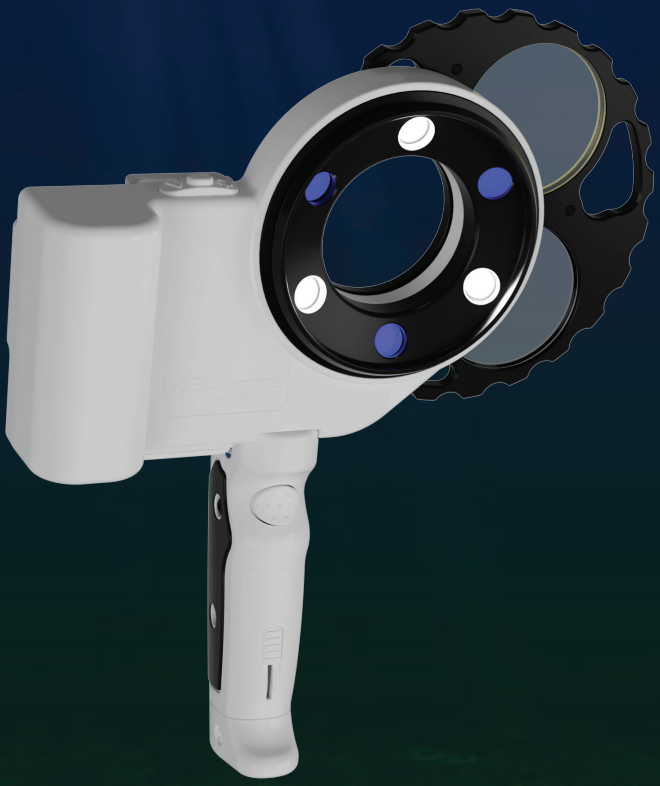
VELSCOPE® MANTIS

Operation Manual



MANTIS
VISION EVOLVED

Manufacturer Information

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1. Introduction

About This Manual

This manual provides information on the safe and effective use of the VELscope Mantis system along with the proper care and maintenance of the device. The dentist, hygienist, and entire team should thoroughly review this manual and become familiar with it and the VELscope Mantis system prior to using the device during patient care.

This manual features a quickstart guide that covers the essentials of setting up and using your VELscope Mantis system.

You can also visit LED Dental Inc.'s website at www.velscope.com, for additional information and training material on how to use VELscope Mantis and its oral mucosal visualization technology.

2. Package Contents

When opening and unpacking the contents of the VELscope Mantis system, you should thoroughly inspect all system components for any noticeable damage or missing parts. If you notice any damage or missing parts, please contact Customer Support. When contacting Customer Support, make sure to have your unit Serial Number (SN) and dealer information available. The SN can be found on the label affixed to the device as well as on the system box.

The VELscope Mantis System Package (6200 Series) contains:

1. Operation Manual (Print Version)
2. Ring Light Unit (with Battery Pack installed)
3. Filter Wheel
4. Handpiece
5. Wall Charger
6. Charging Cable
7. 1 pair of patient Safety Glasses

⚠ **CAUTION:** The VELscope Mantis system is only to be charged with Wall Charger unit supplied with the system (**Merryking AC/DC Adapter Model MKB2-0502400WU** in North America). To order a replacement, please contact VELscope Customer Support at support-velscope@velscope.com or call +1 604-434-4614.

⚠ **CAUTION:** The VELscope Mantis system is only to be used with **PN 6925 VELscope Mantis Battery** (Model: LED-0373400) sold exclusively by LED Dental. To order a replacement, please contact VELscope Customer Support at support-velscope@velscope.com or call +1 604-434-4614.

3. Symbol Guide

Manufacturer

Temperature limitation

Do not reuse

SN Serial Number

Consult Instructions for Use

Earth (ground)

Caution – Consult Accompanying Documents

4. Identification of system parts

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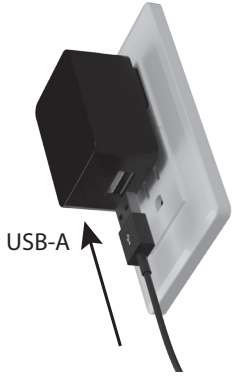
4. Identification of system parts (continued)

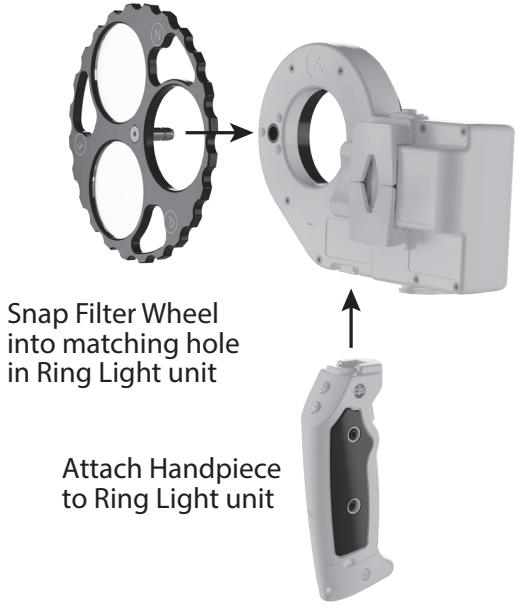
1. Handpiece
2. Ring Light Unit
3. Filter Wheel
4. Polarization Filter
5. Fluorescence Filter
6. User Viewport (showing no filter for direct normal viewing)
7. Jaws (for optional iPhone attachment)
8. USB-C Port Plug
9. USB-C Port
10. Camera Zoom controls (when using iPhone with compatible app)
11. Charging Cable
12. USB-C Connector
13. USB-A Connector
14. USB- A Port (on Wall Charger)
15. Wall Charger
16. Power Button (with integrated green, amber and red indicator LEDs)
17. Rechargeable Battery Compartment
18. Handpiece Toe Release Control (for optional tripod use)
19. Camera Photo Acquisition button (when using iPhone with compatible app)
20. LED Heat Sink
21. White Illumination LED
22. Blue Fluorescence Excitation LED

5. Quick Start Guide

1. Charge the Battery



2. Assemble Mantis Ring Light to Handpiece



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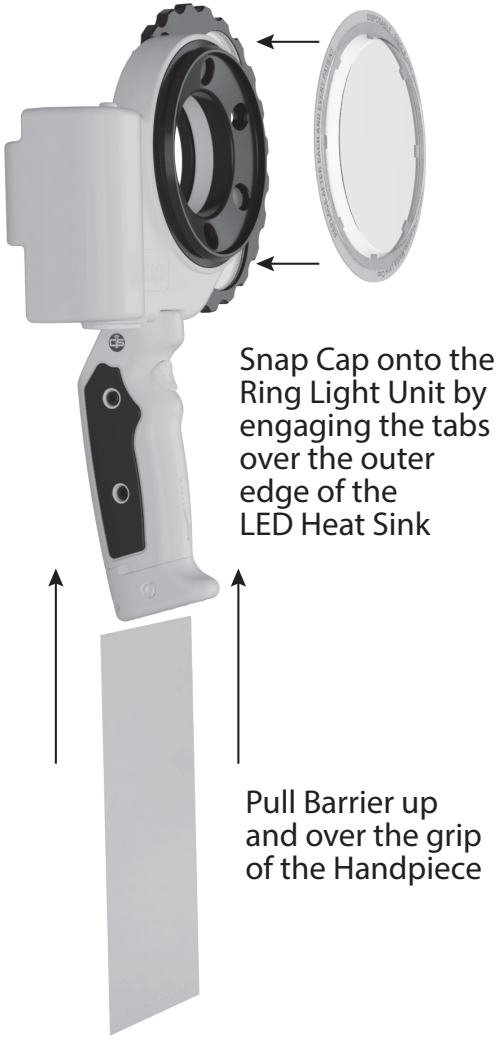
5. Quick Start Guide (continued)

