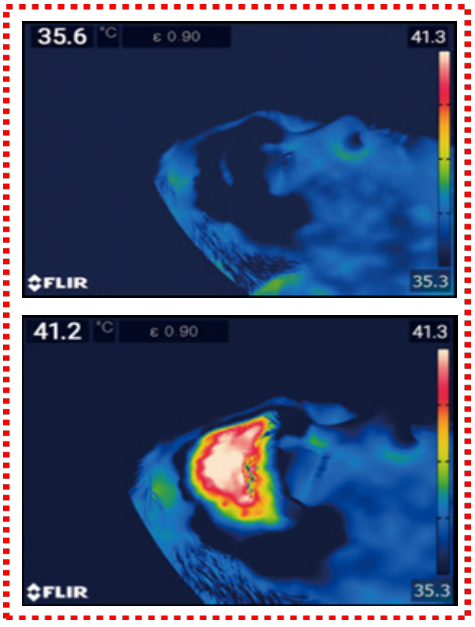
When the order of application was reversed, applying non-invasive RF followed by MFU resulted in a significantly wider and deeper thermal coagulation response compared to RF treatment alone. This outcome suggests that MFU exposure on tissues pre-treated with RF results in a more superficial thermal coagulation response than when using MFU alone.

Thermal Imaging Camera Results Comparing only MFU to Simultaneous MFU+RF Exposure

MFU



Simultaneous MFU+RF

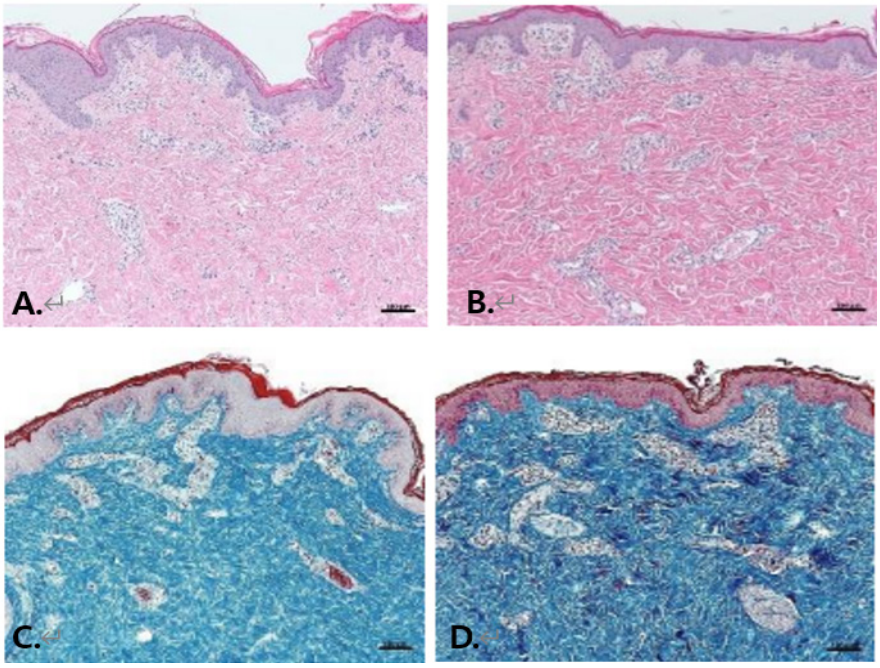


※ Ref: New Doublo 2.0 SD H/P MFU+RF Cross-Exposure Mode, only MFU Exposure Mode, Compared Using Thermal Imaging Camera Results.

The advantages of the synergy effect of MFU+RF compared to only MFU exposure were also reflected in our thermal imaging camera results. As observed in the split face results, when treatments were conducted with the same energy values, the thermal reaction in the skin surface was higher in the areas treated with MFU+RF.

To assess the clinical improvements resulting from this higher thermal reaction, MFU+RF was applied to micro pigs, whose skin closely resembles human skin, and the outcomes were observed.

Tissue Changes Effect of MFU+RF Rejuvenation, H&Es, X50

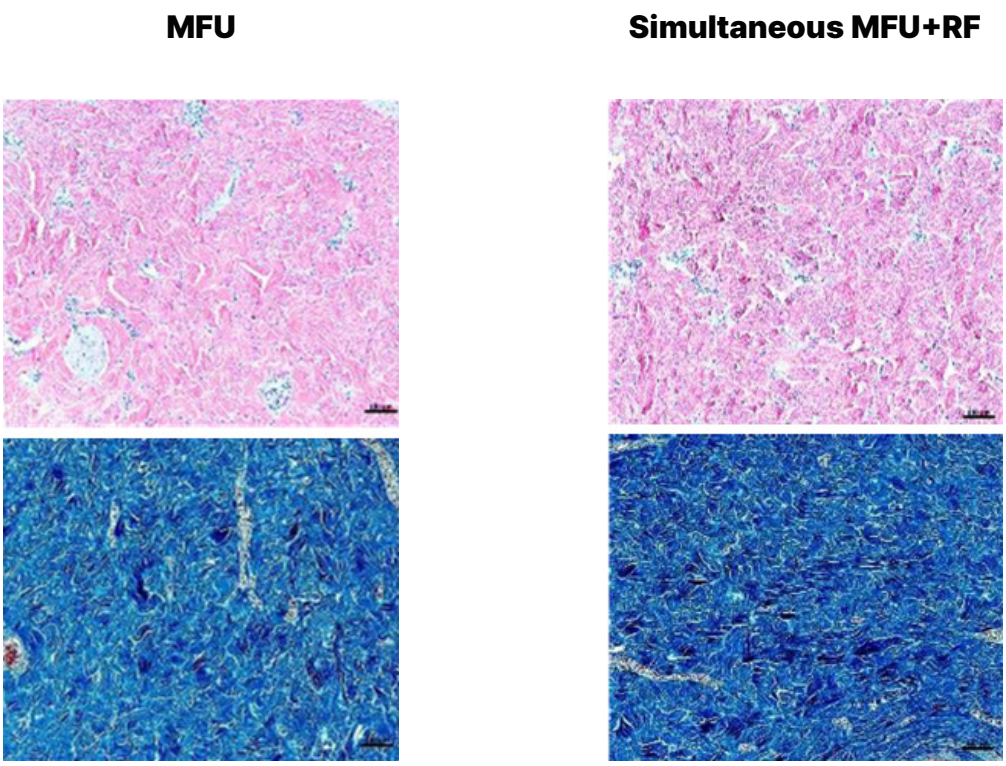


※ Ref: New Doublo 2.0 SD H/P MFU+RF Cross-Exposure Mode, Solo HIFU Exposure Mode, Compared Using Thermal Imaging Camera Results.

A. Pre MFU+RF Exposure H&E Stain
B. Post MFU+RF Exposure H&E Stain: Overall darker red color indicating activated collagen regeneration
C. Pre MFU+RF Exposure MT Stain
D. Post MFU+RF Exposure MT Stain: Overall darker blue color indicating activated elastin regeneration

Compared to before the treatment, the application of MFU+RF showed both collagen and elastin being activated.

Comparison of only MFU and Simultaneous MFU+RF in Pre-Clinical Trials



※ Research Period: 2022.06.07 - 08.04 / Subject: Female Crossbreed Pigs 60-80kg, 5 in total / Research Institution: Seoul National University Bundang Hospital / Study Number: HSBI-PFU-22020

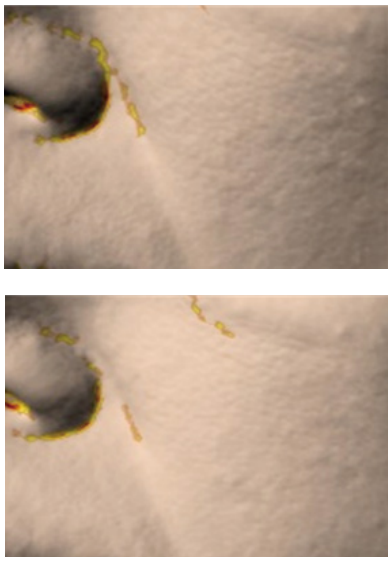
In pre-clinical trials conducted on micro pigs, simultaneous MFU+RF exposure, as compared to only MFU exposure, showed more distinct activation of collagen and elastin. This was observed through Hematoxylin and Eosin (H&E) Staining and Masson's Trichrome (MT) Staining, which are key indicators related to skin elasticity. The increase in collagen activity, indicated by a darker pink in H&E staining, and the increase in elastin activity, marked by a darker blue in MT staining, suggest significantly higher activation of collagen and elastin in tissues treated with simultaneous MFU+RF.

2. MFU & RF Synergy Effect in Vivo Test

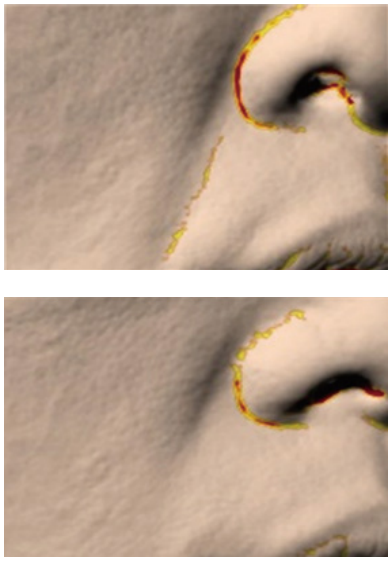
Based on these results, experiments applied to human subjects demonstrated significant improvements in various skin aesthetics indicators compared to MFU only treatments.

Comparison of only MFU and Simultaneous MFU+RF in Pre-Clinical Trials

MFU



MFU+RF



※ Ref. Comparative Human Application Test Results of New Doublo 2.0 SD H/P MFU+RF Cross-Examination Mode vs. MFU Alone Mode – 100% Improvement in Control Group

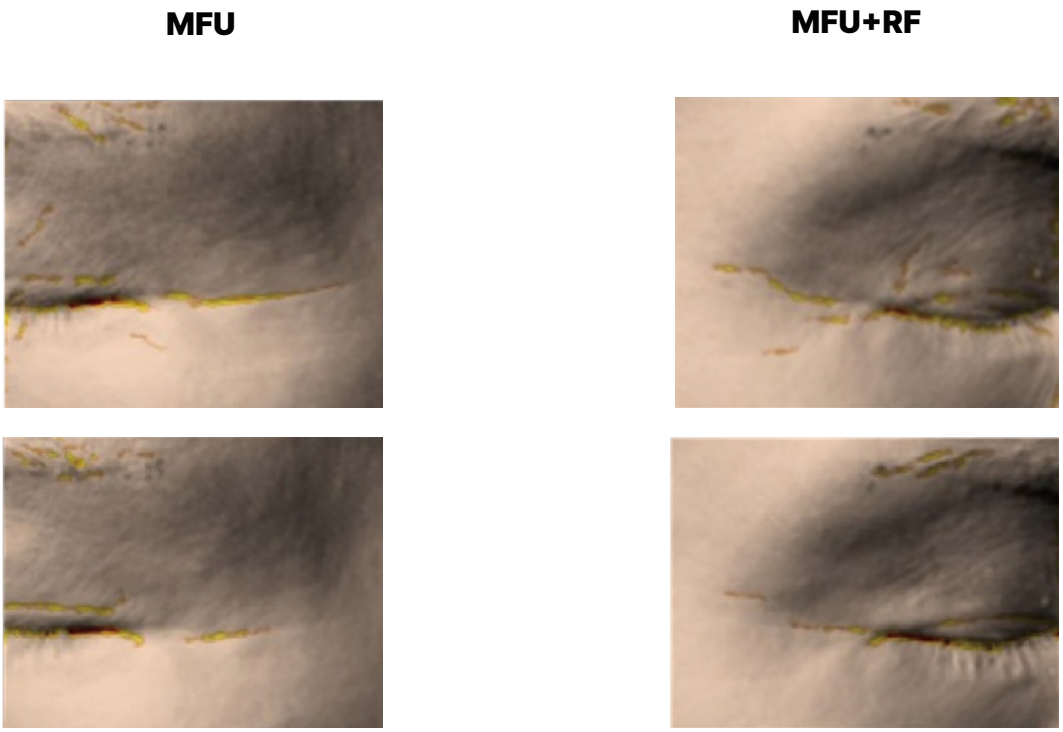
※ Research Period: 2022.06.07 - 08.04 / Subject: Female Crossbreed Pigs 60-80kg, 5 in total / Research Institution: Seoul National University Bundang Hospital / Study Number: HSBI-PFU-22020

Average Depth Difference in Nasolabial Fold Area Through Imaging

Duration	After a Single Use	After 4 Weeks	After 8 weeks
MFU Alone	9.59%	55.99%	65.19%
MFU+RF	12.04%	79.17%	82.67%
Comparative Advantage	1.3 Times	1.4 Times	1.3 Times

Compared to MFU exposure, MFU+RF treatment demonstrated a superior improvement in nasolabial folds, with an average depth reduction up to 1.4 times greater, maintained over 8 weeks.

Comparison of only MFU and Simultaneous MFU+RF for Eye Wrinkle Area Through Imaging



※ Ref: V-RO SD H/P MFU+RF Cross-Exposure Mode, only MFU Exposure Mode, Human Application Test Results: 100% Improvement in Control Group

※ Test Period: 2022.08.18 - 10.13 / Subjects: Healthy Korean Adults aged 30-65 (average 42.8 years), 20 participants / Testing Institution: Hueman Skin Clinical Test Center / Test Number: HM-P220270

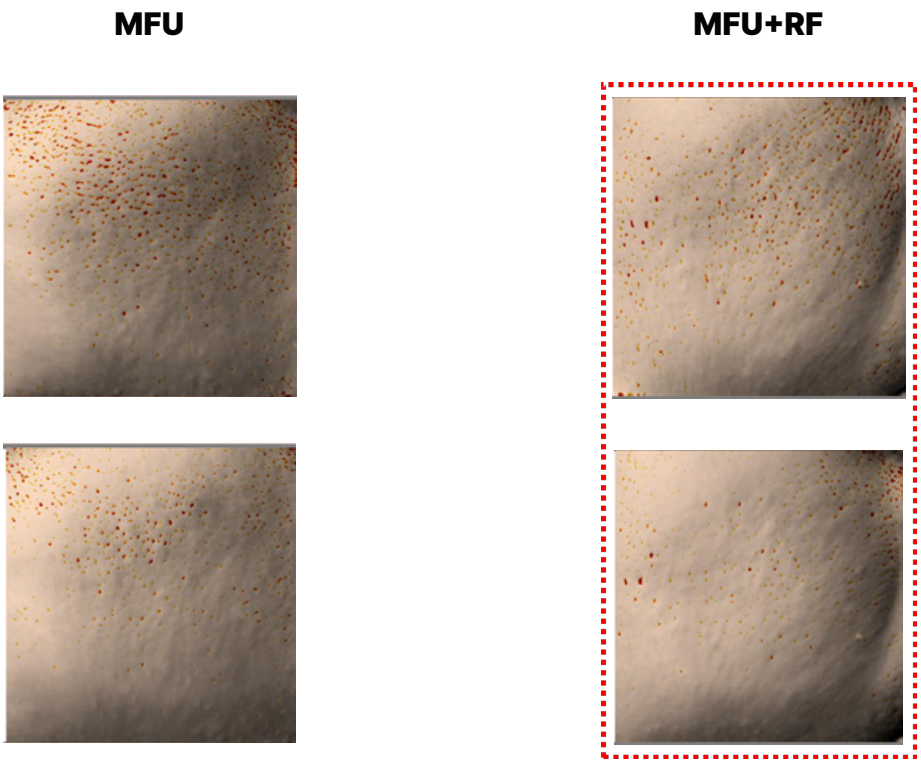
Average Depth Difference in Eye Wrinkle Area Through Imaging

Duration	After a Single Use	After 4 Weeks	After 8 weeks
MFU Alone	7.98%	7.72%	6.38%
MFU+RF	8.21%	12.68%	10.31%
Comparative Advantage	1.0 Times	1.6 Times	1.6 Times

Comparative studies between only MFU and MFU+RF treatments have shown that MFU+RF achieves a faster and higher rate of improvement with long-lasting effects on eye wrinkles. Over an 8-week period, the average depth of eye wrinkles decreased up to 1.6 times more with MFU+RF treatment than with MFU alone.

Besides improvements in nasolabial and eye wrinkles, MFU+RF also showed significant enhancements in overall skin tone and appearance, particularly in pore-related metrics, thereby emphasizing the importance of MFU+RF synergy.

Comparison of only MFU and Simultaneous MFU+RF for Pore Imaging



※ Ref. New Doublo 2.0 SD H/P MFU+RF Cross-Exposure Mode, only MFU Exposure Mode, Human Application Test Results: 100% Improvement in Control Group

※ Test Period: 2022.08.18 - 10.13 / Subjects: Healthy Korean Adults aged 30-65 (average 42.8 years), 20 participants / Testing Institution: Hueman Skin Clinical Test Center / Test Number: HM-P220270

Pore Density Difference Through Imaging

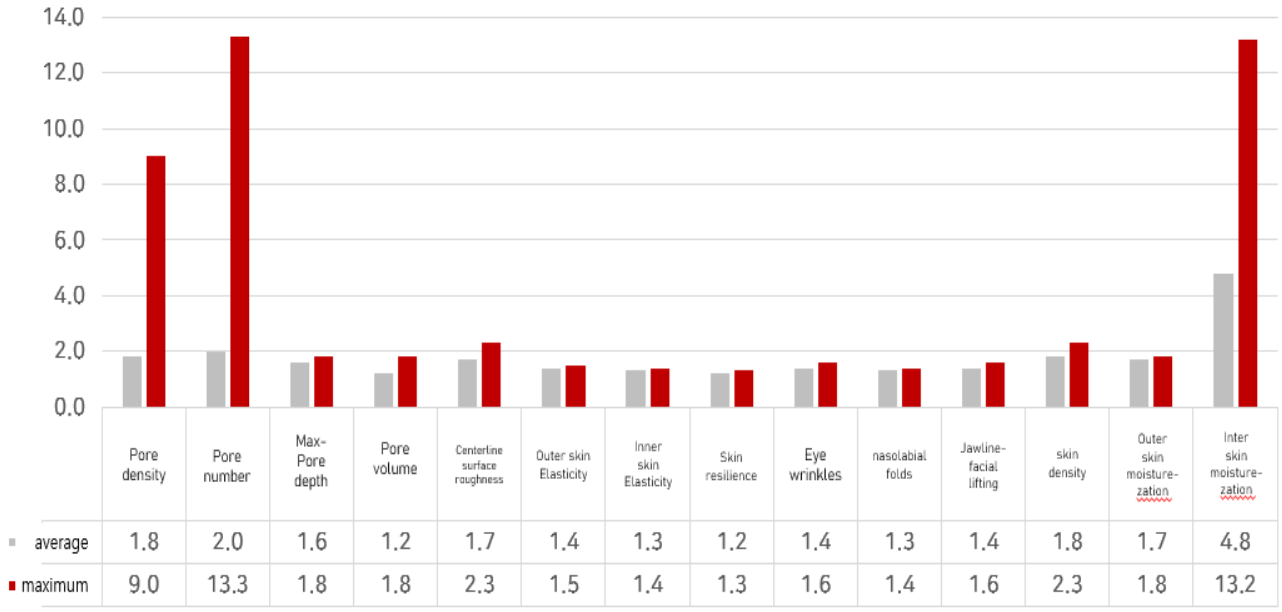
Duration	After a Single Use	After 4 Weeks	After 8 weeks
MFU Alone	2.04%	19.14%	15.74%
MFU+RF	18.51%	24.15%	24.45%
Comparative Advantage	9.0 Times	1.3 Times	1.6 Times

Number of Pores Difference Through Imaging

Duration	After a Single Use	After 4 Weeks	After 8 weeks
MFU Alone	1.37%	18.02%	14.51%
MFU+RF	18.31%	24.23%	24.46%
Comparative Advantage	13.3 Times	1.4 Times	1.7 Times

Compared to only MFU treatment, MFU+RF treatment demonstrated significantly improved effects on pore appearance from the first use. Specifically, it showed up to a 9.0-fold reduction in pore density and up to a 13.3-fold decrease in the number of pores, with these improvements lasting for 8 weeks. These results, along with other various metrics, provide clinical evidence that MFU+RF offers superior outcomes compared to only MFU treatments, establishing a differentiated and enhanced treatment effect.

