Sapphire® plus
LESION DETECTION

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USERS GUIDE

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LESION DETECTION

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Congratulations!

Congratulations on incorporating the adjunctive Lesion Detection Handpiece for your Sapphire® Plus Light. It is the responsibility of every dentist to conduct a thorough evaluation of the oral cavity. Your appreciation of this responsibility is reflected in your decision to integrate the Sapphire Plus Lesion Detection (LD) System into your practice.

Proper use of the Sapphire Plus LD System's natural tissue direct fluorescence visualization technology will greatly enhance the way you examine, detect, and manage oral soft tissue conditions. Your patients will benefit from your ability to perform a more comprehensive oral mucosal examination and provide immediate information that can significantly reduce delays in treatment and the costs associated with the screening and detection process.

The System will improve your ability to detect mucosal abnormalities early. Early detection of mucosal abnormalities can result in the successful treatment and management of most mucosal conditions. This is particularly important, considering that the overall five-year survival rate for oral cancer is only 50-60%, but it can be as high as 80-90% when the disease is discovered and treated in its early stages.

The principal objective of the Sapphire Plus LD System is to enhance the way practitioners examine the oral mucosa and screen for tissue abnormalities, potentially leading to the earlier discovery of pre-cancer, cancer, and other disease processes. This early detection is one of the best mechanisms for enabling treatment success, increasing survival rates, and maintaining a high quality of life.

Proper implementation of the Sapphire Plus LD System will result in a more efficient use of your time and will easily integrate into your practice workflow in a cost-effective manner. Your entire dental team and your patients will rapidly see the benefits offered by the Sapphire Plus LD System and appreciate it as an essential part of a state-of-the-art oral mucosal examination.

For additional information, training, support materials, and tools, please visit us at:
www.denmat.com/sapphirelesiondetection.

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Vice President of Clinical Development and Education
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1.1 About this Manual

This Users Guide provides information on the safe and effective use of the Sapphire® Plus Lesion Detection (LD) 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 Sapphire Plus LD System prior to using the device during patient care.

This manual is not intended to be a comprehensive guide to proper oral mucosal examination, but a supplement on the use of the System and of direct fluorescence visualization during the procedure. For more detailed information about the clinical aspects of using the Sapphire Plus LD System, please refer to the Step-by-Step Examination Guide and Training DVD supplied with your Lesion Detection Handpiece.

Another excellent source of information is The Oral Cancer Foundation. You are encouraged to visit their website (www.oralcancerfoundation.org) and consider joining the foundation.

1.2 The Gold Standard of Diagnosis: Surgical Biopsy

Histological examination is the gold standard and the only accepted method for diagnosing oral cancer. All other techniques are adjunctive modalities to clarify and communicate the need for an appropriate surgical biopsy to be performed.

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

1.3 Glossary

The Sapphire Plus Lesion Detection System ("the System") – Consists of the Sapphire Light Source Unit, the Lesion Detection Handpiece, and any additional examination components.

Sapphire Light Source Unit ("LSU") – Source of blue excitation light, which is transmitted through the Handpiece.

Handpiece – T-shaped handle/scope assembly attached to the LSU that emits the blue excitation light and allows the dentist or health-care provider to view Natural Tissue Fluorescence.

Natural Tissue Fluorescence – Light produced by tissue due to the absorption of light at one wavelength (i.e., blue) followed by the nearly immediate generation of light at longer wavelengths (i.e., green). Fluorescence occurs naturally in oral tissue, but it is not noticed due to the much higher intensity of ambient and 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 be perceived without blocking out the reflected light.

Barrier Cap – Handpiece accessory consisting of a single-use, disposable, protective, asepsis, anti-fog lens cover.

Barrier Sheath – Handpiece accessory consisting of a single-use, disposable, protective, asepsis, plastic barrier used to cover the Handpiece.

2. PACKAGE CONTENTS

SAPPHIRE® PLUS LESION DETECTION SYSTEM PACKAGE

When opening and unpacking the contents of the Sapphire Plus Lesion Detection System Package, you should thoroughly inspect all system components for any noticeable damage or missing parts. If you discover that any parts are damaged or missing, please contact Customer Support at **800/445-0345.**

- Sapphire Plus Lesion Detection Handpiece
- Canon camera with camera attachment & accessories
- 100 Sapphire Plus Lesion Detection Barrier Caps
- 100 Sapphire Plus Lesion Detection Barrier Sheaths
- Users Guide
- 1 pair safety glasses
- 100 pack oral cancer patient brochures
- 1 oral cancer counter card
- 1 Handpiece holder
- DVD training & marketing support documents

3. SAFETY INFORMATION

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.

3.1 Contraindications

The Sapphire® Plus Lesion Detection System should never be used without prior conventional oral mucosal examination with incandescent (white) light.

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

3.2 Precautions

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

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

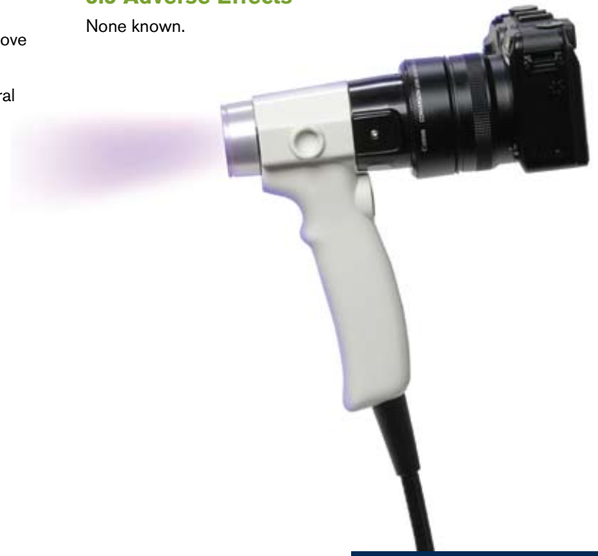
In deciding on the appropriate surgical margin for tumor excision, the surgeon should always remove at a minimum the tissue that was identified from the initial clinical assessment prior to the use of the System. The surgeon should never fail to excise tissue that would have otherwise been removed had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

Caution: Looking directly into the light-emitting port of the Handpiece while in operation should be avoided. All patients should wear protective eyewear (similar to when a composite curing light is being used) to minimize discomfort and the potential for risk of eye injury. A pair of safety glasses are provided with the System.

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

3.3 Adverse Effects

None known.



4. THE SYSTEM

4.1 Overview

The Sapphire® Plus Lesion Detection System is a natural tissue direct fluorescence visualization system to be used as an adjunctive instrument for oral mucosal examination.

The main components of the System are the Sapphire Plus Light Source Unit (LSU) and the viewing Handpiece (with attached fiber-optic light guide). The System is supplied with single-use, multi-function, disposable lens covers (Barrier Caps) and single-use, disposable Handpiece plastic barriers (Barrier Sheaths).

The 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 Handpiece, abnormal tissue may appear as an irregular, dark area that stands out against the otherwise normal, green fluorescence pattern of surrounding healthy tissue.

4.2 Indications for Use

The System 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. The System 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.

4.3 Intended Use

The System is to be used by qualified health-care providers as an adjunctive tool 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.

