HARMONY®XL

The Leader in Expandable
Multi-Application Technology

MODULES OPERATOR'S MANUAL

Alma Lasers™
Wellbeing Through Technology®

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Scope of This Manual

This manual provides a description, technical specifications, operating instructions, ordering information and clinical guides for the Harmony^{XL} modules in the following chapters:

Chapter	Module Name	Wavelength	Clinical Applications
1	**Introduction**		
2	**High Power UV Module**	300 – 380nm	Psoriasis and Vitiligo
3	**Acne Module**	420 – 950nm	Acne clearance
4	**SVL Module**	515 – 950nm	Superficial vascular lesions
5	**VP Module**	540 – 950nm	Vascular and Pigmented lesions
6	**SR Module**	570 – 950nm	Skin rejuvenation
7	**HR Module**	650 – 950nm	Hair removal
8	**ST Module**	NIR	Scar revision and treatment of striae
9	**LED Module**	Yellow	• Increased blood flow, muscle relaxation & pain relief • Treatment of rhytids, fine lines and wrinkles [1]
10	**SVL Module (cooled)**	515 – 950nm	Superficial vascular lesions
11	**VP Module (cooled)**	540 – 950nm	Vascular and Pigmented lesions
12	**SR Module (cooled)**	570 – 950nm	Skin rejuvenation
13	**SSR Module (cooled)**	540 – 950nm	Skin rejuvenation ("S" mode)
14	**SHR Pro Module (cooled)**	• 650 – 950nm • NIR	• Hair removal • Long-term or permanent hair reduction ("S" mode)
15	**SST Module (cooled)**	NIR	Scar revision and treatment of striae ("S mode)
16	**Laser QS 1064/532nm Module**	1064nm & 532nm	Tattoo removal, deep pigmented lesions

[1] In Canada

17	**Laser 1064nm Module**	1064nm	Vascular lesions, leg veins, hair removal and PFB
18	**Laser 1320nm Module**	1320nm	Wrinkles and acne scars
19	• **Pixel Pro Module** • **Laser 2940nm (Low Power) Module**	2940nm	Fractional ablative skin resurfacing
20	**Alex 755 Laser Module**	755nm	Hair removal and Pigmented Lesions

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CHAPTER 1
Introduction

Chapter Contents:

1.1. Scope of This Manual

The purpose of this manual is to offer the Harmony^{XL} operator all of the information required to operate the system and its modules in a safest and most efficient manner.

This manual and the Modules manual have been prepared to aid medical and technical personnel to understand and operate the system. Do not operate the system before reading this manual, the Modules Manual and gaining a clear understanding of system operation. If any part of these manuals is not clear, please contact your Alma Lasers representative for clarification.

Warning

Use of controls or adjustments, or performance of procedures other than those specified herein may put the operator and/or the patient at risk. Therefore, before attempting to use or operate the system, personnel operating the Harmony^{XL} system should read this manual and the Modules Manual, and become thoroughly familiar with all its safety requirements and operating procedures.

The information provided in these manuals is not intended to replace the professional training on the clinical use of the system. Please contact your Alma Lasers representative for current information on available training. For clinical information, refer to the Clinical Guide chapters in the Modules Manual, which include set up guidelines for each application.

These manuals should always accompany the system and all operating personnel must know their location. Additional copies of these manuals are available from Alma Lasers or your local Alma Lasers representative.

Warning

Any laser or pulsed light-emitting device can cause injury if used improperly. High voltages are present inside the Harmony^{XL} system. Personnel who work with lasers or pulsed light sources must always be aware of the possible dangers and must take the proper safeguards as described in the **Safety** chapter of the System manual.

1.2. Module Specifications

The tables on the following pages present the technical specifications of each of the Harmony^{XL} system's modules.

Each of the following chapters in this manual is dedicated to a particular module offering appropriate descriptions, operating instructions, specifications, ordering part numbers and clinical guidance.

1.2.1. AFT, UV, NIR & LED 6.4 cm^2, Non-Laser, Non-Cooled Modules

Module	Applications	Technology	Wavelength (nm)	Pulse Widths / Timers	Spot Size (cm^2)	Pulse Repetition Rate (Hz)	Energy Density (J/cm^2)
High Power UV	Pigment restoration	Pulsed UV	300 – 380	30, 40, 50 msec	6.4	1/2	2000 – 5000 mJ/cm^2
Acne	Acne clearance	AFT	420 – 950	30, 40, 50 msec	6.4	1/2	5 – 25
SVL	Superficial vascular lesions	AFT	515 – 950	10, 12, 15 msec	6.4	2/3	5 – 25
VP	Vascular and pigmented lesions	AFT	540 – 950	10, 12, 15 msec	6.4	2/3	5 – 25
SR	Skin rejuvenation	AFT	570 – 950	10, 12, 15 msec	6.4	2/3	5 – 25
HR	Hair removal	AFT	650 – 950	30, 40, 50 msec	6.4	2/3	5 – 25
ST	Scar revision & Treatment of Striae	Pulsed NIR	NIR	10, 30 & 90 seconds	6.4	2	1 – 7
LED	Various skin conditions	LED	Yellow	Pulsed / CW	N/A	N/A	N/A

1.2.2. AFT 3 cm^2, Non-Laser, Cooled Modules

Module	Applications	Technology	Wavelength (nm)	Pulse Widths / Timers	Spot Size (cm^2)	Pulse Repetition Rate (Hz)	Energy Density (J/cm^2)
SVL	Superficial vascular lesions	AFT	515 – 950	10, 12, 15 msec	3	2/3	5 – 30
VP	Vascular and pigmented lesions	AFT	540 – 950	10, 12, 15 msec	3	2/3	5 – 30
SR	Skin rejuvenation	AFT	570 – 950	10, 12, 15 msec	3	2/3	5 – 30
HR[1]	Hair removal	AFT	650 – 950	30, 40, 50 msec	3	2/3	5 – 30

1.2.3. 'S' Mode 3 cm^2, Cooled Modules

Module	Applications	Technology	Wavelength (nm)	Timers	Spot Size (cm^2)	Pulse Repetition Rate (Hz)	Energy Density (J/cm^2)
SSR	Super skin rejuvenation	In-Motion AFT	540 – 950	1, 3 & 30 seconds	3	2	1 – 15
SHR[1]	Super hair removal	In-Motion AFT	NIR	1, 3 & 30 seconds	3	3	1 – 7
SST	Scar revision & Treatment of Striae	In-Motion AFT	NIR	1, 3 & 30 seconds	3	5	0.5 – 3.5

[1] The cooled HR and cooled SHR are two modules in one: **Cooled SHR Pro**, incorporating two technologies. Refer to Chapter 14.

1.2.4. Laser Modules

Module	Applications	Technology	Wavelength (nm)	Pulse Width / Mode	Spot Size	Pulse Frequency (Hz)	Energy Density / Fluence / Depth
Laser QS 1064 / 532nm	Tattoo removal	Q-Switched Nd:YAG	1064	20 nsec	1, 2, 3, 4, 5, 6 mm	1, 2, 5	400 – 1200 mJ/p
	Tattoo removal, deep pigmented lesions	Q-Switched Nd:YAG	1064	20 nsec	5 x 5 Pixels	1, 2, 5	400 – 1200 mJ/p
	Tattoo removal	FD Q-Switched Nd:YAG	532	20 nsec	2 mm	1, 2, 5	400 – 1200 mJ/p
Laser 1064nm	Vascular lesions	Nd:YAG	1064	10 msec	2 mm	1	30 – 450 J/cm^2
	Leg veins	Nd:YAG	1064	15, 45, 60 msec	6 mm	1	30 – 150 J/cm^2
	Hair removal	Nd:YAG	1064	15 msec	10 mm	1	20 – 50 J/cm^2
Laser 1320nm	Wrinkles and acne scars	Nd:YAG	1320	30, 40, 50 msec	6 mm	1	5 – 40 J/cm^2
Pixel Pro (2940nm)	Fractional ablative skin resurfacing	Er:YAG	2940	Short, Medium, Long	7 x 7 Pixels 9 x 9 Pixels 1 mm 4 mm	5	Short: 300-1200 mJ/P Medium: 600-1800 mJ/P Long: 800-2500 mJ/P
Laser 2940nm	Fractional ablative skin resurfacing	Er:YAG	2940	Short, Medium, Long	7 x 7 Pixels 9 x 9 Pixels 1 mm 4 mm	5	Short: 600-800 mJ/P Medium: 600-1000 mJ/P Long: 600-1400 mJ/P
Alex 755nm	Hair removal	Alexandrite	755		5 mm	2, 4	1 – 32 J/cm^2
	Pigmented lesions	Alexandrite	755		10 mm	2, 4	1 – 8 J/cm^2

CHAPTER 2

High Power UV Module – Psoriasis & Vitiligo

Chapter Contents:

2.1. UV Module Description

The **UV** module has an ultraviolet high-power targeted phototherapy module which uses spectral irradiance in the ultraviolet waveband to target and treat large and small areas while avoiding exposure to healthy skin.

A complete discussion of the UV module clinical applications may be found in Section 2.6.

The UV module has a violet identification section (see Figure 2-1).

Figure 2-1: UV Module (Violet Color Code)

2.2. UV Module Specifications

- **Light Source:** High-pressure xenon lamp
- **Spectrum:** 300 – 380nm
- **Energy Density (Fluence):** 2000 – 5000 mJ/cm^2 adjustable in 100 mJ/cm^2 increments
- **Treatment Area (spot size):** 40 x 16 mm (6.4 cm^2)
- **Pulse Duration:** 30, 40, 50 msec.
- **Pulse Repetition Rate:** 1/2 Hz.

2.3. UV Module Operating Screen

The **UV** module main operating screen (see Figure 2-2) is displayed when the UV module is connected to the system:

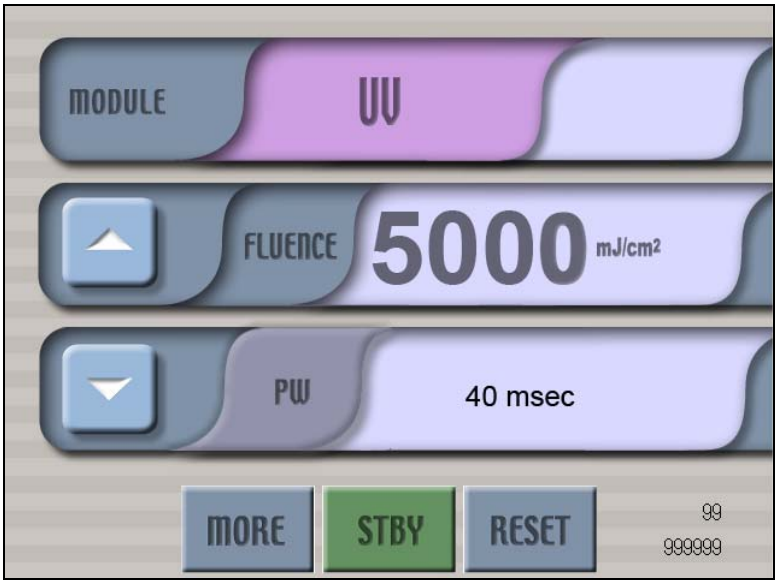

Figure 2-2: UV Module Operating Screen

Operating parameters available in this module:

1. **Fluence** – the available fluence range is from 2000 to 5000 mJ/cm^2 in increments of 100 J/cm^2.
2. **Pulse Width** – three pulse widths are available:
   - 30 ms
   - 40 ms
   - 50 ms

2.4. UV Module Regulatory Labels

Figure 2-3 presents the regulatory identification and caution labels adhered to the UV module connector:

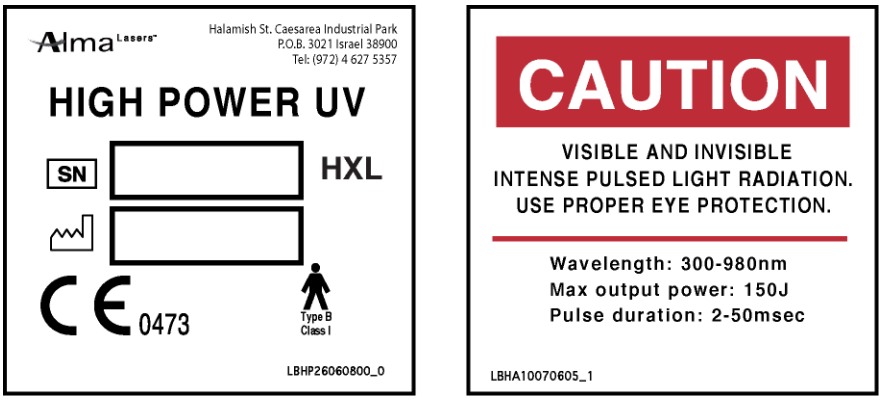

Figure 2-3: UV Module Regulatory Labels

2.5. Ordering Information

The following table offers names and part numbers of accessories specific to the UV module that may be ordered form Alma Lasers.

Table 2-1: UV Module Accessories

Description	*Part No.*
UV (Ultraviolet) Module	AAIP24060801
Masking Templates Set for UV Module	AAIP08110402
UV Safety Glasses 100% UV Protection	OPIP30010501

2.6. UV Module Clinical Guide

The Harmony^{XL} **High Power UV Module** emits light in the **300-380nm** range and is intended for use in all skin types to treat psoriasis, atopic dermatitis (eczema), seborrheic dermatitis and leukoderma - including vitiligo (acquired leukoderma), and hypopigmented skin presenting in striae (stretch marks), post-surgical scars, traumatic scars, acne scars, grafted skin, burn scars, laser skin resurfacing, chemically peeled skin, etc.

Warning

The appropriate protective eyewear should be worn by both the operator and the patient when using this module.

2.6.1. Pre-Treatment

2.6.1.1. Assessing the Condition

The treatment parameters for any given skin condition depend on the lesion type, skin type, depth and density of the lesion to be treated.

2.6.1.2. UV Light Source Indications

The UV Light source (300-380nm) is indicated for:

- The treatment of leukoderma, including vitiligo (acquired leukoderma)
- The treatment of psoriasis, atopic dermatitis (eczema), and seborrheic dermatitis
- Use on all skin types (Fitzpatrick I-VI), including tanned skin

2.6.1.3. UV Light Source Contraindications

- Tanned skin (active tan) through sun exposure in the past 2 weeks or tanning bed use in the previous 30 days
- Active herpes simplex, etc. at the treatment site
- Skin cancer or any other cancer and/or any cancer drug therapy (such as Ducabaxine, Fluorouracil, Methotrexate, etc.)
- History of keloid scarring
- Epilepsy
- UV photosensitivity (e.g., xeroderma pigmentosum)

- Pregnancy; until menstruation returns and end of breast feeding
- Diabetes (because of increased possible photosensitivity and poor wound healing)

2.6.1.4. Minimal Erythema Dose (MED) Test

For an effective treatment, light fluence to a psoriatic lesion should be sufficiently high to induce visible erythema, without adverse side effects to the healthy skin. However, in order to select the appropriate initial fluence for a treatment, the operator should perform a MED test a day or two before therapeutic treatment as follows:

1. Select an uninvolved area of healthy, untanned skin (e.g. upper buttocks/lower back).
2. Using the MED template provided, expose a series of test spots according to skin type, as indicated in Table 2-2.
3. Evaluate the test spots 24 hours following exposure.
4. To determine the patient's MED, identify the lowest dose test spot that exhibits a definitively bordered and uniform slight redness.

Table 2-2: Proposed Range of MED Test Spot Fluence (mJ/cm^2) for the UV Module

Test Spot #	Skin Type I – II	Skin Type III – IV	Skin Type V – VI	Waiting Period
1	2000	2200	2400	24 hours
2	2100	2300	2500	24 hours
3	2200	2400	2600	24 hours
4	2300	2500	2700	24 hours
5	2400	2600	2800	24 hours
6	2500	2700	2900	24 hours

Note

In vitiligo and re-pigmentation reduce the energy by 15%-20%.

2.6.2. Treatment

1. Clean the skin to remove perfumes, cosmetics and sunscreens.
2. Begin initial treatment with predetermined fluence, beginning at approximately 70-90% of the MED and increasing the settings in 10-20% increments at each subsequent treatment (in the absence of side effects). Slight erythema is a desired endpoint 20-24 hours after treatment.
3. A treatment mask may be used to protect the healthy skin from unintended UV exposure.
4. Do not apply gel.
5. Place the module perpendicular to the skin and touch the skin. Do not apply pressure.
6. Set the initial fluence parameter according to the skin test results.
7. Trigger a light pulse by pressing the footswitch.
8. Treatment should overlap the healthy skin at the periphery of the treated sites by approximately one or two millimeters.
9. To start, treatments may be administered twice per week for the first two weeks. Subsequent treatments may remain on the same schedule or be given at the frequency of once every other week, according to the operator's discretion.
10. If prominent adverse reactions are noted from the prior treatment, the next treatment may be skipped or the dose reduced until symptoms resolve.
11. After re-pigmentation, additional maintenance treatments may be continued at the same - or reduced - dose and frequency.

2.6.3. Suggested UV Setup Parameters

Table 2-3: Suggested UV Setup Parameters

Skin Type (Fitzpatrick I – VI)	*Module*	*Pulse Width (msec)*	*Fluence (mJ/cm^2)*	*Comments*
I – II	**UV 300-380nm** (Violet)	30, 40	MED x 0.9	If no adverse effects, increase fluence by 10-20% every 2-3 treatments
III	**UV 300-380nm** (Violet)	30, 40	MED x 0.8	If no adverse effects, increase fluence by 10-20% every 2-3 treatments
IV – VI	**UV 300-380nm** (Violet)	50	MED x 0.7	If no adverse effects, increase fluence by 10-20% every 2-3 treatments

2.6.4. Vitiligo & Re-Pigmentation

The approach to the treatment with the UV module is similar to that of Psoriasis.

- The treatment doses are gradually increased during the course of treatment in various increments. The initial dose and the increments depend on the body location, skin type and skin response.
- The number of sessions is dependent on the body location. Areas that usually respond well, such as the face, neck and bikini line require fewer treatment sessions. Skin types that respond well are usually dark skin (IV-V).
- Re-pigmentation improvement scale should be evaluated using the following clinical scale: complete, moderate, mild, and none.
- Number of session treatments per week: **2**
- Duration of the treatments: 6-10 weeks (this average range may depend on the rate and extent of improvement).

Table 2-4: Initial Treatment Parameters for Vitiligo and Re-Pigmentation

Treatment Area	***Starting Dosage (mJ/cm^2)***	**Resultant Erythema <24 hours after treatment, fluence should be <u>increased</u> by:**	**Resultant Erythema 48-60 hours after treatment, fluence should be <u>decreased</u> by*:***	**Resultant Erythema 60-72 hours after treatment, postpone the next treatment and <u>decrease</u> fluence by*:***
Periocular	2000	5%	5%	10%
Face, scalp, ear, neck, axilla, bikini	2000	10%	10%	15%
Arm, leg, trunk	2000	15%	15%	20%
Wrist	2200	15%	15%	20%
Elbow	2200	20%	20%	25%
Knee	2200	20%	20%	25%
Hand, feet	2300	20%	20%	25%
Finger, toe	2500	20%	20%	25%

2.6.5. Follow-up

- After treatment there is typically mild erythema. At higher fluences blistering can occur, mimicking a severe sunburn reaction. If any blistering or erosions occur, the area should be covered with antibiotic ointment or hydrophilic petrolatum until healed.
- Avoid exposure of the skin to UV (sun exposure or the use of tanning beds) or self-tan for at least 2 weeks
- Avoid picking or scratching the treated area
- Avoid rough handling of the area treated
- Avoid very hot baths / showers / steam baths / sauna
- Avoid exfoliating or peels for 1 week
- Avoid rough sports for 24-48 hrs
- Avoid wearing tight clothing
- Keep the area clean and dry
- Hydrate the body by drinking plenty of water
- Use sun block of at least SPF 30+
- 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:

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CHAPTER 3

Acne Module – Acne Clearance

Chapter Contents:

3.1. Acne Module Description

The **Acne** module has a high-power targeted phototherapy module for clearance of inflammatory acne. It employs Alma Laser's proprietary AFT pulsed light technology in the blue wavelength range (420-950nm) along with adjustable parameters to permeate the tissue and reach the P.acnes target.

A complete discussion of the Acne module clinical applications may be found in Section 3.6.

The Acne module has a blue identification section (see Figure 3-1).

Figure 3-1: Acne Module (Blue Color Code)

3.2. Acne Module Specifications

- **Light Source:** Pulsed light with AFT and EDF
- **Spectrum:** 420 – 950nm
- **Energy Density (Fluence):** 5 – 25 J/cm^2
- **Treatment Area (spot size):** 6.4 cm^2
- **Timers:** 30, 40 & 50 msec
- **Pulse Repetition Rate:** 1/2 Hz
- **Cooling:** None

3.3. Acne Module Operating Screen

The **Acne** module main operating screen (see Figure 3-2) is displayed when the Acne module is connected to the system:

Figure 3-2: Acne Module Operating Screen

Operating parameters available in this module:

1. **Fluence** – the available fluence range is from 5 to 25 J/cm^2 in increments of 1 J/cm^2.
2. **Timers** – 30, 40 & 50 msec
3. **Pulse Repetition Rate** – fixed at 1/2 Hz

3.4. Acne Module Regulatory Labels

Figure 3-3 presents the regulatory identification and caution labels adhered to the Acne module connector:

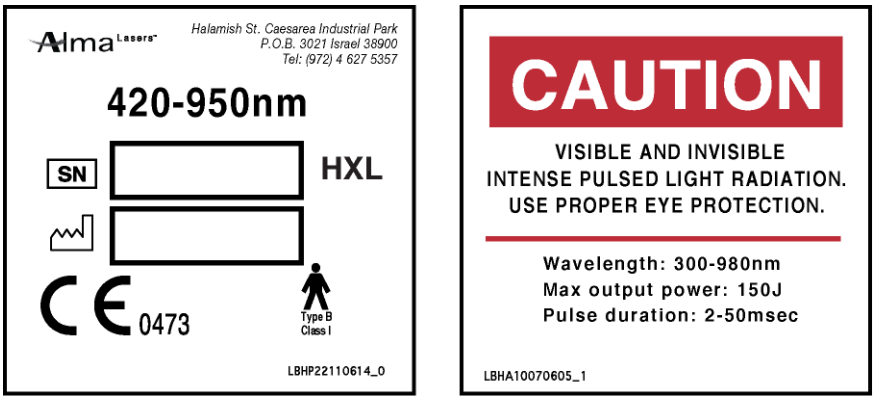

Figure 3-3: Acne Module Regulatory Labels

3.5. Ordering Information

The following table offers names and part numbers of accessories specific to the Acne module that may be ordered form Alma Lasers.

Table 3-1: Acne Module Accessories

Description	*Part No.*
Acne (Super Acne) Module	AAHP02110614
Light Safety Glasses (OD 3+)	OPIP05120501
Dark Safety Glasses (OD 5+)	OPIP05120502

3.6. Acne Module Clinical Guide

The Harmony^{XL} system with the **Acne** (blue color code) module emits visible light in the wavelength range of **420-950nm**. This range targets porphyrins (photo-sensitizers), which are normally produced by the propionibacterium acne (P.acnes). P.acnes are a type of bacteria that colonize inside the sebaceous gland and clog it. A photo-chemical reaction induced by porphyrins, triggered by the 420-950nm wavelength of light, induces the photo excitation process and the destruction of the bacteria.

> ***Warning***
>
> **The appropriate protective eyewear should be worn by both the operator and the patient when using this module.**

3.6.1. Module Operation

The module should be applied to the skin using **Stationary** technique. In this technique the practitioner places the module on the skin for the entire exposure time and fluence conditions. In Stationary technique the module should be positioned in complete contact with the skin and slightly pressed towards the skin. A thin layer of pre-cooled ultrasonic gel should be used during the skin test and the actual treatment on all skin types.

3.6.2. Pre-Treatment

3.6.2.1. Patient Evaluation

Before the treatment, the patient should be evaluated/documented for his/her acne condition, location and type. In addition, acne history that includes medications or other past acne related regimens should be documented.

3.6.2.2. Contraindications

- Tanned skin (active tan) through sun exposure or tanning bed use in the previous 30 days.
- Hypopigmentation (Vitiligo)
- Any inflammatory skin condition e.g., eczema, active herpes simplex, etc., at the treatment site.
- Skin cancer or any other cancer and/or any cancer drug therapy (such as Ducabaxine, Fluorouracil, Methotrexate, etc.).

- History of keloid scarring
- Epilepsy
- St. John's Wort (herbal remedy) for depression in the past three months (because of increased photosensitivity)
- Isotretinoin – Roaccutane in the previous 3-6 months
- Tretinoin – Retin A for the past 2 weeks
- Pregnancy (including IVF)
- Diabetes

The treatment parameters for acne reduction depend on the patient's skin type and the acne lesion type. Therefore, the first steps are assessing the skin type and performing the skin test.

3.6.2.3. Skin Test

Always perform the skin test on the intended treatment area during the first treatment session according to the following parameters and assessment waiting period:

Skin Type (Fitzpatrick I-VI)	***Module***	***Pulse Width (msec)***	***Fluence (J/cm^2)***	***Waiting Period***
I – III	**Acne 420-950nm** (Blue)	30, 40	6 – 8	30 min.
IV – VI	**Acne 420-950nm** (Blue)	50	5	60 min.

3.6.3. Treatment

Treatment can begin after the Acne module has been connected to the Harmony system and the treatment parameters selected (fluence and pulse width) according to the table in Section 3.6.2.3.

1. Clean the skin to remove perfumes, cosmetics and sunscreens.
2. Apply a thin layer (usually 1-2mm thick and 3mm thick for darker skin types) of refrigerated (43-50°F/6-10°C) cooling gel to the treatment site. The gel will provide a thermal sink for the absorbed and reflected energy, provide some cooling to the skin itself, and additional comfort to the patient during treatment.
3. Place the module perpendicular to the skin, pressed lightly to the skin surface ensuring a good seal. It is best not to overlap spots by more than 10%. If overlapping does occur, wait at least one minute between pulses on the same spot.

4. Set the initial fluence parameter according to the skin test results.
5. Trigger a light pulse by pressing the footswitch.
6. Perform one pass (Stationary Mode) on the right side of the face and one pass on the left side. Repeat the passes on each side.
7. Treatments may be administered twice per week over a four week time period (total of 8 treatments).
8. If adverse reactions are observed from the prior treatment, the next treatment may be skipped or the dose reduced until symptoms resolve.
9. It is recommended to cool the area immediately after the treatment (see Appendix B in the System Manual – Post-Treatment Care).

3.6.4. Suggested Setup Parameters

Table 3-2: Acne Suggested Setup Parameters

Skin Type	*Module*	*Pulse Width (msec)*	*Fluence (J/cm²)*
I – III	**Acne 420-950nm** (Blue)	30, 40	8 – 10
IV – VI	**Acne 420-950nm** (Blue)	40, 50	5 – 7

3.6.5. Follow-Up

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

- Patients should be scheduled 48-72 hours after treatment for examination of the treatment site and for additional treatment, if necessary.
- Treatment is complete when satisfactory results are obtained.
- Patients should be instructed to avoid sun exposure after and in between treatments.
- Treatments may be administered twice per week over a four week time period (total of 8 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:

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CHAPTER 4

SVL Module – Superficial Vascular Lesions

Chapter Contents:

4.1. SVL Module Description

The **SVL** module has a high-power targeted phototherapy module for non-invasive treatment of small and shallow vascular lesions. The SVL module allows treatment of a broad spectrum of vascular imperfections be selectively targeting oxyhemoglobin, deoxyhemoglobin and melanin.

A complete discussion of the SVL module clinical applications may be found in Section 4.6.

The SVL module has a turquoise identification section (see Figure 4-1).

Figure 4-1: SVL Module (Turquoise Color Code)

4.2. SVL Module Specifications

- **Light Source:** Pulsed light with AFT and EDF
- **Spectrum:** 515 – 950nm
- **Energy Density (Fluence):** 5 – 25 J/cm^2
- **Treatment Area (spot size):** 6.4 cm^2
- **Available Pulse Widths:** 10, 12, 15 msec
- **Pulse Repetition Rate:** 2/3 Hz
- **Cooling:** None

4.3. SVL Module Operating Screen

The **SVL** module main operating screen (see Figure 4-2) is displayed when the SVL module is connected to the system.

Figure 4-2: SVL Module Operating Screen

Operating parameters available in this module:

1. **Fluence** – the available fluence range is from 5 to 25 J/cm^2 in increments of 1 J/cm^2.
2. **Pulse Width** – three pulse widths are available:
   - 10 msec
   - 12 msec
   - 15 msec
3. **Pulse Repetition Rate** – fixed at 2/3 Hz

4.4. SVL Module Regulatory Labels

Figure 4-3 presents the regulatory identification and caution labels adhered to the SVL module connector:

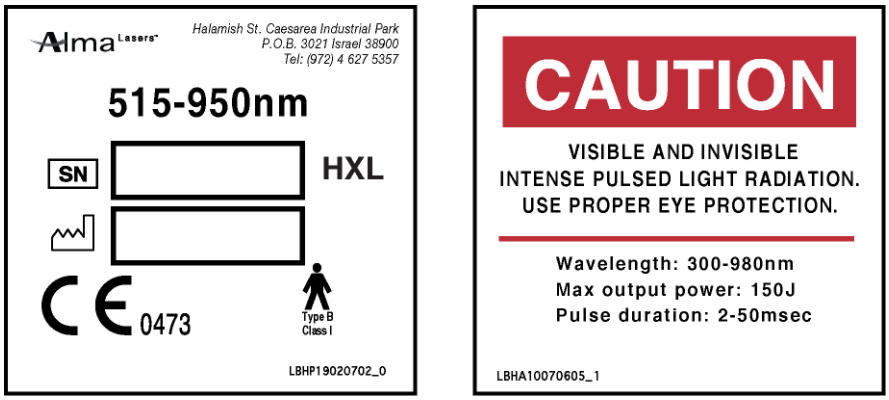

Figure 4-3: SVL Module Regulatory Labels

4.5. Ordering Information

The following table offers names and part numbers of accessories specific to the SVL module that may be ordered form Alma Lasers.

Table 4-1: SVL Module Accessories

Description	*Part No.*
SVL (Superficial Vascular Lesions) Module	AAHP19020702
Light Safety Glasses (OD 3+)	OPIP05120501
Dark Safety Glasses (OD 5+)	OPIP05120502

4.6. SVL Module Clinical Guide

The treatment of superficial (small and shallow) vascular lesions with the Harmony system can be performed using the **SVL** module (turquoise color code).

The SVL module is indicated for superficial vascular lesions such as rosacea, erythema of rosacea, poikiloderma of Civatte or port-wine stains (PWS) in patients with Fitzpatrick's skin type I-III. To treat patients with Fitzpatrick's skin types IV-VI, users should refer to the Clinical Guide for the VP 540-950nm module.