3. Apply Disposable Lens Cap & Handpiece Barrier (sold separately)



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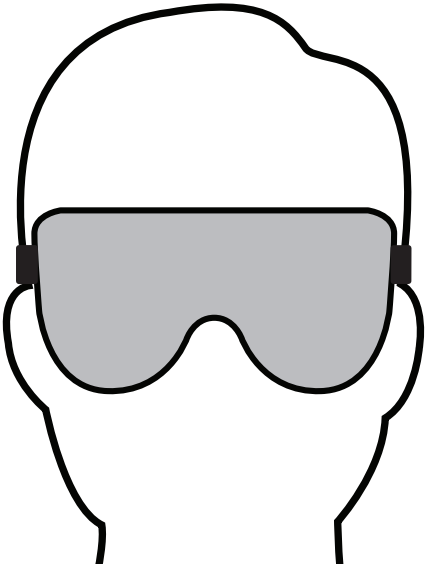
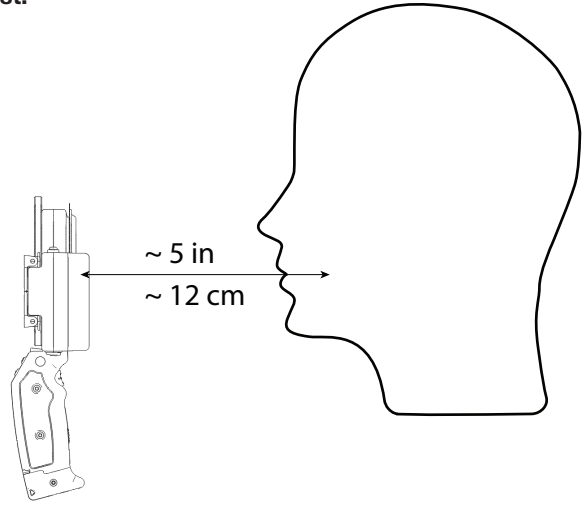
5. Quick Start Guide (continued)

4. Ensure patient is wearing the Safety Glasses provided.



5. Position the Mantis device approx. 12cm (~5 in) from the tissue of interest.



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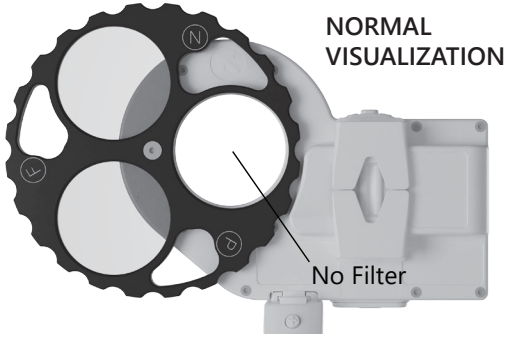
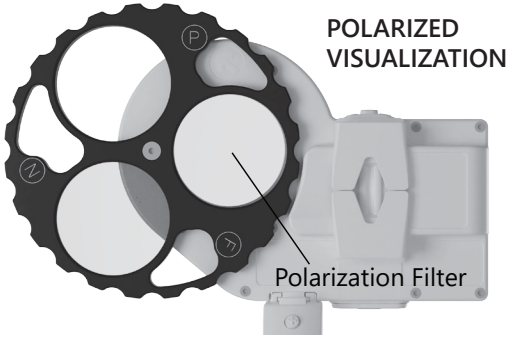
5. Quick Start Guide (continued)

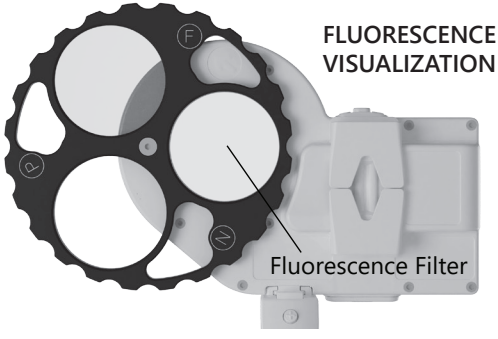
6. Filter Wheel Positions & Visualization Modes



NORMAL VISUALIZATION



POLARIZED VISUALIZATION



FLUORESCENCE VISUALIZATION

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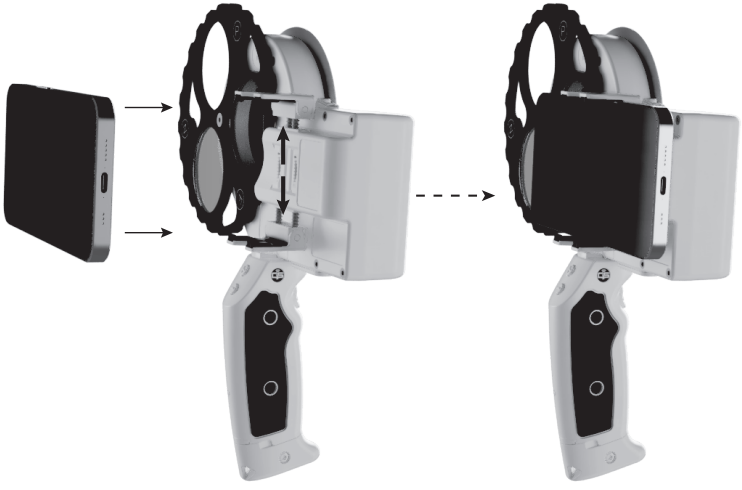
5. Quick Start Guide (continued)

7. Power ON (press for 1 sec)

8. iPhone can be used for photo documentation. Open Jaws, pull them apart and then insert iPhone.



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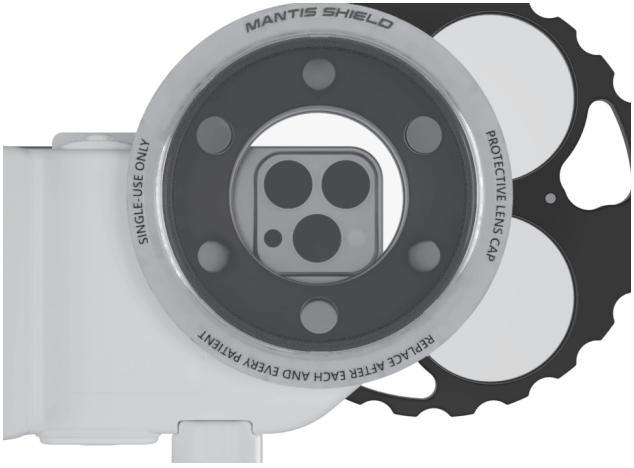
5. Quick Start Guide (continued)

9. Center the iPhone camera in the User Viewport.



10. Bluetooth enabled app allows use of Handpiece zoom and trigger buttons.After exam, turn off unit (press power button for 1 sec).

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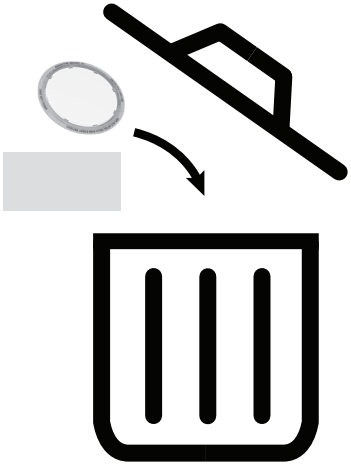
5. Quick Start Guide (continued)

11. After exam, turn off unit (press power button for 1 sec).

12. Discard used disposable lens cap and handpiece barrier.



13. Clean and disinfect unit prior to use on next patient with an alcohol-only based disinfectant and a towelette or an alcohol-only disinfecting wipe, e.g. Wipex™ or equivalent.

6. Safety Considerations

⚠ CAUTION: U.S. Federal law restricts this device to sale by or on the order of a Dentist, Physician, or other appropriately licensed health-care professional.

Contraindications

Patients with a history of photosensitivity or those using photosensitive medications should not be exposed to the light emitted from the VELscope Mantis device.

Precautions

The VELscope Mantis is not a diagnostic device, it is intended to be used as an additional tool to aid in the visualization of intraoral mucosal tissues during a comprehensive oral examination and/or intra and extra oral head and neck exam.

An absence of any findings of abnormal oral tissue from using the VELscope Mantis device is not a guarantee that pathological processes in fact do not exist in the examined tissue. The clinician should rely on their own clinical judgment taking into account all available information about the patient including risk factors, patient history, and extraoral as well as intraoral examinations with palpation, before making clinical decisions on recommendations for the patient.

High-power blue and white light is emitted from the patient-facing side of the VELscope Mantis device. Although the VELscope Mantis system meets international safety standards for blue light output, looking directly at the blue light of the VELscope Mantis device while in operation or shining into the eyes of the patient or anyone else should be avoided. As an added precaution, all patients should wear the protective eyewear supplied with the device to minimize discomfort and the potential for risk of eye injury.

