Omnilux™
Treatment Protocols
THE MOST TRUSTED NAME IN LED PHOTOTHERAPY

- The original leader in non-invasive LED technology since 2003
- More than 30 peer-reviewed published studies that validate its clinical claims and treatment protocols
- Validated by the Journals of Cosmetic and Laser Therapy, Photochemistry and Photobiology B, ASLMS, and many others
- Clinically proven wavelengths, optimized intensities, and unique adjustable dose for the treatment of acne vulgaris, periorbital wrinkles, non-melanoma skin cancers¹, wound healing¹, combination therapies, and pain management
- More FDA approved indications than any other brand
- Global regulatory approvals include U.S. FDA, Medical CE, Japanese MHLW, Korean KFDA, China CFDA, Australian TGA, and many others
- Continuous research for new and novel indications and applications
- Originally developed in partnership with Cancer Research UK
Acne (Mild to Moderate Acne Vulgaris)

Lee SY, You CE and Park MY. Blue and Red Light Combination LED Phototherapy for Acne Vulgaris in Patients with Skin Phototype IV. Lasers in Surgery and Medicine. 2007; 39: 180-188


Goldberg DJ and Russell BA. Combination blue (415 nm) and red (633 nm) LED phototherapy in the treatment of mild to severe acne vulgaris. Journal of Cosmetic and

Skin Rejuvenation


Pain Attenuation (Minor Muscle and Joint Pain)


Review and In-Vivo Studies (Basic Science)


Takezaki S, Omi T, Sato S and Kawana S. Light-emitting diode phototherapy at 630 +/- 3 nm increases local levels of skin-honing T-cells in human subjects. Journal of Nippon Medical School. 2006; 73:75-81


Wound Healing

Calderhead RG, Kubota J, Trelles MA and Ohshiro T. One mechanism behind LED phototherapy for wound healing and skin rejuvenation: key role of the mast cell. Laser Therapy. 2006; 17.3: 141-148


**ALA - PDT Rejuvenation**


**PDT for Dermatologic Indications**


Hutson S. Comparison of Paterson PDT and LED Light Outputs. Internal document of Photo Therapeutics Ltd. DES/Tech/0506. May 28, 2002


This publication, although not exhaustive, is the culmination of many years of clinical work.

The following physicians have played a major part in developing the protocols listed in this document; their work is greatly appreciated.

Contributing Physicians

Dr. William Abramovits
Dr. David Baxter
Dr. Patrick Bowler
Dr. Denis Branson
Dr. Glen Calderhead
Dr. David Goldberg
Dr. J. W. Kim
Dr. Junichiro Kubota
Dr. Sean Lanigan
Dr. Seung Yoon Lee
Dr. Nick Lowe
Dr. Colin Morton
Dr. Kanno Nishiarai
Dr. Tokuya Omi
Dr. Mi Youn Park
Dr. Ashraf Reda
Dr. Bruce Russell
Dr. Neil Sadick
Dr. David Sire
Dr. Shinichiro Takezaki
Dr. Mark Taylor
Dr. Mario Trelles
Dr. Jean Francois Tremblay
Dr. Colin Whitehurst

FDA Clearances

FDA clearance for Omnilux new-U was granted on March 3, 2008 (FDA 510K number K072459) “for use in the treatment of peri orbital wrinkles.”

FDA clearance for Omnilux clear-U was granted on January 16, 2009 (FDA 510K number K081307) “for use in the treatment of mild to moderate acne vulgaris.”

FDA clearance for Omnilux revive2™ and Omnilux plus™ was granted on August 9, 2005 (FDA 510K number K050216) “for use in dermatology for the treatment of peri orbital wrinkles.”

FDA clearance for Omnilux plus was granted on March 15, 2005 (FDA 510K number K043317) for “the relief of minor muscle and joint pain.”

FDA clearance for Omnilux revive2 and Omnilux blue™ was granted on March 18, 2005 (K043329) for “the treatment of mild to moderate acne vulgaris.”

FDA clearance for Omnilux blue was granted on June 20, 2003 (K030883) for “general dermatological conditions and specifically to treat moderate inflammatory acne vulgaris.”

FDA clearance for Omnilux revive2 was granted on July 17, 2003 (K030426) for “use in dermatology for treatment of superficial, benign, vascular and pigmented lesions.”

1 Registration of medical devices and formal approval of protocols is required in many countries. GlobalMed Technologies Ltd is constantly extending both the range of countries in which its products are registered and the range of treatments for which they are approved, however physicians should be aware that not all the protocols in this document are currently approved in every country in which Omnilux is available.
Product Introduction and Specification

Acne Treatments

Omnilux™ light therapy in the treatment of acne vulgaris
Mild to moderate acne: Omnilux blue™ + Omnilux revive2™
Severe acne: Omnilux blue + topical 5-ALA

Photo rejuvenation

Omnilux light therapy in photo rejuvenation
Omnilux plus™ + Omnilux revive2
Omnilux revive2 + topical 5-ALA

Actinic Keratoses, Bowen’s Disease & Superficial Basal Cell Carcinoma

Omnilux light therapy for use in ALA-PDT for the treatment of non melanoma skin cancers

Accelerated Healing

Omnilux light therapy in accelerated healing of wounds

Rosacea

Omnilux revive2 in the treatment of Rosacea

Hyperpigmentation

Omnilux plus™ + Omnilux revive2 in the treatment of hyperpigmentation

Combination Therapies

Botox® & Fillers

Omnilux light therapy used with Botox and fillers

Chemical Peels

Omnilux light therapy used with mild peels
Moderate peels
Deep peels

Laser Resurfacing, Fractionated Lasers and Intense Pulsed Light

Omnilux light therapy used with laser resurfacing, fractionated lasers and intense pulsed light

Micro needling

Omnilux light therapy used with Micro needling

Warnings Associated with Photosensitivity

Common Types of Medications That May Cause Photosensitivity

Available Photosensitizers & Mixing Instructions

Technical Specification for Omnilux plus, Omnilux revive2 and Omnilux blue
The Omnilux™ system is based on narrowband Light Emitting Diodes (LEDs). Clinicians can utilize multiple treatment heads from a single operational base. Each treatment head delivers pure, optimized, narrowband light via a matrix of LEDs carefully positioned to deliver clinically proven light doses to the treatment area.

The three Omnilux treatment heads each emit light at specific, narrowband wavelengths to ensure optimal photobiomodulation of target skin cells and maximum treatment efficacy in a wide range of dermatological conditions including acne vulgaris, periorbital wrinkles, non-melanoma skin cancers, wound healing, combination therapies, and pain management.

<table>
<thead>
<tr>
<th>Omnilux Treatment Head</th>
<th>Wavelength</th>
<th>Output Intensity</th>
<th>Number of LEDs</th>
<th>Standard dose</th>
<th>Dose range</th>
<th>Treatment time (standard dose)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Omnilux blue™</td>
<td>415+/-5 nm</td>
<td>40 mW/cm²</td>
<td>1300</td>
<td>48 J/cm²</td>
<td>blue 1-55 J/cm²</td>
<td>20 mins</td>
</tr>
<tr>
<td>Omnilux revive²™</td>
<td>633+/-6 nm</td>
<td>105 mW/cm²</td>
<td>1680</td>
<td>126 J/cm²</td>
<td>revive2 1-150 J/cm²</td>
<td>20 mins</td>
</tr>
<tr>
<td>Omnilux plus³™</td>
<td>830+/-5 nm</td>
<td>55 mW/cm²</td>
<td>520</td>
<td>66 J/cm²</td>
<td>plus 1-80 J/cm²</td>
<td>20 mins</td>
</tr>
</tbody>
</table>

The articulated design of each Omnilux treatment head allows the clinician to control the area of illumination and shape the light to the exact contours of the treatment area. In this way, the entire treatment area will receive the correct, clinically proven dose of light for optimal light therapy.

Omnilux light therapy is non-invasive, non-ablative and safe for patients. Omnilux stimulates cells athermally without causing damage to the epidermis or dermal tissue. Therefore there is no downtime for patients or unwanted side effects (e.g. erythema, peeling or blistering) as may result from use of a laser or IPL.

Omnilux is simple to operate and allows full treatment of large areas such as the face and chest. The treatment is hands-free with no need for operator presence - hence freeing up valuable clinic time. Omnilux offers significant economic benefits to a practice, especially when compared to laser or IPL. And patients enjoy a calming and relaxing experience.

² When using light only therapies.
OMNILUX LIGHT THERAPY IN THE TREATMENT OF ACNE VULGARIS

HOW IT WORKS
Acne vulgaris is an extremely common and distressing skin condition affecting over 85% of adolescents by the age of 24 years and up to 50% of adults over 25 years. The underlying pathology in acne is a multifactorial process involving:

1 Comodogenesis
corneocyte desquamation
blocks the pilosebaceous follicle

2 Bacterial Colonization
Propionibacterium Acnes colonization in the blocked follicle

3 Seborrhoea
Increased sebum production in the pilosebaceous follicle

4 Inflammatory Process
P. Acnes bacteria recruit pro-inflammatory factors causing a chronic inflammatory process

P. Acnes bacteria endogenously produce the light-sensitive substances coproporphyrin III and protoporphyrin. The Omnilux™ system is equipped to irradiate these substances with wavelengths of light specifically designed to stimulate the porphyrins into synthesizing intracellular singlet oxygen – inducing bacterial death and so eradicating the inflammatory effects of acne.

The wavelength of Omnilux blue™ exactly coincides with the peak cytocidal profile of these light sensitive porphyrins (415 nm) and so is an optimum system for acne clearance. The P. Acnes bacteria weakened by exposure to this 415 nm blue light are also made more susceptible to attack by leukocytes, which are simultaneously photoactivated by the light source.

