

# Alma Lasers™

Wellbeing Through Technology

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## Harmony XL

### Planning Guide & Teaching Tool



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

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## **Section 1: Using This Planning Guide**

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

***You will find key concepts and messages that help you use your HARMONY XL™ more efficiently and safely***

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

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

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

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

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

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

## **Section 2: Definitions and Applications - Harmony XL™**

Congratulations on your purchase of the Harmony XL™ system from Alma. With proper operation and maintenance, trained, qualified practitioners can use the system safely. The operator and all other personnel involved with patient care should be familiar with the maintenance, operation and safety information that is provided during in-servicing and found in the Alma Operator's Manual. Understanding the terminology and principles behind AFT/Laser technology will allow you to provide maximum benefits to your patients and your practice. The following definitions assist you in better understanding of AFT/Laser technology and how to apply it to each modality of the Harmony XL™. During your in-service, the Clinical Specialist will review these principles with you and, along with the Training Tool Manual, will guide you through each modality. We ask that you become familiar with these definitions so that your in-service time can be utilized to the fullest degree.

The Harmony system is an aesthetic working platform that is capable of treating a wide variety of skin applications with Advanced Fluorescence Technology (AFT™) light-based technology, Nd:YAG, Q-Switched Nd:YAG, Er:YAG lasers and near Infrared pulsed light and UV lamp.

The Harmony operates with twelve handpieces that may be connected to the platform.

### **Non-Laser Modules**

- UVB Psoriasis and Vitiligo Pulsed UVB 300 -380 nm (Violet Color Code)
- SAcne Acne clearance AFT 420 – 950nm (Blue Color Code)
- SVL515 1 Superficial vascularLesionsAFT 515 – 950nm (Turquoise Color Code)
- VP 1 Vascular andpigmented lesions AFT 540 – 950nm (Green Color Code)
- VP Vascular andpigmented lesions AFT 540 – 950nm (Green Color Code)
- SR Skin rejuvenation AFT 570 – 950nm (Yellow Color Code)
- LED Various skin conditions LED Yellow wavelength
- HR 1 Hair removal AFT 650 – 950nm (Red Color Code)
- SHR 1 Super hair removal Near infrared 780 – 950nm (Red Color Code)
- ST 1 Scar revision &Treatment of Striae Near infrared 780 – 950nm (Burgundy Color Code) **1With integrated cooling**

## ***Laser Modules***

- Q-Switched 1064/532nm Laser Module – Tattoo Removal
- Nd:YAG 1064nm Laser Module – Vascular Lesions and Leg Veins
- Nd:YAG 1320nm Laser Module – Fine Lines, Wrinkles, Acne & Acne Scars
- Er:YAG 2940nm Laser Module - Skin resurfacing & Fractional ablative Skin Resurfacing2940

## ***Abbreviations and Acronyms***

<b>°C</b>	Degree(s) Centigrade/Celsius
<b>A</b>	Ampere(s)
<b>AC</b>	Alternating current
<b>AFT</b>	Advanced Fluorescence Technology
<b>CFR</b>	Code of Federal Regulations
<b>Cm</b>	Centimeter(s)
<b>cm<sup>2</sup></b>	Centimeter(s) square
<b>EDF</b>	Equally distributed fluence
<b>Er:YAG</b>	Erbium-doped Yttrium Aluminum Garnet
<b>HR</b>	Hair removal
<b>Hz</b>	Hertz
<b>IEC</b>	International Electrotechnical Commission
<b>J</b>	Joule(s)
<b>J/cm<sup>2</sup></b>	Joule(s) per square centimeter
<b>Kg</b>	Kilogram(s)
<b>KTP</b>	Potassium Titanyl Phosphate
<b>LCD</b>	Liquid crystal display
<b>LED</b>	Light emitting diode
<b>LP</b>	Long pulse
<b>m</b>	Meter(s)

## ***Section 3: In-service Objectives***

Our objective for the in-service is to provide appropriate on-site training to the physician and staff members in the use of the Harmony XL™ system.

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

- Patient selection and screening
- Technical use of the Harmony XL™ system
- Understanding of AFT/Laser Technology
- Maintenance of the equipment and accessories
- Correct protocol to establish and adjust treatments parameters
- Managing appropriate patient expectations
- Assessment of tissue and target reaction
- Laser physics and safety
- Data requirements
- Patient information, indications and contraindications
- Sample treatment and patient evaluation forms

## ***Section 4: Preparing Your Patient For a Successful Treatment***

### **Planning for Time**

You may accomplish your in-service in 1-2 full days including patient treatments depending on the number of modules. We recommend that you schedule a **minimum of 10 patients**. You may schedule regular patients. However, you may feel more comfortable beginning with staff, family members and friends.

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

The in-service is divided into four main areas.

- Didactic review of the principles of selective photothermolysis.
- Review of technical aspects of operation, care and maintenance of equipment, documentation of treatment and questions. This portion of the in-service is enhanced by the prior attendance at a course by the physician and/or staff. The entire staff that will be involved with the system should be present. Previous laser experience with competitive products does not relieve any staff member from the in-service day. Staff members that do not attend all portions of the in-service will **not** be eligible to receive Certificates of Attendance for the course.
- Treatment of patients.
- Time to summarize the events of the day and answer questions.

## ***Patient Selection***

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

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

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

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

## *Checklist for In-Service*

<i>ITEM</i>	<i>Y</i>	<i>N</i>
Harmony XL system installed and all accessories available		
Operator's Manual read by all appropriate staff		
Treatment table or bed (height adjustable if available)		
Good lightening		
Stool		
Trolley		
Cold gel (refrigerate the night before)		
Container for ice or cold packs to keep gel cold during treatments		
Alcohol 70%		
4x4 gauze pads		
Soft tissues		
Paper towels		
Loop or other magnification mean		
Cold packs		
Soothing cream (Aloe Vera Gel, Biafine, Flamazine, Silverol, steroids or antibiotics)		
Camera		
Informed Consent Forms		
Scheduled minimum of 10 patients		
Confirmed date with all appropriate staff		
Appropriate protective eyewear for all attendances in the room		
Disposable razors		
Wooden spatulas		
Cryo5 Zimmer		
Plastic Zimmer adaptor		

## ***Section 5: Clinical Guide***

### **Introduction**

The following Clinical Guides are provided to aid professionals in the use of the Harmony XL™ system. It adds to or reinforces information presented in the Operator's Manual concerning instructions for use, precautions and warnings necessary to reduce the risk of injury. All operator's must read the entire Operator's Manual before reviewing this appendix and before operating the system.

### **Training Requirements**

The Harmony system is designed to be operated only by personnel properly trained in its handling and use. All personnel who operate the system must read the operator's manual. This includes physicians, nurses, technical staff or other professional staff members.

Alma Lasers provides in-service training for the Harmony system. At the end of this in-service training, personnel are considered trained for the operation of the Harmony system.

The physician is responsible for contacting the local licensing agencies to determine any credentials required by law for clinical use and operation of the device.

## ***Contraindications***

- ◆ Cancer; in particular, skin cancer
- ◆ Pregnancy (including IVF)
- ◆ Use of photosensitive medication and herbs for which 300 to 2940nm light exposure is contra-  
-indicated
- ◆ Diseases which may be stimulated by light at 300 to 2940nm
- ◆ Prolonged exposure to sun or artificial tanning during the 3 to 4 weeks prior to treatment and  
post treatment
- ◆ Active infection of herpes simplex in the treatment area
- ◆ History of keloids or hypertrophic scarring
- ◆ Diabetes (insulin dependent)
- ◆ Fragile and dry skin
- ◆ Hormonal disorders (that are stimulated under intense light)
- ◆ Use of anticoagulants
- ◆ Epilepsy
- ◆ History of coagulopathies
- ◆ Immune deficiency disease or an immuno-compromised status
- ◆ Oral or topical use of retinoids (Accutane)
- ◆ Oral or topical use of steroids

**Each Harmony module may have its own set of contraindications. Refer to each module's Clinical Guide**

## ***Adverse Effect of Treatment***

The use of the HarmonyXL™ system is similar to the use of other light based Technologies, including AFT pulsed light, UV or Nd:YAG, Er:YAG lasers. Historically, traditional systems have demonstrated the ability to cause a certain degree of controlled and uncontrolled tissue damage (and on rare occasions, severe bleeding). In addition, there are the following risks:

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

## ***Potential Side Effects of Treatment***

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

**We will start with test patches to see how the patient reacts to treatment. If the tests are satisfactory we will then begin a session of treatments.**

## ***UVB 300-380 Psoriasis, Vitiligo and Re-pigmentation (Violet HP)***

**Please read the Clinical Section of the Operating Manual. The following information is abbreviated for your convenience from this clinical section.**

### **Indications:**

Psoriasis, eczema, dermatitis, leukoderma and vitiligo. Hypopigmented skin, stretch marks, post surgical scars, laser resurfacing, grafted skin, burn scars, chemically peeled skin.

