Modular Laser and Pulsed-Light System for Treatment of Cutaneous Abnormalities

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INTRODUCTION

One of the most striking advances in procedural dermatology in the past five years has been the proliferation of energy delivery devices, namely lasers and broadband light-sources. Yet, although lasers have become an important part of dermatology, their narrow electromagnetic spectrum limits their ability to treat a wide range of skin-related abnormalities. In addition, lasers are expensive, occupy large floor space and can be expensive to maintain. In the early 1990's, the advent of intense pulsed light (IPL) devices signaled a revolutionary change in the treatment of cutaneous abnormalities. No longer was it compulsory to use a laser of a specific wavelength and pulse duration to treat a particular skin abnormality. Rather, a variety of skin abnormalitities could be effectively treated with an intense, pulsed, broad spectrum non-coherent flashlamp. Consequently, as indications broadened and clinical experience was gained, new technologies responded to meet market demand.

While the excitement of technological developments was certainly desirable, it became evident that stand-alone lasers or light-based systems were limited in their ability to cover the diverse therapeutic choices and clinical indications available to the clinician. Although individual laser and light-based systems provide much of the patient care in aesthetic medicine today, the market has been seeking a new, technological breakthrough that will give the practitioner and the patient the best therapeutic choices and, at the same time, the highest return on investment.

The Harmony system from Alma Lasers, Inc. (Ft. Lauderdale, Florida) is the first multi-technology system that encompasses pulsed light, laser, UVB, and near-infrared technologies on one platform. This unique capability enables greater versatility and flexibility in regard to therapeutic choices for the clinician and patient alike. The Harmony platform signals a breakthrough in the way laser and light-based procedural dermatology will be performed in the future, since it provides complimentary technologies to enable combined therapeutic regimes. The Harmony system, which is a compact yet powerful system, eliminates the need for dedicated application systems, which may be bulky, have articulated arms, delicate fiber optics and high maintenance costs.

ADVANCED FLUORESCENT TECHNOLOGY: PULSED LIGHT THE HARMONY WAY

The Harmony platform (Fig. 1) incorporates six different light-based handpieces – five operating in the visible / near-infrared spectrum and one in the ultraviolet (UVB). The optical window of each handpiece has been designed in accordance with specific clinical indications and their unique endogenous, biological chromophores (see Table 2):

- Psoriasis and vitiligo (300-380 nm; proteins and lipids)
- Acne clearance (420-950 nm; porphyrins, photosensitizers)
- Vascular and pigmented lesions (540-950 nm; oxy/deoxyhemoglobin, melanin)
- Skin rejuvenation (570-950 nm; melanin, hemoglobin)
- Hair removal (650-950 nm; melanin)
- Deep dermal heating (near-infrared; 780-1,000 nm; non-specific heating)

Fig. 1: The Harmony multi-application, multi-technology platform

Different elements found in the skin absorb different wavelengths. Melanin has a wide absorption spectrum that slowly decreases from the ultraviolet to the near infrared (300-1,000 nm). Oxyhelpglobin strongly absorbs light in the yellow portion of the electromagnetic spectrum (550-600 nm). Before reaching a vascular target however, optical energy must pass through the melanin-laden epidermis. The competition of epidermal melanin may cause fewer photons to reach the intended chromophore, reducing efficacy and increasing epidermal heating. Epidermal melanin content varies by at least an order of magnitude across the range of human skin colors from Fitzpatrick skin type I to VI. However, thermal diffusion not confined to the immediate targeted chromophore (melanin or oxyhemoglobin) can produce unwanted dermal and epidermal damage. In order to overcome this limitation, the Harmony light-energy optimization technology employs two precise, proprietary technologies for epidermal protection and reduction in discomfort: "Advanced Florescence Technology" and "Equally Distributed Fluence".

Advanced Fluorescence Technology (AFT™) is a breakthrough pulsed light technology which optimizes the light emitted from the lamp (see Fig 2). Each AFT handpiece has a special filtering system inside it which converts the lamp's clinically insignificant, shorter wavelength into a clinically optimal spectrum by selectively amplifying emission in the blue, red and green portions of the spectrum. This unique filtering enhances dermal penetration without using excessive energy levels, thus protecting the epidermis. This results in safer and more effective clinical results for hair removal, acne clearance, skin rejuvenation, and vascular and pigmented lesions treatment.

