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Z Y E

Clinical Practice Development Program


ZYE ALEXANDRITE

prepared and revised by Antonio Olivatto and Giovana Milani; FEB 2020

Vydence Medical

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medical

 etherea™



Z Y E



THE WORLD'S
FIRST
SMARTLASER.

SEE MORE AT:
ZYE.ONLINE

ZYE LASER FAMILY

ZYE YAG OR ZYE ALX LASERS

The smartest, most powerful and versatile online connected LASER platform system with either a built-in 755-nm ALX or 1,064-nm Nd:YAG LASER cavity.



ZYE LASER: ALEXANDRITE or Nd:YAG

FULL-CAVITY LASER SYSTEM & PLATFORM

POWER, VERSATILITY AND DESIGN

- 2 models available: ALEX & YAG
- 4 optical fibers, dedicated hps;
- Fully-compatible with all Etherea MX[®] handpieces;
- Squared, flat-top beam profile;



ZYE ALX/YAG[®]: LASER Platform

THE WORLD'S FIRST SMARTLASER



3-24/HR

**Hair
Removal**



8-18/HR

**Hair
Removal**



5-15/LT

**LASER
Tightening**

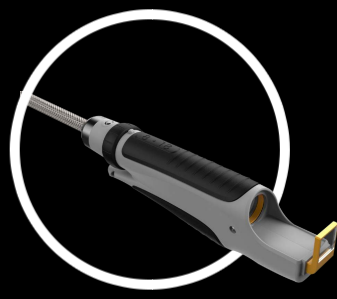


3-10/VL

**Vascular
Lesions**



3-24/HR



8-18/HR



5-15/LT



3-10/VL

handpiece & spot sizes	main features	treatment indications	cooling & temperature control	ZYE ALX* short/long pulsed modes	ZYE ALX* short/long pulsed modes
3-24/HR; 3, 5, 6, 10, 14, 16, 18, 20, 24, +26 round spot top hat beam profile	air-cooling, plug-and-play spots	hair removal vascular lesions short pulsed onychomycosis pigmented lesions	air-cooling system hands-free adapter	Dynamics, 20 Hz LongPulse, 3 Hz	Dynamics, 20 Hz LongPulse, 3 Hz
8-18/HR; 8, 10, 12, 14, 16, 18 squared spot top hat beam profile	Cool-&Clear® sapphire, Telescope® zoom, Flat-Frame® lenses	hair removal pigmented lesions	super contact-cooling down to 4 °C	LongPulse, 3 Hz	LongPulse, 3 Hz
5-15/LT; 5, 10, 15 round spot top hat beam profile	air-cooling, plug-and-play spots; AccuSense® temp control system	LASER tightening short pulsed YAG onychomycosis	real-time skin temp control through bar graph	n/a	Dynamics, 20 Hz INTENSE, cw
3-10/VL; 3, 5, 6, 8, 10 round spot top hat beam profile	Cool-&Clear® sapphire, Telescope® zoom	vascular lesions short pulsed onychomycosis pigmented lesions	super contact-cooling down to 4 °C	Dynamics, 20 Hz LongPulse, 3 Hz	Dynamics, 20 Hz LongPulse, 3 Hz

*operating modes given pulse width;
 • ALX/YAG DYNAMICS: 200-1.000 us; for onychomycosis, non-ablative, thermal-induced peeling;
 • ALX/YAG LONGPULSE: 1-300 ms; hair removal, vascular lesions (e.g. hemangiomas), anti-aging;
 • YAG INTENSE: continuo; YAG LASER tightening for body and face treatments;

ZYE ALX: SMARTLASER PLATFORM

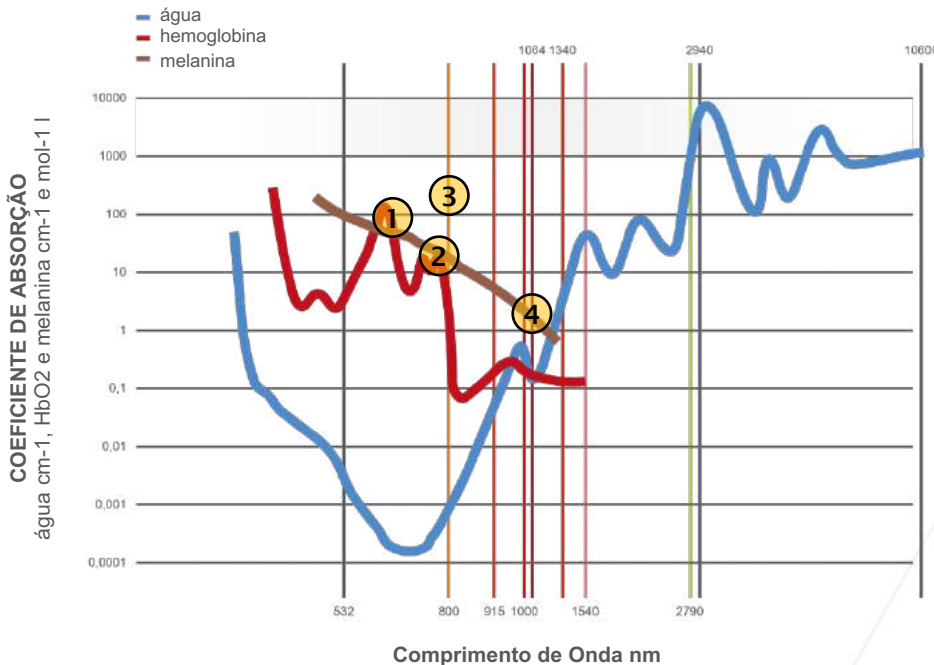
FULL-CAVITY LASER SYSTEM WITH ALEXANDRITE 755 nm



