

REALCLOUD

IMAGING



REALCLOUD HD1

USER GUIDE

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UDI = (01)00864058000326(21) Serial Number

(a unique serial number is assigned and displayed on each device)

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Introduction

RealCloud Imaging Inc, appreciates that you chose a REALCLOUD HD1 intraoral camera. We are confident you will find it produces the best intraoral camera images available, and additionally will provide years of trouble-free operation.

The REALCLOUD HD1 intraoral camera is designed to be an affordable, reliable, and ultra-high-performance image quality HDTV intraoral camera. The combination of utilizing the latest 1/3" large pixel CMOS native full HD resolution imager, and multi-element HD glass optical relay lenses, and image processing performed by a very high quality dedicated image signal processor (ISP), with a very precise easy to use focus mechanism to produce the highest actual perceived visible image quality than any other intraoral camera available.

The REALCLOUD HD1 is a 1080P Full HD resolution intraoral camera that operates on USB 3.0 and USB 2.0.

The REALCLOUD HD1 is designed for years of trouble free use. Constructed of CNC machined aluminum, which is anodized to very high iPhone level quality with an extremely durable finish that will not fade or chip, as often occurs with plastic and/or metal cameras as they age.

The REALCLOUD HD1 has a very precise and versatile focus slider which can be operated from left or right hand as well as from three separate engagement points on the focus slider itself which allows unprecedented control over the focus of the camera.

Package Contents

- 1 REALCLOUD HD1 Camera Hand Piece
- 1 Quick Connect USB Cable
- 1 Handpiece Holder
- 1 Flash Drive (Contains Optional Button Control software and electronic copy of User Guide)
- 1 starter pack of dental sheaths
- 1 Quick Start Guide/Registration card

Product Details

Specifications

Sensor	1/3" HD CMOS (Large Pixel)
Resolution	Native 1920X1080P
Signal Output	USB 2.0, Compatible with USB 3.X
Angle of View	63 degrees
Focus	1mm-infinity
Maximum Magnification	- 640x480: 20X -1280x720: 40X -1920x1080: 80X
Lighting	6 True White LEDs
Distortion	<5%
Driver Type	UVC (USB Video Class)
Operation System	Windows7/Win8/Win10(32/64bit)/ Apple OSX Sierra+
IEC 60601-1-2	TRE18010068
IEC 60601-1	TRS17090382

Symbol References

Symbol	Description
	Caution, refer to accompanying documentation
SN	Manufacturer's serial number
	Conforms to European Union Medical Devices Directive (MDD) 93/42/EEC
	USB 2.0 port
	USB 3.0 port
	Cable alignment indicator

Registration

Please register your new REALCLOUD DH1 camera, this will help us to provide expedited warranty repair service if ever needed.

You can register your camera one of two ways:

- 1) Visit our website and complete the registration page.
<http://www.realcloudimaging.com/registration/>
- 2) Complete the registration card included with your new camera and mail it to RealCloud Imaging, Inc.

Warranty & Repairs

RealCloud Imaging Inc. agrees to guarantee parts and labor for each REALCLOUD HD1 camera purchased by the end user for the term of one year from the date of purchase, when used in accordance with manufacturer instructions. The RealCloud HD1 camera and accessories contain no user serviceable parts. No user or 3rd party should attempt to diagnose, modify, or repair the HD1 camera or accessories without prior consent of RealCloud Imaging Inc. For diagnosis and service options of warranty or non-warranty repairs contact RealCloud Imaging Inc at 515-209-3233.

If a defect occurs in the first ninety days from the date of purchase, RealCloud Imaging Inc. will ship a replacement part with no shipping costs incurred by the end user for the replacement part. RealCloud Imaging Inc. will provide a return shipping label for the defective part.

After the first ninety days, the end user is responsible for shipping the defective part to RealCloud Imaging Inc, for repair or replacement.

In the event a product is returned by the dealer or the end user and the warranty has expired, RealCloud Imaging Inc, will quote an estimated repair/replacement cost for approval by the dealer or end user.

For warranty or non-warranty service a dealer or end user should call RealCloud Imaging Inc. Technical Support Department at 515-209-3233. Please have your camera serial number available when contacting Technical Support.

RealCloud Imaging Inc. can assist with diagnosing REALCLOUD HD1 camera related issues. If RealCloud Imaging Inc. Tech Support diagnoses the REALCLOUD HD1 camera hardware has failed and is covered under warranty or the end user desires an estimate for non-warranty repair work RealCloud Imaging Inc. will issue a "Return Merchandise Authorization" (RMA) number. The RMA number is to be written on the outside of the packaging or box in which the part is shipped back to RealCloud Imaging Inc.

