

1. Which areas can be treated with the SharpLight Technologies devices?

The SharpLight Technologies devices may include up to 4 technologies: DPC (Intense Pulsed Light), RF (Radio Frequency), VermaDerm (Infrared) and Lasers. All of these technologies have been clinically proven to deliver safe, effective and reproducible results offering both face and body treatments.

2. Are aesthetic light-based treatments safe?

Light-based devices have been utilized in aesthetics for over two decades and the technologies continue to advance over the years to optimize the treatments and benefits that can be achieved. In addition, there is significant clinical data, collected over the years, that demonstrates the technological effectiveness of light-based devices when used by qualified specialists on carefully selected patients.

3. How do I know if the treatment is suitable for me?

Both, the results and patients' experience may vary as with any aesthetic procedure. We recommend consulting with a specialist in order to find out what treatment options are right for you.

During the initial consultation appointment, the practitioner will explain the benefits and advise on the contraindications and any possible adverse effects of the specific treatment while considering aspects such as lifestyle and the medical history. As with any energy-based technological devices, it is important to be aware of the potential risks and temporary side effects associated with the treatments. The risks are minimized by having a first consultation to ascertain whether you are suitable for treatment based on medical history and skin type, as well as carrying out a patch test with the recommended settings to prevent trauma to the skin.

4. How many sessions are necessary to get results?

Depending on the specific treatment and the treated area. The specialist will recommend the number of sessions in a treatment course based on the specific treatment i.e. hair reduction, body contouring, acne, skin illumination, tattoo removal, scars; as well as the size of the treated area. Results can be seen after the first sessions however it is important to keep in mind that satisfying, visible results are cumulative, and it is necessary to complete the full series of treatment sessions as recommended by the specialist to achieve long-lasting results.

SharpLight's advanced and safe devices offer excellent, lasting results with minimum discomfort in a relatively small number of treatment sessions. Specialists can personalize a comprehensive and detailed treatment plan to ensure outstanding results and a gradual improvement will be seen as the treatment course progresses.





5. Do I need to follow special post-treatment instructions?

Yes. Depending on the treatment, the specialist will provide a detailed list of both pre-treatment as well as post-treatment measures that need to be followed. These instructions may include: to avoid tanning, to avoid strenuous sport activities, to apply soothing creams / gels, to apply cold packs, to keep the treated area clean and in some cases covered with a dressing and to apply sun block SPF 30 or higher.

During the initial consultation appointment, the specialist will explain all the relevant aspects and explain the pre- and post-treatment instructions for the respective treatment.

ls the treatment painful?

It depends on which technology is used, the treatment performed, the area treated as well as the individual pain threshold. Patients experience various sensations and in cases also a degree of discomfort, stinging or burning sensation immediately after the procedure. During the initial consultation appointment, it is recommended to pose questions regarding the intensity of the treatment and ask for information on the possible sensations felt during the procedure. For example in tattoo removal treatments a topical analgesic may be used prior to the treatment. To ensure a more comfortable and painless treatment, SharpLight's contact cooling tip is helpful in protecting the tissue by decreasing heating on healthy tissue thus preventing superficial skin burns.

What are the possible undesirable effects after a treatment?

It depends on the technology used as well as the treatment performed, in most cases there may be a temporary degree of tenderness in the area treated. Depending on the treatment, patients might show one or more of the following: irritation, itching, a mild burning sensation (similar to sunburn), redness, swelling, blisters, bruising and fragile skin to the touch. During the initial consultation appointment ask the specialist for a complete list of possible side-effects and safe skin care routine after the treatment. Please refer to the user manual for a complete list of side effects, contraindications and risks.

8. Is eye protection necessary for an IPL treatment?

It is necessary to wear the provided protective eyewear during all phototherapy treatment to prevent eye injury. Laser induced eye injury, caused for not using the recommended eye protection, may interfere with vision either temporarily or permanently, in one or both eyes.



MAR-G011 rev.2



9. Why do I need a consultation before the treatment?

Whenever treatments are considered, a face-to-face full consultation with the specialist must be scheduled first to cover aspects such as detailed, professional description and explanation of the treatment options, clarify realistic expectations regarding the results as well as the estimated number of sessions that would be required to achieve them. During the consultation, the specialist will go over the complete and specific list of potential risks the treatment course might pose, including contraindications, possible adverse effects and confirm the suitability according to skin type, lifestyle and medical history.

10. How do I know if I can undergo treatments with SharpLight devices?

The specialist can confirm if you are a suitable candidate for a specific light-based treatment based on an evaluation of the medical history and skin type. There are a number of factors that can prevent you from having technology-based aesthetic treatments. Before the treatment, practitioners will require you to fill out a consent form before receiving any of the possible treatments with the DPC (Intense Pulsed Light), RF (Radio Frequency), VermaDerm (Infrared) and Lasers. This document is very important and you should feel free to ask for further clarifications from the practitioner regarding the information written before you sign.

In addition to the benefits and long-lasting results that can be achieved with the different technologies, each one has its own possible side-effects, treatment contraindications, pre & post treatment care of the area. It is mandatory to consult with your physician before undergoing any aesthetic laser treatments and with the specialist for the complete list of applicable contraindications prior to undergoing a treatment. The consultations must include comprehensive, detailed, professional description and explanation of the treatment sessions and the specialist will inform of any potential safety risks the treatment might pose, expected side-effects, post-treatment care of the treated area and planned progress stages of the treatment.





