Application Note (A10)

Exposure Schedules for Suntanning Products

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Exposure Schedules for Suntanning Products

It is generally accepted that proper use of indoor tanning methods may be safer for the tanner than the uncontrolled environment of outdoor tanning. However, it is a common misconception among consumers that indoor tanning is completely safe from the harmful effects of UV radiation. Many people mistakenly feel comforted when a unit is claimed to be "Food & Drug Administration (FDA) compliant," because this connotes the idea of a "safe" product.

It is important to realize that compliance merely states that the product has met certain performance guidelines set forth by the FDA/CDRH. In its efforts to regulate the industry, the FDA requires products to meet certain electrical, mechanical, and irradiance measurement standards. Suntanning product manufacturers, in turn, have complied by labeling each product with tanning schedules and warning labels explaining the hazards involved with exposure to UV radiation.

Solar radiation (or any light) can be characterized by wavelength, the units of wavelength being the ***nanometer***, which is one-millionth of a millimeter. To facilitate the discussion of the tanning process, we will consider the spectrum of light to be broken into several groups (see Figure 1): ***visible light*** (400-780 nm), ***UVA*** (320-400 nm), ***UVB*** (260-320 nm) and ***UVC*** (200-260 nm). The longer wavelengths penetrate farther into your skin, while the shorter wavelengths do not reach as deeply.