Clinical trials have demonstrated optimum acne clearance when Omnilux blue (415 nm) light is combined with Omnilux revive2™ (633 nm) red light treatment. Omnilux revive2 light minimizes production of pro-inflammatory cytokines. This anti-inflammatory effect reduces the erythema associated with acne lesions and by reducing the inflammatory response, minimizes the eventual possibility of acne scarring. Red light therapy with Omnilux revive2 has also been clinically proven to stimulate fibroblasts, therefore enhancing collagen production resulting in healthier, rejuvenated skin surrounding the acne affected area – adding to the beneficial effects of light therapy in acne.

---


Lee SY et al; ‘Blue and Red Light Combination LED Phototherapy for Acne Vulgaris in Patients with Skin Phototype IV.’ Lasers in Surgery and Medicine. 2007; 39 (2): 180-188

Goldberg DG, Russell B; ‘Combination blue (415 nm) and red (633 nm) LED phototherapy in the treatment of mild to severe acne vulgaris.’ Journal of Cosmetic and Laser Therapy. 2006; 8: 71-75.


MILD TO MODERATE ACNE:

Omnilux blue + Omnilux revive2
light only therapy

Protocol Summary
- 8 alternate Omnilux blue and Omnilux revive2 treatments over a 4-week treatment period.
- Allow at least 48 hours rest time between treatments.
- Never use blue and revive2 together as this reduces the treatment efficacy.
- For optimum efficacy, combine light treatment with an anti-comedonal treatment such as a salicylic acid wash, or gel (used in accordance with the manufacturers guidelines).

See contraindications for light therapy before administering Omnilux light treatment (Appendix 1).

Protocol

Step 1 - Preparing the skin
1. Remove make-up, pollutants and all product residues from the skin.
2. Clean the skin with a suitable skin cleanser (e.g. salicylic acid wash).
3. Fit the protective eye wear to ensure that the pupils are protected from direct illumination. For additional safety patients should be instructed to close their eyes (please refer to Omnilux user guide).

Step 2 - Light therapy
1. Position Omnilux blue or Omnilux revive2 around the face making sure that the LED panels are between 2-6 cm from the skin surface.
2. Follow the user instructions to activate the unit. The required dose is 48 J/cm² for Omnilux blue and 126 J/cm² for Omnilux revive2, or 20 minutes treatment time for each.
3. The treatment course is typically 2 treatments per week for 4 weeks, 8 treatments in total.

Step 3 - Follow-up
A follow-up appointment 12-weeks after the final light therapy session is recommended.

What to expect
Clinical trials using Omnilux blue and Omnilux revive2 light therapy without topical photosensitizer show a reduction of up to 81% in inflammatory acne lesions.

Patients will see some improvement in inflammatory lesions as early as the 4th treatment (two weeks from the start of the treatment period).

Patients may see an increase in comedones (whiteheads and blackheads) during the treatment period and hence the treatment should be combined with an anti-comedonal product such as salicylic acid or Differin.

Improvement continues after light treatments have ended
- In clinical trials, 45% of patients see optimum clearance 4 weeks after the final light treatment.
- 38% achieve best results 8 weeks after the final light treatment.
- 17% reach their optimum result 12 weeks after the final light treatment.

Omnilux mechanism of action is not only through singlet oxygen mediated death of P.acnes (photodynamic therapy), but also through the stimulatory effect of narrowband light on immunoregulatory pathways. This is the reason for the beneficial effects of Omnilux light treatment continuing long after completion of the light therapy treatment course.

Advantages of Omnilux blue and Omnilux revive2 light only therapy
- No patient downtime or pain.
- Inflammatory lesions continue to decline up to 16 weeks after beginning treatment.
- More than 75% of patients respond with excellent results.
- Non-invasive, patient-friendly procedure.

Omnilux blue + Omnilux revive2 light only treatment in cystic acne

Step 1 - Preparing the skin
- Remove make-up, pollutants and all product residues from the skin.

Step 2 - Light therapy
- Position Omnilux blue or Omnilux revive2 around the face ensuring that the LED panels are between 2-6 cm from the skin surface.
- Follow the user instructions to activate the unit. The required dose is 48 J/cm² for Omnilux blue and 126 J/cm² for Omnilux revive2, or 20 minutes treatment time for each.
- The treatment course is typically 2 treatments per week for 4 weeks, 8 treatments in total.

Step 3 - Follow-up
- A follow-up appointment 12-weeks after the final light therapy session is recommended.

What to expect
- Clinical trials using Omnilux blue and Omnilux revive2 light therapy without topical photosensitizer show a reduction of up to 81% in inflammatory acne lesions.
- Patients will see some improvement in inflammatory lesions as early as the 4th treatment (two weeks from the start of the treatment period).
- Patients may see an increase in comedones (whiteheads and blackheads) during the treatment period and hence the treatment should be combined with an anti-comedonal product such as salicylic acid or Differin.

Improvement continues after light treatments have ended
- In clinical trials, 45% of patients see optimum clearance 4 weeks after the final light treatment.
- 38% achieve best results 8 weeks after the final light treatment.
- 17% reach their optimum result 12 weeks after the final light treatment.

Omnilux blue + Omnilux revive2 light only therapy
- No patient downtime or pain.
- Inflammatory lesions continue to decline up to 16 weeks after beginning treatment.
- More than 75% of patients respond with excellent results.
- Non-invasive, patient-friendly procedure.

Omnilux mechanism of action is not only through singlet oxygen mediated death of P.acnes (photodynamic therapy), but also through the stimulatory effect of narrowband light on immunoregulatory pathways. This is the reason for the beneficial effects of Omnilux light treatment continuing long after completion of the light therapy treatment course.

Advantages of Omnilux blue and Omnilux revive2 light only therapy
- No patient downtime or pain.
- Inflammatory lesions continue to decline up to 16 weeks after beginning treatment.
- More than 75% of patients respond with excellent results.
- Non-invasive, patient-friendly procedure.

Photographs courtesy of Dr David Sire, Fullerton, CA, USA
SEVERE ACNE:

**Omnilux blue™ + Topical 5-ALA**

In cases of severe acne, clinicians may choose to use Omnilux blue light in combination with the topical photosensitizer 5-Aminolevulinic acid (5-ALA). This treatment may also be beneficial in cases of acne where previous light-only therapy has failed.

However, clinical data has shown that light only therapies are superior to ALA-PDT for the treatment of mild to moderate acne vulgaris.

ALA-PDT offers another tool in the dermatologist’s armamentarium in the treatment of acne, however adverse effects such as severe post treatment erythema, post-inflammatory hyperpigmentation (PIH) and severe skin peeling and crusting should be taken into account, especially in the case of dark-skinned individuals or those of Asian origin. Prolonged photosensitization, the need to use high factor sun protection, and pain during and after therapy may significantly decrease patient satisfaction and compliance.

Patients must be informed prior to treatment with 5-ALA that there may be side effects associated with the therapy (e.g. erythema, skin peeling, blistering and pain). The severity of these effects will depend on the 5-ALA concentration and contact time (duration that the photosensitizer is in contact with the skin).

### Protocol

**Step 1 - Preparing the skin**

Exfoliating the skin is essential to allow maximum penetration of the photosensitizer and to initiate a localized inflammatory response.

Exfoliate the skin using a choice of:

- Polyethylene based scrub
- Acetone scrub with gauze
- Microdermabrasion
- A mild peel AHAs, BHAs

5 Peels are contraindicated in those with allergic history, significant telangiectasias, and thinly epithelialized scars and in those with a predisposition to post inflammatory hyperpigmentation.

**Step 2 - Applying the photosensitizer**

Concentration and contact time of the photosensitizer used is dependant upon a number of patient variables:

- Skin type
- Extent of sun damage
- Acceptable patient downtime

It is important to educate the patient on the possible downtime that is associated with ALA-PDT (see step 4 - post treatment progression).

There are no accepted guidelines for the use of ALA-PDT for the treatment of acne, however by varying the concentration of the photosensitizer, where possible, varying the contact time, or the dose of light (time of irradiation) side effects can be controlled.

<table>
<thead>
<tr>
<th>Photosensitizer Concentration</th>
<th>Contact Time</th>
<th>Treatment Protocol</th>
<th>Possible Side effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>5%</td>
<td>30 minutes</td>
<td>3 Treatments 7-10 days apart</td>
<td>Minimum downtime Mild Erythema (3-5 days)</td>
</tr>
<tr>
<td>10%</td>
<td>30 minutes</td>
<td>Initial single treatment repeated after 4 weeks if minimal photoreaction occurs</td>
<td>Moderate downtime Moderate erythema (7-10 days) Skin peeling</td>
</tr>
<tr>
<td>20%</td>
<td>30 minutes – 2 hrs Max</td>
<td>Single treatment</td>
<td>Possibilities of severe downtime Severe erythema (up to 21 days) Skin peeling Blistering Crusting</td>
</tr>
</tbody>
</table>

3 Use of Omnilux blue with topical 5-ALA is not FDA cleared for severe acne.

4 In the United States the use of aminolaevulinic acid (ALA) for actinic keratosis (AK) or acne treatments is alleged by DUSA Pharmaceuticals, Inc. to be covered by US patent nos. 6,710,066 and 5,955,490. DUSA sells an ALA product under the name Levulan®, which is FDA approved for AK only. While GlobalMed Technologies reserves its rights with respect to the DUSA patents (including the rights to challenge the patents’ validity and enforceability), GlobalMed Technologies does not endorse or recommend using any ALA product other than Levulan® with an Omnilux lighting product for treatment of AK within the US. Any use of ALA (other than Levulan®) with an Omnilux lighting product within the US should be solely for cosmetic treatments and not for AK nor acne.
**Step 3 - Contact and treatment time**

1. After application of the photosensitizer the patient should avoid direct sunlight or bright lights for the contact period.

