

Clinical Applications - Contour TRL™



Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

Sciton handpieces are supplied non-sterile and require disinfection or sterilization prior to use. Reference "Maintenance" section on how to disinfect or sterilize a handpiece.

Laser fume and/or plume may contain visible tissue particulates.

1.1 Operator Training

Clinicians handling laser and light based devices should complete a training program. Sciton offers a comprehensive training class in the safe operation of the Joule system.

Practitioners may also consider the following additional training:

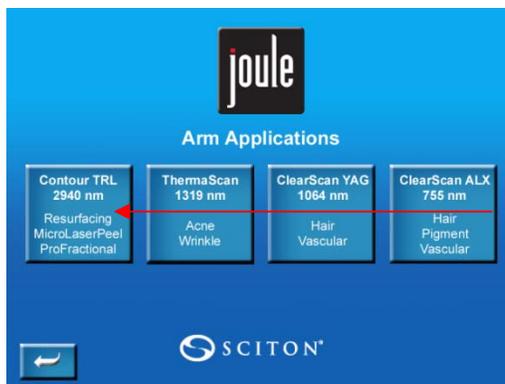
- "Hands-on" training under the preceptorship of a qualified user.
- An accredited training course within the practitioner's specialty.

1.2 2940 nm Er:YAG Contour TRL

Often referred to as the "Erbium" laser, it emits a mid-infrared beam at 2940 nm, which coincides with the highest absorption peak for water. Its principal use is to ablate tissue for a cosmetic improvement of wrinkles and other effects of photoaging.

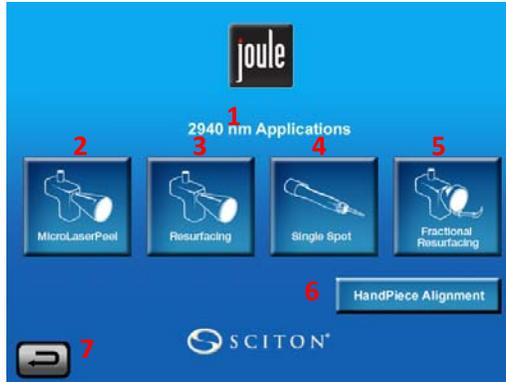
Arm Application Menu Screen

The Arm Application menu screen allows the user to enter the different 2940 nm Contour TRL user application screens.

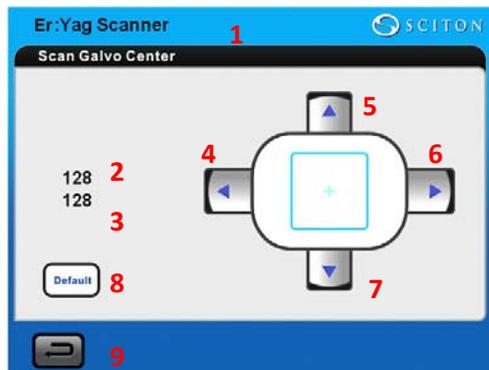


2940 nm Contour TRL softkey

Pressing the ContourTRL softkey will allow the system to enter into the 2940 nm Applications screen.



1. Application Header
The Application Header displays the selected 2940 nm application.
2. MicroLaserPeel application softkey
Attach Contour Scanner and press the softkey to enter the MLP (2940 nm) user screen.
3. Resurfacing application softkey
Attach Contour Scanner and press the softkey to enter the TRL (2940 nm) user screen.
4. Single Spot softkey
Attach the 2 mm or 4 mm single spot handpiece and press the single spot softkey to enter the Single Spot user screen. Attach the Focused Single Spot handpiece and press the Single Spot softkey to enter the Focused Single Spot user screen.
5. Fractional Resurfacing softkey
Attach the ProFractional-XC or ProFractional scanner and press the Fractional Resurfacing softkey to enter the ProFractional-XC (2940 nm) or ProFractional (2940 nm) user screens.
6. Handpiece Alignment softkey
The Contour, ProFractional-XC and ProFractional scanning handpieces have the ability to adjust the scan pattern output center. Press HandPiece Alignment softkey to access the centering screen. The X-axis and Y-axis can be adjusted and stored into memory. This adjustment should be made each time a scanner is attached to the system for the first time and any time the scan pattern output is not centered (edge of aiming beam is cut-off).



1. Scanner Handpiece indicator
 2. Current center settings indicator for x-axis
 3. Current center settings indicator for y-axis
 4. Adjust pattern left softkey
 5. Adjust pattern up softkey
 6. Adjust pattern right softkey
 7. Adjust pattern down softkey
 8. Center scanner to default position softkey
 9. Return to 2940 nm Applications Screen softkey
7. Return to Arm Applications screen softkey.

1.2.1 Indications for Use

The 2940 nm Er:YAG Contour TRL is designed for use in surgical applications requiring the excision, incision, ablation, vaporization, and coagulation of soft tissue, and for skin resurfacing.

Aesthetic Surgery: Skin resurfacing and treatment of wrinkles.

Dermatology & Plastic Surgery: Indications include epidermal nevi, actinic cheilitis, keloids, verrucae, skin tags, anal tags, keratoses, scar revision, debulking benign tumors, and decubitus ulcers. It is also used for laser assisted site preparation for hair transplantation.

2940 nm Er:YAG Contour TRL with ProFractional/ProFractional-XC handpiece and delivery system is intended for use in dermatological procedures requiring skin 2940 nm Er:YAG Contour TRL Resurfacing and coagulation of soft tissue.

1.2.2 Contraindications

The 2940 nm Er:YAG Contour TRL is contraindicated for:

- Patients who are intolerant to anesthesia
- Patients with infectious disease
- Patients with connective tissue disease
- Patients with propensity for keloid formations
- Patients who are immunocompromised
- Patients who are pregnant
- Patients who have used isotretinoin (Accutane) within the past year
- Patients with a medical condition that may affect wound healing
- Patients who use anticoagulant medications

1.2.3 Complications

Complications, though rare, occasionally occur and should be discussed and understood. The patient must understand the importance of the post care instructions and that failure to comply may increase the probability of complications.

The potential complications of 2940 nm Er:YAG Contour TRL are:

- Scarring- hypertrophic and non-hypertrophic
- Burns- from superficial to full thickness
- Extensive tissue destruction
- Ulceration
- Hyperpigmentation
- Hypopigmentation
- Induced hemorrhage
- Edema

1.2.4 Warnings

- In pretreatment work-ups, screen lesions that are located in the close proximity to known arteries or veins in order to locate these circulatory structures.
- Flammable inhalation general anesthetics must not be used. "Flash Fire" may occur. Oxygen levels in the direct operative area must not be higher than 50%.
- Do not allow combustibles or flammables, including drapes and paper panties, in the laser treatment area. Fire prevention/control methods should be in place.

1.2.5 Selective Photothermolysis

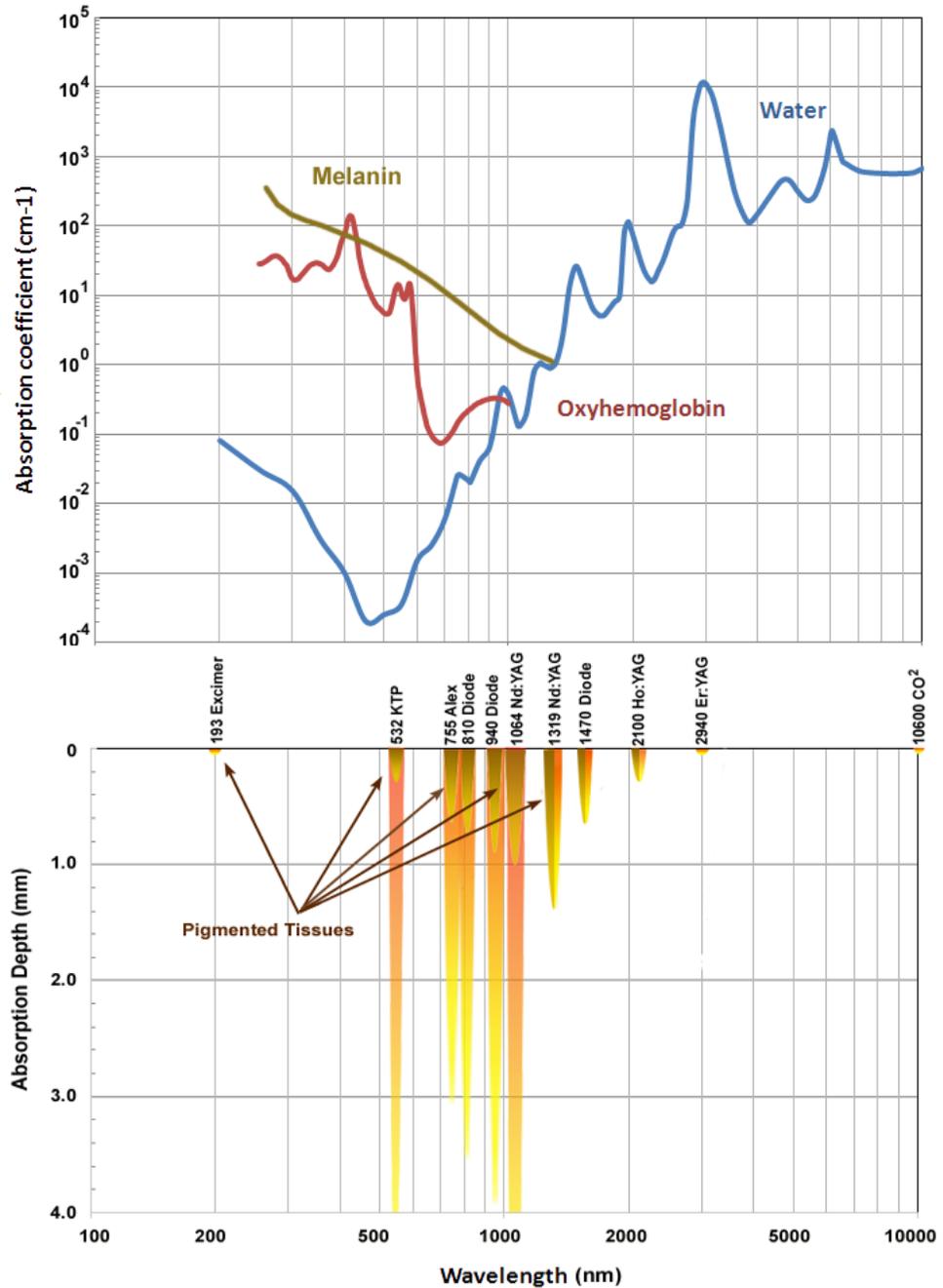
This technique relies on selective absorption of laser light to generate and confine heat at certain cellular targets. The goal of Selective Photothermolysis is to have sufficient energy penetrate to and be absorbed by the desired target while minimizing the effect on the surrounding tissue.