Exercise caution when operating the VELscope Mantis device where the LEDs are on for an extended period of time (>25 mins). The high-power LEDs used in the device generate heat which can warm the front black metal surface of the device. The VELscope Mantis incorporates various safety systems to

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6. Safety Considerations (continued)

shut off the LED's if the temperature of the unit exceeds a safe threshold. In any event, the device is not intended to contact the patient, please ensure a working distance of approximately 12 cm from the oral tissue of interest.

To mitigate the risk of patient cross-contamination and infection, it is recommended to always use a disposable cap for the front light port of the Mantis system and a barrier for the grip of the handpiece. As an extra precaution thoroughly wipe down the device with a disinfectant wipe (e.g. Caviwipe) after an examination and before using it to examine another patient.

The VELscope Mantis device incorporates glass components such as the glass polarization and fluorescence filters in the detachable Filter Wheel and the smaller polarization and excitation filters situated in front of the illumination LEDs. Exercise care when handling the device - dropping onto a hard surface could result in broken glass which may result in glass fragments spilling into adjacent areas which can cause injury.

Do not install the VELscope Mantis system within 25 cm (10 in. approx.) of flammable anesthetic equipment.

Adverse Effects

On rare occasions:

- Patients may experience temporary discomfort after exposure to the blue light emitted by the VELscope Mantis system, including dry mouth, a burning sensation in the mouth or lips, and/or perceived loss of ability to taste. A patient presenting any of these symptoms should be evaluated by his/her physician and should abstain from further examinations with the VELscope Mantis system.
- Users may experience temporary eye discomfort from the bright diffuse blue light reflectance from tissue if viewed directly while in fluorescence visualization mode. This can be avoided by only viewing tissue through the fluorescence filter in the Mantis unit which completely blocks the reflected blue light.

7. The VELscope Mantis System

Overview & Brief Technical Description

The VELscope Mantis medical device is an extraoral, trimodal direct visualization system for helping oral healthcare practitioners examine oral mucosal tissues for abnormalities that can be signs of underlying disease processes. It will be used principally in front-line dental offices.

It incorporates three visualization modes:

1. Non-polarized white light reflectance to allow visualization of the mouth illuminated with white LEDs optimally suited for oral mucosal tissue
2. Polarized white light reflectance which is similar to (1) above except a polarization filter is used to eliminate bright back-reflections from the surface of the tissue and provide improved colour response.
3. Blue light induced natural tissue fluorescence which allows the user to view oral tissues in a different but complementary way and that can highlight tissue features which might not be evident using non-polarized or polarized white light reflectance.

The main components of the VELscope Mantis system are a Ring Light Unit, a removable Filter Wheel, a Handpiece and a Wall Charger to charge the internal lithium ion battery.

The Ring Light Unit contains the illumination system - a ring light consisting of 3 blue LEDs and 3 white LEDs and situated around a central 50mm diameter viewing port. The user selects the desired visualization mode by manually rotating the Filter Wheel (containing 3 circular slots for differing filtering optics) which will situate in the viewing port (a) no filter (non-polarized reflectance) OR (b) a circular polarizing filter (polarized reflectance) OR (c) a long-pass filter (fluorescence visualization).

The powering of the illumination LEDs will be handled automatically by the device based on the position of the filter wheel in one of the 3 specific positions (corresponding to the 3 visualization modes). This will be achieved by the use of magnets attached to the filter wheel, 2 Hall effect switches on the PCB, and a microcontroller sensing the output of the Hall effect switches and then using firmware-controlled logic to turn either the white or blue LED strings on at drive currents specific to the visualization mode in use.

The user can acquire high-quality images by optionally inserting a supported set of iPhone and iPod touch devices into the “jaws” of the device and positioning the camera lenses appropriately in the viewing port. An app is

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7. The VELscope Mantis System (continued)

available that allows the user to adjust and acquire photographs using buttons on the Handpiece.

The user interface consists of a single ON/OFF power button, 3 colored indicator LEDs and the rotatable filter wheel.

The device will be powered by an internal 1-cell lithium-ion battery pack and charged by wired connection to an off-the-shelf, IEC 60601-1 (certified AC/DC wall adapter. It is designed to be operated cordlessly and does not support wired operation: when the cord is attached and the battery is being charged, pressing the power button will NOT turn the device on.

The system is intended to be used with a single-use, multi-function, disposable lens cap that is mounted on the Ring Light Unit and a polyethylene barrier that covers the Handpiece.

Indications for Use

The VELscope Mantis system is intended to be used by appropriately trained healthcare professionals during routine oral examinations of adult patients at least 18 years old to aid in the visualization and photo documentation of oral mucosal tissues. The system incorporates both white light and blue light illumination to allow three different visualization modes: conventional white light reflectance, polarized white light reflectance to reduce glare, and natural tissue autofluorescence. Optional attachment of an iPhone facilitates straightforward photo documentation.

Intended Use - Additional Considerations

The VELscope Mantis system is intended to be used adjunctively with a comprehensive intra and extra oral neck examination. It is an additional visual aid for the clinician during the visual intraoral examination to help visualize patient tissues under conventional white light illumination and also with fluorescence when excited by blue light.

It is intended to help bring the sometimes-subtle appearance of oral abnormalities to the attention of the clinician. If an abnormal area is detected with the use of the VELscope using any of its three visualization modalities, follow the same protocol that would be followed if the area had been discovered by any other means. Note that palpation is an essential part of a properly conducted intra and extraoral head and neck exam and use of the VELscope Mantis system is not intended as a replacement for this.

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7. The VELscope Mantis System (continued)

Design Philosophy

The VELscope is and always has been an adjunctive system – the previous strictly fluorescence-based devices allowed users to see the natural fluorescence response of tissue when excited by blue light, but this visualization method was never intended as a replacement for traditional visualization but as complementary to it. Moreover, it can be argued that one of the things which helped immensely in the use of this novel fluorescence visualization method workable was the ability to turn off the VELscope when confronted by something unusual and then look at the same area under conventional illumination to help the clinician understand what they are looking at. In addition, for photo documentation, it is always important to capture not only the fluorescence response of the tissue but also its presentation under traditional white light. This was challenging since the white light used for photo documentation was not integral to the VELscope and had to be provided from some other source. However, this inevitably resulted in photos of the same area where because of the time taken to switch from white light to fluorescence or vice versa, the views of the tissue were not well-matched. This did not facilitate a straightforward comparison of the two clinical presentations, complicating interpretation. LED attempted to improve this situation with its VELscope Vx Imaging System making use of an iPod touch unit that attached to an adapter magnetically and could be quickly removed from the handpiece to allow the user to use the white LED flash of the iPod to capture a white light picture. However, with the natural movement of the patient and clinician in the interval between shots, matching views between the two imaging modalities was still problematic.

This experience led to the prime design objective of a new system: incorporate both white light and fluorescence visualization in one device and provide a means to quickly switch between one and the other for comparison in real time during an oral examination. The secondary goal was to link this with an ability to easily photo document both visualization modes and make it easier to get white light and fluorescence photographs with a more closely matched field of and angle of view.

One of the other issues with previous versions of the VELscope was the restricted field of view looking through the eyepiece sometimes perceived as a tunnel effect. Another objective of the Mantis was to "open up' this field of view and provide a wider view of the tissue to help with a quicker and easier examination. This is especially important since built-in white light visualization was also desired.

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7. The VELscope Mantis System (continued)

Another important consideration was that if white light illumination and visualization was going to be included in the device, then the white light source selected should be one optimized for visualization of oral tissues. Also, it is important to recognize when we illuminate an object, especially a reflective surface like the oral mucosa, what we see is the combination of the light reflecting off the surface of the tissue ("specular reflectance" which provides information about surface topography and texture) and light that penetrates the tissue, gets absorbed in different ways depending on its wavelength (or colour) and then gets scattered back out to out eyes so we can see it. This "diffuse reflectance" provides the colour information and makes up the bulk of our perception when we look at something (unless it is a mirror, then it is all surface reflected light!). Both specular and diffuse reflectance are important when visually assessing oral tissues:

- Specular reflectance - this allows us to visualize surface texture which if abnormal (e.g. roughness in an area which is normally smooth mucosa) can be a harbinger oral pathology
- Diffuse reflectance – this allows us to visualize colour; for example, the exaggerated redness characterizing erythema or erythroplakia or the whiteness associated with hyperkeratosis or leukoplakia or a combination of both in erythroleukoplakia.

