

1. Operating Instructions

Familiarize yourself with all components and follow all instructions carefully before operating. For complete instructions, refer to section 8 in the User's Manual.

a. Attach the Handpiece Holder

Remove the Handpiece Holder from its packaging and mount it in the desired location on the Light Source Unit (LSU). (See section 8.3 in User's Manual.)

b. Connect the Lesion Detection Handpiece

With the LSU turned off, completely remove the current Handpiece and fiber-optic light guide from the LSU; then insert the fiber-optic light guide of the Lesion Detection Handpiece into the LSU. (See section 8.4 in User's Manual.)

c. Test the Light Source Before Every Examination

When the Lesion Detection Handpiece is placed on the light meter window and the lamp is activated, the system automatically detects the light and changes to the Radiometer Mode. The output reading of power density is shown on the display windows. The Handpiece must be centered directly over the light meter window to get an accurate reading. Set the curing timer to 10 seconds to allow enough time to take the measurement.

d. Before the Sapphire Plus Lesion Detection Examination

Conduct a visual exam using palpation. Make sure a new, unused Barrier Cap and Barrier Sheath are in place, the patient is wearing the safety glasses, and the operatory is dark enough. (See section 8.6 in User's Manual.)

e. During the Examination

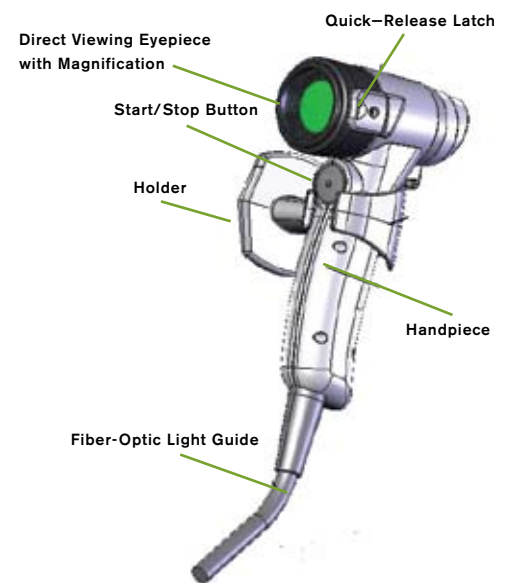
Activate the lamp. Position the Handpiece approx. 4-6 in. in front of the patient's mouth and look through the scope for abnormal tissue. Document any findings. (See section 8.7 in User's Manual.)

f. How to Focus

Press the shutter button lightly (halfway), and the camera will automatically focus on the framed area. The camera focuses, it beeps twice and the indicator lights green. Then press the shutter button fully (all the way) to shoot. Avoid camera shaking by keeping your arms tight against your body while holding the camera firmly by the sides.

g. After the Examination

Deactivate the lamp. Remove and discard the Barrier Cap and Sheath. Properly clean and disinfect. (See section 8.8 in User's Manual.)

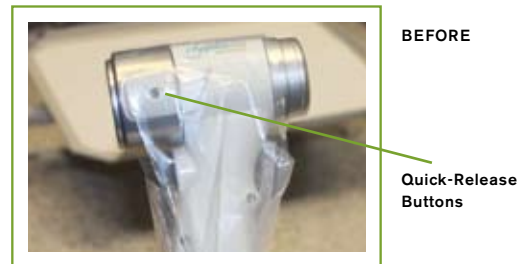


2. Camera Instructions

Camera comes preset to the correct settings. DO NOT adjust the settings on the camera. If settings are changed, refer to section 6.3 in User's Manual.

a. Attach the Camera to the Handpiece

Remove the Direct Viewing Eyepiece from the Lesion Detection Handpiece and attach the camera. (See section 6.3.5 in User's Manual.)



3. Detection

For complete instructions, refer to section 11 in User's Manual.

a. Lesion Detection, Not Cancer Detection

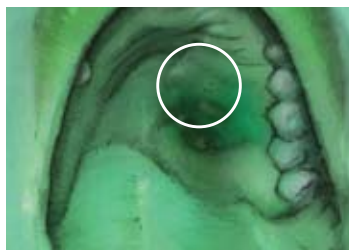
The Sapphire Plus Lesion Detection does not detect, prevent, treat, or cure oral cancer or other diseases, neither does it replace a visual exam. It is a tool that facilitates early detection of oral lesions to help dentists diagnose and treat conditions of the mouth and throat more accurately. (See section 11 in User's Manual.)

b. If a Lesion is Detected

If a lesion is detected, refer to section 11.2 in User's Manual.

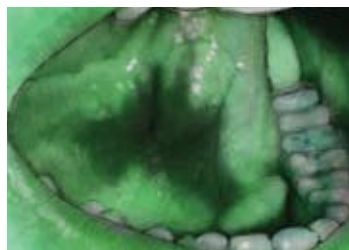


Examples of Clinical Photos



Renderings

Lesion that was to be biopsied and satellite lesions were discovered outside the parameter of biopsy



Renderings

Lesion that didn't look suspicious

Irregular, dark area – confirmed through biopsy to be carcinoma