

primelase

EXCELLENCE

REJUVENATION

PROTOCOL



by cocoon medical

Alex	Diode	Blend	Yag
755 nm	810 nm	1060 nm 940 nm 810 nm	1060 nm



Introduction

This protocol aims to assist professionals in the use of the **primelase** excellence device for skin rejuvenation treatments.

It will also complete or reinforce the information provided in the user manual regarding usage instructions, precautions and the necessary warnings required to reduce the risk of physical injury.

All users must read the entirety of the user manual before studying this protocol and using the device.

This treatment should always be carried out under medical supervision.

primelase excellence is a diode laser platform that can be used for a diverse array of applications (hair removal, removal of pigmented lesions, removal of vascular lesions, etc.); this protocol, however, focuses on skin rejuvenation treatments. The YAG (1060 nm) and BLEND diode applicators (810-940-1060 nm) have demonstrated good results for skin rejuvenation treatments, like the reduction of facial wrinkles. The innovative combined wavelength technology produces a uniform heating of the epidermis and dermis; the energy is absorbed by the melanin in the epidermis, and the water and blood in the dermis, which results in a triple effect: a) improving the texture of the epidermis, b) promoting the production of collagen and elastin fibres that regenerate the dermis, and c) softening wrinkles and boosting circulation to stimulate tissue regeneration.

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1. Background

Skin rejuvenation is performed by specialist dermatologists. The effects of ageing on the skin are typically undesirable for the patient.

For this laser application, **primelase** excellence focuses on skin rejuvenation treatments. Two types of skin ageing can be identified: chrono-ageing, which is the irreversible degeneration of tissue over the course of years, and photo-ageing, where light causes the deterioration of cutaneous structures. Histologically, chrono-ageing is clinically characterised by fine lines; atrophying of the dermis; a reduction of adipose tissue; a reduction of melanocyte activity, and therefore less protection of the facial skin from solar radiation; and a reduction of sebaceous gland activity, which leads to skin dehydration and a progressive decrease of collagen and elastin ¹.

Photo-ageing, from a histological perspective, is characterised by the accumulation of mutations and abnormal elastic material in the skin in addition to its disorganisation (solar elastosis), causing a loss of the skin's mechanical properties which leads to reduced elasticity and firmness, flaccidity, localised changes to pigmentation (hypo and hyperpigmentation), deeper wrinkles and the appearance of furrows along with a progressive decline in collagen ¹.

The objective of this treatment is to reverse the effects of ageing using the **primelase** excellence high-powered diode laser system with its YAG (1060 nm) and BLEND (810-940-1060 nm) diode wavelengths.

Other techniques exist which are used to perform rejuvenation treatments (radiofrequency, ablative laser, chemical peeling, surgical lifting, etc.). These techniques are effective, but most of them are invasive and aggressive, may involve a long and even pain-ridden post-treatment period, and often present an increased risk of adverse side effects. For this reason, other methods have been studied and enhanced in recent years to minimise side effects and allow patients to return to their normal daily lives immediately after treatment, while potentially achieving results that are similar to those of other more aggressive techniques.²⁻³

Laser technology is a great alternative for skin rejuvenation treatments, particularly skin tightening and the treatment of wrinkles, as it is a non-invasive, effective, non-ablative and safe method. The laser parameters must be selected appropriately (fluence and pulse duration) to minimise unwanted side effects and ensure the best possible results.⁴

However, a prior appointment with a dermatologist is required to optimise results and determine whether the patient is a good candidate for this technology.

The use of **cocoon medical** (Barcelona, Spain) **primelase** excellence Model of YAG (1060 nm) and BLEND (810-940-1060 nm) diode laser is an innovative method that has produced good results for skin rejuvenation treatments ⁵.

