Nonablative and Ablative Modular Laser and Pulsed-Light System for the 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, including lasers and light-source devices. 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 require a large amount of floor space and are expensive to maintain. The advent of intense pulsed light (IPL) devices in the early 1990s signaled a revolutionary change in the treatment of cutaneous abnormalities. With these devices, it was no longer necessary to use a laser of a specific wavelength and pulse duration to treat a particular skin abnormality. Rather, a variety of skin abnormalities can now be treated effectively using an intense, pulsed, broad-spectrum, non-coherent flash lamp. Consequently, with the growing indications for this type of treatment and increased clinical experience, new technologies began to develop to meet market demands.

While the excitement accompanying these new technological developments was certainly desirable, it soon became evident that in most cases up-to-the-minute stand-alone lasers or light-based systems had their own self-limitations in treating the diverse therapeutic choices and clinical indications available to the clinician. Although individual laser and light-based systems account for a large portion of patient care in the field of medical aesthetics today, the market is ready for a new, technological breakthrough that will offer both practitioners and patients the best therapeutic choices and at the same time the best return on investment.

The Lovely II™ system developed by Msq Ltd. is the world's first, non-ablative and ablative system that combines different lasers, UVB and pulsed-light source technologies all on a single platform. The system's unique capability allows versatility and flexibility with respect to therapeutic choices for clinician and patient alike, without the need to rely on individual and expensive laser or light-based systems.

The Lovely II platform signals a breakthrough in the future of procedural laser and light-based dermatology. No longer will an individual system need to be dedicated to each aesthetic application (currently ~10-15 such applications are performed routinely); no longer will doctors rely on over-sized systems that take up too much floor space; no longer will systems involve bulky articulated arms, delicate fiber optics, or high service costs. Instead, one powerful system will be able to address a large variety of clinical indications for single or combined therapeutic regimens.

SPECTRUM OF LIGHT

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

- Psoriasis and vitiligo (300-380nm; proteins and lipids)

- Acne clearance (420-950nm; porphyrins and photosensitizers)
- Vascular and pigmented lesions (540nm-950nm;oxy/deoxy-hemoglobin, melanin)
- Skin rejuvenation (570-950nm; melanin, hemoglobin)
- Hair removal (650-950nm; melanin)

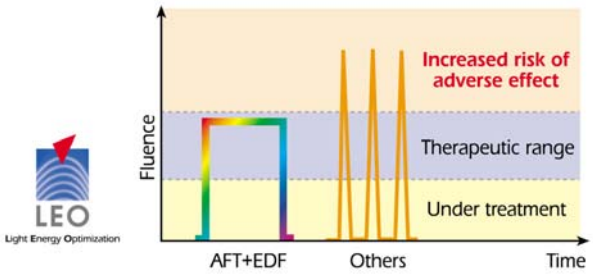
Different elements found in the skin absorb different wavelengths. Melanin has a wide absorption spectrum, which slowly decreases from ultraviolet to near infrared wavelengths (300-1000nm). Oxyhemoglobin strongly absorbs light in the yellow portion of the electromagnetic spectrum (550-600nm). Before reaching its final target however, optical energy should pass through the melanin-concentrated epidermis. The competition from epidermal melanin absorption may cause fewer photons to reach the intended chromophore, thus reducing efficacy. Epidermal melanin content varies by at least an order of magnitude across the range of human skin colors from "white" to "black" (Fitzpatrick skin types I-VI). However, thermal diffusion that is not confined to the immediate targeted chromophore (melanin or oxyhemoglobin) can produce unwanted dermal and epidermal damage. In order to overcome this limitation, the Lovely II employs proprietary light energy optimization **(LEO™)** technology.

LEO technology refines pulse width, pulse shape and fluence parameters within the most efficacious optical energy for wide range of indications by using two precision proprietary technologies:

Advance Fluorescence Technology **(AFT™)** is a special filtering system inside each AFT handpiece that converts the lamp's unused short wavelengths (below the cut-off filter) into a clinically optimal spectrum by selectively amplifying emissions in the blue, red and green portion of the spectrum. This unique filtering system enhances penetration without using excessive energy levels, thus protecting the epidermis, resulting in safer and more effective clinical outcomes for hair removal, acne clearance, skin rejuvenation, and vascular and pigmented lesions.

Equally Distributed Fluence **(EDF™)** represents 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 IPL technology is the unfortunate structure of time sequences of very short duration (2-5msec), yet 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, pigmented alteration, textural changes and even hypertrophic scarring.

