Is a DermaFlash SAM Considered Safe?

DermaFlash™ SAM owners are rightly concerned with their safety and their clients' safety. Most people are aware that ultraviolet light has some negative effects on our skins. So why would someone stick their head in a SAM and be deliberately exposed to UV light? And what exactly are the things that can happen due to UV radiation?

We'll examine these questions and learn more about UV light in the following material. The technical details are put in an appendix for the folks who are interested.

We'll also look at government regulations, our company's policies, and the experimental evidence we have that DermaFlash SAMs do not represent a significant hazard when used as recommended.

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The Brutal Truth

There is no safe level of UV exposure.

Current scientific thinking is that all forms of UV radiation are potentially harmful. A single photon of UV radiation has enough energy to damage cellular structures in the skin.

So why would anyone expose themselves to UV radiation? The answer has to do with the **risks versus the benefits**.

Risks and Benefits

Many aspects of human behavior are known to be risky -- getting on an airplane, driving in a car, walking across the street, etc. Most of us evaluate the risks of these things as very low most of the time and don't think twice about doing them. The average person has enough experience with these activities that he or she can evaluate the risks and make informed judgements based on experience.

But it's more difficult with things like UV radiation that we cannot sense. We have to rely on the measurements and guidance of others.

A good analogy is x-rays. We know the risks of x-rays, but we still use them because they are so useful for diagnosing health problems. Most of us would rather learn about an early cancer using an x-ray rather than choosing not to expose ourselves to the x-ray. Clearly, the benefit outweighs the risk.

Let's understand what the risks UV radiation are. First, we need to learn what the characteristics of the UV radiation the SAM produces. The following graph shows the nature of SAM UV radiation:

