

“愛瑪” 二極體雷射

“Alma” Diode Laser

衛署醫器輸字第 022564 號

使用前請務必詳閱原廠之使用說明書並遵照指示使用。

Model: SOPRANO XL

用途：除毛

禁忌症

有以下情形者，請避免本產品：

1. 癌症
2. 懷孕
3. 使用光敏感藥物會對 810nm 波長產生反應者
4. 罹患對 810nm 波長會產生反應者
5. 3-4 週內曾過度曝曬及使用人工曬黑藥物者
6. 患有單純與帶狀皰疹
7. 蟹足腫體質
8. 糖尿病患者
9. 脆弱及乾燥性膚質
10. 賀爾蒙失調患者
11. 服用抗凝血劑
12. 癩癧
13. 有凝血疾病病史

副作用

1. 嚴重或延長性的發紅及水腫，可能於治療後持續 2-24 小時，甚至延遲數週。
2. 治療部位的不適感包括刺激、刺痛、中度灼熱感與疼痛可能持續 48 小時。
3. 治療後數天到數週可能會有結痂、表皮區域及治療週邊發生色斑沉著的情形。
4. 治療期間隨時穿戴護目鏡以免產生眼部傷害。
5. 治療前務必進行皮膚劑量反應測試，過量的治療能量常造成不必要的副作用。
6. 潛在治療的副作用有不舒服、傷害正常皮膚觸感、造成色素改變、產生斑痕、水腫、皮膚變脆弱及水泡紫斑。

警告注意事項

- 1.當使用緊急按鈕時，可能會產生危險的電壓。
- 2.不適當操作本雷射儀器容易產生各種傷害，請隨時注意各項本手冊的安全防護指示。小心操作仍有可能產生嚴重的灼傷，不要治療於敏感及循環不良的區域，小孩與不合適的人的操作極易產生危險。
- 3.穿戴正確的護目鏡。
- 4.僅有在緊急時才可使用緊急關閉鈕。

規格:

光源	Diode 二極體
波長	810 nm
最大劑量	120 J/cm ²
脈寬	10-1350 毫秒
光點	12 x10 mm
頻率	10 Hz(SHR) 3Hz(HR)
冷卻方式	接觸式氣冷
電力需求	120/230 VAC, 10/6A, 50/60 Hz
體積	35 x 40 x110 公分
重量	50 公斤

雷射配件：

Handpiece Characteristics

手握柄特性	810 ± 10nm(波長) / CW(連續波)	
輸出模式	SHR mode	HR mode
能量(最高)	10 J/cm ²	120J/cm ²
擊發方式	Single pulse	6 pulse
頻率	10 Hz	0.5,1.0, 2.0,3.0 Hz
光點大小	12 *10 mm	

藥商名稱：妮傲絲翠股份有限公司

藥商地址：臺北市內湖區民權東路 6 段 180 巷 6 號 8 樓之 1

製造廠名稱：ALMA LASERS LTD.

製造廠地址：Halamish St., P.O.B. 3021 Caesarea Ind. Park 38900, ISRAEL

A.4. General Contraindications

林示忌症

- Cancer; in particularly, skin cancer
- Pregnancy (including IVF)
- Use of photosensitive medication and herbs for which 810nm light exposure is contra-indicated
- Diseases which may be stimulated by light at 810nm
- Prolonged exposure to sun or artificial tanning during the 3 to 4 weeks prior to treatment and post treatment
- Active infection of herpes simplex in the treatment area
- History of keloid scarring
- Diabetes (insulin dependent)
- Fragile and dry skin
- Hormonal disorders (that are stimulated under intense light)
- Use of anticoagulants
- Epilepsy
- History of coagulopathies

A.5. Adverse Effects of Treatment

副作用

The use of the Soprano^{XL} system is similar to the use of other light-based technologies. Historically, traditional systems have demonstrated the ability to cause a certain degree of controlled and uncontrolled tissue damage. In addition, there are the following risks:

- Severe or prolonged erythema (redness) and edema (swelling) within 2-24 hours of treatment that could last for several weeks.
- Irritation, itching, a mild burning sensation or pain (similar to sunburn) may occur within 48 hours of treatment at the application site.
- Blisters, epidermal erosions, or peri-lesional hyperpigmentation may develop and remain evident for several days to several weeks following treatment.
- Eye damage from reflected or prolonged unprotected exposure to intense light. Protective goggles (appropriate to the wavelength) must be worn during all treatments to prevent eye injury.