### **Treatment considerations:**

- Treatment of Patients with Skin Types I-V
- See list of Contraindications/other considerations
- To start treatments administer 2 per week, then 1 every other week according to operator's discretion.
- For effective treatment perform MED test 24 to 48 hrs prior to treatments, use dose that exhibits uniformed slight redness.
- Refer to Operating Manual for treatment parameter guidelines.

### **Desired Endpoints:**

- Visible erythema without adverse side effects to healthy tissue.

### **Miscellaneous Information:**

- After re-pigmentation, additional treatments may be continued at the same or reduced dose and frequency for maintenance.
- Adverse reactions noted from prior treatment, may skip or reduce dose until symptoms resolve.
- Do not apply gel.
- Treatments should overlap the healthy skin at the periphery of the treated sites by approximately 1 to 2 mm.
- Increase settings in 10-20% increments at treatment (in absence of side effects).

## ***AFT 420-950nm Moderate Inflammatory Acne (Blue HP)***

**Please read the Clinical Section of the Operating Manual. The following information is abbreviated for your convenience from this clinical section.**

### **Indications:**

Moderate Inflammatory Acne Vulgaris

- **SS 6.4cm<sup>2</sup>, 30, 40, 50ms pulse duration, up to 25Joules**

### **Treatment Considerations:**

- Treatment of patients with Skin type I-VI
- Consider a washout period of 14 days for antibiotics to insure quantity of P. Acne bacteria
- See list of Contraindications/other considerations
- Suggest 8 treatments, 2x weekly ( non consecutive days) for up to 6 weeks
- ALA may be used pre TX as desired
- Spot test darker skin

### **Desired Endpoints:**

- Slight epidermal erythema, a soft pink tone visible that should last for 1-2 hours up to 24 hours

### **Miscellaneous Information:**

- Burton Classification – Grade 0-6
  - 0 No acne
  - 1 Sub clinical acne
  - 2 Comedonal acne
  - 3 Mild acne
  - 4 Moderate acne – many inflamed papules and pustules
  - 5 Severe nodular acne
  - 6 Severe cystic acne

### **Science:**

P. acne bacteria produces porphyrins, which absorb 420 nm light. The Porphyrins release a singlet of oxygen, which then destroys the P. acne bacteria.

## ***SVL 515-950nm Vascular Lesions (Turquoise HP)***

**Please read the Clinical Section of the Operating Manual. The following information is abbreviated for your convenience from this clinical section.**

### **Indications:**

Treatment of Superficial Vascular Lesions such as telangiectasia, hemangioma, spider veins, rosacea, poikiloderma, PWS and other superficial vascular lesions.

- SS 6.4 cm<sup>2</sup>, 10, 12, 15 msec at 5-25 J/cm<sup>2</sup>

### **Treatment Considerations:**

- Treatment of Patients with Skin Types I-III.
- See list of Contraindications/other considerations.
- 3 weeks after treatment return for examination and additional treatment if needed.
- Follow up visit in 2 months after last treatment or when satisfactory results are obtained.

### **Desired Endpoints:**

- Darkening of vessel due to blood coagulation and erythema and or edema along the vessel, indication stimulated immune reaction, without change in surrounding epidermis.
- Increase redness with vascularity symptoms of rosacea (excessive reddening or swelling in shape of light guide reduce fluence by 10-20%).
- No effects or changes in vessel increase fluence by 10%.

### **Miscellaneous Information:**

- Assess the lesion type, depth and size, treat larger vessels first and after they are closed proceed to smaller vessels, to avoid refilling small vessels by the larger.
- Templates may be used if vessels are smaller than the light guide to protect collateral tissue surrounding the vessel.
- Cold gel under and on top of templates.
- Cold gel and Zimmer are recommended.
- Avoid hair, lip line.
- Cool after treatment.

## ***VP 540-950nm Benign Vascular and Pigmented Lesions (Green***

**Please read the Clinical Section of the Operating Manual. The following information is abbreviated for your convenience from this clinical section.**

### **Indications:**

Benign vascular and pigmented lesions including dyschromia, hyperpigmentation, melasma and ephelides [freckles]

- **SS 6.4cm<sup>2</sup>, 10, 12, 15ms pulse duration, up to 25 J**

### **Treatment Considerations:**

- Treatment of Patients with Skin Type I-VI
- See list of Contraindications/ other considerations
- Treatment 1X monthly for up to 6 weeks

### **Desired Endpoints:**

- Slight epidermal erythema around lesion
- Increased redness where target is vascular i.e. vascularity symptoms of rosacea
- Disappearance or change in color of small red telangiectasias
- Pigment darkening or graying and/or speckling of brown spot that will flake off in 8-12 days usually
- Morphological changes [raising of the lesion] without changes in epidermis

### **Miscellaneous Information:**

- Patients may need topical anesthesia if pain threshold is low
- Cold gel is important
- Avoid brows-white tape may be applied over brows
- Avoid lip line- spreading tongue over teeth may assist
- Templates may be used to isolate lesion for treatment
- Treat the larger vessels first and only after they are closed proceed to treat the smaller vessels.

## ***SR 570-950nm    Skin Rejuvenation    (Yellow HP)***

**Please read the Clinical Section of the Operating Manual. The following information is abbreviated for your convenience from this clinical section.**

### **Indications:**

*Sun damaged skin i.e. vascular and benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma and ephelides [freckles]*

- ***SS 6.4cm<sup>2</sup>, 10, 12, 15ms pulse duration, up to 25 Joules***

### **Treatment Considerations:**

- Treatment of Patients with Skin Type I-VI
- Consider this mode for full-face brown and red dyschromias associated with photo aging.
- See list of Contraindications/ other considerations
- Treatment 1X monthly for up to 6 months

### **Desired Endpoints:**

- Slight epidermal erythema, a soft pink tone visible which should last for 1-2 hrs up to 24 hrs
- Pigment darkening and or speckling that will flake off in 8-12 days usually
- Disappearance or change in color of small red telangiectasias

### **Miscellaneous Information:**

- Patients may need topical anesthesia if pain threshold is low
- Cold gel is important
- Avoid brows-white tape may be applied over brows
- Avoid lip line- spreading tongue over teeth may assist
- Generally, gel and treat one section at a time removing gel after each section is complete
- Selective 2<sup>nd</sup> pass may be done from 2<sup>nd</sup> tx on when tolerance is assessed
- As chromophore diminishes with successive treatments, the joules/cm<sup>2</sup> may be increased
- Nd:YAG for selective pass on wrinkles may be used following AFT w/1064nm eyewear
- Templates may be used to isolate lesion for treatment

## ***AFT 650-950nm Hair Removal (Red Handpiece)***

**Please read the Clinical Section of the Operating Manual. The following information is abbreviated for your convenience from this clinical section.**

### **Indications:**

Unwanted hair removal

- SS 6.4cm<sup>2</sup>, 30,40,50 msec, 5-25 J/cm<sup>2</sup>

### **Treatment Considerations:**

- Treatment of Patients with Skin Type I-VI.
- See list of contraindications/other considerations.
- Treatment 1X monthly for up to 8 months.

