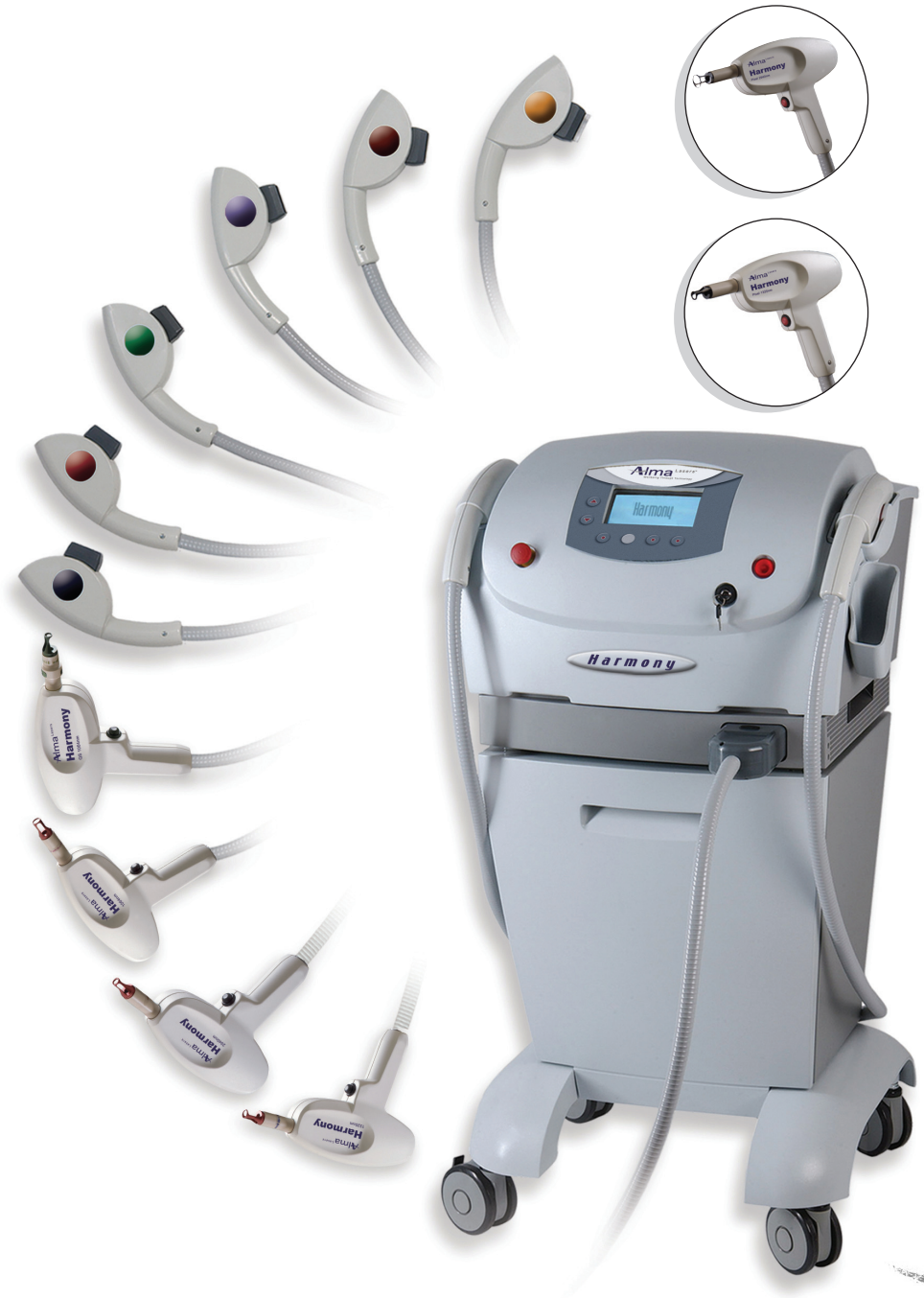
Harmony

MULTI- APPLICATION, MULTI-TECHNOLOGY PLATFORM

OPERATOR'S MANUAL



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Wellbeing Through Technology

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Scope of This Manual

This Operator's Manual incorporates the following chapters:

Chapter 1	**System Review**	Contains a general introduction to the Harmony system.
Chapter 2	**Safety**	Contains explanations and directions concerning safety measures for operating the system, international standard compliance, classifications and regulatory labels.
Chapter 3	**Installation**	Lists electrical, space and environmental requirements for installation of the system.
Chapter 4	**System Description**	Contains a detailed overview of the Harmony system and its various sub-systems and handpieces, including technical specifications for the platform and each of the handpieces.
Chapter 5	**Controls and Indicators**	Describes the control and service panels, footswitch and various connections to the system, and functional indicators.
Chapter 6	**System Operating Instructions**	Explains how to operate the system as a platform, offering basic information and common instructions for operation. Specific operating instructions for each of the handpieces may be found in the appendices.
Chapter 7	**Maintenance**	Provides a detailed review of how to maintain the system.
Chapter 8	**Troubleshooting**	Lists the system error messages that might appear during operation, their probable causes and what corrective actions to perform.
Chapter 9	**Ordering Information**	Provides information on how to order the Harmony system's accessories and spare parts.
Appendix A	**General Clinical Information**	Clinical Guide for pivotal clinical information and pre-procedure activities.
Appendix B	**AFT Acne Module: Acne Clearance**	Clinical Guide for use of the Harmony system for mild to moderate acne.
Appendix C	**AFT VP and LP 1064nm Modules**	Clinical Guide for use of the Harmony system for vascular lesions.
Appendix D	**AFT VP Module: Pigmented Lesions**	Clinical Guide for use of the Harmony system for pigmented lesions.
Appendix E	**AFT SR Module: Skin Rejuvenation**	Clinical Guide for use of the Harmony system for skin rejuvenation.
Appendix F	**AFT HR Module: Hair Removal**	Clinical Guide for use of the Harmony system to remove unwanted hair.

Appendix G	**Skin Tightening Module: Skin Tightening, Scar Revision and Treatment of Striae**	Clinical Guide for use of the Harmony system for skin tightening, scar revision and treatment of striae.
Appendix H	**UVB Module: Psoriasis & Vitiligo**	Clinical Guide for use of the Harmony system for psoriasis and vitiligo.
Appendix I	**Q-Switched Module: Tattoo Removal**	Clinical Guide for use of the Harmony system for tattoo removal.
Appendix J	**1320nm Module: Fine Lines, Wrinkles & Acne Scars**	Clinical Guide for use of the Harmony system for fine lines, wrinkles and acne scars.
Appendix K	**2940nm Module: Skin Resurfacing**	Clinical Guide for use of the Harmony system for skin resurfacing with the 2940nm Er:YAG module.
Appendix L	**Pixel® 2940nm Module: Fractional Ablative Skin Resurfacing**	Clinical Guide for use of the Harmony system for fractional ablative skin resurfacing using the Pixel 2940nm Er:YAG module.
Appendix M	**Pixel 1320nm Module[1]: Fine Lines, Wrinkles, Acne & Acne Scars**	Clinical Guide for use of the Harmony system for fine lines, wrinkles and acne scarring using the Pixel 1320nm Nd:YAG module.
Appendix N	**Post-Treatment Care**	Clinical Guide for all post treatment activities and adverse event handling.
Appendix P	**Electromagnetic Compatibility**	Conditions under which the Harmony system should be operated.

[1] Not available in the USA

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CHAPTER 1

System Overview

Chapter Contents:

1.1. Introduction

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:

- AFT Acne handpiece for acne clearance, with a wavelength range of 420-950nm (Blue)
- AFT VP handpiece for vascular and pigmented lesions, with a wavelength range of 540-950nm (Green)
- AFT SR handpiece for skin rejuvenation, with a wavelength range of 570-950nm (Yellow)
- AFT HR handpiece for hair removal, with a wavelength range of 650-950nm (Red)
- ST handpiece for skin tightening, scar revision and treatment of striae with a wavelength range of 780-950nm (Burgundy)
- UV handpiece for psoriasis and vitiligo, with a wavelength range of 300-380nm (Violet)
- Q-switched Nd:YAG laser handpiece for tattoo removal, with wavelengths of 1064nm and 532nm
- Long pulsed Nd:YAG laser handpiece for vascular lesions and leg veins, with a wavelength of 1064nm
- Long pulsed Nd:YAG laser handpiece for fine lines, wrinkles and acne scars, with a wavelength of 1320nm
- Er:YAG laser handpiece for skin resurfacing, with a wavelength of 2940nm
- Pixel® Er:YAG laser handpiece for fractional ablative skin resurfacing, with a wavelength of 2940nm
- Pixel® Nd:YAG laser handpiece for fine lines and wrinkles, and acne scarring, with a wavelength of 1320nm[1]

Please refer to Appendix A of this manual for a complete list of the Harmony system's clinical indications.

[1] Not available in the USA

1.2. Treatment Parameters

Before treatment initiation, the operator selects the appropriate handpiece and enters the pulse width based on patient's skin type or lesion depth/diameter and the requested fluence; namely, the amount of energy expressed in J/cm^2 to which the treated area is exposed. Each time the operator presses the footswitch, the Harmony emits a single pulse when using the AFT or UV handpieces. Laser emission with the 1064nm Nd:YAG, 1064nm QS Nd:YAG, 2940nm Er:YAG, Pixel® 2940nm Er:YAG and Pixel 1320nm Nd:YAG handpieces, however, is enabled only when the handpiece's trigger and the footswitch are pressed simultaneously.

1.3. Use of this Manual

The Harmony system is designed to meet international safety and performance standards. Personnel operating the system must have a thorough understanding of the proper operation of the Harmony.

This manual has been prepared to aid medical and technical personnel to understand and operate the system. Do not operate the system before reading this manual and gaining a clear understanding of system operation. If any part of this manual 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 system should read this manual and become thoroughly familiar with all its safety requirements and operating procedures.

The information provided in this manual 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 appendices that include set up guidelines for each application.

This manual should always accompany the system and all operating personnel must know its location. Additional copies of this manual are available from Alma Lasers or your local Alma Lasers representative.

For further information about Alma Lasers, visit the company website at: http://www.almalasers.com.

1.4. Physician Responsibility

Federal (USA) law restricts prescription of medical devices for sale by or on the order of a physician, or properly licensed practitioner. The properly licensed practitioner will be responsible for the use and operation of the device and for all operator qualifications. Alma Lasers makes no representations regarding federal, state or local laws or regulations that might apply to the use and operation of any medical device. The physician is responsible for contacting his or her local licensing agencies to determine any credential required by law for clinical use and the operation of the device.

1.5. Maintenance

The Harmony system is a precision, technical medical device that requires periodic routine maintenance service, which must be performed by Alma Lasers authorized technical personnel. Failure to obtain service voids all warranties expressed and implied. Please contact Alma Lasers or your local representative for details.

1.6. Modification of the System

Unauthorized modification of the hardware, software or specifications of the Harmony system voids all warranties, expressed and implied. Alma Lasers takes no responsibility for the use or operation of such a modified device.

1.7. Resale Inspection

The Harmony is a precision, technical medical device. If any Alma Lasers device is resold by anyone other than an authorized sales representative, Alma Lasers offers a resale inspection by an Alma Lasers technician to assure that the device is working in accordance with manufacturer's specifications. Using the device after it has been resold and before it has been inspected is a misuse of the device, which may result in injuries and voids all warranties, expressed and implied.

Alma Lasers also offers service contracts and extended warranties for its devices. For more information about the services or about the costs of inspections or service calls, please contact Alma Lasers or your local representative.

1.8. Abbreviations and Acronyms

°C	Degree(s) Centigrade/Celsius
A	Ampere(s)
AC	Alternating current
AFT	Advanced fluorescence technology
CFR	Code of Federal Regulations
cm	Centimeter(s)
cm^2	Centimeter(s) square
EDF	Equally distributed fluence
Er:YAG	Erbium-doped Yttrium Aluminum Garnet
HR	Hair removal
Hz	Hertz
IEC	International Electrotechnical Commission
J	Joule(s)
J/cm^2	Joule(s) per square centimeter
Kg	Kilogram(s)
KTP	Potassium Titanyl Phosphate
LCD	Liquid crystal display
LED	Light emitting diode
LP	Long pulse
m	Meter(s)
mm	Millimeter(s)
msec	Millisecond
Nd:YAG	Neodymium-doped Yttrium Aluminum Garnet
nm	Nanometers
nsec	Nanoseconds
OD	Optical density
QS	Quality switched
Sec	Second(s)
SR	Skin rejuvenation
ST	Skin tightening

TEC	Thermoelectric cooling
UV	Ultra violet
V	Volt(s)
VAC	Volt(s) alternating current
VP	Vascular / Pigmented lesions
W	Watt(s)

CHAPTER 2

Safety

Chapter Contents:

2.1. Introduction

This chapter describes general safety issues regarding the use of the Harmony system, with special emphasis on optical and electrical safety.

> ***Warning***
>
> Hazardous voltages are energized when the emergency stop button is engaged.

> ***Note***
>
> Federal law (USA) restricts this device to only be sold to, or on the order of a physician or any practitioner licensed by the law of the state in which he or she practices or intends to use or order the use of the device.

The Harmony system is an aesthetic platform for the treatment of moderate inflammatory acne vulgaris, benign pigmented epidermal, cutaneous, and benign cutaneous vascular lesions, deep and superficial vascular disorders, non-ablative treatment of facial wrinkles (skin rejuvenation), tattoo removal, hair removal and stable permanent hair reduction, psoriasis, leukoderma, vitiligo, and atopic and seborrheic dermatitis, ablative skin resurfacing, fine lines and wrinkles, epidermal nevi, atrophic acne scars and other superficial skin lesions.

With proper operation and maintenance, trained and qualified medical practitioners can use the system safely. The supervising physician and all other personnel operating or maintaining the Harmony must be familiar with the safety information provided in this chapter.

The primary consideration should be for the safety of the patient, the physician and other personnel. Patient safety is mainly assured with a well trained staff and a well laid out treatment room. Patient education is also important, including information about the nature of the treatment.

2.2. System Safety Measures

The Harmony system was designed to maximize safety for both patient and personnel. The following are some of the Harmony's preventive safety measures:

2.2.1. Electrical Safety

1. The system is protected by two slow-blow, 5 Amp fuses. Fuses are housed within the power inlet. A SELV Protection Device is placed near the interlock connector inside the system; this device must be replaced as a complete unit (not only the fuses) by Alma Lasers authorized technicians.
2. Software protection, including:
   - The software checks all safety related hardware after the system is switched on.
   - Emission timing is regulated by interrupts every 1 msec.
   - A watchdog cycle continuously monitors operation of the system during treatment.
   - If an error occurs, the system displays a warning message to the operator and disables further operation.
3. A self-test of the attached handpiece is performed when the system is turned on. The test includes handpiece identification.
4. A self-test of the electrical circuitry takes place after the system is turned on. The test circuits continuously monitor system operation during treatment.

2.2.2. Light and Laser Safety

1. Closed lightguide geometry is used to transmit light to the treatment site. Light is emitted only through the front plane of the lightguide.
2. The system incorporates a safety remote interlock connector for connecting an external interlock on the entrance door to the treatment room. The external remote interlock is serially connected with the footswitch; therefore when installed, disables the system and prevents operation when the entrance door is opened.
3. An emergency shutoff knob expedites shutdown when necessary. When pressed, it immediately shuts down system operation.
4. A password on the service screen prevents unauthorized changes to the system's basic operating parameters.

5. The system features two emission indicators: a red emission indicator lamp located on the top of the control panel and a buzzer.
   - The red emission indicator lamp flashes when the system is ready to trigger pulses, and becomes a continuous light when a light pulse is triggered.
   - A warning buzzer sounds when the system is ready to trigger a pulse.
6. Emission is enabled only when the operator switches to **Ready** mode and presses the footswitch (minimum risk).
7. Laser emission (from the laser handpieces) is enabled only if both the footswitch and the handpiece trigger are pressed at the same time. The trigger reduces the risk of unintentional laser emission.
8. Water is circulated through the handpiece as soon as the system is turned on in order to cool the light source.
9. The flow and temperature of the water are monitored in order to eliminate the risk of handpiece overheating. Pulse light is not permitted if the water flow stops or if the water temperature is equal to or higher than 40ºC (104ºF).
10. The system is equipped with a pneumatic footswitch for ease of use. It is pneumatic to eliminate the possibility of any short-circuiting in the footswitch's wiring and to increase its durability to fluids.

Warning

Any laser or pulsed light-emitting device can cause injury if used improperly. High voltages are present inside the Harmony 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 this manual.

2.3. The Treatment Room

The treatment room must be clearly labeled with signs indicating that high intensity light and/or laser energy are in use. The treatment room sign that is supplied with the Harmony system is shown in Figure 2-1.

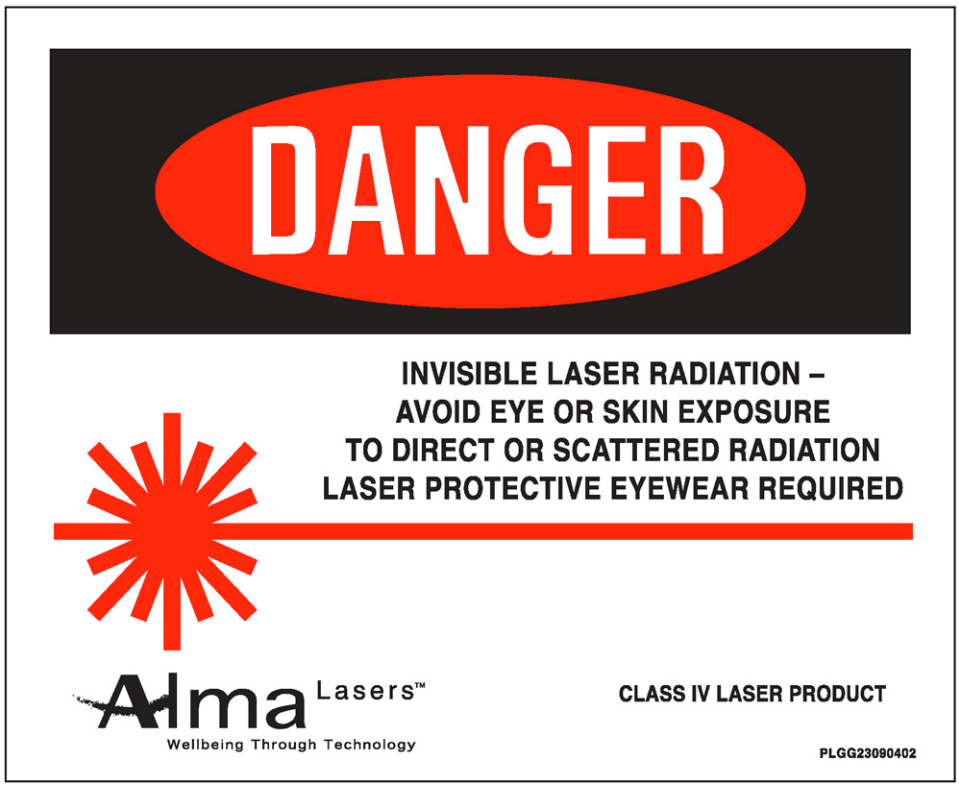


Figure 2-1: Treatment Room Warning Sign

The treatment room should not include any light reflecting objects such as a mirror.

Access to the Harmony treatment room should be allowed only to personnel essential to the procedure and who are well trained in the required safety procedures.

Assure that all of the treatment room personnel are familiar with the Harmony controls and know how to shut down the system instantly.

2.4. General Precautions and Cautions

The following precautions, cautions and warnings must be observed for the safe use of the Harmony system.

2.4.1. Precautions

- Physicians and clinicians should read this manual thoroughly before attempting to operate the Harmony system.
- Any handpiece's lightguide must be kept clean at all times. Remember to clean the cooling gel from the lightguides after each patient.
- The system weighs approximately 88 lbs. (40 kg) and may cause injury if proper care is not used when moving it. The system is well balanced and is designed to be moved, but should always be moved carefully and slowly. Never pull the system by the handpiece.

2.4.2. Cautions

- Only Alma Lasers authorized personnel may service the Harmony system. This includes making internal adjustments to the power supply, cooling system, optics, handpieces, etc.
- Verify that the Harmony is wired for the appropriate electrical voltage of your country (100-120VAC or 220-240VAC).
- Maintenance performed by the operator must only take place when the system is shut down and disconnected from the electrical power source. Performing maintenance procedures with the system powered-up can be hazardous to the operator and/or destructive to the system.
- Always turn off the system when it is not in use.
- Never leave the system in **Ready** mode unattended.
- Never allow untrained personnel to operate the system.
- Never press the footswitch unless the handpiece is safely oriented at a specific and intended target.
- Never leave the system turned on, open or unattended during system maintenance.

2.5. Warnings Related to Laser and Intense Pulsed Light Emission

2.5.1. Burn Hazards

The Harmony system emits a wide wavelength spectrum, which, in part, is invisible to the human eye and can cause third degree burns.

2.5.2. Direct and Reflected Eye Exposure Hazards

It is essential that all people present in the treatment room during the treatment (patient and medical personnel) protect their eyes by wearing Alma Lasers recommended protective eyewear.

It is good practice to instruct the patient to close their eyes during treatment even when wearing protective eye glasses.

If the patient cannot wear the protective eyewear, fit the patient with opaque eye protection that completely blocks light from the eyes.

If the treatment area is very close to the eyes (e.g. eyelids), protect the eyes with corneal shields.

Warning

- Different protective eyewear is indicated for use with AFT, UV, ST, Nd:YAG or Er:YAG handpieces. Make sure you choose the correct type.
- Do not treat eyebrows, eyelashes, or other areas within the bone area surrounding the eye orbit with the Nd:YAG or Er:YAG handpiece. The light emitted by this handpiece can cause serious eye damage or blindness. For maximum safety, the patient must wear metal eye goggles for all facial treatments.

Please refer to Section A.10 of Appendix A in this manual (**Eye Protection**) for a listing of safety eyewear specific to the system's various emitted wavelengths.

2.5.3. Explosion and Fire Hazards

The absorption of optical energy raises the temperature of the absorbing material. Take precautions to reduce the risk of igniting combustible materials in and around the treatment area.

The system is not suitable for use in the presence of flammable mixtures with air or oxygen.

Do not operate in the presence of volatile solvents such as alcohol, gasoline or other solvents.

Do not use any flammable substances such as alcohol or acetone in the preparation of the skin for treatment. If necessary, use soap and water to clean before treatment.

If alcohol is used to clean and disinfect any part of the Harmony system, allow it to dry thoroughly before operating the system.

Flammable materials must be kept at a safe distance from the system.

2.5.4. High Voltage Hazards

The system utilizes 120/230 VAC. To avoid personnel injury, do not operate the system before ensuring that the exterior panels are properly closed. Do not attempt to remove or disassemble the exterior panels.

The Harmony system produces very high voltages in various components. Some components may retain a charge after the power supply has been turned off, so no part of the exterior housing should be removed, except by Alma Lasers authorized personnel.

Whenever system maintenance is performed, never leave the Harmony system turned on, open or unattended.

2.5.5. Grounding the System

The system is grounded through the grounding conductor in the power cord and internal grounding pin.

2.6. System Safety Features

The Harmony system is equipped with a number of safety features. All treatment room personnel should be familiar with the location and operation of these safety features.

2.6.1. Password

The password on the service screen switches the system to **Technician** mode. A separate additional password is required to enter to the **Handpiece Calibration** screen.

These passwords prevent unauthorized modifications of the system's settings.

2.6.2. Emergency Shut-Off Knob

This red knob is used for emergency shutdown. When pressed, it immediately shuts off power to the entire system.

To release the emergency shut-off knob, turn it clockwise. Otherwise, the system will remain off (see Figure 4-1).

2.6.3. Light Emission Indicators

The system features two laser emission indicators: a red LED located on top of the control console and a buzzer.

The red LED has three modes:

- **Off -** when the system is turned on, and in **Standby** mode
- **Blinking** – during **Ready** mode
- **Continuous** – during laser emission (footswitch or footswitch and handpiece trigger are pressed)

The buzzer beeps once when the system switches to **Ready** mode.

2.6.4. Remote Interlock Connector

The system incorporates a safety remote interlock connector for connecting an external interlock on the entrance door to the treatment room. The external remote interlock is serially connected with the footswitch; therefore when installed, it disables the system and prevents operation when the entrance door is opened.

2.6.5. Double-Tiered Security for Laser Emission

Nd:YAG, Q-Switched Nd:YAG or Er:YAG lasing is enabled only when the operator presses both the footswitch and handpiece trigger; therefore accidental lasing may only occur due to double error condition (minimum risk).

2.6.6. Footswitch

The system is equipped with a pneumatic footswitch to eliminate the possibility of short-circuiting in the footswitch wiring and to increase its durability to fluids.