Ship the RMA package to:

RealCloud Imaging Inc.
2625 N Loop Dr. Suite 2130
Ames, IA 50010
Attention RMA Department

SAFETY INSTRUCTIONS

- Do not expose or submerge the camera or cable in water, other liquid, or sprays as it can cause a risk of electrocution or fire hazards.
- Do not store camera in a humid environment.
- Always take the appropriate hygiene measures and precautions to prevent cross contamination risks when handling protective sheaths.
- To eliminate any potential dangers, completely inspect the device, including hand piece surface and lens, both physically and visually before using on a patient.
- For each new patient, use a new disposable sheath to prevent any infectious disease.
- Install the camera in a clean, dry, and well-ventilated dental office environment.
- Disconnect the camera from PC for storage or if not going to be used for several days.
- Do not pull on the USB cable. Disconnect using the quick release at the hand piece
- Do not compress or kink the handpiece cable.
- Do not expose the product to high vibrations.
- Do not drop the handpiece.
- Do not attempt to disassemble the handpiece.
- Handpiece and cable should NEVER be immersed in any liquid.
- Handpiece and cable should NEVER be autoclaved.
- Always use the camera in accordance with the directions and recommendations contained in this User Manual. Do not attempt to modify the camera or use it in system configurations not specified in this document.
- The RealCloud HD1 camera and accessories contain no user serviceable parts. No user or 3rd party should attempt to diagnose, modify, or repair the HD1 camera or accessories without prior consent of RealCloud Imaging Inc. For diagnosis and service options of warranty or non-warranty repairs contact RealCloud Imaging Inc at 515-209-3233.
- To avoid any ocular/vision risk do not look directly at the LED illumination.
- Do not direct the camera illumination at close range to the eyes of the operator or patient.

NOTE:

If the hygienic protection disposable sheath is torn or contamination breached while examining a patient or if the handpiece was cross contaminated while withdrawing the hygienic protector, it is essential to disinfect the handpiece. Refer to the maintenance chapter for proper disinfecting procedures.

Regulatory Requirements

The REALCLOUD HD1 is a FDA listed dental intraoral camera medical device. Intraoral cameras are FDA regulated dental operative unit and accessories under FDA regulation 872.6640 and sub-code NRD.

The REALCLOUD HD1 is manufactured in an FDA listed manufacturing facility and RealCloud Imaging maintains a FDA QSR compliant Quality Management System. RealCloud Imaging, Inc. maintains regulatory compliance required for its locations of distribution.

Safety Compliance Standards

The REALCLOUD HD1 is designed to be safe for both the operator and patient and has been tested and complies with IEC 60601 safety standards, which are higher level medical device safety standards than consumer device safety standards. The REALCLOUD HD1 hand piece is type BF (body floating) equipment and is isolated from ground such as medical equipment in a hospital. Note: To maintain BF floating compliance the PC and accessories must also meet required IEC standards.

Intended Use

This device is intended to be used by trained dental professionals only. The REALCLOUD HD1 intraoral camera is used to view intraoral and extraoral images of a patient's dental anatomy for various modalities including documentation, patient education, and checking dental procedures performed upon a patient.

Follow all precautions in this Users Guide. Also, follow proper safety, use, and HIPAA protocols as defined in your office. As with any device inserted in the oral cavity use professional judgement for safe operation of the device and comfortable use on the patient. Be aware of any possible choking and/or gagging hazards to the patient and use appropriate professional techniques as applicable.

Installation:

The REALCLOUD HD1 camera is flexible with easy no-driver installation on Windows 7, 8, 10 as well as Apple OSX Sierra and higher. When the REALCLOUD HD1 camera is plugged into a USB port on an OSX or Windows PC it will automatically be recognized, and ready for use.

Additionally, for guaranteed compatibility and use with older specific proprietary dental imaging software that does not recognize REALCLOUD HD1 camera button automatically the REALCLOUD HD1 camera ships with a button emulator software which translates the button pushes into keyboard keys and sends them to the imaging software and can be used in older legacy dental imaging software (Dexis 9.x, Old Dentrrix Image, etc....).

For legacy imaging software that doesn't support Full HD image resolution of 1920 x 1080p, the REALCLOUD HD1 can also operate at 1280 x 720p, or even Standard Definition at 640 x 480p resolution.