2. After the appropriate contact time, wipe away any excess photosensitizer and fit the protective eye wear to ensure that the pupils are protected from direct illumination. Follow the user instructions to activate Omnilux blue™. The required dose is 48 J/cm², 20 minutes treatment time. Downtime can be controlled by reducing the dose of light administered (time of illumination).

3. **Pain management:** Depending upon photosensitizer concentration and contact time, ALA-PDT can be painful. Some patients may require analgesia, though the vast majority do not require prescription pre-medication. Consider NSAIDs or acetaminophen. During light treatment, (using a scale of 1-10) discomfort has ranged from 2-8. Higher levels of discomfort correlate to the degree of sun damage, drug concentration, and the reaction time for the drug with the skin. Higher drug concentrations used for longer periods of time will result in more discomfort. Typically, discomfort fades quickly after the light treatment is finished. Any lasting discomfort or erythema can be treated with small doses of medication, including 20% hydrocortisone.

**Further pain management techniques**
- Pass cool air over the treatment area.
- Spray cool sterile water over the treatment area + 4°C (Care should be taken when using electrical appliances near water).
- Commercial cooling systems "smartcool" or "Zimmer cooler."
- Distraction techniques such as music and conversation.

**Step 4 - Post treatment progression**

After light treatment, the degree of erythema and discomfort can vary. Patient’s skin will feel sunburnt and there may be significant peeling and erythema. A greater reaction to treatment also usually indicates a more dramatic result.

After light treatment it is essential that the following guidelines be strictly adhered to.

For the first day:
- Both direct and indirect sunlight and bright lights should be avoided. Normal house lighting is acceptable.
- If the patient must go outdoors after treatment, it is essential to wear total sunblock and a wide brimmed hat.
- Cool compresses will help limit discomfort. Topical sunburn care products, such as aloe, are also helpful.
- Lubrication, such as Vaseline, Eucerin or Aquaphor can be used as needed for comfort. In rare instances, severe dryness can lead to small areas of cracking and bleeding. These areas should be treated with antibiotic ointment.
- Instruct the patient not to pick at the skin or any scabs that may form.

**Step 5 - Follow-up**

The time between maintenance PDT care (treatment to maintain the effects) will depend on skin type, the degree of sun protection, the amount of sun exposure and the treatment protocol followed.

Before and 4 weeks after 4 weekly treatments of 5% ALA-PDT with Omnilux blue

Illustration of possible side effects of ALA-PDT (20% Levulan® DUSA Pharmaceuticals)

Please Note: ALA-PDT has been reported to induce Herpes Simplex Virus (HSV). Prophylaxis for HSV activation should be included in any patient in whom a history of outbreaks is found, or if clinical judgement suggests the patient is at risk.
OMNILUX LIGHT THERAPY IN PHOTO REJUVENATION

Aging is accompanied by a diminishing quantity of collagen in the dermis. The skin loses flexibility and its ability to retain moisture – therefore becoming drier and thinner as the body’s natural regeneration processes slow.

Photoaging compounds these effects, since harmful UVA and UVB rays in sunlight produce enzymes that break down the skin’s supportive structure and prevent formation of new collagen.

Cell activation tests show that Omnilux revive2™ and Omnilux plus™ have specific and unique cell stimulation patterns acting to photobiomodulate cell function and rejuvenate the skin.

Phototherapeutic wavelength-specific actions in raising action potentials of specific cells

<table>
<thead>
<tr>
<th>Nominal Wavelength (nm)</th>
<th>Cell Types / Action Level</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mast</td>
</tr>
<tr>
<td>630 - 670</td>
<td>++</td>
</tr>
<tr>
<td>790</td>
<td>++</td>
</tr>
<tr>
<td>830</td>
<td>++</td>
</tr>
<tr>
<td>904</td>
<td>–</td>
</tr>
<tr>
<td>1064</td>
<td></td>
</tr>
<tr>
<td>10600</td>
<td></td>
</tr>
</tbody>
</table>


HOW IT WORKS

Omnilux revive2 red light is absorbed in the cellular mitochondria and stimulates ATP production leading to increased cellular action potential and enhanced cell vitality. The 633 nm light emitted is potently absorbed by fibroblasts, with a subsequent increase in the speed and efficiency of neo-collagen synthesis. Turnover of aged collagen and elastin fibers results from light stimulation of metalloproteinases (MMPs).

Omnilux plus 830 nm light acts synergistically with revive2 light to achieve optimum efficacy in photo rejuvenation. Omnilux plus is strongly absorbed within fibro-myocytes promoting alignment and increased tone in the newly produced collagen bundles. The composite effect leaves the skin fuller and tighter in appearance. Light-stimulated neo-vascularisation in the treatment area means greater perfusion to the skin, increased oxygenation and removal of toxins and a more glowing residual appearance.


Russell B et al. ‘A study to determine the efficacy of combination LED light therapy (830 nm and 633 nm) in facial skin rejuvenation’. - Journal of Cosmetic and Laser Therapy volume 7 issue 3/4

PHOTO REJUVENATION:

Omnilux plus + Omnilux revive2

Protocol Summary
- A total of 8 alternating – 4 Omnilux plus and 4 Omnilux revive2 treatments – over a 4 week treatment period.
- All Omnilux plus and Omnilux revive2 treatments are of 20 minute duration.
- Allow at least 48 hours rest-time between treatments.
- Never use revive2 and plus together as this reduces the treatment efficacy.

See contraindications for light therapy before administering Omnilux™ light treatment (Appendix 1).

Protocol
Step 1 - Preparing the skin
1 Remove make-up, pollutants and all product residues from the skin.
2 Exfoliate the skin using a choice of:
   - Polyethylene based scrub
   - Microdermabrasion
   - A mild peel AHAs, BHAs
5 Peels are contraindicated in those with allergic history, significant telangiectasias, and thinly epithelialized scars and in those with a predisposition to post inflammatory hyperpigmentation.

Step 2 - Light therapy
1 Fit the protective eye wear to ensure that the pupils are protected from direct illumination. For additional safety patients should be instructed to close their eyes (please refer to Omnilux user-guide). In addition, ensure that the operator is wearing the operator goggles provided.
2 Position Omnilux revive2 or Omnilux plus around the face making sure that the LED panels are between 2-6 cm from the skin surface.
3 Follow the user instructions to activate the unit. The required dose is 126 J/cm² for Omnilux revive2 and 66 J/cm² for Omnilux plus, or 20-minutes treatment time for each.
4 The treatment course is alternating Omnilux plus and Omnilux revive2, two treatments per week for 4 weeks.

Step 3 - Follow-up
A follow-up appointment 12-weeks after the final light therapy session is recommended.

What to expect
Clinical trials using Omnilux revive2 in combination with Omnilux plus light therapy without topical photosensitizer show a significant reduction in skin roughness and density of skin furrows at 9 and 12 week follow-up. 83.9% of patients reported softening of wrinkles after the course of 7-9 light treatments.

Improvements continue to be seen when the light treatments have ended.

Advantages of Omnilux revive2 and Omnilux plus combination light therapy in skin rejuvenation
- No patient downtime or pain.
- Reduction in facial wrinkles and skin furrows continue after completion of the light therapy course.
- More than 70% of patients respond with excellent results.
- Non-invasive, patient-friendly procedure.

Photorejuvenation using combination Omnilux plus and Omnilux revive2

Baseline  week 6  week 9  week 12

Photographs courtesy of Dr Bruce Russell, Portland, OR, USA
PHOTO REJUVENATION:

Omnilux revive2\textsuperscript{TM} + topical 5-ALA\textsuperscript{3,4}

Studies have demonstrated that light only therapies can be considered comparable to ALA-PDT for photorejuvenation.

ALA-PDT offers another tool in the dermatologist’s armamentarium in the treatment of photodamaged skin, however adverse effects such as severe post treatment erythema, post-inflammatory hyperpigmentation (PIH) and severe skin peeling and crusting should be taken into account, especially in the case of dark-skinned individuals or those of Asian origin. Prolonged photosensitization of the skin, and the need to use high factor sun protection, may significantly decrease patient satisfaction level and compliance.

Protocol

Step 1 - Preparing the skin

It is essential to exfoliate the skin to allow maximum penetration of the photosensitizer and to initiate a localized inflammatory response.

Exfoliate the skin using a choice of:
- Polyethylene based scrub
- Acetone scrub with gauze
- Microdermabrasion
- A mild peel AHAs, BHAs\textsuperscript{5}

\textsuperscript{5} Peels are contraindicated in those with allergic history, significant telangectasias, and thinly epithelialized scars and in those with a predisposition to post inflammatory hyperpigmentation.

Step 2 - Applying the photosensitizer (Appendix 2).

Concentration and contact time of the photosensitizer used is dependant upon a number of patient variables:
- Skin type
- Extent of sun damage
- Acceptable patient downtime

It is important to educate the patient on the possible downtime that is associated with ALA-PDT (see step 4 – post treatment progression).

There are currently 3 accepted protocols see table below:

<table>
<thead>
<tr>
<th>Photosensitizer Concentration</th>
<th>Contact Time</th>
<th>Treatment Protocol</th>
<th>Possible Side effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>5%</td>
<td>30 minutes</td>
<td>2 Treatments 7-10 days apart</td>
<td>Minimum downtime Mild Erythema (3-5 days)</td>
</tr>
<tr>
<td>10%</td>
<td>30 mins - 2 hrs</td>
<td>Initial single treatment after 4 weeks if minimal photoreaction occurs</td>
<td>Moderate downtime Moderate erythema (7-10 days) Skin Peeling</td>
</tr>
<tr>
<td>20%</td>
<td>30 mins - 2 hrs max</td>
<td>Single Treatment 1-3 hrs</td>
<td>Possibilities of severe downtime Severe erythema (up to 21 days) Skin peeling Blistering Crusting</td>
</tr>
</tbody>
</table>

\textsuperscript{3} Omnilux revive2 + topical 5-ALA in the treatment of photo rejuvenation is not an FDA cleared indication.

