Analysis of the Dermillume HR1000 LED Helmet for Cranial Applications

The Dermillume HR1000 LED Helmet is a superior medical support device suitable for clinic and home-use:

1. Emits a range of near-infrared wavelengths known to improve circulation, support neuron survival and tissue repair mechanisms.
2. Fluence from very high-powered LEDs is in the range of currently used medical lasers.
3. Design permits safe, reproducible treatments in the professional and home setting.
    - LED positioned a short distance from the scalp, eliminating the possibility of burns.
    - Software controlled to permit reproducible 15 and 30-minute treatments.
    - LED panels positioned to evenly illuminate the 2 frontal lobes, 2 temporal lobes, 1 parietal lobe and occipital lobe with each treatment
    - Specialized training, required for laser use, is not necessary.

Comparison to other DermillumeDevices

The Dermillume HR1000 LED Helmet has been optimized for cranial applications by the inclusion of very recently available high-powered LEDs, and a third NIR wavelength (850nm). It is based on the HR1000, FDA Market approved for professional and Over-The-Counter use.(July 27, 2005, K051681)

Biological Basis for the use of Near-infrared (NIR) light therapy

For a detailed discussion of the metabolic and cellular effects of NIR irradiation on tissues see:

> Larry D Morries,[1] Paolo Cassano,[2] and Theodore A Henderson[1,3] (2015) Neuropsychiatr Dis Treat. 11: 2159–2175. Treatments for traumatic brain injury with emphasis on transcranial near-infrared laser phototherapy

The Primary effect of Near infrared (NIR, 680-980 nm) wavelengths irradiation of mammalian tissues is an efficiency increase of the mitochondrial respiratory chain resulting in increased production of ATP. These effects have been observed in a variety of tissue culture and animal models. In addition NO acts as a vasodilator and thus increases local blood flow and oxygen supply, further supporting repair and or stabilization of damaged tissue.

The key component appears to be the copper centers in Cytochrome Oxidase C, which absorb energy in this wavelength range. Absorption of NIR displaces Nitric Oxide (NO) from the cytochrome oxidase model. This leads to an increase efficiency of the electron transport chain, resulting in high levels of ATP production.

Nerve tissue uses high levels of ATP to maintain critical ion pumps essential to neuron activity. Neural tissue also consumes large amounts of ATP to maintain cellular metabolism. NIR induced improvements of the respiratory chain can mitigate tissue damage, or biochemical imbalances, improving neuron survival.

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Important secondary effects of Near Infrared (NIR, 680-980nm wavelengths) irradiation of mammalian tissues produce long lasting molecular and cellular changes to the mitochondria.

These include improved efficiency of the mitochondrial transport pores and activation of second messenger pathways that alter transcription factor production. Elevations of transcription factors related to neuronal cell survival have been detected. These elevations are persistent over hours and up to days.

Energy Deposition and Penetration

For a detailed analysis of the relationship of wavelength and energy to penetration of neural tissue through the skull, see:

> Jared R. Jagdeo, Lauren E. Adams, Neil I. Brody, Daniel M. Siegel (2012) Transcranial Red and Near Infrared Light Transmission in a Cadaveric Model, PLoS ONE 7(10)

Penetration of NIR through tissues is primarily determined by wavelength and energy. Based on cadaver skull penetration measurements, NIR in the range of 830nm and 940 nm can provide fluence shown to be biologically active at 3 cm depth.

Direct measurements of fluence using an Omnilux New-U hand held device with a 4.7cm x 6.1cm emitter and measured using an Irradian Radiometer Model R203 on two cadaver skulls with soft tissue intact were conducted.

Penetrance of 830nm NIR light at the Temporal area was .9%; the Frontal area was 2.1%; and Occipital area was 11.7% through a cadaver skull with soft tissue intact.

In general, longer wavelengths (up to 1,000 nm) will penetrate deeper, but water adsorbs most energy at 1000 nm and higher. There is some indication that pulsing at 50% on/off results in better penetration but due to the “off” time, actual energy absorption is reduced to less than continuous operation.

Uses of NIR Laser in Human studies

For a study using NIR for the treatment of depression see:

> Henderson TA, Morries LD (2017) Frontiers Psychiatry 8: 1-8 Multi-Watt Near Infrared Phototherapy for the treatment of Comorbid Depression: A single Arm Study.

The authors applied 8-10 Watt 820/850 nm laser treatments positioned over multiple areas of the patient forehead and temporal areas for 9-12 min each area to patients with moderate to severe depression. A significant reduction in the severity of depression was observed after an average of 16 treatments. Each treatment deposited approximately 55-81Joules/cm^2 fluence at the scalp resulting in as much as **2.9J cm2 delivered below the pia**. Amelioration of severe depression persisted for up to 55 months, indicating pervasive cellular and metabolic changes.