2.7. Equipment Classification and Compliance

- Electrical shock protection: Class I, Type B
- Protection against ingress of liquids: ordinary equipment
- Not suitable for use in presence of flammable anesthetic mixture with air or nitrous oxide

The Harmony system complies with the following standards:

- IEC 60601-1 Medical electrical equipment –Part 1:General Requirements for Safety
- IEC 60601-1-1 Medical Electrical Equipment - Part 1-1: General Requirements for Safety - Collateral Standard: Safety Requirements for Medical Electrical Systems A1(1991) + A2 (1995)
- IEC 60601-1-2 Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic compatibility - Requirements and tests (incl. A1)
- IEC 60601-1-4 Medical Electrical Equipment - Part 1-4: General Requirements for Safety - Collateral Standard: Programmable Electrical Medical Systems (incl. A1)
- IEC 60601-2-22 Medical Electrical Equipment - Part 2: Particular Requirements for the Safety of Diagnostic and Therapeutic Laser Equipment
- IEC 60825-1 Safety of Laser Products - Part 1: Equipment Classification, Requirements and User's Guide (incl. A1+A2)

In compliance with these standards, the system is equipped with:

- Laser emission indicators
- Energy and power display
- Emergency shut-off knob
- Remote interlock connector
- Proper labeling

In accordance with the regulations, a recommended routine inspection and maintenance schedule is provided in the **Maintenance** chapter of this manual (see Chapter 7).

2.8. Device Labels

2.8.1. System Labels

The following **Warning**, **Certification** and **Identification** labels are adhered to the Harmony system:

- Identification Label which is located on the service panel. This label contains the following information:
  - Manufacturer's details
  - Name and part number of the system
  - Assurance that the system complies with the US Federal Performance Standards
  - Serial number and date of manufacture
  - The system's electrical requirements
  - Caution: US FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN
  - CE-MDD compliance symbol
  - Caution: Read the User's Manual before operating the unit
  - Degree and type of protection against electric shock

Label # 1 is adhered to systems shipped to 110VAC countries.
Label # 2 is adhered to systems shipped to 230VAC countries.

Label # 1 **Label # 2**

Figure 2-2: Identification Labels

- Light emission warning label, including light source type and radiation parameters, and indicating that the product is a Class IV device (see Figure 2-3 & Figure 2-4), located on the front panel of the system.

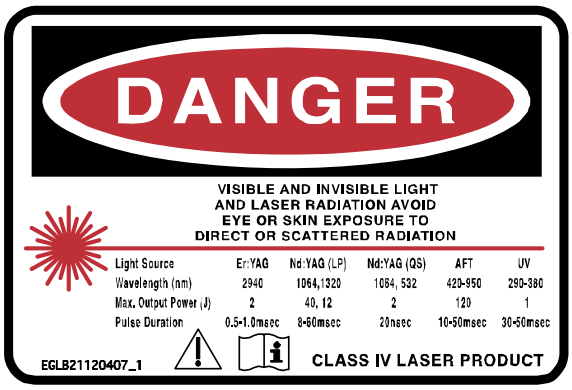


Figure 2-3: Front Warning Label

Or:

Figure 2-4: Front Warning Label

- Non-Coherent light emission warning label, located on the front panel of the system

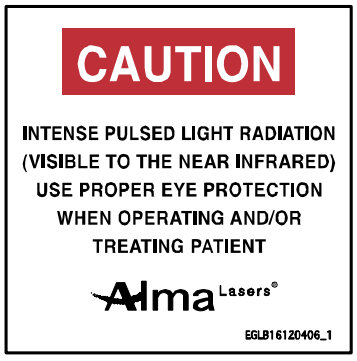


Figure 2-5: Non-Coherent Light Warning Label

- Electrical Requirement and Hazard Label, located next to the power cable connection port

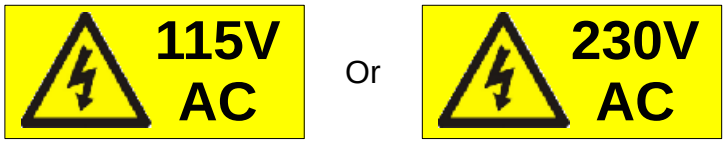


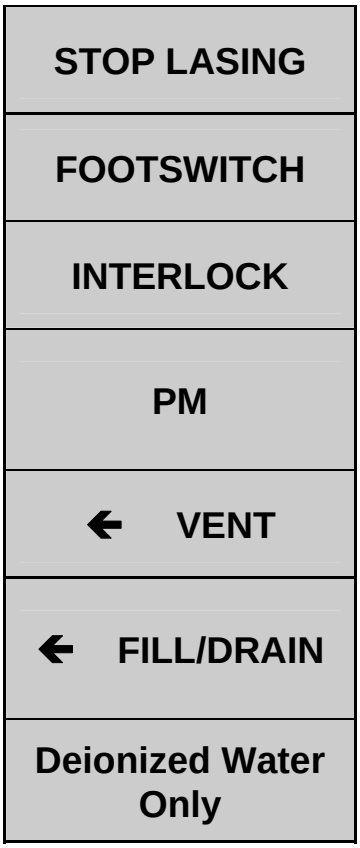
Figure 2-6: Electrical Requirement and Hazard Labels

- Laser aperture warning label, located above the handpiece connection port:

Figure 2-7: Laser Aperture Warning Label on Laser Handpieces

Other informative labels placed around the system:

- **Stop Lasing** label located below the emergency shut-off knob
- **Footswitch** label located on the service panel to identify the footswitch connection port
- **Interlock** label located on the service panel to identify the interlock connection port
- **Power Meter** label identifies the connection port for the external power meter used by the service technician
- **Vent** label identifies the connection port for the air vent of the cooling system's water reservoir
- **Fill/Drain** label identifies the connection port for the accessory used by the service technician to fill or drain the cooling system's water reservoir
- Only deionized water may be introduced into the Harmony's cooling system



2.8.2. Handpiece Labels

- Handpiece identification labels for each handpiece type, located on the handpiece's connector:

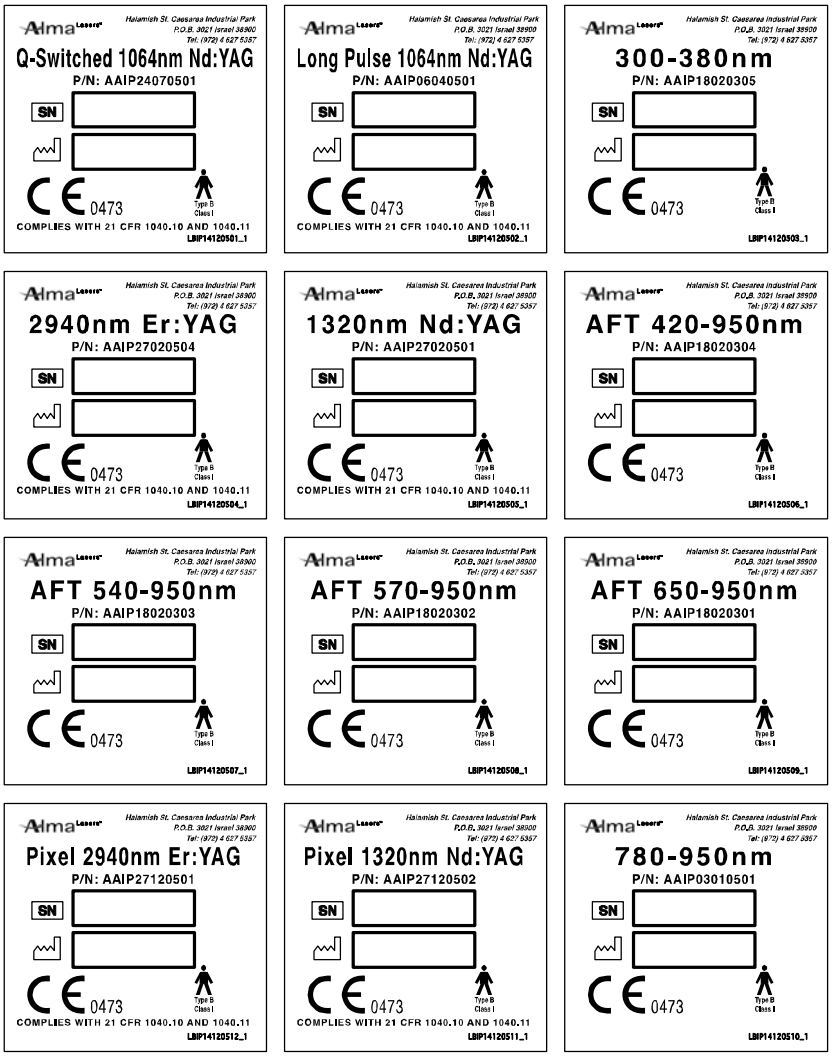


Figure 2-8: Handpiece Identification Labels

- Laser handpiece warning labels for each laser handpiece type, located on the handpiece's connector:

Figure 2-9: Laser Handpiece Warning Labels

- Intense pulsed light aperture warning label, located on the handpiece connectors of the AFT, ST and UV modules:

Figure 2-10: Intense Pulsed Light Aperture Warning Label on AFT, ST and UV Handpieces

2.8.3. Packaging Label

The following label is attached to the Harmony system's shipping crate:

Figure 2-11: Shipping Crate Label

CHAPTER 3
Installation

Chapter Contents:

3.1. Introduction

The Harmony system is designed for installation in an office or a clinic and requires minimal site preparation. When the Harmony system is purchased, complete on-site installation, including initial system testing and calibration, is included.

System transportation and installation is carried out by Alma Lasers authorized technical personnel, who will do the following:

- Unpack the system and position it in its pre-selected location
- Verify the integrity of the system and its components
- Connect system components (handpieces, footswitch, interlock connector)
- Plug the system into a designated electrical outlet
- Fill the cooling system reservoir with deionized water
- Test the system for proper calibration and functional operation of all components and software
- Coordinate the performance of an on-site safety inspection, if required

> ***Note***
>
> Any damage to the packaging or to the system found prior to opening the package should be reported to your Alma Lasers representative and to the insurance carrier.

3.2. Equipment List

The Harmony platform includes the following:

- Harmony system
- Harmony modules which can include the following, depending on which modules have been purchased with the Harmony platform, including:
  - AFT Acne handpiece - 420-950nm (Blue)
  - AFT Vascular and Pigmented Lesions handpiece -540-950nm (Green)
  - AFT Skin Rejuvenation handpiece - 570-950nm (Yellow)
  - AFT Hair Removal handpiece - 650-950nm (Red)
  - ST handpiece for skin tightening procedures - 780-950nm (Burgundy)
  - UV Psoriasis and Vitiligo handpiece - 300-380nm (Violet)
  - Q- Switched Nd:YAG Tattoo Removal handpiece - 1064nm / 532nm

- Long pulse Nd:YAG handpiece for vascular lesions and leg veins - 1064nm
- Long pulse Nd:YAG laser handpiece for non-ablative treatment of wrinkles - 1320nm
- Er:YAG laser handpiece for skin resurfacing - 2940nm
- Pixel® Er:YAG laser handpiece for skin remodeling and laser peeling - 2940nm
- Pixel® Nd:YAG laser handpiece[1] for fine lines & wrinkles, skin tightening and acne scarring - 1320nm

- Set of keys
- Footswitch
- Remote interlock connector
- Three pairs of AFT safety eyewear*
- Two pairs of Nd:YAG (1064nm & 1320nm) safety eyewear*
- Two pairs of Nd:YAG (532nm) safety eyewear*
- Two pairs of Er:YAG (2940nm) safety eyewear*
- Operator's Manual
- Cooling gel
- Water filling kit
- Laser radiation danger sign

3.3. Facility Requirements

Before unpacking the system, ensure that the site meets the requirements described in the following sections.

[1] Not available in the USA
* Depending on which of the Harmony modules have been purchased

3.3.1. Space and Positioning

Space should be allocated with adequate ventilation and free airflow. The working area for the system should be prepared according to the system dimensions presented in Figure 3-1. In order to guarantee proper ventilation, always keep the sides of the system at least 20" (0.5m) from the wall or from other obstructions to air flow. After positioning the system, lock the breaks on the front wheels by pressing the pedals on top of each wheel. Information regarding the risks of reciprocal interference posed by the presence of the device during specific treatments can be found in Appendix P of this manual.

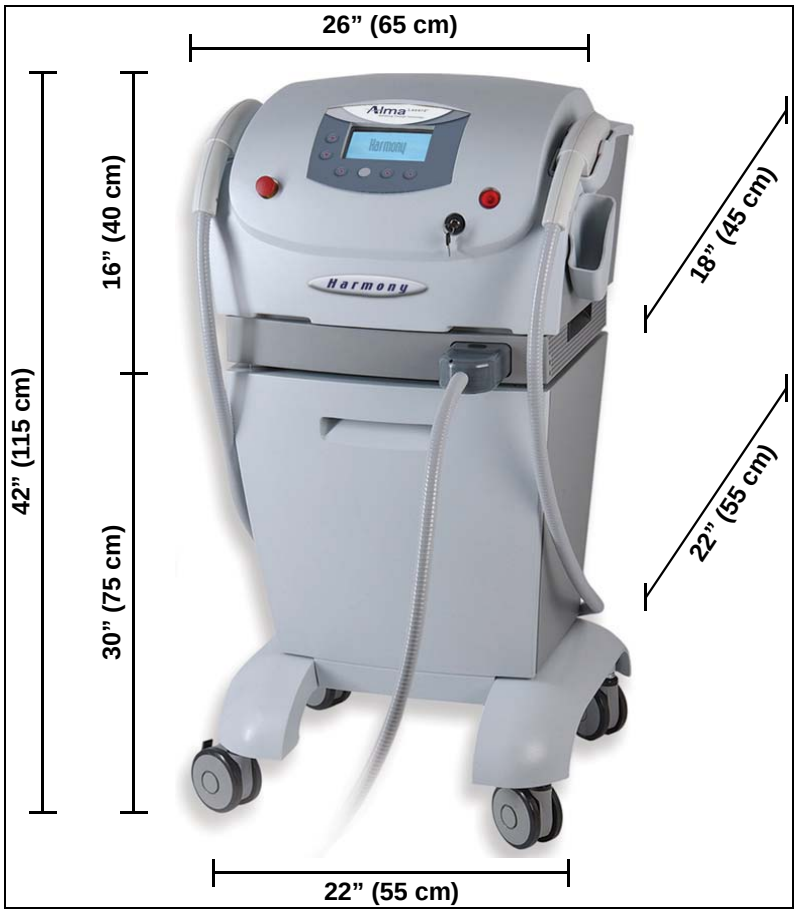


Figure 3-1: System Dimensions

3.3.2. Electrical Requirements

The system is factory pre-wired for the local line voltage, as ordered by the customer. Accordingly, the system will require a separate line supply of:

- 100-120 VAC ±10%, 5A, 50/60 Hz, single phase, ***Or:***
- 220-240 VAC ±10%, 5A, 50/60 Hz, single phase

Input power lines should be free of transients, voltage and current spikes, sags and surges. Consequently, the system power line should not be shared with other heavy variable loads such as elevators, air conditioning systems, large motors, etc.

The system is grounded through the grounding conductor in the power cable that is plugged into the wall power outlet. Good grounding is essential for safe operation.

The main fuse located within the system is rated 3.15A (for 220-240V) or 5A (for 100-120V). When the fuse trips it disconnects power from the system. Only an Alma Lasers technician may restore power after the fuse has tripped.

> ***Caution***
>
> Verify that the Harmony system is wired for the appropriate line voltage of your country (110, 120 or 230V).

3.3.3. Environmental Requirements

Air Quality:

The system should operate in a non-corrosive atmosphere. Corrosive materials such as acids can damage electrical wiring, electronic components and the surfaces of optical components.

Air-borne dust particles should be kept to a minimum. Dust particles absorb light and heat up. Hot particles located on the optical lenses can damage them. Metallic dust is destructive to electrical equipment.

Water Quality:

The system should be operated using deionized water only. Regular tap water contains sediments that may damage the cooling system.

Temperature:

To ensure that the system performs optimally, maintain room temperature between 20°C and 25°C (68°F - 77°F) and relative humidity of less than 80%.

> ***Note***
>
> When the system is used intensively it emits heat. Therefore, it is recommended to install air conditioning in the room in which the system will be used.

3.3.4. Remote Interlock Connection

The Harmony system is equipped with a remote interlock connector to provide maximum safety. The connector is situated on the service panel (see Figure 3-2). An external switch may be connected to this connector to create a remote interlock system. This switch should be mounted on the entrance door, so that if the door opens the switch contacts also open and disable system operation.

To connect the remote interlock:

1. Turn the system off.
2. Remove the connector from the port on the system rear panel.
3. Open the connector cover.
4. Solder the two wires from the door switch to pins 1 & 2 (short-circuited on delivery with a white wire).
5. Close the connector cover.
6. Reconnect to the port on the service panel.
7. Turn the system on.

3.4. Connecting the Footswitch

The footswitch supplied with the system is pneumatically operated for increased safety.

To connect the footswitch, connect the footswitch's black tube to the connection port on the system's service panel (see Figure 3-2).

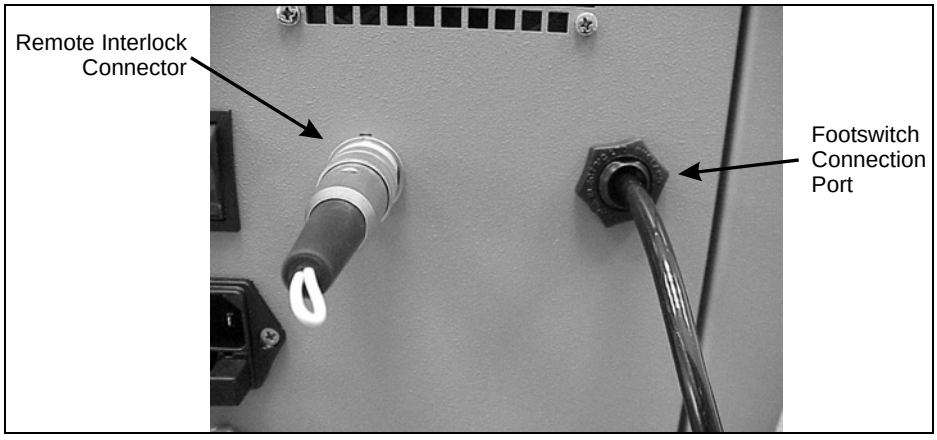


Figure 3-2: Remote Interlock and Footswitch Connections

3.5. Filling the Coolant Reservoir

The cooling system's reservoir must be filled with deionized water. It is imperative that the level of the water in the reservoir be checked every three months and deionized water added if necessary.

This operation is performed by Alma Lasers-authorized technical personnel.

3.6. Cooling System Drainage

If the system is to be stored in a cold area where the temperature may fall below 0ºC (32ºF), the deionized water must be drained from the cooling system. Only Alma Lasers authorized service personnel may perform this procedure.

3.7. Moving the System

The Harmony is a tabletop system and thus can be positioned on a table within the clinic, or on the optional Harmony cart.

To move the system within the clinic, do the following.

If the system is on a clinic table:

1. Disconnect the handpiece and store it in its dedicated carrying case.
2. Disconnect the power cable.
3. Lift the system and move it to its new position.

If the system is on a Harmony cart:

1. Disconnect the handpiece and store it in its dedicated carrying case.
2. Disconnect the power cable.
3. Disengage the front wheel brakes.
4. Move the system to its new position.
5. Re-engage the front wheel brakes.

> ***Caution***
>
> Never use the handpiece or umbilical cable to move the system.

If the system is to be moved to another facility, consult your Alma Lasers service representative.

CHAPTER 4
System Description

Chapter Contents:

4.1. Introduction

This chapter provides a detailed description of the Harmony system. The description covers the system's main components, controls and functional sub-systems, the various handpieces and system & handpiece specifications.

The Harmony system is a multi-application, multi-technology platform that supports:

- Four AFT pulsed light handpieces with AFT (Advanced Fluorescence Technology) & EDF (Equally Distributed Fluence)
- One ST pulsed light handpiece
- One UV (ultraviolet) handpiece
- Six laser handpieces:
  - Nd:YAG (1064nm)
  - Nd:YAG (1320nm)
  - Q-Switched Nd:YAG (1064nm & 532nm)
  - Er:YAG (2940nm)
  - Pixel® Er:YAG (2940nm)
  - Pixel® Nd:YAG (1320nm)[1]

A complete discussion of the handpieces, their uses and technical specifications may be found in Section 4.5 of this chapter.

4.2. System Components and Controls

The Harmony system consists of the following major components (see Figure 4-1):

1. The main console unit that incorporates the control panel, power supply modules, cooling system, switching module, service panel, isolating transformer and a dedicated cart (optional).
2. Handpiece (with umbilical cable and connector) that incorporates the optical head, tissue cooling system (the cold plate) and the handpiece trigger.
3. Footswitch.

[1] Not available in the USA

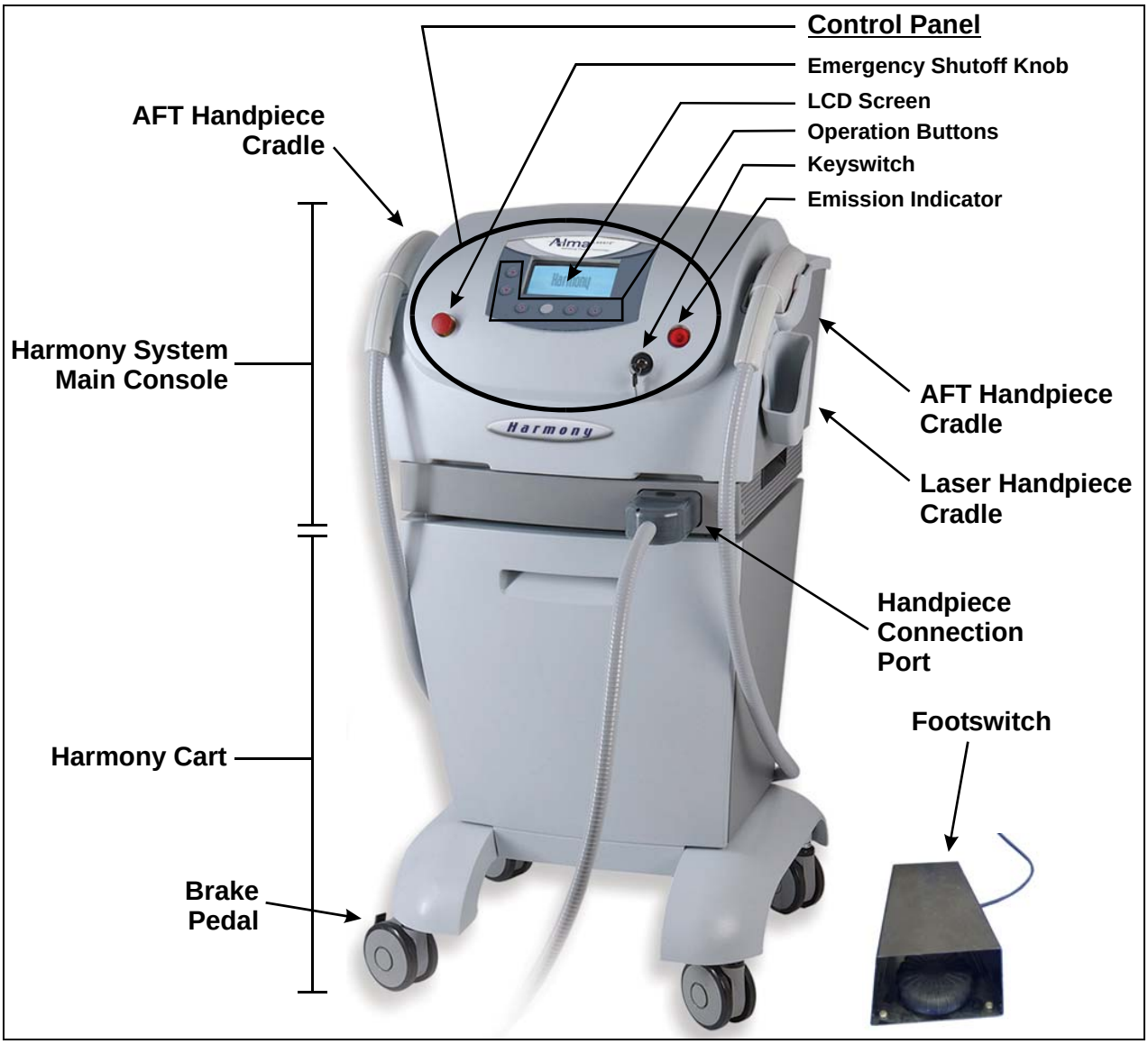


Figure 4-1: Major System Components

Figure 4-2 presents a block diagram of the Harmony system:

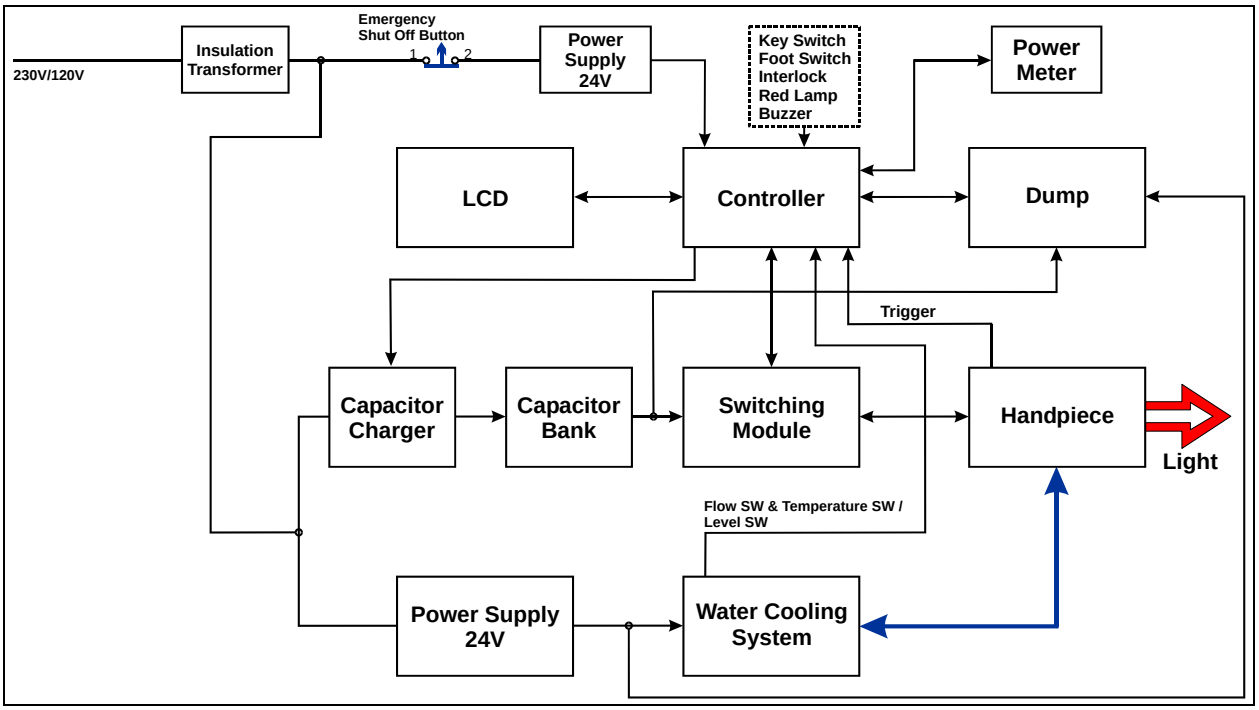


Figure 4-2: Block Diagram

4.2.1. Main Console

The main console incorporates the following components:

- Power supply modules
- Control panel
- Cooling system
- Fans
- Switching module
- Isolating transformer

4.2.2. Power Supply Modules

There are three power supply modules in the system. They are connected to 100-120 VAC from the isolating transformer:

- 24VDC / 100W that supplies power to the fans and water pump.
- Capacitor charger that charges the capacitors bank up to 500V.
- 24VDC / 15W that supplies power to the micro-controller board.