Absorption Curve

Absorption curve shows the relationship of the variation in absorbed laser light as a function of wavelength. The graphic shows absorption spectra of major intracellular absorbers. The molecular absorption coefficients of oxygenated hemoglobin, melanin and water are shown.

Depth of Penetration

Depth of penetration of laser energy for different types of lasers is also illustrated.



Based upon the principles of selective photothermolysis, erbium lasers selectively target tissue containing water resulting in controlled tissue vaporization. The 2940 nm Er:YAG wavelength very closely matches the highest peak of the absorption spectrum for water. Because of the selective properties of 2940 nm Er:YAG, almost all of the energy created by the laser is taken up by heating water. The resulting tissue vaporization leaves very little laser energy that can scatter into the skin and produce nonspecific heating.

1.2.6 Getting Started

1.2.6.1 Consultation/Education

A consultation is essential in order to establish realistic expectations and to gain a full understanding of the patient and his/her treatment goals. The patient must understand the procedure, pre and post care instructions, expectations, contraindications and possible complications prior to beginning any treatment.

1.2.6.2 Medical History

A detailed medical history should be obtained prior to treatment outlining any former or active medical condition or medication that is contraindicated or that could possibly affect the outcome of the treatment.

It is recommended that a brief medical history be taken before beginning any subsequent treatment by reviewing clinical information such as any new medications, skin care, sun exposure, pregnancy etc.

1.2.6.3 Skin Typing

Accurate skin typing is critical to treatment success and the avoidance of complications. It is important to know that in most situations an individual's previous response and genetic tendency to sun exposure will be the biggest indicators in establishing skin type. Some patients, such as Asians and Hispanics, may appear to be a skin type II or III and never tan but react to laser energy like a IV or V skin type. Hence, it is very important not to base skin type on appearance.

The skin type of a patient does not change. Do not confuse skin type with a tan. A person's skin type is something they are born with and it does not change, but the degree of tan can change.

Type	Hair Color	Skin Color and Ethnic Background	Eye Color	Sun Reaction
I	Red, White Blonde	Very fair <i>Scandinavian, Nordic, and North European</i>	Blue	Always burns, never tans
II	Red, Blonde, light brown	Fair <i>North European, Celtic (Scottish, Irish)</i>	Blue, green	Always burns, tans with difficulty and tends to be freckled
III	Sandy Blonde, Brown	Medium <i>Southern Europe</i>	Hazel, green, blue,	Burns initially, tans fairly well and evenly
IV	Brown, Black	Moderate brown, Olive <i>Mediterranean, Latin (Italian, Hispanic)</i>	Hazel, brown	Burns are rarely evident, tans easily
V	Black	Dark Brown <i>(Asian, Middle Eastern, American Indian)</i>	Dark brown, black	Burns are never evident, tans always <i>*some Asian skin always burns and never tans</i>
VI	Black	Black <i>(African-American, Indonesian)</i>	Dark brown, black	Burns are never evident, tans always



Skin type V is the most under-typed skin. Often Asians will look very light and have no history of sun exposure. Occasionally they have "bleached" their skin with hydroquinone. Treating them as a III or IV (based on look and reaction to sun) could result in higher risk of complications. Initially, all Asian skins should be treated as a Skin Type V until reaction to laser light has been determined.

Similarly, not all black skins are of the same degree of darkness and there may be the temptation to type these patients as a lower type.

1.2.6.4 Informed Consent

The process of accepting and confirming treatment must be reviewed, understood and signed by the patient prior to treatment. This document must review the topics discussed during the consultation. It acknowledges that the patient understands the procedure, possible risks and complications and that all questions have been answered.

Reference sample Informed Consent in Appendix of Sciton Operator Manual.

1.2.6.5 Antiviral Medication

To prevent the activation of a herpes simplex virus infection, it is recommended that an antiviral medication be prescribed.

1.2.6.6 Photographs

Pictures should be taken prior to each treatment to document the progress of the treatment. Photographs are useful in demonstrating efficacy of treatment to the patient.

Camera settings, distance, backdrop, and body/face angle, position and expression should be the same for each photography session to maintain similar quality.

The patient should sign a photo release form if before and after pictures are to be used for educational or marketing purposes.

1.2.6.7 Topical Anesthesia

Use a topical preparation, as needed, to alleviate discomfort for sensitive patients or sensitive areas prior to treatment. The manufacturer's guidelines for the application and duration of the anesthetic should be read prior to topical application. Remove before treatment with mild soap and water or an alcohol swab, then plain water. Dry the area thoroughly before treatment.

Reminder: Each patient should be assessed and questioned regarding allergies or sensitivities to ingredients in topical anesthetics prior to application.



Be extremely cautious when applying topical anesthetics to large areas of the body. Lidocaine toxicity has been linked to several deaths.

1.2.6.8 Eye Protection

Eye protection should always be worn by everyone present in the treatment room during any laser or light based treatment. When treating on the patient's face, they should always wear non-reflective, metal goggles or laser approved disposable eye shields. Anytime a procedure is performed on the upper eyelid, internal corneal shields must be worn by the patient.

1.2.6.9 Smoke Evacuator

During surgical procedures using a laser or electrosurgical unit, the thermal destruction of tissue creates a smoke by-product. Research studies have confirmed that this smoke plume can contain toxic gases and vapors such as benzene, hydrogen cyanide, and formaldehyde, bio-aerosols, dead and live cellular material (including blood fragments), and viruses. At high concentrations the smoke causes ocular and upper respiratory tract irritation in health care personnel, and creates visual problems for the clinician. The smoke has unpleasant odors and has been shown to have mutagenic potential.

All medical personnel should consider the vaporized tissue plume to be potentially hazardous both in terms of the particulate matter and infectivity. A smoke evacuator should be used at all times when smoke is created in order to collect the plume. Surgical masks with 0.1µm filtration can be worn in addition to the use of a smoke evacuator.

A Smoke Evacuator contains a suction unit (vacuum pump), a filter, a hose, and an inlet nozzle. A smoke evacuator should have high efficiency in airborne particle reduction and should be used in accordance with the manufacturer's recommendations to achieve maximum efficiency:

- The suction should have a high flow volume with frequent filter changes being made to optimize suction and filter capabilities.
- Filters should be chosen which allow for maximum filtering efficiency.
- The distal end of the smoke evacuator should be as close as possible to the treated area. Smoke evacuator hoses not within one inch of the area treated will capture less than 50% of the smoke and debris created at the ablative site.
- Evacuator suction tips should be cleaned (preferable sterilized) after each procedure.
- Expired filters and used hoses should be treated as a bio-hazard. Surgical masks and gloves should be worn when red-bagging.

1.2.6.10 Skin Thickness

It is important to avoid ablation of the full thickness of both the epidermis and dermis (E+D). Full thickness ablation markedly increases the risk of scarring and long term tissue.

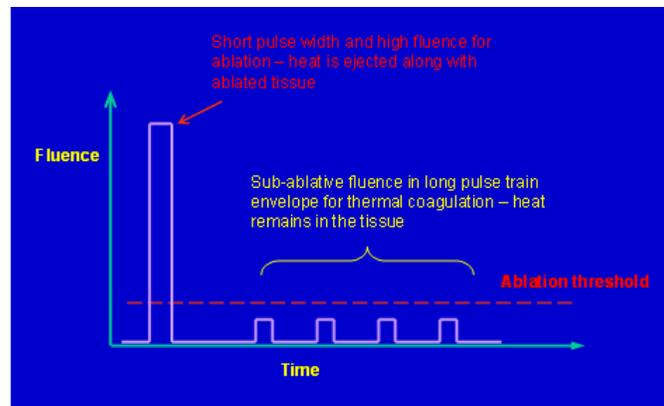
Skin Thickness Chart

Anatomical Region	Epidermis μm	Dermis μm	E+D μm	Hypodermis μm	Total μm
Mental	149	1375	1524	1020	2544
Forehead	202	969	1171	1210	2381
Upper lip	156	1061	1217	931	2148
Lower lip	113	973	1086	829	1915
Tip of nose	111	918	1029	735	1764
Neck	115	138	253	544	797
Cheek	141	909	1050	459	1509
Glabella	144	324	468	223	691
Eyelids	130	215	345	248	593

Note: These measurements can vary from patient to patient and are intended to be used only as a guideline.

1.2.6.11 Use of COAG

Resurfacing, 4 mm Single Spot and ProFractional-XC treatments can deliver high energy erbium pulses interleaved with low-energy erbium pulses to sequentially vaporize and coagulate tissue. By delivering long, low energy, sub-ablative pulses, heat can be deposited into tissue without vaporizing the tissue. Resurfacing, 4 mm Single Spot and ProFractional-XC treatments can deliver energy in very short pulses so that the laser can deposit enough energy to rapidly ablate tissue. Resurfacing, 4 mm Single Spot and ProFractional-XC treatments can also deliver energy at a rate such that heat is carried to lower depths by conduction faster than the laser is depositing it so that the exposed tissue never accumulates enough energy to vaporize. This can result in deep coagulation. By precisely setting the high energy pulse and the low energy long pulse a range of ablation and coagulation depths can be achieved.



1.2.7 Safe Start Protocol for 2940 nm Er:YAG Contour TRL MicroLaserPeel (MLP)

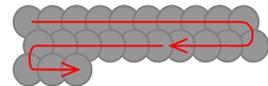
MicroLaserPeel (MLP) is an epidermal laser peel (4 - 50 microns) that precisely ablates or removes the outermost layers of the skin resulting in an improvement of fine lines and wrinkles, reduction of superficial brown spots and an overall improvement in the appearance of skin.