- Hair Removal
- Pigmented Lesions
- Vascular Lesions

ZYE ALX: GOLD STANDARD IN HAIR REMOVAL

WAVELENGTH

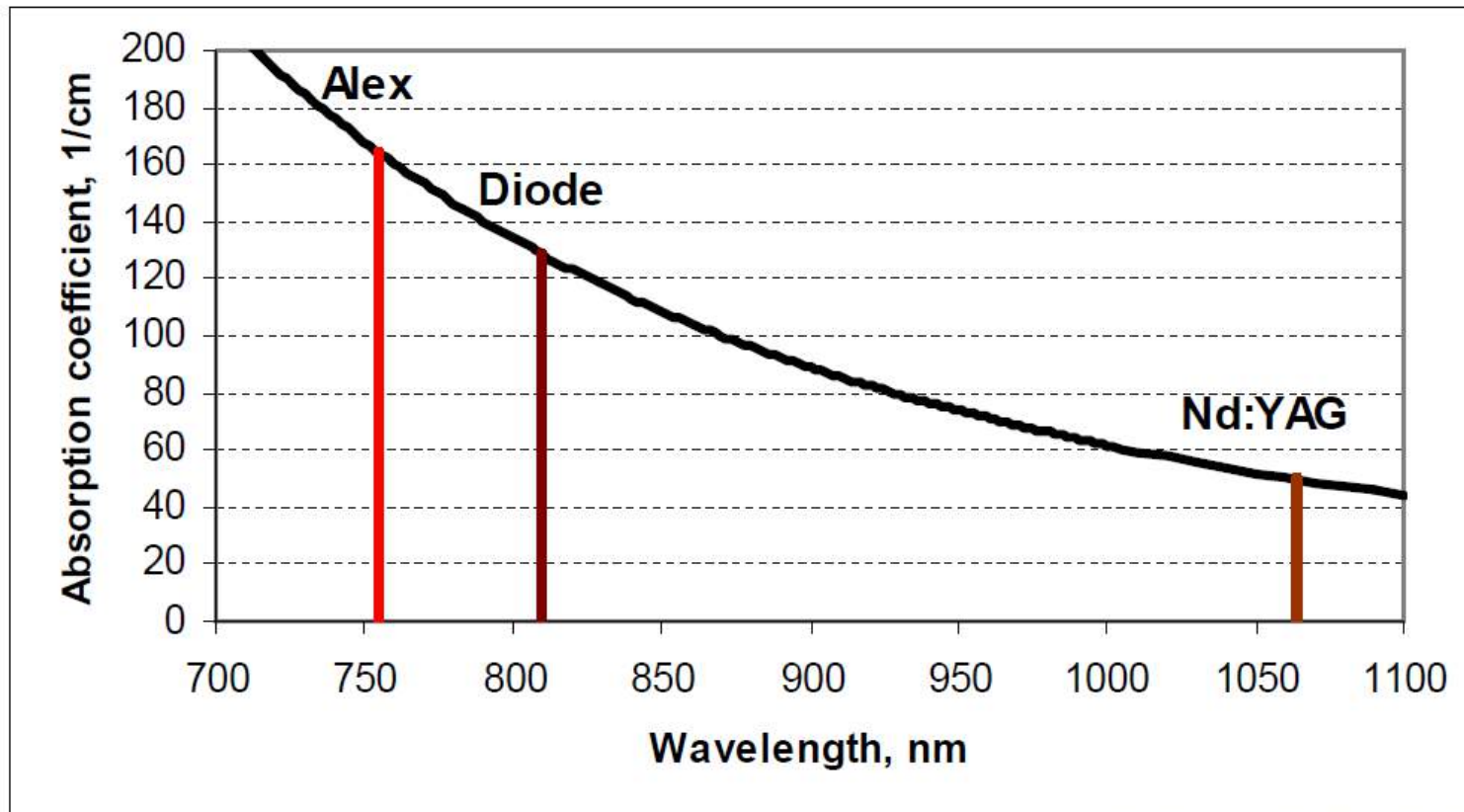


- Ratio of **target chromophore** and absorption curve as a function of **wavelength**;
- **ALEXANDRITE 755 nm**: high affinity with melanin and good relationship with hemoglobin
- **Good penetration** - low affinity for H₂O
- **Greater absorption than ~800 nm e 1.064 nm**;

1. **Ruby 694 nm**;
2. **ALEXANDRITE 755 nm**;
3. **Diode 810/815**;
4. **Nd:YAG 1.064 nm**;

ZYE ALX: GOLD STANDARD IN HAIR REMOVAL

WAVELENGTH: ALEXANDRITE 755-nm



ZYE ALX: GOLD STANDARD IN HAIR REMOVAL

WAVELENGTH VERSUS OTHER MODALITIES

IPL, 590-1.200 nm

- Phototypes I - IV
- Better for dark hair and light skin
- Less precision: security X number of sessions

DIODE LASER, 800/810 nm

- Phototypes I – V
- Better for dark hair
- Sometimes painful treatments

ALEXANDRITE, 755 nm

- Phototypes I – V – gold stand
- All kind of hair
- world standard: effectiveness and safety

Nd:YAG, 1.064 nm

- All phototypes, especially for higher
- darker and thicker hair
- Sometimes painful treatments



LASER DE DIODO 800/808 nm

ALEXANDRITE 755 nm

Nd:YAG 1.064 nm

Large Pulse Width

MODERN ALEXANDRITE

ZYE ALX: GOLD STANDARD IN HAIR REMOVAL

Dermatol Surg. 2000 Feb;26(2):130-4.

Alexandrite laser hair removal is safe for Fitzpatrick skin types IV-VI.

Garcia C¹, Alamoudi H, Nakib M, Zimmo S.

Author information

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755nm Fiber Delivered Handpiece (Zye and One)
755nm

•Intended for the temporary and permanent hair reduction on all skin types (Fitzpatrick I-VI), including tanned skin.
Permanent hair reduction is defined as long-term, stable reduction in hair counts observed at 6, 9, and 12 months after the end of a treatment regime; treatment of benign pigmented lesions; treatment of wrinkles; photocoagulation of dermatological vascular lesions, such as, but not limited to, port wine stains, hemangiomas and telangiectasias.

Predicate Devices: GentleMAX Family of Laser Systems (K133283)

Intended Use / Indications for Use:



The GentleLASE Family of Laser Systems is indicated for the following:

The GentleLASE Family of Laser Systems is indicated for temporary hair reduction. Stable long-term or permanent reduction through selective targeting of melanin in hair follicles. Permanent hair reduction is defined as long-term stable reduction in the number of hairs regrowing after a treatment regime. On all skin types (Fitzpatrick I- VI) including tanned skin. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime.

ALEXANDRITE LASERS at 755 nm (long pulse) have evolved over the years. The idea was to offer longer pulse times with fluences capable of treating different types of hair and phototypes with the same effectiveness as before, but with greater security.