4.2.3. The Control Panel

The Harmony system is controlled by the micro-controller. The Harmony control panel includes the following features:

- The emergency shutoff knob is a red, mushroom-like knob designed for emergency shutdown of the system.
- The LCD display provides information on the status and settings of the Harmony system. The various screens of the display are described in detail in Chapter 6 – **Operating Instructions**.
- The operation buttons are used to select operation parameters. Two buttons are located on the left side of the LCD and an additional four are below the LCD. The functions of the buttons are described in Chapter 6 – **Operating Instructions**.
- The keyswitch turns on the **Main User** menu after the system is activated.
- A light emission indicator (See Section 2.6.3).

4.2.4. The Service Panel

The service panel (see Figure 4-3) is located on the system's back side.
It incorporates all the required controls and connections for the system:

- Main power cable plug-in
- Main switch (green) used to activate the micro-processor and the LCD display
- Power meter connection port
- Remote interlock connector
- Main circuit breaker
- Footswitch connection port
- Connection fittings for water cooling system filling/draining
- Fan grills

Figure 4-3: Service Panel

> ***Caution***
>
> To avoid overheating and system malfunction, do not block the airflow into the system.

4.2.5. Cooling System

The Harmony's cooling system incorporates a water pump, water reservoir, radiator, particle filter, deionizer, flow switch and a fan. The system circulates water from the fan-cooled radiator to the handpiece.

4.2.6. Fans

Two fans are located inside the system. One fan cools the water system and the other fan cools the interior space of the console.

4.2.7. Switching Module

The system ignites the lamp in the handpiece and maintains it in a simmering mode. When the system is switched to Ready mode, a command is delivered from the micro-controller that partially discharges the capacitor bank into the lamp.

4.2.8. Isolation Transformer

The isolation transformer reduces the leakage current in the system to the ground for safety. It is designed as a medical grade unit.

4.2.9. Footswitch

The footswitch is a pneumatic pedal with a metal shroud to prevent accidental activation. The footswitch is connected to the system through the footswitch connector on the service panel.

If an AFT, ST or UV handpiece is connected to the Harmony system, a pulse light emission occurs only when the footswitch is pressed. When any of the laser handpieces are connected, a pulse emission is enabled only when both the footswitch and handpiece trigger are simultaneously pressed.

The footswitch is enabled only when the system is in **Ready** mode. Pressing the footswitch in **Standby** or any other mode will not allow pulse light emission.

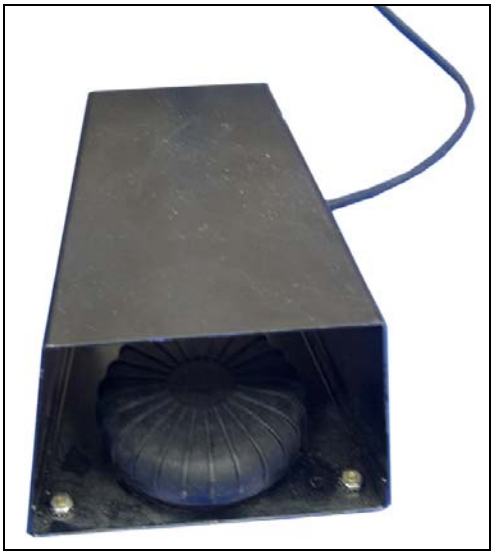


Figure 4-4: Footswitch Pedal with Shroud

4.3. Harmony System Specifications

Application	Technology	Wavelength (nm)	Pulse Width (msec)	Spot Size (mm)	Pulse Repetition Rate (Hz)	Energy Density
Psoriasis and vitiligo	Pulsed UV	300 – 380	30, 40, 50	40 x 16	1/6	200 – 1000 mJ/cm^2
Acne clearance	AFT	420 – 950	30, 40, 50	40 x 16	1/3	5 – 20 J/cm^2
Vascular and pigmented lesions	AFT	540 – 950	10, 12, 15	40 x 16	1/3	5 – 20 J/cm^2
Skin rejuvenation	AFT	570 – 950	10, 12, 15	40 x 16	1/3	5 – 20 J/cm^2
Hair removal	AFT	650 – 950	30, 40, 50	40 x 16	1/3	5 – 20 J/cm^2
Skin tightening, scar revision and treatment of striae	Near infrared	780 – 950	5, 10, 15 Sec.	40 x 16	2	35 – 105 J/cm^2
Vascular lesions and leg veins	Nd:YAG	1064	10, 40, 60	2, 6	2/3, 1/3	30 – 450 J/cm^2
Tattoo removal	Q-Switched	1064	20 nsec.	1, 2	1, 2, 5	400 – 1200 mJ/p
Tattoo removal	FD Q-Switched	532	20 nsec.	2	1, 2, 5	400 – 1200 mJ/p
Fine lines, wrinkles, acne and acne scars	Nd:YAG	1320	30,40,50	6	1/3	5 – 40 J/cm^2
Skin resurfacing	Er:YAG	2940	0.5, 1.0	1, 4	5	200 – 1200 mJ/p
Fractional ablative skin resurfacing	Pixel Er:YAG	2940	–	11 x 11	2	1400 mJ/p
Electrical	100 – 120 VAC, 5A, 50/60 Hz 220 – 240 VAC, 5A, 50/60 Hz					
Weight	88 lbs. (40 kg), Cart – 55 lbs. (25 kg)					
System dimensions (W x D x H)	26" x 18" x 16" (65 x 45 x 40 cm)					
Cart dimensions (W x D x H)	22" x 22" x 30" (55 x 55 x 75 cm)					

4.3.1. Operation and Control Specifications

System Control

- Fully computerized, microprocessor based

Graphic User Interface

- LCD display

Laser Emission Indicators

- Visual, illuminating red indicator:
  - OFF when no lasing occurs
  - Blinking during **Ready** mode
  - Illuminating continuously during laser emission
- Audible indicator
  - Activated during laser emission, when pressing the operation buttons (user-controlled) and upon detection of an error condition

4.3.2. Classifications

CDRH Laser Classification according to 21CFR 1040.10

- Class IV

Laser Classification according to EN 60825-1

- Class 4

Mode of Protection against Electric Shock

- Class I Equipment

Degree of Protection against Electric Shock

- Type B Applied Part

4.4. Harmony Handpieces – General Description

The Harmony system operates with up to twelve handpieces of different types. Each handpiece comprises a complete module and incorporates the entire optical bench that emits the light or laser beam. The Harmony cannot be operated unless a handpiece is connected to the system.

The operating parameters of all Harmony handpieces are pre-programmed.

1. Each of the following handpieces: **Acne**, **VP**, **SR**, **HR**, **UV**, **1320nm Nd:YAG**, **Pixel® 1320nm Nd:YAG** and **Pixel® 2940nm Er:YAG** enables the operator to choose between three pulse widths:
   - Narrow pulse width for light skin
   - Medium pulse width for medium toned skin
   - Wide pulse width for dark skin
2. The **ST** handpiece is pre-programmed with three timed pulses, each with its own range of available fluences:
   - Five second pulse / 5 to 35 J/cm^2 @ 4 Hz
   - Ten second pulse / 10 to 70 J/cm^2 @ 4 Hz
   - Fifteen second pulse / 15 to 105 J/cm^2 @ 4 Hz
3. The **1064/532nm Q-Switched Nd:YAG** handpiece is pre-programmed with three pulse frequencies: **1**, **2** & **5** Hz.
4. The **1064nm Nd:YAG** handpiece is pre-programmed with two pulse different widths and a fluence range, both dependent upon the spot size of the connected lightguide.
5. The **2940nm Er:YAG** handpiece is pre-programmed with three treatment modalities:
   - **Gentle Peel** offering a depth of penetration of 1 – 10 μm
   - **Skin Remodeling** offering a depth of penetration of 10 – 330 μm
   - **Surgi Light** offering a fluence range of 100 – 1200 mJ/P

The handpieces are also preprogrammed to a given energy range based on their intended use. The operator can adjust the energy fluence within the predetermined range.

Each handpiece is connected to the system console by an umbilical cable that houses the wiring and cooling water tubes.

4.4.1. Connecting the Handpiece

The handpiece connector is shown in Figure 4-5 & Figure 4-6. It is designed to enable easy replacement of the handpiece when required. The handpiece connection port is located on the lower-right side of the front panel (see Figure 4-1), and two pins secure the handpiece connector. For insertion and removal of the connector, the upper and lower gray buttons must be pressed at the same time to release those pins (see Figure 4-5 & Figure 4-6).

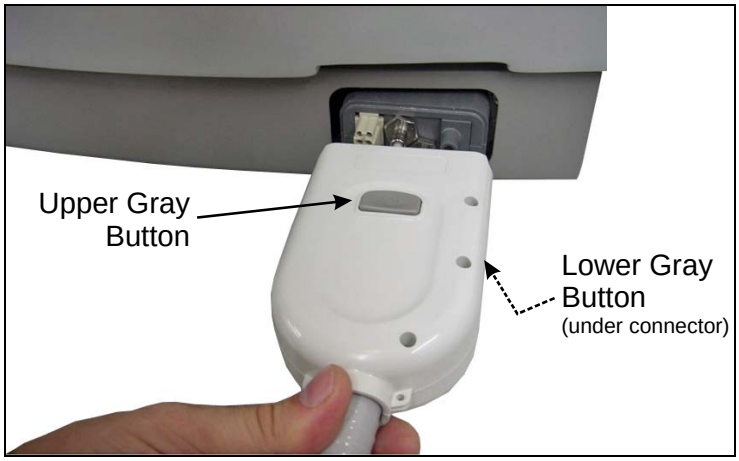


Figure 4-5: Handpiece Connector

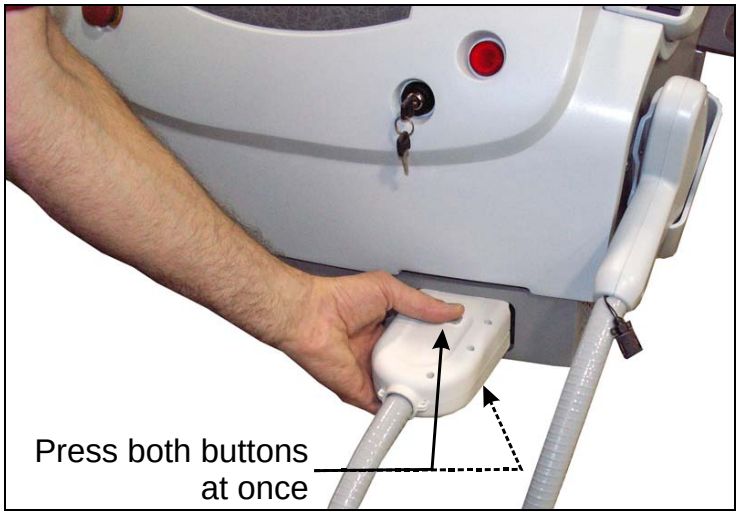


Figure 4-6: Handpiece Connection

4.4.2. AFT, ST and UV Handpieces

Each of these handpieces (see Figure 4-7) has large color-coded circles on the sides of the handpiece's body, identifying that particular handpiece's treatment module (e.g., green circle identifies the **VP** module handpiece (**V**ascular & **P**igmented lesions).

The operator holds the handpiece by its handle in order to position the lightguide against the patient's skin.

The handpiece's light source emits a pulse and is activated by pressing the footswitch. The light passes through an aperture with a filter, into a lightguide that is located on the handpiece tip.

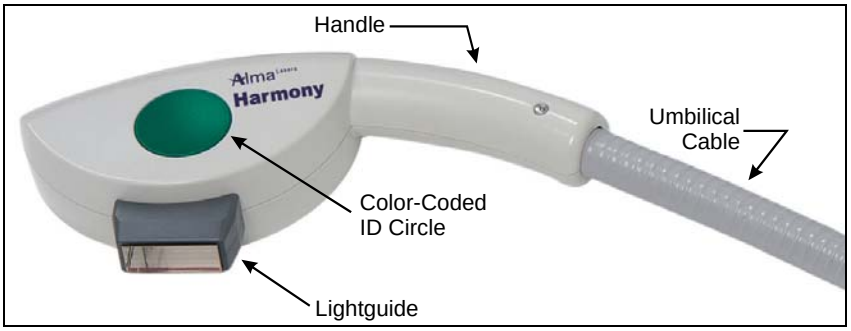


Figure 4-7: AFT Handpiece

The following table specifies the names, wavelengths and ID colors of the Harmony platform's AFT, ST and UV handpieces:

Table 4-1: AFT, ST and UV Handpieces

Handpiece Name	*Wavelength [nm]*	*Color ID*	*See Page*
AFT Acne	420 – 950	Blue	4-15
AFT VP (Vascular/Pigmented)	540 – 950	Green	4-16
AFT SR (Skin Rejuvenation)	570 – 950	Yellow	4-17
AFT Hair Removal	650 – 950	Red	4-18
ST Skin Tightening	780 – 950	Burgundy	4-19
UVB Ultraviolet	300 – 380	Violet	4-20

Caution

- These handpieces contain delicate optical components which may be severely damaged if dropped. Except during treatment, these handpieces should be kept in the cradle at all times.
- When moving the system, the handpiece should be disconnected from the system and stored in its carrying case.

4.4.3. Laser Handpieces

The pistol-shaped laser handpieces (see Figure 4-8) incorporate a solid state Nd:YAG, Q-Switched Nd:YAG or Er:YAG crystal laser medium and a xenon flashlamp as the heart of the optical bench. The laser beam is delivered when the operator presses both the footswitch and the handpiece trigger.

These handpieces house the mechanism that generates and delivers the laser pulse, including:

- The Nd:YAG, Q-Switched Nd:YAG or Er:YAG laser heads
- The laser cooling components
- The handpiece trigger for laser beam emission
- The lightguide assembly that determines the spot size and delivers the laser beam to the treatment site

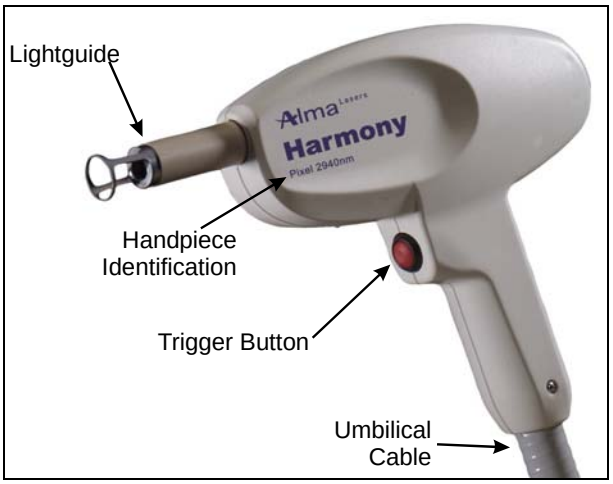


Figure 4-8: Laser Handpiece

The following table specifies the names, wavelengths and ID colors of the Harmony platform's laser handpieces:

Table 4-2: Laser Handpieces

Handpiece Name	*Wavelength [nm]*	*See Page*
Q-Switched Nd:YAG	1064 & 532	4-21
Long Pulse Nd:YAG	1064	4-22
Long Pulse Nd:YAG	1320	4-23
Er:YAG	2940	4-24
Pixel® Er:YAG	2940	4-25
Pixel® Nd:YAG	1320	4-26

Caution

- These handpieces contain delicate optical components which may be severely damaged if dropped. Except during treatment, these handpieces should be kept in the cradle at all times.
- When moving the system, the handpiece should be disconnected from the system and stored in its carrying case.

4.5. Harmony Handpieces – Detailed Descriptions

4.5.1. AFT Acne Module Handpiece

The AFT acne module has a high-power targeted phototherapy handpiece for clearance of inflammatory acne. It employs Alma Laser's proprietary **AFT** (**A**dvanced **F**luorescence **T**echnology) 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 AFT acne module clinical applications may be found in Appendix **B** of this manual.

The AFT acne module handpiece has blue identification circles (see Figure 4-9).

Figure 4-9: AFT Acne Module Handpiece (Blue)

AFT Acne Module Handpiece Specifications:

- **Light Source:** Pulsed light with AFT and EDF
- **Spectrum:** 420 – 950nm
- **Energy Density (Fluence):** 5 – 20 J/cm^2
- **Treatment Area (spot size):** 40 x 16 mm (6.4 cm^2)
- **Pulse Duration:** 30, 40, 50 msec.
- **Pulse Repetition Rate:** ⅓ Hz.

4.5.2. AFT VP Module Handpiece

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

A complete discussion of the AFT VP module clinical applications may be found in Appendices **C** & **D** of this manual.

The AFT VP module handpiece has green identification circles (see Figure 4-10).

Figure 4-10: AFT VP Module Handpiece (Green)

AFT VP Module Handpiece Specifications:

- **Light Source:** Pulsed light with AFT and EDF
- **Spectrum:** 540 – 950nm
- **Energy Density (Fluence):** 5 – 20 J/cm^2
- **Treatment Area (spot size):** 40 x 16 mm (6.4 cm^2)
- **Pulse Duration:** 10, 12, 15 msec.
- **Pulse Repetition Rate:** ⅓ Hz.

4.5.3. AFT SR Module Handpiece

The AFT SR module has a high-power targeted phototherapy handpiece 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 treatment of vascular and pigmented lesions.

A complete discussion of the AFT SR module clinical applications may be found in Appendices **C**, **D** & **E** of this manual.

The AFT SR module handpiece has yellow identification circles (see Figure 4-11).

Figure 4-11: AFT SR Module Handpiece (Yellow)

AFT SR Module Handpiece Specifications:

- **Light Source:** Pulsed light with AFT and EDF
- **Spectrum:** 570 – 950nm
- **Energy Density (Fluence):** 5 – 20 J/cm^2
- **Treatment Area (spot size):** 40 x 16 mm (6.4 cm^2)
- **Pulse Duration:** 10, 12, 15 msec.
- **Pulse Repetition Rate:** ⅓ Hz.

4.5.4. AFT HR Module Handpiece

The AFT HR module has a high-power targeted handpiece 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 AFT HR module clinical applications may be found in Appendix **F** of this manual.

The AFT HR module handpiece has red identification circles (see Figure 4-12).

Figure 4-12: AFT HR Module Handpiece (Red)

AFT HR Module Handpiece Specifications:

- **Light Source:** Pulsed light with AFT and EDF
- **Spectrum:** 650 – 950nm
- **Energy Density (Fluence):** 5 – 20 J/cm^2
- **Treatment Area (spot size):** 40 x 16 mm (6.4 cm^2)
- **Pulse Duration:** 30, 40, 50 msec.
- **Pulse Repetition Rate:** ⅓ Hz.

4.5.5. ST Module Handpiece

The ST module handpiece has a high-power targeted phototherapy handpiece for non-invasive skin tightening, scar revision and treatment of striae. The near-infrared produces deep dermal heating which induces neocollagenesis.

A complete discussion of the ST module clinical applications may be found in Appendix **G** of this manual.

The ST module handpiece has burgundy identification circles (see Figure 4-13).

Figure 4-13: ST Module Handpiece (Burgundy)

ST Module Handpiece Specifications:

- **Light Source:** Pulsed light
- **Spectrum:** 780 – 950nm
- **Energy Density (Fluence):** 35 – 105 J/cm^2
- **Treatment Area (spot size):** 40 x 16 mm (6.4 cm^2)
- **Pulse Duration:** 5, 10, 15 sec.

4.5.6. UVB Module Handpiece

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

A complete discussion of the UVB module clinical applications may be found in Appendix **H** of this manual.

The UVB module handpiece has violet identification circles (see Figure 4-14).

Figure 4-14: UVB Module Handpiece (Violet)

UVB Module Handpiece Specifications:

- **Light Source:** High-pressure xenon lamp
- **Spectrum:** 300 – 380nm
- **Energy Density (Fluence):** 200 – 1000 mJ/cm^2 adjustable in 10 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:** 1/6 Hz.

4.5.7. 1064/532nm Q-Switched Nd:YAG Module Handpiece

The 1064/532nm Q-Switched Nd:YAG module handpiece has a high-power targeted laser handpiece for the non-invasive removal of various colored tattoos, as well as benign pigmented lesions.

A complete discussion of the 1064/532nm Q-Switched Nd:YAG module handpiece's clinical applications may be found in Appendix **I** of this manual.

The Q-Switched Nd:YAG module handpiece is identified by **QS 1064nm** printed on the handpiece (see Figure 4-15).

Figure 4-15: 1064/532nm Q-Switched Nd:YAG Module Handpiece

1064/532nm Q-Switched Nd:YAG Module Handpiece Specifications:

- **Light Source:** Q-Switched Nd:YAG with KTP
- **Wavelength:** 1064 / 532 nm
- **Energy Density (Fluence):** 400 – 1200 mJ/pulse
- **Beam Delivery:** Direct
- **Treatment Area (spot size):** 1, 2 & 3 mm, KTP adapter
- **Pulse Duration:** 20 nsec at 1 msec bursts
- **Pulse Repetition Rate:** 1, 2, 5 Hz.
- **Handpiece Weight:** 350 grams

4.5.8. 1064nm Long Pulsed Nd:YAG Module Handpiece

The 1064nm long pulsed Nd:YAG module handpiece has a high-power targeted laser handpiece for the treatment of vascular lesions and leg veins. The handpiece emits a high energy laser pulse in the 1064nm wavelength and pulse widths up to 60 msec.

A complete discussion of the 1064nm long pulsed Nd:YAG module clinical applications may be found in Appendices **C** & **E** of this manual.

The long pulsed Nd:YAG module handpiece is identified by **1064nm** printed on the handpiece (see Figure 4-16).

Figure 4-16: 1064nm Long Pulsed Nd:YAG Module Handpiece

1064nm Long Pulsed Nd:YAG Module Handpiece Specifications:

- **Light Source:** 1064nm Long pulsed Nd:YAG
- **Energy Density (Fluence):** 30 – 450 J/cm^2
- **Treatment Area (spot size):** Multi-spot 2mm, 6mm
- **Pulse Duration (msec):** 10 msec (2mm); 40, 60 msec (6mm)
- **Pulse Repetition Rate:** ⅔ Hz (10 msec); ⅓ Hz (40, 60 msec)
- **Handpiece Weight:** 350 grams

4.5.9. 1320nm Long Pulsed Nd:YAG Module Handpiece

The 1320nm long pulsed Nd:YAG module handpiece has a high-power targeted laser handpiece 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 1320nm long pulsed Nd:YAG module clinical applications may be found in Appendix **J** of this manual.

The long pulsed Nd:YAG module handpiece is identified by **1320nm** printed on the handpiece (see Figure 4-17).

Figure 4-17: 1320nm Long Pulsed Nd:YAG Module Handpiece

1320nm Long Pulsed Nd:YAG Module Handpiece Specifications:

- **Light Source:** 1320nm Long pulsed Nd:YAG
- **Energy Density (Fluence):** 5 – 40 J/cm^2
- **Treatment Area (spot size):** 6mm
- **Pulse Duration (msec):** 30, 40, 50
- **Pulse Repetition Rate:** ⅓ Hz
- **Handpiece Weight:** 350 grams

4.5.10. 2940nm Er:YAG Module Handpiece

The 2940nm Er:YAG module handpiece has a high-power targeted laser handpiece that enables controlled treatment for skin resurfacing. The precise tissue ablation and small zone of residual thermal damage result in faster re-epithelialization and improved morbidity.

