The AKLARUS Blue and Red Combination System is an effective, drug-free alternative for treating acne & photodamaged skin. The non-invasive Aklarus treatment has been shown to significantly reduce inflammatory acne lesions. The narrow band blue light destroys the P. Acne bacteria while the Red light penetrates deeper stimulating cellular mechanisms responsible for tissue repair and regeneration.

Aklarus Anti-Aging Infrared and Red Combination System is used to treat wrinkles & photodamaged skin by stimulating collagen synthesis and increasing the amount of dermal elastic fibers.

Aklarus Wavelength Specifications: Blue, Red and Infrared

Blue 420nm
10W+/ - 3W Total Output
Standard dose 26J/cm² in 20 Minutes

Red 628nm
20W +/- 3W
Standard dose 52J/cm² in 20 Minutes

Infrared 880nm
16W +/- 3W
Standard dose 42 J/cm² in 20 Minutes
Photodynamic Therapy for non-pigmented skin malignancies

In spite of the successful use of Photodynamic Therapy for actinic keratosis using aminolevulinic acid (ALA) and blue light (410 nm) in our practice, we recognized the limitations of this treatment for more advanced lesions.

The topical photosensitizer methyl aminolevulinic acid (MAL) and the Aklarus Red Light System (628 nm) were chosen based on international phototherapy research studies suggesting this combination as more efficacious for treating thicker non-pigmented skin malignancies.

Patient selection for treatment was based on factors, which made surgical treatment of their disease difficult. These factors included poor patient health, advanced age, tumor size and number of tumors, location and patient preference.

A summary of the MAL/PDT treatment protocol:

1) Infiltration of long acting local anesthetic block in treated area.
2) Shave, debulking of thick portions of the tumor.
3) Treatment of shaved area with a CO2 laser set at 6W superpulse intermittent for hemostasis.
4) MAL application to area with a 3 hour incubation period or a 90 minute incubation period based on absorption due to debrided area.
5) Exposure to red light (628 nm) total dose of 75 J/cm2 for 29 minutes.
6) Local wound care started in 48 hours after exposure with topical antibiotic.
7) Three day course of oral antibiotic post treatment.

A treated area was allowed to heal to early epithelialization. The need for additional treatment was based on clinical response and in some cases biopsy information. Residual atypical areas were selectively treated.
Subject 1

50 year old man with multiple basal cell carcinomas involving the torso and extremities. He also has multiple areas of erythematous, keratotic and nodular changes.

The left anterior shin showed a keratotic nodular lesion measuring approximately 2.5 cm. This area had three treatments. Eight days after the first treatment, the central area approximately 1 cm has some granular changes and bleeding. The surrounding area showed pink epidermis.

Eight days after the second treatment there was still an area of erythema and slight induration. My impression is that there were some response but not as vigorous as the first.

Examination 43 days after the second treatment, showed a residual area of hyperpigmentation, slight keratotic changes and no significant nodularity. A third treatment was performed, which produced a better result.

26 days after third treatment, the area shows hyperpigmentation, pink epidermis without nodularity.

A total of three treatments ere performed with a 3 hour incubation period. Treatment timeline of left anterior leg:

<table>
<thead>
<tr>
<th>Tnt. #</th>
<th>Time interval between treatment days</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-2</td>
<td>33 days</td>
</tr>
<tr>
<td>2-3</td>
<td>46 days</td>
</tr>
</tbody>
</table>
Left leg before 1st treatment

Left leg MAL application

Left leg after laser 1 treatment

8 days after 1st tx L leg

210 day after 3rd tx
Subject 2

78 year old woman who has a past medical history of moderate-to-severe cardiovascular disease. In 2009 a stent was placed secondary to an MI. She is currently on anticoagulation and also on antihypertensive medications.

Examination of the mid right nased showed a ill-defined, pearly plaque with an area of central eschar. The lesion measures approximately 1.5 x 1 cm. A biopsy revealed and infiltrative basal cell carcinoma.

7 days following her first treatment, a moderate eschar was present with mild to moderate edema. After 20 days, an exam showed the eschar was gone and significant improvement with a new epidermis.

A second treatment was performed with a 3 hour incubation period.

<table>
<thead>
<tr>
<th>Txt.#</th>
<th>Time interval between treatment days</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-2</td>
<td>51 days</td>
</tr>
</tbody>
</table>

Examination after 17 days, following her second treatment, showed new pink epidermis with subtle nodular changes. 31 days after her last exam, showed the area progressively more pale, less nodular with slight edema. Overall, she had a very good result.

Four months, 22 days after the second treatment revealed a pale scar with a 3 mm superficial vascular papule. The papule will be treated with CO2 laser.
Nasal basal cell carcinoma at first txt

51 days after first txt

4 months, 22 days after 1st txt
Subject 3

85 year old woman with history of Alzheimer disease, hypertension and osteoporosis. The right upper back shows a 7 x 10.5 cm diffuse nodular papular patch. A biopsy revealed superficial nodular squamous cell carcinoma. There were superficial areas admixed with nodular areas and there was mild to moderate skin laxity in this area.