Comparative Superiority of Improvement Rates between only MFU and MFU+RF



	Pore density	Pore number	Max-Pore depth	Pore volume	Centerline surface roughness	Outer skin Elasticity	Inner skin Elasticity	Skin resilience	Eye wrinkles	nasolabial folds	Jawline-facial lifting	skin density	Outer skin moisture-zation	Inter skin moisture-zation
average	1.8	2.0	1.6	1.2	1.7	1.4	1.3	1.2	1.4	1.3	1.4	1.8	1.7	4.8
maximum	9.0	13.3	1.8	1.8	2.3	1.5	1.4	1.3	1.6	1.4	1.6	2.3	1.8	13.2

A comprehensive analysis of 14 different aspects revealed noticeable improvements, particularly in pore density, number of pores, and skin hydration. The results showed an average of 1.2 to 4.8 times improvement, with a maximum difference of 13.3 times in certain metrics.

Synergy Effect as Confirmed Through Human Application Tests

Post-Treatment Observations at Once

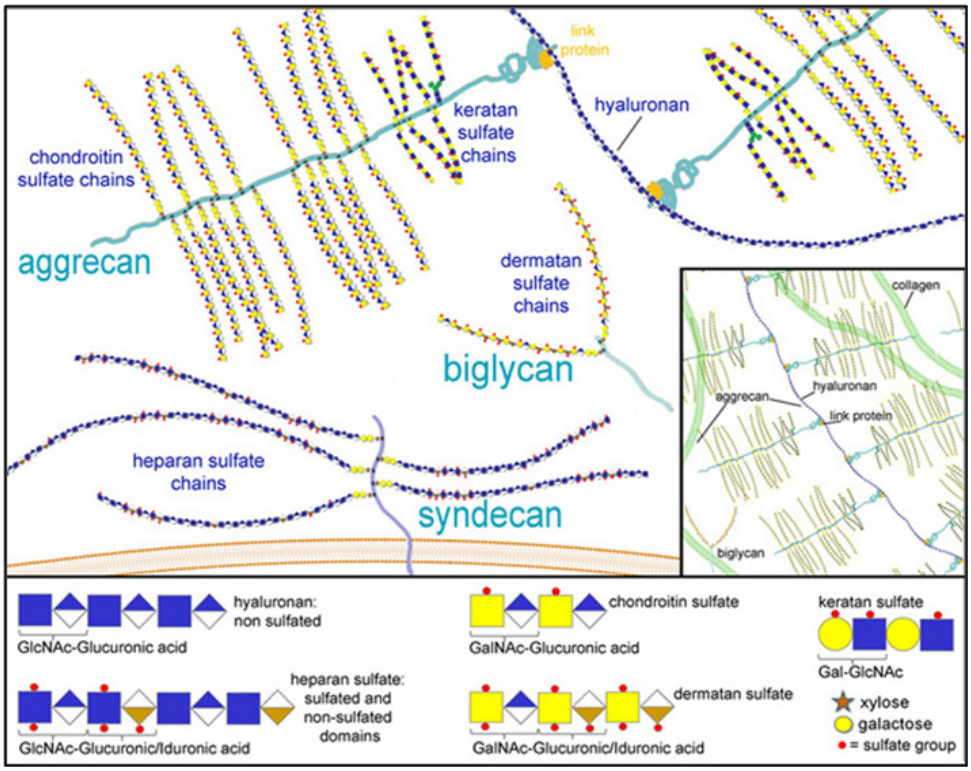
- Improvement in surface skin hydration
- Enhancement in deeper skin hydration

After 4 & 8 Weeks

- Reduction in fine lines around the eyes
- Increased density within the skin layers
- Improved elasticity of the surface skin
- Enhanced elasticity of the deeper skin

The Synergy Effect of MFU+RF, compared to onlyW MFU treatments, has been proven to improve both surface and deep skin hydration in just a single session. These improvements not only last for 4-8 weeks but also extend to enhancements in skin density, surface and deep skin elasticity, and reduction of eye wrinkles. These exceptional results validate the reasons why the simultaneous application of MFU and RF has become an essential protocol in skin aesthetics.

Structure and Types of Glycosaminoglycans (GAGs)



While further large-scale clinical trials are expected to clarify the exact mechanisms behind the improved results observed, it's currently hypothesized that the activation of glycosaminoglycans (GAGs) by RF plays a key role. GAGs, which exist on the external surface of the cell membrane or outside the cell, play a crucial role in forming fibrous structures by arranging and assembling with collagen and elastic fiber molecules in a specific space through bridge bonding. There are six types of GAGs: Hyaluronic Acid, Chondroitin Sulfate, Dermatan Sulfate, Heparan Sulfate, Heparin, and Keratan Sulfate. GAGs can bind with water molecules over 1,000 times their molecular weight. The hypothesis that GAGs in the skin retain water molecules and inhibit the breakdown of collagen and elastic fiber molecules could explain these observations.

3. Improvement of Lower Eyelid (Infraorbital Area) Through MFU+RF Synergy Dotting Treatment

The exceptional effectiveness of the MFU+RF Synergy Effect, as mentioned above, has been highlighted in a recently published letter featuring clinical cases from South Korea. This publication has furthered ongoing activities to establish clinical validity for MFU+RF Synergy treatments.

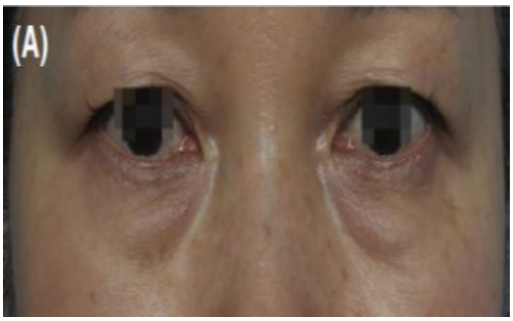
Treatment for Sagging Eyelids in a 53-Year-Old Female Patient

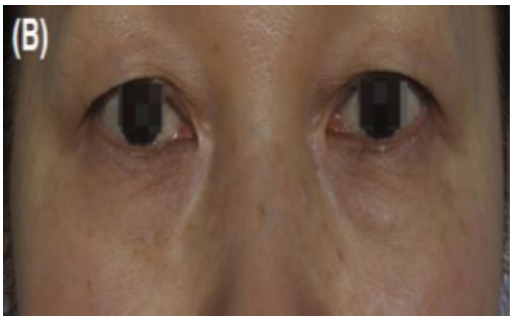
• The treatment was assessed using photographs taken by a dermatologist who did not participate in the treatment.
• The efficacy was rated on a grading scale.

Efficacy Grading Scale

- 0: Worsened
- 1: No change
- 2: Improved
- 3: Significantly improved

Before **After**





Parameter

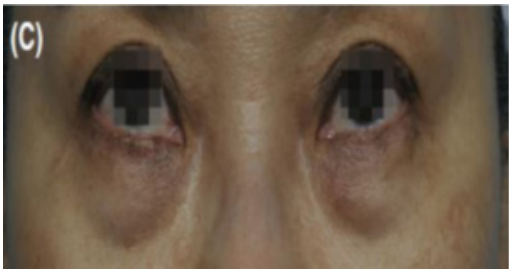
- Depth(mm): 3.0
- Power(J): 0.5
- RF level: 4.0
- Hz: 5
- Total shots: 300

One month after a single treatment, eyelid sagging was rated as 'Greatly Improved (Score=3)'.

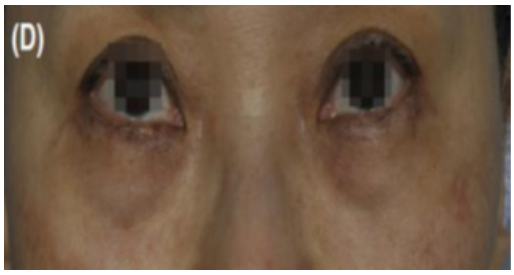
Treatment for Sagging Eyelids in a 55-Year-Old Female Patient

• Two treatment sessions at an interval of two weeks.
• The treatment was assessed using photographs taken by a dermatologist who did not participate in the treatment.
• The efficacy was rated on a grading scale

Before



After



Parameter

- Depth(mm): 3.0
- Power(J): 0.5
- RF level: 4.0
- Hz: 5
- Total shots: 300

One month after the treatment, eyelid sagging was rated as 'Greatly Improved (Score=3)'.

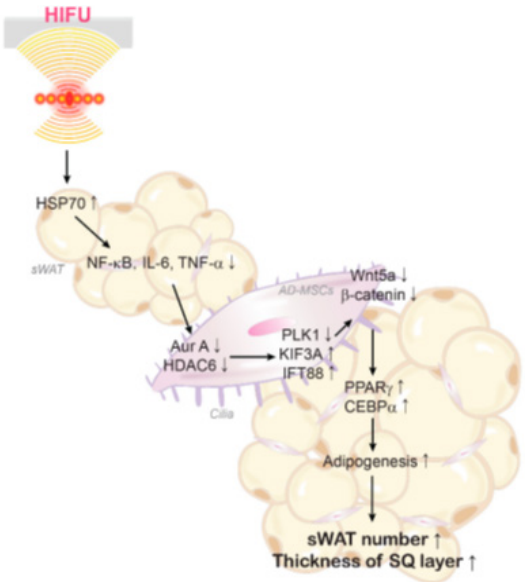
According to the Letter, one of the key advantages of the MFU+RF device, utilizing single dot ultrasound, is its ability to emit energy in the form of individual points rather than lines. This feature allows for precise care of delicate areas like around the eyes, minimizing side effects while accurately treating lower eyelid sagging. The technology is highlighted for its precision in treating such sensitive areas.

The synergy effect of MFU+RF was observed to induce significant skin lifting and tightening by causing contraction in the deep dermal layers and SMAS, as well as remodeling of targeted collagen fibers. Histological analysis of thermal energy revealed that while RF tends to diffuse, MFU focuses on specific points. Therefore, using both devices simultaneously or sequentially can provide different effects on each skin layer, thus producing a synergy effect. This approach, as illustrated in the presented cases, can lead to excellent improvement outcomes.

[2] Potential Hypotheses for Future Utilization

1. Facial Contour Improvement Through Fat Generation

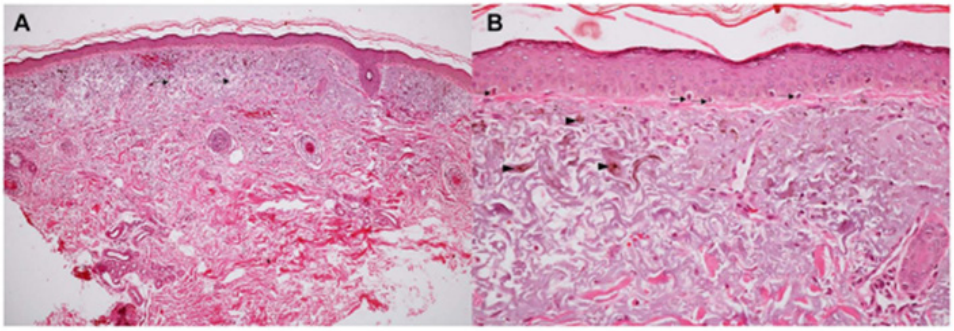
Traditional MFU treatments have been known to reduce fat in specific areas, leading to concerns about adverse reactions like hollowing of the cheeks in patients with less facial fat. Recent studies suggest that MFU, when applied at low energy, can stimulate HSP70 within fat cell fibers, potentially increasing fat generation in subcutaneous white adipose tissue (sWAT). Consequently, MFU was found to induce upregulation of HSP70 in sWAT, which reduces the expression of NF-κB, IL-6, and TNF-α. The decrease in inflammatory cytokine levels was accompanied by a reduction in expression of proteolytic enzymes and an increase in assembly proteins and Wnt5a/β-catenin expression. In animal skin, MFU exposure resulted in increased expression of fat generation signals (PPARγ and CEBPα), an increase in the number of fat cells, and an increase in the thickness of sWAT. This phenomenon, if harnessed effectively, could open up possibilities for non-invasive treatments in cases that traditionally required autologous fat grafting surgery.



2. Treating Melasma Through Strengthening the Basal Layer

New Doublo 2.0, unlike other MFU devices, can be augmented with an RF-Microneedle H/P. This addition expands the range of treatable conditions, with melasma being a notable example. Melasma is a condition characterized by decreased skin elasticity due to photoaging, and an increase in melanocytes and melanophages in the epidermal basal layer.

Histopathological Changes in Dermis Related to Melasma Formation (H&Es)



A. Epidermal melanin deposition and solar elastosis in the dermis (arrow) (H&Es)
B. Increased melanocytes in the epidermal basal layer (arrow) and increased dermal melanophages (arrowhead) (H&Es)

In such cases of melasma, using New Doublo 2.0's Needle RF & SD H/P at 1.5mm can induce basement membrane restoration, leading to the expulsion of deposited pigments between the epidermis and dermis. Concurrently, it can reduce melasma lesions by restoring elasticity fibrosis and reducing aged fibroblasts, decreasing melanin production around secretory effects and melanophage formation, thus inducing a sustained reduction in pigmentation.

Mechanism of Dermal Rejuvenation in Melasma Treatment [1]

1. Basement Membrane Restoration
2. Recovery of Elastosis
3. Reduction in Senescent Fibroblasts
4. Decrease in Melanogenic Paracrine Effect
5. Reduction in Melanophages
6. Regulation of Inflammatory Conditions
7. Decrease in Vascular Dilation

1. Phansuk, Kachanat, et al. "Dermal Pathology in Melasma: An Update Review." Clinical, Cosmetic and Investigational Dermatology 15(2022): 11.

Chapter. 02

New Doublo 2.0 Device Introduction

01
Introduction to the Equipment

[1] New Doublo 2.0: Total Solution for Skin Care

New Doublo 2.0 is a safe and effective MFU & RF Combination Therapy System, independently developed through extensive research and development by the domestic manufacturer, Hi-Ronic Co., Ltd.

HiRonic's MFU & RF Combination Therapy System, New Doublo 2.0

[2] Advantages of V-RO ADVANCE

No.	Components	Quantity	
1	Main body	1 EA	-
2	FL (Focused linear) Handpiece	2 EA	-
3	SD (Synergy Dotting) handpiece	2 EA	Option
4	RM (RF-Microneedle) handpiece	1 EA	Option
5	Power cable	1 EA	-
6	Foot Switch	1 EA	-

Basic Configuration of New Doublo 2.0

Additional Configuration of New Doublo 2.0

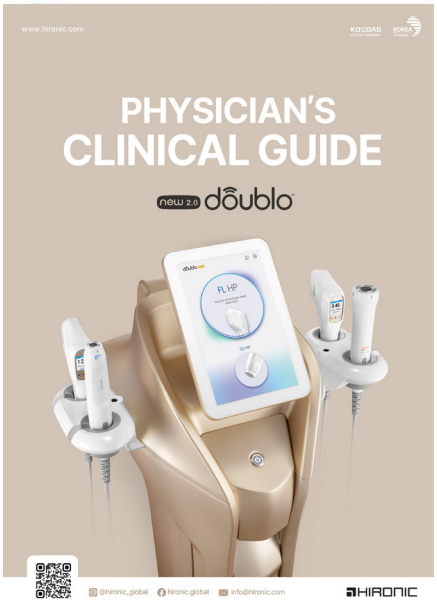
No.	Components	Quantity	
1	FL (Focused linear) Cartridge (S1.5, S2, N3, N4.5, A1.5, A2, A3, A4.5)	1 EA	Option
2	SD (Synergy Dotting) Cartridge (P1.5, P3, P4.5, L1.5, L3, L4.5)	1 EA	Option
3	RM (RF-Microneedle) Tip	2 EA	Option
4	User Manual	1 EA	-

No.1 FL Handpiece Cartridge

No.2 SD Handpiece Cartridge

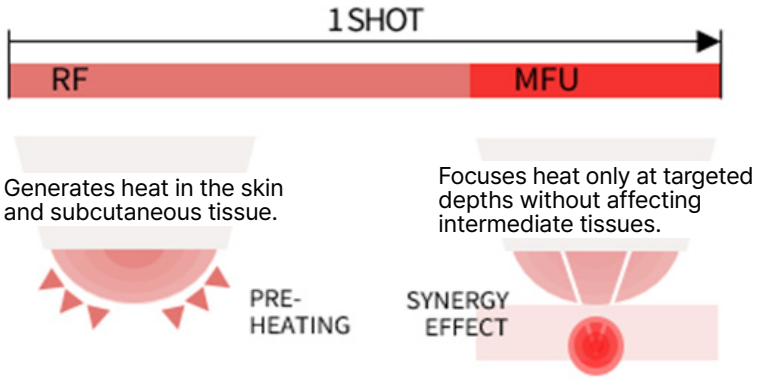
No.3 RF Micro Needle Tip

No.4 User Manual



(1) Simultaneous MFU+RF in One Handpiece: SD Handpiece

With a single handpiece, it's possible to expect a Synergy Effect from both Lifting (MFU) and Tightening (RF), reducing treatment time through the cross-application of these two principles. The efficacy of this approach has been validated through clinical trials and published papers.



(2) Addition of Advanced-Type & Long-Type Cartridges for Treatment Customization According to Skin Layer

New Doublo 2.0 now includes FL cartridges in the Advanced type and SD cartridges in the Long type. Compared to standard cartridges, the Advanced type FL Cartridge maximizes treatment effects, while the Long type SD Cartridge, being 40mm longer, increases the storage capacity for distilled water, enhancing treatment safety.

