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Planning Guide and Teaching Tool



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The information contained in this manual is for use as reference only and does not serve as a substitute for reading the Operator Manual included with your system.

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Section 1: Using This Planning Guide

The planning guide is in **seven sections** for easy reference and review. An added feature is the **bolded** areas listing important facts.

You will find key concepts and messages that help you use your Soprano^{Lite} more efficiently and safely

PRIOR to the scheduled in-service study all sections. Be familiar with definitions, terminology and forms.

Schedule appropriate patients for the in-service day. Schedule the in-service training at least 2 days after installation of your device. This will allow the Alma Representative time to set up and test your equipment. This also allows your practice a window of time to prepare for your in-service day. Proper preparation and proper use of your in-service time will prove to be beneficial to your long-term success.

Write down all your questions. Ask any questions pertaining to patient selection prior to the in-service day. Please contact the Alma Clinical Specialist assigned to your territory.

The **Physician** and **All Staff** should be present at the in-service that will either treat patients or discuss the treatments available with your patients.

Ask your Clinical Specialist about additional programs available from Alma Lasers, Inc to expand your system capabilities and technology advancement.

Note: You may copy this document for your staff, but you may not distribute outside your office.

Section 2: Definitions and Applications

Soprano^{Lite}

Congratulations on your purchase of the Soprano^{Lite} system from Alma Lasers. With proper operation and maintenance, trained, qualified practitioners can use the system safely. The operator and all other personnel involved with patient care should be familiar with the maintenance, operation and safety information that is provided during in-servicing and found in the Alma Operator's Manual.

Understanding the terminology and principles behind Diode technology will allow you to provide maximum benefits to your patients and your practice. The following definitions assist you in better understanding of Diode technology and how to apply it to each modality of the Soprano^{Lite}. During your in-service, the Clinical Specialist will review these principles with you and, along with the Training Tool Manual, will guide you through each modality. We ask that you become familiar with these definitions so that your in-service time can be utilized to the fullest degree.

Soprano^{Lite} Technologies

- SHR – Super Hair Removal (In Motion)
- SHR Stack Sub-Mode
- HR— Hair Removal

Clinical Applications

- The Diode module is intended for the removal of unwanted hair and to effect stable, long-term hair reduction.
- Indicated for use on all skin types (Fitzpatrick Skin Types I-VI).

Soprano^{Lite} Hair Removal (HR)

The Soprano^{Lite} is a diode laser system operating at a wavelength of 810 nm. The system contains 2 modes of removal of unwanted hair, the Hair Removal (HR) and the Super Hair Removal (SHR) modes, and is designed to meet international safety and performance standards.

The Hair Removal (HR) mode of the Soprano^{Lite} system is designed to perform hair removal procedure based upon the principle of selective photothermolysis. This method involves disabling hair regrowth mechanisms by raising the temperature of the hair follicle high enough to damage the follicle's germinative cells without damaging the epidermis and the surrounding tissue. The germinative cells are those cells, which divide and differentiate into the cells comprising the hair follicle. The temperature of the targeted melanin in the hair follicle increases, which results in the target breakdown. Following laser hair removal, the debris of these cells is eliminated from the tissue by phagocytosis.

The Soprano^{Lite} has a sapphire contact-cooling handpiece which allows laser energy to be directed to the hair root while protecting and cooling the surrounding skin for a greater degree of efficacy, safety and comfort.

Selective photothermolysis is the term used to describe a site specific, thermally mediated injury by selectively absorbing light. The photons deposit their energy at the site of absorption and this energy is transformed into heat. Selective photothermolysis is based on the fact that the absorption coefficient of the pigment in the hair follicle is higher than that of the epidermis and dermis for a range of wavelengths, which the Soprano^{Lite} accesses with its 810 nm wavelength.

The goal of epilation is to heat the hair follicle to a temperature high enough to destroy it without damaging the surrounding tissue. We elevate the temperature of the hair follicle which results in damage to the germinative cells responsible for hair growth. The damaged follicle is then eliminated by natural physiological processes (e.g., phagocytosis). As soon as the heat is created it dissipates by conduction and transfer.

Melanin, which is the main absorbing pigment in the hair, hair follicle, and the skin has absorption which decrease with increasing wavelength. In addition, the scattering of the dermis decreases at longer wavelengths. Therefore, longer wavelengths penetrate deeper into the skin. Since melanin concentration in the hair (especially in dark hair) is much higher than that in the epidermis, the deep penetrating wavelengths will be highly absorbed in the hair nearly down the bulb, without substantial damage to the overlying epidermis. The hair will conduct the generated heat to the cells in the hair follicle which thereby will be destroyed. If the hair follicle is relatively superficial, its melanin containing cells can also absorb the light directly through the skin.

Absorption of energy by the skin is a decreasing function of the wavelengths. The longer wavelengths are less absorbed by melanin and are less scattered by the dermis and therefore can penetrate deeper. Pigment destruction occurs when the light energy by the Soprano^{Lite} is absorbed by the melanin contained in hair follicles.

The ideal is to deposit the energy in the target at a rate faster than the rate of cooling of that target or thermal relaxation time. Thermal relaxation time is described as the time it takes for a heated target to drop 50% of its peak temperature value. Commonly, smaller objects heat quicker and cool quicker than larger ones. Therefore, the light energy exposure duration should be less than or equal to the time necessary for cooling the target and appropriate to the target size.