> ***Warning***
>
> **The appropriate protective eyewear should be worn by both the operator and the patient when using this module.**

4.6.1. Pre-Treatment

4.6.1.1. Assessing the Condition

The treatment parameters for any given skin condition depend on the skin type and the lesion type, depth (shallow) and size (small).

In principle, treat the larger (superficial) vessels first and only after they are closed proceed to treat the smaller (superficial) vessels. This avoids refilling the small vessels by the larger, intact feeders.

4.6.1.2. Contraindications

- Tanned skin (active tan) through sun exposure or tanning bed use in the previous 30 days
- Patients with Fitzpatrick skin type VI
- Hypopigmentation (Vitiligo)
- Any inflammatory skin condition e.g. eczema, active herpes simplex, etc. at the treatment site
- Skin cancer or any other cancer and/or any cancer drug therapy (such as Ducabaxine, Fluorouracil, Methotrexate, etc.)
- History of keloid scarring
- Epilepsy
- St. John's Wort (herbal remedy) for depression in the past 3 months (because of increased photosensitivity)

- Isotretinoin – Roaccutane in the previous 3-6 months
- Tretinoin – Retin A in the last 2 weeks
- Pregnancy; until menstruation returns and end of breast feeding
- Diabetes (because of increased possible photosensitivity and poor wound healing)

4.6.1.3. Preparing the Lesion for Treatment

If the lesion is smaller than the lightguide's footprint, use the template provided by Alma Lasers to protect the tissue surrounding the lesion. To use the template, select a suitable pre-cut hole so that only the lesion area is fully exposed to the margin. Place the template on the treatment site and cover it with a thin layer of gel (underneath and on top of the template) before treatment.

4.6.1.4. Skin Test

Always perform a skin test on the intended treatment area according to the following parameters with cooling ON:

Table 4-2: SVL Skin Test parameters

Skin Type (Fitzpatrick I-III)	*Module*	*Pulse Width (msec)*	*Fluence (J/cm^2)*	*Waiting Period*
I – II	**SVL** (Turquoise)	10, 12	14 – 16	30 min
III	**SVL** (Turquoise)	15	12 – 14	30 min

4.6.2. Treatment

- The SVL module will treat superficial redness associated with rosacea or post-acne rosacea.
- Treatment is applied perpendicular to the target and a second pass is usually recommended once appropriate safe settings are found. Do not stack pulses.
- Treatment can begin after the suitable module has been connected to the Harmony system and the treatment parameters (fluence and pulse width) are selected according to the Skin Test table in Section 4.6.1.4.

1. Clean the skin to remove perfumes, cosmetics and sunscreens.
2. Apply a thin layer (usually 1-2mm thick) of refrigerated cooling gel (43-50°F/6-10°C) to the treatment site. The gel will provide a thermal sink for

the absorbed and reflected energy, provide some cooling to the skin itself, and additional comfort to the patient during treatment.

> ***Caution***
>
> Do not treat a vascular lesion through a tattoo or a pigmented lesion that has not been examined by a physician. Any hair covering a vascular lesion must be removed before treatment.

3. Place the SVL module perpendicular to the skin and touch the gel with the lightguide. Do not apply pressure (the lightguide should gently touch the skin).
4. It is best not to overlap treatment spots by more than 10%, but if overlapping does occur wait at least one minute between pulses on the same spot.
5. Set the initial fluence parameter according to the skin test results.
6. Trigger a light pulse by pressing the footswitch only when the light guide is fully with contact to the skin.
7. Wipe off the gel and examine carefully. The desired effect is darkening of the vessel due to blood coagulation and erythema and/or edema along the vessel, indicating a stimulated immune reaction, without changes in the surrounding epidermis.
8. If, along with a good response in the vessel, adverse skin effects occur (such as excessive reddening or swelling in the shape of the lightguide), reduce the fluence by 10-20%.
9. If the skin shows no adverse effects and changes observed in the vessel are unsatisfactory you should increase the fluence by 10-20% and test again.
10. To maximize the cooling/coupling properties of the applied gel, make sure to apply the gel immediately before treatment. After treatment, remove the gel from the treated areas. Do not reuse gel.
11. After treatment, it is recommended to cool the area immediately (see Appendix B in the System Manual – Post-Treatment Care).

4.6.3. Suggested Setup Parameters

Table 4-3: Suggested SVL Setup Parameters

Skin Type (Fitzpatrick I-III)	*Target Vessel Depth*	*Module*	*Fluence (J/cm^2)*	*Pulse Width (msec)*
I – II	Shallow; Small	**SVL** (Turquoise)	16 – 18	10, 12, 15
III	Shallow; Small	**SVL** (Turquoise)	14 – 16	10, 12, 15

4.6.4. Follow-up

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

- Within three weeks after the treatment patients should return for examination of the treatment site and for additional treatment, if necessary.
- If no additional treatment is necessary, patients should return for an additional examination two months later.
- In case of a partial clearance of the lesion, the treatment should be continued using the same parameters and the patient should return for examination and for additional treatment, if necessary after three weeks.
- If no change in the lesion is noted, fluence should be increased by at least 10%.
- Intervals between treatments can be increased in successive treatments.
- Treatment is complete when satisfactory results are obtained.
- 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 Ltd.
14 Halamish St., P.O.B. 3021
Caesarea Industrial Park
Caesarea, Israel 38900
Tel: + (972) 4-627-5357
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Email: info@almalasers.com

Alma Lasers, Inc.
485 Half Day Road, Suite # 100
Buffalo Grove, IL 60089
Tel: 1-224-337-2000
Fax: 1-224-377-2050
Email: contact@almalasers.com
Website: www.almalasers.com

CHAPTER 5

VP Module – Vascular & Pigmented Lesions

Chapter Contents:

5.1. VP Module Description

The **VP** module has a high-power targeted phototherapy module for non-invasive treatment of vascular and pigmented lesions. The VP module allows treatment of a broad spectrum of vascular imperfections be selectively targeting oxyhemoglobin, deoxyhemoglobin and melanin.

A complete discussion of the VP module clinical applications may be found in Section 5.6.

The VP module has a green identification section (see Figure 5-1).

Figure 5-1: VP Module (Green Color Code)

5.2. VP Module Specifications

- **Light Source:** Pulsed light with AFT and EDF
- **Spectrum:** 540 – 950nm
- **Energy Density (Fluence):** 5 – 25 J/cm^2
- **Treatment Area (spot size):** 6.4 cm^2
- **Pulse Widths:** 10, 12, 15 msec
- **Pulse Repetition Rate:** 2/3 Hz
- **Cooling:** None

5.3. VP Module Operating Screen

The **VP** module main operating screen (see Figure 5-2) is displayed when the VP module is connected to the system.

Figure 5-2: VP Module Operating Screen

Operating parameters available in this module:

1. **Fluence** – the available fluence range is from 5 to 25 J/cm^2 in increments of 1 J/cm^2.
2. **Pulse Width** – three pulse widths are available:
   - 10 msec
   - 12 msec
   - 15 msec
3. **Pulse Repetition Rate** – fixed at 2/3 Hz

5.4. VP Module Regulatory Labels

Figure 5-3 presents the regulatory identification and caution labels adhered to the VP module connector:

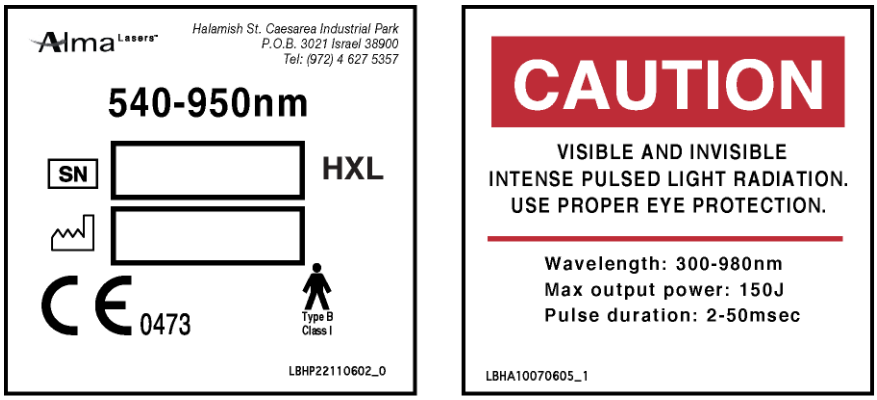

Figure 5-3: VP Module Regulatory Labels

5.5. Ordering Information

The following table offers names and part numbers of accessories specific to the VP module that may be ordered form Alma Lasers.

Table 5-1: VP Module Accessories

Description	*Part No.*
VP (Vascular/Pigmented Lesions) Module	AAHP02110602
Light Safety Glasses (OD 3+)	OPIP05120501
Dark Safety Glasses (OD 5+)	OPIP05120502

5.6. VP Module Clinical Guide for Vascular Lesions

The treatment of Vascular Lesions with the Harmony^{XL} system can be performed using (one – or a combination of) three modules of the following types:
VP 540-950nm (green color code), **SR 570-950nm** (yellow color code) and the **1064nm Long Pulse Nd:YAG** laser module.

- The SR module is discussed in detail in Chapter 7 of this manual.
- The 1064nm laser module is discussed in detail in Chapter 14 of this manual

The VP module is indicated for vascular lesions.

> ***Warning***
>
> **The appropriate protective eyewear should be worn by both the operator and the patient when using this module.**

5.6.1. Pre-Treatment

5.6.1.1. Assessing the Condition

The treatment parameters for any given skin condition depend on the skin type and the lesion type, depth and density.

In principle, treat the larger vessels first and only after they are closed proceed to treat the smaller vessels. This avoids refilling the small vessels by the larger, intact feeders.

5.6.1.2. Contraindications

- Tanned skin (active tan) through sun exposure or tanning bed use in the previous 30 days
- Hypopigmentation (Vitiligo)
- Any inflammatory skin condition e.g. eczema, active herpes simplex, etc. at the treatment site
- Skin cancer or any other cancer and/or any cancer drug therapy (such as Ducabaxine, Fluorouracil, Methotrexate, etc.)
- History of keloid scarring
- Epilepsy
- St. John's Wort (herbal remedy) for depression in the past 3 months (because of increased photosensitivity)

- Isotretinoin – Roaccutane in the previous 3-6 months
- Tretinoin – Retin A in the last 2 weeks
- Pregnancy; until menstruation returns and end of breast feeding
- Diabetes (because of increased possible photosensitivity and poor wound healing)

5.6.1.3. Preparing the Lesion for Treatment

If the lesion is smaller than the lightguide's footprint, use the template provided by Alma Lasers to protect collateral tissue surrounding the lesion. To use the template, select a suitable pre-cut hole so that only the lesion area is fully exposed to the margin. Place the template on the treatment site and cover it with a thin layer of gel (underneath and on top of the template) before treatment.

5.6.1.4. Skin Test

Always perform a skin test on the intended treatment area according to the following parameters:

Table 5-2: Vascular Lesions Skin Test Parameters*

Skin Type (Fitzpatrick I-VI)	*Module*	*Pulse Width (msec)*	*Fluence (J/cm^2)*	*Waiting Period*
I – III	**VP 540-950nm** (green color code)	10, 12	16 – 20	30 min
IV	**VP 540-950nm** (green color code)	15	10 – 14	24 – 48 hours
V – VI	**VP 540-950nm** (green color code)	15	6 – 8	24 – 48 hours

(*) The pulses must not be emitted sequentially!

5.6.2. Treatment

- The VP 540nm module will treat vessels up to < 1mm.
- Treatment is applied perpendicular to the target and a second pass is usually recommended once appropriate safe settings are found. Do not stack pulses. It is recommended to keep the contact cooling on during treatment with the VP module (see Figure 5-2).

- Treatment can begin after the module has been connected to the Harmony^{XL} system and the treatment parameters (fluence and timer interval) are selected according to the Skin Test parameters in Table 5-2.

1. Clean the skin to remove perfumes, cosmetics and sunscreens.

2. Apply a thin layer (usually 1mm thick and 2mm for darker skin types) of refrigerated (43-50°F/6-10°C) cooling gel to the treatment site. This aids skin cooling during the pulse sequence and improves coupling of the light into the skin and additional comfort to the patient during treatment.

> ***Caution***
>
> Do not treat a vascular lesion through a tattoo or a pigmented lesion that has not been examined by a physician. Any hair covering a vascular lesion must be removed before treatment.

3. Place the module's lightguide perpendicular to the skin and touch the gel with the lightguide. Do not apply pressure (the lightguide should gently touch the skin).

4. It is best not to overlap treatment spots by more than 10%, but if overlapping does occur wait at least one minute between pulses on the same spot.

5. Set the initial fluence parameter according to the skin test results.

6. Trigger a light pulse by pressing the footswitch.

7. Wipe off the gel and examine carefully. Remember: darker skin types take longer to respond than lighter skin types. The desired effect is darkening of the vessel due to blood coagulation and erythema and/or edema along the vessel, indicating a stimulated immune reaction, without changes in the surrounding epidermis.

8. If, along with a good response in the vessel, adverse skin effects occur (such as excessive reddening or swelling in the shape of the lightguide), reduce the fluence by 10-20%.

9. If the skin shows no adverse effects and changes observed in the vessel are unsatisfactory you should increase the fluence by 10-20% and test again.

10. To maximize the cooling/coupling properties of the applied gel, make sure to apply the gel immediately before treatment. After treatment, remove the gel from the treated areas. Do not reuse gel.

11. After treatment, it is recommended to cool the area immediately (see Appendix B in the System Manual – Post-Treatment Care).

5.6.3. Suggested VP Setup Parameters for Vascular Lesions

Table 5-3: Suggested VP Setup Parameters for Vascular Lesions*

Skin Type (Fitzpatrick I-VI)	*Max. Number of Repetitions*	*Module*	*Fluence (J/cm²)*	*Pulse Width (msec)*
I – III	2	**VP 540-950nm** (green color code)	19 – 22	10, 12
IV	2	**VP 540-950nm** (green color code)	12 – 19	15
V – VI	2	**VP 540-950nm** (green color code)	6 – 10	15

(*) The pulses must not be emitted sequentially!

5.6.4. Follow-up

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

- Within three weeks after the treatment patients should return for examination of the treatment site and for additional treatment, if necessary.
- If no additional treatment is necessary, patients should return for an additional examination two months later.
- In case of a partial clearance of the lesion, the treatment should be continued using the same parameters and the patient should return for examination and for additional treatment, if necessary after three weeks.
- If no change in the lesion is noted, fluence should be increased by at least 10%.
- Intervals between treatments can be increased in successive treatments.
- Treatment is complete when satisfactory results are obtained.
- 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 Ltd.
14 Halamish St., P.O.B. 3021
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Alma Lasers, Inc.
485 Half Day Road, Suite # 100
Buffalo Grove, IL 60089
Tel: 1-224-337-2000
Fax: 1-224-377-2050
Email: contact@almalasers.com
Website: www.almalasers.com

5.7. VP Module Clinical Guide for Pigmented Lesions

The Pigmented Lesions application of the Harmony^{XL} system can be performed with the **VP 540-950nm** (green color code) and the **SR 570-950nm** (yellow color code) modules.

The SR module is discussed in detail in Chapter 6 of this manual.

The VP module is indicated for pigmented lesions.

> ***Warning***
>
> **The appropriate protective eyewear should be worn by both the operator and the patient when using this module.**

5.7.1. Pre-Treatment

5.7.1.1. Assessing the Condition

The treatment parameters for any given skin condition depend on the skin type and the lesion type, depth and density.

5.7.1.2. Contraindications

- Tanned skin (active tan) through sun exposure or tanning bed use in the previous 30 days
- Hypopigmentation (Vitiligo)
- Any inflammatory skin condition e.g. eczema, active herpes simplex, etc. at the treatment site
- Skin cancer or any other cancer and/or any cancer drug therapy (such as Ducabaxine, Fluorouracil, Methotrexate, etc.)
- History of keloid scarring
- Epilepsy
- St. John's Wort (herbal remedy) for depression in the past 3 months (because of increased photosensitivity)
- Isotretinoin – Roaccutane in the previous 3-6 months
- Tretinoin – Retin A in the last 2 weeks
- Pregnancy; until menstruation returns and end of breast feeding
- Diabetes (because of increased possible photosensitivity and poor wound healing)

5.7.1.3. Preparing the Lesion for Treatment

If the lesion is smaller than the lightguide's footprint, use the template provided by Alma Lasers to protect collateral tissue surrounding the lesion. To use the template, select a suitable pre-cut hole so that only the lesion area is fully exposed. Place the template on the treatment site and cover it with a thin layer of gel (underneath and on top of the template) before treatment.

5.7.1.4. Skin Test

Always perform a skin test on the intended treatment area during the first treatment session according to the following parameters:

Table 5-4: Pigmented Lesions Skin Test Parameters

Skin Type (Fitzpatrick I-VI)	*Module*	*Lesion Color*	*Pulse Width (msec)*	*Fluence (J/cm²)*	*Waiting Period*
I – III	**VP 540-950nm** (green color code)	Light	10, 12	20 – 22	30 min.
		Dark	10, 12	18 – 20	
IV – VI	**VP 540-950nm** (green color code)	Light	12, 15	16 – 19	24 – 48 hours
		Dark	12, 15	8 – 10	
		Dark	12, 15	6 – 8	

5.7.2. Treatment

Treatment may begin after the module has been connected to the Harmony^{XL} system and the treatment parameters (fluence and timer interval) are selected according to the Skin Test parameters in Table 5-4.

1. Clean the skin to remove perfumes, cosmetics and sunscreens.
2. Apply a thin layer (usually 1mm thick and 2mm for darker skin types) of refrigerated (43-50°F/6-10°C) cooling gel to the treatment site. This aids skin cooling during the pulse sequence and improves coupling of the light into the skin.
3. Place the module's lightguide perpendicular to the skin and touch the gel with the lightguide. Do not apply pressure (the lightguide should gently touch the skin).
4. It is best not to overlap treatment sites by more than 10%, but if overlapping does occur wait at least one minute between pulses over the same spot.
5. Set the initial fluence parameter according to the skin test results.

6. Trigger a light pulse by pressing the footswitch.
7. Wipe off the gel and diagnose carefully. Remember: darker skin types take longer to respond than lighter skin types. The desired "positive" effect is to observe a change in lesion color (graying or darkening for brown pigment) or morphological changes (superficial texture change to the lesion), without changes in the surrounding epidermis.
8. If, along with a positive response in the lesions, adverse skin effects occur (such as excessive reddening or swelling in the shape of the lightguide), you should reduce the fluence by 10-20%.
9. If the skin shows no adverse effects and changes observed in the lesions are unsatisfactory, you should increase the fluence by 10-20%.
10. To maximize the cooling/coupling properties of the applied gel, make sure to apply the gel immediately before each pass/treatment. After treatment, remove the gel from treated areas. Do not reuse gel.
11. After treatment, it is recommended to cool the area immediately (see Appendix C in the System Manual – Post-Treatment Care).

5.7.3. Suggested VP Setup Parameters for Pigmented Lesions

Table 5-5: Suggested VP Setup Parameters for Pigmented Lesions

Skin Type (Fitzpatrick I-VI)	*Lesion Color*	*Module*	*Pulse Width (msec)*	*Fluence (J/cm^2)*
I – III	Light	**VP 540-950nm** (green color code)	10, 12	18 – 22
	Dark	**VP 540-950nm** (green color code)	12, 15	16 – 20
IV – VI	Light	**VP 540-950nm** (green color code)	15	10 – 14
	Dark	**VP 540-950nm** (green color code)	15	6 – 8

5.7.4. Follow-up

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

- Within three weeks after the treatment patients should return for examination of the treatment site and for additional treatment, if necessary.
- If no additional treatment is necessary, patients should return for an additional examination two months later.
- In case of a partial clearance of the lesion, the treatment should be continued using the same parameters and the patient should return for examination and for additional treatment, if necessary after three weeks.
- If no change in the lesion is noted, fluence should be increased by at least 10%.
- Intervals between treatments can be increased in successive treatments.
- Treatment is complete when satisfactory results are obtained.
- 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 Ltd.
14 Halamish St., P.O.B. 3021
Caesarea Industrial Park
Caesarea, Israel 38900
Tel: + (972) 4-627-5357
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Email: info@almalasers.com

Alma Lasers, Inc.
485 Half Day Road, Suite # 100
Buffalo Grove, IL 60089
Tel: 1-224-337-2000
Fax: 1-224-377-2050
Email: contact@almalasers.com
Website: www.almalasers.com

CHAPTER 6

SR Module – Skin Rejuvenation

Chapter Contents:

6.1. SR Module Description

The **SR** module has a high-power targeted phototherapy module for skin rejuvenation. It employs Alma Laser's proprietary AFT pulsed light technology in the yellow wavelength range (570-950nm) along with adjustable parameters for effective rejuvenation of the skin.

A complete discussion of the SR module clinical applications may be found in Section 6.6.

The SR module has a yellow identification section (see Figure 6-1).

Figure 6-1: SR Module (Yellow Color Code)

6.2. SR Module Specifications

- **Light Source:** Pulsed light with AFT and EDF
- **Spectrum:** 570 – 950nm
- **Energy Density (Fluence):** 5 – 25 J/cm^2
- **Treatment Area (spot size):** 6.4 cm^2
- **Pulse Widths:** 10, 12, 15 msec
- **Pulse Repetition Rate:** 2/3 Hz
- **Cooling:** None

6.3. SR Module Operating Screen

The **SR** module main operating screen (see Figure 6-2) is displayed when the SR module is connected to the system:

Figure 6-2: SR Module Operating Screen

Operating parameters available in this module:

1. **Fluence** – the available fluence range is from 5 to 25 J/cm^2 in increments of 1 J/cm^2.
2. **Pulse Width** – three pulse widths are available:
   - 10 msec
   - 12 msec
   - 15 msec
3. **Pulse Repetition Rate** – fixed at 2/3 Hz

6.4. SR Module Regulatory Labels

Figure 6-3 presents the regulatory identification and caution labels adhered to the SR module connector:

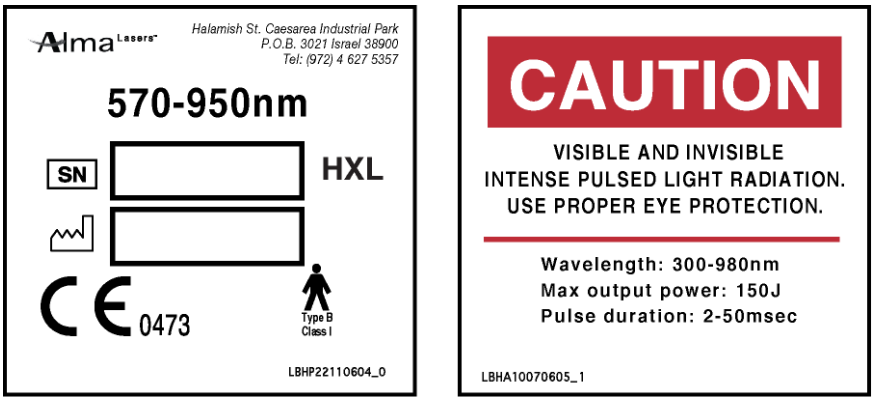

Figure 6-3: SR Module Regulatory Labels

6.5. Ordering Information

The following table offers names and part numbers of accessories specific to the SR module that may be ordered form Alma Lasers.

Table 6-1: SR Module Accessories

Description	*Part No.*
SR (Skin Rejuvenation) Module	AAHP02110604
Light Safety Glasses (OD 3+)	OPIP05120501
Dark Safety Glasses (OD 5+)	OPIP05120502

6.6. SR Module Clinical Guide

The Skin Rejuvenation application of the Harmony^{XL} system is performed using the **SR 570-950nm** (yellow color code) module or the **Long Pulse Nd:YAG (1064nm)** module.

The 1064nm laser module is discussed in detail in Chapter 14 of this manual

The SR 570-950nm module is indicated for the treatment of benign pigmented epidermal lesions, including dyschromia, hyperpigmentation, melasma and ephelides (freckles), and for the non-ablative treatment of facial fine lines & texture improvement (skin rejuvenation).

Warning

The appropriate protective eyewear should be worn by both the operator and the patient when using this module.

6.6.1. Pre-Treatment

6.6.1.1. Assessing the Condition

The treatment parameters for any given skin condition depend on the skin type and the lesion type, depth and density.

6.6.1.2. Contraindications

- Tanned skin (active tan) through sun exposure or tanning bed use in the previous 30 days
- Hypopigmentation (Vitiligo)
- Any inflammatory skin condition e.g. eczema, active herpes simplex, etc. at the treatment site
- Skin cancer or any other cancer and/or any cancer drug therapy (such as Ducabaxine, Fluorouracil, Methotrexate, etc.)
- History of keloid scarring
- Epilepsy
- St. John's Wort (herbal remedy) for depression in the past 3 months (because of increased photosensitivity)
- Isotretinoin – Roaccutane in the previous 3-6 months
- Tretinoin – Retin A in the last 2 weeks

- Pregnancy; until menstruation returns and end of breast feeding
- Diabetes (because of increased possible photosensitivity and poor wound healing)

6.6.1.3. Skin Test

Always perform a skin test on the intended treatment area during the first treatment session according to the following parameters:

Table 6-2: SR Skin Test Parameters

Skin Type (Fitzpatrick I-VI)	*Module*	*Pulse Width (msec)*	*Fluence (J/cm^2)*	*Waiting Period*
I – III	**SR 570-950nm** (yellow color code)	10, 12	16 – 20	30 min.
IV	**SR 570-950nm** (yellow color code)	15	8 – 12	30 min.
V – VI	**SR 570-950nm** (yellow color code)	15	6 – 10	24 – 48 hours

6.6.2. Treatment

Treatment can begin after the suitable module has been connected to the Harmony^{XL} system and the treatment parameters (fluence and timer interval) are selected according to Table 6-2.

> ***Note***
>
> Always perform a skin test on the intended treatment area during the first treatment session.

1. Clean the skin to remove perfumes, cosmetics and sunscreens.
2. Apply a thin layer (usually 1mm thick and 2mm for darker skin types) of refrigerated (43-50°F/6-10°C) cooling gel to the treatment site. The gel will provide a thermal sink for the absorbed and reflected energy, provide some cooling to the skin itself, and additional comfort to the patient during treatment.
3. Place the lightguide perpendicular to the skin and touch the gel with the lightguide. Do not apply pressure (the lightguide should gently touch the skin).
4. Set the initial fluence parameter according to the skin test results.

5. Trigger a light pulse by pressing the footswitch and the module trigger simultaneously.
6. Wipe off the gel.
7. If adverse skin effects occur (such as excessive reddening or swelling in the shape of the lightguide), you should reduce the fluence by 10-20%.
8. If no change in the skin is noted, then the fluence should be increased by 10-20%.
9. To maximize the cooling/coupling properties of the applied gel, make sure to apply the gel immediately before treatment. After treatment, remove the gel from treated areas. Do not reuse gel.
10. After treatment, it is recommended to cool the area immediately (see Appendix B in the System Manual – Post-Treatment Care).

6.6.3. Suggested SR Setup Parameters

Table 6-3: Suggested SR Setup Parameters

Skin Type (Fitzpatrick I-VI)	*Module*	*# of Pulses per Spot **	*Pulse Width (msec)*	*Fluence (J/cm^2)*
I – III	**SR 570-950nm** (yellow color code)	2	10, 12	18 – 24
IV	**SR 570-950nm** (yellow color code)	2	12, 15	10 – 14
V – VI	**SR 570-950nm** (yellow color code)	2	15	6 – 10

(*) The pulses must not be emitted sequentially!

6.6.4. Follow-up

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

- Within three weeks after the treatment patients should return for examination of the treatment site and for additional treatment, if necessary.
- If no additional treatment is necessary, patients should return for an additional examination one month later.
- Intervals between treatments can be increased in successive treatments.
- Treatment is complete when satisfactory results are obtained.
- 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 Ltd.
14 Halamish St., P.O.B. 3021
Caesarea Industrial Park
Caesarea, Israel 38900
Tel: + (972) 4-627-5357
Fax: + (972) 4-627-5368
Email: info@almalasers.com

Alma Lasers, Inc.
485 Half Day Road, Suite # 100
Buffalo Grove, IL 60089
Tel: 1-224-337-2000
Fax: 1-224-377-2050
Email: contact@almalasers.com
Website: www.almalasers.com

CHAPTER 7

HR Module – Hair Removal

Chapter Contents:

7.1. HR Module Description

The **HR** module has a high-power targeted module for hair removal. It employs Alma Laser's proprietary AFT pulsed light technology in the red wavelength range (650-950nm) along with adjustable parameters for effective hair removal.

A complete discussion of the HR module clinical applications may be found in Section 7.6.

The HR module has a red identification section (see Figure 7-1).

Figure 7-1: HR Module (Red Color Code)

7.2. HR Module Specifications

- **Light Source:** Pulsed light with AFT and EDF
- **Spectrum:** 650 – 950nm
- **Energy Density (Fluence):** 5 – 25 J/cm^2
- **Treatment Area (spot size):** 6.4 cm^2
- **Pulse Widths:** 30, 40, 50 msec
- **Pulse Repetition Rate:** 2/3 Hz
- **Cooling:** None

7.3. HR Module Operating Screen

The **HR** cooling module main operating screen (see Figure 7-2) is displayed when the HR module is connected to the system.

Figure 7-2: HR Cooling Module Operating Screen

Operating parameters available in this module:

1. **Fluence** – the available fluence range is from 5 to 25 J/cm^2 in increments of 1 J/cm^2.
2. **Pulse Width** – three pulse widths are available:
   - 30 msec
   - 40 msec
   - 50 msec
3. **Pulse Repetition Rate** – fixed at 2/3 Hz

7.4. HR Module Regulatory Labels

Figure 7-3 presents the regulatory identification and caution labels adhered to the HR module connector:

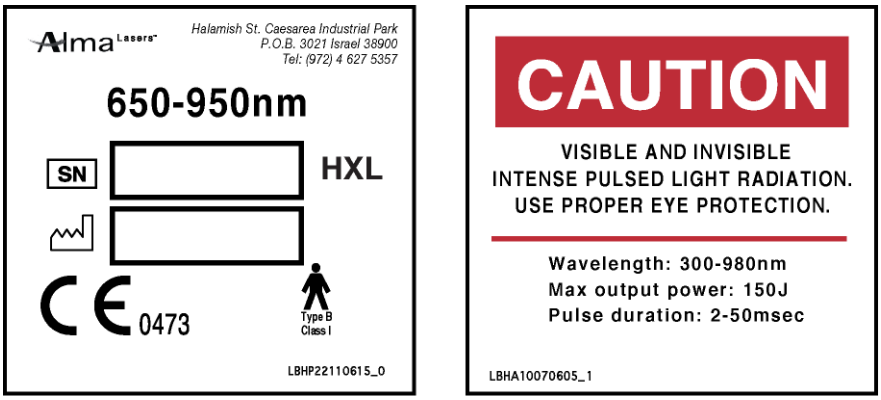

Figure 7-3: HR Module Regulatory Labels

7.5. Ordering Information

The following table offers names and part numbers of accessories specific to the HR module that may be ordered form Alma Lasers.

