

Modular Light-Based System with Advanced Fluorescence Technology (AFT™) for the Treatment of Cosmetic and Aesthetic Skin Irregularities

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2004, Rev 01

Abstract: *Aria*™ is a modular, light-based system featuring the latest generation of state-of-the-art nonablative technology for the cosmetic and aesthetic market. Its proprietary technology, Advanced Fluorescence Technology (AFT™), is based upon a selective high intensity light source which converts UV and other short wavelengths into more usable spectra of blue, green and red visible light. The *Aria* platform represents a significant advancement with respect to electro-optical and light-skin interaction design. With its "all-in-one" design, the *Aria* 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 cm² (fluence) ranges from 5 to 20 J/cm², with a spot size of 6.4 cm² (40 x 16 mm) and a pulse repetition rate of 1/3Hz. In order to achieve safe and effective results, each handpiece emits three different 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 *Aria* is compact (26" x 18" x 16") and portable (55 lbs) 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,

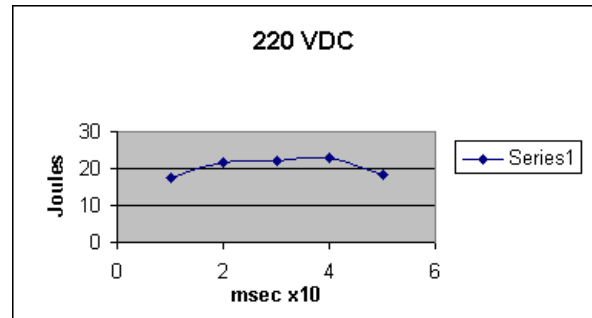
such as unwanted hair, acne vulgaris, facial and leg telangiectasias, age spots, hypopigmentation, wrinkles, psoriasis and other skin irregularities. Contrary to the subjective limitations of a single laser in treating a wide range of skin abnormalities, the *Aria* light-based platform is capable of safely and effectively treating a wide range of cutaneous abnormalities for all skin phenotypes. Furthermore, the *Aria* incorporates significant advancements with respect to electro-optical engineering and light-skin interaction design.

Advanced Fluorescence 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 *Aria* system differs from most commercial Intense Pulsed Light (IPL) systems in three major areas: (1) Pulse length and pulse shape, and (2) AFT technology; and (3) No cooling (3). 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. The *Aria* 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 negates 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 (photodamaged 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 improved safety margin to both patient and clinician.

System Description: The *Aria* 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 *Aria* can be operated using interchangeable AFT handpieces. The light source and the entire optic bench are included in each handpiece, so that the *Aria* 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 *Aria* AFT handpieces are preset according to clinical application and patient skin type. Each handpiece gives the operator the option of three pulse width sequences:



The *Aria* and AFT Handpiece

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 20 J/cm² 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 *Aria* 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 *Aria* 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 & Photothermolysis | Porphyrin; Hgb |
| 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 Results: Clinical trials of the *Aria* system are being conducted at several sites in Israel and Europe. The following table summarizes preliminary clinical results of the *Aria* system applied to various cutaneous indications. The clinical trials indicate that the *Aria* system, with its unique AFT and EDF technologies, is an effective, safe and excellent device. For all clinical applications, including hair removal, acne, vascular/pigmented lesions and skin revitalization, clinical efficacy proved to be excellent, and patients tolerated the treatments with minimal discomfort or down time. Patient satisfaction was very high. In summary, the *Aria* 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.

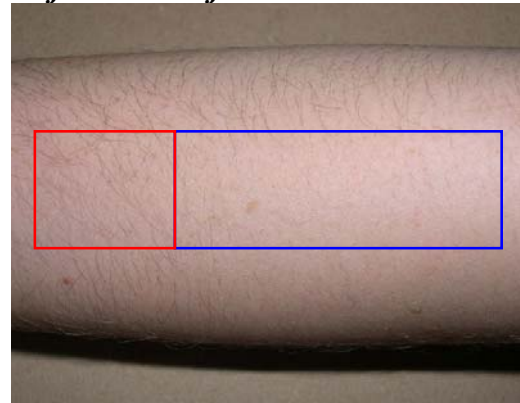
| Application | HR | VL | PL | AC |
|----------------------------------|---------|---------|--------|---------|
| Patients (n) | 400 | 50 | 40 | 20 |
| Skin type | II-V | III-IV | II-IV | II-IV |
| Gender (f/m) | 340/60 | 46/4 | 38/2 | 14/6 |
| N^o. Treatments | 3-7 | 3-5 | 2-4 | 8-10 |
| Intervals (wks) | 6-8 | 3-4 | 2-3 | 72 hrs |
| Energy (J/cm²) | 12-18 | 10-18 | 12-18 | 5-10 |
| Clearance (%) | 80-90 | 75-90 | 70-85 | 70-80 |
| Adverse effects | minimal | minimal | minima | minimal |

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

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Before and After



HR AFT 650nm Handpiece: Unwanted hair. Control (red) and 1 month after 1 treatment (blue); >80% cleared up; skin type II; 17J/cm²; 30msec pulse width. **Courtesy of A. Orenstien, MD.**



VL AFT 540nm Handpiece: Chin Telangiectasia. Before (left) and immediately after (right) a single treatment; >90% cleared up; skin type II; 18J/cm²; 10msec pulse width. **Courtesy of A. Orenstien, MD.**



VL AFT 540nm Handpiece: Age spot. Before (left) and 3 weeks after (right) a single treatment; >90% cleared up; skin type III; 18J/cm²; 12msec pulse width. **Courtesy of A. Orenstien, MD.**