



Alpha System single site Hair removal comparison study POWER-MOTION™ vs Stamping technique

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Ipha System Diode Laser ALD applicator treatment for Hair Removal comparison of single pass: Stamping vs. POWER-MOTION™ mode

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#### **Background:**

Laser hair removal is one of the most common noninvasive aesthetic procedures, with a total market value of \$609M in 2022 and forecast to reach almost \$2 Billion by 2030. Laser hair removal devices based on diode laser technology have long been recognized as one of the most popular and widespread solutions for clinics worldwide; among the devices based on diode laser technology, several different treatment techniques (modes). Until today, the treatment mode considered the most popular and influential was called SINGLE MODE (also known as "stamping"). However, FormaTK Systems Ltd recently introduced a new treatment mode named POWER-MOTION™ as part of the ALPHA and MAGMA Spark Pro Systems.

•*T*he main objective of this study is to compare the effectiveness, comfort, and treatment speed of SINGLE mode in compression with the newly introduced POWER-MOTION<sup>™</sup>.

•SINGLE MODE (also known as "stamping") is a treatment mode focused on delivering high fluence pulses at a lower rate pulse to maximize the damage to the hair follicle located at the area covered by the pulse.

•POWER-MOTION<sup>™</sup> is a new treatment mode focused on maximizing the rate of heat diffusion by using high fluences pulses delivered at a continuous movement over a set treatment area without repetition of pulses over the place. There are two critical anatomical targets for the inactivation of hair follicles: 1) stem cells in a "bulge" of the outer root sheath about 1 mm below the skin surface and 2) the dermal papilla located at the deepest part of the follicle, which varies with hair growth cycle. Laser hair removal technology is based on the absorption of energy by the melanin (endogenous chromophore) in the hair follicle in the anagen phase and the diffusion of the energy into the dermal papillae and surrounding stem cells. Laser hair removal is achieved through follicular unit destruction in anagen phase based on the extended selective photothermolysis concept of heat diffusion1-7. Hence, by increasing the heat diffusion rate, as seen in the thermal images of the new POWER-MOTION™ mode (Figure 1), we expect to see improved end-clinical treatment compared to Single-mode (Figure 2).



Figure 1 - ALD applicator POWER-MOTION™ hair removal mode 15cmX10cm box thermal photos taken with FLIR N95 camera. Courtesy of Formatk System Ltd.



Figure 2 - ALD applicator Single-mode ("stamping") hair removal mode 15cmX10cm box thermal photos taken with FLIR N95 camera. Courtesy of Formatk System Ltd.

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#### **Study Objectives**

The study's objective was to evaluate the safety, effectiveness, comfort, and time of treatment of Single-mode in compression with the newly introduced POWER-MOTION™ mode in a split-body approach while using the Alpha System (FS90000) manufactured by FormaTK Systems Ltd. (Israel).

#### Methods:

The study used the ALPHA System (FS90000) with the ALD 808nm (Advanced Laser Diode) applicator (FS70001) manufactured by FormaTK Systems Ltd (Israel). This was a single-center, prospective study involving five (5) healthy patients treating eight (8) anatomical areas who requested to remove unwanted body hair with a diode laser. Based on the Fitzpatrick skin scale, the study included patients with skin types ranging between 1-3. To minimize individual variants, each anatomical location was treated using a split-body approach where one side was treated using POWER-MOTION<sup>™</sup> mode while the other side was treated using SINGLE mode. For example, in treating female full legs, the right leg was treated using POWER-MOTION<sup>™</sup> while the left leg was treated using SINGLE mode. Additionally, identical treatment energy (J/cm2) parameters were used in both treatment modes. Treatment parameters were determined based on each patient's skin type, where energy ranged between 16J/cm2 and 22J/cm2. Pulse duration was fixed at 40ms for all patients in both treatment modes. Before treatment, each patient signed informed consent. Each patient received at least four treatments with a 5- to 6-week interval between each session and a one-month follow-up after the last treatment. Photographic assessments were performed using both Canon camera DSLR EOS mark 2 with 24-70mm lens.

# Following the study objectives, the data in this study was evaluated using the following:

**1.Treatment effectiveness:** comparing the clinical results based on visual hair follicle count in each treatment and overall, 4-point scoring scale in both modes.

**2.Treatment comfort:** compare the VAS score (pain sensitivity) in both modes.

**3.Total treatment time:** compare the complication time per anatomical area in both modes. Safety: to monitor any side effects during hair removal treatment by both modes.

Clinical photographic images obtained before and after were evaluated by Dr. Nadav Pam, Forma-TK Systems Ltd Clinical director.

Exclusion criteria:

1. Drug-induced photosensitivity (e.g., Isotretinoin, Retin A) 2.Pregnancy and breastfeeding 3.Cancer 4.Epilepsy 5.Severe diseases 6.Auto-immune diseases 7. Frequent episodes of labial Herpes Simplex in case of face Treatment 8.Immunosuppressive pharmacologic therapy 9.Any other medical condition considered contraindicated to the treatment by the investigator 10.Any other hair removal treatments such as drugs, topical creams/lotions, or other phototherapy medical devices.