### **Desired Endpoints:**

- Slight epidermal erythema, a soft pink tone visible which should last for 1-2 hrs up to 24hrs.
- Peri follicular edema and redness (swelling and redness around the follicle).
- Odor of singed hair may or may not be present.

### **Miscellaneous Information:**

- Patients may need topical anesthesia if pain threshold is low.
- Cold gel is important.
- Avoid lip line. Spreading tongue over teeth may assist access to upper lip hair.
- Generally, gel and treat one section at a time removing gel after each section is complete.
- Selective 2<sup>nd</sup> pass may be done from 2<sup>nd</sup> treatment on when tolerance is assessed.
- Darker hair on lighter skin responds best.
- Shaving hair day prior is suggested for a stubble to be visible.
- No tanning or UV 3 weeks pre and post treatment.
- No waxing or plucking prior to and between treatment.
- Zimmer cooling aids comfort and reduction of epidermal redness.
- Cool ice packs after treatment can be effective in removing heat sensation for dense hair.
- Always consider a test patch before proceeding with treatment.

***Non AFT 780-950nm Skin Tightening ST (Burgundy HP)***

**Please read the Clinical Section of the Operating Manual. The following information is abbreviated for your convenience from this clinical section.**

**Indications:**

Skin Tightening, skin remodeling

- **SS 6.4cm<sup>2</sup>, 10, 30, 90 pulse duration, 1-7Joules**

**Treatment Considerations:**

- Treatment of patients with Skin type I-VI.
- See list of Contraindications/other considerations
- 2-6 treatments every 2-4 weeks
- Apply u/s gel at room temp
- Use IR thermometer as suggested

**Desired Endpoints:**

- Slight epidermal erythema
- Skin shall be temporarily red and warm to touch post tx

**Miscellaneous Information:**

- Treat grids 10x10cm until therapeutic temp reaches 39-42 degrees
- Maintain temperature for three (3) passes at 90 seconds each
- Treat 1 grid before moving to next grid
- No downtime

## ***LED Module (Light emitting diode array)***

**Please read the Clinical Section of the Operating Manual. The following information is abbreviated for your convenience from this clinical section.**

### **Indications:**

Topical heating to promote increased blood flow, temporary relaxation of muscles, pain relief

- **Repeat up to 70 seconds**
- **CW up to 70 minutes**

### **Treatment Considerations:**

- Treatment of patients with Skin type I-VI
- See list of Contraindications/other considerations
- Hold handpiece at a distance of 1-2cm from the skin surface (perpendicular to the skin) for the entire exposure time
- CW: treatment should be performed twice per week for 4-5 consecutive weeks (8-10 treatments)
- Repeat: treatment should be performed on 3 to 5 consecutive days post laser or IPL procedure (3-5 treatments)

### **Desired Endpoints:**

- Slight epidermal erythema, a soft pink tone visible that should last for 1-2 hours up to 24 hours

### **Miscellaneous Information:**

- Apply sunscreen daily
- Avoid sun exposure after and in between treatments

## ***SVL Cooled 515-950nm Vascular Lesions(Turquoise HP)***

**Please read the Clinical Section of the Operating Manual. The following information is abbreviated for your convenience from this clinical section.**

### **Indications:**

Treatment of Superficial Vascular Lesions such as telangiectasia, hemangioma, spider veins, rosacea, poikiloderma, PWS and other superficial vascular lesions.

- SS 3cm<sup>2</sup>, 10msec, 12msec, 15msec at 5-30J/cm<sup>2</sup>

### **Treatment Considerations:**

- Treatment of Patients with Skin Types I-V.
- See list of Contraindications/other considerations.
- 3 weeks after treatment return for examination and additional treatment if needed.
- Follow up visit in 2 months after last treatment or when satisfactory results are obtained.

**Caution: Lower the suggested parameters by 5J's and use 2-3mm of cold gel.**

### **Desired Endpoints:**

- Darkening of vessel due to blood coagulation and erythema and or edema along the vessel, indication stimulated immune reaction, without change in surrounding epidermis.
- Increase redness with vascularity symptoms of rosacea (excessive reddening or swelling in shape of light guide reduce fluence by 10-20%).
- No effects or changes in vessel increase fluence by 10%.

### **Miscellaneous Information:**

- Assess the lesion type, depth and size, treat larger vessels first and after they are closed proceed to smaller vessels, to avoid refilling small vessels by the larger.
- Templates may be used if vessels are smaller than the light guide to protect collateral tissue surrounding the vessel.
- Cold gel under and on top of templates.
- Cold gel and Zimmer are recommended.
- Avoid hair, lip line.
- Cool after treatment.

## ***VP Cooled 540-950nm Benign Vascular and Pigmented Lesions (Green HP)***

**Please read the Clinical Section of the Operating Manual. The following information is abbreviated for your convenience from this clinical section.**

### **Indications:**

Benign vascular and pigmented lesions including dyschromia, hyperpigmentation, melasma and ephelides [freckles]

- **SS 3cm<sup>2</sup>, 10, 12, 15ms pulse duration, up to 30 J**

### **Treatment Considerations:**

- Treatment of Patients with Skin Type I-VI
- See list of Contraindications/ other considerations
- Treatment 1X monthly for up to 6 weeks

**Caution: Lower the suggested parameters by 5J's and use 2-3mm of cold gel.**

### **Desired Endpoints:**

- Slight epidermal erythema around lesion
- Increased redness where target is vascular i.e. vascularity symptoms of rosacea
- Disappearance or change in color of small red telangiectasias
- Pigment darkening or graying and/or speckling of brown spot that will flake off in 8-12 days usually
- Morphological changes [raising of the lesion] without changes in epidermis

### **Miscellaneous Information:**

- Patients may need topical anesthesia if pain threshold is low
- Cold gel is important
- Avoid brows-white tape may be applied over brows
- Avoid lip line- spreading tongue over teeth may assist
- Templates may be used to isolate lesion for treatment
- Treat the larger vessels first and only after they are closed proceed to treat the smaller vessels.

## ***SR Cooled 570-950nm Skin Rejuvenation (Yellow HP)***

**Please read the Clinical Section of the Operating Manual. The following information is abbreviated for your convenience from this clinical section.**

### **Indications:**

*Sun damaged skin i.e. vascular and benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma and ephelides [freckles]*

- ***SS 3cm<sup>2</sup>, 10, 12, 15ms pulse duration, up to 30 Joules***

### **Treatment Considerations:**

- Treatment of Patients with Skin Type I-VI
- Consider this mode for full-face brown and red dyschromias associated with photo aging.
- See list of Contraindications/ other considerations
- Treatment 1X monthly for up to 6 months

**Caution: Lower the suggested parameters by 5J's and use 2-3mm of cold gel.**

### **Desired Endpoints:**

- Slight epidermal erythema, a soft pink tone visible which should last for 1-2 hrs up to 24 hrs
- Pigment darkening and or speckling that will flake off in 8-12 days usually
- Disappearance or change in color of small red telangiectasias

### **Miscellaneous Information:**

- Patients may need topical anesthesia if pain threshold is low
- Cold gel is important
- Avoid brows-white tape may be applied over brows
- Avoid lip line- spreading tongue over teeth may assist
- Generally, gel and treat one section at a time removing gel after each section is complete
- As chromophore diminishes with successive treatments, the joules/cm<sup>2</sup> may be increased
- Nd:YAG for selective pass on wrinkles may be used following AFT w/1064nm eyewear
- Templates may be used to isolate lesion for treatment

## ***AFT Cooled 650-950nm Hair Removal***

***(Red Handpiece)***

**Please read the Clinical Section of the Operating Manual. The following information is abbreviated for your convenience from this clinical section.**

### **Indications:**

- SS 3cm<sup>2</sup>, 30, 40, 50 msec at 5-30J/cm<sup>2</sup>

### **Treatment Considerations:**

- Treatment of Patients with Skin Type I-VI.
- See list of contraindications/other considerations.
- Treatment 1X monthly for up to 8 months.