However, quite often the bright surface reflections, while telling us about the nature of surface texture, can obscure the underlying colour response. This problem can be circumvented by illuminating the tissue with polarized white light and then observing the reflectance of the tissue through another polarizing filter with the direction of polarization perpendicular to the one in front of the illuminator. In doing this, almost all of the surface reflections are blocked allowing the observer to have an obscured view of the underlying colour response.

Here's how we addressed these requirements in the VELscope Mantis:

1. The system includes both White and Blue LED's for viewing both white light reflectance and fluorescence with a quick and easy way to switch from one to the other by rotation a filter wheel by 120 degrees.

2. The White LEDs selected have similar characteristics to those used in surgical lighting which makes sense because the intraoral exam is focusing predominantly on the red colour of the oral mucosa rather than the teeth. The white LEDs used in the Mantis have a high colour rendering index (CRI) which means they are more able to faithfully reproduce colour in the object they

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7. The VELscope Mantis System (continued)

are illuminating. In addition, the LEDs also have high "R9", which corresponds to the ability to accurately reproduce the red part of the colour spectrum – important when viewing predominantly red oral tissues.

3. The illumination LEDs are controlled by the position of the Filter wheel. All you do is rotate the wheel to the right slot and the blue or white LEDs come on automatically.

4. There are three positions of the filter wheel corresponding to normal white light reflectance, polarized white light reflectance and fluorescence. You can compare and contrast the three different visualization modes and use them for visual tissue assessment as you see best.

5. The viewport on the VELscope Mantis is almost twice the diameter of eyepiece on the VELscope Vx leading to a considerably larger field of view.

6. The VELscope Mantis comes with a built-in adapter for recent models of iPhone so you can quickly snap your choice of iPhone in, position it such that the lenses are approximately centered in the Eyepiece and easily take high quality white light and fluorescence clinical photographs.

7. We have partnered with the Grip and Shoot company who designed the handpiece portion of the VELscope Mantis. This handpiece has Bluetooth capability and is therefore able to communicate with an iPhone. iPhone Apps are available that that work with the controls on the handpiece to utilize this Bluetooth capability to zoom the iPhone camera using the zoom buttons on the back of the Handpiece and acquire photographs using the trigger button on the front of the Handpiece. Using these apps, you can control zoom and take photos without having to take your hand off the handpiece to touch the iPhone screen.

Description of Components

Ring Light Unit & Filter Wheel

The Ring Light Unit houses the blue and white illumination LEDs and all the associated control circuitry. Both the blue and white LEDs are angled so that when positioned approximately 12cm from the target tissue, optimal illumination results; therefore, this is the recommended working distance for both white light reflectance and fluorescence visualization although good results can be achieved in a working distance of between about 8cm and 20cm from the tissue.

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7. The VELscope Mantis System (continued)

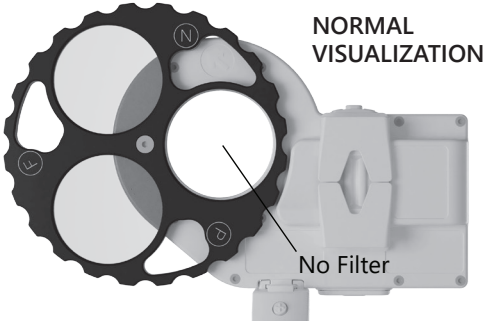
The Ring Light Unit also houses a lithium-ion rechargeable battery which is charged by plugging one end of the Charging Cable into the USB-C port on the underside of the unit, the other end into the Wall Charger and then plugging the Wall Charger into a standard 120V power outlet.

The Ring Light Unit provides a straightforward mechanism for snap-attachment of the VELscope Mantis disposable lens cap, with a groove on the outside of the patient-side Eyepiece Assembly.

The Ring Light Unit will not emit any light until the Filter Wheel is inserted and snapped into place in the Filter Axle hole in the Ring Light Unit AND it is positioned so that one of the three filter positions is correctly aligned with the User Viewport.

The three slots on Filter Wheel are labelled N, P and F which correspond to the three visualization modes as described below:

N – NORMAL REFLECTANCE – the corresponding filter slot is empty and allows the user to view the unfiltered reflectance of the white LEDs from the tissue of interest. In this mode, the VELscope Mantis is effectively acting as a high-quality flashlight by illuminating the tissue with a bright, high CRI/R9, white light. This is a perfect complement to existing methods of intraoral visualization by allowing the user to direct the light and observe any tissue of interest in the mouth through the viewport. Since the user is looking on the central axis of the illumination, it affords a vivid, clear view of the tissue with minimal shadowing. This visualization mode is one the user should be used to and presents visual information and about both surface topography and texture as well as tissue colour.



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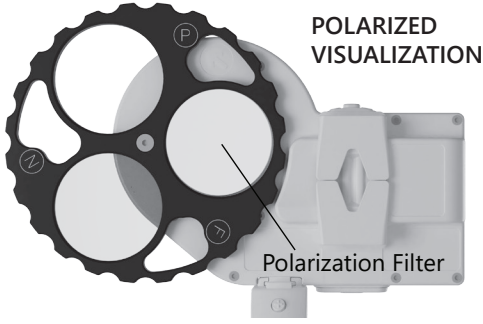
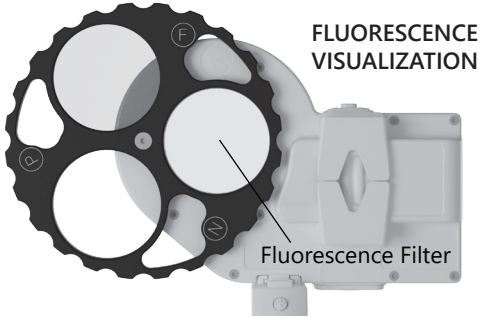
7. The VELscope Mantis System (continued)

P – POLARIZED REFLECTANCE – the corresponding filter slot contains a polarization filter aligned with respect to the filters in front of the illumination LEDs to minimize specular (surface) reflections from the shiny oral mucosa. This has the benefit of suppressing the "glinty" white back-reflection highlights from the illumination light allowing a clearer view of the tissue with improved colour response. This visualization mode is preferred when the user wishes to focus on the various shades of colour in the tissue. However, because surface reflections are blocked, visual information about surface texture and topography is minimized.



F – FLUORESCENCE VISUALIZATION – the corresponding filter slot contains a fluorescence filter that blocks any of the blue excitation light allowing the user to view the natural tissue fluorescence generated at longer wavelengths (green, yellow and red). This visualization mode is useful to allow the user to view the tissue in a completely different way which makes certain types of tissue changes more noticeable than what they would be when viewed with white light normal or polarized reflectance.



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7. The VELscope Mantis System (continued)

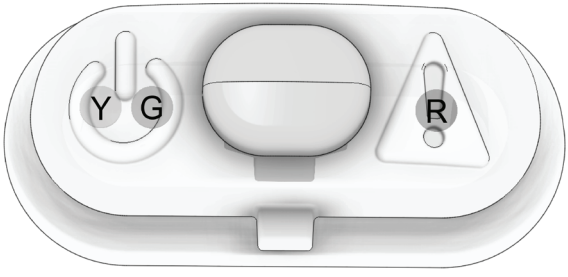
After snapping the filter wheel fully into the Filter Axle hole in the Ring Light Unit, the user controls which LEDs are illuminated by rotating the Filter wheel into one of the three set positions where the N, P on F symbol on the Filter Wheel is positioned at the top of the unit next to the arrow molded into the Ring Light Unit casing. The user will know when the Filter Wheel is in the proper position because there will be a click and tactile sensation when it gets into the proper position.

Assuming that the unit is on, please note that the blue or white LEDs only illuminate when the filter wheel is locked into one of these three positions. The user will notice that when they rotate the filter wheel, the LEDs turn off until they have rotated it to one of the other set positions.

ON/OFF Pushbutton with Integrated LED Indicators

The Ring Light Unit is turned on and off by depressing the Power Button and holding for 1 second.