Product	Modified GentleLASE Family of Laser Systems (GentleLase Pro and GentleLase Pro LE Laser Systems)
Laser type	Flashlamp-excited, Solid state Alexandrite laser
Wavelength	755nm
Pulse duration	3 – 300 ms
Maximum fluence	53 J/cm ²
Spot size	6, 8, 10, 12, 15, 18, 20, 22, 24mm

SPECIFICATIONS

		
Laser Type	Flashlamp excited long-pulse alexandrite laser	Flashlamp excited long-pulse alexandrite laser
Wavelength	755 nm	755 nm
Pulse	Rep Rate up to 1.5 Hz Duration 3 ms	Rep Rate up to 1 Hz Duration 3 ms

Physical Principles

ZYE ALX: LASER PROPERTIES & PHYSICS

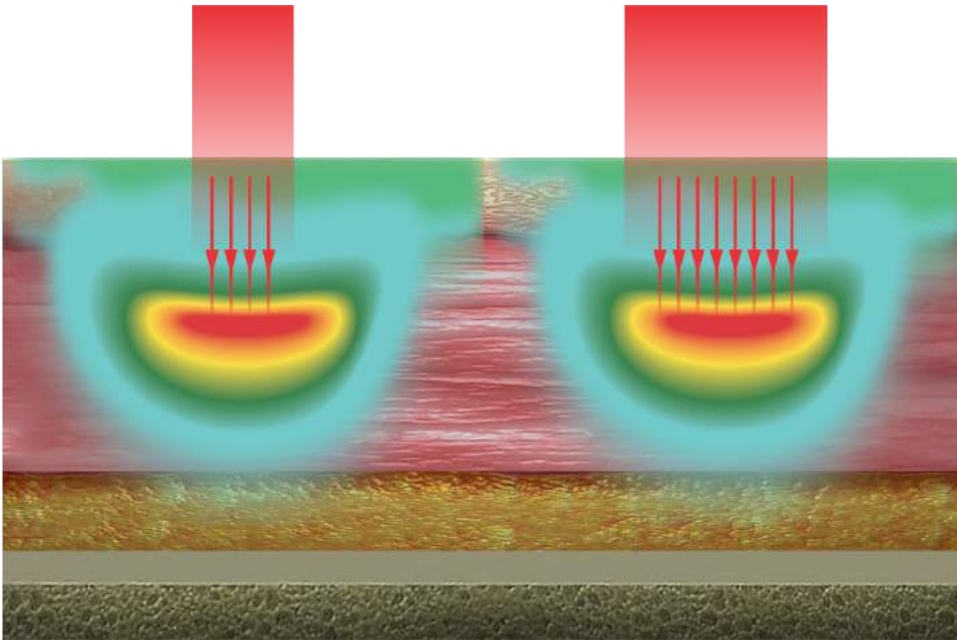
Treatment Parameterisation

$$\text{Fluence} = \frac{\text{Energy Joules}}{\text{Area cm}^2}$$

- ENERGY: Joules
- FLUENCE: J/cm²
- **larger spots result in more energy and less fluence;**
- **smaller spots result in less energy and greater fluence**

ZYE ALX: LASER & TISSUE PROPERTIES

Thermal Relaxation Time



- Pulse duration is the time needed to deliver the desired fluence or energy, which is measured in milliseconds (ms) in IPL's case;
- It must be lower than the **TRT** in order to obtain the proper photothermal effect in the target chromophore;
- **TRT**: between the epidermis and the different treatment targets;
- Time to lose 50% of the heat absorbed by the target chromophore or tissue;

THERMAL SELECTIVITY IS THE DIFFERENCE BETWEEN THERMAL CAPACITY AND THE THERMAL RELAXATION TIME (TRT).