### **Desired Endpoints:**

- Slight epidermal erythema, a soft pink tone visible which should last for 1-2 hrs up to 24hrs.
- Peri follicular edema and redness (swelling and redness around the follicle).
- Odor of singed hair may or may not be present.

### **Miscellaneous Information:**

- Patients may need topical anesthesia if pain threshold is low.
- Cold gel is important.
- Avoid lip line. Spreading tongue over teeth may assist access to upper lip hair.
- Generally, gel and treat one section at a time removing gel after each section is complete.
- Selective 2<sup>nd</sup> pass may be done from 2<sup>nd</sup> treatment on when tolerance is assessed.
- Darker hair on lighter skin responds best.
- Shaving hair day prior is suggested for a stubble to be visible.
- No tanning or UV 3 weeks pre and post treatment.
- No waxing or plucking prior to and between treatment.
- Zimmer cooling aids comfort and reduction of epidermal redness.
- Cool ice packs after treatment can be effective in removing heat sensation for dense hair.
- Always consider a test patch before proceeding with treatment.

## ***SHR (Super Hair Removal) Near Infrared (Red Handpiece)***

**Please read the Clinical Section of the Operating Manual. The following information is abbreviated for your convenience from this clinical section.**

### **Indications:**

- Unwanted hair removal
- **SS 3cm<sup>2</sup>, 1, 3, 30sec, 3Hz, 1-7J/cm<sup>2</sup>**
- **Stationary 1 & 3 sec are used on small areas**
- **In-motion used at 30sec interval for large areas**
- **Grid size is 10x10cm (100cm<sup>2</sup>) for in-motion technique**

### **Treatment Considerations:**

- Treatment of Patients with Skin Type I-VI.
- See list of contraindications/other considerations.
- Treatment 4-8 wk intervals or when any new hair has grown in the treatment area.

### **Desired Endpoints:**

- Slight epidermal erythema, a soft pink tone visible which should last for 1-2 hrs up to 24hrs.
- Peri follicular edema and redness (swelling and redness around the follicle).
- Odor of singed hair may or may not be present.
- In-motion deliver the recommended total energy in 10x1-cm grid at 30 second interval
- Stationary technique use 1 or 3 second interval: up to 10% overlapping is acceptable.

### **Miscellaneous Information:**

- Patients may need topical anesthesia if pain threshold is low.
- Cold gel is important.
- Avoid lip line. Spreading tongue over teeth may assist access to upper lip hair.
- Generally, gel and treat one section at a time removing gel after each section is complete.
- Darker hair on lighter skin responds best.
- Shaving hair day prior is suggested for a stubble to be visible.
- No tanning or UV 3 weeks pre and post treatment.
- No waxing or plucking prior to and between treatment.
- Zimmer cooling aids comfort and reduction of epidermal redness.
- Cool ice packs after treatment can be effective in removing heat sensation for dense hair.
- Always consider a test patch before proceeding with treatment.

## ***Long Pulse Nd:YAG 1064nm Vascular Lesions/Veins***

**Please read the Clinical Section of the Operating Manual. The following information is abbreviated for your convenience from this clinical section.**

### **Indications:**

Unwanted vascular lesions, leg veins and non-ablative treatment of facial wrinkles.

- **2mm SS @ 10ms energy up to 450J... suggest <150J on face**
- **6mm SS @ 15, 45, 60ms up to 150J**
- **10mmSS @ 15msec, 3-50J/cm<sup>2</sup> (Hair Removal only)**

### **Treatment Considerations:**

- Treatment of Patients with Skin Type I-VI
- See list of Contraindications/ other considerations
- Treatment every 3-6wks

### **Desired Endpoints:**

- Slight epidermal erythema, a soft pink tone visible which should last for 1-2 hours up to 24 hours
- Angry vessel look [histamine response after 2-3 minutes]
- Change in vessel color [smudging of vessel look]
- Disappearance of vessel

### **Miscellaneous Information:**

- Topical anesthesia is usually ineffective due to sensation of vessel heat discomfort
- Cool ice packs after treatment can be effective in removing heat sensation
- Second pass can be done as needed **ONLY** after several minutes due to response time needed to compromise vessel
- Avoid vigorous exercise for 24 hrs after treatment
- Compression following treatment may be helpful for 24-48 hrs
- Do not stack pulses
- Spot test for darker skin

## ***Q-Switched Nd:YAG 1064/532nm Tattoo Removal/Benign Pigmented Lesions***

### **Indications:**

Non- invasive removal of various colored tattoos, as well as deep and superficial benign pigmented lesion.

- SS 1 & 2mm, 1,2,5Hz, 400-1200mj/pulse
- SS 2mm,532nm tip

### **Treatment Considerations:**

- Treatment of Patients with Skin Type I-VI (NO TANNED SKIN or SUN EXPOSURE)
- See list of Contraindication/other considerations
- Treatment 8 to 12 weeks apart up to 12 treatments ( spot test recommended & return 6 wks after)

### **Desired Endpoints:**

- Slight epidermal erythema, with a change in tattoo color (whitening effect)
- Excessive reddening or swelling, reduce fluence by 10-20%.

### **Miscellaneous Information:**

- Topical anesthesia (i.e. EMLA) 60 minutes prior, may not be necessary for less dense and older tattoos. Zimmer after treatment to relieve heat sensation (can cause frostbite if held in place).
- Clean and dry area prior to treatment and use laser plume mask, gloves and smoke evacuator during treatment.
- No pulse stacking and overlapping should not exceed 10% with no second passes.
- No changes in tattoo or adverse effects, fluence may be increased by 10% or change spot size with the next treatment. Start with larger spot size on first treatment.
- Use caution with small spot size and high fluence (can cause bleeding).
- Apply antibacterial ointment and keep moist, change dsq. 2 x daily cleaning with soap and water until re-epithelialized.

## ***Long Pulse Nd:YAG 1064nm Hair Removal***

**Please read the Clinical Section of the Operating Manual. The following information is abbreviated for your convenience from this clinical section.**

### **Indications:**

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, PFB

- **10mmSS @ 15msec, recommended for Skin Type IV-VI**
- **6mmSS @ 45,60 msec recommended for Skin Type I-III**

### **Treatment Considerations:**

- Treatment of Patients with Skin Type I-VI
- See list of Contraindications/ other considerations
- Treatment every 6-8wks or any new hair has grown in the treatment area
- In-motion mark grid (using red pen) on a treatment area of about 10x10cm.

### **Desired Endpoints:**

- Slight epidermal erythema, a soft pink tone visible which should last for 1-2 hours up to 24 hours
- Perifollicular erythema/edema
- The smell of burnt hair may sometimes be detected

### **Miscellaneous Information:**

- Cool ice packs after treatment can be effective in removing heat sensation
- Spot test for darker skin

## ***Er:YAG 2940nm***

### **Indications:**

Incisions, excisions, ablations, vaporizations, coagulations (Target is water)

- **Surgi Light Mode, 100-1400mj/P at 5Hz (1mm Tip)**
- **Skin Remodeling Mode, 10-350 µm at 5 Hz (4mm Tip)**
- **Gentle Peel Mode, 1-20 µm at 5 Hz (4mm Tip)**

### **Treatment Considerations:**

- Treatment of patients with Skin type I-IV
- See list of Contraindications/ other considerations
- Treatment 1x monthly until resolution
- Smoke evacuation needed
- No gel suggested

### **Desired Endpoints:**

- Removal of stratum corneum layer with 1 pass
- Pinpoint bleeding 2 passes
- “Shammy” look with deeper vaporizations 3 passes or more

### **Miscellaneous Information:**

- Local or topical anesthesia
- Cross hatching 2<sup>nd</sup> pass suggested
- Cool ice packs after treatment can be effective in removing heat sensation
- Erythema lasting approx 7 days
- Ointment or dressing post op until epithelialization takes place
- Moist gauze compression to control bleeding
- Remove shoulder of wrinkle first followed by cosmetic unit

## ***Er:YAG Pixel 2940nm Skin Resurfacing***

**Please read the Clinical Section of the Operating Manual. The following information is abbreviated for your convenience from this clinical section.**