#### **Results:**

The patients included five patients with one or more anatomical areas that were treated.

Their ages ranged from 37 to 62 years (with a mean age of 35). Regarding skin prototyping for patients according to Fitzpatrick classification:





# Faster treatment duration



#### **Discussion:**

In this prospective study enrolled five healthy patients, three males and two females, ages 37-62 years old (mean 42 years old). Eight anatomical zones were treated, and seven were treated side by side on the same patient with both modalities. In contrast, one anatomical zone was treated only with POWER-MOTION<sup>™</sup> mode in the abdominal area periumbilical area).

•Greater Aesthetic results: All five patients achieved a 4-point scale the highest result of significant improvement after POWER-MOTION<sup>™</sup> mode hair removal while 4 out of 5 patients had only a marked improvement after the treatment with Single-mode hair removal.
•More Hair Removal: POWER-MOTION<sup>™</sup> mode treatments have delivered an average of 14% (ranges (6%-21%) more hair follicle clearance than Stamping mode.

POWER-MOTION<sup>™</sup> mode succeeded more in the overall visual count of hair follicle reduction using the same energy and treatment numbers in similar anatomical zones.

•Better Comfort: Based on user-reported data, participants reported POWER-MOTION™ treatment as 51% more comfortable than Single treatment mode. VAS score is the Visual Analogue Scale, which measures pain intensity ranges from 1-10. VAS Score in PowerMotion mode was 2.5 (ranges 2-3), compared to the Single-mode VAS score of 4.25 (ranges 3-5).

### Better Aesthetic Results





Better Comfort



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•Faster treatment: When treating identical anatomical zones, treatments performed with POWER-MOTION™ mode were up to 3x faster than treatments performed using a single mode. The study combined smaller and larger body target areas for a well-rounded picture of treatment times.

•Side effects: In this study, we had one patient with Fitzpatrick skin type one, two with Fitzpatrick skin type two, and two with Fitzpatrick skin type three. No significant side effects were recorded in patients treated with POWER-MOTION<sup>™</sup> mode except for transient pain/local perifollicular erythema at treated areas, which resolved within an hour from the end of the treatment.

#### In conclusion:

In this prospective study, we have demonstrated that using the traditional SINGLE mode and the new POWER-MOTION<sup>™</sup> mode, with the Alpha systems (FS90000) and the ALD 808nm Applicator (FS70001), are both safe and effective methods for hair removal treatment.

The results of the study support that using the ALD laser diode applicator while using POWER-MOTION<sup>™</sup> mode is superior to Single-mode in achieving more follicular unit destruction in the anagen phase, better aesthetic results, more comfort for the patient, faster treatment time, and no significant side effects.

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#### Back





Hair Count: 30

PW single Mode Hair Count: Hair Count: 7 12

Patient History: Never received hair removal in the past.

Time interval between treatments: 6-8 weeks. Gender: Male.

Pulse width: 40ms

Fluence: 20J/Cm2

#### Abdomen



Hair Count: 15



Hair Count: 2

Patient History: Never received hair removal in the past.

Time interval between treatments: 6-8 weeks. Gender: Female.

Pulse width: 40ms Fluence: 22J/Cm2

#### Back





Hair Count: 30

Left side РМ Hair Count: 6

**Right Side** single Mode Hair Count: 11

Patient History: Received in the past other hair removal modalities.

Time interval between treatments: 6-8 weeks. Gender: Male.

Pulse width: 40ms

Fluence: 22J/Cm2

#### **Armpits**





Hair Count: 32





Hair Count: 32

Hair Count: 5

Patient History: Never received hair removal in the past.

Time interval between treatments: 6-8 weeks. Gender: Female.

Pulse width: 40ms

Fluence: 22J/Cm2

#### **Shoulders**





Hair Count: 26

Hair Count: 7

Hair Count: 12

#### **Right Shoulder - Single Mode**



S MA After 5 Tx

Hair Count: 26

Patient History: Never received hair removal in the past.

Time interval between treatments: 6-8 weeks. Gender: Male.

Pulse width: 40ms

Fluence: 20J/Cm2

#### Shoulders



Hair Count: 36



Hair Count: 10







Hair Count: 26

Patient History: Never received hair removal in the past.

Time interval between treatments: 6-8 weeks. Gender: Male.

Pulse width: 40ms

Fluence: 20J/Cm2

#### **Sheens**



Before Hair Count: 22

After 6 Tx Hair Count: 5

Patient History: Never received hair removal in the past.

Time interval between treatments: 6-8 weeks. Gender: Female.

Pulse width: 40ms

Fluence: 20J/Cm2

#### <u>Armpits</u>





Hair Count: 6

Hair Count: 9



Hair Count: 36

Patient History: Never received hair removal in the past.

Time interval between treatments: 6-8 weeks. Gender: Female.

Pulse width: 40ms

Fluence: 16J/Cm2





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