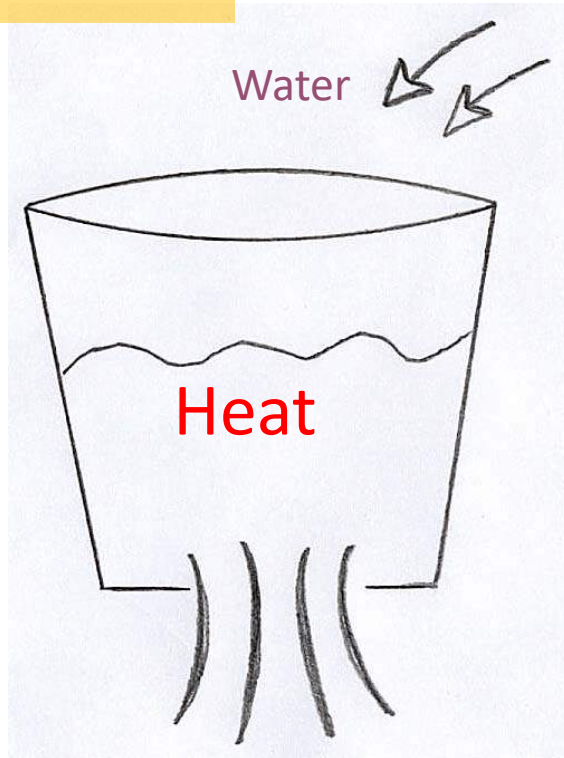
ZYE ALX: LASER & TISSUE PROPERTIES

PULSE WIDTH/DURATION

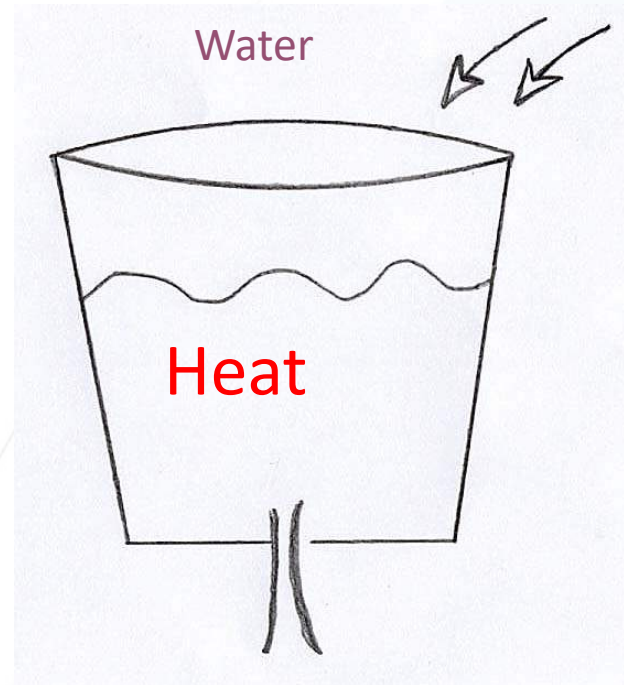
Pulse
width

\leq

TRT
hair



SKIN: $T_R=1$ a 3 mseg



THICK HAIR: $T_R=40$ mseg

ZYE ALX: LASER & TISSUE PROPERTIES

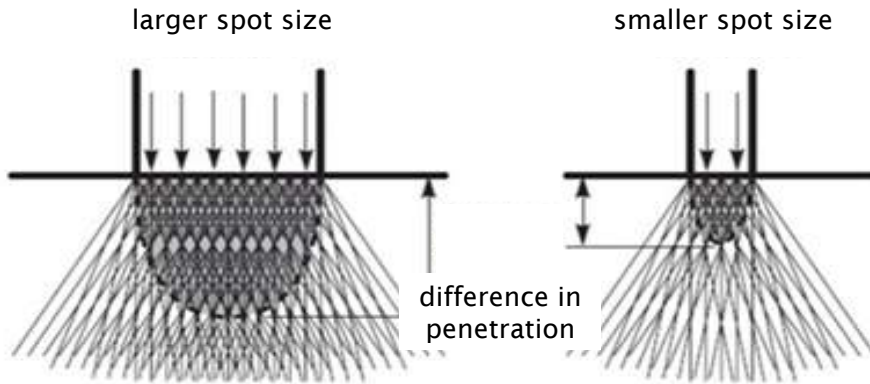
THERMAL RELAXATION TIME

CHROMOPHORE	DIAMETER	APPROX. TRT
tattoo pigment	0.1 μm	800 ns
melanosome	0.5 μm	10-100 ns
MVP vessels	30-100 μm	0.4-20 ms
epidermis	100 μm	1 ms
hair follicle	150-200 μm	3-100 ms
leg veins	3-6 mm	100 ms

- TRT THERMAL RELAXATION TIME AND IT REFERS TO ½ HEAT LOSS

ZYE ALX: LASER & TISSUE PROPERTIES

treatment parameterisation



- **Larger spot sizes** are recommended for treating deeper hairs, ex: bikini area
- **Smaller spot sizes** are recommended for treating superficial hairs: above lips

SPOT SIZE	PENETRATION
1 mm	0.8 mm
3 mm	1.5 mm
7 mm	3 mm
10 mm	4 mm
12 mm	4.5 mm
18 mm	5 mm

BODY AREA	DEEPTH
Scalp	3-5mm
Beard	2-4mm
Moustache	1-2mm
Armpits	3-4mm
Bikini line	3-4mm
Legs	2-3mm

ZYE ALX: LASER & TISSUE PROPERTIES

Treatment Parameterisation

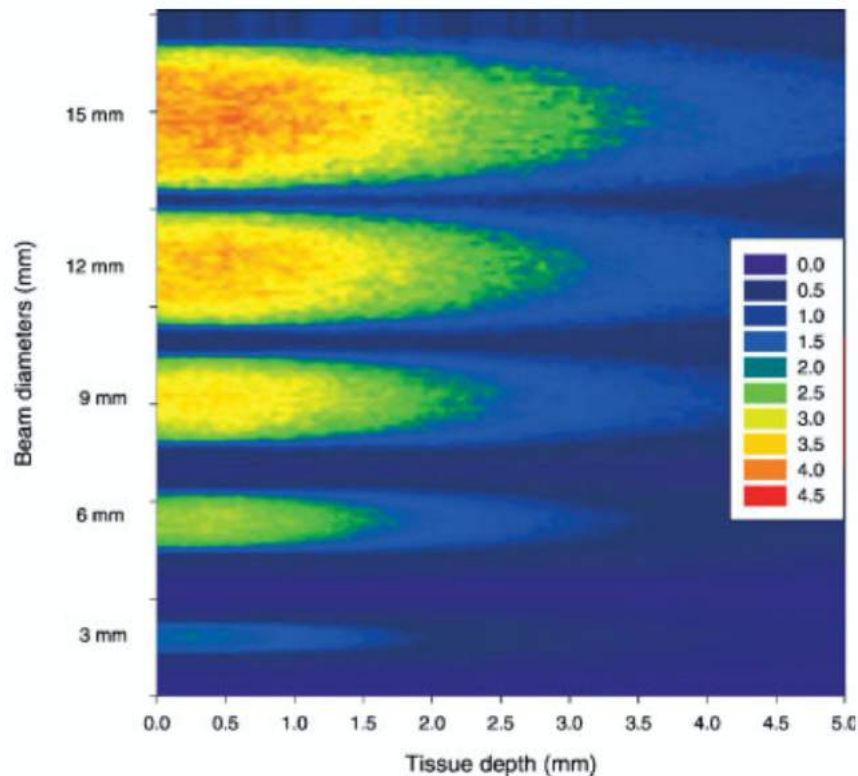


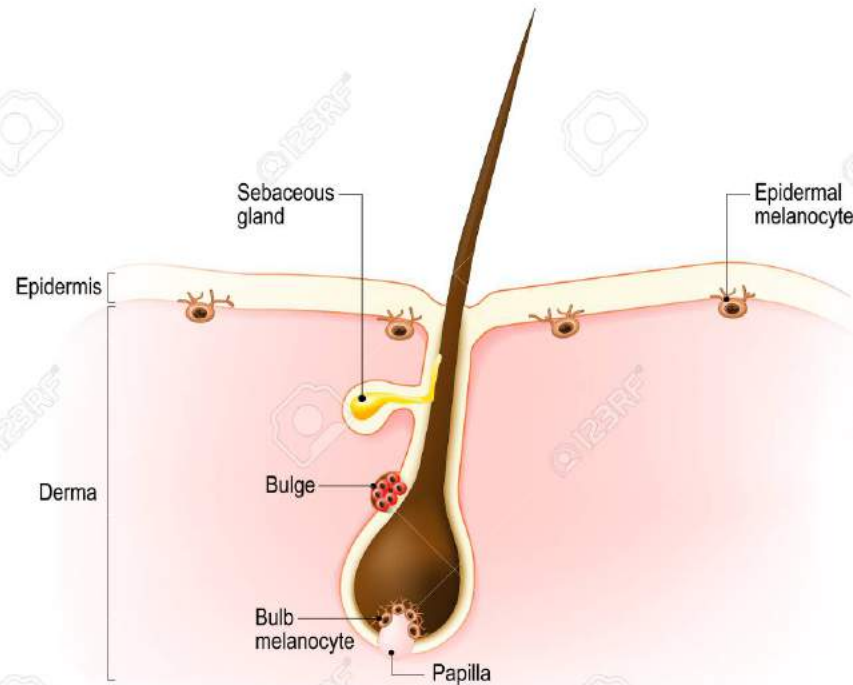
Fig. 4. It shows the distributions of fluence rate in dermis at 1,064-nm laser irradiation for 3-, 6-, 9-, 12-, and 15-mm beam diameters.