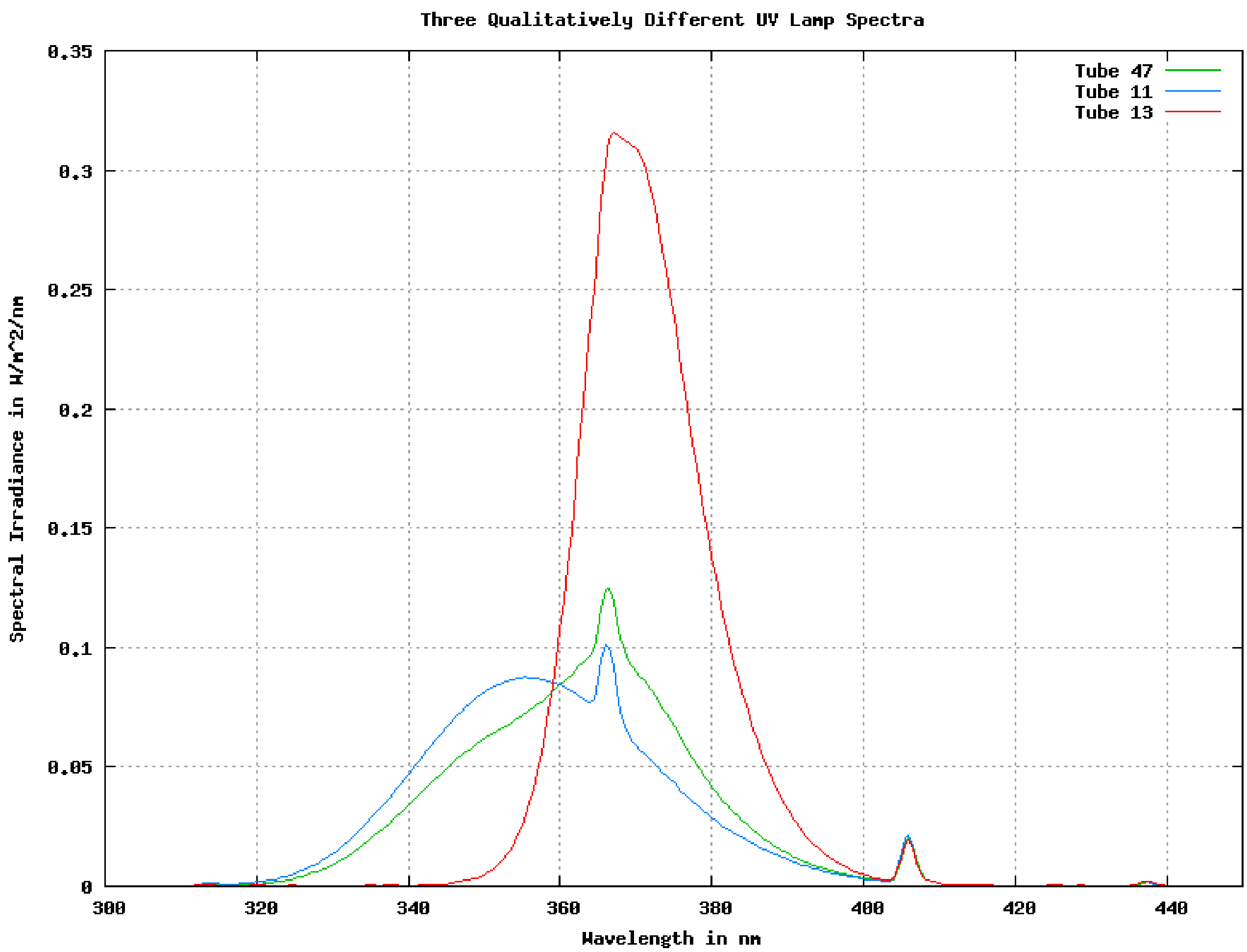


Figure 1.: Three types of UV lamp spectra

This graph of three spectra (each colored line is called a spectrum) shows the wavelength of the UV radiation on the horizontal axis in nm (nanometer or billionths of a meter) and the power of the radiation at the particular frequency.

The total power per unit area of the radiation is calculated from the area under the curve. The three different curves show three different types of UV tubes seen in various samples of UV tubes. This may be more technical than needed, so we'll leave the rest of the technical details for the appendix.

Visible light starts at a wavelength of about 400 nm and goes up to about 700 nm. 400 nm light is a blue-purple light.

From this graph, we learn that SAM tubes only output radiation in what's called the UVa band, which are the wavelengths from 315 nm to 400 nm. This type of radiation is called "longwave" UV. Shorter wavelength UV radiation in the UVb and UVc bands are much more hazardous. We need to look at the risks of UVa radiation.

The Risks of UVa Radiation

A sample of the current scientific literature will show that UVa radiation is known or suspected to be a factor in the following things:

- Ageing (toughening & wrinkling) of skin; also shown in mice.
- Erythema (reddening of skin).
- Suppression of the immune response.
- Cataracts.
- Effects are cumulative (reasonable, as so are x-rays and other ionizing radiation).
- Small increase in skin cancers in mice.
- Plays a role in non-melanoma skin cancer.
- Reduction in skin hydration.
- Increased skin permeability for small, polar alcohols.
- Can result in DNA damage via oxygen radicals and induce mutation in cultured cells.
- >320 nm radiation on fish bred to be melanoma-sensitive to UV was very effective in causing melanoma (so was light in the blue region).
- A epidemiological study demonstrated a relationship with melanoma mortality.

Before you decide to go live in a cave and only come out at night, realize that a lot of this research is aimed at seeing whether a connection exists and usually involve fairly high levels of exposure.

The Benefits of UV Radiation

UV radiation on our skin helps our bodies make vitamin D. Lack of vitamin D can lead to bone diseases such as rickets. Minimal exposure to UV can generate enough vitamin D to avoid these diseases. In addition, western societies typically have diets fortified with vitamin D.

UV radiation in the UVc band is sometimes called "germicidal UV", since it has the ability to kill bacteria. It is widely used for this purpose and is clearly beneficial. Since it is quite hazardous to humans, however, it must be used safely and carefully. It is thus strongly regulated.

A benefit of longwave UV radiation (UVa) is that it can show artifacts on or in human skin that are difficult or impossible to see in visible light. **This is what the SAM was designed for**.

UV radiation is also used in some treatments of skin disease.

Regulatory Guidelines

In the US, the Food and Drug Administration (FDA) regulates importation and use of products that utilize radiation, such as x-rays, UV, and lasers. This makes sense -- though these forms of radiation have valuable uses, they must be used intelligently and within guidelines to avoid harm to people. There are cases, such as the notorious Therac-25 debacle [2], where mistakes cost lives.

The issues are complex; here is an excellent quote from [2]:

> *The issues involved in regulation of risky technology are complex. Overly strict standards can inhibit progress, require techniques behind the state of the art, and transfer responsibility from the manufacturer to the government. The fixing of responsibility requires a delicate balance. Someone must represent the public's needs, which may be subsumed by a company's desire for profits. On the other hand, standards can have the undesirable effect of limiting the safety efforts and investment of companies that feel their legal and moral responsibilities are fulfilled if they follow the standards.*

This statement accurately reflects DermaFlash's position on the safety of UVa radiation in our SAM units. We follow the FDA and ACGIH guidelines, then we go further and ask what else we can do. We won't put our profits ahead of customer safety.

