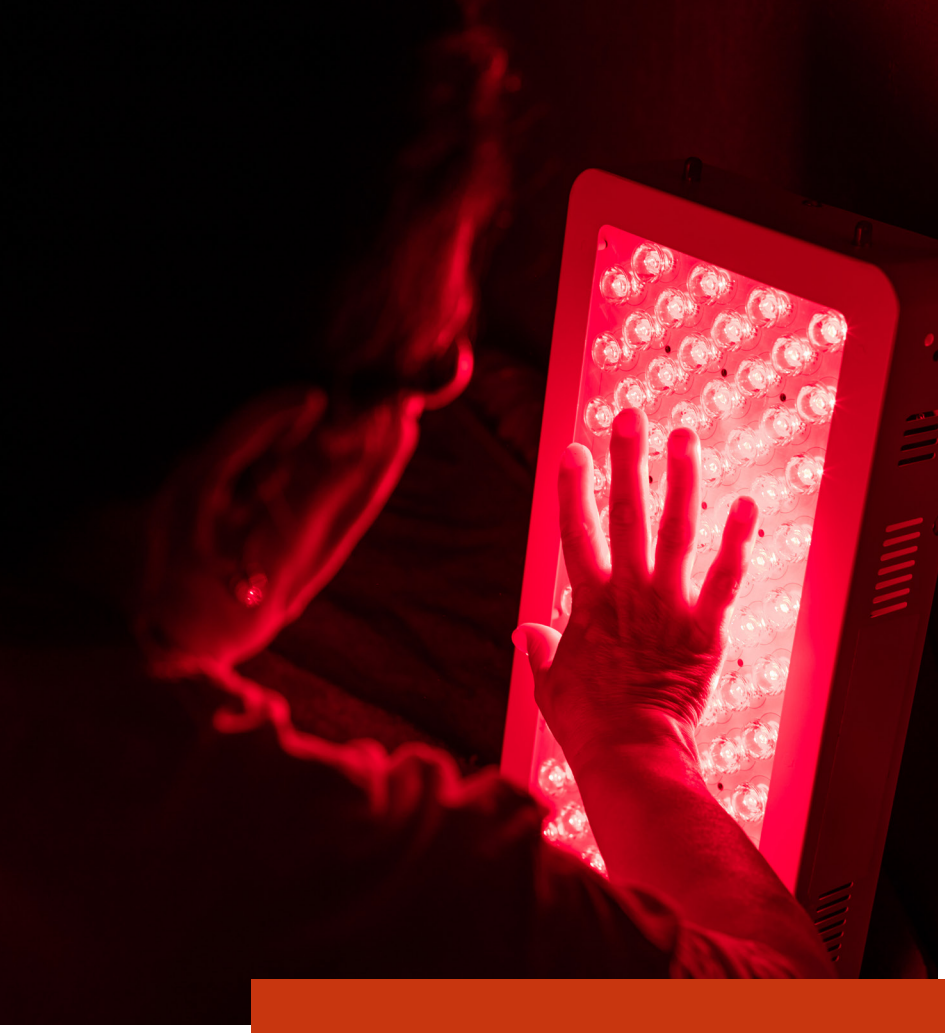

PBM FOUNDATION
PHOTOBIOMODULATION HEALS

PBM Foundation Certification Policy

OBJECTIVES & GOALS

To elevate the field of photobiomodulation by building a pathway for the standardization of the measurement and reporting of photobiomodulation (PBM) device parameters, encouraging consumer safety testing, promoting investment and innovation while discouraging research theft.

Our objective is to launch a certification program to build a public database of certified photobiomodulation vendors, that are accurate in their declaration of LED parameter values and are safe for use.

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PBM DEVICE MEASURING AND REPORTING STANDARDIZATION

Currently, the lack of regulation in the measuring and reporting of photobiomodulation (PBM) device parameters by manufacturers poses a significant issue for both consumers and researchers. Frequently, the declared parameters are often derived from incorrect methodologies and are overstated.