The REALCLOUD HD1 has a dis-connectable cable at the hand piece which allows for easy use in multiple operatories by simply moving the hand piece and having a camera hand piece cable in each operatory already connected to the PC. The REALCLOUD HD1 cable connector has a high reliability connector versus a standard USB connector, and the REALCLOUD HD1 connector is rated for many more connections/disconnections versus standard USB 2.0 cable connectors.

Connections:



1. Connect the REALCLOUD HD1 handpiece to the Quick Connect Cable by aligning the arrows on the cable connector and handpiece. You will hear a clicking sound when completely inserted.



When disconnecting, grasp ODU snap connector and gently pull away from the base of the handpiece.



Note: Do not pull on the cable itself and pull only on the ODU connector as shown above.

2. Plug in the REALCLOUD HD1 Camera assembly into a 2.0 or 3.0 USB port.

Make sure that you plug the REALCLOUD HD1 into a powered USB port. Sometimes, these are located on the front or back of the computer. If your monitor has USB ports, these may not be powered.

3. Upon proper connection, the computer operating system will recognize the camera.

Note: The first time the REALCLOUD HD1 camera is plugged into a Windows computer, it may take a couple of minutes to recognize the driver depending on the Windows version and if Windows is configured to check Windows Update site, but usually will complete within 30 seconds.

Note: OSX will not give you an alert when the camera is plugged in for the first time.

Camera Holder



The camera holder can be mounted on any dental receiver, wall, or cabinet.

Before mounting, always take safety and efficiency into mind to make sure it will be in most convenient location for use and with a minimum risk of being damaged by the dental staff and patient interactions.

Mount the camera holder with the camera cable hanging down in a place that is clear of any cabinet doors or drawers that could damage the cable.

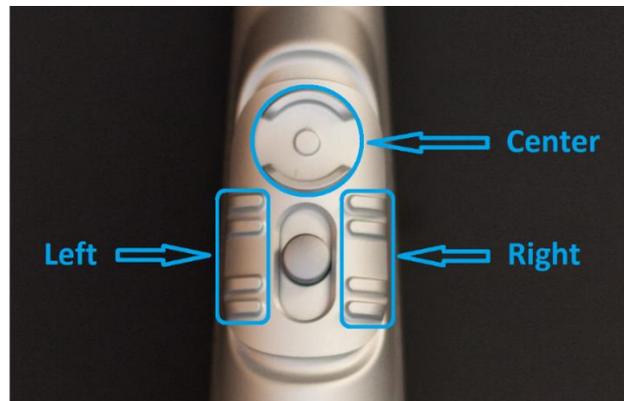
If mounting to sheet rock or wallboard, use the plastic anchors and screws. Over-tightening mounting screws may render the holder unusable if warping or cracking occurs.

Camera Operation/Function:

Focus Slider:

There are two ways to use the REALCLOUD HD1 focus mechanism, either using your thumb, or your index finger.

There are three finger saddles in the focus slider. One on each side for left or right-handed use and a center ring. The center ring is the recommended method of focusing to use.