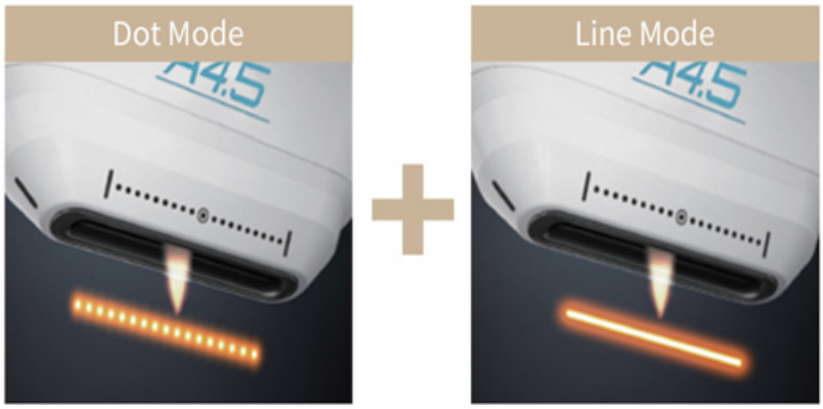
(3) Enhanced Precision with New Advanced FL Cartridge

The new Advanced FL Cartridge, compared to the FL cartridge of the previous model (V-RO LIFTING), offers stronger and more precise treatments due to a reduced curvature radius of the transducer, enhancing its focusing ability.

S/N Type Cartridge	A Type Cartridge
Maintains convenience while enabling mild treatments with less pain.	Reduced curvature radius of the transducer leads to increased energy concentration, enhancing the effectiveness of the treatment.

(4) Dot & Line Mode for Faster and More Thorough Treatments

With a single cartridge, you can choose between Dot & Line mode, allowing for standard or milder treatments tailored to individual skin layers.



(5) Faster, Safer, and More Powerful Performance

The SD cartridge increases the emission speed from 7Hz to 10Hz, a 43% increase, reducing treatment time. Its 40mm longer design prevents rapid temperature changes during prolonged treatments. The RF energy output has increased by 94%, enhancing the thermal effect, reducing pain, and maximizing treatment efficacy.

Increased treatment speed, from 7Hz to 10Hz,compared to the conventional New Doublo

40mm longercartridge design minimizes rapid temperature changes during prolonged treatments.

Enhanced thermal effect due to increased RF output, improving Lifting Synergy.

(6) Patented Safety Features

New Doublo 2.0 incorporates two patented safety sensors to prevent thermal damage. During lifting treatments, if the cartridge lifts off the skin surface or energy is overly concentrated in one area, thermal damage can occur. The FL cartridge has a contact detection sensor that stops shots if not properly adhered to the skin, thus preventing thermal damage. The SD cartridge features a motion detection sensor that automatically stops shots if the handpiece is not moved, thus preventing thermal damage.

Contact Detection Sensor

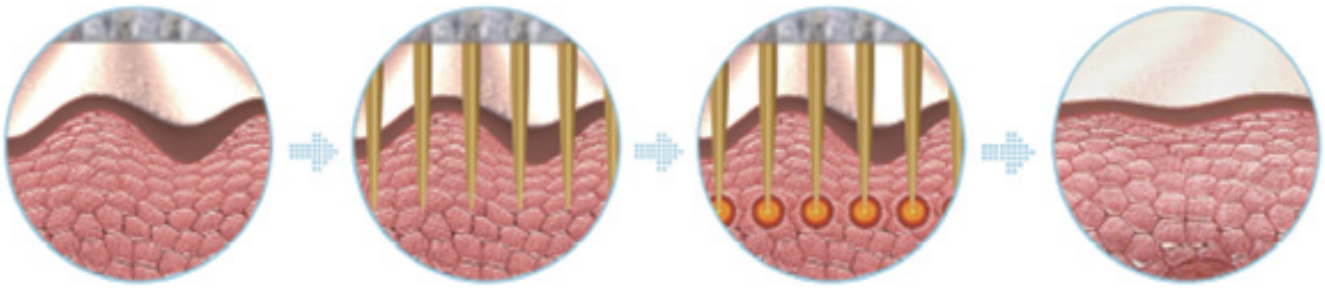
• Prevents burns by halting energy emission if not properly adhered to the skin surface.

Motion Detection Sensor

• Stops energy emission if the handpiece remains stationary, preventing burns.

(7) RM Handpiece Utilizing Microneedle Technology

The RM handpiece operates on the principle of inserting multiple microneedles into the treatment area and using insulated/non-insulated microneedles to deliver radio frequency energy, creating volume heating. The RM handpiece employs a principle where multiple microneedles are inserted into the treatment area, using both insulated and non-insulated microneedles to deliver high-frequency energy. This process generates volume heating, enabling treatments for various skin lesions.



STEP 01
The tip of the micro-needles makes contact with the skin.

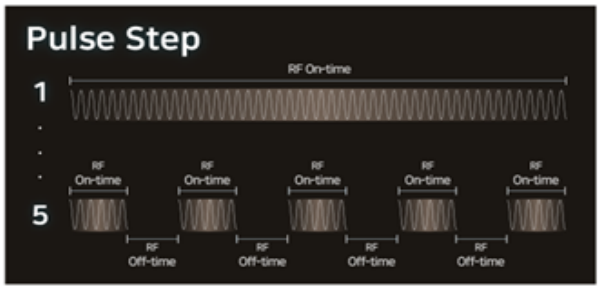
STEP 02
The micro-needles penetrate the skin.

STEP 03
High-frequency energy is delivered,forming a tissue coagulation zone.

STEP 04
Enhanced skin regeneration effects are achieved.

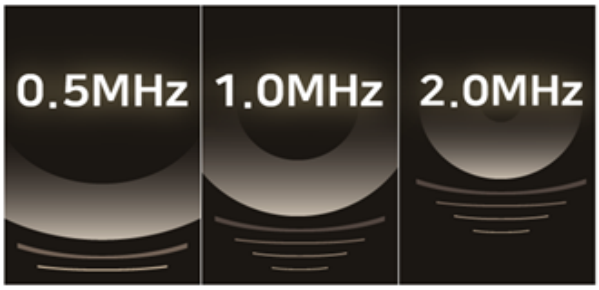
The upgraded New Doublo 2.0 system enhances this technique with its Multi-Pulse & Multi-Frequency System, allowing for more precise, customized treatments.

Multi-Pulse



- Adjustable to a minimum of 1,000 microseconds.
- Capable of controlling a total of 5 pulses.
- The energy is distributed in a manner that alleviates procedural discomfort.
- Capable of delivering energy to deeper and wider areas.

Multi-Frequency

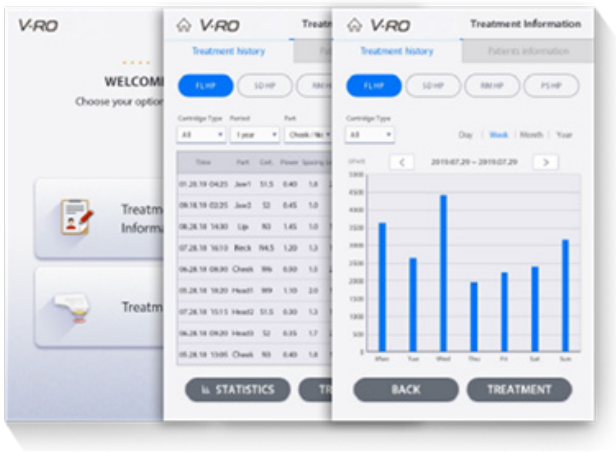


- Multi-frequency control at 0.5/1.0/2.0 MHz
- Customizable energy wavelengths tailored tovarious skin layers.
- Offers treatments customized to each wavelength.

(8) New Doublo 2.0 stands out with its efficient management system

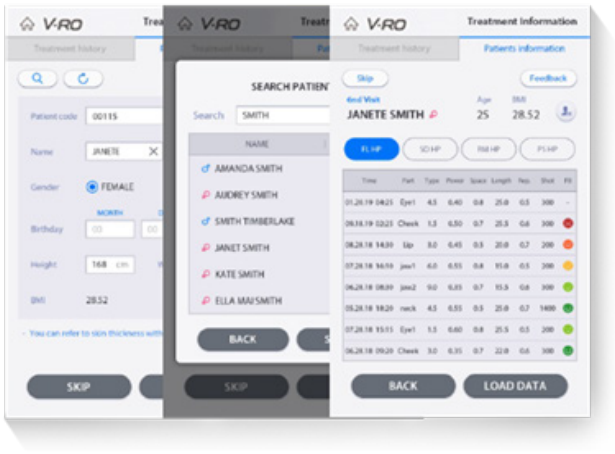
The Treatment Information System (TIS) enables easy remote management of equipment usage and ensures faster after-sales service. Additionally, the Remote Maintenance System (RMS) automatically records patient-specific parameters, further facilitating personalized treatments.

TIS (Treatment Information System)



- Easy remote management of equipment usage
- Upgrades available for both software and hardware, with rapid after-sales service.

RMS (Remote Maintenance System)



- Customized treatments enabled through automatically recorded parameters.
- Equipped with a recording management system for frequently used parameters.

02
Operating Guidelines

[1] Considerations for MFU Treatment

The variables to consider during the procedure include:

(1) Depth(mm)
(2) Power(J)
(3) Spacing(mm)
(4) Shots(Lines)
(5) Area & Skin lines

Taking these variables into account, parameters can be set as follows:

FL H/P Parameter Setting Screen in GUI:
When Cartridge is Mounted & When Selecting DOT/LINE Mode

LINE mode

DOT mode

No.	Naming or Icon	Description
1	LINE/DOT	This sets the energy irradiation mode. - LINE Mode: Irradiates in a linear form. - DOT Mode: Irradiates in a dotted line form.
2	MODE 1/2/3	Pressing the mode button for 3 seconds saves the current treatment settings. (This allows for convenient use of frequently used settings.)
3	FL H/P Start the Procedure	When the FL handpiece is mounted, an image like the one on the screen is displayed. - Face: S1.5 / S2 / N3 / N4.5 / A1.5 / A2 / A3 / A4.5
4-1	INTERVAL(sec)	In LINE mode, set the interval (time) between shots. - 0.1~1.0sec(in 0.1sec increments) - 1.0~3.0sec(in 0.5sec increments)
4-2	SPACING(mm)	In Dot mode, set the distance (length) between dots. - 1.0~2.0mm (in 0.1mm increments) - 2.0~5.0mm (in 0.5mm increments)
5	LENGTH(mm)	Set the irradiation length. - DOT Mode: 5.0~25.0mm (in 1.0mm increments) - LINE Mode: 5.0~25.0mm (in 5.0mm increments)
6	CARTRIDGE TYPE	Display the type of mounted cartridge. - Face: S1.5 / S2 / N3 / N4.5 / A1.5 / A2 / A3 / A4.5
7	MFU POWER(J)	Set the MFU POWER. - 0.1~1.5J ((Please refer to the performance for output values specific to each mode and cartridge.)
8	TOTAL SHOT	Display the total number of shots administered. (Shot count can be set by clicking the alarm button.)
9	AUTO / MANUAL	Choose between automatic and manual modes. - AUTO (Automatic): Save values frequently used for each area. - MANUAL (Manual): Set desired values for use.
10	STANDBY	Indicates the standby state before energy inspection. Clicking STANDBY transitions to READY.
	READY	Pressing the foot switch in the ready state enables energy inspection shots. Clicking READY transitions to STANDBY.

FL H/P Parameter Setting Screen in Manual Mode

LINE mode

DOT mode

No.	Naming or Icon	Description
1	LINE / DOT	Set the energy irradiation mode. - LINE Mode: Irradiates in a linear form. - DOT Mode: Irradiates in a dotted line form.
2-1	INTERVAL(sec)	In LINE mode, set the interval (time) between shots. - 0.1~1.0sec(in 0.1sec increments) - 1.0~3.0sec(in 0.5sec increments)
2-2	SPACING(mm)	In DOT mode, set the distance (length) between dots. - 1.0~2.0(in 0.1mm increments) - 2.0~5.0(in 0.5mm increments)
3	LENGTH(mm)	Set the total irradiation range of the cartridge. - 5.0~25.0mm(in 1.0mm increments)
4	MFU POWER(J)	Set the MFU POWER. - 0.1~1.5J
5	M1 / M2 / M3	Pressing a selected number for 3 seconds saves the current treatment settings to that number. (This allows for convenient use of frequently used settings.)
6	TOTAL SHOT	Display the total number of shots administered. (Shot count can be set by clicking the alarm button.)
7	AUTO / MANUAL	Set the mode to either automatic or manual. - AUTO (Automatic): Save and use frequently used values for each area. - MANUAL (Manual): Set and use desired values.
8	STANDBY	Displays the pre-energy survey standby state. Clicking STANDBY switches to READY.
	READY	Pressing the hand switch/foot switch in READY state initiates an energy survey shot. Clicking READY switches back to STANDBY.

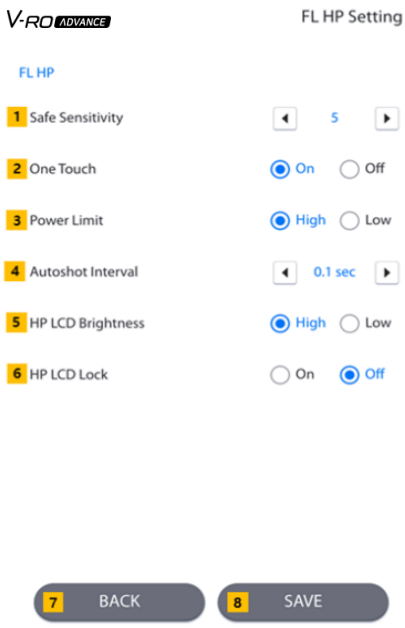
GUI Screen for FL H/P Parameter Settings in Manual Mode

LINE mode

DOT mode

No.	Name or Icon	Description
1	Animation for FL H/P Procedure Progress	An animation similar to the one displayed during an FL handpiece procedure will appear. (Animation activates upon pressing the hand switch/foot switch in READY state.) - LINE mode: Displayed in a linear form. - DOT mode: Displayed as a dotted line.

GUI Screen for Manual Setting of FL H/P



No.	Name or Icon	Description
1	Safe Sensitivity	Setting the Sensitivity of the Skin Contact Detection Sensor Sensitivity range: 1 (Low) to 5 (High).
2	One Touch	Configure the SHOT delivery mode. - On: A single shot is delivered upon pressing the hand switch/foot switch once. - Off: Continuous shot delivery while pressing the hand switch/foot switch.
3	Power Limit	Set the output limit value of the cartridge for patient safety. - High: Maximum output of the cartridge. - Low: Medium output of the cartridge. (Refer to the performance specifications for output values according to mode and cartridge.)
4	Auto shot Interval	Set the interval (time) between continuous shots. - Range: 0.1 to 1.0 seconds (in 0.1-second increments). - 1.5, 2.0, 2.5, 3.0sec
5	H/P LCD Brightness	Set the brightness of the Handpiece's LCD. - High: Increase brightness. - Low: Decrease brightness.
6	H/P LCD Lock	Toggle the Handpiece LCD touch feature On/Off.

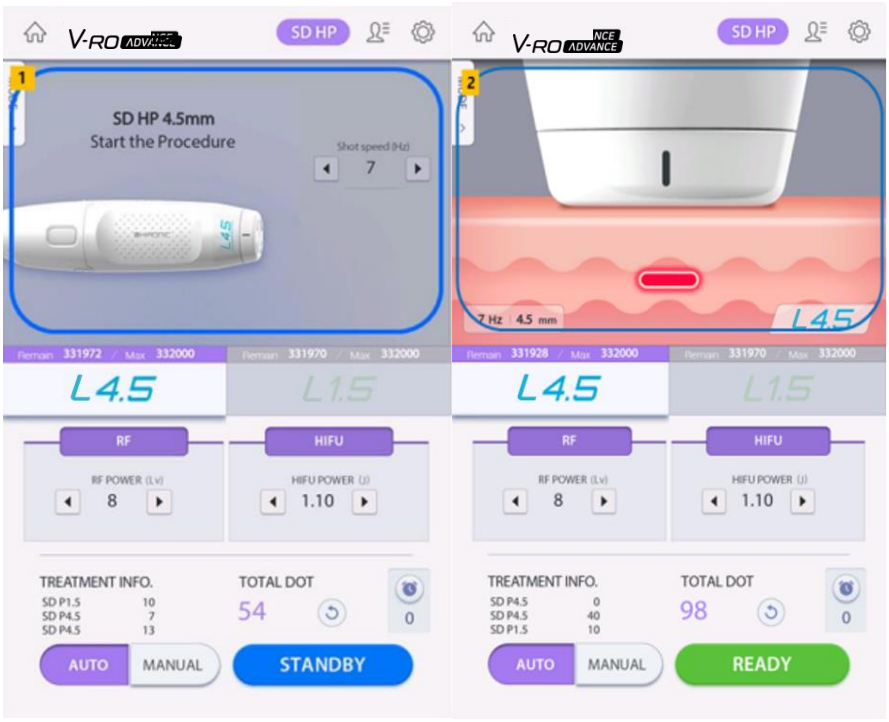
7	BACK	Navigate to the Treatment screen.
8	SAVE	Save the modified settings.

GUI Screen for Setting SD H/P Parameters: AUTO Mode

No.	Name or Icon	Description
1	MODE 1 / 2 / 3	Press and hold the selected number for 3 seconds to save the current treatment settings. (This allows for convenient use of frequently used settings.)
2	SD H/P Start the Procedure	Display Features When the SD Handpiece is Attached An image similar to the one on the screen appears when the SD handpiece is mounted. - P1.5 / P3 / P4.5 / L1.5 / L3 / L4.5
3	Shot speed(Hz)	Set the shot speed. - RF Only Mode: Not applicable. - MFU Only Mode: 1~10Hz - RF/MFU Crossover Mode: 1 to 10Hz.
4	Dot(shot)	Set the recommended shots for each area. - 10 to 5000 shots (in increments of 10 shots)
5	CARTRIDGE TYPE	Displays the type of the installed cartridge. - P1.5, P3, P4.5, L1.5, L3, L4.5
6	Power	Configures the power of both RF and MFU. - RF: 1~10Lv - MFU: 0.1~1.5J

7	TOTAL DOT	Indicates the performed DOT COUNT. (Alarm settings can be configured by clicking the alarm button.)
8	AUTO / MANUAL	Sets the mode to automatic or manual. - AUTO (Automatic): Stores frequently used values by region for convenience. - MANUAL (Manual): Allows customization of desired values for use.
9	STANDBY	Indicates the standby status before energy assessment. Clicking STANDBY transitions to READY.
	READY	Pressing the footswitch in the ready state enables energy assessment. Clicking READY transitions back to STANDBY.

GUI within SD H/P Parameter Settings Screen:
When the cartridge is installed & during energy assessment

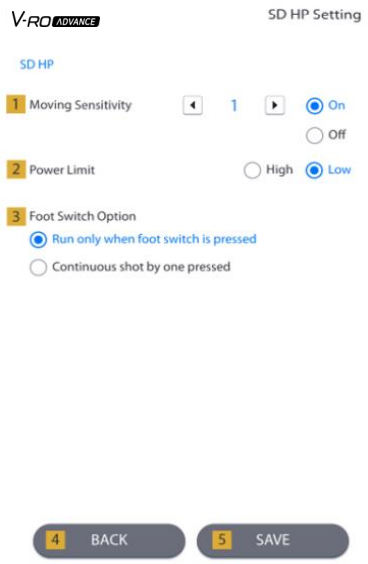


No.	Name or Icon	Description
1	SD H/P Ready Mode	Clicking STANDBY switches to the READY state of the handpiece procedure screen, displaying an image similar to the one shown on the screen.
2	SD H/P Procedure Progress Animation	During the SD handpiece procedure, the screen displays an image similar to the one shown on the screen. (Pressing the footswitch in the READY state activates animation.)