A complete discussion of the 2940nm Er:YAG module clinical applications may be found in Appendix **K** of this manual.

The 2940nm Er:YAG module handpiece is identified by **2940nm** printed on the handpiece (see Figure 4-18).

Figure 4-18: 2940nm Er:YAG Module Handpiece

2940nm Er:YAG Module Handpiece Specifications:

- **Light Source:** 2940nm Er:YAG
- **Energy Density (Fluence):** Up to 1200 mJ/Pulse
- **Beam Delivery:** Direct
- **Treatment Area (spot size):** 1mm and 4mm
- **Modes:** Gentle peel (1-20μm)
Skin remodeling (10-330μm)
Surgi Light (100-1200 mJ/P)
- **Pulse Repetition Rate:** 5 Hz
- **Handpiece Weight:** 350 grams

4.5.11. Pixel® 2940nm Er:YAG Module Handpiece

The Pixel 2940nm Er:YAG module handpiece provides 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 long pulsed Pixel 2940nm Er:YAG module clinical applications may be found in Appendix **L** of this manual.

The Pixel 2940nm Er:YAG module handpiece is identified by **Pixel 2940nm** printed on the handpiece (see Figure 4-19).

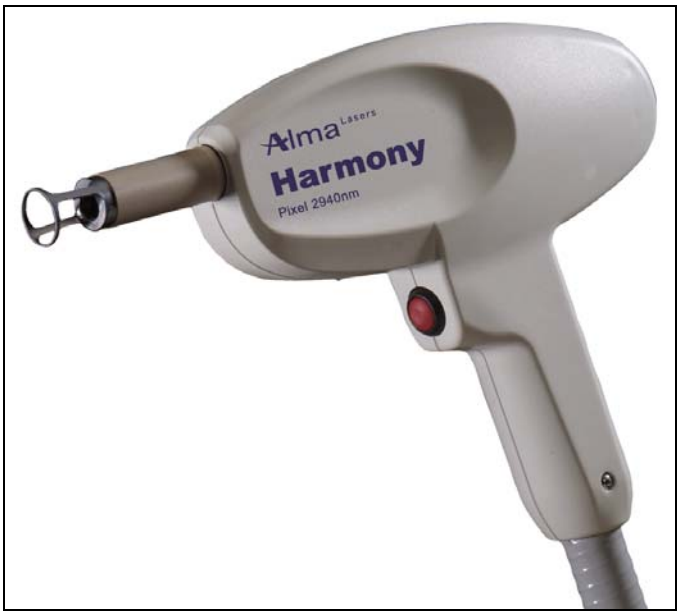


Figure 4-19: Pixel 2940nm Er:YAG Module Handpiece

Pixel 2940nm Er:YAG Module Handpiece Specifications:

- **Light Source:** 2940nm Er:YAG
- **Number of Pixels:** 49 or 81 dots
- **Treatment Area (spot size):** 11 x 11 mm
- **Beam Delivery:** Direct
- **Maximum Pulse Energy:** 1400 mJ/Pulse
- **Maximum Pixel Energy:** 17 mJ/Pixel (81 dot Pixel size)
  28 mJ/Pixel (49 dot Pixel size)
- **Pulse Repetition Rate:** 2 Hz

4.5.12. Pixel® 1320nm Nd:YAG Module Handpiece[2]

The Pixel 1320nm Nd:YAG module handpiece has a high-power targeted laser handpiece for the treatment of fine lines, wrinkles, skin tightening and acne scarring.

A complete discussion of the long pulsed Pixel 1320nm Nd:YAG module clinical applications may be found in Appendix **M** of this manual.

The Pixel 1320nm Nd:YAG module handpiece is identified by **Pixel 1320nm** printed on the handpiece (see Figure 4-20).

Figure 4-20: Pixel 1320nm Nd:YAG Module Handpiece

Pixel 2940nm Nd:YAG Module Handpiece Specifications:

- **Light Source:** 1320nm Nd:YAG
- **Number of Pixels:** 49 or 81 dots
- **Treatment Area (spot size):** 7 x 7 mm
- **Beam Delivery:** Direct
- **Maximum Pulse Energy:** 12 J/Pulse
- **Maximum Pixel Energy:** 150 mJ/Pixel (81 dot Pixel size)
250 mJ/Pixel (49 dot Pixel size)
- **Pulse Width:** 30, 40, 50 msec.
- **Pulse Repetition rate:** 0.5 Hz.

[2] Not available in the USA

CHAPTER 5
Controls and Indicators

Chapter Contents:

5.1. Introduction

This chapter details the controls, indicators and connection ports of the Harmony system:

- Main Switch
- Keyswitch
- Emergency Shut-Off Knob
- Pulse Light Emission Indicator
- Audio Indicator
- Control Panel
- Service Panel
- Footswitch
- Handpiece Trigger

5.2. Main Switch

The main switch is located on the service panel (see Figure 5-5). This is a green switch used to activate the LCD display. A correct operation sequence starts with switching on the main switch prior to turning on the keyswitch.

5.3. Keyswitch

The keyswitch is located on the system's front panel. It is used to turn on the main operating menu after the system is activated. To switch the system into operational mode, the keyswitch is turned a quarter of a turn, clockwise (see Figure 5-1).

Figure 5-1: Keyswitch

> ***Warning***
>
> To avoid misuse of the system, do not leave the key in the keyswitch while the system is unattended.

5.4. Emergency Shut-off Knob

In case of emergency, press the red emergency shut-off knob to stop all system operations. To resume operation, release the knob by turning it a quarter of a turn clockwise.

Figure 5-2: Emergency Shut-Off Knob

5.5. Pulse Light Emission Indicator

The red emission lamp, located on the front panel, indicates the following:

- **Off** - when the system is turned on, and in Standby mode
- **Blinking** – during Ready mode
- **Continuous** – during light emission (footswitch or footswitch and handpiece trigger are pressed)

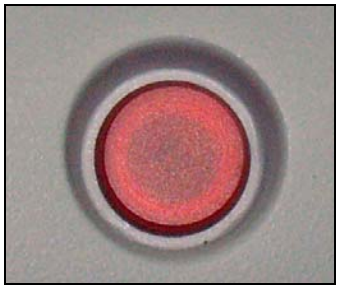


Figure 5-3: Pulse Light Emission Indicator

5.6. Audio Indicator

A single audio signal sounds when the system is set to **Standby** mode or when the footswitch is pressed in **Ready** mode.

5.7. Control Panel

The control panel includes a back-lit LCD graphic display, six control buttons and pulse light emission indicators (audio and visible). The LCD graphic display presents all Harmony screens that are described in Chapter 6 of this manual. The LCD specifies the handpiece that is currently connected to the system, the selected fluence, skin type and number of accumulated pulses (in a specific session and total).

The left-side buttons are used to increase or decrease energy density (fluence) and the four bottom buttons are used to toggle between skin types (pulse width) and **Standby**/**Ready** modes. Refer to Chapter 6 for detailed explanations regarding the control buttons. Figure 5-4 presents a view of the control panel.

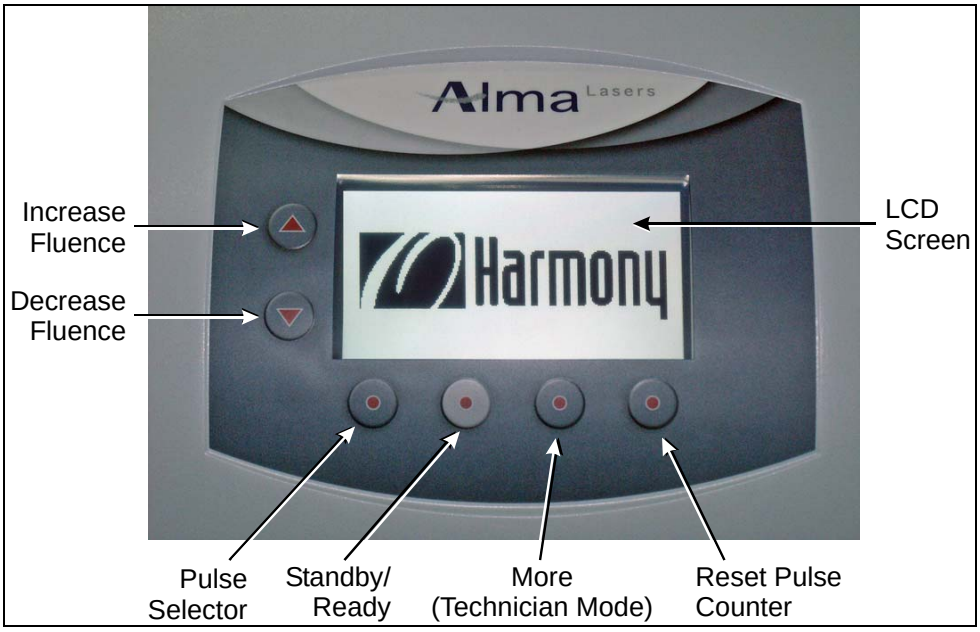


Figure 5-4: Control Panel

5.8. Service Panel

The service panel (see Figure 5-5) incorporates the following system controls and connections:

- Main Switch
- Remote interlock connection port, designed to interrupt emission whenever the treatment room's door is opened
- Power cable connection port
- Footswitch air tube connection port
- Fan grills for air flow to the fans that cool the system's interior and the water in the cooling system

> ***Warning***
>
> If the system is in **Ready** mode, pulse light emission will occur when the footswitch is pressed.

Figure 5-5: Service Panel

5.9. Footswitch

Pulse light emission with the AFT, ST and UV handpieces occurs only when the footswitch is activated.

Laser pulse emission occurs when the footswitch is activated at the same time as the handpiece trigger. This requirement for simultaneous activation of both triggers minimizes the risk of unintentional laser beam emission.

The footswitch (see Figure 5-6) is enabled only when the system is in **Ready** mode. Activation of the footswitch in **Standby** mode does not result in light emission.

The footswitch is a pneumatic pedal that connects to the system through the footswitch connection port on the service panel (see Figure 5-5).

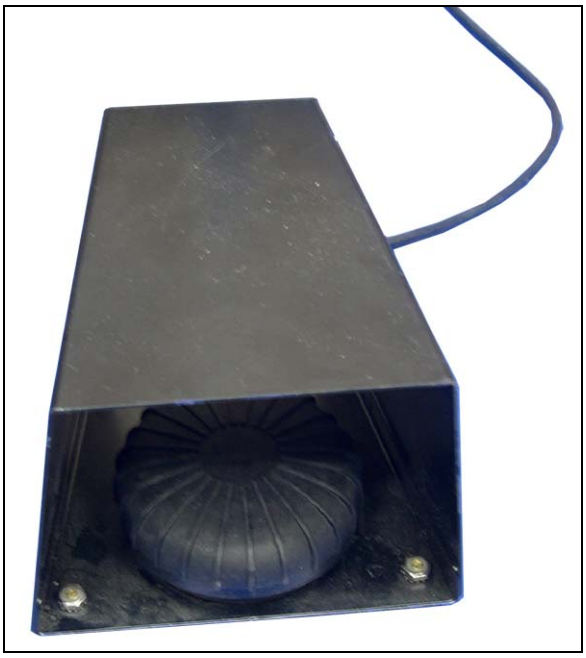


Figure 5-6: Footswitch

> ***Warning***
>
> If the system is in **Ready** mode, laser beam emission occurs when the footswitch and the handpiece trigger are simultaneously activated.

5.10. Handpiece Trigger

The handpiece trigger is the red push button located on the handle (see Figure 5-7). Laser radiation emission is enabled only when both the handpiece trigger and the footswitch are activated.

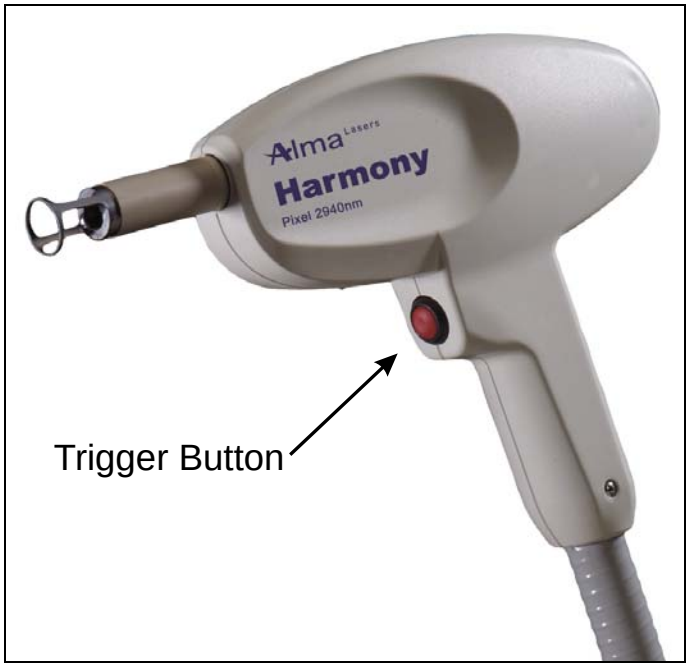


Figure 5-7: Handpiece Trigger

> ***Warning***
>
> If the system is in **Ready** mode, laser beam emission occurs when the footswitch and the handpiece trigger are simultaneously activated.

CHAPTER 6

Operating Instructions

Chapter Contents:

6.1. Introduction

This chapter describes in detail the operating instructions of the Harmony System. Specific treatment parameters and information concerning the therapeutic applications of the system are provided in the Clinical Guides for each application.

Caution

- This system may only be operated by a licensed practitioner, according to the local laws in every country.
- A pulsed light emission danger sign, supplied with this system (see Figure 2-1), should be placed at the entrance to the treatment room whenever the system is in use.
- Improper use or adjustment of this system may invalidate the Harmony service warranty agreement. Please contact your authorized Alma Lasers distributor before attempting to use the system in any manner other than those specified in this manual.

6.2. Turning on the System

1. Plug the system into the mains power outlet.
2. Connect the remote interlock to the treatment room's entrance door, if required (see Chapter 3).
3. Connect the footswitch to the service panel (see Chapter 3).
4. Connect the desired handpiece by pressing the two gray buttons on the top and button of the handpiece connector. While pressed, insert the handpiece connector into its socket on the system's front panel. A click should be heard to indicate proper connection. Make sure that the handpiece is correctly inserted by trying once to pull the connector from its socket.
5. The patient and all personnel in the room should wear safety eyewear specific to the handpiece in use (see Chapter 2).
6. Turn on the green main power switch on the system's service panel; the LCD screen will turn on and the **Harmony Logo** screen will appear (see Figure 6-1).

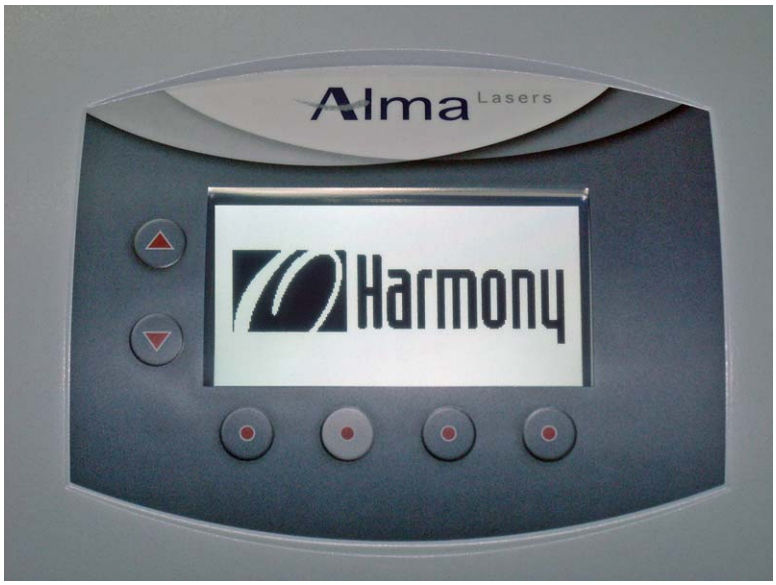


Figure 6-1: Logo Screen

7. Turn the keyswitch clockwise one quarter turn to the **On** position; the **Main Operator** screen appears (See Figure 6-2). The system recognizes the connected handpiece and presents the module's name and wavelength on the screen.

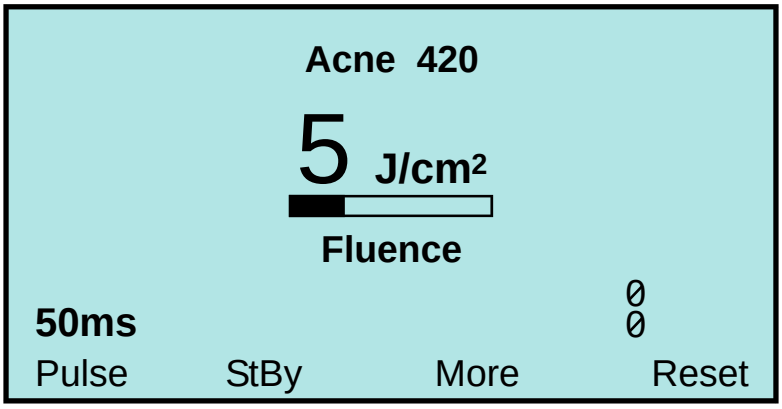


Figure 6-2: Main Operator Screen (sample)

8. A **Please Wait** message appears for 5 seconds until the system is warmed up and ready to operate.
9. The system automatically performs a self-check routine. Operation may proceed only if all checks are completed satisfactorily. This self-test is continuously performed during the entire operation session.
10. If the test fails, an error message appears as described in Section 6.3.
11. If no error was found, the system sets itself to **Standby** mode.

Warning

- The Harmony system emits intense light pulses through the AFT, ST and UV handpieces, and laser pulses through the Nd:YAG, Q-Switched Nd:YAG and Er:YAG handpieces. Make sure that all personnel are protected against accidental exposure to these pulses, either directly from the handpiece or indirectly from a reflecting surface.
- To protect against eye damage and discomfort, make sure that everyone present in the room is wearing Alma Lasers recommended protective eyewear. Refer to Section A.10 in this manual for specific protective eyewear information.
- Never look directly at the pulse coming from the handpiece, even when wearing appropriate protective eyewear.
- Never point the handpiece so that it discharges into free space. Make sure that the handpiece is pointed at the treatment site during actual treatment.

6.3. Error Detection

This system is equipped with self-testing software that continuously monitors system operation by means of watchdog software & circuitry, and by interrupts. The software continuously checks the hardware for any error condition:

- The LCD displays an error message (see Figure 6-3) and disables further operation.
- The audible indicator sounds an alarm signal which is longer than the normal light or laser emission signals.

In such a case you should shut the system down and restart it. If the problem still persists, refer to Chapter 8 – **Troubleshooting** – for further instructions.

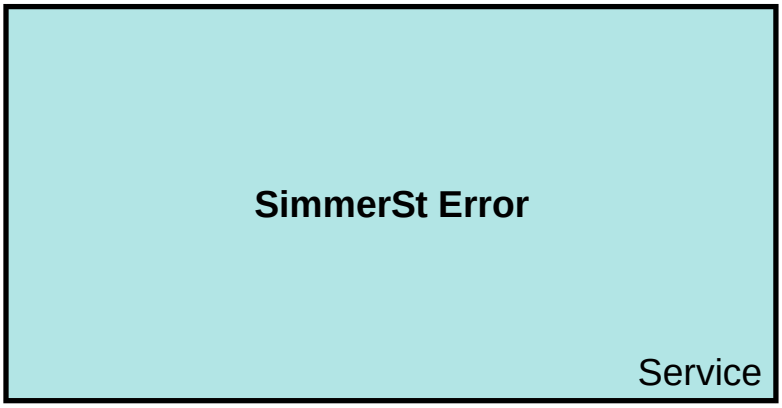


Figure 6-3: Error Message Screen (sample)

6.4. Operating the Modules

In general, the operating parameters in the Harmony modules are set up in the same fashion, with the exception of the **ST** module (see Section 6.4.). Figure 6-4 presents the control panel button functions that are common to all modules:

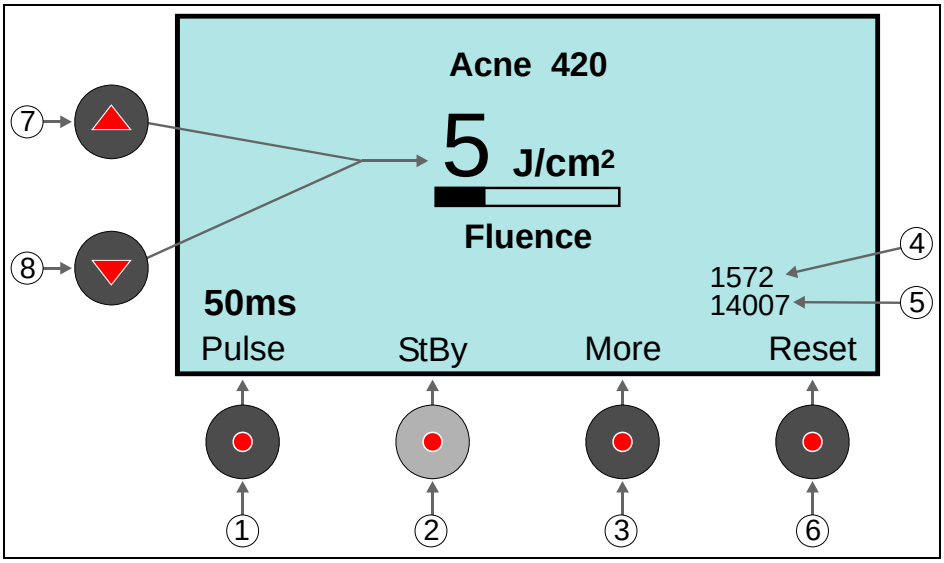


Figure 6-4: Control Panel Functions

1. **Pulse** – this button sets the pulse width (in msec), or the pulse rate (in Hz), wherever applicable. Each press of the button toggles the value to the next one available in that particular module.
2. **StBy** – this button toggles the Harmony system between **Standby** and **Ready** modes. Press this button when you are ready to start the treatment; the tag will change to **Ready** and light emission will be enabled when the footswitch/ trigger or both are pressed. Press the button again to return the system to **Standby** mode.
3. **More** – this is the portal to the system **Technician** mode. The technician mode is accessible only to Alma Lasers authorized service personnel (see Section 6.6.).
4. **Handpiece Pulse Counter** – this field counts the number of light pulses emitted by the handpiece during a treatment session. The counter may be reset to zero when desired.
5. **Total Handpiece Pulse Counter** – this field counts the total number of light pulses emitted by the handpiece, and it cannot be reset. This field will automatically reset to zero only when a new module handpiece is connected to the system.
6. **Reset** – press this button to reset the handpiece pulse counter to zero (see # 4 in Figure 6-4).

7. **Increase Fluence** – press the ▲ button to increase the fluence to the next higher level in the particular module.
8. **Decrease Fluence** - press the ▼ button to decrease the fluence to the next lower level.

> ***Note***
>
> - The following sections present the individual module operating screens and their particular elements.
> - The **Pulse** value shown on the screens are the default values that appear when the handpiece is connected to the system.

