emoled

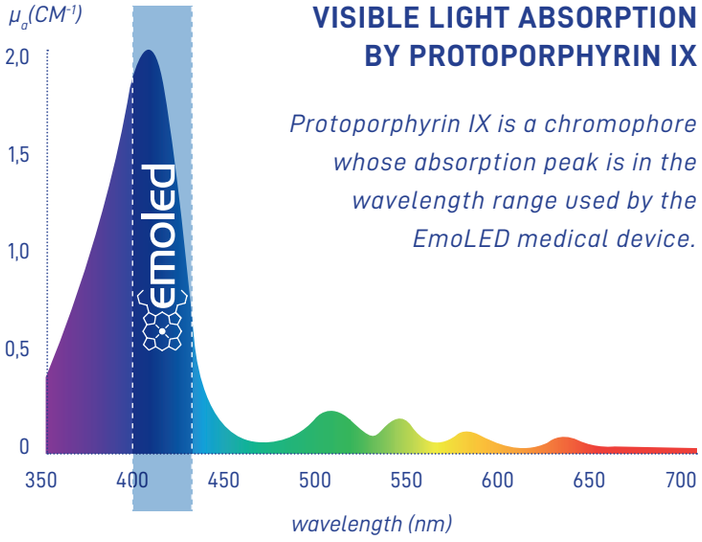
THE COLOUR OF REGENERATIVE SCIENCE

PHOTOBIOMODULATION WITH BLUE LIGHT: A NEW THERAPEUTIC FRONTIER

In human tissues are naturally present certain chromophores capable of absorbing specific light waves in the region of the visible spectrum.
By sending specific photonic energy to targeted chromophores it is possible to induce photochemical and photophysical phenomena at different biological scales functional to the healing of a wound.
This process has been defined **Photobiomodulation** and it is a new therapeutic frontier in *wound healing*.

In particular, it has been observed that Photobiomodualtion with Blue Light has an impact in **reducing inflammation** and producing a **faster and better tissue regeneration**.

Such effects can be explained by the absorption of Blue Light by the **Protoporphyrin IX**, the **Flavins** and the **Fibroblasts**.



VISIBLE LIGHT ABSORPTION BY PROTOPORPHYRIN IX

Protoporphyrin IX is a chromophore whose absorption peak is in the wavelength range used by the EmoLED medical device.

The **Protoporphyrin IX** is contained in various proteins and enzymes as the **Cytochrome C** and the **Cytochrome C Oxidases**, which are essential elements for cellular respiration.