The Power Button functions not only as a Power ON/OFF control but also as a multi-purpose indicator system with green, yellow and red LEDs integrated within it. This is shown schematically below with the position of the LEDs represented by the 3 circles labelled as Y (Yellow LED), G (Green LED) and R (Red LED):



The meanings of these indicator LEDs are different depending on whether the VELscope Mantis is in a battery charging state with the Charging cable connected to to the plugged-in Wall Charger or in an operational state – device is cordless and has been turned on.

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7. The VELscope Mantis System (continued)

Power LED (GREEN)

When you plug the unit in to charge, the GREEN LED flashes while charging and turns solid GREEN when the battery is fully charged.

Once the unit is turned ON (and it only operates when unplugged from the Wall Charger), the GREEN LED turns solid GREEN until the battery depletes to approximately 20% of full charge.

Low/Empty Battery LED (GREEN/YELLOW)

During operation of the device, once the battery decreases to approximately 20% of full charge, the GREEN LED starts to flash. At this point, the device will still operate for a period of time but should be fully charged at the next opportunity. When the battery is fully depleted, the YELLOW LED turns solid and the unit shuts down.

Caution/Warning LED (RED/YELLOW)

If the RED LED is illuminated, it indicates that the unit has overheated. If this occurs, let the unit cool before using again and please contact customer support.

If the RED and YELLOW LEDs are illuminated simultaneously, it indicates that there is a system error. Please contact customer support.

A complete listing of the indicators and their meaning is provided in the following table.

 (continued on next page)

7. The VELscope Mantis System (continued)

YELLOW	GREEN	RED	DEVICE STATUS
Battery Charging (USB cable connected to Wall Charger)			
OFF	FLASHING	OFF	Battery Charging
OFF	SOLID	OFF	Battery Fully Charged
OFF	OFF	OFF	Battery or System Error Contact customer support
No Connection to AC Wall Adapter and Unit OFF			
OFF	OFF	OFF	Device OFF
No Connection to AC Wall Adapter and Unit ON			
OFF	SOLID	OFF	Normal Operation, Battery Charge OK
OFF	FLASHING	OFF	Normal Operation, Battery Charge Low
SOLID	OFF	OFF	Battery Depleted, Recharge Battery
OFF	OFF	SOLID	System Overheating Contact customer support
SOLID	OFF	SOLID	System Error Contact customer support

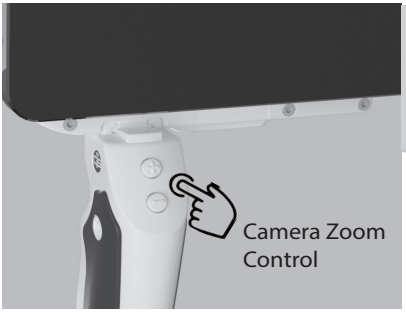
(continued on next page)

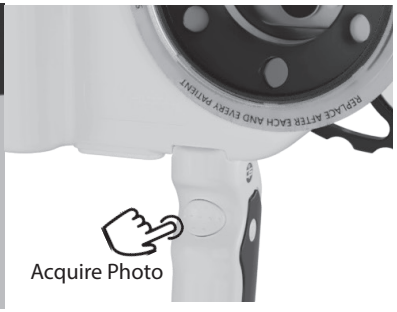
7. The VELscope Mantis System (continued)

Handpiece

For direct visualization, the Handpiece acts as a convenient and ergonomic way to hold the VELscope Mantis device for examining patients.

Without having an iPhone attached, the zoom and buttons on the user side of the handpiece and the trigger button on the patient side have no function.





These controls become functional when using an iPhone with a compatible app for optional photo documentation.

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7. The VELscope Mantis System (continued)

Safety Glasses

The VELscope Mantis system comes with a pair of Safety Glasses. These Safety Glasses are intended to be worn by the patient while the VELscope Mantis device is being used to examine their oral cavity. They serve two purposes:

- To block almost all the blue excitation light if the light from the VELscope Mantis is inadvertently directed towards their eyes with the device in Fluorescence Visualization mode. Notwithstanding, the protection afforded by the Safety Glasses, direct the blue light only toward the patient's mouth and be careful never to shine the bright blue light from the VELscope Mantis into the patient's or anyone's eyes (including your own). It is potentially hazardous and can cause eye damage. See "6. Safety Considerations" on page 14 for more details.

- To reduce the glare of the white light (which is bright and may be uncomfortable for the patient) during white light examinations. In addition to the short wavelength (blue) blocking, the Safety Glasses also reduce the brightness across the visual spectrum (like a pair of sunglasses)

⚠ CAUTION: These Safety Glasses have been chosen specifically for use with the VELscope Mantis system to not only reduce intensity across the whole visual spectrum but also essentially block short wavelength blue light. Do not replace them with other more generic sunglasses. Please contact LED Dental customer service if your Safety Glasses need replacement.

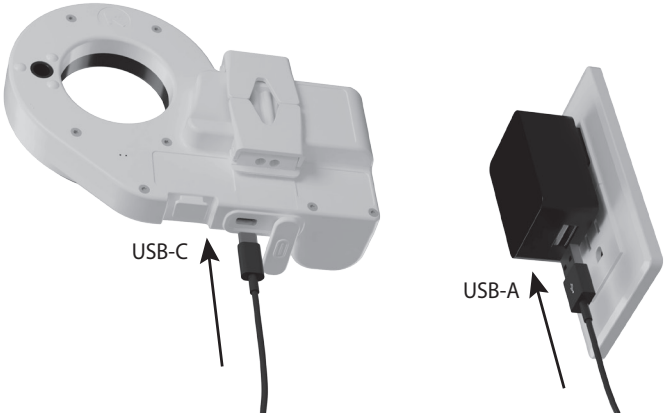
Wall Charger and USB Charging Cable

The Wall Charger is a medical grade AC/DC power adapter suitable for use in your region. Once plugged into the wall and connected via the Charging Cable to the Ring Light Unit, it provides the power to charge the internal

(continued on next page)

7. The VELscope Mantis System (continued)

lithium-ion rechargeable battery. Connect the Wall Charger to the Ring Light Unit by plugging the USB-A end of the Charging Cable into the USB-A port on the Wall Charger and the USB-C end into the corresponding port on the Ring Light Unit.



Rechargeable Battery Pack

- The rechargeable battery pack for the VELscope Mantis device comes pre-installed, and so no additional steps are required other than to fully charge the battery before initial use.
- The battery is charged by connecting the USB-C end of the Charging Cable to the USB-C port on the Ring Light Unit and then plugging the USB-A end into the Wall Charger and then plugging the Wall Charger into a standard power outlet.
- It takes between approximately 3 hours to fully charge the battery from a state of no charge.
- A fully charged battery will power the VELscope Mantis for approximately 60 minutes of continuous operation.
- Please note that when the VELscope Mantis cannot be turned on or operated during charging.

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7. The VELscope Mantis System (continued)

Mantis Shield Disposable

The VELscope Mantis Disposable (sold separately from the VELscope Mantis System) consists of a lens cap and a handpiece barrier.

Mantis Shield Lens Cap

The Mantis Shield Lens Cap is a protective, multifunctional, single-use, disposable lens cover.

It consists of an optical quality, high transmission and non-fluorescent acrylic viewing window and a paperboard flange with tabs to facilitate attachment to the Ring Light Unit.

The primary functions of the lens cap are to:

- Seal off and protect the precise optics of the Ring Light Unit facing the patient from dust, debris, condensation, powder, fingerprints, oils, etc.
- Act as an anti-fog barrier to aid in visualization during examination.
- Provide an asepsis barrier to mitigate the risk of patient-to-patient cross contamination.

Caution: Dispose of the Lens cap properly after use. A new, unused lens cap should always be used on every patient and should be replaced if its film is punctured or damaged during the examination. Failure to do so may increase the risk of cross contamination between patients and of damage to the patient-side window of the Handpiece. The material of the cap does not withstand high temperatures. Do not attempt to sterilize with autoclave, dry heat, or otherwise.

Mantis Shield Handpiece Barrier

The Mantis Handpiece Barrier is a single-use, disposable polyethylene sheath used to enhance asepsis and mitigate the risk of patient-to-patient cross contamination. It fits over the Handpiece of the Mantis system from the bottom up and allows the user to hold the unit without touching it directly.