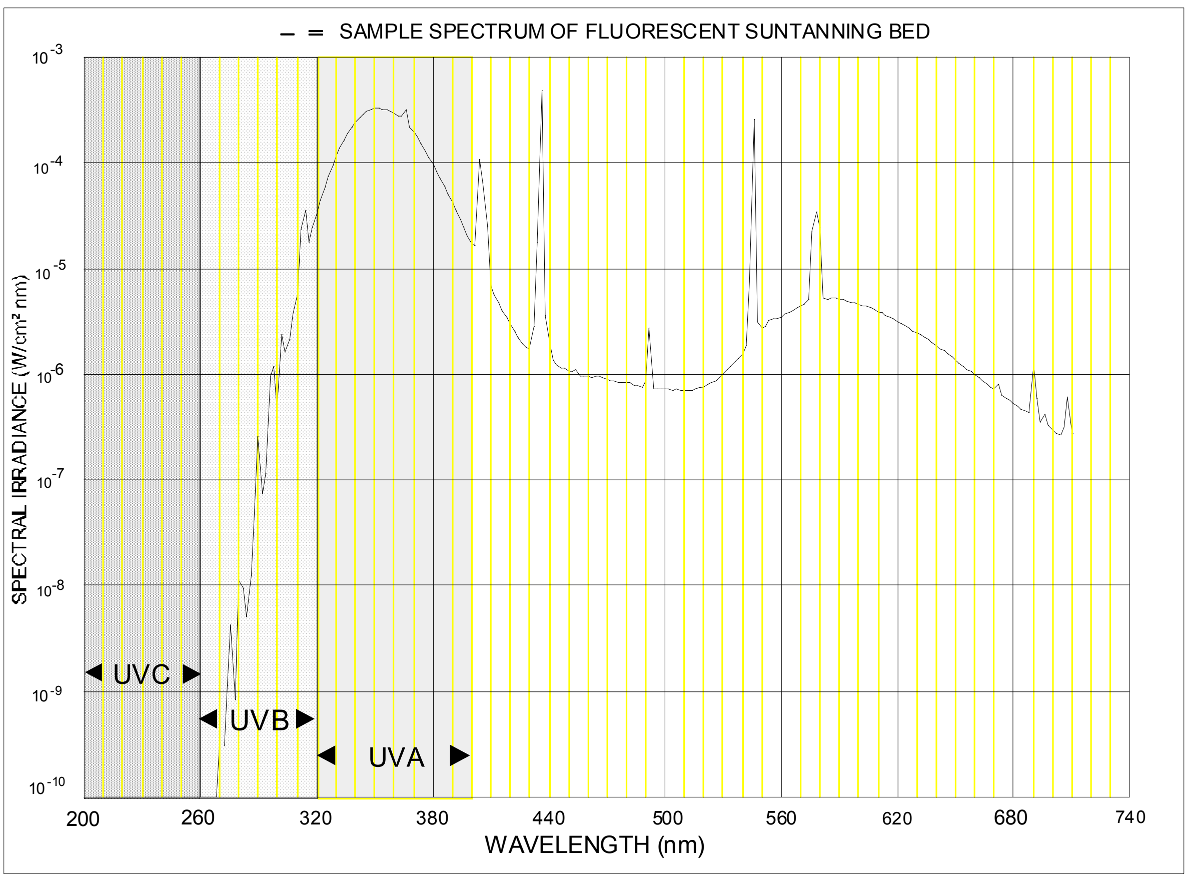


Figure 1

The visible light has little effect on skin color. The shortest, most dangerous wavelengths of UVC light are absorbed by the earth's atmosphere outdoors and are filtered or eliminated in indoor tanning lamps. The UVB is considered to be the burning rays, because these rays are 100 to 1,000 times more effective in biologically stimulating the burning process in the skin. The UVA radiation reaches deeper layers of the skin, however, and also serves a role in the oxidative process of tanning.

The burning process to which we refer is called ***erythema*** (skin pinkening) and describes the biological method that protects the skin from radiation damage. The skin responds to exposure by stimulating melanocyte cell division to produce more ***melanin***, darkening melanin through oxidation, and building up skin thickness (sometimes referred to as the horny layer). It is the darkening of the melanin (***melanogenesis***) that we see as tanning.

Burning occurs when the protective process cannot take place efficiently enough to offset the UV radiation penetrating the skin. The skin becomes red as the capillaries swell in reaction. Increased itching and sensitivity now become painful. A time delay is involved here because, while color is first evident when the pink-colored melanin existing in the skin is oxidized to a brown color, more melanin is being produced which will later rise to the surface layers to add more color. Thus color and pain from sunburn often does not occur until much later than the exposure, after significant erythema (skin-pinkening) has already occurred.

By understanding the tanning and burning process, we can more easily understand the safety factor involved with the various tanning products. Manufacturers can design their products to produce light of different spectral characteristics than in the solar radiation of outdoor tanning.

For instance, the UVB content of the typical suntanning apparatus varies from less than 0.5 percent to about 4 percent of the total output, while the solar spectrum is comprised of approximately 1 percent to 12 percent of these burning rays. On the other hand, the UVA of tanning units is usually much higher, about 10 times the radiation from the sun. This control of the spectral output illustrated one reason why some people believe that indoor tanning can be considered "safer" than outdoor exposure.

Now, let us put together the two key factors that make up the idea of "equivalent exposure." We know that UVB radiation can be 100 times to 1,000 times more effective in stimulating erythema than the UVA, and we also know that tanning products can vary in the amount of the UVA/UVB contained in their output.

It is clear, then, that a unit exposing the skin to high levels of UVB will produce the tanning effect more quickly than a unit with UVA concentrated light. This method requires careful attention to timing, however. The high level of effectiveness of UVB makes a few minutes of overexposure acutely more harmful that an equal such overexposure to UVA.

There are two distinct groups of individuals who demand different performance from tanning products. The first are people who desire to stay in each session as long as possible, either because tanning is a leisurely period of relaxation for them or because they feel they are getting their money's worth. The second group doesn't have time to waste on this sort of thing. They desire to get in and get out as quickly as possible. This group also includes tanning business owners who, if the tanning sessions are shorter, can schedule more session per day with less apparatus, as well as saving electricity costs, thus generating higher profit potential.

The tanning industry has responded to this dichotomy by creating lamps with either very low UVB outputs for a "longer" tan, or lamps with higher UVB outputs for a "quicker" tan. Tanning business owners and others would argue that since the amount of time is determined by the total effective dose of radiation, whether one receives that radiation in 5 minutes or 15 minutes really doesn't make much difference because they are "equivalent doses." All UVA sources emit some UVB to avoid excruciatingly long exposure times. So, with the longer times required in UVA exposure to induce tanning, total exposure to UVB can nearly equal that of tanning with a UVB concentrated source.

The advent of lower UVB output lamps, the differences among tanning unit designs, and the need for a general refining of the regulations imposed on the tanning industry prompted the FDA/CRDH to publish a set of guidelines that manufacturers or importers of suntanning products must meet for any new product introduced in the United States. (The guidelines became effective in September 1986.)

