Operation Manual

VELscope Vx
Enhanced Oral Assessment

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Congratulations!

Congratulations on your decision to incorporate the VELscope Vx Enhanced Oral Assessment system into your practice to aid in the early visualization of mucosal abnormalities. Proper use of VELscope's natural tissue fluorescence direct visualization technology will greatly enhance the way you examine and manage oral soft tissue conditions. Your patients will appreciate your ability to perform a more comprehensive oral mucosal examination and benefit from immediate oral health information that can significantly reduce delays in treatment and the costs associated with the screening and examination process.

It is the responsibility of every dentist to conduct a thorough evaluation of the oral cavity. Your appreciation of this responsibility is reflected in the decision to integrate the VELscope Vx system into your practice. Early discovery of mucosal abnormalities can result in the successful treatment and management of most mucosal conditions.

The role of the VELscope Vx in early visualization of abnormal oral tissue is particularly important in view of oral cancer statistics. The overall five-year survival rate for oral cancer is only 50-60%, but can be as high as 80-90% when the disease is discovered and treated in its early stages[1].

The principal objective of the VELscope Vx system is to enhance the way practitioners examine the oral mucosa and screen for tissue abnormalities, potentially leading to the earlier discovery oral disease. Discovering signs of oral disease early is one of the best mechanisms for improving treatment success, increasing survival rates and maintaining a high quality of life.

Proper implementation of the VELscope Vx system will result in more efficient use of your time, and seamless, cost-effective integration into your practice workflow. Your entire dental team and your patients will rapidly see and value the benefits offered by the VELscope Vx system and appreciate it as an essential component of a state-of-the-art oral mucosal examination.

1. U.S. Department of Health and Human Services: Oral Health in America: A Report of the Surgeon General. U.S. Department of Health and Human Services, National Institute of Dental and Craniofacial Research, National Institutes of Health - Rockville, MD, 2000.

1 Introduction

About This Manual

This manual provides information on the safe and effective use of the VELscope Vx 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 Vx system prior to using the device during patient care.

This manual is not intended to be a comprehensive guide to a proper oral mucosal examination, but a supplement on the use of the VELscope Vx system and on the use of direct fluorescence visualization during the examination procedure. For more detailed information about the clinical aspects of using VELscope Vx, please refer to the Step-by-Step Examination Guide and the training materials available online.

You can also visit LED Dental Inc.'s website at www.velscope.com, for complementary literature and information on how to use VELscope and its fluorescence visualization technology.

Another excellent source of information is the Oral Cancer Foundation. We encourage you to visit their website (www.oralcancerfoundation.org) and consider joining the Foundation.

The Gold Standard of Diagnosis: Surgical Biopsy

Histological examination is the gold standard and the only accepted method for diagnosing oral lesions (including oral dysplasia and cancer). All other techniques are adjunctive modalities to accelerate the need for an appropriate surgical biopsy to be performed.

Oral pathology labs are very often associated with dental schools and are commonly staffed and run by instructors that dentists may have had during their training.

Pathology labs and instructors are both excellent sources of information and guidance for clinicians.

Glossary

Natural Tissue Fluorescence: Light produced by tissue due to the absorption of light at one wavelength (e.g., blue) followed by the nearly immediate generation of light at longer wavelengths (e.g., green). Fluorescence occurs naturally in oral tissue but is not noticed due to the much higher intensity of the reflected light.

Reflectance: The fraction of light that is reflected from a surface. Vision is based on the perception and interpretation of light reflected from the objects being observed. The reflected light from an object is commonly much stronger in intensity (by several orders of magnitude) than the fluorescence induced by the incident light. Consequently, fluorescence cannot usually be perceived without blocking out the reflected light.

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1 Introduction *(continued)*

VELcap Vx: VELscope Vx accessory consisting of a single-use, disposable, protective, asepsis-enhancing, anti-fog lens cover.

VELsheath Vx: VELscope Vx accessory consisting of a single-use, disposable, plastic barrier used to cover the VELscope Vx Handpiece in order to enhance asepsis and help prevent patient-to-patient cross contamination.

Manufacturer Information

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2 Package Contents

When opening and unpacking the contents of the VELscope Vx 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 bottom of the handle of the Handpiece.

The VELscope Vx System Package (4200 Series) contains:

1. Operation Manual (Print Version)
2. Quick Reference Guide (Print Version)
3. Step-by-Step Examination Guide (Print Version)
4. VELscope Vx Handpiece
5. VELscope Vx Battery pack
6. VELscope Vx Charging Cradle
7. External Power Brick
8. Grounded Hospital Grade AC Power Cord
9. 1 Pair Deluxe Safety Glasses
10. 100 Patient Brochures

⚠ **CAUTION:** VELscope Vx system to be operated only with external power brick provided with the system: MENB1060A1200F03 (SL Power).

3 Symbol Guide

Manufacturer

Temperature limitation

Do not reuse

SN **Serial Number**

Consult Instructions for Use

Earth (ground)

Authorized Representative for Europe

Caution – Consult Accompanying Documents

4 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

The VELscope Vx system should never be used without prior conventional oral mucosal examination under incandescent light.

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

Precautions

The clinician should always perform the traditional oral cavity examination by incandescent light prior to conducting the VELscope Vx exam.

The clinician should never, based on the VELscope Vx exam, remove from consideration an abnormality that would have otherwise been investigated based on the traditional oral mucosal examination with incandescent light.

In deciding on the appropriate surgical margin for tumor excision, the surgeon should always remove at a minimum the tissue that was identified from the initial clinical assessment prior to the use of VELscope Vx. The surgeon should never fail to excise tissue that would have otherwise been removed had the VELscope Vx device not been used.