- The figure shows the distribution of the fluence radiated on the tissue with spots of 3, 6, 9, 12, and 15 mm in diameter;
- **difference in the effective penetration of the LASER beam directly associated to the spot size and the ratio of fluence and energy;**

Hair Removal

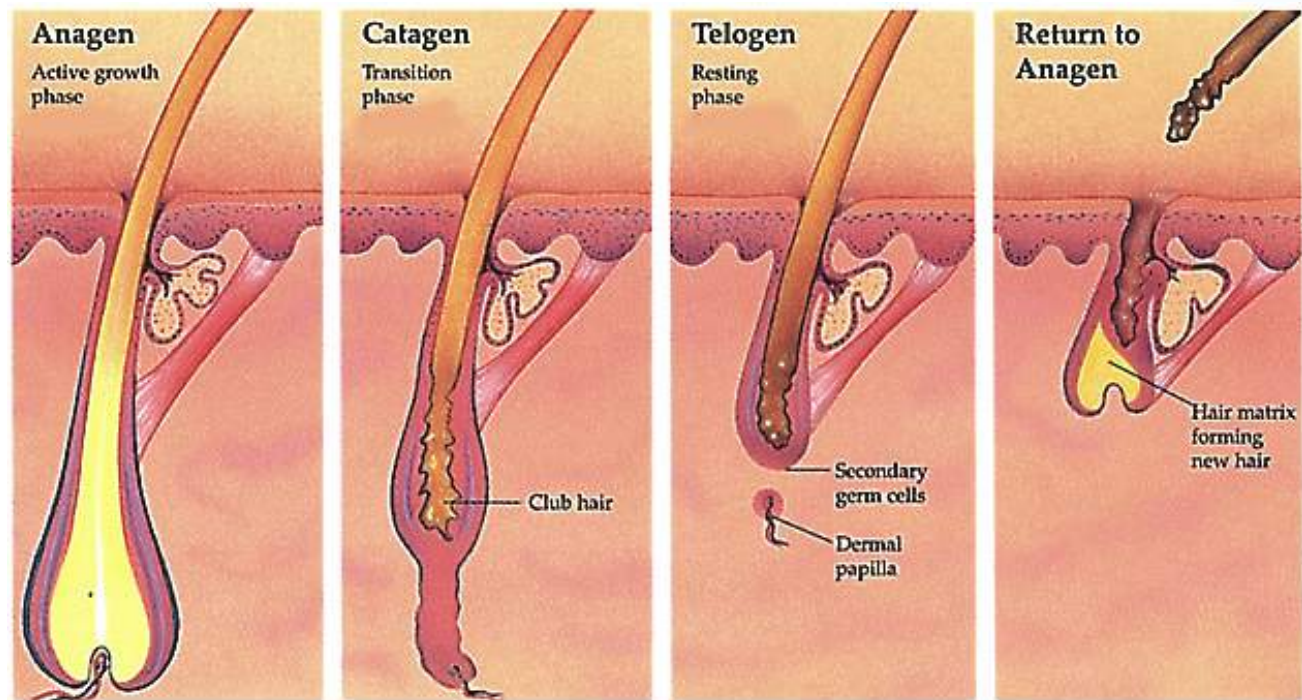
ZYE ALX: GOLD STANDARD IN HAIR REMOVAL

The hair follicle



ZYE ALX: GOLD STANDARD IN HAIR REMOVAL

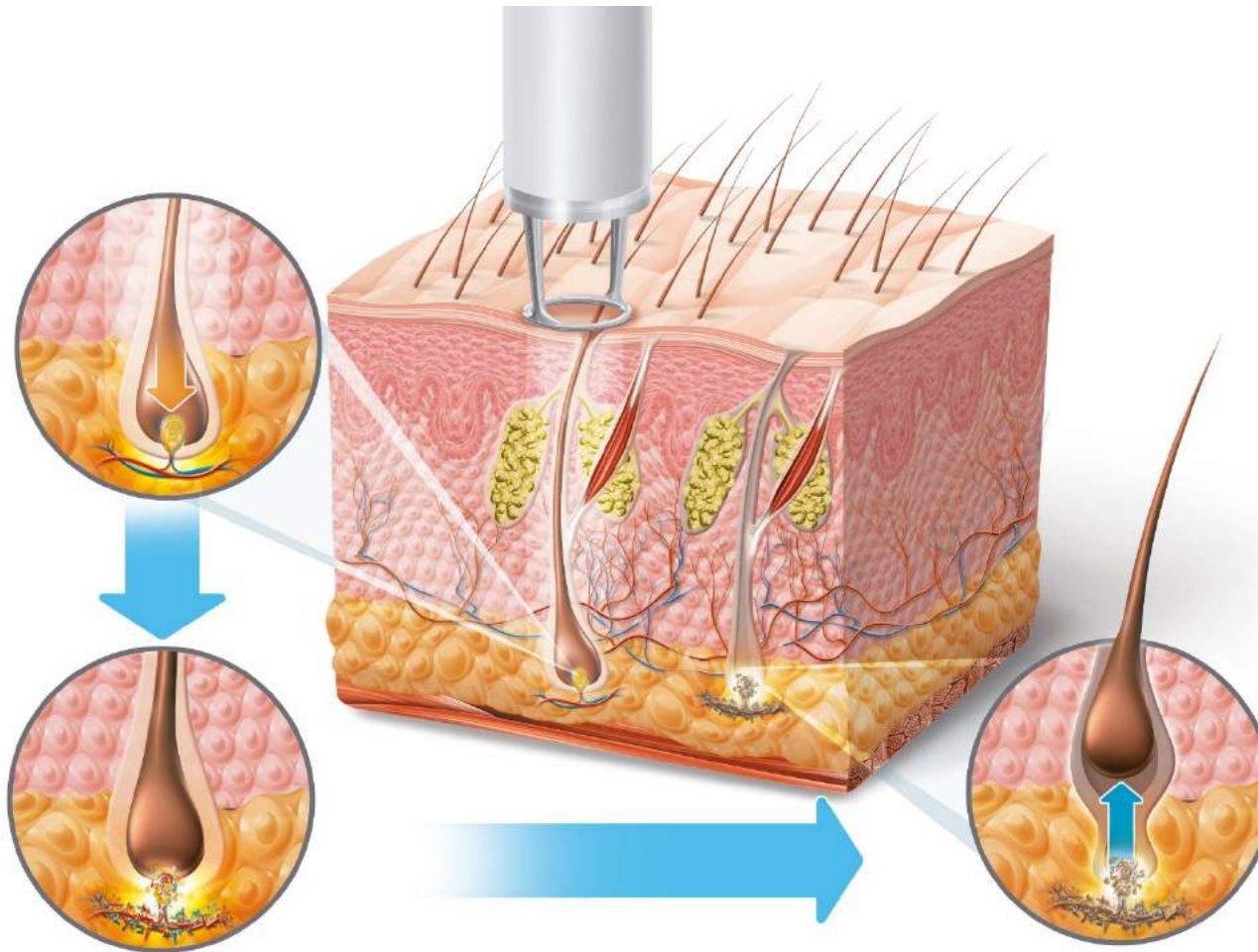
HAIR FOLLICLE CYCLE



- For effective hair destruction, hair must be in the anagen phase
- Hairs from the same area can be in different stages of the growth cycle;

ZYE ALX: GOLD STANDARD IN HAIR REMOVAL

BASIC PRINCIPLE OF ACTION ON TISSUE



1. The target is melanin in the hair follicle.
2. The LASER/LIGHT is absorbed by the hair shaft
3. The heat is conducted to the bulb,
4. The surrounding cells are destroyed: such as the bulb itself and the bulge.