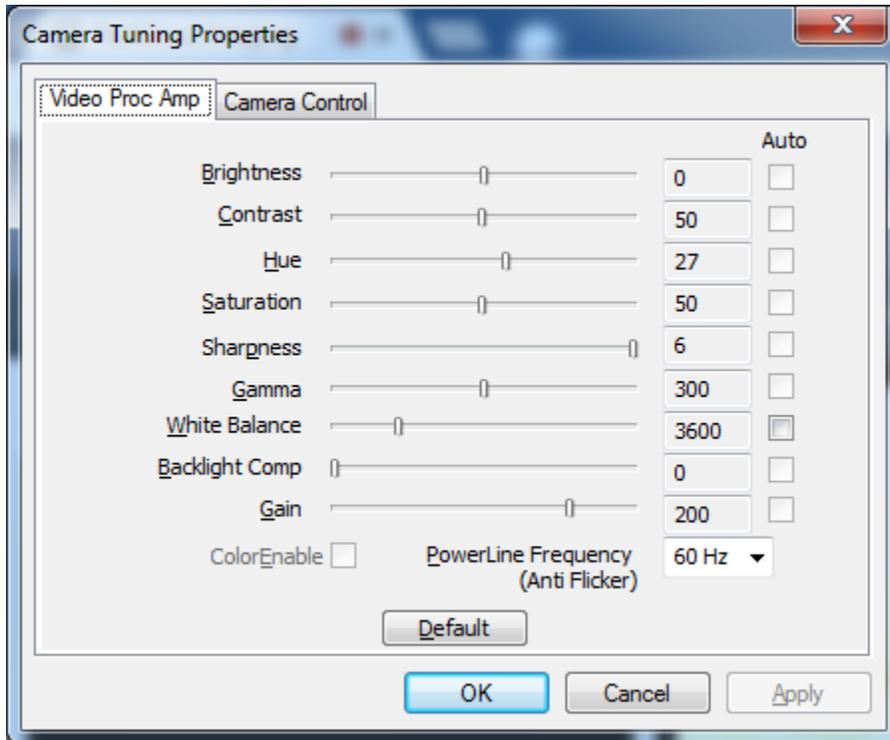


To focus the camera, move the slider forward or back until the image becomes in focus. To focus close-up, move the slider toward the tip of the handpiece; to focus further away move the slider towards the base of the handpiece.

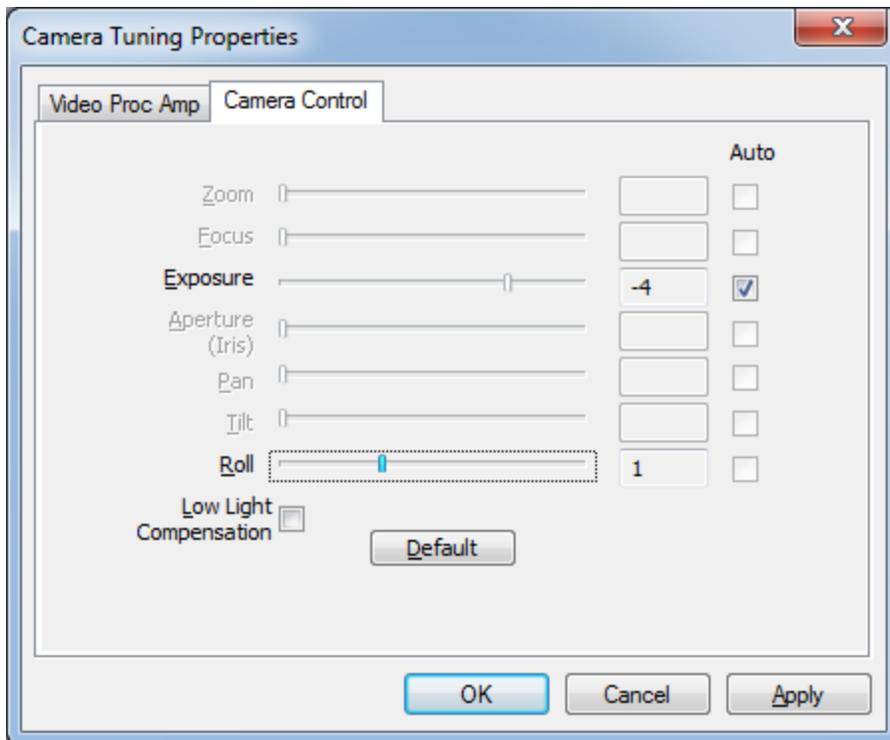
Note: Resting the handpiece and/or your hand on the opposing arch will help stabilize the camera for clear crisp images.

Camera Tuning Properties:

Access to the REALCLOUD HD1 camera settings page will depend on your imaging application, please refer to your imaging application manual.



On the Video Proc Amp tab, you can adjust the brightness, contrast, hue, saturation, sharpness, gamma, white balance, and/or gain if needed.



On the Camera Control tab, you can adjust the Roll (image orientation).