Table 7-1: HR Module Accessories

Description	*Part No.*
HR (Hair Removal) Module	AAHP02110615
Light Safety Glasses (OD 3+)	OPIP05120501
Dark Safety Glasses (OD 5+)	OPIP05120502

7.6. HR Module Clinical Guide

The Harmony^{XL} system with the **HR 650-950nm** module is indicated for the removal of unwanted hair and to effect stable long-term or permanent hair reduction.

> ***Warning***
>
> **The appropriate protective eyewear should be worn by both the operator and the patient when using this module.**

7.6.1. Pre-Treatment

7.6.1.1. Patient Evaluation

Before hair removal procedures, the patient should be evaluated for the presence of conditions that may cause hypertrichosis:

- Hormonal
- Familial
- Drug (i.e., corticosteroids, hormones, immunosuppressive self or spousal use of minoxidil)
- Tumor

7.6.1.2. Contraindications

- History of local or recurrent skin infection
- Pregnancy (including IVF procedure)
- History of herpes simplex, especially perioral
- History of genital herpes, important when treating the pubic or bikini area
- History of keloids/hypertrophic scaring
- Isotretinoin – in the past 3-6 months
- Retin-A – in the past 2 weeks
- Epilepsy
- History of Koebnerizing skin disorders, such as vitiligo and psoriasis
- Previous treatment modalities – method, frequency and date of last treatment, as well as response

- Recent (in the past 2 weeks) suntan or exposure to a tanning bed
- Tattoos or nevi present
- Past or ongoing medical condition (diabetes, epilepsy, high or low blood pressure, or others)
- Present medications:
  - Photosensitizing medications
  - Gold therapy

7.6.1.3. Skin Test

Always perform a skin test on the intended treatment area during the first treatment session according to the following parameters in the table below.

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

Table 7-2: HR Skin Test Parameters

Skin Type (Fitzpatrick I-VI)	*Module*	*Pulse Width (msec)*	*Fluence (J/cm^2)*	*Waiting Period*
I	**HR 650-950nm** (Red)	30	20	30 minutes
II	**HR 650-950nm** (Red)	30	18	30 minutes
III	**HR 650-950nm** (Red)	40	16	30 minutes
IV	**HR 650-950nm** (Red)	50	12	24 – 48 hours
V	**HR 650-950nm** (Red)	50	8	24 – 48 hours
VI	**HR 650-950nm** (Red)	50	6	24 – 48 hours

7.6.2. Treatment

Treatment can begin after the HR module is connected and the treatment parameters are selected (fluence and timer interval) according to Table 7-2.

1. Clean the skin to remove perfumes, cosmetics and sunscreens.
2. Apply a thin layer (usually ~1 mm and ~2 mm for darker types) of refrigerated cooling gel (43-50°F/6-10°C) to the treatment site. The gel will provide a thermal sink for the absorbed and reflected energy, provide some cooling to the skin itself, and additional comfort to the patient during treatment.
3. Place the module perpendicular to the skin and touch the skin to ensure a good seal. Do not apply excessive pressure on the skin.
4. Set the initial fluence parameter according to the skin test results.
5. Trigger a light pulse by pressing the footswitch.
6. Examine the treatment site for any change of the skin color and morphological changes around the follicles (erythema/edema). The smell of burnt hair may sometimes be detected, although a lack of smell does not necessarily indicate that the present parameters are ineffective.
7. It is recommended to wait 30 minutes after a test shot has been triggered for skin types I-IV, and 24-48 hours for skin types V and VI before proceeding.
8. If there are no noticeable changes in the hair follicles, or adverse effects, increase the settings by 10-20% (skin types I-IV). Do not increase settings on skin type V or VI until the initial test has been reviewed 24-48 hours after treatment.
9. If adverse skin effects occur (such as excessive reddening) before good follicular response is achieved, reduce the settings by 10-20%.
10. Make the above adjustments and test again on an adjacent area until adverse effects on the skin no longer appear.
11. After treatment it is recommended to cool the area immediately (see Appendix B in the System Manual – Post-Treatment Care).

7.6.3. Suggested HR Setup Parameters

The following table shows the recommended parameters based on the patient hair color and skin type:

Table 7-3: Suggested HR Setup Parameters

Skin Type (Fitzpatrick I-VI)	Hair Color	Module	Fluence (J/cm^2)	Pulse Width (msec)
I	Light	**HR 650-950nm** (Red)	20 – 25	30, 40
	Dark	**HR 650-950nm** (Red)	20 – 25	30, 40
II	Light	**HR 650-950nm** (Red)	20 – 25	30, 40
	Dark	**HR 650-950nm** (Red)	20 – 25	30, 40
III	Light	**HR 650-950nm** (Red)	18 – 24	30, 40
	Dark	**HR 650-950nm** (Red)	18 – 24	30, 40
IV	Light	**HR 650-950nm** (Red)	16 – 20	40, 50
	Dark	**HR 650-950nm** (Red)	14 – 18	40, 50
V	Light	**HR 650-950nm** (Red)	Up to 15	50
	Dark	**HR 650-950nm** (Red)	Up to 13	50
VI	Light	N/A	N/A	N/A
	Dark	**HR 650-950nm** (Red)	Up to 10	50

Caution

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

7.6.4. Follow-Up

Measures presented below are only the manufacturer's recommendations 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 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:

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14 Halamish St., P.O.B. 3021
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485 Half Day Road, Suite # 100
Buffalo Grove, IL 60089
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Fax: 1-224-377-2050
Email: contact@almalasers.com
Website: www.almalasers.com

CHAPTER 8

ST Module – Scar Revision & Treatment of Striae

Chapter Contents:

8.1. ST Module Description

The Harmony **ST NIR** (burgundy color code) module emits light in the near infrared spectrum generated by a pulsed-light source. The ST module can be used to treat cutaneous lesions such as striae, stretch marks and scar revision.

A complete discussion of the ST module clinical applications may be found in Section 8.6.

The ST module has a burgundy identification section (see Figure 8-1).

Figure 8-1: ST Module (Burgundy Color Code)

8.2. ST Module Specifications

- **Light Source:** Pulsed light
- **Spectrum:** Near Infrared
- **Energy Density (Fluence):** 1 – 7 J/cm^2
- **Treatment Area (spot size):** 6.4 cm^2
- **Timers:** 10, 30, 90 seconds
- **Pulse Repetition Rate:** 2 Hz
- **Cooling:** None

8.3. ST Module Operating Screen

The **ST** module main operating screen (see Figure 8-2) is displayed when the ST module is connected to the system:

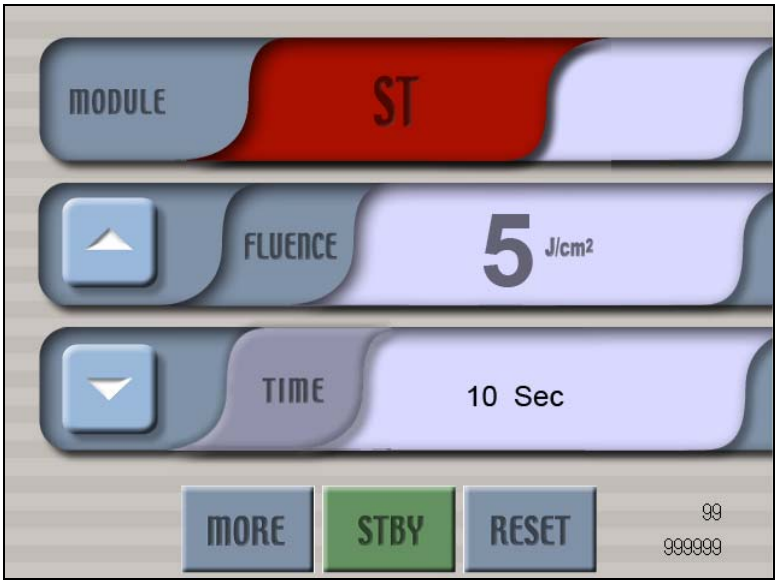

Figure 8-2: ST Module Operating Screen

Operating parameters available in this module:

1. **Fluence** – the available fluence range is from 1 to 7 J/cm^2 in increments of 1 J/cm^2.
2. **Timers** – there are three timer settings in this module:
   - 10 Seconds
   - 30 Seconds
   - 90 Seconds

8.4. ST Module Regulatory Labels

Figure 8-3 presents the regulatory identification and caution labels adhered to the ST module connector:

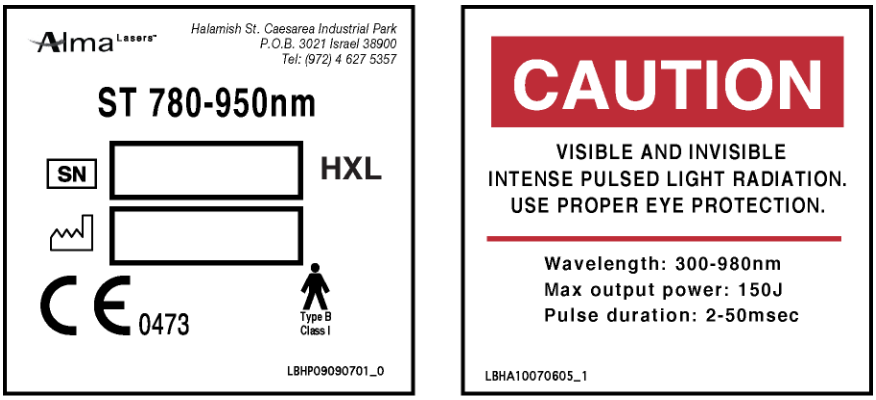

Figure 8-3: ST Module Regulatory Labels

8.5. Ordering Information

The following table offers names and part numbers of accessories specific to the ST module that may be ordered form Alma Lasers.

Table 8-1: ST Module Accessories

Description	*Part No.*
ST Module	AAHP09090701
Light Safety Glasses (OD 3+)	OPIP05120501
Dark Safety Glasses (OD 5+)	OPIP05120502

8.6. ST Module Clinical Guide

The Harmony **ST NIR** (burgundy color code) module emits light in the near infrared spectrum generated by a pulsed-light source. The ST module can be used to treat cutaneous lesions such as striae, stretch marks and scar revision.

Caution

The appropriate protective eyewear should be worn by both the operator and the patient when using this module.

8.6.1. Pre-Treatment

8.6.1.1. Assessing the Condition

The treatment parameters for any given skin condition depend on the lesion type, skin type, depth and density of the lesion to be treated.

8.6.1.2. Contraindications

- Tanned skin (active tan) through sun exposure or tanning bed use in the previous 30 days
- Whole body tattoos or very large areas
- Eye-liner or lip-liner tattoos in treatment area
- Hypopigmentation (Vitiligo)
- Any inflammatory skin condition e.g., eczema, active herpes simplex, etc. at the treatment site
- Skin cancer or any other cancer and/or any cancer drug therapy (such as Ducabaxine, Fluorouracil, Methotrexate, etc.)
- History of keloid scarring
- Epilepsy
- Gold therapy
- Photosensitizing drugs; tetracycline, St. John's Wort (herbal remedy) in the past 3 months for depression (because of increased photosensitivity)
- Isotretinoin – Roaccutane in the previous 3-6 months
- Tretinoin – Retin A in the last 2 weeks
- Diabetes (owing to possible photosensitivity and poor wound healing)
- Pregnancy
- Impaired immune system
- Scleroderma

8.6.2. Module Operation

The module can be applied to the skin using two different free-hand techniques: **Stationary** and **In-Motion** (recommended technique). In stationary technique, the practitioner places the module on the skin for the entire exposure time and fluence conditions. In the in-motion technique, the module is moved continuously on the skin for the entire exposure time and fluence conditions. In the stationary technique, the module should be positioned in complete contact with the skin and slightly pressed towards the skin. In the in-motion technique, the module should be moved along the skin in continuous circular movements within the treatment area.

8.6.2.1. Module Parameters

J/cm²	*10 sec[1]*	*30 sec[1]*	*90 sec[1]*
1	10	30	90
2	20	60	180
3	35	90	270
4	40	120	360
5	55	150	450
6	60	180	540
7	70	210	630

The ST module delivers between 1-7 J/cm^2 per pulse.

The time interval options for the module operation are 10, 30 and 90 seconds. The time elapsed is displayed on the screen for each interval, along with auditory beep.

The total fluence depends on the exposure time. In stationary technique (10 second exposure) the total fluence is 10-70 J/cm^2 (see above table). The fluence delivered when using the In-Motion technique depends on the size of the treatment area.

[1] Energy settings in J/cm^2 are displayed vertically

8.6.3. Skin Test

Always perform a skin test on the intended treatment area (forehead, face, or neck areas). After covering the area with thin (<1mm) layer of cold ultrasonic gel, place the module on the skin according to the following exposure settings/techniques. The skin test should be performed on the treatment area.

8.6.3.1. Face

Mode	*Test Spot No.*	*Exposure Time [Sec]*	*Fluence [J/cm^2]*	*Accumulative Fluence*
In-Motion	1	30	4	120
In-Motion	2	30	5	150
In-Motion	3	30	6	180

8.6.3.2. Abdomen

Mode	*Test Spot No.*	*Exposure Time [Sec]*	*Fluence [J/cm^2]*	*Accumulative Fluence*
In-Motion	1	30	4	120
In-Motion	2	30	5	150
In-Motion	3	30	6	180

8.6.4. Treatment

After the ST module has been connected to the Harmony system and suitable settings (time exposure and fluence) have been selected, the treatment can begin.

8.6.4.1. In-Motion Protocol

1. Clean the skin to remove perfumes, cosmetics and sunscreens.
2. In areas where hair exists, the hair must be shaved or trimmed.
3. Provide appropriate eye protection (OD>5) goggles for the patient and the medical staff in the enclosed treatment room.

4. Apply room-temperature ultrasonic gel (thin layer ~1mm) to the skin and place the module perpendicular to the skin. During the treatment add ultrasonic gel to the treatment area as needed. ***Do not*** apply pressure (the lightguide should gently touch the skin).
5. Skin tissue heating is specific to the individual patient and area, and therefore should be monitored/gauged to the individual patient's tolerance.
6. Clinical end-points: skin should appear red/pink (mild-moderate erythema); patient should report that the skin feels warm.
7. If no visible end-points appear but the patient reports deep heat sensation during the treatment, do not repeat treatment.

8.6.4.2. Stationary Protocol

1. In the stationary technique, up to 10% overlapping is an acceptable tolerance.
2. Set the initial exposure time and fluence parameters according to the skin test results.
3. Trigger a pulse by continuously pressing the footswitch for the entire time interval; the module will stop emitting light automatically unless interrupted by the operator (releasing the footswitch). In order to continue, the footswitch must be pressed again.
4. Treatment parameters may be increased by 10% every other treatment and subjected to the conditions in the area treated and the patient's tolerance.
5. Clinical end-points: skin should appear red/pink (mild-moderate erythema); patient should report that the skin feels warm.
6. Following treatment, gently cleanse the ultrasonic gel from the treated area.
7. If adverse skin effects occur (such as excessive reddening or swelling), you may either reduce the exposure time or reduce the fluence.
8. After treatment, it is recommended to cool the area immediately (see Appendix B in the System Manual – Post-Treatment Care).

> ***Note***
>
> Always perform a skin test on the intended treatment area during the first treatment session.

8.6.5. Suggested Setup Parameters

The face/neck and the abdomen are divided into 6 bilateral areas: upper-right (1); upper-left (2); mid-right (3); mid-left (4); lower-right (5); lower-left (6).

8.6.5.1. Face

Area	*Exposure Time [Sec]*	*Fluence [J/cm^2]*	*Accumulative Fluence*
Forehead, Neck	30	4 – 7	120 – 210
Submental, Cheeks, Jowls	90	5 – 7	450 – 630

8.6.5.2. Abdomen

Area	*Exposure Time [Sec]*	*Fluence [J/cm^2]*	*Accumulative Fluence*
Upper Abdomen	90	5 – 7	450 – 630
Mid-Lateral Abdomen	90	5 – 7	450 – 630
Lower Abdomen	90	5 – 7	450 – 630

If the patient is uncomfortable with the temperature after 3 x 90 sec passes stop treatment for this session. Passes may be increased if the patient has easily tolerated 3 passes of 90 seconds each.

8.6.6. Follow-Up

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

- Patients should be invited four weeks after treatment for examination of the treatment site and for additional treatment, if necessary.
- Treatment is complete when satisfactory results are obtained.
- 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 Ltd.
14 Halamish St., P.O.B. 3021
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Alma Lasers, Inc.
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Email: contact@almalasers.com
Website: www.almalasers.com

CHAPTER 9
LED Module

Chapter Contents:

9.1. LED Module Description

The LED module (see Figure 9-1) incorporates an array of diodes that emit yellow light. The module may be configured to operate in one of the following modes:

- **Continuous Wave**
- **Repeat**

A complete discussion of the LED module clinical applications may be found in Section 9.6.

Figure 9-1: LED Module

9.2. LED Module Specifications

- **Light Source:** Light emitting diode array
- **Spectrum:** Yellow
- **Optical Power:** 1.5 Watts
- **Pulse Mode # 1:** Repeat (Pulsed)
- **Pulse Mode # 2:** CW (Continuous Wave)
- **Timers:** Repeat - up to 70 seconds
  CW - up to 70 minutes

9.3. LED Module Operating Screen

The **LED** module main operating screen (see Figure 9-2) is displayed when the LED module is connected to the system:

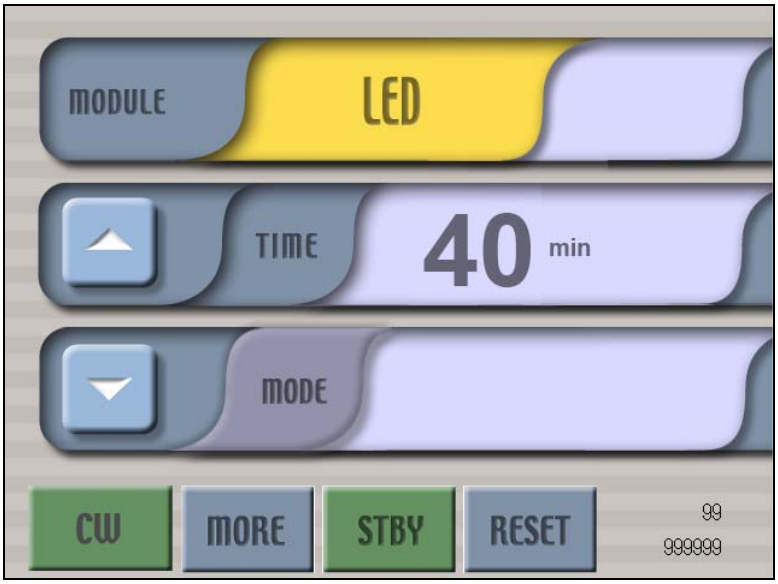

Figure 9-2: LED Module Operating Screen

Operating parameters available in this module:

1. **Operating Mode** – the LED module can be operated in one of the following wave modes:
   - **Repeat** (pulsed)Wave
   - **CW** (Continuous Wave)
2. **Wave Duration**:
   - Repeat – up to 70 seconds
   - CW – up to 70 minutes

9.4. LED Module Regulatory Labels

Figure 9-3 presents the regulatory identification and caution labels adhered to the LED module connector:

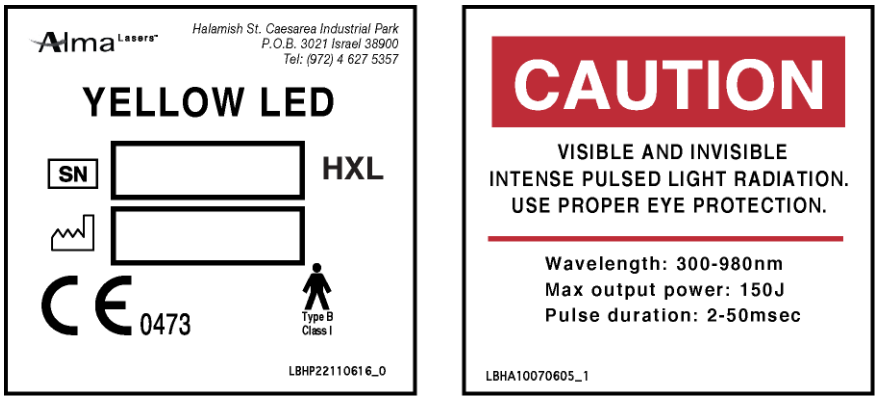

Figure 9-3: LED Module Regulatory Labels

9.5. Ordering Information

The following table offers names and part numbers of accessories specific to the LED module that may be ordered form Alma Lasers.

Table 9-1: LED Module Accessories

Description	*Part No.*
LED (Yellow) Module	AAHP02110616
Light Safety Glasses (OD 3+)	OPIP05120501
Dark Safety Glasses (OD 5+)	OPIP05120502

9.6. LED Module Clinical Guide

The Harmony^{XL} system with the **LED** module emits 590nm (yellow) diode light.

The clinical indications of the LED module include:

- Topical heating to promote increased blood flow
- Temporary relaxation of muscles
- Relief of pain
- Periorbital wrinkles and rhytids (only in Canada)

> ***Note***
>
> In Canada the module is indicated for the treatment of rhytids, fine lines and wrinkles.

The LED module can be operated in one of two modes: continuous wave (CW) and Repeat (pulsed) wave.

> ***Warning***
>
> **The appropriate protective eyewear should be worn by both the operator and the patient when using this module.**

9.6.1. Pre-Treatment

9.6.1.1. Patient Evaluation

Before LED treatment procedures, the patient should be evaluated for the presence of pre-existing conditions of skin disease that may cause skin sensitivity or photosensitivity.

9.6.1.2. Contraindications

- History of cancer
- Active inflammatory skin disorder
- Drug-related photosensitivity

9.6.1.3. Skin Test

Always perform a skin test on the intended treatment area during the first treatment session according to the following parameters in the table below.

Table 9-2: LED Skin Test Parameters

Skin Type (Fitzpatrick I-VI)	Module	Time of Exposure (sec / min)*	Mode	Waiting Period (minutes)
I	LED	30 / 20	Repeat/CW	10
II	LED	30 / 20	Repeat/CW	10
III	LED	30 / 20	Repeat/CW	10
IV	LED	30 / 20	Repeat/CW	10
V	LED	30 / 20	Repeat/CW	10
VI	LED	30 / 20	Repeat/CW	10

(*) Pulsed/CW

9.6.2. Treatment

Treatment can begin after the LED module is connected to the system and the treatment parameters are selected according to the table in Table 9-2.

1. Clean the skin to remove perfumes, cosmetics and sunscreens.
2. Identify the treatment area and position the patient accordingly.
3. Patient should be seated in a chair or lying down on a treatment bed.
4. Provide appropriate eye protection (or eye shields) for the patient and the medical staff inside the enclosed treatment room.
5. Select the operating mode according to the clinical indication –
   - **CW** (Continuous Wave), up to 70 minutes, or
   - **Repeat**, up to 70 seconds
6. Hold the module at a distance of 1-2 cm (0.4"-0.8") from the skin surface (perpendicular to the skin) for the entire exposure time.
7. Continuous Wave mode (CW): treatment should be performed twice per week for 4-5 consecutive weeks (8-10 treatments).
8. Repeat mode: treatment should be performed on 3 to 5 consecutive days post-laser or IPL procedure (3-5 treatments).

9.6.3. Suggested LED Setup Parameters

The following table shows the recommended parameters based on the patient hair color and skin type:

Table 9-3: Suggested LED Setup Parameters

Skin Type (Fitzpatrick I-VI)	Module	Time of Exposure (sec / min) *	Mode
I	LED	30 / 20	Repeat/CW
II	LED	30 / 20	Repeat/CW
III	LED	30 / 20	Repeat/CW
IV	LED	30 / 20	Repeat/CW
V	LED	30 / 20	Repeat/CW
VI	LED	30 / 20	Repeat/CW

(*) Pulsed/CW

9.6.4. Follow-Up

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

- Patients should apply daily sunscreen with SPF 30 between treatments and at least one week after the last treatment.
- Patients should be instructed to avoid sun exposure after and in between treatments.
- Patient should return for examination 1 and 3 months after the last treatment and for additional treatment, if necessary.
- If no additional treatment is necessary, the patient should return for an additional re-examination six months later.

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 Ltd.
14 Halamish St., P.O.B. 3021
Caesarea Industrial Park
Caesarea, Israel 38900
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Alma Lasers, Inc.
485 Half Day Road, Suite # 100
Buffalo Grove, IL 60089
Tel: 1-224-337-2000
Fax: 1-224-377-2050
Email: contact@almalasers.com
Website: www.almalasers.com

CHAPTER 10

SVL Cooled Module – Superficial Vascular Lesions

Chapter Contents:

10.1. SVL Cooled Module Description

The **SVL** cooled module has a high-power targeted phototherapy module for non-invasive treatment of small and shallow vascular lesions. The SVL cooled module allows treatment of a broad spectrum of vascular imperfections be selectively targeting oxyhemoglobin, deoxyhemoglobin and melanin.

A complete discussion of the SVL cooled module clinical applications may be found in Section 10.6.

The SVL cooled module has a turquoise identification section (see Figure 10-1).

This module incorporates a contact-cooling mechanism.

Figure 10-1: SVL Cooled Module (Turquoise Color Code)

10.2. SVL Cooled Module Specifications

- **Light Source:** Pulsed light with AFT and EDF
- **Spectrum:** 515 – 950nm
- **Energy Density (Fluence):** 5 – 30 J/cm^2
- **Treatment Area (spot size):** 3 cm^2
- **Available Pulse Widths:** 10, 12, 15 msec
- **Pulse Repetition Rate:** 2/3 Hz
- **Cooling:** TEC

10.3. SVL Cooled Module Operating Screen

The **SVL** cooled module main operating screen (see Figure 10-2) is displayed when the SVL cooled module is connected to the system.

The **SVL** cooled module's contact cooling mechanism can be turned on or off by touching the appropriate soft-key in the bottom-left corner of the screen:

- **COOLING ON** (default mode)
- **COOLING OFF** (touch the **COOLING ON** softkey)

Figure 10-2: SVL Cooled Module Operating Screen

Operating parameters available in this module:

1. **Fluence** – the available fluence range is from 5 to 30 J/cm^2 in increments of 1 J/cm^2.
2. **Pulse Width** – three pulse widths are available:
   - 10 msec
   - 12 msec
   - 15 msec
3. **Pulse Repetition Rate** – fixed at 2/3 Hz

10.4. SVL Cooled Module Regulatory Labels

Figure 10-3 presents the regulatory identification and caution labels adhered to the SVL cooled module connector:

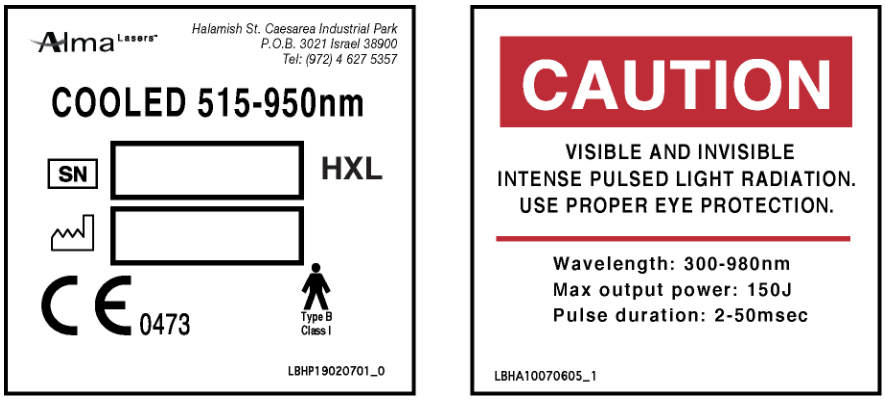

Figure 10-3: SVL Cooled Module Regulatory Labels

10.5. Ordering Information

The following table offers names and part numbers of accessories specific to the SVL cooled module that may be ordered form Alma Lasers.

Table 10-1: SVL Cooled Module Accessories

Description	*Part No.*
SVL (Superficial Vascular Lesions) Cooled Module	AAHP19020701
Light Safety Glasses (OD 3+)	OPIP05120501
Dark Safety Glasses (OD 5+)	OPIP05120502

10.6. SVL Cooled Module Clinical Guide

The treatment of superficial (small and shallow) vascular lesions with the Harmony^{XL} system can be performed using the **SVL Cooled** (turquoise color code) module (spot size 3 cm^2).

The SVL cooled module is indicated for superficial vascular lesions such as rosacea, erythema of rosacea, poikiloderma of Civatte or port-wine stains (PWS) in patients with Fitzpatrick's skin type I–IV.

Warning

The appropriate protective eyewear should be worn by both the operator and the patient when using this module.

10.6.1. Pre-Treatment

10.6.1.1. Assessing the Condition

The treatment parameters for any given skin condition depend on the skin type and the lesion type, depth (shallow) and size (small).

In principle, treat the larger (superficial) vessels first and only after they are closed proceed to treat the smaller (superficial) vessels. This avoids refilling the small vessels by the larger, intact feeders.

10.6.1.2. Contraindications

- Tanned skin (active tan) through sun exposure or tanning bed use in the previous 30 days
- Patients with Fitzpatrick skin type V & VI
- Hypopigmentation (Vitiligo)
- Any inflammatory skin condition e.g. eczema, active herpes simplex, etc. at the treatment site
- Skin cancer or any other cancer and/or any cancer drug therapy (such as Ducabaxine, Fluorouracil, Methotrexate, etc.)
- History of keloid scarring
- Epilepsy
- St. John's Wort (herbal remedy) for depression in the past 3 months (because of increased photosensitivity)

- Isotretinoin – Roaccutane in the previous 3-6 months
- Tretinoin – Retin A in the last 2 weeks
- Pregnancy; until menstruation returns and end of breast feeding
- Diabetes (because of increased possible photosensitivity and poor wound healing)

10.6.1.3. Preparing the Lesion for Treatment

If the lesion is smaller than the lightguide's footprint, use the template provided by Alma Lasers to protect the tissue surrounding the lesion. To use the template, select a suitable pre-cut hole so that only the lesion area is fully exposed to the margin. Place the template on the treatment site and cover it with a thin layer of gel (underneath and on top of the template) before treatment.