2. Biological effects

1060 nm diode laser technology is a good method for skin rejuvenation treatments, given that it is only mildly absorbed by the melanin in the epidermis and therefore penetrates

deeper into the dermis, resulting in more effective wrinkle treatment than other diode lasers with shorter wavelengths (810 nm). This effect can be achieved because it is possible to induce neocollagenesis through heat; elevating the dermis temperature activates the Hsp70 family of proteins, which can then activate regenerative mechanisms. Additionally, skin retraction is also induced by the heat, making the skin tauter.

The second, and most innovative, method is provided by the **primelase** excellence platform's exclusive BLEND applicator (810-940-1060 nm). The innovative combined wavelength technology produces more uniform heating of the skin as a whole (epidermis and dermis), which allows different layers of the skin to be treated simultaneously. The melanin in the epidermis, and the water and blood in the dermis are acted upon, which results in a triple effect: improving the texture of the epidermis, b) promoting the production of collagen and elastin fibres, and boosting circulation. With this technique, tissue regeneration and renewal is achieved through a distinctive multi-layered method.

3. Diagnosing the status of the patient

Before performing the **primelase** excellence treatment, an appointment should be made with the dermatologist where they will carry out an initial skin evaluation and complete the medical history of the patient. This allows the realistic expectations for the treatment to be evaluated. The primary indicator of a successful treatment is achieving the end-point: the treated skin must reach 41-43°C during the treatment, as this will activate collagen stimulation and promote synthesis, encouraging skin tautness.

During this first visit, an initial evaluation will be performed and the medical history of the patient will be covered, along with providing the patient with information related to potential alternative therapies, contraindications, realistic expectations for the treatment, potential side effects and complications of the treatment. In addition, the informed consent of the patient will also be obtained.

During the initial evaluation the medical practitioner must take into account:

- Fitzpatrick scale phototype
- An examination of the skin for moles, warts and/or vascular lesions that may limit the treatment
- Reaction to sun exposure

When analysing the patient's medical history the medical practitioner must take into account:

- Age
- The family history of melanoma
- Prior treatments that may have been performed
- The potential existence of a herpes simplex infection
- History of psoriasis or vitiligo due to the Koebner phenomenon
- History of hypertrophic scarring or keloids
- Recent exposure to the sun or UVA
- Toxic and pharmacological records

The patient must be informed of potential therapeutic alternatives:

- Chemical peeling
- Ablative or non-ablative fractional lasers
- Radio frequency
- Surgical lifting

The patient will be informed of the contraindications of the treatment:

- Topical or oral use of retinoids and vitamin A derivatives
- Photosensitivity
- Pregnancy
- The presence of an active infection in the treatment area
- Active herpes simplex virus infection.
- A history of abnormal scars
- A history of inflammatory skin conditions
- A history of immunodepression
- Recent sun exposure <15 days
- History of hyper or hypopigmentation
- Healing abnormalities
- Active or recent malignant pathology (cancer), within the 5 years, use of anticancer drugs
- Vitiligo
- Psoriasis
- The presence of a dysplastic nevus in the treatment area
- The presence of tattoos in the treatment area
- Isotretinoin treatment in the last 6 months

The precautions that must be taken before beginning the treatment will be covered:

- Avoid sunbathing or UVA treatments for at least 15 days before and after the treatment.

The patient will be informed of the possible side effects:

- Reddening or erythema and inflammation: affecting the treatment area for a short period (hours to days)
- Blisters
- Papules or pustules
- Pain

The patient will be informed of the potential complications:

- Changes to the pigmentation of the skin: increasing (hyperpigmentation) or reducing (hypopigmentation) the colour
- Scarring

The number of sessions that will be required to achieve a satisfactory result is typically between 3 and 6, depending on a range of factors such as skin type, the depth of the wrinkles, the treatment area and/or the patient's own regenerative capacity. A good equation to use for estimation is one session per decade lived over 30 years, with a minimum of 3.

The optimal interval between sessions is 4-6 weeks. Once the treatment is considered to be complete, maintenance sessions may be required in order to maintain the results that have been achieved.

