

primelase HR

EXCELLENCE



20x9



30x9



30x17

Diode^{810nm}



GUÍA RÁPIDA DE FOTODEPILACIÓN
QUICK GUIDE TO PHOTODEPILATION



This protocol aims to help professionals in the use of the **primelase® HR excellence** device.

Complete and reinforce the information presented in the user manual regarding the instructions, precautions and contraindications to ensure the optimal use of the equipment.

All users should read the entire user manual before applying this protocol and using the device.

primelase® HR excellence is a device that is intended to be used for treatments of permanent hair removal using diode laser technology, the fundamental principle of which is a selective photothermolysis, that consists in a specific destruction of a hair follicle due to an increase of the temperature induced by a high power beam that is selectively absorbed by the melanin present in the hair.

primelase HR

EXCELLENCE

QUICK GUIDE TO PHOTODEPILATION

ENGLISH

Contents

Spot Diode 20x9

- 1. Definition of indicators 44**
- 2. Static treatment mode 44**
 - 2.1 Beginning a treatment with the maximum value 44
 - 2.2 Beginning a treatment using the predetermined value..... 44
- 3. Dynamic treatment mode..... 50**
 - 3.1 Beginning the treatment 50

Spot Diode 30x9

- 1. Definition of indicators 56**
- 2. Static treatment mode 56**
 - 2.1 Beginning a treatment with the maximum value 56
 - 2.2 Beginning a treatment using the predetermined value..... 56
- 3. Dynamic treatment mode..... 62**
 - 3.1 Beginning the treatment 62

Spot Diode 30x17

- 1. Definition of indicators 68**
- 2. Static treatment mode 68**
 - 2.1 Beginning a treatment with the maximum value 68
 - 2.2 Beginning a treatment using the predetermined value..... 68
- 3. Dynamic treatment mode..... 74**
 - 3.1 Beginning the treatment 74

Diode^{810nm}

20x9



1. Definition of indicators

The indicators that are defined here are those that are used in the work tables.

Static mode:

- 1. Predetermined values:** these are the fluence values that are suggested for the Pre-Assessment Test (PAT) which is performed prior to the first treatment, they have been established to ensure safe treatments.
- 2. Maximum value:** these are the maximum fluence values with which optimal effectiveness can be achieved, however they may result in a treatment that is less comfortable for the patient. A deviation range of 20% has been incorporated in compliance with the IEC 60601-2-22 basic safety standard for medical LASER devices.

The maximum fluence values must not be used with frequencies of 1, 2 or 3Hz without first performing gradual increases in fluence consistent with the Pre-Assessment Test and also performing sessions that warrant the increase, which both produce no adverse effects.

The maximum specified fluence for the skin phototype must not be exceeded and should only be used with a frequency of 1Hz and without overlapping shots. Reducing the value by 2 J/cm² is recommended when using 2 and 3Hz.

Dynamic mode:

- 3. Recommended values:** these are the suggested values for pulse duration, fluence, accumulated energy and frequency with which excellent effectiveness can be achieved.

2. Static treatment mode

In this section the procedure for performing a treatment in static mode with the primelase HR excellence device is briefly explained.

2.1 Beginning a treatment with the maximum value

In the first session, a shot that is 5 J/cm² under the lowest maximum value specified in the treatment table must be applied. If a reduction of 5 J/cm² results in a value lower than the predetermined value, the latter must be applied to begin the treatment.

2.2 Beginning a treatment using the predetermined value

In the first session, start by using the predetermined fluence value specified in the treatment table.

In the second session and any subsequent sessions, use the fluence value from the last session and follow the same steps as for the first session.

1. Apply a single shot to the treatment area, always at 1Hz. Continue with two more shots on the skin adjacent to the previous shot, in the same manner with an overlap of 50%.
2. Assess the reaction of the skin, positive reaction – endpoint – or clinical signs of effectiveness and safety.
3. If these signs – endpoint – are not present and there are no adverse effects, this procedure can be repeated on a different area of underlying skin while increasing the fluence in increments of 1 J/cm² every 3 shots until the desired effect is achieved. The maximum fluence value must never be exceeded.
4. If adverse effects are detected on the skin (like excessive redness) or the treatment is not being tolerated by the patient (variable follicular response), decrease the fluence in increments of 1 J/cm² until signs of effectiveness and safety are achieved.
5. Always monitor the reaction of the skin (endpoint).
6. You can change the frequency if the parameters were set at 1Hz and there were no adverse effects. You are advised to perform a series of 3 shots with the last selected fluence value (J/cm²) and the new frequency selected. Assess the tolerance of the patient before proceeding with the treatment (the maximum frequency for 400 ms is 2Hz).
7. Record the data in the patient's file: the optimum treatment fluence at the selected frequency with the corresponding pulse length.