GUI within SD H/P Parameter Settings Screen: Manual Mode

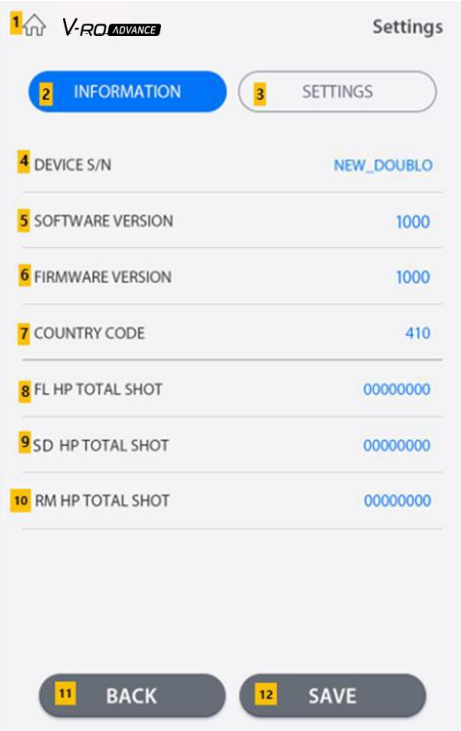
No.	Name or Icon	Description
1	RF	Configures values such as RF POWER (Lv), RF ON TIME (ms/shot), RF OFF TIME (ms/shot), and more. - RF POWER: 1~10Lv - RF ON TIME: 50~450ms/shot - RF OFF TIME: 50~450ms/shot
2	MFU	Sets the values for MFU POWER (J) and SHOT SPEED (Hz). - MFU POWER: 0.1~1.5J - SHOT SPEED: 1~10Hz
3	M1 / M2 / M3	Pressing a selected number for 3 seconds stores the current procedure settings in that number. (Allows convenient storage of frequently used values.)
4	TOTAL COUNT	Displays the number of dots performed. (Shot count settings can be configured by clicking the alarm button.)
5	AUTO / MANUAL	Choose between automatic and manual modes. - AUTO (Automatic): Save values frequently used for each area. - MANUAL (Manual): Set desired values for use.
6	STANDBY	Indicates the standby state before energy inspection. Clicking STANDBY transitions to READY.
	READY	Pressing the foot switch in the ready state enables energy inspection shots. Clicking READY transitions to STANDBY.

GUI within SD H/P Manual Setting Configuration Screen



No.	Name or Icon	Description
1	Moving Sensitivity	Adjusts the motion detection sensor function to either ON or OFF and fine-tunes its sensitivity.
2	Power Limit	Provides the option to limit the cartridge's output for patient safety. - High: Generates the maximum output value of the cartridge. - Low: Generates the mid-level output value of the cartridge. (Refer to performance specifications for modes and cartridge-specific output values.)
3	Foot Switch Option	Selects whether a single shot or continuous shots will be performed when the footswitch is activated once.
4	BACK	Transitions to the Treatment screen.
5	SAVE	Saves the modified information.

GUI within RM H/P Parameter Configuration Screen: Auto Mode



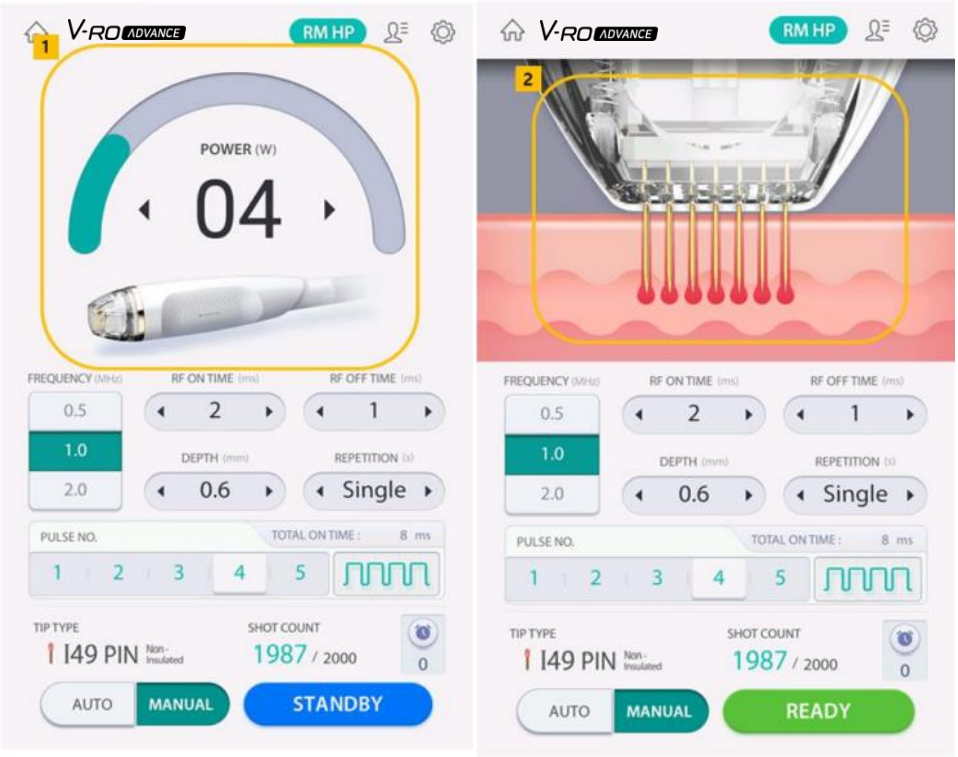
No.	Name or Icon	Description	
1		Transitions to the handpiece selection screen for the procedure.	
2	RM H/P	Represents the RM handpiece.	
3	Displays patient information		Appears when patient information is loaded on the patient information input page.
			Appears on the screen when patient information is skipped on the patient information input page.
			Navigates to the Settings screen.

GUI within RM H/P Parameter Configuration Screen: Auto Mode

No.	Name or Icon	Description
1	Procedure Area Configuration	You can select from a total of seven areas: Forehead/Eyes/Cheeks/Nasolabial Folds/Nose/Jawline + Chin/Neck. You have the option to choose from three different procedure modes.
2	POWER(W)	Adjust the power setting within the range of 1 to 20W, in 1W increments.
3	SAVE	Save the current procedure settings in the EASY GUIDE.
4	EASY GUIDE	Set the procedure values to the stored values by selecting the corresponding button. By pressing and holding a button for 3 seconds, you can assign a name to the procedure setting, making it more convenient to use frequently used values.
5	FREQUENCY(MHz)	Adjust the frequency settings. - 0.5 / 1.0 / 2.0MHz
6	RF ON TIME(ms)	Configure the RF inspection time. - 1~30ms (in increments of 1ms). - 30~100ms (in increments of 5ms). - 100~950ms (in increments of 10ms). (A warning popup will appear for durations exceeding 400ms).

7	RF OFF TIME(ms)	Set the RF non-inspection time. - 1~30ms (in increments of 1ms). - 30~100ms (in increments of 5ms). - 100~1,000ms (in increments of 10ms).
8	DEPTH(mm)	Define the needle penetration depth. - 0.1~3.5mm (in increments of 0.1mm).
9	REPETITION	Configure the RF inspection repetition interval (time). - Single / 0.2~0.8s / 1.0s / 2.0s
10	PULSE NO	Set the pulse count. - PULSE NO.: 1~5
11	TOTAL ON TIME	Display the total RF inspection time. - 1~4,750ms
12	TIP TYPE	Indicate the installed tip TYPE. - 25PIN (Insulated/Non-insulated). - 49PIN (Insulated/Non-insulated).
13	SHOT COUNT	Show the number of shots used and the total number of shots for RF Microneedle tips. (You can adjust the shot count by clicking the alarm button.)
14	AUTO / MANUAL	Choose between automatic and manual modes. - AUTO (Automatic): Save values frequently used for each area. - MANUAL (Manual): Set desired values for use.
15	STANDBY	Indicates the standby state before energy inspection. Clicking STANDBY transitions to READY.
	READY	Pressing the foot switch in the ready state enables energy inspection shots. Clicking READY transitions to STANDBY.

GUI for RM H/P Parameter Configuration Screen: When RM Tip is Attached & During Energy Inspection



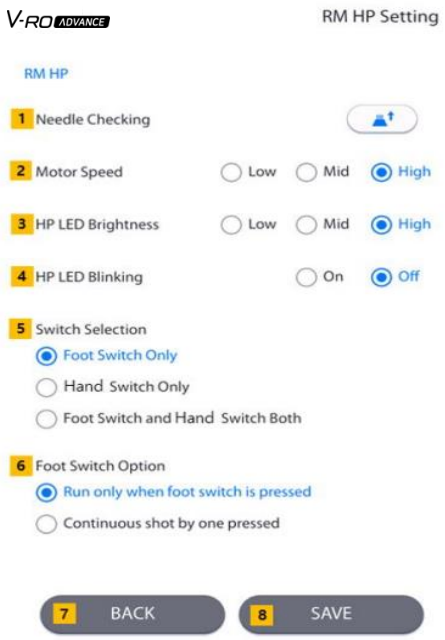
No.	Name or Icon	Description
1	RM H/P Ready Mode	Clicking STANDBY transitions to the READY state of the handpiece procedure screen, displaying an image identical to the screen.
2	RM H/P Procedure in Progress Animation	During RM handpiece procedure, an image identical to the screen is displayed. (Activating the animation is achieved by pressing the output button of the FL handpiece while in the Ready state.)

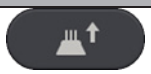
GUI for RM H/P Parameter Configuration Screen: Manual Mode

No.	Name or Icon	Description
1	POWER(W)	Adjust the power setting. - 1~20W (in increments of 1W).
2	FREQUENCY(MHz)	Configure the frequency setting. - 0.5 / 1.0 / 2.0 MHz
3	RF ON TIME(ms)	Set the RF inspection time. - 1~30ms (in increments of 1ms). - 30~100ms (in increments of 5ms). - 100~950ms (in increments of 10ms). (A warning popup will appear for durations exceeding 400ms).
4	RF OFF TIME(ms)	Set the RF non-inspection time. - 1~30ms (in increments of 1ms). - 30~100ms (in increments of 5ms). - 100~1000ms (in increments of 10ms).
5	DEPTH(mm)	Define the needle penetration depth. - 0.1~3.5mm (in increments of 0.1mm).
6	REPETITION	Configure the RF inspection repetition interval (time). - Single / 0.2~0.8s / 1.0s / 2.0s

7	PULSE NO	Set the pulse count. - PULSE NO.: 1~5
8	TOTAL ON TIME	Display the total RF inspection time. - 1~4,750ms
9	TIP TYPE	Indicate the installed TIP TYPE. - 25PIN (Insulated / Non-insulated). - 49PIN (Insulated / Non-insulated).
10	SHOT COUNT	Show the number of shots used and the total number of shots for RF Microneedle tips. (You can adjust the shot count by clicking the alarm button.)
11	AUTO / MANUAL	Configure the automatic or manual mode. - AUTO (Automatic): Store frequently used values for each area. - MANUAL (Manual): Set desired values for use.
12	STANDBY	Indicates the standby state before energy inspection. Clicking STANDBY transitions to READY.
	READY	Pressing the foot switch in the ready state enables energy inspection shots. Clicking READY transitions to STANDBY.

GUI for RM H/P Manual Setting Configuration Screen

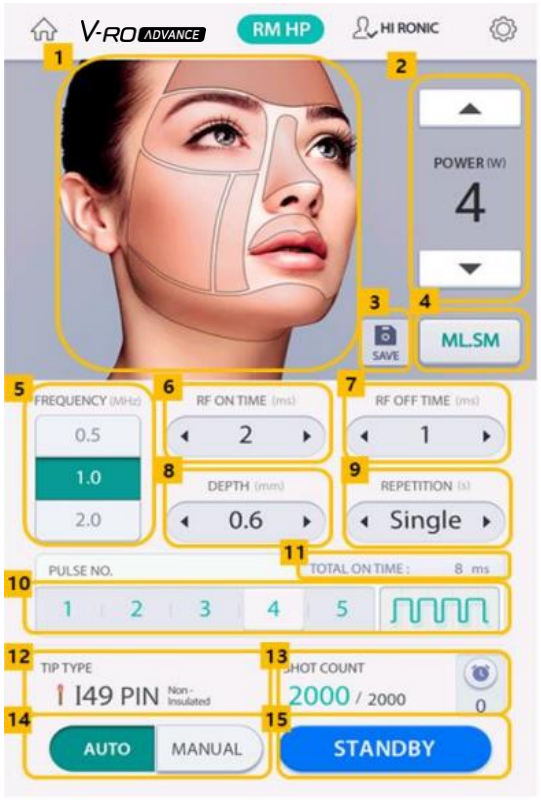


No.	Name or Icon	Description
1	Needle Checking	 Selecting this option will extend the needles outward from the tip.
		 Selecting this option will retract the needles inside the tip.
2	Motor Speed	You can adjust the motor speed that moves the RF Microneedle tip. - Low: 250Hz - Mid: 330Hz - High: 500Hz
3	H/P LED Brightness	Configure the brightness of the LED on the handpiece. - Low, Mid, High
4	H/P LED Blinking	Choose whether the LED on the handpiece blinks or not.
5	Switch Selection	Select the operating mode of the handpiece. - Foot Switch Only - Hand Switch Only - Foot Switch and Hand Switch Both
6	Foot Switch Option	When using the foot switch, choose between single or continuous inspection.
7	BACK	Move to the Treatment screen.
8	SAVE	Save the modified information.

GUI for RM H/P Parameter Configuration Screen: Select Mode

No.	Name or Icon	Description	
1		Navigates to the handpiece selection screen for the procedure.	
2	RM H/P	Represents the RM handpiece.	
3	Displays patient information.		Displayed when patient information is LOADED on the patient information input page.
			Displayed on the screen when patient information is SKIPPED on the patient information input page.
			Moves to the Settings screen.

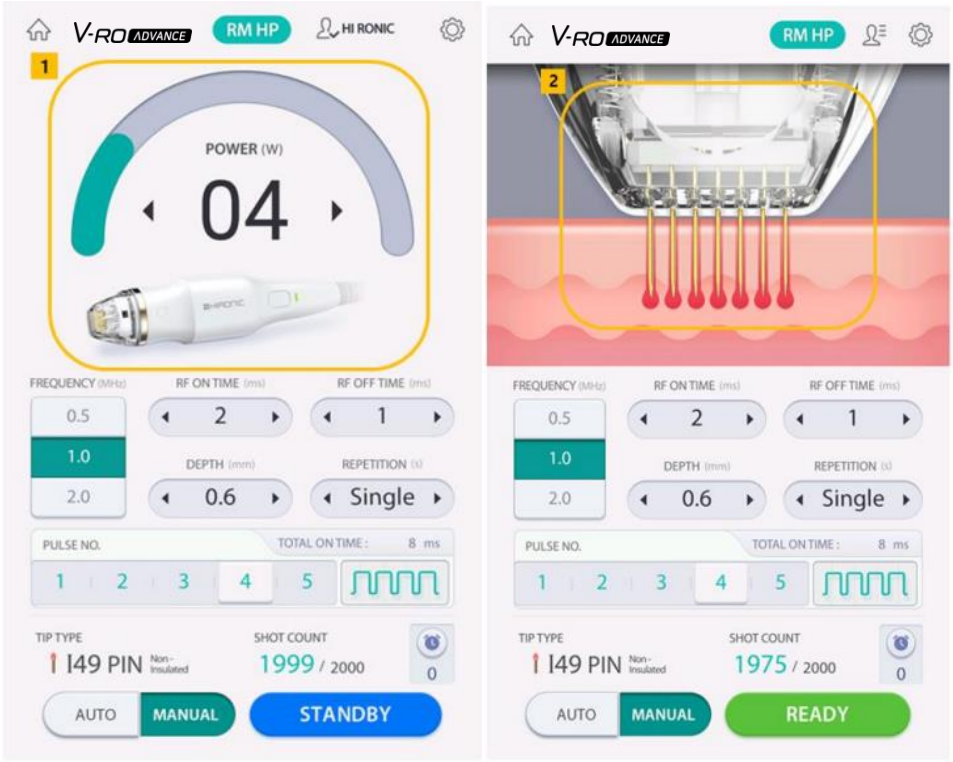
GUI within RM H/P Parameter Configuration Screen: Auto Mode



No.	Name or Icon	Description
1	Procedure Area Configuration	You can select seven different areas: forehead, eyes, cheeks, laugh lines, nose, chin, and chin & chin lines. Choose from three different treatment modes.
2	POWER(W)	Adjust the power settings. - 1~20W (in increments of 1W).
3	SAVE	Save the setup information.
4	EASY GUIDE	Configure the quick guide settings.
5	FREQUENCY(MHz)	Set the frequency. - 0.5 / 1.0 / 2.0MHz
6	RF ON TIME(ms)	Set the RF inspection time. - 1~30ms (in increments of 1ms). - 30~100ms (in increments of 5ms). - 100~950ms (in increments of 10ms). (A warning popup will appear for durations exceeding 400ms).

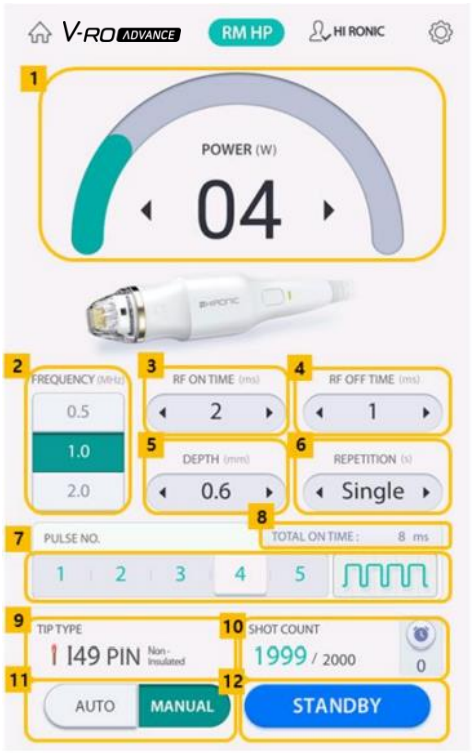
7	RF OFF TIME(ms)	Set the RF non-inspection time. - 1~30ms (in increments of 1ms). - 30~100ms (in increments of 5ms). - 100~1000ms (in increments of 10ms).
8	DEPTH(mm)	Define the needle penetration depth. - 0.1~3.5mm (in increments of 0.1mm).
9	REPETITION	Configure the RF inspection repetition interval (time). - Single / 0.2~0.8s / 1.0s / 2.0s
10	PULSE NO	Set the pulse count. - 1~5pulse
11	TOTAL ON TIME	Display the total RF inspection time. - 1~4,750ms
12	TIP TYPE	Indicate the installed tip TYPE. - 25PIN (Insulated / Non-insulated). - 49PIN (Insulated / Non-insulated).
13	SHOT COUNT	Show the number of shots used and the total number of shots for RF Microneedle tips. (You can adjust the shot count by clicking the alarm button.)
14	AUTO / MANUAL	Choose between automatic and manual modes. - AUTO (Automatic): Save values frequently used for each area. - MANUAL (Manual): Set desired values for use.
15	STANDBY	Indicates the standby state before energy inspection. Clicking STANDBY transitions to READY.
	READY	Pressing the foot switch in the ready state enables energy inspection shots. Clicking READY transitions to STANDBY.