The System is adjunctive to and is intended to be used in combination with a traditional oral mucosal examination with incandescent (white) light. The System in no way diminishes the importance of the traditional examination and expertise of the clinicians conducting the examination. As such:

- The clinician should always perform the traditional oral cavity examination by incandescent light prior to conducting the exam with Sapphire® Plus Lesion Detection.
- The clinician should never, based on the Sapphire Plus Lesion Detection 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 the System and use his/her own clinical judgment as to what the best course of action should be.
- The Sapphire Plus Lesion Detection System is further intended to be used by a surgeon adjunctively to his/her clinical assessment to help determine the extent of diseased tissue around a clinically apparent pre-cancerous or cancerous lesion.
- The conventional clinical assessment of the lesion under white light should always be conducted prior to the assessment made with the System.
- 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 the System. The surgeon should never fail to excise tissue that would have otherwise been removed had the System not been used.
- The surgeon should take into consideration the assessment made with the System 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.

4.4 Description

The Sapphire® Light Source Unit (LSU) is a high-intensity light for multiple clinical applications. A specially designed filter provides peak performance in the visible light spectrum required for curing, whitening, and lesion detection yet effectively reduces unwanted ultraviolet (UV) and infrared (IR) wavelengths. Switches on the control panel have a wide range of presets. Bright numeric Display Windows provide visual indication of settings, and an audio signal indicates completion of the timed cycles.

4.4.1 SAPPHIRE SUPREME LIGHT

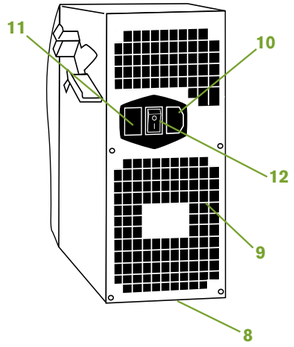
Sapphire Supreme lights are characterized by a blue control panel with the following components:

1. LSU: Generates light
2. Control Panel
   a. Lamp Start/Stop Button
   b. Timer Preset Switches
   c. Standard Curing Mode Switch
   d. Optional Curing Mode Switch

Note: Press the Optional key (2d) to enter the extended optional bL mode. The Sapphire will run up to 1 hour.

3. Display Windows: Four-digit digital display of the preset time, program mode, and light meter
4. Light Guide Receptacle: Source of light output; receives fiber-optic light guide
5. Light Guide: Flexible optical device for delivery of light
6. Lesion Detection Handpiece
   a. Lamp Start/Stop Button
   b. Quick-Release Eyepiece
   c. Disposable Barrier Cap
7. Internal Light Meter Window

8. Lamp Access: Provides access to the lamp
9. Cooling Fan: Provides cooling to the LSU
10. Power Module: Accepts AC power cord
11. Fuse Holders: Contains the main fuses
12. Power Switch: Turns power ON (I) and OFF (0)



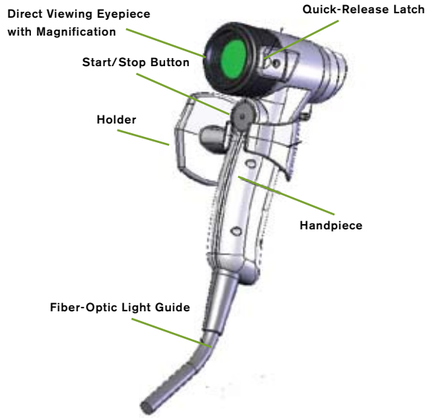
4.4.2 SAPPHIRE PLUS LIGHT

The Sapphire Plus is identified by a silver control panel and logo on the front cover. When the Lesion Detection Handpiece is installed in the light source the operator will be prompted to enter into the Scope Mode. Press the Right Arrow Key until the indicator light to the left of Scope in the Mode Indicator area is on. Press SELECT. The Sapphire Plus is in the Scope Mode and the activator button on the Lesion Detection Handpiece will start and stop the lamp.

1. Control Wheel; Advance, Increase, Decrease
2. Control Wheel; Select Setting and Mode
3. Mode Indicator
4. Start/Stop
5. Key switch

4.4.3 LESION DETECTION HANDPIECE (WITH LIGHT GUIDE)

The Handpiece is a T-shaped handle/scope assembly that holds the optical components of the System.



The Handpiece has a start/stop button, which activates the lamp in the Sapphire Light Source Unit (LSU).

The Handpiece has the following key functions:

- Projects a blue excitation light onto the target area
- Filters out the reflected blue light to allow direct visualization of the resulting natural tissue fluorescence
- Proprietary filtering provides for an optimized view of the oral mucosa
- The quick-release eyepiece allows magnified direct viewing
- Quick-release camera adapter allows photo-documentation of exam results

The Handpiece has a fiber-optic light guide, which transmits the excitation light from the LSU to the Handpiece. Its length provides an effective working distance from the LSU to the Handpiece.

Caution: The light guide attached to the Handpiece is a delicate fiber-optic cable that can be damaged if not handled with care. Do not over-bend or kink the fiber-optic light guide. It has a minimum bending radius of 1.5 in. (4 cm). Do not operate the System without the fiber-optic light guide properly connected to the LSU.

4.4.4 BARRIER CAP

The Barrier Cap is a protective, multi-functional, *single-use*, disposable lens cover, designed to fit on the front of the Handpiece.

The primary functions of the Barrier Cap are:

- To seal off and protect the precision optics of the Handpiece from dust, debris, condensation, powder, fingerprints, oils, etc.
- To act as an anti-fog barrier to aid in the visualization during examination
- To provide an asepsis barrier to mitigate the risk of patient-to-patient cross-contamination

Warning: Dispose of the Barrier Cap properly after use. A new, unused Barrier Cap should always be used on every patient. 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 Barrier Cap does not withstand chemicals or high temperatures. Do not attempt to clean or sterilize with autoclave, dry heat, or otherwise.

4.4.5 BARRIER SHEATH

The Barrier Sheath is a *single-use*, disposable, plastic barrier designed to cover the Handpiece. It is used to enhance asepsis and mitigate the risk of patient-to-patient cross-contamination.

Warning: Dispose of the Barrier Sheath properly after use. A new, unused Barrier Sheath 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 Sheath does not withstand chemicals or high temperatures. Do not attempt to clean or sterilize with autoclave, dry heat, or otherwise.

4.4.6 SAFETY GLASSES

The protective eyewear provided with the Sapphire Plus Lesion Detection System must be worn by the patient during the examination. Additional eyewear is available through Den-Mat Holdings. See Section 15 for ordering information.

4.4.7 CALIBRATION LOG

Test the light output using the internal light meter before every examination. See Testing the Light Output in Section 8.5 for complete instructions on testing the light source.

A Calibration Log is provided to document light output. Make additional copies for future use.

If the light output is 00 75 or higher, record the value, date, and your initials in the Calibration Log.

Warning: Do not perform the examination if light output is under 00 75. For troubleshooting, see the Service section of your Sapphire Plus or Sapphire Supreme Operator's Manual or call 800/445-0345 for assistance.

4.4.8 MARKETING MATERIALS

In order to support you with the Sapphire Plus Lesion Detection System, we have provided you with a wide variety of marketing materials and patient management forms. These materials will help you communicate, both in your practice and to your community, the potentially life-saving power that your practice now offers with Sapphire Plus Lesion Detection.