The FDA follows the published guidelines of ACGIH (American Conference of Governmental Industrial Hygienists) for UV exposure [3, 4].

The requirements are technical in nature and are relegated to an appendix. In a nutshell, DermaFlash™ SAMs have UV exposures less than the ACGIH limit values when used as directed by this document.

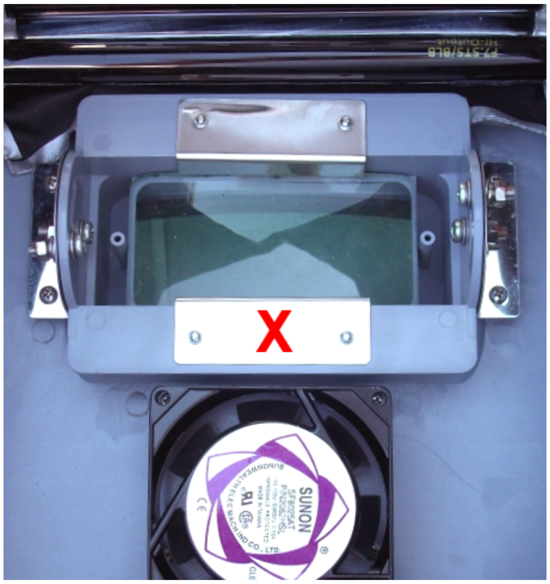
DermaFlash Guidelines

Our guidelines are:

- Ensure we meet regulating agency guidelines.
- Use a factor of safety of at least 2 to account for production process variations.
- Ensure we are comfortable enough with our levels so that we would be willing to expose ourselves and our families to these levels.
- Monitor continuing research and revise our policies as needed.

DermaFlash Recommendations

1. Position the tip of the client's nose 9 inches away from the back of the magnifier (the red X in the following figure).



2. Clients should be exposed to no more than <u>three</u> 3-minute SAM sessions per day.
3. Clients should wear UV-blocking safety glasses while being evaluated in a SAM or PhotoSAM™. This is both to minimize the UV exposure to the eyes and to provide a mechanical barrier to glass fragments in case a UV tube shatters. We recommend the UVEX S1600 safety glasses or their equivalent.

If you leave the protective plastic shields on the UV lamps in your SAM, your clients can do without the safety glasses, but we recommend they close their eyes while they are in the SAM and not looking in the mirror at their faces.

4. DermaFlash asks that clients who are photosensitive for whatever reason not be exposed to the UV light of the SAM. The client should first get his physician's approval before being evaluated with a SAM.

Summary

Through careful measurement, comparison to established US guidelines and DermaFlash™ company policies, we've found that DermaFlash™ SAMs do not constitute a significant hazard due to UV radiation. See the technical details in the appendix to see how this was determined from experimental data.

We've also given some recommendations about using the SAM and things to tell your clients. Feel free to give a copy of this document to your clients.

Finally, should you have any questions or concerns about the safety of your SAM (or any technical questions), feel free to call us and talk to a member of the technical staff. Please visit the website http://www.dermaflash.com/ for contact details.

Appendix: Technical Details

In this appendix, we'll present the technical details of how DermaFlash calculates the risk associated with UV exposure in the SAM.

Some of this information is covered in more detail in the DermaFlash Technical Reference [5], available for purchase at http://www.dermaflash.com. If you have any questions, please contact DermaFlash to talk with a technical representative.

Measurement Methods

A fundamental tool for measuring UV, optical, and infrared radiation is a spectroradiometer, also (somewhat incorrectly) called a spectrophotometer. This instrument measures optical radiation power per unit area as a function of wavelength, sometimes called spectral irradiance. DermaFlash uses a spectroradiometer whose calibration is traceable to NIST for UV irradiance measurements. The absolute accuracy of the spectroradiometer is specified at ±5%, which includes both random and systematic variations. The spectroradiometer is connected to a cosine detector with a 1 m fiber optic cable.

Individual UV lamps are measured in a special test fixture that keeps the measurement geometry constant. In addition, the line voltage applied to the tube is regulated, as a 1% variation in line voltage leads to a 1% variation in irradiance.

When measuring irradiance in a SAM, a fixture is used to position the detector at the same location in the SAM. The detector position is approximately at the tip of the nose of a client using the SAM. This location is 10 inches (25.4 cm) from the plastic case of the SAM, is on a horizontal line from the center bottom of the magnifier glass, and intersects a line connecting the middle screws of the vertical strips of metal holding the light-blocking shroud.

