# **Revision History**

Revision	Description of change	ECN No.
А	Original Release	1097
В	Improved chart of light absorption, Karu	1155
С	Update product references, general review update	1164

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### 1.0 PURPOSE

Provide a summary document of the effects of LED colors for RevLight products.

### 2.0 SCOPE

This document applies to the RevLight technology based products such as the Model 1029 and Panel Pulastor series designed and manufactured by SubCon Manufacturing Corporation.

# 3.0 RESPONSIBILITIES

Engineering is responsible for the creation and maintenance of this document.

# 4.0 REFERENCES

88-0000150 Design History File - Supplemental Reference Research Materials 77-D000174 Model 1029 Technical File



### 5.0 DEFINITIONS

Acne vulgaris - A common skin disease that affects 85-100% of people at some time during their lives. It is characterized by noninflammatory follicular papules or comedones and by inflammatory papules, pustules, and nodules in its more severe forms. Acne vulgaris affects the areas of skin with the densest population of sebaceous follicles; these areas include the face, the upper part of the chest, and the back. The pathogenesis of acne vulgaris is multifactorial. Four key factors are responsible for the development of an acne lesion. These factors are follicular epidermal hyperproliferation with subsequent plugging of the follicle, excess sebum, the presence and activity of P.acnes, and inflammation.

P.acnes - Propionibacterium acnes. Propionibacterium species are inhabitants of the skin and usually are nonpathogenic. As a result, they are common contaminants of blood and body fluid cultures. These species are slow-growing, gram-positive anaerobic bacilli.

# 6.0 GENERAL

The use of low levels of visible or near infrared light for reducing pain, inflammation and edema, promoting healing of wounds, deeper tissues and nerves, and preventing tissue damage has been known for almost forty years since the invention of lasers. Originally this was thought to be a special property of laser light (soft or cold lasers), but with more research the subject has now broadened to include photobiomodulation and photobiostimulation using non-coherent light. Currently, low-level laser (or light) therapy (LLLT), also known as "cold laser", "soft laser", "biostimulation" or "photobiomodulation" is practiced as part of physical therapy in many parts of the world and is applied to many thousands of people worldwide each day.

The most fundamental principal of photochemistry is that the light must be absorbed before anything can occur. The biostimulation effects of light alone are well documented, including how visible light operates primarily through a photochemical process and infrared light operates primarily through a photophysical process. However, RevLight

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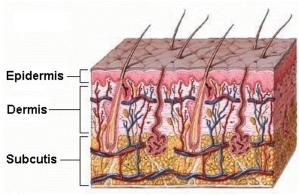


technology based products apply modulated light to the skin and work under the key principals that both the modulation of the light energy and the specific wavelength are both of primary importance as the light is the carrier and delivery method of the modulated energy. The light color is used to control how and where the light is absorbed. The light also controls where the modulated energy is delivered. The one exception where the LED color is of primary importance is with the 420nm LED light. It has low skin penetration and is specifically used because of its negative effect on P.acne in the treatment of moderate inflammatory acne vulgaris.

### 7.0 LED Color and Skin Effects

The skin's characteristics vary (i.e., thickness, color, texture) from person to person and also vary throughout the body. For instance, the head contains more hair follicles than anywhere else, while the soles of the feet contain none. In addition, the soles of the feet and the palms of the hands have much thicker layers. The skin is made up of three primary layers -

- The epidermis is the outer layer of skin and the thickness of the epidermis varies in different types of skin. It is the thinnest on the eyelids at .05 mm and the thickest on the palms and soles at 1.5 mm.
- The dermis is the middle layer of the skin and is held together by a protein called collagen, made by fibroblasts (skin cells that give the skin its strength and resilience). The dermis also varies in thickness depending on the location of the skin. It is .3 mm on the eyelid and 3.0 mm on the back.
- The subcutis is the deepest layer of skin and is also known as the subcutaneous layer or the hypodermis. The subcutis, consisting of a network of collagen and fat cells, varies in thickness throughout the body and from person to person.



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Given the obvious differences in complexion from person to person, coupled with the complex makeup up of the skin layers throughout the body, it becomes obvious that it is impossible to establish a singular overall relationship to the color of light and the depth of penetration. The following charts attempt to summarize light penetration and the variances in the results highlights the complexity of the question.