RAPID TRANSITION OF THE INFLAMMATORY PHASE

FLAVINS

↓

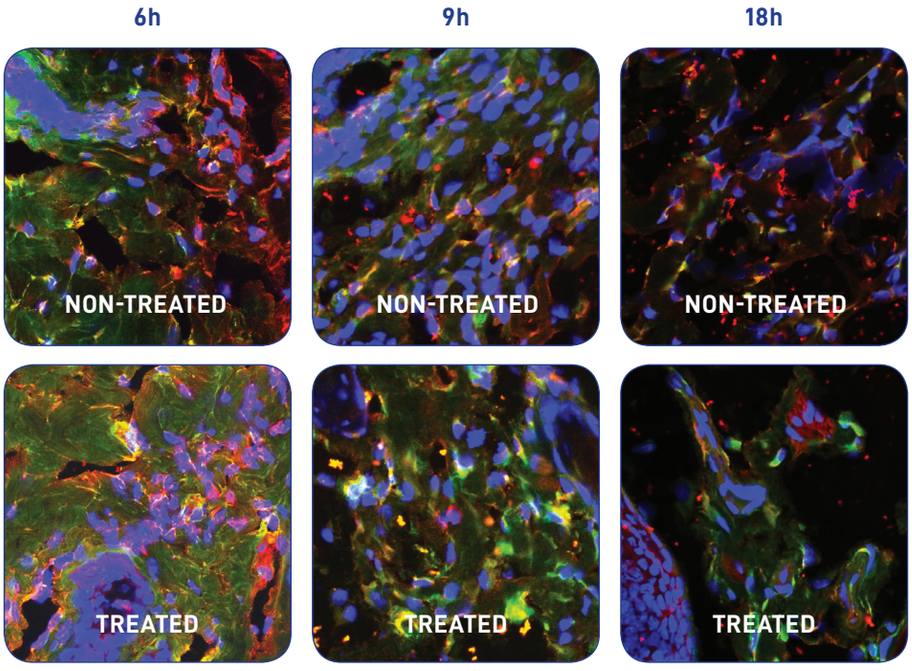
ROS

↓

- TISSUE RESPONSE STIMULATION THROUGH PRODUCTION OF PRO-INFLAMMATORY AGENTS (TNFα, IL-6, IL-8)
- MACROPHAGES TRANSITION M1→M2 THROUGH ACTION OF T LYMPHOCITES
- RELEASE OF PROANGIOGENETIC FACTORS (VEGF) AND eNOS INDUCTION THROUGH HIF1α PRODUCTION

Blue Light excites **Flavins** stimulating the production of ROS, intracellular signaling elements. ROS stimulate the overcoming of the ulcer's inflammatory phase, inducing a limited increase of inflammatory factors, and promote angiogenesis.

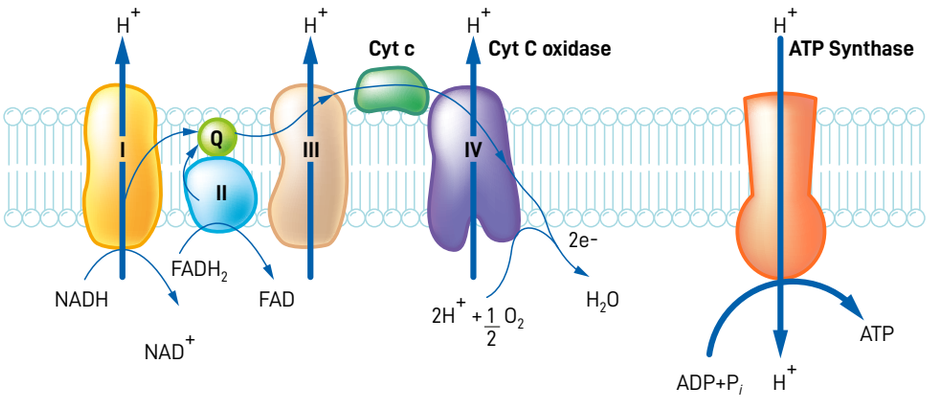
A rapid transition of the inflammatory phase has been observed in the in vivo studies on animal models of acute wounds treated with Blue Light. Clinical observations on chronic skin lesions treated with Blue Light have shown a stimulation effect in the transition from the inflammatory phase, associated with reduction of pain, and a revitalization of the healing process.



ANIMAL MODEL OF ACUTE WOUND. MACROPHAGES TRANSITION

Macrophages of the pro-inflammatory subpopulation (M1, red) and macrophages of the pro-healing subpopulation (M2, green): comparison between treated wound vs non-treated. In the treated wound at 9h there is a majority of pro-healing macrophages, indicating a more advanced transition phase.

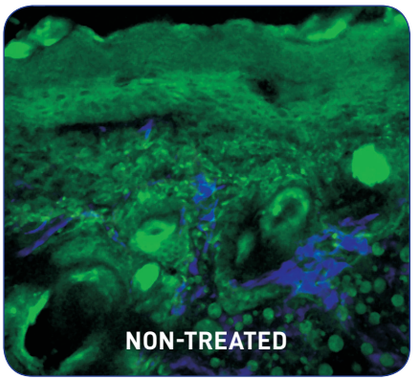
FASTER AND BETTER TISSUE REGENERATION

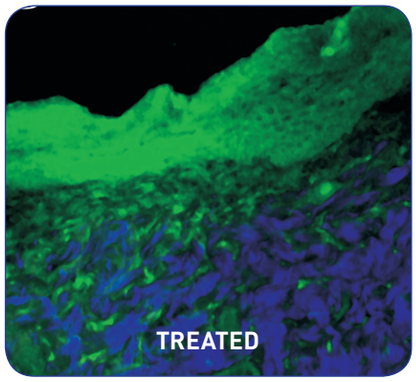


The **Cytochrome C** and the **Cytochrome C Oxidases** are hemoproteins within the electronic transport chain; when irradiated with Blue Light they amplify the cells respiration thus increasing the ATP production and consequently the cells metabolisms.

