

VELscope® (LED Dental Inc.) (Project # 07-007) (11/08)



The VELscope® (Visually Enhanced Lesion Scope) is a hand-held based device that is marketed to augment the detailed visual and digital soft tissue exam in the diagnosis of suspicious oral and pharyngeal mucosal lesions. The VELscope® uses a mercury-based light source combined with filters to produce visible light in the 400-460 nanometer range that is advertised to cause tissue autofluorescence which allows clinicians to distinguish between normal and abnormal tissues. Since the initiation of this evaluation LED Dental Inc. has introduced the Vantage lamp, a more powerful light source that is purported to provide more tissue discrimination, especially in situations

of increased ambient light, while supporting photo-documentation. The VELscope® has a two-year warranty (except V1 light source units).

Manufacturer:

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Suggested Retail Price:

- \$4,995.00 VELscope® System Package with V1 Lamp
 Contains:
 - VELscope Operation Manual
 - VELscope User's Guide
 - VELscope Light Source Unit (LSU)
 - VELscope Handpiece with attached fiber-optic light guide
 - LSU Base Stand
 - 1 Pair Deluxe Safety Glasses
- \$6,995.00 VELscope® System Package with Vantage Lamp
 (contents as listed above)
- \$495.00 Replacement V1 Lamp
- \$495.00 Replacement Vantage Lamp
- \$249.00 VELcaps (100)
- \$39.95 VELsheaths (250)
- \$105.00 VELtractors (100)

Government Price:

- \$3,066.20 VELscope® System Package with V1 Lamp
 (contents as listed above)
- \$4,293.91 VELscope® System Package with Vantage Lamp
 (contents as listed above)
- \$306.31 Replacement V1 Lamp
- \$306.31 Replacement Vantage Lamp
- \$164.34 VELcaps (100)
- \$26.37 VELsheaths (250)
- \$69.30 VELtractors (100)

ADVANTAGES

- + Meets electrical safety requirements
- + Easy set up and use
- + Instructions complete and easy to understand
- + Useful adjunct to a thorough visual and digital soft tissue clinical exam
- + Possesses useful benefit in the determination of surgical borders and post-surgical evaluations
- + Integrated light power meter
- + Light spectrum similar to that of FDA-cleared bronchoscopic mucosal examination units

DISADVANTAGES

- Tongue depressors and/or mirror reported easier to use than unit's VELtractor cheek retractor
- Heat from prolonged and close tissue examination may cause patient discomfort

SUMMARY AND CONCLUSIONS:

The VELscope® is a visible-light-based unit marketed to serve as an adjunct to a thorough visual and digital oral and pharyngeal soft tissue exam. The VELscope® met all DECS electrical safety requirements and was found to be easy to set up and use. The manufacturer-supplied instructions were reported to be complete and easy to understand while the suggested clinical protocol was straightforward. Furthermore, the handheld unit was easy to use and provided adequate access for the intraoral tissue examination. DECS laboratory testing confirmed that the VELscope® light spectrum is very similar to that reported with bronchoscopy units that are FDA-cleared for the detection of lung cancer. Evaluation of the unit's built-in light function indicator suggests that VELscope usage at distances of more than seven inches may not provide reliable results. Depending on duration of use, the VELscope can promote a temperature rise ranging from approximately 10 to 20°F above baseline. Therefore, close, prolonged tissue examination should be discouraged. Experienced clinical evaluators used the VELscope in over 150 exams and reported that the VELscope was simple to use and functioned as a useful adjunct to the standard visual and digital soft tissue exam. The VELscope® was also described as possessing potential benefit assisting in the determination of surgical borders. However, evaluators did express an underlying concern that some clinicians may see the VELscope® as a replacement and forgo the gold standard visual and digital soft tissue exam. The **VELscope®** is rated **Acceptable** for use in US Air Force dental facilities.