Three basic elements are required to achieve successful ***selective photothermolysis*** and they are:

1. A wavelength that reaches and is preferentially absorbed by the desired target.
2. Sufficient fluence to reach a damaging temperature within the target.
3. An exposure duration less than or equal to the time necessary for the cooling of the target, with a delay appropriate for epidermal cooling between the pulses.

The Soprano^{Lite} HR mode enables the user to adjust the parameters based on skin type and target size. The system will start you with default settings to use as a baseline but it is most important to use your own expertise to assess the reaction of the individual target and skin and to make adjustments accordingly.

Soprano^{Lite} Super Hair Removal (SHR)

The Super Hair Removal (SHR) mode of the Soprano^{Lite} system is designed to perform hair removal procedure based upon a novel principle, in which there is disabling of the hair regrowth mechanisms by raising the temperature of the hair follicle, its surrounding dermis and the follicle's germinative cells gradually and moderately to a lower temperature as opposed to conventional HR, but high enough to damage the target without damaging the epidermis. In this method of hair removal, the stem cells of the hair, located in the less 'melanin-rich' environment of the hair bulge, are severely damaged, making it difficult for the hair to regenerate its' growth.

In the revolutionary SHR mode of the Soprano^{Lite} photo-thermal event by which preset parameters - wavelength, pulse duration/shape, low fluence, and super fast repetition rate laser beam, cause step-wise, accumulative, heat build-up to both the dermis and hair follicle, with **minimal** discomfort, and minimal-to-no adverse side effects.

Section 3: In-service Objectives

Our objective for the in-service is to provide appropriate on-site training to the physician and staff members in the use of the Soprano^{Lite} system.

Upon completion of the in-service, the physician and his staff will have a reasonable understanding of:

- Patient selection and screening
- Technical use of the Soprano^{Lite} system
- Understanding of Diode Technology
- Maintenance of the equipment and accessories
- Correct protocol to establish and adjust treatments parameters
- Managing appropriate patient expectations
- Assessment of tissue and target reaction
- Laser physics and safety
- Data requirements
- Patient information, indications and contraindications
- Sample treatment and patient evaluation forms

Section 4: Preparing Your Patient For Successful Treatment

Planning for Time

You may accomplish your in-service in one full day including patient treatments. We recommend that you schedule a **minimum of 8-10 patients**. You may schedule regular patients. However, you may feel more comfortable beginning with staff, family members and friends. Please refer to this planning guide to reference any patients who may not be a candidate for Laser HR treatment.

Plan to spend approximately **30 minutes per patient**. Establish proper expectations for treatment with patients before your in-service day. Schedule your day as a regular office day, allowing for 15 minute intervals between patients. The didactic session is in the morning. Please discuss arrangements of your schedule with your Clinical Specialist when she contacts you to schedule your in-service day.

The in-service is divided into four main areas.

- Didactic review of the principles of the HR and SHR mode, technical aspects of operation, care and maintenance of equipment, documentation of treatment, safety and questions. The entire staff that will be involved with the system should be present. Previous laser experience with competitive products does not relieve any staff member from the in-service day. Staff members that do not attend all portions of the In-service will **not** be eligible to receive Certificates of Attendance for the course.
- Hands-on “buttonology” of Soprano^{Lite} system.
- Treatment of patients.
- Time to summarize the events of the day and answer questions.

Patient Selection

Family members, friends and staff may be chosen for the initial in-service, as much discussion is usually occurring during treatment and it may be more comfortable than scheduling regular patients. We would recommend starting with as many different skin and hair types and colors as possible such as skin types I-VI, thick and thin hair, and dark and light hair. Please make sure your patient's understand this is a teaching experience and we will not be doing full treatments.

We ask that you exclude any patient with a tan or who has been exposed to the sun in the past three to four weeks. Exposure would include biking, hiking, gardening, sports etc. Patients who use tanning beds are included in this category.

We ask that you exclude any patient who is planning to be in the sun after the treatment and any patient who has recently used a self tanning lotion should be excluded.

Also patients who are considered contraindicated for **Soprano^{Lite}** treatment should be excluded. Those are patients that are pregnant, using photosensitive medications, tanned skin, diabetes, history of keloid scarring, on anticoagulants and any patient with a history of bleeding coagulopathies. ***Those patients will not be treated during the training session.***

Checklist for In-service

Please refer to the following check list for equipment, supplies and other information in order to prepare for the in-service.

ITEM	Y	N
Soprano^{Lite} system installed and all accessories available		
Operator's Manual read by all appropriate staff		
Treatment table or bed (height adjustable if available)		
Good lighting		
Stool		
Trolley		
Cold gel (refrigerate the night before)		
Container for ice or cold packs to keep gel cold during treatments		
Alcohol 70%		
4x4 gauze pads		
Soft tissues		
Paper towels		
Loop or other magnification mean		
Cold packs		
Soothing cream (Aloe Vera gel, Biafine, Flamazine, Silverol, steroids, antibi-		
Camera		
Informed Consent Forms		
Scheduled minimum of 10 patients		
Confirmed date with all appropriate staff		
Appropriate protective eyewear for all attendances in the room		
Disposable razors		
Wooden spatulas		

Section 5: Clinical Guide

The **Soprano^{Lite}** diode module is intended for the removal of unwanted hair and to effect stable, long-term hair reduction. The **Soprano^{Lite}** is indicated for use on all skin types (Fitzpatrick Skin Types I-VI), including tanned skin.