Equally Distributed Fluence (EDF) is an innovation in electrical engineering that enables emission of square-shaped pulses in order to achieve true long-pulse performance with moderate peak power throughout the entire pulse. One of the major limitations of today's pulsed light technology is the structure of a timed sequence of very short duration (2-5 ms), and very high peak power pulses. While this approach can supply sufficient average power to properly affect many cutaneous targets, it also increases the likelihood of adverse side effects such as blistering, pigment alteration, textural changes and even hypertropic scarring. By comparison, Harmony's equally distributed fluence profile delivers similar heating (because the average power is similar), but is safer to the skin because the peak power is lower. This innovative pulse output enables treatment of dark skin safely and ensures even greater safety of lighter skin tones. In fact, Harmony's equally distributed fluence profile is so effective, it eliminates the need for the complex integrated cooling systems that are generally required on other pulsed light systems. For greater patient comfort, an external cold-air device can be connected easily to any AFT handpiece. (Fig. 3).

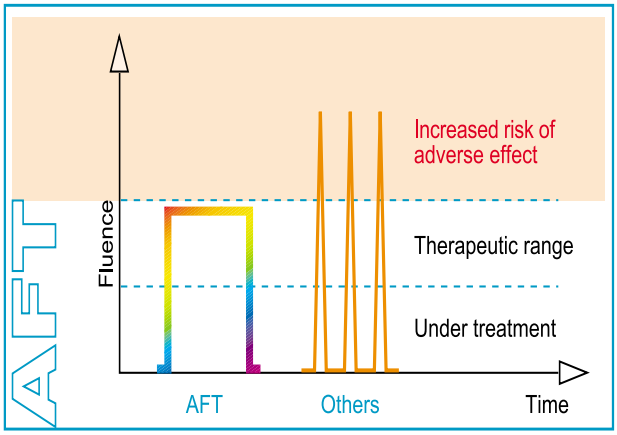


Fig. 2: Advantages of AFT pulsed light technology

Fig. 3: AFT hair removal handpiece with Zimmer connector

LASERS ON THE HARMONY PLATFORM

The Harmony platform also features four discrete laser modalities: (Fig. 4)

- A long pulse, near infrared neodymium-doped yttrium-aluminum-garnet (Nd:YAG) at 1064 nm
- A Q-Switched neodymium-doped yttrium-aluminum-garnet (Nd:YAG) at 1064 nm
- A long pulse neodymium-doped yttrium-aluminum-garnet (Nd:YAG) at 1320 nm
- An Erbium yttrium-aluminum-garnet (Er:YAG) at 2940 nm

Each handpiece is pistol shaped, lightweight (350-500 gr.) and ergonomically designed for accurate, fatigue-free procedures. The pulse widths and repetition rates (pulses per second) are pre-programmed according to the handpiece's intended application. Each laser cavity resides inside the handpiece and the beam is delivered via a glass light guide at the distal end, eliminating the

need for expensive, fragile fiber assemblies. The light-guide assemblies determine each spot size and ensure precise energy delivery to the treatment area.

Fig. 4: Versatile Harmony laser modules

MULTIPLE TECHNOLOGIES – ONE PLATFORM

The Harmony pulsed-light and laser system is compact (26" x 18" x 16") and transportable (88 lbs). The computer-controlled system has a short learning curve and minimal maintenance. Harmony comprises a main console, a universal connector that receives each laser or light-based AFT handpiece, and a footswitch. In addition, there is a simple array of controls and indicators, including a main-power switch, a key switch, an emergency shut-off knob, an emission indicator and an LCD display screen. The system's console resides on an ergonomically designed, easily movable cart.

Harmony operates with up to ten interchangeable handpieces representing five different technologies:

1. AFT (4 handpieces)
2. UVB (1 handpiece)
3. Nd:YAG (3 handpieces + 1 adaptor)
4. Near-infrared (1 handpiece)
5. Er:YAG (1 handpiece)

In all cases, the photon source resides inside each handpiece and has been pre-configured to a certain energy range according to its intended use. The operator can adjust the fluence within the pre-determined range, and in most cases, choose the pulse duration or repetition rate, Each AFT handpiece enables the operator to choose between three pulse widths: a narrow pulse width for light skin (Fitzpatrick I-II), a medium pulse width for medium skin (Fitzpatrick III) or a wide pulse width for dark skin (Fitzpatrick IV-VI). In the case of laser handpieces, the operator can choose between up to 3 different repetition rates. The current specifications for each handpiece are given in Table 1.

The universal connector enables simple swapping of handpieces whenever needed. The connector's socket is located on the right side of the front panel below the LCD display. Each handpiece is connected to the system console with a flexible umbilical cord containing wiring and cooling-water tubes. The system can only be operated when a given handpiece is connected to the main console, which can automatically sense and recognize which handpiece has been connected, as well as set up the necessary parameters, pulse widths and fluences for each handpiece's application.