The following is a list of the marketing materials available to you:

- Mucosal Charts
- Health Information & History
- Dental & Oral Health Information
- Oral Health Risk Factors
- Soft Tissue Evaluation Form
- Press Release Announcing Sapphire Plus Lesion Detection in Your Practice
- Patient Letter Announcing Sapphire Plus Lesion Detection in Your Practice
- Letter Requesting Biopsy
- Letter for Positive Biopsy
- Sapphire Plus Lesion Detection Patient Education DVD
- Sapphire Plus Lesion Detection & Oral Cancer Brochure
- Sapphire Plus Lesion Detection Counter Card
- Tv Coverage Offer

For additional information, training, support materials, and tools, please visit us at:
www.denmat.com/sapphirelesiondetection.

4.4.9 REORDERING THE BARRIER CAP AND SHEATH

To protect your patients from cross-contamination and to avoid causing damage to the Handpiece, order replacement Barrier Caps and Barrier Sheaths from Den-Mat®. Each box includes 100 Barrier Caps and 100 Barrier Sheaths.

Warning: It is important that you use only one Barrier Cap and Barrier Sheath per patient. Do not reuse or attempt to sterilize the Barrier Cap or Barrier Sheath. Dispose of the Barrier Cap and Barrier Sheath after each use. Failure to follow these instructions may increase the risk of cross-contamination between patients, affect the optics, or damage the Handpiece.

4.5 Principles of Operation

Traditional oral mucosal examination tools rely on reflected light to visualize the oral cavity. The Sapphire® Plus Lesion Detection System uses natural 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 different 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 System induces natural tissue fluorescence by illuminating the oral cavity with a bright blue light. This tissue fluorescence is, by several orders of magnitude, less bright than the blue excitation light used to illuminate the tissue. The light system allows you to visualize the tissue fluorescence by blocking out the blue excitation light. In addition proprietary optical technology and lens magnification provides for an enhanced view of the tissue fluorescence.

The oral cavity is viewed through the Handpiece, which is connected to the LSU by means of a flexible fiber-optic light guide.

5.1 Attaching The Handpiece Holder

1. Remove the Handpiece holder from packaging.
2. Locate the adhesive on bottom of holder.
3. Determine if the holder will be mounted to the right or left side of the Sapphire Plus LSU.

Note: The holder can be mounted to any other flat surface that can support the weight of the scope. Two screw holes are also available for use. It is not recommended to use adhesive to mount holder to a painted or papered wall.

4. Remove the protective layer from the adhesive.
5. Place the holder and press firmly along all sides of the bottom flange.

Important: Allow the adhesive to set 24 hours before applying any weight to the holder

5.2 Connecting the Lesion Detection Handpiece

1. Make sure the power switch on the back of the LSU is in the OFF (O) position.
2. Remove the light guide cable of the Curing Handpiece from the receptacle on the front of the LSU. Store the Curing Handpiece in a safe, dry place.
3. Insert the light guide cable of the Lesion Detection Handpiece into the receptacle until it clicks into place and stops. Make sure the light guide cable is pushed in all the way, but do not force it.
4. Turn the power to the ON (I) position.

Important: Before every examination, you must use the internal light meter on the LSU to check light output and verify that it is generating sufficient light. See Testing the Light Output in Section 8.5 for complete instructions on testing the light source.

5.2.1 ROOM LIGHTING CONSIDERATIONS

Visualization of tissue fluorescence with the System is optimized when the ambient light level is minimized. A darkened examining area is the ideal setting for performing a Sapphire® Plus Lesion Detection examination.

5.2.2 HANDPIECE REACH

The fiber-optic light guide of the System provides for a maximum effective reach of approximately 5.5 ft (1.7 m). The LSU should be placed in close proximity to allow proper manipulation and use of the Handpiece.

The System is designed to allow the LSU to be placed on a conventional dental countertop (32 in. [approx. 80 cm] or higher) without the fiber-optic light guide reaching the floor when the Handpiece is resting in the holder.

However, care should be taken to ensure that the fiber-optic light guide does not drape on the floor so as to avoid crushing, stepping on, or running over it with the casters of any other equipment in the operatory.

Avoid dropping the Handpiece. Damage may occur to optical components.

6.1 The Importance of Photo-Documentation

The Sapphire® Plus Lesion Detection System offers a camera with a customized lens for attachment to the Lesion Detection Handpiece to produce the most accurate photographs for documentation. This is a unique feature that allows the dentist to capture images of the fluorescing or non-fluorescing mucosa.

Documentation is extremely beneficial for two very important reasons:

1. An image of findings provides greater communication between the patient, dentist, and specialist as well as a reference for future examinations. Additionally, being able to reference an image enhances accuracy and efficiency for biopsy or excision, especially if the condition is not easily apparent or below the surface.

2. The second highest cause of dental malpractice in the US is failure to diagnose oral cancer. These claims are not only the most difficult to defend but are amongst the most costly malpractice suits.[1] Photo documentation allows you to keep records of your findings and protect your practice.

1. Grzegorek DM. A fighting partner. RDH. 2009 Mar;29(3):72.

6.2 When to Use Photo-Documentation

It is extremely important that you document every case using the attachable digital camera in order to protect yourself and your practice as well as ensure accuracy when referring patients to a specialist.

If no lesions or abnormal tissue are discovered, photograph the oral cavity through the Handpiece to document that no lesions or abnormalities were present at the time of the exam. Retain these photographs for your patient files and for future reference.

If lesions or abnormal tissue are discovered, photograph the site through the Handpiece to document findings for your patient files, for future reference, or for referral to an oral surgeon for diagnosis and treatment.

6.3 Basic Canon® Camera Settings and Usage

Your Canon camera has come preassembled and preset with the optimal settings for your Sapphire Plus Lesion Detection. These instructions are for you to reference or use if your camera is reset. DO NOT change these settings unless they do not match the settings indicated in this section.

Note: Refer to your Canon Operations Manual or visit www.canon.com for advanced usage instructions.

6.3.1 CHARGE THE BATTERY

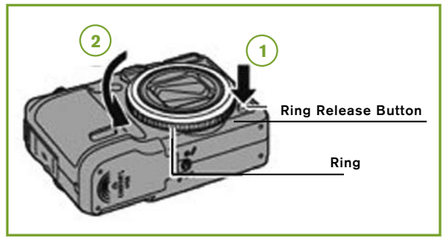
1. Although your battery may have a slight charge, the first thing you will want to do is charge the battery overnight. You will find the charger and battery in the camera case.

6.3.2 ATTACHING THE HANDPIECE ADAPTER TO THE CANON® CAMERA

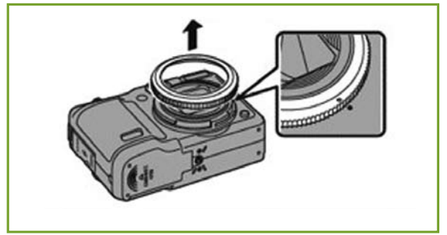
Note: The camera comes to you pre-programmed to work correctly with the scope. The adapter for the scope is also attached to the camera for your convenience.

1. Be sure that the camera is turned off.

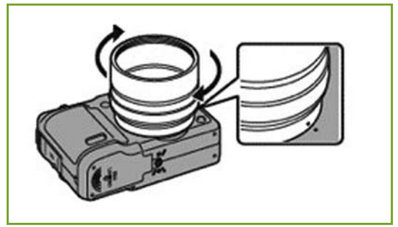
2. Press the ring release button (1), hold it down, and turn the ring in the direction of the arrow (2).