The epidermis is a robust and resilient structure with an average thickness, on the face, of about 110 microns. It functions as a physical barrier to protect the deeper dermis, and retain the skin's hydration. It is often the source of fine lines and discolorations in aging skin. The MLP, 4-50 microns in selected depth, will not fully penetrate the epidermal barrier of the skin. Therefore the safety, shortened recovery time, and ease of care with these procedures produce a treatment that is preferred by many patients and physicians.

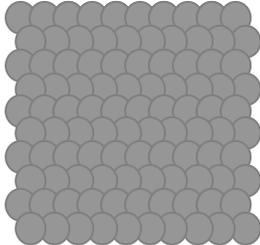
Contour Scanner



The Contour Scanner is used for both MLP and Resurfacing treatments. The scanner handpiece consists of 2 galvanometers and collimating optics contained in a housing. The galvanometers allow the beam to be scanned to form two dimensional spots on the skin surface.

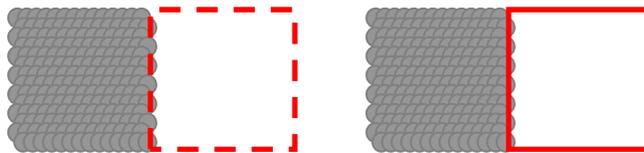


Spots are scanned in a serpentine manner.



Complete scan with 30% overlap.
Spot size equals 4 mm.
Scanned area shown is a pattern size 8 which is 27 mm x 27 mm.

The Contour Scanner allows for complete and uniform application of the laser energy by delivering 4 mm spots of energy within a designated pattern shape and size. Aiming beam is represented by red square and shows the user the area to be treated. The energy will be delivered inside the red square. When the red square is "dancing" the system is in Standby. When the red square is solid the system is in Ready.



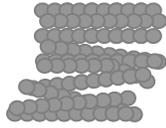
Standby

Ready

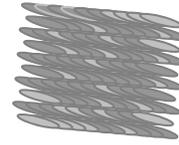
Care should be taken to apply adjoining scans without gap or excessive overlap of the previously scanned area. Align each scan pattern up to each other to avoid gap or overlap as shown above.

To achieve uniform treatment as shown, the scanner should always be:
 (a) held with a steady hand during the scanning process, and
 (b) held perpendicular and within 6 inches of the skin surface.

Examples of incorrect scanning:



Scanner not held steadily

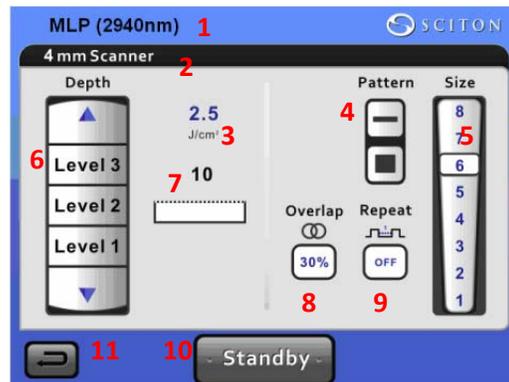


Scanner not held perpendicular to skin surface

Many physicians divide the total ablation evenly between two passes to avoid the presence of scanner patterns on the skin (i.e., 40 micron ablation performed as two 20 micron passes). If two passes are performed, the scanner should be rotated on the 2nd pass to avoid the presence of scanner patterns on the skin.

MLP (2940 nm) User Screen

Attach the Contour Scanner to the articulated arm. Press the MicroLaserPeel softkey on the 2940 nm application screen and the system will enter the MLP (2940 nm) application screen.



Note: This application covers 100% of the skin within the scanned pattern; it does not produce a "fractional" effect.

1. Application and wavelength indicator
Application and wavelength indicator shows which treatment screen the user is in and which wavelength is being used for the treatment.
2. Handpiece indicator
Handpiece indicator shows which handpiece is being used for the treatment.
3. Ablation fluence indicator
Ablation fluence indicator shows the amount of fluence or energy being delivered based on the depth of the ablation selected. 1J/cm² = 4 microns of ablation.
4. Pattern shape softkeys
Pattern shape can be adjusted from a square to a rectangle to assist in more complete coverage of a treatment area by tapping either the rectangle or square softkey.
5. Pattern size adjustment softkeys
Pattern size can be adjusted from 1 to 8; 8 x 8 mm to 30 x 30 mm square and 12 x 6 mm to 27 x 6 mm rectangle by tapping the desired numbered softkey.
6. Ablation depth softkeys
Ablation depth relates to the amount of tissue to be removed. The ablative depth may be set by tapping the softkeys: Level One = 10 microns, Level Two = 20 microns or Level Three = 30 microns. The laser may also be set manually from 4 -50 micron ablation depth by tapping or holding down the up ▲ or down ▼ arrow softkeys.
7. Tissue diagram indicator
Tissue diagram gives the user a quick reference to the amount of ablative energy being delivered

to tissue. The more superficial the depth of treatment the smaller the tissue diagram and the deeper the treatment depth the bigger the tissue diagram.

8. Pattern spot overlap softkeys

Spot overlap within the scanned pattern may be adjusted from 10 - 50% (30% is default) by tapping the overlap softkey.



9. Pattern repeat softkey

Pattern repeat allows the user to set an amount of time between consecutive scans of 0.5, 1.0, 1.5 or 2.0 seconds by tapping the repeat softkey. Repeat can also be turned off so that each scan pattern is delivered by lifting and depressing the footswitch.

10. System status softkey

System status softkey will allow the user to put the system in Standby or Ready mode.

11. Return to 2940 nm Applications screen softkey

Return to 2940 nm application softkey will return the system to the previous screen.

1.2.7.1 Precautions

- Patients must be carefully evaluated by the physician for their risk of scarring versus the treatment benefit.
- Treatment should be done in a conservative fashion in areas where the skin is thin, such as the temple and forehead areas.
- Post-treatment hyperpigmentation may occur after 3-4 weeks.
- Direct and intentional sun exposure should be avoided for 7-10 days, then daily use of sun block is recommended to avoid pigment related complications.
- Patients who smoke may experience delayed healing and decreased benefit.
- Particulate debris on the lens of the scanner may result in laser beam scattering and an incorrect setting for depth of treatment. Cleaning the lens prior to, and during treatment, is essential to ensure accurate treatment settings.
- Treating with overlapping scans or at settings much higher than those recommended by the protocol may lead to undesirable outcomes. Attention to technique and conservative treatment is recommended.
- Selection of patients must include evaluation of Fitzpatrick Skin Type (I-VI). The MicroLaserPeel is a purely ablative procedure without the coagulation mode that may lead to long term or permanent hypo- or hyper-pigmentation issues. However, darker skin types may have transient pigmentary loss with more aggressive MicroLaserPeel (40-50 micron) treatment. The transitory loss can be a natural healing phenomenon with a potential period of 3 to 30 days.

MLP on non-facial tissues: The epidermis of the neck, chest, hands and general body surfaces is thinner than that of the face and has fewer adnexal healing structures. Peels beyond 20 microns are not recommended in a single treatment. Retreatment may occur as early as 8 weeks. This procedure may not be ideal for patients with known healing deficiencies.

1.2.7.2 2940 nm Er:YAG Contour TRL MicroLaserPeel

Treatment Basics

- Patient should be positioned based on the area to be treated. The position should be comfortable to the patient and such that the treatment provider has good access to area to be treated and the control panel display screen.
- A mild cleanser should be used to remove any dirt, makeup or moisture from the treatment site. Follow with an alcohol gauze. Allow alcohol to evaporate before treatment. Use special care around the eyes.
- If topical anesthetic is to be used, apply as directed prior to treatment. Before beginning treatment, ensure that topical has been completely removed from surface of skin.
- Prepare for adequate smoke evacuation.
- Attach the Contour Scanner that has previously been cleaned with an alcohol gauze to the articulated arm.
- Enter settings into the control panel display screen based on condition and area to be treated.



Verify that scanner preview pattern is centered prior to treatment. If pattern is not centered, refer to Section 7.6 for instructions on how to center the scan pattern.

Treatment Starting Parameters

Application	Indication	Ablation Depth (µm)	% of Overlap
MicroLaserPeel	Fine lines and wrinkles, minor lesions, and superficial hyperpigmentation	Up to 50 microns	10 - 50%

- The Contour Scanner should be held perpendicular and to within 6 inches of the skin surface at all times for efficient and uniform ablation. Move patient if necessary to accomplish a 90 degree angle.
- To confirm that laser and accessories are performing normally, it is useful for the operator to first test on a nonflammable inanimate object like a wooden tongue depressor. Treating a test area prior to beginning treatment will determine the patient's response threshold and help them understand the audible and sensory components of the treatment.
- Match the trailing edge of one scan pattern to the leading edge of the next. There should be no overlap between scans. Patterns should "line up" right next to each other. Refer to Section 7.6.6.1. Ablative depth can be divided into two equal passes to cover accidental missed or overlapped scans and for greater patient comfort.
- Particulate debris on the optics of the scanner may result in laser beam scattering and an incorrect setting for fluence. Scanner optics should be cleaned throughout treatment with a gauze moistened with water. If alcohol is used, clean with the water gauze first and then the alcohol and allow to dry completely before continuing with the treatment.
- The desired endpoint is erythema within a few minutes of laser application. The redness and healing (often similar in appearance to varying degrees of sunburn) will increase with the ablation depth and will vary by patient.

Post-Treatment

- **OBSERVATIONS**
Some possible side effects: erythema, localized edema, urticaria, sun burn sensation, flaking and tightness of skin.
Side effects after MLP can be observed for 12-48 hours after treatment, depending upon depth of peel.
- **INTERVENTION**
Cool compresses or ice packs can provide immediate comfort after treatment.



An occlusive barrier such as Aquaphor will provide protection and comfort to treated area and should be used until skin has re-epithelialized.