\textsuperscript{4} In the United States the use of aminolaevulinic acid (ALA) for actinic keratosis (AK) or acne treatments is alleged by DUSA Pharmaceuticals, Inc. to be covered by US patent nos. 6,710,066 and 5,955,490. DUSA sells an ALA product under the name Levulan\textsuperscript{\textregistered}, which is FDA approved for AK only. While GlobalMed Technologies reserves its rights with respect to the DUSA patents (including the rights to challenge the patents’ validity and enforceability), GlobalMed Technologies does not endorse or recommend using any ALA product other than Levulan\textsuperscript{\textregistered} with an Omnilux lighting product for treatment of AK within the US. Any use of ALA (other than Levulan\textsuperscript{\textregistered}) with an Omnilux lighting product within the US should be solely for cosmetic treatments and not for AK nor acne.

Step 3 - Contact and treatment time

1. After application of the photosensitizer the patient should be kept away from direct sunlight or bright lights for the contact period.
2. After the appropriate contact time, wipe away any excess photosensitizer, fit the protective eye wear to ensure that the pupils are protected from direct illumination. Follow the user instructions to activate Omnillux revive2, the required dose is 96 J/cm\textsuperscript{2} or 16-minute treatment time. Downtime can be controlled by reducing the dose of light administered (time of illumination).
3. Pain management: Depending upon photosensitizer concentration and contact time. ALA-PDT can be painful. Some patients may require analgesia, though the vast majority do not require prescription pre-medication. Consider NSAIDs and/or acetominophen. During light treatment, (using a scale of 1-10), discomfort has ranged from 2-8. Higher levels of discomfort correlate to the degree of sun damage, drug concentration, and the reaction time for the drug with the skin. Higher drug concentrations used for longer periods of time will result in more discomfort. Typically, discomfort fades quickly after the light treatment is complete. Any lasting discomfort or erythema can be treated with small doses of medication, including 20% hydrocortisone.

Further pain management techniques
- Pass cool air over the treatment area.
- Spray cool sterile water over the treatment area + 4\textdegree C. (Care should be taken when using electrical appliances near water).
- Commercial cooling systems “smartcool” or “Zimmer cooler.”
- Distraction techniques such as music and conversation.

ALA-PDT (20% Levulan\textsuperscript{\textregistered} DUSA Pharmaceuticals) for skin rejuvenation and the treatment of photo damaged skin

![Before - A smooth complexion with minimal skin imperfections.](Image 305x262 to 414x433)

![After - A marked improvement in skin texture and color.](Image 417x263 to 525x434)

Photography courtesy of Dr Mark Taylor, Gateway Aesthetics, Salt Lake City, UT, USA

![Possible Side effects](Image 526x304 to 634x485)
Step 4 - Post treatment progression

After light treatment, the degree of erythema and discomfort can vary. Patient’s skin will feel sunburnt and there may be significant peeling and erythema. A greater reaction to treatment also usually indicates a more dramatic result.

After light treatment it is essential that the following guidelines be strictly adhered to:

1. Both direct and indirect sunlight and bright lights should be avoided. Normal house lighting is acceptable.

2. If the patient must go outdoors after treatment, it is essential to wear total sun block and a wide brimmed hat.

3. Cool compresses will help limit discomfort. Topical sunburn care products, such as aloe, are also helpful.

4. Lubrication, such as Vaseline, Eucerin, or Aquaphor can be used as needed for comfort. In rare instances, severe dryness can lead to small areas of cracking and bleeding. These areas should be treated with antibiotic ointment.

5. Instruct the patient not to pick the skin or scabs that may form.

Long Term:
The time between maintenance PDT care (treatment to maintain the effects) will depend on skin type, the degree of sun protection, the amount of sun exposure and the treatment protocol followed.

Illustration of possible side effects of ALA-PDT (20% Levulan® DUSA Pharmaceuticals)

Please Note: ALA-PDT has been reported to induce Herpes Simplex Virus (HSV). Prophylaxis for HSV activation should be included in any patient in whom a history of outbreaks is found, or if clinical judgement suggests the patient is at risk.

OMNILUX LIGHT THERAPY FOR USE IN ALA-PDT FOR THE TREATMENT OF NON MELANOMA SKIN CANCERS

Topical photodynamic therapy (PDT) has optimal efficacy in:

1. Non-hyperkeratotic actinic keratoses (AKs) on the face and scalp.
2. Bowen’s disease.
3. Superficial Basal cell carcinomas (sBCCs) (less than 2 mm thick).

- Adjunctive therapy to remove thick actinic keratotic crusts or de-bulk nodular basal cell tumours via curettage may also permit effective topical PDT in these indications.
- Due to high recurrence rates and their metastatic potential, topical photosensitizer-PDT is not advised for invasive squamous cell carcinoma.
- Particular care should be taken when treating lesions on the eyelids, nose, lips and genitalia where photosensitizer uptake by normal surrounding skin/mucosa along with edema formation within restricted areas may increase the pain of PDT.

AKs/BOWEN’S DISEASE/sBCCs:

**Omnilux + topical 5-ALA**

Omnilux revive²™ and Omnilux blue™ can both be used to activate the photosensitive product Protoporphyrin IV.

It is recommended that Omnilux blue should only be used for very superficial AKs. Omnilux revive² can be used to treat AKs, Bowen’s disease and superficial Basal cell carcinomas.

Protocol

**Step 1 - Lesion preparation:**

1. Gently remove surface crust, without drawing blood ('blunt decrusting') either by:
   - gauze soaked in saline using disposable forceps
   - light abrasion of lesion using the edge of a scalpel blade
   - gentle use of a mildly abrasive finger pad, (e.g. cardio-preps).
2. Try to minimize abrasion of healthy surrounding tissue. This preparation does not require local anesthesia and does not need to be sterile but the doctor/nurse should wear gloves during the procedure.

**Step 2 - Apply the photosensitizer (Appendix 2).**

1. Apply photosensitizer to cover the entire surface of the lesion as well as a minimum 5 mm margin around each lesion. A thin layer of cream (1-2 mm) should be applied. The photosensitizer may sting if the skin is broken or ulcerated.
2. An adhesive dressing should occlude the lesion in order to retain cream at site (e.g. Tegaderm™, 3M, UK). In particularly sensitive (e.g. around eyes) or confined areas (e.g. sharply curved regions around nose), reinforcing the seal with Transpore™ tape or equivalent may be necessary. It is preferable that, during the incubation period, a further dressing is applied to minimize ambient light exposure (e.g. Mepore®, Molnlycke Health Care, Sweden). Another option is to use a light-occluding layer of 8 or 16-ply blue gauze swab taped into place with Transpore.
3. The patient is then free to leave with the instruction to return after the incubation period.

**Step 3 - Treatment visit**

1. Patient returns for removal of bandages and excess cream is wiped clear.
2. Optional pre-treatment application of a topical anesthetic, applied following removal of excess 5-ALA, 45 or 60 minutes respectively prior to illumination (i.e. at 3-5 hours). Alternatively, patients are injected subcutaneously around the lesion (disposable hypo needles, 10 ml syringes) with a local anesthetic (0.5% Marcaine: Bupivocaine or the less potent 1% lignocaine) and bleeding, if any, is stemmed using cotton wool swabs.

---

3 Omnilux revive² • Topical 5-ALA treatment is not FDA cleared for AKs, Bowen’s Disease or sBCCs.
4 In the United States the use of aminolaevulinic acid (ALA) for actinic keratosis (AK) or acne treatments is alleged by DUSA Pharmaceuticals, Inc. to be covered by US patent nos. 6,710,066 and 5,955,490. DUSA sells an ALA product under the name Levulan®, which is FDA approved for AK only. While GlobalMed Technologies reserves its rights with respect to the DUSA patents (including the rights to challenge the patents’ validity and enforceability), GlobalMed Technologies does not endorse or recommend using any ALA product other than Levulan® with an Omnilux lighting product for treatment of AK within the US. Any use of ALA (other than Levulan®) with an Omnilux lighting product within the US should be solely for cosmetic treatments and not for AK nor acne.
Patients should wear protective eye wear when the area of illumination is within their field of vision. Similarly the doctor/nurse administering PDT should wear suitable filter spectacles to limit the transmission of the high intensity light, to avoid discomfort and temporary disturbance of color perception that could occur if the operator were to look directly at the light. However the light is not harmful.

Depending on the site, the patient is then made comfortable by either sitting or lying down. The illumination field should include a border around each lesion of at least 5 mm.

Dependent upon lesion type use the following light parameters. A single Omnirux revive2 treatment of 16-minute duration (16 minutes equates to 96 J/cm²) OR A single Omnirux blue treatment of 5 minutes duration (5 minutes equates to 12 J/cm²).

Step 4 - Aftercare

1. Following photodynamic therapy, areas where the topical photosensitizer has been applied must be protected from sunlight for 48 hours. After 48 hours, the patient can remove the dressing (unless it is still oozing) and can wash, bathe or shower as usual.

2. Advise the patient that the treated area may crust, which is normal, and that it is important not to disturb or pick it. They must not rub the treated area, but gently dab it dry. The treated area heals over a period of 3-6 weeks.