GUI for RM H/P Parameter Configuration Screen: When RM Tip is Attached & During Energy Inspection



No.	Name or Icon	Description
1	RM H/P Ready Mode	Click on "STANDBY" to switch to the READY state handpiece procedure screen, displaying an image identical to the one on the screen.
2	Perform the RM H/P Procedure Animation	During the RM handpiece procedure, an image identical to the screen will be displayed. (Press the output button of the FL handpiece while in the Ready state to activate the animation.)

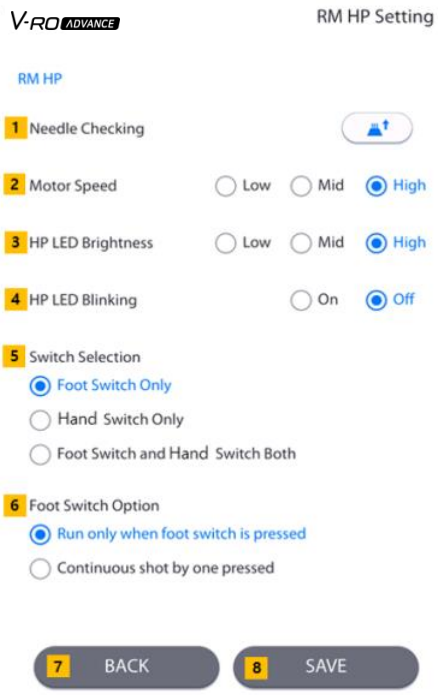
GUI for RM H/P Parameter Configuration Screen: Manual Mode

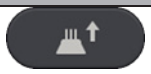


No.	Name or Icon	Description
1	POWER	Adjust the power setting. - 1~20W (in increments of 1W).
2	FREQUENCY(MHz)	Configure the frequency setting. - 0.5 / 1.0 / 2.0MHz
3	RF ON TIME(ms)	Set the RF inspection time. - 1~30ms (in increments of 1ms). - 30~100ms (in increments of 5ms). - 100~950ms (in increments of 10ms). (A warning popup will appear for durations exceeding 400ms).
4	RF OFF TIME(ms)	Configure the RF Examination Time. - 1~30ms (in 1ms increments) - 30~100ms (in 5ms increments) - 100~1000ms (in 10ms increments)
5	DEPTH(mm)	Set the Needle Penetration Depth. - 0.1~3.5mm (in 0.1mm increments)
6	REPETITION	Adjust the RF Examination Interval (Time). - Single / 0.2~0.8s / 1.0s / 2.0s

7	PULSE NO	Configure the Pulse Count. - PULSE NO.: 1~5
8	TOTAL ON TIME	Display the Total RF Examination Time. - 1~4,750ms
9	TIP TYPE	The currently attached TIP TYPE is displayed. - 25PIN (Insulated / Non-insulated) - 49PIN (Insulated / Non-insulated)
10	SHOT COUNT	Display the number of shots used and the total number of shots for the RF Microneedle tip. (Click the alarm button to configure the shot count.)
11	AUTO / MANUAL	Configure the mode to Automatic (AUTO) or Manual (MANUAL). - AUTO (Automatic): Stores frequently used values for each area for convenient use. - MANUAL (Manual): Set desired values for use.
12	STANDBY	Indicates the standby state before energy inspection. Clicking STANDBY transitions to READY.
	READY	Pressing the foot switch in the ready state enables energy inspection shots. Clicking READY transitions to STANDBY.

GUI for RM H/P Manual Setting Configuration Screen

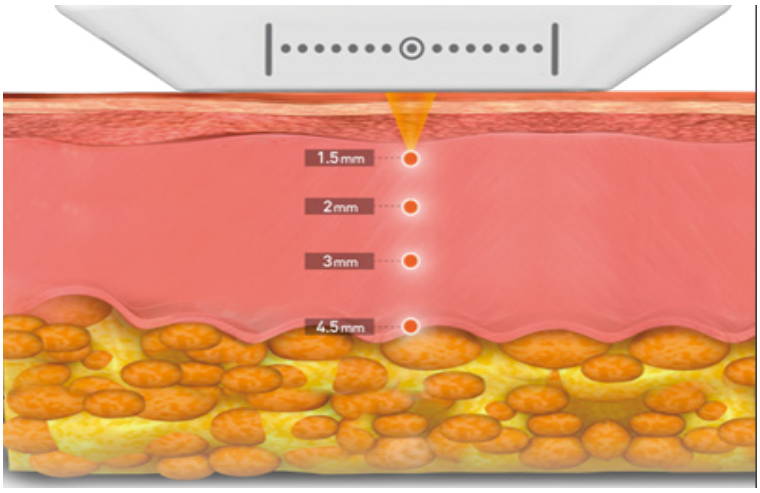


No.	Name or Icon	Description
1	Needle Checking	 Selecting this option will extend the needles outward from the tip.
		 Selecting this option will retract the needles inside the tip.
2	Motor Speed	You can adjust the motor speed that moves the RF Microneedle tip. - Low: 250Hz - Mid: 330Hz - High: 500Hz
3	H/P LED Brightness	Configure the brightness of the LED on the handpiece. - Low, Mid, High
4	H/P LED Blinking	Choose whether the LED on the handpiece blinks or not.
5	Switch Selection	Select the operating mode of the handpiece. - Foot Switch Only - Hand Switch Only - Foot Switch and Hand Switch Both
6	Foot Switch Option	When using the foot switch, choose between single or continuous inspection.
7	BACK	Move to the Treatment screen.
8	SAVE	Save the modified information.

(1) Depth

The most crucial consideration during the procedure is selecting the target depth based on the treatment objectives.

Diagram illustrating the focal positions for each depth



The target depth for promoting epidermal remodeling through the heat transfer effect, stimulating collagen regeneration, and aiding in tightening and wrinkle improvement corresponds to a depth of 1.5mm to 2.0mm. Therefore, it is recommended to set the target depth to 1.5mm to 2.0mm when targeting thin areas of the skin (such as the forehead and eye area) or when targeting the relatively superficial upper dermis. When utilizing the heat coagulation effect, delivering heat energy to the dermis and SMAS layers of the skin, it helps in restoring skin elasticity, resulting in face lifting and tightening effects. The recommended target depths for achieving these effects are 3.0mm and 4.5mm. When targeting the subcutaneous layer, the recommended target depth is 3.0mm, while when targeting the deep dermis or SMAS layer, the recommended target depth is 4.5mm. Targeting the deep dermis at a depth of 3.0mm triggers robust collagen regeneration.

Over the following 2 to 4 weeks, as the skin tightens, continuous production of collagen and elastic fibers is predicted to occur over 3 to 6 months, resulting in tissue tightening. By disrupting the fatty layer beneath the skin surface at approximately 3mm depth, there is also an effect similar to facial contouring through fat fragmentation. Focusing on the SMAS layer at a depth of 4.5mm creates heat coagulation areas smaller than 1mm, which, over time, can lead to contour lifting effects as they contract and relax.

(2) Power

Power refers to the intensity of the MFU. Furthermore, power can be adjusted in various ways. However, the clinical effectiveness of MFU is more closely related to the number of shots than to power. As the intensity increases, the size of the heat coagulation points tends to increase.

POWER	Intensity of ultrasound energy (adjustable size of the thermal coagulation zone)	Low	High

(3) Spacing

Spacing refers to the distance between dots. A narrower spacing means a relatively stronger parameter since it allows for the examination of more dots. However, as the spacing narrows, there is an increased risk of overlap of heat coagulation points, which can lead to a higher risk of side effects. Therefore, when increasing the power, it is advisable to widen the spacing.

SPACING	Spacing between two DOTs (Thermal Coagulation Zones)	3mm	1.5mm

(4) Length

Length sets the total length of the examination range and can be adjusted appropriately for the treatment area.

LENGTH	Length between the first and last Thermal Coagulation Zone.	10mm	20mm

(5) Shots (Lines)

The parameter that clinically makes the most significant difference is the number of shots when performing MFU. People with larger facial volumes and larger faces may require more shots, while those with smaller faces or areas with less volume to treat may achieve sufficient results with a relatively lower number of shots.

(6) Area & Skin lines

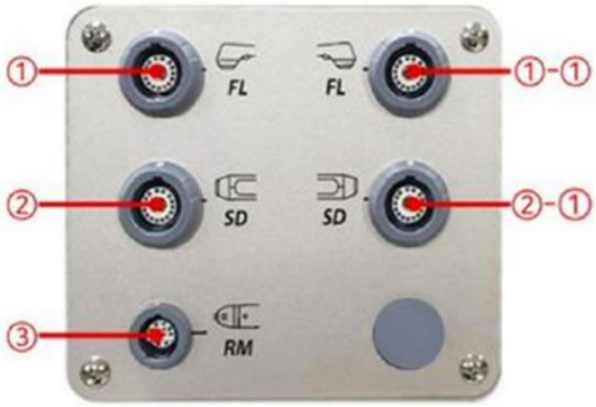
When performing MFU, the direction of the cartridge does not have a significant impact on the treatment results, but there are some considerations to maximize effectiveness. In areas where side effects are more likely to occur, excessive energy during treatment or poor cartridge contact can lead to hypertrophic or atrophic scars when side effects occur.

It is recommended to perform treatments in areas prone to side effects with caution or to skip those areas to minimize potential complications. Conversely, it is known that in safe areas, relatively strong parameters can be used without significant concerns. In this context, strong parameters include not only increasing power but also examining a large number of shots.

Additionally, as mentioned earlier, the direction in which wrinkles develop should be considered. The Relaxed Skin Tension Lines on the face follow the direction of gravitational force and become more pronounced with age. When performing MFU treatments, it is recommended to consider these directions and vectors of sagging.

03
Handpiece Introduction

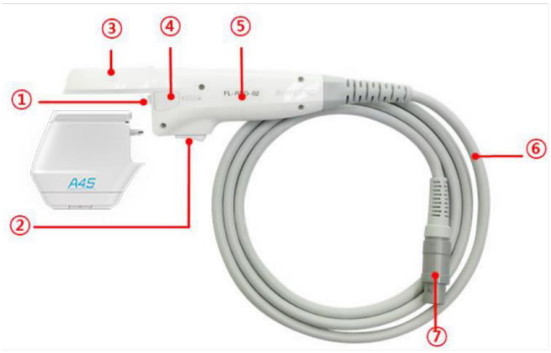
The New Doublo 2.0 Handpiece Connector,
which allows for the simultaneous use of up to 5 different handpieces

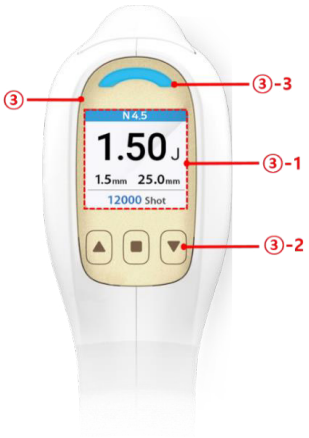


The New Doublo 2.0 offers three types of handpieces: the FL handpiece, which uses a line-type Focused Linear (FL) cartridge for quick treatments; the SD handpiece, which uses a dot-type Synergy Dotting (SD) cartridge that allows simultaneous MFU and RF treatments; and the RM handpiece, which enables RF Microneedle (RM) treatments. The design allows for the simultaneous use of up to 5 different handpieces, eliminating concerns about impedance changes during treatments and the inconvenience of changing handpieces based on treatment depth, resulting in significant improvements. Furthermore, it offers the advantage of performing Microneedle RF treatments at a reasonable cost, eliminating the need to purchase a separate RF device. This enables the application of various treatment programs. Additionally, it offers two convenient operation methods: handpiece and foot switch. Compared to previous series, the reduction in the weight of the handpiece enhances the convenience for the practitioner.

No.	Product Name	Description
1 / ①-①	FL Handpiece Connector	Connector for connecting the FL handpiece
2 / ②-①	SD Handpiece Connector	Connector for connecting the SD handpiece
3-1	RM Handpiece Connector	Connector for connecting the RM/RM handpiece

New Doublo 2.0 FL Handpiece and Component Information





No.	Product Name	Description
1	Cartridge Connection Port	Connecting Handpiece and Cartridge
2	Hand Switch	Press to control ultrasound output
3-1	Information Display LCD	Display cartridge information - Cartridge Type - Power (J) - Interval (sec): LINE mode selection - Spacing (mm): DOT mode selection - Length (mm) - Remain (Remaining Shot Count): STANDBY selection - Shot (Treatment Shot Count): READY selection - Lock/Unlock: LCD touch lock/unlock
3-2	Power Adjustment Button	Cartridge Power Adjustment Button
	STANDBY/READY Selection Button	STANDBY/READY Selection Button
3-3	Status Indicator LED	Display cartridge status - Standby: Blue LED - Ready: Green LED - During energy inspection: Orange LED - When cartridge is not connected: Red LED
4	Cartridge Release Button	Press to release the cartridge
5	Handpiece Body	Used as a handle during the procedure
6	Cable	Cable that transmits output to the handpiece and cartridge
7	Main Unit Connection Port	Part connected to the rear handpiece connection port on the main unit

New Doublo 2.0 SD Handpiece and Component Information

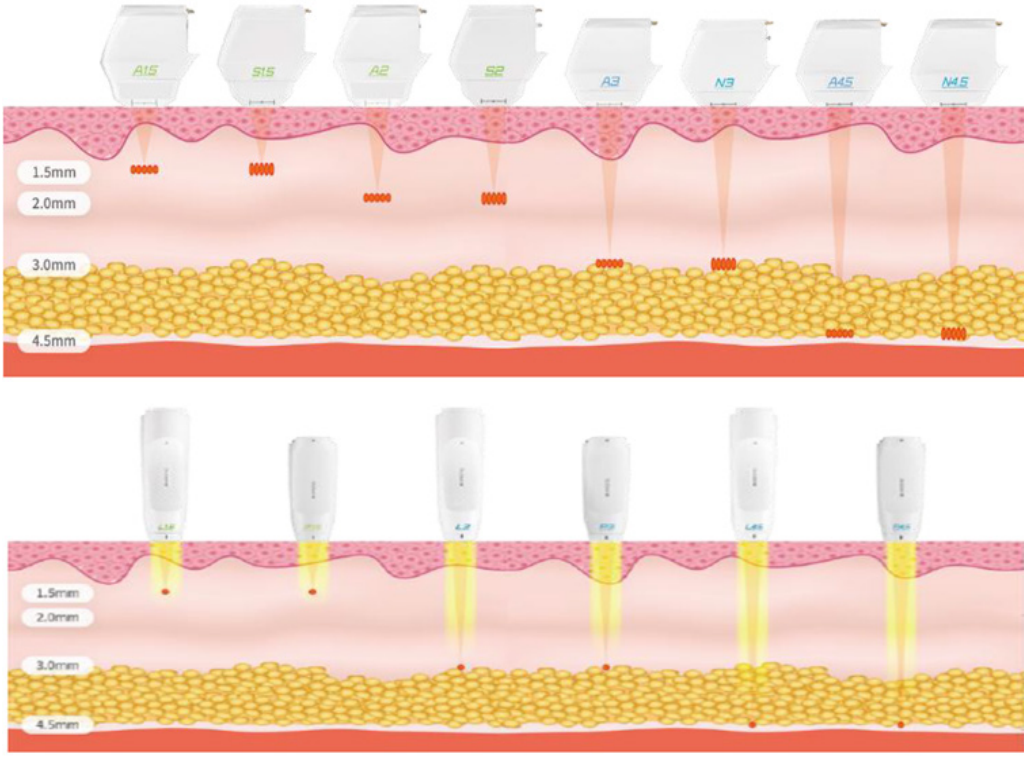
No.	Product Name	Description
1	Cartridge Coupling Port	Area where the SD cartridge board connector is coupled
2	Hand Switch	Press to control ultrasound output
3	Handpiece Body	Used as a handle during the procedure
4	Cable	Cable that transmits output to the handpiece and cartridge

New Doublo 2.0 RM Handpiece and Component Information

No.	Product Name	Description
1	RM Tip Connection Port	Area where the RM Tip is connected
2	Handpiece Body	Used as a handle during the procedure
3	Cable	Cable connecting the main unit and handpiece

04
Introduction to Cartridges

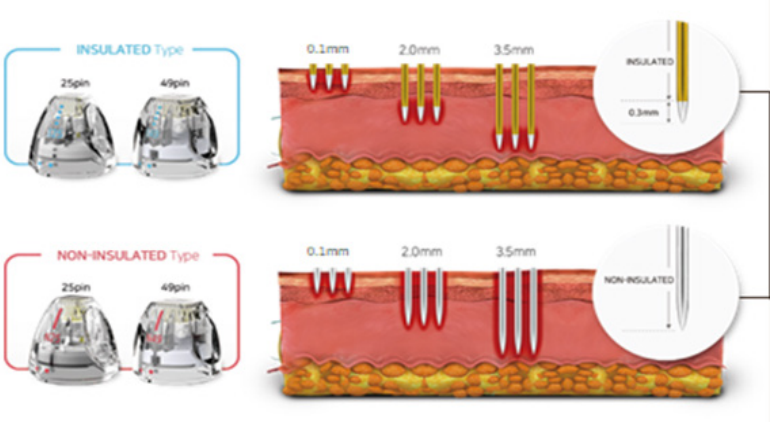
Types of Cartridges and Diagram Showing Areas of Action on the Skin by Actual Cartridges



For FL (MFU), there are a total of 8 types based on the depth of energy desired. Each cartridge is structured to provide intuitive information about the depth it targets through its naming. S1.5 (1.5mm), S2 (2.0mm), N3 (3.0mm), N4.5 (4.5mm) offer comfortable procedures with less pain compared to other devices, while the Advanced types A1.5 (1.5mm), A2.0 (2.0mm), A3.0 (3.0mm), A4.5 (4.5mm) deliver higher effectiveness. To enhance procedural convenience, cartridges have been slimmed down to ensure a clear view angle for the practitioner. This allows the practitioner to perform procedures with greater confidence while visually confirming the treatment area.

The SD cartridge (MFU+RF) comes in 6 different types based on the depth of energy desired. Each cartridge is designed to include both MFU and RF at different depths. The cartridge types include P1.5 (1.5mm), P3 (3.0mm), P4.5 (4.5mm), and L1.5 (1.5mm), L3.0 (3.0mm), L4.5 (4.5mm), which consider clinical convenience with distillation and size enlargement. What sets it apart is its dot pen-type cartridge, which enables more delicate treatment in areas where performing procedures with line-type energy cartridges may be inconvenient (such as around the eyes, mouth, etc.). Additionally, it provides the advantage of reduced pain due to RF treatment, resulting in a positive response from clients receiving the treatment.

Types of RF Microneedle Tips and Diagram Showing How They Affect the Skin



The RM Tip, which is attached to the RM (RF-Microneedle) handpiece, comes in a total of 4 types, divided by the number of pins and insulation. The 25-pin type is recommended for use on skin that is thick, oily, has wide pores, and exhibits scarring on the face. The 49-pin type is recommended for use on skin that is thin, has narrow pores, and has minimal scarring but shows a decrease in elasticity.
Insulated needles have the entire tip coated with gold, except for the 0.3mm needle tip, to concentrate RF energy only at the tip end. Insulated needles are used for pore reduction and scar improvement. Non-insulated needles have the entire needle uncoated, allowing energy to be delivered throughout the entire inserted needle. Non-insulated needles are primarily used for dermal improvement and enhancing elasticity.