Application	Technology	Wavelength (nm)	Pulse Width (msec)	Spot Size (mm)	Pulse Repetition Rate (Hz)	Energy Density
Pigment restoration	Pulsed UV	300-380	30, 40, 50	40x16	1/6	200-1000 mJ/cm^2
Acne clearing	AFT	420-950	30, 40, 50	40x16	1/3	5-20 J/cm^2
Vascular and pigmented lesions	AFT	540-950	10, 12, 15	40x16	1/3	5-20 J/cm^2
Skin rejuvenation	AFT	570-950	10, 12, 15	40x16	1/3	5-20 J/cm^2
Hair removal	AFT	650-950	30, 40, 50	40x16	1/3	5-20 J/cm^2
Deep dermal heating	Near Infrared	780-1000	5, 10, 15 Sec.	40x16	2	35-105 J/cm^2
Leg and reticular 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	5, 7, 10	400-1200 mJ/p
Tattoo removal	FD Q-Switched	532	20 nsec	2	5, 7, 10	400-1200 mJ/p
Wrinkles 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

Table 1 Specifications of technologies available on the Harmony platform

CLINICAL EFFICACY

Hair Removal The 650-950 nm (red-coded) AFT handpiece is indicated for the removal of unwanted hair for all skin phenotypes (I-VI), including permanent hair reduction. The hair removal process with AFT technology is based on selective photothermolysis, which combines selective absorption of the light energy by the melanin in the hair follicle with suitable pulse energy and widths (thermokinetic selectivity). The hair removal AFT handpiece provides equally distributed fluence in pulse durations of 30, 40, and 50 msec. In cases where prolonged coverage rate and higher incident light dose are needed, and in order to increase the threshold for possible epidermal damage, or reduce pain and distress, a Zimmer Cryo 5 cold air chiller can be connected in-line with the AFT handpiece using a special connector. With this method, both the quartz light guide and the epidermis are cooled in parallel.

Prior to treatment, the unwanted hair area should be trimmed, cleaned and dried. It is advisable to apply a thin layer of pre-chilled ultrasound get to the treatment site. The light guide should be positioned perpendicular to, and in contact with the skin's surface. The coverage rate can reach 128 cm^2 per minute (1/3 Hz with a spot size of 6.4 cm^2), with minimal overlapping. Pulse emission is manual, via the footswitch. Based on clinical results with ~ 500 patients in Europe and Israel, the average number of treatments required to achieve patient satisfaction (>loss, more than three months after the last treatment) in the axilla or bikini line was 4-6, with intervals of 6-8 weeks between treatments.

Acne Clearance The blue-coded AFT handpiece is indicated for the treatment of mild-to-moderate inflammatory acne vulgaris. The handpiece's 420-950 nm wavelengths permeate the tissue and affect the skin flora of the propionibacterium acnes (P. acnes bacteria). The high-intensity light triggers a photochemical reaction of the porphyrins produced by P. acnes, which produce free, singlet oxygen, that in turn, attacks and destroys the bacteria. The recommended treatment protocol consists of two passes on the acne-affected area with energy lebels between 5-7 J/cm^2 , twice a week for 4-5 weeks (monotherapy). In order to enhance the clinical outcome, 30% glycolic or salicylic acid peels are recommended after every other treatment (combination therapy). Based on clinical results, a significant reduction in acne symptoms occurs after the 4th treatment and persists 3-6 months after the last treatment.

Benign Vascular and Pigmented Lesions, including Skin Rejuvenation The green and yellow-coded AFT handpieces offer comprehensive and effective treatment for a wide range of vascular and pigmented lesions and cosmetic flaws. The green coded, 540-950 nm AFT handpiece is used to treat a broad range of vascular conditions including telangiectasias, port wine stains, hemangiomas, rosacea, angiomas, etc. These wavelengths are also ideal for the treatment of areas of the skin containing high concentrations of melanin, typically caused by sun exposure, aging or congenital factors. The lesions can be either raised or flat and are usually a cosmetic rather than a medical concern. However, suspicious epidermal-dermal keratoses should always be properly diagnosed prior to treatment.