Step 5 - Follow-up

There remains no proven 'best practice,' but review at 6-8 weeks following therapy is the earliest time to determine the need for further PDT. There is the option of a 'double treatment' protocol that has been described for sBCC where treatment is performed twice, 7 days after the initial treatment.

Bowen’s disease before and after 20% ALA-PDT

Photographs courtesy of Dr Colin Morton, Falkirk, Scotland


Morton CA, Whitehurst C, McColl JH, Moore JV, Mackie RM; 'Photodynamic therapy for large or multiple patches of Bowen’s disease and basal cell carcinoma' - Archive of Dermatology, 137, 319-324.

Morton CA, Burden AD; 'Treatment of multiple scalp basal cell carcinomas by photodynamic therapy' - Clinical and Experimental Dermatology, 26, 33-36.


OMNILUX LIGHT THERAPY IN ACCELERATED HEALING OF WOUNDS

The combination of Omnilux plus and Omnilux revive2 light treatment applied at specific times enables acceleration of the wound healing response. For patients who have reduced skin integrity we suggest a 4 week course of alternating Omnilux revive2™ and Omnilux plus™ – 2 treatments per week (total 8 treatments).

What to expect

- Accelerated evolution and enhanced final appearance of scarring.
- Accelerated resolution of erythema and edema.
- Pain reduction at the site.
- Rejuvenated appearance of the treated skin surface.

Omnilux plus + Omnilux revive2

Protocol Summary

- A total of 8 light treatments – 5 Omnilux plus and 3 Omnilux revive2 treatments over a 21 day treatment period.
- Omnilux plus treatments are pre operatively, immediately post-operatively, 24 hours post-op, 3 days post-op and 21 days post-op.
- Omnilux revive2 treatments are 7, 10 and 14 days post-operatively.
- All Omnilux plus and Omnilux revive2 treatments are of 20 minute duration.
- Never use revive2 and plus together as this reduces the treatment efficacy.

Accelerated healing of wounds using combination Omnilux plus and Omnilux revive2 light therapy

Full face Fractional Er: YAG resurfacing LED therapy. LEFT image clearly shows extensive scabbing post surgery as a result of various laser passes which result in dermal RTD. 6 day image clearly demonstrates complete healing and practically no residual erythema after exposure to LED therapy.

Photographs courtesy of Dr Mario Trelles. Cambrils, Spain

Protocol

Step 1

1. If the face is being treated, fit the protective eye wear to ensure that the pupils are protected from direct illumination.

   For additional safety patients should be instructed to close their eyes (please refer to Omnilux user-guide). If other areas of the body are being treated ensure that the patient is wearing suitable eye protection to prevent passive exposure to light. In addition, ensure that the operator is wearing the operator goggles provided.

2. Position Omnilux revive2 or Omnilux plus around the treatment area to fit the contour of the area as accurately as possible, making sure that the LED panels are between 2-6 cm from the skin surface.

3. Follow the user instructions to activate the unit. The required dose is 126 J/cm² for Omnilux revive2 and 66 J/cm² for Omnilux plus, or 20 -minutes treatment time for each.

4. The treatment course is as follows:

<table>
<thead>
<tr>
<th></th>
<th>Immediately pre-op</th>
<th>Immediately post-op</th>
<th>1 day post-op</th>
<th>3 days post-op</th>
<th>7 days post-op</th>
<th>10 days post-op</th>
<th>14 days post-op</th>
<th>21 days post-op</th>
</tr>
</thead>
<tbody>
<tr>
<td>Omnilux plus</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Omnilux revive2</td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
</tbody>
</table>

5 Omnilux is not FDA cleared for accelerated healing of surgical wounds.

6 For blepharoplasty or eye surgery use Omnilux revive2 only.
OMNILUX LIGHT THERAPY IN THE TREATMENT OF ROSACEA

Rosacea is a common chronic inflammatory acneform disorder of the facial pilosebaceous units. Capillaries have an increased reactivity leading to facial flushing and telangiectasia.

The cosmetic effects of Rosacea are debilitating to patients. The course of the disorder is often prolonged and recurrences are common.

Common management measures include topical metronidazole, oral doxycycline or Isotretinoin for individuals with more severe disease.

The use of Omnilux light therapy in rosacea (as light treatment alone or alongside a course of bi-daily topical Metronidazole) offers excellent efficacy in erythema reduction and overall facial cosmetic enhancement.

In addition, the anti-inflammatory effects of the Omnilux revive2™ treatments act to prolong time-to-recurrence of the condition.

Rosacea: Omnilux revive2 light only therapy

Protocol

Step 1- Preparing the skin
1 Remove make-up, pollutants and all product residues from the skin.
2 Clean the skin with a suitable skin cleanser.
3 Fit the safety goggles to ensure that the pupils are protected from direct illumination. For additional safety patients should be instructed to close their eyes (please refer to Omnilux user guide manual).

Step 2- Light therapy
1 Position Omnilux around the face making sure that the LED panels are between 2-6 cm from the skin surface.
2 Follow the user instructions to activate the unit. The required dose is 48 J/cm² for Omnilux blue and 126 J/cm² for Omnilux revive2, or 20 minutes treatment time for each.
3 The treatment course is typically 2 treatments weekly for 5 weeks, 10 light treatments in total.
4 Metronodazole gel or cream, 0.75% b.d. is an effective adjunct to rosacea light therapy sessions.

Step 3- Follow-up
A follow-up appointment 12-weeks after the final light therapy session is recommended.


7 Omnilux light therapy is not FDA cleared for the treatment of rosacea.
OMNILUX IN TREATING HYPERPIGMENTATION

There have been several important studies using LED phototherapy for the treatment of pigmentation. Lee et al (2006, 2007) reported lighter skin after LED phototherapy, while treating acne and periorbital wrinkles. In separate studies global improvement and reduction in melanin levels were registered in phototype IV skin types after treatment with red (633 nm) light. More recently in vitro studies have demonstrated that NIR reduced melanin production and tyrosinase expression, not only in a normal human melanocyte monoculture but also in a three-dimensional multiple cell type culture.

What to expect
- A reduction in brown spots or pigment patches.
- An evening of skin tone.
- Reduction in the risk of hyperpigmentation if used pre and post invasive intervention.

Omnilux in treating hyperpigmentation

<table>
<thead>
<tr>
<th>Protocol Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>A typical program is a total of 8-10 treatments over 4-5 weeks.</td>
</tr>
<tr>
<td>Using Omnilux phototherapy to prepare the skin in advance of more invasive procedures to significantly reduce the risk of post inflammatory pigmentation.</td>
</tr>
<tr>
<td>All Omnilux plus and Omnilux revive2 treatments are 20-minute duration.</td>
</tr>
<tr>
<td>Never use Omnilux revive2 and Omnilux plus together as this reduces the treatment efficacy.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Protocol</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Fit the protective eye wear to ensure that the pupils are protected from direct illumination.</td>
</tr>
<tr>
<td>2 For additional safety patients should be instructed to close their eyes (please refer to Omnilux user-guide). In addition, ensure that the operator is wearing the operator goggles provided.</td>
</tr>
<tr>
<td>3 Position Omnilux revive2 or Omnilux plus around the treatment area to fit the contour of the area as accurately as possible, making sure that the LED panels are between 2-6 cm from the skin surface.</td>
</tr>
<tr>
<td>4 Follow the user instructions to activate the unit. The required dose is 126 J/cm² for Omnilux revive2 and 66 J/cm² for Omnilux plus, or 20 -minutes treatment time for each.</td>
</tr>
<tr>
<td>5 The treatment course is as follows:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Treatment program</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Invasive procedure</strong></td>
</tr>
<tr>
<td><img src="image" alt="" /></td>
</tr>
<tr>
<td><strong>Omnilux plus</strong></td>
</tr>
<tr>
<td><strong>Omnilux revive2</strong></td>
</tr>
</tbody>
</table>


Lee SY et al. ‘Blue and Red Light Combination LED Phototherapy for Acne Vulgaris in Patients with Skin Phototype IV.’ Lasers in Surgery and Medicine. 2007; 39 (2): 180-188

---

8 Omnilux revive2 and Omnilux plus are not FDA cleared for the treatment of hyperpigmentation.

9 If no adjunctive treatment is being used, commence treatment with Omnilux plus.
OMNILUX LIGHT THERAPY USED WITH BOTOX AND FILLERS

(e.g. Restylane® or Juvederm®)

The use of Omnilux light treatments pre- and post- botox injection or filler treatment, displays enhanced clinical results when compared to matched controls.

Used with Botox injection, Omnilux revive2™ light treatment minimizes the possibility of bruising or swelling at the injection site and provides an increased longevity to the effects of the Botox. The light treatment provides the skin with supplementary vascular activity and results in a healthier, plumper skin appearance.

Used with fillers, adjunctive Omnilux light treatments decrease the incidence of hematoma formation and provide the additional benefits of enhanced overall skin rejuvenation.

Botox & Fillers:
Omnilux light treatment alone

Protocol Summary
- Two protocol options:
  i) Short therapy course, 3 Omnilux revive2 light treatments over 5 days
  ii) Extensive therapy course, 8 alternating Omnilux plus™ and Omnilux revive2 light treatments over 4 weeks.

- All Omnilux treatments are of 20-minute duration.
- Allow at least 24 hours rest-time between treatments.

Protocol
Step 1 - Fit safety goggles
Fit the safety goggles to ensure that the pupils are protected from direct illumination. For additional safety patients should be instructed to close their eyes (please refer to Omnilux user-guide manual). In addition, ensure that the operator is wearing the operator goggles provided.