Each type of unit introduced must undergo testing, and data supporting the calculation of timer settings and tanning schedules must be submitted to the appropriate agencies before certification can take place. These times are derived from measurements of the unit's ***spectral irradiance*** (i.e. the lamp's "power" falling on a given surface area at a given distance from the source at each wavelength interval). The spectral irradiance values in Watts/centimeter^2 are then modified and used in a formula with the ***MED*** factor to determine a minimal time of exposure. (MED is the minimal erythemal dose, or the effective dose, of UV exposure required to cause pinkening of the skin.)

Two calculations are used to determine the tanning schedules on tanning units. One calculates the maximum recommended time for a reddening of the skin to occur (T_e, or maximum erythemal time). The other calculates the maximum recommended time for a darkening of the skin to occur (T_m, or maximum melanogenic time). Since different individuals will either tan or burn first, both times are considered, and the shortest one is recommended for deriving tanning schedules.

The reaction of Type II individuals is used to decide how the irradiance values are to be modified. The skin types are rather imprecisely defined for Caucasian skin as being Types I (never tans, always burns) through IV (always tans, hardly ever burns). Two other types (V and VI) also exist, but have not typically been users of tanning equipment to date. Type I individuals will probably also not be using the product, since they rarely tan; thus, the required exposure schedules on suntanning equipment are not directed towards those individuals. Type II is generally used for calculations, since it is the most sensitive skin type who would generally use this type of product. Extrapolation of tanning schedules to other skin types may then be accomplished, if so desired.

When using phototherapy for treating various skin disorders, the individual's skin sensitivity can be determined more accurately by exposing small areas of previously unirradiated skin with various amounts of UV to ascertain how much irradiation is required to cause erythema. This method is rather impractical for the large population of suntanning equipment users, however. In the more practical setting, the individual is usually asked a series of questions to determine his/her skin type.

To derive the maximum exposure times, the spectral irradiance of the unit first must be measured. This is a rather complex and technical process.

A ***spectroradiometer*** measures the irradiance of the suntanning unit's output at each wavelength (see Figure 2). The spectroradiometer's calibration is extremely important; it should be calibrated using a known reference light source, and it must remain stable throughout the measurement. The instrumentation must be capable of measuring very small wavelength intervals over the entire range required. It must have a very narrow bandpass (the number of wavelengths that are allowed to pass through the instrument at each measurement point); high wavelength accuracy and precision; extremely low stray light levels; and a wide dynamic range (the lowest to highest range of signal of light level that can be measured by an instrument). The instrumentation must be calibrated against ***NIST*** (National Institute of Standards and Technology) traceable standards.

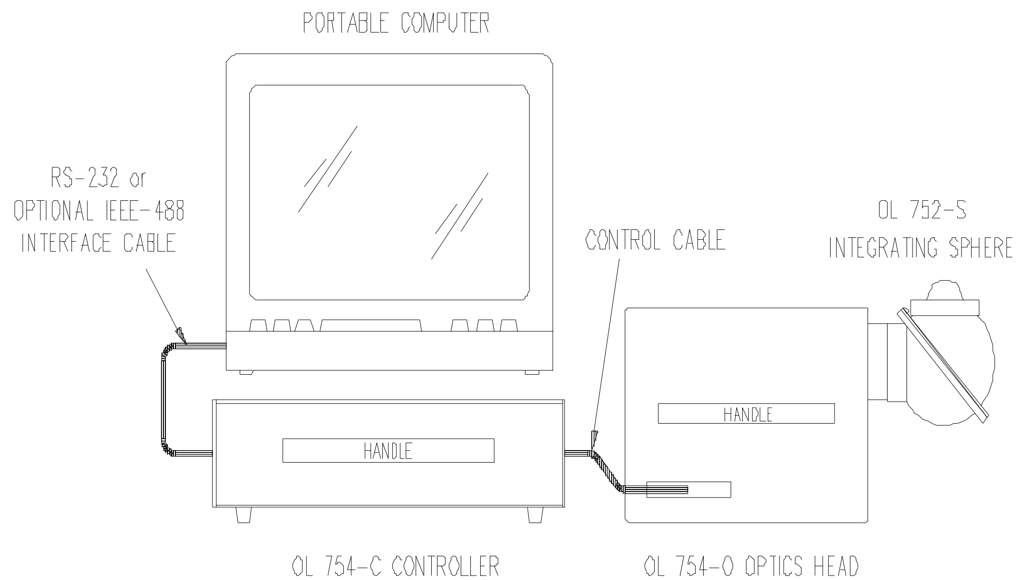
Equally as important as using high-caliber measuring instrumentation is having the proper training and background necessary to make accurate measurements. Many variables and difficulties that can influence the measurements may be encountered. Thus, this type of testing is best performed by a qualified calibration laboratory experienced in these types of measurements and utilizing high quality measurement instrumentation.

