



QUANTUM DEVICES, INC.

***EnLightenment* – Protocol for the Purchase and Use of Light Therapy**

Barneveld, WI June 23, 2006: Quantum Devices, Inc. (QDI), the award-winning leader and sole innovator of the HEALS™ (High Emissivity Aluminiferous Light-emitting Substrate) lighting technology for NASA and DARPA, has adopted a proactive policy to demystify the use of photon energy in the Aesthetic and Medical markets. In the interest of Public Safety and full disclosure, QDI will endeavor to disclose inaccurate and deceitful claims, when encountered, as Bad Science (BS) followed by the currently accepted, scientific facts as FACT.

The following is a short list of the BS that currently permeates the Aesthetic market, followed by the FACTS. QDI intends to expand this list with periodic updates, as they become available.

An EnLightened and Informed Customer Is a Brilliant Product Advocate

BS = Bad Science

Fact = Truth

BS: Cosmetic light devices do not require FDA clearance or approval

FACT: FDA's Center for Devices and Radiological Health (CDRH) is responsible for regulating firms who manufacture, repackage, relabel, and/or import medical devices sold in the United States. In addition, CDRH regulates radiation-emitting electronic products (medical and non-medical) such as lasers, x-ray systems, ultrasound equipment, microwave ovens and color televisions.

The basic regulatory requirements that manufacturers of medical devices distributed in the U.S. must comply with are:

- ❖ Premarket Notification 510(k), unless exempt, or Premarket Approval (PMA),
- ❖ Establishment registration on form FDA-2891,
- ❖ Medical Device Listing on form FDA-2892,
- ❖ Quality System (QS) regulation,
- ❖ Labeling requirements, and
- ❖ Medical Device Reporting (MDR)

BS: Cosmetic light devices are not medical devices and therefore do not require FDA clearance or pre market approval.

FACT: The FDA considers any device that defines a biological effect in its operational claims to be a Medical Device and subject to the regulations above.

BS: Product X is the most powerful cosmetic lighting device available in the field today.

FACT: The Radiant Power Output (RPO) of any lighting device is measured in radiometric units and not electrical units. Beware of the vendor that cannot define the difference and cannot provide you with the radiometric parameters of their device. If you decide to purchase, be sure to request a Certificate of Compliance defining the final test radiometric parameters for the device and the calibration standard traceability. In the event you may require future litigation to resolve an issue of nonconformance, this Certificate of Compliance could prove invaluable.

BS: Pulsing the lighting device and the Frequency at which the pulsing takes place improves the efficacy of the lighting device.

FACT: Pulsing is a carryover from the early days of Low Level Laser Therapy (LLLT). Pulsing was thought to extend the operational lifetime of the Laser and increase the Radiant Power Output (RPO). WRONG! With any pulsing scheme there is an off time that is relative to the on time and the result is a decrease in total RPO. For example a 50% duty cycle, 50% on and 50% off, will result in a 50% reduction in RPO. A 10% duty cycle may allow for a very impressive momentary peak RPO but this peak must be integrated over the 90% off time of the duty cycle. No Albert, there is no free lunch in Quantum Physics.

BS: Vendor X has a variable pulsing frequency lighting device that can match the frequency of any biological system of interest.

FACT: The only frequency of concern is the absorption wavelength of the biological systems chromophores. There is no verifiable scientific evidence to support the need for a variable, pulsating frequency lighting device. We have evolved under the steady state radiation of a star, we call the Sun, that produces a 1,000 W/m², an area roughly the size of a foldable card table. If we had evolved under a pulsar, the concept of a variable frequency lighting device may have some merit.

BS: Lasers are more powerful than LED's and therefore are a better choice for a Medical Lighting Device.

FACT: High Power Lasers are a very good tool for surgery, cauterizing wounds and piping light energy into the body cavity via fiber optic catheter. Lasers are a poor tool for covering large areas with uniform Irradiance. The low powered lasers the FDA has approved for external body applications can not compete with the HEALS™ (High Emissivity Aluminiferous Light-Emitting Substrate) LED technology.

Low Power Lasers have an output aperture of 1mm² or less. When the Laser device is brought into intimate contact with the surface of the anatomy the coherent properties of the Laser become diffused and scattered into incoherent (typical light) energy.

Laser energy is very monochromatic with a single bandwidth of typically 1 nanometer. Most of the chromophores of interest have bandwidths of several tens of nanometers.

These two issues combined with nonexistent or just poor radiant energy measurement techniques are probably the three issues most responsible for the glacially slow acceptance of LLLT as a professionally accepted medical technology.

HEALS™ LED's are made of the same semiconductor materials as many of the Laser Diodes described above but they emit their energy in a Lambertian distribution, which is the sum of reflections in all directions. This property of the LED chip provides an excellent opportunity to fabricate chip arrays into mosaic patterns that can be designed to provide a very uniform energy distribution over very large areas.

The HEALS™ LED design also provides an excellent heat sink for maintaining chip junction temperatures thereby allowing the LED chip to be driven at elevated electrical current specifications. These elevated drive currents provide an RPO increase of 4-5 times the RPO of the typical packaged LED. In comparison to the FDA ceiling on the RPO for low level laser devices the HEALS™ technology can out produce LLLT's RPO by a factor of 10.

Glossary

Radiant Power is the total power of electromagnetic radiation emitted by a source (lamp, light emitting diode, black body radiator like the sun or molten metal, etc.) and is measured in watts (W). Since the optical radiation generated by lamps is usually not emitted as a more or less parallel beam, the measurement of the radiant power must be measured with a measurement geometry that acquires the radiant power independently of its spatial distribution. The most accurate method is to use an calibrated integrating sphere with a broad band detector traceable to NIST standards.

Irradiance (E_e) is the amount of radiant power impinging upon a surface per unit area. **Radiant emittance** (L_e) describes the intensity of optical radiation emitted or reflected from a certain location on an emitting or reflecting surface in a particular direction. **Radiant exitance** (M_e) quantifies the radiant power per area, emitted or reflected from a certain location on a surface. These are radiometry terms for the power of electromagnetic radiation at a surface, per unit area. "Irradiance" is used when the electromagnetic radiation is incident on the surface. The other two terms are used interchangeably for radiation emerging from a surface. The SI (Système International) units for all of these quantities are watts per square meter (W/m^2). These quantities are sometimes called intensity, but this usage leads to confusion with radiant intensity, which has different units.