4500 Handle Kit

Instructions for Use

UroViu corporation

CAUTION	
⚠	SALE AND USE Federal law (USA) restricts this device to sale by or on the order of a physician.

Notice

Model Number: Handle REF: 4500 and Charging Cradle REF: 4500-CH

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About this document

This Instruction for Use (IFU) provides instructions on how to use the UroViu Handle Kit safely and effectively, when connected to a compatible Single-Use UroViu Endoscope for its intended use of visualization of the bladder and urethra, or cervical canal and uterine cavity. For the purposes of this document, the word “cannula” refers to all compatible Single Use Endoscopes. It is important to read and observe the information provided in this manual prior to use for proper performance, correct operation, and to ensure patient and operator safety. The user is responsible to thoroughly review these instructions and to operate this device as indicated as detailed in these instructions. Contact UroViu for additional copies of this IFU and any additional questions or support required for training and service.
Instructions for Use originally issued in English.

Compatible Single Use Endoscopes: Uro-GHD, Uro-G, Uro-V, Uro-N, Hystero-V (refer to UroViu website for updates).

Warranty

UroViu Corporation (UroViu) warrants that the device supplied is free from defects in materials or workmanship. This warranty is valid only if the product is supplied to the end user by an UroViu approved agent or distributor and has been maintained in accordance with procedures documented in the Instructions for Use. If failure occurs from manufacturing defects within 6 months of purchase, UroViu will replace the defective item.

1. Intended Use

1.1. Intended Use

1.1.1. This product is used in combination with a compatible UroViu cannula and is intended to be used to permit viewing of the urethra and bladder or cervical canal and uterine cavity for the purpose of performing diagnostics.

1.2. Indications for Use

1.2.1. Indications for Use are described in each UroViu Cannula instructions for use (IFU).

1.3. Contraindications

1.3.1. Refer to the UroViu Cannula IFU

2. Symbols, Warnings and Precautions

This section contains important safety information related to use of the UroViu Handle in combination with a UroViu Cannula. Other important safety information is repeated throughout this manual in sections that relate specifically to the precautionary information. Read all text surrounding all warning and precautionary information prior to performing any procedure with this equipment.

2.1. **Symbol Legend**

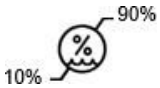
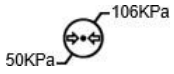
The following symbol conventions are used in this manual, and/or on the UroViu Endoscope product labeling.

SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD REFERENCE	STANDARD TITLE
	Manufacturer	Indicates the medical device manufacturer.	ISO 15223-1 #5.1.1	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied.
			EN 980 #5.12	Symbols for use in the labeling of medical devices.
			ISO 7000 -3082	Graphical symbols for use on equipment.
	Date of Manufacture	Indicates the date when the medical device was manufactured.	ISO 15223-1 #5.1.3	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			EN 980 #5.6	Symbols for use in the labeling of medical devices.
			ISO 7000-2497	Graphical symbols for use on equipment.
	Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified.	ISO 15223-1 #5.1.6	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.

SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD REFERENCE	STANDARD TITLE
			EN 980 #5.10	Symbols for use in the labeling of medical devices.
			ISO 7000-2493	Graphical symbols for use on equipment.
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.	ISO 15223-1 #5.1.7	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			EN 980 #5.5	Symbols for use in the labeling of medical devices.
			ISO 7000-2498	Graphical symbols for use on equipment.
	Medical Device	Indicates that the device is a Medical Device	ISO 15223-1:2021	Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements
	Follow instructions for use	Refer to instruction manual/booklet.	IEC 60601-1 Table D.2, Symbol 10	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.

SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD REFERENCE	STANDARD TITLE
			ISO 7010-M002	Graphical symbols – Safety colors and safety signs – Registered safety signs.
	DO NOT use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.	ISO 15223-1 #5.2.8	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			EN 980 #6.3	Symbols for use in the labeling of medical devices.
			ISO 7000-2606	Graphical symbols for use on equipment.
	Type BF applied part	To identify a Type BF applied part complying with IEC 60601-1. Type BF refers to classification of the nature of patient contact and degree of patient protection from risk of electrical shock.	IEC 60601-1 Table D.1. Symbol 20	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.
			IEC 60417 #5333	Graphical Symbols for Use on Equipment.
	Stand-by	To identify the switch or switch position by means of which part of the equipment is switched on in order to bring it into the stand-by condition.	IEC 60601-1 Table D.1 symbol 29	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.
			IEC TR 60878 #5009	Graphical Symbols for electrical equipment in medical practice.

SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD REFERENCE	STANDARD TITLE
⚠CAUTION	Caution	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.	IEC 60601-1 Table D.1 symbol 10	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.
			ISO 7000-0434A	Graphical symbols for use on equipment
⚠WARNING	Alarm warning sign	Displayed on the Monitor screen to signify a potential or actual hazardous situation exists for physician awareness or response is required.	IEC 60601-1-8:2007+A11:2017 Annex C No. 1 Reference 60417-5307	General requirements for basic safety and essential performance — Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems (IEC 60601-1-8:2006)
	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully.	ISO 15223-1 #5.3.1	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			ISO 7000-0621	Graphical symbols for use on equipment.
	Keep dry	Indicates a medical device that needs to be protected from moisture.	ISO 15223-1 #5.3.4	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			ISO 7000-2626	Graphical symbols for use on equipment.
			EN 980 #5.21	Symbols for use in the labeling of medical devices.
SYMBOL	**SYMBOL TITLE**	**EXPLANATORY TEXT**	**STANDARD REFERENCE**	**STANDARD TITLE**
	This side up	To indicate correct upright position of the transport package.	ISO 7000-0623	Graphical symbols for use on equipment.

	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.	ISO 15223-1 #5.3.7	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			ISO 7000-0632	Graphical symbols for use on equipment.
			EN 980 #5.17.3	Symbols for use in the labeling of medical devices.
	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed.	ISO 15223-1 #5.3.8	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			ISO 7000-2620	Graphical symbols for use on equipment.
	Atmospheric pressure limitation	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.	ISO 15223-1 #5.3.9	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			ISO 7000-2621	Graphical symbols for use on equipment.

2.2. **General Warnings**

The following warnings identify known operations, procedures or practices that should be heeded immediately or risk injury or death to patient or Operator.

2.2.1. The UroViu Endoscopic platform (Handle plus Cannula) is for use only by health care providers with adequate training in endoscopy.
2.2.2. Choose a cannula that is appropriate for the patient and indication. Follow the cannula's IFU for operating cannula.
2.2.3. If a liquid distension medium is used, strict fluid intake and output surveillance should be maintained.
2.2.4. The Endoscopic Platform contains no user-serviceable components within its handle, other than its rechargeable battery. To avoid electrical shock or damage, the unit must not be disassembled. Doing so will void the warranty.
2.2.5. Inspect the integrity of the unit and condition before powering-on the fully assembled Endoscopic Platform. Do not use the system if indications of external damage are observed.
2.2.6. Do not operate the Endoscopic Platform if any shipping damage or other defects to the equipment are noted during inspection. Immediately notify UroViu Corporation Customer Service if any defect is found.
2.2.7. Follow all disinfecting procedures provided for the Endoscopic Platform handle: See Section 10.
2.2.8. The Endoscopic Platform image can only be viewed with the LCD display on the handle. A separate video monitor cannot be used.
2.2.9. Use only the battery charger (docking station or cradle) provided with the device. Use of other chargers may damage the device and will void the warranty.
2.2.10. Charge the battery at room temperature.
2.2.11. Do not charge the battery near a heat source.
2.2.12. Do not connect the UroViu Handle to an insecure host computer (i.e., a computer lacking proper cybersecurity measures). It is possible that malware on an insecure computer can damage the handle, corrupt patient data, and/or compromise the confidentiality of the patient data.

2.3. **Cautions**

The following cautions identify known operations, procedures, or practices which should be addressed promptly or risk undesired outcomes or material damage.

2.3.1. Federal Law restricts the device to sale by or on the order of a licensed health care professional.
2.3.2. Do not misalign the connectors between the removable cannula and the UroViu Handle during assembly, as damage may occur.
2.3.3. When detaching the cannula from the handle, be sure that fluid does not contact the connector in the handle.
2.3.4. Minimum battery operating time is 37 minutes (~31% battery). The battery should be returned to the docking station after each procedure.
2.3.5. No portion of the UroViu Handle should be opened for cleaning or disinfecting.
2.3.6. Do not pour water or any cleaning solution directly onto the handle during cleaning or disinfection. Doing so may damage electronic components and reduce product life.
2.3.7. Do not oversaturate the cloth with fluids during the cleaning or disinfecting processes, excess cleaning material may seep into the handle causing electrical damage to the unit.
2.3.8. Do not immerse any component of the handle into solutions during the cleaning or disinfecting processes, as damage to the electronic components may occur.
2.3.9. This device has been tested and found to comply with limits for medical devices to the IEC 60601-1-2, EN 60601-1-2: 2002, Medical Device Directive 93/42/EEC. These limits are designed to provide reasonable protection against harmful interference in a typical

medical installation.