It is important to note that this instrumentation is not the same as the portable, handheld UVA and UVB meters, which are not suitable for these types of measurements. The typical, relatively inexpensive UVA and UVB meters are only practical for monitoring the relative reduction in UV intensity of a lamp over time.

For instance, when the lamp's output falls to a certain value on the meter due to aging, a decision can then be made as to when to replace the lamp. Calibration of these broadband meters is typically made at only one wavelength, and inaccuracies of up to 20 percent to 30 percent between identical meters are not uncommon. Linearity (the accuracy of response of the instrument at various input intensities) is oftentimes assumed or untested. This could result in errors when measuring sources that vary widely in intensity. Thus, while they can provide some useful relative information, the absolute values obtained from these types of meters should be treated with caution.

Unfortunately, many users of these meters are not informed enough to interpret the readings obtained and often draw incorrect conclusions from them. No spectral information on the lamps is provided, so attempting to compare lamps that have significantly different spectral output shapes could be very misleading. Also, since the tanning effectiveness of different wavelengths varies widely (according to the action spectrum), and the meter cannot account for this, no information regarding a particular lamp's tanning effectiveness can be assumed, either.

The only valid way to measure a lamp for its absolute spectral output is with a relatively expensive spectroradiometer system and trained lab personnel.



Spectroradiometer System
Figure 2

After the lamp's spectral intensity is measured, the next task is to determine the effect of this particular tanning unit's UV irradiance on a person's skin. This is known as the "effective dose."

Since not all wavelengths are equally effective at tanning, or at causing erythema, each wavelength can be weighted as to how effective it is, relative to other wavelengths. The weighting factors are determined by the biologically effective action of the different wavelengths on the Type II individuals, known as the "action spectrum." (See Figures 3 and 4.)

The erythemal effectiveness of UVB at 296 nm is considered higher than any other portion of the spectrum, thus representing the peak of the action spectrum. All other wavelengths' effectiveness is expressed relative to this maximum value at 296 nm (a process known as normalization). Thus, if we apply a given weight from the action spectrum to each corresponding wavelength measured from the tanning source, we can obtain an effective spectral irradiance for the source.

