

Treatment Guidelines for SP-Mode® Microsecond Laser Technology

The following treatment guidelines relate to using SP-Mode® Microsecond Laser Technology with the LIGHTLas 532, LIGHTLas 577, LIGHTLas 810, TruScan and TruScan Pro laser systems.

All information contained herein has been compiled in good faith from results of various generic clinical studies and investigations, and intended to serve as general guidance only. While SP-Mode® Microsecond Laser Technology provides a highly effective and minimally invasive treatment, LIGHTMED strongly recommends that all physicians new to this technique seek professional peer training, and gain proficiency of current peer recommended treatment methods prior to commencing treatment.

Introduction:

Advances in laser technology are constantly evolving, offering physicians groundbreaking and novel treatment approaches to achieving optimum clinical outcomes for patients. In the past, retina tissue would be sacrificed during surgery. Yet now, physicians are able to treat the central macula, and stimulate recovery and rejuvenation without even leaving a footprint. Patients with chronic visual deficits, who are resistant to cutting-edge therapies, have experienced their vision dramatically improve rapidly over weeks, even days. Diseases previously thought to be inescapable may respond to this therapy without toxicity or even treatment discomfort.

Technological advances in laser using semiconductors have also enabled treatment customization with a diversity of wavelengths, streamlined in a single multi-modality platform. The ability to treat at a threshold below detection gives physicians optimism as never before.

LIGHTMED's LIGHTLas 532, LIGHTLas 577, LIGHTLas 810, TruScan and TruScan Pro models come standard with Conventional Continuous Wavelength (CW) and SP-Mode® Microsecond Laser Technology treatment options.

Q: What is SP-Mode® Microsecond Laser Technology?

SP-Mode® Microsecond Laser Technology is an advanced laser technology where the treatment occurs below the level that causes visible thermal damage. It targets the underlying pathology of vision loss by stimulating the very cells that can nurture the damaged tissue. Unlike traditional lasers, this effect is achieved with short microsecond bursts of laser energy that cycle on and off so that each exposure to the tissue does not generate enough heat to cause thermal damage.

Studies have shown that physicians are now able to:

- Eliminate laser-induced thermal tissue damage and treatment side effects
- Deliver a broader range of treatment modalities
- Treat disorders at a much earlier stage
- Provide repeat treatment in retinal and glaucoma applications

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SP-Mode® stimulates the nurturing cells to support retinal healing, known as RPE or Retinal Pigment Epithelium, without leaving any visible damage. During SP-Mode® treatment, the temperature elevation is confined in the RPE and the neurosensory retina is spared; therefore, the laser leaves no visible mark and is safe for the retina. With SP-Mode®, it may be possible to achieve the desired therapeutic effect and resolve various retinal disorders without induction of pain and iatrogenic burns caused by visible photocoagulation.

Q: How does it work?

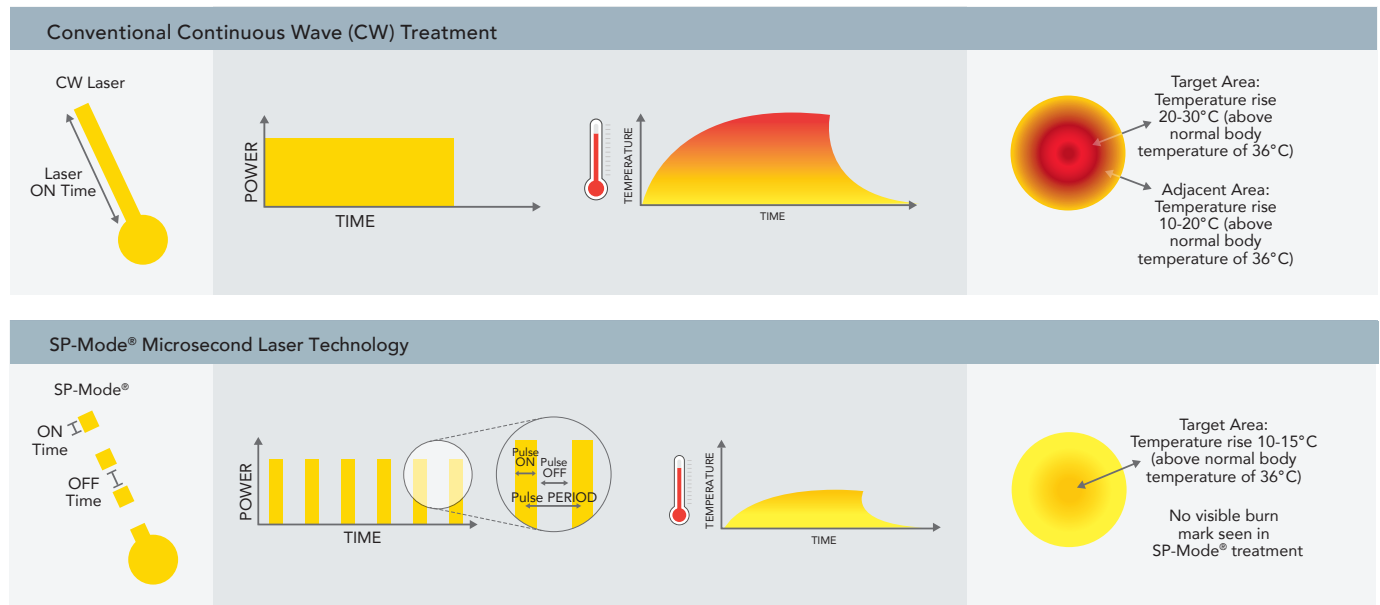
SP-Mode® exploits two key principles to achieve clinically effective, yet non-traumatic photocoagulation:

- **Selectivity:** SP-Mode® targets the RPE and isolates the heat to the tissue.
- **Cold Photocoagulation:** Low-duty cycle (5% to 15% “ON” and 95% to 85% “OFF”) allows for relaxation time between pulses; thus, thermal damage is minimized, creating a significant safety margin over traditional Continuous Wave (CW) laser.