Step 2 - Position the LED panels
1 Position Omnilux around the face making sure that the LED panels are between 2-6 cm from the skin surface.
2 Follow the user instructions to activate the unit. The required dose is 126 J/cm² for Omnilux revive2 or 66J/cm² for Omnilux plus – 20-minutes treatment time.
3 The treatment courses are as follows:

Short therapy course

<table>
<thead>
<tr>
<th>Treatment day</th>
<th>3 days post botox or filler</th>
<th>5 days post botox or filler</th>
</tr>
</thead>
<tbody>
<tr>
<td>Botox or filler treatment</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Omnilux revive2</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

Extensive therapy course – Botox

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Week 1 (days 1-7)</th>
<th>Week 2 (days 8-14)</th>
<th>Week 3 (days 15-21)</th>
<th>Week 4 (days 22-28)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Botox</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Omnilux revive2</td>
<td>Immediately after the procedure</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Omnilux plus</td>
<td>2 days later</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

Extensive therapy course – Fillers

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Week 1 (days 1-7)</th>
<th>Week 2 (days 8-14)</th>
<th>Week 3 (days 15-21)</th>
<th>Week 4 (days 22-28)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fillers</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Omnilux plus</td>
<td>Immediately before the procedure</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Omnilux revive2</td>
<td>2 days later</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

Step 3 - Follow-up
A follow-up appointment 6-weeks after the final light therapy session is recommended.

10 Omnilux light therapy is not FDA cleared for use with Botox or Fillers.
OMNILUX LIGHT THERAPY USED WITH MILD CHEMICAL PEELS

Chemical peels can benefit a wide range of skin conditions and generally the concept of peeling is often regarded as a gradual program where the client will have between 2-6 peels, depending on the type and concentration of the peel.

For all peels, Omnilux is an ideal adjunctive light therapy, which can be used before the peel to prepare the skin’s reparative cells or after the peel to enhance tissue regeneration, increase cell vitality and reduce downtime.

Omnilux and Superficial peels

Protocol

Step 1 - Preparing the skin
Remove make-up, pollutants and all product residues from the skin.
Clean the skin with a suitable skin cleanser.
Post treat with Omnilux plus™ after each peel. Follow step 2 “Light therapy” use Omnilux plus 20 minutes - 66 J/cm².
Carry out your desired peel as per your peel instructions.

Step 2 - Light therapy
1. Fit the safety goggles to ensure that the pupils are protected from direct illumination. For additional safety patients should be instructed to close their eyes (please refer to Omnilux™ user guide).
2. Position Omnilux plus™ or Omnilux revive2™ around the face making sure that the LED panels are between 2-6 cm from the skin surface.
3. Follow the user instructions to activate the unit. The required dose is 66 J/cm² for Omnilux plus and 126 J/cm² for Omnilux revive2, or 20-minutes’ treatment time for each.

Post Peel Care
With all peels
1. Instruct the patient not to touch or scratch the treated area; follow the post peel protocols as per your normal routine.
2. When combining Omnilux with a chemical peel, review the list of products and drugs contraindicated for use with Omnilux.
3. Patient should avoid direct sun exposure post-treatment. Instruct the patient to apply a total sun block before going outdoors.
4. Avoid applying products to the face that may increase skin irritation such as abrasive products, permanent wave solutions, chemical hair removers or waxes, electrolysis, products with alcohol, astringents, alpha hydroxy acids, or other products that may irritate your skin.

Protocol - Omnilux and superficial peels

<table>
<thead>
<tr>
<th></th>
<th>Week 1 (days 1-7)</th>
<th>Week 2 (days 8-14)</th>
<th>Week 3 (days 15-21)</th>
<th>Week 4 (days 22-28)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Superficial Peels</strong></td>
<td>1 peel on day 1 (before light treatment)</td>
<td>1 peel on day 8</td>
<td>1 peel on day 15</td>
<td>No peel</td>
</tr>
<tr>
<td><strong>Omnilux plus</strong></td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td><strong>Omnilux revive2</strong></td>
<td>2 days post peel</td>
<td>2 days post peel</td>
<td>2 days post peel</td>
<td>2 days post peel</td>
</tr>
</tbody>
</table>

Omnilux plus and Omnilux revive2 are not FDA cleared for the use in combination with Chemical peels to improve clinical outcome.
OMNILUX LIGHT THERAPY USED WITH MODERATE CHEMICAL PEELS

Omnilux and Moderate peels

Protocol

Step 1 - Preparing the skin
Remove make-up, pollutants and all product residues from the skin.
Clean the skin with a suitable skin cleanser.
Pretreat with Omnilux plus™ before each peel. Follow step 2 “Light therapy” use Omnilux plus 20 minutes – 66 J/cm².
Carry out your desired peel as per your peel instructions.

Step 2 - Light therapy
1. Fit the safety goggles to ensure that the pupils are protected from direct illumination. For additional safety patients should be instructed to close their eyes (please refer to Omnilux™ user guide).
2. Position Omnilux plus™ or Omnilux revive2™ around the face making sure that the LED panels are between 2-6 cm from the skin surface.
3. Follow the user instructions to activate the unit.
The required dose is 66 J/cm² for Omnilux plus and 126 J/cm² for Omnilux revive2, or 20-minutes’ treatment time for each.

Protocol- Omnilux and moderate peels

<table>
<thead>
<tr>
<th></th>
<th>Week 1 (days 1-7)</th>
<th>Week 2 (days 8-14)</th>
<th>Week 3 (days 15-21)</th>
<th>Week 4 (days 22-28)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Moderate Peels</strong></td>
<td>1 peel on day 1 (before light treatment)</td>
<td>1 peel on day 15 (before light treatment)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Omnilux plus</td>
<td>✓ (Pre-treatment)</td>
<td>✓ (Post treatment)</td>
<td>✓ (Pre-treatment)</td>
<td>✓ (Post treatment)</td>
</tr>
<tr>
<td>Omnilux revive2</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

Post Peel Care
With all peels:
1. Instruct the patient not to touch or scratch the treated area; follow the post peel protocols as per your normal routine.
2. When combining Omnilux with a chemical peel, review the list of products and drugs contraindicated for use with Omnilux.
3. Patient should avoid direct sun exposure for 24-48 hours post-treatment. Instruct the patient to apply a total sun block before going outdoors.
4. Avoid applying products to the face that may increase skin irritation such as abrasive products, permanent wave solutions, chemical hair removers or waxes, electrolysis, products with alcohol, astringents, alpha hydroxy acids, or other products that may irritate your skin.

**Note:** Omnilux plus and Omnilux revive2 are not FDA cleared for the use in combination with Chemical peels to improve clinical outcome.
OMNILUX LIGHT THERAPY USED WITH DEEP CHEMICAL PEELS

Omnilux and deep peels

Protocol

Step 1 – Preparing the skin
Remove make-up, pollutants and all product residues from the skin.
Clean the skin with a suitable skin cleanser.
Pretreat with Omnilux plus™ before each peel. Follow step 2 “Light therapy” use Omnilux plus 20 minutes – 66 J/cm². Carry out your desired peel as per your peel instructions.

Step 2 – Light therapy
1. Fit the safety goggles to ensure that the pupils are protected from direct illumination. For additional safety patients should be instructed to close their eyes (please refer to Omnilux™ user guide).
2. Position Omnilux revive2™ or Omnilux plus™ around the face making sure that the LED panels are between 2-6 cm from the skin surface.
3. Follow the user instructions to activate the unit. The required dose is 66 J/cm² for Omnilux plus and 126 J/cm² for Omnilux revive2, or 20-minutes’ treatment time for each.

Protocol- Omnilux and deep peels

<table>
<thead>
<tr>
<th>Step</th>
<th>Deep Peels</th>
<th>Omnilux plus</th>
<th>Omnilux revive2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Week 1 (days 1-7)</td>
<td>1 x deep peel</td>
<td>Pre-treat with Omnilux plus</td>
<td>No light therapy treatment post peel</td>
</tr>
<tr>
<td>Week 2 (days 8-14)</td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Week 3 (days 15-21)</td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Week 4 (days 22-28)</td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

Post Peel Care
With all peels
1. Instruct the patient not to touch or scratch the treated area; follow the post peel protocols as per your normal routine.
2. When combining Omnilux with a chemical peel, review the list of products and drugs contraindicated for use with Omnilux.
3. Patient should avoid direct sun exposure for 48-72 hours post-treatment. Instruct the patient to apply a total sun block before going outdoors.
4. Avoid applying products to the face that may increase skin irritation such as abrasive products, permanent wave solutions, chemical hair removers or waxes, electrolysis, products with alcohol, astringents, alpha hydroxy acids, or other products that may irritate your skin.

Omnilux plus and Omnilux revive2 are not FDA cleared for the use in combination with Chemical peels to improve clinical outcome.
OMNILUX LIGHT THERAPY USED WITH LASER RESURFACING, FRACTIONATED LASERS AND INTENSE PULSED LIGHT

Omnilux plus used together with Omnilux revive2 light treatments can drastically reduce pain, erythema, swelling, bruising and downtime that many patients experience after laser therapy, fractionated lasers and Intense Pulsed Light. Omnilux light therapy not only speeds the re-epithelialization process following these procedures, but also adds to the improved skin quality.

Protocol

Step 1 - Light treatment
1. Fit the protective eye wear to ensure that the pupils are protected from direct illumination. For additional safety patients should be instructed to close their eyes (please refer to Omnilux user-guide). In addition, ensure that the operator is wearing the operator goggles provided.

2. Position Omnilux revive2 or Omnilux plus around the face making sure that the LED panels are between 2-6 cm from the skin surface.

3. Follow the user instructions to activate the unit. The required dose is 126 J/cm² for Omnilux revive2 and 66 J/cm² for Omnilux plus, or 20-minute treatment time for each.