⚠ CAUTION: Although the output for the VELscope Vx system meets international safety standards for light output, looking directly into the light-emitting port of the VELscope Vx Handpiece while in operation should be avoided. All patients should wear protective eyewear (as when a composite curing light is being used) to minimize discomfort and the potential for risk of eye injury. A pair of Deluxe Safety Glasses is provided with the VELscope Vx system.

Note: The patient-side of the VELscope Vx Handpiece has the following Caution symbol printed twice onto the outside of the housing:

This is to indicate that this is the side where the bright blue excitation light is emitted from the Handpiece and looking directly at this side of the unit while the device is emitting light is to be avoided.

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4 Safety Considerations *(continued)*

Do not install the VELscope Vx 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 Vx 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 Vx system.

5 The VELscope Vx System

Overview

The VELscope Vx system is a natural tissue fluorescence direct visualization system to be used as an adjunctive instrument for oral mucosal examination.

The main components of the VELscope Vx system are the viewing Handpiece, the Charging Cradle and an external power brick. The system is intended to be used with a single-use, multi-function, disposable lens cover (VELcap Vx) and a single-use, disposable Handpiece plastic barrier (VELsheath Vx).

The VELscope Vx Handpiece emits a safe, visible blue light into the oral cavity, which excites the oral tissue and causes it to fluoresce. The oral cavity can then be examined in real time, enhancing the practitioner's ability to quickly identify suspicious tissue that may require further investigation. When viewed through the VELscope Vx Handpiece, abnormal tissue typically appears as an irregular, dark area that stands out against the otherwise normal, green fluorescence pattern of surrounding healthy tissue.

Indications for Use

VELscope Vx is intended to be used by a dentist or health-care provider as an adjunct to traditional oral examination by incandescent light to enhance the visualization of oral mucosal abnormalities that may not be apparent or visible to the naked eye, such as oral cancer or premalignant dysplasia.

VELscope Vx is further intended to be used by a surgeon to help identify diseased tissue around a clinically apparent lesion and thus aid in determining the appropriate margin for surgical excision.

Intended Use

VELscope Vx is to be used by qualified health-care providers to enhance the identification and visualization of oral mucosal abnormalities by exciting the tissue with blue light and allowing the direct visualization of the resulting natural tissue fluorescence.

VELscope Vx is complementary to and is intended to be used in combination with a traditional oral mucosal examination with incandescent (white) light. VELscope Vx in no way diminishes the importance of this examination. Accordingly:

- The clinician should always perform the traditional oral cavity examination by incandescent light prior to conducting the VELscope Vx exam.
- The clinician should never, based on the VELscope Vx exam, remove from consideration an abnormality that would have otherwise been investigated based on the traditional oral mucosal screening exam.
- The clinician should re-examine the oral cavity under incandescent light after finding a potential abnormality using VELscope Vx and use his/her own clinical judgment as to what the best course of action should be.

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VELscope Vx is further intended to be used by a surgeon adjunctively to his/her clinical assessment to help assess the extent of diseased tissue around a clinically apparent precancerous or cancerous lesion.

- The conventional clinical assessment of the lesion under white light should always be conducted prior to the VELscope Vx assessment.
- In deciding on the appropriate surgical margin for tumor excision, the surgeon should remove at a minimum the tissue that was identified from the initial clinical assessment prior to the use of VELscope Vx. The surgeon should never fail to excise tissue that would have otherwise been removed had the VELscope Vx device not been used.
- The surgeon should take into consideration the VELscope Vx assessment but always use his/her own clinical judgment in making the final decision as to the area of tissue that will be removed during tumor excision.

Description of Components

Handpiece

The VELscope Vx Handpiece is a completely integrated fluorescence visualization solution that incorporates cutting-edge blue LED technology to deliver a bright blue excitation light, as well as proprietary filtering to allow direct viewing of the resulting natural tissue fluorescence. In addition, a compact rechargeable battery enables fully cordless operation.

Basic Function

The Handpiece has the following key functions:

- Projects an approximately 4 cm diameter spot of blue excitation light at about 10 cm from its front face.
- Filters out reflected blue light to allow direct visualization of the resulting natural tissue fluorescence.
- Provides an optimized view of the oral mucosa via proprietary filtering mechanisms.
- Allows for straightforward activation and deactivation of the LED array light source by a conveniently placed push button.
- Provides a straightforward mechanism for snap-attachment of the VELcap Vx disposable, with a groove on the outside of the housing around the patient-side viewing port.

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- Reduces glare and helps protect interior optics with a removable, bayonet-mounted Eyepiece. The Eyepiece can be removed to allow for the attachment of a camera adapter.
- Houses a connector in the base of the handle for connection to the external power brick, either when seated inside the Charging Cradle or when connected directly with the charging cable.

Figure 1. VELscope Vx Handpiece with the VELcap Vx attached.

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5 The VELscope Vx System *(continued)*

Handpiece Control & Indicators

ON/OFF Pushbutton

The Handpiece is straightforward to use with a single push button on the front (patient side) to turn the blue excitation light on and off. A single press turns on the light and a second, single press turns it off; continuous pressure on the button is not required.

Indicator LEDs

There are three status indicator LEDs:

- Battery LED (GREEN)
- Power Connection LED (WHITE)
- Caution LED (AMBER)

See page 14 for a summary of meaning of these status indicators.