Regulatory Guidelines

As stated in the main text, the FDA follows the guidelines of the American Conference of Governmental Industrial Hygienists (ACGIH). The exposure time t_{max} in seconds to reach the TLV® (threshold limit value; see reference [4]) is

$$t_{max} = \frac{30}{E_{eff}} \qquad (1)$$

where E_{eff} (in W/m^2) is the effective irradiance relative to a monochromatic source at 270 nm. For a broadband source of UV radiation, E_{eff} is calculated by the formula

$$E_{eff} = \sum_{180}^{400} E_\lambda S(\lambda) \Delta\lambda \qquad (2)$$

where

$$E_\lambda = \text{spectral irradiance in } W/(m^2 \cdot nm)$$
$$S(\lambda) = \text{relative spectral effectiveness (unitless)}$$
$$\Delta\lambda = \text{band width in nm}$$

The relative spectral effectiveness $S(\lambda)$ is given as a table of values in reference [4].

A computer program is used to perform the indicated summation. This is just a weighted sum of the measured spectrum values. Since our spectroradiometer measures the spectral irradiance every 0.5 nm, the computer program linearly interpolates within the relative spectral effectiveness table.

One note from reference [4] is that a person can receive the recommended TLV exposure in 5 minutes outside in the summer sun near noon at a latitude of 40 degrees and less.