Chapter. 03

Clinical Application of New Doublo 2.0

01
FL / SD Handpiece

[1] Rejuvenation

a. Pre-Treatment Considerations

Due to individual variations in patient response to the energy values within the parameters, it is recommended to perform a test shot before proceeding with the procedure.
Practitioners should apply ultrasound gel to their own arms and facial areas before the procedure and use a test shot to confirm the appropriate heat sensation before treatment.

b. During Treatment Considerations

Increasing the energy intensity can result in a larger thermal focal zone and can have a greater impact on surrounding tissues, inducing effects such as the production of collagen/elastin, fat reduction, and SMAS contraction to a greater extent. However, to use higher energy intensity, it is essential to ensure adequate spacing to prevent thermal damage due to overlap of the thermal focal zones.
In cases where skin contact is uncertain, energy may adhere to the skin surface, leading to scratch-like burns. To prevent this, the cartridge should be closely adhered to the skin contact surface during treatment. New Doublo 2.0 is designed to require precise cartridge adhesion to the skin when the patented contact sensor function is activated. Energy is only emitted when the cartridge is accurately adhered to the skin.
Areas around the eyes that have a risk of visual impairment are not treated, and treatment in the thyroid gland area is also not recommended. Caution is required when treating areas around the eyes and lips where sensory nerves are close to the skin surface. Especially in the supraorbital (above the eye) area, nerve distribution is present, and nerve damage can occur, so treatment is not recommended. Additionally, areas close to the bone may experience pain and nerve damage during MFU treatment. The degree of pain varies from person to person, so it is recommended to adjust the energy based on the patient's response. Pain during treatment is influenced by the conductivity of ultrasound, so appropriate coupling agents must be chosen for precise conduction. The thickness of the ultrasound gel applied can affect how ultrasound is converted into thermal focal points. Air pockets can create impedance differences during ultrasound transmission between the skin and the probe, causing pain.

Therefore, it is recommended to maintain an appropriate gel thickness during application and adjust the position of the cartridge and the patient's posture during treatment.

If the patient moves or exerts irregular pressure during the procedure, welts, a reaction characterized by redness on the skin surface, may appear. This reaction typically subsides within 3-4 hours, but in some cases, it may last up to 24 hours. Patients should be appropriately informed about this. If there is an insufficient amount of distilled water inside the cartridge for proper operation, it can be replenished using a syringe or other means.

Impedance Variations Depending on the Medium

Table 1. The Ultrasound Properties of Various Media, Including Soft Tissue Found in the Body

Medium	Density (kg/m^3)	Speed of Ultrasound (m/s)	Acoustic Impedance ($kg/(m^2 \cdot s)$)
Air	1.3	330	429
Water	1000	1500	1.5×10^6
Blood	1060	1570	1.66×10^6
Fat	925	1450	1.34×10^6
Muscle (average)	1075	1590	1.70×10^6
Bone (varies)	1400–1900	4080	5.7×10^6 to 7.8×10^6
Barium titanate (transducer material)	5600	5500	30.8×10^6

[FL handpiece: S1.5, S2, N3, N4.5, A1.5, A2, A3, A4.5 Cartridge]

- When confirming cartridge contact, ensure that the treatment area is kept perpendicular to the contour of the face during the procedure.
- Be cautious not to perform repetitive scans of the same area during treatment. When moving the handpiece in the opposite direction of the transducer's progression inside the cartridge during treatment, it may exhibit a similar pattern to when the transducer is fixed in place and energy is applied. Therefore, special attention is required. Treating in the direction perpendicular to the transducer's progression is not problematic.
- When performing cheek treatments, maintain an appropriate density of treatment while ensuring that treatment intervals do not overlap. Treat in the direction moving away from the lower jaw. Direct treatment on the lower jaw or facial nerves may lead to discomfort and a higher risk of potential side effects.
- During lower eyelid treatments, ask the patient to pull their cheek downwards to facilitate the contraction of the lower eyelid tissue. Start the treatment from the inside next to the nose.

- For chin treatments, pay attention to cartridge contact and consider lifting the chin to target the appropriate area effectively.
- When performing treatments around the mouth, position a dental roll between the inside of the mouth and the treatment area to ensure that the treatment area remains flat when the cartridge is applied. (You can use a dry and folded gauze as an alternative.) Avoid the prohibited treatment areas above the lower jaw nerve (refer to the treatment program) and only treat the necessary lines in the area around the mouth.
- Do not perform treatments directly on the eyes or in a manner or location where ultrasound energy can reach the eyes. When treating under the eyes, it is useful to pull the skin around the eye to prevent energy from being transmitted inside the eye while maintaining contact with the cartridge. When treating under the eyes for wrinkles, treat in a crosshatch pattern and be careful not to overlap in the same spot. It is recommended to start from above the eyebrow and move in a fan-shaped direction downward. At the same time, be cautious to avoid transmitting energy to the nerves. When treating the lower eyelids, ask the patient to pull their cheek downward to facilitate the contraction of the lower eyelid tissue, and start the treatment from the inside next to the nose. After energy has been applied, move the cartridge as a whole to avoid repeated treatment in the area just outside the edge of the eye.
- When performing treatments above the eyebrows, if the forehead bone interferes with the treatment or if the patient's sensory response is sensitive, you can change the direction of the cartridge. If the patient feels like their head is being pulled during the treatment, move the treatment slightly to the side or towards the end by about 2-3 mm from the inside of the eyebrow before starting a new treatment. When treating the forehead, make sure to avoid applying energy to the nerves above the eyes while the cartridge is in contact.
- Do not deliver energy below the line drawn in the middle of the neck or above the thyroid cartilage or the airway.

[SD handpiece: P1.5, P3, P4.5, L1.5, L3, L4.5 Cartridge]

- When using the SD handpiece for treatment, ensure that the cartridge adheres to the skin. Instead of treating in separate lines, maintain continuous movement by keeping the handpiece in close contact. Adjust the SD handpiece movement to match the Hz setting. When using high-energy settings, move at a fast pace and avoid treating the thyroid gland area. When pausing or completing the treatment, place the handpiece on the holder in the Standby state.
- When performing standalone treatments without RF or MFU combination, turn off the MFU tab when performing only RF, and turn off the RF tab when performing only MFU.

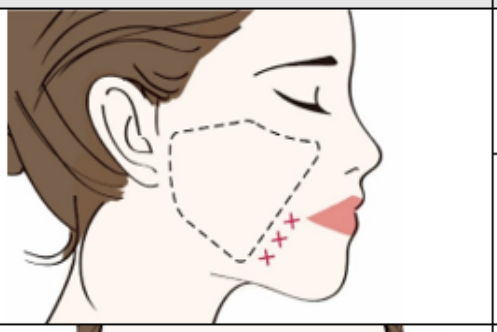
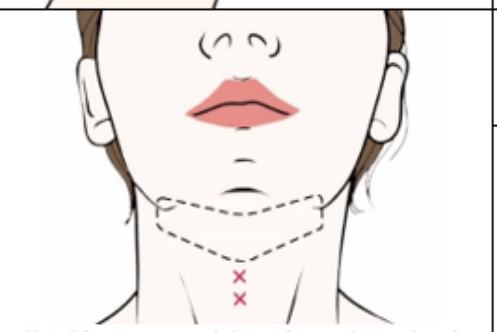
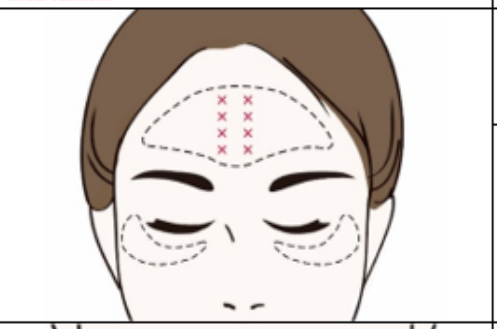
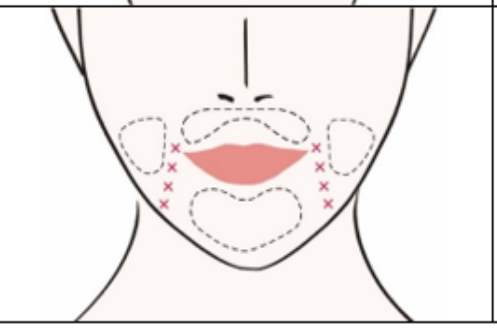
SD Handpiece Contact Area

- When moving too quickly, there is a risk that the focused ultrasound energy may not be effectively absorbed by the tissue and may scatter, leading to suboptimal results. It is recommended to perform the treatment at an appropriate speed, pushing in the direction of lymphatic flow, similar to lymphatic drainage. (Based on a 7 MHz reference, an average movement of 1.5 to 2.0 cm per second is recommended: approximately half the contact area of the SD handpiece). This can enhance immediate effects such as waste material elimination.
- In the case of high-frequency treatments, the sensation of heat may vary depending on the use of gel or high-frequency cream. It is advisable to check the characteristics of the gel or high-frequency cream being used beforehand and make appropriate adjustments during treatment.
- During high-frequency treatments, it is recommended that both the patient and the practitioner remove metallic accessories (necklaces, earrings, etc.) to avoid potential induction of high-frequency energy.
- When performing cheek treatments, it is recommended to start from the inside of the cheek and move outward towards the direction of the ear. The outer part of the cheek contains dense tissue, so adjust the speed of movement while performing the treatment as densely as possible.
- For treatments under the chin, tilt the head backward and draw lines or patterns while avoiding the area under the earlobe, especially in cases of double chin treatment.
- When treating the lower area around the eyes, gently pull down the skin below the eyes and draw lines. Additionally, for areas around wrinkles, press on the wrinkles while performing the treatment, and use P3 or L3 for deep wrinkles or thicker skin.
- For treatments on the upper part of the eyebrows, draw lines towards the philtrum (the groove between the nose and upper lip). If there are deep creases in the forehead, pull the skin towards the philtrum to ensure contact with the handpiece. Use P1.5 or L1.5 for thin wrinkles, and P3 or L3 for thick skin with wrinkles.

※ Select the cartridge type based on the depth of the skin.

c. Treatment Protocol

1. FL(Focused Linear): Line Mode

Treatment Area		Cartridge	Power (J)	Interval (sec)	Length (mm)	Total Shot
Cheek		A3 N3	0.30~0.40	0.2	25	Min: 100 Max: 200
		A4.5 N4.5	0.70~0.80			
Lower Chin	 ※ Note: It is not recommended to perform neck procedures in a linear fashion.	A3 N3	0.30~0.45	0.2	25	Min: 100 Max: 150
		A4.5 N4.5	0.80~0.90			
Forehead+ Eyerim		A1.5 S1.5	0.10~0.20	0.4	25	Min: 50 Max: 100
		A2 S2	0.15~0.30	0.3		
Mouth		A2 S2	0.15~0.30	0.3	25	Min: 50 Max: 100

※ This treatment protocol is based on the FL300+SD3,000 Shot Combination. For FL, maintain a probe interval of 2-3mm per shot, and for SD, administer the treatment slowly while rubbing.

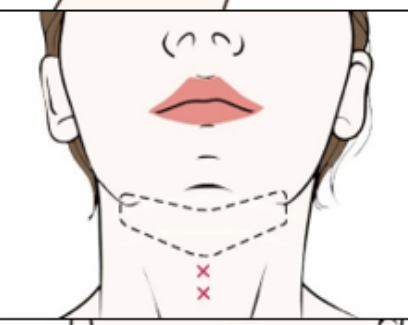
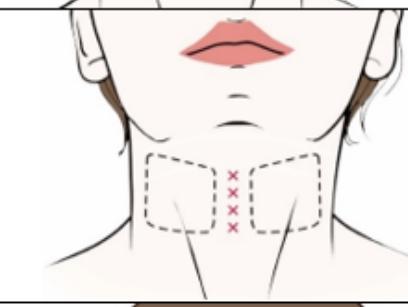
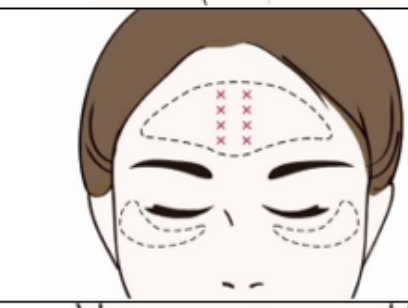
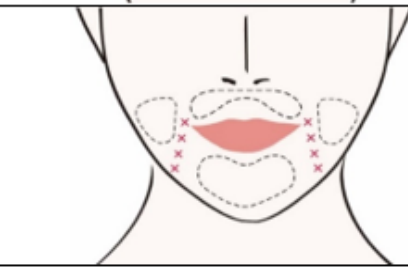
※ Please ensure that you are well-versed in the user manual before proceeding with the procedure. This Treatment Guide provides recommendations, so make adjustments based on the patient's skin thickness and condition.

※ Avoid treatment around areas marked with an 'X' as they may contain nerves.

※ When performing the procedure in FL LINE mode, it is not recommended to use an interval of 0.1 seconds.

※ The SD handpiece can be used at a maximum frequency of 10Hz.

2. FL(Focused Linear): Dot Mode

Treatment Area		Cartridge	Power (J)	Spacing (mm)	Length (mm)	Total Shot
Cheek		A3 N3	0.35~0.45	1.5	25	Min: 100 Max: 200
		A4.5 N4.5	1.05~1.30	1.7		
Lower Chin		A3 N3	0.30~0.50	1.5	25	Min: 100 Max: 150
		A4.5 N4.5	1.10~1.35	1.7		
Neck		A2 S2	0.15~0.25	1.2	25	Min: 50 Max: 100
Forehead+ Eyerim		A1.5 S1.5	0.15~0.25	1.2	25	Min: 50 Max: 100
		A2 S2	0.20~0.35			
Mouth		A2 S2	0.20~0.35	1.2	25	Min: 50 Max: 100

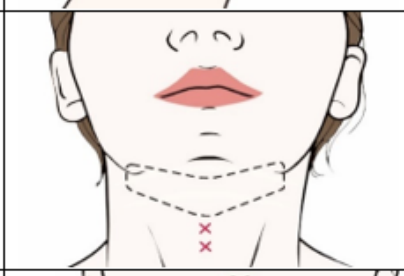
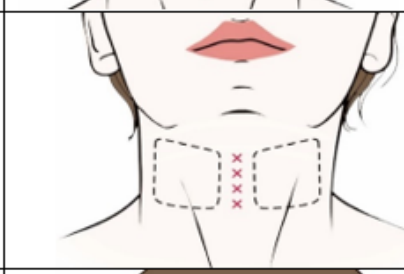
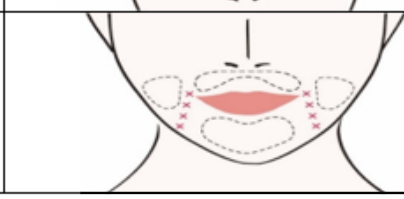
※ This treatment protocol is developed based on the FL300+SD3,000 Shot Combination. For FL, it is recommended to maintain an interval of 2-3mm between shots, while for SD, apply the treatment slowly with a rubbing motion.

※ Ensure that you thoroughly familiarize yourself with the user manual before performing the procedure. This Treatment Guide provides recommendations, so please adjust it according to the patient's skin thickness and condition.

※ The 'X' marks indicate the presence of nerves, so please avoid treating those areas.

※ When conducting the procedure in FL LINE mode, it is not advisable to use a 0.1-second interval between shots.

3. SD(Synergy Dotting): MFU+RF Mode

Treatment Area		Cartridge	HIFU Power (J)	RF Power (Lv)	Hz	Total Shot
Cheek		L1.5 P1.5	0.10~0.20	4~6	6~8	Min: 1,600 Max: 2,800
		L3 P3	0.30~0.50			
		L4.5 P4.5	1.05~1.25			
Lower Chin		L3 P3	0.30~0.50	4~6	6~8	Min: 600 Max: 1,300
		L4.5 P4.5	1.05~1.25			
Neck		L1.5 P1.5	0.10~0.20	4~6	6~7	Min: 500 Max: 800
		L3 P3	0.25~0.35			
Forehead+ Eyerim		L1.5 P1.5	0.15~0.25	4~6	6~7	Min: 700 Max: 1000
Mouth		L1.5 P1.5	0.15~0.25	4~6	6~7	Min: 500 Max: 800
		L3 P3	0.30~0.40			

※ This treatment protocol is formulated based on the FL300+SD3,000 Shot Combination. For FL, it is advisable to maintain a probe interval of 2-3mm per shot, while for SD, please administer the treatment slowly using a rubbing technique.

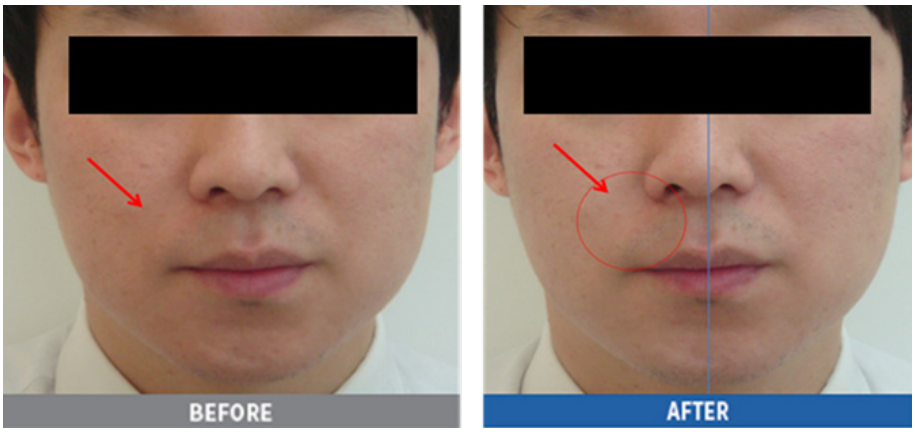
※ Prior to performing the procedure, it is imperative that you thoroughly acquaint yourself with the user manual. This Treatment Guide provides recommended guidelines; therefore, make necessary adjustments according to the patient's skin thickness and condition.

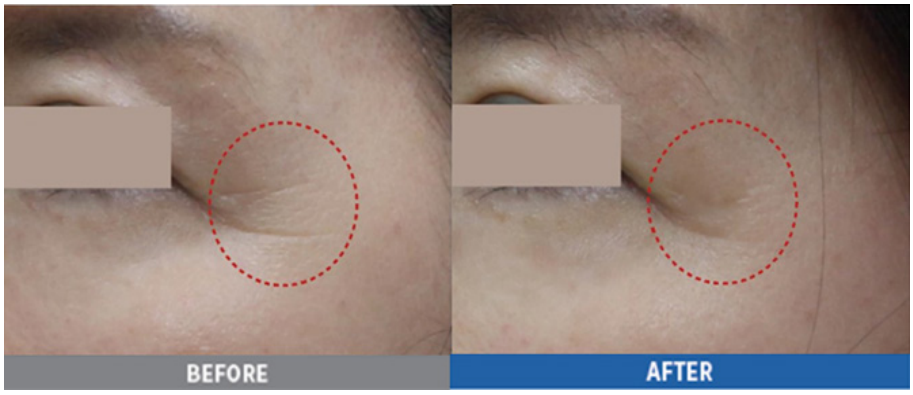
※ Areas marked with an 'X' indicate the presence of nerves, so kindly avoid treating these areas.

