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Dye-VL Pro Module— Vascular & Pigmented Lesions

The information contained in this manual is for use as a reference only and does not serve as a substitute for reading the Operator Manual included with your system.

ALMA LASERS, INC.
485 Half Day Road
Suite 100
Buffalo Grove, IL 60089
1-25-13

Phone: 224-377-2000
Fax: 224-377-2050

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Introduction

The **Dye-VL Pro** module has a high-power targeted phototherapy module for non-invasive treatment of vascular and pigmented lesions. The Dye-VL Pro module allows treatment of a broad spectrum of vascular imperfections be selectively targeting oxyhemoglobin, deoxyhemoglobin and melanin.

The Dye-VL Pro module may be operated in two separate modes: **Dye-VL** (default mode) and **Dye-SVL**.

The Dye-VL Pro module has a light green identification section.

Dye-VL Pro Module Specifications

- **Light Source:** Pulsed light with AFT and EDF
- **Spectrum:** 500 – 600nm
- **Treatment Area (spot size):** 3 cm^2

Dye-VL Pro Clinical Guide for Vascular & Pigmented Lesions

The treatment of vascular lesions with the Harmony^{XL} system can be performed using the Dye-VL Pro 500-600nm (light green color code) module.

The Dye-VL Pro module is indicated for vascular lesions and pigmented lesions.

Warning

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

Indications for Use

The Advanced Fluorescence Technology (AFT) 500-600 nm Dye-VL Pro module is indicated for:

- The treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma and ephelides (freckles), lentigines, nevi, melasma, and café-au-lait macules.
- The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations.
- Use on skin types (Fitzpatrick I-IV)

Contraindications

- Tanned skin (active tan) through sun exposure or tanning bed use in the previous 30 days
- Hypopigmentation (Vitiligo)
- Any inflammatory skin condition e.g. eczema, active herpes simplex, etc. at the treatment site
- Skin cancer or any other cancer and/or any cancer drug therapy (such as Ducabaxine, Fluorouracil, Methotrexate, etc.)
- History of keloid scarring
- Epilepsy
- St. John's Wort (herbal remedy) for depression in the past 3 months (because of increased photosensitivity)
- Isotretinoin – Roaccutane in the previous 3-6 months
- Tretinoin – Retin A in the last 2 weeks
- Pregnancy; until menstruation returns and end of breast feeding
- Diabetes (because of increased possible photosensitivity and poor wound healing)

Pre-Treatment

Assessing the Condition

The treatment parameters for any given skin condition depend on the skin type and the lesion type, depth and density.

In principle, treat the larger vessels first and only after they are closed proceed to treat the smaller vessels. This avoids refilling the small vessels by the larger, intact feeders.

Preparing the Lesion for Treatment

If the lesion is smaller than the light guide's footprint, use the template provided by Alma Lasers to protect collateral tissue surrounding the lesion. To use the template, select a suitable pre-cut hole so that only the lesion area is fully exposed to the margin. Place the template on the treatment site and cover it with a thin layer of gel (underneath and on top of the template) before treatment.

Skin Test

Always perform a skin test on the intended treatment area before the first treatment session with the cooling mode On and according to the following parameters:

Vascular & Pigmented Lesions Skin Test Parameters

Fitzpatrick Skin Type	Module	Pulse Width (msec)	Fluence (J/cm^2)	Waiting Period
I – II	Dye-VL Pro 500-600nm (light green color code)	10, 12	10 – 12	30 min
III	Dye-VL Pro 500-600nm (light green color code)	10,12	8 – 10	30 min
IV	Dye-VL Pro 500-600nm (light green color code)	12, 15	5– 6	24 – 48 hours*

(*) It is imperative to wait 48 hours

Treatment Vascular Lesions

- The Dye-VL Pro cooled module will treat vessels up to < 1mm.
- Treatment is applied perpendicular to the target and a second pass is usually recommended once appropriate safe settings are found. Do not stack pulses.
- Treatment can begin after the module has been connected to the Harmony^{XL} system and the treatment parameters (fluence and timer interval) are selected according to the Skin Test parameters.
- Clean the skin to remove perfumes, cosmetics and sunscreens.
- Apply a thin layer (usually 1mm thick and 2mm for darker skin types) of refrigerated cooling gel to the treatment site. This aids skin cooling during the pulse sequence and improves coupling of the light into the skin and additional comfort to the customer during treatment.
- Cooling means, such as small ice packs or forced cold air/Zimmer are recommended (i.e., post-treatment).

