Helios™

Sun Safely™

Helios™ - Sun Safely™

Executive Summary

Helios™ is a revolutionary application that allows people to maximize the health effects of sun exposure while minimizing potential negative effects. Helios™ lets people limit their sun exposure to a Minimal Erythema Dose (MED) of UltraViolet-B (UVB) sunlight– the same dose currently used clinically and safely by doctors to treat skin conditions.

Helios™ employs several synergistic modalities in order to provide a hyper-accurate estimation of a tanner's MED and allows the tanner's MED estimate to be fine-tuned for their specific physiology and environment. Using the tanner's MED, Helios™ determines an ideal exposure time for the specific tanner in their specific location and helps the tanner track and cease their sun exposure when the MED has been reached.

Helios™ - The Light of the Sun

UV radiation (UV) has a complex relationship with human biology. UV has been classified as a carcinogen at high exposures, and excessive exposure to UV carries profound health risks, including atrophy, pigmentary changes, wrinkling and malignancy. Additionally, excessive UV is epidemiologically and molecularly linked to the three most common types of skin cancer, basal cell carcinoma, squamous cell carcinoma and malignant melanoma, which together affect more than a million Americans annually.

However, UV at lower exposure levels actually benefits human health by mediating natural synthesis of vitamin D and endorphins in the skin. In fact, UV therapy is sometimes used as a treatment for various common skin conditions, including psoriasis, acne, and eczema, as well as psychological conditions such as depression and mood regulation. Clinically, the dosage of UV light is prescribed according to an individual's skin sensitivity. Thus, to establish the proper dosage of UV light to administer to a patient, the patient is sometimes screened to determine a Minimal Erythema Dose (MED), which is the amount of UV radiation that will produce minimal erythema (sunburn or redness caused by engorgement of capillaries) of an individual's skin within a few hours following exposure. There is currently no easy way to determine an appropriate MED UV dose without conducting formal MED testing, requiring observation hours after testing, or informal trial and error testing with the risks of under- or over-dosing. Formal MED testing comprises exposing several areas of skin to differing UV levels and then viewing the skin after 24-48 hours to determine which area(s) of skin dosage presents unacceptable erythema. The maximum MED is the UV dose that is less than the dose producing unacceptably high erythema.

Additionally, UV light includes both the UVA spectrum and the UVB spectrum. Although some research may indicate that UVA light exposure may have some negative effects, UVA has traditionally been thought of as the "tanning" portion of the UV spectrum as opposed to UVB which has traditionally been thought of as the "burning" portion of the UV spectrum. UVB, the chief cause of skin reddening and sunburn, tends to damage the skin's more superficial epidermal layers. It plays a key role in the development of skin cancer and a contributory role in tanning and photoaging. Most tanning beds attempt to maximize UVA and minimize UVB to provide the safest exposure for patrons. Thus, the MED may be expressed as total UV exposure or UVB exposure in practice.

Helios™ - How It Works

Helios™ Mission: Determine a tanner's MED under their current ambient conditions in an effective and useful way, use the MED to determine an exposure time, help the tanner track their exposure time, and monitor the results to fine-tune the target exposure time for the next tan.

Helios™ focuses on preventing the increased carcinoma risks that are more strongly prevalent with regard to exposure and dosage with UVB specifically rather than just full-spectrum UV light itself. In this regard, we calculate our MED to arrive at a maximum allowable UVB exposure dose.

I. Determining a Tanner's MED

Helios™ employs several synergistic modalities in order to provide a hyper-accurate estimation of a tanner's MED and allows the tanner's MED estimate to be fine-tuned. These modalities include:

1. Skin Pigmentation

Skin complexion is among the most important determinants of UV sensitivity and skin cancer risk. The "Fitzpatrick Scale" is a semi-quantitative scale made up of six phototypes that describe skin color by basal complexion, melanin level, inflammatory response to UV and cancer risk. Basically, the fairer the skin, the easier it is for UV to cause inflammation (sunburn). MED, therefore is highest in dark-skinned persons since more UV radiation is needed to "burn" eumelanin-rich skin. In contrast, fair-skinned people whose skin expresses predominantly pheomelanin have low MEDs.

In order to ascertain the tanner's Fitzpatrick Scale score, we have the tanner take a picture with their mobile phone of the lightest-colored portion of their skin that will be exposed directly to the sun. We can then determine how light or dark their skin is from the picture and classify them on the Fitzpatrick Scale (FS). Although the classic FS has six phototypes, we actually break the skin color into 50 phototypes to allow for a much finer estimation of basic skin pigmentation.