Lovely's EDF, in contrast, delivers similar heat (because the average power is similar) but is safer to the skin because the peak power is lower. This innovation pulse output enables safe treatment of dark skin and ensures even greater safety with lighter skin tones. In fact, Lovely's EDF is so effective it obviates the need for the complex integrated cooling systems that are generally required with IPL systems.



LASER CONVERGENCE

The Lovely II™ platform features 4 discrete laser modalities (non-ablative and ablative): a long pulse, neodymium- doped yttrium- aluminum- garnet (Nd:YAG) at **1064nm** for the treatment of enlarged and deep leg veins and fine wrinkles; quality switched (QSW) Nd:YAG at **1064/532nm** with KTP for the treatment of dark and light ink tattoos and dermal pigmented lesions; **1320nm** Nd:YAG for the treatment of wrinkles and acne scars and; **2940nm** erbium YAG (Er:YAG) for skin resurfacing. Each handpiece is pistol-shaped and connected to the system console with an umbilical cord containing wiring and cooling water tubes. The pulse widths and repetition rates (pulse per second) are preprogrammed according to the handpiece's intended application.

Versatile light and laser technology *(from upper left): LEO (6.4cm^2); LP Nd:YAG(6mm), QSW Nd:YAG 1064/532nm with KTP(2mm) and Er:YAG(4mm) handpieces.*

BRINGING IT ALL TOGETHER

The Lovely pulsed-light and laser system is compact (65 x 45 x 40cm) and transportable (40kg without cart). The computer-controlled system requires just a short learning curve and minimal maintenance. The Lovely II system is comprised of a main console, a universal connector that receives each laser or light-based LEO handpiece, and a footswitch. In addition, it includes a simple array of controls and indicators, including a main-power switch. The Lovely II system is comprised of controls and indicators, including a main switch, a key switch, an emergency shut-off knob, a pulse laser and light emission indicator, and an LCD display screen. The system's console resides on an ergonomically designed, movable cart.

Lovely II operates with up to nine interchangeable handpieces representing three different technologies:

- LEO – 4
- UVB – 1
- Laser – 4

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 energy fluence within the pre-determined range, and in most cases choose the pulse duration or repetition rate. Each LEO handpiece enables the operator to choose between three pulse widths: narrow pulse width for light skin type (Fitzpatrick I-II); medium pulse width for darker skin type (Fitzpatrick III), or wide pulse width to be used on dark skin types (Fitzpatrick IV-VI). In the case of laser handpieces, the operator can choose between three different repletion rates.

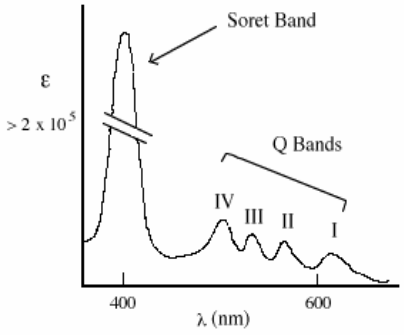
The universal connector enables simple swapping of handpieces whenever needed. The connector's socket is located on the right side of the front panel below the LCD display. Each handpiece is connected to the system console with a flexible umbilical cord containing wiring and cooling-water tubes. The 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 energy fluences for each handpiece's application.

CLINICAL EXCELLENCE

Hair removal: The 650-950nm (red-coded) AFT handpiece is indicated for the removal of unwanted hair for all skin phenotypes (I-VI) as well as for tanned skin, including permanent hair reduction. The hair removal process 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 stores optional pulse widths of 30, 40, and 50 msec at equally distributed fluences (EDF). In cases where prolonged coverage rate and higher incident light doses 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. In this way both the quartz light guide and the epidermis are cooled in parallel.

Prior to treatment, the area of the unwanted hair should be trimmed, cleaned and dried. It is advisable to apply a thin layer of pre-chilled ultrasound gel. The light guide should be positioned perpendicular to and in contact with the skin surface. The coverage rate can reach 128cm^2/minute (1/3 Hz with spot size of 6.4cm^2), with minimal overlapping. Pulse emission is manual through a footswitch. Based on clinical results from ~500 patients in Europe and Israel, the average number of treatments required to achieve patient satisfaction (>80% loss; more than 3 months after the last treatment) in the axilla and bikini line areas was 4-6, each separated by intervals of 6-8 weeks.