Contraindications

- Cancer; in particularly, skin cancer
- Pregnancy (including IVF)
- Use of photosensitive medication and herbs for which 810nm light exposure is contraindicated
- Diseases which may be stimulated by light at 810nm
- Prolonged exposure to sun or artificial tanning during the 3 to 4 weeks prior the treatment and post treatment
- Active infection of herpes simplex in the treatment area
- History of keloid scarring
- Diabetes (insulin dependent)
- Fragile and dry skin
- Hormonal disorders (that are stimulated under intense light)
- Use of anticoagulants or history of coagulopathies
- Epilepsy
- Tattoos

Adverse Effects of Treatment

The use of the Soprano^{Lite} system is similar to the use of other laser-based technologies. Historically, traditional systems have demonstrated the ability to cause a certain degree of controlled and uncontrolled tissue damage. In addition, there are the following risks:

- Severe or prolonged erythema (redness) and edema (swelling) within 2-24 hours of treatment that could last for several weeks.
- Irritation, itching, a mild burning sensation or pain (similar to sunburn) may occur within 48 hours of treatment at the application site.
- Blisters, epidermal erosions, or peri-lesional hyperpigmentation may develop and remain evident for several days to several weeks following treatment.
- Eye damage from reflected or prolonged unprotected exposure to laser light. Protective goggles (appropriate to the wavelength) must be worn during all treatments to prevent eye injury.
- It is important to observe tissue reaction during treatment. Poor patient screening and excessive optical energy may cause thermal damage and cause unwanted adverse effects.

Potential Side Effects of Treatment

- Discomfort – when a laser pulse is triggered, some patients experience various degrees of discomfort. Some patients describe the sensation as stinging, while others liken it to a rubber band snap or a burning sensation that may last for up to one hour after treatment. Most patients tolerate the sensation during treatment, but some patients may require a topical anesthetic.
- Damage to Natural Skin Texture – in some cases, a crust or blister may form. Normal wound care should be followed.
- Change of Pigmentation – there may be a change of pigmentation in the treated area. Most cases of hypopigmentation or hyperpigmentation occur in people with skin types IV to VI, or when the treated area has been exposed to sunlight within 3 weeks before or after treatment. In some patients, hyper-pigmentation occurs despite protection from the sun. This discoloration usually fades in three to six months, but in rare cases, (mainly hypo-pigmentation) the change of pigment may be permanent.
- Scarring – there is a chance of scarring; such as, enlarged hypertrophic or keloid scars. To reduce the chance of scarring, it is important to carefully follow all pre- and post-treatment instructions.
- Excessive Swelling – immediately after treatment, especially on the nose and cheeks, the skin may swell temporarily. Swelling usually subsides within hours, but may continue for up to seven days.
- Fragile Skin – the skin at or near the treatment site may become fragile. If this happens makeup should be avoided, and the area should not be rubbed (as this might tear the skin).
- Bruising – purpura, or bruising, may appear on the treated area which may last from a few hours to several days.

Eye Protection

- It is essential that all people present in the treatment room during the treatment (patient and medical personnel) protect their eyes by wearing Alma Lasers recommended protective eyewear.
- **Diode Laser Module:** all personnel must use safety eyewear and must ascertain that the eyewear provides adequate protection **810nm (OD>7)**.
- It is good practice to instruct the patient to close their eyes during treatment even when wearing protective eye glasses.
- If the patient cannot wear the protective eyewear, fit the patient with opaque eye protection that completely blocks light from the eyes.
- If the treatment area is very close to the eyes (e.g. eyelids), protect the eyes with corneal shields.

Optical Safety

- Guard against accidental exposure to laser emission.
- Never look directly at the laser emission from the Soprano^{Lite} handpiece or at any reflecting surface, even when wearing protective eyewear.
- Always set the system to **Standby** mode when there is a pause in treatment; this prevents inadvertent laser emission.
- Press the footswitch and handpiece trigger only when the beam is aimed at the target tissue under direct visualization.

Fire Safety

- Remove any hair from the treatment site. Use only drapes soaked in sterile water near the treatment site if required.
- Make sure a fire extinguisher (rated for electrical fires) is available at all times.
- Avoid the use of flammable tissue-prepping agents or allow the material to completely evaporate before using the laser.
- Do not use the laser in the presence of flammable, explosive anesthetic gases or oxygen.
- Any oxygen tubes present in the room should be of a laser-safe type.

Definitions

Fluence

The energy density output, measured in Joules per squared centimeter (J/cm^2), is set by the user for every treatment. The fluence is the total energy delivered in the selected pulse type (measured in Joules), divided by the spot size (measured in cm^2).

With a large spot size (12 x 10 mm) the scattering effect is minimized, resulting in a constant fluence and deeper penetration. The greater the fluence is, the higher the temperature of the target hair, the surrounding tissue and the epidermis.

KiloJoules (kj)

The accumulative or total energy delivered to tissue for a given area. The product of the Fluence (J/cm^2) x Time (seconds) divided by 1000.

Pre-Treatment

The treatment parameters for hair removal depend on the skin type, and color, type, density and depth of hair to be treated. Once treatment parameters are selected, shave and clean the treatment site to eliminate any surface hair and debris that could interfere with the treatment.

Topical Anesthesia HR Mode

Due to the unique Blend Mode capabilities and the DualChill Technique in the Soprano^{Lite} diode laser system, the procedure can be administered without topical anesthesia. However, there may be patients who prefer to undergo the treatment using a topical anesthetic (such as Emla®) which renders the procedure without any sensation.

