

EVO Clinical Guide

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1. Introduction

The Lasermach™ diode laser therapy system is indicated for the removal of unwanted hair and to effect stable long-term or permanent hair reduction.

Warning

The appropriate protective eyewear should be worn by both the operator and the patient when using this module.

2. Operation

The system may be operated under 2 different modes: Professional and Aesthetics. In the Aesthetics mode, the parameters (pulse width, fluence etc) has been fixed in system, choose the skin type and position (body – arms, chest, back, legs, axilla, bikini line etc) , follow the system process.

In the professional mode, all the parameters can be adjusted according to the operator's estimation. The operator need to evaluate the clinical endpoint of the therapy. The applicator screen of Lasermach™ Pro display the total energy of current treatment, that can help to verify the endpoint.

Chapter 3 and 5 suggest the skin test and treatment deliver energy.

Note

The operator start Aesthetics mode first.

3. Pre-Treatment

3.1. Patient Evaluation

Before hair removal procedures, the patient should be evaluated/documentated for the presence of conditions that may cause hypertrichosis :

- Hormonal
- Familial
- Drugs (i.e., corticosteroids, hormones, immunosuppressive self or spousal use of minoxidil)
- Tumor
- Photosensitizing drugs (gold therapy, etc)

3.2. Contraindications

- History of local or recurrent skin infection
 - Pregnancy (including IVF procedure)
 - History of herpes simplex, especially perioral
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- History of genital herpes, important when treating the pubic or bikini area
- History of keloids/hypertrophic scarring
- Implantable device (pacemaker, AICD etc.)
- Isotretinoin – past and present
- Epilepsy
- History of Koebnerizing skin disorders, such as vitiligo and psoriasis
- Previous treatment modalities – method, frequency and date of last treatment, as well as response
- Recent (less than 2 weeks) suntan or exposure to a tanning bed
- Tattoos or nevi present on the treated area.
- Past or ongoing medical condition (diabetes, epilepsy, high or low blood pressure, or others)

3.3. Skin Test

Always perform a skin test on the intended treatment area before the first treatment session. Professional mode, according to the parameters in Table 1.

The treatment parameters for hair removal depend on the skin type, hair color, hair type, and the density and depth of the hair. Initially, shave the treatment site to eliminate any surface hair that could interfere with the treatment. Mark a grid (using a red pen) on an area of 10x10 cm (100cm²). Treat with the **In-Motion (Professional mode ,Frequency sets 2Hz** technique within each treatment grid.

Aesthetics mode, choose one skin type, operation starts from the lowest energy.

Table 1: Professional mode Skin Test Parameters*

Skin Type (Fitzpatrick I-VI)	Fluence (J/cm²)	Total Energy [kJ] *
I	7	2.0
II	7	2.0
III	7	2.0
IV	5	2.0
V	4	2.0

4. Treatment

Treatment can begin after the applicator is connected and the treatment parameter (fluence) is selected according to Table 2.

1. Shave the treatment site to eliminate any surface hair that could interfere with the treatment; remove any hairs debris with adhesive tape.