The interaction between Blue Light and Cytochrome C has been observed in the laboratories of CNR-IFAC using Raman spectroscopy. In a cell pellet irradiated with Blue Light an increased presence of Cytochrome C in its reduced form compared to its oxidized form has been recorded. This confirms the impact of Blue Light on cells metabolism.

Fibroblasts are the primary responsible for the extracellular matrix and collagen deposition during the remodeling phase. Blue Light can modulate their metabolic activity stimulating a faster and better restitutio ad integrum of the skin or, on the contrary, it can inhibit it when it is pathologically altered.





ANIMAL MODEL OF ACUTE WOUND. COLLAGEN DISTRIBUTION.
Collagen (blue) and extracellular matrix (green) in an in vivo model of acute wound at 8 days from injury: comparison between treated vs non-treated. Collagen (type 1) distribution and morphology are better in the treated wound.

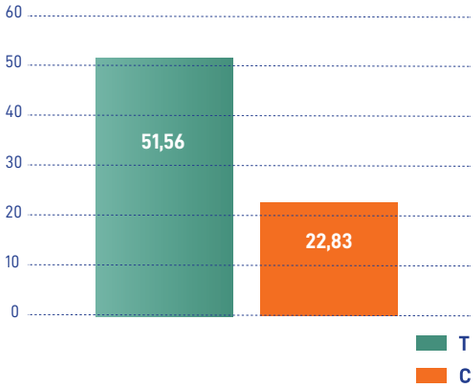
IFAC-CNR researchers demonstrated that Blue Light increases the metabolism of Fibroblasts extracted from healty tissue; they also obtained the directly opposite effect of inhibiting the cell activity of Fibroblasts extracted from keloids without tampering with their vitality.

A NEW THERAPY FOR HARD-TO-HEAL WOUND

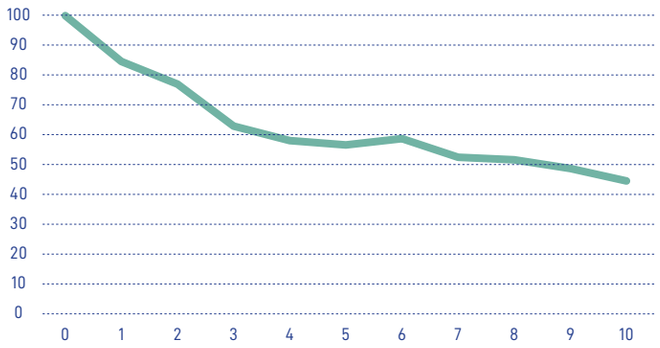
BLUR (BLUE LIGHT FOR ULCERS REDUCTION) STUDY

In a multi-center, prospective, controlled study with 90 patients suffering from venous, arterial and mixed ulcers and surgical dehiscence **(mean age of skin lesions: 67,8 months)** the effectiveness of EmoLED used in combination with the standard therapy has been demostrated: at 10 weeks the **difference in the mean percentage lesion's area reduction between treated lesions and control was 125,8%** with a treatment of 60 seconds once a week. In patients who at first visit reported pain (VAS ≥ 4) it has been recorded 23%, 42%, 54% reduction of the symptom respectively after one treatment, after 4 treatments, at 10 weeks.

Mean (%) reduction of the lesion's area at ten weeks.
Lesions treated with emoled (T)
vs lesions treated only with soc (C).