Additionally, we are aware that color control may vary from phone to phone (or tablet) and may even vary within specific models of a phone. Consequently, we can tweak our basic FS estimate in two ways. First, we know what phone the tanner is using because we take that information directly from the phone. We then have a table of gamma/color corrections for each phone that we can apply to the picture. Additionally, if available, we allow the tanner to take a picture of an object of a known color so that we can color scale their individual phone. For example, if a can of Coke is available, we can analyze the red of the Coke (the color of the Coke can being uniform worldwide) and scale the tanner's self picture with the correction. Similarly, the brown of a bottle of Coppertone™ tanning lotion may be used.

2. <u>Medical History Questionnaire</u>

Medical history can be very important in determining a safe MED. For example, tanners that have already had one skin carcinoma are 2.5 times more likely to have another carcinoma and consequently should have a lower MED. Thus we query the tanner about their age and medical history including whether they or any of their relatives have had a skin carcinoma. We also ask about their previous tanning experiences and whether they find that they tan better or worse than people having a similar color of skin.

3. <u>Current Medications</u>

Many medications can impact a tanner's sensitivity to UV and thus the tanner's MED. Consequently, we ask the tanner if they are on any of the known UV-sensitizing medications and then scale their MED by a previously determined factor based on what medication they are taking.

4. <u>Sun Protection - Tanning lotion or clothes</u>

Tanning lotions having an SPF protection factor reduce the about of UV radiation that impacts the skin. SPF 2 blocks out approximately 50 percent of ultraviolet rays; SPF 10 blocks out about 85 percent of ultraviolet rays; and, SPF 15 blocks out approximately 95 percent of ultraviolet rays. However, tanning products operate in different ways – some are broad UV spectrum and some are predominantly UVA or UVB absorbers.

For example, solutions containing Parsol® 1789 are highly effective filters against the sun's UVA rays. Many of the leading SPF manufacturers have begun using Parson 1789 because currently it is the only sunscreen that also contains skincare properties. Conversely, zinc oxide is a microfine powder that physically screens the skin from light and thus blocks both UVA and UVB. Additionally, Ethylhexyl Methoxycinnamate (Octyl Methoxycinnamate) is becoming an increasingly popular UVB absorber, especially in PABA-free and sensitive skin sun products.

Thus, the tanner selects their tanning product from our list and we provide a scaling factor based on the ingredients in the product. If their product is not on our list, then they can review the ingredients in their product and provide us with the SPF provided by the product.

Also, if the tanner wants to measure their UV exposure under clothing, we allow them to enter the specific SPF of the clothing if known and provide them with a menu of common clothing types and their associated SPFs if they don't know.

5. Tanner selectable factor

We have found that some tanners want to have their MED scaled up or down. For example, a tanner may be more worried about the possible carcinoma effects and thus only wants to have an exposure of 75% of MED. On the other hand, a tanner may want to obtain a little more intense tan than their MED, but still not want to be burned too badly. Consequently, after determining the user's MED, we allow the user to determine a Target MED that can either be the actual MED or scaled up or down in 1% increments.

II. Determining a Tanner's Exposure Time

Once we have the tanner's target MED, we then want to tell the tanner how long they should remain exposed to the sun to reach the MED. To do this, Helios™ again employs several synergistic modalities in order to provide a hyper-accurate estimation of a tanner's exposure time and allows the tanner's exposure time estimate to be fine-tuned. These modalities include:

1. Direct UV Intensity Sensing

Most modern mobile phones are equipped with a UV sensor. Thus, we have the tanner leave their mobile phone in the full sun that they are experiencing and measure the intensity of the UV received. However, current UV sensors are broad-band in that they detect the total intensity of both UVA and UVB, while MED is primarily based on UV. Consequently, we scale the received full-spectrum UV intensity as discussed below in order to determine when the UVB-based MED has been reached.

2. Time-Of-Day Scaling

We know the location of the tanner, so we know their local time. Thus, in time of day scaling we use a scaled percentage of received UV intensity as UVB. That percentage rises as a bell curve centered at noon up to a maximum of 13% as shown in the example below for Darwin, Australia.