2. Clean the skin to remove perfumes, cosmetics and sunscreens.
 3. Mark a grid (using a red pen) on an area of treatment of about 10x10 cm. Mark additional adjacent grids as needed based on the area size.
 4. Provide appropriate eye protection (OD>5) goggles for the patient and the staff in the enclosed treatment room.
 5. Apply a thin layer (usually 1-2mm thick) of refrigerated (43-50°F / 6-10°C) cooling ultrasonic gel to the treatment site. The gel will provide: a) a thermal sink for the absorbed and reflected energy, thus providing some cooling to the skin itself; b) comfort to the patient during treatment and; c) friction reduction/lubrication during the **In-Motion** technique.
 6. Set the initial fluence and pulse width (same fluence, more pulse width less pain) parameter according to the skin test results and the size of the treatment area.
 7. In most cases, pulse width should be set for more than 60 ms for large areas; the less than 50ms should be selected for very small areas on the face, like the upper lip and chin (using the **Stationary (frequency sets 1Hz)** technique rather than the **In-Motion (frequency sets more than 2 Hz)** technique).
 8. Place the applicator perpendicular to the skin and touch the skin to ensure a good seal. Do not apply excessive pressure on the skin.
 9. Treat within the grid area in an **In-Motion** technique according to the recommended parameters and passes.
 10. **Professional mode, In-Motion Technique:**
 - Move the applicator on the surface of the skin and, only when the crystal is in full contact and "in-motion", then trigger the footswitch.
 - Move the applicator in continuous linear or circular motions, to cover the entire grid area. This repeated pattern may last several minutes, depending on the recommended total energy (**kJ**) you wish to deliver in the grid area.
 - After completing a single interval, raise the applicator from the skin, re-position at the point where you began treatment in this grid and repeat another interval on the entire grid area.
 - After completing the recommended number of intervals, move to the contra-lateral side and repeat as above.
 - Check skin reaction; if the skin reaction is not apparent - repeat. Repeat until clinical end points are visible.
 - Observe for erythema or perifollicular erythema/edema (i.e., end points).
 - Examine the treatment site for change of skin color and morphological changes around the follicles (erythema/edema). The smell of burnt hair may sometimes be detected, although its absence does not necessarily indicate that the present parameters are ineffective.
 11. **Stationary(1Hz) Technique:** apply ultrasonic gel to the treatment area.
 - In the **Stationary** technique, use the frequency of 1 Hz; up to 10% overlapping is an acceptable tolerance.
 12. Set the fluence parameters according to the parameters indicated in Table 1 (provided that the patient has tolerated the skin test).
 13. Trigger a pulse by continuously pressing the button for the entire time interval; the applicator will stop emitting light automatically unless interrupted by the operator (releasing the footswitch). In order to continue, the button must be pressed again. The aesthetics mode will record the current process until the entire process finished, enough energy has been delivered to the area.
 - Check skin reaction; if the skin reaction is not apparent - repeat. Repeat until clinical end points are visible.
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 - Examine the treatment site for change of skin color and morphological changes around the follicles (erythema/edema). The smell of burnt hair may sometimes be detected, although its absence does not necessarily indicate that the present parameters are ineffective.
14. If there are no noticeable changes on the skin (Skin Types IV-VI) or near the hair follicles, do not repeat.
 15. If adverse skin effects occur (such as excessive reddening) before the desired follicular response is achieved, adjust the treatment parameters to reduce the aggressiveness of the treatment.
 16. After treatment it is recommended to cool the area immediately with cold (water based) cloth or gauze, and apply Aloe Vera gel.

5. Suggested Setup Parameters

The treatment parameters for hair removal depend on the skin type, hair color, hair type and the density & depth of the hair. Treat using with the **In-Motion** technique within each treatment grid.

Table 2: Professional mode Suggested Setup Parameters

Skin Type (Fitzpatrick I-VI)	Fluence (J/cm²)	Total Energy [kJ] *
I	7	3.2
II	7	3.2
III	7	3.2
IV	3	3.2
V	2	2.8
VI	1	2.8

(*) The total energy is adjusted for a 100cm² area at 3Hz frequency. In the Stationary mode (1Hz) multiple

pulses/repetitions should be employed until clinical end-points are visible.

Table 3: Suggested Total Energy (kJ) delivered per Anatomic Area

Anatomic Area	Number of Grids	Total Energy (kJ)
Chest & Abdomen	12	38 – 40
Axilla	1	3.2
Back	12	38 – 40
Bikini	1	3.2
Upper Arm	6	18 – 20
Lower Arm	5	16 – 18
Upper Leg	10	32 – 34
Lower Leg	8	25 – 27

6. Follow-Up

Measures presented below are only the manufacturer's recommendations for follow-up. They may serve as a basis for defining your treatment regimen.

7. Patients should return for examination of the treatment site between 4 to 6 weeks after treatment and for additional treatment, if necessary.
 8. If no additional treatment is necessary, the patient should return for an additional re-examination three to four months later, or when any new hair has grown in the treatment area.
 9. If there has been partial hair clearance, treatment should be continued and the patient should return between 4 to 6 weeks for examination and for additional treatment, if necessary.
 10. If no change is noted, treatment parameters and the amount of total energy (i.e. number of passes) should be changed. With multiple treatments, increase the time intervals between treatment sessions (after the second one), to allow any new hair to grow in the treatment area. New growth will vary based on the body area (growth cycle) and on the individual patient (gender, hormonal problems, etc.).
 11. Patients should be instructed to avoid sun exposure for several days after treatment.
 12. Treatment intervals: treatment is reapplied (assuring there have been no adverse reactions) at 4-8 week intervals.
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