6.4.1. AFT Acne Module

The **AFT Acne** module main operating screen (see Figure 6-5) is displayed when the AFT Acne handpiece is connected to the system:

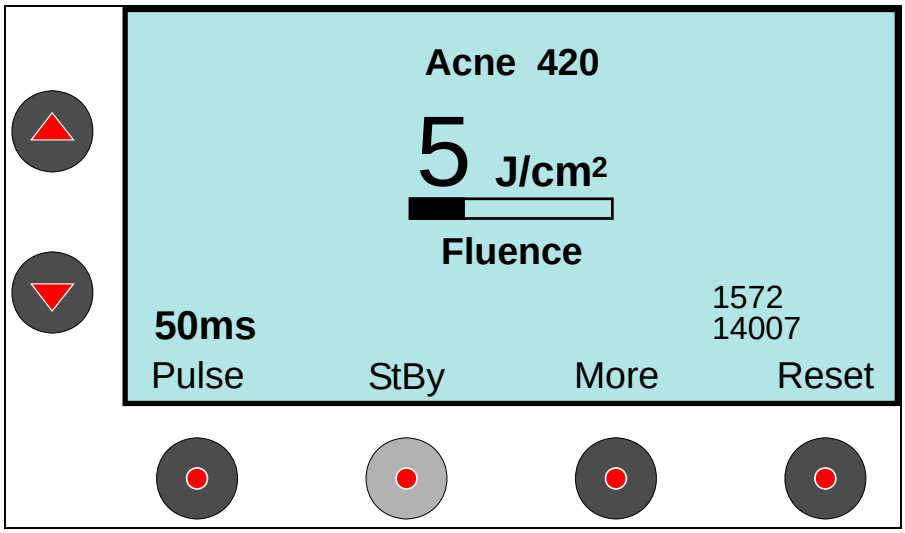


Figure 6-5: AFT Acne Module Operating Screen

Operating parameters available in this module:

1. **Fluence** – the available fluence range is from 5 to 20 J/cm^2 in increments of 1 J/cm^2.
2. **Pulse Width** – three pulse widths are available:
   - 30 ms
   - 40 ms
   - 50 ms (default)

6.4.2. AFT VP Module

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

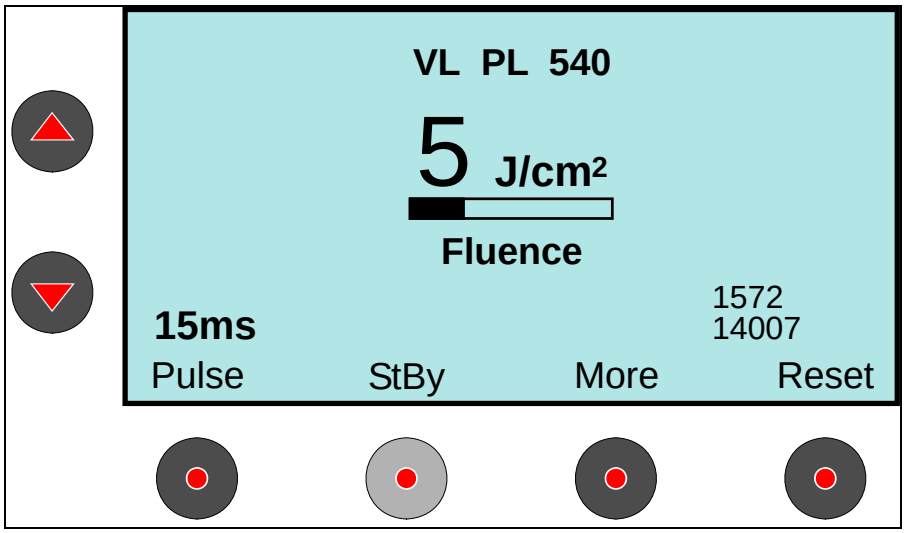


Figure 6-6: AFT VP Module Operating Screen

Operating parameters available in this module:

1. **Fluence** – the available fluence range is from 5 to 20 J/cm^2 in increments of 1 J/cm^2.
2. **Pulse Width** – three pulse widths are available:
   - 10 ms
   - 12 ms
   - 15 ms (default)

6.4.3. AFT SR Module

The **AFT SR** module main operating screen (see Figure 6-7) is displayed when the AFT SR handpiece is connected to the system:

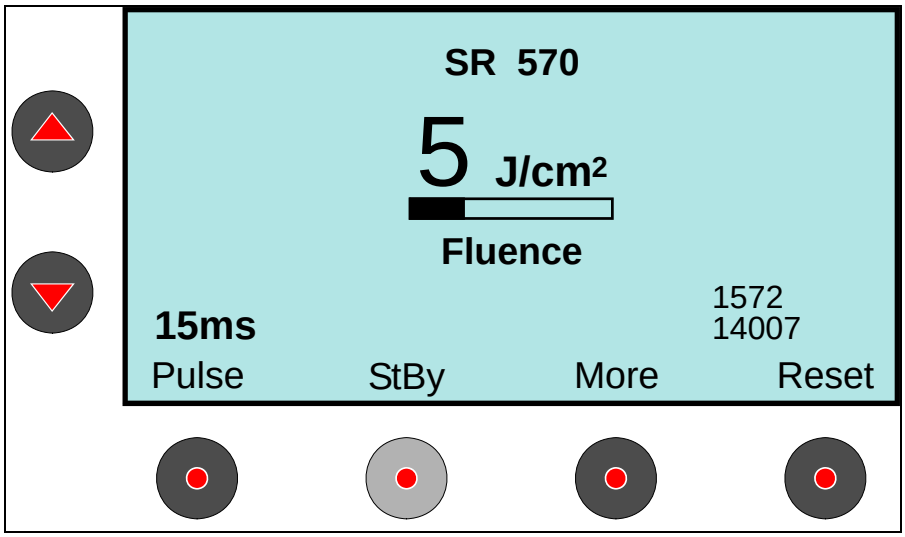


Figure 6-7: AFT SR Module Operating Screen

Operating parameters available in this module:

1. **Fluence** – the available fluence range is from 5 to 20 J/cm^2 in increments of 1 J/cm^2.
2. **Pulse Width** – three pulse widths are available:
   - 10 ms
   - 12 ms
   - 15 ms (default)

6.4.4. AFT HR Module

The **AFT HR** module main operating screen (see Figure 6-8) is displayed when the AFT HR handpiece is connected to the system:

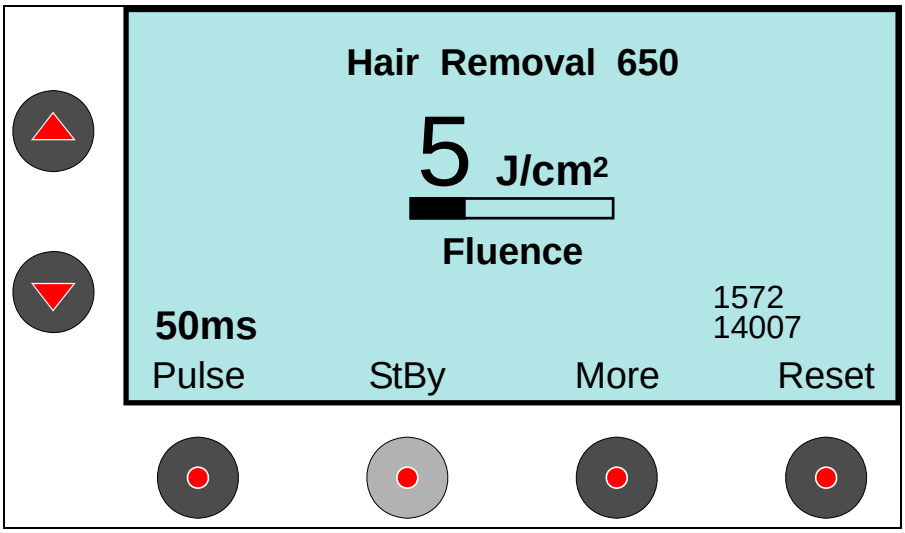


Figure 6-8: AFT HR Module Operating Screen

Operating parameters available in this module:

1. **Fluence** – the available fluence range is from 5 to 20 J/cm^2 in increments of 1 J/cm^2.
2. **Pulse Width** – three pulse widths are available:
   - 30 ms
   - 40 ms
   - 50 ms (default)

6.4.5. ST Module

The **ST** module main operating screen (see Figure 6-9) is displayed when the ST handpiece is connected to the system:

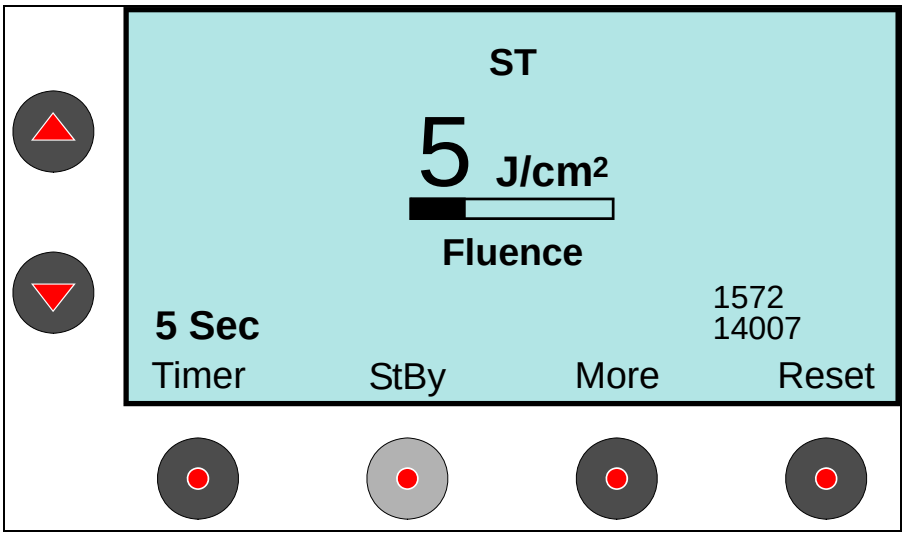


Figure 6-9: ST Module Operating Screen

Operating parameters available in this module:

There are three **Timer** settings in this module, and each timer setting provides a separate level of available fluences:

1. **5 Sec** – the available fluence range with the 5 second timer setting (default) is: **5**, **10**, **15**, **20**, **25**, **30** & **35** J/cm^2
2. **10 Sec** – the available fluence range with the 10 second timer setting is: **10**, **20**, **30**, **40**, **50**, **60** & **70** J/cm^2
3. **15 Sec** – the available fluence range with the 15 second timer setting is: **15**, **30**, **45**, **60**, **75**, **90** & **105** J/cm^2

6.4.6. UVB Module

The **UVB** module main operating screen (see Figure 6-10) is displayed when the UV handpiece is connected to the system:

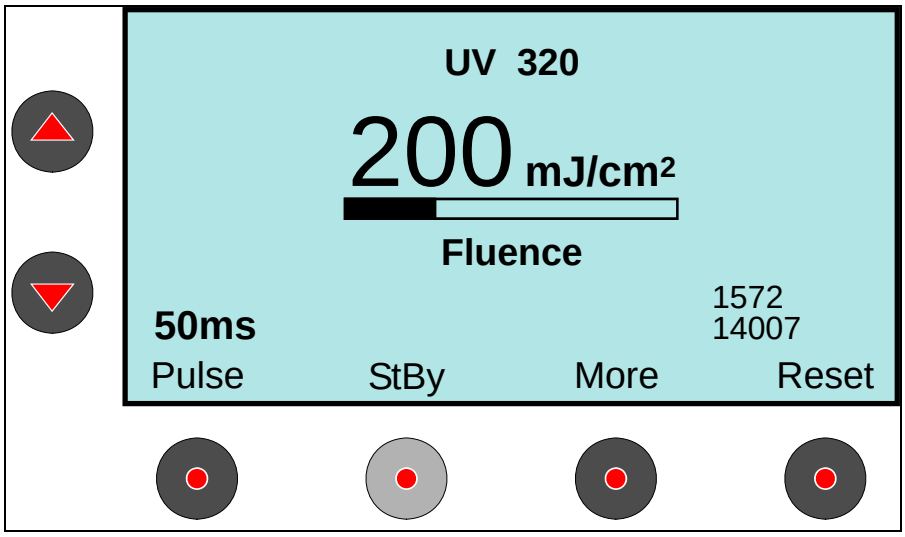


Figure 6-10: UVB Module Operating Screen

Operating parameters available in this module:

1. **Fluence** – the available fluence range is from 200 to 1000 J/cm^2 in increments of 10 J/cm^2.
2. **Pulse Width** – three pulse widths are available:
   - 30 ms
   - 40 ms
   - 50 ms (default)

6.4.7. 1064/532nm Q-Switched Nd:YAG Module

The **Q-Switched Nd:YAG** module main operating screen (see Figure 6-11) is displayed when the Q-Switched Nd:YAG laser handpiece is connected to the system:

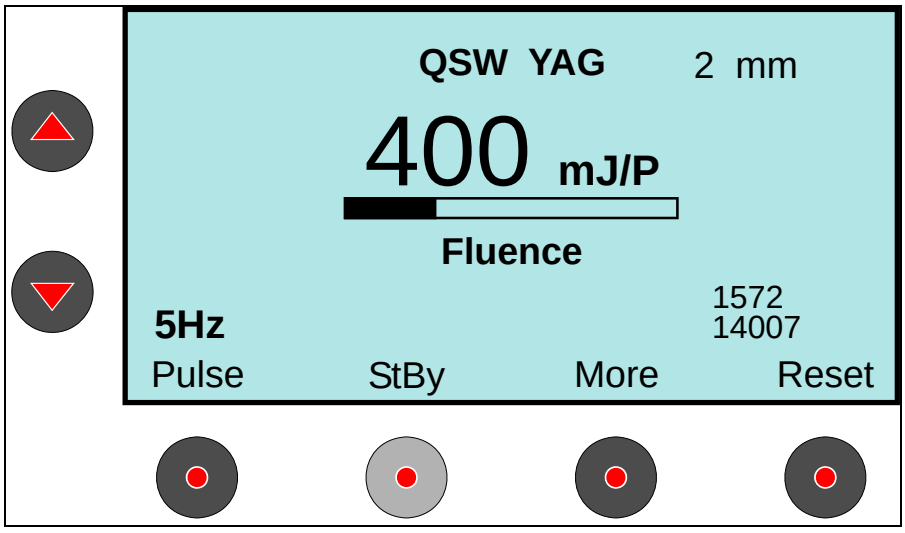


Figure 6-11: 1064/532nm Q-Switched Nd:YAG Module Operating Screen

Operating parameters available in this module:

1. There are three tips (**1 mm**, **2 mm** & **3 mm**) and a **KTP** (1064/532nm) adapter available for use with this laser handpiece. 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 J/cm^2 in increments of 100 J/cm^2.
3. **Pulse Frequency** – three pulse frequencies are available:
   - 1 Hz
   - 2 Hz
   - 5 Hz (default)

6.4.8. 1064nm Long Pulse Nd:YAG Module

The **1064nm Long Pulse Nd:YAG** module main operating screens (see Figure 6-12 & Figure 6-13) are displayed when the Long Pulse Nd:YAG 1064nm laser handpiece is connected to the system:

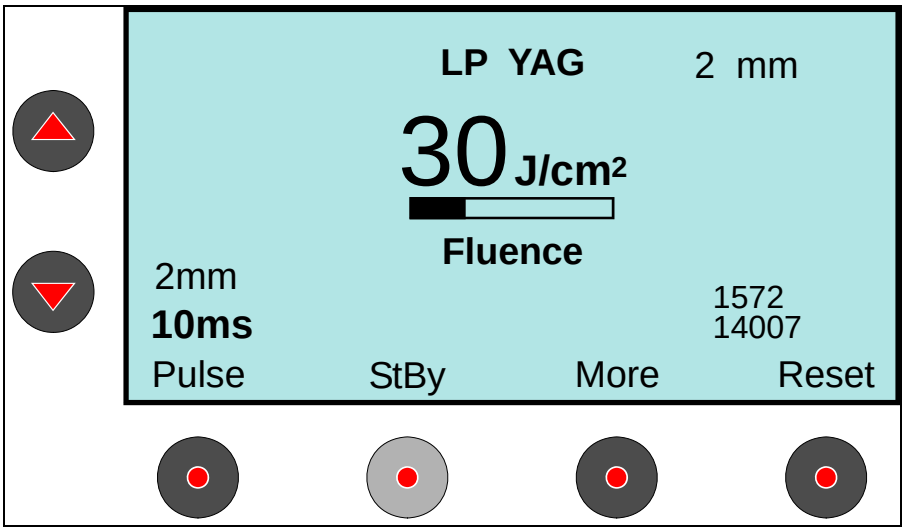


Figure 6-12: 1064nm Long Pulse Nd:YAG Screen with 2mm Tip

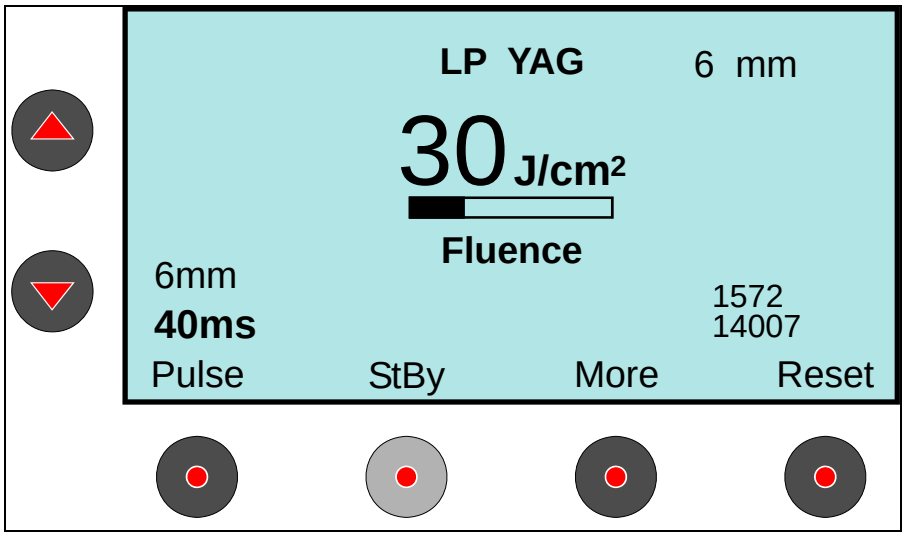


Figure 6-13: 1064nm Long Pulse Nd:YAG Screen with 6mm Tip

Operating parameters available in this module:

1. There are two tips (**2 mm** & **6 mm**) available for use with this laser handpiece. The system automatically recognizes the resident tip and displays its size in the top-right corner of the screen.
2. **Fluence** –
   - With the **6 mm** tip; the available fluence range is from 30 to 150 J/cm^2 in increments of 10 J/cm^2
   - With the **2 mm** tip; the available fluence range is from 30 to 450 J/cm^2 in increments of 10 J/cm^2
3. **Pulse Width** –
   - One pulse width is available with the **2 mm** tip: **10** ms
   - Two pulse widths are available with the **6 mm** tip: **40** & **60** ms

6.4.9. 1320nm Long Pulse Nd:YAG Module

The **1320nm Long Pulse Nd:YAG** module main operating screen (see Figure 6-14) is displayed when the Long Pulse Nd:YAG 1320nm laser handpiece is connected to the system:

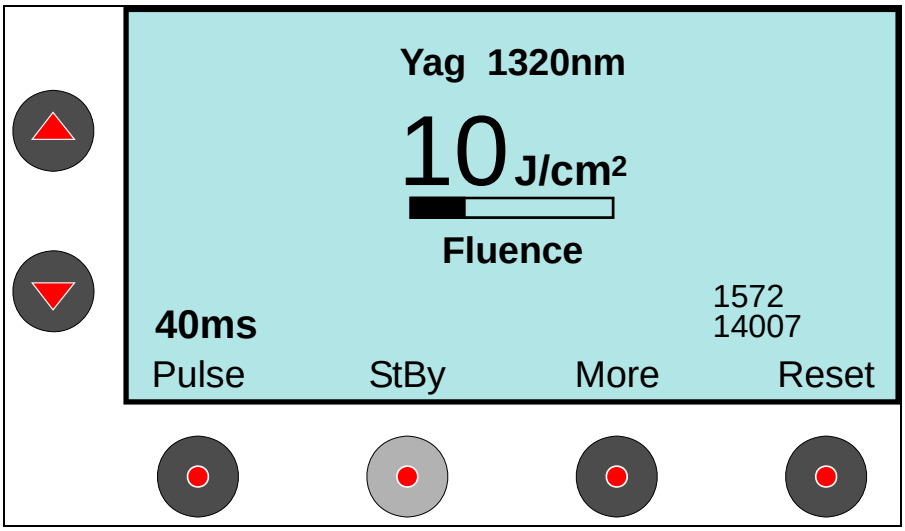


Figure 6-14: 1320nm Long Pulse Nd:YAG Module Operating Screen

Operating parameters available in this module:

1. **Fluence** – the available fluence range is from 10 to 40 J/cm^2 in increments of 1 J/cm^2.
2. **Pulse Width** – three pulse widths are available:
   - 30 ms
   - 40 ms (default)
   - 50 ms

6.4.10. 2940nm Er:YAG Module

The **2940nm Er:YAG** module main operating screens (see Figure 6-15 through Figure 6-17) are displayed when the Er:YAG 2940nm laser handpiece is connected to the system:

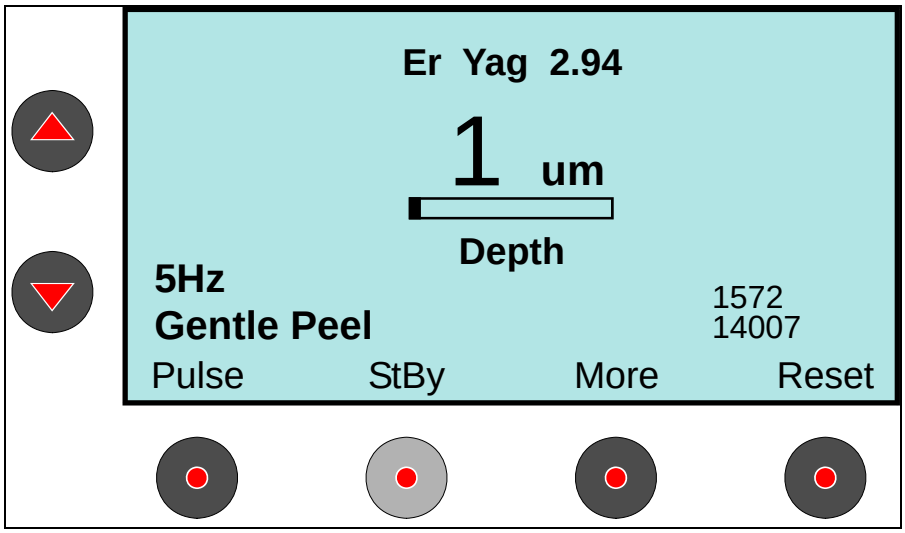


Figure 6-15: 2940nm Er:YAG Operating Screen – Gentle Peel

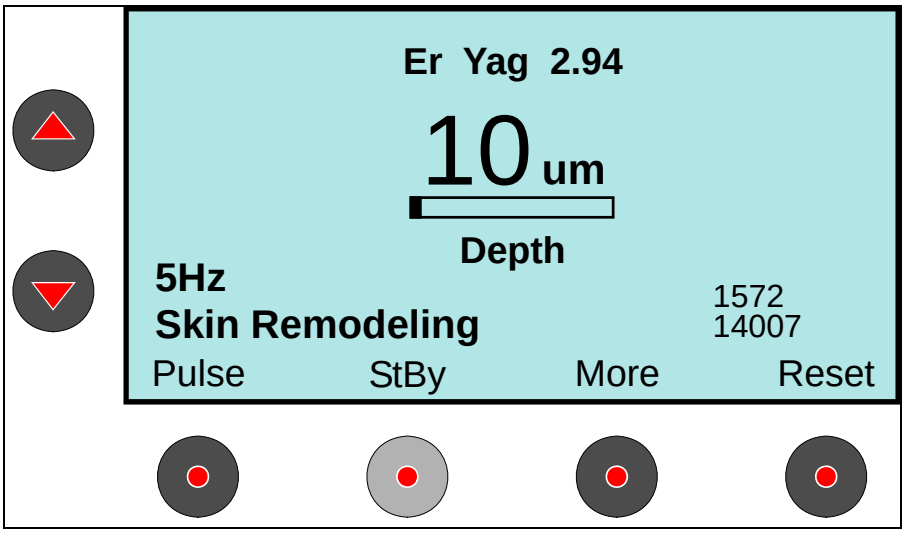


Figure 6-16: 2940nm Er:YAG Operating Screen – Skin Remodeling

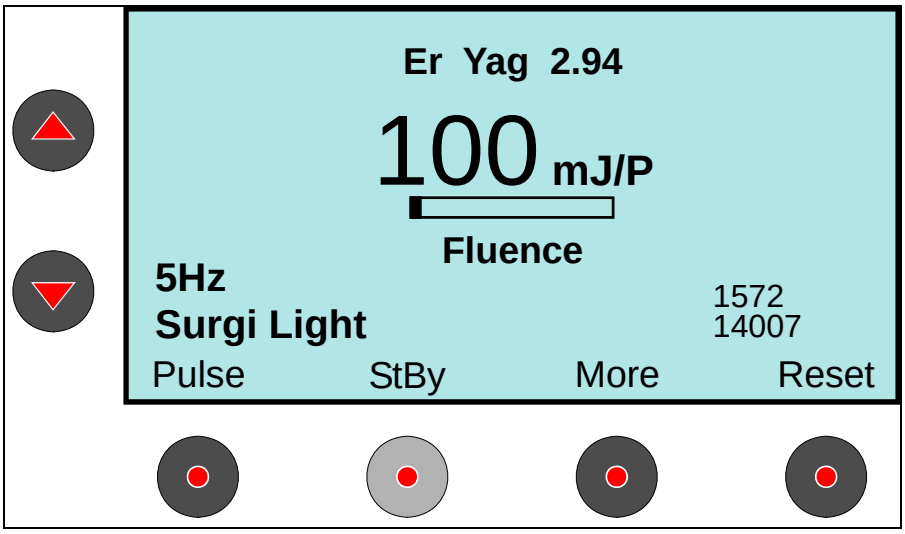


Figure 6-17: 2940nm Er:YAG Operating Screen – Surgi Light

Operating parameters available in this module:

There are three treatment modality settings in this module, and each modality setting provides a separate level of available fluences:

1. **Gentle Peel** – the depths of penetration available with the Gentle Peel setting (default) is **1** to **20 µm**, in increments of 1 µm.
2. **Skin Remodeling** – the depths of penetration available with the Skin Remodeling setting is **10** to **330 µm**, in increments of 10 µm.
3. **Surgi Light** – the level of fluences available with the Surgi Light setting is **100** to **1200 mJ/P**, in increments of 100 mJ/P.

> ***Note***
>
> The pulse frequency in this module is set at **5 Hz** and cannot be changed.