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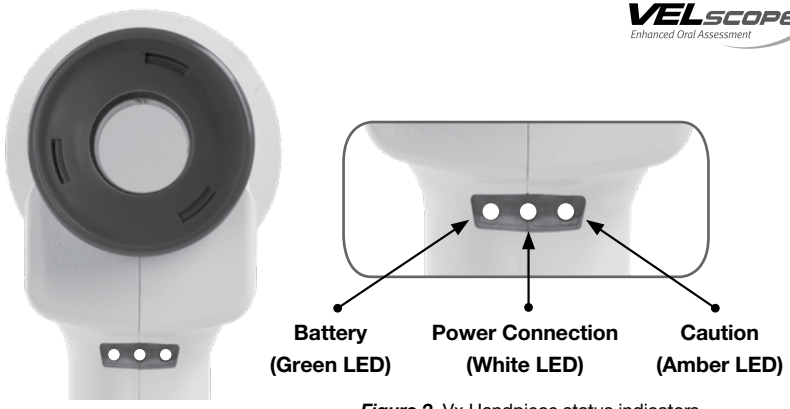

Figure 2. Vx Handpiece status indicators.

Battery Green	Power Connection White	Caution Amber	Device Status
Normal Operation Cordless			
Off	Off		Blue Light Off, or Blue Light ON & Battery >15%
Flashing	Off		Blue Light On Recharge Battery Soon
Off	Off		Blue Light NOT coming on - Recharge Battery
Normal Operation Connected Directly to External Power Brick or in Charging Cradle			
Flashing	Solid		Charging
Solid	Solid		Fully Charged
Off	Solid		Blue Light On Normal Operation
Problem Detected			
		Flashing: Duration – 10 Secs.	Blue Light Shuts Off Wait 1 minute – if problem recurs, see Operation Manual

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A detailed explanation of the various indicators is provided below.

- **Power Connection LED (WHITE)**
  The white Power Connection LED turns on SOLID WHITE and remains ON whenever the Handpiece is connected to the external power either directly (with the cord plugged into the base of the Handpiece) or when sitting inside the properly connected Charging Cradle. This is true even when you press the ON/OFF button to turn on the excitation light if you are bypassing the battery and using the unit – powered directly from the power supply.
- **Battery LED (GREEN)**
  The green Battery LED indicator scheme is context-sensitive depending on whether the unit is powered ON (emitting blue light) or whether it is turned OFF and connected to the power supply, i.e. being charged.
  - **Powered ON**
    The green Battery LED remains off until the power in the battery has only about 2 minutes of life remaining, at which point it will flash continuously to indicate that the Handpiece will turn off soon unless the battery is recharged.
  - **Charging**
    The green Battery LED will flash continuously a few times per second while the battery is being charged. Note: due to the heat generated from the unit (from the high-power blue LEDs and the battery itself), there may be times, while attempting to charge the unit after use, when the Battery LED will delay its continuous flashing cycle. The unit is NOT MALFUNCTIONING. The battery has built-in protection circuitry, designed to prolong the life of the battery, which prevents charging when its internal temperature is above a certain limit. Leave the unit charging and once the battery has cooled down (it may take a few minutes) it will start to charge and the Battery LED will begin to flash. Note also that while connected to the power supply the white Power Connection LED should always be lit, to indicate that the unit is connected and functioning properly.

    Once the battery has charged fully, the green Battery LED will stop flashing and turn SOLID GREEN to indicate that the battery is fully charged.

    Note: Once you remove the fully charged Handpiece from the Charging Cradle (or unplug the power cable if it is connected directly to the Handpiece), both the white Power Connection LED and the green Battery LED will turn OFF. When you turn the unit ON to use it in the cordless operation mode, both of these indicator LEDs will remain OFF. As stated above, if you use the Handpiece long enough to drain battery sufficiently, the green Battery LED will start to flash.

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- **Caution LED (AMBER)**
  The amber Caution LED is not something you should see lit during normal operation. It indicates that a problem has occurred that has caused the unit to shut down. Possible reasons why this might occur are:
  - **Overheating:** your VELscope Vx Handpiece contains sophisticated electronic circuitry that constantly monitors internal temperatures and attempts to maintain them within the proper operating range. However, in certain unusual or extreme circumstances, such as extended usage in unusual ambient environmental conditions, the unit may overheat. If it does, the unit will power itself down and the amber Caution LED will flash for 10 seconds. If this happens, wait a minute or so for the Handpiece to cool and then you may continue to use it.
  - **Fan Malfunction:** the unit constantly measures the proper operation of the fan; if, for any reason, the fan does not operate when intended, the unit will power down and the amber Caution LED will flash for 10 seconds.

    If the amber Caution LED continues to come on in normal operation, your unit may need repair. Please contact Customer Support.

Charging Cradle

The VELscope Vx system comes with a Charging Cradle (depicted in Figure 3 on next page). The Charging Cradle serves two purposes:

1. Convenient resting place and stand for the Vx Handpiece when not in use.
2. Charging station in which the rechargeable battery in the Handpiece gets automatically charged, provided that the Charging Cradle is properly connected to the external power brick.

The Vx Handpiece will only fit into the Charging Cradle in one orientation, as shown in Figure 3. Do not use excessive force when placing the Handpiece inside the Charging Cradle – the Cradle is designed to easily accommodate the Handpiece and ensure an electrical connection without undue force from the user. Excessive force may damage the connectors.

The Charging Cradle also incorporates a removable plastic insert which can be removed from the Cradle and cleaned as required.