10.6.1.4. Skin Test

Always perform a skin test on the intended treatment area according to the following parameters with cooling ON:

Table 10-2: Cooled SVL Skin Test Parameters

Fitzpatrick Skin Type	*Module*	*Pulse Width (msec)*	*Fluence (J/cm²)*	*Waiting Period*
I – III	**Cooled SVL-950nm** (turquoise color code)	10, 12	15 – 20	30 min
IV	**Cooled SVL-950nm** (turquoise color code)	12, 15	8 – 14	45 – 60 min

10.6.2. Treatment

- The SVL cooled module will treat superficial vascular redness associated with rosacea or post-acne rosacea.
- Treatment is applied perpendicular to the target and a second pass is usually recommended once appropriate safe settings are found. Do not stack pulses.
- Treatment can begin after the suitable module has been connected to the Harmony system and the treatment parameters (fluence and timer interval) are selected according to the Skin Test table in Table 10-2.

1. Clean the skin to remove perfumes, cosmetics and sunscreens.

2. Apply a thin layer (usually 1-2mm thick) of refrigerated cooling gel (43-50°F/ 6-10°C) to the treatment site. The gel will provide a thermal sink for the absorbed and reflected energy, provide some cooling to the skin itself, and additional comfort to the patient during treatment.

> ***Caution***
>
> Do not treat a vascular lesion through a tattoo or a pigmented lesion that has not been examined by a physician. Any hair covering a vascular lesion must be removed before treatment.

3. Place the SVL cooled module perpendicular to the skin and touch the gel with the lightguide. Do not apply pressure (the lightguide should gently touch the skin).
4. It is best not to overlap treatment spots by more than 10%, but if overlapping does occur wait at least one minute between pulses on the same spot.
5. Set the initial fluence parameter according to the skin test results.
6. Trigger a light pulse by pressing the footswitch only when the light guide is fully with contact to the skin.
7. Wipe off the gel and examine carefully. The desired effect is darkening of the vessel due to blood coagulation and erythema and/or edema along the vessel, indicating a stimulated immune reaction, without changes in the surrounding epidermis.
8. If, along with a good response in the vessel, adverse skin effects occur (such as excessive reddening or swelling in the shape of the lightguide), reduce the fluence by 10-20%.
9. If the skin shows no adverse effects and changes observed in the vessel are unsatisfactory you should increase the fluence by 10-20% and test again.
10. To maximize the cooling/coupling properties of the applied gel, make sure to apply the gel immediately before treatment. After treatment, remove the gel from the treated areas. Do not reuse gel.
11. After treatment, it is recommended to cool the area immediately (see Appendix B in the System Manual – Post-Treatment Care).

10.6.3. Suggested Setup Parameters

Table 10-3: Suggested Cooled SVL Setup Parameters

Skin Type (Fitzpatrick I-III)	*Target Vessel Depth*	*Module*	*Fluence (J/cm^2)*	*Pulse Width (msec)*
I – III	Shallow; Small	**Cooled SVL-950nm** (turquoise color code)	15 – 25	10, 12, 15
IV	Shallow; Small	**Cooled SVL-950nm** (turquoise color code)	7 – 18	12, 15

10.6.4. Follow-up

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

- Within three weeks after the treatment patients should return for examination of the treatment site and for additional treatment, if necessary.
- If no additional treatment is necessary, patients should return for an additional examination two months later.
- In case of a partial clearance of the lesion, the treatment should be continued using the same parameters and the patient should return for examination and for additional treatment, if necessary after three weeks.
- If no change in the lesion is noted, fluence should be increased by at least 10%.
- Intervals between treatments can be increased in successive treatments.
- Treatment is complete when satisfactory results are obtained.
- 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 Ltd.
14 Halamish St., P.O.B. 3021
Caesarea Industrial Park
Caesarea, Israel 38900
Tel: + (972) 4-627-5357
Fax: + (972) 4-627-5368
Email: info@almalasers.com

Alma Lasers, Inc.
485 Half Day Road, Suite # 100
Buffalo Grove, IL 60089
Tel: 1-224-337-2000
Fax: 1-224-377-2050
Email: contact@almalasers.com
Website: www.almalasers.com

CHAPTER 11

VP Cooled Module – Vascular & Pigmented Lesions

Chapter Contents:

11.1. VP Cooled Module Description

The **VP** cooled module has a high-power targeted phototherapy module for non-invasive treatment of vascular and pigmented lesions. The VP cooled module allows treatment of a broad spectrum of vascular imperfections be selectively targeting oxyhemoglobin, deoxyhemoglobin and melanin.

A complete discussion of the VP cooled module clinical applications may be found in Section 11.6.

The VP cooled module has a green identification section (see Figure 11-1).

This module incorporates a contact-cooling mechanism.

Figure 11-1: VP Cooled Module (Green Color Code)

11.2. VP Cooled Module Specifications

- **Light Source:** Pulsed light with AFT and EDF
- **Spectrum:** 540 – 950nm
- **Energy Density (Fluence):** 5 – 30 J/cm^2
- **Treatment Area (spot size):** 3 cm^2
- **Pulse Widths:** 10, 12, 15 msec
- **Pulse Repetition Rate:** 2/3 Hz
- **Cooling:** TEC

11.3. VP Cooled Module Operating Screen

The **VP** cooled module main operating screen (see Figure 11-2) is displayed when the VP cooled module is connected to the system.

The VP cooled module's contact cooling mechanism can be turned on or off by touching the appropriate soft-key in the bottom-left corner of the screen:

- **COOLING ON** (default mode)
- **COOLING OFF** (touch the **COOLING ON** softkey)

Figure 11-2: VP Cooled Module Operating Screen

Operating parameters available in this module:

1. **Fluence** – the available fluence range is from 5 to 30 J/cm^2 in increments of 1 J/cm^2.
2. **Pulse Width** – three pulse widths are available:
   - 10 msec
   - 12 msec
   - 15 msec
3. **Pulse Repetition Rate** – fixed at 2/3 Hz

11.4. VP Cooled Module Regulatory Labels

Figure 11-3 presents the regulatory identification and caution labels adhered to the VP cooled module connector:

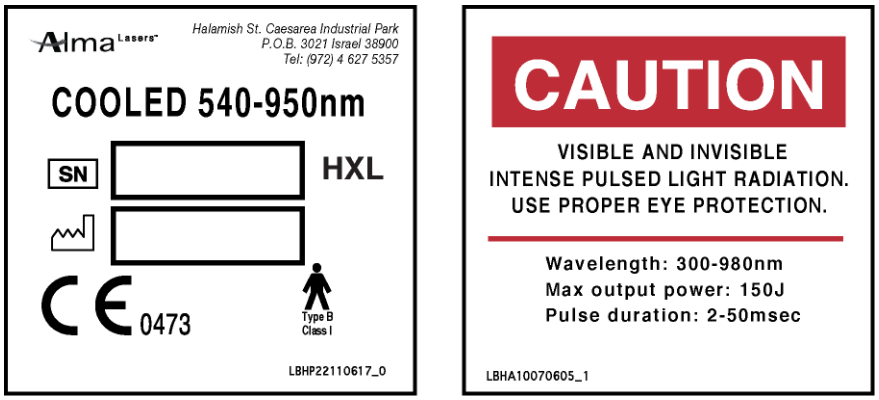

Figure 11-3: VP Cooled Module Regulatory Labels

11.5. Ordering Information

The following table offers names and part numbers of accessories specific to the VP cooled module that may be ordered form Alma Lasers.

Table 11-1: VP Cooled Module Accessories

Description	*Part No.*
VP (Vascular/Pigmented Lesions) Cooled Module	AAHP02110617
Light Safety Glasses (OD 3+)	OPIP05120501
Dark Safety Glasses (OD 5+)	OPIP05120502

11.6. VP Cooled Module Clinical Guide for Vascular Lesions

The treatment of Vascular Lesions with the Harmony^{XL} system can be performed using (one – or a combination of) three modules of the following types:
VP 540-950nm (green color code), **SR 570-950nm** (yellow color code) and the **1064nm Long Pulse Nd:YAG** laser module.

- The SR module is discussed in detail in Chapter 7 of this manual.
- The 1064nm laser module is discussed in detail in Chapter 14 of this manual

The VP cooled module (with integrated contact cooling) is indicated for vascular lesions.

> ***Warning***
>
> **The appropriate protective eyewear should be worn by both the operator and the patient when using this module.**

11.6.1. Pre-Treatment

11.6.1.1. Assessing the Condition

The treatment parameters for any given skin condition depend on the skin type and the lesion type, depth and density.

In principle, treat the larger vessels first and only after they are closed proceed to treat the smaller vessels. This avoids refilling the small vessels by the larger, intact feeders.

11.6.1.2. Contraindications

- Tanned skin (active tan) through sun exposure or tanning bed use in the previous 30 days
- Hypopigmentation (Vitiligo)
- Any inflammatory skin condition e.g. eczema, active herpes simplex, etc. at the treatment site
- Skin cancer or any other cancer and/or any cancer drug therapy (such as Ducabaxine, Fluorouracil, Methotrexate, etc.)
- History of keloid scarring
- Epilepsy

- St. John's Wort (herbal remedy) for depression in the past 3 months (because of increased photosensitivity)
- Isotretinoin – Roaccutane in the previous 3-6 months
- Tretinoin – Retin A in the last 2 weeks
- Pregnancy; until menstruation returns and end of breast feeding
- Diabetes (because of increased possible photosensitivity and poor wound healing)

11.6.1.3. Preparing the Lesion for Treatment

If the lesion is smaller than the lightguide's footprint, use the template provided by Alma Lasers to protect collateral tissue surrounding the lesion. To use the template, select a suitable pre-cut hole so that only the lesion area is fully exposed to the margin. Place the template on the treatment site and cover it with a thin layer of gel (underneath and on top of the template) before treatment.

11.6.1.4. Skin Test

Always perform a skin test on the intended treatment area with the cooling mode On and according to the following parameters:

Table 11-2: Vascular Lesions Skin Test Parameters

Skin Type (Fitzpatrick I-VI)	*Module*	*Pulse Width (msec)*	*Fluence (J/cm^2)*	*Waiting Period*
I – III	**Cooled VP 540-950nm** (green color code)	10, 12	20 – 24	30 min
IV	**Cooled VP 540-950nm** (green color code)	12, 15	14 – 18	24 – 48 hours
V – VI	**Cooled VP 540-950nm** (green color code)	15	8 – 14	24 – 48 hours

11.6.2. Treatment

- The VP 540nm cooled module will treat vessels up to < 1mm.
- Treatment is applied perpendicular to the target and a second pass is usually recommended once appropriate safe settings are found. Do not stack pulses. It is recommended to keep the contact cooling on during treatment with the VP cooled module (see Figure 11-2).

- Treatment can begin after the module has been connected to the Harmony^{XL} system and the treatment parameters (fluence and timer interval) are selected according to the Skin Test parameters in Table 11-2.

1. Clean the skin to remove perfumes, cosmetics and sunscreens.

2. Operate the module with **Cooling** mode **ON**.

3. Apply a thin layer (usually 1mm thick and 2mm for darker skin types) of refrigerated (43-50°F/6-10°C) cooling gel to the treatment site. This aids skin cooling during the pulse sequence and improves coupling of the light into the skin and additional comfort to the patient during treatment.

4. Other cooling means, such as small ice packs or forced cold air/Zimmer are also recommended (i.e., post-treatment).

> ***Caution***
>
> Do not treat a vascular lesion through a tattoo or a pigmented lesion that has not been examined by a physician. Any hair covering a vascular lesion must be removed before treatment.

5. Place the module's lightguide perpendicular to the skin and touch the gel with the lightguide. Do not apply pressure (the lightguide should gently touch the skin).

6. It is best not to overlap treatment spots by more than 10%, but if overlapping does occur wait at least one minute between pulses on the same spot.

7. Set the initial fluence parameter according to the skin test results.

8. Trigger a light pulse by pressing the footswitch.

9. Wipe off the gel and examine carefully. Remember: darker skin types take longer to respond than lighter skin types. The desired effect is darkening of the vessel due to blood coagulation and erythema and/or edema along the vessel, indicating a stimulated immune reaction, without changes in the surrounding epidermis.

10. If, along with a good response in the vessel, adverse skin effects occur (such as excessive reddening or swelling in the shape of the lightguide), reduce the fluence by 10-20%.

11. If the skin shows no adverse effects and changes observed in the vessel are unsatisfactory you should increase the fluence by 10-20% and test again.

12. To maximize the cooling/coupling properties of the applied gel, make sure to apply the gel immediately before treatment. After treatment, remove the gel from the treated areas. Do not reuse gel.

13. After treatment, it is recommended to cool the area immediately (see Appendix B in the System Manual – Post-Treatment Care).

11.6.3. Suggested Cooled VP Setup Parameters for Vascular Lesions

Table 11-3: Suggested Cooled VP Setup Parameters for Vascular Lesions*

Skin Type (Fitzpatrick I-VI)	*Target Vessel Depth*	*Module*	*Fluence (J/cm^2)*	*Pulse Width (msec)*
I – III	2	**Cooled VP 540-950nm** (green color code)	22 – 26	10, 12
IV	2	**Cooled VP 540-950nm** (green color code)	18 – 24	12, 15
V – VI	2	**Cooled VP 540-950nm** (green color code)	8 – 16	15

*(*) Cooling mode **ON***

11.6.4. Follow-up

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

- Within three weeks after the treatment patients should return for examination of the treatment site and for additional treatment, if necessary.
- If no additional treatment is necessary, patients should return for an additional examination two months later.
- In case of a partial clearance of the lesion, the treatment should be continued using the same parameters and the patient should return for examination and for additional treatment, if necessary after three weeks.
- If no change in the lesion is noted, fluence should be increased by at least 10%.
- Intervals between treatments can be increased in successive treatments.
- Treatment is complete when satisfactory results are obtained.
- 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 Ltd.
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Email: info@almalasers.com

Alma Lasers, Inc.
485 Half Day Road, Suite # 100
Buffalo Grove, IL 60089
Tel: 1-224-337-2000
Fax: 1-224-377-2050
Email: contact@almalasers.com
Website: www.almalasers.com

11.7. VP Cooled Module Clinical Guide for Pigmented Lesions

The Pigmented Lesions application of the Harmony^{XL} system can be performed with the **VP 540-950nm** (green color code) and the **SR 570-950nm** (yellow color code) modules.

The SR module is discussed in detail in Chapter 7 of this manual.

The VP cooled module (with integrated contact cooling) is indicated for pigmented lesions.

> ***Warning***
>
> **The appropriate protective eyewear should be worn by both the operator and the patient when using this module.**

11.7.1. Pre-Treatment

11.7.1.1. Assessing the Condition

The treatment parameters for any given skin condition depend on the skin type and the lesion type, depth and density.

11.7.1.2. Contraindications

- Tanned skin (active tan) through sun exposure or tanning bed use in the previous 30 days
- Hypopigmentation (Vitiligo)
- Any inflammatory skin condition e.g. eczema, active herpes simplex, etc. at the treatment site
- Skin cancer or any other cancer and/or any cancer drug therapy (such as Ducabaxine, Fluorouracil, Methotrexate, etc.)
- History of keloid scarring
- Epilepsy
- St. John's Wort (herbal remedy) for depression in the past 3 months (because of increased photosensitivity)
- Isotretinoin – Roaccutane or Tretinoin – Retin A for the treatment of acne or other dermatological conditions in the previous 3-6 months
- Pregnancy; until menstruation returns and end of breast feeding

- Diabetes (because of increased possible photosensitivity and poor wound healing)

11.7.1.3. Preparing the Lesion for Treatment

If the lesion is smaller than the lightguide's footprint, use the template provided by Alma Lasers to protect collateral tissue surrounding the lesion. To use the template, select a suitable pre-cut hole so that only the lesion area is fully exposed. Place the template on the treatment site and cover it with a thin layer of gel (underneath and on top of the template) before treatment.

11.7.1.4. Skin Test

Always perform a skin test on the intended treatment area during the first treatment session with the cooling mode On and according to the following parameters:

Table 11-4: Pigmented Lesions Skin Test Parameters

Skin Type (Fitzpatrick I-VI)	*Module*	*Lesion Color*	*Pulse Width (msec)*	*Fluence (J/cm^2)*	*Waiting Period*
I – III	**Cooled VP 540-950nm** (green color code)	Light	10, 12	22 – 26	30 min.
		Dark	10, 12	20 – 22	
IV	**Cooled VP 540-950nm** (green color code)	Light	12, 15	16 – 18	24 – 48 hours
		Dark	15	12 – 16	
V – VI	**Cooled VP 540-950nm** (green color code)	Dark	15	8 – 16	24 – 48 hours

11.7.2. Treatment

Treatment may begin after the module has been connected to the Harmony^{XL} system and the treatment parameters (fluence and timer interval) are selected according to the Skin Test parameters in Table 11-4.

1. Clean the skin to remove perfumes, cosmetics and sunscreens.
2. Operate the module with **Cooling** mode **ON**.
3. Apply a thin layer (usually 1mm thick and 2mm for darker skin types) of refrigerated (43-50°F/6-10°C) cooling gel to the treatment site. This aids skin cooling during the pulse sequence and improves coupling of the light into the skin.
4. Other cooling means, such as small ice packs or forced cold air/Zimmer are also recommended (i.e., post-treatment).
5. Place the module's lightguide perpendicular to the skin and touch the gel with the lightguide. Do not apply pressure (the lightguide should gently touch the skin).
6. It is best not to overlap treatment sites by more than 10%, but if overlapping does occur wait at least one minute between pulses over the same spot.
7. Set the initial fluence parameter according to the skin test results.
8. Trigger a light pulse by pressing the footswitch.
9. Wipe off the gel and diagnose carefully. Remember: darker skin types take longer to respond than lighter skin types. The desired “positive” effect is to observe a change in lesion color (graying or darkening for brown pigment) or morphological changes (superficial texture change to the lesion), without changes in the surrounding epidermis.
10. If, along with a positive response in the lesions, adverse skin effects occur (such as excessive reddening or swelling in the shape of the lightguide), you should reduce the fluence by 10-20%.
11. If the skin shows no adverse effects and changes observed in the lesions are unsatisfactory, you should increase the fluence by 10-20%.
12. To maximize the cooling/coupling properties of the applied gel, make sure to apply the gel immediately before each pass/treatment. After treatment, remove the gel from treated areas. Do not reuse gel.
13. After treatment, it is recommended to cool the area immediately (see Appendix B in the System Manual – Post-Treatment Care).

11.7.3. Suggested Cooled VP Setup Parameters for Pigmented Lesions

Table 11-5: Suggested Cooled VP Setup Parameters for Pigmented Lesions*

Skin Type (Fitzpatrick I-VI)	Lesion Color	Module	Pulse Width (msec)	Fluence (J/cm^2)
I – III	Light	**Cooled VP 540-950nm** (green color code)	10, 12	25 – 30
	Dark	**Cooled VP 540-950nm** (green color code)	15	24 – 28
VI	Light	**Cooled VP 540-950nm** (green color code)	10, 12	18 – 23
	Dark	**Cooled VP 540-950nm** (green color code)	15	12 – 17
V – VI	Dark	**Cooled VP 540-950nm** (green color code)	15	10 – 16

*(*) Cooling mode **ON***

11.7.4. Follow-up

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

- Within three weeks after the treatment patients should return for examination of the treatment site and for additional treatment, if necessary.
- If no additional treatment is necessary, patients should return for an additional examination two months later.
- In case of a partial clearance of the lesion, the treatment should be continued using the same parameters and the patient should return for examination and for additional treatment, if necessary after three weeks.
- If no change in the lesion is noted, fluence should be increased by at least 10%.
- Intervals between treatments can be increased in successive treatments.
- Treatment is complete when satisfactory results are obtained.
- 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 Ltd.
14 Halamish St., P.O.B. 3021
Caesarea Industrial Park
Caesarea, Israel 38900
Tel: + (972) 4-627-5357
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Email: info@almalasers.com

Alma Lasers, Inc.
485 Half Day Road, Suite # 100
Buffalo Grove, IL 60089
Tel: 1-224-337-2000
Fax: 1-224-377-2050
Email: contact@almalasers.com
Website: www.almalasers.com

CHAPTER 12

SR Cooled Module – Skin Rejuvenation

Chapter Contents:

12.1. SR Cooled Module Description

The **SR** cooled module has a high-power targeted phototherapy module for skin rejuvenation. It employs Alma Laser's proprietary AFT pulsed light technology in the yellow wavelength range (570-950nm) along with adjustable parameters for effective rejuvenation of the skin.

A complete discussion of the SR cooled module clinical applications may be found in Section 12.6.

The SR cooled module has a yellow identification section (see Figure 12-1).

This module incorporates a contact-cooling mechanism.

Figure 12-1: SR Cooled Module (Yellow Color Code)

12.2. SR Cooled Module Specifications

- **Light Source:** Pulsed light with AFT and EDF
- **Spectrum:** 570 – 950nm
- **Energy Density (Fluence):** 5 – 30 J/cm^2
- **Treatment Area (spot size):** 3 cm^2
- **Pulse Widths:** 10, 12, 15 msec
- **Pulse Repetition Rate:** 2/3 Hz
- **Cooling:** TEC

12.3. SR Cooled Module Operating Screen

The **SR** cooled module main operating screen (see Figure 12-2) is displayed when the SR cooled module is connected to the system:

Figure 12-2: SR Cooled Module Operating Screen

Operating parameters available in this module:

1. **Fluence** – the available fluence range is from 5 to 30 J/cm^2 in increments of 1 J/cm^2.
2. **Pulse Width** – three pulse widths are available:
   - 10 msec
   - 12 msec
   - 15 msec
3. **Pulse Repetition Rate** – fixed at 2/3 Hz

12.4. SR Cooled Module Regulatory Labels

Figure 12-3 presents the regulatory identification and caution labels adhered to the SR cooled module connector:

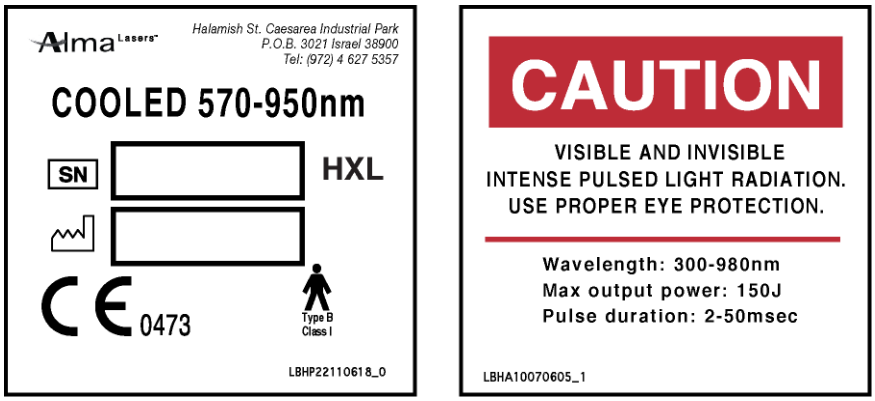

Figure 12-3: SR Cooled Module Regulatory Labels

12.5. Ordering Information

The following table offers names and part numbers of accessories specific to the SR cooled module that may be ordered form Alma Lasers.

Table 12-1: SR Cooled Module Accessories

Description	*Part No.*
SR (Skin Rejuvenation) Cooled Module	AAHP02110618
Light Safety Glasses (OD 3+)	OPIP05120501
Dark Safety Glasses (OD 5+)	OPIP05120502

12.6. SR Cooled Module Clinical Guide

The Skin Rejuvenation application of the Harmony^{XL} system is performed using the **SR 570-950nm** (yellow color code) module or the **Long Pulse Nd:YAG (1064nm)** module.

The 1064nm laser module is discussed in detail in Chapter 14 of this manual

The SR 570-950nm cooled module is indicated for the treatment of benign pigmented epidermal lesions, including dyschromia, hyperpigmentation, melasma and ephelides (freckles), and for the non-ablative treatment of facial fine lines & texture improvement (skin rejuvenation).

Warning

The appropriate protective eyewear should be worn by both the operator and the patient when using this module.

12.6.1. Pre-Treatment

12.6.1.1. Assessing the Condition

The treatment parameters for any given skin condition depend on the skin type and the lesion type, depth and density.

12.6.1.2. Contraindications

- Tanned skin (active tan) through sun exposure or tanning bed use in the previous 30 days
- Hypopigmentation (Vitiligo)
- Any inflammatory skin condition e.g. eczema, active herpes simplex, etc. at the treatment site
- Skin cancer or any other cancer and/or any cancer drug therapy (such as Ducabaxine, Fluorouracil, Methotrexate, etc.)
- History of keloid scarring
- Epilepsy
- St. John's Wort (herbal remedy) for depression in the past 3 months (because of increased photosensitivity)
- Isotretinoin – Roaccutane in the previous 3-6 months
- Retin-A – In the past 2 weeks

- Pregnancy; until menstruation returns and end of breast feeding
- Diabetes (because of increased possible photosensitivity and poor wound healing)

12.6.1.3. Skin Test

Always perform a skin test on the intended treatment area during the first treatment session according to the following parameters:

Table 12-2: Cooled SR Skin Test Parameters

Skin Type (Fitzpatrick I-VI)	*Module*	*Pulse Width (msec)*	*Fluence (J/cm^2)*	*Waiting Period*
I – III	**Cooled SR 570-950nm** (yellow color code)	10, 12	20 – 24	30 min.
VI	**Cooled SR 570-950nm** (yellow color code)	12, 15	16 – 20	30 min.
V – VI	**Cooled SR 570-950nm** (yellow color code)	15	8 – 16	24 – 48 hours

12.6.2. Treatment

Treatment can begin after the suitable module has been connected to the Harmony^{XL} system and the treatment parameters (fluence and timer interval) are selected according to Table 12-2.

> ***Note***
>
> Always perform a skin test on the intended treatment area during the first treatment session.

1. Clean the skin to remove perfumes, cosmetics and sunscreens.
2. Apply a thin layer (usually 1mm thick and 2mm for darker skin types) of refrigerated (43-50°F/6-10°C) cooling gel to the treatment site. The gel will provide a thermal sink for the absorbed and reflected energy, provide some cooling to the skin itself, and additional comfort to the patient during treatment.
3. Place the lightguide perpendicular to the skin and touch the gel with the lightguide. Do not apply pressure (the lightguide should gently touch the skin).
4. Set the initial fluence parameter according to the skin test results.

5. Trigger a light pulse by pressing the footswitch and the module trigger simultaneously.
6. Wipe off the gel.
7. If adverse skin effects occur (such as excessive reddening or swelling in the shape of the lightguide), you should reduce the fluence by 10-20%.
8. If no change in the skin is noted, then the fluence should be increased by 10-20%.
9. To maximize the cooling/coupling properties of the applied gel, make sure to apply the gel immediately before treatment. After treatment, remove the gel from treated areas. Do not reuse gel.
10. After treatment, it is recommended to cool the area immediately (see Appendix B in the System Manual – Post-Treatment Care).

12.6.3. Suggested Cooled SR Setup Parameters

Table 12-3: Suggested Cooled SR Setup Parameters

Skin Type (Fitzpatrick I-VI)	*Module*	*Pulse Width (msec)*	*Fluence (J/cm^2)*
I – III	**Cooled SR 570-950nm** (yellow color code)	10, 12	22 – 26
IV	**Cooled SR 570-950nm** (yellow color code)	15	16 – 22
V – VI	**Cooled SR 570-950nm** (yellow color code)	15	10 – 16

12.6.4. Follow-up

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

- Within three weeks after the treatment patients should return for examination of the treatment site and for additional treatment, if necessary.
- If no additional treatment is necessary, patients should return for an additional examination one month later.
- Intervals between treatments can be increased in successive treatments.
- Treatment is complete when satisfactory results are obtained.
- 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 Ltd.
14 Halamish St., P.O.B. 3021
Caesarea Industrial Park
Caesarea, Israel 38900
Tel: + (972) 4-627-5357
Fax: + (972) 4-627-5368
Email: info@almalasers.com

Alma Lasers, Inc.
485 Half Day Road, Suite # 100
Buffalo Grove, IL 60089
Tel: 1-224-337-2000
Fax: 1-224-377-2050
Email: contact@almalasers.com
Website: www.almalasers.com

CHAPTER 13

SSR Module – Super Skin Rejuvenation

Chapter Contents:

13.1. SSR Module Description

The **SSR** module has a high-power targeted phototherapy module for skin rejuvenation. It employs Alma Laser's proprietary AFT pulsed light technology along with adjustable parameters for effective rejuvenation of the skin.

A complete discussion of the SSR module clinical applications may be found in Section 13.7.

The SSR module has a green identification section (see Figure 13-1).

This module incorporates a contact-cooling mechanism.

Figure 13-1: SSR Module (Green Color Code)

13.2. SSR Module Specifications

- **Light Source:** Pulsed light with AFT and EDF
- **Energy Density (Fluence):** 1 – 15 J/cm^2
- **Treatment Area (spot size):** 3 cm^2
- **Timers:** 1, 3 & 30 seconds
- **Pulse Repetition Rate:** 2 Hz
- **Cooling:** TEC

13.3. SSR Module Operating Screen

The **SSR** module main operating screen (see Figure 13-2) is displayed when the SSR module is connected to the system:

The **SSR** module's contact cooling mechanism can be turned on or off by touching the appropriate soft-key in the bottom-left corner of the screen:

- **COOLING ON** (default mode)
- **COOLING OFF** (touch the **COOLING ON** softkey)

Figure 13-2: SSR Module Operating Screen

Operating parameters available in this module:

1. **Fluence** – the available fluence range is from 1 to 15 J/cm^2 in increments of 1 J/cm^2.
2. **Timers** – 1, 3 & 30 seconds
3. **Pulse Repetition Rate** – fixed at 2 Hz

13.4. Total Energy in the SSR Module

The SSR module's operating screen exhibits the total energy applied per session, counted in Kilojoules (see **kJ** counter in top-right corner of Figure 13-2):

> ***Note***
>
> If the system stays in **SSR** mode during patient rotation, it is important to reset the Total Energy by pressing the **Reset** key.

13.5. SSR Module Regulatory Labels

Figure 13-3 presents the regulatory identification and caution labels adhered to the SSR module connector:

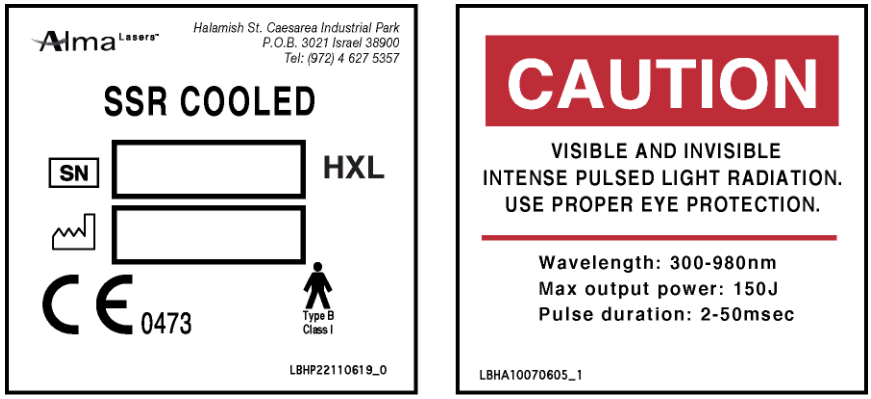

Figure 13-3: SSR Module Regulatory Labels

13.6. Ordering Information

The following table offers names and part numbers of accessories specific to the SSR module that may be ordered form Alma Lasers.