4. Parameters

The suggested parameters for the treatment are listed in tables 1 and 2. These parameters are based on the clinical experience of medical practitioners who have performed rejuvenation treatments. The specialists must use their clinical knowledge and experience when determining the parameters for the treatment, as they must be adjusted in accordance with the skin type of the patient or the presence of a tan, and also to verify that the clinical end-point has been achieved during the treatment. In this case, the end-point is heating the skin to 41-43°C.

The parameters recommended for normal skin are a frequency of 2Hz, a fluence of 10 J/cm² and a pulse of 400 ms. The total treatment time per area will depend on the size of the area, as shown in tables 1 and 2.

The treatment finishes when the temperature of the skin reaches 41-43°C. Unlike radiofrequency protocols and adipolysis treatments, once the skin has been heated to 41-43°C it is not necessary to maintain that temperature in order to stimulate neocollagenesis and retract the existing collagen so that the skin is tightened.

The method for performing the treatment involves continuously moving the head of the laser applicator, sweeping it across the entire treatment area. The use of excessively high fluences may lead to pain caused by intense heat and oedema. Therefore, starting with the lowest possible fluence is always recommended. Gradual increases should be made until the maximum fluence is reached, which, while still being comfortable, will allow the end-point to be achieved.

Yag ^{1060nm} M 10x10 | 1060nm



Skin phototype (Fitzpatrick I-VI)	Area (cm ²) -approximate value-	Fluence (J/cm ²)	Pulse duration (ms)	Frequency (Hz)	Duration (minutes)	Treatment
I-II	15x7 Forehead, nec kline, etc.	10-12	400	2	6	Sweeping movement, no contact with the skin
	7x7 Cheekbones, cheeks, jowls, hands				3	
	7x3 Mouth wrinkles, eyes and chin				1:30	
III-IV	15x7 Forehead, neckline, etc.	8-10	400	2	6	
	7x7 Cheekbones, cheeks, jowls, hands				3	
	7x3 Mouth wrinkles, eyes and chin				1:30	
V-VI	15x7 Forehead, neckline, etc.	5-6	400	2	8	
	7x7 Cheekbones, cheeks, jowls, hands				4	
	7x3 Mouth wrinkles, eyes and chin				2	

Blend ^{1060nm} ^{940nm} ^{810nm} L 20x9 XL 30x9



Skin phototype (Fitzpatrick I-IV)	Area (cm ²) -approximate value-	Fluence (J/cm ²)	Pulse duration (ms)	Frequency (Hz)	Duration (minutes)	Treatment
I-II	15x7 Forehead, neckline, etc.	10-12	400	2	6	Sweeping movement, no contact with the skin
	7x7 Cheekbones, cheeks, jowls, hands				3	
	7x3 Mouth wrinkles, eyes and chin				1:30	
III-IV	15x7 Forehead, neckline, etc.	8-10	400	2	6	
	7x7 Cheekbones, cheeks, jowls, hands				3	
	7x3 Mouth wrinkles, eyes and chin				1:30	

5. Step by step

General clarifications:

A spacer must be added to the applicator head to ensure that it does not come into direct contact with the skin. The use of a transparent and colourless aloe vera cream is also recommended to allow the head of the diode laser applicator to move across the skin.

Prior preparation:

- Classify the phototype according to the Fitzpatrick scale.
- Examine the skin for moles, warts and/or vascular lesions that may limit the treatment.
- Ensure that the patient does not use makeup or sunbathe during the days leading up to the treatment.
- If hair is present, shaving the treatment area is recommended.

