PBM FOUNDATION
PHOTOBIOMODULATION HEALS

pbmfoundation.org
304.716.6235 | scot@pbmfoundation.org

164 University Drive
Shepherdstown, WV 25443

DEVICE TESTING PROTOCOL

1 OBJECTIVES

First, to recommend and follow a set of standard operating procedures (SOPs) for the test environment. These SOPs may be adjusted subsequent to the experiences encountered during the pilot. Conduct a pilot study determining if device accurately delivers the dose of Photobiomodulation (PBM) light as claimed by Participating Manufacturer (e.g. marketing, regulatory, website). This includes measuring wavelength, beam divergence, and intensity mW/cm^2 (milliWatts per centimeter squared). This also includes determining if device consistently delivers claimed dosage after repeated use (see item 3.8).

2 TESTING ENVIRONMENT

2.0 Have trained professionals to properly take the measurements and interpret the results.

2.1 Keep the testing equipment calibrated.

2.2 Use industry-standard test methods for repeatability.

2.3 Take measurements in a proper environment controlling stray/ambient light.

2.4 Establish and following standard operating procedures (SOPs).

3 DEVICE TESTING

3.0 Participating Manufacturer will deliver five (5) identical devices to testing site.

3.1 Device packaging will be identical to how device is shipped to customers.

3.2 Upon arrival at testing site, each packaged device will be brought into testing room.

3.3 Devices will only be unpacked in testing room with personnel following operating procedures.

3.4 Devices will only be stored in testing room or other area that complies with SOPs; Movement and access to device will only be done by personnel following SOPs.

3 DEVICE TESTING CONTINUED

3.5 Each device will be tested to determine wavelength, beam divergence, and intensity.

3.6 Each device will be turned on a minimum of 10 times in the method and duration described in Participating Manufacturer's user guide or operating manual.

3.7 Within each device set, two stress tests will be performed on two sample sets;

3.71 with a minimum of turning device on, for dosage duration recommended by manufacturer, at least 3.1 100 times to determine the amount of degradation, if any;

3.72 each device's use cycle (turned on and off as described in Participating Manufacturer's user guide or operating manual) with be done five (5) times without pause, and then five (5) times with five (5) minute pause between use cycle.

3.8 Devices will be returned to Participating Manufacturer's documented point of origin.

4 DOCUMENTATION

4.0 Each device will be logged in using standardized accepted electronic process or forms, including name of manufacturer, model identification (number), serial number, date/time of being logged in, and name of personnel filling in form.

4.1 As each device is tested, it will be logged in using standardized accepted forms or electronic processes, including name of manufacturer, model identification (number), serial number, device testing/measuring device used, date/time of test, and name of personnel filling in form.

4.2 Test results for each device will be logged in using standardized accepted electronic process or forms, including name of manufacturer, model identification (number), serial number, device testing/measuring device used, date/time of test, test results, and name of personnel filling in form.

4.3 Person testing device will document any anomalies (i.e, sparks, excess heat, malfunction) observed during test.

4.4 Person testing device will document any anomalies in testing equipment.

4.5 Form will be signed [dated with time] by person who conducted the test. It will then be reviewed/co-signed [dated with time] by testing supervisor.

4.6 Raw data files and final reports, including electronic archives shall be provided back to PBM Foundation.

4.7 The final reports will consist of objective data and results only as outlined above.

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