Less definitive results using a similar treatment paradigm have been observed in patients with traumatic brain injury when the treatments are extended to 4-72 months.

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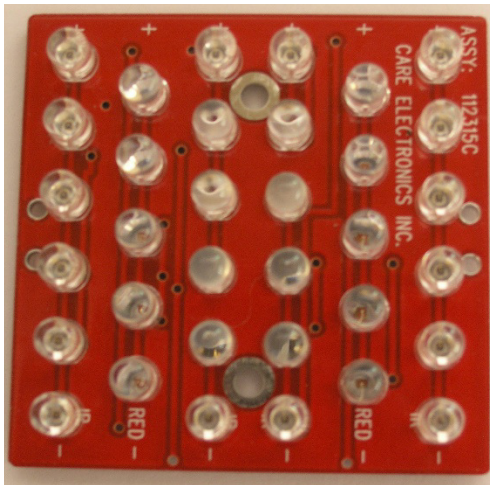
For a study using NIR laser or the treatment of traumatic brain injury subsequent to military service see:

> Morries, LD,Cassano,P and HendersonTD:Neuropsychiatr Dis Treat. 2015; 11: 2159–2175.Treatments for traumatic brain injury with emphasis on transcranial near-infrared laser phototherapy

Symptoms of headache, sleep disturbance, cognition, mood dysregulation, anxiety, and irritability improved in patients having traumatic brain injury subsequent to military service after 10 treatments with NIR laser therapy. Ten or more treatments were delivered over 2 months using 810nm and 980 nm NIR delivered in a sweeping motion of the temporal or frontal lobes. Total treatment time and area covered were not revealed.

Description of the Dermillume HR1000 LED Helmet

- Software controlled to permit reproducible 15 and 30-minute treatments.
- LED panels positioned to evenly illuminate the 2 frontal lobes, 2 temporal lobes, 1 parietal lobe and occipital lobe with each treatment.



Six LED (6.35 x 6.35 cm (2.5 x 2.5 inch) panels are attached to the inner surface of a sports helmet to position the LEDs approximately 2.5 cm (1 inch) from the scalp surface. This ensures reasonable comfort treatments and prevents accidental skin burns.

The arrays are operated through a hand-held software controlled panel and uses standard 120 Volt power. The array automatically turns off at 15 or 30 minutes.

Six LED panels containing a mixture of high power 660nm, 850 nm and 940 nm high power Red and NIR LEDs. The 940nm and 850nm LEDs are a mixture of 3° and 10° viewing angle, distributed on the panel to provide even coverage.

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The following calculations provide an estimate of the energy deposited in the top three cm of the human brain in three areas:

Jagdeo, Adams, Brody, and Siegel used a cadaver skull with the soft tissue attached to determine LED light penetration to the brain. Their findings were Frontal Lobe 2.1%; Temporal Lobe .9%; Occipital Lobe 11.7%.

Power delivered from Helmet			**Power Delivered to scalp**		**Energy deposited**	
total LED area (cm^2)	W (total)	mW/cm2	Scalp Area illuminated (cm^2)	Power at scalp (mW/cm^2)	Fluence at scalp (J/cm^2)	Estimated Fluence at 3 cm below Pia Occipital Lobe (J/cm^2)
241.94	49.00	202.54	394.63	145.8	223.50	26.15
Power delivered from Helmet			**Power Delivered to scalp**		**Energy deposited**	
total LED area (cm^2)	W (total)	mW/cm2	Scalp Area illuminated (cm^2)	Power at scalp (mW/cm^2)	Fluence at scalp (J/cm^2)	Estimated Fluence at 3 cm below Pia Frontal Lobes (J/cm^2)
241.94	49.00	202.54	394.63	145.8	223.50	4.7
Power delivered from Helmet			**Power Delivered to scalp**		**Energy deposited**	
total LED area (cm^2)	W (total)	mW/cm2	Scalp Area illuminated (cm^2)	Power at scalp (mW/cm^2)	Fluence at scalp (J/cm^2)	Estimated Fluence at 3 cm below Pia Temporal Lobes (J/cm^2)
241.94	49.00	202.54	394.63	145.8	223.50	2.01

Suitability of the Dermillume HR1000 LED Helmet for cranial treatments

The NIR fluence from a 30 minute irradiation (2.01 to 26.15 Jcm^2) is within the range of several clinical studies showing marked improvement using NIR lasers which delivered 2.9J cm2.

This high-powered LEDs in the Dermillume HR1000 LED Helmet deliver a safe, reproducible treatment suitable for use both at the clinic and at home, allowing treatment one or more times daily. The device is simple to use and requires no special training, unlike laser technology.

It may be suitable for NIR treatment alone or as an adjunct to treatments with other modalities for instance with traumatic brain injury, stroke or depression.