### **Indications:**

Skin resurfacing and laser peeling skin types I-V (Target is water)

- **Number of Pixels 49 or 81 dots in 11 x 11mm SS up to 1400mj/pulse**
- **1, 1.5, 2ms pulse width (short, medium, long PW)**

### **Treatment Considerations:**

- Treatment of patients with Skin type I-V
- See list of Contraindications/ other considerations
- 3 treatments 4 weeks apart
- Stacking and mj control depth of penetration
- No pressure, light touch/glide method
- No gel suggested
- Smoke evacuation needed

### **Desired Endpoints:**

- Removal of stratum corneum layer 1 pass (50 microns approx)
- 2-3 passes produces erythema and slight edema
- White desiccated tissue look

### **Miscellaneous Information:**

- No anesthesia or topical anesthesia. May be used as needed
- Cool ice packs after treatment can be effective in removing heat sensation
- Erythema lasting approx 3-7 days
- Ointment post op until epithelialization takes place
- Moist cool gauze application to remove heat discomfort post op
- 20% of tissue ablated leaving 80% intact per pass
- Remove shoulder of wrinkle first followed by cosmetic unit

## ***Er:YAG High Power Pixel 2940nm Skin Resurfacing***

**Please read the Clinical Section of the Operating Manual. The following information is abbreviated for your convenience from this clinical section.**

### **Indications:**

Skin resurfacing and laser peeling skin types I-V (Target is water)

- **7x7 (49 pixels) @ 51mj per pixel 9x9 (81 pixels) @ 31mJ per pixel**
- **Energy Density (Fluence) in Short mode: 300-1200 mJ/P @ 2Hz**
- **Energy Density (Fluence) in Medium mode: 600-1800 mJ/P @ 2 Hz**
- **Energy Density (Fluence) in Long mode: 800-2500 mJ/P @ 2 Hz**

### **Treatment Considerations:**

- Treatment of patients with Skin type I-V
- See list of Contraindications/ other considerations
- 3 treatments 4 weeks apart
- Stacking and mj control depth of penetration
- No pressure, light touch/glide method
- No gel suggested
- Smoke evacuation needed

### **Desired Endpoints:**

- Removal of stratum corneum layer 1 pass (50 microns approx)
- 2-3 passes produces erythema and slight edema
- White desiccated tissue look

### **Miscellaneous Information:**

- Topical Anesthesia is strongly recommended for settings over 1400mJ.
- Cool ice packs after treatment can be effective in removing heat sensation
- Erythema lasting approx 3-7 days
- Ointment post op until epithelialization takes place
- Moist cool gauze application to remove heat discomfort post op
- 20% of tissue ablated leaving 80% intact per pass
- Remove shoulder of wrinkle first followed by cosmetic unit
- Do not perform Pixel treatments over Botox or Restylane for two weeks post injection
- Use an anti-viral before treatments if there is a history of cold sores

## ***Pixel Treatment Consideration***

1. **Indications:** Skin resurfacing, scars- acne & full thickness, stretchmarks, enlarged pores, rough skin textured, hyperpigmentation, fine lines and wrinkles.
2. **Anesthesia:** There is no pain associated with a conservative or aggressive treatment. Therefore, no dyes or topical anesthetics are needed. During and post treatment cooling with the Zimmer Cryo 5 is used to minimize redness and sun burn feeling.
3. **Size of Pixel:** 7 x 7 tip for more aggressive and stacking treatments on scars, etc. 9x9 tip for periorbital, full passes and less aggressive treatments.
4. **Depth of penetration:** 20-50 microns ablation plus 75 microns thermal injury zones on single passes. Up to 150 microns on triple stacking.
5. **Fluence on skin:** conservative 600-800, moderate 1000, aggressive up to 1400 mj/pulse.
6. **Number of passes:** conservative 1, moderate 2, aggressive 3 passes plus stacking. When doing multiple passes, change direction- i.e. one pass horizontal and one pass vertical.
7. **Stacking on problem areas:** 2-3 pulses in the exact same place.
8. **Time for full face treatment:** 5-20 minutes.
9. **Treatment areas:** face, neck, chest, hands and body scars.
10. **Down time on first treatment:** redness and sun burn feeling for a couple hours or up to 2 days if aggressive. Pale (conservative) to dark brown (aggressive) pixel pattern and leathery feeling 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, patients with more moisture in their skin experience more redness and sensation and greater results in fewer treatments. Therefore, a patient with dry skin may require more treatments.
11. **Number of sessions:** 3 for aggressive to 5 for conservative treatments at 2-4 weeks apart. Results will continue to improve once treatments are complete over 6 months.
12. **Post treatment care:** Immediately after treatment, apply wound healing product such as Humatrix or Biafine and cool with Zimmer. Send patient home with Aquaphor or equal to apply as needed for next 2 days. Instruct to only cleans, moisturize and use sunscreen for the next 7 days. Discontinue Obagi, RetinA, etc. regimen until day 7. On day 7 microderm or use an aggressive exfoliator or micro peel. Make-up can be applied to minimize pixel appearance.
13. **Precautions:** Do not Pixel over Botox or Restylan, for two weeks post injection. Use an antiviral before treatments if there is a history of cold sores. Make sure skin is clean and dry before treatment.
14. **Treatment price:** \$500-\$800 per 20 minute session.

## ***POST TREATMENT CARE***

1. Aerobic exercise should be avoided for 24 hours.
2. Hot baths are not advised for 24 hours (quick showers are recommended).
3. If the skin is broken or a blister appears apply an antibiotic ointment and notify the company clinical trainer.
4. Cold packs, Aloe Vera or any other cooling preparation may be used to ease a temporary discomfort.
5. Sun exposure is to be avoided for at least 3 weeks before treatment and then for the following 3 weeks. A total sun block, not a sun screen, should be applied if it is impossible to comply. If further treatment is needed a **commitment to stay out of the sun is necessary**. If there is sun exposure there are certain minor complications that may occur that should be discussed fully.
6. If compression has been applied, remove it in 24 hours.
7. Makeup can be applied as long as the skin is not ruptured.

Any questions or concerns please do not hesitate to contact the clinical trainer of the company

## ***Section 6: Forms***

- **Medical History Form**
- **Harmony ST Consent Form**
- **Harmony Skin Rejuvenation Consent Form**
- **Tattoo Removal Consent Form**
- **Acne Treatment Consent Form**
- **Laser Vein Treatment Consent Form**
- **Harmony Pixel Consent Form**
- **Laser Hair Consent**
- **Vascular/Pigmented Lesions Disclosure & Consent**
- **Post Laser/Light Treatment Care – Vascular/  
Pigmented Lesions**
- **Harmony Skin Rejuvenation Consultation**
- **Pt. FAQ's Harmony Skin Rejuvenation**
- **Acne AFT Treatment Form**
- **Fitzpatrick Skin Types**

## Sample Medical History

Name: \_\_\_\_\_

Address: \_\_\_\_\_

Home Phone: \_\_\_\_\_ Work: \_\_\_\_\_ Cell: \_\_\_\_\_

Age: \_\_\_\_\_ Referred by: \_\_\_\_\_

### Have you ever had the following?

- Current or history of cancer, especially malignant melanoma or recurrent non-melanoma skin cancer, or pre-cancerous lesions such as multiple dysplastic nevi.
- Any active infection.
- Diseases which may be stimulated by light at 515 nm to 1200 nm, such as history of recurrent Herpes Simplex, Systemic Lupus Erythematosus, or Porphyria.
- Use of photosensitive medication and/or herbs that may cause sensitivity to 515 - 1200 nm light exposure, such as Isotretinoin, tetracycline, or St. John's Wort.
- Immunosuppressive diseases, including AIDS and HIV infection, or use of immunosuppressive medications.
- Patient history of Hormonal or endocrine disorders, such as polycystic ovary syndrome or diabetes, unless under control.
- History of bleeding coagulopathies, or use of anticoagulants
- History of keloid scarring.
- Very dry skin.
- Exposure to sun or artificial tanning during the 3-4 weeks prior to treatment.
- Are you pregnant?  Yes  No
- What medications are you taking (including aspirin)? \_\_\_\_\_
- Daily consumption of alcohol \_\_\_\_\_
- Allergies: \_\_\_\_\_
- Are you taking any herbal preparations?(St. John's Wort, etc.) \_\_\_\_\_  
If yes, list \_\_\_\_\_
- Do you wear contact lenses?  Yes  No