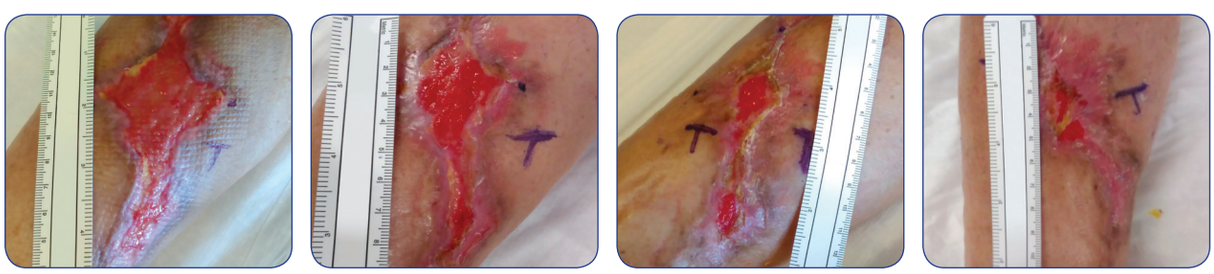


Progression of perceived pain in ten weeks.
Patients with VAS≥4 at first visit.



Typical progression of an ulcer treated with emoled in combination with standard therapy.

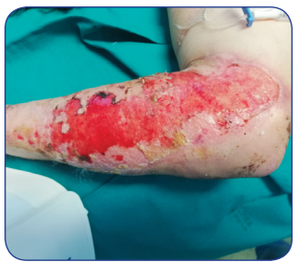
1/2 weeks	3/4 weeks	5/6+ weeks
- Increasing wound edge - More vital periwound skin - Decreasing inflammation - Decreasing hyperemia - Significant reduction of pain	- Improving wound bed - Increasing angiogenesis - Increasing granulation tissue	- Reduction of skin lesion - Increasing periwound skin tropism



Clinical observations report EmoLED's therapeutic outcomes in patients with **chronic wounds of various etiology non-responding to standard therapies.**

Progression of a deep burn with failed autologous skin graft, treated with EmoLED
for 60 seconds every two weeks for a total of 4 treatments.

Clinical case, Severe Burns Center, Maurizio Bufalini Hospital, Cesena.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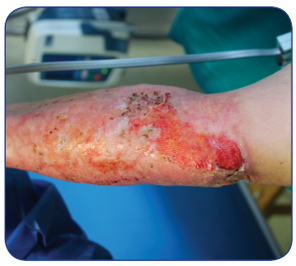
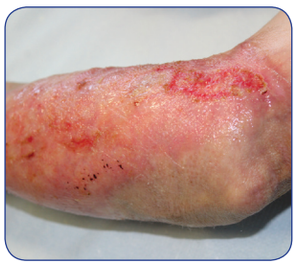
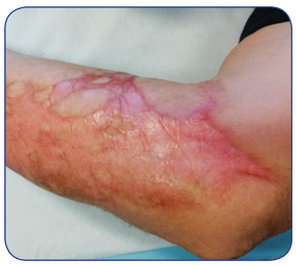
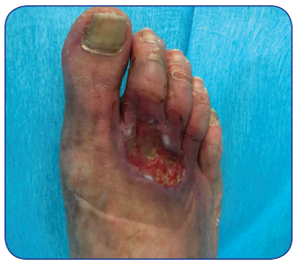

2 weeks


3 weeks


5 months (follow up)

Progression of a vasculitic ulcer treated with EmoLED
with two consecutive applications of 60 seconds once a week for 4 weeks;
age of the ulcer: one year.

Clinical case, Department of Dermatology, University of Pisa.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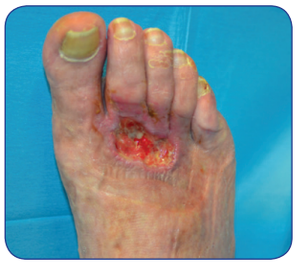
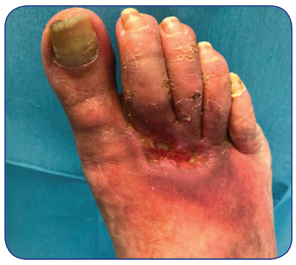
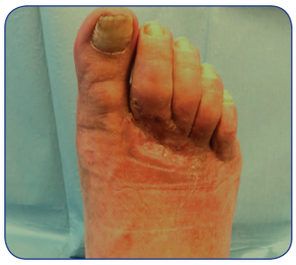
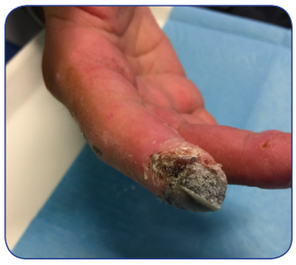

2 weeks


4 weeks


control

Progression of an acral ulcer on a patient affected by scleroderma,
treated with EmoLED once a week for 14 weeks.