- INTERVAL between 2940 nm Er:YAG Contour TRL MicroLaserPeel is approximately 4-8 weeks depending upon depth of peel and the health and integrity of skin being treated.

Concurrent Procedures

Noninvasive light-based treatments like hair reduction or collagen stimulation may occur prior to a 2940 nm Er:YAG Contour TRL MicroLaserPeel.

Check with manufacturer for guidelines on using injectables in conjunction with 2940 nm Er:YAG Contour TRL MicroLaserPeel.

1.2.8 Safe Start Protocol for TRL 2940 nm Er:YAG Contour TRL Resurfacing

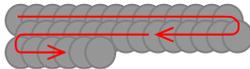
2940 nm Er:YAG Contour TRL Resurfacing is a dermal laser peel (50 microns and beyond) that precisely ablates or removes layers of the skin resulting in an improvement of deeper lines and wrinkles, acne scars and an overall improvement in the appearance of skin.

The dermis is a thick layer of fibrous and elastic tissue (made mostly of collagen, elastin, and fibrillin) that gives the skin its flexibility and strength. The dermis lies immediately underneath the epidermis and is about four times thicker. The dermis contains nerve endings, sweat glands and oil glands, hair follicles, and blood vessels.

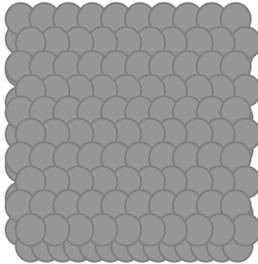
Contour Scanner



The Contour Scanner is used for both MLP and Resurfacing treatments. The scanner handpiece consists of 2 galvanometers and collimating optics contained in a housing. The galvanometers allow the beam to be scanned to form two dimensional spots on the skin surface.

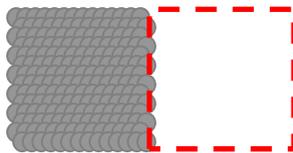


Spots are scanned in a serpentine manner.

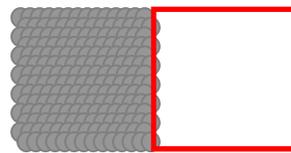


Complete scan with 50% overlap.
Spot size equals 4 mm.
Scanned area shown is a pattern size 8 which is 30 mm x 30 mm. To achieve uniform treatment as shown, the scanner should be:
(a) held with a steady hand during the scanning process, and
(b) held perpendicular and within 6 inches of the skin surface at all times.

The Contour Scanner allows for complete and uniform application of the laser energy by delivering 4 mm spots of energy within a designated pattern shape and size. Aiming beam is represented by red square and shows the user the area to be treated. The energy will be delivered inside the red square. When the red square is "dancing" the system is in Standby. When the red square is solid the system is in Ready.



Standby

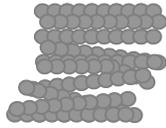


Ready

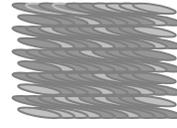
Care should be taken to apply adjoining scans without gap or excessive overlap of the previously scanned area. Align each scan pattern up to each other to avoid gap or overlap as shown above.

To achieve uniform treatment as shown, the scanner should always be:
(a) held with a steady hand during the scanning process, and
(b) held perpendicular and within 6 inches of the skin surface.

Examples of incorrect scanning:



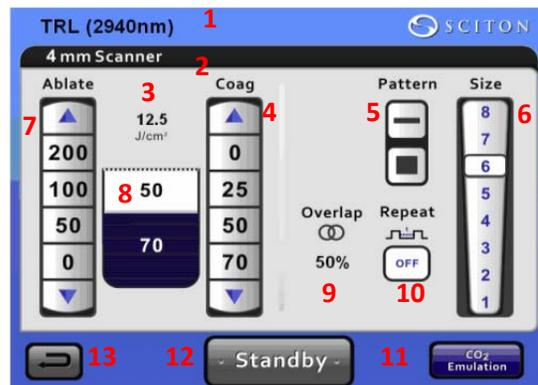
Scanner not held steadily



Scanner not held perpendicular to skin surface

Resurfacing User Screen

Attach the Contour Scanner to the articulated arm. Press the Resurfacing softkey on the 2940 nm application screen and the system will enter the TRL (2940 nm) application screen.



Note: This application covers 100% of the skin within the scanned pattern; it does not produce a "fractional" effect.

1. Application and wavelength indicator
Application and-wavelength indicator shows which treatment screen the user is in and which wavelength is being used for the treatment.
2. Handpiece indicator
Handpiece indicator shows which handpiece is being used for the treatment.
3. Ablation fluence indicator
Ablation fluence indicator shows the amount of fluence or energy being delivered based on the depth of the ablation selected. 1J/cm² = 4 microns of ablation.
4. Coagulation depth softkeys
Coagulation depth may be set by tapping the default softkeys of 0, 25, 50 or 70 microns and can also be adjusted from 0 - 130 microns by tapping or holding down the up ▲ or down ▼ arrow softkeys. See Section 8.6.5.11 for explanation of COAG.
5. Pattern shape softkeys
Pattern shape can be adjusted from a square to a rectangle to assist in more complete coverage of a treatment area by tapping or holding down the up ▲ or down ▼ arrow softkeys.
6. Pattern size adjustment softkeys
Pattern size can be adjusted from 1 to 8; 8 x 8 mm to 30 x 30 mm square and 12 x 6 mm to 30 x 6 mm rectangle by tapping or holding down the up ▲ or down ▼ arrow softkeys.
7. Ablation depth adjustment softkeys
Ablation depth relates to the amount of tissue to be removed. The ablative depth may be set by tapping the default softkeys of 0, 25, 50 or 100 microns. The laser may also be set manually from 0 - 200 microns by tapping or holding down the up ▲ or down ▼ arrow softkeys.
8. Tissue diagram indicator
Tissue diagram gives the user a quick reference to the amount of ablative and COAG (if selected) energy being delivered to tissue. The deeper the treatment depth the bigger the tissue diagram. The amount of COAG selected is represented under the tissue diagram in dark shade and will increase in size as the COAG depth is increased.

1. Pattern spot overlap indicator
Spot overlap within the scanned pattern is fixed at 50%.



2. Pattern repeat softkey
Pattern repeat allows the user to set an amount of time between consecutive scans of 0.5, 1.0, 1.5 or 2.0 seconds by tapping the repeat softkey. Repeat can also be turned off so that each scan pattern is delivered by lifting and depressing the footswitch.
3. Emulate softkey for Er:YSGG or CO₂ preset settings
Emulate softkey allows the user to choose settings that would emulate either a YSGG treatment with 20 microns of ablation and 20 microns of COAG or a CO₂ like treatment with 70 microns of ablation and 50 microns of COAG by tapping the emulate softkey.
4. System status softkey
System status softkey allows the user to put the system in Standby or Ready
5. Return to 2940 nm Applications screen softkey
Return to 2940 nm application softkey will return the system to the previous screen.

1.2.8.1 Precautions

- Patients must be carefully evaluated by the physician for their risk of scarring versus the treatment benefit, especially with selection of coagulation setting when using the Contour TRL.
- Treatment should be done in a conservative fashion in areas where the skin is thin, such as the temple and forehead areas.
- Post-treatment hyperpigmentation may occur after 3-4 weeks.
- Direct and intentional sun exposure should be avoided for 7-10 days, then daily use of sun block is recommended to avoid pigment related complications.
- Patients who smoke may experience delayed healing and decreased benefit.
- Particulate debris on the lens of the scanner may result in laser beam scattering and an incorrect setting for depth of treatment. Cleaning the lens prior to, and during treatment, is essential to ensure accurate treatment settings.
- Treating with overlapping scans or at settings much higher than those recommended by the protocol may lead to undesirable outcomes. Attention to technique and conservative treatment is recommended.
- Selection of patients must include evaluation of Fitzpatrick Skin Type (I-VI). 2940 nm Er:YAG Contour TRL Resurfacing is an ablative procedure selected with or without the coagulation mode. Note that using coagulation mode while ablating the epidermis may lead to long term or permanent hypo or hyper-pigmentation issues in skin types IV-VI. However, darker skin types may have transient pigmentary loss in the more aggressive pure ablative resurfacing (50+ microns). This transitory loss is a natural healing phenomenon with a potential period of 3 to 30 days.
- **Anesthesia:** Ablation of more than 50 microns usually requires the use of general anesthesia, conscious sedation, or injection of local anesthesia. Proper safety protocols should be followed for all anesthesia types.
- **2940 nm Er:YAG Contour TRL Resurfacing on non-facial tissues:** The epidermis of the neck, chest, hands and general body surfaces is thinner than that of the face and has fewer adnexal healing structures.
Peels beyond 20 microns are not recommended in a single treatment. COAG should not be added to treatments performed on non-facial tissue. Retreatment may occur as early as 8 weeks. This procedure may not be ideal for patients with known healing deficiencies.

1.2.8.2 2940 nm Er:YAG Contour TRL Resurfacing

Treatment Basics

2940 nm Er:YAG Contour TRL Resurfacing is considered a more advanced treatment. Sciton recommends that each user attend a Preceptor training course prior to offering 2940 nm Er:YAG Contour TRL Resurfacing treatments to their patients. Treatment specifics will be reviewed and discussed during the preceptorship.



Verify that scanner preview pattern is centered prior to treatment. If pattern is not centered, refer to Section 7.6 for instructions on how to center the scan pattern.

Treatment Starting Parameters

Application	Indication	Ablation Depth (µm)
Resurfacing	moderate wrinkles, lesions and shallow scars	100
	deep wrinkles and scars	400 - 800
<p><i>Tissue coagulation is the addition of heat to produce a zone of thermal necrosis. As an option, Contour TRL scanner allows the user to select coagulation depths of 0-130 microns.</i></p>		

Post-Treatment

- OBSERVATIONS**
 Some possible side effects: erythema, edema, urticaria, sun burn sensation, oozing and crusting, flaking and tightness of skin.
 Side effects 2940 nm Er:YAG Contour TRL Resurfacing can be observed for 7-10 days after treatment, depending upon depth of peel.
- INTERVENTION**
 Intervention measures will be discussed during preceptorship.
- INTERVAL** between 2940 nm Er:YAG Contour TRL Resurfacing treatments is approximately 8-12 weeks depending upon depth of peel.