- It is important to observe tissue reaction during treatment. Poor patient screening and excessive optical energy may cause thermal damage and cause unwanted adverse effects.

A.6. Potential Side Effects of Treatment

副作用

- **Discomfort** – when a pulse is triggered, some patients experience various degrees of discomfort. Some patients describe the sensation as stinging, while others liken it to a rubber band snap or a burning sensation that may last for up to one hour after treatment. Most patients tolerate the sensation during treatment, but some patients may require a topical anesthetic.
- **Damage to Natural Skin Texture** – in some cases, a crust or blister may form. Normal wound care should be followed.
- **Change of Pigmentation** – there may be a change of pigmentation in the treated area. Most cases of hypopigmentation or hyperpigmentation occur in people with skin types IV to VI, or when the treated area has been exposed to sunlight within 3 weeks before or after treatment.

In some patients, hyper-pigmentation occurs despite protection from the sun. This discoloration usually fades in three to six months, but in rare cases, (mainly hypo-pigmentation) the change of pigment may be permanent.

- **Scarring** – there is a chance of scarring; such as, enlarged hypertrophic or keloid scars. To reduce the chance of scarring, it is important to carefully follow all pre- and post-treatment instructions.
- **Excessive Swelling** – immediately after treatment, especially on the nose and cheeks, the skin may swell temporarily. Swelling usually subsides within hours, but may continue for up to seven days.
- **Fragile Skin** – the skin at or near the treatment site may become fragile. If this happens makeup should be avoided, and the area should not be rubbed (as this might tear the skin).
- **Bruising** – purpura, or bruising, may appear on the treated area which may last from a few hours to several days.

A.7. Eye Protection

- It is essential that all people present in the treatment room during the treatment (patient and medical personnel) protect their eyes by wearing Alma Lasers recommended protective eyewear.

2.1. Introduction

This chapter describes general safety issues regarding the use of the Soprano^{XL} system, with special emphasis on optical and electrical safety.

Warning

Hazardous voltages are energized when the emergency stop button is engaged.

Note

Federal law (USA) restricts this device to sale by, or on the order of a physician or any practitioner licensed by the law of the state in which he or she practices or intends to use or order the use of the device.

With proper operation and maintenance, trained and qualified medical practitioners can use the Soprano^{XL} system safely. The supervising physician and all other personnel operating or maintaining the Soprano^{XL} must be familiar with the safety information provided in this chapter.

The primary consideration should be for the safety of the patient, the physician and other personnel. Patient safety is mainly assured with a well trained staff and a well laid out treatment room. Patient education is also important, including information about the nature of the treatment.

5. The system features two emission indicators: a red emission indicator lamp located on the top of the control panel and a buzzer.
 - The red emission indicator lamp flashes when the system is ready to trigger pulses, and becomes a continuous light when a pulse is triggered.
 - A warning buzzer sounds when the system is ready to trigger a pulse.
6. Emission is enabled only when the operator switches to **Ready** mode and presses the footswitch (minimum risk).
7. Laser emission (from the diode module) is enabled only if both the footswitch and the handpiece trigger are pressed at the same time. The trigger reduces the risk of unintentional laser emission.
8. Water is circulated through the module as soon as the system is turned on in order to cool the light source.
9. The flow and temperature of the water are monitored in order to eliminate the risk of module overheating. Light emission is not permitted if the water flow stops or if the water temperature is equal to or higher than 40°C (104°F).
10. The system is equipped with a pneumatic footswitch for ease of use. It is pneumatic to eliminate the possibility of any short-circuiting in the footswitch's wiring and to increase its durability to fluids.

