A GUIDE TO POLYCHROMATIC AND MONOCHROMATIC DIFFUSE REFLECTANCE SPECTROSCOPY FOR ANALYSIS OF SUNSCREEN PROTECTION FOR HUMAN SKIN

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INTRODUCTION

Diffuse reflectance spectroscopy is a technique used in the field of dermatology for assessing optical properties of skin and drugs or topical ingredients applied to the skin. It can measure skin proliferation, photodamage that has occurred to the skin, blood content, and even diagnose certain skin cancers. Evaluation of sunscreen protection on human skin using diffuse reflectance spectroscopy was initially limited to the UVA portion of the spectrum, but recently a technique was devised that allows for determination of ultraviolet (UV) protection across the entire solar UV spectrum (290-400nm). This technique named "Hybrid Diffuse Reflectance Spectroscopy*" (HDRS) provides a fast and simple assessment of sunscreen protection *in vivo* that could replace extensive sunburning and damaging exposures to human test subjects as currently mandated by regulatory bodies across the globe. This guide provides the background, theory, and techniques of HDRS measurement methods for assessing sunscreen product protection.

BACKGROUND

How to Assess the Protection Provided by Topical Sunscreens?

Historically, the assessment of sunscreen protection has been accomplished by using human subjects and exposing them to enough UV radiation to cause a visible sunburn (erythema) reaction on their skin. Testing was initially conducted outdoors with actual sunlight, and the exposure doses were measured to determine the amount of exposure required without a sunscreen on the skin compared to the exposure required with a sunscreen on the skin, and the ratio of the two values was called "P" or Protection Factor, later Sun Protection Factor (SPF). Outdoor testing of sunscreen efficacy is difficult at best due to unpredictability of weather conditions and differences introduced by changing UV spectral distribution and quantity varying by the hour, season, and atmospheric conditions. Dr. Blum[1] was the first to report sunscreen testing in a laboratory with various UV sources, and after many observations of the test results stated:

* While the technique is known as diffuse reflectance spectroscopy, the measurements are obtained from incident light directed towards sunscreen that is applied to the surface of the skin by optical fibers. The light that passes through the sunscreen is diffused within the skin. A small portion of this diffused light is reflected back out of the skin through the sunscreen a second time (remitted) and collected by optical fibers.

"The actual evaluation of the protection afforded by a given sunburn preventive under controlled laboratory conditions, is beset with difficulty and great accuracy is not to be expected. Even with the best of laboratory measurements, it is difficult to estimate in more than a general way, the appropriateness of the protection afforded by a given sunburn preventive to the need of a particular condition of exposure to sunlight. All these factors permit claims to be made which, while not actually false, may be quite misleading to the user of a sunburn preventive."

Solar Simulator for Laboratory SPF testing

Invention of the modern solar UV simulator[2] and a UV sensor radiometer[3] that had the same response to sunburning UV radiation on skin by Daniel Berger, founder of Solar Light Company, gave the means to conduct repeatable sunscreen SPF testing in the laboratory. The FDA provided the first codified procedure to measure sunscreen SPF using these devices in 1978. Berger later engineered a Multiport® solar simulator with 6 output beams that has become the standard solar simulator around the globe for testing high SPF sunscreens.

Alternative Methodologies

Human testing of sunscreens with high sunburning doses of simulated sunlight to assess the protectiveness of sunscreens using sunburning UV exposures has been adopted globally as the current "gold standard" for product SPF labeling. The procedures to determine the SPF values are difficult, time consuming, and harmful to the human subjects, and manufacturers of sunscreen products have struggled for decades to come up with predictive alternative *in vitro* procedures to guide formulation development and qualify final product efficacy claims. Standard dilute solution spectroscopy[4] grossly overestimated efficacy as it does not consider any of the critical factors of film formation and uniformity on human skin. Thin film spectroscopy using various substrates has also proven to be unreliable[5] primarily due to variation in application by human operators, and the unpredictability of the interaction between sunscreen formulation ingredients and the surface of the numerous substrates considered for testing[6]. Replacing human operators with robots to provide consistent applications has improved the repeatability of applications, however the variability between the *in vitro*

spectroscopic SPF predictions and *in vivo* test results remains high[7], and are currently limited to emulsion-based products, without any validation of water resistance properties on the plastic plate substrate.