2.3.10. Due to the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare environments (for example cellular phones, etc.) it is possible that high levels of such interference, due to close proximity to or strength of a source, may result in a disruption of the performance of this device.

2.3.11. The Endoscopic Platform is not designed for use in environments in which strong interference may impact the performance of the equipment. If this occurs, the site of use should be surveyed to determine the source of this disruption, and the following action may be taken to eliminate the source:

- Remove, reorient or relocate the interfering equipment;
- Increase the separation between the interfering equipment and the UroViu Handle; and
- Incrementally turn off equipment in the vicinity to identify the interfering device.

2.3.12. Do not attempt to transport or ship the UroViu Handle without using proper packaging to protect the product.

3. Preparation for Use

3.1. **Unpacking and Inspection**

3.1.1. The UroViu Handle ships with a charging cradle (docking station), one AC Adaptor, one USB cable, and one connector socket rubber cap.

- Packing Materials. Save the packing materials for potential future transportation and storage of the UroViu Handle Kit.
- Inspection. Inspect all components for damage during shipment, or discrepancies upon arrival.

WARNING
⚠**WARNING** Do not operate the UroViu Handle if any shipping damage or other defects to the equipment are noted during inspection. Immediately notify UroViu Corporation Customer Support if any defect is found.

3.2. **Power Requirements and Charging**

3.2.1. The handle operates on DC voltage from an internal rechargeable battery source. The handle must be fully charged before the initial use. A fully charged battery will provide at least 2 hours of continuous operating time under normal operating conditions.

- Place handle on the charging cradle. See figure 1.
- Connect the AC adapter to the charging cradle power port.
- Plug the AC adapter to a wall outlet.

- Continue to charge until the battery power indicator on the touch screen shows 100%, indicating that the battery is fully charged. The UroViu Handle is ready for use.

Figure 1. Handle on Cradle Charging station

WARNING

⚠WARNING Use only the battery charger provided with the device. Use of other chargers may damage the device and will void the warranty

3.3. **Electromagnetic Capability**

3.3.1. As in the case of other electrical medical equipment, the UroViu Handle requires precautions to ensure electromagnetic compatibility (EMC) with other electrical medical devices. To ensure EMC, the UroViu Handle must be installed and operated according to the EMC information provided in this manual.

CAUTION

⚠CAUTION This device has been tested and found to comply with limits for medical devices to the IEC 60601-1-2, EN 60601-1-2: 2002, Medical Device Directive 93/42/EEC. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

⚠CAUTION The UroViu Handle is not designed for use in environments in which strong interference may impact the performance of the equipment. If this occurs, the site of use should be surveyed to determine the source of this disruption, and the following action may be taken to eliminate the source:

- Remove, reorient, or relocate the interfering equipment;
- Increase the separation between the interfering equipment and the UroViu Handle; and
- Incrementally turn off equipment in the vicinity to identify the interfering device.

3.3.2. General Requirements Summary

Standards	Description	Severity Level or Limit	Criteria	Results
IEC/EN 60601-1-2:2007/AC:2010 Clause 4.1	General requirements for electromagnetic compatibility of equipment and systems.	Per Section One, Clause 4	Review	Complies
IEC/EN 60601-1-2:2007/AC:2010 Clause 5	Identification, marking, and documents	See requirements called out in standard	Review	Complies

3.3.3. Guidance and Manufacturer's Declaration—Electromagnetic Emissions

The UroViu Handle is intended for use in the electromagnetic environment specified below. The customer or the user of the UroViu Handle should assure that it is used in such an environment.

EMISSIONS TEST SUMMARY			
Test Type	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted Emissions EN 550011:2009+A1:2010 CISPR 11:2009+1:2010	Class B, Group 1 150 kHz to 30 MHz	Class B, Group 1 150 kHz to 30 MHz	The UroViu Handle uses RF energy for its internal function. Nearby electronic equipment may be affected.
Radiated Emissions EN 550011:2009+A1:2010 CISPR 11:2009+1:2010	Class B, Group 1 30 MHz to 1 GHz	Class B, Group 1 30 MHz to 1 GHz	The UroViu Handle uses RF energy for its internal function. Nearby electronic equipment may be affected.
Harmonic Current Emissions IEC/EN 61000-3-2:2006/A2:2009	Class A device	Per Clause 5 of the Standard	None
Voltage Fluctuations/Flicker IEC/EN 61000-3-3:2008	Per Clause 5 of the Standard	Per Clause 5 of the Standard	None

3.3.4. Guidance and Manufacturer's Declaration—Electromagnetic Immunity

The UroViu Handle is intended for use in the electromagnetic environment specified below. The customer or the user of the UroViu Handle should assure that it is used in such an environment.

IMMUNITY TEST SUMMARY			
Test Type	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic Discharge (ESD) IEC/EN 61000-4-2	± 2, 4, 6 kV contact discharge ± 2, 4, 8 kV air discharge	± 2, 4, 6 kV contact discharge ± 2, 4, 8 kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated Immunity IEC/EN 61000-4-3	80 MHz - 2.5 GHz 3 V/m 80% @ 1 kHz	80 MHz - 2.5 GHz 3 V/m 80% @ 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the UroViu Handle, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: 80 MHz to 800 MHz $d = (3.5 / E1)\sqrt{P}$ 800 MHz to 2.5 GHz $d = (7 / E1)\sqrt{P}$ *where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).*
Conducted Immunity (AC Power) (I/O Lines) IEC/EN 61000-4-6	0.15 - 80 MHz 3 Vrms 1 kHz	0.15 - 80 MHz 3 Vrms 1 kHz	

IMMUNITY TEST SUMMARY			
Test Type	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
			Conducted Immunity: d = (3.5/V1)√P Field strength from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Electrical Fast Transients (AC Power) IEC/EN 61000-4-4	±2 kV AC Mains N/A I/O Lines 5/50 5 kHz	±2 kV AC Mains N/A I/O Lines 5/50 5 kHz	Mains power quality should be that of a typical commercial or hospital environment.
Surge Line to Line (AC Power) IEC/EN 61000-4-5	±1 kV Line to Line ±2 kV Line to Ground	±1 kV Line to Line ±2 kV Line to Ground	Mains power quality should be that of a typical commercial or hospital environment.
Magnetic Immunity IEC/EN-61000-4-8	3 A/m 50/60 Hz	3 A/m 50/60 Hz	Video display terminals and other electron-beam devices (e.g., X-ray image intensifiers) may use a justification for lower IMMUNITY COMPLIANCE LEVELS, as allowed by 6.2.1.10.
Voltage Dips & Interruptions IEC/EN 61000-4-11	0% UT .5 cycle 0% UT 1 cycle 70% UT 25 cycles 0% UT5 Sec	0% UT .5 cycle 0% UT 1 cycle 70% UT 25 cycles 0% UT5 Sec	Mains power quality should be that of a typical. Commercial or hospital environment. If the user of the UroViu Handle requires continued operation during power mains interruptions, it is recommended that the UroViu Handle be powered from an

IMMUNITY TEST SUMMARY			
Test Type	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
			uninterruptible power supply or a battery.

3.4. **Environmental Requirements**

3.4.1. The UroViu Handle, battery and accessories must be disposed of according to local laws and hospital practices relating to obsolete electronic equipment at the end of their expected life.

4. Description of Components

4.1. **Reusable Handle**

4.1.1. The handle contains most of the electronics, including a power on/off button, a video capture button, a video processor, a display unit (LCD display), a rechargeable battery, battery management electronics, microcontrollers, and firmware. The device uses a 3.7V rechargeable Lithium ion battery that can last more than 2 hours of continuous use. The battery is charged through an electric port on the handle to connect to a 5V DC charging cradle. Full battery charge requires approximately 4 hours to complete. Docking the reusable handle in the charging cradle between uses and when not in use will ensure handle is ready for the next procedure. Figure 2 shows the reusable handle. The screen has touch screen function for user interaction.

1. Power On/Off
2. LCD Monitor with Touch Panel User Interface
3. Cannula locking connector
4. Cannula electric port/ charging port
5. Battery compartment cap
6. Video capture – PHOTO/REC

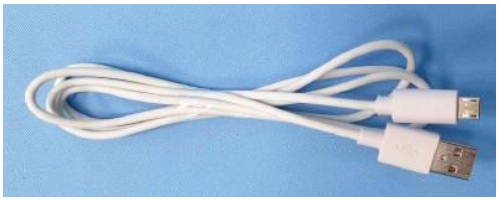
Figure 2. UroViu Handle

4.2. **Charging Cradle**

4.2.1. The charging cradle (see Figure 3) has dual functions. It allows the battery to be charged while stored. In addition, it allows the video recordings and images to be downloaded from the internal memory of the handle to an external computer.