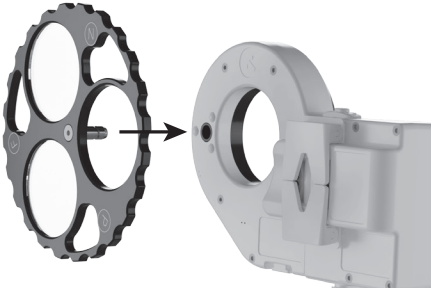
Caution: Dispose of the handpiece barrier properly after use. A new, unused barrier should always be used on every patient and should be replaced if it is torn or damaged during the examination procedure. Failure to do so may increase the risk of cross contamination between patients. The material of the barrier does not withstand high temperatures. Do not attempt to sterilize with autoclave, dry heat, or otherwise.

8. Assembly & Set Up

General Instructions

1. If this is the first time you are operating the unit, it is recommended to fully charge the Battery.

2. Ensure that the Filter Wheel is properly installed into the Ring Light Unit by pushing the Filter Wheel axle firmly into the corresponding hole in the Ring Light Unit. It should fit firmly into place. Rotate the wheel to the desired position: N, P or F; once again, you should feel the wheel snap into position when it is properly rotated to one of the three slots.



3. If the Handpiece is not attached, then attach it now.

The Handpiece attaches to the Ring Light Unit by engaging the tab at the base with the locking mechanism on the top of the Handpiece as shown below:

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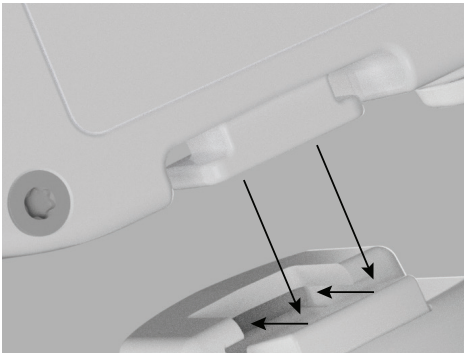
8. Assembly & Set Up (continued)



Once the tab of the Ring Light Unit is properly pushed into the slot on the Handpiece, you should hear a click. Make sure the Ring Light Unit is properly locked into the Handpiece before operating the VELscope Mantis device.

Other Considerations

Ambient Light

Visualization of tissue fluorescence with the VELscope Mantis system is optimized when the ambient light level is minimized. A darkened examining area is the ideal setting for performing a fluorescence examination.

Environmental

Please see "Environmental Limits" on page 47 for the operating and non-operating environmental limits.

Electrical Safety

Only use the certified, medical-grade Wall Charger supplied with the VELscope Mantis system.

Liquid Ingress

⚠ CAUTION: Although the VELscope Mantis system has been designed to minimize the chance of liquid ingress, it is not waterproof. Exercise care when using the unit and especially while cleaning it to minimize the unit being exposed to free liquid.

9. Cleaning and Infection Control

General Considerations

The VELscope Mantis Ring Light Unit, Filter Wheel, Handpiece, Charging Cable and Wall Charger are **NOT STERILIZABLE WITH AUTOCLAVE, DRY HEAT, OR OTHERWISE.**

The VELscope Mantis Ring Light Unit, Filter Wheel, Handpiece, Charging Cable and Wall Charger are **NOT SUBMERSIBLE IN ANY LIQUIDS**. Do not submerge or allow any liquids to enter the device or any of its components. Doing so will severely damage the system and will void the warranty

All disposable accessories are designed for single use on an individual patient and should be properly disposed of after use. Disposable components are not designed to withstand effective disinfection or sterilization; therefore, reuse can lead to cross contamination from patient to patient.

Attempting to reuse VELscope Mantis Disposable components will have a detrimental effect on the optical and clinical performance of the VELscope Mantis system.

Filter Wheel and Optical Filters

It is recommended to first remove the Filter Wheel before the cleaning and disinfecting the external surfaces of the Ring Light Unit and Handpiece.

To clean the Filter Wheel, wipe down the black aluminum filter frame with an alcohol-only based disinfectant and towelette or an alcohol-only disinfecting wipe, e.g. Wipex™ or equivalent.

If the optical filters need cleaning – for example, if you see dust or any type of non-uniform coating on the optical surfaces – carefully blow away any dust and then clean carefully with lint-free tissue dampened with a mild liquid solvent such as a commercially available lens cleaning solution, or simply 70% isopropyl alcohol. Once any residues have been removed, use a dry lint-free tissue to wipe away any final liquid.

Patient Safety Glasses

The Patient Safety Glasses should be cleaned with soap and water after each use. Do not use alcohol or alcohol-based products as they will degrade the glasses.

The glasses should be inspected before and after each use, and should be

 (continued on next page)

9. Cleaning and Infection Control (continued)

properly disposed of and replaced when showing signs of deterioration, or once they have exceeded their useful life.

Ring Light Unit and Handpiece

After each use, be sure to remove and properly dispose of the used disposable lens cap and handpiece barrier before cleaning and disinfection.

Once the Filter Wheel is removed the plastic and aluminum surfaces of the Ring Light Unit and Handpiece can be easily wiped down with an alcohol-only based disinfectant and a towelette or an alcohol-only disinfecting wipe, e.g. Wipex™ or equivalent. The filters in front of the LEDs should only need to be cleaned periodically as needed. Use the same methods as described above to clean these filters.

Patient Safety Glasses

The Safety Glasses should be cleaned with soap and water after each use. Do not use alcohol or alcohol-based products as they will degrade the glasses.

The glasses should be inspected before and after each use and should be properly disposed of and replaced when showing signs of deterioration, or once they have exceeded their useful life.

Contact LED Dental customer support to order a replacement pair of Patient Safety Glasses.

⚠ CAUTION:

Refrain from using disinfectants containing bleach, quaternary ammonium compounds, hydrogen peroxide, phenolics and other disinfectantns as these are known to degrade the PC-ABS plastic used in the device housing.

⚠ CAUTION:

DO NOT immerse in any liquid or use excessive cleaning fluid when cleaning the system. The VELscope Mantis components are not waterproof and excess fluid can penetrate the system and cause damage to internal components. This damage is not covered under the warranty.

⚠ CAUTION:

Exercise care while cleaning the optical filters as using excessive force on the glass surfaces may dislodge the filters.

10. Operating Instructions

Fundamentals of Oral Soft Tissue Examinations and the VELscope Mantis

It is important to understand that the VELscope Mantis is to be used adjunctively with a comprehensive oral examination using larger context of the intra and extra oral head and neck examination where both visual and tactile (i.e. palpation) means are used to assess both extra oral and intra oral tissues in the head and neck area. While this is sometimes referred to as "oral cancer screening" its purpose is more general – to detect suspect tissue that may be indicative of underlying pathology so that it can be followed-up on appropriately.

The VELscope Mantis is intended as a complementary aid for the visual intraoral part of this examination. Its use in no way diminishes the importance of either the extraoral visual or tactile examination or the intraoral tactile examination. Whether an area of suspect tissue is detected using traditional methods or using the VELscope Mantis device, the next steps should be the same: use all information available including patient history information as well as examination results to compile a differential diagnosis and then decide on appropriate follow-up actions, e.g. reappointment at a later date to check status, referral to specialist etc.

Use of the VELscope Mantis outside the context of a visual assessment tool in the oral cavity is off label use and not supported by the manufacturer.

System Preparation

1. Prior to using the VELscope Mantis system, please read and follow the instructions provided in Section "8. Assembly & Set Up" on page 30 to ensure that your system is appropriately assembled and ready to use on patients.

    a. Inspect the unit before use on a new patient to ensure that there is no visible damage (such as cracked filters) and that it has been appropriately cleaned and disinfected after its use on the previous patient.

    b. If there is any visible or obvious damage to the unit, do not use for patient examinations. Call LED Dental customer support.