Warning

- Any light or laser emitting device can cause injury if used improperly. High voltages are present inside the Soprano^{XL} system. Personnel who work with lasers must always be aware of the possible dangers and must take the proper safeguards as described in this manual.
- Use carefully. May cause serious burns. Do not use over sensitive skin areas or in the presence of poor circulation. The unattended use of the Soprano^{XL} system by children or incapacitated persons may be dangerous.

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2.5. Warnings Related to Laser/Intense Light Emission

2.5.1. Burn Hazards

The Soprano^{XL} emits high-intensity light/laser radiation which is invisible to the human eye and can cause third degree burns.

2.5.2. Direct and Reflected Eye Exposure Hazards

It is essential that all people present in the treatment room during the treatment (patient and medical personnel) protect their eyes by wearing Alma Lasers recommended protective eyewear.

It is good practice to instruct the patient to close their eyes during treatment even when wearing protective eye glasses.

If the patient cannot wear the protective eyewear, fit the patient with opaque eye protection that completely blocks light from the eyes.

If the treatment area is very close to the eyes (e.g. eyelids), protect the eyes with corneal shields.

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Warning

Different protective eyewear is indicated for use with the Diode or NIR modules. Make sure you choose the correct type.

2.5.3. Safety Eyewear

- All personnel must use safety eyewear and must ascertain that the eyewear provides adequate protection: for the diode laser module OD>6 at wavelength range of 750-890nm, and for the NIR module OD>2 at 720-1090nm.
- The safety glasses and opaque eye protectors supplied with the system offer adequate protection for both modules, and more can be ordered from your Alma Lasers representative.

2.6. System Safety Features

The Soprano^{XL} system is equipped with a number of safety features. All treatment room personnel should be familiar with the location and operation of these safety features.

2.6.1. Emergency Shut-Off Knob

This red knob is used for emergency shutdown. When pressed, it immediately shuts off power to the entire system.

To release the emergency shut-off knob, turn it clockwise. Otherwise, the system will remain off.

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Caution

Use the emergency shut-off knob only in the event of an emergency.

2.6.2. Light Emission Indicators

The system features two light emission indicators: a red LED located on top of the control console and a buzzer.

The red LED has three modes:

- **Off** - when the system is turned on, and in **Standby** mode
- **Blinking** – during **Ready** mode
- **Continuous** – during light emission (handpiece trigger and/or footswitch are pressed)

The buzzer beeps:

- Once when the system switches to **Ready** mode
- Intermittently during light emission, at the same rate as the pulse repetition rate: i.e., if the repetition rate is 2 Hz (pulses per second), the buzzer will beep two times per second.

4.5. System Specifications

4.5.1. Diode Laser Module Output

Laser Type

- CW
- GaAlAs diode laser array

Wavelength

- 810 ± 10 nm

Application Modes

- **SHR** mode – single pulse type
- **HR** mode – 6 pulse types: **I**, **II**, **III**, **IV**, **V** & **VI**

Fluence

- **SHR** mode – up to 10 J/cm^2 in increments of 1 J/cm^2
- **HR Pulse Types I** through **VI** – up to 120 J/cm^2 in increments of 1 J/cm^2

Pulse Repetition Rate

- **SHR** mode – 10.0 Hz
- **HR Pulse Types I** through **VI** – 0.5, 1.0, 2.0, 3.0 Hz

Spot Size

- 12 x 10 mm

Output Stability

- $\pm 10\%$

4.5.2. NIR Module Output

Light Technology

- Near-infrared light

Output Power

- Up to 100 Watts

Power Control

- PWM

Exposure Mode

- Pulsed

Spot Size

- 30 x 60 mm (18 cm²)

4.5.3. Operation and Control

System Control

- Fully computerized, microprocessor based

Graphic User Interface

- LCD touch-screen

Light/Laser Emission Indicators

- Visual, illuminating red indicator:
 - ✓ OFF when no lasing occurs
 - ✓ Blinking during **Ready** mode
 - ✓ Illuminating continuously during light emission
- Audible indicator:
 - ✓ Activated during light emission, when pressing the operation softkeys (user-controlled) and upon detection of an error condition