Topical anesthetics are generally applied for a period of time (up to 1 hour) prior to treatment. Be certain to remove all of the topical anesthetics prior to treatment.

Any use of topical anesthesia is at the physician's discretion, and should be used according the manufacturer's recommendations.

Photography

It is recommended to take “before and after” photographs to document the treatment progress. These photographs provide objective evidence because many patients are not able to assess the progress of treatment through the gradual improvement.

Standard conditions and similar camera speed, flash and focal distance should be used to photograph all patients. This consistency enables an objective comparison of photos taken at different times.

Pre-Treatment

General

During the first visit the physician (or an authorized staff member) should:

- Take a detailed patient medical history, including previous treatment modalities, and examine the dermatological condition for suitability of treatment with the Soprano^{Lite} system.
- Exclude from treatment anyone who has had prolonged sun exposure or artificial tanning during the last 48 hours.
- Exclude from treatment anyone who is expecting to have prolonged sun exposure during the upcoming month.
- Patients with a history of herpes simplex in the treatment area should take preventive medication (such as Zovirax) prior to treatment.
- Determine why the patient is seeking treatment and understand his/her expectations.
- Discuss treatment goals with the patient.
- It is recommended to shave the treatment area 12-24 hrs. prior to treatment.

Counseling

During the first visit, the physician (or an authorized member of the staff) should:

- Determine why the patient is seeking the treatment and clearly understand his/her expectations

- Discuss the treatment with the patient:
 - ▶ The Soprano^{Lite} therapy may consist of multiple treatments given over several months
 - ▶ There may be some discomfort or pain associated with the treatment
 - ▶ Transient erythema/edema may appear immediately following the treatment
 - ▶ Gradual recovery of the dermatological condition may take a few months
 - ▶ There is a small risk of adverse reactions, such as changes in the texture and pigmentation of the skin, which are usually transient

Handpiece Operation SHR Mode

The Soprano^{Lite} handpiece in **SHR** mode will be applied to the skin using the **In-Motion** technique. In this technique the handpiece is moved continuously on the skin surface in sweeping ("paint-brush") motions. The handpiece can be moved in straight or circular movements within the treatment area. Before applying the handpiece to the skin the practitioner should feel on his/her own skin that the sapphire contact cooling (tip) of the handpiece is cold. The handpiece should be moved at an average speed of 5 cm² per second.

Using the handpiece on the skin in a stationary mode is strictly prohibited!

General

The treatment parameters for hair removal depend on skin type, hair color, type, density and depth of hair to be treated. Once treatment parameters are selected, shave and clean the treatment site to eliminate any surface hair and debris that could interfere with the treatment. Mark the treatment area with 10 x 15 cm grids using 8 landmarks. The number of grids needed to cover a given area may vary according to the (body) size of each individual.

SHR Mode Skin Test Soprano^{Lite}

Fluence is critical to optimize the treatment efficacy and minimize any expected side effects. Always perform a skin test on the intended treatment area during the first treatment session according to the following parameters:

SHR Mode Skin Test Parameters

Skin Type	Fluence (J/cm ²)	Accumulative (kJ)	Grid Size (cm ²)
I-III	10	8-10	10 x 15
IV	8	8-10	10 x 15
V	7	7-9	10 x 15
VI	5	7-9	10 x 15

- Always perform a skin test on the intended treatment area during the first treatment session.
- It is recommended to wait 15 minutes for skin type I-III and 30 minutes for skin types IV-VI.
- Shave the area.
- Cover the treatment area (150cm²) with a coat (1-2mm) of cold ultrasonic gel.
- **If patient complains of excessive discomfort, discontinue treatment and assess skin reaction.**

Treatment

General

The Soprano^{Lite} system has recommended preset parameters that correlate to the desired treatment area. Once selecting the desired treatment area from the system's touch screen, the screen displays the recommended fluence (expressed in J/cm²), total energy (expressed in kJ), treatment time (expressed in seconds) and number of grids. The default fluence and total energy parameters can be adjusted by the operator when the system is in **Standby** mode.

Treatment can begin after the **Treatment Area** has been selected from the system's touch screen.

Treatment can begin after the **Treatment Area** has been selected from the system's touch screen.

Warning

Delivering excessive energy to the treatment site can result in thermal damage to the skin, possibly leading to hypertrophy and/or atrophy and/or abnormal pigmentation

1. Always perform a skin test to establish the cutaneous reaction when beginning treatment.
2. Ensure that the patient is lying comfortably with eye protection in place. All personnel in the treatment room should wear appropriate eye protection as well. The operator should have good access to the treatment area and to the controls of the Soprano^{Lite} system.
3. Clean the skin to remove perfumes, cosmetics and sunscreens.
4. Cover the treatment area (150cm^2) with a thin coat (1-2mm) of cold ultrasound gel.
5. Select the appropriate **Treatment Area** from the system's touch screen.
6. Carefully diagnose the skin test.
7. If necessary, adjust the default fluence (expressed in J/cm^2) and total energy (expressed in kJ) parameters displayed on the screen.
8. Verify that the handpiece tip is cold. The **In-Motion** technique should be initiated only with active sapphire contact cooling and a thin layer of gel on the treated area. No other cooling means are necessary (i.e. Zimmer).
9. Place the handpiece perpendicular to the skin and establish contact with the skin. Press the tip against the skin with moderate pressure to make good contact.
10. If the pulse has the desired effect, continue treatment with the same fluence. Mark a grid (using a red pen) on an area of about $10 \times 15 \text{ cm}$.
11. Start treatment by simultaneous activation of the handpiece trigger and the footswitch, and treat within the grid area in an "In-Motion" technique.