Concurrent Procedures

Noninvasive light-based treatments like hair reduction or collagen stimulation may occur prior to a 2940 nm Er:YAG Contour TRL Resurfacing procedure. All other procedures should not be performed concurrently.

Check with manufacturer for guidelines on using injectables in conjunction with 2940 nm Er:YAG Contour TRL Resurfacing treatments.

1.2.9 Safe Start Protocol for 2940 nm Er:YAG Contour TRL Single Spot Treatment

The 2 mm or 4 mm single spot handpiece can be used to treat unwanted lesions such as Actinic Keratoses (AK) or Seborrheic Keratoses (SK), acne scars and hypertrophic scars. The handpiece can also be used to treat missed spots of a full face treatment.

Single Spot Handpiece

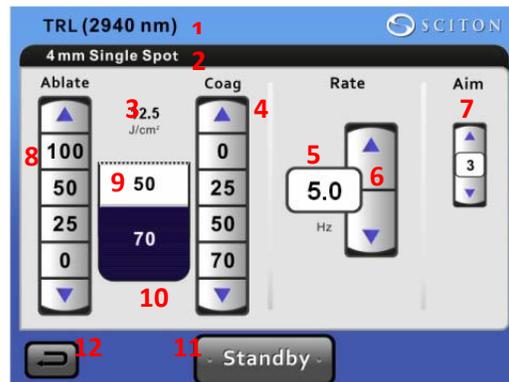
The Single Spot handpiece consists of a hollow tube housing two lenses and a removable bayonet. The bayonet distance guide assures appropriate distance to tissue and accurate spot size delivery.

2 mm & 4 mm Handpieces



4 mm Single Spot Screen

Attach the 4 mm single spot handpiece to the articulated arm. Press the Single Spot softkey on the 2940 nm application screen and the system will enter the TRL (2940 nm) application screen.

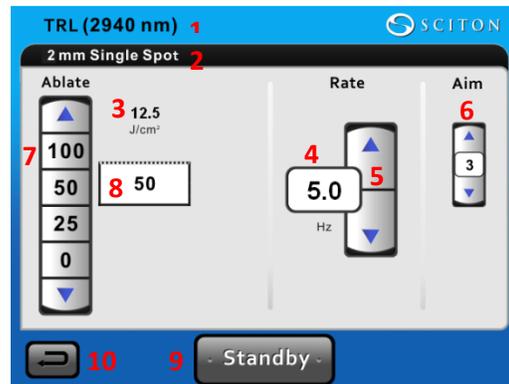


Note: This application covers 100% of the skin within the 4 mm single spot treated; it does not produce a "fractional" effect.

1. Application and wavelength indicator
Application and-wavelength indicator shows which treatment screen the user is in and which wavelength is being used for the treatment.
2. Handpiece Spot Size indicator
Handpiece spot size indicates that the 4 mm single spot handpiece is attached to the articulated arm.
● 4 mm spot size
3. Ablation fluence indicator
Ablation fluence indicator shows the amount of fluence or energy being delivered based on the depth of the ablation selected. 1J/cm² = 4 microns of ablation.
4. Coagulation depth softkeys
Coagulation depth may be set by tapping the default softkeys of 0, 25, 50 or 70 microns and can also be adjusted from 0 - 130 microns by tapping or holding down the up ▲ or down ▼ arrow softkeys. See earlier section for explanation of COAG.

5. Repetition rate indicator
Repetition rate is the length of time between each single spot delivery when the footswitch is held down continuously. The rate is measured in Hz.
6. Repetition rate adjustment softkeys
Repetition rate adjustment softkeys allow the user to increase or decrease each single spot delivery 1 Hz (1 spot per second) up to 42 Hz (42 spots per second) by tapping or holding down the up ▲ or down ▼ arrow softkeys.
7. Aiming beam intensity softkey
Aiming beam intensity allows the user to make the aiming beam lighter or brighter in intensity. MIN, 1, 2, 3, 4, 5 or MAX intensity can be selected by tapping the Aim softkey.
8. Ablation depth softkeys
Ablation depth relates to the amount of tissue to be removed. The ablative depth may be set by tapping the default softkeys of 0, 25, 50 or 100 microns. The laser may also be set manually from 0 - 200 microns by tapping or holding down the up ▲ or down ▼ arrow softkeys.
9. Tissue diagram indicator
Tissue diagram gives the user a quick reference to the amount of ablative and COAG (if selected) energy being delivered to tissue. The deeper the treatment depth the bigger the tissue diagram.
10. COAG indicator
The amount of COAG selected is represented under the tissue diagram in black and will increase in size as the COAG depth is increased.
11. System status softkey
System status softkey allows the user to put the system in Standby or Ready.
12. Return to 2940 nm applications screen softkey
Return to 2940 nm application softkey will return the system to the previous screen.

2 mm Single Spot Screen



Note: This application covers 100% of the skin within the 2 mm single spot treated; it does not produce a "fractional" effect.

1. Application and wavelength indicator
Application and-wavelength indicator shows which treatment screen the user is in and which wavelength is being used for the treatment.
2. Handpiece Spot Size indicator
Handpiece spot size indicates that the 2 mm single spot handpiece is attached to the articulated arm.
 - 2 mm spot size
3. Ablation fluence indicator
Ablation fluence indicator shows the amount of fluence or energy being delivered based on the depth of the ablation selected. 1J/cm² = 4 microns of ablation.
4. Repetition rate indicator
Repetition rate is the length of time between each single spot delivery when the footswitch is held down continuously. The rate is measured in Hz.
5. Repetition rate adjustment softkeys
Repetition rate adjustment softkeys allow the user to increase or decrease each single spot delivery 1 Hz (1 spot per second) up to 42 Hz (42 spots per second) by tapping or holding down the up ▲ or down ▼ arrow softkeys.

6. Aiming beam intensity softkey
Aiming beam intensity allows the user to make the aiming beam lighter or brighter in intensity. MIN, 1, 2, 3, 4, 5 or MAX intensity can be selected by tapping the Aim softkey.
7. Ablation depth softkeys
Ablation depth relates to the amount of tissue to be removed. The ablative depth may be set by tapping the default softkeys of 0, 25, 50 or 100 microns. The laser may also be set manually from 0 - 200 microns by tapping or holding down the up ▲ or down ▼ arrow softkeys.
8. Tissue diagram indicator
Tissue diagram gives the user a quick reference to the amount of ablative energy being delivered to tissue.
9. System status softkey
System status softkey allows the user to put the system in Standby or Ready.
10. Return to 2940 nm applications screen softkey
Return to 2940 nm application softkey will return the system to the previous screen.

1.2.9.1 Precautions

- Patients must be carefully evaluated by the physician for their risk of scarring versus the treatment benefit, especially with selection of coagulation setting when using the single spot handpiece.
- Treatment should be done in a conservative fashion in areas where the skin is thin, such as the temple and forehead areas.
- Post-treatment hyperpigmentation may occur after 3 - 4 weeks.
- Direct and intentional sun exposure should be avoided for 7 - 10 days, then daily use of sun block is recommended to avoid pigment related complications.
- Patients who smoke may experience delayed healing and decreased benefit.
- Particulate debris on the lens of the handpiece may result in laser beam scattering and an incorrect setting for depth of treatment. Cleaning the lens prior to, and during treatment, is essential to ensure accurate treatment settings.
- Treating at settings much higher than those recommended by the protocol may lead to undesirable outcomes. Attention to technique and conservative treatment is recommended.
- Selection of patients must include evaluation of Fitzpatrick Skin Type (I-VI). The 2940 nm Er:YAG Contour TRL Single Spot treatment is an ablative procedure selected with or without the coagulation mode. Note that using coagulation mode (available only with 4 mm handpiece) while ablating the epidermis may lead to long term or permanent hypo or hyper-pigmentation issues in skin types IV-VI. However, darker skin types may have transient pigmentary loss in the more aggressive pure ablative single spot treatments (50+ microns). This transitory loss is a natural healing phenomenon with a potential period of 3 to 30 days.

1.2.9.2 2940 nm Er:YAG Contour TRL Single Spot Treatment

Treatment Basics

- Patient should be positioned based on the area to be treated. The position should be comfortable to the patient and such that the treatment provider has good access to area to be treated and the control panel display screen.
- A mild cleanser should be used to remove any dirt, makeup or moisture from the treatment site. Follow with an alcohol gauze. Allow alcohol to evaporate before treatment. Use special care around the eyes.
- If topical anesthetic is to be used, apply as directed prior to treatment. Before beginning treatment, ensure that topical has been completely removed from surface of skin.
- Prepare for adequate smoke evacuation.
- Attach the 2 mm or 4 mm single spot handpiece that has been cleaned with an alcohol gauze, to the articulated arm.
- Enter settings into the control panel display screen based on condition and area to be treated. When treating with 2940 nm Er:YAG Contour TRL Single Spot in combination with a MLP, the single spot treatment can be performed before or after the MLP.

Treatment Starting Parameters

Application	Indication	Ablative Depth (µm)	Repetition Rate (Hz)
2 mm single spot	Actinic Keratoses, Seborrheic Keratoses, Acne Scars	10	1 - 5
4 mm single spot	Actinic Keratoses, Seborrheic Keratoses, Acne Scars	10 - 20	1 - 5

Tissue coagulation is the addition of heat to produce a zone of thermal necrosis. As an option, the 4 mm single spot handpiece allows the user to select coagulation depths of 0 - 70 microns.

- The single spot handpiece should be held perpendicular. Move patient if necessary to accomplish a 90 degree angle. Use the bayonet distance guide to help achieve this angle and proper distance to tissue for efficient and uniform ablation.
- To confirm that laser and accessories are performing normally, it is useful for the operator to first test on a nonflammable inanimate object like a wooden tongue depressor. Treating a test area prior to beginning treatment will determine the patient's response threshold and help them understand the audible and sensory components of the treatment.
- Particulate debris on the optics of the handpiece may result in laser beam scattering and an incorrect setting for fluence. Handpiece optics should be cleaned throughout treatment with a moistened wipe. If alcohol is used, allow the alcohol to dry completely before continuing with the treatment.