Technology	Treatment Type	Contraindications	Expected Common Side-Effects	Post Treatment Care
DPC (IPL)	Hair reduction Skin rejuvenation Skin tightening Acne Vascular lesions	pacemaker, metal plates or implants in the treated area, HIV, cancer/ precancerous lesions, heart diseases, arthritis, fractures, muscular tissue diseases, during pregnancy and breast feeding, fertility treatments, hemorrhages, immunosuppressive conditions, liver and kidney diseases, arthritis, endocrine diseases, epilepsy, fractures, hormonal changes/ imbalance, blood pressure problems, tendency of developing active Herpes Simplex infection, skin diseases in the past and present, such as Psoriasis, Dermatitis, Vitiligo, tattoo / makeup tattoo in the treated area, light-induced / heat-induced diseases, consumption of Retinoids during the previous 6 months, fragile, dry or sensitive skin, tanned skin	When a light pulse is emitted onto the skin surface, some patients experience various degrees of discomfort, similar to a stinging or burning sensation for up to 1 hour following the treatment.	Patients must apply sun block of at least SPF 50 and protect the treated area from exposure to sunlight on a daily basis. The sun protection must be reapplied every couple of hours throughout the day.
RF (RADIOFREQUENCY)	Contouring for face & body, Cellulite Reduction		In addition, a mild to medium burning sensation, may occur within 48 hours following the treatments; the intensity varies for each individual and depends on the technology as well as the treatment. Redness, irritation and swelling may occur within 24 hours after the treatment. In some cases, purple bruising or blisters may appear on the treated area. With some technologies, there is a risk of temporary changes in skin texture or pigmentation of the treated area following the treatment.	Depending on the treatment the specialist might recommend the use of soothing ointments/gels. After some treatments it is advised not to apply makeup for up to 2-3 days following the treatment. The skin at or near the treatment site may become fragile and the area should not be scratched or rubbed. In some cases it is advised not to participate in rough sports or similar activities for several days following treatment, until the skin returns to its
VERMADERM (IR)	Skin tightening & Firming			
Er:YAG Laser	Textural rejuvenation and improvement of the skin's aesthetics			
Nd:YAG Laser	Vascular lesions		When treating pigmented lesions an immediate darkening of the lesion is expected.	normal condition. Treated areas should be kept clean between treatments. Use of mild soap or
QS Laser	Tattoo removal (different color inks will have different removal efficiency)		Some laser treatments, for example tattoo removal, vascular lesions, are uncomfortable and even painful. In such cases a topical analgesic may be used prior to procedure.	non-irritating cleanser may be recommended by the specialist. If necessary, the treated area should be covered with a dressing following the treatment.

The treatment contraindications are not limited to those listed in this document. It is obligatory to consult with a professional prior to undergoing any SharpLight Technologies treatments to verify and confirm if you are a suitable candidate for the respective treatment.



i RISKS AND WARNING (NON-INCLUSIVE LIST):

Intended Purpose

The Omnimax Device Series along with its optional Handpieces, uses IPL, IR, Laser and RF technologies and is intended for use in aesthetic and cosmetic applications and in selective treatments in medical specialties of dermatology, through the transmission of energy to human skin.

Intended Use and Indication for Use: In EU:

The Omnimax Device Series are intended for the following **dermatological medical treatments**: Pigmented Lesions (including Epidermal and Benign), Vascular Lesions, Acne vulgaris, Scars (injury), Skin Lesions, Leg Veins, Pseudofolliculitis Barbae, Melasma.

The Omnimax Device Series are intended for the following **aesthetic and cosmetic applications:** Hair Removal, Skin Rejuvenation, Skin Firming, Skin Lifting, Skin tightening, Skin Laxity, Skin Rejuvenation, Fractional Ablative Skin Resurfacing, Wrinkle Reduction, Acne, Scars (non-injury), Tattoo Removal, Cellulite and Circumference Reduction, Face and Body Contouring, by phototherapy (Laser, IPL-DPC and IR) and radiofrequency treatments.

In US: The Omnimax Device Series along with its optional Handpieces, uses IPL, IR, Laser and RF technologies and is intended for use in aesthetic and cosmetic applications and in selective treatments in medical specialties of dermatology, through the transmission of energy to human skin.

The indications are only relevant where they were approved by the Regulatory Authorities.

Environment of use: The device is intended to be used in cosmetic clinics, hospitals and private clinics.

Intended Patient Population: The device is intended for adult patients only.

Intended User: Operators of the devices are professionals qualified in aesthetic and dermatological treatment applications who were trained by a manufacturer's representative.

Safety / Warnings / Cautions

The following Safety notes / warnings / cautions are taken from Information for Use files MAR-00835 (Omnimax S3) and MAR-00836 (Omnimax S4).

- Only certified and trained personnel is allowed to perform treatments with the Omnimax.
- The information provided herein serves as a supplement to the specific safety guidelines indicated in each application treatment protocol.
- All operators must study the specific application safety guidelines thoroughly prior to any attempt to operate the device.
- Operation of the device is allowed only when protective disposable gloves and specified eyewear are in use.
- The Omnimax system is a pulsed-light energy source for medical and aesthetic applications. The system emits intense pulsed light energy which may, if improperly used, result in injury of the treated skin area thermal damage to the treated skin.
- To avoid accidental / unnecessary exposure to light emission, carefully and accurately follow the guidelines and parameters detailed in the User Manual.

Clinical Safety

Patient safety is primarily assured by a certified and trained staff. Patient health questionnaire and consent forms must be completed, signed and reviewed before scheduling any treatment.

- Ascertain that all personnel of the facility are familiar with the system's controls and know how to shut down the system in case of an emergency.
- Never direct the pulsed light at anything other than the treatment intended area.

Please refer to the operator manual for a complete list of intended use, contraindications, side effects and risks.