Figure 3. The VELscope Vx Handpiece standing inside the Charging Cradle

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External Power Brick

The External Power Brick is a medical grade power supply that, when properly plugged into an AC outlet with the provided hospital grade AC power cord, provides electrical power to the VELscope Vx Handpiece. The VELscope Vx system can only be used with the power supply brick provided with the system.
It can be connected in two ways:

1. Into the back of the Charging Cradle. This is the normal configuration which you will probably use most, if not all, of the time. In this configuration, the Handpiece operates in cordless mode, and must be placed back into the Charging Cradle to recharge the battery.
2. There may be occasions (e.g. extended usage with no time between examinations to recharge the battery) when it is convenient to bypass the rechargeable battery and operate the unit directly from the External Power Supply. To do this, unplug the cable from the Charging Cradle and connect it directly into the base of the Vx Handpiece. The Handpiece can then be used even if the battery has no charge left. Note that, when operated this way, the battery will not charge while the unit is powered ON. Once you turn the Handpiece off, the battery will charge after a 10 second delay (as long as it is not too hot to charge immediately after shutdown) and the green Battery LED will start to flash.

⚠ **CAUTION:** When removing the cable from either the back of the Charging Cradle or the bottom of the Handpiece, be careful to squeeze the tabs on the side of the connector to disengage it. Failure to do so may cause damage to the connector.

Rechargeable Battery

The VELscope Vx Rechargeable Battery is a custom designed battery pack designed for an extremely demanding high-power application – generation of enough bright blue excitation light to induce bright oral soft tissue fluorescence that can be easily viewed and photographed. With this in mind, there are limitations on both how long it can power the Handpiece continuously on a full charge and its overall life before needing replacement.

- On a full charge, operated cordless, with a new battery, the VELscope Vx Handpiece can be expected to run continuously for approximately 12 minutes before draining the battery. Given that a typical examination with the VELscope Vx takes approximately 2-3 minutes, this is more than enough charge.
- The Rechargeable Battery is rated by the manufacturer for 400 full discharges. How this translates into actual battery life in a real world scenario in a dental practice depends heavily on how it is used:

  a. How many examinations per hour are conducted?

  b. Is the Handpiece put back on the Charging Cradle immediately after use?

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  c. How often are longer examinations required (e.g. an area of interest requires photo-documentation etc.)?

- To extend battery life, we recommend use of the VELscope Vx Handpiece for as long as you need to for a particular examination (typically 2-3 minutes) and then immediate replacement into the Charging Cradle for return to a full charge before subsequent usage.
- A battery completely drained of charge takes approximately 1 hour to recharge to full capacity. To recharge a battery with a partial charge takes proportionately less time.

VELsheath Vx

The VELsheath Vx is a single-use, disposable plastic barrier used to enhance asepsis and mitigate the risk of patient-to-patient cross contamination.

WARNING: Dispose of the VELsheath Vx properly after use. A new, unused VELsheath Vx 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 VELsheath Vx does not withstand high temperatures. Do not attempt to sterilize with autoclave, dry heat, or otherwise.

VELcap Vx

The VELcap Vx is a protective, multifunctional, single-use, disposable lens cover.

The primary functions of the VELcap are to:

- Seal off and protect the precise optics of the Handpiece 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.

Figure 4. A VELcap Vx Disposable attached to the patient side of the Handpiece.

WARNING: Dispose of the VELcap Vx properly after use. A new, unused VELcap Vx 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 VELcap Vx does not withstand high temperatures. Do not attempt to sterilize with autoclave, dry heat, or otherwise.

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Principles of Operation

Traditional oral mucosal examination tools rely on reflected light to visualize the oral cavity. VELscope Vx uses tissue fluorescence rather than reflectance. Natural tissue fluorescence is caused by “fluorophores” that, when excited by light of an appropriate wavelength (for example, blue), will emit their own light at a longer wavelength (for example, green). The resulting fluorescence can reveal a great deal about cellular, structural, and/or metabolic activity changes that are often directly related to disease processes occurring inside the tissue.

The VELscope Vx system induces natural tissue fluorescence by illuminating the oral cavity with a bright blue light. This tissue fluorescence is many thousand times less bright than the blue excitation light reflected from the tissue. Viewing the tissue through the Handpiece allows you to directly visualize the tissue fluorescence because the reflected blue excitation light is completely blocked by the filters situated along the viewing path. In addition, proprietary optical filtering technology provides for an enhanced view of the tissue fluorescence.

Brief Technical Description

The VELscope Vx model is a significant step forward from its predecessor VELscope models, because the Mercury / Metal Halide lamp from previous models has been replaced by 16 1W blue LEDs arranged in a circular array around the patient-side optical viewing window of the Handpiece. The array is focused to provide an approximately 4 cm-diameter spot of blue excitation power at about 10 cm from the front face of the unit. The total optical output power is approximately 1W with the wavelength in the 400-460nm range. The clinician views the natural tissue fluorescence excited by the blue excitation light directly, by observing through the filters along the optical tube between the clinician and patient-side viewing windows. These filters not only block all the blue excitation light, but also perform proprietary filtering to help improve contrast between normal and abnormal tissue. These filters have the same performance characteristics as in previous VELscope models. Thus, the optical performance of this LED-driven solution is comparable to the VELscope Vantage system, which has been delivering superb, industry-leading performance to clinicians around the globe for years.

Due to the heat generated by these blue LEDs, the system optimizes performance by dynamically controlling the LED’s and utilizing a custom-designed heat sink and a high-performance fan.

The other significant design improvement over previous models is the addition of a custom-designed lithium ion rechargeable battery, to enable fully cordless operation of the unit. The battery is user-replaceable by removing the cover on the base of the handle, removing the expired battery, inserting the replacement battery, and screwing the cover back into place. The old battery should be disposed of safely.

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The Charging Cradle that comes with the system has a conveniently small footprint, and is weighted to reduce the risk of knocking the system over when the Handpiece is inserted.