※ When conducting the procedure in FL LINE mode, it is not recommended to use a 0.1-second interval between shots.

※ The SD handpiece can be utilized at a maximum frequency of 10Hz.

d. Before & After





[2] Hyperhidrosis

a. Precautions Before Treatment

The following are contraindications and considerations that must be observed before proceeding with the procedure in consultation with a physician:

- If there is an infectious skin condition.
- In cases of bleeding disorders or when taking aspirin.
- If a cardiac pacemaker is implanted.
- During pregnancy.
- High Blood Pressure
- Implants
- Medication Allergies

b. Precautions During Treatment

- The recommended interval between treatments is a minimum of 2-4 weeks, with 3-5 sessions suggested.
- The number of treatment sessions and energy settings may vary depending on the improvement of the condition.
- During treatment, avoid overlapping at thermal coagulation points. It is possible to perform an additional 1-pass treatment based on the degree of erythema after the initial 1-pass treatment.
- Adjust the energy level and depth of treatment according to the indications.
- In areas with thin skin or adjacent to bones, such as the forehead, eye area, nasolabial folds, and temples, the depth should be set to less than 1.0mm, and the energy level should be adjusted to a maximum of level 5.

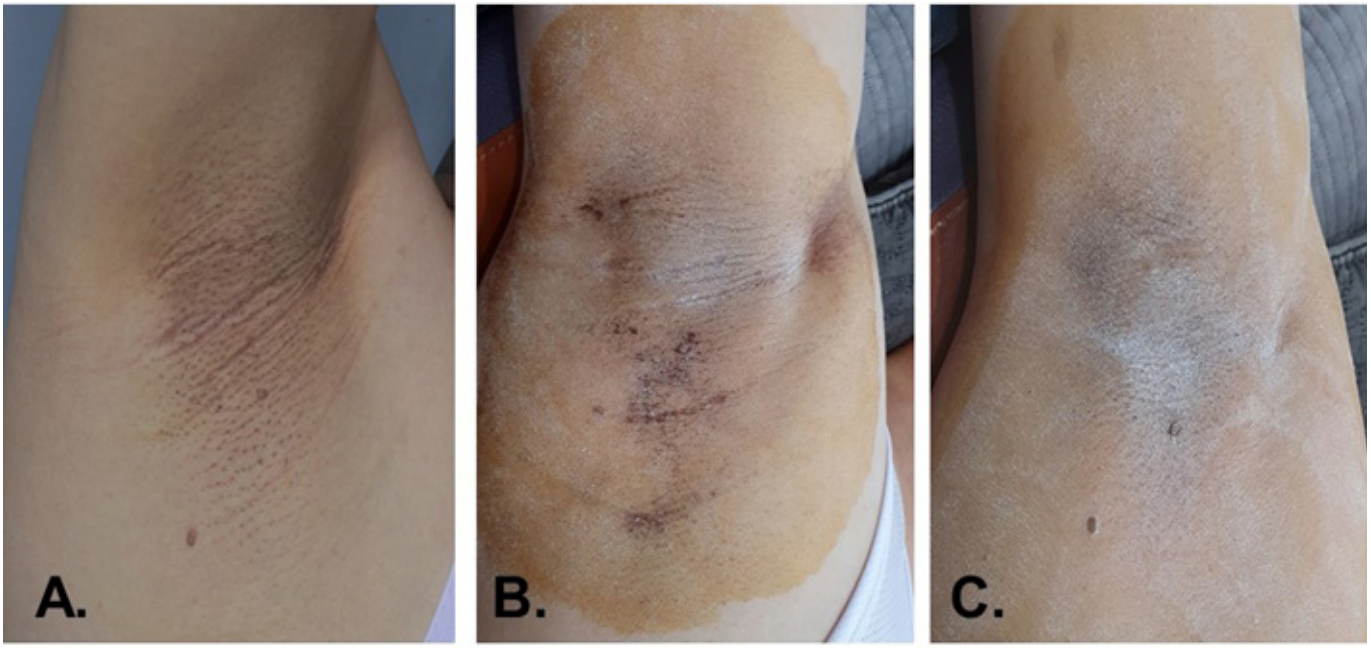
c. Treatment Program

Treatment Area	Cartridge	Power (J)	Spacing (mm)	Length (mm)	Total Shot
Armpit	N4.5	1.2	2-3	25	20
	N3	0.45	2-3	25	20

※ Do not perform treatments with a depth of less than 1mm.

※ Prior to performing the procedure, it is essential to thoroughly familiarize yourself with the user manual. This Treatment Guide provides recommendations, so please adjust it according to the patient's skin thickness and condition.

d. Before & After



Iodine-Starch Test (IST). A. Before Treatment B. IST Before Treatment C. IST 2 Weeks After Treatment

02
RM Handpiece

[1] Rejuvenation

a. Pre-Treatment Considerations

The following are contraindications and considerations that must be observed before proceeding with the procedure in consultation with a physician:

- If there is an infectious skin condition.
- In cases of bleeding disorders or when taking aspirin.
- If a cardiac pacemaker is implanted.
- During pregnancy.
- High Blood Pressure
- Implants
- Medication Allergies

b. During the Procedure Precautions

- The recommended interval between treatments is a minimum of 2-4 weeks, with 3-5 sessions suggested.
- The number of treatment sessions and energy settings may vary depending on the improvement of the condition.
- During treatment, avoid overlapping at thermal coagulation points. It is possible to perform an additional 1-pass treatment based on the degree of erythema after the initial 1-pass treatment.
- Adjust the energy level and depth of treatment according to the indications.
- In areas with thin skin or adjacent to bones, such as the forehead, eye area, nasolabial folds, and temples, the depth should be set to less than 1.0mm, and the energy level should be adjusted to a maximum of level 5.

c. Treatment Program

Indication	Tip	Depth (mm)	Target	Frequency (MHz)	RF Power(ms)	On Time (ms)	Off Time (ms)	Pulse	Repetition (S)
RJV	N25 / N49	0.7	Forehead	2	8	20	10	5	0.3
	N25 / N49	1.0	Eyerim	2					
	N25 / N49	1.2	Nose	1					
	N25 / N49	1.5	Cheek	1					
	N25 / N49	1.2	Mouth	1					
	N25 / N49	1.2	Chin	1					

※ The tip is disposable and should not be reused.

※ Apply anesthesia cream before the procedure, and once adequate anesthesia is achieved, proceed with disinfection before treatment to prevent infection.

※ Please ensure to thoroughly familiarize yourself with the user manual for detailed precautions before use.

d. Before & After

[2] Melasma

a. Pre-Treatment Considerations

The following are contraindications and considerations that must be observed before proceeding with the procedure in consultation with a physician:

- If there is an infectious skin condition.
- In cases of bleeding disorders or when taking aspirin.
- If a cardiac pacemaker is implanted.
- During pregnancy.
- High Blood Pressure
- Implants
- Medication Allergies

b. During the Procedure Precautions

- The recommended interval between treatments is a minimum of 2-4 weeks, with 3-5 sessions suggested.
- The number of treatment sessions and energy settings may vary depending on the improvement of the condition.
- During treatment, avoid overlapping at thermal coagulation points. It is possible to perform an additional 1-pass treatment based on the degree of erythema after the initial 1-pass treatment.
- Adjust the energy level and depth of treatment according to the indications.
- In areas with thin skin or adjacent to bones, such as the forehead, eye area, nasolabial folds, and temples, the depth should be set to less than 1.0mm, and the energy level should be adjusted to a maximum of level 5.

c. Treatment Program

Indication	Tip	Depth (mm)	Target	Frequency (MHz)	RF Power (ms)	On Time (ms)	Off Time (ms)	Pulse	Repetition (S)
Melasma	N25	0.5	All	2	2	20	10	5	0.3

※ The tip is disposable and should not be reused.

※ Apply anesthesia cream before the procedure, and once adequate anesthesia is achieved, proceed with disinfection before treatment to prevent infection.

※ Please ensure to thoroughly familiarize yourself with the user manual for detailed precautions before use.

d. Before & After

[3] Rosacea

a. Pre-Treatment Considerations

The following are contraindications and considerations that must be observed before proceeding with the procedure in consultation with a physician:

- If there is an infectious skin condition.
- In cases of bleeding disorders or when taking aspirin.
- If a cardiac pacemaker is implanted.
- During pregnancy.
- High Blood Pressure
- Implants
- Medication Allergies

b. During the Procedure Precautions

- The recommended interval between treatments is a minimum of 2-4 weeks, with 3-5 sessions suggested.
- The number of treatment sessions and energy settings may vary depending on the improvement of the condition.
- During treatment, avoid overlapping at thermal coagulation points. It is possible to perform an additional 1-pass treatment based on the degree of erythema after the initial 1-pass treatment.
- Adjust the energy level and depth of treatment according to the indications.
- In areas with thin skin or adjacent to bones, such as the forehead, eye area, nasolabial folds, and temples, the depth should be set to less than 1.0mm, and the energy level should be adjusted to a maximum of level 5.

c. Treatment Program

Indication	Tip	Depth (mm)	Target	Frequency (MHz)	RF Power (ms)	On Time (ms)	Off Time (ms)	Pulse	Repetition (S)
RSC	N25	0.8	Forehead	1	12	30	10	5	0.3
	N25	0.8	Eyerim	1					
	N25	1.0	Nose	1					
	N25	1.2	Cheek	1					
	N25	1.2	Mouth	1					
	N25	1.2	Chin	1					

※ The tip is disposable and should not be reused.

※ Apply anesthesia cream before the procedure, and once adequate anesthesia is achieved, proceed with disinfection before treatment to prevent infection.

※ Please ensure to thoroughly familiarize yourself with the user manual for detailed precautions before use.

[4] Acne

a. Pre-Treatment Considerations

The following are contraindications and considerations that must be observed before proceeding with the procedure in consultation with a physician:

- If there is an infectious skin condition.
- In cases of bleeding disorders or when taking aspirin.
- If a cardiac pacemaker is implanted.
- During pregnancy.
- High Blood Pressure
- Implants
- Medication Allergies

b. During the Procedure Precautions

- The recommended interval between treatments is a minimum of 2-4 weeks, with 3-5 sessions suggested.
- The number of treatment sessions and energy settings may vary depending on the improvement of the condition.
- During treatment, avoid overlapping at thermal coagulation points. It is possible to perform an additional 1-pass treatment based on the degree of erythema after the initial 1-pass treatment.
- Adjust the energy level and depth of treatment according to the indications.
- In areas with thin skin or adjacent to bones, such as the forehead, eye area, nasolabial folds, and temples, the depth should be set to less than 1.0mm, and the energy level should be adjusted to a maximum of level 5.

c. Treatment Program

Indication	Tip	Depth (mm)	Target	Frequency (MHz)	RF Power (ms)	On Time (ms)	Off Time (ms)	Pulse	Repetition (S)
ACN	I49	0.7	Forehead	1	10	50	20	3	0.3
	I49	1.0	Eyerim	1					
	I49	0.8	Nose	1					
	I49	1.0	Cheek	1					
	I49	1.2	Mouth	1					
	I49	1.2	Chin	1					

※ The tip is disposable and should not be reused.

※ Apply anesthesia cream before the procedure, and once adequate anesthesia is achieved, proceed with disinfection before treatment to prevent infection.

※ Please ensure to thoroughly familiarize yourself with the user manual for detailed precautions before use.

d. Before & After

[5] Wrinkle

a. Pre-Treatment Considerations

The following are contraindications and considerations that must be observed before proceeding with the procedure in consultation with a physician:

- If there is an infectious skin condition.
- In cases of bleeding disorders or when taking aspirin.
- If a cardiac pacemaker is implanted.
- During pregnancy.
- High Blood Pressure
- Implants
- Medication Allergies

b. During the Procedure Precautions

- The recommended interval between treatments is a minimum of 2-4 weeks, with 3-5 sessions suggested.
- The number of treatment sessions and energy settings may vary depending on the improvement of the condition.
- During treatment, avoid overlapping at thermal coagulation points. It is possible to perform an additional 1-pass treatment based on the degree of erythema after the initial 1-pass treatment.
- Adjust the energy level and depth of treatment according to the indications.
- In areas with thin skin or adjacent to bones, such as the forehead, eye area, nasolabial folds, and temples, the depth should be set to less than 1.0mm, and the energy level should be adjusted to a maximum of level 5.
- Adjust the needle depth based on the presence of pores, scars, or the treatment area on the full face, and perform the treatment in 1-pass increments.

c. Treatment Program

Indication	Tip	Depth (㎜)	Target	Frequency (MHz)	RF Power (ms)	On Time (ms)	Off Time (ms)	Pulse	Repetition (S)
WRK	N25 / N49	0.7	Forehead	1	7	30	20	5	0.3
	N25 / N49	1.0	Eyerim	1					
	N25 / N49	1.2	Nose	0.5					
	N25 / N49	1.5	Cheek	0.5	10				
	N25 / N49	1.2	Mouth	0.5					
	N25 / N49	1.2	Chin	0.5					

※ The tip is disposable and should not be reused.

※ Apply anesthesia cream before the procedure, and once adequate anesthesia is achieved, proceed with disinfection before treatment to prevent infection.

※ Please ensure to thoroughly familiarize yourself with the user manual for detailed precautions before use.

[6] Scar

a. Pre-Treatment Considerations

The following are contraindications and considerations that must be observed before proceeding with the procedure in consultation with a physician:

- If there is an infectious skin condition.
- In cases of bleeding disorders or when taking aspirin.
- If a cardiac pacemaker is implanted.
- During pregnancy.
- High Blood Pressure
- Implants
- Medication Allergies

b. During the Procedure Precautions

- The recommended interval between treatments is a minimum of 2-4 weeks, with 3-5 sessions suggested.
- The number of treatment sessions and energy settings may vary depending on the improvement of the condition.
- During treatment, avoid overlapping at thermal coagulation points. It is possible to perform an additional 1-pass treatment based on the degree of erythema after the initial 1-pass treatment.
- Adjust the energy level and depth of treatment according to the indications.
- In areas with thin skin or adjacent to bones, such as the forehead, eye area, nasolabial folds, and temples, the depth should be set to less than 1.0mm, and the energy level should be adjusted to a maximum of level 5.
- Adjust the needle depth based on the presence of pores, scars, or the treatment area on the full face, and perform the treatment in 1-pass increments.

c. Treatment Program

Indication	Tip	Depth (㎜)	Target	Frequency (MHz)	RF Power (ms)	On Time (ms)	Off Time (ms)	Pulse	Repetition (S)
SCR	N49	0.7	Forehead	2	10	40	20	5	0.3
	N49	1.0	Eyerim	2					
	N49	1.2	Nose	2					
	N49	1.5	Cheek	2					
	N49	1.2	Mouth	2					
	N49	1.2	Chin	2					

※ The tip is disposable and should not be reused.

※ Apply anesthesia cream before the procedure, and once adequate anesthesia is achieved, proceed with disinfection before treatment to prevent infection.

※ Please ensure to thoroughly familiarize yourself with the user manual for detailed precautions before use.

d. Before & After

Chapter. 04

Q & A

Q. How is High-Intensity Focused Ultrasound (HIFU) Generated?

High-Intensity Focused Ultrasound (HIFU) therapy involves using intense ultrasound energy focused at one point, resulting in temperatures of 65-100°C, which are used to ablate tissues. When focusing ultrasound energy about ten thousand times stronger than that used for diagnostic purposes at a single point, heat is generated at the focal point. This principle is similar to how a magnifying glass concentrates sunlight to create heat at a specific focal point. Ultrasound itself is harmless to the human body, and heat is generated only at the focal point where the ultrasound is concentrated. Therefore, it is possible to treat internal lesions non-invasively without the need for scalpels, needles, or general anesthesia.

Q. What Temperature Does Tissue Degeneration Occur?

Actinin, a protein, starts to denature at temperatures above 50°C, while collagen denatures between 60-70°C, and Prolyl 4-Hydroxylase denatures between 60-70°C as well.

Q. Why is the Skin Contact Temperature Managed Below 43°C?

Maintaining a skin contact temperature below 43°C is crucial because when the epidermal temperature reaches 40-42°C, tissue temperature exceeds this range, leading to deep tissue heating and promoting the production of collagen and elastin.

Q. Why is Spacing Adjustment Necessary Depending on the Intensity of MFU (Microfocused Ultrasound)?

As the intensity of MFU increases, spacing needs to be widened during the procedure. When the intensity is high, the range of thermal coagulation points expands. Failing to maintain appropriate spacing may lead to tissue denaturation beyond the intended target.

Q. Why Are Different Frequencies (2MHz/4MHz/7MHz) Used for Cartridges?

- Different frequencies are used depending on the purpose to perform treatments with various energy and depths.
- For areas such as the forehead, nasolabial folds, and around the eyes, where the skin and subcutaneous tissue are thin, a shallow penetration depth is required. Therefore, treatments are conducted using 7MHz or 10MHz transducers. However, it is advisable to avoid treating areas close to the supraorbital and infraorbital nerves.
- When treating deeper layers on the cheeks, start with 4MHz and then follow up with 7MHz to address shallower layers. In general, using a higher 7MHz frequency is recommended for individuals with thinner skin. For the jawline, consider the thickness of the fat tissue. If it is thin, use 7MHz; if there is a significant fat layer, use 4MHz for the procedure.
- Higher frequencies are more suitable for treating thinner layers. With higher frequencies, ultrasound wavelengths become shorter, allowing for more effective penetration into thin or superficial tissues. Using higher-frequency ultrasound makes it easier to access thinner skin or layers just below the skin's surface, making it more suitable for treating epidermal tissues.

Q. How Long Does It Take for Collagen Regeneration to Occur?

Collagen regeneration occurs over a period of 4 weeks (28 days).

Q. What Does Collagen Have to Do with Wrinkle Elasticity and Lifting?

Collagen and elastin, among the components in the dermis, play a role in the skin's elasticity.

Q. Why is a Treatment Interval of 3-4 Weeks Typically Mentioned?

his is because the typical skin regeneration cycle is 4 weeks (28 days).

Q. Does that mean I can't get another treatment the day after today's procedure?

Getting another treatment right after today's procedure can slow down the skin regeneration process and may lead to permanent skin damage.

Q. What precautions should I take when treating neck wrinkles, for example?

- When treating the neck, it's important to be cautious around the thyroid gland and the nerves distributed in the area.
- Nerves are usually distributed deeper, but pressing too hard on the skin during the procedure can transmit energy to the nerves, so care should be taken.

Q. How can I prevent eye damage?

Based on our study (Efficacy of single dot ultrasound combined with radiofrequency for low eyelid laxity: periorbital area and mid face with parameters of a 3.0mm depth, 0.5J power, 4.0 RF level, 5Hz), it is possible to treat the area above the eyes, between the upper part of the skin, and the brow bone by excluding the eye area and pulling it upwards.

