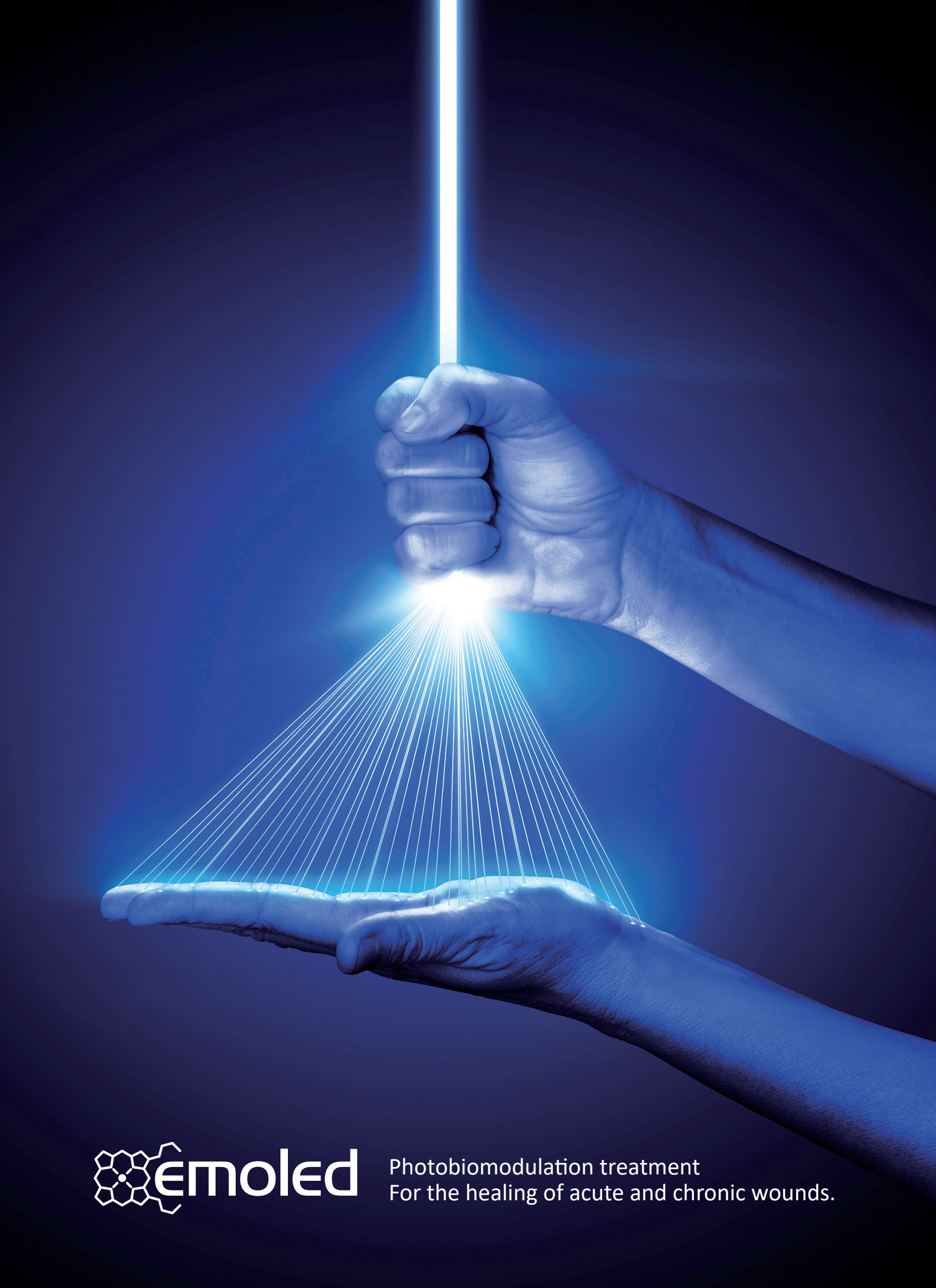
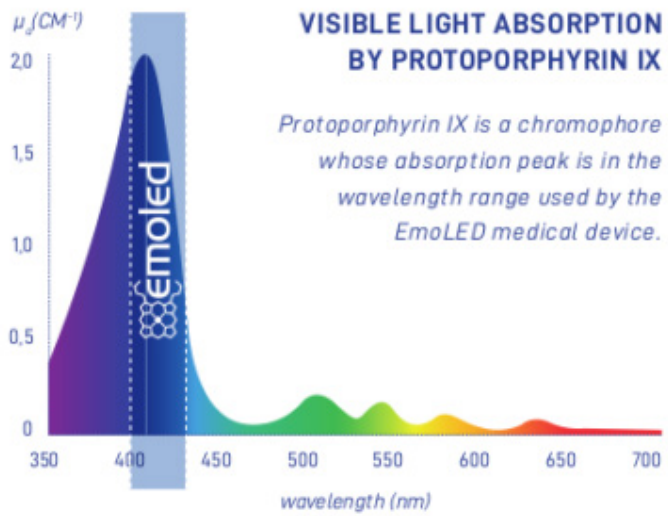
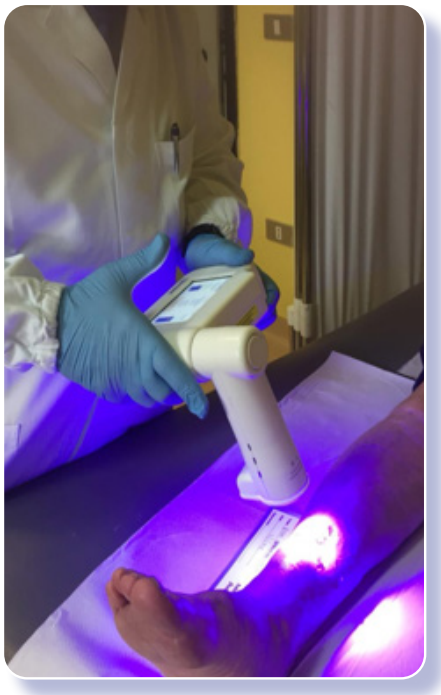