The Charging Cradle’s main function, apart from ergonomics, is to provide a convenient conduit for DC electrical power from the external medical-grade power supply to the Handpiece, to allow charging of the battery while the Handpiece is inserted inside the cradle. The External Power Brick is connected to the back of the Charging Cradle, and the connection to the Handpiece occurs when the connector in the base of the Handpiece engages with the corresponding connector protruding from the bottom of the recessed compartment of the cradle.

6 Installation & Set Up

Initial Setup

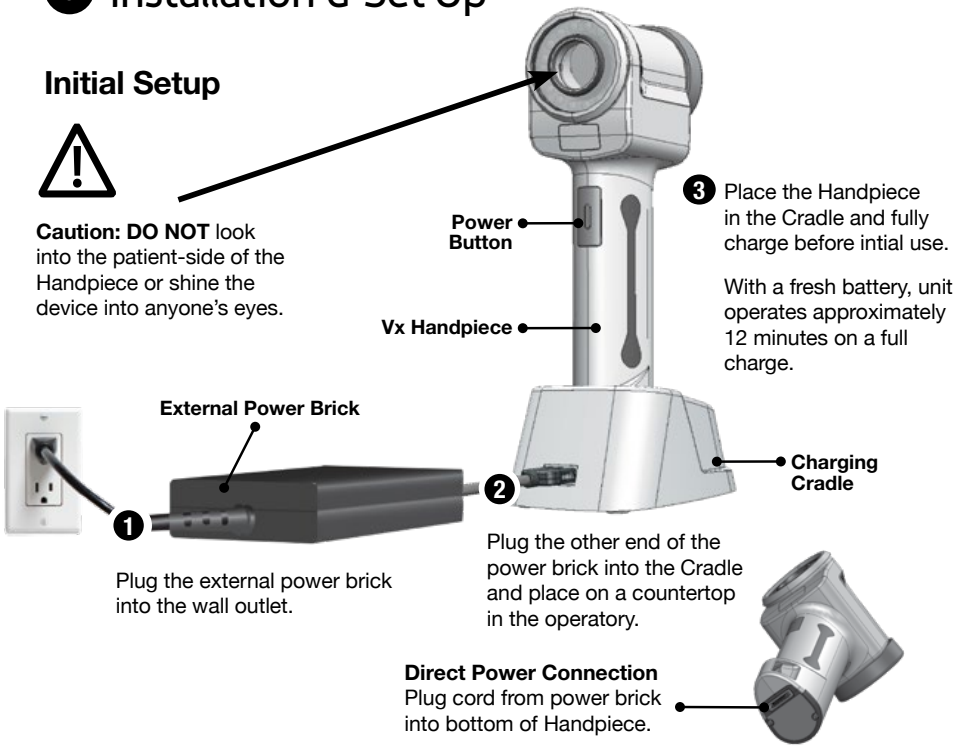

Figure 5. Initial setup of the VELscope Vx system.

General Instructions

The setup of the VELscope Vx system is straightforward (see Figure 5):

1. Remove the Handpiece, Battery Pack, Charging Cradle, External Power Supply and AC Power Cord from the VELscope System Box.
2. Install Battery Pack according to the instructions on page 29 under "Rechargeable Battery Replacement".
3. Find a countertop in the dental operatory conveniently located with respect to the dental unit and place the Charging Cradle in the desired location.
4. Insert one end of the AC Power Cord into the External Power Supply Brick and plug the other end into an AC wall outlet. The External Power Supply Brick can sit on the floor or on the countertop as desired.

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6 Installation & Set Up *(continued)*

5. To make provision for operation of the Vx Handpiece powered directly from the External Power Supply with a cord, ensure the AC wall outlet is within about 6-7 feet (2 meters) of the dental unit.
6. Route the cable from the External Power Supply as desired and insert the connector into the receptacle on the back of the Charging Cradle.
7. Place the Handpiece in the Charging Cradle to start charging the battery. The green Battery LED will start to flash, indicating that the Battery is charging (there may be a few seconds delay while the unit "reads" the amount of charge in the battery).
8. To maximize battery life, it is preferable to let the battery fully charge for its first use, so let the Handpiece rest in the Charging Cradle until the Battery LED goes SOLID GREEN, indicating that the battery is fully charged.
9. You may now use the VELscope Vx Handpiece as convenient, replacing it in the Charging Cradle between uses.

Other Considerations

Ambient Light

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

Ventilation

As with most light sources, the VELscope Vx Handpiece does generate heat. The unit requires adequate air flow for ventilation and cooling. The air intake for the Handpiece is through the metal grill just behind the front face around the head of the unit. The exhaust ports are at the rear base of the handle of the Handpiece, one on either side. Ensure that neither of these are blocked or obstructed while using the unit.

Environmental

Please see VELscope System Vx Specifications in Section 11 for the operating and non-operating environmental limits.

Electrical Safety

WARNING: Only use the supplied grounded power cord. The External Power Supply should only be connected to a properly grounded power outlet.

Liquid Ingress

⚠ **CAUTION:** Because of the air intake grills and exhaust ports on the unit, the VELscope Vx Handpiece is neither splash-proof nor drip-proof. Take care not to let liquid enter into the Handpiece, as it could cause damage to internal electrical components.

7 Cleaning and Infection Control

General Considerations

The VELscope Vx Handpiece, Charging Cradle and External Power Supply are **NOT STERILIZABLE WITH AUTOCLAVE, DRY HEAT, OR OTHERWISE.**

The VELscope Vx Handpiece, Charging Cradle and External Power Supply 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 the VELcap Vx will have a detrimental effect on the optical and clinical performance of the VELscope Vx system.