2. If unsure whether the unit has been disinfected after the previous patient, following the cleaning and disinfection steps in section "9. Clean-

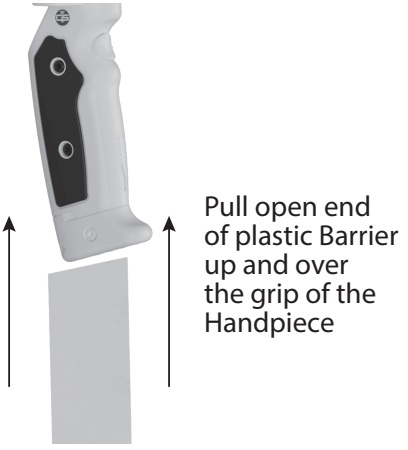
 (continued on next page)

10. Operating Instructions (continued)

ing and Infection Control" on page 32.

3. Remove a VELscope Mantis lens cap and Handpiece barrier from the dispenser box.

   a. Insert the Handpiece into the open end of the barrier pull up from the bottom so that it covers the entire Handpiece.



   b. Snap the lens cap onto the front of the Ring Light Unit by engaging the paper tabs over the outside edge of the black heat sink:

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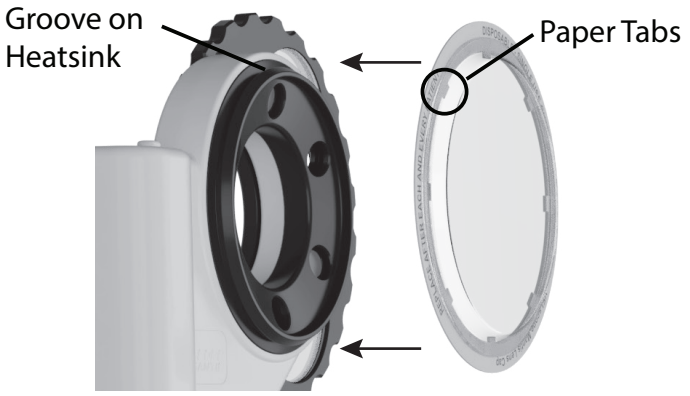
10. Operating Instructions (continued)



i. Hold the Lens Cap by the rim.

ii. Position parallel to the front face of the unit and gently press on by engaging the paper tabs into the groove on the outside edge of the black heat sink.

iii. Ensure that, once applied, the Lens Cap window is situated parallel to the face of the unit.

iv. Do not apply excessive force.

v. Avoid touching the clear plastic window as this may leave residues which could obscure the view through the VELscope Mantis.

4. The VELscope Mantis system is now ready for use on patients.

Prior to the VELscope Mantis Examination

1. Ensure that the patient is wearing the Safety Glasses provided with the system.

2. If necessary, darken the dental operatory to reduce the ambient light to an acceptable level while performing a fluorescence examination.

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10. Operating Instructions (continued)

⚠ CAUTION: For the fluorescence examination, it is important that you take all practicable steps to reduce the ambient light level appropriately. Failure to do so may decrease the contrast between brighter and darker areas observed under fluorescence examination, and thus adversely affect your ability to visualize intrinsic tissue fluorescence. Some basic precautions may include:

- Turning off the dental operatory light.
- Turning off the overhead lights if possible.
- Pulling the blinds on the windows if possible.
- Turn the patient away from a direct source of light (e.g. windows) while conducting the VELscope Mantis examination, if possible.

VELscope Mantis Examination

1. Before turning the unit on, ensure that the front of the unit is not directed toward anyone's eyes (including your own).

⚠ CAUTION: *During the fluorescence examination, exercise caution when blue light is being emitted from the device. Ensure that the light is only being directed into the mouth of the patient and is not inadvertently shone into the patient's, or anybody else's eyes, including your own. The blue light from the device will cause discomfort and possible eye injury if viewed directly.*

2. Position the device approximately 5 in. (12 cm) from the oral tissue of interest.

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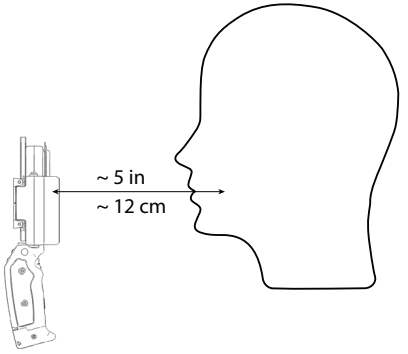
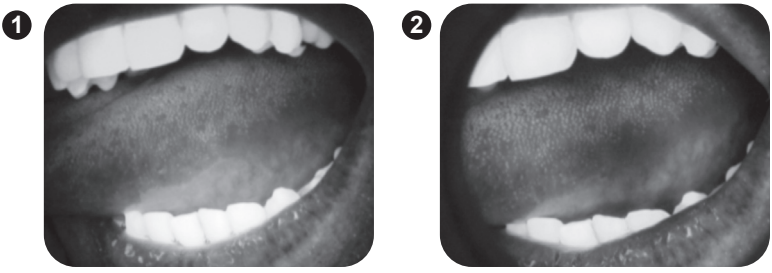
10. Operating Instructions (continued)



⚠ **CAUTION**: *The VELscope Mantis Handpiece emits a cone of blue light from the ring of blue LEDs situated around the front face of the unit. At distances of less than 8-10 cm from the front face, the beam pattern will create a dark central area, because the light from the 3 LEDs has not yet formed a uniform spot. Be sure to position the VELscope at least 8-10 cm from the target tissue to avoid the artificial appearance of a loss of fluorescence. See below for an illustration of this effect.*



The image on the left shows the view through the VELscope Mantis with the unit around 5 in. (12 cm) from the tissue. The image on the right demonstrates how positioning the Handpiece too close to the tissue results in an artificial loss of fluorescence caused by the dark spot in the illumination pattern at distances less than ~8-10 cm from the front of the unit.

3. Rotate the Filter Wheel to the desired visualization mode: Normal, Polarized or Fluorescence as described in "Ring Light Unit & Filter Wheel" on page 20.

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10. Operating Instructions (continued)

4. Press and hold the power button for 1 second to turn the unit on.

5. If the Battery has not been charged recently and/or you are unsure of the battery charge, observe the LED indicator that can be seen by looking at the Power Button from above. If the indicator is Green, then the battery has at least a 20% charge. If you see a flashing amber LED, it indicates the battery charge is less than 20% and you should charge the unit at the next opportunity.

6. Conduct an intra-oral examination using VELscope Mantis device by viewing the soft tissue of the oral cavity through the User Viewport.

7. To change the visualization mode, simply rotate the Filter Wheel to the desired position; you should feel the Filter Wheel lock into position when properly positioned in one of the three visualization modes: N, P or F.

8. Selecting either N or P will cause the white LEDs to turn ON, while selecting F will cause the blue illumination LEDs to turn ON. You will notice that the white LEDs are brighter when the Filter Wheel is in the P position compared to the N position. This is by design and is intended to provide the user with a similar observed tissue brightness when viewing the tissue through the Polarization Filter compared to when viewing it directly while in the N position. See “Ring Light Unit & Filter Wheel” on page 20 for a discussion of the differences between viewing normal and polarized white light reflectance.

9. By rotating the filter wheel between its three positions, you can quickly compare and contrast the visual presentation of the tissue when viewed normally, with polarized reflectance and with natural tissue fluorescence.

10. Remember that palpation is an essential part of oral examinations and

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10. Operating Instructions (continued)

can sometimes help to detect areas of interest that might be hard to see visually.

11. If you discover an area of tissue that needs additional follow-up, you may use an iPhone to photo document the area. Insert the iPhone into the Jaws of the Ring Light Unit and position it so that the lenses of the iPhone are approximately centered in the User Viewport.

12. You may then either take photographs of the area with an app of your choice or you may download the Grip and Shoot app from the app store. Using the Grip and Shoot app is beneficial because it you can take advantage of the Bluetooth capability of the Handpiece and use the zoom buttons on the back of the Handpiece to zoom the image and the trigger button on the front of the Handpiece to acquire a photograph.

13. The VELscope Mantis device has been designed to easily switch between visualization modes and allow rapid acquisition of normal white light reflectance, polarized white light reflectance and fluorescence. Use the hand that is holding the Handpiece to acquire the photograph and your other hand to rotate the Filter Wheel, and you should be able to acquire, if desired, a full set of photographs of all 3 visualization modes in a short amount of time.