4.5.4. Physical

Dimensions

- 35 cm wide x 40 cm deep x 110 cm high
- 14" wide x 16" deep x 43.3" high

Weight

- 50 Kg (110 lbs)

4.5.5. System Requirements

Power Supply

- 120VAC, 10A, 50-60 Hz, single phase
- 230VAC, 6A, 50-60 Hz, single phase

4.5.6. Delivery Systems

Modules

- Multi-use
- Non-sterile

Skin Cooling

- Thermo-electrical cooling (TEC)
- Cooling temperature: 4°C (39°F)

4.5.7. Classifications

CDRH Laser Classification according to 21CFR 1040.10

- Class IV

Laser Classification according to EN 60825-1

- Class 4

Mode of Protection against Electric Shock

- Class I Equipment

Degree of Protection against Electric Shock

- Type B Equipment

SOPRANO[®]XL

Virtually Painless Laser Hair Removal





SOPRANO^{XL}

Virtually Painless Laser Hair Removal

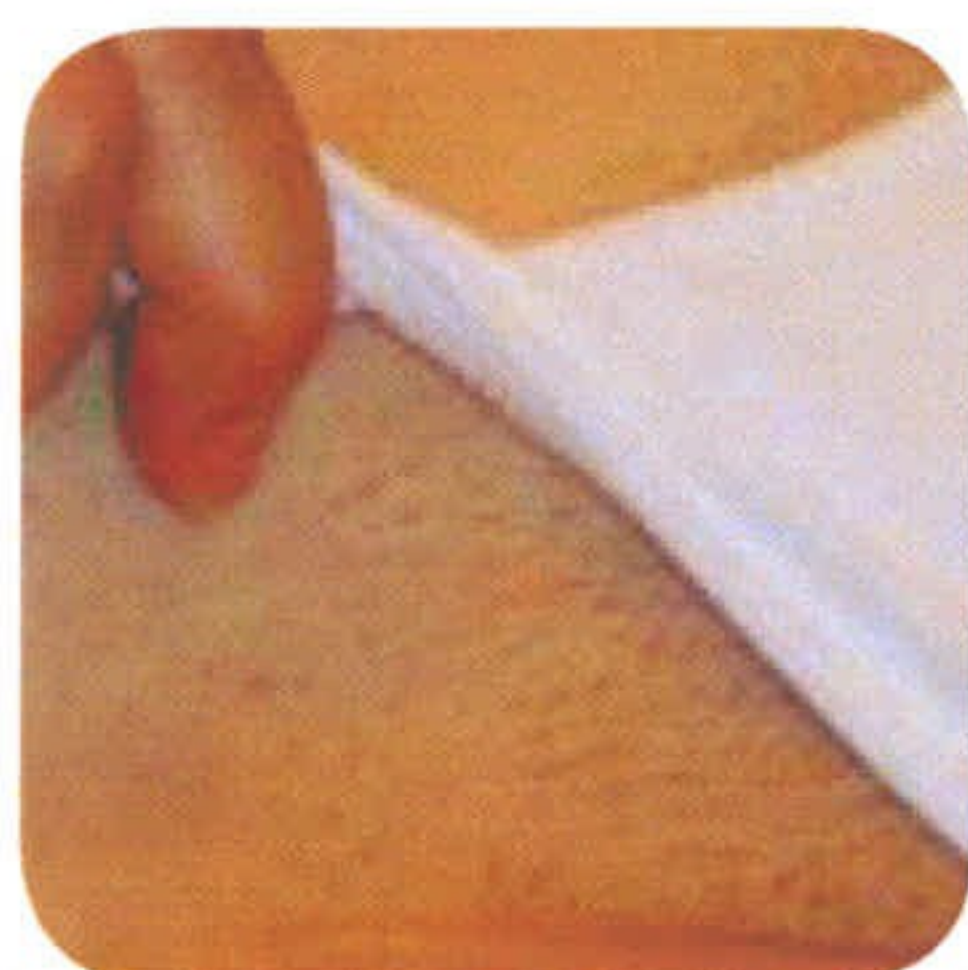
The Soprano^{XL} is a revolutionary diode laser system for permanent hair reduction. It's the world's first laser hair removal system that is virtually painless—and it's available exclusively from Alma Lasers.