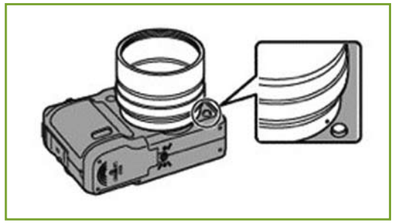


3. When the mark ○ on the ring and the mark ● on the camera are aligned, lift off the ring.



4. Align the mark ● on the conversion lens adapter with the mark ● on the camera, and turn the adapter in the direction of the arrows until locked.





6.3.3 SET CAMERA DATE AND TIME

1. Turn the power on and set the date and time using the dial. (This is only necessary for the first power-on or if the date and time are deleted or changed.) Depending on your time zone, you may not have to adjust the date and time.

   a. With the camera on, press the menu button located on the back of the camera, bottom right.

   b. Once in the menu, there are four tabs across the top of the screen. Navigate to the 2nd tab by pressing the right side of the middle dial found on the rear of the camera on the right side.

   c. Press the bottom side of the middle dial and navigate to the time zone and date/time settings.

   d. To choose Time Zone, press the Func/Set button found in the middle of the 2 dials on the back of the camera.

   e. Press the Func/Set button again to select time zone.

   f. Navigate right or left with the middle dial to choose your current time zone.

   g. Press the Func/Set button to choose.

   h. Press the Menu button to return to the main menu.

   i. Repeat process for date/time settings.

   j. To exit the menu, press the Menu button.

Your Canon® Camera has a flip out rear preview screen. The camera comes with the screen in the closed position. Pull out on the right side of the screen to flip it out.

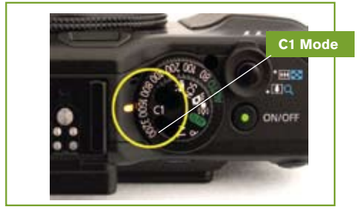
Flip the screen forward so the screen is facing the front of the camera. Close the screen by flipping it back towards the camera body. You can now see the screen. This is a new feature that protects the screen and allows multiple viewing angles.

6.3.4 ADJUSTING CAMERA SETTINGS

Turn the power on. The camera is pre-programmed with all settings stored in the C1 mode. You just turn it on and shoot. Do not change settings! This reference guide is in case settings are changed.

The following settings need to be set only if the C1 stored settings were deleted.

The camera is pre-programmed with all settings stored in the C1 Mode, the ISO set to 1600 and the exposure (dial found on the left side of the top of the camera) set to 0 (zero). These settings are necessary for the camera to operate correctly. You just turn it on and shoot. DO NOT change the settings! Refer to this section only if these settings were deleted or changed.



A. Top Camera Settings

B. Exposure, ISO & Mode

1. If for any reason the C1 Mode is deleted, please adjust the settings on the top of the camera as follows. (The camera does not have to be on to make these adjustments.)

   a. Locate the exposure dial on the top of the camera on the left side. Turn the exposure dial to 0 (zero).

   b. Locate the ISO dial. This is the outer dial on the top of the camera on the right side. Turn the ISO dial to 1600.

   c. Locate the Mode dial. This is the dial inside the ISO dial. Turn the Mode dial to Tv.

C. Adjust the Zoom

The camera must be turned on to continue.

1. Locate the Zoom lever above the On/Off button on top of the camera.
2. Push the Zoom lever clockwise and zoom to 11x. On the display monitor on the back of the camera, the zoom bar graph will show white, yellow, then blue while zooming in. When the camera is set on the first blue mark, the zoom is at 11x. The zoom numerical setting is displayed shortly after the Zoom lever is released. Continue to adjust the internal settings on the rear of camera.

D. Rear Camera Settings • Shutter Speed

1. Press the Macro (flower) button once. Press again to select the Macro (flower) setting. Press Set when done.
2. Set the shutter speed using the ridged outer dial on the back right of the camera. Rotate until you see the number setting on the bottom left of the camera's display monitor read 1/80.

E. Function Setup

This is all done on the back of the camera by following the prompts on the screen.

1. In the middle of the dial on the back right side, press the Func/Set button to access settings. A vertical settings menu will appear on the left side of the screen.
2. Verify the settings by pressing on the top or bottom of the middle dial to navigate through the menu. As each setting on the menu is highlighted, move the middle dial right or left to change the settings. Once set, continue navigating up or down to the next setting.

The correct settings are as follows
(in order from top to bottom):

- AWB = AWB
- My Colors = Off
- BKT = Off
- +/- (Flash) = 0
- Nx ND filter = Off
- Box icon = Single shot (single box icon)
- M2 = Image size

3. Once the correct settings are selected, press the Func/Set button to close the menu.
4. Verify the flash is turned off by pressing the button with the lightning bolt icon (found on the middle dial). Press once to confirm either on of off. When settings are done the icon zooms away (2 sec).
5. Press the Metering Light (•) button to the top right of the dial. Set to Evaluative Mode by turning the outer ridged dial.
6. Press the Menu button on the bottom right and verify settings as follows. Use middle dial to navigate left and right across tabs and up and down to navigate within tabs.

All values should read as follows:

- AF Frame = Flexizone
- Digital Zoom = Standard
- AF-Point Zoom = Off
- Servo AF = Off
- Continuous AF = On
- AF Assist Beam = On
- Safety MF = On
- Flash Control – no changes
- i-Contrast = Off
- Safety Shift = Off
- Review Info = Off
- Blink Detection = Off
- Custom Display – no changes
- Reverse Disp. = On
- IS Mode = Continuous
- Converter = None
- Date Stamp = Off
- Record raw + L = Off
- Set shortcut button – no changes
- Save Settings = Save Settings

7. Press Func/Set to save everything to memory.

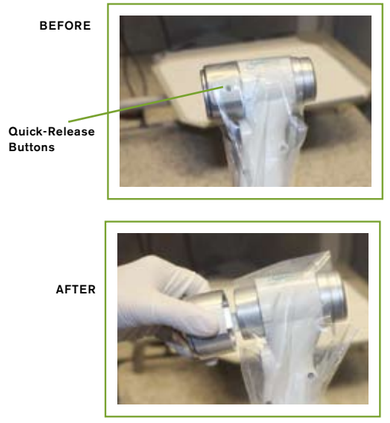
8. The display monitor will show: "Save current settings?" Use the inner dial pressing left or right to select C1 as the destination. C1 appears on the display.
9. Press Func/Set button. This saves all settings to C1 location.
10. Press Menu button to close Menu settings.

You are now done with your settings. Each time the Power is turned on and the Mode dial on top of the camera is set to C1, the camera will automatically return to all the pre-set functions.

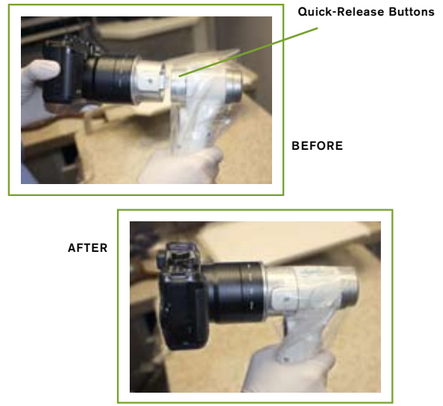
Note: When in use the camera may go into sleep mode. When this happens, touching any button will wake the camera up.

6.3.5 ATTACHING AND DETACHING THE CAMERA

1. Remove the Direct Viewing Eyepiece from the Handpiece by pressing both Quick-Release Buttons at the same time and then pull the Eyepiece away.