A total of three treatments were performed with a 3 hour incubation period. Treatment timeline:

<table>
<thead>
<tr>
<th>Txt. #</th>
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</tr>
</thead>
<tbody>
<tr>
<td>1-2</td>
<td>14 days</td>
</tr>
<tr>
<td>2-3</td>
<td>60 days</td>
</tr>
</tbody>
</table>

Eight days after her first treatment the central area of nodularity had an eschar that was cleaned and there was a small area of granulation tissue. Overall, the erythematous patch appeared less keratotic and smaller.

A second treatment was performed focusing on the nodular areas. Following her second treatment exam shows an area of erythema and clearing of the areas of superficial involvement. Overall this area appeared to contract.

Following the third treatment, a residual central nodular lesion remained surrounded by healed epidermis. A biopsy of the residual lesion of right upper back showed nodular infiltrating basal cell carcinoma approximately 1.5 x 2 cm. A Mohs micrographic excision was preformed followed by a primary closure.
Treated area after 3 txs and Mohs excision of residual central lesion

Exam at 1st txt

Debriedment 2nd txt

Before 2nd treatment

22 days after 1st txt
Subject 4

80 year old woman with long history of sun exposure. Patient is on long-term anticoagulation for a mechanical heart valve. The right nasal dorsum showed a nodular ill-defined mass and associated subcutaneous component measuring 1 x 1.5 cm. Biopsy revealed squamous cell carcinoma.

A total of two treatments performed with a three hour incubation period.

Treatment Timeline:

<table>
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<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>#1-2</td>
<td>20 days</td>
</tr>
</tbody>
</table>

Eight days after first treatment noted a small residual eschar and slight irregularity and erythema to the base of the lesion.

Twenty days after her first treatment showed a residual, erythematous, nodular margin anteriorly and on the right side of the previous margin base. Therefore, the second treatment was performed.

Ten days after her second treatment, exam revealed new pink epidermis without evidence of nodularity.
Pretreatment of nasal squamous cell carcinoma

First treatment of debridement following CO2 laser

9 days after 1st treatment

MAL application

Exam before 2nd txt

Debridement of 2nd txt

176 days after 2nd txt
Subject 5

71 year old man with a past medical history significant for severe COPD. He is oxygen dependant with long term oral and inhaled steroids. Past history shows many years of treatments for pre-malignant and malignant face and scalp lesions. Treatments included cryotherapy, laser treatment, topical 5-FU, ALA/PDT and Mohs surgery with reconstruction.

Scalp exam with first treatment revealed three keratotic/nodular patches, each approximately 2 cm in diameter.

A single treatment with a 90 minute incubation period, which resulted in clearing of all three lesions.

50 days after treatment, previously treated areas show no evidence of nodularity with new pink epidermis.
Before 1st txt

50 days after 1st txt
Subject 6

87 year old man who has had a history of multiple nasal skin malignancies, which required treatments, including Mohs surgery with reconstruction. His medical history is significant for severe cardiovascular disease, requiring anticoagulation.

Nasal skin exam at first treatment sowed diffuse keratotic changes with superficial ulcerations on right inferior and superior nasal tip.

After the first treatment, most of the diffuse keratotic erythematous changes were cleared, however a second treatment was performed to treat residual nodular areas on the mid-nasal tip.

A total of two treatments were performed with a three hour incubation period.

Treatment Timeline:

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<td>46 days</td>
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</table>

One month after the second treatment, all areas cleared with pink epidermis at the mid and right nasal tip.

Seven months after the second treatment, a new keratotic shallow ulcerative lesion developed on the left superior aspect of the previously treated area. This area will receive addition treatment.
Before first tx

7 months after 2nd tx lesion developed adjacent to previously treated area

36 days after second tx
Subject 7

70 year old man who has had a history of sun exposure and prior superficial keratotic lesion removals.

The right temple shows a 1.7 cm erythematous keratotic patch that is ulcerative. A biopsy revealed a nodular basal cell carcinoma.

8 days after treatment shows new pink epidermis without nodularity in the treated area.
Ulcerative nodular basal cell carcinoma at time of txt

Right temple lesion at time of txt

8 days after first txt
Subject 8

76 year old man with a long history of sun exposure. He does have a history of cardiovascular disease and possible abdominal aortic aneurysm, had a Greenfield filter placed in 2005 and is currently on Coumadin.

The vertex scalp shows a keratotic patch measuring approximately 1.5 cm with an associated subcutaneous component.

One treatment was performed with a 90 minute incubation period.

7 days after first treatment, there is a slight depression from the eschar and some granulation tissue. No evidence of nodularity. A biopsy revealed actinic keratosis with ulceration.

55 days after treatment, the scalp exam shows new pink epidermis with minimal depression, no nodularity.