Acne Clearance: The blue-coded handpiece is indicated for the treatment of mild-to-moderate inflammatory acne vulgaris. The pulsed light handpiece's 420-950 nm wavelength permeates the tissue and affect the skin flora of the proprioni bacterium acne (P. acnes) through two major therapeutic wavelength: The blue light (420nm) in the soret band triggers a photochemical reaction of the porphyrins produced by the P. acnes, which produces free singlet oxygen that in turn attacks and destroys the P. acnes bacteria; (see Figure below) the red light (630nm) Q bands for deeper penetration and anti-inflammatory effect by influencing cytokinase release from macrophages. This combined antibacterial and anti-inflammatory action enhances acne symptoms regression. The recommended treatment protocol consists of two passes of 4-5 biweekly pulsed light treatments on the acne-affected area, with energy levels between 5-10 J/cm^2. In order to enhance clinical outcomes, 30% glycolic or salicylic acids peels are recommended every other treatment.



Typical UV-Visible absorption spectrum of a porphyrin

Benign vascular and pigmented lesions, including skin rejuvenation: The green and yellow LEO handpieces offer comprehensive and effective treatment for a wide range of vascular and pigmented lesions and cosmetic flaws. The 540-950nm LEO handpiece successfully treats a broad range of vascular conditions, including telangiectasias, port wine stains, hemangiomas, rosacea, and angiomas. These wavelengths are also ideal for treating areas of the skin with high concentrations of melanin, typically caused by sun exposure, aging or congenital factors. The wavelengths delivered by the yellow-coded, 570-950nm LEO™ handpiece are designed to be absorbed by both oxyhemoglobin and melanin to treat different age-related and photo-damaged skin irregularities. Although the pigmented and vascular lesions handpieces have similar optical windows, the differences between them allow for variation in threshold dose and depth of penetration in relation to their respective chromophores–melanin and hemoglobin. Clinical experience with the 540-950 nm handpiece shows a >90% clearance rate after 1-2 treatments for facial telangiectasiaa (spider veins) 0.1-0.5mm in diameter. Similarly, after 3-4 treatments, the 570-950 nm handpiece has demonstrated significant clearance of pigmented lesions, such as lentigos simplex and other cutaneous irregularities of photodamaged skin.

Handpiece (wavelength)	Fluence (J/cm^2)	Pulse width (msec)	Spot size (cm^2)
AC 420-950 nm	5-20	30,40,50	6.4
VL 540-950 nm	5-20	10,12,15	6.4
PL 570-950 nm	5-20	10,12,15	6.4
HR 650-950 nm	5-20	30,40,50	6.4
UVB 300-380 nm	0.1-0.8 mJ	30,40,50	6.4
LP 1064nm Nd:YAG Laser	30-200 30-600	10, 40, 60	2 & 6mm
QSW 1064/532nm Nd:YAG Laser	400-1000mJ/P	20nsec at 1 msec bursts	1 - 3 mm
LP 1320nm Nd:YAG Laser	35	up to 15	2 & 6mm
Er:YAG 2940nm Laser	1.2	0.5-1.0msec	4 mm

AC=acne clearance; **VL**=vascular lesion;**PL**=pigmented lesion; **HR**=hair removal;**LP**=long pulse; **QSW**=quality switched; **Er:YAG**=erbium YAG.

Psoriasis and vitiligo: The purple-coded 300-380nm handpiece is indicated for the treatment of psoriasis, leukoderma, including vitiligo (acquired leukoderma), atopic dermatitis (eczema), and seborrheic dermatitis. In human skin, UVB chromophores include DNA, proteins and lipids. However, unlike other light-based treatments that have thermal effects, the absorption of UVB light by the skin elicits non-thermal photochemical reactions. These UVB photochemical reactions delete activated T-lymphocytes and reduce epidermal hyperplasia (psoriasis). The targeted UVB treatment protocol consists of multiple (8-10) biweekly treatments on the psoriatic or hypopigmented area. Previous clinical experience indicates excellent plaque remission.

Tattoos: The Q-Switched 1064/532nm Nd:YAG laser with KTP adaptor is used for the removal of professional, amateur, traumatic tattoos containing black, blue, green or red pigment as well as benign pigmented lesions. Clinical experience with the QSW handpiece has demonstrated excellent safety and efficacy, including with dark skin (IV-VI) tattoos.