Epidermal Lesions

When treating for Actinic Keratoses (AK) or Seborrheic Keratoses (SK), the goal is to remove the epidermis to the appropriate depth of the lesion.

Using either the 2 mm spot or 4 mm spot choose the 10 micron setting and a repetition rate of 1 - 5 hertz. Ablate the area by making a pass covering the entire lesion. Use a 4 x 4 gauze sponge and wipe any residue from the area to assess the lesion clearance. Make additional passes until the lesion is gone. Pinpoint bleeding indicates that the papillary dermis has been reached and further passes should be avoided.

Acne Scars

These are generally assessed as if histology is mid papillary to upper reticular. It is better to avoid treatment into the reticular dermis.

Select either the 2 mm or 4 mm single spot handpiece based on the size of the lesion being treated, set the ablative depth to 10 microns and the repetition rate to 1 - 5 Hz. Trace the outer margins of the acne scars to smooth down the ridges. The idea is to decrease the highly demarcated ridges to blend into the valleys. After smoothing down the ridges in an area, use the Contour Scanner and set the laser to the appropriate depth (extending to the papillary dermis) and treat the entire area to promote uniform healing.

Post-Treatment

- **OBSERVATIONS**
Some possible side effects: erythema, localized edema, urticaria, sun burn sensation, flaking and tightness of skin.
Side effects after single spot treatment can be observed for 12 - 48 hours after treatment, depending upon depth of treatment.
- **INTERVENTION**
Cool compresses or ice packs can provide immediate comfort after treatment.
An occlusive barrier such as Aquaphor will provide protection and comfort to treated area and should be used until skin has re-epithelialized.
- **INTERVAL** between single spot treatments is approximately 4 - 8 weeks depending upon depth of treatment and the health and integrity of skin being treated.

Concurrent Procedures

Noninvasive light-based treatments like hair reduction or collagen stimulation may occur prior to a single spot treatment. When treating with the 2940 nm Er:YAG Contour TRL Single Spot in combination with a MLP, the single spot treatment can be performed before or after the MLP.

Check with manufacturer for guidelines on using injectables in conjunction with 2940 nm Er:YAG Contour TRL Single Spot treatments.

1.2.10 Safe Start Protocol for using the 2940 nm Er:YAG Contour TRL Focused Spot Treatment

The Focused handpiece is designed for use in surgical applications requiring the excision, incision, ablation, vaporization and coagulation of soft tissue.

1.2.10.1 Focused Handpiece

The Focused Single Spot handpiece consists of a hollow tube housing a lens and a removable bayonet. The bayonet distance guide assures appropriate distance to tissue and accurate spot size delivery. The spot size becomes larger away from the focal point. The handpiece uses specialized optics to generate an approximately 0.7 mm diameter spot. The spot size is determined by the energy, repetition rate (Hz) and the distance. This spot size is desirable for precise tissue ablation.



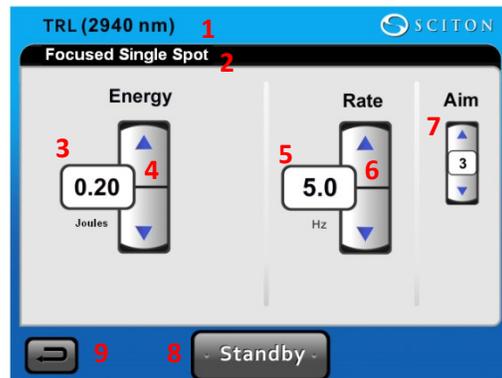
Focusing handpiece



Bayonet distance guide

1.2.10.2 Focused Single Spot Screen

Attach the Focused Single Spot handpiece to the articulated arm. Press the Single Spot softkey on the 2940 nm application screen and the system will enter the TRL (2940 nm) application screen.



1. Application and wavelength indicator
Application and-wavelength indicator shows which treatment screen the user is in and which wavelength is being used for the treatment.
2. Handpiece Spot Size indicator
Handpiece spot size indicates that the Focused Single Spot handpiece is attached to the articulated arm.
3. Energy indicator
Energy indicator shows the amount of energy being delivered in Joules.

4. Energy adjustment softkeys
Energy adjustment softkeys allow the user to increase or decrease energy by 0.1 Joules by tapping or holding down the up ▲ or down ▼ arrow softkeys.
5. Repetition rate indicator
Repetition rate is the amount of time between each single spot delivery when the footswitch is held down continuously. The rate is measured in Hz
6. Repetition rate adjustment softkeys
Repetition rate adjustment softkeys allow the user to increase or decrease each single spot delivery from 1 Hz (1 spot per second) up to 50 Hz (50 spots per second) by tapping or holding down the up ▲ or down ▼ arrow softkeys.
7. Aiming beam intensity softkey
Aiming beam intensity allows the user to make the aiming beam lighter or brighter in intensity. MIN, 1, 2, 3, 4, 5 or MAX intensity can be selected by tapping the Aim softkey.
8. System status softkey
System status softkey allows the user to put the system in Standby or Ready.
9. Return to 2940 nm Applications screen softkey
Return to 2940 nm application softkey will return the system to the previous screen.

1.2.10.3 Precautions

- Patients must be carefully evaluated by the physician for their risk of scarring versus the treatment benefit.
- Treatment should be done in a conservative fashion in areas where the skin is thin, such as the temple and forehead areas.
- Post-treatment hyperpigmentation may occur.
- Direct and intentional sun exposure should be avoided for 7 - 10 days, then daily use of sun block is recommended to avoid pigment related complications.
- Patients who smoke may experience delayed healing and decreased benefit.
- Particulate debris on the lens of the handpiece may result in laser beam scattering and an incorrect setting for depth of treatment. Cleaning the lens prior to, and during treatment, is essential to ensure accurate treatment settings.
- Treating at settings much higher than those recommended by the protocol may lead to undesirable outcomes. Attention to technique and conservative treatment is recommended.
- Selection of patients must include evaluation of Fitzpatrick Skin Type (I - VI). The Focused Single Spot treatment is an ablative procedure. Darker skin types may have transient pigmentary loss in the more aggressive single spot treatments (50+ microns). This transitory loss is a natural healing phenomenon.

1.2.10.4 2940 nm Er:YAG Contour TRL Focused Single Spot Treatment

Treatment Basics

- Patient should be positioned based on the area to be treated. The position should be comfortable to the patient and such that the treatment provider has good access to area to be treated and the control panel display screen.
- A mild cleanser should be used to remove any dirt, makeup or moisture from the treatment site. Follow with an alcohol gauze. Allow alcohol to evaporate before treatment.
- If topical anesthetic is to be used, apply as directed prior to treatment. Before beginning treatment, ensure that topical has been completely removed from surface of skin.
- Prepare for adequate smoke evacuation.
- After cleaning the Focused Single Spot Handpiece with alcohol gauze, attach to the articulated arm.
- Enter settings into the control panel display screen based on condition and area to be treated.

Treatment Starting Parameters

Application	Indication	Energy (J)	Repetition Rate (Hz)	Ablative Depth* (μm)
Focused Single Spot	Surgical applications requiring the excision, incision, ablation and coagulation of soft tissue	0.1 - 0.5	1 - 10	120 – 600

- The Focused Single Spot Handpiece should be held perpendicular. Move patient if necessary to accomplish a 90 degree angle. Use the bayonet distance guide to help achieve this angle and proper distance to tissue for efficient and uniform ablation.
- To confirm that laser and accessories are performing normally, it is useful for the operator to first test on a nonflammable inanimate object like a wooden tongue depressor. Treating a test area prior to beginning treatment will determine the patient's response threshold and help them understand the audible and sensory components of the treatment.
- To gain comfort of delivering pulses with this handpiece, it is suggested to practice on a stack of Post-it notes or a tongue blade for determining speed, accuracy, and approximation of degree of depth. The Focused Handpiece will provide a spot size of approximately 0.7 mm. The spot size is controlled by the speed, energy and the distance used.
** Note: As an example, choosing 0.1 J at 1 Hz will approximate a fluence of 30 J/cm² and an ablation depth of 120 μm . Choosing 0.5 J will approximate a fluence of 150 J/cm² and an ablation depth of 600 μm .*
- Particulate debris on the optics of the handpiece may result in laser beam scattering and an incorrect setting for fluence. Handpiece optics should be cleaned throughout treatment with a gauze moistened with alcohol.

Post-Treatment

- **OBSERVATIONS**
 Some possible side effects: erythema, localized edema, urticaria, sun burn sensation, flaking and tightness of skin.
 Side effects after Focused Single Spot treatment can be observed for 12 - 48 hours after treatment, depending upon depth of treatment.
- **INTERVENTION**
 Cool compresses or ice packs can provide immediate comfort after treatment.
 An occlusive barrier such as Aquaphor will provide protection and comfort to treated area and should be used until skin has reepithelialized.



- **INTERVAL**

If treated area requires touch up or additional treatment, this may be done in approximately 4-8 weeks depending upon the status of the healing process of the treated.

Concurrent Procedures

Noninvasive light-based treatments like hair reduction or collagen stimulation may occur prior to a 2940 nm Er:YAG Contour TRL Focused Single Spot Treatment . When treating with the 2940 nm Er:YAG Contour TRL Focused Single Spot in combination with a MLP, Focused Single Spot can be performed before or after the MLP.

Check with manufacturer for guidelines on using injectables in conjunction with 2940 nm Er:YAG Contour TRL Focused Single Spot treatments.