Warning

It is important to contact the skin prior to laser beam emission

"In-Motion" Technique:

- Move the handpiece on the surface of the skin and, only when the handpiece is in full contact and "in-motion", then trigger the footswitch.
- Move the handpiece inside the market grid at an average speed of 5 cm/sec (single pass).

- The module should always be in constant movement, where the **In-Motion** principle is to move the module away from the “hot” spot/area to the neighboring “colder” spot area.
 - After completing the recommended number of kJ’s, move to the adjacent marked grid and repeat as above.
12. If the hair density of the treatment area is high and the hair color is dark, the speed of the In-Motion circular motion should be increased: make sure to use effective cooling means.
13. The patient should report comfortable tolerable heat sensation in the treated area during the procedure. If patient is reporting discomfort, reduce fluence by 1 J/cm^2 .
14. Add cold gel to the treatment grid area as required.
15. Occasionally examine the treatment site for a change in skin color and morphological changes around the follicles (erythema/edema). The smell of burnt hair may sometimes be detected, although absence of this phenomenon does not necessarily indicate that the present fluence is ineffective.
16. Clinical end-points: erythema, hyperemia, perifollicular erythema and edema.
17. If adverse skin effects occur (such as excessive reddening) before good follicular response is achieved, decrease fluence by 5-10% to reduce the aggressiveness of the treatment.
18. If the skin shows no end points and no morphological changes are observed, you may raise the fluence by 5-10% until the desired effect is achieved.
19. After treatment it is recommended to cool the area immediately.

Warning

The light emitted by the Soprano^{Lite} laser system is capable of causing serious eye damage or blindness. For maximum safety, metal goggles must be worn by the patient for all facial treatments.

Treatment Parameters SHR Mode

The Soprano^{Lite} system is equipped with a set of SHR application mode settings. Once the desired treatment area is selected from the system's touch screen, the screen displays the recommended preset parameters of fluence (expressed in J/cm²), total energy (expressed in kJ), treatment time (expressed in seconds) and number of grids. These presets are based on successful results obtained by experienced operators. In addition, operators can adjust and set their own parameter values.

The SHR application mode treatment parameters consist of laser energy (Fluence), accumulative energy (kJ) and a high repetition rate. For each treatment in SHR mode, the fluence and total energy parameters can be adjusted by the operator.

At a fluence of up to 10 J/cm², the pulse repetition rate is fixed at 10 Hz.

Suggested Setup Parameters for SHR Mode

	1.2 cm² handpiece	2 cm² handpiece			
Skin Type Fitzpatrick I-VI*	Fluence (J/cm²)	Grid Size (cm²)	Accumulative Energy (kJ)	Grid Size (cm²)	Accumulative Energy (kJ)
I-III	8-10	150	8-10	300	12-20
IV	6-8	150	8-10	300	12-20
V	5-7	150	7-9	300	12-18
VI *Must patch test	5	150	7-9	300	12-18

- Skin test must be done before first treatment with any mode on the intended treatment area.
- It is recommended to wait 15 min for skin types I-III and 30 min for skin types IV-VI in SHR mode.
- New settings for each subsequent treatment should be based on hair and skin clinical findings of the previous treatment
- No waxing, plucking, threading, bleaching or chemical depilatories prior to or in-between treatments.
- For very dense areas lower the fluence and assess skin reaction
- No external cooling, cryo or Zimmer recommended with SHR Mode
- All fluencies are based on patient tolerance and skin reaction Do not increase fluence if there has been ANY adverse skin reaction at lower setting

SHR Mode—Suggestions for Treating Thin, Light Colored Hair

The Soprano^{Lite} System delivers laser energy at a fluence of up to 20 J/cm².

For patients with skin types I-IV with thin, vellus, light colored hair, it is advisable to increase the fluence to over 10 J/cm² in order to apply maximal damage to this type of hair. For patients with light skin types, the lighter the hair color and the thinner the hair in the desired treatment area, the higher the selected fluence (J/cm²) should be.

The operator should be aware that at a fluence of 10-20 J/cm², the pulse repetition rate reduces as the fluence increases. At fluence settings between 10-20 J/cm², the pulse repetition rate is reduced as the fluence increases according to the following table:

Fitzpatrick Skin Type	Fluence (J/cm ²)	Repetition Rate (Hz)
I-III	20	5
I-III	18	6
IV	16	6
IV	14	7
IV	12	8

Note:

It is not recommended to treat hair that is lighter than the surrounding skin.

SHR Stack Mode

The Soprano^{Lite} System is equipped with a set of SHR Stack sub-mode application settings. These presets are based on successful results obtained by experienced users. In addition, the users can select and set their own parameter values.

The SHR Stack sub-mode application is available at a fluence of up to 10 J/cm² and a fixed repetition rate of 10 Hz.

Suggested Setup Parameters for SHR Sub-Mode*

Skin Type (Fitzpatrick I-VI)	Fluence (J/cm ²)	# of Stacks per Pulse	Accumulative Energy (kJ)
I	8	5	3-4
II	7	5-4	3-4
III	7	4	3-4
IV	6	4-3	3-4
V	5	3	2.5-3.5
VI	5	2	2-3

(*) Based on ~50 cm² area

- Skin test must be done before the first treatment.
- New settings of each subsequent treatment should be based on hair and skin clinical findings of the previous treatment.
- All fluences are based on patient tolerance and skin reaction. Do not increase fluence if there has been ANY adverse skin reaction at a lower setting.