Clinical case, Scleroderma unit, AOU S. Luigi Gonzaga, Orbassano (TO).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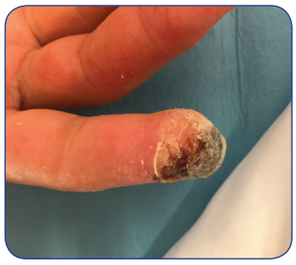
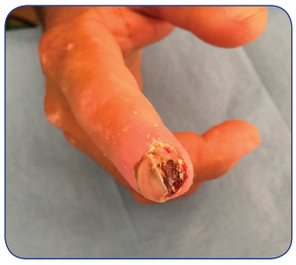

4 weeks


6 weeks


14 weeks

INSTRUMENT FOR AN EFFECTIVE PHOTOBIOMODULATION SUPPORTING THE HEALING OF SKIN LESIONS

EmoLED is a Medical Device conceived for the healing of skin lesions. It uses LED sources emitting Blue Light and it is provided with a sophisticated optical system to obtain an homogeneous and controlled light beam. The selected wave lengths, in the interval of 400-430nm, correspond to the absorbtion spectrum of certain chromophores contained in tissues. Interacting with such elements, EmoLED activates the physiological healing process of a lesion in a **natural and non-invasive way**.

Its mode of action is based on Photobiomodulation: the direct transfer of photonic energy from the device to the patient without the presence of external mediators (chemical or pharmaceutical additives). EmoLED mode of action is **covered by an international patent**.

EmoLED is **designed and produced in Italy**, in accordance with Class IIa Medical Device.

Treatment with EmoLED is an aid to conventional therapy and it is applied as part of the wound bed preparation. **60 seconds** is the duration of a single application.

EASY TO USE FOR THE HEALTHCARE PROFESSIONAL AND SAFE FOR THE PATIENT

SIMPLE:

Light, compact, **portable** and instantly ready for use, the device must be employed only by authorized personnel.

INTUITIVE:

Provided with touch screen and user friendly interface: it is possible to insert the lesion dimensions and the device calculates how many applications are needed to cover the entire wound surface.

NO CONTACT WITH THE PATIENT:

the optical head must be kept at 4cm from the patient, an **optoelectronic sensor** and a timer help the operator to keep the proper distance and time for every single application, ensuring the patient to receive the proper “dose” of energy.

SAFE:

an accessory for visual comfort and protective glasses are provided for the operator. No adverse events or collateral effects have been recorded and treatment is well tolerated by patients.

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PRODUCT:	EmoLED v.1
PRODUCT CODE:	980 0010 001
GMDN CODE:	61721
DIMENSIONS:	176X162X48 mm
WEIGHT:	780 g
RISK CLASS:	IIa
PHOTOBIOLOGICAL RISK GROUP:	RG III
LIGHT SOURCE:	The light radiation is generated by 6 LED sources. The emitted radiation is made uniform over the entire area by the optical system of the Device.
SPECTRAL BANDWIDTH:	400-430 nm
POWER DENSITY/IRRADIANCE:	120 mW/ cm^2
IRRADIATED AREA:	20 cm^2
TREATMENT DISTANCE:	3-5 cm (distance sensor inside)
POWER OUTPUT:	2,3 W - max emission variation 1%
ENERGY DENSITY/FLUENCE:	7,2 J/ cm^2
POWER SUPPLY:	Lithium-ion rechargeable batteries. Battery life: 150 applications.
CHARGER:	AC/DC 24Vdc, 2.5A
PACKAGING:	Includes: - Battery charger with connection cable - UV and Blue light protection glasses - Visual comfort accessory - User Manual - EVA bag for protection and transport
CE CERTIFICATION:	Certificate n° G1 18 02 99242 002
CND:	M040499
RDM:	1693661/R


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Distanza
5 cm
4 cm
3 cm
Applicazione
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