Handpiece

Exercise care to protect the precise optics of the VELscope Vx Handpiece. The VELcap Vx has been designed, not only to prevent cross contamination, but also to protect the optical elements from contaminants, dust, and debris.

After each use, be sure to remove (and properly dispose of) the used disposable VELsheath Vx and VELcap Vx before cleaning and disinfecting the VELscope Vx Handpiece. The external surfaces of the Handpiece should then be wiped down with a hospital-grade surface disinfectant and a towelette or gauze, e.g. Caviwipes™ or equivalent.

A new VELcap Vx should be placed on the Handpiece immediately after cleaning to protect the optical elements from dust and powder during inactivity.

Handpiece Filters

The filters contained in your VELscope Handpiece are precise optical elements that require special care and cleaning. In order to keep your VELscope working at peak performance it is recommended that the outside optical surfaces be cleaned when needed. Failure to follow these instructions may result in damage to your Handpiece filters, which is not covered by warranty.

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7 Cleaning and Infection Control *(continued)*

If you see dust or any type of non-uniform coating on the optical surfaces, they need to be cleaned as follows:

1. Use a rubber blower (commercially available) to carefully blow away any dust on the surface of the optics. It is important to clear any dust before you try to apply any cleaners, as the dust is abrasive and could scratch the glass coatings.
2. Once the dust is removed, inspect the optical surfaces for any type of filmy residue or fingerprints. If such contaminants are found, wipe ONCE gently with a lint-free tissue damped with a mild liquid solvent (such as a commercially available lens cleaning solution, or simply 50-% isopropyl alcohol). Discard the tissue - DO NOT REUSE IT! Repeat this procedure until the entire surface is clean.

⚠ **CAUTION:** Exercise care when cleaning the protective glass in the Eyepiece. Do not press too hard on the glass surface. Excessive force may dislodge it.

Charging Cradle

The Charging Cradle may be cleaned similarly to the Handpiece – wipe down with a hospital-grade surface disinfectant and a towelette or gauze. In addition, the plastic Cradle Insert may be removed and cleaned as desired. To remove Cradle Insert, squeeze the top edge at the sides to release.

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.

⚠ **CAUTION:**

DO NOT immerse in any liquid or use excessive cleaning fluid when cleaning the system. The Vx Handpiece and Charging Cradle are not water resistant and excess fluid can penetrate the system and cause damage to internal components. This damage is not covered under the warranty.

WARNING:

Ensure that liquid does not pool down in the Charging Cradle near the electrical connector. Any residual liquid present near the connector in the Charging Cradle may cause an electrical short and a possible fire hazard.

8 Operating Instructions

Essential Steps for Oral Soft Tissue Examinations Before Using the VELscope Vx

1. Begin by carefully assessing, reviewing and documenting the patient's relevant medical and dental history.
2. Conduct a thorough extra-oral and intra-oral examination both visually and manually, palpating all of the structures of the head and neck.
3. You are now ready to repeat the intra-oral examination using VELscope Vx by viewing the oral cavity through the Handpiece to enable the visualization of the tissue's natural fluorescence.

System Preparation

1. Prior to using the VELscope Vx system, please read and follow the instructions provided in Section 6 to ensure that your system is appropriately assembled, installed, and ready to use on patients.
2. Observe the Battery LED indicator on the Vx Handpiece while in the Charging Cradle; if it is SOLID GREEN, the Handpiece is fully charged.
3. Remove the Vx Handpiece from the Charging Cradle and slide a new disposable VELsheath Vx barrier over the Handpiece.

Figure 6. Application of the VELsheath Vx disposable.

Apply the VELsheath Vx before the VELcap Vx. The VELsheath Vx has been designed specifically for the VELscope Vx Handpiece with cutouts on the top to help ensure that the clinician and patient-side optics and the air intake grills are not covered. Take care that the VELsheath Vx is not drawn down tight over the grills or the exhaust openings at the base of the handle when holding the barrier-protected Handpiece, as this may impede the airflow and affect the thermal performance of the unit.

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4. Attach a new disposable VELcap Vx onto the front face of the unit.

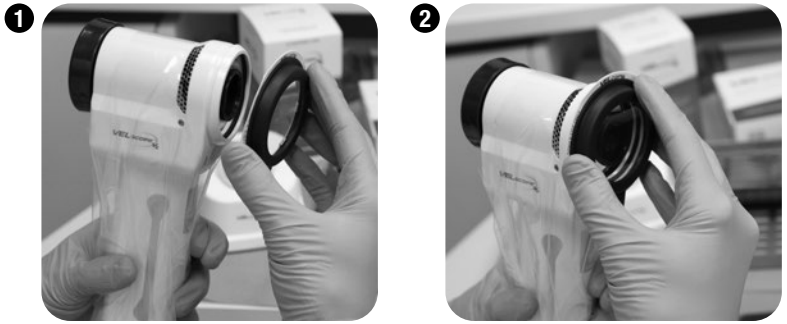

Figure 7. Attaching the VELcap Vx disposable.

- Attach the VELcap Vx as Follows:
  Hold the VELcap Vx by the rim.
- Position parallel to the front face of the unit and gently press on by engaging the paper tabs into the groove on the outside of the Handpiece.
- Ensure that, once applied, the VELcap Vx window is situated parallel to the face of the unit.
- Do not apply excessive force.
- Avoid touching the clear plastic window as this may leave residues which could obscure the view through the VELscope Vx.

5. The VELscope Vx system is now ready for use on patients.

Prior to the VELscope Vx 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.

(continued on next page)

8 Operating Instructions *(continued)*

⚠ CAUTION: 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 VELscope examination, and adversely affect your ability to discover tissue abnormalities. 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) for the duration of the VELscope Vx examination, if possible.

