



BBL BROADBAND LIGHT: ACNE TREATMENT SAFE START PROTOCOL

Indications for use

The Sciton Profile system with BBL is indicated for use with 420-nm and 560-nm filters for mild to moderate inflammatory and pustular inflammatory acne vulgaris.

The indication for use is for light treatment alone. Some users have treated in conjunction with aminolevulinic acid HCl (ALA) though this has not been cleared for use for this indication.

The table lists some parameters used for light devices for acne treatment. The pulse widths were determined by the type of device used. In general, exposure was non-thermal except for PDL treatments, where there may be some additional vascular treatment and reduction of erythema due to the short pulses used.

Acne vulgaris ¹	150 J/cm ²	550 – 700 nm	
Photorejuvenation ²	40 J/cm ²	615 - 1200 nm	
Actinic keratoses ³	10 J/cm	412 – 422 nm	
Actinic keratoses ⁴	4 – 30 J/cm ²	595 nm	
Actinic keratoses ⁵	150 J/cm ²	580 – 740 nm	

The article by Taub gives comprehensive tables of parameters used for ALA-PDT in the treatment of AKs, acne, basal cell carcinomas, Bowen’s disease, photo-rejuvenation etc. In general treatment with ALA and blue light used about 10 J/cm², and treatment with wavelengths > 560 were performed at 60 to 150 J/cm².

BBL parameters

The BBL can be used to provide exposure with low photo-thermal response by using long pulse widths, low per pulse fluence settings and multiple passes or pulse stacking to achieve any desired light dose. Cooling can be used to enable faster treatments (pulse stacking)

¹ Honcharu W et al., Topical ALA-Photodynamic Therapy for the Treatment of Acne Vulgaris, Soc for Invest Derm 115:183-192, 2000.

² Ruiz-Rodrigues R et al. Photodynamic Photorejuvenation. Dermatol Surg 28:8, 2002.

³ Piacquadio DJ et al. Photodynamic Therapy with Aminolevulinic Acid Topical Solution and visible Blue Light in the treatment of Multiple Actinic keratoses of the face and Scalp. Arch Derm 140: 40-46, 2004.

⁴ Alexiades-Armenakas MR, Geronemus RG. Laser-Mediated Photodynamic Therapy of Actinic Keratoses. Arch Dermatolog 139:1313-1320, 2003.

⁵ Taub AF. Photodynamic Therapy in Dermatology. J Drugs Dermatol 3:8-25, 2004

while avoiding unwanted thermal results. In some case photo-thermal results may be desirable so normal BBL protocol for photo-rejuvenation could be used.

The table gives examples of how to achieve different exposure levels.

Treatment type	Filter	Fluence setting	Pulse width	Treatment
Blue light @ 10 J/cm ²	420 nm	4 – 5 J/cm ²	200 ms	Two passes
Yellow light @ 45 J/cm ²	560 nm	15 J/cm ²	200 ms	3 pulses at 0.5 Hz or 3 passes
Red light @ 100 J/cm ²	590 nm	15 J/cm ²	200 ms	6 pulses at 0.5 Hz or 6 passes

Surface Cooling

Contact surface cooling clamps the skin surface at a predetermined temperature so that treatments will be consistent regardless of the patient's nominal skin temperature. The thermodynamic properties of skin are very similar for all patients and a reproducible thermal response can be achieved by setting surface cooling temperature, BBL fluence, and BBL pulse width. Adjusting these settings will allow you to adjust the treatment to different skin conditions with reproducible treatment temperatures.

Although absorption of the BBL light in melanin may be desirable, some epidermal cooling may be beneficial to protect the skin. The BBL contact cooling plate with a layer of gel insures that the skin is adequately protected from overheating regardless of skin type.

Patient Selection

Profile BBL therapy is contraindicated for those patients who:

- are hypersensitive to light;
- take medication that is known to increase sensitivity to sunlight, such as accutane and gold treatment therapy;
- have seizure disorders triggered by light;
- have suspicious pigmented lesions;
- have very recent sun exposure or tanning.

Classification of Skin Types

The following table offers a broad guidance to identifying skin types based on hair, skin and eye color as well as sun reaction.

Fitzpatrick Scale

Type	Hair Color	Skin Color	Eye Color	Sun Reaction
I	Red	Light	Blue-green	Burn, never tan
II	Blonde	Light	Blue	Burn, may tan
III	Brown	Medium	Brown	Burn, then tan
IV	Brown-black	Moderate brown	Brown-black	Tan
V	Black	Dark brown	Dark	Tan
VI	Black	Black (African)	Dark	Tan

Consultation / Treatment

The consultation or initial visit allows an exchange of views between practitioner and patient in an attempt to reach a decision regarding treatment. The patient must understand the procedure, pre and post care instructions, and expectations before the procedure is performed.

Patient Education (Expectations)

Patients must understand that results vary with each individual. Multiple treatments may be necessary over a time span (1-2 week intervals) to reduce acne lesions in most areas. Results should be evaluated several weeks post treatment.

The BBL light pulse is often described as a wave of heat with the sensation of a pinprick. A topical anesthetic may be necessary.

Patient History

A thorough history of previous treatment methods, current medications, allergies and pigmentary problems should be discussed. Exclusion criteria may include but are not limited to: photosensitivity, seizure disorders triggered by light, keloid formation, immunosuppression, use of light sensitizing medication, and/or history of poor wound healing.