The wavelengths delivered by the yellow-coded, 570-950 nm AFT handpiece are designed to be absorbed by both oxyhemolobin and melanin to treat different age-related and photo damged skin irregularities. Although the yellow and green-coded handpieces have similar optical windows, the difference allows a variation in threshold dose and depth of penetration in relation to their target chromophores, melanin and hemoglobin. This makes the yellow-coded 570-950 nm handpiece a powerful, yet gentler option for skin rejuvenation, especially for conditions that are mainly pigmented. The green-coded 540-950 nm handpiece delivers a more aggressive treatment, especially for conditions that have a vascular component. Clinical experience with the 540-950 nm handpiece shows >90% clearance rate after 1-2 treatments for facial telangiectasias (spider veins) 0.1-.05mm in diameter. Similarly, the 570-950 nm handpiece has shown significant clearance of pigmented lesions such as lentigos simplex and other cutaneous irregularities of photodamaged skin after 3-4 treatments.

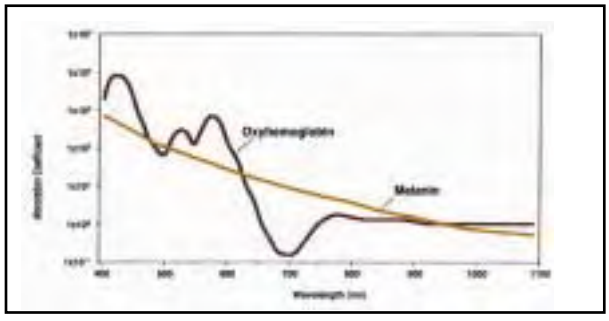
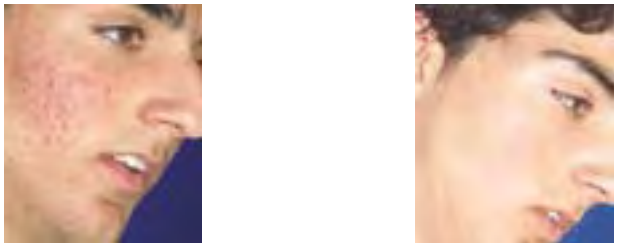


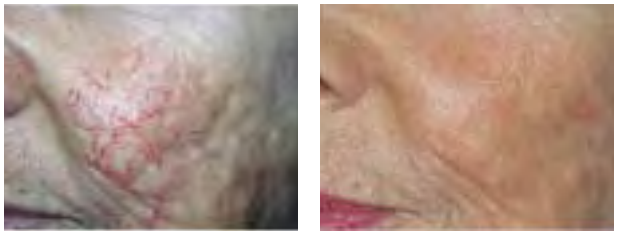
Fig. 5: Absorption spectra of oxyhemoglobin and melanin

Psoriasis and Vitiligo The purple-coded, 300-380 nm handpiece is indicated for the treatment of psoriasis, leukoderma (including vitiligo, or acquired leukoderma), atopice dermatitis (ezema), and seborrheic dermatitis. In human skin, UVB chromophores include DNA, proteins and lipids. However, unlike the thermal effects of other light-based treatments, the absorption of UVB light in the skin elicits non-thermal, photochemical reactions. These UVB photochemical reactions delete activated t-lympocytes and reduce epidermal hyperplasia (psoriasis). The targeted UVB treatment protocol consists

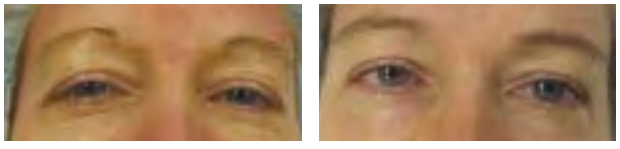
AFT 540 VP Module after 5 Tx. 14-18 J/cm²@10 msec. Photos Courtesy: BCK Patel M.D. FRCS, Professor Chief, Divison of Facial, Orbital and Oculoplastic Surgery, University of Utah, Salt Lake City, Utah, USA



AFT 420 Acne Module after 12 Tx.7 J/cm² @ 50 msec. Double pass 6 biweekly. Photos Courtesy: Prof. Arie Orenstien, M.D. Sheba Medical Center, Israel



AFT 540 VP Module after 2 Tx. 16-17 J/cm²@10 msec. Photos Courtesy: BCK Patel M.D. FRCS, Professor Chief, Divison of Facial, Orbital and Oculoplastic Surgery, University of Utah, Salt Lake City, Utah, USA



After Er YAG Module Tx 3Passes of Gentle Peel @20µm Skin Remodeling @ 200µm Gentle Peel @20µm. Photos Courtesy: Kyle Holmes, M.D., - Davis Laser Center, CA, USA

AFT 540 VP Module after 4 Tx. 14 J/cm²@12 msec. Photos Courtesy: Guilherme Olsen de Almeida, M.D. Hospital Sirio-Libanes, Sao Paulo, Brazil

ST Module after 2 Tx. 35 J/cm²@5 sec. With Zimmer cooling program 3 AFT 540 VP Module after 5 Tx. 14-18 J/cm²@10 msec Photos Courtesy: Ilan Karavani M.D. President of the Benelux Society for Dermatological Surgery, Antwerp, Belgium

of multiple (usually 8-10) biweekly treatments on the psoriatic or hypopigmented area. Earlier clinical experience indicates excellent dermatoses remission.