Leg Veins: The long-pulsed 1064 nm Nd:YAG laser is used for treating and eliminating deep leg vein lesions with a spot size of 2 and 6 mm and an energy density of 30-600 J/cm^2 and 30-200 J/cm^2, respectively. The handpiece is indicated for coagulation and hemostasis of vascular lesions and soft tissue, including treatment and clearance of superficial and deep telangiectasias (venulectasias) and reticular veins (0.1-4.0 mm diameter) of the leg. In addition, the handpiece is used for non-ablative treatment of facial wrinkles (skin rejuvenation), improving the appearance of photo-aged skin. Recent research supports the application of 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 Lovely II platform with the 540-950nm LEO handpiece (short) and the long-pulse, 1064nm Nd:YAG handpiece (long).

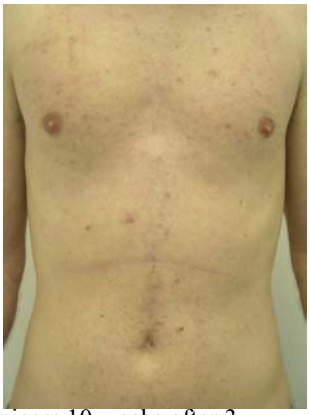
Facial Wrinkles: The 1064nm and 1320nm, long-pulse Nd:YAG is also indicated for non-ablative treatment of facial wrinkles (skin rejuvenation), improving the appearance of photo-aged skin and treating acne scars. Patients are usually treated at 4-week intervals.

Skin Resurfacing: The 2940nm Er:YAG laser handpiece is indicated for ablative resurfacing procedures including mild to moderate rhytides, elastosis, lentigens and atrophic scars (acne, surgical). The collimated Er:YAG handpiece offered precise tissue ablation (4 mm spot size; collimated) with minimal coagulative damage of the superficial (water-containing) cutaneous tissue. The max fluence is $1.2J/cm^2$ at 1000µsec, $0.8J/cm^2$ at 750 µsec and $0.6J/cm^2$ at 500 µsec pulse widths, respectively. Early clinical experience indicates excellent safety and efficacy results for senile keratosis and lentigo.

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

BEFORE & AFTER


Nose Telangiectasia: 540nm + LP 1064nm Nd:YAG Hand pieces: Immediately after 1 treatment.

Hair Removal: 650nm Hand piece; 10 weeks after 3 treatments.


Port Wine Stain: 540nm Handpiece; 4 weeks after 4 treatments.

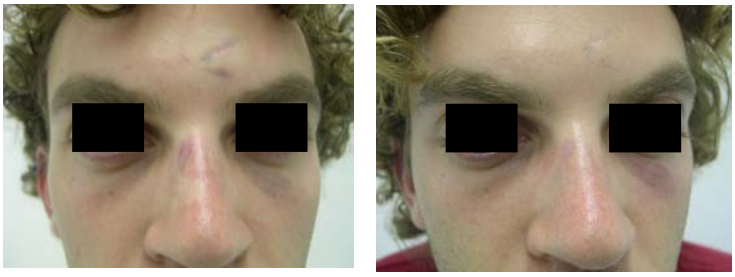

Solar Lentigos: 2940nm Er:YAG laser Handpiece; 4 weeks after 3 treatments.

LEO 650 nm Handpiece for hair removal with parallel air cooling connector (Zimmer).

BEFORE & AFTER

Professional Tattoo Removal: Q-Switched 1064/532nm Nd:YAG Handpiece; 4 weeks after 2 treatments.

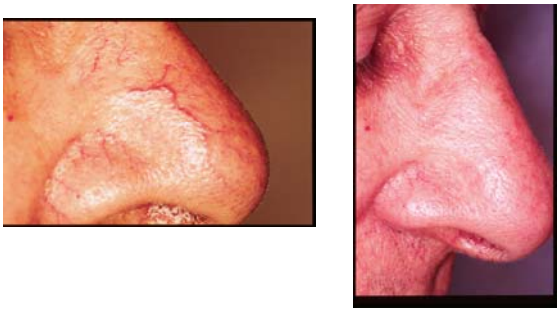
Long Pulse 1064nm Nd:YAG Laser Handpiece



Forehead and Nose Traumatic Tattoo: Nd:YAG Q-Switched 1064nm laser Handpiece; 4 weeks after 3 treatments.

Forehead Traumatic Tattoo: Nd:YAG Q-Switched 1064nm laser Handpiece; 4 weeks after 1 treatment.

Q-Switched 1064/532nm Nd:YAG Laser Handpiece with a quick-snap, disposable tip.



Nose Telangiectasias (Arborized): Long pulse Nd:YAG 1064nm laser Handpiece; 4 weeks after 3 treatments.