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

- always burns, never tans  always burns, sometimes tans
- sometimes burns, sometimes tans  always tans
- Hispanic  Asian  Mediterranean  Middle Eastern  Black

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

Do you use chemical sun tanning lotions? \_\_\_\_\_ Are you planning a holiday in the sun? \_\_\_\_\_

Reason for visit (area to be treated) \_\_\_\_\_

Prior treatment (if any) \_\_\_\_\_

## ***Harmony ST Consent Form (Sample)***

**Patient name:** \_\_\_\_\_

**Treatment sites :** \_\_\_\_\_

**I duly authorize \_\_\_\_\_ to perform the Harmony ST Deep Dermal Heating procedure and any other measures which in their opinion may be necessary.**

I understand that the Harmony ST is a pulsed light emitting device designed for Deep Dermal Heating and that clinical result may vary in different skin types. I understand there is a possibility of short-term effects such as reddening, blistering, scabbing, temporary bruising and temporary discoloration of the skin, as well as rare side effects such as scarring and permanent discoloration. These effects have been fully explained to me \_\_\_\_\_ **(patient's initials)**

Clinical results may vary depending on individual factors, including medical history, skin type, patient compliance with pre/post treatment instructions, and individual response to treatment.

I understand that treatment by the Harmony ST Deep Dermal Heating system involves a series of treatments and the fee structure has been fully explained to me \_\_\_\_\_ **(patient's initials)**

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

I confirm that I am not pregnant at this time, and that I have not taken Accutane within the last 6 months. I do not have a pacemaker or internal defibrillator. I also have completed a medical history checklist and been informed about what I must do and "not do" before, during and after the series of treatments.

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

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

Patient Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Witness: \_\_\_\_\_

## ***Harmony Skin Rejuvenation Consent Form (Sample)***

**Patient name :** \_\_\_\_\_

**Treatment sites :** \_\_\_\_\_

**I duly authorize \_\_\_\_\_ to perform the Harmony Skin Rejuvenation procedure and any other measures which in their opinion may be necessary.**

I understand that the Harmony is a device used for skin rejuvenation and that clinical results may vary in different skin types. I understand there is a possibility of short-term effects such as reddening, blistering, scabbing, temporary bruising and temporary discoloration of the skin, as well as rare side effects such as scarring and permanent discoloration. These effects have been fully explained to me \_\_\_\_\_ **(patient's initials)**

Clinical results may vary depending on individual factors, including medical history, skin type, patient compliance with pre/post treatment instructions, and individual response to treatment.

I understand that treatment by the Harmony Skin Rejuvenation system involves a series of treatments and the fee structure has been fully explained to me \_\_\_\_\_ **(patient's initials)**

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

I confirm that I am not pregnant at this time, and that I have not taken Accutane within the last 6 months. I do not have a pacemaker or internal defibrillator.

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

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

Patient Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Witness: \_\_\_\_\_

## ***Consent to undergo tattoo removal (Sample)***

In signing this document, I give permission to: \_\_\_\_\_, or their designate to treat my tattoo with laser.

I understand that the goal of this procedure is improved appearance and eradication of my tattoo. I understand that every individual is unique, and it is very difficult to guarantee a specific result. Thus, I realize that I may require a series of treatments to achieve my objectives. \_\_\_\_\_ **initial**

I agree to call the clinic if I have any difficulty after my treatment. \_\_\_\_\_ **initial**

I agree to follow the aftercare protocol which includes washing my treated area twice daily, applying recovery ointment four to six times daily, and inspecting my treated area regularly. **I will keep my treated area out of the sun for a minimum of one month.** I understand that good care helps to minimize risk of complications. \_\_\_\_\_ **initial**

I understand that although uncommon, complications can occur. It has been explained to me that these complications include: local infection, pigmentation changes, scarring, redness, swelling, tenderness, and temporary worsening of the appearance of my tattoo. I understand that many of these complications are temporary, however I acknowledge that although uncommon the pigmentation changes and scarring can be permanent. \_\_\_\_\_ **initial**

If I have forgotten to tell the clinic staff of my health problems, medications, allergies, or other important information about me, I will do so now. I will inform the doctor if I am pregnant. \_\_\_\_\_ **initial**

I hereby give my permission to undergo tattoo removal.

\_\_\_\_\_  
Print your name

\_\_\_\_\_  
Signature

Date: \_\_\_\_\_

## ***Consent for Acne Treatment (Sample)***

Your permission is necessary before commencing any treatments. The permission form is intended to be a tool to ensure that you have been informed about your procedure, the risks and the benefits, and to provide you with a chance to ask your questions.

Acne treatment using the Harmony AFT is a gradual process. Most individuals require 8 to 12 treatments to reduce the acne. The light is pulsed over the face and it feels like a mild rubber band snap. After a procedure, the skin is often pink in its appearance, and there can be some mild transient worsening of the acne before it improves. Before and after a treatment, we would ask you to strictly avoid tanning for 4 weeks. \_\_\_\_\_ **initial.**

There are a few risks with any light based treatment. The majority of individuals have no problems with the treatments. Up to 5% of people may experience bruising – which can be very deep purple for a week or sometimes a little longer. Uncommon side effects would include blistering and pigmentation changes. Rare / unexpected risks would include scarring. For men, there is a concern that the light emitted may reduce their beard hair. \_\_\_\_\_ **initial.**

Many acne medications cause the skin to be sensitive to light. Please remind the staff at every visit about your medications. We will likely request that you stop taking your oral medications and creams several days before each treatment. If you have taken a drug called **Accutane** within the last year, you must inform the staff immediately, as this medication may leave you light sensitive for an extremely long time and we do not wish to burn you with the light treatments. If you took **Accutane** – we must delay your treatment. \_\_\_\_\_ **initial.**

Ultimately, we are here to help you & want your experience to be a pleasant one. Please call us with any of your concerns. The contact number for any concerns is:\_\_\_\_\_. You will be provided with a card with this number on it.

In signing, I \_\_\_\_\_(print name) give permission to undergo a acne treatment.

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

## ***Consent to undergo laser vein treatment (Sample)***

In signing this document, I give permission to: \_\_\_\_\_, or their designate to treat my veins with laser.

I understand that the goal of this procedure is improved appearance and eradication of my veins. I understand that every individual is unique, and it is very difficult to guarantee a specific result. Thus, I realize that I may require a series of treatments to achieve my objectives. \_\_\_\_\_ **initial**

I agree to call the clinic if I have any difficulty after my treatment. \_\_\_\_\_ **initial**

I agree to follow the aftercare protocol which includes washing my veins twice daily, applying recovery ointment four to six times daily, and inspecting my veins regularly. **I will keep my veins out of the sun for a minimum of one month.** I understand that good vein care helps to minimize risk of complications. \_\_\_\_\_ **initial**

I understand that although uncommon, complications can occur. It has been explained to me that these complications include: local infection, pigmentation changes, scarring, redness, swelling, tenderness, and temporary worsening of the appearance of my veins. I understand that many of these complications are temporary, however I acknowledge that although uncommon the pigmentation changes and scarring can be permanent. \_\_\_\_\_ **initial**

If I have forgotten to tell the clinic staff of my health problems, medications, allergies, or other important information about me, I will do so now. I will inform the doctor if I am pregnant. \_\_\_\_\_ **initial**

I hereby give my permission to undergo vein removal.