ZYE ALX: GOLD STANDARD IN HAIR REMOVAL

BASIC PRINCIPLE OF ACTION ON TISSUE

Body area	Anagen hair (%)	Telogen duration	Density (cm ²)
Scalp	85	4 months	350
Beard	70	10 weeks	500
Moustache	65	6 weeks	500
Armpits	30	3 months	65
Bikini line	30	3 months	70
Legs	20	4 months	60

Lebster J. Elman M. Biological and clinical aspects in laser hair removal. J Dermatol Treatment 2004; 15; 72-83.

ZYE ALX: GOLD STANDARD IN HAIR REMOVAL

GLOBAL EFFICACY



- Studies show that there is an 80% reduction in hair after a series of treatments;
- 755nm or 1064nm do not treat white, blond, red or gray hair;
- Garcia et al, 2000: 150 pat, IV/V, 40ms, 1hz, 13 a 24J/cm², spot10mm or 12,5mm. 40% reduction – 3ttx 2% problems after.

Images: E. Bernstein. BLINDED, BILATERAL HAIR REMOVAL STUDY COMPARING THE ALEXANDRITE LASER WITH MPX MODE PRELIMINARY RESULTS 6 SUBJECT SUBSET. Available in:
<http://www.cynosurechina.com/uploadfile/2014/0618/20140618031231775.pdf>
GARCIA C, ALAMOUDI H, NAKIB, M, ZIMMO S. ALEXANDRITE LASER HAIR REMOVAL IS SAFE FOR FITZPATRICK SKIN TYPES IV-VI. DERMATOL SURG 2000;26:130-134.

ZYE ALX: GOLD STANDARD IN HAIR REMOVAL

FUNDAMENTAL PILLARS OF LASER HAIR REMOVAL

EFFICACY	SPEED	COMFORT
<ul style="list-style-type: none">• Wavelength• Correct fluency• Pulse duration• Beam quality	<ul style="list-style-type: none">• Spot size• Repetition rate (Hz)	<ul style="list-style-type: none">• Cooling

- **Efficacy:** less sessions (+ROI) = patient satisfaction;
- **Speed:** less time in the room, duration of the treatment;
- **Comfort:** greater adherence to treatments



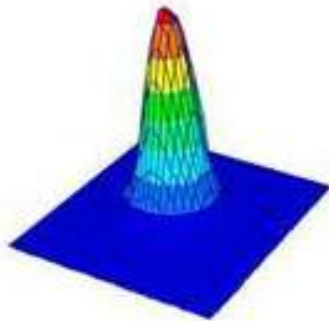
VYDENCE ZYE/ALEX	
Wavelength	755 nm
Spot sizes <i>Plug-and-Play</i>	3, 5, 6, 8, 10, 12, 14, 15, 16, 18, 22, 24, +26 mm
Spot sizes <i>Zoom Digital</i>	8-18 mm 3-10 mm
Power	55 J
Pulse duration	0.3 to 300 ms
speed	Dynamics: up to 20 Hz LongPulse: up to 3 Hz
cooling	Sapphire window or air-cooling
Consumables	no
Platform	yes

ZYE ALX: GOLD STANDARD IN HAIR REMOVAL

BEAM HOMOGENISATION

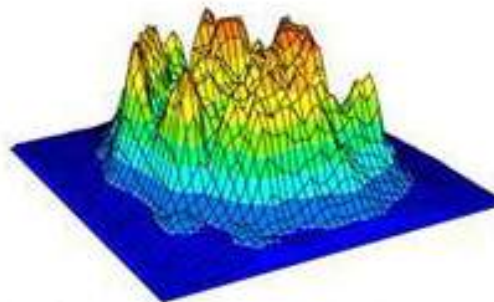
- **Homogeneous top hat beam;**
- **Greater safety:** no localized overheating points;
- **Greater treatment efficiency:** no risk of undertreatment areas, with untreated points;

Gaussian beam



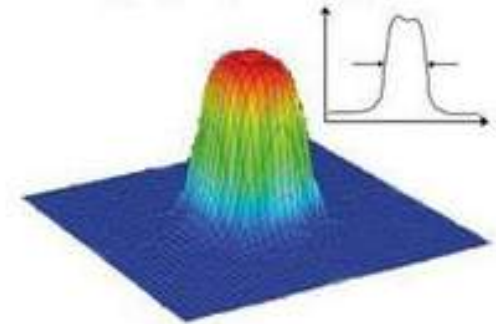
stable resonator with single mode
lasing: gas laser (He-Ne, Ar, etc.),
solid state lasers (Nd:YAG)

Multimode beam



stable resonator with multimode
lasing: solid state lasers (Nd:YAG),
gas laser (CO₂)

Flat-top (top-hat) beam



unstable resonator:
excimer lasers

ONE ALX: HANDPIECE 8-18/HR

COOLING SYSTEM COOL-&-CLEAR AND SQUARE SPOT - FLAT FRAME



OPTICAL DIGITAL ZOOM
ZYE TELESCOPE® integrated into the handpiece, with automatic spot size adjustment and interface parameterization.

SIMULTANEOUS COOLING **COOL-&-CLEAR®**

- Sapphire window for more comfort and visibility;
- Prevents dispersion of treated follicles, preventing, for example, from reaching the inner lenses of the handpiece
- Up to 4 °C minimum temperature

FLAT-FRAME® OPTICAL TECHNOLOGY

- Microlenses for uniformization and homogenization of the beam in top hat;
- Square format: increases the coverage density by region without leaving untreated areas;
- Increases the speed of the procedure by 25%;
- Lower risk of undertreatment areas, with untreated points;

ONE ALX: HANDPIECE 3-24/HR

SPOT PLUG-AND-PLAY 3-24 mm AND AIR COOLING



ADAPTER FOR AIR COOLING SYSTEM: allows the use of attached accessory device and does not require consumables,

increases the rentability of the procedure and increases the usability of the LASER

MULTIPLE SPOTS PLUG-AND-PLAY WITH AUTOMATIC RECOGNITION: 3 – 24mm spot sizes, round



