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The Alpha System
One-year follow-up hair removal study using ALD laser Diode, split body comparison, 3rd generation POWER-MOTION™ mode Vs. 1st generation Stamping mode

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The Alpha System Diode Laser ALD applicator treatment for Hair Removal comparison of split body comparison, 3rd generation POWER-MOTION™ mode Vs. 1st generation Stamping mode.

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2. ***Veronika Yehoshua Certified cosmetologist. Clinical Instructor***

1,2FormaTK Systems Ltd Medical equipment manufacturer in Tirat Carmel - Yozma St 3, Tirat Carmel– Clinical Department.

Background:

Laser hair removal is a widely performed non-invasive aesthetic procedure to reduce unwanted hair growth. This procedure uses concentrated light beams to target hair follicles, effectively damaging them and inhibiting future hair growth. As of the latest data, the market for laser hair removal is growing. In 2022, the global market value for laser hair removal was estimated to be approximately USD 1.3 billion. The market is expected to continue expanding, driven by increasing demand for non-invasive cosmetic procedures, advancements in laser technology, and growing awareness of the benefits of laser hair removal. Projections indicate that the market could reach around USD 3.9 billion by 2030, with a compound annual growth rate (CAGR) of about 15%. This growth is supported by rising disposable incomes, expanding aesthetic clinics, and the growing trend of maintaining a well-groomed appearance. 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 hair removal treatment modes considered the most popular and influential were the first-generation "Single" mode (also known as “stamping”) and the second-generation "Fast" Mode (also known as "In-motion"). However, Forma-TK Systems Ltd recently introduced a new hair removal treatment mode named 3rd generation POWER-MOTION™ as part of the ALPHA and MAGMA Spark Pro Systems

1. The main objective of this study is to compare the effectiveness, comfort, and treatment speed of 1st generation SINGLE mode in compression with the newly introduced 3rd generation POWER-MOTION™ hair removal mode.

2. The first-generation SINGLE MODE (also known as “stamping”) is a traditional hair removal treatment mode that delivers high-fluence pulses at a lower rate to maximize the damage to the hair follicle in the area covered by the pulse.

3. 3rd generation POWER-MOTION™ is a new hair removal treatment mode focused on maximizing the rate of heat diffusion by using high-fluence pulses delivered in continuous movement over a set treatment area without repetition of pulses throughout the treatment area

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 power 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 ALD laser Diode 808m, new 3rd generation POWER-MOTION™ hair removal mode (Figure 1), we expect to see improved end-clinical treatment compared to Single-mode (Figure 2).

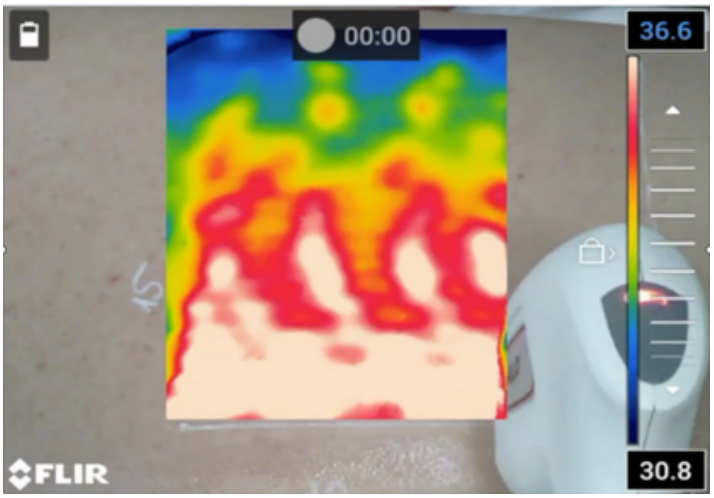


Figure 1 - ALD applicator 3rd generation POWER-MOTION™ hair removal mode 15cmX10cm box thermal photos taken with FLIR N95 camera. Courtesy of Formatk System Ltd.

