

“Global EMC engineers were **very creative in identifying performance issues** and were able to **shorten the time to achieve compliance with stringent medical standards.**” Dr. Stephen Abrams, Co-Founder, Quantum Dental Technologies.



Global EMC's (GEMC) business focus is supporting new technologies and supporting product developers beyond initial prototypes and nearing commercial launch. GEMC's compliance engineers ensure compliance for innovations to compete in today's international markets for broad market acceptance. Many new products fail to achieve significant acceptance by failing to meet international safety standards required for acceptance in both domestic and foreign markets.

Quantum Dental Technologies was founded by Dr. Stephen Abrams and Dr. Andreas Mandelis to tackle one of the most common problems in clinical practice; the early detection and ongoing monitoring of tooth decay . They took the PTR-LUM technology that Dr. Mandelis pioneered and created The Canary System™; a low power laser system that can detect and monitor very early stages of tooth decay. , It may soon replace the long established dental practice of the dental explorer, mirror and x-rays for searching for cavities.

The Canary System™ has a very different approach to caries detection. The Canary System looks directly at the status of the enamel crystal by using PTR-LUM technology that measures converted heat (PTR) and light (LUM) signatures emitted from the tooth surface. Rapid, safe pulses of laser light allow one to examine the tooth surface, while slower pulses allow the laser light to penetrate up to 5 mm below the tooth surface. As the decay grows, the Canary Number increases. With remineralization, the Canary Number decreases. The system is so sensitive it detects very small changes in heat, much less than that generated by a dental curing light. They have spent the last 10 years and published over 40 papers studying and validating the linkage between the Canary Number and early tooth decay, erosion lesions and cracks in teeth.

The Canary can detect small early areas of decay as well as decay detected by conventional techniques. It is safe with no harmful exposure to x-rays. The Canary can detect lesions as small as 50 microns up to 5 mm. below the tooth surface. These unique characteristics allow a dentist to detect decay in a vast number of clinical situations. When decay is detected early, the area can be either stabilized with remineralization therapies or actually healed.

As the product was nearing completion, Quantum Dental Technologies approached GEMC to ensure that their final product was both safe for dental practitioners and patients. Global's Engineers have significant early design and compliance medical device experience and worked closely with Quantum

completing a construction review, early product safety test and de-bugging to ensure compliance to IEC 60601-1 standards for medical devices.

The initial Quantum design included several unapproved components and GEMC worked with Quantum to qualify components or refer them to alternative options. The leading edge technology that gives The Canary System™ its technical edge is a low powered laser that identifies potential cavities earlier and more accurately than x-rays; and with significantly lower risk to patients. However, the laser introduces more factors to be tested to ensure compliance with stringent medical device safety standards.

GEMC's laser experts confirmed that Canary's laser was well suited to its purpose but helped Canary incorporate redundant safety systems and identified options for a more robust system, resulting in improved safety and laser performance. Following several design changes, GEMC's team confirmed the laser compliance and approval of the entire Canary system to IEC 60601-1, IEC 60601-1-2 & IEC 60601-2-22 (Class 3B laser – one of the most stringent requirements) for medical devices (North American and European markets).

“We found the Global EMC engineers very creative in identifying performance issues and recommending options or alternative remedies to laser issues, the protective casing and other components. Our team developed the technology that enhances the patients' experience at his dental check-up, and Global's experience and expertise on laser and product safety issues complimented our work to ensure we meet the most current medical device safety standards.” noted Canary co-founder, Dr. Stephen Abrams. “Their knowledgeable engineers greatly shortened the time to complete the process and to better prepare us for our market launch.”