Tattoos The Q-Switched 1064nm Nd:YAG laser is ideal for the removal of professional, amateur, or traumatic tattoos containing black, blue or green pigment. The clinical experience with the handpiece shows excellent safety and efficacy, including dark skin (IV-VI) tattoos.

Leg Veins The long-pulse, 1064nm Nd:YAG laser is used for the treatment and elimination of deeper leg veins using a spot size of 6 mm and an energy density of 35-140 J/cm². The handpiece is indicated for the coagulation and hemostasis of vascular lesions and soft tissue, including treatment and clearance of superficial and deep temangiectasias (venulectasias) and reticular veins (0.1-4.0 mm diameter) of the leg. Combined therapies have become increasingly popular, as results have often eclipsed those of single modalities. Recent research supports applying a sequence of long and short wavelength pulses during varicose vein closure in order to achieve the most efficacious vessel heating. This approach is available on the Harmony platform with the

540-950 nm AFT handpiece (short) and the long-pulse, 1064 nm Nd:YAG handpiece.

Facial Wrinkles The 1320 nm Nd:YAG laser handpiece is indicated for the non-ablative treatment of facial wrinkles, improving the appearance of photo-aged skin. Such dermal remodeling is thought to occur through increased collagen I deposition with collagen reorganization into parallel arrays of compact fibrils. Patients are usually treated at 4-week intervals. Non-ablative or subsurface remodeling represents the newest approach to improving photo-damaged skin and is available as part of the Harmony platform.

Skin Tightening The near-infrared 780-1,000nm handpiece is intended for use for deep dermal heating and is indicated for the treatment of lax skin in areas such as face, neck and underarm. The spectrum provided targets the water and proteins within the dermis. The heat generated helps to stimulate new collagen and (in most cases) re-align the current structure. The mechanism supports also the treatment of cutaneous lesions such as striae, stretch marks - scar revision and reduce the presence of wrinkles. The handpiece can be used synergetically with AFT handpieces (420nm, 540nm, 570nm) and near infrared laser handpieces (1064, 1320nm) to treat acne and atrophic acne scars, where an increase in tissue temperature can improve clinical resolution. The treatment protocol includes 4-6 treatments spaced by 1 month intervals in between each session. No special pre or post treatment preparations are needed, thus reducing patient's downtime significantly.

Skin Resurfacing. The Erbium YAG laser handpiece is indicated for for minimally ablative resurfacing procedures including wrinkles and scar revision. The Er:YAG handpiece delivers precise tissue ablation utilizing either a 1mm or 4 mm spot size with minimal collateral thermal damage of the superficial (water-containing) cutaneous tissue. The Er:YAG 2940 nm handpiece features 3 different programs for free hand procedures: gentle peeling, skin remodeling and surgical incisions. The precise tissue ablation and small zone of residual thermal damage results in faster re-epitheliazation and improved morbidity.

CONCLUSIONS

The Harmony system is the first generation of modular, non-invasive and non-ablative, multi-application laser and light-based systems capable of treating, safely and effectively, a wide range of cutaneous abnormalities for all skin phenotypes. The Harmony system is superior with respect to its modularity, versatility, efficacy, size, electro-optical design and safety.

Module	Wavelength	Primary Biological End-Points	Acute Clinical End-Points
AFT blue-coded	420-950 nm	Porphyrin photoexcitation and singlet oxygen production	Mild erythema
AFT green-coded	540-950 nm	Erythrocytic coagulation, endothelial wall closure	Vessel discoloring, fading
AFT yellow-coded	570-950 nm	Melanosome cavitation and rupture	Mild erythema
AFT red-coded	650-950 nm	Bulge and bulb thermal damage	Perifollicular erythema
UVB purple-coded	300-380 nm	UVB-induced apoptosis of T-cells	Erythema within 24 hours
Near infrared	780-1000 nm	Lipids, connective tissue	Erythema, hyperemia
LP Nd:YAG	1064 nm	Water	Erythema, vessel stenosis
LP Nd:YAG	1320 nm	Water	Erythema
QS Nd:YAG	1064 nm	Pigment; ink	Cavitation, epidermal whitening
Er:YAG	2940 nm	Water	Evaporation, erythema

Table 2: Biological end-points of treatments with Harmony light and laser handpieces

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