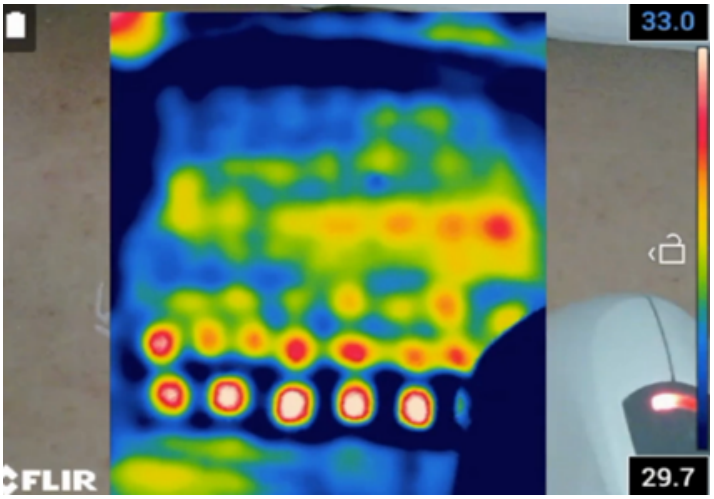


Figure 2 - ALD applicator 1st generation Single-mode ("stamping") hair removal mode 15cmX10cm box thermal photos taken with FLIR N95 camera. Courtesy of Formatk System Ltd.

Study Objectives

The study's objective was to follow up for one year on the patient results after completing at least eight treatments of hair removal with the 1st generation Single-mode ALD diode laser in comparison with 3rd generation POWER-MOTION™ ALD diode laser in a split-body approach while using the Alpha System (FS-90000) manufactured by Forma-TK Systems Ltd. (Israel).

Methods:

·This was a single-center, prospective study involving three healthy patients treating five anatomical areas who requested to remove unwanted body hair with the Alpha system using ALD 808nm diode laser.

·Based on the Fitzpatrick skin scale and using the milo (a melanin meter), the study included healthy adult patients with skin types ranging from 1 to 3.

·The study follow-up time was one year. Each patient received at least eight treatments, with a 5 to 6-week interval between each session and a one-month follow-up after the last treatment.

·The study used the ALPHA System (FS-90000) with the ALD 808nm (Advanced Laser Diode) applicator (FS-70001) manufactured by Forma-TK Systems Ltd (Israel).

·To minimize individual variants, each anatomical location was treated using a split-body approach where one side was treated using 3rd generation POWER-MOTION™ hair removal mode. In contrast, the other side was treated using 1st generation SINGLE stamping hair removal mode. For example, in treating female full legs, the right leg was treated using 3rd generation POWER-MOTION™ while the left leg was treated using 1st generation 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.

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: 1. compare the VAS score (pain sensitivity) in both modes.

3. Total treatment time: compare the complication time per anatomical area in both modes.

4. 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

Inclusion criteria:

• Healthy adult subjects aged between 18 and 70 who have unwanted body hair
• Fitzpatrick skin types 1-3
• All participants agree to refrain from exposure to the sun or solarium (solar lamps) during the whole study period.
• All patients will be informed about the study objectives, terms of treatments, eventual benefits, and adverse effects and will express their willingness to participate deliberately in this clinical study.
• All participants signed an appropriate informed consent form.

Exclusion criteria:

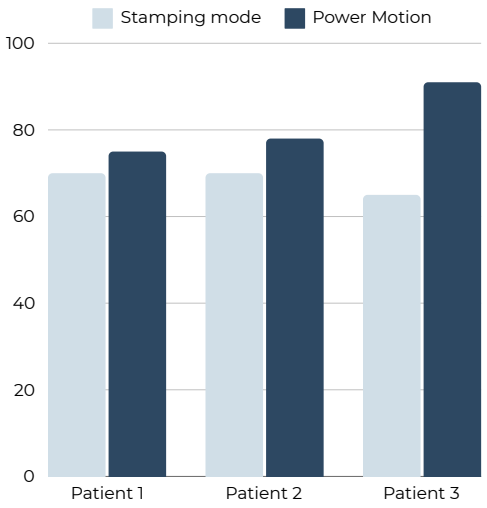
1. Fitzpatrick skin type 4-6
2. Drug-induced photosensitivity (e.g., Isotretinoin, Retin A
3. Pregnancy and breastfeedin
4. Cancer
5. Epilepsy
6. Severe diseases
7. Auto-immune diseases
8. Frequent episodes of labial Herpes Simplex in case of face Treatment
9. Immunosuppressive pharmacologic therapy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