Endpoint: A positive reaction on the skin (endpoint), which is a sign of effectiveness and safety, consists of an erythematous reaction and/or perifollicular oedema (around the hair follicle) of varying intensity and/or slight erythema on the skin, with a sensation of mild pain or hypersensitivity experienced by the patient which can be compared to hot pinpricks and an absence of other signs, especially in dark phototypes, and always an absence of adverse effects

Diode ^{810nm} 20x9 | STATIC MODE



Skin phototype (Fitzpatrick I-VI)	Hair colour	Hair thickness	Fluence (J/cm ²)		Pulse duration (ms)	Fluence (J/cm ²)
			Maximum range			Predetermined
I	Blond	Fine	32	40	AUTO	15
		Thick/Dense	28	35		14
	Brown	Fine	27	33		14
		Thick/Dense	24	31		13
	Black	Fine	24	31		13
		Thick/Dense	19	24		12
II	Blond	Fine	24	31	AUTO	14
		Thick/Dense	24	30		13
	Brown	Fine	23	29		13
		Thick/Dense	19	24		12
	Black	Fine	19	24		12
		Thick/Dense	17	21		11
III	Blond	Fine	19	24	AUTO	13
		Thick/Dense	17	22		11
	Brown	Fine	16	20		11
		Thick/Dense	13	16		10
	Black	Fine	13	16		10
		Thick/Dense	10	13		9
IV	Blond	Fine	NE	NE	30	NE
		Thick/Dense	NE	NE		NE
	Brown	Fine	12	15		10
		Thick/Dense	10	13		9
	Black	Fine	10	13		9
		Thick/Dense	10	12		8
V	Blond	Fine	NE	NE	100	NE
		Thick/Dense	NE	NE		NE
	Brown	Fine	12	15		11
		Thick/Dense	11	14		10
	Black	Fine	11	14		10
		Thick/Dense	9	11		7
VI	Blond	Fine	NE	NE	400	NE
		Thick/Dense	NE	NE		NE
	Brown	Fine	NE	NE		NE
		Thick/Dense	NE	NE		NE
	Black	Fine	10	12		8
		Thick/Dense	9	11		7

SPECIAL CONSIDERATIONS primelase HR excellence – 20x9 - 810 nm

Phototype IV / Any hair morphology::

The AUTO pulse duration can be used at any stage of the treatment as long as the tolerance of the patient permits it, in accordance with the fluences shown in the table below.

If a treatment with a pulse length of 30 ms cannot be carried out due to the tolerance of the patient, use a pulse length of 100 ms during the first treatment sessions and then move to a pulse length of 30 ms when the tolerance of the patient permits.

Recommended fluences for the AUTO pulse duration for phototype IV in addition to those specified in the parameter table for 810nm with a 20x9 spot.

Skin phototype (Fitzpatrick I-VI)	Hair colour	Hair thickness	Fluence (J/cm ²)		Pulse duration (ms)	Fluence (J/cm ²)
			Maximum range			Predetermined
IV	Light/blond	Fine	NE	NE	AUTO	NE
		Thick/Dense	NE	NE		NE
	Brown	Fine	10	12		7
		Thick/Dense	8	10		6
	Black	Fine	8	10		6
		Thick/Dense	7	9		5

Recommended fluences for the 100ms pulse duration for phototype IV in addition to those specified in the parameter table for 810nm with a 20x9 spot.

Skin phototype (Fitzpatrick I-VI)	Hair colour	Hair thickness	Fluence (J/cm ²)		Pulse duration (ms)	Fluence (J/cm ²)
			Maximum range			Predetermined
IV	Light/blond	Fine	NE	NE	100	NE
		Thick/Dense	NE	NE		NE
	Brown	Fine	15	19		13
		Thick/Dense	13	16		12
	Black	Fine	13	16		12
		Thick/Dense	12	15		11

Phototype V / Any hair morphology

The AUTO pulse duration can be used at any stage of the treatment as long as the tolerance of the patient permits it, in accordance with the fluences shown in the table below:

Recommended fluences for the AUTO pulse duration for phototype V in addition to those specified in the parameter table for 810nm with a 20x9 spot.

Skin phototype (Fitzpatrick I-VI)	Hair colour	Hair thickness	Fluence (J/cm ²)		Pulse duration (ms)	Fluence (J/cm ²)
			Maximum range			Predetermined
V	Light/blond	Fine	NE	NE	AUTO	NE
		Thick/Dense	NE	NE		NE
	Brown	Fine	6	7		5
		Thick/Dense	5	6		4
	Black	Fine	5	6		4
		Thick/Dense	4	5		3

If the tolerance of the patient permits it, and especially with patients with thicker hair, the 30 ms pulse duration can be used at any stage of the treatment, in accordance with the fluences shown in the table below.

Recommended fluences for the 30ms pulse duration for phototype V in addition to those specified in the parameter table for 810nm with a 20x9 spot

Skin phototype (Fitzpatrick I-VI)	Hair colour	Hair thickness	Fluence (J/cm ²)		Pulse duration (ms)	Fluence (J/cm ²)
			Maximum range			Predetermined
V	Light/blond	Fine	NE	NE	30	NE
		Thick/Dense	NE	NE		NE
	Brown	Fine	8	10		7
		Thick/Dense	7	9		6
	Black	Fine	7	9		6
		Thick/Dense	6	8		5

Phototype IV / Any hair morphology

The 100ms pulse duration can be used at any stage of the treatment as long as the tolerance of the patient permits it, in accordance with the fluences shown in the table below:

Recommended fluences for the 100ms pulse duration for phototype VI in addition to those specified in the parameter table for 810nm with a 20x9 spot.