Procedure:

- Cleanse, degrease and disinfect the treatment area.
- The patient, medical practitioner and the staff must wear appropriate protective eyewear.
- Demarcate the treatment area, dividing it into a grid (approximate sizes: 15x7 cm², 7x7 cm², 7x3 cm² depending on the area being treated).
- Apply gel to the skin in the treatment area to achieve an equal delivery of energy and make the treatment more comfortable.
- Add a spacer to the laser applicator head. (Figure 1 - Figure 2- Figure 3)

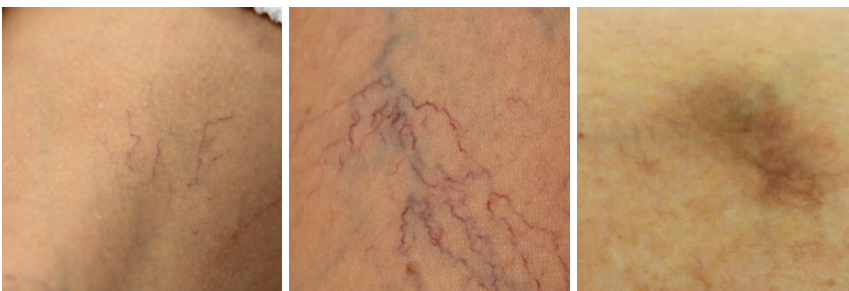


Figure 1. BLEND applicator, 20x9 mm² spot

Figure 2. BLEND applicator, 20x9 mm² spot

Figure 3. YAG applicator 10x10 mm² spot

- Select the treatment parameters on the screen of the **primelase** excellence device (figure 4).



Figure 4. primelase Screen

- Rest the head (with the spacer) on the treatment area and discharge in a sweeping fashion across the whole area, make multiple passes until the time is up (Figure 5).



Figure 5. The head of the diode LASER applicator, with the spacer fitted, resting on the skin and discharging

- If the patient experiences intense pain, decrease the fluence by 1 J/cm². If the patient experiences severe pain, stop the treatment immediately, inspect the treatment area and pre-emptively apply a post-treatment burn protocol.
- Alternate between horizontal, vertical and diagonal sweeps to avoid creating a stripy pattern on the face of the patient. (Figure 6)



Figure 6. Discharging in a sweeping fashion

- To control the temperature of the skin being treated, use a non-contact thermometer throughout the session. (Figure 7)



Figure 7. Non-contact thermometer reading the temperature of the skin being

- Control the total treatment time per area in accordance with the parameters table.
- Stop the treatment if the skin reaches the end-point (41-43°C) before the treatment time is over. (Figure 8 and Figure 9)



Figure 8. Non-contact thermometer reading 41.7 °C (end-point)



Figure 9. Before (left) and after (right) the facial rejuvenation treatment

6. Post-treatment

Immediate post-treatment recommendations

- Applying 14% Eflornithine in ointment after each session is recommended to avoid and prevent the formation of hair caused by a paradoxical effect. (Figure 10)



Figure 10. Apply cream to the face of the patient following the treatment

Post-treatment recommendations

- Medium-strength corticosteroid cream.
- Moisturiser.
- Sun exposure must be avoided from day one and an SPF 50 sunscreen must be used to avoid hyperpigmentation.

Post-treatment assessment visit

The assessment of the success of the treatment is performed one month after the last session. It is appraised with before and after photographs, with an estimated improvement of 10-30%.

The number of sessions depends on the age of the patient, with a minimum of 3. 1 session is added for every decade over the age of 30 that the patient has lived. The optimal interval between sessions is 4-6 weeks.

7. Final Results

The effectiveness and safety of primelase excellence treatments have been proven. The final results of the treatment can be seen in the following photographs.



Figure 11. Nasolabial fold rejuvenation before and after treatment



Figure 12. Wrinkle before and after treatment

8. References

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EXCELLENCE

A multitreatment diode laser platform developed with the exclusive technology of **cocoon medical**. With a maximum power of 4.800 W and different wavelengths (755 nm, 810 nm, 940 nm and 1060 nm) it enables to perform up to five different treatments.

Alex	Diode	Blend	Yag
755 nm	810 nm	1060 nm 940 nm 810 nm	1060 nm

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