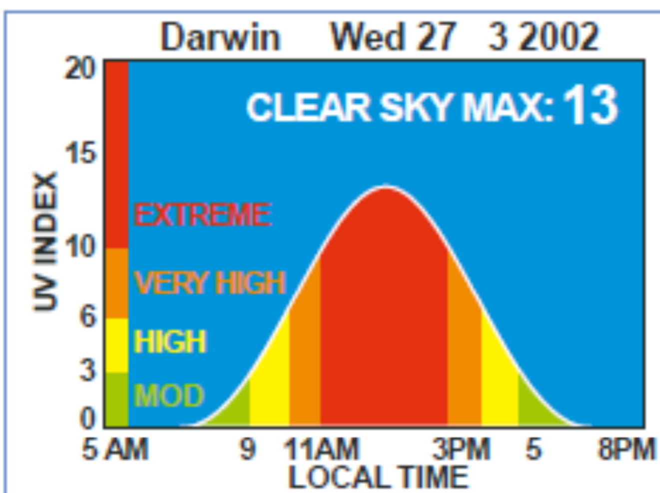


Figure 5: A graphic representing dangerous hours (Bureau of Meteorology, Australia)[2]

3. Geo-Temporal Model Scaling

Time of day is a useful, but clunky scaling factor because of issues such as the large geographic extent of time zones and daylight savings time. For example, both eastern Maine and Western Indiana are on east-coast time, but are literally 1,000 miles apart. Thus, the intensity of UVB emission when it just turns "noon" east-coast time is going to be significantly different in the two locations.

Thus, we have created a geo-temporal model wherein we receive a tanner's location and look up the sunrise/sunset times for that location. For example, even though Maine and Indiana are in the same time zone, their sunrise/sunset times differ. We can then determine the maximal UVB time as the midpoint between the local sunrise and sunset and map the local time and length of day onto the curve above.

4. Cloud Conditions

Cloud conditions influence the amount UV – both UVA and UVB - that reaches the ground. Additionally, although we can measure total UV from the sensor, UVB light is blocked more readily by clouds. In fact, the U.S. National Weather Service and Environmental Protection Agency, for example, use 89 percent UVB transmission for scattered clouds, 73 UVB percent transmission for broken clouds and 32 percent UVB transmission for overcast conditions. However, clouds can also cause sunlight to reflect and produce a local strengthening (rather than reduction) of UVB that is even higher than a clear day. The UVB reflected from the cloud is actually magnified on the ground. However, the point on the ground where the magnification takes place moves as the clouds do. For example, a survey conducted at six U.S. cities in 1994 found cumulus clouds could produce temporary raises in surface UV-B by 25% and in 2004 Australian researchers reported that the UV-B rays were up to 40% stronger under partly cloudy skies in specific locations due to cloud reflection.

Thus, in one version we just allow a tanner to estimate cloud conditions and use the NWS UVB scaling numbers. In a second version, we use the current NWS weather condition information for the location of the tanner to scale – or present the weather data to the tanner and ask them to confirm. In a third version, we allow the tanner to select the NWS-scaled numbers, but also give them the option of selecting no cloud adjustment, a minimal cloud safety factor of +10%, a significant cloud safety factor of +25% or a super-safety factor of +40%.

5. Altitude

We know the tanner's altitude from the GPS on their mobile phone. It is also known that relative UVB levels increase 24% with every 1000m above sea level. Thus we scale up the UVB level linearly with altitude above sea level.

6. Post-Tan MED Adjustment

We want to find out if the tanner got sunburned during their tanning session and, if so, adjust their MED down in the future. UVB takes about 72 hours for the real burn to set in, so after 72 hours we send the tanner a link to our tan adjustment survey. We ask if they got undesirably sunburned. If so, we ask them whether the burn was "a little", "somewhat", "significantly", or "greatly" more than expected and adjust the MED by 5, 10, 20, or 40% based on their answer. Additionally, if they experienced any blistering, the MED is reduced by 50%. For multiple blisters, a 75% reduction is imposed.

On the other hand, we ask whether they felt they had too little sun and whether the amount was "a little", "somewhat", "significantly", or "greatly" to little and then adjust the MED by 5%, 10%, 15%, or 20% based on their answer.

We also let them enter a direct percentage adjustment up or down if they want.

III. When The MED Is Reached

When Helios™ is running on the tanner's mobile phone, it displays the total time for the MED and the remaining time to reach the MED. When the time expires, an alarm is provided through the mobile phone – the alarm may be audible, vibratory, or both. The tanner may then be queried for their "end of tan" photo which may be used for real-time tan confirmation described below.

We advise tanners to determine their MED separately for their fronts and backs due to the different skin conditions. For example, the lightest portion of the back may be the lower back or the back of the thighs or calves. On the other hand, the lightest portion on the front may be the stomach, or under the pectorals/breasts, or the tops of the thighs. Additionally, the currently exposed lightest spot may vary with fashion choices during the current tan. Consequently, tanners completing one side should then determine a new MED for their rear side. Additionally, we ask that the tanner identify the body portion that they are taking a photo of so that we can perform a direct comparison in future photos of the same area in future tans. In fact, we provide the tanner with a menu of commonly body parts including stomach, top of thigh, back of thigh, calf, back, upper arm, underside of forearm, and other (specify) that they may choose from.