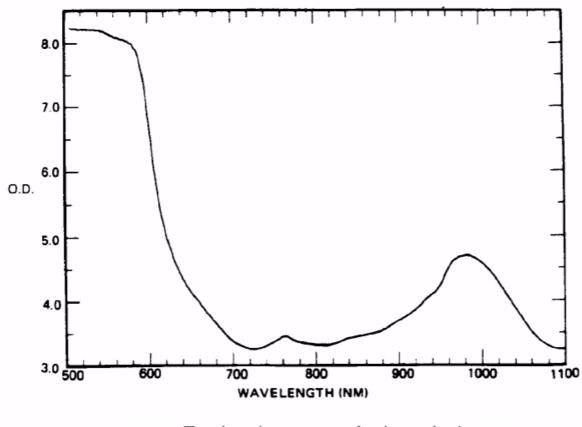
However, some general guidelines can be developed for the selection of LED color for specific uses.

- The light is always absorbed by each layer of the skin starting with the epidermis. As light passes through the skin it is absorbed to a more or less degree based on the color of the light. When the color absorption is less effective more light is allowed to pass further into the skin.
- Both infrared and red light from 600nm through 1400nm do well at penetrating into the subcutis layer. Revitalight and Hand Spa products use 625nm red and 940nm infrared light to provide an effective and penetrating light application.
- Shorter wavelength colors from amber (590nm) through cyan (480nm) have progressively shallower
  penetration and are more useful for areas where the skin is naturally thin (joints, finger nails, etc.) or
  when it is desired to concentrate on the epidermis and dermis layers.
- Short wavelengths from blue (470nm) through violet (400nm) are the least penetrative colors and are useful for applications concentrating on the skin surface, epidermis and upper dermis areas. Revitalight products use 455nm blue light for surface application and 420nm violet light for specifically for moderate inflammatory acne vulgaris.

Utilization of select, high output LEDs coupled with proprietary optics that focus and apply the light would, by itself, result in a highly effective design as a source engine for light therapy. To increase the effectiveness, the light is also modulated by select subset of Nogier frequencies. The advanced technology combines two or more biologically significant modulation frequencies with a highly effective light generator to provide a uniquely superior light therapy device with the application safety of LED light.

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The absorption spectrum of a human hand.

From: Smith KC. The Photobiological Basis of Low Level Laser Radiation Therapy. In: Laser Theray. Laser Therapy. Jan - Mar 1991; 3(1):19-24.

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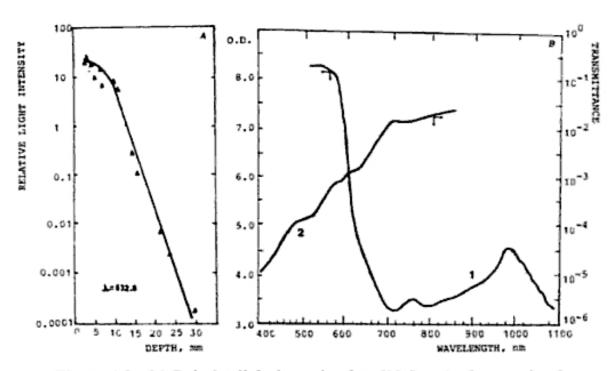
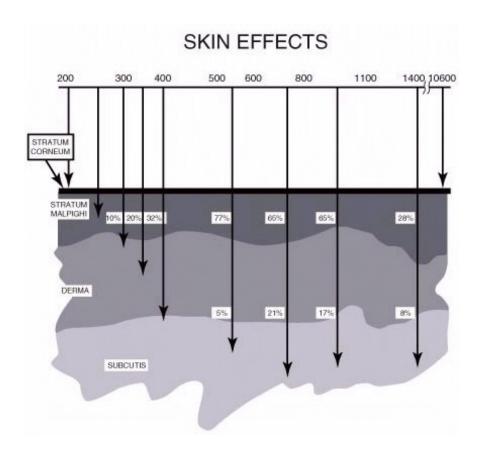


Figure 4.2. (a) Relative light intensity ( $\lambda = 632.8$  nm) of transmitted light as a function of tissue depth (Dougherty et al., 1978), and (b): (1) absorption spectrum of a human band (Smith, 1977), and (2) the spectral transmittance through a human scull with thickness 13 mm (Parrish and Deutsch, 1984).

From: KARU TL. Photobiology of low power laser therapy, In: Laser Science Technology, an International Handbook, Vol 8, Letokov V.S. et al., eds., Harwood Academic Publishers, London, 1989.

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Depth of penetration into the skin for different wavelengths of laser radiation. From: Lawrence Berkeley National Laboratory, University of California, Berkeley, California 94720 LBNL/PUB-3000, HEALTH AND SAFETY MANUAL, Revised May 2005

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