Results:

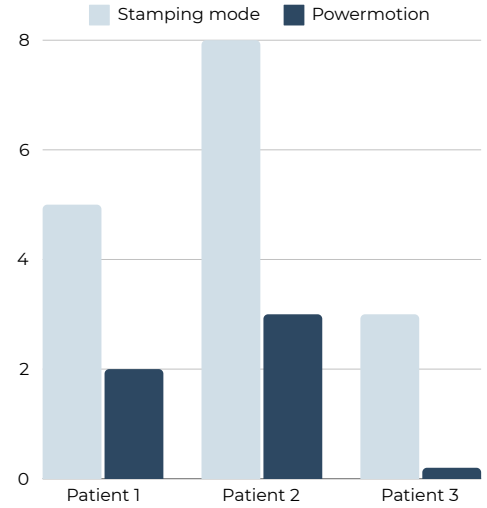
• In this study, we had one patient with Fitzpatrick skin type one and two with Fitzpatrick skin type three.
• The patients included three (1 male and two females) with five anatomical zones treated who completed a one-year follow-up and at least eight treatments, with a 5-6-week interval between each session and a one-month follow-up after the last treatment.
• Their ages ranged from 37 to 42 years (with a mean age of 39).

Number	Age	Gender	Fitzpatrick skin type
Patient 1	37	Male	3
Patient 2	42	Female	3
Patient 3	39	Female	1

Over all Improvement Rated

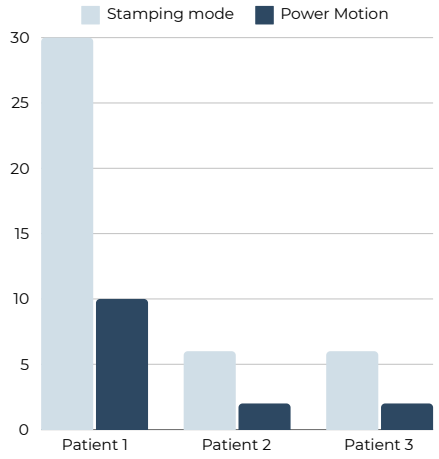


Number of Hair Follicle Count at the last meeting

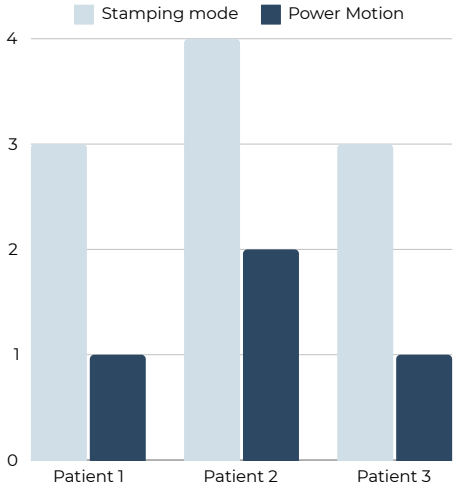


Study data:

Treatment Time (min)



VAS Score (pain level during treatment



Discussion:

· Greater Aesthetic results: All three patients achieved in all five treatment zones on a 4-point scale, with the highest significant improvement on the side treated with ALD laser diode 3rd generation POWER-MOTION™ mode hair removal while the zones treated side with 1st generation reached only 2 out of 4 to significant improvement.

·More Hair Removal: 3rd Generation POWER-MOTION™ mode treatments have delivered an average of 12% (ranges (8%-16%) more hair follicle clearance than 1st generation Stamping mode at the same treatment parameters in similar anatomical zones (split body).

· Less treatments with 3rd Generation:

3rd Generation POWER-MOTION™ had achieved better clinical results in fewer treatments than 1st generation Single stamping with longer-lasting effects at follow-up treatments.

Per each treatment, beginning from the very first treatment, POWER-MOTION™ had removed more terminal hair follicles in the anagen stage.