DRS & HDRS TECHNOLOGY EVALUATIONS OF SUNSCREENS – A SOLUTION TO SUNSCREEN EFFICACY TESTING

UVA-PF Testing Method Development

Research initiated by Drs. Nikoforos Kollias and Robert Gilles at Mass General Hospital led to the first adaption of DRS equipment for sunscreen efficacy testing. Dr. Kollias's DRS equipment was initially used as a skin spectrofluorimetry to assess skin properties such as proliferation status, the extent of collagen and elastin cross-linking, skin cancers, and other UV induced phenomena [8, 9, 10,11,12 ,13 ,14]. Diffuse reflectance spectrofluorimetry involves excitation of chromophores in the skin using one wavelength of light, while monitoring the fluorescence at a different (higher) wavelength. This is typically done by scanning a range of excitation wavelengths while measuring at a fixed wavelength, or conversely if the excitation wavelength is known, by scanning a range of (longer) wavelengths to determine the fluorescence range.

Much research was being conducted during the late 1990's and early 2000's to establish reliable methods to assess the protection of sunscreens in the UVA range, both *in vitro* and *in vivo*. Researchers at L'Oreal collaborated with Drs. Kollias and Gilles to adapt the diffuse reflectance spectrofluorimeter equipment to assess the absorption properties of sunscreens applied to the skin[15]. This was accomplished by synchronizing the two monochromators and comparing the signal remitted from the skin, first without the sunscreen and then with the sunscreen on the skin. The square root of the ratio is the apparent transmission of the sunscreen at the wavelength being evaluated. (Eqn 1a.)

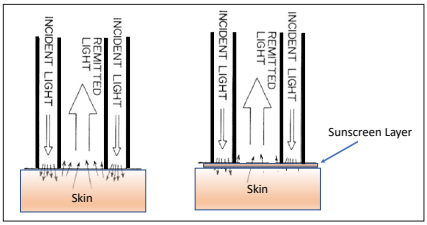

Figure 1. Fiber optic probe demonstrating the principle of diffuse reflectance spectroscopy with and without sunscreen applied to the skin. (adapted from Kollias et al, 1986[16])

$$T(\lambda) = \sqrt{((I_0(\lambda))/(I_r(\lambda)))} \quad \textbf{(1a.)} \qquad A(\lambda) = -\log T(\lambda) \quad \textbf{(1b.)}$$

WHERE: **T(λ)** is the transmission at a given wavelength λ

I_0 **(λ)** is the remitted light at wavelength λ with no sunscreen on skin

I_r **(λ)** is the remitted light at wavelength λ with sunscreen on the skin

A(λ) is the apparent absorbance of the sunscreen on the skin

This technique was used to assess the photostability of sunscreens applied to human skin and then exposed to UV light[17]. Further work was conducted to equate the absolute Ultraviolet A protection factor (UVA-PF) that can be calculated using the DRS UVA absorption spectra with *in vivo* evaluations of sunscreens[18]. The ISO24443 *in vitro* test method for determination of UVA protection of sunscreens was published in 2012 and provided most of the industries needs for determining UVA-PF values of marketed sunscreen products as required for broad spectrum protection claims, and little work was done to further develop DRS methodology for UVA-PF determinations. The ISO24443 UVA-PF method still required input of the known *in vivo* SPF value of the sunscreen. Meanwhile, the need for a non-invasive (non-sunburning) alternative method to determine SPF values of sunscreens became more pressing with increasing testing demands and concerns for test subjects.

Monochromatic Diffuse Reflectance Spectroscopy – A Full Spectrum Solution

In vitro thin film spectroscopy has proven invaluable in providing the shape of full spectrum absorption scans of sunscreens on poly(methyl methacrylate) plates (PMMA), however, determination of the absolute scale of absorbance of these scans has proven to be a difficult task[5] due to differences in operator spreading and the differences in surface interactions between various sunscreen formulations with the PMMA plates affecting film integrity and consistency. Using human skin as the substrate for the sunscreen overcomes this later limitation. There remains a primary limitation to DRS in the evaluation of sunscreen absorption on skin in its ability to measure remitted light in the UVB range due to the skin's reluctance to remit energy at wavelengths below around 320nm. Proteins, DNA, and melanin all absorb ultraviolet B radiation (UVB) very strongly, so that few incident UVB photons are remitted from the

skin for measurement. This is further complicated by the fact that absorption is doubled due to passing through the sunscreen layer during DRS measurements. Thus, spectroscopy of sunscreen on the surface of the skin is limited to evaluations in the UVA range 320-400nm.