Skin phototype (Fitzpatrick I-VI)	Hair colour	Hair thickness	Fluence (J/cm ²)		Pulse duration (ms)	Fluence (J/cm ²)
			Maximum range			Predetermined
VI	Light/blond	Fine	NE	NE	100	NE
		Thick/Dense	NE	NE		NE
	Brown	Fine	NE	NE		NE
		Thick/Dense	NE	NE		NE
	Black	Fine	7	9		6
		Thick/Dense	6	8		5

3. Dynamic treatment mode

In this section the procedure for performing a treatment in dynamic mode with the primelase HR excellence device is briefly explained. The dynamic mode is ideal for initial treatment sessions with patients who have a higher sensitivity to pain and/or more dense hair.

3.1 Beginning the treatment

The dynamic mode is ideal for initial treatment sessions with patients who have a higher sensitivity to pain and/or more dense hair.

Mark the area to be tested by dividing or segmenting the treatment area into a grid of equally sized squares (10x10 cm² or 15x10 cm², depending on the area of the body being treated).

Make a selection according to the parameter table, depending on the skin phototype, hair characteristics and selected grid:

1. *Pulse duration:*
2. *Fluence*
3. *Accumulated energy*
4. *Frequency*

Shorter pulses will deliver better hair removal results, and the patient may feel a pinching sensation. Longer pulses will result in a more comfortable treatment.

Select the pulse frequency, the recommended value is 10Hz. If you choose a lower frequency (5Hz minimum), the treatment will take longer but may be more comfortable.

Hold the head on the treatment area in a perpendicular fashion.

Begin the treatment by moving the head of the device horizontally or vertically in a sweeping motion (slide the head across the grid until the required energy is automatically administered in the established timeframe). Maintain a constant speed and ensure an even sweep of the entire grid.

The approximate average speed of movement for each grid is **10 cm per second**.

The device should stop automatically when the selected time limit and number of shots have been reached. However, the treatment must be stopped if the patient reports excessive heat or if you notice an erythema or excessive reddening.

Optimal treatment in dynamic mode can be defined as one that is both comfortable for the patient (optimal tolerance) and produces slight erythema or perifollicular inflammation (positive reaction).

You are advised to switch to the static system after the first or second treatment session, depending on the tolerance of the patient. When switching to static mode, we will follow the parameter selection method outlined in previous sections.

Recommended values: suggested minimum values for pulse duration and maximum values for fluence and accumulated energy, with which a comfortable, fast and effective treatment can be obtained.

- *To optimise results it is possible to increase **the fluence in increments of 1 J/cm² and/or the accumulated energy in increments of 0.5 kJ, depending on the tolerance of the patient** (increasing the values will result in less comfort and longer treatment times).*
- *If at the beginning of a treatment a patient is unable to tolerate it, stop the treatment and decrease the fluence by 1J/cm².*
- *If during a treatment the patient is unable to tolerate it, or if you notice an erythema or excessive reddening, the treatment must be stopped and the accumulated energy lowered by 0.5kJ.*
- *For subsequent sessions, you can start by using the last applied parameters. Always observe the reaction of the skin (check the patient's file).*

Diode ^{810nm} **L** 20x9 | DYNAMIC MODE



Skin phototype (Fitzpatrick I-VI)	Grid (cm x cm)	Pulse duration (ms)	Fluence (J/cm ²)	Accumulated energy (kJ)	Pulse duration (ms)	Fluence (J/cm ²)	Accumulated energy (kJ)	Frequency Hz
		Hair thickness						
		Thick hair			Fine hair			
I	15X10	3	7	4	4	10	5.5	10
	10X10	3	7	2.5	4	10	3.5	10
II	15X10	3	6	4	3	8	5.5	10
	10X10	3	6	2.5	3	8	3.5	10
III	15X10	3	5	3	3	6	4	10
	10X10	3	5	2	3	6	2.5	10
IV	15X10	3	4	3	3	5	4	10
	10X10	3	4	2	3	5	2.5	10
V	15X10	3	2	2.5	3	4	4	10
	10X10	3	2	1.5	3	4	2.5	10
VI	15X10	9	2	2.5	9	4	3	5
	10X10	9	2	1.5	9	4	2	5

Diode^{810nm}

30x9



1. Definition of indicators

The indicators that are defined here are those that are used in the work tables.

Static mode:

- 1. Predetermined values:** these are the fluence values that are suggested for the Pre-Assessment Test (PAT) which is performed prior to the first treatment, they have been established to ensure safe treatments.
- 2. Maximum value:** these are the maximum fluence values with which optimal effectiveness can be achieved, however they may result in a treatment that is less comfortable for the patient. A deviation range of 20% has been incorporated in compliance with the IEC 60601-2-22 basic safety standard for medical LASER devices.