emoled
Photobiomodulation treatment
For the healing of acute and chronic wounds.

A TGA registered photobiomodulation (PBM) medical device utilizing visible blue light for use in the healing of acute, chronic and complex wounds.



"Photobiomodulation is a non-thermal process involving endogenous chromophores eliciting photophysical and photochemical events without UV.

The PBM process results in beneficial therapeutic outcomes including but not limited to, the alleviation of pain or inflammation, immunomodulation and promotion of wound healing and tissue regeneration"
- *Australian Medical Photobiomodulation Association*



Photobiomodulation with EmoLED is a new frontier for wound management, made increasingly attractive as a treatment modality that is easy to use, quickly applied, non-invasive and **painless**.

Histological analysis of post-EmoLED treated biopsies confirm a superior morphology of wounded tissue and organization of dermal collagen.[1]

Additional in vitro analysis reports a significant alteration to the inflammatory response including mast cell degranulation, reactive oxygen species and polarisation of macrophages between phenotypes.[2]

The recent publication of the B.L.U.R. clinical trial has confirmed the net effect of these attributes on healing, publishing a significantly greater percentage of re-epithelialization in chronic wounds vs standard care alone following 10 weeks of treatment (p=0.007).[3]

EmoLED delivers treatment to 20cm^2 area of target tissue per application through a focused beam comprised of 6 advanced LEDs. A simple user interface automatically calculates treatment parameters with only a few user inputs with published reports of efficacy in a range of etiologies including;

- **Burns + Donor Sites**[4]
- **Venous, Pressure and Diabetic Ulcers**[3,5]
- **Keloids + Scarring**[6,7]

B.L.U.R | Blue-Light for Ulcer Reduction Clinical Trial[3]

ClinicalTrials.gov Identifier: NCT04018924

Blue Light for Ulcers Reduction

- Multicentre, Prospective Controlled Clinical Trial
- **Target Group:** Non-Healing Wounds
- **Sample Size:** n= 90 Patients, 119 Wounds
- **Intervention:** SOC vs SOC + EmoLED Once Weekly
- **Observation Period:** 10 Weeks