· Better Comfort: The VAS score is the Visual Analogue Scale, which measures pain intensity from 1 to 10. The VAS Score in PowerMotion mode was 1.2 (ranges 1-2), compared to the Single-mode VAS score of 3.2 (range 3-4).

· Faster treatment: When treating identical anatomical zones, treatments performed with 3rd generation POWER-MOTION™ mode were up to 3x faster than treatments performed using 1st generation Single mode. (This study combined smaller and larger body target areas for a well-rounded picture of treatment times.)

·Side effects: No significant side effects were recorded in patients treated with either 1st generation single stamping or 3rd generation POWER-MOTION™ 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 one-year follow-up study, we have demonstrated that using the Alpha systems (FS-90000) with ALD (Advance laser Diode) 808nm Applicator (FS-70001), both with the 1st generation single mode and the new 3rd generation POWER-MOTION™ hair removal mode, are safe and effective methods for hair removal treatment for skin types 1 -3.

The study's results support that using the ALD laser diode applicator in 3rd generation POWER-MOTION™ mode is superior to 1st generation Single-mode in achieving:

*More destruction of the terminal hair follicles in the anagen phase in treatment zones.
*Significant overall aesthetic improvement.
*Better comfort for the patient during treatment.
*Faster treatment time.
*Fewer treatments are required to reach the desired endpoint.
*Without significant side effects.

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Back: patient 1

Hair Count: 23

Left side
PW
Hair Count:
2

Right Side
Stamping mode
Hair Count:
5

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

Pulse width: 40ms **Fluence:** 20J/Cm2

Abdomen: patient 3 - only PowerMotion

Hair Count: 15

Hair Count: 0

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

Pulse width: 40ms **Fluence:** 22J/Cm2

Legs: patient 3

Left Legs - PowerMotion

Hair Count: 22

Hair Count: 0

Right Legs - Single Mode

Hair Count: 22

Hair Count: 3

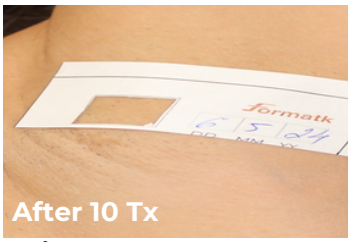
Time interval between treatments: 6-8 weeks.
Gender: Female.

Pulse width: 40ms **Fluence:** 20J/Cm2

Armpits: patient 2

Left Armpit - PowerMotion

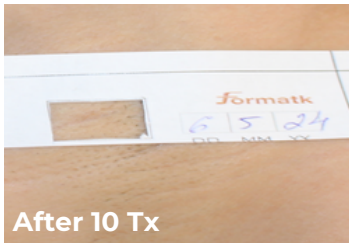
Hair Count: 36



Hair Count: 3

Right Armpit - Single Mode

Hair Count: 36



Hair Count: 8

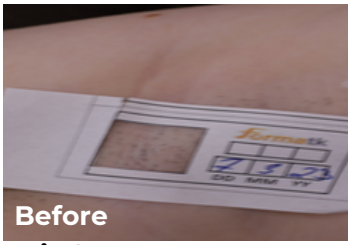
Time interval between treatments: 6-8 weeks.

Gender: Female.

Pulse width: 40ms **Fluence:** 16J/Cm2

Armpits: patient 3

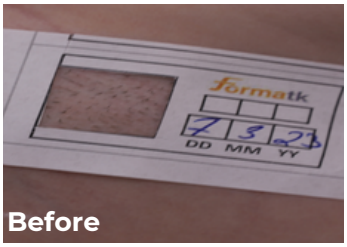
Left Armpit - PowerMotion



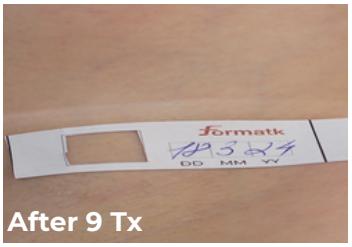
Hair Count: 32

Hair Count: 0

Right Armpit - Single Mode



Hair Count: 32



Hair Count: 3

Time interval between treatments: 6-8 weeks.

Gender: Female.

Pulse width: 40ms **Fluence:** 20J/Cm2

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