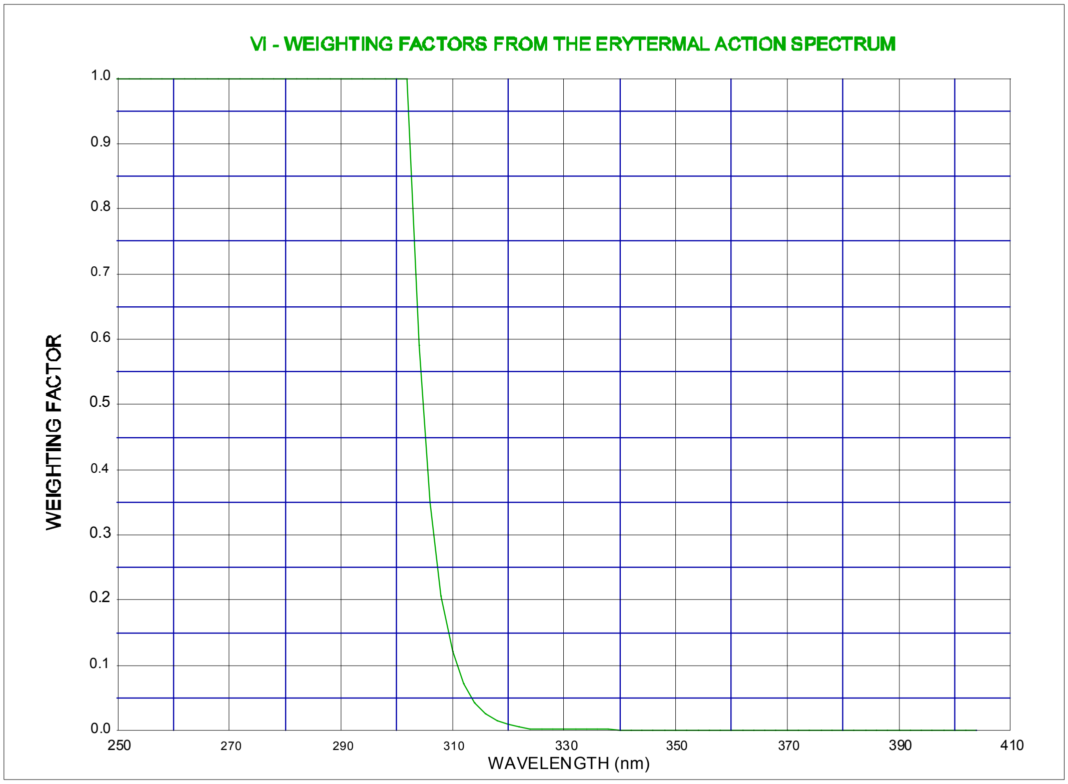


Figure 3

Specifically looking at the formula for T_e (maximum erythemal exposure time), we have:

$$T_e\,(\text{seconds}) = \frac{642\,J\;/M^2}{\sum V_i \;\; R_i}$$

where: 642 *Joules/Meter*^{2} = 4x the MED time (where 1 standard MED equals 156J/M^2 at 296nm for Type II skin)

V_i	=	weighting factor from the erythemal action spectrum for each specific wavelength
R_i	=	Measured Spectral irradiance in Watts/Meter^2 (irradiance at each corresponding wavelength)
3	=	Summation of weighted values at each wavelength

To obtain the T_e time, one would multiply the measured spectral irradiance value at each wavelength by its corresponding weighting factor, then sum all these products {(V_i * R_i) + (V_i * R_i) ...etc.). Divide this sum into the constant 642J/M^2, and this will yield the T_e time in seconds.

The calculation of T_m maximum melanogenic time follows the same general rules, except that values assigned as the constant and the spectral weighting factors (derived from a separate action spectrum)

$$T_m\,(\text{seconds}) = \frac{1{,}836\,\text{J}/\text{M}^2}{\sum J_i R_i}$$

are different.

where: 1,836 *Joules/Meter*^{2} = 4x the MMD (minimal melanogenic dose) where i standard MMD = 458J/M^2 at 296nm

J_i = weighting factor from the melanogenic action spectrum for each specific wavelength