Q. What happens if I continue to apply energy in the same area?

Continuously applying energy in the same area can lead to heat damage or tissue denaturation and contraction. If done incorrectly, it can render regeneration impossible, so caution is necessary.

Q. Why do people express varying degrees of pain even when using the same power during the procedure?

This variation is due to differences in individuals' skin conditions and pain thresholds.

Q. Is there no problem with the effectiveness in such cases?

Effectiveness can vary from person to person, and the treatment should be adjusted considering the thickness of the customer's skin.

Q. It is known that 3mm treatment targets the area below the dermis and can lead to fat reduction. Is this accurate?

In terms of skin structure principles, it is accurate, but there can be individual variations.

Q. Is it okay to perform the procedure above areas with hair?

It is recommended to avoid treating sensitive nerve areas.

Q. What are the main components of the ultrasound gel?

The primary component is water, making up the majority of its composition.

Q. The recommendation is to use 300 shots, but do they all need to be the same?

Generally, 300 shots are recommended, but it is advisable to consider factors like skin thickness and surface area when determining the exact number.

Q. How many shots should be used when using SD?

For a full-face treatment, it is recommended to use between 3,000 to 4,000 dots.

Q. When using SD, which should be done first, FL or something else? What is the reason for this?

It is recommended to perform FL first. To ensure that the MFU's coagulation points reach accurately, performing RF first may affect the MFU depth due to skin tissue expansion and relaxation.

Q. Laser treatments are said to be ineffective for darker skin types, but is MFU affected by skin type?

MFU is advantageous in that it can be performed regardless of skin type; it is not influenced by skin type.

Q. In conclusion, what are the differences when comparing RF and MFU?

The main difference is that RF provides immediate tightening, while MFU is more focused on lifting.

Q. What are the advantages of MFU compared to lasers?

Lasers may have downtime but are excellent for regeneration effects, while MFU has no downtime but excels in lifting effects rather than regeneration. MFU's color-blind characteristic is also an advantage.

Q. When performing SD-type procedures, does the treatment direction, such as vector direction, matter?

For New Doublo 2.0, which primarily aims for lifting, it is more effective to perform the procedure in an upward direction from below.

Q. When performing SD, does it not result in dots missing and glancing off if you move it while treating?

During SD procedures, it is recommended to move the patient's face in the direction of gravity (vertically) while performing the treatment. Even if the patient's face is fixed, it is still recommended to perform the procedure with the SD handpiece's surface at a right angle to the facial surface. To ensure accurate energy delivery, overlapping by 50% every 2 seconds is often recommended. As energy accumulates, heat may be felt more rapidly. Even if the treatment speed increases, scanning at 7Hz, delivering 7 shots per second, allows for sufficient energy delivery.

Q. Why is the MFU energy weak in the SD handpiece? Wouldn't it have been better to design it to only emit RF? Is there a specific reason?

RF and MFU are cross-examined, and if energy accumulates too much, there can be a risk during the procedure. Additionally, the perception of energy can vary depending on the thickness of the skin. Therefore, it is advisable to maintain an intermediate value. When RF heat sensation is combined with MFU, it is expected to provide a more synergistic treatment effect.

Q. During RM treatment, I proceeded with the automatic settings, and there is no bleeding, just a slight unevenness. Is it the right depth? Should I proceed deeper to the point where there is a slight bleeding?

The appropriate depth can vary depending on the indication, but for scars, it should be to the point where there is a slight bleeding. The recommended depths are around 0.5-0.7mm for the forehead, eye area, and chin, and 1.0-1.5mm for the jaw and cheeks.

Q. What is the role of high frequency (RF) in the treatment?

- High frequency (RF) stimulates the skin by passing electric currents through it, and the heat generated as a result promotes the synthesis of collagen and elastin in the skin.
- It acts on the patient's deep skin collagen, improving skin tone, contour, and texture while providing a skin tightening effect. This non-invasive treatment has been clinically proven to be safe and effective.
- Even with just one treatment, it can stimulate the synthesis of new collagen in the patient's internal collagen, inducing both immediate and delayed responses.
  * Immediate response: The protein length shortens due to the denaturation of collagen proteins caused by heating with high frequency, resulting in skin contraction.
  * Delayed response: As damaged tissues regenerate due to high-frequency heating, collagen synthesis increases, promoting collagen creation.

Q. Is there any benefit to using the line type? What is the maximum temperature it can reach? How does it differ from dot lines?

The line type allows for faster treatments and, although the energy per point is smaller compared to dots, it can provide a more even treatment as it is connected in lines. (The target temperature is around 50-60°C.)

Q. When and why is the frequency changed in the RM function, and what is the principle behind it?

When high-frequency current flows, it generates heat energy, which is applied to the tissue, causing coagulation and denaturation of the tissue. The range of heat generation is inversely proportional to the frequency, so higher frequencies result in a narrower range, which increases accuracy. However, using a high-frequency device for larger areas may lead to more treatment sessions and longer-lasting swelling and bruising. Lower frequencies widen the range of heat generation but decrease accuracy. The penetration depth of energy varies with frequency and depends on the depth of the skin tissue.

Q. What is the RMS function, and how does it benefit users?

RMS allows remote checking of equipment failure history, enabling quick response in case of after-sales service issues. It also allows remote software and firmware updates.

Q. What are the criteria for applying warranty to equipment and cartridges from a user's perspective? Is it based on the purchase date?

The warranty for equipment and cartridges is based on the shipping date from our side and may differ from the user's purchase date. This is done to reduce the hassle of confirming the user's purchase date from your side and to enhance the accuracy of record-keeping.

Chapter. 05

Pre and Post Treatment Guidelines

01
MFU+RF

[1] Pre-Treatment Precautions

1.1 Contraindicated Patients

• Pregnant women or those with the potential to become pregnant.
• Individuals with systemic or localized skin diseases or cases involving grafts or foreign materials within the treatment area.
• Patients using anticoagulants or other medications that interfere with blood clotting (except for non-steroidal anti-inflammatory drugs, including aspirin).
• Patients undergoing chronic steroid or immunosuppressive therapy.
• Patients with contraindications for MFU treatment.
- Patients with psychiatric disorders.
- Patients with connective tissue disorders or conditions associated with the subcutaneous layer.

1.2 Caution

Patients who have undergone the following treatments may not achieve the desired cosmetic effect with New Doublo 2.0 treatment and should avoid radiation in the periocular area for injury prevention

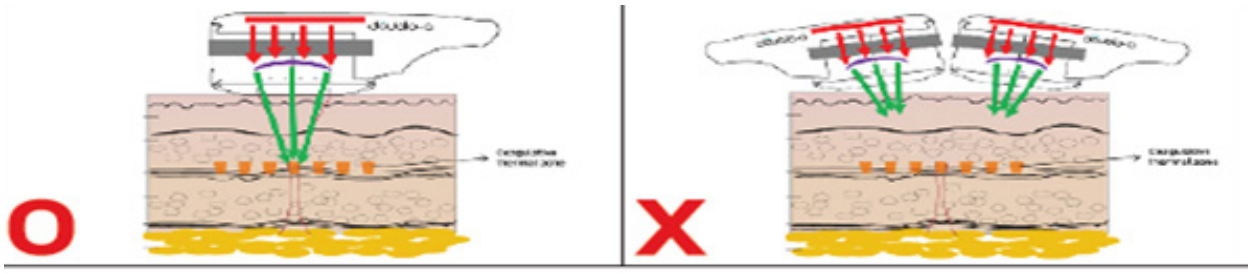
• Any fat-dissolving therapy administered within the treatment area.
• Loss of sensation or sensory impairment within the treated area.
• Known or suspected systemic or chronic diseases.
• Wounds or the following types of scars: atrophic, sclerotic, keloid, or surgical scars.

1.3 Pre-Treatment Checklist

• Ensure proper preparation of the handpiece and cartridge. / Verify if the patient is suitable for treatment.

[2] Precautions During Treatment

• Exercise caution not to apply an excessive amount (thick layer) of ultrasound gel.
• During the procedure, be careful to avoid direct energy exposure to the bones.
• Take into consideration the location of blood vessels and nerves when performing the procedure.
• Ensure that during the procedure, the cartridge and the skin contact surface remain in contact with the skin and do not detach.



Correct Method Incorrect Method

• If the cartridge and the skin contact area you intend to treat are not aligned vertically, the following conditions may occur: Erythema, Blisters, Epidermal damage

[3] Precautions During Treatment

• After the procedure, exercise caution with sauna visits and alcohol consumption for approximately 7 days.
• If erythema occurs, it typically disappears within around 1 hour.
• For maximum treatment effectiveness, it is recommended to use a regenerative pack stored at room temperature rather than a cold pack.
• Makeup can be applied immediately after the procedure, and when going outside, use sunscreen (SPF50 or higher).
• After the procedure, use alcohol swabs to remove ultrasound gel from the non-vinyl coated part of the cartridge, then use a dry towel or swab to remove moisture.
• Be cautious not to damage the film part as it can also be easily damaged by fingernails.

02
Microneedle RF

[1] Pre-Treatment Considerations

The following are contraindications and considerations that must be observed before proceeding with the procedure in consultation with a physician.

- If there is an infectious skin condition.
- In cases of bleeding disorders or when taking aspirin.
- If a cardiac pacemaker is implanted.
- During pregnancy.
- High Blood Pressure
- Implants
- Medication Allergies

[2] During the Procedure Precautions

- The recommended interval between treatments is a minimum of 2-4 weeks, with 3-5 sessions suggested.
- The number of treatment sessions and energy settings may vary depending on the improvement of the condition.
- During treatment, avoid overlapping at thermal coagulation points. It is possible to perform an additional 1-pass treatment based on the degree of erythema after the initial 1-pass treatment.
- Adjust the energy level and depth of treatment according to the indications.
- In areas with thin skin or adjacent to bones, such as the forehead, eye area, nasolabial folds, and temples, the depth should be set to less than 1.0mm, and the energy level should be adjusted to a maximum of level 5.
- Adjust the needle depth based on the presence of pores, scars, or the treatment area on the full face, and perform the treatment in 1-pass increments.

[3] During the Procedure Precautions

- On the day of the procedure, please refrain from facial cleansing, exfoliation, and sauna.
- You may experience a burning sensation and temporary bleeding immediately after the procedure, which is a normal reaction. Redness may persist for about 1-2 days.
- From 3 days after the procedure, light makeup is allowed. Since dryness may occur, it's advisable to use hydrating and soothing masks for moisturization.
- After the procedure, you may notice the formation of dead skin cells or flakes. Do not attempt to manually remove them; let them naturally exfoliate.
- Avoid vigorous exercise, alcohol consumption, and saunas for a minimum of 7-10 days after the procedure to ensure optimal healing.
- To prevent pigmentation issues due to the skin's weakened state after the procedure, diligently apply sunscreen with an SPF of 30 or higher and prioritize sun protection.

Chapter. 06

Section

01
Cautions

Precautions When Combining MFU with Other Procedures
MFU is a relatively safe treatment device, but there are some contraindications and points to be aware of.

[1] Contraindications for MFU Treatment

Absolute contraindications include the following

- Patients with autoimmune diseases, diabetes, cancer, AIDS, HIV, or other immunosuppressive conditions, or those taking immunosuppressive medications.
- Individuals who have started or are planning to take antiplatelet agents, anticoagulants, thrombolytic agents, or anti-inflammatory drugs within 2 weeks of treatment.
- Individuals with coagulation disorders who are currently taking anticoagulants (except for high-dose aspirin, daily dosage of 81mg or more).
- Individuals with sunburned skin, those who have tanned using artificial tanning devices, or those who may be exposed to strong sunlight within 1 week (7 days) before or after treatment, as well as patients with a high sensitivity to sunlight due to medication.
- Patients with open wounds at the treatment site.
- Patients with severe acne or cystic acne at the treatment site.
- Patients with metal stents or dental implants at the treatment site.
- Patients with implanted devices containing electrical components.
- Patients with systemic or localized skin diseases that may affect the wound healing process.
- Doctors must verify whether patients fall into the categories below before use. If you need further assistance or have more text to be rephrased, please let me know.

- Patients with acute illnesses
- Patients using electronic medical devices for cardiac monitoring
- Pregnant women and infants
- Patients with hypertension
- Patients with sensory impairments
- Individuals currently menstruating
- Patients with active acute or chronic conditions, including skin disorders

- Pregnant or breastfeeding women (pregnancy testing and consultation with a specialist are recommended for women of childbearing age before the procedure)
- Patients taking aspirin or medications containing aspirin
- Patients with blood clotting disorders or other blood-related clotting conditions
- Patients with cardiovascular or other medical conditions
- Patients with skin conditions or sensory abnormalities in the treatment area
- Patients with a history of dermabrasion or liposuction in the treatment area
- Individuals with photosensitivity disorders or those taking photosensitizing drugs
- Patients with a tendency for keloids or hypertrophic scarring
- Patients receiving chronic steroid treatment or immunosuppressive therapy
- Individuals aged 65 or older
- Patients with skin conditions such as herpes, wounds, psoriasis, eczema, or rashes in the treatment area

[2] When undergoing MFU in conjunction with other cosmetic procedures, it's essential to consider the following points:

MFU treats relatively deeper tissue layers compared to traditional light-based treatments like lasers. Therefore, there can be interactions between MFU and other cosmetic procedures. Patients who have undergone cosmetic surgery, botox, fillers, fat grafting, dental implants, or other similar procedures need to be cautious when considering MFU. Here are specific considerations for MFU in combination with various procedures:

1) MFU and Cosmetic Surgery

While MFU and cosmetic surgery are not directly related, it's advisable to wait approximately 3 months after cosmetic surgery, once the scars have fully healed, before undergoing MFU. Performing MFU when there is still swelling may lead to undesired results.

2) MFU and Dental Treatments

MFU and dental treatments are generally unrelated, but some patients may experience discomfort in areas with dental implants or orthodontic appliances. To address this, it's advisable to remove orthodontic appliances before MFU treatment. For areas with dental implants, using gauze over the implants during the procedure can help prevent discomfort.

3) When considering MFU in combination with fat grafting or filler procedures, it's important to keep the following points in mind

MFU delivers energy deep into the fat layer, which can potentially affect fat grafting results. It is generally recommended to wait at least 2-3 months after fat grafting before undergoing MFU treatment to ensure the safety and effectiveness of both procedures.
Additionally, if a second fat grafting procedure is planned after MFU treatment, it's important to be aware that fibrous changes in the fat layer and subcutaneous tissue may make the second fat grafting procedure more challenging. Patients should be informed of this and understand that complete volume reduction may not be achievable. In contrast to autologous fat, fillers have relatively higher viscosity. MFU is less likely to significantly impact the placement or effects of fillers. Therefore, you can proceed with MFU treatment independently of filler injections. However, it's worth noting that if MFU is applied directly over areas with recent filler injections, patients may experience more discomfort compared to treating normal skin. It's advisable to consider this when planning the treatment.

[3] After MFU treatment, patients should be aware of the following precautions

- Refrain from drinking alcohol and using saunas on the day of the procedure.
- It's normal to experience temporary redness, warmth, and mild swelling immediately after the treatment. If temporary swelling or redness occurs, applying a cold compress is recommended.
- If blisters develop or redness persists for more than 2-3 days, or if you experience persistent tingling or nerve pain, it is advisable to visit the clinic for a consultation and examination.

02

Patient Consent Form (Template)

Patient's Name		Date of Birth	
Current Medications		Name of Medication	
Allergies		Allergy Name	
Past Medical History		Medical Condition	
History of Previous Procedures		Name of Procedure	

▶ If you have a skin condition on the desired treatment area, the procedure can be performed after the skin has fully healed.

▶ However, the following conditions may limit or restrict the procedure:

- Pregnant women or those who may become pregnant.
- Cases where grafts or foreign substances are inserted within the treatment area.
- Individuals currently taking anticoagulants or other medications that affect blood clotting.
- Patients undergoing chronic steroid or immunosuppressive therapy.

MFU treatment is performed with the purpose of improving facial sagging, enhancing elasticity, reducing fat, and improving pigmentation, among other objectives. Depending on the desired outcome, a series of treatments over a specified period may be necessary to achieve the best results. It's important to note that even when the procedure is performed correctly, the following symptoms may occur:

Redness (Erythema) Swelling (Edema)	Redness and swelling at the treatment site may occur immediately after the procedure but typically resolve within a few hours.
Pain	Discomfort or tenderness upon contact with the treated area may be felt during energy delivery, and discomfort and tenderness may occur after the procedure.
Bruising	Minor bruising, which usually resolves within a few days, may occur due to damage to blood vessels in the connective tissue.
Nerve Sensitivity	Temporary muscle weakness may occur if there is inflammation of the motor nerves. Temporary numbness may occur if there is inflammation of sensory nerves. Temporary pain, altered sensation, and tingling may be experienced as well.

- While significant improvement is observed in most cases after MFU treatment, some patients may perceive only a minimal difference due to variations in their skin condition. To achieve the best results, the appropriate application of the treatment program provided by the clinician is essential.

- Refunds are not possible for any reason after the completion of the procedure, and the same policy applies even when using package deals partially.

- I acknowledge that I have familiarized myself with the consent form and understand the expected outcomes of the treatment and the post-treatment care procedures. I consent to the treatment.

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This product is classified as a 'medical device,' and it is essential to read and follow the 'precautions for use' and 'instructions for use.'
New Doublo 2.0 is a focused ultrasound stimulation system.

Intended Uses

1. Focused Ultrasound Stimulation System: A device used for eyebrow lifting by coagulating tissue using focused ultrasound.
2. General Electrosurgical Device: A device used for coagulation using high-frequency current.
3. High-Frequency Stimulator: A device that applies high-frequency energy to the human body for pain relief.

If you have any inquiries, please feel free to contact us at the following:

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Customer Support Center: **1599-4299**

System Specifications

Type	Depth, Frequency	RF Frequency	Model Name				Power	Hz
SD (HIFU+ RF)	1.5mm, 7MHz	2MHz Bipolar RF	P1.5		L1.5		Lv 1 - 10	Max. 10Hz*
	3.0mm, 7MHz	2MHz Bipolar RF	P3.0		L3.0			
	4.5mm, 4MHz	2MHz Bipolar RF	P4.5		L4.5			

* 7 - 10 Hz depending on power level

Type	Depth, Frequency	Model Name				DOT Mode	LINE Mode	Spacing	Length
FL (HIFU)	1.5mm, 7MHz	S1.5		A1.5		0.1J - 0.5J	0.1J - 0.5J	1.0 - 5.0mm	5.0 - 25mm
	2.0mm, 7MHz	S2.0		A2.0		0.1J - 1.0J	0.1J - 0.8J		
	3.0mm, 7MHz	N3.0		A3.0		0.1J - 1.0J	0.1J - 1.0J		
	4.5mm, 4MHz	N4.5		A4.5		0.1J - 1.5J	0.1J - 1.0J		

Type	Needle Type	Needle Size	Model Name		Needle Depth	Repetition	RF On Time	RF Off Time	Pulse
RM (Bipolar)	Insulated	25pin (8X8mm)	I25		0.1~3.5 mm	Single 0.2s~2.0s	1~950 ms	1~1,000 ms	1~5 pulse
		49pin (12X12mm)	I49						
	Non-insulated	25pin (8X8mm)	N25						
		49pin (12X12mm)	N49