

Product Specifications

ViziLite PRO Dimensions	Length: 8.5" (215 mm) Width: 2.6" (66 mm) Height: 2.1" (54 mm) Weight: 11 oz (312 grams) with battery pack
AC Supply Connection	100-240 Volts AC ± 10%, 50-60 Hz
Charging Circuit Performance	Charging circuit provides correct voltage and current characteristics for charging battery pack: Constant current then constant voltage, 8.4 Volts, 1.0 A, @ 20°C Fully discharged battery pack charges to 100% in approximately 3 hours
Battery Charger Power Output	9 VA, Nominal
Battery Pack Specifications	Output: 7.4 Volts nominal @ 2000 mAh Type: Lithium-Ion Performance: Approximately 100 one-minute examinations starting with 100% charge Battery Pack Life: 500 full recharge cycles Safety: Batteries are protected from over-charging, over-discharging and short-circuiting by means of a built-in safety circuit
Output Working Distance	Approximately 3" (76 mm)
Output LEDs	5 violet high-power LEDs (Light Emitting Diodes) arranged in a circular pattern
Output LED Wavelength	400–450 nm (violet)
Operating Conditions	Operating temperature: 6°C – 30°C (43°F – 86°F) Relative humidity of 95% or less
Transportation & Storage Conditions	0°C – 50°C (32°F – 122°F) Relative humidity of 95% or less
Atmospheric Pressure	Within 70kPa – 106kPa in operating, transportation and storage conditions

ViziLitePRO[®]

ORAL LESION SCREENING SYSTEM

Accessories and Replacement Parts

Item	Reorder Part #
ViziLite PRO Screening Unit	PLS1001
Disposable Protective Lens Covers (pack of 100)	PLS1007
Patient Protective Eyewear	PLS1008
ViziLite PRO Eyepiece Replacement	PLS1016
Li-Ion Battery Charger (100-240 VAC)	PLS1017

Symbols Glossary



Consult instruction manual for use



Dispose of properly



Professional use only



Serial number



Caution



Li-Ion Battery



Temperature limits



Optical radiation

Symbols Glossary available at: denmat.com/symbols

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ViziLitePRO[®]

ORAL LESION SCREENING SYSTEM



Instructions for Use



CONTENTS:

- (1) ViziLite PRO Screening Unit
- (1) Li-Ion Battery Charger
- (1) Patient Protective Eyewear
- (25) Disposable Protective Lens Covers
- (1) Instructions for Use
- (1) Warranty Information Card

Warnings and Precautions

Not Sterile - Refer to "Cleaning and Disinfecting" section.

Risk Group 2, CAUTION - Possibly Hazardous optical radiation emitted from this product. The ViziLite PRO device produces high intensity light output. Do not look directly at the light emitted from this unit or point the light directly at the operator, assistant, or any person in the room.

Do not use the device without suitable eye protection for the patient. One pair of patient protective eyewear is included with this unit. Additional patient protective eyewear is available from DenMat. Refer to "Accessories and Replacement Parts" section.

Do not attempt to use the device while it is connected to the charger. The output LEDs cannot be activated while the battery charger is connected to the device.



Battery Disposal: The battery pack contains rechargeable Lithium-Ion batteries (Li-Ion). Recycle or dispose of battery pack according to national, state, and local regulations.

Intended Use

The ViziLite PRO Oral Lesion Screening System is a device intended for use as an adjunct to traditional oral examination to enhance the visualization of oral mucosal abnormalities.



General Description

The ViziLite PRO device contains five (5) shortwave violet output LEDs (A) that generate biofluorescence and enhance visualization in the oral cavity. On the patient side of the device, the LEDs emit light through a clear plastic lens (B), which is secured in place by a black retaining ring (C). Single-use protective lens covers (D) help keep the clear plastic lens clean and prevent cross contamination. The lens covers are installed by inserting the three small tabs into the three openings on the retaining ring. One lens cover should be installed prior to the examination and discarded after use.

The ViziLite PRO device is powered by a rechargeable lithium-ion battery. The battery is located inside the handle (E) and is secured by an end cap (F) which is not to be removed. The end cap is laser-etched with a six-digit serial number that is unique to the device.

A lithium-ion battery charger (G) is provided with the device. To initiate charging, insert the wall plug (H) into the wall outlet and insert the charger plug (I) into the charging jack (J) on the handle of the device. An LED battery charge indicator (K) is located on the charger.

An on/off button (L) is located on the viewing side of the handle. An LED battery level indicator (M) is located just above the on/off button on the viewing side of the handle. An eyepiece (N) and optical viewing filter (O) increase contrast between healthy and abnormal tissue and improve visualization.