Roll setting #0 equals a positive image



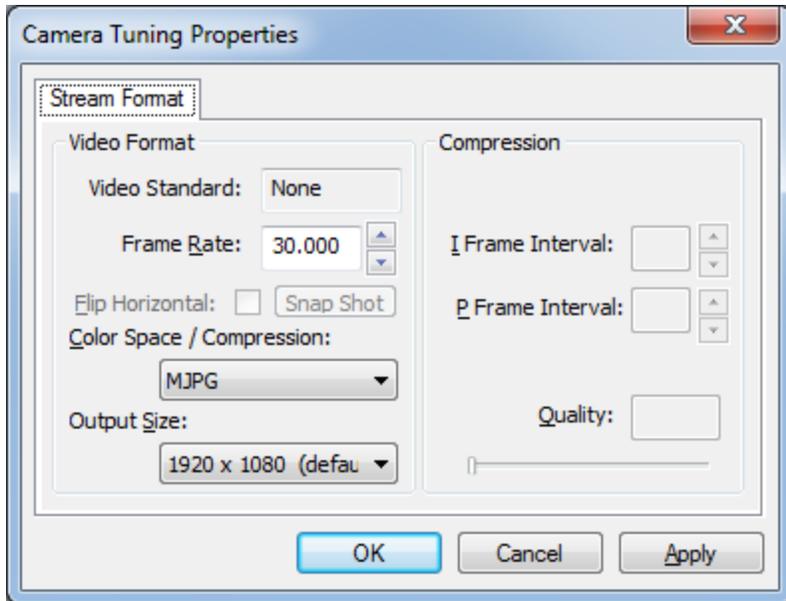
Roll setting #1 equals a mirrored image



Roll setting #2 equals a flipped image



Roll setting #3 equals both a mirrored and flipped image



On the Stream Format tab, you can select an output size resolution (1920 x 1080, 1280 x 720, or 640 x 480) but the Frame Rate should always be 30 fps and the Color Space should be MJPG. Changing either the frame rate or color space/compression could mess with some imaging software’s operation including frame rate and/or image quality.

Camera Handpiece Button:

The button on the handpiece controls turning the LED ON or OFF and controls capturing an image as described below.

LED ON/OFF Control: The LED ON/OFF is synchronized with the imaging software and has a 10-minute automatic time-out. When the imaging software is opened and tries to display a live image, the camera LED will turn on automatically. When the imaging software exits or stops using the camera, the LED turns OFF automatically.

Note: When the LED is ON, you can also turn off the LED immediately by a double button press. When the LED is OFF, a quick single press of the button turns the LED ON for 10 minutes.

Note: Some imaging applications may be displaying video or communicating with the camera when no video is shown. In this case, push the button twice to turn off the camera LEDs as needed.

Capture Image Control: When the camera button is pushed and released (without holding the button for longer than 3 seconds) the camera will pause the live video image for review.

When an image is paused on the screen for review, a single push and release of the button resumes the live video stream. When the live video display is paused, a single push and hold of the button for 3 seconds will save/acquire the paused video image to the imaging software.

Note: If the imaging software being used supports UVC Still Pin capture, then no optional REALCLOUD HD1 button control software is needed. This may require settings in the imaging

software to be changed to configure it for Still Pin capture. If the imaging software in use does not support UVC Still Pin capture, then RealCloud Imaging, Inc. supplies software that allows the button push to be forwarded as keyboard keystrokes, which most older legacy imaging software supports. RealCloud Imaging, Inc. has created installation instruction PDFs for many of the common imaging software's which can be downloaded from our website and are also included on the flash drive that comes with the REALCLOUD HD1 camera.

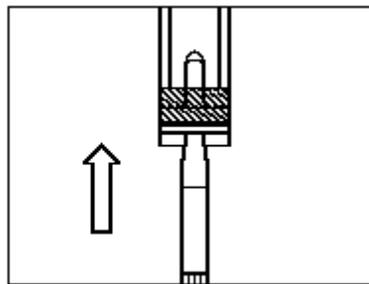
Using the Camera on Patients:

Disposable Hygiene Sheath:

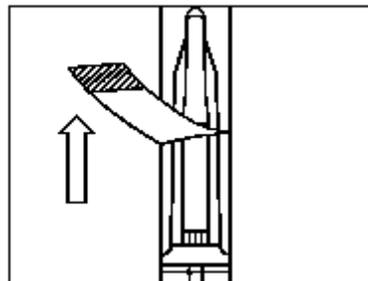
The disposable hygiene sheaths are designed for a single use only and when using the camera in the oral cavity.

When using the camera for extraoral photographs, the disposable hygiene sheaths are not needed or recommended as they may cause reflections of light to be captured in the image.

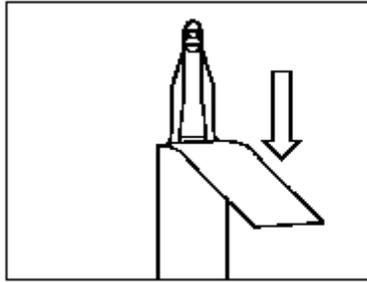
- A. **Handpiece Insertion:** With the camera lens side down towards the white paper backing, slide the handpiece beneath the blue tab into the sheath opening. Push the handpiece to the end of the sheath.



- B. **Protective Covering Removal:** Hold the handpiece at the cable end and pull the blue tab removing the protective cover in the direction shown. Avoid handling or touching the clean inner sheath. Discard cover.