Table 13-1: SSR Module Accessories

Description	*Part No.*
SSR (Super Skin Rejuvenation) Module	AAHP12070701
Light Safety Glasses (OD 3+)	OPIP05120501
Dark Safety Glasses (OD 5+)	OPIP05120502

13.7. SSR Module Clinical Guide

The Skin Rejuvenation application of the Harmony^{XL} system is performed using the **SSR** (green color code) module. The SSR module is indicated for the treatment of benign pigmented epidermal lesions, including dyschromia, hyperpigmentation, melasma and ephelides (freckles), and for the non-ablative treatment of facial fine lines & texture improvement (skin rejuvenation).

> ***Warning***
>
> **The appropriate protective eyewear should be worn by both the operator and the patient when using this module.**

13.7.1. Module Operation

The SSR module may be operated with 3 different time intervals: 1, 3 and 30 seconds.

In the 1-second and 3-second intervals, the module is used employing the **Stationary** technique. In the 30-second interval, the module is used employing the **In-Motion** technique (see Section 13.7.3). The 1-second and 3-second intervals are used on small areas where you want to treat localized, small, superficial pigmented or vascular lesions (i.e., back of the hand or upper lip). The 30-second interval is used on large areas where you want to treat signs of photodamage/ photoaging irregularities (dyschromia, lentigines, freckles etc).

The SSR module incorporates thermo-electric coupling (TEC) technology; the module can be operated under two conditions: **Cooling On** (default) and **Cooling Off**.

The module spot size is 3cm^2 and the pulse repetition rate is fixed at 2 Hz. The total energy delivered at any given time interval is expressed in kilojoules (**kJ**).

Ultrasonic gel should be used in both **Stationary** and **In-Motion** techniques.

13.7.2. Pre-Treatment

13.7.2.1. Assessing the Condition

The treatment parameters for any given skin condition depend on the skin type and the lesion type, depth and density.

13.7.2.2. Contraindications

- Hypopigmentation (Vitiligo)
- Any inflammatory skin condition e.g., eczema, active herpes simplex, etc., at the treatment site
- Skin cancer or any other cancer and/or any cancer drug therapy (such as Ducabaxine, Fluorouracil, Methotrexate, etc.)
- History of keloid scarring
- Epilepsy
- St. John's Wort (herbal remedy) for depression in the past three months (because of increased photosensitivity)
- Isotretinoin – Roaccutane or Tretinoin – In the past 3-6 months
- Retin A - In the past 2 weeks
- Pregnancy (including IVF)
- Diabetes

13.7.2.3. Skin Test

Always perform a skin test on the intended treatment area during the first treatment session, with the **Cooling** mode **On** and according to the following parameters:

Table 13-2: SSR Skin Test Parameters

Skin Type (Fitzpatrick I-VI)	*Fluence (J/cm^2)*	*Cooling [On/Off] **	*Total Energy [kJ] ***
I – III	8 – 9	On	1.8
IV	6 – 7	On	1.8
V – VI	4 – 5	On	1.8

The 1-second and 3-second time intervals are indicated for the **Stationary** technique.

(*) Ultrasonic gel must be applied to the skin in both Cooling **On** or **Off** modes.

(**) The total energy is adjusted for 10x10 cm (100cm^2) area.

Important: a thin coat of ultrasonic gel must be applied on the skin for ALL skin types.

13.7.3. Treatment (In-Motion Technique)

Treatment can begin after the SSR module has been connected to the Harmony^{XL} system and the treatment parameters selected (fluence) according to Table 13-3.

1. Clean the skin to remove perfumes, cosmetics and sunscreens.
2. Provide appropriate eye protection (OD>5) goggles for the patient and the medical staff in the enclosed treatment room.
3. Apply a thin layer (usually 1-2mm thick for all skin types) of refrigerated cooling gel (43-50°F/6-10°C) to the treatment site. The gel will provide: a) a thermal sink for the absorbed and reflected energy, thus providing some cooling to the skin itself; b) comfort to the patient during treatment and; c) friction reduction/lubrication during the In-Motion technique.
4. Set the initial fluence parameter according to the skin test results.
5. Apply the **In-Motion** technique:
   - Move the module on the surface of the skin and, only when the module is in full contact and "in-motion", then trigger the footswitch.
   - Move the module in continuous linear or circular motions, to cover the entire grid area. This repeated pattern may last several minutes, depending on the recommended total energy (**kJ**).
   - After completing a single interval, raise the module from the skin, re-position at the point where you began treatment in this grid and repeat another interval on the entire area.
   - After completing the recommended number of intervals, move to the contra-lateral side and repeat as above.
6. In most cases, operation time intervals should be set for 30 seconds for large areas; the 1-second and 15-second intervals should be selected for small areas on the face, chest or back (using the Stationary technique rather than the In-Motion technique).
7. Place the module perpendicular to the skin, pressed lightly to the skin surface.
8. Perform the recommended cycles on the right and left side of the face. Repeat the intervals on each side.
9. Clinical end points: mild-to-moderate erythema for skin types I-IV; mild erythema for skin types V-VI.
10. If adverse reactions are observed from the prior treatment, the next treatment may be skipped or the dose reduced until the symptoms resolve.
11. It is recommended to cool the area immediately after the treatment (see Appendix C in the System Manual – Post-Treatment Care).

> ***Note***
>
> Always perform a skin test on the intended treatment area during the first treatment session.

13.7.4. Suggested Setup Parameters

Table 13-3: SSR Suggested Setup Parameters

Skin Type (Fitzpatrick I-VI)	*Fluence (J/cm^2)*	*Cooling [On/Off] **	*Total Energy [kJ] ***
I – III	10 – 12	On	1.8 – 2.1
IV	8 – 9	On	1.8 – 2.1
V – VI	7 – 8	On	1.8 – 2.1

(*) Ultrasonic gel must be applied to the skin.

(**) The total energy is adjusted for 10x10 cm (100cm^2) area. The 1-second and 3-second time intervals are indicated for the **Stationary** technique

13.7.5. Stationary Protocol

1. In the stationary technique, use the 3-second interval; up to 10% overlapping is an acceptable tolerance.
2. Set the initial exposure time and fluence parameters according to Table 13-2.
3. Trigger a pulse by continuously pressing the footswitch for the entire time interval; the module will stop emitting light automatically unless interrupted by the operator (releasing the footswitch). In order to continue, the footswitch must be pressed again.
4. Check skin reaction; if there is no apparent skin reaction – repeat until clinical end points are visible.
5. Treatment parameters may be increased by 10% every other treatment and subjected to the conditions in the area treated and patient's tolerance.
6. Following treatment, gently cleanse the ultrasonic gel from the treated area.
7. If adverse skin effects occur (such as excessive reddening or swelling), you may either reduce the exposure time (1 sec interval) or reduce the fluence.
8. It is recommended to cool the area immediately after the treatment (see Appendix C in the System Manual – Post-Treatment Care).

13.7.6. Treatment of Small Areas

Table 13-4: Small Area Parameters, 3-25 cm^2, 3 Seconds, In-Motion

Skin Type (Fitzpatrick I-VI)	Fluence (J/cm^2)	Cooling [On/Off]	Total Energy [kJ]
I – III	8 – 9	On	1.0 – 1.2
IV	6 – 7	On	1.0 – 1.2
V - VI	4 – 5	On	1.0 – 1.2

Table 13-5: Small Area Parameters, 3-25 cm^2, 1 Second, In-Motion

Skin Type (Fitzpatrick I-VI)	Fluence (J/cm^2)	Cooling [On/Off]	Total Energy [kJ]
I – III	10 – 12	On	1.0 – 1.2
IV	8 – 9	On	1.0 – 1.2
V - VI	7 – 8	On	1.0 – 1.2

Table 13-6: Small Area Parameters, Up To 3 cm^2, 3 Seconds, Stationary*

Skin Type (Fitzpatrick I-VI)	Fluence (J/cm^2)	Cooling [On/Off]**
I – III	8 – 9	On
IV	6 – 7	On
V - VI	5 – 6	On

(*) Repeat twice.
(**) Apply gel.

Table 13-7: Small Area Parameters, Up To 3 cm^2, 1 Second, Stationary*

Skin Type (Fitzpatrick I-VI)	Fluence (J/cm^2)	Cooling [On/Off]**
I – III	10 – 12	On
IV	8 – 9	On
V - VI	6 – 7	On

(*) Repeat twice.
(**) Apply gel.

13.7.7. Follow-up

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

- Within three weeks after treatment patients should return for examination of the treatment site and for additional treatment, if necessary.
- If no additional treatment is necessary, patients should return for an additional examination one month later.
- Intervals between treatments can be increased in successive treatments.
- Treatment is complete when satisfactory results are obtained.
- Patients should be instructed to avoid sun exposure after and in between treatments.
- Treatment intervals: treatment is reapplied (assuring there have been no adverse reactions) every 3-4 weeks.

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 Ltd.
14 Halamish St., P.O.B. 3021
Caesarea Industrial Park
Caesarea, Israel 38900
Tel: + (972) 4-627-5357
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Alma Lasers, Inc.
485 Half Day Road, Suite # 100
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Fax: 1-224-377-2050
Email: contact@almalasers.com
Website: www.almalasers.com

CHAPTER 14

SHR Pro Module – Super Hair Removal

Chapter Contents:

14.1. SHR Pro Module Description

The **SHR Pro** module incorporates two separate wavelengths in one module, both effecting long-term or permanent hair reduction:

- Proprietary AFT pulsed light in the red wavelength range along with adjustable parameters.
- Near infrared wavelength range.

A complete discussion of the SHR Pro module clinical applications may be found in Section 14.6.

The SHR Pro module has a red identification section (see Figure 14-1).

This module incorporates a contact-cooling mechanism.

Figure 14-1: SHR Pro Module (Red Color Code)

14.2. SHR Pro Module Specifications

14.2.1. HR Mode

- **Light Source:** Pulsed light with AFT and EDF
- **Energy Density (Fluence):** 5 – 25 J/cm^2
- **Treatment Area (spot size):** 3 cm^2
- **Pulse Widths:** 30, 40, 50 msec
- **Pulse Repetition Rate:** 2/3 Hz
- **Cooling:** TEC

14.2.2. SHR Mode

- **Light Source:** Near Infrared pulsed light
- **Energy Density (Fluence):** 1 – 7 J/cm^2
- **Treatment Area (spot size):** 3 cm^2
- **Timer:** 1, 3 and 30 seconds
- **Pulse Repetition Rate:** 3 Hz
- **Cooling:** TEC

14.2.3. SHR Pro Module Operating Screens

The **SHR Pro** module main operating screen (see Figure 14-2) is displayed when the SHR Pro module is connected to the system.

- To switch from **HR** to **SHR** mode, press the **PW** soft-key on the **HR** screen.
- To switch from **SHR** to **HR** mode, press the **Time** soft-key on the **SHR** screen

The SHR Pro module's contact cooling mechanism can be turned on or off by touching the appropriate soft-key in the bottom-left corner of the screen:

- **COOLING ON** (default mode)
- **COOLING OFF** (touch the **COOLING ON** softkey)

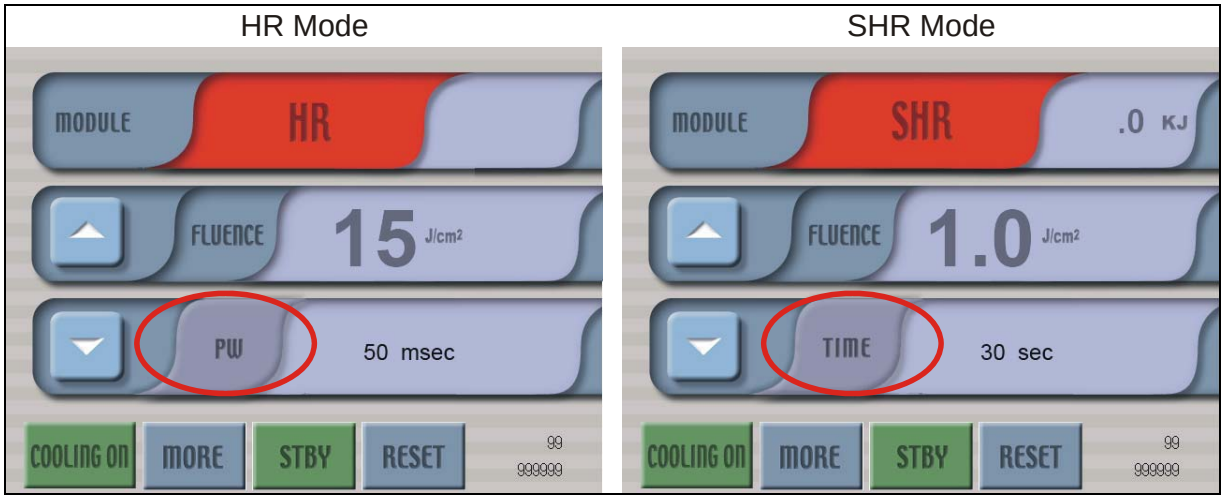

Figure 14-2: SHR Pro Cooling Module Operating Screens

Operating parameters available in HR mode:

1. **Fluence** – the available range is from 5 to 25 J/cm^2 in increments of 1 J/cm^2.
2. **Pulse Width** – three pulse widths are available:
   - 30 msec
   - 40 msec
   - 50 msec
3. **Pulse Repetition Rate** – fixed at 2/3 Hz

Operating parameters available in SHR mode:

1. **Fluence** – the available fluence range is from 1 to 7 J/cm^2 in increments of 1 J/cm^2.
2. **Timer** – 1, 3 and 30 seconds
3. **Pulse Repetition Rate** – fixed at 3 Hz

14.3. Total Energy in the SHR Pro Module

The SHR Pro module's **SHR** operating screen exhibits the total energy applied per session, counted in Kilojoules (see **kJ** counter in top-right corner of Figure 14-2):

> ***Note***
>
> If the system stays in **SHR Pro** mode during patient rotation, it is important to reset the Total Energy by pressing the **Reset** key.

14.4. SHR Pro Module Regulatory Labels

Figure 14-3 presents the regulatory identification and caution labels adhered to the SHR Pro module connector:

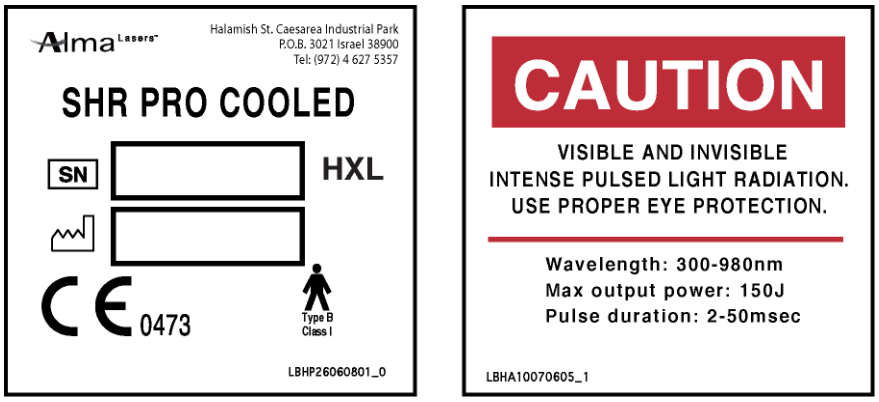

Figure 14-3: SHR Pro Module Regulatory Labels

14.5. Ordering Information

The following table offers names and part numbers of accessories specific to the SHR Pro module that may be ordered form Alma Lasers.

Table 14-1: SHR Pro Module Accessories

Description	*Part No.*
SHR Pro (Super Hair Removal) Module	AAHP24060804
Light Safety Glasses (OD 3+)	OPIP05120501
Dark Safety Glasses (OD 5+)	OPIP05120502

14.6. SHR Pro Module Clinical Guide – HR Mode

The Harmony^{XL} system with the **SHR Pro** module is indicated for the removal of unwanted hair and to effect stable long-term or permanent hair reduction.

> ***Warning***
>
> **The appropriate protective eyewear should be worn by both the operator and the patient when using this module.**

14.6.1. Pre-Treatment

14.6.1.1. Patient Evaluation

Before hair removal procedures, the patient should be evaluated for the presence of conditions that may cause hypertrichosis:

- Hormonal
- Familial
- Drug (i.e., corticosteroids, hormones, immunosuppressive self or spousal use of minoxidil)
- Tumor

14.6.1.2. Contraindications

- History of local or recurrent skin infection
- Pregnancy (including IVF procedure)
- History of herpes simplex, especially perioral
- History of genital herpes, important when treating the pubic or bikini area
- History of keloids/hypertrophic scaring
- Isotretinoin – In the past 3-6 months
- Retin-A – In the past 2 weeks
- Epilepsy
- History of Koebnerizing skin disorders, such as vitiligo and psoriasis
- Previous treatment modalities – method, frequency and date of last treatment, as well as response
- Recent suntan or exposure to a tanning bed

- Tattoos or nevi present
- Past or ongoing medical condition (diabetes, epilepsy, high or low blood pressure, or others)
- Present medications:
  - Photosensitizing medications
  - Gold therapy

14.6.1.3. Skin Test

Always perform a skin test on the intended treatment area during the first treatment session according to the following parameters in the table below.

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

Table 14-2: Cooled HR Skin Test Parameters

Skin Type (Fitzpatrick I-VI)	*Mode*	*Pulse Width (msec)*	*Fluence (J/cm^2)*	*Waiting Period*
I	**HR**	30	26 – 28	30 minutes
II	**HR**	30	24 – 26	30 minutes
III	**HR**	40	22 – 24	30 minutes
IV	**HR**	50	18 – 20	24 – 48 hours
V	**HR**	50	14 – 16	24 – 48 hours
VI	**HR**	50	10 – 12	24 – 48 hours

14.6.2. Treatment

Treatment can begin after the SHR Pro module is connected, set to **HR** mode and the treatment parameters are selected (fluence and timer interval) according to Table 14-2.

1. Clean the skin to remove perfumes, cosmetics and sunscreens.
2. Apply a thin layer (usually ~1 mm and ~2 mm for darker types) of refrigerated cooling gel (43-50°F/6-10°C) to the treatment site. The gel will provide a thermal sink for the absorbed and reflected energy, provide some cooling to the skin itself, and additional comfort to the patient during treatment.
3. Place the module perpendicular to the skin and touch the skin to ensure a good seal. Do not apply excessive pressure on the skin.

4. Set the initial fluence parameter according to the skin test results.
5. Trigger a light pulse by pressing the footswitch.
6. Examine the treatment site for any change of the skin color and morphological changes around the follicles (erythema/edema). The smell of burnt hair may sometimes be detected, although a lack of smell does not necessarily indicate that the present parameters are ineffective.
7. It is recommended to wait 30 minutes after a test shot has been triggered for skin types I-IV, and 24-48 hours for skin types V and VI before proceeding.
8. If there are no noticeable changes in the hair follicles, or adverse effects, increase the settings by 10-20% (skin types I-IV). Do not increase settings on skin type V or VI until the initial test has been reviewed 24-48 hours after treatment.
9. If adverse skin effects occur (such as excessive reddening) before good follicular response is achieved, reduce the settings by 10-20%.
10. Make the above adjustments and test again on an adjacent area until adverse effects on the skin no longer appear.
11. After treatment it is recommended to cool the area immediately (see Appendix B in the System Manual – Post-Treatment Care).

14.6.3. Suggested HR Setup Parameters

The following table shows the recommended parameters based on the patient hair color and skin type:

Table 14-3: Suggested HR Setup Parameters

Skin Type (Fitzpatrick I-VI)	Hair Color	Mode	Fluence (J/cm^2)	Pulse Width (msec)
I	Light	**HR**	26 – 30	30
	Dark	**HR**	26 – 30	30
II	Light	**HR**	24 – 30	30
	Dark	**HR**	24 – 30	30
III	Light	**HR**	22 – 30	40
	Dark	**HR**	22 – 30	40
IV	Light	**HR**	18 – 26	40
	Dark	**HR**	18 – 26	50
V	Light	**HR**	14 – 20	50
	Dark	**HR**	14 – 20	50
VI	Light	N/A	N/A	N/A
	Dark	**HR**	10 – 14	50

Caution

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

14.6.4. Follow-Up

Measures presented below are only the manufacturer's recommendations 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 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 Ltd.
14 Halamish St., P.O.B. 3021
Caesarea Industrial Park
Caesarea, Israel 38900
Tel: + (972) 4-627-5357
Fax: + (972) 4-627-5368
Email: info@almalasers.com

Alma Lasers, Inc.
485 Half Day Road, Suite # 100
Buffalo Grove, IL 60089
Tel: 1-224-337-2000
Fax: 1-224-377-2050
Email: contact@almalasers.com
Website: www.almalasers.com

14.7. SHR Pro Module Clinical Guide – SHR Mode

The Harmony^{XL} system with the **SHR Pro** module is indicated for the removal of unwanted hair and to effect stable long-term or permanent hair reduction.

> ***Warning***
>
> **The appropriate protective eyewear should be worn by both the operator and the patient when using this module.**

14.7.1. Module Operation in SHR Mode

The module may be operated under 3 different time intervals: 1, 3 and 30 seconds. In the 1- and 3-second interval the module is used in **Stationary** technique. In the 30-second interval the module is used in the **In-Motion** technique (see Section 14.7.3). The 1- and 3-second intervals are used on small areas (face - mustache, chin etc). The 30-second interval is used on larger areas (body – arms, chest, back, legs, axilla, bikini line etc).

The SHR Pro NIR module incorporates thermo-electric coupling (TEC) technology; the module can be operated under two conditions: cooling ON (default) and cooling OFF. The spot size is 3 cm^2 and the pulse repetition rate is fixed at 3 Hz. Ultrasonic gel should be used in both techniques in OFF or ON cooling modes. Appropriate eye protection for the client and the operator is mandatory.

14.7.2. Pre-Treatment

14.7.2.1. Patient Evaluation

Refer to Section 14.6.1.1

14.7.2.2. Contraindications

Refer to Section 14.6.1.2

14.7.2.3. Skin Test

Always perform a skin test on the intended treatment area before the first treatment session according to the parameters in Table 14-4.

The treatment parameters for hair removal depend on the skin type, hair color, hair type, and the density and depth of the hair. Initially, shave the treatment site to eliminate any surface hair that could interfere with the treatment. Mark a grid (using a red pen) on an area of 10x10 cm ($100cm^2$). Treat with the **In-Motion** technique within each treatment grid, as per treatment description in Section 14.7.3.

Table 14-4: SHR Pro Skin Test Parameters

Skin Type (Fitzpatrick I-VI)	*Fluence (J/cm^2)*	*Cooling [On/Off] **	*Total Energy [kJ] ***
I	7	On	2.0
II	7	On	2.0
III	7	On	2.0
IV	6	On	2.0
V	5	On	2.0
VI	5	On	2.0

The 1-second and 3-second time intervals are indicated for the **Stationary** technique.

(*) Ultrasonic gel must be applied to the skin in both Cooling **On** or **Off** modes.

(**) In-Motion technique; the total energy is adjusted for 10x10 cm or 4x25cm ($100cm^2$) area.

14.7.3. Treatment

Treatment can begin after the SHR Pro module is connected, set to **SHR** mode and the treatment parameter (fluence), treatment interval, and cooling (On/Off) is selected according to Table 14-5.

1. Shave the treatment site to eliminate any surface hair that could interfere with the treatment; remove any hairs debris with adhesive tape.
2. Clean the skin to remove perfumes, cosmetics and sunscreens.
3. Mark a grid (using a red pen) on an area of treatment of about 10x10 cm. Mark additional adjacent grids as needed based on the area size.
4. Provide appropriate eye protection (OD>5) goggles for the patient and the medical staff in the enclosed treatment room.

5. Apply a thin layer (usually 1-2mm thick) of refrigerated (43-50°F / 6-10°C) cooling gel to the treatment site when module cooling is Off or On. The gel will provide: a) a thermal sink for the absorbed and reflected energy, thus providing some cooling to the skin itself; b) comfort to the patient during treatment and; c) friction reduction/lubrication during the **In-Motion** technique.
6. Set the initial fluence and operation time interval (1, 3 or 30 sec) parameter according to the skin test results and the size of the treatment area.
7. In most cases, operation time intervals should be set for 30 seconds for large areas; the 1- and 3-second interval should be selected for very small areas on the face, like the upper lip and chin (using the **Stationary** technique rather than the In-Motion technique).
8. Place the module perpendicular to the skin and touch the skin to ensure a good seal. Do not apply excessive pressure on the skin.
9. Treat within the grid area in an **In-Motion** technique according to the recommended parameters and passes.
10. **In-Motion Technique:**
    - Move the module on the surface of the skin and, only when the module is in full contact and "in-motion", then trigger the footswitch.
    - Move the module in continuous linear or circular motions, to cover the entire grid area. This repeated pattern may last several minutes, depending on the recommended total energy (**kJ**).
    - After completing a single interval, raise the module from the skin, re-position at the point where you began treatment in this grid and repeat another interval on the entire area.
    - After completing the recommended number of intervals, move to the contra-lateral side and repeat as above.
    - Check skin reaction; if the skin reaction is not apparent - repeat. Repeat until clinical end points are visible.
    - Observe for erythema or perifollicular erythema/edema (i.e., end points).
    - Examine the treatment site for change of skin color and morphological changes around the follicles (erythema/edema). The smell of burnt hair may sometimes be detected, although its absence does not necessarily indicate that the present parameters are ineffective.
11. **Stationary Technique:** apply ultrasonic gel to the treatment area in both On and Off cooling modes.
    - In the **Stationary** technique, use the 1- or 3-second interval; up to 10% overlapping is an acceptable tolerance.
12. Set the fluence parameters according to the parameters indicated in Table 14-4 (provided that the patient has tolerated the skin test).

13. Trigger a pulse by continuously pressing the footswitch for the entire time interval; the module will stop emitting light automatically unless interrupted by the operator (releasing the footswitch). In order to continue, the footswitch must be pressed again.
    - Check skin reaction; if the skin reaction is not apparent - repeat. Repeat until clinical end points are visible.
    - Observe for erythema or perifollicular erythema/edema (i.e., end points).
    - Examine the treatment site for change of skin color and morphological changes around the follicles (erythema/edema). The smell of burnt hair may sometimes be detected, although its absence does not necessarily indicate that the present parameters are ineffective.
14. If there are no noticeable changes on the skin (Skin Types IV-VI) or near the hair follicles when the cooling is On, do not repeat.
15. If adverse skin effects occur (such as excessive reddening) before the desired follicular response is achieved, adjust the treatment parameters to reduce the aggressiveness of the treatment.
16. After treatment it is recommended to cool the area immediately with cold (water based) cloth or gauze, and apply Aloe Vera gel.

14.7.4. Suggested Setup Parameters

The treatment parameters for hair removal depend on the skin type, hair color, hair type and the density & depth of the hair. Treat using with the **In-Motion** technique within each treatment grid, as per the explanation in Section 14.7.3.

Table 14-5: SHR Pro Suggested Setup Parameters

Skin Type (Fitzpatrick I-VI)	*Fluence (J/cm^2)*	*Cooling [On/Off] **	*Total Energy [kJ] ***
I	7	On	2.0 – 2.6
II	7	On	2.0 – 2.6
III	7	On	2.0 – 2.6
IV	6	On	2.0 – 2.6
V	5	On	2.0 – 2.6
VI	5	On	2.0 – 2.6

(*) Ultrasonic gel must be applied to the skin in both Cooling **On** or **Off** modes.

(**) The total energy is adjusted for 10x10 cm or 4x25cm (100cm^2) area at 30 sec intervals. The 1- and 3-second operation is indicated for the **Stationary** technique. In the Stationary mode multiple pulses/repetitions should be employed until clinical end-points are visible.

Table 14-6: Suggested Total Energy (kJ) delivered per Anatomic Site

Anatomical Area	Surface Area (cm^2) *	Number of Grids	Total Energy (kJ)
Chest & Abdomen	1500	15	25 – 30
Axilla	100	1	2.0 – 2.6 **
Back	1800	18	30 – 36
Bikini	100	1	2.0 – 2.6 **
Upper Arm	800	8	14 – 16 **
Lower Arm	600	6	10 – 12 **
Upper Leg	1200	12	20 – 24 **
Lower Leg	1000	10	18 – 20 **

(*) Based on full surface area/circumference

(**) Unilateral

14.7.5. Treatment of Small Areas

Table 14-7: Small Area Parameters, 3-25 cm^2, 1 or 3 Seconds, In-Motion

Skin Type (Fitzpatrick I-VI)	Fluence (J/cm^2)	Cooling [On/Off]	Total Energy [kJ]
I – III	5 – 6	On	Up to 0.6
IV	4 – 5	On	Up to 0.6
V - VI	3 – 4	On	Up to 0.6

*Table 14-8: Small Area Parameters, Up To 3 cm^2, 1 or 3 Seconds, Stationary**

Skin Type (Fitzpatrick I-VI)	Fluence (J/cm^2)	Cooling [On/Off]	Total Energy [kJ]
I – III	5	On	Up to 0.1
IV	4	On	Up to 0.1
V - VI	3	On	Up to 0.1

(*) Repeat twice.

14.7.6. Follow-Up

Refer to Section 14.6.4

CHAPTER 15

SST Module – Super Skin Tightening

Chapter Contents:

15.1. SST Module Description

The Harmony **SST** module emits light in the near infrared spectrum generated by a pulsed-light source. The SST module can be used to treat cutaneous lesions such as striae, stretch marks – scar revision and reduce the presence of wrinkles.

A complete discussion of the SST module clinical applications may be found in Section 15.7.

The SST module has a burgundy identification section (see Figure 15-1).

This module incorporates a contact-cooling mechanism.