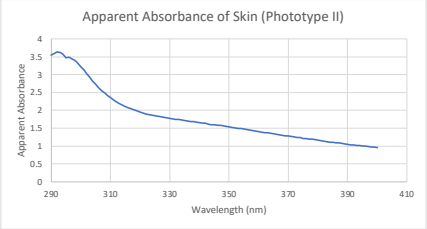

Figure 2. Skin apparent absorbance as measured with a monochromatic DRS device.

Ruvolo, Kollias and Cole[18] developed a method to overcome this limitation by taking the absorbance values from an *in vitro* absorbance scan of a sunscreen and grafting the shape of the UVB absorbance values onto the absorbance values of the sunscreen spectrum as measured with DRS equipment, resulting in a "hybrid" *in vivo-in vitro* assessment of the absorption properties of the sunscreen on human skin.

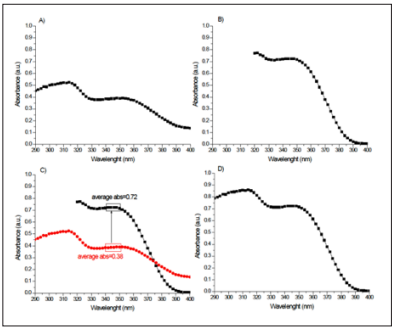

Figure 3. A) represents the in vitro scan of the sunscreen absorbance on a PMMA plate 290-400nm, showing the correct spectral shape over the entire range. B) shows the spectrum with the correct shape and absolute amplitude as measured by DRS across the UVA spectrum 320-400nm. C) the spectra are normalized in this example at 345nm by multiplying each wavelength of the in vitro spectrum by the factor 0.72/0.38, and the UVB section of the in vitro measurement is then grafted or "mended" onto the end of the DRS spectrum to provide the missing portion of the DRS spectrum. D) shows the completed hybrid spectrum which can be used to calculate SPF, UVA-PF, Critical Wavelength (CW), and UVA1/UV ratios. Excellent correlation was demonstrated between the hybrid diffuse reflectance measurements and in vivo SPF measurements for 15 sunscreens. Adapted from From Ruvolo et al, (18)

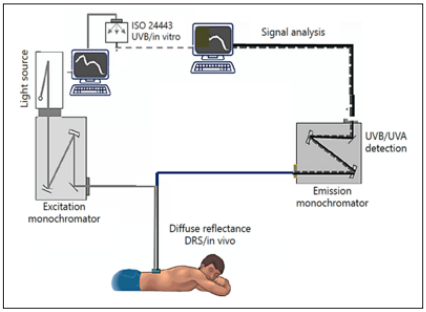

Figure 4. Schematic depiction of the monochromatic DRS technique for measurement of sunscreen efficacy on human subjects. DRS measurements are made on skin with no sunscreen applied, and again with sunscreen applied, and the absorbance of the sunscreen is calculated as the square root of the ratio of the two measurements as a function of wavelength (320-400nm). A separate in vitro full spectrum scan of the sunscreen (using ISO24443) is then scaled to match the DRS spectrum in the UVA portion of the spectrum, and the UVB portion is then "mended" onto the DRS spectrum for an absolute magnitude full spectral scan 290-400nm. Adapted from Rohr et al, (20).

To account for sunscreens that degrade during UV exposure, compensation must be made to account for this loss of protection during sunlight exposure. Adopting the UV exposure challenge procedure from ISO24443, the post-irradiated spectrum from the *in vitro* PMMA plate measurement is compared with the pre-irradiated spectrum to determine the extent of the photodegradation for each specific sunscreen, and the un-irradiated DRS spectrum is adjusted by the degradation absorbance losses (Scalar Ratio of Photodegradation – SRPD(λ)) at each specific wavelength. The post-irradiation UVB *in vitro* spectrum is used for the final "mended" hybrid spectrum after scaling the photodegradation adjusted DRS spectrum[19].