1.2.11 Safe Start Protocol for 2940 Er:YAG Contour TRL ProFractional/ProFractional-XC

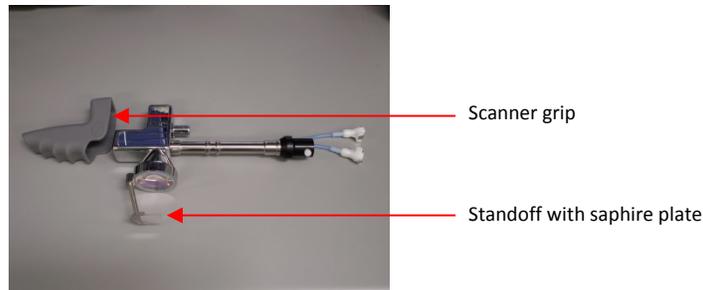
ProFractional/ProFractional-XC works on the principle of fractionated photothermolysis. Due to the efficient water absorption characteristics of 2940 nm Er:YAG laser, the ProFractional/ProFractional-XC is able to penetrate deeply into the dermis by ablating clean channels of tissue to a selected depth and instantly vaporizing the tissue within the channel. These channels are surrounded by healthy tissue, speeding healing time and reducing downtime for the patient.

ProFractional energy delivery is limited to the channels, minimizing patient discomfort.

ProFractional-XC permits the user to provide more heat to the treated channels of tissue resulting in additional coagulation by creating a zone of thermal necrosis.

1.2.11.1 ProFractional Scanner (250 µm spot delivery)

The ProFractional Scanner Handpiece consists of 2 galvanometers and collimating optics contained in a housing. The galvanometers allow the beam to be scanned to form two dimensional spots on the skin surface.

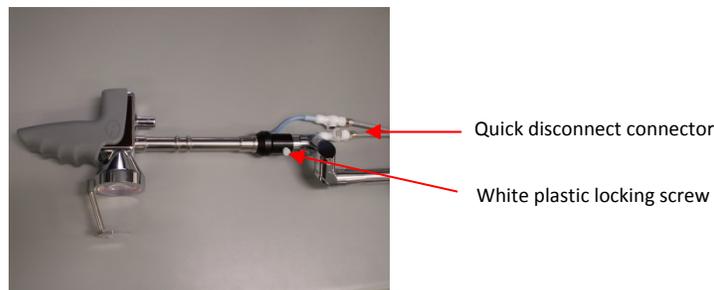


Scanner grip provides for a more comfortable hold while using the scanner. The grip is an option for the user and can be used with any Sciton scanner.

Note: When using scanner grip, make sure it fits tightly on the scanner housing.

Standoffs permit the user to position the focal plane of the laser energy onto the skin surface for consistent results. The user has an option of a standoff with or without a glass plate.

Water from the laser system is circulated through the end of the scanner to help keep the handpiece cool for the user during scanner use.



A white plastic locking screw is used to lock the handpiece in place after it is screwed to the end of the articulated arm.



ProFractional quick disconnect connector

Attach the quick disconnect connectors on the end of the handpiece to the tubing connected to the back of the laser.

The ProFractional Scanner allows fractional application of the laser energy by delivering 250 μm spots of energy within a pattern that ranges from 1.5 mm x 1.5 mm to 15 mm x 15 mm in size. Aiming beam is represented by red square and shows the user the area to be treated. The energy will be delivered inside the red square. When the red square is “dancing” the system is in Standby. When the red square is solid the system is in Ready.



Care should be taken to apply adjoining scans without gap or excessive overlap of the previously scanned area. Line each scan pattern up to each other to avoid gap or overlap as shown above.

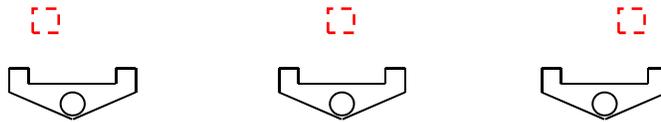
1.2.11.2 ProFractional Screen

Attach the ProFractional Scanner to the articulated arm. Press the Fractional Resurfacing softkey on the 2940 nm application screen and the system will enter the ProFractional (2940 nm) application screen.



1. Application and wavelength indicator
Application and wavelength indicator shows which treatment screen the user is in and which wavelength is being used for the treatment.
2. Handpiece indicator
Handpiece indicates that which handpiece is attached to the articulated arm.
3. Ablation depth indicator
Ablation depth relates to the amount of tissue to be removed.
4. Ablation depth adjustment softkeys
Ablation depth may be set by tapping or holding down the up ▲ or down ▼ arrow softkeys.
5. Ablation fluence indicator
Ablation fluence indicator shows the amount of fluence or energy being delivered based on the depth of the ablation selected. 1 J/cm² = 4 microns of ablation.

6. Treatment area percentage indicator
Treatment area percentage shows what percentage of the tissue is being treated.
7. Treatment area percentage adjustment softkeys
Treatment area percentage can be adjusted from 1.5% up to 30% by tapping or holding down the up ▲ or down ▼ arrow softkeys.
8. Pitch indicator
Pitch relates to the distance between adjacent treated zones. When the percentage of area treated is changed, pitch is automatically adjusted. The higher the percentage of area treated the smaller the distance between treated zones.
9. Pattern size adjustment softkeys
Pattern size can be adjusted from a size 1 which is 1.5 mm x 1.5 mm to an 8 which is 15 mm x 15 mm by tapping the desired numbered softkey.
10. Pattern repeat softkey
Pattern repeat will allow the user to set an amount of time between consecutive scans of 0.5, 1.0, 1.5 or 2.0 seconds by tapping the Repeat softkey. Repeat can also be turned off so that each scan pattern is delivered by lifting and depressing the footswitch.
11. Pattern center adjustment softkey
Pattern center allows the user to offset the area to be treated to the upper left corner, upper middle or upper right corner of the standoff by tapping the Center softkey.

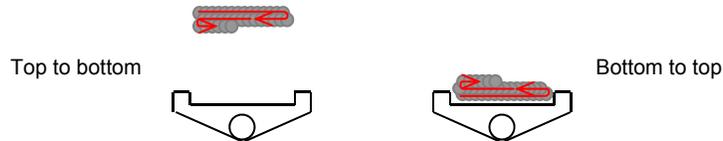


Offset to upper left

Offset to upper middle

Offset to upper right

12. Scan Pattern direction softkey
Scan pattern direction allows the user to change the direction of the scan being delivered from the top to bottom or bottom to top of the standoff.



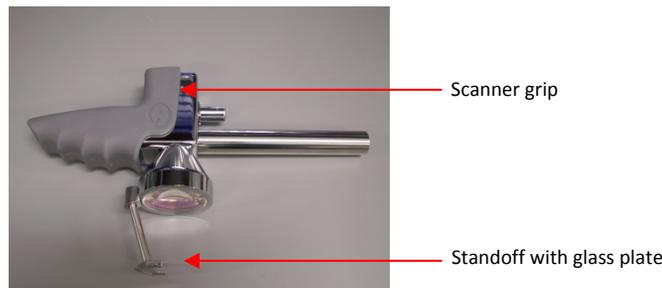
Top to bottom

Bottom to top

13. System status softkey
System status softkey will allow the user to put the system in Standby or Ready.
14. Return to 2940 nm applications screen
Return to 2940 nm application softkey will return the system to the previous screen.

1.2.11.3 ProFractional-XC Scanner (430µm spot delivery)

The ProFractional-XC Scanner Handpiece consists of 2 galvanometers, micro lens array and focusing optics contained in a housing.



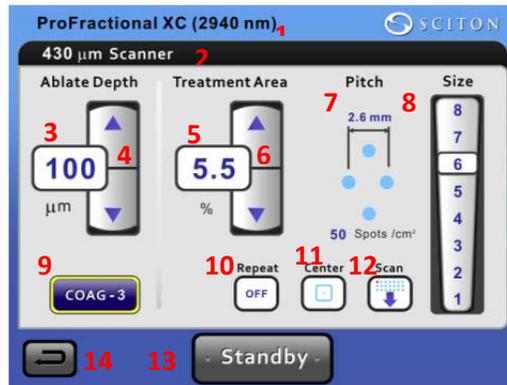
The scanner grip provides for a more comfortable hold while using the scanner. The grip is an option for the user and can be used with any Sciton scanner.

Note: When using scanner grip, make sure it fits tightly on the scanner housing.

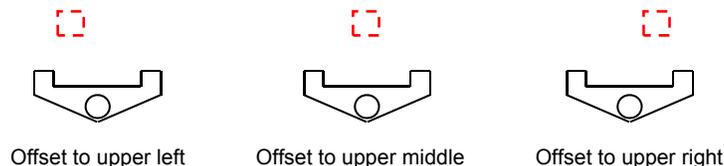
Standoffs permit the user to position the focal plane of the laser energy onto the skin surface for consistent results. The user has an option of a standoff with or without a glass plate.

1.2.11.4 ProFractional-XC Scanner (430µm spot delivery)

Attach the ProFractional-XC Scanner to the articulated arm. Press the Fractional Resurfacing softkey on the 2940 nm application screen and the system will enter the ProFractional-XC (2940 nm) application screen.

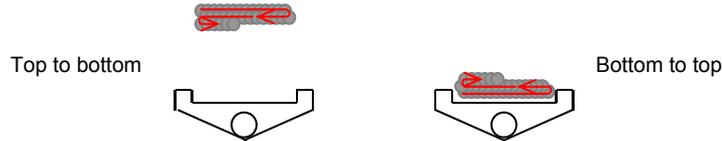


1. Application and wavelength indicator
Application and wavelength indicator shows which treatment screen the user is in and which wavelength is being used for the treatment.
2. Handpiece indicator
Handpiece indicates which handpiece is attached to the articulated arm.
3. Ablation depth indicator
Ablation depth refers to the depth of the micro-column of ablated tissue.
4. Ablation depth adjustment softkeys
Ablation depth may be set by tapping or holding down the up ▲ or down ▼ arrow softkeys.
5. Treatment area percentage indicator
Treatment area percentage shows what percentage of the tissue is being treated.
6. Treatment area percentage adjustment softkeys
Treatment area percentage can be adjusted to 5.5%, 11% or 22% by tapping the up ▲ or down ▼ arrow softkeys.
7. Pitch indicator
Pitch relates to the distance between adjacent treated zones. When the percentage of area treated is changed, pitch is automatically adjusted. The higher the percentage of area treated the smaller the distance between treated zones.
8. Pattern size adjustment softkeys
Pattern size can be adjusted from a size 1 which is 1.3 mm x 1.3 mm to an 8 which is 20 mm x 20 mm by tapping the desired numbered softkey.
9. Coagulation depth adjustment softkey
COAG depth can be turned off or adjusted to three levels by tapping the COAG softkey; COAG-1 equals approximately 50 µm, COAG-2 equals approximately 100 µm and COAG-3 equals approximately 150 µm. Refer to earlier section for explanation of COAG.
10. Pattern repeat softkey
Pattern repeat will allow the user to set an amount of time between consecutive scans of 0.5, 1.0, 1.5 or 2.0 seconds by tapping the Repeat softkey. Repeat can also be turned off so that each scan pattern is delivered by lifting and depressing the footswitch.
11. Pattern center adjustment softkey
Pattern center allows the user to offset the area to be treated to the upper left corner, upper middle or upper right corner of the standoff by tapping the Center softkey.