Figure 15-1: SST Module (Burgundy Color Code)

15.2. SST Module Specifications

- **Light Source:** Near-infrared pulsed light
- **Energy Density (Fluence):** 0.5 – 3.5 J/cm^2
- **Treatment Area (spot size):** 3 cm^2
- **Timers:** 1, 3 and 30 seconds
- **Pulse Repetition Rate:** 5 Hz
- **Cooling:** TEC

15.3. SST Module Operating Screen

The **SST** module main operating screen (see Figure 15-2) is displayed when the SST module is connected to the system:

The SST module's contact cooling mechanism can be turned on or off by touching the appropriate soft-key in the bottom-left corner of the screen:

- **COOLING ON** (default mode)
- **COOLING OFF** (touch the **COOLING ON** softkey)

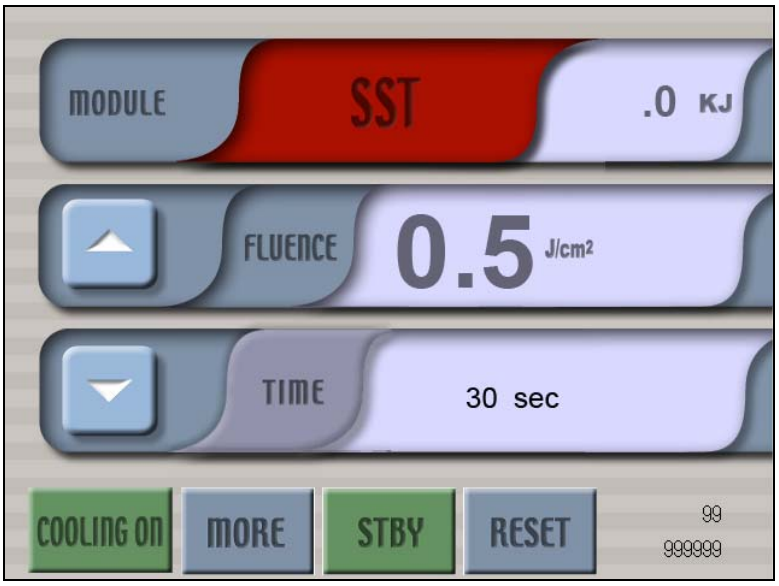

Figure 15-2: SST Module Operating Screen

Operating parameters available in this module:

1. **Fluence** – the available fluence range is from 0.5 to 3.5 J/cm^2 in increments of 0.1 J/cm^2.
2. **Timer** – 1, 3 and 30 seconds
3. **Pulse Repetition Rate** – fixed at 5 Hz

15.4. Total Energy in the SST Module

The SST module's operating screen exhibits the total energy applied per session, counted in Kilojoules (see **kJ** counter in top-right corner of Figure 15-2):

> ***Note***
>
> If the system stays in **SST** mode during patient rotation, it is important to reset the Total Energy by pressing the **Reset** key.

15.5. SST Module Regulatory Labels

Figure 15-3 presents the regulatory identification and caution labels adhered to the SST module connector:

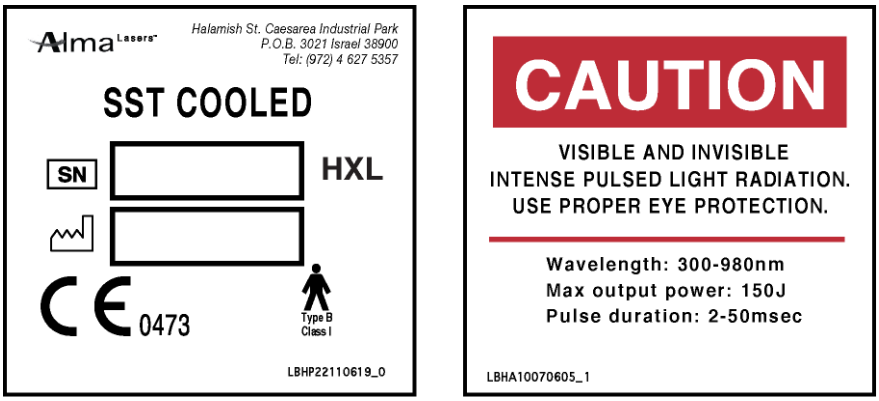

Figure 15-3: SST Module Regulatory Labels

15.6. Ordering Information

The following table offers names and part numbers of accessories specific to the SST module that may be ordered form Alma Lasers.

Table 15-1: SST Module Accessories

Description	*Part No.*
SST Module	AAHP25040702
Light Safety Glasses (OD 3+)	OPIP05120501
Dark Safety Glasses (OD 5+)	OPIP05120502

15.7. SST Module Clinical Guide

The Harmony^{XL} SST module (burgundy color code) emits light in the near infrared spectrum generated by a pulsed-light source. The SST module can be used to treat cutaneous lesions such as striae, stretch marks – scar revision and reduce the presence of wrinkles.

> ***Warning***
>
> **The appropriate protective eyewear should be worn by both the operator and the patient when using this module.**

15.7.1. Module Operation

The SST module may be operated with 3 different time intervals: 1, 3 and 30 seconds.

In the 1-second and 3-second intervals, the module is used employing the **Stationary** technique. In the 30-second interval, the module is used employing the **In-Motion** technique (see Section 15.7.3). The 1-second and 3-second intervals are used on small area (face – upper lip, under chin, etc.). The 30-second interval is used on large areas (body – abdomen, neck, arms, and chest).

The SST module incorporates thermo-electric coupling (TEC) technology; the module can be operated under two conditions: **Cooling ON** (default) and **Cooling OFF**.

The spot size is 3 cm^2 and the pulse repetition rate is fixed at 5 Hz. The total energy delivered at any given time interval is expressed in kilojoules (**kJ**).

15.7.2. Pre-Treatment

15.7.2.1. Assessing the Condition

The treatment parameters for any given skin condition depend on the lesion type, skin type, depth and density of the lesion to be treated.

15.7.2.2. Contraindications

- Whole body tattoos or very large areas
- Eye-liner or lip-liner tattoos in treatment area
- Hypopigmentation (Vitiligo)
- Any inflammatory skin condition e.g., eczema, active herpes simplex, etc. at the treatment site

- Skin cancer or any other cancer and/or any cancer drug therapy (such as Ducabaxine, Fluorouracil, Methotrexate, etc.)
- History of keloid scarring
- Epilepsy
- Photosensitizing drugs; gold therapy, tetracycline, St. John's Wort (herbal remedy) in the past 3 months for depression (because of increased photosensitivity)
- Isotretinoin (Roaccutane or Tretinoin) – In the previous 3-6 months
- Retin – A – In the past 2 weeks
- Diabetes (owing to possible photosensitivity and poor wound healing)
- Pregnancy
- Impaired immune system
- Scleroderma

15.7.2.3. Skin Test

Always perform a skin test on the intended treatment area (forehead, face, abdomen or neck areas). After covering the area with a thin layer (~1mm) of room temperature ultrasonic gel, place the module on the skin according to the following exposure settings/techniques.

Table 15-2: SST Skin Test Parameters – Face/Neck

Skin Type (Fitzpatrick I-VI)	*Fluence (J/cm^2)*	*Total Energy [kJ]**	*Cooling***
I – III	3.5	5.8	On
IV	3.2	5.8	On
V – VI	2.8	5.8	On

Table 15-3: SST Skin Test Parameters – Abdomen

Skin Type (Fitzpatrick I-VI)	*Fluence (J/cm^2)*	*Total Energy [kJ]**	*Cooling***
I – III	3.5	6.4	On
IV	3.2	6.4	On
V – VI	2.8	6.4	On

Table 15-4: SST Skin Test Parameters – Thigh and Upper Arm

Skin Type (Fitzpatrick I-VI)	*Fluence (J/cm^2)*	*Total Energy [kJ]**	*Cooling***
I – III	3.5	6.4	On
IV	3.2	6.4	On
V – VI	2.8	6.4	On

(*) The number of cycles and the total energy are adjusted for a 10x15 cm (150cm^2) area.

(**) Ultrasonic gel must be applied to the skin in both Cooling **On** or **Off** modes.

The 1-second and 3-second time intervals are indicated for the Stationary technique.

15.7.3. Treatment

Treatment can begin after the SST module has been connected to the Harmony^{XL} system and the treatment parameters selected (time exposure and fluence) according to the Suggested Setup Parameters tables in Section 15.7.4.

15.7.3.1. In-Motion Protocol

1. Clean the skin to remove perfumes, cosmetics and sunscreens.
2. In areas where hair exists, the hair must be shaved or trimmed.
3. Provide appropriate eye protection (OD>5) goggles for the patient and the medical staff in the enclosed treatment room.
4. Apply room-temperature ultrasonic gel (thin layer ~1mm) to the skin and place the module perpendicular to the skin. During the treatment add ultrasonic gel to the treatment area as needed. ***Do not*** apply pressure (the lightguide should gently touch the skin).
5. Skin tissue heating is specific to the individual patient and area, and therefore should be monitored/gauged to the individual patient's tolerance.
6. Clinical end-points: skin should appear red/pink (mild-moderate erythema); patient should report that the skin feels warm.
7. If no visible end-points appear but the patient reports deep heat sensation during the treatment, do not repeat treatment.

15.7.3.2. Stationary Protocol

1. In the stationary technique, up to 10% overlapping is an acceptable tolerance.
2. Set the initial exposure time and fluence parameters according to the skin test results.
3. Trigger a pulse by continuously pressing the footswitch for the entire time interval; the module will stop emitting light automatically unless interrupted by the operator (releasing the footswitch). In order to continue, the footswitch must be pressed again.
4. Treatment parameters may be increased by 10% every other treatment and subjected to the conditions in the area treated and the patient's tolerance.
5. Clinical end-points: skin should appear red/pink (mild-moderate erythema); patient should report that the skin feels warm.
6. Following treatment, gently cleanse the ultrasonic gel from the treated area.
7. If adverse skin effects occur (such as excessive reddening or swelling), you may either reduce the exposure time or reduce the fluence.
8. After treatment, it is recommended to cool the area immediately (see Appendix B in the System Manual – Post-Treatment Care).

> ***Note***
>
> Always perform a skin test on the intended treatment area during the first treatment session.

15.7.4. Suggested Setup Parameters (In-Motion Protocol)

For treatment purposes, the face/neck and the abdomen should be divided into six bilateral areas: upper-right (1); upper-left (2); mid-right (3); mid-left (4); lower-right (5); lower-left (6).

Table 15-5: SST Suggested Setup Parameters – Face/Neck

Skin Type (Fitzpatrick I-VI)	*Fluence (J/cm^2)*	*Total Energy [kJ]**	*Cooling***
I – III	3.5	5.4 – 7.4	On
IV	3.2	5.4 – 7.4	On
V – VI	2.8	5.4 – 7.4	On

Table 15-6: SST Suggested Setup Parameters – Abdomen

Skin Type (Fitzpatrick I-VI)	Fluence (J/cm^2)	Total Energy [kJ]*	Cooling**
I – III	3.5	5.8 – 7.8	On
IV	3.2	5.8 – 7.8	On
V – VI	2.8	5.8 – 7.8	On

Table 15-7: SST Suggested Setup Parameters – Thigh and Upper Arm

Skin Type (Fitzpatrick I-VI)	Fluence (J/cm^2)	Total Energy [kJ]*	Cooling**
I – III	1.5	5.8 – 7.8	On
IV	1.2	5.8 – 7.8	On
V – VI	0.8	5.8 – 7.8	On

(*) The number of cycles and the total energy are adjusted for a 10x15 cm (150cm^2) area.

(**) Ultrasonic gel must be applied to the skin in both Cooling **On** or **Off** modes.

The 1-second and 3-second time intervals are indicated for the Stationary technique.

15.7.5. Treatment of Small Areas

Table 15-8: Small Area Parameters, 3-25 cm^2, 1 or 3 Seconds, In-Motion

Skin Type (Fitzpatrick I-VI)	Fluence (J/cm^2)	Cooling [On/Off]	Total Energy [kJ]
I – III	3.5	On	3.5 – 4.5
IV	3.0	On	3.5 – 4.5
V - VI	2.5	On	3.5 – 4.5

*Table 15-9: Small Area Parameters, Up To 3 cm^2, 1 or 3 Seconds, Stationary**

Skin Type (Fitzpatrick I-VI)	Fluence (J/cm^2)	Cooling [On/Off]	Total Energy [kJ]
I – III	3.0	On	0.2 – 0.4
IV	2.5	On	0.2 – 0.4
V - VI	2.0	On	0.2 – 0.3

(*) Repeat twice.

15.7.6. Follow-Up

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

- Patients should be invited four weeks after treatment for examination of the treatment site and for additional treatment, if necessary.
- Treatment is complete when satisfactory results are obtained.
- Patients should be instructed to avoid sun exposure after and in between treatments.
- Treatment intervals: treatment is reapplied (assuring there have been no adverse reactions) at 2-4 week intervals.

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 Ltd.
14 Halamish St., P.O.B. 3021
Caesarea Industrial Park
Caesarea, Israel 38900
Tel: + (972) 4-627-5357
Fax: + (972) 4-627-5368
Email: info@almalasers.com

Alma Lasers, Inc.
485 Half Day Road, Suite # 100
Buffalo Grove, IL 60089
Tel: 1-224-337-2000
Fax: 1-224-377-2050
Email: contact@almalasers.com
Website: www.almalasers.com

CHAPTER 16

Laser QS 1064/532nm Module – Tattoo Removal

Chapter Contents:

16.1. Laser QS 1064/532nm Module Description

The Laser QS 1064/532nm module has a high-power targeted laser module for the non-invasive removal of various colored tattoos, as well as deep and superficial, benign pigmented lesions.

The module can be operated in Laser QS or FD Laser QS modes, depending on the connected tip.

A complete discussion of the Laser QS 1064/532nm module's clinical applications may be found in Section 16.6 of this manual.

The Laser QS 1064/532nm module is identified by **QS 1064nm** printed on the module (see Figure 16-1).

Figure 16-1: 1064/532nm Laser QS Module

16.2. Laser QS 1064/532nm Module Specifications

16.2.1. Standard Tip Module Specifications

- **Light Source:** Q-Switched Nd:YAG
- **Wavelength:** 1064nm
- **Pulse Width:** fixed at 20 nsec
- **Spot Size:** 1, 2 mm (3, 4, 5 & 6 mm optional)
- **Pulse Frequency:** 1, 2, 5 Hz
- **Energy Density (Fluence):** 400 – 1200 mJ/pulse

16.2.2. 532nm KTP Tip Module Specifications

- **Light Source:** FD Q-Switched Nd:YAG
- **Wavelength:** 532nm
- **Energy Density (Fluence):** 400 – 1200 mJ/pulse
- **Tip Spot Size** 2 mm
- **Pulse Width:** fixed at 20 nsec
- **Pulse Frequency:** 1, 2, 5 Hz

16.3. Laser QS 1064/532nm Module Operating Screens

The **Laser QS 1064/532nm** module main operating screen (see Figure 16-2) is displayed when the Laser QS 1064/532nm laser module is connected to the system:

Figure 16-2: Laser QS 1064/532nm Module Operating Screen with Standard Tip

Operating parameters available in this module:

1. There are six standard tips (**1 mm** through **6 mm**), and one **532nm KTP 2 mm** tip available for use with this laser module. The system automatically recognizes the resident tip and displays its size in the top-right corner of the screen.
2. **Fluence** – the available fluence range is from 400 to 1200 mJ/pulse in increments of 100 mJ/pulse.
3. **Pulse Frequency:** 1, 2, 5 Hz
4. **Pulse Width:** fixed at 20 nsec

16.4. Laser QS 1064/532nm Module Regulatory Labels

Figure 16-3 presents the regulatory identification and caution labels adhered to the Laser QS 1064/532nm module connector:

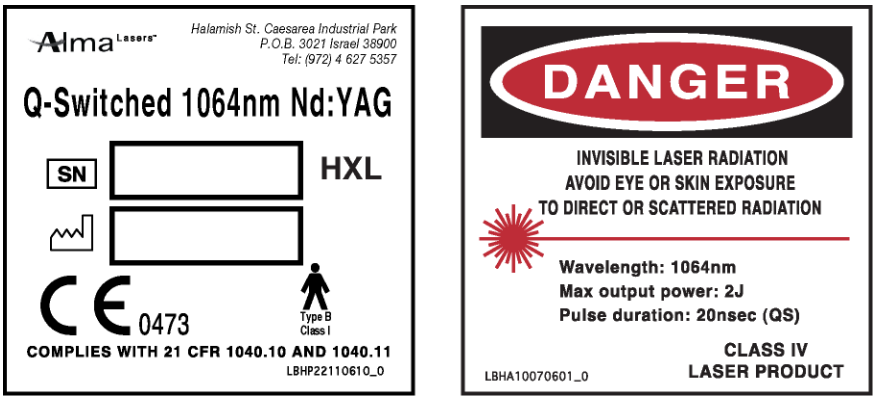

Figure 16-3: Laser QS 1064/532nm Module Regulatory Labels

16.5. Ordering Information

The following table offers names and part numbers of accessories specific to the Laser QS 1064/532nm module that may be ordered form Alma Lasers.

Table 16-1: Laser QS 1064/532nm Module Accessories

Description	*Part No.*
Laser QS 1064/532nm Module (inc. 1, 2 & 3 mm tips)	AAHP02110610
1 mm tip for Laser QS 1064/532nm Module	AAVS22030620
2 mm tip for Laser QS 1064/532nm Module	AAVS17030660
3 mm tip for Laser QS 1064/532nm Module	AAVS17030680
4 mm tip for Laser QS 1064/532nm Module	AAVS18030680
5 mm tip for Laser QS 1064/532nm Module	AAVS18030690
6 mm tip for Laser QS 1064/532nm Module	AAVS22030690
2 mm KTP tip for Laser QS 1064/532nm Module	AAVS22030610
Safety Glasses for 1064nm (OD 7+)	OPIP04120502
KTP Safety Glasses for FD QS 1064nm	OPIP11040401

16.6. Laser QS 1064/532nm Module Clinical Guide

The **Laser QS 1064/532nm (1064nm** and **532nm KTP)** module is indicated for tattoo removal and the treatment of benign epidermal pigmented (solar lentigines, nevi of Ota and Ito and Café-au-lait macules) and superficial vascular lesions. The Laser QS 1064nm tip is indicated for the treatment of deep pigmented lesions. The 1064nm and 532nm (bright green light) wavelength and the nanosecond pulse domain is chosen based upon the significant attraction to a dark pigment chromophore while minimizing the nonspecific thermal effects from the primary endogenous chromophores.

Warning

- **The appropriate protective eyewear should be worn by both the operator and the patient when using this module.**
- **When using the 532nm KTP tip appropriate eyewear protection must be used by both the practitioner and the patient (and anyone else in the room).**
- **Different eyewear is indicated and therefore must be used for the 1064nm vs. the 532nm wavelength.**

16.6.1. Pre-Treatment

16.6.1.1. Assessing the Condition

The treatment parameters for any given skin condition depend on the skin type and the lesion type, depth and density.

Before treatment the practitioner should conduct a full tattoo patient history: When was the tattoo placed? What inks/dyes were used? Where were the inks mixed together to make the color? Is there any white ink in the tattoo to the patient's knowledge? Has the patient attempted to remove or alter the tattoo previously? If so - how? Has the patient used oral retinoids with in the past year? History of herpes infection or cold sores? History of keloid formation or easy scarring, current suntan, tanning bed or bronze use? Fitzpatrick skin type?

The treatment parameters for tattoos depend on the skin and on the characteristics of the tattoo itself (i.e., professional, amateur or traumatic). Color, depth, skin type, age of the tattoo and density of colors are all important factors when deciding on parameters for tattoo removal. The composition of an amateur tattoo is elemental carbon and the professional - organic dyes mixed with metallic elements. Response rate for tattoo removal is a function of pigment depth, total pigment volume as well as surface area.

16.6.1.2. Absolute Contraindications

- Cellulitis (MRSA)
- Psoriasis
- Lichen Planus
- Lichen Nitidus
- Renal Failure (Acute or Chronic)
- Malignancy
- Multiple Sclerosis
- Vitiligo
- Immunosuppression
- Keloids
- Certain Medications (i.e. Accutane)
- Collagen Vascular Diseases

16.6.1.3. Relative Contraindications

- Poorly Controlled Diabetes Mellitus
- Thrombocytopenia
- Peripheral Vascular Disease
- Anemia
- Bleeding Disorders
- Rheumatoid Arthritis/ Juvenile Rheumatoid Arthritis
- Subnormal Intelligence or Psychiatric Disorders
- History of Post-Inflammatory Hyperpigmentation
- Chronic Disease (Crohn’s Disease, IBD, etc.)

16.6.1.4. Preparing the Tattoo for Treatment

Most practitioners will apply a topical anesthetic (i.e. EMLA) on the tattoo area 60 minutes before treatment. This may not be necessary for tattoos that are less dense based upon the design or on the age of the tattoo. The Laser QS Harmony^{XL} module has different spot size tips. It may be desirable to alternate the spot size beginning with a large spot size tip on the first treatment.

16.6.1.5. Skin Test

Always perform a skin test on the intended treatment area during the first treatment session according to the following parameters. It is important to ensure that the patient is not tanned.

> ***Warning***
>
> Appropriate protective eyewear protection must be used by both the practitioner and the patient (and anyone else in the room).

Table 16-2: Tattoo Removal Skin Test Parameters for Blue, Black & Green Tattoos (standard tips)

Skin Type	Spot Size	Pulse Repetition Rate (Hz)	Energy (mJ)	Waiting Period
I – VI	1, 2, 3 mm	1, 2, 5	500 – 700	4 – 6 Weeks

Table 16-3: Tattoo Removal Skin Test Parameters for Red Tattoos (KTP tip)

Skin Type	Spot Size	Pulse Repetition Rate (Hz)	Energy (mJ)	Waiting Period
I – III	3 mm	1, 2, 5	600	4 – 6 Weeks
IV – VI	3 mm	1, 2, 5	400 – 600	4 – 6 Weeks

> ***Note***
>
> It is recommended that the patient return for treatment six weeks after the skin test.

16.6.2. Treatment

1. Clean and dry the skin to remove the EMLA cream from the tattoo area.
2. Appropriate protective eyewear protection must be used by both the practitioner and the patient (and anyone else in the room).
3. Place the module perpendicular to the tattooed skin.
4. Overlapping should not exceed 10%.
5. Set the initial fluence parameter according to the skin test results
6. Trigger the Laser QS laser by pressing the footswitch and the module trigger simultaneously.
7. Diagnose carefully. Remember: darker skin types take longer to respond than lighter skin types. The desired effect is a change in tattoo color (whitening effect), without changes in the surrounding epidermis.
8. If, along with a good response in the tattoo, adverse skin effects occur (such as excessive reddening or swelling in the shape of the lightguide), you should reduce the fluence by 10-20% and attempt to treat in an adjoining area.
9. If the skin shows no adverse effects or extended side effects and changes observed in the tattoo color are unsatisfactory, you may increase the fluence.
10. After treatment it is recommended to cool the area immediately, apply antibacterial ointment and cover the treated tattoo area with sterile pad gauze.
11. Recommended treatment intervals: between eight and twelve weeks.

> ***Note***
>
> The Laser QS 1064nm module can remove black, blue & green pigmented tattoos with the 1064nm wavelength, and red & brown pigments with the 532nm KTP wavelength.

16.6.3. Suggested Setup Parameters

Table 16-4: Suggested Setup Parameters for Blue, Black & Green Tattoos

Skin Type	Spot Size	Wavelength	Pulse Repetition Rate (Hz)	Energy (mJ/P)
I – VI	2, 3	1064nm	1, 2, 5	600 – 1000

Table 16-5: Suggested Setup Parameters for Red Tattoos

Skin Type	Wavelength	Pulse Repetition Rate (Hz)	Energy (mJ/P)
I – III	532nm KTP	1, 2, 5	800 – 1100
IV – VI	532nm KTP	1, 2, 5	700 – 1000

Caution

Small spot size and high fluence often cause bleeding.

16.6.4. Post-Treatment Care

- Apply a layer of Polysporin ointment, Petrolatum, or Bacitracin, beneath a dressing of nonstick gauze and paper tape.
- Instruct the patient to change the dressing twice daily after first gently cleansing the area with soap and water; continue until re-epithelialized.
- Keep the area moist with antibiotic ointment at all times.
- Apply Aloe Vera gel for soothing.
- Avoid direct exposure to the sun on the treatment area; use UVA/UVB sun blockers.

16.6.5. Follow-Up

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

- Patients should return no sooner than eight weeks after the last treatment, for examination of the treatment site and for additional treatment, if necessary.
- If no additional treatment is necessary, the patient should return for a follow-up examination after two months.
- If there has been partial clearance of the tattoo, treatment should be continued, and the patient should return after a minimum of eight weeks for examination and for additional treatment, if necessary.
- If no change is noted in the tattoo, fluence should be increased by at least 10%, and the patient should return no sooner than four weeks for an examination.
- Intervals between treatments can be increased in successive treatments.
- Treatment is complete when satisfactory results are obtained.
- 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 Ltd.
14 Halamish St., P.O.B. 3021
Caesarea Industrial Park
Caesarea, Israel 38900
Tel: + (972) 4-627-5357
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Email: info@almalasers.com

Alma Lasers, Inc.
485 Half Day Road, Suite # 100
Buffalo Grove, IL 60089
Tel: 1-224-337-2000
Fax: 1-224-377-2050
Email: contact@almalasers.com
Website: www.almalasers.com

CHAPTER 17

Laser 1064nm Module – Vascular Lesions, Leg Veins, Hair Removal and PFB

Chapter Contents:

17.1. Laser 1064nm Module Description

The Laser 1064nm module has a high-power targeted laser for the treatment of vascular lesions and leg veins. The module emits a high energy laser pulse in the 1064nm wavelength and timer intervals up to 60 msec.

A complete discussion of the Laser 1064nm module clinical applications may be found in Section 17.6.

The Laser 1064nm module is identified by **1064nm** printed on the module (see Figure 17-1).

Figure 17-1: Laser 1064nm Module

17.2. Laser 1064nm Module Specifications

- **Light Source:** Nd:YAG
- **Wavelength:** 1064nm
- **Pulse Frequency:** 1 Hz

- **Operating Parameters with 2 mm Tip:**
  - ✓ **Pulse Widths:** 10 msec
  - ✓ **Energy Density (Fluence):** 30 – 450 J/cm^2

- **Operating Parameters with 6 mm Tip:**
  - ✓ **Pulse Widths:** 15, 45, 60 msec
  - ✓ **Energy Density (Fluence):** 30 – 150 J/cm^2

- **Operating Parameters with 10 mm Tip:**
  - ✓ **Pulse Width:** 15 msec
  - ✓ **Energy Density (Fluence):** 20 – 50 J/cm^2

17.3. Laser 1064nm Module Operating Screens

The **Laser 1064nm** module main operating screen (see Figure 17-2) is displayed when the Laser 1064nm laser module is connected to the system:

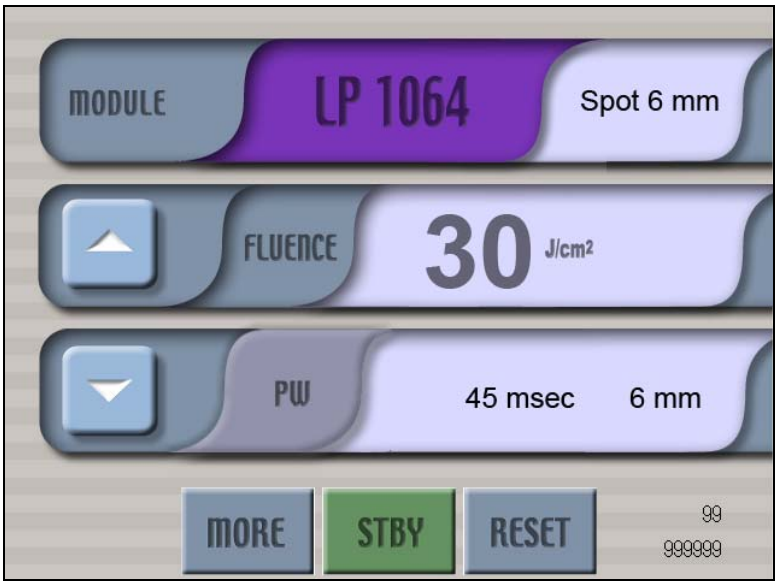

Figure 17-2: Laser 1064nm Screen

Operating parameters available in this module:

1. There are three tips (**2**, **6** & **10 mm**), available for use with this laser module. The system automatically recognizes the resident tip and displays its size in the top-right corner of the screen.
2. **Vascular Lesions** – using the 2 mm tip delivers:
   - Fluence: 30 – 450 J/cm^2
   - Pulse Frequency: fixed at 1 Hz
   - Pulse Widths: 10 msec
3. **Leg Veins** – using the 6 mm tip delivers:
   - Fluence: 30 – 150 J/cm^2
   - Pulse Frequency: fixed at 1 Hz
   - Pulse Widths: 15, 45 and 60 msec
4. **Hair Removal** – using the 6mm / 10mm tips deliver:
   - Fluence: **6mm tip:** 30 – 150 J/cm^2 / **10mm tip:** 20 – 50 J/cm^2
   - Pulse Frequency: fixed at 1 Hz
   - Pulse Widths: 6mm tip: 45, 60 msec
10mm tip: fixed at 15 msec

17.4. Laser 1064nm Module Regulatory Labels

Figure 17-3 presents the regulatory identification and caution labels adhered to the Laser 1064nm module connector:

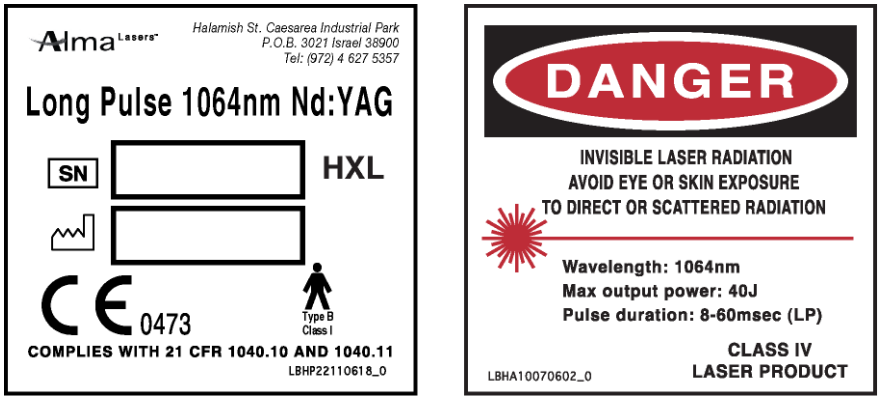

Figure 17-3: Laser 1064nm Module Regulatory Labels

17.5. Ordering Information

The following table offers names and part numbers of accessories specific to the Laser 1064nm module that may be ordered form Alma Lasers.

Table 17-1 Laser 1064nm Module Accessories

Description	*Part No.*
Laser 1064nm Module (inc. 2 & 6 mm tips)	AAHP02110608
2 mm tip for Laser 1064nm Module	AAVS06040501
6 mm tip for Laser 1064nm Module	AAIP04040501
10 mm tip for Laser 1064nm Module	AAIP29050701
Safety Glasses for 1064nm (OD 7+)	OPIP04120502

17.6. Laser 1064nm Module Clinical Guide

The Laser 1064nm module is indicated for:

- Coagulation and hemostasis of vascular lesions and soft tissue using one of two optical tips (2mm and 6mm)
- Non-ablative treatment of facial wrinkles
- Permanent hair reduction and PFB

> ***Warning***
>
> **The appropriate protective eyewear should be worn by both the operator and the patient when using this module.**

17.6.1. Assessing the Condition

The treatment parameters for any given skin condition depend on the skin type and the lesion type, depth and density.