Rohr et al[20] reported on assessment of 80 sunscreen products of all forms (emulsions, sprays, sticks, gels) ,and UV filter combinations up to SPF values over 100, showing a high degree of correlation between HDRS measurements and *in vivo* SPF results conducted at their laboratory. These data showed the dramatic impact of photostability plays in the final SPF values, changing the r^2 correlation factor from 0.483 to 0.973 when accounting for the photostability of the products using the SRPD (λ) correction described above. Moreover, the slope of the correlation changed from 1.27 (over prediction of SPF) to 1.05 after adjustment for

photodegradation.

Measurements using the monochromatic DRS protocol expose the skin to very low doses of UV radiation, and can be conducted without any exposure to UVB wavelengths. The intensity of the Solar Light Monochromatic DRS devices are on the order of 0.3 mW/cm^2 at any wavelength with a total accumulated dose of 0.1 mJ/cm^2 UVA, and less than 0.05% of an Standard Erythemal Dose (SED)[21]. This is the equivalent of about less than 1 second of exposure to outdoor summer sunlight at noon.

The UV challenge for photodegradation of the sunscreen samples is conducted on the PMMA plates *in vitro*, eliminating the need to expose the sunscreen while on human skin.

DRS spectroscopy solves the problem of sunscreen interaction with the substrate that occurs with PMMA plastic plates as the substrate is actual human skin. Thus, all types of sunscreen forms (emulsions, sticks, powders, spray products) are interacting during the test as they would during actual product use on consumer skin.

Another advantage of DRS methodology is that testing can also be conducted on human skin as challenged by water immersion, sweating, and sand and towel resistance. Such a test was reported evaluating the persistence of sunscreen samples on skin after extensive exercise and sweating[22].

Polychromatic DRS – A Novel Simplification of DRS Methodology

While developing plans for a compact monochromatic DRS device for Solar Light, Dr. Curtis Cole, (a consultant to Solar Light) came to the realization that HDRS evaluation of sunscreens could also be accomplished without the need for two, or even one monochromator. By using a light source with a spectrum identical to the UVA source employed for *in vivo* UVA-PF clinical protocols, together with a detector system with a response spectrum similar to the skin's Persistent Pigment Darkening (PPD) action spectrum, a direct measure of UVA-PF values could be accomplished without the need for a light dispersive element. This estimate of the UVA-PF could then be used to scale a full *in vitro* absorbance scan from which SPF, as well as Critical Wavelength and other assessments could be calculated. Working with scientists and engineers at Solar Light a prototype was developed and tested with a set of sunscreen samples[23].

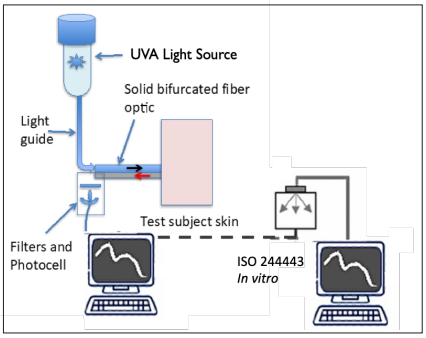

Figure 5. Schematic depiction of polychromatic DRS system for direct measurement of UVA-PF values of sunscreen on human skin. The UVA-PF values are used to scale a full spectrum in vitro absorbance scan of the sunscreen, from which estimates of SPF, and CW can be calculated. Correlations between DRS determined SPFs and UVA-PFs with in vivo results were very strong with slopes close to 1, indicating a 1:1 correspondence between the results. Adapted from Cole et al, (23).

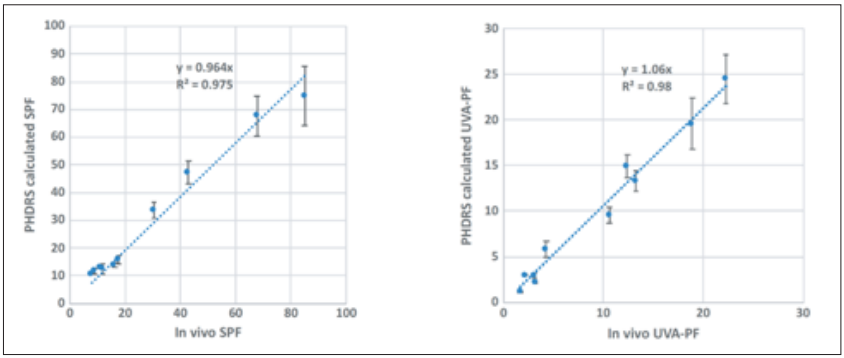

Figure 6. Correlations of SPF and UVA-PFs as determined by PHDRS device and in vivo SPF or UVA-PF (ISO24443) results.