12. Scan Pattern direction softkey

Scan pattern direction allows the user to change the direction of the scan being delivered from the top to bottom or bottom to top of the standoff.



13. System status softkey

System status softkey will allow the user to put the system in Standby or Ready.

14. Return to 2940 nm applications screen

Return to 2940 nm application softkey will return the system to the previous screen.

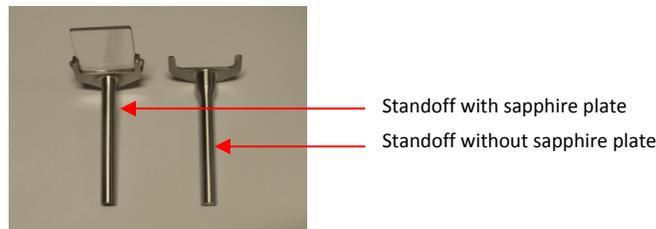
1.2.11.5 Precautions

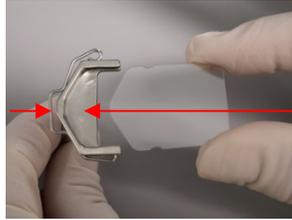
- Patients must be carefully evaluated by the physician for their risk of scarring versus the treatment benefit, especially with selection of coagulation setting when using the ProFractional-XC.
- Treatment should be done in a conservative fashion in areas where the skin is thin, such as the temple and forehead areas.
- Post-treatment hyperpigmentation may occur after 3-4 weeks.
- Direct and intentional sun exposure should be avoided for 7-10 days, then daily use of sun block is recommended to avoid pigment related complications.
- Patients who smoke may experience delayed healing and decreased benefit.
- Selection of patients must include evaluation of Fitzpatrick Skin Type (I-VI). ProFractional and ProFractional-XC, without COAG, can safely and comfortably treat patients with Fitzpatrick skin types I through VI without pigmentary changes but it is recommended that a test spot be done on darker skin type patients first. Some patients may experience transitory lines of demarcation with more aggressive ProFractional/ProFractional-XC treatments. These lines resolve in a few days after treatment.
- If COAG is used with ProFractional-XC it may pose a risk of long term or permanent hypo or hyperpigmentation, especially in darker skin types. Therefore, the COAG option with ProFractional-XC is not recommended for use in Skin Types IV-VI.
- Particulate debris on the lens of the scanner and/or glass plate standoff may result in laser beam scattering and an incorrect setting for depth of treatment. Cleaning the lens and glass plate standoff prior to, and during treatment, is essential to ensure accurate treatment settings.
- Treating with overlapping scans or at settings much higher than those recommended by the protocol may lead to undesirable outcomes. Attention to technique and conservative treatment is recommended.

1.2.11.6 ProFractional & ProFractional-XC Standoffs

The removable ProFractional and ProFractional-XC standoffs are used to position the focal plane of the laser energy onto the skin surface. The scanner should always be held perpendicular to the skin surface for consistent results. The disinfected standoff should be attached to the handpiece and held gently with continuous skin contact during the entire treatment for precise focus and uniform delivery of energy.

The standoff with or without a sapphire plate can be used for ProFractional /ProFractional-XC treatment. The two different standoffs are supplied to provide options for the treatment provider.





Push metal wire in the middle to release sapphire plate from standoff holder

Sapphire plate being removed for cleaning

1.2.11.6.1

Standoff Disinfection

Standoffs should be removed from scanner and disinfected in a high-level disinfectant or autoclaved after each use.

Suggested high-level disinfectants are:

Cidex Plus 28 Day Solution
 Sporicidin® Sterilizing and Disinfecting Solution
 Metricide High Level Disinfectant/Sterilant

More disinfectants are available by referencing FDA website at:
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofSingle-UseDevices/ucm133514.htm>

- Follow the manufacturer's instructions for a high-level disinfection or autoclave procedure.
- Gloves should always be worn when handling a standoff during and after the treatment.

1.2.11.6.2

Treating Body Tissue

The epidermis of body skin is thinner than that of the face and has fewer adnexal healing structures. Peels beyond 100 microns in depth and more than 5% ProFractional or 5.5% ProFractional-XC in treatment area percentage are not recommended in a single treatment. Re-treatment may occur as early as 8 weeks. Treating body skin may not be ideal for patients with known healing deficiencies.

- *Note: COAG is not recommended on body skin.*

1.2.11.6.3

Device Tissue Effects

The following table summarizes ablative and thermal damage at various depth settings:

Expected Depth (µm)	Measured Depth (µm)	Measured Width (µm)	Lateral Thermal Damage (µm)	Deep Thermal Damage (µm)
100 µm	207	343	42	67
300 µm	337	313	67	100
1000 µm	702	367	117	283

1.2.11.7 2940 Er:YAG Contour TRL ProFractional/ProFractional-XC

Treatment Basics

- Patient should be positioned based on the area to be treated. The position should be comfortable to the patient and such that the treatment provider has good access to area to be treated and the control panel display screen.
- A mild cleanser should be used to remove any dirt, makeup or moisture from the treatment site. Wipe the area with an alcohol gauze. Allow alcohol to evaporate before treatment. Use special care around the eyes.
- If topical anesthetic is to be used, apply as directed prior to treatment. Before beginning treatment, ensure that topical has been completely removed from surface of skin.
- Prepare for adequate smoke evacuation when using a standoff without a sapphire plate.
- Attach clean handpiece with highly disinfected or autoclaved standoff to articulated arm.
- Enter settings into the control panel display screen based on condition and area to be treated.

ProFractional Treatment Starting Parameters

Application	Ablation Depth	Fluence	Treatment Area
Skin Resurfacing	25 - 100 μm	6.3 - 25 J/cm^2 (displayed only)	1.5 - 30%

ProFractional-XC Treatment Starting Parameters

Application	Ablation Depth	Coagulation Depth	Fluence	Treatment Area
Skin Resurfacing and coagulation	25 - 100 μm	COAG-1 approx 50 μm	5 - 25 J/cm^2 (displayed only)	5.5 - 22%
<p><i>Tissue coagulation is the addition of heat to produce a zone of thermal necrosis. As an option, Sciton ProFractional-XC device provides three levels of coagulation:</i></p> <p style="text-align: center;"> <i>COAG-1 equals approximately 50 μm</i> <i>COAG-2 equals approximately 100 μm</i> <i>COAG-3 equals approximately 150 μm</i> </p>				

- ProFractional/ProFractional-XC handpiece should be held perpendicular to the skin surface at all times. Move patient if necessary to accomplish this 90 degree angle. The disinfected standoff should be attached to the handpiece and held in continuous contact with tissue during the entire treatment for precise focus and uniform delivery of energy.
- To confirm that laser and accessories are performing normally, it is useful for the operator to first test on a nonflammable inanimate object like a wooden tongue depressor. Treating a test area prior to beginning treatment will determine the patient's response threshold and help them understand the audible and sensory components of the treatment.
- Match the trailing edge of one scan pattern to the leading edge of the next. There should be no overlap between scans. Patterns should "line up" beside each other.
- Patient response can vary. Generally, treating at deeper depths (higher energy delivery) and a greater treatment area percentage (% of skin) both result in greater efficacy, but also a longer healing time.
- Ablation depth and treatment area percentage should be selected based on the condition treated, expected outcome, patient pain tolerance, and expected downtime for healing after assessing the individual patients needs.
- Because skin is thinner on the forehead, it is recommended that depth and treatment area percentage settings be more conservative in that area.
- The desired endpoint is erythema within a few minutes of laser application. Incidental pinpoint to punctuate bleeding may occur during the treatment but usually resolves within a few minutes to hours after the completion of treatment. Redness (often similar in appearance to varying degrees of sunburn) and healing time will be greater the deeper the ablation depth, the greater the

treatment area percentage (% of skin), and with the addition of COAG and will vary from patient to patient.

- ProFractional/ProFractional-XC pattern marks are typically very transient and usually resolve within 2-3 days after treatment. However, in rare cases this patterning can be seen for up to 4 weeks post treatment and usually completely resolves without intervention.
- Particulate debris and blood on the optics of the scanner and glass plate standoff may result in laser beam scattering and an incorrect setting for fluence. Scanner optics and glass plate standoff should be cleaned throughout treatment with a moistened wipe. If alcohol is used, allow the alcohol to dry completely before continuing with the treatment.

Post-Treatment

- **OBSERVATIONS**

Pinpoint or punctuate bleeding during and immediately following treatment.

Erythema and edema noted for approximately 12-48 hours after treatment depending on depth and percentage of area treated.

- **INTERVENTION**

Cool compresses or ice packs can provide immediate comfort after treatment.

An occlusive barrier such as Aquaphor will provide protection and comfort to treated area and should be used until skin has reepithelialized.

- **INTERVAL** between ProFractional/ProFractional-XC treatments is 2 - 6 weeks depending upon depth, treatment area percentage and level of COAG, if used.

Concurrent Procedures

2940 Er:YAG Contour TRL ProFractional/ProFractional-XC treatments may be given in combination with other procedures. If a patient is undergoing a BBL or MLP procedure, these treatments should be performed before the ProFractional/ProFractional-XC.

Check with manufacturer for guidelines on using injectables in conjunction with 2940 Er:YAG Contour TRL ProFractional/ProFractional-XC treatments.