Virtually painless?

The Soprano^{XL} works by safely and gently heating the dermis to a temperature that damages the hair follicle and prevents re-growth, yet does not injure the surrounding skin.

How the Soprano^{XL} works

The Soprano^{XL} uses gold standard 810-nm diode laser technology and combines it with exclusive IN-MotionTM technology. Energy penetrates deep into the dermis with high average power and a rapid 10 pulse-per-second repetition rate.



Before

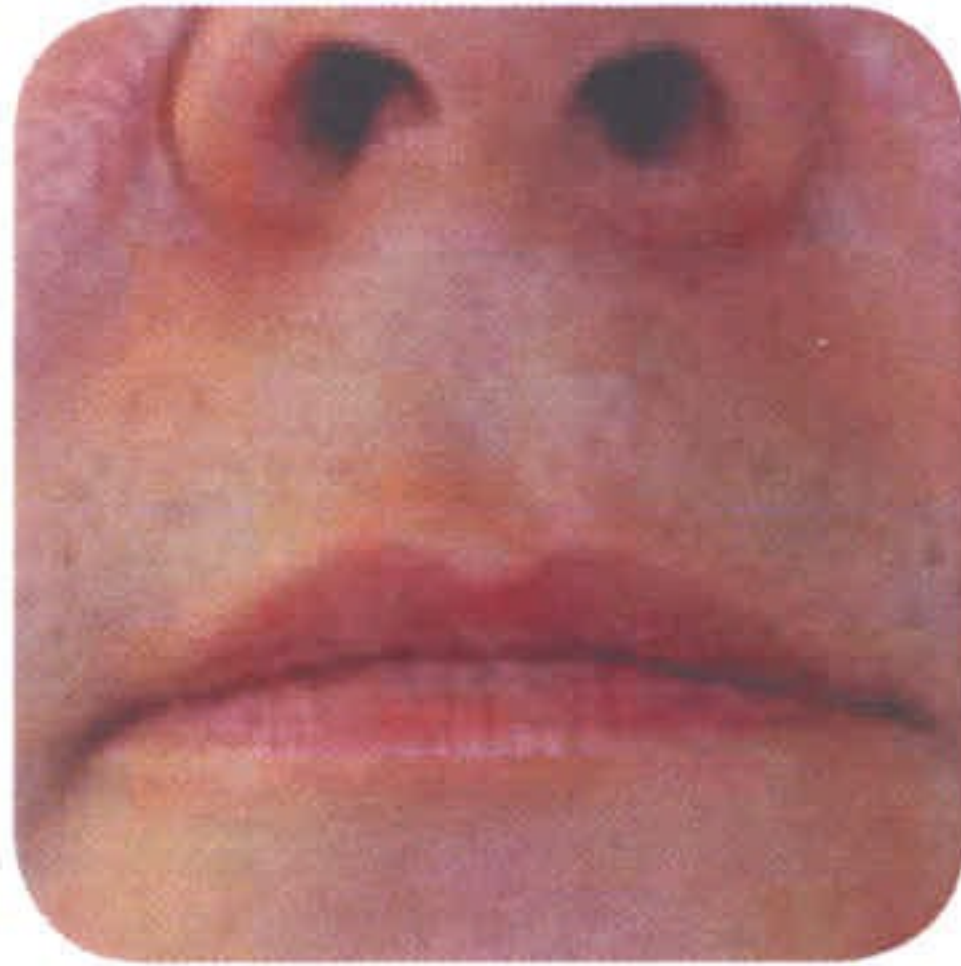


After

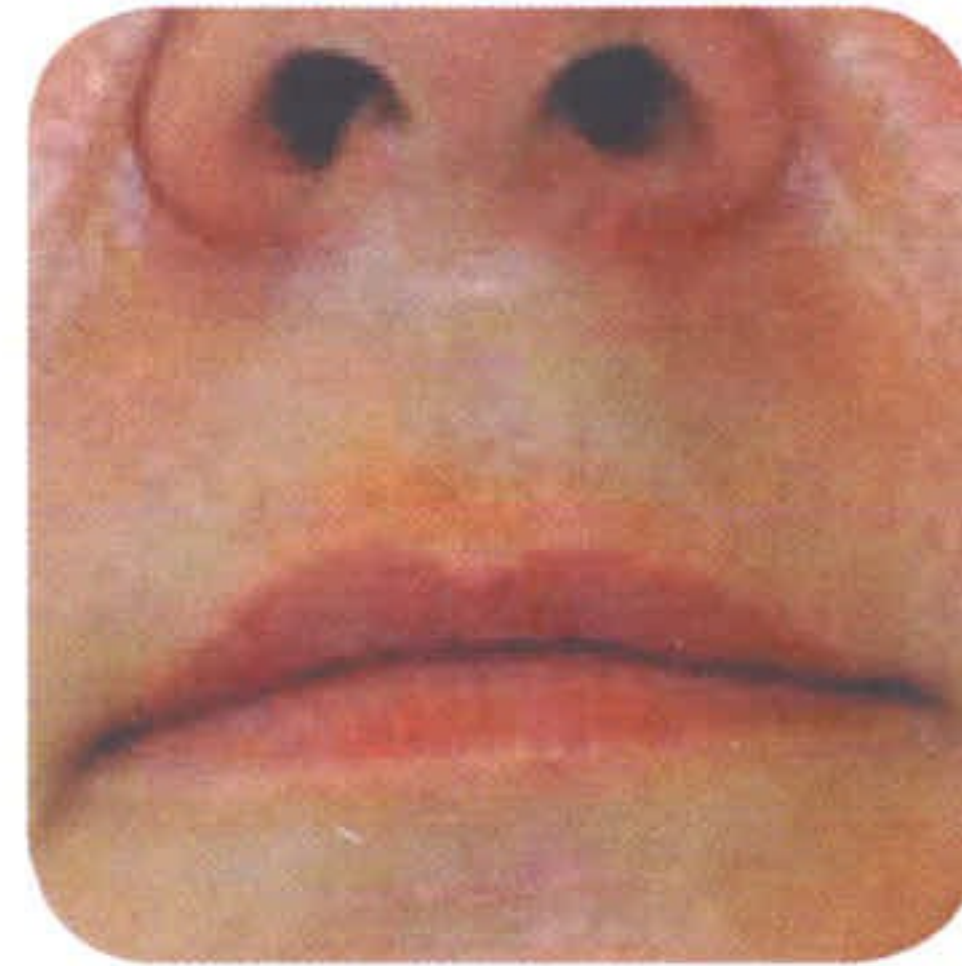
Photos courtesy: Kyle Holmes, MD

IN-MotionTM 

Patients often can't believe how effective Soprano^{XL} is—without pain.



Before



After

Photos courtesy: Kyle Holmes, MD



Before



After

Photos courtesy: Kyle Holmes, MD



Before



After

Technical Specifications

Hair Removal	
Light Source	Diode (continuous wave)
Wavelength	810 nm
Fluence	up to 120 J/cm ²
Pulse Duration	10 - 1,350 ms
Spot Size	12 x 10 mm
Repetition Rate	up to 10 Hz SHR Mode, up to 3 Hz HR Pulsed Mode
Cooling	DualChill contact cooling, plus integrated adapter for Zimmer Cryo 5
Electrical	120/230 VAC, 10/6 A, 50/60 Hz
Dimensions	13" x 16" x 43" (35 x 40 x 110 cm)
Weight	110 lbs. (50 kg)



About Alma Lasers

Alma Lasers, Ltd. is a global developer, manufacturer and provider of laser, light-based and radiofrequency devices for aesthetic and medical applications. Since 1980, the founders of Alma Lasers have been at the forefront of innovative multi-technology / multi-application systems designed to meet the unique needs of today's practitioners.

Alma's mission is to provide modular, cost-effective and high-performance systems that enable practitioners to confidently offer safe, effective and profitable aesthetic treatments to their patients.

www.almalasers.com

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