Real World Patient Enrollment Characteristics

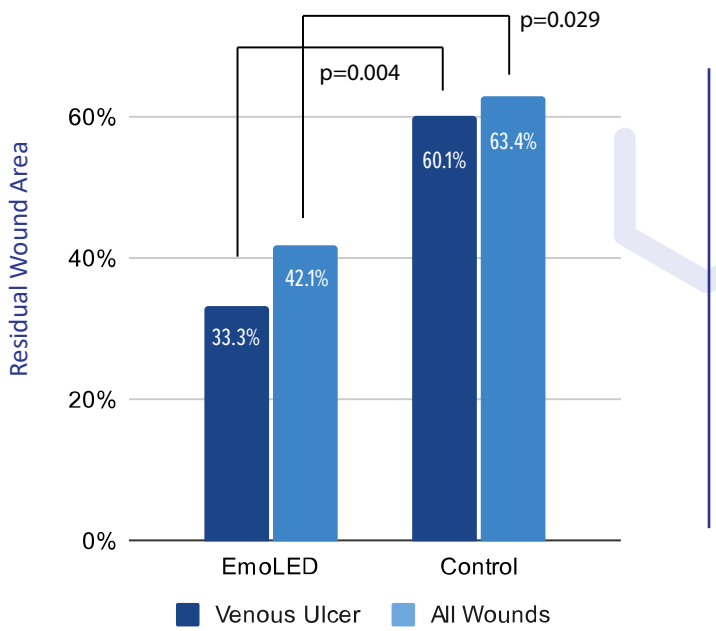
Aetiology	Number of Wounds
Venous	75 (63%)
Mixed and Arterial	25 (21%)
Other	19 (16%)
Total Wounds	119 (100%)
Average Duration of Wound	**67 Months / 5.5 Years**

- Half the wound receives EmoLED therapy
- Patient used as self-control
- Results free of variability between patients

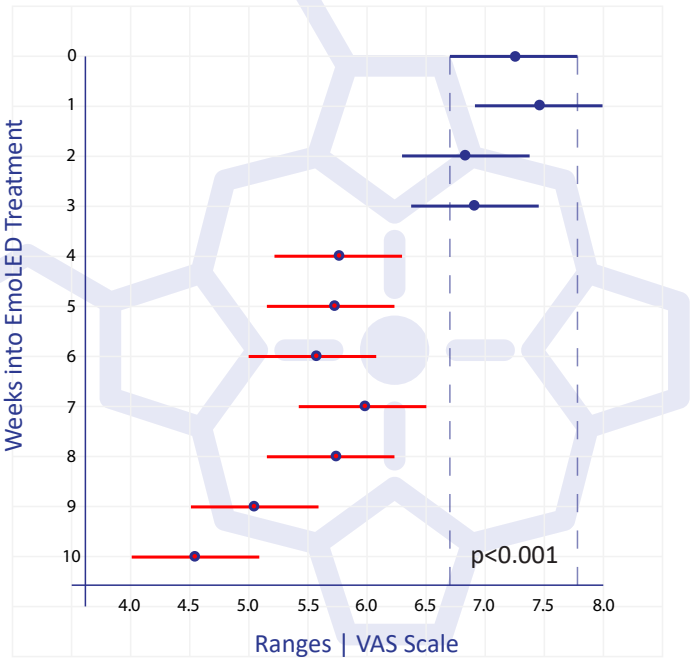
The BLUR study was designed to investigate the effectiveness and safety of the EmoLED device when used as a therapy for non-healing wounds in daily clinical practice by assessing wound area treated with EmoLED in addition to standard of care (SoC) compared with wounded area treated with standard care alone for an observation period of 10 weeks.

The outcomes reported in the BLUR study are uniquely translatable into real-world clinical practice with a design to yield paired, head-to-head data by dividing the wound area in half and applying the effects of photobiomodulation to one half in patients with wounds greater than 5cm2 (>30%) thereby removing statistical variation between different patients respective healing potential associated with different commorbidities and existing health status that inherently hinders timely healing.