Caution

Do not treat a vascular lesion through a tattoo or a pigmented lesion that has not been examined by a physician. Any hair covering a vascular lesion must be removed before treatment.

- Place the module's lightguide perpendicular to the skin and touch the gel with the lightguide. Do not apply pressure (the lightguide should gently touch the skin).
- It is best not to overlap treatment spots by more than 10%, but if overlapping does occur wait at least one minute between pulses on the same spot.
- Set the initial fluence parameter according to the skin test results.
- Trigger a light pulse by pressing the footswitch.
- Wipe off the gel and examine carefully. Remember: darker skin types take longer to respond than lighter skin types. The desired effect is darkening of the vessel due to blood coagulation and erythema and/or edema along the vessel, indicating a stimulated immune reaction, without changes in the surrounding epidermis.
- If, along with a good response in the vessel, adverse skin effects occur (such as excessive reddening or swelling in the shape of the lightguide), reduce the fluence by 10-20%.
- If the skin shows no adverse effects and changes observed in the vessel are unsatisfactory you should increase the fluence by 10-20% and test again.
- To maximize the cooling/coupling properties of the applied gel, make sure to apply the gel immediately before treatment. After treatment, remove the gel from the treated areas. Do not reuse gel.
- After treatment, it is recommended to cool the area immediately.

Treatment Pigmented Lesions

Treatment can begin after the module has been connected to the Harmony^{XL} system and the treatment parameters (fluence and pulse width) are selected according to the Skin Test parameters .

- Clean the skin to remove perfumes, cosmetics and sunscreens.
- Apply a thin layer (usually 1mm thick and 2mm for darker skin types) of refrigerated cooling gel to the treatment site. This aids skin cooling during the pulse sequence and improves coupling of the light into the skin and additional comfort to the customer during treatment.
- Other cooling means, such as small ice packs or forced cold air/Zimmer are also recommended (i.e., post-treatment).
- Place the module's lightguide perpendicular to the skin and touch the gel with the lightguide. Do not apply pressure (the lightguide should gently touch the skin).
- It is best not to overlap treatment sites by more than 10%, but if overlapping does occur wait at least one minute between pulses over the same spot.
- Set the initial fluence parameter according to the skin test results.
- Trigger a light pulse by pressing the footswitch.
- Wipe off the gel and diagnose carefully. Remember: darker skin types take longer to respond than lighter skin types. The desired “positive” effect is to observe a change in lesion color (graying or darkening for brown pigment) or morphological changes (superficial texture change to the lesion), without changes in the surrounding epidermis.
- If, along with a positive response in the lesions, adverse skin effects occur (such as excessive reddening or swelling in the shape of the lightguide), you should reduce the fluence by 10-20%.
- If the skin shows no adverse effects and changes observed in the lesions are unsatisfactory, you should increase the fluence by 10-20%.
- To maximize the cooling/coupling properties of the applied gel, make sure to apply the gel immediately before each pass/treatment. After treatment, remove the gel from treated areas. Do not reuse gel.
- After treatment, it is recommended to cool the area immediately.

Suggested Setup Parameters for Vascular & Pigmented Lesions

Fitzpatrick Skin Type	Module	Pulse Width (msec)	Fluence (J/ cm²)	Waiting Period
I – II	**Dye-VL Pro 500-600nm** *(light green color code)*	10, 12	10 – 13	Spot test 30 min
III	**Dye-VL Pro 500-600nm** *(light green color code)*	10,12	8-11	Spot test 30 min.
IV	***Dye-VL Pro 500-600nm*** *(light green color code)*	12, 15	5-7	Spot test 24 – 48 hrs.

