Modular Light-Based System with Light Energy Optimization (LEO™) Technology for the Treatment of Cosmetic and Aesthetic Skin Irregularities

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Abstract **Lovely I™** is a modular, light-based system featuring the latest generation of state-of-the-art nonablative technology for the cosmetic and aesthetic market. The ***Lovely I*** light energy optimization (LEO™) proprietary technology incorporates significant advancements with respect to electro-optical engineering and light-skin interaction design using AFT™ and EDF™. Advanced fluorescence technology (AFT), is based on a selective high intensity light source which converts UV and other short wavelengths into more usable spectra of blue, green and red visible light. In order to enhance skin-light interaction, the ***Lovely I*** system delivers lower peak power but at an equally distributed fluence (EDF) for pulse widths of up to 50 msec. With its modular and versatile design, the ***Lovely I*** platform offers four interchangeable handpieces for different clinical applications: removing unwanted hair (650-950 nm, red), clearing up acne (420-950 nm, blue), removing pigmented and vascular lesions (540-950 nm, green) and revitalizing the skin (570-950 nm, yellow indicator). For each handpiece, the energy density per cm^2 (fluence) ranges from 5 to 20 J/cm^2, with a spot size of 6.4 cm^2 (40 x 16 mm) and a pulse repetition rate of 1/3Hz. In order to achieve safe and most effective results, each handpiece has three distinct pulse width modes: narrow pulse width (short, 10-30 msec) for light skin (Fitzpatrick skin type I-II), medium pulse width (medium, 12-40 msec) for darker skin (Fitzpatrick skin type III-IV), and broad pulse width (long, 15-50 msec) to be used on dark skin (Fitzpatrick skin type V-VI). The ***Lovely I*** is compact (65 x 45 x 40 cm) and portable (25 Kg) and fits easily on a table top.

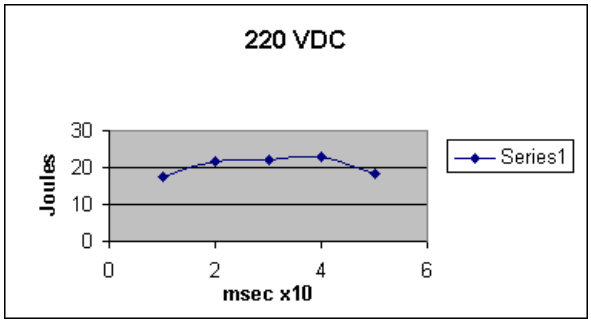
Introduction Over the past several years, demand for nonlaser, nonablative skin procedures with minimum down time has been growing steadily. At the same time, the spectrum of potential indications for cutaneous light-based technology has expanded significantly. Indeed, as more and more patients demand low-risk procedures with minimal down time, if any, the number of new light-based devices available on the market has grown. In some cases, these devices have begun to replace existing laser treatments for a wide range of nonablative cutaneous indications, such as unwanted hair, acne vulgaris, facial and leg telangiectasias, age spots, hypo-pigmentation, wrinkles, psoriasis and other skin irregularities. Contrary to the subjective limitations of a single laser in treating a wide range of skin abnormalities, the ***Lovely I*** light-based platform is capable of safely and effectively treating a wide range of cutaneous abnormalities for all skin phenotypes. Furthermore, the ***Lovely I*** light energy optimization (LEO™) proprietary technology incorporates significant advancements with respect to electro-optical engineering (AFT™) and light-skin interaction design (EDF™).

Advanced Technology

AFT, or light-induced fluorescence, is a patented technology comprised of a selective high-intensity light source which converts UV and other short wavelengths into more optimal spectra. Light 'rejected' by the AFT goes through a second 'filter' and is converted into usable visible spectra that enhance spectral emission. The enhanced peak wavelengths and their respective visible colors can be classified as follows: "A"=blue, for clearing up acne, "F"=green, for revitalizing the skin, and "T"=red, for hair removal.

The ***Lovely I*** system differs from most commercial Intense Pulsed Light (IPL) systems in three major areas: pulse length and pulse shape; AFT technology; and no cooling. In most IPL systems, the pulse shape usually consists of one to three pulses, where each pulse has a pulsed width of about 2-4 msec and a delay between pulses of around 5-50 msec. The peak power of each pulse is high, with each pulse in the sequence lower in energy than its predecessor, due to a drop in voltage on the capacitor bank.

In order to enhance skin-light interaction, the ***Lovely I*** system delivers lower peak power but at an equally distributed fluence (EDF) rate for pulse widths of up to 50 msec, achieved by a series of many pulses to compensate for the decrease in capacitor voltage. Consequently, the EDF's moderate peak power and its AFT handpiece preclude the need to use contact cooling (i.e., sapphire) as required in other IPL systems.