1. The Snooze Button

We also offer the tanner the option to hit the "Snooze" button to reset the alarm for a later time. The snooze may either be for a predetermined time such as 5 minutes or a time selected by the user or for a predetermined additional percentage of the MED, such as 5% or a percentage selected by the user.

2. MED/Exposure Time Factor Influence Summary

Helios™ also displays for the tanner how it arrives at both the MED and the Exposure time, including each factor and the adjustment it provides, so that the tanner can better understand the factors influencing the MED and exposure time. These summaries can be viewed during or after tanning. Additionally, the user may in real-time decide to adjust any of the factors impacting MED and/or exposure time and Helios™ then calculates the revised MED and implements the revised Exposure Time.

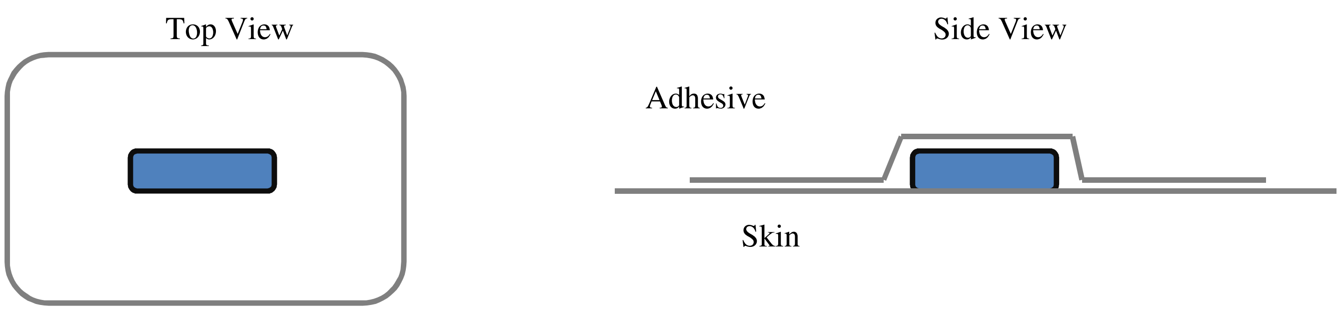
3. Tan Records/Archiving

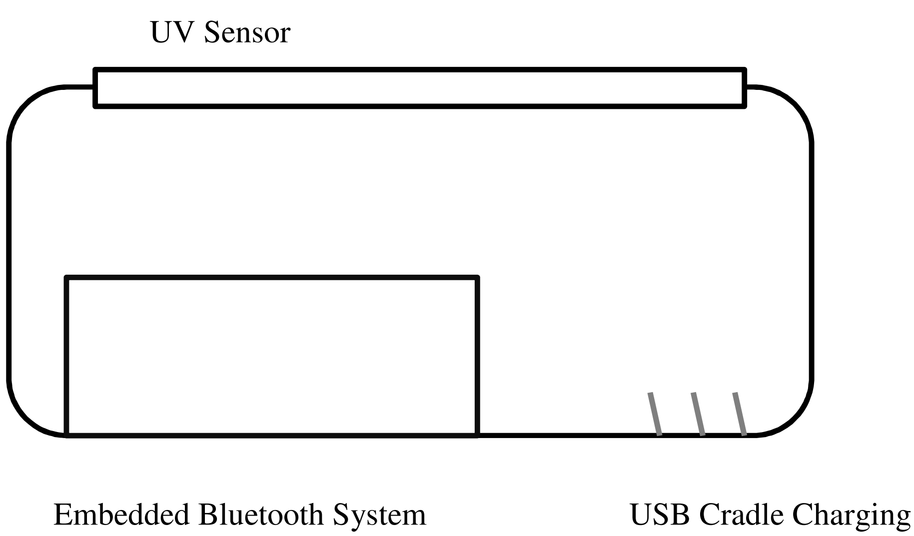
Helios™ also tracks all tanning activity of the tanner including the MED and exposure time and how they were determined, as well as the geographic location, time of day, and photos. All tanning activity is archived as the Helios™ servers and is available for later reference by the tanner and use by various Helios™ system elements.