VELscope Vx Examination

1. Before removing the Vx Handpiece from the Charging Cradle, minimize the possibility of shining the light into the eyes of anybody in the operatory (including yourself) by ensuring that the Handpiece is OFF and not emitting blue light.

⚠ CAUTION: Exercise caution when blue light is being emitted from the Handpiece. 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 light from the Handpiece will cause discomfort and possible eye injury if viewed directly.

2. Remove the Handpiece from the Charging Cradle and position it approximately 3-4 in. (8-10 cm) from the mouth of the patient.

⚠ CAUTION: The VELscope Vx 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 cm from the front face, the beam pattern will create a dark central area, because the light from the 16 individual LEDs has not yet formed a uniform spot. Be sure to position the VELscope at least 8 cm from the target tissue to avoid the artificial appearance of a loss of fluorescence. See Figure 8 for an illustration of this effect.

3. Turn on the blue excitation light by depressing the ON/OFF button on the front of the Vx Handpiece.
4. After a few seconds, check that the Battery LED indicator is not flashing. If it is, you only have a few minutes of charge left on the rechargeable battery. Keep this in mind while conducting the VELscope examination. If the battery runs out of charge during the examination, the Handpiece will shut down completely. If this happens, remember that you have the option of detaching the cable from the back of the Charging Cradle, plugging it directly into the base of the Vx Handpiece and continuing the examination by running the Handpiece directly from the External Power Supply.

(continued on next page)

8 Operating Instructions *(continued)*

5. Conduct an intra-oral examination using VELscope Vx by viewing the soft tissue of the oral cavity through the Vx Handpiece to enable the visualization of the tissue's natural fluorescence.
6. When viewed through the VELscope Handpiece, abnormal tissue typically appears as an irregular, dark area that stands out against the otherwise normal, green fluorescence pattern of surrounding healthy tissue. This difference in appearance assists you in differentiating between healthy mucosa and areas of concern that may require further action.

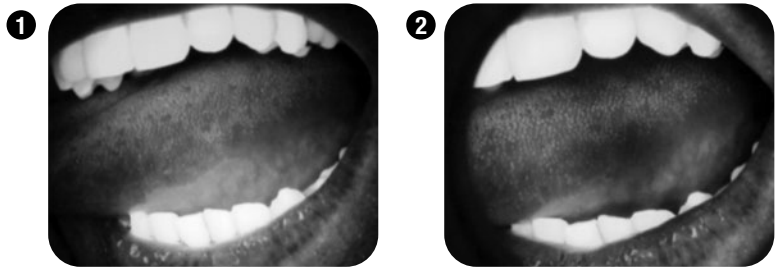

Figure 8. The image on the left shows the view through the VELscope Vx with the Handpiece around 3-4 in. (8-10 cm) from the tissue. The image on the right demonstrates how positioning the Handpiece too close to the tissue results in an artificial loss of fluorescence caused by the dark spot in the illumination pattern at distances less than ~8 cm from the front of the unit.

7. Document all findings – both normal and abnormal – in the patient's clinical record.
8. Re-examine any suspicious regions under white light as follows:

   a. Re-evaluate the region under white light.

   b. Re-palpate the region.

   c. Identify any benign conditions that might have caused the region to appear dark under VELscope examination.

Some benign conditions that may appear dark under VELscope include: traumatic lesions (e.g., chronic irritation), pigmented lesions (e.g., melanotic macule), vascular lesions (e.g., hemangioma), common infections (e.g., herpes labialis), and inflammatory conditions (e.g., Apthous ulcers).

9. If, after re-examination, the lesion cannot be ruled out as benign, observe the suspicious tissue thorough the VELscope Handpiece while applying a light amount of pressure in a sweeping motion with the back side of an explorer (or similar instrument) to diffuse any superficial blood from the area (i.e., blanching). If the green fluorescence returns with this pressure, then the lesion may be of

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an inflammatory nature and appropriate care to remove the possible cause may be recommended. A follow-up visit for re-evaluation should be scheduled in approximately 2 weeks as indicated below

10. **If you suspect an abnormal mucocutaneous lesion, a follow-up visit for re-evaluation should be scheduled in approximately 2 weeks.** If the lesion has not resolved after this follow-up time, you should proceed with further investigation of the suspicious tissue according to your regular standard of care, or refer the patient to a specialist. It is your clinical judgment which will ultimately determine the course of action appropriate for each case.

11. Document all findings. It is recommended that all areas of concern be photo-documented both under standard lighting conditions and through the VELscope Handpiece.

For further guidance on the clinical use of the VELscope Vx system please refer to the training materials provided on the VELscope website – www.velscope.com.

After the VELscope Vx Examination

1. Turn the VELscope Vx Handpiece OFF by depressing the ON/OFF button.
2. Remove and discard the disposable VELsheath Vx and VELcap Vx.
3. Return the Handpiece to the Charging Cradle to recharge the battery.
4. The VELscope Vx Handpiece should be cleaned and disinfected according to Section 7 above.

Storage

Use only the original or equally protective packaging when storing the VELscope Vx system. Observe the storage (non-operating) conditions specified in Section 11.

Other Features of Your VELscope Vx System

Because of the heat generated inside the Vx Handpiece, a high-performance fan is required to keep the temperature at an optimal level during use. When you turn the unit OFF, you will notice that the fan continues to run at full speed for a short amount of time (maximum 10 seconds). This is to help the unit cool down in preparation for charging the battery and/or the next usage. After this initial 10 seconds the fan automatically switches to a lower speed. This continues to cool the unit at a slower rate but, for your convenience, decreases the fan noise. Once the internal temperature reaches a set lower limit, the fan will shut off completely.