SHR Stack Sub- Mode — with the Tapered Lightguide Adaptor



Suggested Setup Parameters for SHR Sub-Mode — with the Tapered Lightguide Adaptor

Skin Type	Fluence (J/cm ²)	Stacked Pulses	Passes
I-III	7-8	3-4	2-3
IV	6-7	2-3	2-3
V-VI	5-6	2-3	2-3

- Suggested settings refer to lasing of 1-3 hair follicles.
- **Stationary** mode only.
- Skin test must be done before the first treatment.
- New settings of each subsequent treatment should be based on hair and skin clinical findings of the previous treatment.
- All fluences are based on patient tolerance and skin reaction. Do not increase fluence if there has been **ANY** adverse skin reaction at a lower setting.

LHR MODE

HR Mode Skin Test

Fluence is critical to optimize the treatment efficacy and minimize any expected side effects. Always perform a skin test on the intended treatment area during the first treatment session according to the following parameters:

HR Mode Skin Test Parameters

Skin Type	Pulse Type	Hair Type	Fluence (J/cm ²)
I	I	Coarse/Dark Fine/Light	45J 35J
II	I	Coarse/Dark Fine/Light	40J 30J
III	II	Coarse/Dark Fine/Light	35J
IV	III	Coarse/Dark Fine/Light	30J
V-VI	IV or V	All must undergo a patch test	15J

- All skin tests and treatments must be done with Zimmer (Cryo 5).
- Patch test must be done before the first treatment.
- New settings for each subsequent treatment should be based on hair and skin clinical findings of the previous treatment.
- It is recommended to wait 30 minutes for skin types I-III and 45 minutes for skin types IV-VI.

Topical Anesthesia

Due to the unique BlendMode capabilities and the DualChill Technique incorporated into the Soprano^{Lite} diode laser module, the procedure can be administered without topical anesthesia. However, there may be patients who prefer to undergo the treatment using a topical anesthetic (such as Emla®) which renders the procedure without any sensation.

Topical anesthetics are generally applied for a period of time (up to 1 hour) prior to treatment. Be certain to remove all of the topical anesthetics prior to treatment.

Any use of topical anesthesia is at the physicians discretion, and should be used according to the manufacturer's recommendation.

Warning

No waxing, plucking, threading, bleaching or chemical depilatories prior to or in-between treatments.

Treatment HR Mode

In order to enter **HR** mode, press the **HR** button located in the upper left corner of the **Treatment Area Selection** screen.

The default fluence and pulse repetition rate parameters are displayed on each **Pulse Type Program** screen. These parameters can be adjusted by the operator when the system is in **Standby** mode.

Treatment can begin after the treatment parameters are selected (**Pulse Type**, **Fluence** and **Pulse Repetition Rate**).

1. Ensure that the patient is lying comfortably with eye protection in place. All personnel in the treatment room should wear appropriate eye protection as well. The operator should have good access to the treatment area and to the controls of the Soprano^{Lite} system.
2. Clean the skin to remove perfumes, cosmetics and sunscreens.
3. Press the **Reset** softkey to reset the pulse counter.
4. Choose the appropriate settings (**Application Mode, Pulse Type, Fluence and Rep Rate**). Once the parameters are chosen, the operator may choose to save these settings. This enables the operator to use these settings for groups of patients with similar characteristics who visit the practice.
5. Verify that the handpiece tip is cold.
6. Place the handpiece perpendicular to the skin and establish contact with the skin. Press the tip against the skin with moderate pressure to make good contact.

Warning

It is important to contact the skin prior to laser beam emission

7. Always perform a skin test to establish the cutaneous reaction when beginning treatment.
8. Carefully diagnose the skin test.
9. If the pulse has had the desired effect, continue treatment with the same parameters.
10. Start treatment by simultaneous activation of the handpiece trigger and the footswitch.
11. Occasionally examine the treatment site for a change in skin color and morphological changes around the follicles (erythema/edema). The smell of burnt hair may sometimes be detected, although the absence of this phenomenon does not necessarily indicate that the present set of parameters is ineffective.
12. If adverse skin effects occur (such as excessive reddening) before good follicular response is achieved, adjust the treatment parameters to reduce the aggressiveness of the treatment. Aggressiveness may be reduced by either decreasing the fluence by 5-10% or by changing the pulse type to a less aggressive one (moving to a higher pulse type).
13. If the skin shows no adverse effects and no morphological changes are observed, you may raise the energy by 5-10% until the desired effect is achieved.
14. After treatment it is recommended to cool the area immediately

Note:

It is not recommended to treat hair that is lighter than the surrounding skin.

Treatment Parameters HR

The Soprano^{Lite} system is equipped with a set of **HR** application mode settings. These presets are based on successful results obtained by experienced users. In addition, users can select and set their own parameter values.

The HR application mode treatment parameters consist of laser pulse parameters (**Pulse Type Program**) and laser energy (**Fluence**). For each treatment with the LHR mode, these parameters are to be set by selecting one of the two pulse type programs, and then selecting the treatment fluence and repetition rate.