<u>IV. Advanced Helios™ Systems</u>

1. <u>Helios™ Wearable™</u>

For recumbent tanners, recording UV intensity using a mobile-phone based sensor is just fine. However, it is difficult to use the phone-based UV sensor when engaging in activities such as hiking or biking, for example. For this market, Helios™ has developed an adhesive, wearable sensor that may be attached to the body or clothing of an active person. The sensor is approximately the size of a one-a-day vitamin and includes a USB charging connection that allows the sensor to be charged when placed in the supplied USB-connected cradle. To use, an athlete places the charged sensor against their skin (for example) and then tapes it to their skin using the single-use, UV-transparent adhesive patches that are supplied with the sensor. The senor itself is Bluetooth paired with the athlete's mobile phone and relays UV readings to the mobile phone.





2. **Helios^{TM} Safety^{TM}**

We also market Helios^{TM} for use with sun safety alerting rather than tanning. That is, some people have extreme sun sensitivities and in some cases can even get a sunburn through their clothing. Consequently, instead of using the UVB MED of Helios^{TM} as a tanning tool, the MED may be used as a safety alert when the person has been exposed to the sun for too long and needs to seek shelter indoors.

V. Helios™ – Underlying Technology

Helios™ primarily operates as a mobile app on a tanner's mobile phone (with the alternative of Helios™ Wearable™) and uses a wide variety of hardware on the tanner's phone including the camera, GPS, and UV sensor. The mobile phone data is relayed over the internet to our cloud-based servers hosted by Amazon using a SAAS model. Additional services may be accessed over the internet by our servers to perform the services described above.

Thus, our infrastructure needs are fairly conservative because we primarily operate over the preexisting smartphone and cloud computing infrastructure.

VI. Future Developments

1. Real-Time Tan Confirmation

The tanning process or increased pigmentation occurs in two phases. The first one is immediate pigment darkening (IPD). IPD is a rapid darkening of the skin which begins during exposure to UV radiation and its maximum effect is visible immediately. It is caused by a change in melanin already present in the skin. IPD is most obvious in skin where significant pigmentation already exists. It occurs after exposure to the longer wavelength of UVA or visible light. IPD may fade within minutes of small exposures or may last several days after longer exposures and blend in with delayed tanning.

Delayed tanning, induced mostly by UVB exposure, is the result of increased epidermal melanin and first becomes visible 72 hours after exposure. Both UVA and UVB radiation start delayed tanning by creating an excited condition in the melanocytes which in turn releases more melanin into the skin. The degree of IPD is primarily a reflection of the person's skin type.

Consequently, because UVA provides a relatively immediate darkening of the skin (single digit minutes) we can use the tanner's current skin color as they are tanning to confirm our estimate of their target MED. For example, we know their starting skin color from their photo and at any time during tanning they can take another photo of the same area (we typically prefer about three inches away from the skin) and we can evaluate the color – basically telling them "they look more/less red than expected".

However, the target MED is calculated based on UVB dose, so it can't be used for determining the UVA-based color change. However, we do monitor the total UV intensity, so we can calculate the total UVA at any point. However, one problem is that we don't know exactly how much UVA-induced skin darkening will take place before the UVB-determined MED is reached. We can make broad, bulk initial estimates from the Fitzpatrick Scale, but the accuracy is erratic.

However, one way that we have found reasonable success is when we are comparing a tanner's current tanning with a previous tan. Simply put, they should experience about the same tan as before. Consequently, we can ask a tanner to periodically take photos of the same spot for a reference and then use them in subsequent tanning evaluations to estimate the UVA exposure at that time, which we can then use to estimate the total UV and thus UVB – and if the estimated UVB is different from our expected UVB we can alert the tanner.

2. Helios™ Social

We can harness the information provided to our servers from a large number of tanners that might be tanning at a similar location. For example, we can integrate this with real-time tan confirmation if we see that several tanners at a beach are experiencing more UV than expected, we can advise the other tanners on the beach and use the information to scale everyone's MED - or at least alert them that the other tanners are experiencing over-exposure and we recommend that they adjust their MED by X%. This can be called an over-sun alert.

Additionally, the Helios™ users can make their locations known to other Helios™ users, like Uber does with taxis. When tanner's icon is selected a picture of the tanner's choice and/or the tanners name and description may be displayed at the choice of the tanner.

Also, we can send out advertisements to the Helios™ tanners. The advertisements may be structured so that all tanners on a specific beach get an ad or that tanners receive the add just before they reach their MED (which indicates that they are likely done tanning for the day.

Other Patents

The CEO passed on your recommendation to search the PTO's website, so I did. I made a list of the patents below. The CEO says that all of these patents look pretty close to what we came up with. However, the CEO says that you are the best patent attorney around and that you will be able to find a way to get us our patent without infringing on these other patents.

Patents:
US 20130262033 A1
US 20140368629 A1
US 20140348403 A1