2. Attach the camera to the Handpiece by lining up the Quick-Release Buttons of the Handpiece lens adapter with the latches on the Handpiece. Slide the Quick-Release Buttons into place until they click on both sides.
3. To detach the camera from the Handpiece, press the Quick-Release Buttons at the same time and pull the camera away. Replace the Direct Viewing Eyepiece.



Note: Make sure the Direct Viewing Eyepiece or the camera are always in place. Do not leave the scope of the Handpiece open.

Note: Your camera has come preset with the optimal settings for your Sapphire® Plus Lesion Detection. Do not change these settings unless they do not match the settings indicated. If the settings are incorrect or have been reset, see Section 6.3.4 to correct the settings.

Warning: Before every examination, you must use the light meter on the LSU to check light output and verify that it is generating sufficient light. See Testing the Light output in Section 8.5 for complete instructions on testing the light source.

6.4 Using the Lesion Detection Handpiece with the Camera

Note: See Connecting the Handpiece (Section 5.2) and Attaching and Detaching the Camera (Section 6.3.5) for more detailed instructions.

For Sapphire Supreme users, set the LSU in the bL (Bleaching) mode in Optional (default) mode. For Sapphire Plus users, simply verify that the LSU is in the Scope (SCOP) mode (refer to your Sapphire Plus Operator's Manual for more information). Position the front of the scope about 1-2 inches away from the target. Take photos through the Lesion Detection Handpiece and without the Handpiece using incandescent (white) light for the purpose of patient files and comparison.

Tip: Adjust your distance from the target, moving closer or farther to find the optimal distance and focal point. Generally, keeping within 1-2 inches achieves the best image.

Note: Images are for illustration purposes only. Barrier Cap and Barrier Sheath must be used at all times.

6.4.1 TAKING PHOTOS THROUGH THE HANDPIECE

1. Hold the scope of the Handpiece with camera attached 1-2 inches away from the target. Look through view finder of the camera to view the target.

2. Press the shutter button halfway down, allowing the camera to focus (focus point on screen will turn green when focus is achieved).

3. Press shutter button completely to take picture. Image will preview for 2 seconds.

4. Take multiple images. Even if the preview is on, once you press the shutter button to focus, you're ready to shoot.

6.4.2 TAKING PHOTOS WITHOUT THE HANDPIECE

1. Remove the camera from the Handpiece by pressing the Quick-Release Buttons (see Section 6.3.5 for instructions on removing the camera). Place the Handpiece in a safe place with the fiber-optic light guide safely off the ground where it won't be tripped over or pulled to the ground.

2. Leave the Handpiece lens adapter on the camera.

3. The camera should remain in the C1 mode.

4. Reduce the zoom level from 11x to 8.5x (see Section 6.3.4, Part C for instructions on adjusting the zoom level).

5. Use the operatory lights to sufficiently illuminate the oral cavity.

6. Manually focus the camera while adjusting your distance from the target, moving closer or farther to find the optimal distance and focal point. Be sure you are close enough to capture the target clearly.

7. Once you have the target in frame at the correct distance and the subject is in focus, hold the camera steady and press the shutter button to take the photo.

6.5 Previewing Photo-Documentation

It is possible to view images saved on the camera on either a Tv or a computer monitor.

To view images from the camera on a Tv:

1. Connect A/V output cable provided with the camera to the camera and to an available video input on the Tv.

2. Turn on Tv and choose appropriate aux video input on Tv.

3. Press preview button on the back of the camera (blue "play" button to the right of the eyepiece on the rear of the camera).

4. Images will appear on Tv, controlled by the camera.

5. Use middle dial on the rear of camera to switch between images, left and right.

To view images from the camera on a computer:
Use Application Software provided with camera. Follow instructions in Canon® Operations Manual for correct usage and advanced features.

6.6 Troubleshooting

If you are experiencing technical issues with your camera, please call the Technical Support Line: **877/872-3514.**

If you call and are not directly connected to a technical representative, please leave a message. Your call will be returned as soon as a representative is available. Additional information is also available at www.canon.com. It's a great resource for dentist and staff.

7.1 General Considerations

• The Sapphire® Plus LSU, Handpiece, and fiber-optic light guide are NOT STERILIZABLE WITH AUTOCLAVE, DRY HEAT, OR OTHERWISE.

• The LSU, Handpiece, and fiber-optic light guide 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 disinfections or sterilization; therefore, reuse can lead to cross-contamination from patient to patient.

• Attempting to reuse the Barrier Cap will have a detrimental effect on the optical and clinical performance of the System.

7.2 Sapphire Light Plus Source Unit (LSU)

The external surfaces of the LSU should be cleaned and disinfected between each patient with a hospital-grade surface disinfectant and a towelette or gauze. Make sure no residues are left on the internal light meter window because this will affect its operation.

7.3 Fiber-Optic Light Guide

The external sheathing of the fiber-optic light guide should be cleaned and disinfected between each patient with a hospital-grade surface disinfectant and a towelette or gauze.

7.4 Lesion Detection Handpiece

• Exercise extreme care to protect the precision optics of the Handpiece. The Barrier Cap has been designed not only to prevent cross-contamination but also to protect the optical elements from contaminants, dust, and debris.

Caution: It is important to ensure that the patient side of the optical path is always protected with a Barrier Cap to keep any debris or contaminants away from the optical elements. Dust, powder, fingerprints, oil, or residues on the optical elements of the Handpiece may have a detrimental effect on the performance of the system.

• After each use, be sure to remove and properly dispose of the used Barrier Cap and Barrier Sheath before cleaning and disinfecting the Handpiece. The external surfaces of the Handpiece should then be wiped down with a hospital-grade surface disinfectant and a towelette or gauze.

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

7.4.1 HANDPIECE FILTER CLEANING

In order to keep your Lesion Detection Handpiece working at peak performance, it is highly recommended that the front and rear glass filters be cleaned when needed. If you see dust or contamination on the filters, they need to be cleaned as follows:

1. Use a rubber blower (commercially available) to carefully blow away any dust on the surface. It is important to clear any dust before you try to apply any cleaners because the dust is abrasive and could scratch the glass coatings.

2. Once the dust is removed, inspect the filter 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.

8.1 Using Your Sapphire® Plus Lesion Detection for the First Time

You received two Sapphire Plus Lesion Detection boxes, manuals, and a camera bag in your Sapphire Plus Lesion Detection package.

1- Box of barrier caps and barrier sheaths

1- Box containing the scope

1- Camera bag containing the Canon camera, preconfigured with scope adaptor attached

8.2 Initial Setup

The Sapphire Plus Lesion Detection System includes a holder for the scope when not in use. The holder is mounted to either the right or left side of the LSU. Follow all the instructions carefully to avoid damaging system components. Familiarize yourself with all system features before use.

1. Make sure the power switch on the back of the LSU is in the Off (O) position.

2. Install the AC power cord into the power inlet on the back of the LSU and into a grounded AC socket.

8.3 Attaching the Lesion Detection Handpiece Holder

1. Remove the Handpiece holder from packaging.

2. Locate the adhesive on bottom of holder.

3. Determine if the holder will be mounted to the right or left side of the Sapphire Plus LSU.

Note: The holder can be mounted to any other flat surface that can support the weight of the scope. Two screw holes are also available for use. It is not recommended to use adhesive to mount holder to a painted or papered wall.

4. Remove the protective layer from the adhesive.

5. Place the holder and press firmly along all sides of the bottom flange.

Important: Allow the adhesive to set 24 hours before applying any weight to the holder.