Patient Documentation Forms

- Consent: the process of accepting and confirming treatment must be reviewed, understood and signed by the patient prior to treatment. This document must review

the topics discussed during consultation and acknowledges that the patient understands the procedure and that all questions have been answered.

- Review post care instructions and confirm that the patient will adhere to such instructions throughout the course of their treatment. (Sample post care instructions are included with the Practice Support Kit CD.)
- Upon patient's assessment, the case provider must determine the need for medications or creams. These can be given before the procedure and used throughout the treatment.
- Post-treatment appointments are scheduled for: treatment assessment, patient evaluation and routine therapy.

Photographs

Before and after photographs should be taken throughout the course of the treatment to monitor patient response to therapy. Photographs should be taken prior to treatment and during follow-up visits.

Pre Treatment Procedure

For better results, patients are to avoid sun exposure, tanning beds and tanning creams for 2-3 weeks prior to treatment and throughout the course of their BBL treatment. Sunless tanning lotions must also be avoided for 2-3 weeks prior to treatment. However, if sun exposure is not avoidable a reduced fluence may be used and treatment sessions increased.

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1. PRE-TREATMENT CONSIDERATIONS

1.1. CLEAN SKIN

Use a mild cleanser to remove any dirt, makeup, or moisture from the treatment area. Follow with an alcohol wipe. Allow alcohol to evaporate before treatment. Use special care around the eyes.

1.2. HANDPIECE CLEANING

Clean the cooling plate with an alcohol swab. Check the cooling plate during long procedures and clean as necessary.

1.3. EYE PROTECTION

Always use eye protection for the patient, the operator, and anyone in the BBL treatment room during the treatment.

CAUTION: Tattooed areas should not be treated. Tattoo ink may absorb light energy resulting in a color change in tattoo ink or a risk of epidermal damage.

2. SETTING TREATMENT PARAMETERS

2.1. COOLING

2.1.1. COOLING TEMPERATURE

- 15°C is recommended. A coating of colorless gel, KY, surgilube or water should be used in conjunction with the system for better heat removal, improved optical coupling, and lubrication for sliding the plate over skin. The gel will fill irregularities in the skin simulating full contact of the cooling crystal.

CAUTION: Clean the cooling plate with a soft cotton gauze moistened with alcohol before every treatment. A dirty cooling plate may lead to an incorrect setting for fluence.

2.2. FLUENCE

Patient response can vary, so fluences should begin low and be increased gradually after assessing the individual patient response. Total exposure will be about 10J/cm² delivered in 2 passes of 4 to 5 J/cm² for the 420-nm filter; 45 J/cm² delivered in 3 passes of 15 J/cm² for the 560-nm filter; or ; 90 J/cm² delivered in 6 passes of 15 J/cm² for the 560-nm filter.

Treatment type	Filter	Fluence setting	Approx. Pulse width	Treatment
Blue light @ 10 J/cm ²	420 nm	4 – 5 J/cm ²	200 ms	Two passes
Yellow @ 45 J/cm ²	560 nm	15 J/cm ²	200 ms	3 pulses at 0.5 Hz or 3 passes
Red light @ 90 J/cm ²	590 nm	15 J/cm ²	200 ms	6 pulses at 0.5 Hz or 6 passes

2.3. PULSE WIDTH

This is not a photothermal treatment so the longest pulse width available from the system control panel should be used. This will be about 200 ms for most systems.

3. TECHNIQUE

3.1. TEST AREA

Treating a test area before a patient's first treatment can establish their response threshold and help establish safe starting parameters. The test area should be monitored for response for a period of five to ten minutes.

3.2. HANDPIECE POSITION

Position the patient so the HANDPIECE can be held perpendicular to the skin surface. Move the patient if necessary so that the treatment area is easy to reach. A coating of colorless gel, KY, surgilube or water should be used in conjunction with the system for better heat removal, improved optical coupling, and lubrication for sliding the plate over skin. The gel should be used as a very thin film on the bottom surface of the cooling plate.

3.3. TREATMENT METHOD

Match the “trailing edge” of the next BBL treatment area to the “leading edge” of the previous area. Use edge of the cooling plate for convenience in treating small areas or near the boundary of cosmetic regions.

3.4. INTERVAL

Recommended treatment interval is 1 week. Results should become noticeable within 1 or 2 treatments. Tightness of the treated area may be noticed immediately after treatment.

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1. Pre-Treatment:

- Clean area to be treated
- Clean hand piece prior to each treatment
- **Eye Protection - Always use eye protection for the patient, the operator and anyone in the treatment room**

2. Treatment:

- Set Cooling Temperature: 15°C is recommended.
- Set Pulse width.

Treatment type	Filter	Fluence setting	Approx. Pulse width	Treatment
Blue light @ 10 J/cm ²	420 nm	4 – 5 J/cm ²	200 ms	Two passes
Yellow @ 45 J/cm ²	560 or	15 J/cm ²	200 ms	3 pulses at 0.5 Hz or 3 passes
Red light @ 90 J/cm ²	590 nm	15 J/cm ²	200 ms	6 pulses at 0.5 Hz or 6 passes

- POSITION HANDPIECE COOLING PLATE in full contact with treated area. Use a thin film of colorless gel, KY, surgilube or water with the system for better heat removal, improved optical coupling, and lubrication for sliding the plate over skin. Gel will insure contact in areas with highly irregular surfaces.