The maximum fluence values must not be used with frequencies of 1, 2 or 3Hz without first performing gradual increases in fluence consistent with the Pre-Assessment Test and also performing sessions that warrant the increase, which both produce no adverse effects.

The maximum specified fluence for the skin phototype must not be exceeded and should only be used with a frequency of 1Hz and without overlapping shots. Reducing the value by 2 J/cm² is recommended when using 2 and 3Hz.

Dynamic mode:

- 3. Recommended values:** these are the suggested values for pulse duration, fluence, accumulated energy and frequency with which excellent effectiveness can be achieved.

2. Static treatment mode

In this section the procedure for performing a treatment in static mode with the primelase HR excellence device is briefly explained.

2.1 Beginning a treatment with the maximum value

In the first session, a shot that is 5 J/cm² under the lowest maximum value specified in the treatment table must be applied. If a reduction of 5 J/cm² results in a value lower than the predetermined value, the latter must be applied to begin the treatment.

2.2 Beginning a treatment using the predetermined value

In the first session, start by using the predetermined fluence value specified in the treatment table.

In the second session and any subsequent sessions, use the fluence value from the last session and follow the same steps as for the first session.

1. Apply a single shot to the treatment area, always at 1Hz. Continue with two more shots on the skin adjacent to the previous shot, in the same manner with an overlap of 50%.
2. Assess the reaction of the skin, positive reaction – endpoint – or clinical signs of effectiveness and safety.
3. If these signs – endpoint – are not present and there are no adverse effects, this procedure can be repeated on a different area of underlying skin while increasing the fluence in increments of 1 J/cm² every 3 shots until the desired effect is achieved. The maximum fluence value must never be exceeded.
4. If adverse effects are detected on the skin (like excessive redness) or the treatment is not being tolerated by the patient (variable follicular response), decrease the fluence in increments of 1 J/cm² until signs of effectiveness and safety are achieved.
5. Always monitor the reaction of the skin (endpoint).
6. You can change the frequency if the parameters were set at 1Hz and there were no adverse effects. You are advised to perform a series of 3 shots with the last selected fluence value (J/cm²) and the new frequency selected. Assess the tolerance of the patient before proceeding with the treatment (the maximum frequency for 400 ms is 2Hz).
7. Record the data in the patient's file: the optimum treatment fluence at the selected frequency with the corresponding pulse length.

Endpoint: *A positive reaction on the skin (endpoint), which is a sign of effectiveness and safety, consists of an erythematous reaction and/or perifollicular oedema (around the hair follicle) of varying intensity and/or slight erythema on the skin, with a sensation of mild pain or hypersensitivity experienced by the patient which can be compared to hot pinpricks and an absence of other signs, especially in dark phototypes, and always an absence of adverse effects.*

Diode^{810nm} XL 30x9 | STATIC MODE



Skin phototype (Fitzpatrick I-VI)	Hair colour	Hair thickness	Fluence (J/cm ²)		Pulse duration (ms)	Fluence (J/cm ²)
			Maximum range			Predetermined
I	Blond	Fine	32	40	AUTO	14
		Thick/Dense	24	30		13
	Brown	Fine	23	28		13
		Thick/Dense	21	26		12
	Black	Fine	21	26		12
		Thick/Dense	17	21		11
II	Blond	Fine	21	26	AUTO	13
		Thick/Dense	20	25		12
	Brown	Fine	20	25		12
		Thick/Dense	17	21		11
	Black	Fine	17	21		11
		Thick/Dense	14	18		10
III	Blond	Fine	18	22	AUTO	12
		Thick/Dense	15	19		10
	Brown	Fine	14	18		10
		Thick/Dense	11	14		9
	Black	Fine	11	14		9
		Thick/Dense	10	12		8
IV	Blond	Fine	NE	NE	30	NE
		Thick/Dense	NE	NE		NE
	Brown	Fine	11	14		9
		Thick/Dense	10	12		8
	Black	Fine	10	12		8
		Thick/Dense	9	11		7
V	Blond	Fine	NE	NE	100	NE
		Thick/Dense	NE	NE		NE
	Brown	Fine	12	15		11
		Thick/Dense	11	14		10
	Black	Fine	11	14		10
		Thick/Dense	9	11		7
VI	Blond	Fine	NE	NE	400	NE
		Thick/Dense	NE	NE		NE
	Brown	Fine	NE	NE		NE
		Thick/Dense	NE	NE		NE
	Black	Fine	10	12		8
		Thick/Dense	9	11		7

SPECIAL CONSIDERATIONS primelase HR excellence – 30x9 - 810 nm

Phototype IV / Any hair morphology:

The AUTO pulse duration can be used at any stage of the treatment as long as the tolerance of the patient permits it, in accordance with the fluences shown in the table below.

If a treatment with a pulse length of 30 ms cannot be carried out due to the tolerance of the patient, use a pulse length of 100 ms during the first treatment sessions and then move to a pulse length of 30 ms when the tolerance of the patient permits.

Recommended fluences for the AUTO pulse duration for phototype IV in addition to those specified in the parameter table for 810 nm with a 30x9 spot.