8.4 Connecting the Lesion Detection Handpiece

The Lesion Detection Handpiece has been designed to work with both Sapphire Plus and Sapphire Supreme lights.

1. If another handpiece is installed, remove the fiber-optic light guide of the Handpiece that is currently installed from the LSU. Store the Handpiece in a safe, dry place.

8.4.1 SAPPHIRE SUPREME LIGHT

1. Insert the proximal end of the Lesion Detection Handpiece's fiber optic light guide into the light guide receptacle on the front of the LSU.

2. Turn the power switch on the back of the system to the On (|) position.

3. Press the Optional Button once to enter the Bleaching Mode.

Important: Before every examination, you must use the internal light meter on the LSU to check light output and verify that it is generating sufficient light. See Testing the Light Output in section 8.5 for complete instructions on testing the light source.

8.4.2 SAPPHIRE PLUS LIGHT

1. Insert the proximal end of the Lesion Detection Handpiece's fiber optic light guide into the light guide receptacle on the front of the LSU.

2. Install the key switch on the side of the LSU and turn it to the On position by rotating it toward the front of the light source.

3. Turn the power switch on the back of the system to the On (|) position.

Note: If the key is not on when the LSU is powered on, the Display Windows will show "Lo cd" (locked)—turn the key on. If the Sapphire Plus LSU is powered on without a handpiece installed, the error message "No HP" (no handpiece) will appear on the Display Windows—install the Lesion Detection Handpiece.

4. With the Lesion Detection Handpiece installed, the Display Windows will flash "Ch HP" (choose Handpiece).

5. Press the right arrow key on the Control Wheel to advance to the Scope Mode and press the Select Button.

Important: Before every examination, you must use the internal light meter on the LSU to check light output and verify that it is generating sufficient light. See Testing the Light Output in section 8.5 for complete instructions on testing the light source.

8.5 Testing the Light Output

8.5.1 SAPPHIRE SUPREME AND SAPPHIRE PLUS

Test the light output using the Sapphire LSU internal light meter before every examination. With the LSU curing timer set to 10 seconds, activate the lamp. Place the front of the scope directly on top of the light meter window so that the window is in the center of the illumination spot (view the positioning over the meter window through the scope while doing this); then check the reading on the four-digit display windows without moving the scope.

8.5.2 CALIBRATION LOG

A Calibration Log is provided to document light output. Make additional copies for future use.

If the light output is 00 75 or higher, record the value, date, and your initials in the Calibration Log.

Warning: Do not perform the examination if light output is under 00 75. For troubleshooting, see the Service section of your Sapphire® Plus or Sapphire Supreme Operator's Manual or call 800/445-0345 for assistance.

What If the LSU Is Not Generating Sufficient Light Output?

If the display window reads under 00 75, make sure the fiber-optic light guide is inserted all the way into the LSU receptacle.

Warning: Do not perform the examination if the LSU is not generating proper light output. This may adversely affect the results of the exam.

8.6 Before the Examination

The Sapphire Plus Lesion Detection System does not detect, prevent, treat, or cure oral cancer, neither does it replace a visual exam. It is an adjunctive tool that facilitates early detection of oral lesions (which could be pre-cancer, cancer, other disease processes, or completely benign) in order to help dentists more accurately diagnose and treat conditions of the mouth and throat.

Note: It is the responsibility of the dentist or physician to conduct a visual exam of the mouth and throat before proceeding with the Sapphire Plus Lesion Detection exam. The dentist is also responsible for documenting and confirming any findings, determining the proper treatment, and monitoring any areas of concern. These instructions are a supplemental guide only and are not to replace regular examination and treatment procedures.

1. Ensure that a new, unused Barrier Cap and Barrier Sheath are in place.

2. Ensure that the patient is wearing safety glasses.

3. If necessary, darken the dental operatory to reduce the ambient light to an acceptable level.

Caution: It is very 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 examination and adversely affect your ability to discover tissue abnormalities.

8.7 During the Examination

1. Turn the lamp on by pressing the Start switch on the Handpiece or front panel. When the examination is completed the LSU can be left in a Power On Standby Mode or power can be turned off. The Power On/Off switch on the back panel of the light source (see Section 4.4 for location) is used to switch power On (I) and Off (0).

2. Use the Start switch on the Lesion Detection Handpiece or Front Panel to activate the lamp.
3. Position the front, patient side, of the Handpiece approximately 4-6 inches in front of the patient's mouth.

Caution: Exercise caution when blue light is being emitted from the Handpeice. Ensure that the light is only being directed into the mouth of the patient and is not inadvertently shone into the patient's eyes, or anyone else's in the operatory, including yours. The light from the Handpiece will cause discomfort and possible eye injury if viewed directly.

Tip: Adjust your distance from the target, moving closer and farther to find the optical distance and focal point. Generally, keeping within 1-2 inches achieves the best image.

4. Conduct an intra-oral examination using the Sapphire® Plus Lesion Detection by viewing the oral cavity through the Handpiece to enable the visualization of the tissue's natural fluorescence.
5. When viewed through the 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.

Note: For further guidance on the clinical use of the Sapphire Plus Lesion Detection System, please refer to the Step-by-Step Examination Guide provided with the Handpiece.

8.7.1 WHEN TO USE PHOTO-DOCUMENTATION

It is extremely important that you document every case using the attachable digital camera in order to protect yourself and your practice as well as ensure accuracy when referring patients to a specialist.

If no lesions or abnormal tissue are discovered, photograph the oral cavity through the Handpiece to document that no lesions or abnormalities were present at the time of the exam. Retain these photographs for your patient files and for future reference.

If lesions or abnormal tissue are discovered, photograph the site through the Handpiece to document findings for your patient files, for future reference, or for referral to a cancer specialist or oral surgeon for diagnosis and treatment.

8.8 After the Examination

1. The system can be turned on and off by pressing the Start/Stop switch on the Handpiece or LSU.

Note: The LSU can be left on if you plan to use the device throughout the day.

2. Remove and discard the disposable Barrier Sheath and Barrier Cap.
3. The Handpiece and LSU should be properly cleaned and disinfected according to Section 7.

Caution: The metallic handle at the end of the light guide can get hot during normal operation.

8.9 Unplugging and Moving the LSU

If the light is to be used at another location, unplug the power cord from the wall and the power inlet on the back of the LSU. Unplug the fiber-optic light guide from the LSU. Use the recessed carrying handle on the top of the LSU to carry it. To reassemble, refer to Section 8.

8.10 Storage

When the Handpiece is not in use, it should be stored in its original packaging or in another protective container to prevent damage from impact, water, and other contamination.

9. TROUBLESHOOTING

Minor problems can be quickly identified and resolved. These are usually related to the electrical power connection or light guide connection. All other malfunctions must be diagnosed and repaired by Den-Mat® Holdings, LLC.

Do not attempt any internal repairs. There are no user-serviceable parts. Repairs may only be performed by an authorized Den-Mat Account Representative. Any unauthorized attempt at repair will void the system warranty.

Caution: Orange safety glasses must be worn during testing.

SYMPTOM - On/Off Button on scope does not activate the lamp.