Print you name: \_\_\_\_\_

Patient Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Witness: \_\_\_\_\_

## ***Harmony Pixel Consent Form (Sample)***

**Patient name** \_\_\_\_\_

**Treatment sites** \_\_\_\_\_

**I duly authorize \_\_\_\_\_ to use the Harmony Pixel 2940nm Er:Yag system to perform fractional ablative skin resurfacing and any post treatment medical requirements that may be necessary.**

I understand that the Harmony Pixel is a laser device designed for fractional ablative skin resurfacing and that clinical result may vary in different skin types. I understand there is a possibility of short-term effects such as reddening, blistering, scabbing, temporary bruising and temporary discoloration of the skin, as well as rare side effects such as scarring and permanent discoloration . These effects have been fully explained to me \_\_\_\_\_ **(patient’s initials)**

Clinical results may vary depending on individual factors, including medical history, amount of sun damage or textural problems, skin type, patient compliance with pre/post treatment instructions, and individual response to treatment.

I understand that treatment by the Harmony Pixel 2940nm Er:Yag system involves a series of treatments and the fee structure has been fully explained to me \_\_\_\_\_ **(patient’s initials)**

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

I confirm that I am not pregnant at this time, and that I have not taken Accutane within the last 6 months. I do not have a pacemaker or internal defibrillator. I also have completed a medical history checklist and been informed about what I must do and “not do” before, during and after the series of treatments.

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

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

Print you name: \_\_\_\_\_

Patient Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Witness: \_\_\_\_\_

## ***Laser Hair Consent (Sample)***

In signing this document, I give permission to the clinic staff of: \_\_\_\_\_ to perform laser hair removal.

I understand that the goal of this procedure is the gradual permanent reduction of my hair. I understand that every individual is unique, and it is very difficult to guarantee a specific number of treatments needed. It is expected that I will require four to six treatments for the body and six to eight treatments for the face, give or take one treatment. \_\_\_\_\_ **initials**

I agree to call the clinic if I have any difficulty after my treatment. The number to call is: \_\_\_\_\_. \_\_\_\_\_ **initials**

I acknowledge that I have not waxed the treated area within the previous six weeks nor have I plucked the hair from the area being treated. **I acknowledge that I have not been sun tanning for the previous FOUR weeks.** \_\_\_\_\_ **initials**

Although uncommon, I understand that complications can occur. It has been explained to me that these complications include: a sunburn feeling, redness, local tenderness and mild swelling, occasionally blistering, very rarely pigmentation changes and scarring. \_\_\_\_\_ **initials**

I understand that how I take care of my skin after treatment influences my risk of complications. I agree to wash my skin gently twice-daily and apply an antibacterial cream for the first week. **I agree to stay out of the sun or to use sufficient sun block for FOUR weeks following my treatment.** I agree to call the clinic if I develop any markings on my skin after treatment, and I will not pick at them. \_\_\_\_\_ **initials**

I have not taken Accutane within the last 12 months. \_\_\_\_\_ **initials**

I am not currently pregnant. \_\_\_\_\_ **initials**

I am a not allergic to topical anesthetics (topical freezing). \_\_\_\_\_ **initials**

If I have forgotten to tell the clinic staff of my health problems, medications, allergies, or other important information about me, I will do so now. I will inform the doctor if I become pregnant. \_\_\_\_\_ **initials**

I hereby give my permission to undergo laser hair removal

Patient Signature: \_\_\_\_\_ Date: \_\_\_\_\_

## ***Disclosure and Consent—Laser/Light Assisted Treatment of Vascular***

- ◆ I (we) voluntarily request laser/light assisted treatment of lesions that I have proclaimed as “unwanted” in the following areas: \_\_\_\_\_.
- ◆ I (we) voluntarily consent and authorize that this laser/light assisted treatment be performed by the staff of this clinic, including physicians, technicians, associates, technical assistants, and other health care providers as deemed necessary by the staff of this clinic. I (we) hereby release this clinic, its staff, and any other participating health care providers from any and all liability for any adverse effects that may result from this treatment and related procedures.
- ◆ For the purposes of accurate record keeping in connection with the care and treatment which I am receiving and will subsequently receive from this clinic, I (we), the undersigned, consent to have this clinic’s staff take before, during, and after treatment close-up photographs of the involved area(s) and the anatomical region surrounding the involved area(s). These photographs shall be used for medical records and shall be treated with the same confidentiality as the remainder of my record at this clinic.
- ◆ I (we) recognize that this laser/light assisted treatment is not an exact science and I (we) acknowledge that no guarantees or assurances have been made to me (us) as to the result or cure. There are risks related to the performance of these procedures. I (we) understand and acknowledge that the risks that may occur in connection with this particular procedure may include the following:
  1. Infection – Albeit rare, skin infection is a possibility any time a skin procedure is performed. I acknowledge and understand that although rare, it is possible for a skin infection to become a blood-borne wide spread infection.
  2. Blood clots in veins and lungs –Albeit extremely rare, it may be possible to develop a blood clot associated with this treatment that goes (embolizes) to the heart and/or lungs.
  3. Allergic reactions – Although uncommon, I could possibly develop an allergic reaction to medicines applied to the treated area and that I could possibly develop an allergic reaction to any medications that may be prescribed for me.
  4. Hemorrhage and bruising – Bruising in the treated area is possible, especially if, within the last ten (10) days, I (we) have taken aspirin or aspirin-containing products, or other medications that “thin” the blood.
  5. Recurrence of the lesion – I may not experience permanent results even with multiple treatments.
  6. Painful or unattractive scarring – Scarring is a rare complication of laser assisted treatment, but scarring is possible because the skin surface is disrupted by the laser. To minimize the chances of scarring, it is most important that I follow ***all postoperative instructions*** carefully.
  7. Discomfort and pain – Some discomfort will be experienced during and after the laser treatment. I give my permission for the administration of topical and/or local injection of anesthesia when and if deemed appropriate.
  8. Pigment changes (skin color) – During the healing process, the treated area may become either lighter or darker in color than the surrounding skin. This is usually temporary, but on a rare occasion, it may be permanent.
  9. Poor healing – The resultant open wound may require more than the usual one to three weeks to heal.
  10. Sun exposure – Once the surface has healed, it may be pink and sensitive to the sun. Treated areas should be blocked completely, that a sun block with and SPF greater than 40 should be used at all times in areas not protected by clothing, whether or not I am in the sun.
  11. Blindness and eye damage – The laser, without protective eyewear, may cause visual loss including blindness. ***It is important to keep these shields on at all times*** during the procedure and that I ***should keep my eyes closed*** in order to protect my eyes from accidental laser exposure.

- ◆ I (we) understand and acknowledge that I have been informed by means of visual aids, as well as individual discussion, that multiple treatments are often required to cause long-term results and that some patients have no results even with multiple treatments. The usual number of treatments required is two to three, but more treatments may be required.
- ◆ I (we) have been given an opportunity to ask questions about my condition, alternate forms of anesthesia and treatment, the procedure to be used, and the risks and hazards involved, and I (we) believe that I (we) have sufficient information to give the informed consent. By signing below, I (we) certify that I (we) have read and fully understand the contents of this document and that I (we) have received and understand all of the disclosures referred to herein. I certify that I am a competent adult of at least 18 years of age, or that if I am a minor under the age of 18, I understand that the consent of my parent/legal guardian having legal custody will also be required before treatment.

Signature of Patient: \_\_\_\_\_

Print Name of Patient: \_\_\_\_\_

Signature of Person Authorized to Consent for Patient: \_\_\_\_\_

Print Name : \_\_\_\_\_ Relationship: \_\_\_\_\_

Date: \_\_\_\_\_ Witness: \_\_\_\_\_

## ***Post Laser/Light Treatment Care—Vascular/Pigmented Lesions***

1. Be careful with hot water and do not bathe with very hot water until healed.
2. Keep the area moist with Aloe Vera gel, or Aquaphor Healing Ointment until inflammation resolves and the area is healed.
3. Keep the treated area out of the sun. If sun is unavoidable, cover it or block it with SPF 40 or above for at least 4 weeks following treatment.
4. Keep clothing from rubbing the treated area and avoid other irritation to the area.
5. Do not use hairspray on or around the treated area.
6. Notify the clinic should you have any prolonged redness, excessive puffiness, or other unusual side effects.