4. The treatment course is as follows:

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Immediately Pre-resurfacing</th>
<th>Laser, IPL or fractionated technology</th>
<th>Immediately Post procedure</th>
<th>1 Day post procedure</th>
<th>3 Days post procedure</th>
<th>7 Days post procedure</th>
<th>10 Days Post</th>
<th>14 Days Post</th>
<th>21 Days Post</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedure treatment</td>
<td>✔️</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Omnilux plus</td>
<td>✔️</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Omnilux revive2</td>
<td></td>
<td></td>
<td></td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5. A follow-up appointment 6–weeks after the final light therapy session is recommended.

Photograph courtesy of Dr Denis Branson, Fayetteville, NY, USA

12 Omnilux light therapy is not FDA cleared for use with laser resurfacing, fractionated lasers and Intense Pulsed Light.
OMNILUX LIGHT THERAPY USED WITH MICRO NEEDLING

Micro needling is the creation of many tiny, microscopic punctures in the epidermal and dermal layers of the skin using sterile stainless steel needles for the purposes of inducing collagen synthesis and treating the visible signs of aging while preserving the epidermis.

Micro needling triggers a controlled wound healing response and therefore compliments the stimulatory effects of Omnilux plus and Omnilux revive2.

What to expect
- Stimulates the body’s natural wound healing response.
- Reduction in pain and discomfort.
- Accelerated resolution of erythema and side effects.

Omnilux + micro needling

Protocol Summary
- A typical micro needling program is a total of 4 treatments (1 micro needling session every 4 weeks).
- A maximum of 28 Omnilux treatments (7 Omnilux treatments over 4 weeks).
- The number of Omnilux treatments is dependent upon the patient’s availability and should be tailored to balance efficacy with patient compliance.
- If practical, pre-treat the treatment area with Omnilux plus.
- All Omnilux plus and Omnilux revive2 treatments are 20-minute duration.
- Never use Omnilux revive2 and Omnilux plus together as this reduces the treatment efficacy.

Treatment program for a single micro needling session

<table>
<thead>
<tr>
<th>Micro needling session</th>
<th>Omnilux plus</th>
<th>Omnilux revive2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 1</td>
<td>Pretreat the treatment area with Omnilux plus</td>
<td>Treat after 2 days if patient returns</td>
</tr>
<tr>
<td>Day 3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Day 7</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Day 9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Day 14</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Day 16</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Day 24</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Repeat as Week 1

 Protocol
1. Fit the protective eye wear to ensure that the pupils are protected from direct illumination.
2. For additional safety patients should be instructed to close their eyes (please refer to Omnilux user-guide). In addition, ensure that the operator is wearing the operator goggles provided.
3. Position Omnilux revive2 or Omnilux plus around the treatment area to fit the contour of the area as accurately as possible, making sure that the LED panels are between 2-6 cm from the skin surface.
4. Follow the user instructions to activate the unit. The required dose is 126 J/cm² for Omnilux revive2 and 66 J/cm² for Omnilux plus, or 20 -minutes treatment time for each.
5. The treatment course is as follows:

Week 1
- Day 1 Day 3 Day 7 Day 9 Day 14 Day 16 Day 24

Week 2
- Day 7

Week 3
- Day 14

Week 4
- Day 24


13 Omnilux is not FDA cleared for use with micro needling.
Warnings associated with Photosensitivity

Several medical conditions, medications, and chemicals can cause photosensitivity. Photosensitivity may produce a rash of varying severity.

- **DO NOT** use the Omnilux LED system to treat anyone who suffers from, Lupus erythematosus, photosensitive eczema or Albinism. If you use the Omnilux LED system to treat someone who suffers from Lupus erythematosus, photosensitive eczema or Albinism you may cause a severe skin reaction.

**Photosensitivity** is a common side effect of various medications. These can include certain antibiotics, chemotherapy drugs, and diuretics.

Below is a list of common types of medications that may cause photosensitivity.

**Appendix 1: Common types of medications that may cause photosensitivity**

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Specific group or common name</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antibiotics</td>
<td><strong>Fluoroquinolones:</strong> Ciprofloxacin (Cipro), Levofloxacin (Levaquin), Lomefloxacin (Maxaquin), Norfloxacin (Noroxin), Ofloxacin (Floxin)&lt;br&gt;<strong>Tetracyclines:</strong> Demeclocycline (Declomycin), Doxycycline (Vibramycin), Minocycline (Minocin), Oxytetracycline (Terramycin)&lt;br&gt;<strong>Others:</strong> Azithromycin (Zithromax), Capreomycin (Capastat), Ceftazidime (Fortaz), cycloserine (Seromycin), Metronidazole (Flagyl), Nalidixic acid (NegGram), pyrazinamide, sulfamethoxazole/trimethoprim (Bactrim)</td>
<td>The treatment can be administered as long as the medication has not been taken in the last 5 days.</td>
</tr>
<tr>
<td>Non-steroidal anti-inflammatory drugs (NSAIDs)</td>
<td>Diclofenac (Voltaren, Cataflam), Naproxen (Anaprox)</td>
<td>If the client is currently taking the medication it is at their discretion as to whether they commence the treatment. There is a &lt;1/100 chance of a light reaction. If the client has stopped taking the medication for ≥ 1 day, then the treatment can be administered.</td>
</tr>
<tr>
<td>Diuretics</td>
<td>Furosemide, Bumetanide, Hydro-chlorothiazide.</td>
<td>The treatment can be administered as long as the medication has not been taken in the last 5 days.</td>
</tr>
<tr>
<td>Treatments for hair growth</td>
<td>Minoxidil (Rogaine).</td>
<td>If the client is currently on the medication it is at their discretion as to whether they commence the treatment. There is &lt;0.5/100 chance of a light reaction. If the client has stopped taking the medication for ≥ 5 days then the treatment can be administered.</td>
</tr>
<tr>
<td>Treatments for acne</td>
<td>Isotretinoin (Accutane, Roaccutane) Tretinoin (topical) – (Renova, Retin-A), Tazarotene (Tazorac)</td>
<td>If the client is currently on the medication it is at their discretion as to whether they commence the treatment. There is between a 5/100 and a 10/100 chance of a light reaction. If the client has stopped taking the medication for ≥ 5 days then the treatment can be administered.</td>
</tr>
</tbody>
</table>
### Drug Class

<table>
<thead>
<tr>
<th>Specific group or common name</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Anti-arthritic or immunosuppressant</strong></td>
<td>Azathioprine (Imuran, Azasan). The treatment can be administered as long as the medication has not been taken in the last 5 days.</td>
</tr>
<tr>
<td><strong>Anti-Cancer</strong></td>
<td>Bexarotene (Targretin), Capecitabine (Xeloda), Dacarbazine (DTIC), Epirubicin (Ellence), Fluorouracil (5-FU), Interferon alfa (Intron A, Alferon-N), Methotrexate (Mexate), Pentostatin (Nipent), Procarbazine (Matulane), Tretinoin, oral (Vesanoid), Vinblastine (Velban, Velbe). If the client is currently on the medication it is at their discretion as to whether they commence the treatment. There is between a 1/100 and 5/100 chance of a light reaction. If the client has stopped taking the medication for ≥ 5 days then the treatment can be administered.</td>
</tr>
<tr>
<td><strong>Antifungals</strong></td>
<td>Flucytosine (Ancobon), Griseofulvin (Fulvicin, Gris-PEG), Terconazole (Terazol), Voriconazole (VFEND). The treatment can be administered as long as the medication has not been taken in the last 5 days.</td>
</tr>
<tr>
<td><strong>Antihypertensive</strong></td>
<td>Captopril (Capoten), Diltiazem (Cardizem, Tiazac), Enalapril (Vasotec), Nifedipine (Procardia), Sotalol (Betapace). The treatment can be administered as long as the medication has not been taken in the last 5 days.</td>
</tr>
<tr>
<td><strong>Antihypertensive - others</strong></td>
<td>Amiodarone (Cordarone, Pacerone), Fenofibrate (Tricor), Quinidine. If the client is currently on the medication it is at their discretion as to whether they commence the treatment. There is a 10/100 chance of a light reaction. If the client has stopped taking the medication for ≥ 5 days then the treatment can be administered.</td>
</tr>
<tr>
<td><strong>Anti-cholesterol</strong></td>
<td>Fluvastatin (Lescol), Lovastatin (Mevacor), Pravastatin (Pravachol), Simvastatin (Zocor). If the client is currently on the medication it is at their discretion as to whether they commence the treatment. There is a &lt;0.5/100 chance of a light reaction. If the client has stopped taking the medication for ≥ 5 days then the treatment can be administered.</td>
</tr>
<tr>
<td><strong>Anti-Psychotic</strong></td>
<td>Phentothazines: Chlorpromazine (Thorazine), Fluphenazine (Prolixin), Perphenazine (Trilafon), Prochlorperazine (Compazine), Thoridazine (Mellaril), Trifluoperazine (Stelazine). The treatment can be administered as long as the medication has not been taken in the last 5 days.</td>
</tr>
<tr>
<td><strong>Cardiovascular</strong></td>
<td>Thiazide diuretics Bendroflumethiazide (Corzide), Chlorthalidone (Thalitone), Hydrochlorothiazide (Microzide), Hydroflumethiazide (Diuril), Indapamide (Lozol), Methyclothiazide (Enduron), Metolazone (Zaroxolyn), Polythiazide (Renese). The treatment can be administered as long as the medication has not been taken in the last 5 days.</td>
</tr>
</tbody>
</table>
## Appendix 1: Common types of medications that may cause photosensitivity (continued)