The type of photocoagulation may be determined by the thermal change induced in time and space. The types of treatment may be characterized as:

- **Supra-Threshold** – visible mark in the exposure of the laser.
- **Threshold** – with mark slightly visible at the end or immediately after the laser exposure.
- **Sub-Threshold** (SP-Mode® Microsecond Laser Technology) - no visible mark.

SP-Mode® Microsecond Laser Technology avoids cell necrosis, apoptosis, formation of bubble with micro-explosions and hyperthermia of the retina.



In SP-Mode®, there are two important time intervals:

- The time “ON” is the duration of irradiation time, in which the laser is turned on.
- The time “OFF” is the interval between successive “ON” periods, which enables the retina the relaxation time and allows for cooling. This regulates the additive effect of each pulse of laser power.

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The ratio of irradiation time during one cycle is known as the duty cycle. One cycle is 1/500th of a second or 2 milliseconds, which equals 2000 microseconds. When the duty cycle is set to 10%, irradiation is ON for 0.2 milliseconds and OFF for 1.8 milliseconds with irradiation repeated during this process. Duty cycle and power are adjusted to provide the required level of energy to be applied to the target cells. The repetition rate is how quickly each pulse is delivered. Duty cycle and repetition rate determine the additive effect of elevated temperature produced by each SP-Mode® pulse.

Types of Treatments:

Ongoing clinical studies and publications demonstrate the SP-Mode® as a very safe and effective treatment indicated for MOST cases and conditions of retinal photocoagulation. SP-Mode® has also been shown to be highly effective in clinical cases of:

- Diabetic Macular Edema
- Macular Edema from Retinal Vein Occlusions (CRVO, BRVO)
- Central Serous Retinopathy
- SP-Mode® Transclerall Cyclophotocoagulation (SP-Mode® TSCPC)*

Pre-Treatment:

SP-Mode® with the LIGHTMED laser can be performed by delivering the laser through a slit lamp, LIO (Laser Indirect Ophthalmoscope), or probe.

Ocular Mainster (Standard) Focal / Grid Laser Lens			
Product Code	Static Field of View	Laser Spot Mag.	Image Mag.
OMRA-S	90°	1.05x	.96x
OMRA-S-2	90°	1.05x	.96x

Volk (Standard) Area Centrallis Laser Lens			
Product Code	Static Field of View	Laser Spot Mag.	Image Mag.
Area Centrallis	70° / 84°	1.06x	.94x

Treatment:

SP-Mode® treatment power must first be clinically evaluated by physicians. The example below uses the titration method for treating macular edema. Power may differ for individual patients. In order to determine this power experimentally:

- Activate the laser in SP-Mode®.
- Set laser power to 600mW, duty cycle to 5% (0.1 milliseconds ON, 1.9 milliseconds OFF), duration of irradiation to 200 milliseconds (0.2s), and interval to 200 milliseconds (0.2s).
- Position the laser lens on the patient's eye and make a visible test burn applied outside the posterior pole, nasal to the optic disc, avoiding any areas of edema or hemorrhage.
- When firing the laser, increase power incrementally, and carefully observe the lesion until a light grey discoloration (burn mark) is produced, indicating the optimum treatment power threshold range. Record that SP-Mode® power setting then divide in half.

*Refer to the TSCPC Treatment Guidelines on www.lightmed.com for more information on this treatment protocol.

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- For example, if the SP-Mode® power needed to make a light grey burn mark using 5% duty cycle is 640mW, then reduce the power to 320mW.
- After reducing the power in half, apply laser several times on non-edematous area to make sure the laser does not induce any tissue reaction.
- After confirming that the laser does not cause a tissue reaction, apply high-density sub-threshold laser to the entire treatment area and repeat the sub-threshold laser applications as necessary.

Clinical research indicates that higher density or confluent laser spots may enhance the clinical effectiveness of SP-Mode®, which enriches the area of activation of the RPE.

In other words, the greater the number of pulses, the lower the energy required per pulse to achieve the same level of effectiveness, which in turn can also overcome the limitations in use of laser power. It is not recommended to increase the spot size beyond the recommended treatment protocols because this can affect the safety and desired clinical outcome of the laser treatment.

Post-Treatment:

- Post-operative topical medication is not routinely necessary.
- Patients are usually seen post-operative follow up within 4-6 weeks, monitored at monthly intervals in the short term. Improvement in patient vision may continue for several months after treatment.
- Ongoing care is determined at the frequency determined by the patient's underlying conditions under the discretion of the physician.
- SP-Mode® treatment may be performed repeatedly over the previously treated lesions as indicated and recommended by the physician.

Conclusion:

Information derived from various ongoing clinical studies indicate when used by qualified physicians following recommended parameters, SP-Mode® treatments are very safe with no known adverse side-effects.

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