ViziLite PRO Features

Optical Viewing Filter – The ViziLite PRO device includes a special optical filter to improve contrast between healthy and abnormal tissue and to improve visualization.

Rechargeable Battery – The custom lithium-ion battery pack is rated for 500 full recharge cycles. The battery pack is protected from overcharging, over discharging and short circuiting by means of a built-in safety circuit. When the battery is fully charged, the ViziLite PRO device will operate for over 100 one-minute examinations.

Light Output Regulation – The ViziLite PRO output LEDs maintain full power until the battery is depleted.

Auto Shutoff – Once activated and after five minutes of continuous operation, the violet output LEDs will automatically turn off and the unit will return to standby mode to conserve battery power.

Charging the ViziLite PRO

The ViziLite PRO device should be fully charged prior to initial use. To initiate charging, insert the wall plug into the wall outlet and insert the charger plug into the charging jack on the handle of the device.

After the charger plug has been inserted into the charging jack, the multicolor LED battery charge indicator on the charger will display one of the following two colors, indicating various states of battery charging:



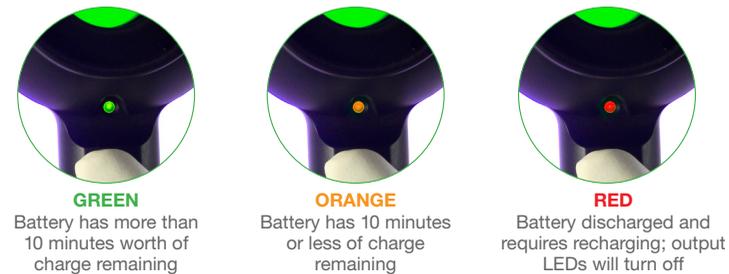
⚠ To ensure the device is fully charged, wait for the LED battery charge indicator on the charger to turn green before disconnecting the charger.

⚠ Do not attempt to use the device while it is connected to the charger.

Operating Instructions

Pressing the green on/off button once turns the device on and generates power to the five (5) violet output LEDs. Pressing the on/off button a second time turns off the five violet output LEDs and returns the unit to standby mode.

During use, the LED battery level indicator on the handle will display one of the following three colors, indicating various states of remaining battery power:



⚠ To activate the device, the charger plug must be removed from the charging jack on the handle. The device cannot be activated if the charger plug is inserted into the charging jack, even if the charger is unplugged from the wall outlet.

Step-by-Step Examination Guide

- ⚠ Ensure the patient is wearing suitable protective eyewear during the procedure.
1. Review the patient's medical and dental history.
2. Thoroughly examine the patient's head and neck both visually and manually using the operator overhead light.
3. Grasp the tongue with a gauze pad and gently pull it forward and to the sides to examine both the lateral surfaces and the base.
4. Peel the thin protective film from both sides of a disposable protective lens cover using the tabs marked "Remove Film".
5. Install the lens cover on the patient side of the device by inserting the three tabs into the three openings on the retaining ring.
6. Press the green on/off button and begin screening the oral cavity with the ViziLite PRO. The device should be held near the opening of the mouth – but not touching the lips – at approximately 3" working distance. Abnormal tissues will appear as dark areas among the bright fluorescence of surrounding healthy tissues.
7. Note any suspicious areas and re-examine the oral cavity first under white light and then again using the ViziLite PRO device.
8. Document suspicious lesions or take photographs.
9. Optional: Use an oral lesion marking system to validate the suspicious lesion.
10. Tactfully inform and instruct the patient about your findings and take appropriate actions.

Cleaning and Disinfecting

The ViziLite PRO handle and end cap are constructed of lightweight aluminum. The eyepiece is constructed of delrin. These three components may be wiped down with Cavicide or a similar disinfection product.

The ViziLite PRO optical viewing filter and clear plastic lens may be cleaned using either a mild soap and water solution or a common household glass cleaner:

- Optical Viewing Filter – Lightly dampen the end of a cotton swab and apply to the filter using a light circular motion.
- Clear Plastic Lens – Lightly dampen a clean, soft microfiber cloth and apply to the lens using a light circular motion.

The disposable protective lens covers will help keep the clear plastic lens clean and prevent cross contamination. Lens covers should be discarded after use.

⚠ Do not spray solution directly onto the handle, end cap, eyepiece, optical viewing filter or clear plastic lens.

⚠ Do not immerse the ViziLite PRO device in solution.

⚠ Take caution to prevent liquids from entering any openings on the handle, eyepiece, charging jack or elsewhere on the device.

⚠ Do not autoclave the ViziLite PRO device. Doing so will damage the device and invalidate the warranty.