In principle, treat the larger vessels first and only after they are closed proceed to treat the smaller vessels. This avoids refilling the small vessels by the larger, intact feeders.

17.6.2. Indications for Use

The Laser 1064nm module is indicated for treatment and clearance of:

- Benign vascular lesions such as, but not limited to treatment of:
  - ✓ Port wine stains
  - ✓ Hemangiomas
  - ✓ Warts
  - ✓ Superficial and deep telangiectasias (venulectasias)
  - ✓ Reticular veins (0.1-4.0 mm diameter) of the leg
  - ✓ Rosacea
  - ✓ Venus lake
  - ✓ Leg veins
  - ✓ Spider veins
  - ✓ Poikiloderma of Civatte
  - ✓ Angiomas
  - ✓ Facial and leg veins

- Removal of unwanted hair, for stable long term, or permanent, hair reduction through selective targeting of melanin in hair follicles
- Removal or lightening of unwanted hair (with and without adjuvant preparation)
- Treatment of pseudofolliculitis barbae (PFB)

17.6.3. Contraindications

17.6.3.1. Vascular Lesions, Veins and Wrinkles

- Tanned skin (active tan) through sun exposure or tanning bed use in the previous 30 days
- Hypopigmentation (Vitiligo)
- Any inflammatory skin condition e.g. eczema, active herpes simplex, etc. at the treatment site
- Skin cancer or any other cancer and/or any cancer drug therapy (such as Ducabaxine, Fluorouracil, Methotrexate, etc.)
- History of keloid scarring
- Epilepsy
- St. John's Wort (herbal remedy) for depression in the past 3 months (because of increased photosensitivity)
- Isotretinoin – Roaccutane in the previous 3-6 months
- Tretinoin – Retin A in the last 2 weeks
- Pregnancy; until menstruation returns and end of breast feeding
- Diabetes (because of increased possible photosensitivity and poor wound healing)

17.6.3.2. Hair Removal and PFB

- History of local or recurrent skin infection
- Pregnancy (including IVF)
- History of herpes simplex, especially perioral
- History of genital herpes, important when treating the pubic or bikini area
- History of keloids/hypertrophic scaring
- Isotretinoin – past and present
- Epilepsy

- History of Koebnerizing skin disorders, such as vitiligo and psoriasis
- Previous treatment modalities – method, frequency and date of last treatment, as well as response
- Tattoos or nevi present on the treated area
- Past or ongoing medical condition (diabetes, epilepsy, high or low blood pressure, or others)

17.6.4. Vascular Lesions

17.6.4.1. Preparing the Lesion for Treatment

If the lesion is smaller than the lightguide's footprint, use the template provided by Alma Lasers to protect collateral tissue surrounding the lesion. To use the template, select a suitable pre-cut hole so that only the lesion area is fully exposed to the margin. Place the template on the treatment site and cover it with a thin layer of gel (underneath and on top of the template) before treatment.

17.6.4.2. Skin Test

Always perform a skin test on the intended treatment area according to the following parameters:

Table 17-2: Skin Test Parameters for Vascular Lesions

Skin Type (Fitzpatrick I-VI)	*Module*	*Pulse Width (msec)*	*Fluence (J/cm^2)*	*Waiting Period*
I – III	Laser 1064nm; 6mm tip	15, 45, 60	80 – 100	2 – 4 hours
	Laser 1064nm; 2mm tip	10	200	2 – 4 hours
IV – VI	Laser 1064nm; 6mm tip	15, 45, 60	60 – 80	48 – 72 hours
	Laser 1064nm; 2mm tip	10	150	48 – 72 hours

17.6.4.3. Treatment

- The Laser 1064nm laser module has three optical tips for vascular lesions that are replaceable; to detach, grasp the tip at its base and turn counter-clockwise. To attach the tip – grasp the tip and thread it onto the aperture end of the module by turning it clockwise until snug.
- The 2mm tip is used to treat vessels 0.5 to 1.5mm in diameter (available fluence up to 450 J/cm^2). The 6mm tip is used to treat vessels 1.5 to 4mm in diameter (available fluence up to 150 J/cm^2).

Treatment is applied perpendicular to the target and a second pass is usually recommended once appropriate safe settings are found. Do not stack pulses.

Appropriate cooling methods, such as cold air, are recommended when using the Laser 1064nm module.

Treatment can begin after the module and the appropriate tip have been connected to the Harmony^{XL} system and the treatment parameters (fluence and pulse width) are selected according to Table 17-2.

1. Clean the skin to remove perfumes, cosmetics and sunscreens.
2. Cooling means such as ice pack or forced cold air/Zimmer are recommended.

> ***Caution***
>
> Do not treat a vascular lesion through a tattoo or a pigmented lesion that has not been examined by a physician. Any hair covering a vascular lesion must be removed before treatment.

3. The module tip should be slightly pressed against the vessel/vascular lesion.
4. It is best not to overlap treatment spots by more than 10%, but if overlapping does occur wait at least one minute between pulses on the same spot.
5. Set the initial fluence parameter according to the skin test results.
6. Trigger a laser pulse by pressing the footswitch and the module trigger simultaneously.
7. Examine carefully. Remember: darker skin types take longer to respond than lighter skin types. The desired effect is darkening of the vessel due to blood coagulation and erythema and/or edema along the vessel, indicating a stimulated immune reaction, without changes in the surrounding epidermis.
8. If, along with a good response in the vessel, adverse skin effects occur (such as excessive reddening or swelling in the shape of the lightguide), reduce the fluence by 10-20%.
9. If the skin shows no adverse effects and changes observed in the vessel are unsatisfactory you should increase the fluence by 10-20% and test again.
10. After treatment, it is recommended to cool the area immediately (see Appendix B in the System Manual – Post-Treatment Care).

17.6.4.4. Vascular Lesions Suggested Setup Parameters

Table 17-3: Vascular Lesions Suggested Setup Parameters

Skin Type (Fitzpatrick I-VI)	*Target Vessel Depth*	*Module*	*Fluence (J/cm^2)*	*Pulse Width (msec)*
I – III	Deep	Laser 1064nm; 6mm tip	Up to 150	15, 45, 60
I – III	Superficial	Laser 1064nm; 2mm tip	Up to 350	10
IV – VI	Deep	Laser 1064nm; 6mm tip	Up to 120	15, 45, 60
IV – VI	Superficial	Laser 1064nm; 2mm tip	Up to 250	10

17.6.5. Non-Ablative Treatment of Facial Wrinkles

17.6.5.1. Skin Test

Always perform a skin test on the intended treatment area during the first treatment session according to the following parameters:

Table 17-4: Skin Test Parameters for Facial Wrinkles

Skin Type (Fitzpatrick I-VI)	Module	Pulse Width (msec)	Fluence (J/cm^2)	Waiting Period
I – III	Laser 1064nm; 6mm tip	45, 60	80 – 100	5 – 7 days
IV – VI	Laser 1064nm; 6mm tip	45, 60	60 – 80	5 – 7 days

17.6.5.2. Treatment

Treatment can begin after the module has been connected to the Harmony^{XL} system and the treatment parameters (fluence and time interval) are selected according to Table 17-4.

> ***Note***
>
> Always perform a skin test on the intended treatment area during the first treatment session.

1. Clean the skin to remove perfumes, cosmetics and sunscreens.
2. Cooling means such as ice pack or forced cold air/Zimmer are recommended.
3. The 6mm module tip should be slightly compressed and centered over the wrinkle.
4. Set the initial fluence parameter according to the skin test results.
5. Trigger a laser pulse by pressing the footswitch and the module trigger simultaneously.
6. If adverse skin effects occur (such as excessive reddening or swelling in the shape of the lightguide), you should reduce the fluence by 10-20%.
7. If no change in the skin is noted, then the fluence should be increased by 10-20%.
8. After treatment, it is recommended to cool the area immediately (see Appendix C in the System Manual – Post-Treatment Care).

17.6.5.3. Facial Wrinkles Suggested Setup Parameters

Table 17-5: Facial Wrinkles Suggested Setup Parameters

Skin Type (Fitzpatrick I-VI)	*Module*	*# of Pulses per Spot*	*Pulse Width (msec)*	*Fluence (J/cm^2)*
I – III	Laser 1064nm; 6mm tip	1	45, 60	Up to 150
IV – VI	Laser 1064nm; 6mm tip	1	45, 60	Up to 120

17.6.6. Hair Removal & Treatment of Pseudofolliculitis Barbae (PFB)

17.6.6.1. Pre-Treatment Patient Evaluation

Before hair removal procedures, the patient should be evaluated/ documented for the presence of conditions that may cause hypertrichosis:

- Hormonal
- Familial
- Drug (i.e., corticosteroids, hormones, immunosuppressive self or spousal use of minoxidil)
- Tumor
- Photosensitizing drugs (gold therapy, etc.)

17.6.6.2. Skin Test for Hair Removal and PFB

Always perform a skin test on the intended treatment area before the first treatment session according to the parameters in Table 17-6.

The treatment parameters for hair removal depend on the skin type, hair color, hair type and the density & depth of the hair. Initially, shave the treatment site to eliminate any surface hair that could interfere with the treatment.

Table 17-6: Skin Test Parameters for Hair Removal & PFB Treatment

Skin Type (Fitzpatrick I-VI)	*Module*	*Tip/ Spot Size*	*Pulse Width (msec)*	*Fluence (J/cm^2) **	*Waiting Period*
I	Laser 1064nm	6mm	45, 60	80 – 100	5 – 7 days
II	Laser 1064nm	6mm	45, 60	70 – 80	5 – 7 days
III	Laser 1064nm	6mm	45, 60	70 – 80	5 – 7 days
IV	Laser 1064nm	6mm	45, 60	60 – 70	5 – 7 days
	Laser 1064nm	10mm	15	40 – 50	5 – 7 days
V	Laser 1064nm	6mm	45, 60	50 – 60	5 – 7 days
	Laser 1064nm	10mm	15	40 – 50	5 – 7 days
VI	Laser 1064nm	6mm	45, 60	40 – 50	5 – 7 days
	Laser 1064nm	10mm	15	40 – 50	5 – 7 days

(*) Ultrasonic gel must be applied to the skin.

17.6.6.3. Treatment

Treatment can begin after the module and tip are connected and the treatment parameters are selected according to Table 17-7.

> ***Caution***
>
> External cooling means must be applied to the skin, e.g., cold pack, Zimmer, etc.

1. Shave the treatment site to eliminate any surface hair that could interfere with the treatment; remove any hair debris with adhesive tape.
2. Clean the skin to remove perfumes, cosmetics and sunscreens.
3. Provide appropriate eye protection (OD>7) goggles for the patient and the medical staff in the enclosed treatment room.
4. Set the initial fluence and pulse width parameters according to the skin test results.
5. Apply ultrasonic gel to the treatment area.
6. Place the module perpendicular to the skin and touch the skin to ensure a good seal. Do not apply excessive pressure on the skin.
7. Observe for erythema or perifollicular erythema/edema (i.e., end-points).
8. Examine the treatment area for change of skin color and morphological changes around the follicles (erythema/edema). The smell of burnt hair may sometimes be detected, although its absence does not necessarily indicate that the present parameters are ineffective.
9. If there are no noticeable changes on the skin (Skin Types IV-VI) or near the hair follicles **do not repeat**.
10. 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.
11. After treatment it is recommended to cool the area immediately with cold cloth or gauze and apply Aloe Vera gel.

17.6.6.4. Suggested Setup Parameters for Hair Removal and PFB

The treatment parameters for hair removal depend on the skin type, hair color, hair type and the density & depth of the hair.

Table 17-7: Suggested Setup Parameters

Skin Type (Fitzpatrick)	Hair Color	Fluence (J/cm^2)	Pulse Width (msec)
I	Light	80 – 100	45*, 60
	Dark	80 – 100	45*, 60*
II	Light	80 – 100	45*, 60*
	Dark	80 – 100	45*, 60*
III	Light	80 – 100	45*, 60*
	Dark	80 – 100	45*, 60*
IV	Light	80 – 100 40 – 50**	45*, 60* 15**
	Dark	80 – 100 40 – 50**	45*, 60* 15**
V	Light	30 – 40	15**
	Dark	40 – 50	15**
VI	Light	30 – 40	15**
	Dark	40 – 50	15**

(*) 6mm spot size

(**) 10mm spot size

17.6.7. Follow Up

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

17.6.7.1. Vascular Lesions and Leg Veins

- Within three weeks after the treatment patients should return for examination of the treatment site and for additional treatment, if necessary.
- If no additional treatment is necessary, patients should return for an additional examination two months later.

- In case of a partial clearance of the lesion, the treatment should be continued using the same parameters and the patient should return for examination and for additional treatment, if necessary after three weeks.
- If no change in the lesion is noted, fluence should be increased by at least 10%.
- Intervals between treatments can be increased in successive treatments.
- Treatment is complete when satisfactory results are obtained.
- Patients should be instructed to avoid sun exposure after and in between treatments.

17.6.7.2. Hair Removal and PFB

- Patients should return for examination of the treatment site between six to eight weeks after 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 and the number of passes 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.
- Treatment intervals: treatment is reapplied (assuring there have been no adverse reactions) at 4-8 week intervals.

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 Ltd.
14 Halamish St., P.O.B. 3021
Caesarea Industrial Park
Caesarea, Israel 38900
Tel: + (972) 4-627-5357
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Email: info@almalasers.com

Alma Lasers, Inc.
485 Half Day Road, Suite # 100
Buffalo Grove, IL 60089
Tel: 1-224-337-2000
Fax: 1-224-377-2050
Email: contact@almalasers.com
Website: www.almalasers.com

CHAPTER 18

Laser 1320nm Module – Wrinkles and Acne Scars

Chapter Contents:

18.1. Laser 1320nm Module Description

The Laser 1320nm module has a high-power targeted laser module for the treatment of fine lines and wrinkles, acne and acne scars. The 1320nm wavelength achieves deep penetration and selective targeting of water-containing tissue to induce treatment by affecting a rise in dermal temperature. In acne treatment, the dermal heating achieved disrupts the sebaceous glands while involution of the glands induces a long-term remission of the acne.

A complete discussion of the Laser 1320nm module clinical applications may be found in Section 18.6.

The Laser 1320nm module is identified by **1320nm** printed on the module (see Figure 18-1).

Figure 18-1: Laser 1320nm Module

18.2. Laser 1320nm Module Specifications

- **Light Source:** Nd:YAG
- **Wavelength:** 1320nm
- **Pulse Widths:** 30, 40, 50 msec
- **Pulse Repetition Rate:** 1 Hz
- **Tip Spot Size:** 6 mm
- **Energy Density (Fluence):** 5 – 40 J/cm^2

18.3. Laser 1320nm Module Operating Screens

The Laser 1320nm module main operating screen (see Figure 18-2) is displayed when the Laser 1320nm laser module is connected to the system:

Figure 18-2: Laser 1320nm Module Screen

Operating parameters available in this module:

1. There is one **6 mm** tip available for use with this module. The system automatically recognizes the resident tip and displays its size in the top-right corner of the screen.
2. **Wrinkles & Acne Scars** – using the 6 mm tip delivers:
   - Fluence: 5 – 40 J/cm^2
   - Pulse Frequency: 1 Hz.
   - Pulse Widths: 30, 40, 50 msec

18.4. Laser 1320nm Module Regulatory Labels

Figure 18-3 presents the regulatory identification and caution labels adhered to the Laser 1320nm module connector:

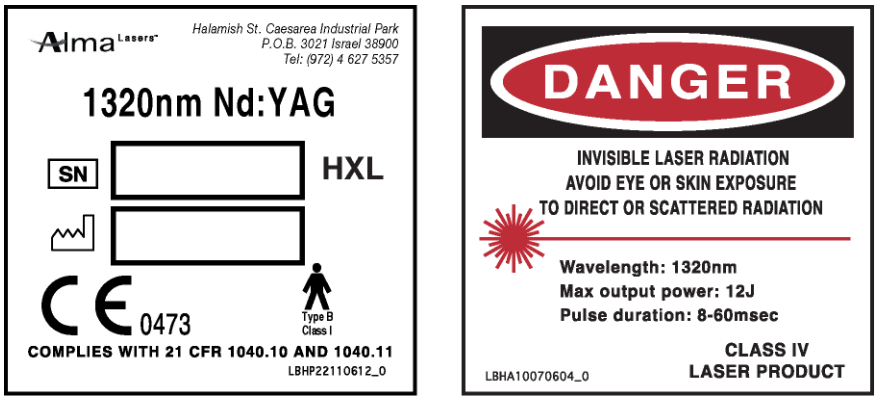

Figure 18-3: Laser 1320nm Module Regulatory Labels

18.5. Ordering Information

The following table offers names and part numbers of accessories specific to the Laser 1320nm module that may be ordered form Alma Lasers.

Table 18-1 Laser 1320nm Module Accessories

Description	*Part No.*
Laser 1320nm Module (inc. 6 mm tip)	AAHP02110612
6 mm tip for Laser 1320nm Module	AAIP04040501
Safety Glasses for 1320nm (OD7+)	OPIP24070501

18.6. Laser 1320nm Module Clinical Guide

The Laser 1320nm module is indicated for the non-ablative treatment of facial wrinkles (periorbital and perioral) and fine lines, atrophic acne (rolling and boxcar) scars and mild-to-moderate inflammatory acne vulgaris.

The thermal energy delivered at optimal pulse durations penetrates the skin and starts a wound healing response.

The result in both modes is an increase in collagen fiber density, alignment, homogenization, and contraction in the papillary dermis.

Warning

The appropriate protective eyewear should be worn by both the operator and the patient when using this module.

18.6.1. Pre-Treatment

18.6.1.1. Assessing the Condition

The treatment parameters for any given skin condition depend on the skin type and the lesion type, depth and density.

18.6.1.2. Contraindications

- Tanned skin (active tan) through sun exposure or tanning bed use in the previous 30 days
- Hypopigmentation (Vitiligo)
- Any inflammatory skin condition e.g., eczema, active herpes simplex, etc. at the treatment site
- Skin cancer or any other cancer and/or any cancer drug therapy (such as Ducabaxine, Fluorouracil, Methotrexate, etc.)
- A history of keloid scarring
- Epilepsy
- St. John's Wort (herbal remedy) for depression in the past 3 months (because of increased photosensitivity)
- Isotretinoin – Roaccutane or Tretinoin – Retin A for the treatment of acne or other dermatological conditions in the previous 3-6 months
- Pregnancy; until menstruation returns and end of breast feeding
- Diabetes (owing to possible photosensitivity and poor wound healing)

18.6.1.3. Skin Test

Always perform a skin test on the intended treatment area during the first treatment session according to the following parameters.

Table 18-2: Skin Test Parameters

Skin Type (Fitzpatrick I-VI)	Module	Pulse Width (msec)	Fluence (J/cm^2)	Waiting Period
I – III	Laser 1320nm; 6mm tip	30, 40	25 – 30	5 – 7 days
IV – VI	Laser 1320nm; 6mm tip	40, 50	15 – 20	5 – 7 days

> ***Note***
>
> Treated area must be cooled before, during and after the treatment with ice-packs or the Zimmer air cooling device.

18.6.2. Treatment

After the Laser 1320nm module has been connected to the Harmony^{XL} system and the treatment parameters (fluence and timer interval) have been selected according to Table 18-3, treatment can begin. The number of passes depends on skin reaction and clinical end-points (slight erythema). Treatments should be spaced 4 weeks apart and every 6 months during the maintenance period.

> ***Note***
>
> Always perform a sensitivity test patch on the intended treatment area during the first treatment session.

1. Clean the skin to remove perfumes, cosmetics and sunscreens.
2. Apply cooling (Zimmer or ice pack) to the intended treatment area for 5-10 seconds prior to lasing. Keep the cooling tool available during the full course of the treatment.
3. Set the initial fluence parameter according to the skin test results.
4. Place the module tip perpendicular to the skin and touch the skin with the tip. The tip should slightly be compressed against the target tissue.
5. Trigger a laser pulse by pressing both the footswitch and module trigger simultaneously.
6. Apply 3-4 passes (non-sequential) on the target area. In a more rapid fashion, apply one pass of the laser across the entire facial area (from the maxillary prominence to the mandible).

7. Immediately after lasing stops, apply cooling means to the treated area (or continue cooling from the Zimmer air cooling device). It is appropriate to use an ice pack for 5 seconds and continue lasing thereafter.
8. Visualize the treated area and check for adverse side effects.
9. If adverse skin effects occur (such as excessive reddening or swelling in the shape of the lightguide), you may either increase the timer interval or reduce the fluence by 20%. Recheck your settings against the skin test results and settings.
10. After treatment, it is recommended to cool the area immediately (see Appendix B in the System Manual – Post-Treatment Care).

> ***Caution***
>
> It is imperative that the tips and their lenses remain clean and free of debris. The tips and the lenses must be cleaned with a cotton swab and warm water after each treatment. During long treatments, the operator should visually inspect the tip attachment and clean it as necessary. Refer to Chapter 7 in the System Manual - Maintenance.

18.6.3. Suggested Setup Parameters

Table 18-3: Suggested Setup Parameters

Skin Type (Fitzpatrick I-VI)	*Module*	*Pulse Width (msec)*	*Fluence (J/cm^2)*	*Number of Passes*
I – III	Laser 1320nm; 6mm tip	30, 40	Up to 40	3 – 4
IV – VI	Laser 1320nm; 6mm tip	40, 50	Up to 30	3 – 4

18.6.4. Follow-up

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

- Patients should return no sooner than three weeks after treatment. This planned examination of the treatment site should provide a progress evaluation and additional treatment opportunity, if required.
- If there has been a partial effect, treatment should be continued and the patient should return after three weeks for examination and additional treatment, if necessary.
- If no additional treatment is necessary, the patient should return for a follow-up examination after two months.
- If no change is noted, fluence should be increased by at least 10%.
- Intervals between treatments can be increased in successive treatments.
- Treatment is complete when satisfactory results are obtained.
- 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 Ltd.
14 Halamish St., P.O.B. 3021
Caesarea Industrial Park
Caesarea, Israel 38900
Tel: + (972) 4-627-5357
Fax: + (972) 4-627-5368
Email: info@almalasers.com

Alma Lasers, Inc.
485 Half Day Road, Suite # 100
Buffalo Grove, IL 60089
Tel: 1-224-337-2000
Fax: 1-224-377-2050
Email: contact@almalasers.com
Website: www.almalasers.com

CHAPTER 19

Pixel & Pixel Pro 2940nm Modules – Fractional Ablative Skin Resurfacing

Chapter Contents:

19.1. Pixel and Pixel Pro 2940nm Modules Description

Two laser modules are described in this chapter:

- **Pixel 2940nm** module (low power)
- **Pixel Pro 2940nm** module (high power)

The Pixel & Pixel Pro 2940nm modules – when using a standard tip – enable controlled treatment for skin resurfacing. The precise tissue ablation and small zone of residual thermal damage result in faster re-epithelialization and improved morbidity.

The Pixel & Pixel Pro 2940nm modules – when using a Pixel tip – provide technology for fractional ablative skin resurfacing and laser peeling, employing a gradual procedure that stimulates the replacement of aged and photo-damaged skin.

A complete discussion of the Pixel Pro and Laser 2940nm modules' clinical applications may be found in Section 19.6.

The Pixel & Pixel Pro 2940nm modules are identified by **2940nm** printed on the module (see Figure 19-1).

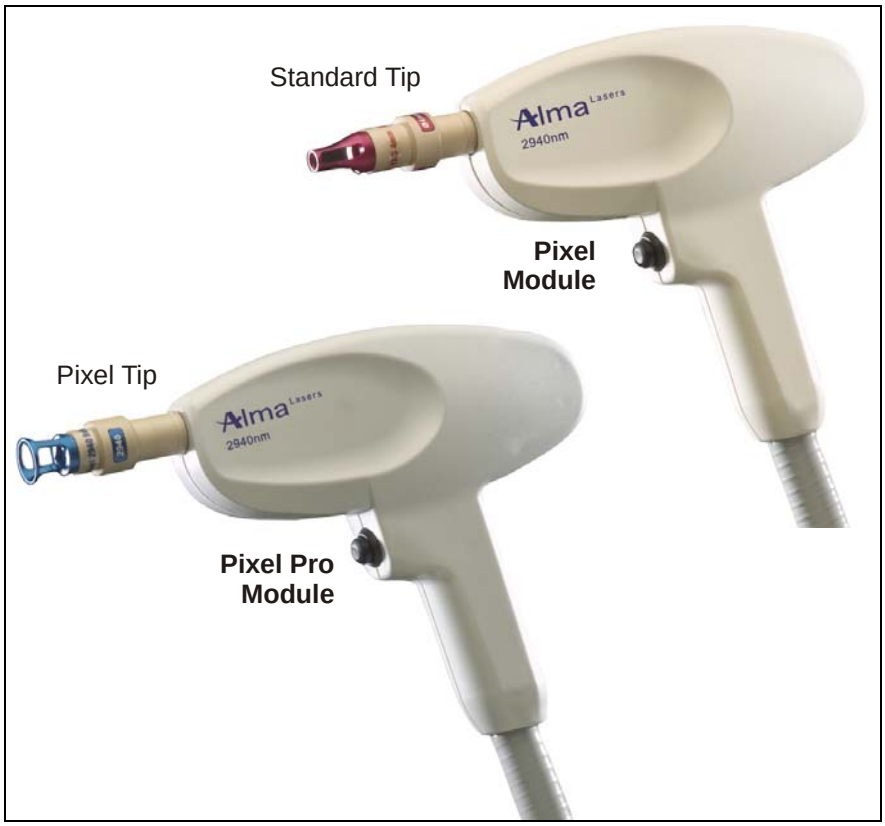

Figure 19-1: Laser 2940nm Modules

19.2. Pixel & Pixel Pro Modules Specifications

- **Light Source:** Er:YAG
- **Wavelength:** 2940nm
- **Available Tips:** 1 mm, 4 mm (Standard)
  7 x 7 Pixel and 9 x 9 Pixel

- **Operating Parameters with 1 mm Tip in *Surgi Light* mode:**
  - ✓ **Energy Density (Fluence):** 100 – 1400 mJ/P
  - ✓ **Pulse Frequency:** 5 Hz

- **Operating Parameters with 4 mm Tip in *Skin Remodeling* mode:**
  - ✓ **Depth:** 10 – 350 μm
  - ✓ **Pulse Frequency:** 5 Hz

- **Operating Parameters with 4 mm Tip in *Gentle Peel* mode:**
  - ✓ **Depth:** 1 – 20 μm
  - ✓ **Pulse Frequency:** 5 Hz

- **Pixel Pro Module's Operating Parameters with 7x7 & 9x9 Pixel Tips:**
  - ✓ **Energy Density (Fluence) in *Short* mode:** 300 – 1200 mJ/P
  - ✓ **Energy Density (Fluence) in *Medium* mode:** 600 – 1800 mJ/P
  - ✓ **Energy Density (Fluence) in *Long* mode:** 800 – 2500 mJ/P
  - ✓ **Pulse Frequency:** 5 Hz

- **Pixel 2940nm Module's Operating Parameters with 7x7 & 9x9 Pixel Tips:**
  - ✓ **Energy Density (Fluence) in *Short* mode:** 600 – 800 mJ/P
  - ✓ **Energy Density (Fluence) in *Medium* mode:** 600 – 1000 mJ/P
  - ✓ **Energy Density (Fluence) in *Long* mode:** 600-1400 mJ/P
  - ✓ **Pulse Frequency:** 5 Hz

19.3. Pixel & Pixel Pro 2940nm Modules Operating Screen

The Pixel & Pixel Pro 2940nm modules' main operating screen (see Figure 19-2) is displayed when either of the modules is connected to the system:

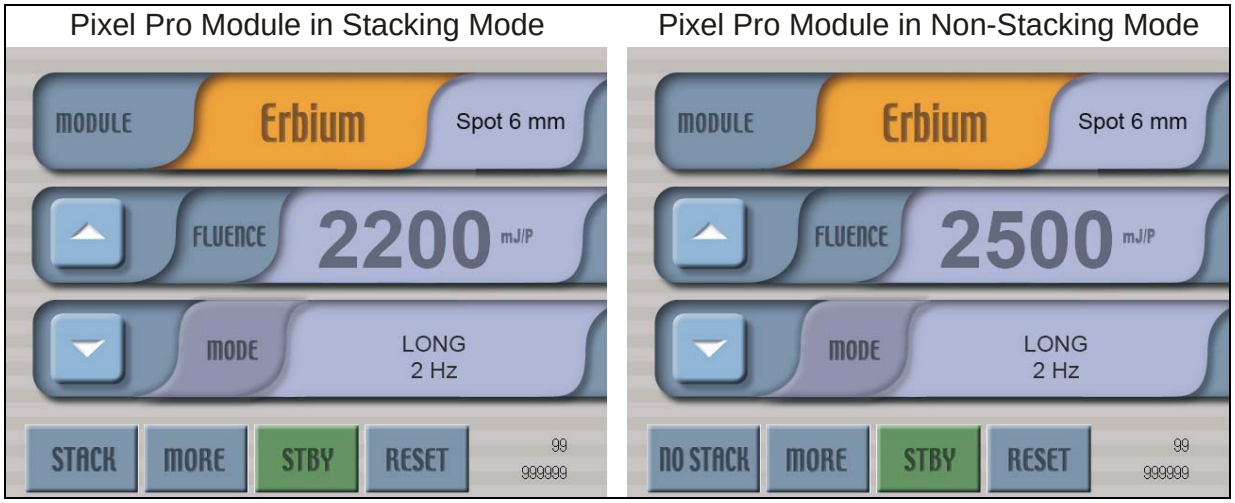

Figure 19-2: Erbium 2940nm Modules Screens

19.4. Pixel & Pixel Pro Modules Regulatory Labels

Figure 19-3 presents the regulatory identification and caution labels adhered to the modules' connectors:

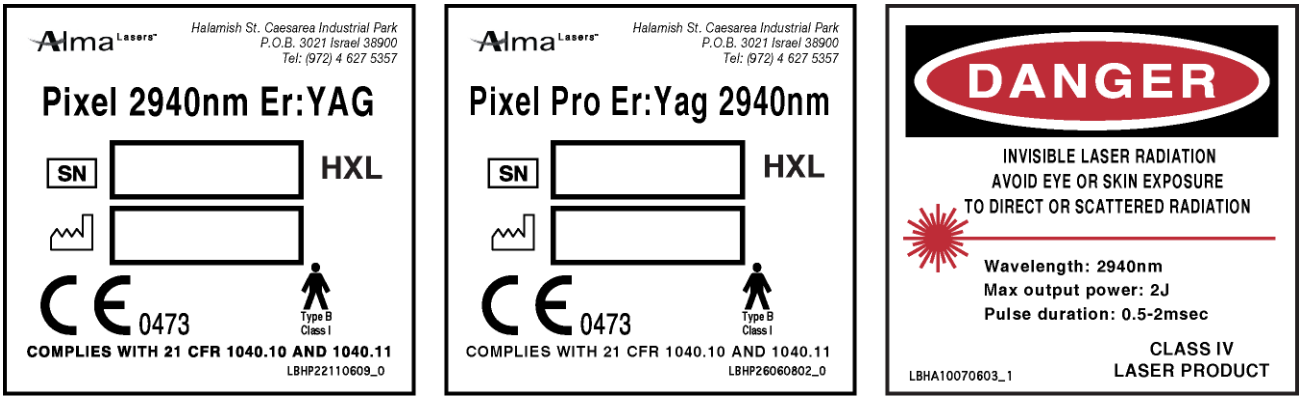

Figure 19-3: Laser 2940nm Modules Regulatory Labels

19.5. Ordering Information

The following table offers names and part numbers of accessories specific to the Pixel & Pixel Pro 2940nm modules that may be ordered form Alma Lasers.