6.4.11. Pixel® 2940nm Er:YAG Module

The **Pixel® 2940nm Er:YAG** module main operating screen (see Figure 6-18) is displayed when the Pixel® 2940nm Er:YAG laser handpiece is connected to the system:

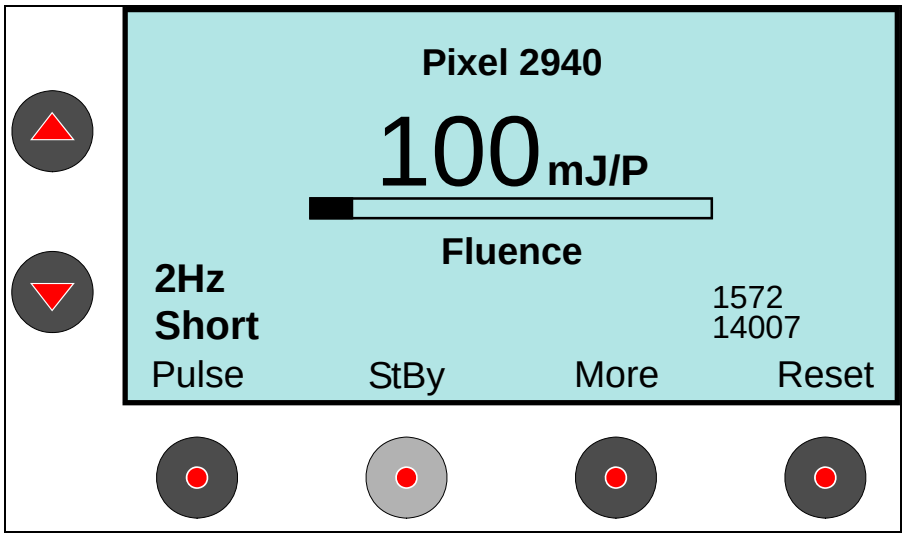


Figure 6-18: Pixel® 2940nm Er:YAG Module Operating Screen

Operating parameters available in this module:

There are three **Pulse Width** settings in this module, and each setting provides a separate level of available fluences:

1. **Short** – the available fluence levels with the short pulse setting (default) are **100** to **600 mJ/P** in increments of 100 mJ/P.
2. **Medium** – the available fluence levels with the medium pulse setting are **100** to **1000 mJ/P** in increments of 100 mJ/P.
3. **Long** – the available fluence levels with the long pulse setting are **100** to **1400 mJ/P** in increments of 100 mJ/P.

> ***Note***
>
> The pulse frequency in this module is set at **2 Hz** and cannot be changed.

6.4.12. Pixel® 1320nm Nd:YAG Module[1]

The **Pixel® 1320nm Nd:YAG** module main operating screen (see Figure 6-19) is displayed when the Pixel® 1320nm Nd:YAG laser handpiece is connected to the system:

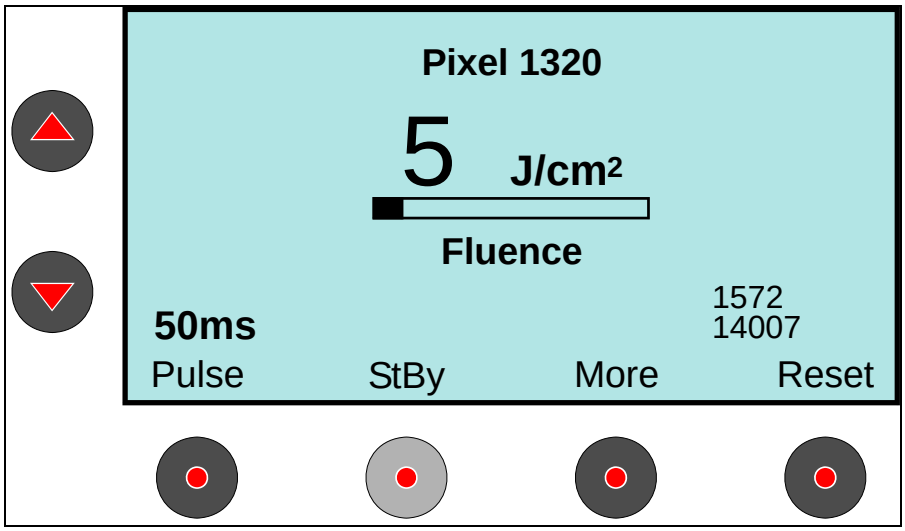


Figure 6-19: Pixel® 1320nm Nd:YAG Module Operating Screen

Operating parameters available in this module:

1. **Fluence** – the available fluence range is from 1 to 12 J/cm^2 in increments of 1 J/cm^2.
2. **Pulse Width** – three pulse widths are available:
   - 30 ms
   - 40 ms
   - 50 ms (default)

[1] Not available in the USA

6.5. Changing Operation Parameters during Operation

Any of the operating parameters may be changed during operation as follows:

1. Release the footswitch.
2. Change from **Ready** to **Standby** mode by pressing the **StBy** button on the control panel.
3. Change the setup parameters as desired.
4. Change from **Standby** to **Ready** mode by pressing the **StBy** button on the control panel.

6.6. Technician Mode

The **More** button on the Harmony control panel switches the system to **Technician** mode. Only an authorized Alma Lasers technician is allowed to access this mode, therefore access is password-protected. This mode is used to view and change laser settings during the 6-month maintenance procedure and whenever else required.

> ***Caution***
>
> Do not attempt to access the **Technician** mode. Changing parameters may impair the safety and effectiveness of the Harmony System.

6.7. Pause in Operation

As a standard safety measure, whenever pulse light emission is not immediately required, the system should be set to **Standby** mode. If the operator should leave the room, the system should be turned off as described in Section 6.8.

6.8. System Shut-Down

Turn off the system as follows:

1. Set the system to **Standby** mode by pressing the **StBy** button.
2. Turn off the keyswitch; the Harmony Logo screen appears (see Figure 6-1).
3. Turn off the main switch on the service panel.
4. Disconnect the power cable from the mains power outlet.

> ***Note***
>
> To turn off the system in an emergency situation, push the emergency shut-off knob. To resume operation, turn the knob to release it and turn the system off and back on again. A complete start-up procedure will be necessary to return to operation.

5. Clean the handpiece according to the instructions given in Chapter 7 – **Maintenance**.
6. Insert the handpiece in its cradle or disconnect and return it to its appropriate carrying case.

> ***Warning***
>
> Do not leave the key in the keyswitch unattended. It may lead to unauthorized use of the system.

CHAPTER 7
Maintenance

Chapter Contents:

7.1. Introduction

This chapter contains maintenance instructions for the Harmony system.

Routine maintenance may be performed by clinic staff unless otherwise specified. Any maintenance procedure not mentioned in this chapter must be performed only by Alma Lasers authorized technical personnel.

The system is designed to operate reliably without any need for operator maintenance. However, the outer surfaces of the system should be kept clean for hygienic reasons and the lightguides should be cleaned between sessions to enable effective treatment.

> ***Warning***
>
> Maintenance by the operator should be performed only when the system is shut down and disconnected from the mains power source. Performing maintenance procedures with the system turned on may be hazardous to the operator and/or destructive to the system.

7.2. Periodic Service

The system should be periodically inspected and maintained to keep it in peak operating condition.

The following routine service operations should be performed by Alma Lasers authorized technical personnel every 6 months:

- General system check
- Interior inspection, including cleaning accumulated layers of dust
- Verification of the light/laser output power rates with a power meter
- Cooling system:
  - Check the water level in the cooling system; refill if necessary
  - Replace the deionizer filter
  - Clean the radiator
  - Check the water quick-connector O-rings on the handpieces

Warning

- The Harmony system generates hazardous voltages within the main console.
- The interior of the system may be serviced only by Alma Lasers authorized technical personnel.

7.3. Service Information

In communications with Alma Lasers authorized representatives regarding the system, always include the part number and serial number indicated on the identification label located on the system service panel.

Warning

- Unauthorized servicing or modification of this system not described in this manual may expose the operator or patient to potential high voltage and laser radiation hazards.
- Improper use or adjustment of this system may invalidate the service warranty agreement.

Questions or problems should be referred to your Alma Lasers representative, or to the Alma Lasers Service Centers at:

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

Alma Lasers, Inc.
6555 NW 9th Avenue
Suite 303
Fort Lauderdale, FL 33309
Tel: (954) 229-2240
Fax: (954)229-8310
Email: contact@almalasers.com

Website: www.almalasers.com

7.4. Routine Maintenance

The following routine maintenance procedures should be performed by the clinic staff on a regular basis determined by the clinic protocol.

Warning

- The Harmony system generates high voltages and pulsed light/laser radiation when powered up.
- Always turn the system off and unplug the power cable before performing maintenance procedures.
- The interior of the system or its components may be serviced only by Alma Lasers authorized technical personnel.

7.4.1. Cleaning and Disinfecting the System

The outer surface of the system may be wiped clean with a soft cotton cloth swabbed in 70% alcohol.

7.4.2. Cleaning and Disinfecting the AFT, ST & UV Handpieces

Preventive inspection of the AFT, ST & UV handpieces should be performed after each treatment. The inspection consists of checking the output surface of the lightguide. If the handpiece tip is dirty, it should be cleaned with a damp cotton cloth.

The outer surface of the handpiece body and the umbilical cable may be wiped clean with a soft cotton cloth swabbed in 70% alcohol.

Caution

- Never immerse any part of the handpiece in water, nor hold it under running water.
- The window of the lightguide should be cleaned at the end of each session to remove gel and dirt to avoid interference in light distribution, which may reduce effectiveness of subsequent treatments.

7.4.2.1. AFT, ST & UV Handpiece Parts Identification

The handpiece assembly includes the following parts (see Figure 7-1):

1. Handpiece
2. Lightguide
3. Lightguide sleeve
4. Umbilical cable
5. Connector

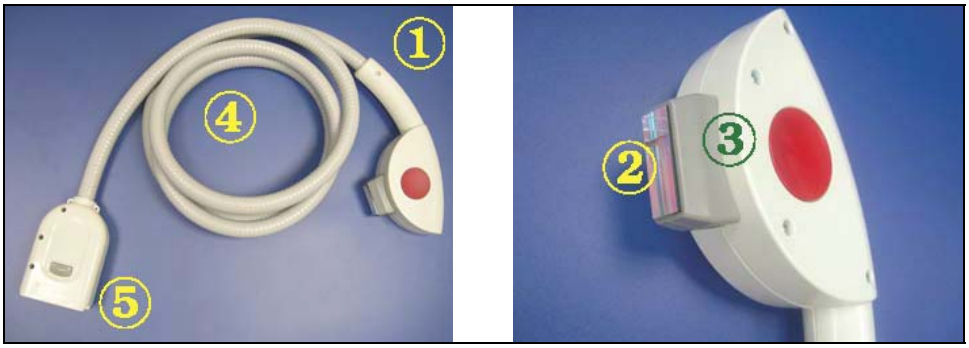


Figure 7-1: Handpiece Assembly Identification

The lightguide sleeve (see Figure 7-2) is marked internally (on its distal side) with a **FRONT** arrow (**A**).

The lightguide sleeve should always be re-assembled over the lightguide with the arrowed **FRONT** mark directed distally (front direction with respect to the handpiece [**B**]).

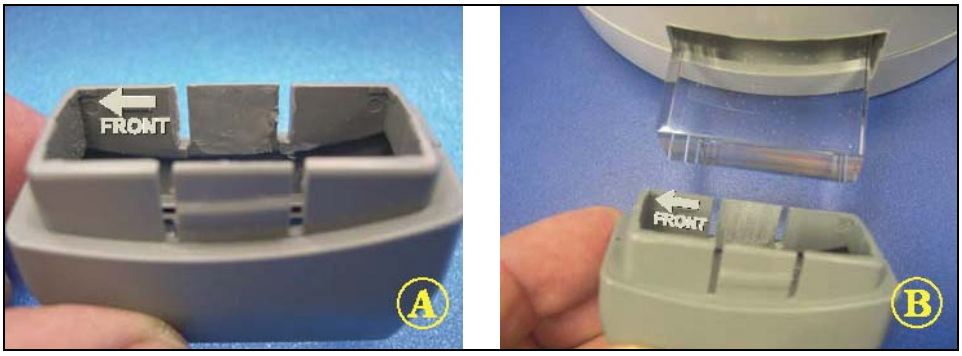


Figure 7-2: Lightguide Sleeve

7.4.2.2. Cleaning & Disinfection Instructions

Refer to Figure 7-3:

1. Turn the system off.
2. Clean the external surface of the lightguide with a soft cloth or a cotton ball.
3. Wipe and clean any traces of gel from the lightguide sleeve external surface using a dry cloth.
4. Grasp the lightguide sleeve (**1**) and pull it off the handpiece.
5. The exposed lightguide (glass) should be observed for stains or ultrasonic gel debris (**2**).
6. Clean the external lightguide surfaces with warm water using a small soft cloth or a cotton ball (no water should be allowed inside the lightguide assembly).
7. The lightguide external surface should be disinfected using 70% alcohol antiseptic solution.
8. Immerse the lightguide sleeve in hot water (**3**) and clean inside and outside using a dry soft cloth.
9. Both the lightguide and the lightguide sleeve should be completely dry before reassembly!
10. Insert the lightguide sleeve fully over the lightguide with the **FRONT** arrow directed distally (**4** & **5**).

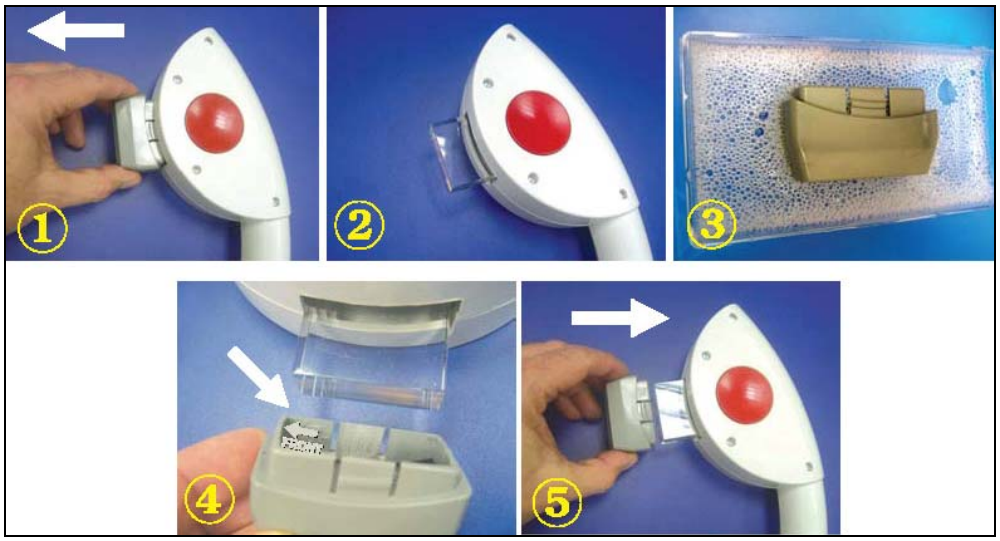


Figure 7-3: Cleaning/Disinfecting the AFT, ST & UV Handpiece

7.4.3. Cleaning and Disinfecting the Laser Handpieces

The cleaning and disinfection instructions should be applied to the following lasers modules and their tips:

- Nd:YAG Q-Switched 1064/532nm handpiece (1, 2 & 3mm tips)
- Nd:YAG 1064nm handpiece (2 and 6mm tips)
- Nd:YAG 1320nm handpiece (6mm tip)
- Er:YAG 2940nm handpiece (1 and 4mm tips)
- Pixel® 2940nm Er:YAG handpiece (11 x 11mm spot size tip)
- Pixel® 1320nm LP Nd:YAG handpiece[1] (7 x 7mm spot size tip)

It is imperative that the above laser tips, Pixel® tips and their protective shields remain clean and free of dirt. The laser tips, Pixel tips and the protective shields 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. For disinfection use 70% alcohol.

The outer surface of the handpiece body and the umbilical cable may be wiped clean with a soft cotton cloth swabbed in 70% alcohol.

Caution

- Never immerse any part of the handpiece in water, nor hold it under running water.
- The window of the lightguide should be cleaned at the end of each session to remove gel and dirt to avoid interference in light distribution, which may reduce effectiveness of subsequent treatments.

7.4.3.1. Laser Handpiece Tip Parts Identification

The laser handpiece tip consists of the following parts (see Figure 7-4):

1. Tip body
2. Guiding tip
3. Removable protective shield
4. The guiding tip may be pulled out of its base in the body of the tip, and the removable protective shield can be pushed out of the tip body with your finger.

[1] Not available in the USA

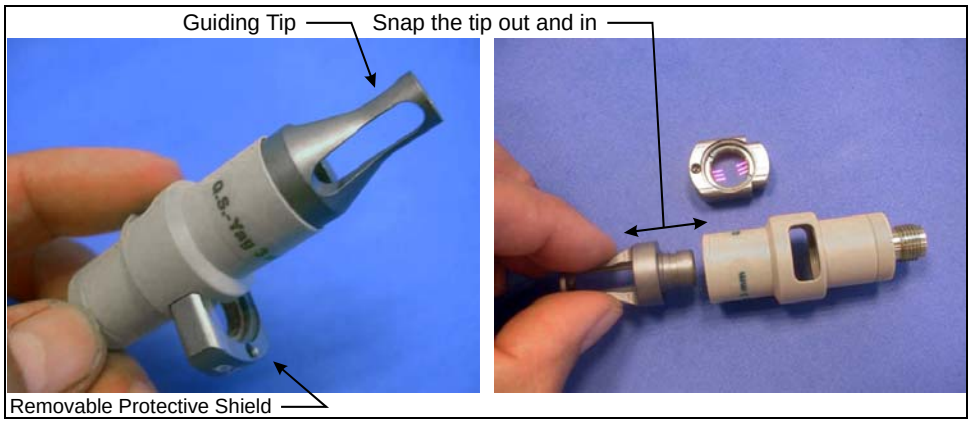


Figure 7-4: Disassembling the Laser Handpiece Tip

7.4.3.2. Cleaning & Disinfection Instructions

1. Turn the system off.
2. Unscrew the tip from the laser handpiece.
3. Pull the guiding tip out of the tip body and push the removable protective shield out of the tip body.
4. Wipe and clean any traces of gel or dirt from the three components using a dry cloth.
5. Clean the external surfaces of the tip body and all the surfaces of the guiding tip with warm water using a small soft cloth or cotton ball.
6. Both sides of the removable protective shield should be cleaned using 70% alcohol antiseptic solution.
7. All components of the tip should be completely dry before reassembly!

> ***Note***
>
> Some laser handpiece tips may not have protective shields.

CHAPTER 8
Troubleshooting

Chapter Contents:

8.1. Introduction

The Harmony laser system is equipped with a self-testing software routine that continuously monitors the system operation. If a system malfunction is detected, an error message will appear on the LCD display.

An error will disable the system operation and the operator should turn the system off using the keyswitch and the main switch.

The following troubleshooting tables do not attempt to list all possible system failures. Any fault not listed should be referred to Alma Lasers Service personnel.

> ***Warning***
>
> Do not attempt to open or disassemble the system covers.

8.2. Troubleshooting Guides

Table 8-1 provides a list of alarms and error messages that may appear on the screen, their possible causes and corrective actions to be performed. If the corrective actions listed in the table do not solve the problem, contact your Alma Lasers Service representative.

Table 8-2 lists some probable system malfunctions for which no messages are displayed. If the corrective actions listed in the tables do not solve the problem, contact your Alma Lasers service representative.

The following troubleshooting guides do not attempt to list all possible system failures. Any fault not listed should be referred to your Alma Lasers service representative.

Please advise the Alma Lasers Service Department of all error messages that occur, with the exceptions of **Head finished** and **Connect interlock**.

Table 8-1: Error Message Troubleshooting Guide

Error Message/Alarm	*Probable Cause*	*Corrective Action*
Charge time limit	System malfunction	Call Alma Lasers Service
Connect interlock	Treatment room door (with installed remote interlock connection switch) has been opened	1. Close the door, restart the system via the keyswitch and resume normal operation 2. Make sure the remote interlock is properly connected to the service panel
Discharge time limit	System malfunction	Call Alma Lasers Service
FlowSw OFF error	Cooling system malfunction	1. Turn system off, wait 1 minute and restart; resume normal operation 2. If problem persists, call Alma Lasers Service
Head error VB1=0 VB2=0	System software malfunction	Call Alma Lasers Service
Head failed RES error	Handpiece software malfunction	1. Replace handpiece and resume normal operation; return defective handpiece to Alma Lasers for diagnostics. 2. If problem persists, call Alma Lasers Service
Head finished	Handpiece has reached the end of its rated lifetime	Replace the handpiece
Head not calibrated for this machine	1. Handpiece malfunction 2. System malfunction	1. Replace handpiece and resume normal operation; return defective handpiece to Alma Lasers for diagnostics. 2. Call Alma Lasers Service
Head not recognized	System malfunction	Call Alma Lasers Service
Ibutton Inc failed	1. Handpiece connection 2. System malfunction	1. Reconnect the handpiece to the system and resume normal operation 2. Call Alma Lasers Service
Leakage error	Electrical malfunction	Call Alma Lasers Service

Table 8-1: Error Message Troubleshooting Guide (continued)

Error Message/Alarm	Probable Cause	Corrective Action
Joules limit error	1. Handpiece malfunction	1. Replace handpiece and resume normal operation; return defective handpiece to Alma Lasers for diagnostics. If problem persists, call Alma Lasers Service.
	2. System malfunction	2. Call Alma Lasers Service
No head unlimited machine	1. Handpiece is not connected or not properly connected to the system	1. Reconnect the handpiece properly to the system and resume normal operation
	2. System malfunction	2. Call Alma Lasers Service
Simmer St error	1. Handpiece light source malfunction	1. Replace handpiece and resume normal operation; return defective handpiece to Alma Lasers for diagnostics
	2. Electrical malfunction	2. Call Alma Lasers Service
Vcaps > 30	Electrical system discharge malfunction	Turn system off, wait 1 minute and restart; resume normal operation
Vcaps out of range	System malfunction	Call Alma Lasers Service
Water system error	Cooling system malfunction	1. Turn system off, wait 1 minute and restart; resume normal operation 2. If problem persists, call Alma Lasers Service

Table 8-2: System Malfunctions Troubleshooting Guide

Symptom	Probable Cause	Corrective Action
System does not start	Power disconnected	• Check power cable • Plug cable into wall
	Internal fuse blown	Call Alma Lasers customer support
	Red emergency shutoff knob is engaged	Release emergency shutoff knob by turning it clockwise
Monitor does not respond when the system is on	The monitor is not receiving power	Make sure the power cable in the rear of the monitor is connected

CHAPTER 9
Ordering Information

Chapter Contents:

9.1. Ordering Information Parts List

This chapter offers information necessary for ordering standard parts that should be kept on hand.

The following table displays the names and part numbers of the items by which you should place your orders with your Alma Lasers distributor.

Description	*Part No.*
AFT Acne Handpiece	AAIP18020304
AFT VP (Vascular/Pigmented) Handpiece	AAIP18020303
AFT SR (Skin Rejuvenation) Handpiece	AAIP18020302
AFT HR (Hair Removal) Handpiece	AAIP18020301
ST (Skin Tightening) Handpiece	AAIP03010501
UV (Ultraviolet) Handpiece	AAIP18020305
Masking Templates Set for UVB Module	AAIP08110402
1064/532nm Q-Switched Nd:YAG (Tattoo) Handpiece	AAIP24070501
1064nm Long Pulse Nd:YAG (Deep Leg Veins) Handpiece	AAIP06040501
1320nm Long Pulse Nd:YAG (Wrinkles) Handpiece	AAIP27020501
2940nm Er:YAG (Skin Resurfacing) Handpiece	AAIP27020504
Pixel® 2940nm Er:YAG Handpiece	AAIP29050601
Pixel® 1320nm Nd:YAG Handpiece[1]	AAIP27120502
AFT Light Safety Glasses (OD 3+)	OPIP05120501
AFT Dark Safety Glasses (OD 5+)	OPIP05120502
UV Safety Glasses 100% UV Protection	OPIP30010501
Nd:YAG Safety Glasses for 1064nm (OD 7+)	OPIP04120502
Nd:YAG Safety Glasses for 1320nm (OD7+)	OPIP24070501
Er:YAG Safety Glasses for 2940nm (OD 6+)	OPIP24010501
KTP Safety Glasses for FD QS Nd:YAG	OPIP11040401
Opaque Eye Protectors	OPIP01120501
Footswitch Pedal	EGGG28100110
Laser Danger Sign	PIGG23090402
Remote Interlock Connector	WAID21100102
Set of Spare Operation Keys	EGIP14010306

[1] Not available in the USA

APPENDIX A

Clinical Guide – General Clinical Information

Chapter Contents:

A.1. Introduction

The following Clinical Guides are provided to aid professionals in the use of the Harmony 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 operators must read the entire Operator's Manual before reviewing this appendix and before operating the system.

A.2. 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.