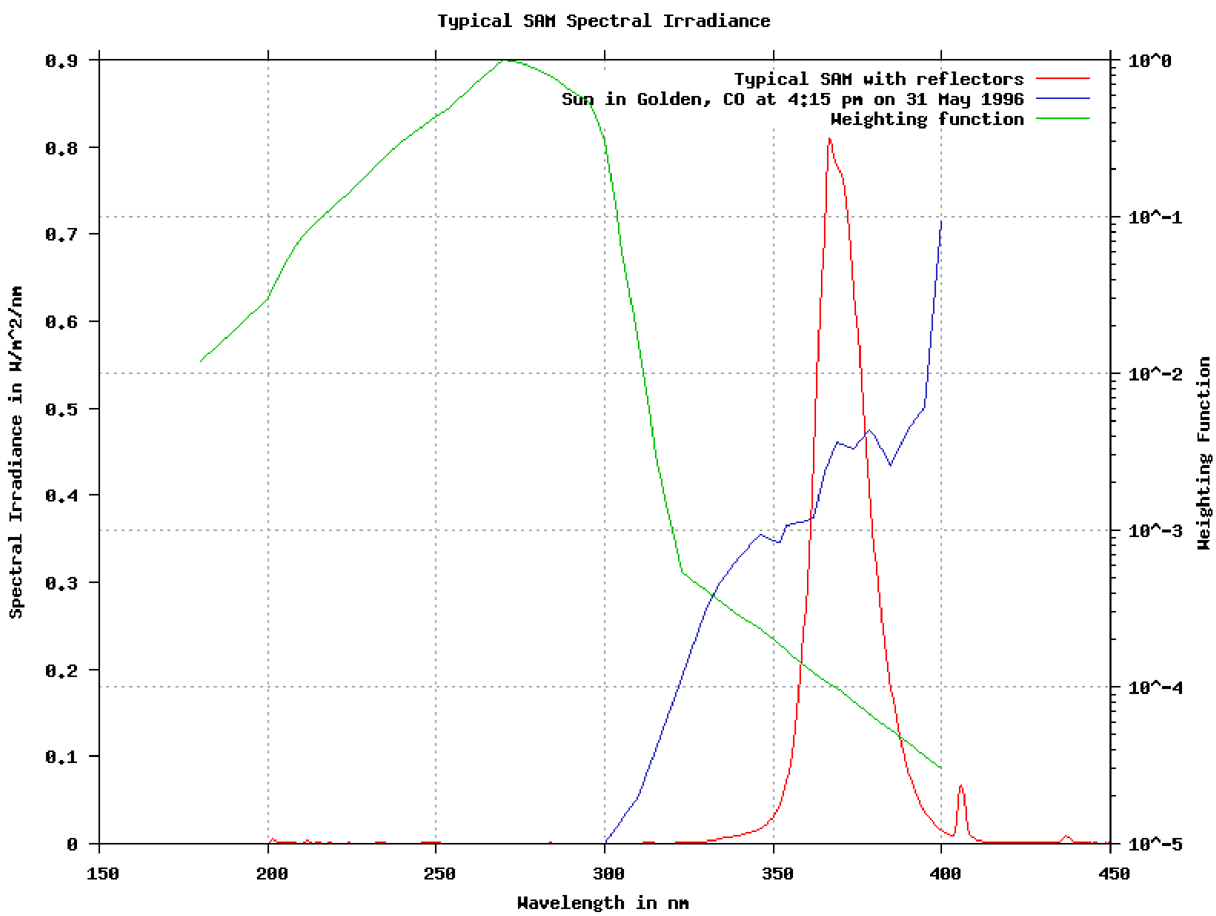
DermaFlash Guidelines

Reference [4] points out that the time to the threshold limit value of UV radiation exposure is not a fine line between a safe region to operate and one that is definitely hazardous. The limits are derived from literature data, clinical experience, and the collective judgement of numerous industrial hygienists. Their intent is to provide guidelines to allowed exposures for workers exposed to various hazards.

DermaFlash chooses to respect the ACGIH guidelines. To provide margin for process variations and measurement error, we've chosen to base our guidelines on **one half** of the t_{max} value calculated using the ACGIH methods.

Actual Data

Here's a typical SAM spectrum at the fixture position described above:



The integration time for the spectroradiometer was 50 ms and the number of spectra averaged was 10. Note this spectrum is for a SAM with the DermaFlash reflectors installed. The ACGIH weighting function is also plotted (it's defined from 180 nm to 400 nm).

The total UV power over the 180-400 nm band was 15.9 W. The calculated E_{eff} value over the same band is 0.02437 W/m^2. Thus, the time to the TLV® is

$$t_{max} = \frac{30\ J/m^2}{0.02437\ W/m^2} = 1231 \text{ seconds} = 20.52 \text{ minutes.}$$

Because of the strong weighting in the 180-300 nm region, the spectroradiometer's noise is "amplified" and contributes significantly to the E_{eff} value. If we just calculate E_{eff} over the 300-400 nm band, the value is 0.0056 W/m^2. If we used this value to get t_{max}, it would be four times as long. But we'll stick with the ACGIH recommended method, as it's more conservative.

The graph also includes a spectrum for the sun in Golden, CO (12 miles west of Denver) at 4:15 pm [6, page 19]. The total UV power over the 180-400 nm band was 37.1 W. The calculated E_{eff} value is 1.71 W/m^2, leading to

$$t_{max} = \frac{30\ J/m^2}{1.71\ W/m^2} = 17.5 \text{ seconds}$$

The large difference between these two times to the TLV® is caused by the large effect of the weighting function in calculating the effective irradiance, especially for the solar wavelengths near 300 nm.

Common sense would indicate that most of us could be out in the sun for longer than 17.5 seconds. This shows that the TLV values are conservative -- they're intended to address the situation of workers exposed to hazards day after day. If one ignored the ACGIH weighting factor and just used the ratio of UV irradiances = 37/16 = 2.3, we'd see that a DermaFlash exposure for 10 minutes is the same as 10/2.3 = 4.3 minutes in the sun at Golden, CO on the specified day and time. Few people would worry about spending 5 minutes in the summer sun.

DermaFlash's Recommendation

Because of the DermaFlash policy of using half the ACGIH time value, we thus get the DermaFlash-recommended daily limit of SAM UV exposure of 10 minutes. Based on this, we recommend no more than three 3-minute SAM sessions per day per client.

Note we do not claim a SAM session is safe -- one should understand that any UV exposure entails some risk. But that risk is less than standing out in the summer sun for the same time in the southern half of the US.

Most clients will only be examined in the SAM a few times -- not a daily exposure as is implicit in the ACGIH limits. Thus, we can see that the risk to a client from the SAM is very low.

References

[1] World Health Organization, "Global disease burden from solar ultraviolet radiation", July 2006, http://www.who.int/mediacentre/factsheets/fs305/en/index.html

[2] Leveson, N., et. al., "An Investigation of the Therac-25 Accidents", *IEEE Computer*, Vol. 26, No. 7, July 1993, pp. 18-41, http://courses.cs.vt.edu/~cs3604/lib/Therac_25/Therac_1.html.

[3] S. Miller (Laboratory Leader, Optical Radiation Safety and Devices, U.S. Food and Drug Administration), private communication with the author, April 2006.

[4] American Conference of Governmental Industrial Hygienists, "2006 TLVs® and BEIs®", Publication #0106, http://www.acgih.org/store/ProductDetail.cfm?id=1824. TLV® and BEI® are registered trademarks of the American Conference of Governmental Industrial Hygienists.

[5] Peterson, D., "The DermaFlash Technical Reference", DermaFlash, 2006. Can be purchased from http://www.dermaflash.com.

[6] DeCusatis, C., ed., "Handbook of Applied Photometry", Springer, 1998.