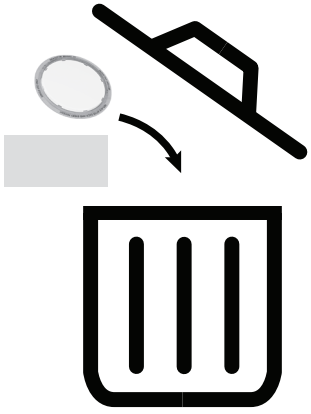
14. Document all findings. It is recommended that all areas of concern be photo-documented using all three visualization modes.

For further guidance on the clinical use of the VELscope Mantis system please refer to the training materials provided on the VELscope website.

10. Operating Instructions (continued)

After the VELscope Mantis Examination

1. Turn the device off by pressing and holding the Power Button for 1 second.
2. Remove and discard the used Lens Cap and Handpiece Barrier.



3. Clean and disinfect the device as described in "9. Cleaning and Infection Control" on page 32

Storage

Use only the original or equally protective packaging when storing the VELscope Mantis system. Observe the storage (non-operating) conditions specified in "Environmental Limits" on page 47.

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11. Routine Maintenance

General Considerations

The VELscope Mantis device is a high-quality system that does not require any maintenance by the user, other than eventual replacement of the rechargeable battery. However, the entire system should be routinely inspected for any deterioration or damage that may compromise proper operation. If any problem is noticed or you have any concerns about the integrity of the system, contact Customer Support.

Warning: No modification of this equipment is allowed.

Note: Do not attempt any internal repair: Other than Rechargeable Battery replacement, there are no user-serviceable parts inside. Removal of protective covers may result in electrical shock and should only be attempted by a service technician authorized by LED Dental. Any unauthorized access to the internal components will void your warranty.

LED Dental will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist Authorized Service Personnel to repair those parts of the system that are designated by LED Dental as repairable by such Authorized Service Personnel.

Rechargeable Battery Replacement

1. Locate the four battery compartment screws on the back side of the Ring Light Unit and unscrew with a small Philips No. 1 screwdriver - see below:

2. Remove the Battery Compartment Cover.

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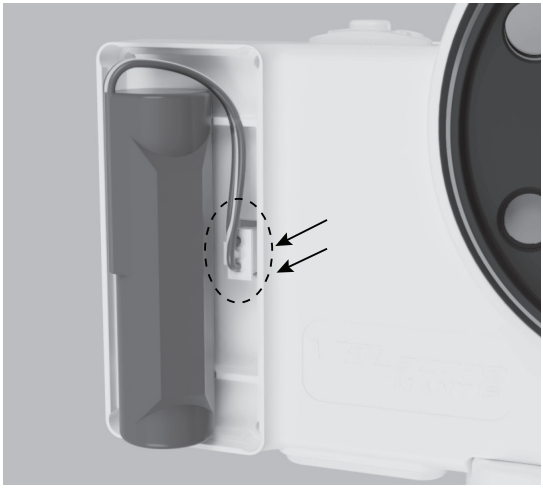
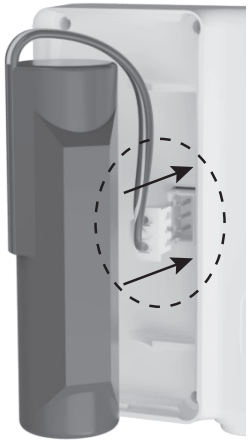
11. Routine Maintenance (continued)

3. Remove the old VELscope Mantis Rechargeable Battery by pulling the connector on the short cable from the battery out of the mating connector on the device. Only pull on the small connector, not the wires.



4. Insert the connector from the end of the cable from the new battery pack and insert it into the mating connector on the device.



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11. Routine Maintenance (continued)

5. The connector has an orientation and can only be inserted one way: the grooves on the connector align with the mating slots on the mating connectorin the Ring Light Unit.

6. Position the battery pack witihin the compartment so that it is full contained (inlcuding the cable leads) inside the compartment and position the battery compartment cover in its original position. Note that there is a rectangular mark on the bottom of the battery compartment cover - be sure the cover is oriented with this mark on the bottom when reattaching the battery cover.
7. Reinsert the four screws and tighten with the Philips No. 1 screwdriver.
8. Fully charge the battery before initial use.

12. VELscope Mantis Disposal Instructions

Disposal of VELscope Mantis system components

The VELscope Mantis hardware contains electronic components and should be recycled or disposed of following local or regional guidelines and regulations for electronics. Remove the battery before disposal, and follow local guidelines.

Lithium Ion Battery disposal

At the end of life of the lithium ion battery, its disposal is subject to local regulations that may vary by country. Please consult these regulations before disposing or recycling of the lithium ion battery from the VELscope Mantis. In particular:

- Do not incinerate.
- Do not cut, puncture or otherwise affect the integrity of the black housing of the battery pack.
- Do not dispose as unsorted municipal waste but recycle according to local regulations.

Disposal of Mantis Shield disposables after use

Used Mantis Shiield disposables should be considered to be biomedical waste and disposed of appropriately according to local guidelines on the handling of biomedical waste products.

13. Registration, Warranty and Disclaimer

Registration

Please register your VELscope System online at www.velscope.com. Registration is essential in helping provide you with the best customer support possible. It is also important for the delivery of advisory notices (including product recall notices).

Warranty and Disclaimer

The VELscope Mantis system is designed to be used as an adjunctive tool for oral mucosal examination only, and this warranty is not applicable to other uses.

LED Dental Inc. (LED Dental) warrants this equipment to the original purchaser against qualifying defects in material and workmanship for one (1) years from the date of purchase, as long as original proof of purchase is provided to LED Dental to its satisfaction.

This warranty is void if the product is not used or maintained according to the Operation Manual provided with the device, or if it has been in any way abused, tampered with, improperly serviced or maintained, or if the serial number is defaced or removed. Service must be performed by LED Dental or those authorized by LED Dental only.

This warranty does not cover malfunctions resulting from exposure to the elements, such as water.

Expected degradation of materials and parts resulting from regular wear and tear, including, but not limited to, discoloration, crazing or minor cracking of plastic parts appearing with time, and degradation with time of push buttons, power cords, and scratching or wearing of paint surfaces, are not considered defects in material or workmanship and thus are not covered under warranty.

Defects in material or workmanship of the accessories of the VELscope Mantis system, including, but not limited to, electronic documentation and other electronic media, patient safety glasses, Mantis Shield Disposables, are covered under warranty only within 30 days from the date of purchase.

Should you require repair service, please contact Customer Support to obtain instructions and a return material authorization (RMA) number. Return the unit insured for full value in original or equally protective packaging. Any damage caused during shipping due to improper packaging will not be covered under warranty and will be the responsibility of the original purchaser. The original purchaser is responsible for any shipping and handling charges when returning product for servicing.

Please contact Customer Support if you have any questions regarding this Warranty Certificate.

14. VELscope Mantis System Specifications

Handpiece Dimensions ..... (H x W x D) 4.7” x 0.8” x 1.8” (12 x 2 x 4.5 cm)
Ring Light Unit Dimensions..... (H x W x D) 4.7” x 6.3” x 2.0” (12 x 16 x 5 cm)
Filter Wheel Dimensions..... (Diameter) 4.9” (12.4 cm)
Mantis Weight..... 0.9 lbs (0.41 kg)
Wall Charger..... MKB2-0502400WU
- Input Voltage .....120-240 VAC
- Input Frequency ..... 50/60 Hz
- Input Current 0.4A
- Output ..... 2.4A Max @ 5 VDC (12W)

USB Charging Cable (USB-C/USB-A) ....(Length) (2.0m)

Optical

Nominal Output Power (400–430nm) ~ 1W
Illumination Spot Nominal Diameter (@ 12 cm working distance) ~ 1.5” (4 cm)
Nominal working distance (front face of unit to tissue) ~ 5” (12 cm)

Environmental Limits

Temperature ..... (operating) 60 – 77°F (16 – 30°C)
Temperature ..... (non-operating) 32 – 122°F (0 – 50°C)
Relative Humidity..... (operating) 20% – 80% (non-condensing)
Relative Humidity..... (non-operating) 10% – 95% (non-condensing)
Maximum Altitude (operating) ..... 10,000 ft (70 kPa)
Maximum Altitude (non-operating) ..... 10,000 ft (70kPa)

15. Compliance with Standards

- ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes.
- ISO 14971 Medical devices – Application of risk management to medical devices.
- IEC 62133-2 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems.

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