A.3. Intended Uses and Indications

A.3.1. AFT Pulsed Light Source Indications

The Advanced Fluorescence Technology (AFT) 420-950nm wavelengths are indicated for:

- The treatment of moderate inflammatory acne vulgaris
- The treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, and ephelides (freckles)
- The treatment of cutaneous lesions including warts, scars and striae
- The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations
- The removal of unwanted hair and to effect stable long-term or permanent hair reduction
- Indicated for use on all skin types (Fitzpatrick I-VI), including tanned skin

A.3.2. 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

A.3.3. 1064nm Nd:YAG Laser Source Indications

The 1064 nm Nd:YAG lasers (Long Pulsed and Q-Switched) are 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
- Benign cutaneous lesions, such as:
  - Warts
  - Scars
  - Striae
  - Psoriasis
- Benign pigmented lesions such as, but not limited to:
  - Lentigos (age spots),
  - Solar lentigos (sun spots)
  - Café au lait macules
  - Seborrheic keratoses

  - Nevi and nevus of Ota
  - Chloasma
  - Verrucae
  - Skin tags
  - Keratoses
  - The removal of black, blue or green tattoos (significant reduction in the intensity of black and/or blue/black tattoos)
  - Plaques
- Pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.
- The non-ablative treatment of facial wrinkles, such as, but not limited to:
  - Periocular wrinkles
  - Perioral wrinkles
- Laser skin resurfacing procedures for the treatment of:
  - Acne scars
  - Wrinkles
- 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)
- Pseudofolliculitis barbae (PFB)
- Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar
- Indicated for use on all skin types (Fitzpatrick I-VI), including tanned skin

A.3.4. 532nm Nd:YAG Laser Source Indications

The 532 nm Frequency-Doubled (FD) Nd:YAG lasers (Long Pulsed and Q-Switched) are indicated for:

- Incision, excision, ablation, vaporization of soft tissue
- Tattoo removal
  - Light blue
  - Yellow
  - Red

- Green

- Vascular lesions
  - Hemangiomas (Port wine stains/ birthmarks, and cavernous, cherry, and spider hemangiomas)
  - Angiomas (cherry, spider)
  - Telangiectasia
  - Spider nevi
- Benign pigmented lesions
  - Café-au-lait (macules)
  - Lentigines (senile and solar)
  - Freckles (ephelides)
  - Chloasma
  - Nevi
  - Nevus spillus
  - Nevus of Ota
  - Becker's nevi
- Other pigmented cutaneous lesions
  - Verrucae
  - Skin tags
  - Keratoses
  - Plaques

A.3.5. 1320nm Nd:YAG Laser Source Indications

1320 nm Nd:YAG laser is indicated for the treatment of:

- Back acne
- Atrophic acne scars
- Mild to moderate inflammatory acne vulgaris
- Fine lines and wrinkles
- Periorbital wrinkles
- Perioral wrinkles

A.3.6. 2940nm Er:YAG Laser Source Indications

2940 nm Er:YAG laser is indicated for use in soft tissue (skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs, and glands):

- Keratoses
- Skin resurfacing
- Treatment of wrinkles
- Epidermal nevi
- Telangiectasia
- Spider veins
- Actinic chelitis
- Keloids
- Verrucae
- Skin tags
- Anal tags
- Scar revision (including acne scars)
- Debulking benign tumors
- Debulking cysts
- Superficial skin lesions
- Diagnostic biopsies
- Decubitis ulcers

A.3.6.1. General Surgery

- Surgical incision/excision, vaporization, ablation, and coagulation of soft tissue where skin incision, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors and lesions, tissue ablation, and/or vessel coagulation may be indicated.

A.3.6.2. Genitourinary

Treatment of:

- Lesions of the external genitalia, anus, penis, scrotum, and urethra (includes condyloma acuminate, giant perineal condyloma, and verrucous carcinoma), vulvar lesions, polyps, and familial polyps of the colon

A.3.6.3. Gynecology

Treatment of:

- Cervical intraepithelial neoplasia (CIN), herpes simplex, endometrial adhesions, cysts, and condyloma

A.3.6.4. Oral/Maxillofacial

Treatment of:

- Benign oral tumors, oral and glossal lesions, and gingivectomy

A.3.6.5. Otorhinolaryngology/ Head and Neck (ENT)

Treatment of:

- Ear, nose and throat lesions, polyps, cysts, hyperkeratosis
- Excision of carcinogenic tissue and oral leukoplakia

A.3.6.6. Ophthalmology

Treatment of:

- Soft tissue surrounding the eye and orbit

A.3.6.7. Podiatry

Treatment of:

- Warts, plantar verrucae, large mosaic verrucae
- Matrixectomy

A.4. General Contraindications

- Cancer; in particularly, 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
- History of keloids or hypertrophic scarring
- Active infection of herpes simplex in the treatment area
- Diabetes (insulin dependent)
- Fragile and dry skin
- Hormonal disorders (that are stimulated under pulsed 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.

A.5. Accessories

To optimize the system performance and enhance patient safety, the Harmony system features the following accessories:

1. Assorted masking templates - 320, 420, 540, 570 and 650nm modules
2. Vessel gauge – 540nm AFT and 1064nm, 1320nm laser modules
3. MED template – 320nm UV module
4. Facial mask – Post-treatment skin cooling
5. Safety eyewear – refer to Section A.10 for details

6. AFT Zimmer adapter[1] – 570nm, 650nm AFT modules (Zimmer, Cryo 5) for use with all AFT handpieces as necessary
7. Laser Zimmer adapter[2] – 1064nm, 532nm ,1320nm modules (Zimmer, Cryo 5)

A.6. Adverse Effects of Treatment

The use of the Harmony 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.
- Chronic exposure to intense UV light (i.e. intense sunlight) can cause premature aging of the skin and may provide the precursors for skin cancer. UV treatment modalities have been used in dermatological practice for years and their safety profiles are well documented.
- 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. The most common adverse effects of treatment are specified in Section A.7.

[1] May be purchased
[2] These accessories should be used in accordance with Alma Lasers instructions of use

A.7. 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.

A.8. Pre-Treatment Information – Assessing the Condition

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

A.9. General

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

- Take a detailed patient medical history, including previous treatment modalities, and examine the dermatological condition for suitability of treatment with the Harmony system.
- Patients with a history of herpes simplex in the treatment area should take preventive medication (such as Zovirax™) prior to treatment.

A.9.1. Counseling

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

- Determine why the patient is seeking the treatment and clearly understand his/her expectations.
- Discuss the treatment with the patient:
  - The Harmony therapy may consist of multiple treatments given over several months.
  - There may be some discomfort or pain associated with the treatment.
  - Transient erythema/edema may appear immediately following the treatment.
  - Gradual recovery of the dermatological condition may take a few months.
  - There is a small risk of adverse reactions, such as changes in the texture and pigmentation of the skin, which are usually transient (see Adverse Effects of Treatment on page A-9 and Potential Side Effects of Treatment on page A-10).

A.10. Eye Protection

It is essential that all people present in the treatment room during the treatment (patient and medical personnel) protect their eyes by wearing Alma Lasers recommended protective eyewear.

It is good practice to instruct the patient to close their eyes during treatment even when wearing protective eye glasses.

If the patient cannot wear the protective eyewear, fit the patient with opaque eye protection that completely blocks light from the eyes.

If the treatment area is very close to the eyes (e.g. eyelids), protect the eyes with corneal shields.

Warning

- Different protective eyewear is indicated for use with AFT, UV, ST, Nd:YAG or Er:YAG handpieces. Make sure you choose the correct type.
- Do not treat eyebrows, eyelashes, or other areas within the bone area surrounding the eye orbit with the Nd:YAG or Er:YAG handpiece. The light emitted by this handpiece can cause serious eye damage or blindness. For maximum safety, the patient must wear metal eye goggles for all facial treatments.

The following table summarizes protective eyewear specifications (for each handpiece and light source) for the patient and attending personnel in the treatment room.

Handpiece (color code)	***Light Source***	***Optical Density of Protective Eyewear for Patient***	***Optical Density of Protective Eyewear for Attending Personnel***
UV (Violet)	UV 300-380nm	100% UV filtration	**100%** UV filtration
Blue, Green, Yellow & Red	AFT 420-950nm	**5+** (also referred to as Dark safety glasses AFT)	**3+** (also referred to as Light safety glasses AFT)
ST (Burgundy)	780-950nm	**5+** (also referred to as Dark safety glasses AFT)	**3+** (also referred to as Light safety glasses AFT)
LP[3] or QS[4] Nd:YAG	1064nm Nd:YAG	**7+** (also referred to as Nd:YAG safety glasses)	**7+** (also referred to as Nd:YAG safety glasses)
LP Nd:YAG	1320nm Nd:YAG[5]	**7+** (also referred to as Nd:YAG safety glasses)	**7+** (also referred to as Nd:YAG safety glasses)
Er:YAG	2940nm Er:YAG[6]	**6+** (also referred to as Er:YAG safety glasses)	**6+** (also referred to as Er:YAG safety glasses)
FD QS Nd:YAG	532nm	**5+** (also referred to as KTP)	**5+** (also referred to as KTP)

[3] LP = Long Pulse
[4] QS = Quality Switched
[5] Nd:YAG & Pixel Nd:YAG Handpieces
[6] Er:YAG & Pixel Er:YAG Handpieces

A.11. Optical Safety

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

A.12. Fire Safety

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

A.13. Photography

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

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

A.14. Skin Test

Energy and fluence are critical to optimize the treatment efficacy and minimize side effects. In order to select the appropriate fluence for a new treatment, the operator should perform a skin test before treatment as follows:

1. Select a representative area of healthy skin adjunctive to the treatment area.
2. Use the MED test for the psoriasis application as explained in Appendix H.
3. Apply a coat of a pre-cooled gel on the representative area (usually 1-2 mm thick and 3 mm thick for darker skin types).
4. Trigger a therapeutic pulse according to the parameters for the specific application as detailed in Appendices B-M.
5. Evaluate the skin test results for skin types I-VI after 30 minutes and for skin types IV-VI 24 to 48 hours later.
6. The desired result is mild erythema (for skin types I-IV only – erythema is much more difficult to observe in skin types V and VI). If erythema did not occur on skin types I-IV using the recommended parameters, increase the fluence by 1 J/cm^2 and repeat steps 3-5.

APPENDIX B

Clinical Guide – Acne Clearance

Chapter Contents:

B.1. Introduction

The Harmony system with the **AFT Acne** (Blue) handpiece 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.

Caution

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

B.2. Pre-Treatment

B.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.

B.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 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)

The treatment parameters for the 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.

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

B.3. Treatment

Treatment can begin after the AFT Acne handpiece has been connected to the Harmony system and the treatment parameters selected (fluence and pulse width) according to the table in Section B.4.

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 handpiece 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 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 N – Post-Treatment Care).

B.4. Suggested Setup Parameters

Skin Type	*Handpiece*	*Fluence (J/cm^2)*	*Pulse Width (msec)*
I – III	**AFT Acne 420-950nm** (Blue)	8 – 10	30, 40
IV – VI	**AFT Acne 420-950nm** (Blue)	7 – 8	40, 50

B.5. 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 be invited 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.

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

Alma Lasers, Inc.
6555 NW 9th Avenue
Suite 303
Fort Lauderdale, FL 33309
Tel: (954) 229-2240
Fax: (954)229-8310
Email: contact@almalasers.com

Website: www.almalasers.com

APPENDIX C

Clinical Guide – Vascular Lesions

Chapter Contents:

C.1. Introduction

The treatment of Vascular Lesions with the Harmony system can be performed using (one – or a combination of) three handpiece of the following types: **AFT VP 540-950nm** (Green), **AFT SR 570-950nm** (Yellow) and the **1064nm Long Pulse Nd:YAG** laser handpieces.

The AFT VP and SR modules are indicated for vascular lesions and pigmented lesions.

The Long Pulse Nd:YAG 1064nm laser is indicated for coagulation and hemostasis of vascular lesions and soft tissue using one of two optical tips (2mm and 6mm).

Caution

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

C.2. Pre-Treatment

C.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.

C.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 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)

C.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.

C.2.4. Skin Test

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

Skin Type (Fitzpatrick I-VI)	***Handpiece***	***Pulse Width (msec)***	***Fluence (J/cm^2)***	***Waiting Period***
I – III	**AFT VP 540-950nm** (Green)	10, 12	12-16	30 min
	AFT SR 570-950nm (Yellow)	10, 12	12-16	30 min
	Long Pulse Nd:YAG Laser (1064nm); **6mm** tip	40, 60	80-100	2-4 hours
	Long Pulse Nd:YAG Laser (1064nm); **2mm** tip	10	200	2-4 hours
IV – VI	**AFT VP 540-950nm** (Green)	15	7-10	24-48 hours
	AFT SR 570-950nm (Yellow)	15	8-11	24-48 hours
	Long Pulse Nd:YAG Laser (1064nm); **6mm** tip	40, 60	68-80	48-72 hours
	Long Pulse Nd:YAG Laser (1064nm); **2mm** tip	10	150	48-72 hours

C.3. Treatment

- The AFT VP 540nm (Green) and AFT SR 570nm (Yellow) handpieces will treat vessels up to < 1mm.
- The 2mm tip of the 1064nm Nd:YAG laser is used to treat vessels 0.5 to 1.5mm in diameter (available fluence up to 450 J/cm^2). The 6mm tip of the 1064nm Nd:YAG laser is used to treat vessels 1.5 to 4mm in diameter (available fluence up to 150 J/cm^2).
- The long pulse 1064nm Nd:YAG laser handpiece has 2 optical tips that are replaceable; to detach, grasp the tip at its base and turn counter-clockwise. To attach either the 6mm or 2mm tip – grasp the tip and thread it onto the aperture end of the handpiece 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 Nd:YAG laser handpiece.

Treatment can begin after the suitable handpiece 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 C.2.4.

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 cooling gel (43-50°F/6-10°C) to the treatment site only when the AFT handpiece is used. With the long pulse laser Nd:YAG handpiece gel is not used. Other cooling means such as ice pack or forced cold air/Zimmer are recommended. 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 AFT handpiece perpendicular to the skin and touch the gel with the lightguide. Do not apply pressure (the lightguide should gently touch the skin). In case of the Long Pulse Nd:YAG (1064nm) laser handpiece, the 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. If you use one of the AFT handpieces, trigger a light pulse by pressing the footswitch. If you use the Nd:YAG laser handpiece, trigger a light pulse by pressing the footswitch and the handpiece trigger simultaneously.
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 N – Post-Treatment Care).

C.4. Suggested Setup Parameters

Skin Type (Fitzpatrick I-VI)	*Target Vessel Depth*	*Handpiece*	*Fluence (J/cm^2)*	*Pulse Width (msec)*
I – III	Surface	**AFT 540-950nm** (Green)	Up to 20	10, 12, 15
	Surface	**AFT 570-950nm** (Yellow)	Up to 20	10, 12, 15
	Deep	**Long Pulse Nd:YAG** Laser (1064nm); **6mm** tip	Up to 150	40, 60
I – III	Surface	**Long Pulse Nd:YAG** Laser (1064nm); **2mm** tip	Up to 450	10
IV – VI	Surface	**AFT 540-950nm** (Green)	Up to 16	12, 15
	Surface	**AFT 570-950nm** (Yellow)	Up to 16	12, 15
	Deep	**Long Pulse Nd:YAG** Laser (1064nm); **6mm** tip	Up to 150	40, 60
IV – VI	Surface	**Long Pulse Nd:YAG** Laser (1064nm); **2mm** tip	Up to 250	10

C.5. 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.

- 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.
Halamish, P.O. Box 3021
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Fort Lauderdale, FL 33309
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Website: www.almalasers.com

APPENDIX D

Clinical Guide – Pigmented Lesions

Chapter Contents:

D.1. Introduction

The Pigmented Lesions application of the Harmony system can be performed with the **AFT VP 540-950nm** (Green) and the **AFT SR 570-950nm** (Yellow) handpieces.

> ***Caution***
>
> **The appropriate protective eyewear should be worn by both the operator and the patient when using these handpieces.**

D.2. Pre-Treatment

D.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.

D.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 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)

D.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. 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.

D.2.4. Skin Test

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

Skin Type (Fitzpatrick I-VI)	*Handpiece*	*Lesion Color*	*Pulse Width (msec)*	*Fluence (J/cm^2)*	*Waiting Period*
I – III	**AFT VP 540-950nm** (Green)	Light	10, 12	13 – 15	30 min.
		Dark		12 - 14	
	AFT SR 570-950nm (Yellow)	Light	10, 12	14 - 16	30 min.
		Dark		13 - 15	
IV – VI	**AFT VP 540-950nm** (Green)	Light	15	10 - 12	24 - 48 hours
		Dark		8 - 10	
	AFT SR 570-950nm (Yellow)	Light	15	10 - 12	24 - 48 hours
		Dark		8 - 10	

D.3. Treatment

Treatment may begin after the suitable handpiece has been connected to the Harmony system and the treatment parameters (fluence and pulse width) are selected according to the table.

1. Clean the skin to remove perfumes, cosmetics and sunscreens.
2. Apply a thin layer (usually 1-2mm thick and 3mm 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 AFT handpiece 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 N – Post-Treatment Care).

D.4. Suggested Setup Parameters

Skin Type (Fitzpatrick I-VI)	*Lesion Color*	*Handpiece*	*Pulse Width (msec)*	*Fluence (J/cm^2)*
I – III	Light	**AFT VP 540-950nm** (Green)	10, 12	Up to 20
	Dark	**AFT VP 540-950nm** (Green)	15	Up to 20
	Light	**AFT SR 570-950nm** (Yellow)	10, 12	Up to 20
	Dark	**AFT SR 570-950nm** (Yellow)	15	Up to 20
IV – VI	Light	**AFT VP 540-950nm** (Green)	10, 12	Up to 15
	Dark	**AFT VP 540-950nm** (Green)	15	Up to 15
IV – VI	Light	**AFT SR 570-950nm** (Yellow)	10, 12	Up to 15
	Dark	**AFT SR 570-950nm** (Yellow)	15	Up to 15

D.5. 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.

- 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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APPENDIX E

Clinical Guide – Skin Rejuvenation

Chapter Contents:

E.1. Introduction

The Skin Rejuvenation application of the Harmony system is performed using the **AFT SR 570-950nm** (Yellow) handpiece or the **Long Pulse Nd:YAG (1064nm)** handpiece. The AFT 570-950nm handpiece 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). The long pulse Nd:YAG laser (1064 nm) handpiece is indicated for the non-ablative treatment of facial wrinkles.

Caution

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

E.2. Pre-Treatment

E.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.

E.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 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)

E.2.3. Skin Test

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

Skin Type (Fitzpatrick I-VI)	*Handpiece*	*Pulse Width (msec)*	*Fluence (J/cm^2)*	*Waiting Period*
I – III	**AFT SR 570-950nm** (Yellow)	10, 12	13 – 16	30 min.
	Long-Pulse Nd:YAG (1064nm) 6mm Tip	40, 60	80 – 100	5 – 7 days
IV – VI	**AFT SR 570-950nm** (Yellow)	12	8 – 12	30 min.
	Long-Pulse Nd:YAG (1064nm) 6mm Tip	40, 60	60 – 80	5 – 7 days

E.3. Treatment

Treatment can begin after the suitable handpiece has been connected to the Harmony system and the treatment parameters (fluence and pulse width) are selected according to the table in Section E.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. Apply a thin layer (usually 1-2mm thick and 3mm for darker skin types) of refrigerated (43-50°F/6-10°C) cooling gel to the treatment site (only when the AFT handpiece is used; gel is not used with the long pulse laser handpiece; other cooling means such as ice pack or forced cold air/Zimmer are recommended). 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 AFT handpiece perpendicular to the skin and touch the gel with the lightguide. Do not apply pressure (the lightguide should gently touch the skin).

In the case of the long pulse Nd:YAG (1064nm) handpiece, the 6mm 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 light pulse by pressing the footswitch (if using the AFT handpiece), or press the footswitch and the handpiece trigger simultaneously (if using the long pulse Nd:YAG handpiece).
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 N – Post-Treatment Care).

E.4. Suggested Setup Parameters

Skin Type (Fitzpatrick I-VI)	*Handpiece*	*# of Pulses per Spot*	*Pulse Width (msec)*	*Fluence (J/cm^2)*
I – III	**AFT SR 570-950nm** (Yellow)	2	10, 12	Up to 18
	Long-Pulse Nd:YAG (1064nm) 6mm Tip	1	40, 60	Up to 150
IV – VI	**AFT SR 570-950nm** (Yellow)	2	15	Up to 16
	Long-Pulse Nd:YAG (1064nm) 6mm Tip	1	40, 60	Up to 100

E.5. 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.

- 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:

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APPENDIX F

Clinical Guide – Hair Removal

Chapter Contents:

F.1. Introduction

The Harmony system with the **AFT HR 650-950nm** (Red) handpiece is indicated for the removal of unwanted hair and to effect stable long-term or permanent hair reduction.

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

F.2. Pre-Treatment

F.2.1. 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

F.2.2. 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
- Implantable device (pacemaker, AICD etc.)
- 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
- 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

F.2.3. 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.

Skin Type (Fitzpatrick I-VI)	*Handpiece*	*Pulse Width (msec)*	*Fluence (J/cm^2)*	*Waiting Period*
I	**AFT HR 650-950nm** (Red)	30	15	30 minutes
II	**AFT HR 650-950nm** (Red)	30	15	30 minutes
III	**AFT HR 650-950nm** (Red)	40	12	30 minutes
IV	**AFT HR 650-950nm** (Red)	50	9	24-48 hours
V	**AFT HR 650-950nm** (Red)	50	7	24-48 hours
VI	**AFT HR 650-950nm** (Red)	50	5	24-48 hours

F.3. Treatment

Treatment can begin after the AFT HR (650-950nm) handpiece is connected and the treatment parameters are selected (fluence and pulse width) according to the table in Section F.4.

1. Clean the skin to remove perfumes, cosmetics and sunscreens.
2. Apply a thin layer (usually 1-2mm thick and 3mm 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 handpiece 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 N – Post-Treatment Care).

F.4. Suggested Setup Parameters

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

Skin Type (Fitzpatrick I-VI)	*Hair Color*	*Handpiece*	*Fluence (J/cm^2)*	*Pulse Width (msec)*
I	Light	**AFT HR 650-950nm** (Red)	15 – 20	30
	Dark	**AFT HR 650-950nm** (Red)	10 – 20	30
II	Light	**AFT HR 650-950nm** (Red)	15 – 20	40
	Dark	**AFT HR 650-950nm** (Red)	10 – 20	30
III	Light	**AFT HR 650-950nm** (Red)	15 – 20	40
	Dark	**AFT HR 650-950nm** (Red)	10 – 17	40
IV	Light	**AFT HR 650-950nm** (Red)	15 – 17	50
	Dark	**AFT HR 650-950nm** (Red)	10 – 15	40
V	Light	**AFT HR 650-950nm** (Red)	Up to 15	50
	Dark	**AFT HR 650-950nm** (Red)	Up to 13	50
VI	Light	N/A	N/A	N/A
	Dark	**AFT HR 650-950nm** (Red)	Up to 12	50

Caution

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

F.5. 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 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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APPENDIX G

Clinical Guide – Skin Tightening, Scar Revision and Treatment of Striae

Chapter Contents:

G.1. Introduction

The Harmony **ST 780 - 950nm** (Burgundy) handpiece emits light in the near infrared spectrum generated by a pulsed-light source. The ST handpiece is identified by a burgundy center coded circle. The handpiece allows exposure time and energy conditions for the duration of 5, 10 or 15 seconds and (accumulative) fluence of up to 35, 70 and 105 J/cm^2, respectively. The spectrum provided targets collagen and proteins within the dermis. The heat generated will help to stimulate collagen and (in most cases) re-align the current collagen structure. This regrowth module can be used to treat cutaneous lesions such as striae, stretch marks - scar revision and reduce the presence of wrinkles.

Caution

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

G.2. Pre-Treatment

G.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.

G.2.2. 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
- Implanted devices such as pacemakers or defibrillators
- 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 or Tretinoin – Retin A in the previous 3-6 months for the treatment of acne or other dermatological conditions
- Diabetes (owing to possible photosensitivity and poor wound healing)
- Pregnancy
- Impaired immune system
- Scleroderma

G.3. Handpiece Operation

The handpiece can be applied on the skin only in a stationary mode. In the stationary mode the practitioner places the handpiece on the skin for the entire exposure time and fluence conditions.

G.3.1. Handpiece Parameters

5 sec[1]	***10sec[1]***	***15 sec[1]***
5	10	15
10	20	30
15	30	45
20	40	60
25	50	75
30	60	90
35	70	105

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

G.4. Skin Test

Always perform a skin test (single pass) on the intended treatment area. After covering the area with a thin (<1mm) layer of ultrasonic gel, the operator should place the handpiece on 3 different predetermined testing areas (adjacent) according to the following exposure conditions order:

G.4.1. Face

Order	*Mode*	*Exposure Time (Sec)*	*Fluence (J/cm^2)*	*Spot Size (cm^2)*
1st	Stationary	10	20	6.4
2nd	Stationary	10	30	6.4
3rd	Stationary	10	40	6.4

G.4.2. Abdomen

Order	*Mode*	*Exposure Time (Sec)*	*Fluence (J/cm^2)*	*Spot Size (cm^2)*
1st	Stationary	10	30	6.4
2nd	Stationary	10	40	6.4
3rd	Stationary	10	50	6.4

G.5. Treatment

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

1. Clean the skin to remove perfume, cosmetics and sunscreens.
2. In areas where hair exists (e.g., face or abdomen), the hair must be shaved or trimmed.
3. Provide appropriate eye protection for the patient and the medical staff inside the treatment room. Refer to Section A.10 for specific protective eyewear details.
4. Apply a thin layer (<1mm) of gel to the treatment area prior to treatment. Place the handpiece perpendicular to the skin. Do not apply pressure (the tip should gently touch the skin). Trigger one pulse with the handpiece.
5. Each area will be treated with 2 or 3 passes (not stacked); the number of passes (accumulative energy) may vary from patient to patient based on the size of the area to be treated.
6. Up to 10% overlapping is an acceptable tolerance, but try to avoid overlapping.
7. Set the initial exposure time and fluence parameters according to the skin test results.
8. Trigger pulses by pressing the footswitch continuously; the handpiece will stop emitting light when the footswitch is released. In order to continue, the footswitch must be pressed again.
9. Skin tissue heating is "Patient and Area" specific and therefore should be monitored uniquely for each individual (use a laser thermometer when necessary).
10. Treatment parameters may be increased by 10% every other treatment and subjected to the conditions in the area treated and patient's tolerance.