Skin phototype (Fitzpatrick I-VI)	Hair colour	Hair thickness	Fluence (J/cm ²)		Pulse duration (ms)	Fluence (J/cm ²)
			Maximum range			Predetermined
IV	Light/blond	Fine	NE	NE	AUTO	NE
		Thick/Dense	NE	NE		NE
	Brown	Fine	10	12		7
		Thick/Dense	8	10		6
	Black	Fine	8	10		6
		Thick/Dense	7	9		5

Recommended fluences for the 100ms pulse duration for phototype IV in addition to those specified in the parameter table for 810 nm with a 30x9 spot.

Skin phototype (Fitzpatrick I-VI)	Hair colour	Hair thickness	Fluence (J/cm ²)		Pulse duration (ms)	Fluence (J/cm ²)
			Maximum range			Predetermined
IV	Light/blond	Fine	NE	NE	100	NE
		Thick/Dense	NE	NE		NE
	Brown	Fine	14	17		13
		Thick/Dense	13	16		12
	Black	Fine	13	16		12
		Thick/Dense	12	15		11

Phototype V / Any hair morphology

The AUTO pulse duration can be used at any stage of the treatment as long as the tolerance of the patient permits it, in accordance with the fluences shown in the table below:

Recommended fluences for the AUTO pulse duration for phototype V in addition to those specified in the parameter table for 810 nm with a 30x9 spot.

Skin phototype (Fitzpatrick I-VI)	Hair colour	Hair thickness	Fluence (J/cm ²)		Pulse duration (ms)	Fluence (J/cm ²)
			Maximum range			Predetermined
V	Light/blond	Fine	NE	NE	AUTO	NE
		Thick/Dense	NE	NE		NE
	Brown	Fine	6	7		5
		Thick/Dense	5	6		4
	Black	Fine	5	6		4
		Thick/Dense	4	5		3

If the tolerance of the patient permits it, and especially with patients with thicker hair, the 30 ms pulse duration can be used at any stage of the treatment, in accordance with the fluences shown in the table below.

Recommended fluences for the 30ms pulse duration for phototype V in addition to those specified in the parameter table for 810 nm with a 30x9 spot.

Skin phototype (Fitzpatrick I-VI)	Hair colour	Hair thickness	Fluence (J/cm ²)		Pulse duration (ms)	Fluence (J/cm ²)
			Maximum range			Predetermined
V	Light/blond	Fine	NE	NE	30	NE
		Thick/Dense	NE	NE		NE
	Brown	Fine	8	10		7
		Thick/Dense	7	9		6
	Black	Fine	7	9		6
		Thick/Dense	6	8		5

Phototype VI / Any hair morphology

The 100ms pulse duration can be used at any stage of the treatment as long as the tolerance of the patient permits it, in accordance with the fluences shown in the table below:

Recommended fluences for the 100ms pulse duration for phototype VI in addition to those specified in the parameter table for 810 nm with a 30x9 spot.

Skin phototype (Fitzpatrick I-VI)	Hair colour	Hair thickness	Fluence (J/cm ²)		Pulse duration (ms)	Fluence (J/cm ²)
			Maximum range			Predetermined
VI	Light/blond	Fine	NE	NE	100	NE
		Thick/Dense	NE	NE		NE
	Brown	Fine	NE	NE		NE
		Thick/Dense	NE	NE		NE
	Black	Fine	7	9		6
		Thick/Dense	6	8		5

3. Dynamic treatment mode

In this section the procedure for performing a treatment in dynamic mode with the primelase HR excellence device is briefly explained. The dynamic mode is ideal for initial treatment sessions with patients who have a higher sensitivity to pain and/or more dense hair.

3.1 Beginning the treatment

The dynamic mode is ideal for initial treatment sessions with patients who have a higher sensitivity to pain and/or more dense hair.

Mark the area to be tested by dividing or segmenting the treatment area into a grid of equally sized squares (30x10cm² / 20x15cm² and/or 15x10cm², depending on the area of the body being treated).

Make a selection according to the parameter table, depending on the skin phototype, hair characteristics and selected grid:

1. *Pulse duration:*
2. *Fluence*
3. *Accumulated energy*
4. *Frequency*

Shorter pulses will deliver better hair removal results, and the patient may feel a pinching sensation. Longer pulses will result in a more comfortable treatment.

Select the pulse frequency, the recommended value is 10Hz. If you choose a lower frequency (5Hz minimum), the treatment will take longer but may be more comfortable.

Hold the head on the treatment area in a perpendicular fashion.

Begin the treatment by moving the head of the device horizontally or vertically in a sweeping motion (slide the head across the grid until the required energy is automatically administered in the established timeframe). Maintain a constant speed and ensure an even sweep of the entire grid.

The approximate average speed of movement for each grid is **10 cm per second**.

The device should stop automatically when the selected time limit and number of shots have been reached. However, the treatment must be stopped if the patient reports excessive heat or if you notice an erythema or excessive reddening.

Optimal treatment in dynamic mode can be defined as one that is both comfortable for the patient (optimal tolerance) and produces slight erythema or perifollicular inflammation (positive reaction).