Advantages of the polychromatic DRS approach vs monochromatic include simplified equipment design and construction eliminating both the emitting and detecting monochromators and associated software and a much faster data acquisition time. Evaluation of a single test subsite can be accomplished within a 2-3 second touch of the fiber optic probe to the subsite, as compared with a 30 -120 second scan time for a monochromatic scan of a single test subsite. This allows for making more measurements within the same (or shorter) time frame for a given test site. The polychromatic approach utilizes the *in vitro* scan shape scaled by the polychromatic UVA-PF value in place of the DRS UVA absorbance scan. Computations and compensation for photodegradation after that are virtually identical to the monochromatic HDRS computations.

DEVELOPMENT OF AN ISO STANDARD FOR HDRS EVALUATION OF SUNSCREENS

With the preliminary success of both monochromatic and polychromatic devices in assessing sunscreen efficacy and the growing urgency to find alternative methods to invasive *in vivo* human clinical testing, HDRS was proposed to be developed as an ISO standard method. To qualify for consideration as an ISO method, data from a multicenter trial was requested to provide ample confidence of success before acceptance as a New Work Item.

Multi-Laboratory Studies of Proposed HDRS Test Methodology

A multi-laboratory (4) ring test[24] was organized to assess 25 sunscreen samples using HDRS techniques. Samples consisted of 23 emulsion products, and 2 spray products. The test samples contained a wide variety of viscosities and UV filters and combinations thereof, including only organic UV filters, only inorganic filters, and combinations of the two. SPFs ranged from 7 to 66, with UVA-PFs ranging from 1.2 to 28. Three monochromatic DRS devices, and one polychromatic DRS device participated in the testing, with clinical test locations in Europe, South America, and North America. Test results showed good consistency of results between the four laboratories, and between the monochromatic DRS and polychromatic DRS data.

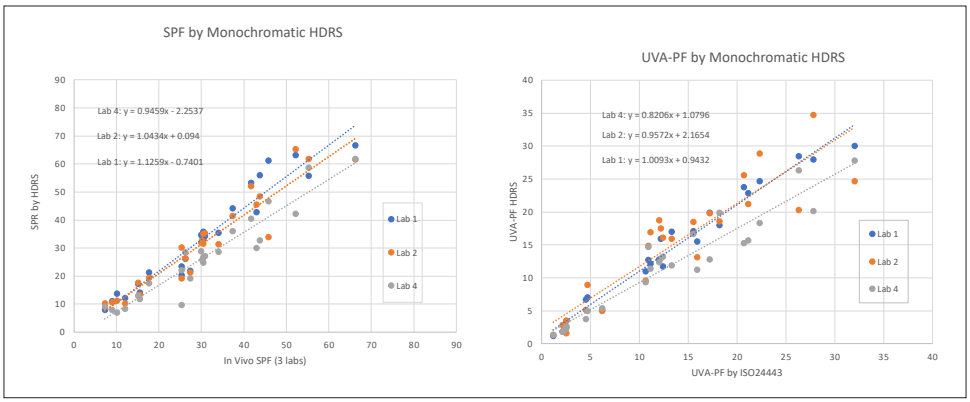

Figure 7. Results from the three monochromatic DRS devices for the 25 test samples for SPF and UVA-PF compared with in vivo SPF and both in vivo and in vitro UVA-PF (ISO 24443) results.

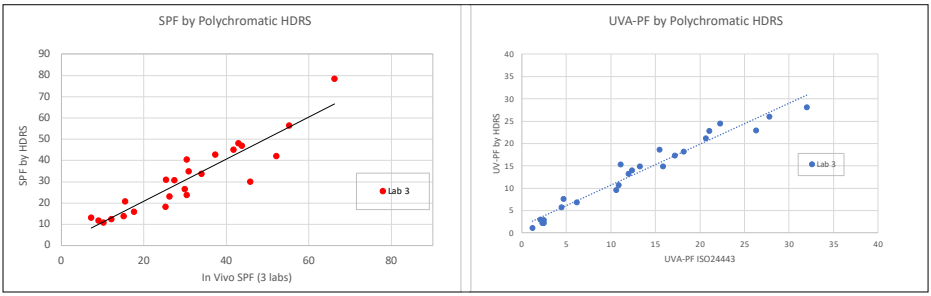

Figure 8. Results from the polychromatic DRS device for the 25 test samples for SPF and UVA-PF compared with in vivo and in vitro UVA-PF (ISO24443) results.