ZYE ALX: GOLD STANDARD IN HAIR REMOVAL

SPEED AND VERSATILITY

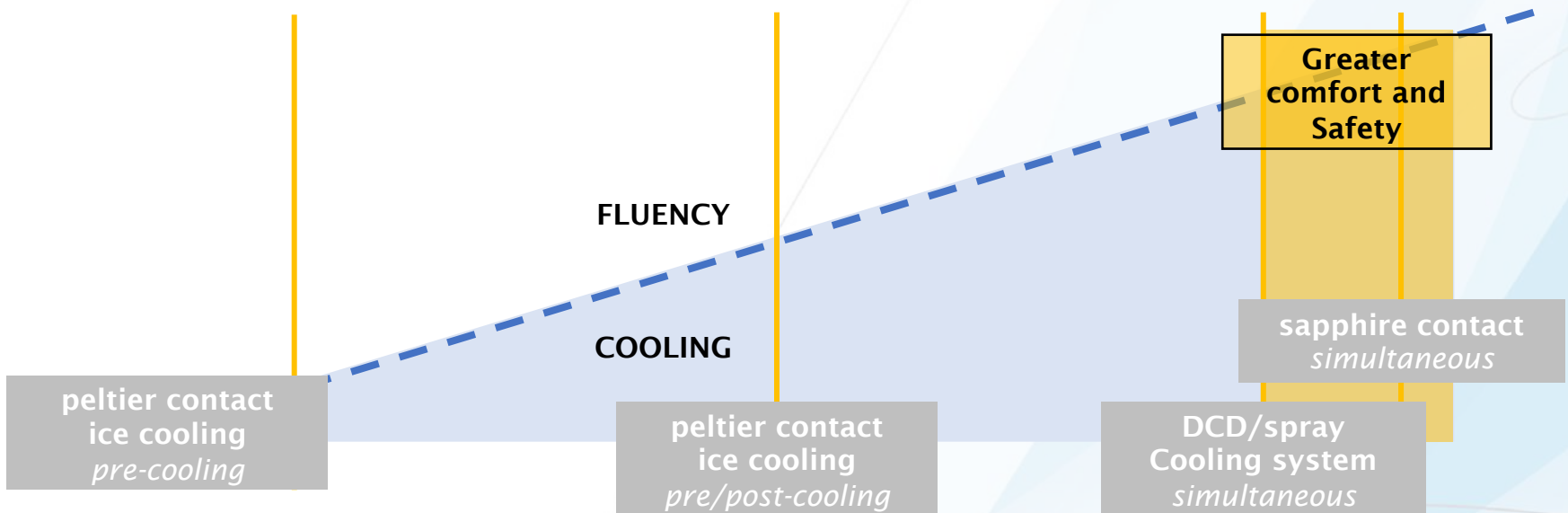


- Square spot: 25% bigger
- High treatment speed,
- Available spots: handpiece 3-24 / HR[®] (round); handpiece 8/18 /HR[®] (square)
- Reaches up to 3 Hz with smaller spots and shorter pulse times;

ZYE ALX: GOLD STANDARD IN HAIR REMOVAL

COOLING EFFICIENCY

- Cooling allows high levels of fluency to be delivered and ensures efficacy;
- The better and more efficient the cooling, the greater the comfort and safety during the treatment;



Treatment Protocol

ZYE ALX: GOLD STANDARD IN HAIR REMOVAL

TREATMENT PROTOCOL

- For the procedure, keep the **skin clean and dry**;
- **Short hair** (shave on the day of the treatment or the day before);
- **Be very careful** with active tan;
- **No stacking**;
- Average of **4 to 6 sessions**
- **Interval of 30 to 45 days**



ZYE ALX: GOLD STANDARD IN HAIR REMOVAL

END POINT & POST-TREATMENT CARE



END POINTS

- Edema and perifollicular erythema;
- Some patients may experience considerable edema and / or erythema;
- Fine hair may not show edema and perifollicular erythema;

POST-TREATMENT

- Use aloe vera gel;
- Topical corticoids
- Sunscreen SPF 30+;

ZYE ALX: GOLD STANDARD IN HAIR REMOVAL

APPLICATION TECHNIQUE

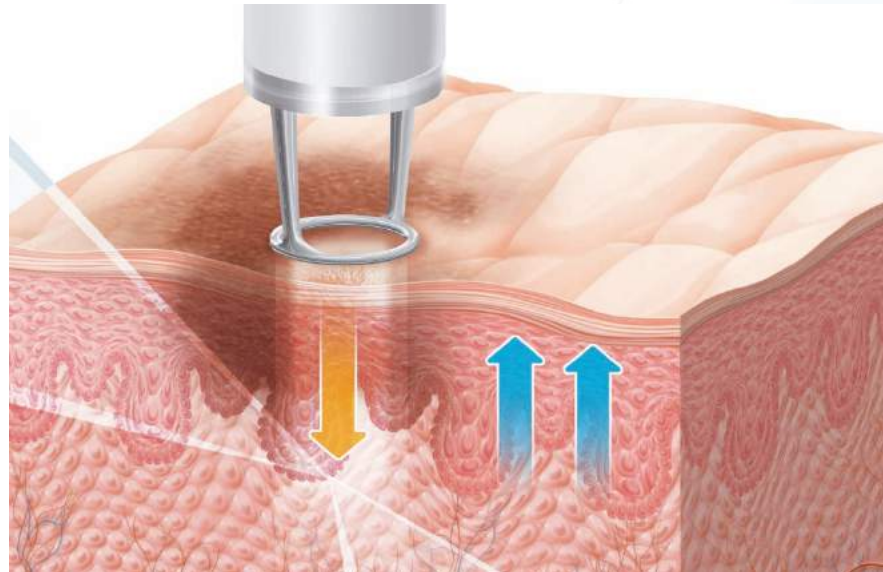


- **TOTAL CONTACT:** the spacer / tip must be in full contact with the skin surface;
- **PERPENDICULAR:** the applicator must always be at 90 ° with the skin surface;

ZYE ALX: SUPERFICIAL PIGMENTARY LESIONS

THERAPEUTIC OPTION FOR BENIGN LESIONS

- **ZYE ALX with a 3 ms pulse can be used to remove:** melanosus, hyperpigmentation, lentigo, ephelides, café-au-lait spots in phototypes I-IV



ZYE ALX: VASCULAR LESIONS

THERAPEUTIC OPTION FOR VASCULAR LESIONS

- ZYE ALX can be used to treat: telangiectasias and hemangiomas in phototypes I-III**

