

Multi-Center Clinical Study to Evaluate the Safety and Effectiveness of The Canary System™ (PTR-LUM Technology)



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□ The Canary System™, based on PTR-LUM technology, was evaluated for safety and effectiveness as part of the 2nd Health Canada approved multi-centered (4 sites) clinical trial (n = 98 patients).

□ **Objectives:** 1. Evaluate safety and effectiveness in a wide range of clinical scenarios (ICDAS 00 – 06); 2. Develop treatment scale relating Canary Number (CN) to caries lesion severity; 3. Evaluate ability of the CN to detect and monitor changes in lesion severity over time following the use of remineralization therapies.

□ **Protocol:** 1. Informed consent; 2. Screening Visit (Risk assessment and eligibility); 3. Assessment Visit (Scans with The Canary System™ using 2 Hz and 5 Hz (5 measurements per frequency)). 4. Follow-up Call to assess safety. 5. Multiple Assessment Visits

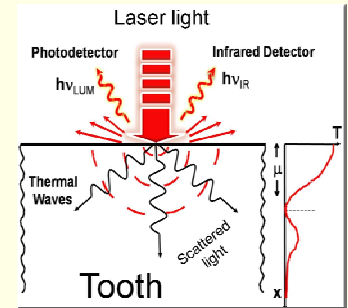
The Canary System™ Technology

When a modulated light source (660-nm laser beam) strikes the tooth surface, the light is converted into:

1. Heat (<1°C), which moves deep into the tooth as waves of thermal energy (PTR).
2. Longer wavelength luminescent light (LUM) which emanates from near surface structures

Changes in the tooth microstructure, due to caries, causes corresponding changes in the optical and thermal properties of the tooth and the resultant PTR-LUM response .

Canary Numbers were generated from measures of PTR-LUM amplitude and phase responses on sound and carious enamel (ICDAS 00 – 06).



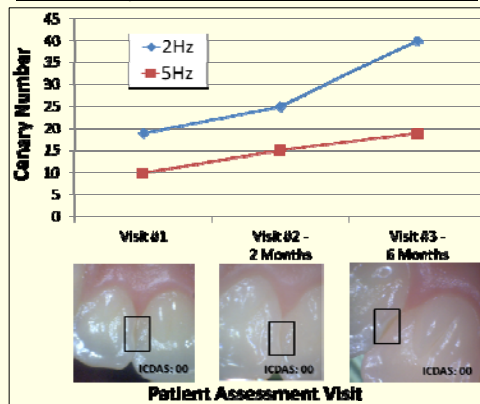
Clinical Trial Results

Case Study #1: Reproducibility

Visit # 1
ICDAS: 00
CN_{AVG} (2Hz) = 8
CN_{AVG} (5Hz) = 4

Visit # 2 (5 months Later)
ICDAS: 00
CN_{AVG} (2Hz) = 8
CN_{AVG} (5Hz) = 3

Case Study #2: Proximal Lesion Detection



Case Study #3: Lesion Detection

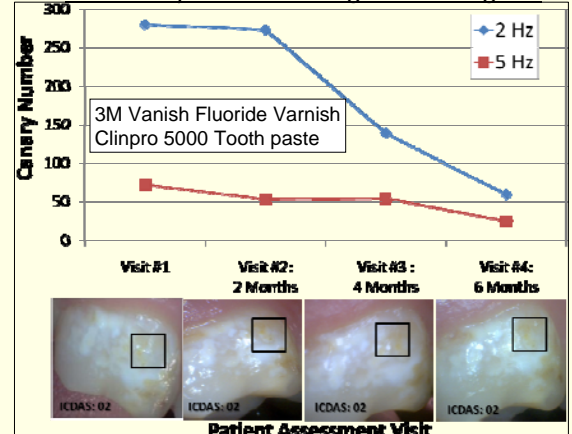
ICDAS: 03

Lingual View of Lesion

2 Hz = 228
5 Hz = 73

2 Hz = 161
5 Hz = 26

Case Study #4: Monitoring Lesion Progress



Clinical Ranking	Frequency	PTR Amp	PTR Phase	LUM Amp	LUM Phase	Canary Number
Sound (ICDAS 00)	2 Hz	35 ± 5	23 ± 13	45 ± 7	1.12 ± .02	1 - 27
	5Hz	35 ± 6	15 ± 8	45 ± 7	1.44 ± 0.3	1 -12
Early Lesions (ICDAS 01 – 02)	2 Hz	75 ± 44	80 ± 25	44 ± 5	1.17 ± 0.2	28 - 235
	5Hz	50 ± 30	51 ± 27	44 ± 6	1.44 ± 0.3	13 - 39
Advanced Lesions (ICDAS 03 – 05)	2 Hz	329 ± 186	111 ± 16	44 ± 5	1.27 ± 0.3	236 & above
	5Hz	150 ± 100	86 ± 27	44 ± 5	1.52 ± 0.4	40 & above

The Canary System™:

- Did not cause any adverse events or soft/hard tissue trauma.
- Canary Numbers discriminated between sound and carious occlusal, proximal and smooth surface enamel.
- Tracked lesion activity over time after exposure to remineralization agents.
- Showed good reproducibility.

Conclusion

The Canary System™ proved to be an effective and safe caries detection and monitoring device