Ultrasonic gel must be applied to the skin.

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.

- Within three weeks after the treatment customers should return for examination of the treatment site and for additional treatment, if necessary.
- If no additional treatment is necessary, customers should return for an additional examination two months later.
- In case of a partial clearance of the lesion, the treatment should be continued using the same parameters and the customer should return for examination and for additional treatment, if necessary after three weeks.
- If no change in the lesion is noted, fluence should be increased by at least 10%.
- Intervals between treatments can be increased in successive treatments.
- Treatment is complete when satisfactory results are obtained.
- Patients should be instructed to avoid sun exposure after and in between treatments.

Dye-SVL Mode Clinical Guide (In-Motion & Stationary)

The Skin Rejuvenation application of the Harmony^{XL} system is performed using the Dye-VL Pro (green color code) module in Dye-SVL mode.

Warning

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

Indications for Use

The Dye-VL Pro module in Dye-SVL mode is indicated for:

- The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations.
- Use on skin types (Fitzpatrick I-IV).

Contraindications

- Hypopigmentation (Vitiligo)
- Any inflammatory skin condition e.g. eczema, active herpes simplex, etc. at the treatment site
- Skin cancer or any other cancer and/or any cancer drug therapy (such as Ducabaxine, Fluorouracil, Methotrexate, etc.)
- History of keloid scarring
- Epilepsy
- St. John's Wort (herbal remedy) for depression in the past 3 months (because of increased photo sensitivity)
- Isotretinoin – Roaccutane in the previous 3-6 months
- Retin A in the last 2 weeks
- Pregnancy (including IVF)
- Diabetes

Dye SVL Module Operation

The Dye-VL Pro module in Dye-SVL mode may be operated with 3 different time intervals: 1, 3 and 30 seconds.

In the 1-second and 3-second intervals, the module is used employing the **Stationary** technique. In the 30-second interval, the module is used employing the **In-Motion** technique. The 1-second and 3-second intervals are used on small areas where you want to treat localized, small, superficial pigmented or vascular lesions (i.e., back of the hand or upper lip). The 30-second interval is used on large areas where you want to treat signs of photodamage/ photoaging irregularities (dyschromia, lentigines, freckles, etc.).

The Dye-VL Pro module incorporates thermo-electric coupling (TEC) technology; the module can be operated in two conditions: **Cooling On** (default) and **Off**.

The module spot size is 3cm^2 and the pulse repetition rate is fixed at 3 Hz. The total energy delivered at any given time interval is expressed in kilojoules (**kJ**).

Ultrasonic gel should be used in both **Stationary** and **In-Motion** techniques.

Pre-Treatment

Assessing the Condition

The treatment parameters for any given skin condition depend on the skin type and the lesion type, depth and density.

Skin Test

Always perform a skin test on the intended treatment area before the first treatment session, with the **Cooling** mode **On** and according to the following parameters:

Dye-SVL Skin Test Parameters (30 second intervals)

Skin Type (Fitzpatrick I-VI)	Fluence (J/cm²)	Cooling (On/Off) *	Total Energy (kJ) **
I – II	3—4	On	2.4—3.2
III	2—3	On	1.6—2.4
IV	2	On	1.6

The 1-second and 3-second time intervals are indicated for the **Stationary** technique

(*) Ultrasonic gel must be applied to the skin in both Cooling **On** or **Off** modes

(**) The total energy is adjusted for 10x10 cm (100cm²) area.

Important: a thin coat of ultrasonic gel must be applied on the skin for ALL skin types.

Treatment Dye-SVL Mode (In-Motion)

Treatment can begin after the Dye-VL Pro module has been connected to the Harmony^{XL} system and the treatment parameters selected (fluence).