Significantly More Re-Epithialiasation at 10 Weeks



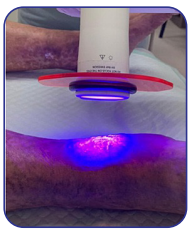
Significantly Lower Pain Rating at 4 Weeks



EmoLED Blue Light Photobiomodulation: Case Studies

Venous Leg Ulcers

No. of Treatments: 7, Once Weekly
Wound Duration: 6 months
Patient Age: 76, Commorbidites: CVI



Sacral Pressure Ulcers

Patient Age: 64, Paraplegic, 14 Treatments - Twice Weekly

Trauma

Patient Age: 84, Post-Fall Failed Flap, Surgical Debridement + EmoLED Twice Weekly

Burns

Patient Age: 67, 15% TBSA, Failed Graft, Surgical Debridement + EmoLED Twice Weekly

For More Case Examples visit www.emoled.com

EmoLED: Potential of Photobiomodulation

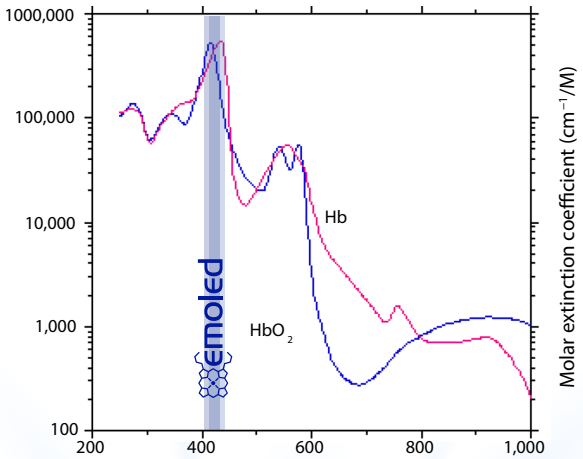
Blue-LED Light Induces Hemostasis

Both oxygenated and deoxygenation hemoglobin exhibits narrow, intense absorption peaks in the visible blue range (410 and 430 nanometers)[8]

When irradiating a bleeding wound with EmoLED the light is mainly significantly absorbed by hemoglobin naturally present in these areas, causing a local temperature increase within blood resulting in a fast thermo-initiated coagulation effect.[1]

EmoLED studies show the devices spectral emission is able to induce a temperature rise in a bleeding wound without inducing thermal damage to the healthy surrounding tissue.[1]

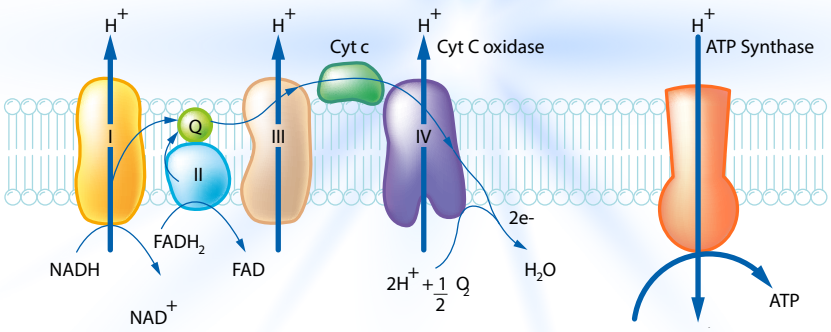
Absorption spectra of oxy/deoxygenated hemoglobin molecules



Photobiomodulation of Local Cellular Activity

This PBM process starts with the absorption of specific wavelengths of blue light by components of the mitochondrial respiratory chain including Cytochrome C, initiating the signaling of active molecules including cytokines, nitrogen monoxide (NO), ROS and growth factors stimulating the up-regulation of ATP synthesis, cellular metabolism and proliferation.[9]

Spectroscopy of the Cytochrome C redox state evidences a significant affect following blue light irradiation. This is resultant of the light absorption properties of the Cyt C containing the heme group, responsible for absorbing in the blue range of the spectrum.[9]