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Specific group or common name</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Antimalarial</strong></td>
<td>Chloroquine (Aralen), Hydroxychloroquine (Plaquenil), Pyrimethamine (Daraprim), Pyrimethamine/sulfadoxine (Fansidar), Quinine.</td>
<td>The treatment can be administered as long as the medication has not been taken in the last 5 days.</td>
</tr>
<tr>
<td><strong>Antiretroviral</strong></td>
<td>Ritonavir (Norvir), Saquinavir (Fortovase, Invirase), Zalcitabine (Hivid).</td>
<td>If the client is currently on the medication it is at their discretion as to whether they commence the treatment. There is approximately a 2/100 chance of a light reaction. If the client has stopped taking the medication for ≥ 5 days then the treatment can be administered.</td>
</tr>
<tr>
<td><strong>Antiviral</strong></td>
<td>Amantadine (Symmetrel), Acyclovir (Zovirax).</td>
<td>If the client is currently on the medication it is at their discretion as to whether they commence the treatment. There is approximately a 1/100 chance of a light reaction. If the client has stopped taking the medication for ≥ 5 days then the treatment can be administered.</td>
</tr>
<tr>
<td><strong>Antihistamines</strong></td>
<td>Cetirizine (Zyrtec), Diphenhydramine (Benadryl), Loratadine (Claritin), Promethazine (Phenergan).</td>
<td>The treatment can be administered as long as the medication has not been taken in the last 5 days.</td>
</tr>
<tr>
<td><strong>Anticonvulsants</strong></td>
<td>Carbamazepine (Tegretol), Felbamate (Felbatol), Gabapentin (Neurontin), Lamotrigine (Lamictal), Oxcarbazepine (Trileptal), Topiramate (Topamax), Valproic acid (Depakene).</td>
<td>If the client is currently on the medication it is at their discretion as to whether they commence the treatment. There is a 1/100 chance of a light reaction. If the client has stopped taking the medication for ≥ 5 days then the treatment can be administered.</td>
</tr>
<tr>
<td><strong>Sedatives</strong></td>
<td>Alprazolam (Xanax), Chlordiazepoxide (Librium), Zaleplon (Sonata), Zolpidem (Ambien).</td>
<td>If the client is currently on the medication it is at their discretion as to whether they commence the treatment. There is a 1/100 chance of a light reaction. If the client has stopped taking the medication for ≥ 5 days then the treatment can be administered.</td>
</tr>
<tr>
<td><strong>Anti-arthritis</strong></td>
<td>Ridaura, Gold 50.</td>
<td>If yes, the treatment cannot be administered.</td>
</tr>
</tbody>
</table>

Other substances not listed above can also cause photosensitivity

Common examples of these substances are:

- St John’s Wort, Coal tar, Deodorants, antibacterial soaps, artificial sweeteners, naphthalene (mothballs), petroleum products, brightening agents found in laundry detergent, and cadmium sulphide (a chemical injected into the skin during tattooing).
Appendix 2: Available Photosensitizers & Mixing Instructions

Ready to Use Photosensitizers

A Within the United States

1 Levulan® (20% ALA) delivered in a kerastick (5-Aminolaevulinic acid (5-ALA) in an alcoholic dilutent), available from DUSA pharmaceuticals.\(^ {14} \)

2 ALA Powder* (with or without dilutent)\(^ {15} \) – SOLELY FOR COSMETIC TREATMENTS.

B Outside the United States

1 Metvix (20% Methyl ester of ALA).\(^ {16} \) Available from Galderma.

2 ALA Powder + dilutent (20% ALA) delivered in a kit form containing ALA powder and dilutent.\(^ {15} \)

Raw product

3 ALA powder\(^ {15} \)

Products 3 is the active pharmaceutical ingredient and can be prepared to varying concentrations by a pharmacist (mixing instructions detailed below)

\(^ {14} \) FDA approval for actinic keratosis only.

\(^ {15} \) Not FDA cleared.

\(^ {16} \) Available in Europe – Indicated for basal cell carcinomas and actinic keratosis only.

Available in the USA - indicated for treatment of thin and moderately thick, non-hyperkeratotic, non-pigmented actinic keratoses of the face and scalp in immunocompetent patients when used in conjunction with lesion preparation in the physician’s office when other therapies are considered medically less appropriate.

In the United States the use of aminolaevulinic acid (ALA) for actinic keratosis (AK) or acne treatments is alleged by DUSA Pharmaceuticals, Inc. to be covered by US patent nos. 6,710,066 and 5,955,490. DUSA sells an ALA product under the name Levulan®, which is FDA approved for AK only. While GlobalMed Technologies reserves its rights with respect to the DUSA patents (including the rights to challenge the patents’ validity and enforceability), GlobalMed Technologies does not endorse or recommend using any ALA product other than Levulan® with an Omnilux lighting product for treatment of AK within the US. Any use of ALA (other than Levulan®) with an Omnilux lighting product within the US should be solely for cosmetic treatments and not for AK nor acne.

Procedure for preparing 5, 10 and 20% 5-ALA Cream from the Active Pharmaceutical Ingredient and Unguentum M or Eucerin:

<table>
<thead>
<tr>
<th>5% ALA</th>
<th>10% ALA</th>
<th>20% ALA</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.125 g 5-ALA</td>
<td>0.25 g 5-ALA</td>
<td>0.5 g 5-ALA</td>
</tr>
<tr>
<td>0.125 g sterile water</td>
<td>0.25 g sterile water</td>
<td>0.5 g sterile water</td>
</tr>
<tr>
<td>2.25 g Unguentum M</td>
<td>2 g Unguentum M</td>
<td>1.5 g Unguentum M</td>
</tr>
</tbody>
</table>

The 5-ALA powder should be dissolved completely in the water.

This solution should be added to the Unguentum M or Eucerin (or similar lipophilic cream) and mixed thoroughly. Once prepared the cream should be used immediately or can be stored for up to 3 weeks in a refrigerator.
Appendix 3: Technical specification for Omnilux plus, Omnilux revive2 and Omnilux blue

### Omnilux revive2™

Omnilux revive2™ has both a rejuvenating and anti-inflammatory effect on the skin. Proven to increase cellular energy (ATP) which in turn “kick starts” cellular renewal. Highly absorbed by fibroblasts increasing the synthesis of collagen it has also been proven to stimulate blood circulation and lymphatic flow to eliminate toxins, accelerate healing and calm the skin.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Output intensity</td>
<td>105 mW/cm²</td>
</tr>
<tr>
<td>Output wavelength</td>
<td>633 +/- 6 nm</td>
</tr>
<tr>
<td>Standard dose</td>
<td>126 J/cm²</td>
</tr>
<tr>
<td>Treatment time (standard dose)</td>
<td>1-20 minutes</td>
</tr>
<tr>
<td>Dose range (adjustable)</td>
<td>1-150 J/cm²</td>
</tr>
</tbody>
</table>

- Alone or alternating with Omnilux plus for the treatment of periorbital wrinkles and the visible signs of photodamage
- Alternating treatments with Omnilux blue for the treatment of mild to moderate acne vulgaris
- Use alone as an adjunct to fillers, microdermabrasion, micro needling etc. – helps calm the skin and reduce the risk of PIH
- Alone or alternating with Omnilux plus to accelerate wound healing post-surgical procedures
- Use with a topical photosensitizer for the treatment of non-melanoma skin cancers

### Omnilux blue™

Omnilux blue™ is successfully used to activate coproporphyrin III present in the P.acnes bacteria. Its versatility also allows it to be used to activate the photosensitizer 5- Aminolaevulinic acid in the treatment of superficial actinic keratosis.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Output intensity</td>
<td>40 mW/cm²</td>
</tr>
<tr>
<td>Output wavelength</td>
<td>415 +/- 5 nm</td>
</tr>
<tr>
<td>Standard dose</td>
<td>48 J/cm²</td>
</tr>
<tr>
<td>Treatment time (standard dose)</td>
<td>20 minutes</td>
</tr>
<tr>
<td>Dose range (adjustable)</td>
<td>1-55 J/cm²</td>
</tr>
</tbody>
</table>

- Alternating with Omnilux revive2 for the treatment of mild to moderate acne vulgaris
- Use with a topical photosensitizer for the treatment of superficial actinic keratosis

### Omnilux plus™

Omnilux plus™ is the most deeply penetrating wavelength, working indirectly through cell membrane absorption to stimulate complex cellular processes that result in increased collagen, elastin and growth factor production to treat the visible signs of photodamage and stimulate cellular repair mechanisms essential in the wound healing process.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Output intensity</td>
<td>55 mW/cm²</td>
</tr>
<tr>
<td>Output wavelength</td>
<td>830 +/- 5 nm</td>
</tr>
<tr>
<td>Standard dose</td>
<td>66 J/cm²</td>
</tr>
<tr>
<td>Treatment time (standard dose)</td>
<td>20 minutes</td>
</tr>
<tr>
<td>Dose range (adjustable)</td>
<td>1-80 J/cm²</td>
</tr>
</tbody>
</table>

- Alternating with Omnilux revive2 for the treatment of periorbital wrinkles and the visible signs of photodamage
- Alternating with Omnilux revive2 to accelerate wound healing post-surgical/post-invasive procedures
- Alone or alternating with Omnilux revive2 to treat or reduce the risk of PIH
- Alone as part of a muscle and sport injury rehabilitation program

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight (complete unit)</td>
<td>26lbs/11.8kg</td>
</tr>
<tr>
<td>Unit dimensions (H x W x D)</td>
<td>14” x 7” x 19” / 35.5 x 17.8 x 48 cm</td>
</tr>
<tr>
<td>Head dimensions (L x W)</td>
<td>12.5” x 14” / 32 x 35 cm</td>
</tr>
<tr>
<td>Dimensions of LED head active area (L x W)</td>
<td>6” x 14” / 15 x 35 cm</td>
</tr>
</tbody>
</table>