Suggested Setup Parameters for HR Mode

Skin Type	Pulse Type	Hair Type	Fluence (J/cm²)
I	I	Coarse/Dark Fine/Light	45–50J 35–45J
II	I	Coarse/Dark Fine/Light	40–45J 30–40J
III	II	Coarse/Dark Fine/Light	35–50J 35–45J
IV	III	Coarse/Dark Fine/Light	30–45J 30–40J
V-VI	IV or V	All must undergo a	15–25J

- **Zimmer (Cryo 5) is recommended in HR mode.**
- Patch test must be done for the first treatment. It is recommended to wait 30 min for skin types I-III and 45 min for skin types IV-VI in HR mode.
- New settings for each subsequent treatment should be based on hair and skin clinical findings of the previous treatment.
- All fluencies are based on patient tolerance and skin reaction. Do not increase fluence if there has been **ANY** adverse skin reaction at a lower setting.

Post-Treatment Care

Cold (not frozen) packs should be applied immediately post-treatment to cool the treatment site, reduce swelling and ease discomfort. Pre-chilled 10x10 cm gauze pads, previously soaked with water may be used.

Care should be taken to prevent trauma to the treated area for the first four or five days following the treatment: avoid hot baths, aerobic exercise, massage, etc.

- **Exposure to Sunlight**—patients should apply high-factor sun protection (SPF>30), and protect the treated area from exposure to direct sunlight for at least one month post-treatment. Tanning after treatment sessions may enhance melanin regeneration, which may result in hyper-pigmentation.
- **Makeup**—makeup may be applied on the day following treatment unless blistering or crusts develop. Since the skin is sensitive during this period, take special care while removing makeup to avoid damage to the skin, which can predispose the site to infection.
- **Other Post-Treatment Recommendations**—if the treatment site is exposed to dirt, it should be covered with a dressing for ten days. Patients should be advised not to participate in rough sports or similar activities for several days following the treatment, until the skin returns to its normal condition.

Concluding Treatment

Determining when treatment should be concluded is left to the discretion of the professional staff, or to the patient achieving satisfaction with the treatment results.

Follow-Up

Measures presented below are only the manufacturer's recommendation for follow-up. They may serve as a basis for defining your treatment regimen.

- Patients should return for examination of the treatment site between six to eight weeks after the treatment and for additional treatment, if necessary.
- If no additional treatment is necessary, the patient should return for an additional re-examination three to four months later, or when any new hair has grown in the treatment area.
- If there has been partial hair clearance, treatment should be continued and the patient should return between six to eight weeks for examination and for additional treatment, if necessary.

- If no change is noted, treatment parameters should be changed. With multiple treatments, increase the time intervals between treatment sessions (after the second one), to allow any new hair to grow in the treatment area. New growth will vary based on the body area (growth cycle) and on the individual patient (gender, hormonal problems, etc.)
- Patients should be instructed to avoid sun exposure after and in between treatments.

All adverse side effects should be reported to the treating physician with a follow-up report sent to the Director of Clinical Operations at Alma Lasers.

Alma Lasers, Inc.

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Section 6: Forms

- **Sample Medical History Form**
- **Sample Soprano^{Lite} Consent Form**
- **Sample Soprano^{Lite} Laser Log**
- **Fitzpatrick Skin Types**
- **Hair Growth Cycle**

Sample Medical History

Name _____
Address _____
Home Phone _____ Business Phone _____
Age _____ Referred by _____

Have you ever had the following?

- Current or history of cancer, especially malignant melanoma or recurrent non-melanoma skin cancer, or pre-cancerous lesions such as multiple dysplastic nevi.
- Any active infection.
- Diseases which may be stimulated by light at 515 nm to 1200 nm, such as history of recurrent Herpes Simplex, Systemic Lupus Erythematosus, or Porphyria.
- Use of photosensitive medication and/or herbs that may cause sensitivity to 515 - 1200 nm light exposure, such as Isotretinoin, tetracycline, or St. John's Wort.
- Immunosuppressive diseases, including AIDS and HIV infection, or use of immunosuppressive medications.
- Patient history of Hormonal or endocrine disorders, such as polycystic ovary syndrome or diabetes, unless under control.
- History of bleeding coagulopathies, or use of anticoagulants
- History of keloid scarring.
- Very dry skin.
- Exposure to sun or artificial tanning during the 3-4 weeks prior to treatment.

Are you pregnant? _____

What medications are you taking (including aspirin)? _____

Daily consumption of alcohol _____

Allergies: _____

Are you taking any herbal preparations? (St. John's Wort, etc.) _____

If yes, list _____

Do you wear contact lenses? _____

Skin type (when exposed to the sun **without protection** for about 1 hour)

always burns, never tans _____

always burns, sometimes tans _____

sometimes burns, sometimes tans _____

always tans _____

Hispanic, Asian, Mediterranean, Middle Eastern _____

Black _____

When were you last exposed to the sun (including tanning booth)? _____

Do you use chemical sun tanning lotions? _____

Are you planning a holiday in the sun? _____

Reason for visit (area to be treated) _____

Prior treatment (if any) _____

*Sample Informed Consent

*This is only a sample and should be modified for the treatment performed.

Warning: The sample Informed Consent provided by Alma Lasers, Inc should be used by the Physician in the context of his or her experience and the laws of the state in which he or she practices.

Informed Consent Soprano^{Lite} Hair Removal

Patient name _____

Treatment sites _____

I duly authorize _____ to perform the Soprano^{Lite} Laser Hair Removal procedure and any other measures which in their opinion may be necessary.