As evidence of modulating metabolism and proliferation of human fibroblasts, scratch tests performed in co-cultures of HaCaT cells and fibroblasts demonstrated that a light source at 420nm can stimulate significantly greater cellular migration in comparison to untreated samples in the same time period. (Figure 3a)[10]

Supporting the Inflammatory Phase

EmoLED offers a novel means of physically probing aspects of the wounds typical inflammatory response, clinical investigations in vitro and in vivo report a rapid transition through the inflammatory phase yielding a greater level of re-epithelialization. This is evidenced by showcasing a highly controlled healing environment such as that produced by a donor site over 15 days

Regional Melanoma Centre, Florence, Italy
Dr L Borgognoni
Data on file.

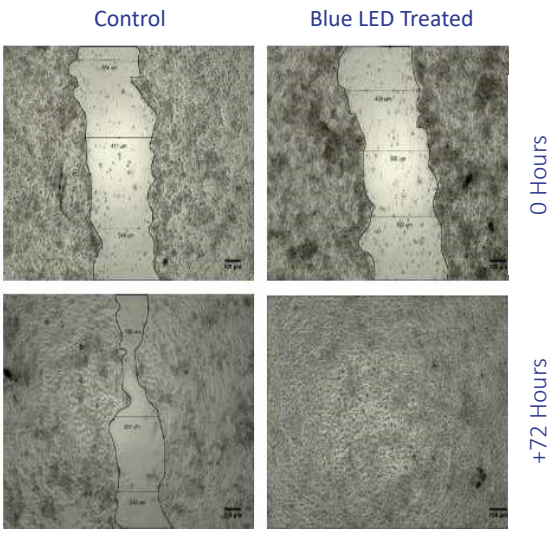
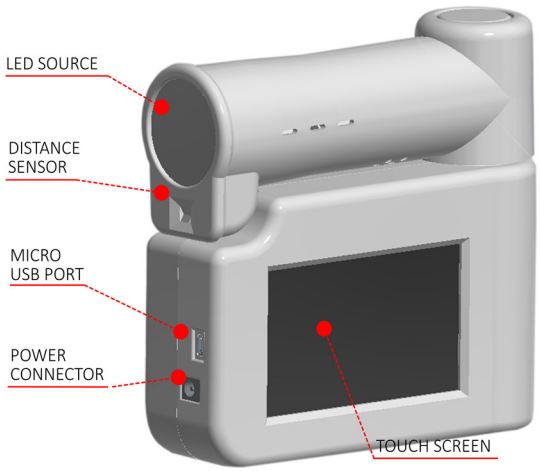


Figure 3a HaCaT Scratch Test

EmoLED: User Guide

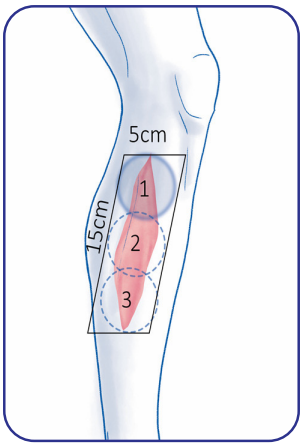


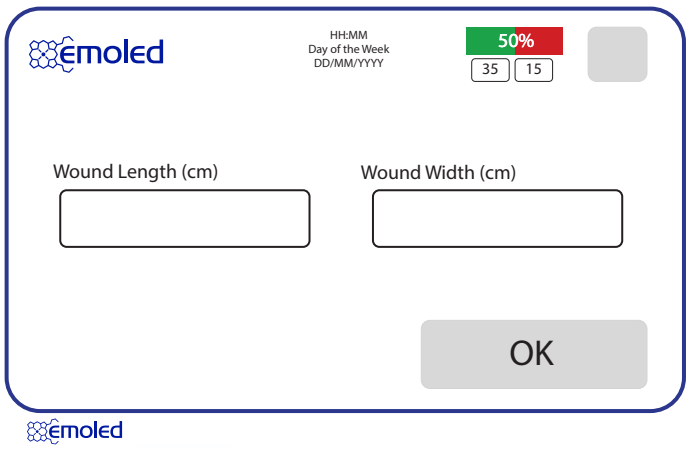
EmoLED is a light-weight hand-held device.
There are two parts, atop the control body is a rotating optical head where the LED lights source is located and is projected from.