Equally Distributed Fluence (EDF)

Thus, the skin and its targeted chromophores, melanin and oxyhemoglobin, are exposed to an appropriate level of energy density, since the energy is delivered more effectively. In practice, as we learned more about the mechanism of hair removal, acne clearance, pigmented, vascular lesions and skin photo rejuvenation (photodamged and photoaged), it became evident that longer (pulse width) and moderate delivered energy parameters are both safer and efficacious when treating nonablative cutaneous abnormalities. These latest observations were applied to all AFT handpieces where a new electro-optical design and integration of pulse width sequences (train of many pulses) with a "gentler" peak power and EDF pulse shape and length and improved safety margin to both patient and clinician.

System Description The ***Lovely I*** system consists of the following major components: a main unit, four (optional) AFT handpieces and a footswitch. The system also comprises controls and indicators, including a main switch, a key switch, an emergency shut-off knob, a pulse light emission indicator and a control panel. The ***Lovely I*** can be operated using interchangeable AFT handpieces. The light source and the entire optic bench are included in each handpiece, so that the ***Lovely I*** system cannot be operated unless a handpiece is connected to it. The AFT handpiece houses mechanisms that generate and deliver the light pulse. The light passes through a filtered

aperture into a glass light guide located on the handpiece tip. The pulse widths of all ***Lovely I*** AFT handpieces are preset according to clinical application and patient skin type. Each handpiece gives the operator the option of three pulse width sequences:

narrow pulse width (short mode; 10-30 msec) for light skin, medium pulse width (medium mode; 12-40 msec) for darker skin, and long pulse width (long mode; 15-50 msec) to be used on the darkest skin types. Each handpiece has a fixed energy range between 5 to 20J/cm^2 that can be easily adjusted before and during treatment.

The AFT handpieces are marked with different colors to represent different applications: 420-950 nm (blue) for clearing up acne, 540-950 nm (green) for treating pigmented and vascular abnormalities, 570-950 nm (yellow) for revitalizing the skin, and 650-950 nm (red) for hair removal (Figure 2). The parameters of ***Lovely I*** are summarized in Table 1.

Parameters	**Characteristic**
Light Source	AFT
Wavelengths (nm)	420, 540, 570, 650 – 950
Pulse Method	Pulsed, single
Fluence (J/cm^2)	5-20
Pulse width (msec)	10,12,15, 20,30,40, 50
Spot size (mm)	16 x 40
Pulse/sec (Hz)	1/3

Clinical Applications The ***Lovely I*** system with its four AFT handpieces is indicated for the treatment of a wide range of cutaneous abnormalities. These include moderate inflammatory acne vulgaris (blue handpiece), benign pigmented epidermal lesions including dyschromia, hyper-pigmentation, melasma, ephelides (freckles), telangiectasias, spider veins, (green and yellow handpieces), and effective, stable, long-term or permanent removal or reduction of unwanted hair (red handpiece). Since treatment protocols vary for each of the above conditions, the practitioner must read the relevant protocol prior to administering the treatment. The following table outlines the operational mechanisms and targeted chromophores for each application.

	Operational Mechanism	**Chromophore**
HR	Photothermolysis	Melanin
AC	Photochemical	Porphyrin
PL	Photothermolysis	Melanin
VL	Photothermolysis	Hgb
SR	Photothermolysis	Hgb

HR=hair removal; **AC**=clearing up acne; **PL**=pigmented lesions; **VL**=vascular lesions; **SR**=skin revitalization.; Hgb=hemoglobin

Clinical Excellence Clinical experience with the ***Lovely I*** and its LEO™ proprietary technology demonstrates excellent clinical results with high degree of safety. For all clinical applications, including hair removal, acne, vascular/pigmented lesions and skin revitalization, patients tolerated the treatments with minimal discomfort or down time. Patient satisfaction was very high. In summary, the ***Lovely I*** modular working station has proven to be reliable, safe and effective in treating a wide range of aesthetic and cosmetic skin abnormalities for all skin phenotypes.

The following table and before and after photos summarizes clinical results of the ***Lovely I*** system applied to various cutaneous indications.

Application	HR	VL	PL	AC
Patients (n)	500	95	70	45
Skin type	II-V	III-IV	II-IV	II-IV
Gender (f/m)	370/130	72/23	58/12	27/18
N°. Treatments	3-7	3-5	2-4	8-10
Intervals (wks)	6-8	3-4	2-3	72 hrs
Energy (J/cm^2)	12-18	10-18	12-18	5-10
Clearance (%)	80-90	75-90	70-85	70-80
Adverse effects	minimal	minimal	minimal	minimal

HR = hair removal; **VL**=vascular lesions;
PL=pigmented lesions; **AC**=clearing up acne

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WPLOVI/Rev 02/AUG 04

Before and After

HR AFT 650nm Handpiece: Unwanted hair. Before (left) and after (right) 3 months after 5 treatment; skin type IV; 17J/cm^2; 50msec. **Courtesy of A. Orenstien, MD.**

VL AFT 540nm Handpiece: Solar lentigos. Before (left) and after (right) 2 treatments 3 months after; skin type III; 18J/cm^2; 15msec pulse width. **Courtesy of A. Orenstien, MD.**

VL AFT 540nm Handpiece: *Port Wine Stain*. Before (left) and after (right) 4 treatments; skin type IV; 18J/cm^2; 12msec pulse width. **Courtesy of A. Orenstien, MD.**