I understand that the Soprano^{Lite} is a device used for laser hair removal and that clinical results may vary in different skin types and hair types. I understand there is a possibility of short-term effects such as reddening, blistering, scabbing, temporary bruising and temporary discoloration of the skin, as well as rare side effects such as scarring and permanent discoloration. These effects have been fully explained to me _____ (patient's initials)

Clinical results may vary depending on individual factors, including medical history, skin and hair type, patient compliance with pre/post treatment instructions, and individual response to treatment. I understand that epilation with the Soprano system is a safe alternative to methods used for removing unwanted hair, such as shaving, waxing, chemical epilation and electrolysis.

I understand that treatment by the Soprano^{Lite} laser hair removal system involves a series of treatments and the fee structure has been fully explained to me _____ (patient's initials)

I certify that I have been fully informed of the nature and purpose of the procedure, expected outcomes and possible complications, and I understand that no guarantee can be given as to the final result obtained. I am fully aware that my condition is of cosmetic concern and that the decision to proceed is based solely on my expressed desire to do so.

I confirm that I am not pregnant at this time, and that I have not taken Accutane within the last 6 months.

I consent to the taking of photographs and authorize their anonymous use for the purposes of medical audit, education and promotion.

I certify that I have been given the opportunity to ask questions and that I have read and fully understand the contents of this consent form.

Patient Signature_____

Date_____

Witness Name _____ Signature_____

Date_____

(Sample Laser Log)

SOPRANO^{Lite} LASER LOG

Date: _____

Patient: _____

Doctor: _____

Laser Operator: _____

Procedure: _____

Fitzpatrick Skin Type: I II III IV V VI

Medical History completed: Yes No

Laser:

Soprano^{Lite} SHR _____ **Soprano^{Lite} HR** _____

Soprano^{Lite} SHR Settings:

Joules: _____ Kj's _____ Hz 10Hz

Soprano^{Lite} HR Settings:

Pulse Type: _____ Joules: _____ Hz: _____

Laser Safety Checklist followed? Yes No If no, explain:

Notes: _____

Signature: _____

Fitzpatrick Skin Types	Example	Tanning
I		Never tans Always burns
II		Occasionally tans Usually burns
III		Tans on average Sometimes burns
IV		Usually tans Rarely burns
V		Mostly tans Almost never burns
VI		Never burns

The Hair Growth Cycle

When performing photo-epilation, it is important to keep the hair growth cycle in mind.

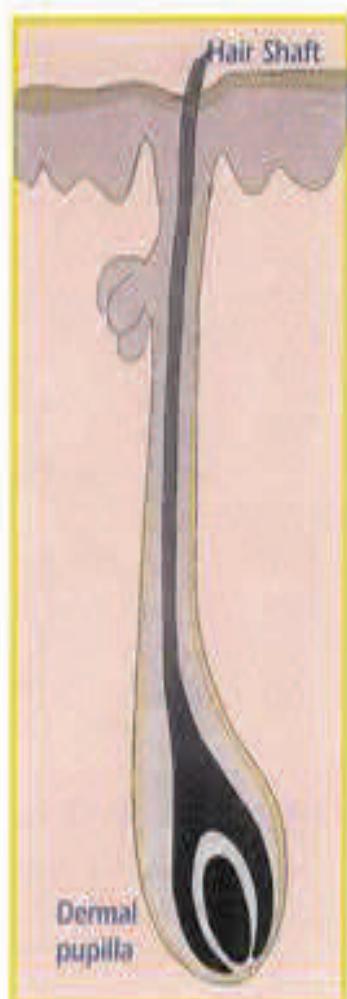
The hair growth cycle consists of three stages of growth:

Anagen—active growth

Catagen and Telogen—various stages of dormancy/testing (no growth)

At any given time, a patient's hair can be at all of these three stages of the growth cycle. Only hairs in the Anagen active growing stage are successfully treated by photo-epilation. The hair in the Catagen and Telogen stage of growth at the time of treatment will later enter the Anagen stage and appear as "new growth." This is the reason that hair removal generally requires more than one treatment. It is important to explain this to patients.

Anagen Stage



Catagen Stage



Telogen Stage



Body Area	% Anagen Hair	Telogen Stage	Follicles density (1/cm ²)
Beard	70	10 weeks	500
Upper Lip	65	6 weeks	500
Axillae	30	3 months	65
Pubic Area	30	12 weeks	70
Arms	20	18 weeks	80
Legs and Thighs	20	24 weeks	60
Breasts	30	n/a	65

Section 7: Safety Issues

1. Eyewear – when using the 810nm diode laser, it is very important that appropriate protective eyewear be provided for staff and patient. The light can cause severe eye damage.

Note:

When using 810nm diode laser, it is essential that everybody in the room wears the appropriate eyewear - this is a laser and the light can be absorbed in the cornea or retina and cause irreversible damage

2. Treatment area should be shaved prior to treatment.
3. The appropriate sign should always be posted on the door.
4. Make sure that the staff is aware of the emergency shut off button.
5. The staff and physician are encouraged to read all the materials accompanying the **Soprano^{Lite}** and specifically the operator's manual.
6. A complete medical history of each patient should be routine to determine if the patient is taking any medications that would affect their response or if there are any conditions that are contraindicated.
7. Do not use **Soprano^{Lite}** in the presence of explosives or other flammable materials.
8. Never permit reflective objects such as jewelry, watches, surgical instruments or mirrors to intercept the laser.
9. Do not expose any skin except the test and treatment area to the laser.
10. Make sure that the windows are well covered to avoid exposure to the laser outside the clinic.
11. Do not leave the key in an unintended system.

Notes: