

PureClear Digital Inspection Scope

Models:

Inspection Control Modules	Inspection Borescope
CD-USB	CB2-60
CD-HDMI	CB2-110
	CB2-200
	CB1-110

Instructions For Use (IFU)

Table of Contents

Symbol Descriptions3
GENERAL WARNINGS3
Intended Use
Indications for Use
Contraindications for Use
Complete Inspection Scope Workstation4
Contents: Inspection Control Module (USB and HDMI Models)
Inspection Borescope
Digital Inspection Scope Features5
Digital Inspection Scope Accessories6
Unpacking the Device7
Unpacking Inspection7
Routine Maintenance7
Startup Procedure8
Connecting or Switching aN Inspection Borescope with the Control Module
Medical Scope Viewer Software *CD-USB ONLY 9
Installing Medical Scope Viewer Software
Using Medical Scope Viewer Software9
Selecting the Video Device or Camera10
Capturing Still Pictures10
Capturing Video Images10
Setting File Name1
Setting Location for Saved Files1

Creating New Folder Location for Saved Files12
Renaming Saved Files12
Deleting Saved Files12
Performing Inspection13
Verifying Operation14
Compatible Cleaning, Disinfecting and Sterilization Methods 15
Cleaning15
Manual Cleaning16
Cleaning Between Uses16
High-Level Disinfecting (Inspection Borescope ONLY)16 Disposal of Waste Products17
Troubleshooting and Servicing17
Warranty 18
Specifications 18
Power Source Requirements18
Illumination Source18
Physical Properties19
Optical19
Connectors and Cables19
Environmental Conditions19
Waterproof Rating / Ingress Protection Rating 19
Manufacturer19



Symbol Descriptions

(3)	Read this operating manual for additional warnings and instructions for use
À	WARNING
M	Date of manufacture
	Manufactured by
REF	Reference Number
SN	Serial Number
EC REP	European Authorized Representative

GENERAL WARNINGS



- 1. Follow the instructions for cleaning, disinfecting and sterilizing provided in this document.
- 2. Do not autoclave the Digital Inspection Scope.
- 3. Do not attempt to service any part of this product.
- 4. To ensure operator safety, read and understand this manual before using the Digital Inspection Scope.
- 5. The Digital Inspection Scope emits visible light energy from its distal end when powered on. Avoid looking directly at this emitted light or directing it toward others.
- 6. Carefully inspect the external surfaces of the Digital Inspection Scope and any accessories to ensure they are smooth and free of any protrusions or sharp edges.
- 7. Light leaks may be common and possibly noticeable when inspecting the flexible portion of the Inspection Borescope. This does not have an effect on its function, but it should be monitored for light output. If the image on your monitor is too dark to visualize, this may be caused by damaged light fibers and may require repair or replacement of the Inspection Borescope
- 8. Do not bend the Inspection Borescope to a radius less than 0.50" (12.7 mm). This may cause damage.
- 9. Do not apply excessive force to the Inspection Borescope. If you feel resistance, or an obstruction hinders its path, you may gently attempt to manipulate or rotate the device to avoid the obstacle. You may also slowly withdraw it a short distance and try advancing again. Applying excessive force to the Inspection Borescope can result in damage.
- 10. Avoid rubbing the Inspection Borescope against sharp edges. This can cause damage.



Intended Use

The Digital Inspection Scope is used for visual inspection of medical devices.

Indications for Use

Visual Inspection of channels, lumens and inner components, during reprocessing of medical devices and endoscopes, to visually verify that they are free of damage, debris or moisture.

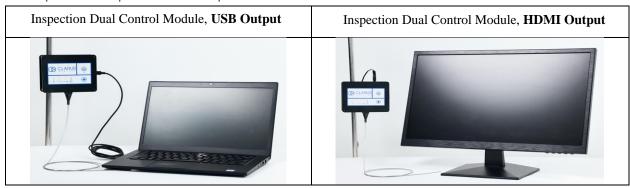
Contraindications for Use

The Digital Inspection Scope is not intended for human use.

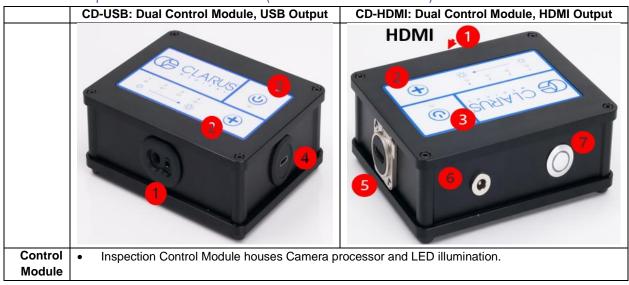
Product Description

The Digital Inspection Scope allows for enhanced visual inspection by providing light, vision, magnification, and the option for documentation in hard-to-see crevices, channels, and lumens in medical devices.

Complete Inspection Scope Workstation



Contents: Inspection Control Module (USB and HDMI Models)





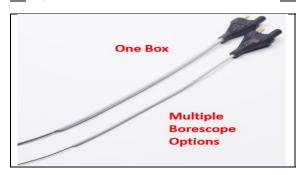
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Features	Digital Inspection Scope Connection	Digital Inspection Scope Connection
	2. Illumination Control	2. Illumination Control
	3. Power Cycle	3. Power Cycle
	4. USB(Type C) Out	4. N/A
	5. N/A	5. HDMI Out
	6. N/A	6. Power Input
	7. N/A	7. System Power Button
Cables	USB A to USB C Cable	HDMI to HDMI Cable
		Power Cable
Software	USB Flash Drive (Containing Medical Scope	N/A
	Viewer Software & Instructions for Use)	

Inspection Borescope

All Digital Inspection Borescope models work in both USB and HDMI Inspection Control Module



- CB2-60: 1.83mm O.D. and 60cm Working Length
- CB2-110: 1.83mm O.D. and 110cm Working Length
- CB2-200: 1.83mm O.D. and 200cm Working Length
- CB1-110: 1.06mm O.D. and 110cm Working Length

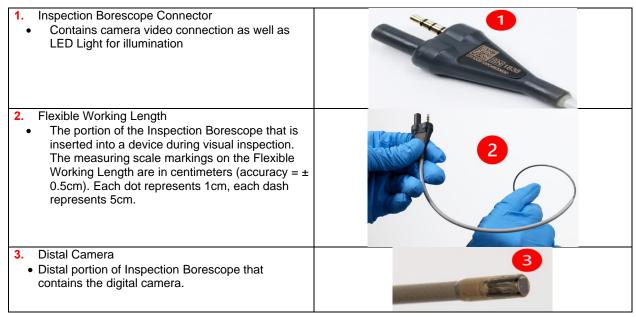
Digital Inspection Scope Features

The user features of the Digital Inspection Scope (FIGURE 1) and Accessories (FIGURE 2) are shown in the following illustrations.

Light / Illumination settings: 5 light settings Light on Control Module indicates setting level 5 th setting is OFF Press Light button to advance to next setting 5 th setting turns the light OFF	CLARUS O
Power Cycle Button	•
Press button to RESET camera	CLARUS CLARUS







Digital Inspection Scope Accessories

Accessory	Image	Description
USB Camera Cable		Plugs into USB port on computer. *(USB Control Module ONLY)
HDMI Cable		Plugs into HDMI Port on monitor. *(HDMI Control Module ONLY)
Power Adapter Cable		Power source *(HDMI Control Module ONLY)
USB Flash Drive	C CLARUS	Plugs into a Computer USB Port (contains) • Medical Scope Viewer Software • Instructions for Use



Rubber Cord Holders	80	Rubber cord holders may be attached to Control Module to manage the working length of the inspection borescope
Flexible Mount		(Sold Separately) Connects the Inspection Control Module to external surface (Shelf, Pole, etc)

Unpacking the Device

The Digital Inspection Scope has been thoroughly inspected and carefully packaged before shipping. Once the device is removed from its container, it should be carefully inspected for shipping damage. If there is any damage, contact the shipping carrier and Pure Processing immediately.



WARNING: Do not attempt to use the Digital Inspection Borescope if it appears to be damaged.



WARNING: The Digital Inspection Scope is **NOT STERILE** as supplied from Pure Processing. The user must follow the protocol for cleaning and disinfecting or sterilizing described in the Instructions for Cleaning and Disinfecting or Sterilizing section.

Unpacking Inspection

Prior to use, inspect the Inspection Borescope for signs of wear or damage. Operation can be verified by following the steps in the Verifying Operation section of this manual.



WARNING: Carefully inspect the external surfaces of the Inspection Borescope and any accessories to assure they are smooth and free of any protrusions or sharp edges.

Routine Maintenance

There are no user serviceable parts within the Digital Inspection Scope. No user maintenance beyond cleaning is required. Refer all service or replacement needs to Pure Processing. The contact information is listed at the end of this document.



Startup Procedure

<u>CD-USB</u>	<u>CD-HDMI</u>
1. Open the Windows PC viewer software	1. Plug the Control Module into a source of AC power
	using Power Adapter.
2. Connect the Control Module to PC using USB	2. Connect Control Module to ANY HDMI Monitor
Cable	using HDMI cable
3. Plug the Inspection Borescope into Control	3. IF NEEDED-Select correct monitor input on
Module	monitor
4. In the viewer software, click "Settings" and Select	4. Power button set to ON (Green Light Present)
"USB Video Device"	
5. Press the Power Cycle Button	5. Plug Inspection Borescope into the Control
	Module
	6. Press Power Cycle Button

Connecting or Switching a Inspection Borescope with the Control Module

- 1. Unplug the Inspection Borescope from the Control Module
- 2. Connect a new or different size Digital Inspection Borescope
- 3. Press Power Cycle Button

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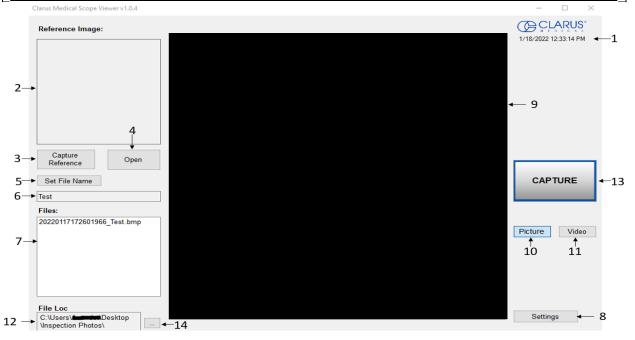
Medical Scope Viewer Software *CD-USB ONLY

Installing Medical Scope Viewer Software

- System Requirements: MS Windows version 10.
- Install the Scope Viewer Software from the USB flash drive on a computer

Using Medical Scope Viewer Software

#	Name	Function
1	Date & Time	Date and time display.
2	Reference Image Window	Displays a Reference Image.
3	Capture Reference Image Button	Captures still image being displayed in the Main Image Window.
4	Open Button	Opens the file location (File Loc) where images are being saved and allows you to select image that is displayed in Reference Image Window.
5	Set File Name Button	Click to set a file name that will appear when capturing images.
6	File Name Box	Text box for creating a File Name.
7	Files Box	Displays captured images that are stored in the in File Loc folder.
8	Settings Button	Click to select the video camera settings.
9	Main Image Window	Displays the image from the camera.
10	Picture Button	Click to select the picture option when capturing still images.
11	Video Button	Click to select the video option when capturing video images.
12	File Loc Box	Location where captured images are being saved.
13	Capture Button	Option to click for capturing images. Also used to start/stop video images.
14	Ellipse Button	Opens window for browsing file locations to save images



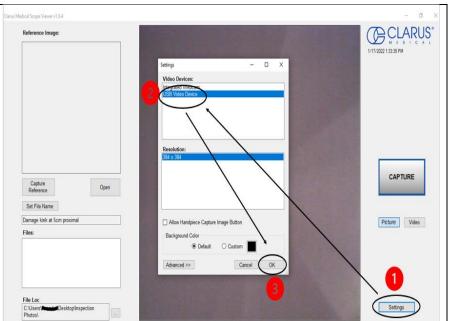
Page 9 of 19



Selecting the Video Device or Camera

Follow the directions below to select the video device or camera used to capture images using the Medical Scope Viewer Software.

- Click the 'Settings' Button in the lower left of the Medical Scope Viewer Software to display a list of video devices or cameras that are being detected by your computer.
- Select a device for capturing images using the Medical Scope Viewer.
 - a. The example below shows an Integrated Webcam and USB Video Device on the computer. Select the USB Video Device for the Digital Inspection Borescope.
- 3. Click 'OK' to view the selected Video Device.



Capturing Still Pictures

Follow the instructions below for capturing still pictures from the Main Image Window.

1. Select the 'Picture' Button on the software



- 2. Use any of the following options to capture an image:
 - a. Click 'Capture' on the Medical Scope Viewer Software (FIGURE above).
 - b. Press the space bar on your computer keyboard.
- 3. Note: When an image is captured, "Picture Captured" in red text will flash on the lower portion of the screen and a new file will appear in the Files Box.

Capturing Video Images

Follow the instructions below for capturing video from the Main Image Window.

1. Select the 'Video' Button on the software



- 2. Use any of the following options to start and stop the video:
 - a. Click the 'Capture' Button on the Medical Scope Viewer Software (FIGURE above).
 - b. Press the space bar on your computer keyboard.
- 3. When the video is recording, "Recording" in red text will appear toward the bottom of the software window.

Page 10 of 19



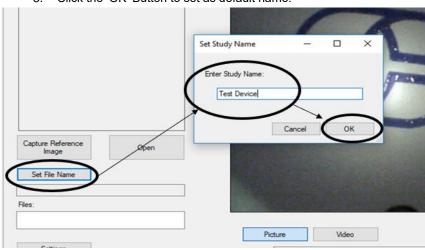
4. To stop recording, use any method as described in Step 2 above for starting the video. Note: The Image Capture Button will now read 'Stop Video' while recording.

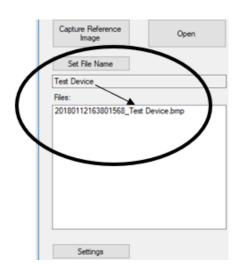


Setting File Name

Following the steps below allows you to create a file name that will appear after the underscore when capturing images using the Medical Scope Viewer Software.

- 1. Click 'Set File Name' Button.
- 2. Enter the characters that you would like to be included in file name.
- 3. Click the 'OK' Button to set as default name.

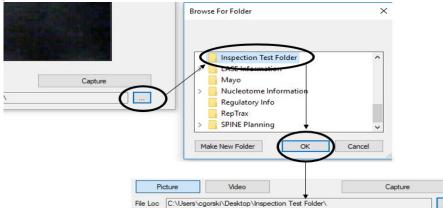




Setting Location for Saved Files

Following the steps below allows you to set the file location of saved images using the Medical Scope Viewer Software.

- 1. Click the Ellipse Button
- 2. Select the file location where you would like to save captured images.
- 3. Click 'OK' to set the File Loc for saved files.



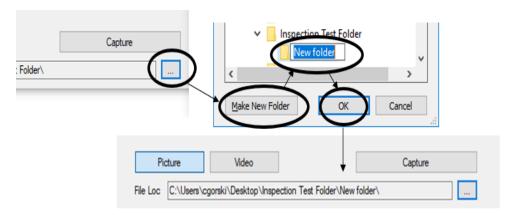




Creating New Folder Location for Saved Files

Following the steps below allows you create a new file location for saved images using the Medical Scope Viewer Software.

- 1. Click the Ellipse Button
- 2. Click the 'Make New Folder' Button.
- 3. Create a name for the new folder.
- 4. Click the 'OK' Button to create the new file in File Loc.



Renaming Saved Files

1. Right Click on file name within Viewing Software and select "Rename"

Deleting Saved Files

The Files Window in the Medical Scope Viewer displays image files that are being stored in the File Loc. To delete files, either:

- Right Click on file name within Viewing Software and select "Delete"
- Navigate to the location (shown in the File Loc) on your computer, outside of the Medical Scope Viewer software.



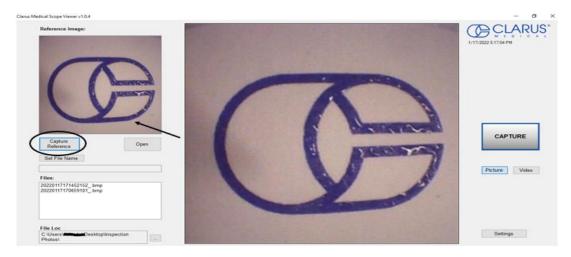
Displaying Reference Image

There are two ways to display a still image in the Reference Image Window on the Medical Scope Viewer Software.

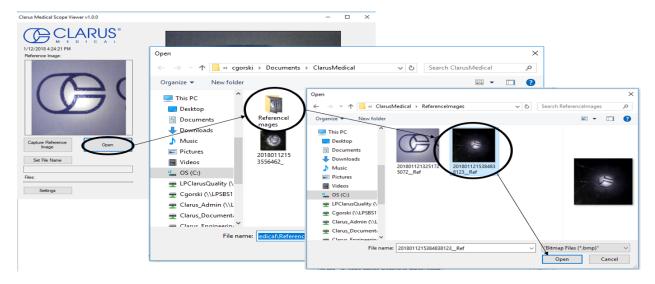
To display an image currently being displayed in the Main Image Window, click 'Capture Reference Image'
Button. NOTE: The images will be saved in a file folder titled "Reference Images" in the designated File Loc.

Page 12 of 19





- To display a saved image in the Reference Image Window from your File Loc:
 - a. Click the 'Open' Button
 - b. Click on the Reference Images Folder.
 - c. Select the file that you would like to display.
 - d. Click the 'Open' Button, to display the image in the Reference Image Window.



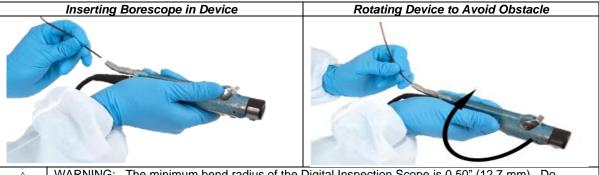
Performing Inspection

Following the steps listed below will ensure the proper use and best performance of the Inspection Borescope. Follow these steps prior to inspection.

- 1. Secure the Inspection Scope into an arm fixture (optional).
- Grasp the Inspection Borescope near its distal end and gently insert the Flexible Working Length into the intended device as shown in.
- 3. Adjust light with the Illumination button for ideal lighting.
- 4. Use short advancements while keeping your fingers close to the device's opening. View the monitor while inserting into the device. If an obstruction hinders the path of the Inspection Borescope, gently attempt to manipulate or rotate it to avoid the obstacle.

Page 13 of 19







WARNING: The minimum bend radius of the Digital Inspection Scope is 0.50" (12.7 mm). Do not bend the Inspection Borescope into sharper bend or damage could occur.



WARNING: Do not apply excessive force to the Inspection Borescope. If you feel resistance, or an obstruction hinders the path of the Inspection Borescope, gently attempt to manipulate or rotate the device to avoid the obstacle. You may also slowly withdraw a short distance and try advancing again. Applying excessive force to the Inspection Borescope past an obstacle could result in damage to the device.

Once the device has reached the end of the area you are inspecting, retract the scope slowly while looking for debris or damage.

Verifying Operation

Following the steps listed below will ensure the proper use and performance of the Inspection Borescope. The Inspection Borescope can be checked for normal operation by connecting it as described in the Startup section of this manual.

Normal operation includes:

- An image appearing on your computer monitor or HDMI Monitor.
- A blinking light on Control Module near the 'Power Cycle" button indicates the image feed is transmitting.
- White light will emit from the distal end of the Inspection Borescope.
- An LED light on the Control Module front panel will indicate the light intensity setting of the device.



Compatible Cleaning, Disinfecting and Sterilization Methods



WARNING: The Digital Inspection Scope system is provided non-sterile. Before initial use and after each use, the external surfaces of the Inspection Borescope should be cleaned.

WARNING: The Control Modules provided for the Digital Inspection Scope system are not waterproof. The Control Modules are to be wiped only. Do not soak or submerge the Control Modules.



WARNING: Cleaning does not disinfect or sterilize the Inspection Borescope. Be sure to follow your institution's specific cleaning and disinfecting or sterilizing procedures in consultation with this manual. The user is responsible to ensure that their procedures result in disinfection or sterilization, whichever is required.



WARNING: Do not clean, disinfect, or sterilize the Digital Inspection Scope system or its accessories using an ultrasonic cleaner, washer sanitizer, washer pasteurizer, washer sterilizer, steam autoclave, or any method with a processing temperature above 60°C (140°F). Use of these processes will result in damage to the instrument and void its warranty.



WARNING: Follow the disinfectant manufacturer's instructions for disinfecting.

WARNING: High level disinfecting does not result in terminal sterilization. Bacterial endospores may still remain viable after high level disinfecting.

Cleaning

The Inspection Borescope has fluid ingress protection rating of IPX7 (Waterproof) and can withstand immersion in fluid up to 1 meter in depth for up to 30 minutes.

The Inspection Borescope is made of the same material as other common endoscopes. Any wipe, solution or low-temperature (≤ 60°C (140°F)) method intended for the reprocessing of endoscopes is likely compatible with the Inspection Borescopes if used according to the product labeling. See below chart for details.

The Inspection Borescope is manufactured with materials known to be compatible with the STERRAD® Systems listed below in the table.

The Control Module has a fluid ingress protection rating of:

- USB: IPX5 (Water resistant) and can withstand a sustained, low pressure water jet spray for up to three minutes.
- HDMI: IPX4 (Water resistant) can withstand splashing water from any direction. See below chart for details.

The Control Module and cables are not waterproof and should not be immersed. It may be cleaned with wipes containing solutions in the table below. Do not soak the Control Modules or cable accessories.

Compatible agents to clean, disinfect or sterilize the are listed in the below charts. Follow the cleaning agent manufacturer's Instructions for Use.

Wipes and Solutions Containing (Inspection Borescope AND Control Module):		
Hydrogen Peroxide Isopropyl Alcohol (IPA)		
Sodium Hypochlorite (bleach)	Ortho-Phenylphenol	
Quaternary Ammonium		

Low Temperature Sterilization Systems (Inspection Borescope ONLY):	
Ethylene Oxide (EtO)	STERRAD® 100S System (Standard)
STERRAD® NX System (Standard, Advanced)	STERRAD® 100NX System (Standard)
STEDIC® Liquid Chamical Starilization Systems	STERIS V-PRO® Low Temperature Sterilization Systems
STERIS® Liquid Chemical Sterilization Systems	(Non-Lumen Cycle)

Solutions Containing (Inspection Borescope ONLY):

Page 15 of 19



Alcohol Ethoxylates	Neutral or Near-Neutral pH Detergents
Enzymatic Cleaning Solutions	Enzymatic Detergents
Glutaraldehyde	Hydrogen Peroxide (7.35%) with Peracetic Acid (0.23%)
Accelerated Hydrogen Peroxide (AHP)	Ortho-phthalaldehyde (OPA)
Peracetic Acid	Sodium Borate, Decahydrate
Sodium Xylene Sulfonate	Tetrapotassium Pyrophosphate
Trisodium Nitrilotriacetate	

Manual Cleaning

• Follow the cleaning agent manufacturer's Instructions for Use and precautions regarding health hazards, dispensing, measuring and storage of cleaning agents.

Cleaning Between Uses

 Wipe down the Inspection Borescope system with a compatible wipe. Follow the wipe manufacturer's Instructions for Use.



High-Level Disinfecting (Inspection Borescope ONLY)

- Select only the disinfecting solutions listed in the compatible disinfecting methods section.
- Follow all recommendations regarding health hazards, dispensing, measuring and storage from the manufacturer of the cleaning and disinfecting agents.
- Soak the Inspection Borescope in the selected disinfecting solution per the solution manufacturer's Instructions for Use
- Rinse the Inspection Borescope with critical (sterile) water, again, following the instructions of the disinfecting solutions manufacturer.
- Dry with a sterile, soft, lint-free cloth or sponge. Ensure that the distal tip and proximal end are dried. Air drying could leave deposits on the optical surfaces which could result in a degraded image.



Disposal of Waste Products

The Digital Inspection Scope System does not produce any waste materials. At the end of the device's life, the Digital Inspection Scope System components may be disposed of with standard electrical products. Follow local regulations for proper disposal of electrical products.

Troubleshooting and Servicing

Condition	Appearance	Cause	Correction	
No image	Main Image Window is black.	The Inspection Borescope System was not connected to computer when the software was opened.	Unplug USB Connection on Camera Cable and plug in again.	
No image	Main Image Window is black.	 USB Video Device not selected, or without the borescope connected. Check HDMI Monitor "Input" Selection 	If no image, go to the 'Settings' Tab and select USB Video Device.	
No light	No light when borescope pointed at surface.	No power to light source or power connections are not secure.	 Check the Camera Cable connections and make sure the computer is powered on. HDMI-Make sure System Power Button is "ON" 	
Low light	No image or very dark image. Weak light pattern when borescope pointed at surface.	Light setting too low.	Cycle through light intensity levels/settings until a clear image is obtained	
Low light	No image or very dark image. Weak or light pattern when borescope pointed at surface.	Broken light fibers in borescope.	Replace Inspection Borescope (The user must judge when the Inspection Borescope is no longer adequate for use, but as a guide, when 10% of the image or illumination has been degraded or lost it is recommended that a replacement be acquired).	
No image or distorted image	No image or heavily distorted, cracked appearance.	Broken image sensor and/or internal cables.	 Press Power Cycle button Replace Inspection Borescope.* 	
Overly bright image	White-out type reflection.	Light Intensity is too bright.	Cycle through light intensity levels/settings until a clear image is obtained	
Blurry image or overly bright image	Distorted image. Light often reflective and image appears brightly colored.	Debris or film on lens.	Wipe off end of Inspection Borescope with soft cloth.	
Image does not capture	When you click the Capture Button, the still image or video is not captured.	The File Loc path may have changed or the folder name does not exist.	Set up a new Windows File Loc folder.	



Warranty

The Digital Inspection Scope System is warranted, when new, to be free of defects in material and workmanship and to perform in accordance with the manufacturer's specifications when subject to normal use service for a period of 1 year from the date of purchase. Pure Processing at its option, will either repair or replace any components found to be defective or at variance from manufacturer's specifications within this time at no cost to the purchaser. It shall be the purchaser's responsibility to return the device directly to Pure Processing after receiving a Returned Material Authorization Number from Pure Processing Customer Service Department. Prior to returning the device, it shall be the purchaser's responsibility to clean and disinfect the device and to package it in a manner that minimizes the possibility of shipping damage.

EXCEPT TO THE EXTENT PROVIDED ABOVE, PUREPROCESSING MAKES NO REPRESENTATION OR WARRANTY TO THE PURCHASER OR TO ANY THIRD PARTY, WHETHER WRITTEN, ORAL, STATUTORY, EXPRESS OR IMPLIED, CONCERNING THE DEVICE, INCLUDING BUT NOT LIMITED TO ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT SHALL PURE PROCESSING BE LIABLE FOR ANY SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, WHETHER FOR BREACH OF ANY WARRANTY, FOR BREACH OR REPUDIATION OF ANY OTHER TERM OR CONDITION OF SALE, OR FOR LIABILITY ON THE BASIS OF NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, EVEN IF PURE PROCESSING SHALL HAVE BEEN ADVISED IN ADVANCE OF THE LIKELIHOOD THEREOF.

REPAIR OR REPLACEMENT OF THE DEVICE AS PROVIDED ABOVE SHALL BE THE SOLE AND EXCLUSIVE REMEDY FOR ANY BREACH OF THE WARRANTY GIVEN ABOVE.

Specifications

Power Source Requirements

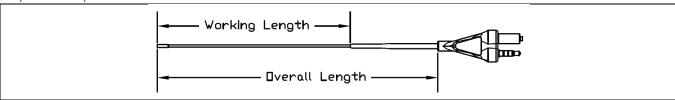
- USB Control Module: Electrical Power for the Digital Inspection Scope System is supplied by a USB port on a computer.
- HDMI Control Module: Medical grade power supply
 - o INPUT 100-240VAC, ~1A, 47-63Hz (from wall outlet)
 - OUTPUT 5V, 2A (to enclosure)

Illumination Source

LED within the Inspection Control Module



Physical Properties



	Control Modules		Inspection Borescopes			
	<u>USB</u>	<u>HDMI</u>	CB2-60	CB2-110	CB2-200	CB1-110
Borescope Working Length (cm)	N/A	N/A	60cm	110cm	200cm	110cm
Borescope Overall Length	N/A	N/A	78cm	128cm	218cm	128cm
Borescope Diameter (at Distal Camera)	N/A	N/A	1.83mm	1.83mm	1.83mm	1.06mm
Control Module Dimensions (LxWxH)	5.25" x 3.90" x 1.85"	5.25" x 3.90" x 1.85"	N/A	N/A	N/A	N/A
Control Module Weight	1.20 lbs	1.20 lbs	N/A	N/A	N/A	N/A

Optical

Field of View	120° in air
Angle of View	0°
Resolution	CB2-200, CB2-110, CB2-60: 160,000 Pixel or 400 Pixel x 400 Pixel format
	CB1-110: 40,000 Pixel or 200 Pixel x 200 Pixel format

Connectors and Cables

USB Control Module: USB Type A Male Connector

HDMI Control Module: HDMI Camera Cable: HDMI type A male to HDMI type A Male

Environmental Conditions

Storage and transport

Humidity: 10 to 100% (condensing)

Temperature: -20°C to +60°C Pressure: 600 hPA to 900 hPA

Normal Operation

Humidity: 0-100% (condensing)
Temperature: +5°C to +40°C

Waterproof Rating / Ingress Protection Rating

• CD-USB: IPX5 (Water Resistant)

• CD-HDMI: IPX4 (Water Resistant)

• Borescope (ALL CB): IPX7 (Waterproof)

Manufacturer

Clarus Medical, LLC 13355 10th Ave., Ste 110 Plymouth, MN 55441 USA www.clarus-medical.com admin@clarus-medical.com Tel 763-525-8403





MPS Medical Product Services Borngasse 20 35619 Braunfels, Germany

Page 19 of 19

601575-001-A