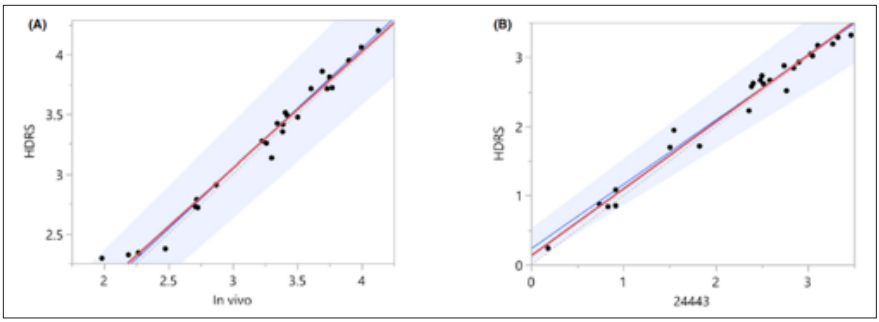

Figure 9. Passing-Bablok plots combining results of all 4 laboratories for SPF (A), and UVA-PF (ISO24443) (B). The blue bands depict the 95% confidence interval for the regression. Note the data are presented in the ln transformed domain as the data are log-normally distributed.

While regression analysis can provide a good impression of the similarity between two measures (HDRS and *in vivo* results), it has been proven to be less than ideal in confirming equivalence of two measures. Regression analysis and dependence on the correlation coefficient to indicate the goodness of the relationship between two measures can be heavily influenced by certain data values having a long moment arm. Bland-Altman[25, 26], devised an analysis which assesses the limits of agreement between two measures across the entire range of values, without the heavier weighting factors for higher values, and assesses overall bias between the two measures. It has become the preferred analysis for the biomedical field to demonstrate bioequivalence of two independent measures. Applying the Bland-Altman analysis to the SPF data comparing HDRS values

compared with *in vivo* determined SPF values (in ln transformed domain), we can find the limits of agreement of the two test methods.

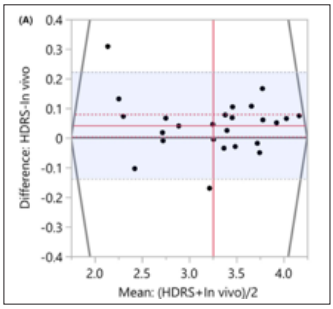

Figure 10. Bland-Altman analysis of SPF data determined via HDRS methods and in vivo clinical SPF evaluations. The analysis shows a slight bias in favor of HDRS results of +4% vs in vivo SPF, and the 95% range of agreement between the two methods of -14% to + 20% over the entire range of values from SPF 7 to SPF 66.

Based on these successful results, HDRS methodology was accepted as a New Work Item for development as ISO23698 in 2018.

Current Status HDRS Test Methodology

As of 2022, HDRS test methodology for sunscreen protection analysis has been recommended by Cosmetics Europe (CE) to be considered as alternative methods to ISO24444.

"Considering that correct use of these two methods (in vitro "double plate" method and HDRS method) requires adequate training and experience, we strongly recommend that CE members (and the test laboratories with whom they work) familiarize themselves with them as soon as possible so that, prior to the publication of the final ISO standards, they may be considered as alternative SPF tests to ISO24444:2019.

However, until such time that these two methods are published as final ISO standards, in the event of discrepancies in results with ISO24444:2019, the latter should continue to be considered as the gold standard."

A large-scale multi-center validation study is being conducted by the Alt-SPF Consortium 2022-2023 comparing alternative methods (including monochromatic and polychromatic HDRS instrumentation) with ISO24444(2019) *in vivo* SPF testing (see https://www.alt-spf.com). ISOTC217-WG7 has compiled a comprehensive set of acceptance criteria that must be met for validation of ISO23698 (HDRS).