Table 19-1 Laser 2940nm Module Accessories

Description	*Part No.*
Pixel Pro Module (inc. 1 & 4mm and 7x7 & 9x9 Pixel tips)	AAHP24060802
Pixel 2940nm Module (inc. 1 & 4mm and 7x7 & 9x9 Pixel tips)	AAIP09070710
1 mm tip for Laser 2940nm Modules	AAVS04040660
4 mm tip for Laser 2940nm Modules	AAVS03400690
7 x 7 Pixel mm tip for Laser 2940nm Modules	AAVS07020650
9 x 9 Pixel mm tip for Laser 2940nm Modules	AAVS06020650
Safety Glasses for 2940nm (OD 6+)	OPIP24010501

19.6. Pixel & Pixel Pro 2940nm Modules Clinical Guide

The Skin Resurfacing application of the Harmony^{XL} system is performed using the Pixel & Pixel Pro 2940nm modules with standard 1mm or 4mm tips. The modules are indicated for ablative resurfacing procedures including wrinkles and scar revision. The modules deliver precise tissue ablation utilizing either the 1mm or 4mm spot size with minimal collateral thermal damage of the superficial (water-containing) cutaneous tissue.

Fractional Ablative Skin Resurfacing is performed with the Harmony^{XL} system using the 7x7 or 9x9 Pixel tips. The Pixel mode is indicated for fractional ablative resurfacing procedures including fine lines, wrinkles and scar revision.

The Pixel mode's operation is based on the principle of fractional ablative skin resurfacing where only a fraction of the skin mosaic is injured, leaving uninjured skin areas. The intact, undamaged skin around the treatment site promotes quicker healing for a faster recovery.

The 2940nm module can be used with two different matrix size tips - 7x7 matrix (49 pixels) or 9x9 matrix (81 pixels).

Depending on the Pixel matrix used, the Pixel laser single shot produces high energy density and depth of penetration which can range between 100-150 microns in an area of about 1.2 cm^2. The fewer number of Pixels (49 pixels vs. 81 pixels), the greater the penetration depth. Each Pixel matrix has a repetition rate of 5 Hz.

Warning

The appropriate protective eyewear should be worn by both the operator and the patient when using these modules.

19.6.1. Pre-Treatment

19.6.1.1. Assessing the Condition

The treatment parameters for any given skin condition depend on the skin type and the lesion type, depth and density.

19.6.1.2. Contraindications

- Bacterial or viral infection
- Impaired immune system
- Patient has used Isotretinoin in the past 6-9 months
- Scleroderma

- Extensive radiation therapy
- Poor healing in the treatment area
- Pregnancy and breast feeding
- Skin type VI

Other possible contraindications may include irregular pigmentation of the skin, Vitiligo or Psoriasis and recurrent infections (prior eye lift surgery is a possible contraindication for resurfacing of the face).

19.6.1.3. Skin Test

The purpose of the skin test is to rule out any unexpected adverse side effects that may be induced by the skin's response. Always perform a skin test on the intended treatment area during the first session according to the following sequence:

Table 19-2: Skin Test Parameters for the Standard 1mm & 4mm Tips

Module	*Mode*	*Spot Size*	*Ablation Depth (μm)*	*Energy (mJ/P)*	*Frequency (Hz)*
Laser 2940nm	Gentle Peel	4 mm	1 – 20	---	2
Laser 2940nm	Skin Remodeling	4 mm	10 – 350	---	2
Laser 2940nm	Surgi Light	1 mm	---	100 – 1400	2

Table 19-3: Skin Test Parameters for the Pixel Pro Module with 7x7 and 9x9 Pixel Tips

Test Spot #	*Matrix Dots*	*Energy (mJ/P)*	*Pulse Mode*	*Frequency (Hz)*	*Number of Passes / Stacks*[1]
1	9 x 9 7 x 7	1200 1200	L L	5	1 / 3
2	9 x 9 7 x 7	1600 1600	L L	5	1 / 3
3	9 x 9 7 x 7	2000 2000	L L	5	1 / 3

Table 19-4: Skin Test Parameters for the Pixel 2940nm Module with 7x7 and 9x9 Pixel Tips

Test Spot #	Matrix Dots	Energy (mJ/P)	Pulse Mode	Frequency (Hz)	Number of Passes / Stacks[1]
1	9 x 9 7 x 7	600 600	L L	5	1 / 3
2	9 x 9 7 x 7	800 800	L L	5	1 / 3
3	9 x 9 7 x 7	1000 1000	L L	5	1 / 3

It is recommended also that treating physicians familiarize themselves with Er:YAG treatment based on clinical literature; general pre- and post-treatment procedures are provided below. These general guidelines are not intended to be a substitute for clinical education, judgment, and/or experience of the physician.

19.6.1.4. Prior to Treatment Day

1. Pretreatment with topical hydroquinone, Tretinoin and or/glycolic acid preparations for skin types III– V may be helpful in reducing the potential risk of post-laser resurfacing hyperpigmentation.
2. Prophylactic oral antiviral agents may be helpful for the prevention of facial herpes simplex Virus 1 (HSV-1) reactivation until full re-epithelialization occurs. It is generally recommended to begin prophylactic antiviral agents 24 hours prior to laser resurfacing and continuing as described by the agent protocol.

19.6.1.5. Treatment Day [1]

1. Clean the skin to remove perfume, cosmetics and sunscreens.
2. Anesthesia is required for most applications of the standard Er:YAG laser as well as for the Pixel Er:YAG laser. Topical anesthesia (example: EMLA cream) is normally sufficient for most patients. Remove all topical anesthetics just prior to treatment.
3. Provide appropriate eye protection (or eye shields) for the patient and the medical staff inside the enclosed treatment room. Goggles should be OD 6+ and labeled for 2940nm.
4. Set the initial fluence and pulse mode parameters according to the condition being treated. The system allows for a choice of three treatment modes.
5. Place the module perpendicular to the skin. Do not apply pressure (the tip should gently touch the skin). Do not apply gel to the skin prior to treatment.

[1] It is advisable to use smoke evacuation and a mask during the procedure.

6. Up to 20% overlapping is acceptable.
7. Trigger a laser pulse by pressing both the footswitch and module trigger simultaneously.
8. Depth of treatment should be customized to the specific indication (scars vs. wrinkles).
9. Following treatment gently cleanse the treated area of skin fragments with a moist cloth using normal saline solution.
10. If adverse skin effects occur (such as excessive reddening or swelling), you may either change the pulse frequency or reduce the fluence.

19.6.2. Treatment Using Pixel Mode

It is recommended also that treating physicians familiarize themselves with Er:YAG treatment based on clinical literature; general pre- and post-treatment procedures are provided below. These general guidelines are not intended to be a substitute for clinical education, judgment, and/or experience of the physician.

1. Anesthesia: Prior to treatment the skin in the areas intended for treatment should be cleansed with a mild, non-alcoholic, non-abrasive agent. A commercially available topical anesthetic cream should be applied one hour prior to treatment. During and post-treatment cooling with the Zimmer Cryo 5 can be used to minimize redness or a sunburned feeling.
2. It is advisable to use a smoke evacuator and a mask during the procedure.
3. Matrix size: use the 7x7 tip for more aggressive and stacking technique on scars, etc. The 7x7 matrix should be used when greater penetration is required. Use the 9x9 tip for periorbital, full passes and less aggressive treatments.
4. Depth of penetration with a low power Pixel: 25-50 microns ablation plus 75-100 microns thermal injury zones on 3-5 stacks.
5. Depth of penetration with a high power Pixel: 50-100 microns ablation plus 100-125 microns thermal injury zones with 3-5 stacks.
6. Fluence on skin with the high power Pixel module: conservative 1200-1600, moderate 1700-2000, aggressive up to 2500 mJ/P.
7. Fluence on skin with the low power Pixel module: conservative 600-800, moderate 1000, aggressive up to 1400 mJ/pulse.
8. Free-hand (random passes): the Pixel 2940nm tip is moved randomly on the treatment area and repeated passes are employed.
9. The free-hand passes technique is recommended for indications such as photo-damage/photo-age signs and symptoms.
10. Free-hand with the high power module: number of passes: 1 = conservative, 2 = moderate, 3 = aggressive.

11. Free-hand with the low power module: number of passes: 2 = conservative, 3 = moderate, 4= aggressive.
12. Stationary (stacking): the tip of the Pixel 2940nm is placed stationarily on the treatment area and repeated pulses are employed.
13. Stationary technique is recommended for structures residing below the epidermis such as acne scars, fine lines, wrinkles, etc.
14. Stationary with the high power module: number of stacks: 2 = conservative, 4 = moderate, 6 = aggressive. The number of stacks depends on the structure topography (acne scars vs. hypertrophic scar vs. wrinkles) and the desired level of penetration i.e., the greater the number of stacks, the higher the penetration.
15. Stationary with the low power module: number of stacks: 3 = conservative, 5 = moderate, 7 = aggressive. The number of stacks depends on the structure topography (acne scars vs. hypertrophic scar vs. wrinkles) and the desired level of penetration i.e., the greater the number of stacks, the higher the penetration.
16. Downtime after first treatment: redness and sunburn feeling for several hours or up to 2 days if aggressive treatment has been performed. Pale (conservative) to dark brown (aggressive) Pixel pattern on days 3-5 with flaking. Swelling in aggressively treated areas through day 5. Full recovery by days 5-7. Down time is decreased with subsequent treatments. Since this is an Erbium laser, patients with more moisture in their skin may experience more redness and sensation and achieve better results in fewer treatments. Similarly, a patient with dry skin may require more treatments.
17. Number of sessions: three for aggressive to five for conservative treatments at 2-4 weeks apart. Results will continue to improve over 6 months once treatments are complete.
18. Precautions: Do not perform Pixel 2940nm treatments over Botox or Restylane for two weeks post-injection. Use an anti-viral before treatments if there is a history of cold sores. Make sure the skin is clean and dry before treatment.

> ***Note***
>
> Always perform a skin test on the intended treatment area during the first treatment session (see Section 19.6.1.3.).

19.6.2.1. Prior to Treatment Day

1. Pre-treatment with topical hydroquinone, Tretinoin and or/glycolic acid preparations for skin types III- IV may be helpful in reducing the potential risk of post-laser resurfacing hyperpigmentation.
2. Prophylactic oral anti-viral agents may be helpful for the prevention of facial Herpes simplex virus 1 (HSV-1) reactivation until full re-epithelialization

occurs. It is generally recommended to begin prophylactic anti-viral agents 24 hours prior to laser resurfacing and continuing as described by the protocol of the agent.

19.6.2.2. Treatment Day [2]

1. Clean the skin to remove perfumes, cosmetics and sunscreens.
2. Provide appropriate eye protection for the patient (or eye shields) and for the medical staff inside the enclosed treatment room. Goggles should be OD≥6 and labeled for the 2940nm wavelength.
3. Set the initial energy levels according to the skin test, treatment area, and clinical indication.
4. Place the module perpendicular to the skin. ***Do not*** apply pressure (the tip should gently touch the skin). Do not apply gel to the skin prior to treatment.
5. The treatment technique can be either stationary (for deeper penetration) over-lapping pulses on the same area, or non-stationary – random, non-overlap passes.
6. In the non-stationary mode, up to 50% overlapping is acceptable.
7. Trigger a laser pulse by pressing both the footswitch and module simultaneously.
   - **Endpoint:** erythema
   - **Number of Treatments:** 2 – 4
   - **Treatment Intervals:** 3 – 4 weeks
8. Depth of treatment should be individualized to the specific indication (scars vs. wrinkles).
9. Following treatment, gently cleanse the treated area from skin fragments with a moist cloth and follow post-op care guidelines.
10. If adverse skin effects occur (such as excessive reddening or swelling), you may either change the program mode or reduce the fluence.

> ***Caution***
>
> It is imperative that the Pixel tips and their lenses remain clean and free of debris. The Pixel tips and the lenses must be cleaned with a cotton swab and warm water after each treatment. During long treatments, the operator should visually inspect the tip attachment and clean it as necessary. Refer to Chapter 7 in the System Manual - Maintenance.

[2] It is advisable to use smoke evacuation and a mask during the procedure

19.6.3. Suggested Setup Parameters

Table 19-5: Suggested Setup Parameters for the Standard Tips

Module	Mode	Spot Size	Ablation Depth (μm)	Energy (mJ/P)	Frequency (Hz)
Laser 2940nm	Gentle Peel	4mm	1 – 20	---	5
Laser 2940nm	Skin Remodeling	4mm	10 – 350	---	5
Laser 2940nm	Surgi Light	1mm	---	100 – 1400 mJ/P	5

Table 19-6: Suggested Setup Parameters for the Pixel Pro Module with Pixel Tips

Spot Size (mm)	Matrix Dots	Energy (mJ/P)	Pulse Mode	Number of Passes/Stacks*	Frequency (Hz)
11 x 11	9 x 9 7 x 7	1400 1800	L L	1-3 /2-6 1-3 / 2-6	5
11 x 11	9 x 9 7 x 7	1600 2000	L L	1-3 / 2-6 1-3 / 2--6	5
11 x 11	9 x 9 7 x 7	1800 2500	L L	1-3 / 2-6 1-3 / 2-6	5

Note – Pixel Pro Module: 7 x 7 matrix = 49 Pixels = 51 mJ/Pixel
9 x 9 matrix = 81 Pixels = 31 mJ/Pixel

Table 19-7: Suggested Setup Parameters for the Pixel 2940nm Module with Pixel Tips

Spot Size (mm)	Matrix Dots	Energy (mJ/P)	Pulse Mode	Number of Passes/Stacks*	Frequency (Hz)
11 x 11	9 x 9 7 x 7	1000 1000	L L	2-4 / 3-7 2-4 / 3-7	5
11 x 11	9 x 9 7 x 7	1200 1200	L L	2-4/ 3-7 2-4 / 3-7	5
11 x 11	9 x 9 7 x 7	1400 1400	L L	2-4 / 3-7 2-4 / 3-7	5

Note – Pixel 2940nm Module: 7 x 7 matrix = 49 Pixels = 28 mJ/Pixel
9 x 9 matrix = 81 Pixels = 17 mJ/Pixel

(*) The number of passes or stacks depends on the desired level of penetration i.e., the greater the penetration, the greater the number of passes/stacks.

19.6.4. Post-Treatment Care & Follow-Up

Meticulous wound care (open or closed techniques) is crucial after skin resurfacing; below are the Alma Lasers recommendations for follow-up. Physicians may refer to them, and then determine their own suitable regime.

- **Open wound care technique:** allow ongoing surveillance of resurfaced skin; this will minimize the feeling of claustrophobia by the patient. These regimens, theoretically, would seem to be less likely to foster infection, since there is no dressing under which bacteria may be trapped. However, open methods may be more painful and inconvenient for the patient.
  - During open wound care technique, soak with 0.25% acetic acid, normal saline, or cool tap water for 20 minutes every 2-4 hours, followed by gentle wiping of the skin.
  - Cold compresses are immediately followed by the application of a bland emollient ointment. Popular ointments include Catrix®-10 (Lescarden) and Aquaphor® Healing Ointment (Beiersdorf AG).
- **Closed wound care technique:** provides a semi-occlusive environment that may protect the wound from exogenous bacteria and foster exchange of oxygen and water vapor. Drainage of the wound exudates via the dressing may prevent excess crust and simplify wound management.
  - For the closed wound care technique popular dressings include the composite foam Flexzan® (Dow Hickam Pharmaceuticals), the hydrogel product 2nd Skin® (Bionet), the plastic mesh N-terface® (Winfield Laboratories), and the polymer film Silon-TSR® (Bio Med Sciences).
  - The frequency of soaks and ointment application decreases as reepithelialization progresses and is tapered off when re-epithelialization is complete (normally within 5-6 days).
- By 7-10 days after the procedure, soaks are replaced with gentle cleansing, and patients switch to the application of a moisturizer-sunscreen.
- Following re-epithelialization, gentle cleansings begin a day or two later. The use of ointment is replaced during the day by use of a lighter moisturizer-sunscreen. At night time, ointment is more slowly replaced.
- Patients should return to the clinic 3-7 days post-treatment for examination of the treatment site and for additional treatment, if necessary.
- If no additional treatment is necessary, the patient should return for an additional examination after two months.
- Treatment is complete when satisfactory results are obtained.
- Avoid sun exposure during pre- and post-operative period.

- If adverse side effects occur (hyperpigmentation), sun protection and spot-resurfacing depigmenting agents such as hydroquinone will help obtain resolution.
- 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 Ltd.
14 Halamish St., P.O.B. 3021
Caesarea Industrial Park
Caesarea, Israel 38900
Tel: + (972) 4-627-5357
Fax: + (972) 4-627-5368
Email: info@almalasers.com

Alma Lasers, Inc.
485 Half Day Road, Suite # 100
Buffalo Grove, IL 60089
Tel: 1-224-337-2000
Fax: 1-224-377-2050
Email: contact@almalasers.com
Website: www.almalasers.com

CHAPTER 20

Alex 755 Laser Module – Hair Removal and Pigmented Lesions

Chapter Contents:

20.1. Alex 755 Laser Module Description

The Alex 755 laser module has a high-power targeted laser. The module emits a high-energy laser pulse at the 755nm wavelength for two clinical indications:

- Permanent Hair Reduction
- Treatment of Benign Pigmented Lesions

A complete discussion of the Alex 755 laser module clinical applications may be found in Section 20.6.

The Alex 755 laser module is identified by **755nm** printed on the module (see Figure 20-1).

Figure 20-1: Alex 755 Laser Module

20.2. Alex 755 Laser Module Specifications

- **Light Source:** Alexandrite
- **Wavelength:** 755nm
- **Pulse Frequency:** 2 Hz & 4 Hz
- **Energy Density (Fluence) with 5 mm Tip:** 1 – 32 J/cm^2
- **Energy Density (Fluence) with 10 mm Tip:** 1-8 J/cm^2

20.3. Alex 755 Laser Module Operating Screens

The **Alex 755 Laser** module main operating screen (see Figure 20-2) is displayed when the Alex 755 laser module is connected to the system:

Figure 20-2: Alex 755 Laser Screen

Operating parameters available in this module:

1. There are two tips (**5** & **10 mm**), available for use with this laser module. The system automatically recognizes the resident tip and displays its size in the top-right corner of the screen.
2. **Hair Removal** – using the 5 mm tip delivers:
   - Fluence: up to 32 J/cm^2
   - Pulse Frequency: 2 Hz or 4 Hz
3. **Pigmented Lesions** – using the 10 mm tip delivers:
   - Fluence: 1 – 8 J/cm^2
   - Pulse Frequency: 2 Hz or 4 Hz

20.4. Alex 755 Laser Module Regulatory Labels

Figure 20-3 presents the regulatory identification and caution labels adhered to the Alex 755 laser module connector:

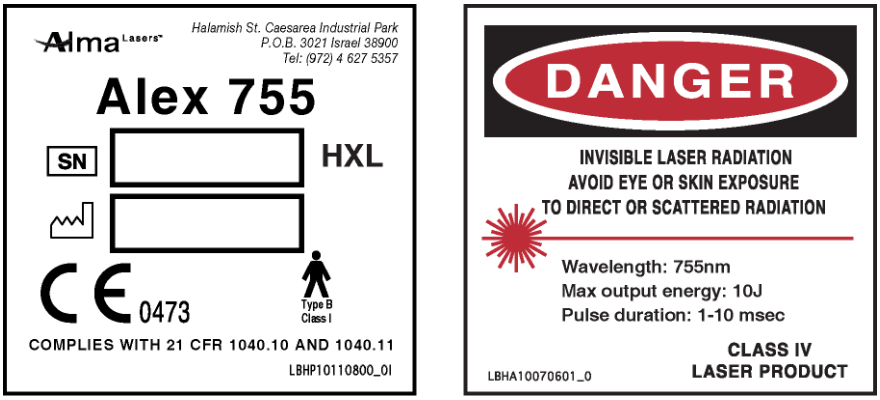

Figure 20-3: Alex 755 Laser Module Regulatory Labels

20.5. Ordering Information

The following table offers names and part numbers of accessories specific to the Alex 755 laser module that may be ordered form Alma Lasers.

Table 20-1 Alex 755 Laser Module Accessories

Description	*Part No.*
Alex 755 Laser Module (including 2 tips)	AAIP15100890
5 mm tip for Alex 755 Laser Module	AAVS24100801
10 mm tip for Alex 755 Laser Module	AAVS25110840
Safety Glasses for 755nm (OD 7+)	OPIP04120502

20.6. Alex 755 Laser Module Clinical Guide

The clinical effect of the alexandrite laser is based on the principle of selective photothermolysis. Energy emitted at a wavelength of 755nm (red) is strongly absorbed by dark pigments, such as melanin, but only rather weakly by hemoglobin. As a result, laser radiation is scattered deep into the dermis and impinges on red-light absorbing dark hair shafts and pigmented follicular cells, thus elevating their temperature and creating coagulation.

Energy density has to be sufficiently high to damage the targeted tissue while pulse duration should not exceed the thermal relaxation time of a typical follicle radius to avoid thermal conduction to the skin surrounding the follicle.

> ***Warning***
>
> **The appropriate protective eyewear should be worn by both the operator and the patient when using this module.**

20.6.1. Indications for Use

The Alex 755 laser module is indicated for treatment and clearance of:

- Benign pigmented lesions.
- Removal of unwanted hair for stable long term, or permanent hair reduction through selective targeting of melanin in hair follicles.

20.6.2. Pigmented Lesions

20.6.2.1. Assessing the Condition

The treatment parameters for any given skin condition depend on the skin type and the lesion type, depth and density.

In principle, treat the larger vessels first and only after they are closed proceed to treat the smaller vessels. This avoids refilling the small vessels by the larger, intact feeders.

20.6.2.2. Contraindications

- Tanned skin (active tan) through sun exposure or tanning bed use in the previous 30 days
- Hypopigmentation (Vitiligo)

- Any inflammatory skin condition e.g. eczema, active herpes simplex, etc. at the treatment site
- Skin cancer or any other cancer and/or any cancer drug therapy (such as Ducabaxine, Fluorouracil, Methotrexate, etc.)
- History of keloid scarring
- Epilepsy
- St. John's Wort (herbal remedy) for depression in the past 3 months (because of increased photosensitivity)
- Isotretinoin – Roaccutane in the previous 3-6 months
- Tretinoin – Retin A in the last 2 weeks
- Pregnancy; until menstruation returns and end of breast feeding
- Diabetes (because of increased possible photosensitivity and poor wound healing)

20.6.2.3. Preparing the Lesion for Treatment

If the lesion is smaller than the lightguide's footprint, use the template provided by Alma Lasers to protect collateral tissue surrounding the lesion. To use the template, select a suitable pre-cut hole so that only the lesion area is fully exposed to the margin. Place the template on the treatment site and cover it with a thin layer of gel (underneath and on top of the template) before treatment.

20.6.2.4. Skin Test

Always perform a skin test on the intended treatment area according to the following parameters:

Table 20-2: Skin Test Parameters for Pigmented Lesions

Skin Type (Fitzpatrick I-VI)	*Module*	*Fluence (J/cm^2)*	*Waiting Period*
I - III	Alex 755 Laser; 10mm tip	7 – 8	2 – 4 hours
IV	Alex 755 Laser; 10mm tip	6 – 7	48 – 72 hours
IV- VI	Alex 755 Laser; 10mm tip	5 – 6	48 – 72 hours

20.6.2.5. Treatment

The Alex 755 laser module has two optical tips for pigmented lesions that are replaceable; to detach, grasp the tip at its base and turn counter-clockwise. To attach the tip – grasp the tip and thread it onto the aperture end of the module by turning it clockwise until snug.

Treatment is applied perpendicular to the target and a second pass is usually recommended once appropriate safe settings are found. Do not stack pulses. Appropriate cooling methods, such as cold air, are recommended when using the Alex 755 laser module.

Treatment can begin after the module and the appropriate tip have been connected to the Harmony^{XL} system and the treatment parameters (fluence and pulse width) are selected according to Table 20-2.

1. Clean the skin to remove perfumes, cosmetics and sunscreens.

2. Cooling means such as ice pack or forced cold air/Zimmer are recommended.

> ***Caution***
>
> Do not treat pigmented lesion through a tattoo or a pigmented lesion that has not been examined by a physician. Any hair covering a pigmented lesion must be removed before treatment.

3. The module tip should be slightly pressed against the pigmented lesion.

4. It is best not to overlap treatment spots by more than 10%, but if overlapping does occur wait at least one minute between pulses on the same spot.

5. Set the initial fluence parameter according to the skin test results.

6. Trigger a laser pulse by pressing the footswitch and the module trigger simultaneously.

7. Examine carefully. Remember: darker skin types take longer to respond than lighter skin types. The desired effect is darkening of the pigmented lesion and its melanocytes as well as erythema and/or edema along the pigment, indicating a stimulated immune reaction, without changes in the surrounding epidermis.

8. If, along with a good response in the pigment, adverse skin effects occur (such as excessive reddening or swelling in the shape of the lightguide), reduce the fluence by 10-20%.

9. If the skin shows no adverse effects and changes observed in the vessel are unsatisfactory you should increase the fluence by 10-20% and test again.

10. After treatment, it is recommended to cool the area immediately (see Appendix B in the System Manual – Post-Treatment Care).

20.6.2.6. Pigmented Lesions Suggested Setup Parameters

Table 20-3: Pigmented Lesions Suggested Setup Parameters

Skin Type (Fitzpatrick I-VI)	*Target Vessel Depth*	*Module*	*Fluence (J/cm^2)*
I – III	Deep	Alex 755 Laser; 10mm tip	7 – 8
I – III	Superficial	Alex 755 Laser; 10mm tip	7 – 8
IV – VI	Deep	Alex 755 Laser; 10mm tip	6 – 7
IV – VI	Superficial	Alex 755 Laser; 10mm tip	6 – 7

20.6.2.7. Follow Up

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

- Within three weeks after the treatment patients should return for examination of the treatment site and for additional treatment, if necessary.
- If no additional treatment is necessary, patients should return for an additional examination two months later.
- In case of a partial clearance of the lesion, the treatment should be continued using the same parameters and the patient should return for examination and for additional treatment, if necessary after three weeks.
- If no change in the lesion is noted, fluence should be increased by at least 10%.
- Intervals between treatments can be increased in successive treatments.
- Treatment is complete when satisfactory results are obtained.
- Patients should be instructed to avoid sun exposure after and in between treatments.

20.6.3. Hair Removal

20.6.3.1. Contraindications

- History of local or recurrent skin infection
- Pregnancy (including IVF)
- History of herpes simplex, especially perioral
- History of genital herpes, important when treating the pubic or bikini area
- History of keloids/hypertrophic scaring
- Isotretinoin – past and present
- Epilepsy
- History of Koebnerizing skin disorders, such as vitiligo and psoriasis
- Previous treatment modalities – method, frequency and date of last treatment, as well as response
- Tattoos or nevi present on the treated area
- Past or ongoing medical condition (diabetes, epilepsy, high or low blood pressure, or others)

20.6.3.2. Pre-Treatment Patient Evaluation

Before hair removal procedures, the patient should be evaluated/ documented for the presence of conditions that may cause hypertrichosis:

- Hormonal
- Familial
- Drug (i.e., corticosteroids, hormones, immunosuppressive self or spousal use of minoxidil)
- Tumor
- Photosensitizing drugs (gold therapy, etc.)

20.6.3.3. Skin Test for Hair Removal and PFB

Always perform a skin test on the intended treatment area before the first treatment session according to the parameters in Table 20-4.

The treatment parameters for hair removal depend on the skin type, hair color, hair type and the density & depth of the hair. Initially, shave the treatment site to eliminate any surface hair that could interfere with the treatment.

Table 20-4: Skin Test Parameters for Hair Removal

Skin Type (Fitzpatrick I-VI)	Tip/ Spot Size (mm)	Fluence (J/cm^2) *	Waiting Period
I	5	22 – 25	5 – 7 days
II	5	22 – 25	
III	5	20 – 22	
IV	5	18 – 20	
V	5	12 – 16	
VI	5	10 – 12	

(*) Ultrasonic gel must be applied to the skin.

20.6.3.4. Treatment

Treatment can begin after the module and tip are connected and the treatment parameters are selected according to Table 20-5.

> ***Caution***
>
> External cooling means must be applied to the skin, e.g., cold pack, Zimmer, etc.

1. Shave the treatment site to eliminate any surface hair that could interfere with the treatment; remove any hair debris with adhesive tape.
2. Clean the skin to remove perfumes, cosmetics and sunscreens.
3. Provide appropriate eye protection (OD>7) goggles for the patient and the medical staff in the enclosed treatment room.
4. Set the initial fluence and pulse width parameters according to the skin test results.
5. Apply ultrasonic gel to the treatment area.
6. Place the module perpendicular to the skin and touch the skin to ensure a good seal. Do not apply excessive pressure on the skin.
7. Observe for erythema or perifollicular erythema/edema (i.e., end-points).
8. Examine the treatment area for change of skin color and morphological changes around the follicles (erythema/edema). The smell of burnt hair may sometimes be detected, although its absence does not necessarily indicate that the present parameters are ineffective.
9. If there are no noticeable changes on the skin (Skin Types IV-VI) or near the hair follicles, **do not attempt** to redo/overlap (sequentially) in the same area.

10. 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.
11. After treatment it is recommended to cool the area immediately with cold cloth or gauze and apply Aloe Vera gel.

20.6.3.5. Suggested Setup Parameters for Hair Removal

The treatment parameters for hair removal depend on the skin type, hair color, hair type and the density & depth of the hair.

Table 20-5: Suggested Setup Parameters

Skin Type (Fitzpatrick)	*Fluence (J/cm²)*	*Tip/Spot Size (mm)*
I-II	25 – 30	5
III	22 – 24	5
IV	18 – 21	5
V	12 – 17	5
VI	8 – 11	5

20.6.3.6. Follow Up

Measures presented below are only the manufacturer's recommendations 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 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 and the number of passes 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.

- Treatment intervals: treatment is reapplied (assuring there have been no adverse reactions) at 4-8 week intervals.

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:

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