9 Routine Maintenance

General Considerations

The VELscope Vx 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 Battery Cover on the underside of the VELscope Vx Handpiece.
2. Unscrew the two machine screws with a small Phillips screwdriver.
3. Remove the Battery Cover.
4. Remove the old VELscope Vx Rechargeable Battery by simply tipping the Handpiece so that its base is pointing slightly downwards. The old battery should simply drop out.
5. Gently insert the new VELscope Vx Rechargeable Battery. The battery and its enclosure inside the Vx Handpiece are shaped so that the battery can only fit in one orientation although you will need to ensure that the end of the battery with the five gold-colored contacts is the end that is inserted into the Handpiece first.
6. Put the Battery Cover back in place and screw the two machine screws back into place to attach the cover securely. Do not over-tighten the screws.
7. Place the VELscope Vx Handpiece into the Charging Cradle to charge the new battery to full capacity before use. The green Battery LED on the Vx Handpiece should start to flash to indicate that the Vx Rechargeable Battery is charging.
8. When the Battery LED on the Handpiece turns to solid green, your VELscope Vx system is ready to use.

10 VELscope Vx Disposal Instructions

Disposal of VELscope Vx system components

The VELscope hardware (including handpiece, cradle and power supply) contain 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.

European Union (EU) only

The major components of the VELscope system bear the Waste Electrical and Electronic Equipment (WEEE) symbol. According to the WEEE directive, users of electrical and electronic equipment such as the VELscope Vx must not dispose of such equipment as normal, unsorted municipal waste but use the collection framework available to them for the return, recycle, recovery of WEEE.

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 Vx. 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 VELcap Vx and VELsheath Vx disposables after use

Used VELcap Vx and VELsheath Vx disposable should be considered to be biomedical waste and disposed of appropriately according to local guidelines on the handling of biomedical waste products.

11 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 Vx 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 Vx system, including, but not limited to, electronic documentation and other electronic media, patient safety glasses, VELcaps and VELsheaths, 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.

12 VELscope Vx System Specifications

Handpiece Dimensions ..... (H x W x D) 8.6” x 2.4” x 3.4” (22 x 6 x 9 cm)
Charging Cradle Dimensions..... (H x W x D) 2.5” x 4” x 7” (6 x 10 x 18 cm)
Handpiece Weight ..... 0.9 lbs (0.41 kg)
Charging Cradle Weight .....1.7 lb (0.76 kg)
External Power Brick..... MENB1060A1200F03, SL Power[1]
Input Voltage .....100 – 240 V
Input Frequency ..... 50-60 Hz
Amperage..... 1.5A Max @ 100VAC Input
Output ..... 5A Max @ 12 VDC
Power Cord ..... Hospital Grade[2]
Duty Cycle ..... 5 min. ON; 15 min. OFF

Optical

Nominal Output Power (400–460nm) ~ 1W
Illumination Spot Diameter (@ 10 cm working distance) ~ 1.5” (4 cm)
Minimum working distance (front face of unit to tissue) ~ 3” (8 cm)

Environmental

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
Maximum Altitude (non-operating).... 35,000 ft

[1] VELscope Vx system to be operated only with external power supply provided with the system: MENB1060A1200F03 (SL Power).

[2] Grounding Reliability can only be achieved when equipment is connected to an equivalent receptacle marked “Hospital Only” or “Hospital Grade”.

13 Compliance with Standards

- ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes
- EN ISO 14971 Medical devices – Application of risk management to medical devices
- EN 60601-1 Medical Electrical Equipment – Part 1: General Requirements for Safety
- EN 60601-1-2 Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral standard: Electromagnetic compatibility – Requirements and tests
- EN 1041:2008 Information supplied by the manufacturer of medical devices
- ISO 15223-1:2012 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements

14 Electromagnetic Compatibility

The VELscope Vx system needs special precautions regarding Electromagnetic Compatibility (EMC) and needs to be installed and put into service according to the EMC information provided herein.

Portable and mobile RF communications equipment can affect the VELscope Vx system.

The VELscope Vx system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the VELscope Vx system should be observed to verify normal operation in the configuration in which it will be used.

WARNING: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the VELscope Vx system or shielding the location.

Guidance and manufacturer's declaration – electromagnetic emissions		
The VELscope Vx System is intended for use in the electromagnetic environment specified below. The customer or the user of the VELscope Vx System should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The VELscope Vx System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The VELscope Vx System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings for domestic purposes.
Harmonic emissions IEC 60000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 60000-3-2	Complies	

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14 Electromagnetic Compatibility *(continued)*

Guidance and manufacturer's declaration – electromagnetic immunity			
The VELscope Vx System is intended for use in the electromagnetic environment specified below. The customer or the user of the VELscope Vx System should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential Mode ±2 kV common mode	±1 kV differential Mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the VELscope Vx System requires continued operation during power mains interruptions, it is recommended that the VELscope Vx System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

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Guidance and manufacturer's declaration – electromagnetic immunity			
The VELscope Vx System is intended for use in the electromagnetic environment specified below. The customer or the user of the VELscope Vx System should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the VELscope Vx System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the VELscope Vx System is used exceeds the applicable RF compliance level above, the VELscope Vx System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the VELscope Vx System.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

Recommended separation distances between portable and mobile RF communications equipment and the VELscope Vx System			
The VELscope Vx System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the VELscope Vx System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the VELscope Vx system as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

This Class A digital apparatus complies with Canadian ICES-003.

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with this Operation Manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his/her own expense. Modifications not expressly approved by LED Dental Inc. could void the user's authority to operate the equipment under FCC rules.

Notes

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