You are advised to switch to the static system after the first or second treatment session, depending on the tolerance of the patient. When switching to static mode, we will follow the parameter selection method outlined in previous sections.

Recommended values: suggested minimum values for pulse duration and maximum values for fluence and accumulated energy, with which a comfortable, fast and effective treatment can be obtained.

- *To optimise results it is possible to increase **the fluence in increments of 1 J/cm² and/or the accumulated energy in increments of 0.5 kJ, depending on the tolerance of the patient** (increasing the values will result in less comfort and longer treatment times).*
- *If at the beginning of a treatment a patient is unable to tolerate it, stop the treatment and decrease the fluence by 1 J/cm².*
- *If during a treatment the patient is unable to tolerate it, or if you notice an erythema or excessive reddening, the treatment must be stopped and the accumulated energy lowered by 0.5 kJ.*
- *For subsequent sessions, you can start by using the last applied parameters. Always observe the reaction of the skin (check the patient's file).*

Diode^{810nm} XL 30x9 | DYNAMIC MODE



Skin phototype (Fitzpatrick I-VI)	Grid (cm x cm)	Pulse duration (ms)	Fluence (J/cm ²)	Accumulated energy (kJ)	Pulse duration (ms)	Fluence (J/cm ²)	Accumulated energy (kJ)	Frequency Hz
		Hair thickness						
		Thick hair			Fine hair			
I	30x10/ 20x15	4	6	7	5	9	10	10
	15x10	4	6	3.5	5	9	5	10
II	30x10/ 20x15	3	5	7	4	7	9	10
	15x10	3	5	3.5	4	7	4.5	10
III	30x10/ 20x15	3	4	6	3	5	7	10
	15x10	3	4	3	3	5	3.5	10
IV	30x10/ 20x15	3	3	5	3	4	7	10
	15x10	3	3	2.5	3	4	3.5	10
V	30x10/ 20x15	3	2	5	3	3	6	10
	15x10	3	2	2.5	3	3	3	10
VI	30x10/ 20x15	9	2	4	9	3	6	5
	15x10	9	2	2	9	3	3	5

Diode^{810nm}

30x17



1. Definition of indicators

The indicators that are defined here are those that are used in the work tables.

Static mode:

- 1. Predetermined values:** these are the fluence values that are suggested for the Pre-Assessment Test (PAT) which is performed prior to the first treatment, they have been established to ensure safe treatments.
- 2. Maximum value:** these are the maximum fluence values with which optimal effectiveness can be achieved, however they may result in a treatment that is less comfortable for the patient. A deviation range of 20% has been incorporated in compliance with the IEC 60601-2-22 basic safety standard for medical LASER devices.

The maximum fluence values must not be used with frequencies of 1, 2 or 3Hz without first performing gradual increases in fluence consistent with the Pre-Assessment Test and also performing sessions that warrant the increase, which both produce no adverse effects.

The maximum specified fluence for the skin phototype must not be exceeded and should only be used with a frequency of 1Hz and without overlapping shots. Reducing the value by 2 J/cm² is recommended when using 2 and 3Hz.

Dynamic mode:

- 3. Recommended values:** these are the suggested values for pulse duration, fluence, accumulated energy and frequency with which excellent effectiveness can be achieved.

2. Static treatment mode

In this section the procedure for performing a treatment in static mode with the primelase HR excellence device is briefly explained.

2.1 Beginning a treatment with the maximum value

In the first session, a shot that is 5 J/cm² under the lowest maximum value specified in the treatment table must be applied. If a reduction of 5 J/cm² results in a value lower than the predetermined value, the latter must be applied to begin the treatment.

2.2 Beginning a treatment using the predetermined value

In the first session, start by using the predetermined fluence value specified in the treatment table.

In the second session and any subsequent sessions, use the fluence value from the last session and follow the same steps as for the first session.

1. Apply a single shot to the treatment area, always at 1Hz. Continue with two more shots on the skin adjacent to the previous shot, in the same manner with an overlap of 50%.
2. Assess the reaction of the skin, positive reaction – endpoint – or clinical signs of effectiveness and safety.
3. If these signs – endpoint – are not present and there are no adverse effects, this procedure can be repeated on a different area of underlying skin while increasing the fluence in increments of 1 J/cm² every 3 shots until the desired effect is achieved. The maximum fluence value must never be exceeded.
4. If adverse effects are detected on the skin (like excessive redness) or the treatment is not being tolerated by the patient (variable follicular response), decrease the fluence in increments of 1 J/cm² until signs of effectiveness and safety are achieved.
5. Always monitor the reaction of the skin (endpoint).
6. You can change the frequency if the parameters were set at 1Hz and there were no adverse effects. You are advised to perform a series of 3 shots with the last selected fluence value (J/cm²) and the new frequency selected. Assess the tolerance of the patient before proceeding with the treatment (the maximum frequency for 400 ms is 2Hz).
7. Record the data in the patient's file: the optimum treatment fluence at the selected frequency with the corresponding pulse length.