The current situation poses challenges for both researchers and consumers. Researchers depend on precise device specification reporting to select parameters for research and to ensure that grant funds are not squandered. Likewise, consumers rely on accurate manufacturer specification reporting to make informed choices.

The PBM Foundation has partnered with Optronics Lab and Megalab Group Inc., a specialist in spectroscopic measurement services and equipment, to perform LED spectral profile measurements, based on relevant parameters and accurate methodology.

The goals are to establish consistent LED parameter testing protocols, rigorous methodology and transparent reporting.

PBM DEVICE SAFETY AND TESTING

Another problem faced by this industry is the lack of safety testing by photobiomodulation devices that are introduced to the market.

Given that PBM devices are electronic in nature, there is the risk of malfunction or unwanted emissions.

To qualify for certification, non-medical PBM devices must be tested and certified safe by independent bodies such as TUV, SGS, Megalab, etc. All safety tests must be done in accordance with the same standards (EN 55032:2015, EN 55035:2017, ETSI EN 301 489-1 v2.2.3, ETSI EN 301 489-17 v3.2.2 EN62368-1:2014, IEC 62471:2006)

PROMOTING INNOVATION AND INVESTMENT

The photobiomodulation industry requires investment and innovation to grow. The PBM Foundation will only certify vendors that have invested in their own product development.

To be certified, a vendor must have developed their own product from the ground up to discourage private labeling from mass-production manufacturers. The device's form factor and technology must be unique to them and not share almost identical form factor traits and technology with other devices on the market, from the same manufacturer.

THE PHOTOBIOMODULATION INDUSTRY REQUIRES INVESTMENT AND INNOVATION TO GROW.

DISCOURAGING RESEARCH THEFT AND MISINFORMATION

The parameters used in photobiomodulation research can vary greatly, depending on wavelength, power density, form factor, areas targeted etc. It is misleading and inaccurate to generalize all forms of photobiomodulation as the same, given that the parameters used to achieve these results can vary greatly, depending on the device or technology used during research.

Currently, some companies are engaged in "research theft," where photobiomodulation research conducted by other organizations are alluded to being accomplishable by their device, even though the parameters are different. To make matters worse, these companies often allude to disease states without any proof with their technology.

It is not fair on companies or organizations that have invested in their own research, to have other companies or organizations allude to non-associated research as attributable to their own device, when that is not true. To encourage more research investment and discovery in this field, the fact that parameters and form factors used can greatly influence outcomes should be made clear.

To discourage this form of misinformation, we are encouraging standards by categorizing companies engaged in research theft on the PBM Foundation's website.

GOALS OVERVIEW

Standardization and certification in the photobiomodulation industry, particularly when it comes to safety and testing the spectral profiles of LED devices for declared parameters, is crucial for several reasons:

CREDIBILITY:

Standardized testing methods and parameters help establish credibility within the industry. When manufacturers and researchers adhere to common testing standards, it becomes easier to trust and compare the results of different products and studies.

CONSISTENCY:

Standardization ensures that measurements and data collection are consistent across different devices and laboratories. This consistency is essential for making meaningful comparisons and drawing accurate conclusions about the efficacy and safety of LED devices.

CONSUMER PROTECTION:

Standardization helps protect consumer interests. When consumers purchase photobiomodulation devices, they rely on the declared parameters to make informed decisions. If the testing methods are standardized, consumers can have confidence that the product's specifications are accurate and reliable.

CONSUMER SAFETY:

Devices that have been certified by the PBM Foundation will either be medical devices or certified as safe according to EN 55032:2015, EN 55035:2017, ETSI EN 301 489-1 v2.2.3, ETSI EN 301 489-17 v3.2.2 EN62368-1:2014, IEC 62471:2006 standards.

PREVENTING RESEARCH THEFT AND MISINFORMATION:

The discouragement of research theft and misinformation will protect consumers.