CORRECTIVE ACTION – Verify the display on the light source is on. This indicates System power is on and System controller is receiving power. Press the Start Button on the front of the light source. If this activates the lamp it isolates the symptom to the Handpiece or fiber-optic light guide. The cable may not be plugged all the way into the light source. Remove the light guide and reinstall as instructed in Section 8.4. If lamp still doesn't activate, clean the three silver contact rings on the handle of the fiber-optic light guide. Use a coarse towel or soft scouring pad damp with isopropyl alcohol and clean the rings of oxidation that may prevent electrical contact. Rotate the Handpiece 1/3 turn while reinstalling. If the lamp still does not activate, contact your Den-Mat Account Representative for instructions.

SYMPTOM – Light meter value is not above 00 75

CORRECTIVE ACTION – Verify the fiber-optic light guide handle is fully inserted into the receptacle on the LSU. Install as instructed in Section 8.4. Check the fiber-optic light guide for damage. Verify the light meter window on the front of the scope and barrier cap are clean and free of any residue. Verify the front of the Lesion Detection Handpiece is centered and placed directly against the light meter window. If the light meter value is still not above 00 75, contact your Den-Mat Account Representative for instructions.

For assistance, call **800/445-0345.**

10. WARRANTY

The Sapphire® Plus Lesion Detection ("the System") is warranted to be free of defects in workmanship, materials, and malfunctions for one year from the date of original shipment when used under normal operating conditions as described in this manual. The warranty applies to the original purchaser only and does not apply to or cover any third party buyer or user. The warranty does not cover any damage that may have occurred as a result of misuse, improper operation, alteration, adjustments, or neglect.

Within the one-year warranty period, if service is required, the System must be returned to Den-Mat® Holdings, LLC ("Den-Mat"), for diagnostics and repair. Contact the factory to receive Return Authorization prior to shipping. The Return Authorization will include a pick-up notice (Call Tag) for a common carrier to return the merchandise to Den-Mat. Freight charges for returns within the warranty period will be paid by Den-Mat, pending the results of the evaluation to determine the cause of the failure or damage. Freight charges for returns outside of the warranty period will be paid by the customer. The outside shipping container and any accompanying documents must be clearly marked "Repair Return." Use only the original shipping container or other adequate shipping materials to protect the System in transit. All returns will be evaluated for the cause and extent of failure or damage by Den-Mat Service Representatives. Subject to the results of this evaluation, Den-Mat will authorize warranty repair or will contact the customer with a price quotation for the cost of repairs for failures and damages occurring as a result of misuse, improper operation, or for merchandise outside of the warranty period.

This is a limited warranty and the liability of Den-Mat is to repair or replace the System. Den-Mat has no liability to refund any part of the purchase price and no liability for consequential damages, loss of profits, and damages to person or injury by reasons of any defects in said System from any cause whatsoever.

Any buyer who purchases said System acknowledges their familiarity with the terms, conditions, and provisions of this limited warranty and purchases said System agreeing to such terms, conditions, and provisions.

Buyer purchases the System from Den-Mat on the terms, conditions, and provisions of this limited warranty and waives all other rights and claims against Den-Mat for any damages or remedies exceeding said limited warranty.

Den-Mat Holdings, LLC
2727 Skyway Drive
Santa Maria, CA 93455 USA
800/445-0345 · 805/922-8491
www.denmat.com

11. DETECTION

11.1 Adjunctive Lesion Detection Aid, Not Cancer Detection

The Sapphire® Plus Lesion Detection System does not detect, prevent, treat, or cure oral cancer, neither does it replace a visual exam. It is an adjunctive tool that facilitates early detection of oral lesions (which could be pre-cancer, cancer, other disease processes, or completely benign) in order to help dentists more accurately diagnose and treat conditions of the mouth and throat.

Note: It is the responsibility of the dentist or physician to conduct a visual exam of the mouth and throat before proceeding with the Sapphire Plus Lesion Detection exam. The dentist is also responsible for documenting and confirming any findings, determining the proper treatment, and monitoring any areas of concern. These instructions are a supplemental guide only and are not to replace regular standard of care examinations and treatment procedures.

11.2 If a Lesion is Detected

If a lesion is discovered, the doctor should re-examine under white light and follow their differential diagnosis to determine the source and cause of the lesion. The clinician should document the findings by attaching the camera and taking multiple photographs of the area of concern. The clinician may want to have the patient back in two weeks to evaluate whether the area of concern has changed. If the lesion has not cleared up, document with the camera and proceed with further investigation of the suspicious tissue according to the regular standard of care.

The dentist should determine the appropriate course of action for each case according to standard clinical features (i.e., patient history, clinical appearance, etc.). Based on protocol established by various cancer organizations for any general practitioner conducting an oral cancer screening, any patient with a spot that looks suspicious should be referred to a specialist, who will then determine if a biopsy (the only definitive means of diagnosing oral cancer) is needed. If a biopsy is done, the specialist will then provide an enhanced, detailed clinical evaluation.

When dealing with patients in such matters, it is important to empathize with the patient while communicating simply and directly without causing alarm over something that may be benign. It is important that the patient understands and has confidence that what is being done is necessary and beneficial.

11.3 Examples

What do I say?

Talk about what you are doing. Tell the patient you are looking with your eyes and feeling with your fingers. Let them know that you will be looking through the Sapphire Plus Lesion Detection for "anything that doesn't belong." Talk the patient through it, explain what you are feeling and seeing, and let them know this is a non-negotiable part of their exam.

What do you say and do for a patient who does not want the exam?

"We will waive the fee this time because we care about your health"; "We will waive the fee this time and apply the fee next time"; or "This is our standard of care at this practice."

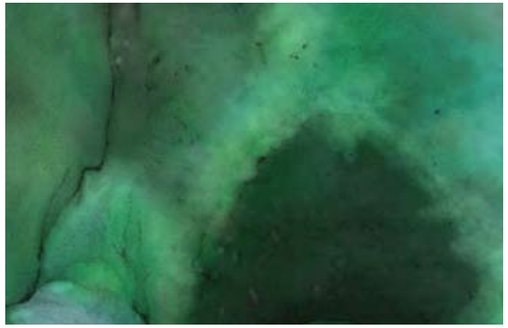
What do you say if you find something?

Tell them what you would say if you noticed something without the System. Chances are, you would first try to understand what the problem could be and try to resolve it. Then you would have the patient come back in approximately two weeks to see if the problem had resolved. If the lesion persisted and you were unable to determine its cause, you would most likely refer the patient to a specialist. In other words, the same familiar protocols apply.

12. EXAMPLES OF CLINICAL PHOTOS (RENDERINGS)

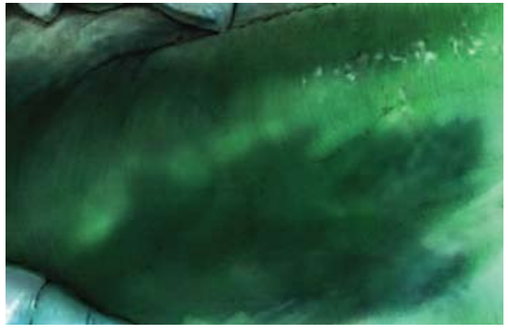
Abnormal epithelial tissue showing loss of fluorescence

No apparent lesion



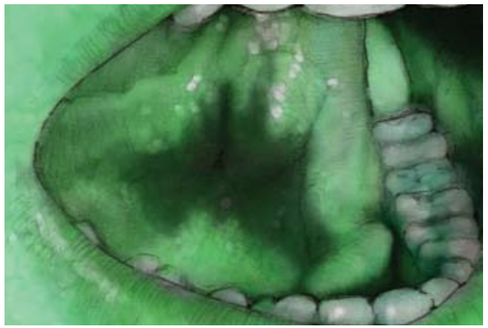
Irregular, dark area (notice borders are irregular and well delineated) – confirmed through biopsy to be carcinoma in situ (CIS)

Visible leukoplakia



Irregular, dark area – confirmed through biopsy to be severe dysplasia

Lesion that didn't look suspicious



Irregular, dark area – confirmed through biopsy to be carcinoma

Enlarged lesion was to be excised

Because of Sapphire® Plus Lesion Detection, satellite lesions were discovered outside the parameter of planned excision

How To Speak To Your Patients About Oral Cancer & Sapphire® Plus Lesion Detection

Whenever a patient has any kind of a medical test or examination related to a possibly life-threatening condition, there is understandably apprehension due to fear of a negative outcome–especially if the patient has some habits (such as tobacco and/or alcohol use) that put them at higher risk. Therefore, it is imperative that the procedure is introduced in such a way that the person is not frightened into refusing to have it performed.