- C. **Paper Backing Removal:** Beginning at top end of the handpiece, peel the paper backing in the direction shown and discard. Avoid handling or touching the clean inner sheath.



- D. **Focus Slider:** Optional, at the focus slider move the sheath back towards the tip of the handpiece, adding additional room to move the focus slider easier.
- E. **After use:** Remove sheath from the handpiece and dispose of sheath properly. It is recommended to disinfect the handpiece after each use (see Disinfecting Procedures section in the manual).

Note: Inspect the sheath for any breaches before and after each use on a patient.

Basic camera operations:

1. Start the imaging software you use to capture images from an intraoral camera and select the option to capture or acquire images.
2. To focus the camera, move the slider forward or back until the image becomes sharply in focus. To focus close-up, move the slider toward the tip of the handpiece; to focus far away move the slider towards the base of the handpiece.
Resting the handpiece or your hand on the opposing arch will help stabilize the image for clear crisp images.
3. Press the button to pause or save the picture as described in this User Guide.

Helpful camera usage tips:

- **Position Handpiece** - Place the camera handpiece into your hand, holding it like a pencil, or alternatively grasp the handle of the camera and use your thumb to focus and press capture button. Center the camera handpiece in your hand so it is comfortable and balanced.

Supported Imaging Software:

Imaging software may require a button control software to be installed. Please refer to the Imaging software setup guide instructions on our website or on the provided flash disk which gives setup instructions for each of the imaging software below. If the imaging application you use is not listed below, please check our website as we are supporting more imaging applications on a regular basis.

- Ascend Imaging
- Apteryx X-rayVision 3.x & 4.x
- DEXIS 9.4.6 and higher
- DEXIS Imaging Suite 10.x & 11.x
- Carestream-Kodak Dental Imaging 6.12 and higher
- Schick CDR DICOM 5.4 and higher
- DBSWIN 5.14.1 and higher
- EVAsoft/ProImage 3.4 and higher
- MiPACS 4.0 and higher
- Patterson Imaging-Eaglesoft 15.x and higher
- Progeny Imaging 1.16.x and higher
- Romexis 5.1.1 and higher
- Sidexis 4.2 and higher
- SOTA Image 2.4.x and higher
- Vatech EzDent-i 3.0.0.2 and higher
- Visix 7.7.13 and higher
- VixWin 3.5 and higher
- XDR 3.2 and higher

Maintenance

The camera does not need any additional maintenance if it is used according to the manufacturer's use and cleaning instructions. The RealCloud HD1 camera and accessories contain no user serviceable parts. Every time the camera is used, it is important to follow the disinfecting procedure below.

Recommended Disinfecting Procedure:

Using a disinfecting wipe e.g. **Caviwipes™** or alcohol wipes (Lysol wipes from the grocery store are not appropriate), remove any excess moisture from the wipe, wipe the handpiece (and cable if needed) without pressure. Wait at least 30 seconds. This allows the first application to dry. Then, using a fresh wipe, disinfect the handpiece and cable a second time. Place the handpiece in a clean environment and put on a new disposable hygiene sheath. Discard used gloves.

Do not scrub, rinse, immerse in liquid, or autoclave the handpiece or cable.

Do not wipe the surface using benzene, decide, acidic or corrosive chemicals, or glutaraldehyde as this may degrade the lens, or damage the handpiece material.

Troubleshooting

PROBLEMS	PROBABLE CAUSES	SOLUTIONS
No image displays on the screen and the camera LEDs are not on	Connection problem	Check the connecting cable is correctly connected to the handpiece and to the computer
An image displays, but it is not clear (blurry)	Hygienic sheath	Check the hygienic sheath is correctly positioned on the camera
An image displays on the screen, but the quality is not satisfactory	Camera driver configuration	Check the camera configuration in the Imaging software (brightness, contrast, saturation, etc.)
Video image is slow or choppy	<ol style="list-style-type: none"> 1) Slow/older computer 2) Unsupported display card drivers 	<ol style="list-style-type: none"> 1) Lower the camera resolution output size 2) Install the latest display card drivers
An image is displayed, but the button will not capture	Camera button software not installed or configured properly	See installation section of User Guide
Imaging application reports that the camera is not detected	<ol style="list-style-type: none"> 1) Connection problem 2) Incompatible USB chipset drivers 	<ol style="list-style-type: none"> 1) Check the connecting cable is correctly connected to the handpiece and to the computer 2) <ol style="list-style-type: none"> A. Unplug and re-plug the cable from the handpiece B. Install a powered USB hub between the computer and the camera C. Update the USB chipset drivers