### **Important Facts to Remember**

1. There will be redness, and occasionally, mild blistering of the treated areas lasting for several hours to 3 - 14 days.
2. The treated area might “crust”, “flake”, or look like a “cat scratch”. This should resolve within 3 - 14 days.
3. Each area to be treated usually requires two or more treatments approximately 2-12 weeks apart.
4. It might be impossible to remove the lesion forever. Even though the lesion may be diminished or “disappear” for long periods of 3-6 months, it might return in the future. The fact that the lesion responded to treatment and was disabled for an extended period almost invariably means it will respond to future treatment.
5. Medications Dispensed: \_\_\_\_\_ use as directed.

Signature of Patient: \_\_\_\_\_

Print Name of Patient: \_\_\_\_\_

Signature of Person Authorized to Consent for Patient: \_\_\_\_\_

Print Name : \_\_\_\_\_ Relationship: \_\_\_\_\_

Date: \_\_\_\_\_ Witness: \_\_\_\_\_

## Harmony Skin Rejuvenation Consultation

Personal Information			
Name		Home Phone	
Address		Work Phone	
City		State	
Postal Code		Date of Birth	
Referred by		Gender	Male/ Female

Medical History			
Bleeding disorder, bruise easily		Endocrine / hormone issues	
Pigmentation disorder		Pacemaker / defibrillator	
History of cold sores		Accutane within 6 months	
History of keloid scarring		History of skin cancer	
Dermatological conditions		Photoallergic	
<b>List any medications taken</b>			
<b>Medical conditions</b>			
<b>List any allergies</b>			

### Contraindications:

- ◆ Tanned skin (active or passive)
- ◆ Accutane taken in last 6 months
- ◆ History of keloid scarring
- ◆ Any abnormal or undiagnosed pigmentation should be avoided
- ◆ Atypical moles or malignancy
- ◆ Non-intact skin (i.e. sores, psoriasis, eczema, infection, rash) should be avoided
- ◆ Recent chemical or mechanical peeling in treatment area (within 2 weeks)
- ◆ Laser resurfacing in treatment area within 3 months
- ◆ Any medical condition involving impairment of skin structure, esp healing patterns
- ◆ Poorly controlled diabetes
- ◆ Pregnancy

### Precautions: (treat with caution if patient has any of following risk factors)

- ◆ Medications that may cause photosensitivity to light 540-950 nm
- ◆ Healing impaired
- ◆ History of skin cancer in treatment area, family history of melanoma

Skin Type Assessment			
Fitzpatrick Skin type	I II III IV V VI	Ethnicity	
Tan present	Yes / No	Sunscreen daily?	Always/ Sometimes/ Never
Skin care regimen			
Vascular lesions			
Pigmented lesions			
Textural irregularities			

*\*Improvements achieved by each treatment may not be evident until weeks later.*

Hair Assessment			
Location (circle)	Upper lip	Chin	Sideburns Forehead Cheeks Other_____
Hair density	Sparse/ Medium/ Dense	Hair thickness	Fine/ Medium/ Coarse
Hair color		Other	

*\*counsel patient that hairs in treatment area may also be reduced or miniaturized as result of skin rejuvenation treatment. Base line photos/photodocumentation is recommended.*

#### **Possible Side Effects:**

- ◆ Temporary mild discomfort from treatment, may feel warmth or tingling
- ◆ Temporary swelling, redness in treatment area
- ◆ Temporary 'darkening' of pigmented lesions before becoming lighter
- ◆ Superficial scabbing, crusting or blister
- ◆ Transient or permanent dyschromia from epidermal injury

#### **Treatment Schedule:**

- ◆ Treatment done at monthly intervals. May retreat as soon as 3 weeks for some patients.
- ◆ 5 treatments in treatment series. Some lesions may fade significantly after a single treatment. Collagen stimulation is a delayed and cumulative response, 5 treatments recommended for this indication.
- ◆ Maintenance treatments may be done to help maintain results, or to treat new lesions.

## ***Patient FAQ's—Harmony Skin Rejuvenation***

### ***HOW DOES THE HARMONY REJUVENATE MY SKIN?***

*The Harmony uses gentle light to restore skin to a more youthful state. Brown spots (pigmented imperfections) from sun damage and aging, red blotchiness from spider vessels or rosacea (vascular imperfections), and rough skin texture will improve over a treatment series.*

### ***IS TREATMENT WITH THE HARMONY SAFE?***

Treatment is very safe for the skin. There are many advances in the Harmony technology that make it unparalleled for skin safety, without compromising effectiveness for treatment. There are no long term health hazards from light used in the Harmony. Both have been used for decades in medicine, surgery, and aesthetics without adversity.

### ***WHAT KIND OF RESULTS CAN I EXPECT FROM HARMONY TREATMENT?***

Each Harmony treatment will result in gradual lightening and improvement of pigmented and vascular imperfections. Textural improvements are appreciated towards the end of the treatment series.

### ***HOW FREQUENTLY DO I NEED TREATMENTS?***

Treatments are repeated every month for a total of 5 treatments.

### ***DOES THE TREATMENT HURT?***

The sensation is often described as “hot pinch”, or “snapping” feeling. The sensation only lasts for fraction of a second, and you may feel warmth or a tingling sensation for a short time afterward. Most people tolerate treatment without topical anesthetic, but individuals who are more sensitive may prefer to have the skin numbed before treatment.

### ***WHAT HAPPENS AFTER EACH TREATMENT?***

Temporary pinkness in the skin lasts a very short time, and most people return to work or normal activities immediately after treatment. The improvement in pigmented and vascular irregularities can often be appreciated by the time you return for your next treatment a month later. Brown spots temporarily go darker before they lighten.

### ***WHO SHOULD GET HARMONY TREATMENT FOR SKIN REJUVENATION?***

Anyone who wants to improve the signs of sun damage and aging in the skin, such as pigmented and vascular irregularities, uneven or rough skin texture. Skin rejuvenation can be done on face, neck, chest, hands, arms. Discuss your candidacy for this treatment with your Harmony clinician.

## Acne AFT Treatment Form (Sample)

Patient Name: \_\_\_\_\_ Pre Photo Taken: \_\_\_\_\_

Date: \_\_\_\_\_ Clinician Treating: \_\_\_\_\_ Treatment Number: \_\_\_\_\_

Description of acne prior to treatment: \_\_\_\_\_

- ◆ Mild inflammatory:- few comedones, mild erythema, no cysts
- ◆ Moderate inflammatory: - several comedones, plus erythema, no cysts
- ◆ Severe inflammatory: - comedones and cysts present with erythema

Treatment: - Parameters: \_\_\_\_\_ Joules: \_\_\_\_\_ Pulse Width: \_\_\_\_\_

Response to Treatment:

- ◆ Immediate: \_\_\_\_\_
- ◆ 48 hr F/U (optional): \_\_\_\_\_
- ◆ Prior to subsequent Rx: \_\_\_\_\_

Side effects or complications noted: \_\_\_\_\_

Date: \_\_\_\_\_ Clinician Treating: \_\_\_\_\_ Treatment Number: \_\_\_\_\_

Description of acne prior to treatment: \_\_\_\_\_

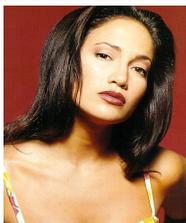
- ◆ Mild inflammatory:- few comedones, mild erythema, no cysts
- ◆ Moderate inflammatory: - several comedones, plus erythema, no cysts
- ◆ Severe inflammatory: - comedones and cysts present with erythema

Treatment: - Parameters: \_\_\_\_\_ Joules: \_\_\_\_\_ Pulse Width: \_\_\_\_\_

Response to Treatment:

- ◆ Immediate: \_\_\_\_\_
- ◆ 48 hr F/U (optional): \_\_\_\_\_
- ◆ Prior to subsequent Rx: \_\_\_\_\_

Side effects or complications noted: \_\_\_\_\_

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

## ***Section 7: Safety Issues***

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

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