- Clean the skin to remove perfumes, cosmetics and sunscreens.
- Provide appropriate eye protection (OD>5) goggles for the customer and the operating staff in the enclosed treatment room.
- Apply a thin layer (usually 1-2mm thick for all skin types) of refrigerated cooling 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 customer during treatment and; c) friction reduction/lubrication during the In-Motion technique.
- Set the initial fluence parameter according to the skin test results.
- Apply the **In-Motion** technique:
  - Move the module on the surface of the skin and, only when the module is in full contact and "in-motion", then trigger the footswitch.
  - Move the module 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**).
  - After completing a single interval, raise the module from the skin, re-position at the point where you began treatment in this grid and repeat another interval on the entire area.
  - After completing the recommended number of intervals, move to the contra-lateral side and repeat as above.
- In most cases, operation time intervals should be set for 30 seconds for large areas; the 1-second and 3-second intervals should be selected for small areas on the face, chest or back (using the Stationary technique rather than the In-Motion technique).
- Place the module perpendicular to the skin, pressed lightly to the skin surface.
- Perform the recommended cycles on the right and left side of the face. Repeat the intervals on each side.
- End-points: mild-to-moderate erythema for skin types I-IV.
- If adverse reactions are observed from the prior treatment, the next treatment may be skipped or the dose reduced until the symptoms resolve.
- It is recommended to cool the area immediately after the treatment.

Note

Always perform a skin test on the intended treatment area during the first treatment session.

Suggested Setup Parameters

Dye-SVL Suggested Setup Parameters (30 second intervals)

Skin Type (Fitzpatrick I-VI)	Fluence (J/cm²)	Cooling (On/Off) *	Total Energy (kJ) **
I – II	3—4	On	3.2—4.3
III	2—3	On	2.1—3.2
IV	2	On	2.1

(*) Ultrasonic gel must be applied to the skin

(**) The total energy is adjusted for 10x10 cm (100cm²) area. The 1-second and 3-second time intervals are indicated for the **Stationary** technique

Stationary Protocol

- In the stationary technique, use the 3-second interval; up to 10% overlapping is an acceptable tolerance.
- Set the initial exposure time and influence parameters according to the Table.
- Trigger a pulse by continuously pressing the footswitch for the entire time interval; the module will stop emitting light automatically unless interrupted by the operator (releasing the footswitch). In order to continue, the footswitch must be pressed again.
- Check skin reaction; if there is no apparent skin reaction – repeat until end- points are visible.
- Treatment parameters may be increased by 10% every other treatment and subjected to the conditions in the area treated and customer's tolerance.
- Following treatment, gently cleanse the ultrasonic gel from the treated area.
- If adverse skin effects occur (such as excessive reddening or swelling), you may either reduce the exposure time (1 sec interval) or reduce the fluence.
- It is recommended to cool the area immediately after the treatment.

Treatment of Small Areas

*Small Area Parameters, 3-25 cm² , 3 Seconds, In-Motion**

Skin Type (Fitzpatrick I-VI)	Fluence (J/cm²)	Cooling (On/Off) *	Total Energy (kJ) **
I – II	3—4	On	0.3—0.4
III	2—3	On	0.2—0.3
IV	2	On	0.2

*Small Area Parameters, 3-25 cm² , 1 Second, In-Motion**

Skin Type (Fitzpatrick I-VI)	Fluency (J/cm²)	Cooling (On/Off) *	Total Energy (kJ) **
I – II	3—4	On	0.3—0.4
III	2—3	On	0.2—0.3
IV	2	On	0.2

(*) Apply gel

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.

- Within three weeks after the treatment customers should return for examination of the treatment site and for additional treatment, if necessary.
- If no additional treatment is necessary, customers should return for an additional examination two months later.
- Intervals between treatments can be increased in successive treatments.
- Treatment is complete when satisfactory results are obtained.
- Customers should be instructed to avoid sun exposure after and in between treatments.
- Treatment intervals; treatment is reapplied (assuring there have been no adverse reactions) every 3-4 weeks.