R_i = same as above

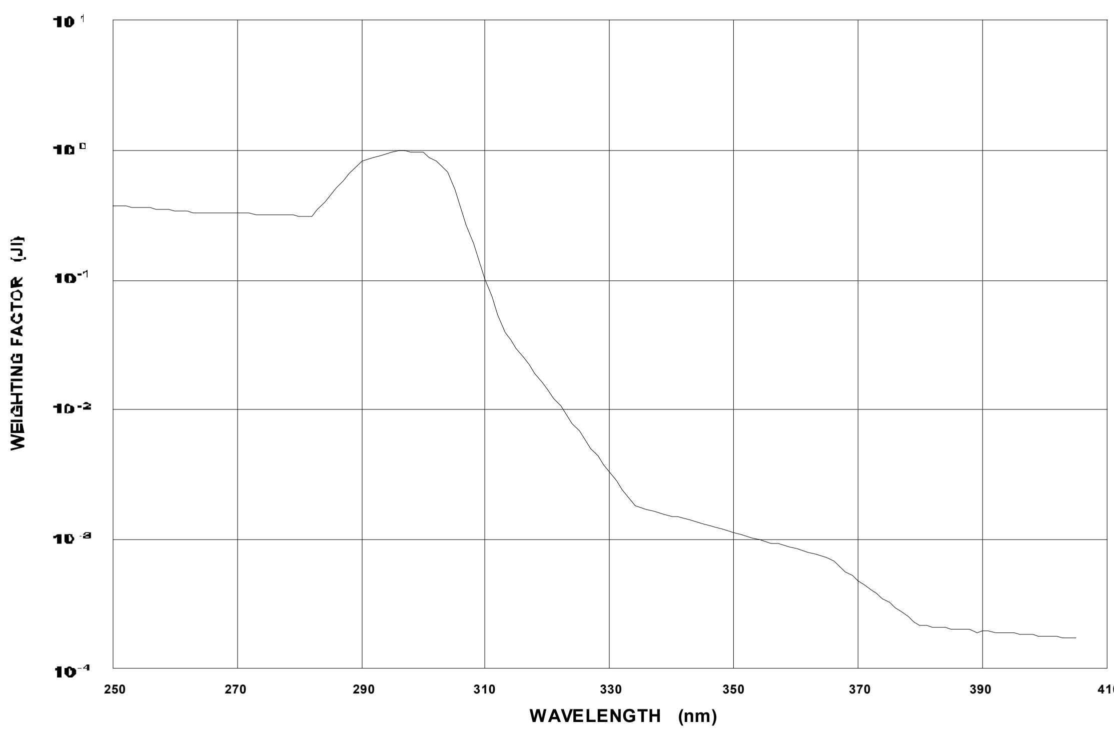


Figure 4
Melanogenic Action Spectrum

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                              Te/Tm Printout
--------------------------------------------------------------------------
File Name : SUNBED.dat
Designation: SAMPLE SPECTRUM OF FLUORESCENT SUNTANNING BED
Units     : Irradiance [W/(cm² nm)]
Date      : 890712
Wavelength Range:  200 -  710 nm @ 2 nm
--------------------------------------------------------------------------
Sunlamp Calculations  (over range: 200 - 440 nm at 2 nm):

MAXIMUM EXPOSURE TIMES:
     Maximum Erythemal time      Te       - 27.571 minutes
     Maximum Melanogenic time   Tm     - 74.595 minutes
     First Week Max time        .75MED -  5.170 minutes

IRRADIANCE RATIOS:
     Ratio (200-260)/(260-320)  -  0.000000
     Ratio (260-320)/(320-400)  -  0.022626
```

Figure 5
Sample Sunlamp Calculations

Whichever value is less between the T_e and the T_m time is used as the maximum exposure limit, or timer interval, for the particular product. It is typically the T_e time that is shorter that the T_m time. When the maximum exposure time (whether T_e or T_m) is ascertained (and thus the maximum timer setting is also known), the manufacturer can proceed with creating tanning schedules for Type II skin, based on the following guidelines:

"The recommended exposure schedule should provide for exposures of no more than 0.75 MED three times the first week, gradually increasing the exposure the following weeks until maximum tanning has occurred (approximately four weeks total) and then provide for maintenance of a tan by biweekly or weekly exposures of up to four (4) MEDs or four (4) MMDs, whichever is less." (Aug 4, 1985, publication by the FDA Office of Compliance.)

These calculations do not take into account the effect of certain medications, disorders, and so forth that may significantly affect a person's reaction to UV.

Although using Type II schedule for less sensitive skin types (i.e. Types III and IV) should prevent any burning, the exposure schedule may be inadequate to provide tanning, thus, these individuals may not be satisfied with the product's performance. The manufacturer has the option of developing alternate tanning schedules for these individuals not to exceed the calculated maximum timer interval (T_e or T_m). These alternate schedules must be supported by adequately documented test data, reference to the technical literature, research, or other appropriate corroborative evidence.

The complications involved with calculating the formulas mentioned, as well as the extreme accuracy needed to make the irradiance measurements, are indicative of the importance of proper procedure when testing tanning devices.

From this brief discussion, it can be seen that the many factors of UV measurements make the task appropriate only for experienced laboratory technicians who use highly accurate and precise instruments. Product manufacturers do well to entrust their certification testing to a capable lab, and tanning center operators must protect their own interest by demanding proper testing and evaluation of exposure schedules.