When introducing the screening exam to a patient, you might say something like this:

As you may know, we conduct an oral health examination during every patient's annual hygiene checkup to screen for various oral diseases, including oral cancer. Now we can do an even better job of this because our practice has recently invested in a wonderful new screening device called Sapphire Plus Lesion Detection. This device helps us to screen for a wide variety of things, including inflammation, infections, and even cancerous and pre-cancerous tissue.

There is a slight charge for the Sapphire Plus Lesion Detection screening, but it's possible that your insurance company will cover the cost. Even if it isn't covered by your insurance, however, we strongly recommend that all patients have this screening.

So, may we proceed with the screening?

If the patient resists, you might respond as follows:
This of course is your decision, but you might want to reconsider. Perhaps the most important reason to do this screening is the fact that oral cancer is more prevalent than most people realize. In fact, it's estimated to strike over three times as many people as cervical cancer. And, unlike most other forms of cancer, the incidence of oral cancer is actually growing each year. One possible reason for this is that certain strains of HPV known to cause cervical cancer have now been shown to be strongly associated with oral cancer as well.

Another reason it's important to have an annual oral cancer screening is the fact that if oral cancer is detected in early stages, the five-year survival rate can be 80% or even higher. If it's detected in late stages, however, the survival rate can be as low as 28%.

The Sapphire Plus Lesion Detection device enhances our normal exam because it allows us to see things we haven't been able to see before. This means that if you do have something that concerns us, there's a much better chance that we'll catch it at an earlier stage. The procedure adds only a few minutes to our normal exam and it's totally pain-free and comfortable. Fortunately, the odds are that you don't have oral cancer, but this screening helps us–and you–be sure.

Would you like to proceed with the screening?

If the patient asks what will happen if the screening does detect something, you might respond this way:

If we do discover something, you should know that it very likely is not oral cancer. It could simply be some trauma that results from some other irritation, such as if you chew the inside of your cheek or if you recently ate some real hot food. However, if what we see does cause us some concern, we will generally ask you to come back in a few weeks so we can re-evaluate the tissue. If it hasn't improved, we'll probably arrange for a biopsy and have it evaluated by an oral pathologist. If the evaluation indicates that what you have is cancerous or pre-cancerous, we would then refer you to specialists who will be able to provide the necessary management and care.

Again, the odds are that we aren't going to find any cancerous or pre-cancerous lesions, but this screening is just a smart precaution–just like annual mammograms, Pap smears, and prostate exams.

The addition of Sapphire® Plus Lesion Detection makes your Sapphire Plus Light one of the most versatile pieces of equipment in your practice. In addition to helping you screen for lesions, your Sapphire Plus Light boosts whitening power and speeds curing time.

- Whiten smiles up to 12 shades in under an hour
- Sensitivity-free whitening
- No harmful UV rays
- Fast curing in 3-5 seconds
- Delivers the greatest total energy in the shortest time
- Focused beam of light powers through porcelain for deep curing
- Maintains greatest power at the farthest distance
- Save up to $40,000 a year with reduced chair time for curing

Below are just a few of the products that are ideal for use with your Sapphire Plus Light:

LUMINEERS®

LUMINEERS, the original thin veneer, are highly durable, ultra-thin porcelain shields that bond directly to existing teeth to create natural-looking, attractive smiles. No shots and no painful removal of sensitive tooth structure is required in most cases. And LUMINEERS are proven to last over 20 years! With LUMINEERS, you can create incredible smiles and greatly improve your profit and success.

- Instant whitening that lasts
- Ultra-thin design for a minimally invasive procedure
- Extraordinarily strong porcelain for unmatched durability
- No shots and no pain*
- No drilling of sensitive tooth structure*

*In most cases.

Virtuoso® Universal

Clinically proven and award-winning Virtuoso Universal is a true universal restorative material for anterior and posterior applications. It's worry-free and easily polishes to a natural-looking luster, making it indistinguishable from the tooth for years to come.

- Restoration of anterior and posterior teeth
- Class I and II restorations
- Direct composite veneers
- Exceptional esthetics
- Wear- and stain-resistant
- Wide shade range

Infinity® SE

Infinity SE bonds wherever you need it, and any restoration placed with Infinity is there to stay. Plus, this versatile cement saves you time, which both you and your patients will appreciate.

- Crown & bridge, zirconium, all-porcelain, and PFM cementations
- Amalgam bondings
- Maryland bridges and other resin-retained prostheses
- Endodontic post and core systems
- Resin and ceramic inlays and onlays
- Fluoride-releasing base/liner

Ultra-Bond® Plus

Ultra-Bond Plus is a multi-purpose, dual-cure, ADA Type II restorative and cement. It's designed to match the physical properties of tooth structure and all porcelains. Ultra-Bond Plus creates stronger restorations that last longer.

- Cementation of LUMINEERS
- Porcelain inlays and onlays
- Full porcelain crowns
- Porcelain veneers

PRODUCT REORDER & PRICE LIST

As you screen your patients for oral cancer with Sapphire® Plus Lesion Detection, we at Den-Mat® are making sure you have the support you need to provide the best oral health care for your patients.

Below is a complete list of the components for you to order as you use Sapphire Plus Lesion Detection in your practice. Call a Den-Mat representative to order: **800/445-0345**

Product	List Price	Part Number
Sapphire Plus Lesion Detection Handpiece Package	$2,395	#033395500
• Sapphire Plus Lesion Detection Handpiece • 100 Sapphire Plus Lesion Detection Barrier Caps • 100 Sapphire Plus Lesion Detection Barrier Sheaths • User's Guide • 1 pair safety glasses • 100 pack oral cancer patient brochures • 1 oral cancer counter card • 1 Handpiece holder • DVD training & marketing support documents		
Canon® Camera and Sapphire Plus Lesion Detection Attachments	$1,094	#910333915
• Canon camera with attachments & accessories • 1 camera bag		
Sapphire Plus Lesion Detection Accessories—Ordered Separately		
• Sapphire Plus Lesion Detection Infection Control Pack - 100 Barrier Caps - 100 Barrier Sheaths	$250	#033391800
• 1 oral cancer counter card	$15	#912840100
• 100 pack oral cancer patient brochures	$25	#910254100
• Handpiece holder	$15	#044391059
• 1 pair safety glasses	$15	#043921901
• 1 camera bag	$75	#080075004

Prices are subject to change without notice.