Located directly beneath the emission window at the tip of the optical head is a distance sensor to guide application at the correct parameter.

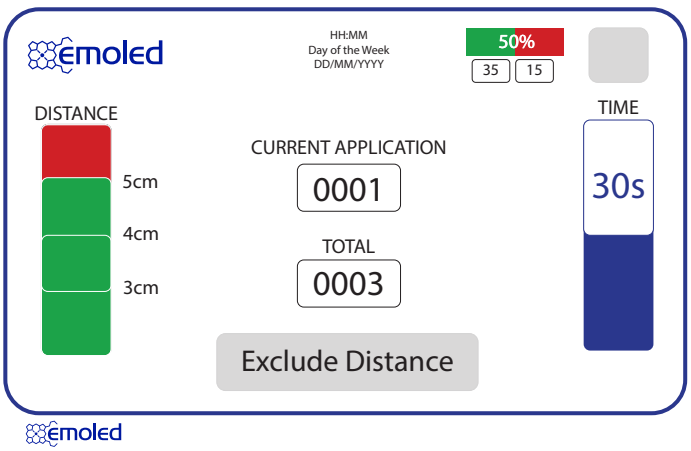
The main body features a power button to the rear, charging ports to the side and a resistance-touch screen on the front to receive and display treatment details.

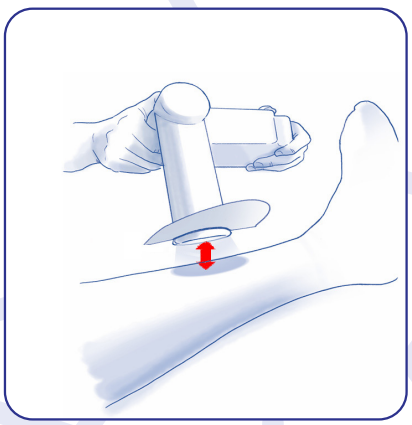
**The touch-screen works while wearing gloves*





EmoLED projects a 20cm2 circular beam at a distance of 4cm from the wound. The home screen (shown above) requires simple input of wound width and length in cm to automatically calculate the number of repeated applications required to cover the entire wounded area for treatment





Upon inputing wound size and initiating EmoLED the in-treatment display screen (shown above) displays:
1. The total number of applications to be provided 2. The application number currently being applied
3. Wound-distance visual to maintain correct distance 4. Time remaining for the current application.

For full EmoLED product user guides and manuals please contact Rehacare directly.

EmoLED: Technical Specifications

Product	Emoled V0.1
Product Code	980 0010 001
TGA Risk Class	IIa
Photo-biological Risk	RG III
ARTG Indication	EmoLED uses Blue Light between 400 and 430 nanometers (nm) to provide an adjuvant therapy for the healing of acute and chronic wounds. It is a portable and contact-less device powered by rechargeable batteries. It is intended to be used by a health-care professional in a clinical setting.
Light Source	6x propriety LED sources made uniform over the area by the devices optical system.
Spectral Bandwidth	400-430 nanometers
Power Density/Irrad	120mW/cm2
Irradiated Area	20cm2
Energy Density/Fluence	7.2j/cm2
Treatment Distance	4cm +/- 1cm
Power Output	2.3W- Max Variation 1%
Power Supply	Rechargeable Lithium-Ion ¬150 Treatments per Charge
Charger	AC/DC 24Vdc, 2.5A
Packaging	Included: - Battery Charger with Connection Cable - UV & Blue Light Protection Classes - Visual Comfort Filter - EVA Storage Bag + User Manual (USB)
CE Certification	G1 18 02 99242 002

Photobiomodulation with EmoLED

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