Meanwhile, the CE recommendation N^{0} 26 has published the details of both methods so that laboratories and manufacturers can begin to utilize these alternative methods prior to completion of the validation of ISO 23698 or ISO 23695. Local regulations apply for use of the results of these alternative SPF test methods prior to acceptance by local authorities of pending ISO Standard Method Publications. It is prudent for test laboratories to obtain necessary equipment for such alternative methods and become familiar with the protocols and computations required prior to the finalization of the ISO standards, and to utilize these alternative methods as screening tools for ongoing *in vivo* testing.

SUMMARY

HDRS evaluation of sunscreens has advantages over other alternative methods in that it can be utilized on all sunscreen product forms as it uses real human skin and thus can be relied upon to provide the best predicted performance of the extremely large number of product formulations on human skin. It can also be utilized to evaluate the water resistance, sweat resistance, or sand resistance of a given product that cannot be shown with other test substrates. Thus, HDRS methodology can be used to assess full protection performance of sunscreen formulations for both SPF and UVA-PF in one test protocol. This can all be accomplished without skin damaging UV exposures and within a few seconds for data acquisition. Instead of a three-day test protocol with subjects having to return multiple times to the laboratory, a single short test period can provide test results for multiple products for a given test subject. HDRS can be predicted to replace all conventional invasive SPF and UVA-PF clinical test procedures within the decade.

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ABOUT SOLAR LIGHT COMPANY, LLC

Measuring the effectiveness of sunscreen products against sunburn is of critical importance throughout the world.

With over 50 years of proven know-how and support for SPF test and measurement, Solar Light Company, LLC is the leading supplier of dedicated SPF test and measurement solutions and services.

Our global partners use our products to ensure product quality and accelerate time-to-market for crucial sun protection products vital to human health.

IN VITRO SUNSCREEN PROTECTION FACTOR ANALYZERS

In vitro SPF Analyzers by Solar Light Company, LLC are fully-automated turnkey solution for quick, efficient, and accurate UV transmittance analysis of creams, gels, lotions, powders, sprays and other SPF and cosmetic delivery systems.

NON-INVASIVE SUNSCREEN PROTECTION FACTOR SYSTEMS

Polychromatic and Monochromatic DRS Systems from Solar Light Company, LLC provide results in less than a minute for SPF>50 on all skin types. Hybrid DRS (HDRS) software to manage instruments, resources and SOPS for clinical trials management and formulation development to secure your workflows to ensure reliable data and quality results.

IN VIVO SUNSCREEN PROTECTION FACTOR SIMULATORS

In vivo Solar Simulators by Solar Light Company, LLC, relied upon by over 95% of the the world's SPF testing laboratories for their unparalleled quality, accuracy, and reliability, are the gold standard simulators for *in vivo* SPF testing.

STANDARDS AND COMPLIANCE

SPF solutions by Solar Light Company, LLC comply with the most current regulatory guidelines. Methods and protocols that integrate certified reference standards and IQ/OQ procedures to achieve repeatable and predictive results. NIST-traceable standards, sensors and spectroradiometers are used for performance verification.

PRE-IRRADIATION SIMULATION

Pre-irradiation Solar Simulators by Solar Light Company, LLC are specifically designed for the pre-irradiation step during *in vitro* SPF testing. These simulators produce solar UV radiation in the 290-400nm range, easily configured by the user to provide UVA or UVB only, UVA+B, or full spectrum sunlight.

SOLAR®
LIGHT

SPF SOLUTIONS FOR TODAY...

For over 50 years, Solar Light Company, LLC's suite of test and measurement solutions have been relied upon by the world's SPF testing laboratories for their unparalleled quality, accuracy, and reliability to measure sun protection products.

...AND SPF SOLUTIONS FOR TOMORROW

We will continue to support you with our current products and new capabilities to meet future regulatory requirements that transform productivity to accelerate time-to-market for crucial sun protection products vital to human health.

- VALIDATION & COMPLIANCE
- PRE-IRRADIATION SOLAR SIMULATORS
- IN VITRO SPF ANALYZERS
- IN VIVO SPF SOLAR SIMULATORS
- NON-INVASIVE SPF SYSTEMS

100 East Glenside Avenue, Glenside, PA 19038 USA
(215) 517-8700 | SolarLight.com | HDRS@SolarLight.com