Endpoint: A positive reaction on the skin (endpoint), which is a sign of effectiveness and safety, consists of an erythematous reaction and/or perifollicular oedema (around the hair follicle) of varying intensity and/or slight erythema on the skin, with a sensation of mild pain or hypersensitivity experienced by the patient which can be compared to hot pinpricks and an absence of other signs, especially in dark phototypes, and always an absence of adverse effects.

Diode^{810nm} **XXL** 30x17 | STATIC MODE



Skin phototype (Fitzpatrick I-VI)	Hair colour	Hair thickness	Fluence (J/cm ²)		Pulse duration (ms)	Fluence (J/cm ²)
			Maximum range			Predetermined
I	Blond	Fine	16	20	AUTO	13
		Thick/Dense	14	18		12
	Brown	Fine	14	17		12
		Thick/Dense	13	16		11
	Black	Fine	13	16		11
		Thick/Dense	11	14		10
II	Blond	Fine	13	16	AUTO	12
		Thick/Dense	12	15		11
	Brown	Fine	12	15		11
		Thick/Dense	11	14		10
	Black	Fine	11	14		10
		Thick/Dense	10	13		9
III	Blond	Fine	12	15	AUTO	11
		Thick/Dense	10	13		9
	Brown	Fine	10	13		9
		Thick/Dense	10	12		8
	Black	Fine	10	12		8
		Thick/Dense	9	11		7
IV	Blond	Fine	NE	NE	30	NE
		Thick/Dense	NE	NE		NE
	Brown	Fine	10	12		8
		Thick/Dense	9	11		7
	Black	Fine	9	11		7
		Thick/Dense	8	10		6
V	Blond	Fine	NE	NE	100	NE
		Thick/Dense	NE	NE		NE
	Brown	Fine	11	14		10
		Thick/Dense	10	13		9
	Black	Fine	10	13		9
		Thick/Dense	8	10		6
VI	Blond	Fine	NE	NE	400	NE
		Thick/Dense	NE	NE		NE
	Brown	Fine	NE	NE		NE
		Thick/Dense	NE	NE		NE
	Black	Fine	10	12		8
		Thick/Dense	9	11		7

SPECIAL CONSIDERATIONS primelase HR excellence– 30x17 - 810 nm

Phototype IV / Any hair morphology:

The AUTO pulse duration can be used at any stage of the treatment as long as the tolerance of the patient permits it, in accordance with the fluences shown in the table below.

If a treatment with a pulse length of 30 ms cannot be carried out due to the tolerance of the patient, use a pulse length of 100 ms during the first treatment sessions and then move to a pulse length of 30 ms when the tolerance of the patient permits.

Recommended fluences for the AUTO pulse duration for phototype IV in addition to those specified in the parameter table for 810 nm with a 30x17 spot.

Skin phototype (Fitzpatrick I-VI)	Hair colour	Hair thickness	Fluence (J/cm ²)		Pulse duration (ms)	Fluence (J/cm ²)
			Maximum range			Predetermined
IV	Light/blond	Fine	NE	NE	AUTO	NE
		Thick/Dense	NE	NE		NE
	Brown	Fine	9	11		6
		Thick/Dense	7	9		5
	Black	Fine	7	9		5
		Thick/Dense	6	8		5

Recommended fluences for the 100 ms pulse duration for phototype IV in addition to those specified in the parameter table for 810 nm with a 30x17 spot.

Skin phototype (Fitzpatrick I-VI)	Hair colour	Hair thickness	Fluence (J/cm ²)		Pulse duration (ms)	Fluence (J/cm ²)
			Maximum range			Predetermined
IV	Light/blond	Fine	NE	NE	100	NE
		Thick/Dense	NE	NE		NE
	Brown	Fine	13	16		12
		Thick/Dense	12	15		11
	Black	Fine	12	15		11
		Thick/Dense	11	14		10

Phototype V / Any hair morphology

The AUTO pulse duration can be used at any stage of the treatment as long as the tolerance of the patient permits it, in accordance with the fluences shown in the table below:

Recommended fluences for the AUTO pulse duration for phototype V in addition to those specified in the parameter table for 810 nm with a 30x17 spot.

Skin phototype (Fitzpatrick I-VI)	Hair colour	Hair thickness	Fluence (J/cm ²)		Pulse duration (ms)	Fluence (J/cm ²)
			Maximum range			Predetermined
V	Light/blond	Fine	NE	NE	AUTO	NE
		Thick/Dense	NE	NE		NE
	Brown	Fine	5	6		4
		Thick/Dense	4	5		3
	Black	Fine	4	5		3
		Thick/Dense	4	5		3

If the tolerance of the patient permits it, and especially with patients with thicker hair, the 30 ms pulse duration can be used at any stage of the treatment, in accordance with the fluences shown in the table below.

Recommended fluences for the 30ms pulse duration for phototype V in addition to those specified in the parameter table for 810 nm with a 30x17 spot.