RESEARCH ADVANCEMENT:

As companies are encouraged to conduct their own research to convey device efficacy, this would help published research in this field advance. Additionally, standardized LED power density testing can help researchers better understand the technology they work with.

Ultimately, standardization not only benefits the industry itself but also the consumers who rely on the products and the researchers working to expand our understanding of photobiomodulation's potential benefits.

BENEFITS OF PBM FOUNDATION CERTIFICATION

MANUFACTURER:

- You will be able to display our PBM CERTIFIED LOGO on your product, website, marketing materials, and media.
- Your customers will be able to display our PBM CERTIFIED LOGO for your device in their facilities, and on their websites, marketing materials, and media.
- Your device will be listed as CERTIFIED on the PBM website, which averages 200 daily visits.
- PBM Foundation will announce your device's certification on our social media platforms, which average 100,000 views.
- PBM Foundation surrogate speakers will mention your device when referencing Certification.
- The PBM Foundation team stands ready to advise you on how to maximize your certification.

MEDICAL PROFESSIONALS & HEALTHCARE CENTERS:

- You will be able to display our PBM CERTIFIED LOGO in your facilities, and on your websites, marketing materials, and media.
- The PBM Foundation team stands ready to advise you on how to maximize your certification.

RESEARCHERS:

- You will be able to cite the PBM Certification in your study documentation. This provides a credible independent validation of your device's dosage.

TESTING AND EVALUATION

The testing will be performed by Optronics Lab and Megalab Group Inc.,using an OL 770VIS/NIR High-Speed Multi-Channel Spectroradiometer equipped with an ND filter wheel and an IS-1 1 inch integrating sphere, equipped with a 1.0mm aperture. The system will be calibrated with a NIST traceable 1000-watt lamp standard of Spectral Irradiance.

Measurement tests will be performed in accordance to how the device is meant to be operated, based on the instructional manual. The measurement tests will accurately simulate what an end user will receive from a surface power density (mW/cm^2) and wavelength (nm) perspective.

At present, the two tested characteristics for photobiomodulation device measurements are wavelength and power density, otherwise known as irradiance.

- Wavelength (nm) on the electromagnetic spectrum determines the penetration and therapeutic effect.
- Surface power density or irradiance (mW/cm2) determines the intensity or concentration of light energy that lands on a surface area of biological tissue. This in turn determines the depth of penetration and dosage within the tissue area.

Wavelength accuracy is an important variable, as the biological effect is dependent on the type of wavelength.

We consider surface power density and not power density. Despite sharing the same unit of measurement (mW/cm^2), surface power density is superior because it considers form factor variables – which might add distance or additional resistance, which can vary greatly between devices.

In our certification process, we give significant consideration to surface power density, as it can only be increased through advancing LED technology and optimized form factors, without generating heat. As an illustration, in the context of brain photobiomodulation, a high surface power density is crucial to achieve the necessary intensity for penetrating through the scalp and skull.

Surface power density is more important than total power (W). Total power can be increased by using many weak, generic LED diodes to reach a high value, given that each tiny power can contribute to the total sum. In the context of dosage, increasing the time can also lead to a higher dosage vs total power.

CERTIFICATION PROCESS

1. Contact us to initiate the certification process
2. Provide us with the requested documents (safety, product development)
3. Send your device for measurement testing to Optronics Labs and Megalab Group Inc.
4. Make the necessary changes under the following section in “Standards”
5. Pay the requested certification fee

STANDARDS

To maintain PBM Foundation Certification, devices must meet and abide by these standards.

- Refrain from engaging in research theft. Certified vendors must not misrepresent research from other research organizations, if the research did not utilize their device. If a company wishes to discuss or highlight published research from other organizations on their public-facing platforms, a clear disclaimer must be visible at the top of website pages or at the bottom of social media posts. (“This study was not performed with our device(s). The parameters and form factor are different, which will influence the outcome with our device(s).”)