    The patient should tolerate the treatment with low to moderate levels of discomfort. Sensitivity to heat is a determining factor to stop treatment. If the patient does not experience the sensation of heat or does not indicate that the temperature of the tissue is getting warmer, use 3 passes as the maximum per-treatment session.

    Remember: it is recommended to use this handpiece only on skin types I-IV.
11. Following the treatment gently cleanse the treated area from gel (do not reuse gel).

12. If adverse skin effects occur (such as excessive reddening or swelling), you may either change the exposure time or reduce the fluence.
13. After treatment the area should be cooled with 4 x 4 gauze pads for 5-10 minutes.
14. Treatment intervals: treat every 3-4 weeks for the facial/neck/chest area and every 2 weeks for the abdomen area.
15. The ST handpiece is frequently used in combination therapy with one or more of the Harmony AFT handpieces.

G.6. Suggested Setup Parameters

G.6.1. Face

Mode	*Area*	*Exposure Time (Sec)*	*Fluence (J/cm^2)*	*# of Passes**
Stationary	Forehead	10	20 – 35	3
Stationary	Submental	10	40 – 60	3
Stationary	Cheeks	10	40 – 60	3

G.6.2. Abdomen

Mode	*Area*	*Exposure Time (Sec)*	*Fluence (J/cm^2)*	*# of Passes**
Stationary	Upper abdomen	5, 10, 15	20 – 60	1 to 3
Stationary	Mid-lateral abdomen	5, 10, 15	20 – 60	1 to 3
Stationary	Lower abdomen	5, 10, 15	20 – 60	1 to 3

(*) If the patient is uncomfortable with the temperature after 2 passes, stop treatment for this session. Passes may be increased to 3 if the patient has easily tolerated 2 passes. Do not exceed 3 passes per treatment session.

G.7. 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 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:

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APPENDIX H

Clinical Guide – Psoriasis and Vitiligo

Chapter Contents:

H.1. Introduction

The Harmony **UV Handpiece** (Violet) 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 resurfacing skin, chemically peeled skin, etc.

Caution

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

H.2. Pre-Treatment

H.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.

H.2.2. 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)

H.2.3. 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 H-1.
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 H-1: Proposed Range of MED Test Spot Fluence (mJ/cm^2) for the UV Handpiece

Test Spot #	*Skin Type I – II*	*Skin Type III – IV*	*Skin Type V – VI*	*Waiting Period*
1	400	470	550	24 hours
2	430	510	570	24 hours
3	460	530	590	24 hours
4	490	550	610	24 hours
5	510	570	630	24 hours
6	550	600	650	24 hours

Note

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

H.3. 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 handpiece 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.

H.4. Suggested Setup Parameters

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

H.5. Vitiligo & Re-Pigmentation

The approach to the treatment with the UV handpiece 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 H-2: Initial Treatment Parameters for Vitiligo and Re-Pigmentation

Treatment Area	***Starting Dosage (mJ/cm^2)***	**Resultant Erythema <24 hours after treatment, fluence should be increased by:**	**Resultant Erythema 48-60 hours after treatment, fluence should be decreased by:**	**Resultant Erythema 60-72 hours after treatment, postpone the next treatment and decrease fluence by:**
Periocular	350	5%	5%	10%
Face, scalp, ear, neck, axilla, bikini	400	10%	10%	15%
Arm, leg, trunk	500	15%	15%	20%
Wrist	650	15%	15%	20%
Elbow	650	20%	20%	25%
Knee	650	20%	20%	25%
Hand, feet	650	20%	20%	25%
Finger, toe	750	20%	20%	25%

H.6. 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.

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APPENDIX I

Clinical Guide – Tattoo Removal

Chapter Contents:

I.1. Introduction

The **Q-Switched Nd:YAG (1064nm** and **532nm KTP)** handpiece 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 1064nm and 532nm (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.

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

I.2. Pre-Treatment

I.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.

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.

I.2.2. Contraindications

I.2.2.1. 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

I.2.2.2. 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.)

I.2.3. 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 Q-Switched Harmony handpiece 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.

I.2.4. 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.

Table I-1: Spot Size 2mm (1064nm)

Skin Type (Fitzpatrick I-VI)	*Handpiece*	*Frequency (Hz)*	*Tattoo Color*	*Waiting Period*	*Fluence (J/cm^2)*
I – III	Q-Switched Nd:YAG 1064nm)	1, 2, 5	Black/Blue/ Green	4 – 6 weeks	500
IV – VI	Q-Switched Nd:YAG 1064nm)	1, 2, 5	Black/Blue/ Green	4 – 6 weeks	400

Table I-2: Spot Size 2mm (532nm KTP)

Skin Type (Fitzpatrick I-VI)	*Handpiece*	*Frequency (Hz)*	*Tattoo Color*	*Waiting Period*	*Fluence (J/cm^2)*
I – III	Q-Switched Nd:YAG 532nm KTP	1, 2, 5	Red	4 – 6 weeks	600
IV – VI	Q-Switched Nd:YAG 532nm KTP	1, 2, 5	Red	4 – 6 weeks	400-600

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

I.3. Treatment

1. Clean and dry the skin to remove the EMLA gel.
2. Place the handpiece perpendicular to the tattooed skin.
3. Overlapping should not exceed 10%.
4. Set the initial fluence parameter according to the skin test results
5. Trigger light pulses by pressing the footswitch and the handpiece trigger simultaneously.
6. 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.
7. 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.
8. 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.
9. After treatment it is recommended to cool the area immediately, apply antibacterial ointment and cover the treated tattoo area with sterile pad gauze.
10. Recommended treatment intervals: between eight and twelve weeks.

> ***Note***
>
> Note: The Q-Switched Nd:YAG handpiece can remove black, blue and green pigmented tattoos with the 1064nm wavelength and red pigments with the 532nm KTP wavelength.

I.4. Suggested Setup Parameters

Tattoo Color	*Handpiece*	*Wavelength / Spot Size (mm)*	*Fluence (mJ/P)*	*Frequency (Hz)*
Black	Q-Switched Nd:YAG	1064nm / 2, 3	500 – 1200	1, 2, 5
Green	Q-Switched Nd:YAG	1064nm / 2, 3	500 – 1200	1, 2, 5
Blue	Q-Switched Nd:YAG	1064nm / 2, 3	500 – 1200	1, 2, 5
Red	Q-Switched Nd:YAG	532nm / 2	500 – 1200	1, 2, 5

> ***Caution***
>
> Small spot size and high fluence often cause bleeding.

I.5. 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.

I.6. 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 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:

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APPENDIX J

Clinical Guide – Fine Lines, Wrinkles and Acne Scars

Chapter Contents:

J.1. Introduction

The **1320nm Long Pulse Nd:YAG** laser handpiece and its 6mm spot size tip are 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 is an increase in collagen fiber density, alignment, homogenization, and contraction in the papillary dermis.

Caution

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

J.2. Pre-Treatment

J.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.

J.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 or Tretinoin – Retin A in the previous 3-6 months for the treatment of acne or other dermatological conditions

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

J.2.3. Skin Test

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

Skin Type (Fitzpatrick I-VI)	*Handpiece*	*Pulse Width (msec)*	*Fluence (J/cm^2)*	*Waiting Period*
I – III	**Long Pulse Nd:YAG** (1320nm)	30, 40	25 - 30	5 – 7 days
	Long Pulse Nd:YAG (1320nm)	50	20 – 25	5 – 7 days
IV – VI	**Long Pulse Nd:YAG** (1320nm)	30, 40	15 – 20	5 – 7 days
	Long Pulse Nd:YAG (1320nm)	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.

J.3. Treatment

After the Nd:YAG 1320nm handpiece has been connected to the Harmony system and the treatment parameters (fluence and pulse width) have been selected according to the **Recommended Setup Parameters** table, 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 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 Nd:YAG 1320nm laser handpiece 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 handpiece 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 pulse width 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 N – Post-treatment Care).

J.4. Suggested Setup Parameters

Skin Type (Fitzpatrick I-VI)	*Handpiece*	*Number of Passes*	*Pulse Width (msec)*	*Fluence (J/cm^2)*
I – III	Long Pulse Nd:YAG (1320nm)	3 – 4	30, 40	Up to 40
IV – VI	Long Pulse Nd:YAG (1320nm)	3 – 4	40, 50	Up to 30

J.5. 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 return no sooner than three weeks after treatment.
- 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.
- 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:

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APPENDIX K

Clinical Guide – Skin Resurfacing

Chapter Contents:

K.1. Introduction

The Skin Resurfacing application of the Harmony system is performed using the **2940nm Er:YAG** (Erbium-Yttrium-Aluminum-Garnet) laser handpiece. The 2940nm Er:YAG laser is indicated for ablative resurfacing procedures including wrinkles and scar revision. The Er:YAG handpiece delivers precise tissue ablation utilizing either a 1mm or 4mm spot size with minimal collateral thermal damage of the superficial (water-containing) cutaneous tissue.

Caution

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

K.2. Pre-Treatment

K.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.

K.2.2. Contraindications

- Bacterial or viral infection
- Impaired immune system
- Patient has used Isotretinoin in the past 6-9 months
- Scleroderma
- Extensive radiation therapy
- Burns in the treatment area
- Poor healing in the treatment area
- 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).

K.2.3. Skin Test

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

Handpiece	*Mode*	*Ablation Depth (μm)*	*Energy (mJ/P)*	*Frequency (Hz)*	*Spot Size*
Er:YAG (2940nm)	Gentle Peel	10	---	5	4mm
Er:YAG (2940nm)	Skin Remodeling	50	---	5	4mm
Er:YAG (2940nm)	Surgi Light	---	500 mJ/P	5	1mm

K.3. Treatment

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.

K.3.1. Prior to Treatment Day

1. Pretreatment 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 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.

K.3.2. Treatment Day[1]

1. Clean the skin to remove perfume, cosmetics and sunscreens.
2. Anesthesia is required for most applications of the Er:YAG laser. Topical anesthesia (i.e. 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 handpiece 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.
6. Up to 20% overlapping is acceptable.
7. Trigger a laser pulse by pressing both the footswitch and handpiece 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.

K.4. Suggested Setup Parameters

Handpiece	*Mode*	*Ablation Depth (μm)*	*Energy (mJ/P)*	*Frequency (Hz)*	*Spot Size*
Er:YAG (2940nm)	Gentle Peel	1 – 20	---	5	4mm
Er:YAG (2940nm)	Skin Remodeling	10 – 350	---	5	4mm
Er:YAG (2940nm)	Surgi Light	---	100 – 1200 mJ/P	5	1mm

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

K.5. Post-Treatment Care & Follow-Up

Meticulous wound care (open or closed techniques) is crucial after skin resurfacing; below are 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:

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APPENDIX L

Clinical Guide – Pixel® 2940nm for Fractional Ablative Skin Resurfacing

Chapter Contents:

L.1. Introduction

Fractional Ablative Skin Resurfacing is performed with the Harmony system using the **Pixel 2940nm Er:YAG** laser handpiece. The Pixel 2940nm Er:YAG laser is indicated for ablative resurfacing procedures including fine lines, wrinkles and scar revision.

The mode of operation of the Pixel 2940nm Er:YAG handpiece 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 Pixel 2940nm Er:YAG handpiece can be used with two different matrix sizes - 7x7 matrix (49 pixels) or 9x9 matrix (81 pixels). The 7x7 matrix yields 28 mJ/Pixel and the 9x9 matrix yields 17 mJ/Pixel. Depending on the matrix used the Pixel 2940nm laser single shot produces high energy density and depth of penetration which can range between 50 -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. The mode of operation is set at a fixed repetition rate of 2 Hz and a pulse width of 2 msec.

Caution

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

L.2. Pre-Treatment

L.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.

L.2.2. Contraindications

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

- Burns in the treatment area
- Poor healing in the treatment area
- 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).

L.2.3. 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:

Pass Order	*Ablative Depth (μm)*	*Energy (mJ/P)*	*Pulse Width (msec)*	*Frequency (Hz)*	*Number of Passes*[1]	*Matrix*
1st	~25	400	2	2	1	9 x 9
2nd	~50	500	2	2	1	9 x 9
3rd	~75	600	2	2	1	9 x 9

L.3. Treatment Techniques

1. Anesthesia: there is no pain associated with this treatment, typically. Therefore, no dyes or topical anesthetics are needed. 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 7 x 7 tip for more aggressive and stacking treatments 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: 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.

[1] The number of passes depends on the desired level of penetration i.e., the greater the penetration the greater the number of passes.

6. Number of passes: 1 = conservative, 2 = moderate, 3 = aggressive. When doing multiple passes, it is advisable to change direction – i.e., do one pass horizontally and one pass vertically. **The number of passes depends on the desired level of penetration i.e., the greater the number of stacked passes, the greater the penetration.**
7. Stationary (stacked passes): the tip of the Pixel 2940nm is placed stationarily on the treatment area and repeated passes are employed.
8. Free-hand (random passes): the tip of the Pixel 2940nm is moved randomly on the treatment area and repeated passes are employed.
9. Stacking on problem areas: 2-3 pulses in the exactly same place.
10. Treatment areas: face, neck, chest, hands and full body.
11. 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.
12. 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.
13. 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 L.2.3.).
- **It is recommended 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.**

L.3.1. 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.

L.3.2. 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 Pixel 2940nm handpiece 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) – overlapping 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 handpiece simultaneously.
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.

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

> ***Caution***
>
> It is imperative that the Pixel tips and their protective shields remain clean and free of debris. The Pixel tips and the protective shields 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 Section 7.4.3 of this manual.

L.4. Suggested Setup Parameters

Matrix Size	*Pulse Width (msec)*	*Ablation Depth (μm)*	*Energy (mJ/P)*	*Frequency (Hz)*	*Spot Size (mm)*
9 x 9 7 x 7	2 2	50 – 75 75 – 100	500 – 600	2	11 x 11
9 x 9 7 x 7	2 2	75 – 100 100 – 125	600 – 800	2	11 x 11
9 x 9 7 x 7	2 2	100 – 125 125 – 150	800 – 1000	2	11 x 11

> ***Note***
>
> 7 x 7 matrix = 49 Pixels = 28 mJ/Pixel
> 9 x 9 matrix = 81 Pixels = 17 mJ/Pixel

L.5. 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:

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APPENDIX M

Clinical Guide – Pixel® 1320nm for Fine Lines, Wrinkles, Acne and Acne Scars

Chapter Contents:

M.1. Introduction

The **Pixel 1320nm Nd:YAG** laser handpiece 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 mode of operation of the Pixel 1320nm Nd:YAG handpiece is based on the principle of fractional photothermolysis where only a fraction of the skin mosaic is injured, leaving uninjured skin areas to facilitate rapid wound healing.

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

Caution

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

M.2. Pre-Treatment

M.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.

M.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.)
- 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)

M.3. Skin Test

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

Skin Type (Fitzpatrick I-VI)	*Pixel Dot*	*Pulse Width (msec)*	*Spot Size (mm)*	*Fluence (J/cm^2)*
I – II	9 x 9	30, 40	7 x 7	22 – 30
III	9 x 9	50	7 x 7	26 – 32
IV – V	9 x 9	30, 40	7 x 7	20 – 28
VI	9 x 9	50	7 x 7	22 – 26

M.4. Treatment

After the suitable settings and matrix size (7 x 7 or 9 x 9) have been selected and the Pixel 1320nm Nd:YAG handpiece is connected to the Harmony System, and the treatment parameters (fluence and pulse mode) were selected, treatment may begin. All of the following body areas are suitable for treatment: face, neck, chest or arm.

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 perfume, cosmetics and sunscreens.
2. Apply cooling on the intended treatment area for 5-10 seconds prior to lasing. Keep the cooling tool available during the full course of treatment.
3. Set the initial fluence parameter according to the skin test results.

4. Place the Pixel 1320nm Nd:YAG laser handpiece perpendicular to the skin and touch the skin with the tip. The tip should be slightly compressed against the target tissue.
5. To discharge the laser, it is necessary to press the footswitch and the handpiece trigger simultaneously.
6. Apply 3-4 passes 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. Visualize the treated area and check for adverse side effects.
8. If adverse skin effects occur (such as excessive reddening or swelling in the shape of the lightguide), you may either increase the pulse width or reduce the fluence by 20%. Recheck your setting against your skin test results and settings.
9. After treatment, it is recommended to cool the area immediately (see Appendix N – Post-treatment Care).

Caution

It is imperative that the Pixel tips and their protective shields remain clean and free of debris. The Pixel tips and the protective shields 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 Section 7.4.3 of this manual.

M.5. Suggested Setup Parameters

Skin Type (Fitzpatrick I-VI)	*Number of Passes*	*Fluence (J/cm^2)*	*Pulse Mode (msec)*	*Pixel Dot*
I – III	3 – 4	Up to 40	30, 40	7x7 or 9x9
IV – VI	3 – 4	Up to 30	40, 50	7x7 or 9x9

7 x 7 matrix = 49 pixels = 250mJ/Pixel
9 x 9 matrix = 81 pixels = 150mJ/Pixel

The 7 x 7 matrix should be used when greater penetration is required.

M.6. 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 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 partial affect, treatment should be continued and the patient should return after three weeks for examination and for additional treatment, if necessary.
- If no additional treatment is necessary, the patient should return for an additional examination two months later.
- If no change is noted, fluence should be increased by at least 10%.
- Intervals between treatments can be prolonged 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:

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APPENDIX N

Clinical Guide – Post-Treatment Care

Chapter Contents:

N.1. Immediate Post-Treatment Care

Cold (not frozen) packs should be applied immediately after treatment to cool the treatment site, reduce swelling and ease discomfort. Chemical cold packs are not recommended if their temperature is below 39°F/4°C.

N.2. Exposure to Sunlight

Patients should use a high sun-block (above 30 SPF) and protect the treated area from exposure to sunlight for at least one month following treatment. Tanning after treatment sessions may enhance melanin regeneration, which may result in hyper-pigmentation.

N.3. Cosmetics

In most treatment regimens, except for skin resurfacing or tattoo removal, makeup can be applied immediately after treatment. However, it is advised that patients notify their physician and stop wearing makeup if the treatment site scales or crusts.

N.4. Other Post-Treatment Recommendations

- Avoid exposing the treatment site to unsanitary conditions.
- Patients should be advised not to participate in rough sports or similar activities for several days following treatment (until the skin returns to its normal condition).
- Treatment areas should be kept clean and moist between treatments. A mild soap or non-irritating cleanser may be recommended.
- Care should be taken to prevent trauma to the treated area for the first four or five days following treatment: no hot baths, no aerobic exercise, massage, etc.

N.5. Treatment of Adverse Effects

If there are any adverse effects, treatment should be discontinued until the treatment site has healed.

N.6. Concluding Treatment

Determining when treatment should be concluded is left to the physician's discretion, or to the patient's satisfaction with the results of treatment.

N.7. Follow-up

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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APPENDIX P

Electromagnetic Compatibility

Chapter Contents:

P.1. Cable Lengths and Replacements

Table P-1: Harmony Cable Lengths and Possible Replacements

Description	*Part Number*	*Cable Length*	*Recommended Replacement*
AFT Acne Handpiece	AAIP18020304	2M	No replacement parts. Only cables manufactured by Alma Lasers may be used.
AFT Vascular Handpiece	AAIP18020303	2M	
AFT SR (Skin Rejuvenation) Handpiece	AAIP18020302	2M	
AFT HR (Hair Removal) Handpiece	AAIP18020301	2M	
ST (Skin Tightening Handpiece	AAIP03010501	2M	
UV (Ultraviolet) Handpiece	AAIP18020305	2M	
Q- Switched Nd:YAG 1064/ 532nm (Tattoo) Handpiece	AAIP24070501	2M	
Long Pulse Nd:YAG 1064nm (Deep Leg Veins) Handpiece	AAIP06040501	2M	
Long Pulse Nd:YAG 1320nm (Wrinkles) Handpiece	AAIP27020501	2M	
Er:YAG 2940nm (Skin Resurfacing) Handpiece	AAIP27020504	2M	
Pixel® 2940nm Er:YAG Handpiece	AAIP29050601	2M	
Pixel® 1320nm Nd:YAG Handpiece	AAIP27120502	2M	
Remote Interlock Connector Cable	Obtained locally	5M	2-wire 22 AWG single shielded control cable. Shield must be connected to the shielding pin of the system's interlock connector.
Footswitch	EGGG28100110		There is no electrical connection in this cable. May be replaced by PVC tube of appropriate diameter.

P.2. Electromagnetic Emission – Guidance and Manufacturer Declaration

The Harmony system is intended for use in the electromagnetic environment specific in Table P-2. The customer or the user of the Harmony system should assure that that it is used in such an environment.

Table P-2: Electromagnetic Emission

Emission Test	*Compliance*	*Electromagnetic Environment – Guidance*
RF Emissions CIRSPR 11	Group 1	The equipment uses RF energy only for its internal function. Therefore, its emissions are very low and not likely to cause any interference in nearby electronic equipment.
RF Emissions CIRSPR 11	Class A	The Harmony system is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emission IEC 61000-3-2	Class A	
Voltage Fluctuations / Flicker Emissions IEC 61000-3-3	Complies	

P.3. Electromagnetic Immunity – Guidance and Manufacturer Declaration

The Harmony system is intended for use in the electromagnetic environment specific in Table P-3. The customer or the user of the Harmony system should assure that that it is used in such an environment.

Table P-3: Electromagnetic Immunity

Immunity Test	*IEC 60601 Test Level*	*Compliance Level*	*Electromagnetic Environment – Guidance*
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV Contact ±8 kV Air ±6 kV Indirect	±2,3 and 6 kV Contact ±2,4 and 8 kV Air ±2,3 and 6 kV Indirect	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic materials, the relative humidity should be at least 30%.
Electrical fat transient/burst IEC 61000-4-4	±2 kV for Power Supply Lines ±1 kV for Input/Output lines	±2 kV ±1 kV Interlock port	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV Differential mode ±2 kV Common Mode	±1 kV Phase-Neutral ±2 kV Phase-Earth, Neutral-Earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% Ut (>95% dip in Ut) for 0.5 cycle 40% Ut (60% dip in Ut) for 5 cycles 30% Ut (70% dip in Ut) for 25 cycles <5% Ut (>95% dip in Ut) for 5 sec	<5% Ut (>95% dip in Ut) for 0.5 cycle 40% Ut (60% dip in Ut) for 5 cycles 30% Ut (70% dip in Ut) for 25 cycles <5% Ut (>95% dip in Ut) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Harmony requires continued operation during power mains interruption, it is recommended that the Harmony be powered from an uninterruptible power supply.
Power frequency magnetic field (50-60Hz) IEC 61000-4-8	3A/m	3A/m 50Hz	Power magnetic fields should be at a level characteristic with a typical commercial or hospital environment.

Table P-3: Electromagnetic Immunity (continued)

Immunity Test	*IEC 60601 Test Level*	*Compliance Level*	*Electromagnetic Environment – Guidance*
Conducted RF IEC 61000-4-6	3Vrms 150 kHz to 80 MHz	3V	Portable and mobile RF communication equipment should be used no closer to any part of the Harmony, including cables, than the recommended separation distance calculated from the equipment applicable to the frequency of the transmitter. **Recommended separation distance:** $d = 1{,}17\sqrt{P}$ $d = 1{,}17\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}23\sqrt{P}$ 800 MHz to 2,5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strength from fixed RF transmitters, as determined by an electromagnetic suite survey, should be less than the compliance level in each frequency range. Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m. Interference may occur in the vicinity of equipment with the following symbol: 
Radiated RF IEC 61000-4-3	3V/m 80 MHz to 2.5 GHz	3V/M	

Note

These guidelines may not apply to any situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

P.4. Recommended Separation Distances between Portable and Mobile RF Communication Equipment and the Harmony

The Harmony system is intended for use in an electromagnetic environment in which radiated disturbances are controlled. The customer or the user of the Harmony system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the Harmony system as recommended in Table P-4, according to the maximum output power of the communication equipment.

Table P-4: Recommended Separation Distances

Rated Maximum Output Power of transmitter W	***Separation Distance According to Frequency of Transmitter M***		
	150 KHz to 80 MHz $d = 1{,}17\sqrt{P}$	***80 MHz to 800 MHz*** $d = 1{,}17\sqrt{P}$	***80 MHz to 2.5 GHz*** $d = 2{,}23\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.71	3.71	7.37
100	11.7	11.7	23.3
For transmitters rated at maximum output power not listed above, the recommended separation distance (d) in meters can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter's manufacturer.			

Note

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.