Skin phototype (Fitzpatrick I-VI)	Hair colour	Hair thickness	Fluence (J/cm ²)		Pulse duration (ms)	Fluence (J/cm ²)
			Maximum range			Predetermined
V	Light/blond	Fine	NE	NE	30	NE
		Thick/Dense	NE	NE		NE
	Brown	Fine	7	9		6
		Thick/Dense	6	8		5
	Black	Fine	6	8		5
		Thick/Dense	6	7		4

Phototype VI / Any hair morphology

The 100ms pulse duration can be used at any stage of the treatment as long as the tolerance of the patient permits it, in accordance with the fluences shown in the table below:

Recommended fluences for the 100 ms pulse duration for phototype VI in addition to those specified in the parameter table for 810 nm with a 30x17 spot.

Skin phototype (Fitzpatrick I-VI)	Hair colour	Hair thickness	Fluence (J/cm ²)		Pulse duration (ms)	Fluence (J/cm ²)
			Maximum range			Predetermined
VI	Light/blond	Fine	NE	NE	100	NE
		Thick/Dense	NE	NE		NE
	Brown	Fine	NE	NE		NE
		Thick/Dense	NE	NE		NE
	Black	Fine	7	9		6
		Thick/Dense	6	8		5

3. Dynamic treatment mode

In this section the procedure for performing a treatment in dynamic mode with the primelase HR excellence device is briefly explained. The dynamic mode is ideal for initial treatment sessions with patients who have a higher sensitivity to pain and/or more dense hair.

3.1 Beginning the treatment

The dynamic mode is ideal for initial treatment sessions with patients who have a higher sensitivity to pain and/or more dense hair.

Mark the area to be tested by dividing or segmenting the treatment area into a grid of equally sized squares (30x10cm² / 20x15cm² and/or 15x10cm², depending on the area of the body being treated).

Make a selection according to the parameter table, depending on the skin phototype, hair characteristics and selected grid:

1. *Pulse duration:*
2. *Fluence*
3. *Accumulated energy*
4. *Frequency*

Shorter pulses will deliver better hair removal results, and the patient may feel a pinching sensation. Longer pulses will result in a more comfortable treatment.

Select the pulse frequency, the recommended value is 10Hz. If you choose a lower frequency (5Hz minimum), the treatment will take longer but may be more comfortable.

Hold the head on the treatment area in a perpendicular fashion.

Begin the treatment by moving the head of the device horizontally or vertically in a sweeping motion (slide the head across the grid until the required energy is automatically administered in the established timeframe). Maintain a constant speed and ensure an even sweep of the entire grid.

The approximate average speed of movement for each grid is 10 cm per second.

The device should stop automatically when the selected time limit and number of shots have been reached. However, the treatment must be stopped if the patient reports excessive heat or if you notice an erythema or excessive reddening.

Optimal treatment in dynamic mode can be defined as one that is both comfortable for the patient (optimal tolerance) and produces slight erythema or perifollicular inflammation (positive reaction).

You are advised to switch to the static system after the first or second treatment session, depending on the tolerance of the patient. When switching to static mode, we will follow the parameter selection method outlined in previous sections.

Recommended values: suggested minimum values for pulse duration and maximum values for fluence and accumulated energy, with which a comfortable, fast and effective treatment can be obtained.

- *To optimise results it is possible to increase **the fluence in increments of 1 J/cm² and/or the accumulated energy in increments of 0.5 kJ, depending on the tolerance of the patient** (increasing the values will result in less comfort and longer treatment times).*
- *If at the beginning of a treatment a patient is unable to tolerate it, stop the treatment and decrease the fluence by 1 J/cm².*
- *If during a treatment the patient is unable to tolerate it, or if you notice an erythema or excessive reddening, the treatment must be stopped and the accumulated energy lowered by 0.5 kJ.*
- *For subsequent sessions, you can start by using the last applied parameters. Always observe the reaction of the skin (check the patient's file).*

Diode^{810nm} **XXL** 30x17 | DYNAMIC MODE



Skin phototype (Fitzpatrick I-VI)	Grid (cm x cm)	Pulse duration (ms)	Fluence (J/cm ²)	Accumulated energy (kJ)	Pulse duration (ms)	Fluence (J/cm ²)	Accumulated energy (kJ)	Frequency Hz
		Hair thickness						
		Thick hair			Fine hair			
I	30x10/ 20x15	6	5	9	7	6	11	10
	15x10	6	5	4.5	7	6	5.5	10
II	30x10/ 20x15	6	5	8	7	6	10	10
	15x10	6	5	4	7	6	5	10
III	30x10/ 20x15	5	4	6	6	5	8	10
	15x10	5	4	3	6	5	4	10
IV	30x10/ 20x15	4	3	5	5	4	7	10
	15x10	4	3	2.5	5	4	3.5	10
V	30x10/ 20x15	3	2	5	4	3	7	10
	15x10	3	2	2.5	4	3	3.5	10
VI	30x10/ 20x15	9	2	5	9	3	7	5
	15x10	9	2	2.5	9	3	3.5	5



primelase HR

EXCELLENCE

Plataforma de LASER de diodo desarrollada con la exclusiva tecnología de **cocoon medical**. Tiene una potencia máxima de 4800W y cuenta con diferentes longitudes de onda (755, 810, 940 y 1060nm) para poder trabajar todos los fototipos de piel y tipos de vello durante todas las épocas del año.

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