TABLE 1. Absorption Coefficients for Respective Chromophores of Interest

	532 nm	595 nm	755 nm	800 nm	1,064 nm
Hb	219 cm ⁻¹	114 cm ⁻¹	8.4 cm ⁻¹	4.1 cm ⁻¹	0.3 cm ⁻¹
HbO ₂	237 cm ⁻¹	36 cm ⁻¹	3 cm ⁻¹	4.4 cm ⁻¹	3 cm ⁻¹
Blood (68% oxy, 32% deoxy)	231 cm ⁻¹	61 cm ⁻¹	4.7 cm ⁻¹	4.3 cm ⁻¹	2.1 cm ⁻¹
Melanin (12% volume fraction)	67 cm ⁻¹	46 cm ⁻¹	21 cm ⁻¹	17 cm ⁻¹	7 cm ⁻¹
Ratio (melanin/blood)	0.3	0.5	4.5	4	3.3

Ross EV, Meehan, KJ, Gilbert S, Domankevitz Y. OPTIMAL PULSE DURATIONS FOR THE TREATMENT OF LEG TELANGIECTASIAS WITH AN ALEXANDRITE LASER. Lasers Surg Med 2009; 41:104–109

ETHEREA-MX INTEGRATION WITH IMPROVEMENTS

Z Y E

etherea^{MX}
LIGHTSOURCE SOLUTIONS

ATHENA

TECNOLOGIA PARA O
TRATAMENTO ÍNTIMO
FEMININO A LASER



SPOT INLIFT

LASER LIFTING ATRAVÉS DE
TRATAMENTO INTRAORAL



IPL-SQ®

TECNOLOGIA IPL
COM PULSO DIGITAL
MICROPROCESSADO



DUALMODE®

ERTIAG DE PULSO DUPLQ,
COM EFEITO CDAGULATIVO
COMBINADO



INTENSE-IR®

TECNOLOGIA DE LUZ PARA SKIN
TIGHTENING EM FACE E CORPO



PRODEEP®

LASER FRACIONADO
NÃO-ABLATIVO COM
EFEITO SUBDERMICO



ACROMA®

LASER Q-SWITCHED
FRACIONADO E 2
COMPRIMENTOS DE ONDA



LONGPULSE®

LASER ND:YAG DE PULSO VARIÁVEL
- MICROPULSADO OU PULSO LONGO



GOSMOOTH®

PADRÃO OUBRO EM RESURFACING
FRACIONADO NÃO-ABLATIVO



ZYE PLATAFORM

MULTIPLE POSSIBILITIES

- Acroma – cut the hair before treatment
- IPL-Sq: with ZYE Yag for thin and light hair
- LongPulse: with ZYE Alex for tanned skin (small areas)



ZYE ALX: Benchmarking Competitors

	VYDENCE ZYE/ALEX	QUANTA DUETTO MT	CANDELA GentleMax
Is the gold standard wavelength for hair removal?	755 nm dedicated +7 handpieces MX very versatile ✓	755 nm single or +1,064-nm less versatile ±	755 nm single or +1,064-nm less versatile ±
Available number and spot sizes: + versatile and + fast	3, 5, 6, 8, 10, 12, 14, 15, 16, 18, 22, 24, +26 mm ✓	12, 14, 18 mm circular, with few options ✗	1.5, 3, 6, 8, 10, 12, 15, 18 mm circular ±
Spots with digital zoom: convenience, agility and usability	8-18 mm 3-10 mm ✓	no low usability low agility ✗	no low usability low agility ✗
Output energy: greater fluency in larger spots, + results	55 J good repetition rate with higher fluences ✓	52 J but uses 2 LASER rods and misaligns easily ±	53 J good repetition rate with higher fluences ✓
Different pulse width for different skin types: + safety	0.3 to 300 ms ✓	0,3-300 ms various indications ✓	0,25 a 300 ms various indications ✓
higher repetition rate, faster treatment	3 Hz long pulse fast hair removal +short pulse ✓	2 Hz long pulse hair removal slow + short pulse ±	3 Hz fast long pulse hair removal +short pulse ✓
Cooling type: quality implies comfort and safety	sapphire window or air-cooling ✓	peltier no preview ±	spray cryogen burn risk ✗
Equipments without consumables translate into savings	no ✓	high maintenance rate and high cost of lamps ±	cryogen spray replacement cost ✗
Dedicated LASER with platform together brings + versatility	yes ✓	No, less versatile ✗	No, less versatile ✗

REFERENCES

1. Leinster J, Elman M. BIOLOGICAL AND CLINICAL ASPECTS IN LASER HAIR REMOVAL. J Dermatol Treatment 2004; 15; 72-83.
2. Amin SP, Goldberg DJ. CLINICAL COMPARISON OF FOUR HAIR REMOVAL LASERS AND LIGHT SOURCES. J Cosmet Laser Ther. 2006 Jun;8(2):65-8.
3. Nanni CA, Alster TS. LONG-PULSED ALEXANDRITE LASER-ASSISTED HAIR REMOVAL AT 5, 10, AND 20 MILLISECOND PULSE DURATIONS. Lasers Surg Med 1999; 24:332-337.
4. Lloyd JR, Mirrov M. LONG TERM EVALUATION OF THE LONG-PULSED ALEXANDRITE LASER FOR THE REMOVAL OF BIKINI HAIR AT SHORTENED TREATMENT INTERVALS. Dermatol Surg 200;26:633-637.
5. GOLDBERG, DJ, AHKAMI, R. EVALUATION COMPARING MULTIPLE TREATMENTS WITH A 2-MSEC AND 10-MSEC ALEXANDRITE LASER FOR HAIR REMOVAL. LASERS SURG MED 1999;25:223-228.
6. Traffeli JP, Kwan JM, Meehan KJ, Domankevitz Y, Gilbert S, Kenneth M, Ross EV. USE OF A LONG-PULSE ALEXANDRITE LASER IN THE TREATMENT OF SUPERFICIAL PIGMENTED LESIONS. Dermatol Surg 2007;33:1-7.
7. GARCIA C, ALAMOUDI H, NAKIB, M, ZIMMO S. ALEXANDRITE LASER HAIR REMOVAL IS SAFE FOR FITZPATRICK SKIN TYPES IV-VI. DERMATOL SURG 2000;26:130-134.
8. Laughlin SA, Dudley DK. LONG-TERM HAIR REMOVAL USING A 3-MILLISECOND ALEXANDRITE LASER. J Cutan Med Surg. 2000 Apr;4(2):83-8.
9. Ross EV, Meehan, KJ, Gilbert S, Domankevitz Y. OPTIMAL PULSE DURATIONS FOR THE TREATMENT OF LEG TELANGIECTASIAS WITH AN ALEXANDRITE LASER. Lasers Surg Med 2009; 41:104-109.
10. Raulin C, Greve B. TEMPORARY HAIR LOSS USING THE LONG-PULSED ALEXANDRITE LASER AT 20 MILLISECONDS. Eur J Dermatol 2000 Mar;10(2):103-6.