WARNING	
⚠WARNING	Use only the battery charger provided with the device. Use of other chargers may damage the device and will void the warranty.
⚠WARNING	Charge the battery at room temperature.
⚠WARNING	Do not charge the battery near a heat source

a. Power Supply



b. USB

Figure 3. Charging Cradle

5. Device Classification and Technical Specification

5.1. **Device Classification: FDA Class II, HH Device Classification Type BF Applied Part**

5.2. **Technical Specifications**

Handle Dimensions	
Length	176 mm
Diameter	36 mm
Weight	265 g
LCD Touch Screen Display Panel	
Diagonal Size of Display Area	4.3in
Horizontal	112.2 mm
Height	73.9 mm
AC Adapter Requirements	
Input Power Range	100-240V 0.5A
Frequency	50/60Hz
Battery Specifications	
Battery Type	18650 Lithium Ion Rechargeable
Capacity	3100 mAs
Maximum Voltage of fully charged battery	3.7V power rating 3100 mAh
Full Charge Time	4 hours
Operating time	2 hours
Internal Storage	
SD-Card	8GB
Site Requirements – Operating conditions	
Operating Temperature	-10°C to 70 °C
Operating Humidity	10% - 90%
Air Pressure	50 KPa – 106 KPa
Transport and Storage	
Temperature	-10°C to 70°C
Relative Humidity	90% RH @ 60°C to 10% RH @ 0°C
Atmospheric Pressure	50 KPa - 106 KPa

6. Basics of Operation and Procedure

6.1. **Cannula attachment and detachment**

IMPORTANT
Only a Handle with Firmware above revision 4.1.001 is compatible with the Uro-GHD cannulas (Reference 1588)

In preparation for use, attach the cannula to the electrical connector on the UroViu Handle per the following:

6.1.1. Peel apart the proximal end of the package.
6.1.2. Rotate the sterile single-use disposable cannula to ensure that the USB male connector aligns with the USB female connector within the handle.
6.1.3. Connect the cannula to the UroViu Handle and press it fully into place until a subtle “click” of the connector detent mechanism is felt. (Figure 4, left image)
6.1.4. Once cannula is connected, insert the male USB connector of the disposable cannula into the USB female connector on the handle. (Figure 4, right image)

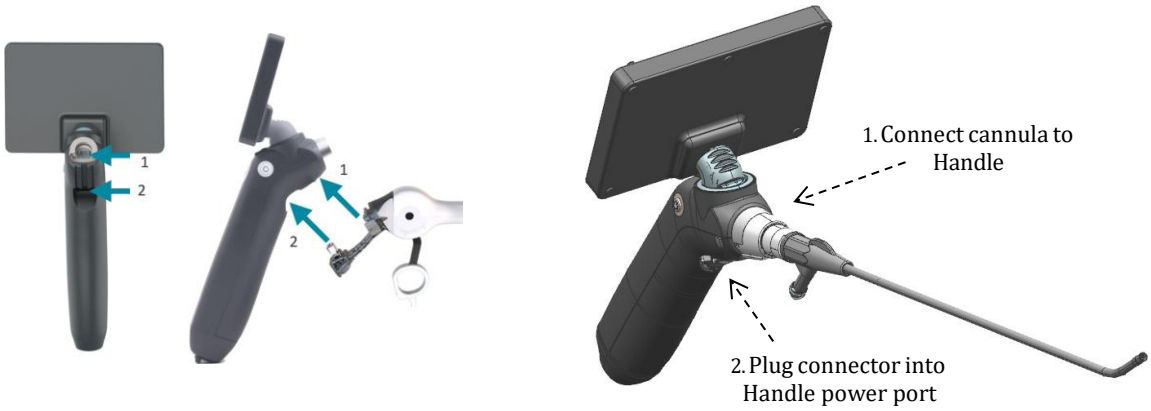


Figure 4. Attach Cannula to Handle

6.2. **Power Button Function** – Press and hold Power Button (Figure 5) for 1 second to turn handle on or off.

Figure 5. Power On/Off Button

6.2.1 Live image

Turn ON the Handle when the cannula is connected. Press the "Camera" button on the screen and verify you have a live image

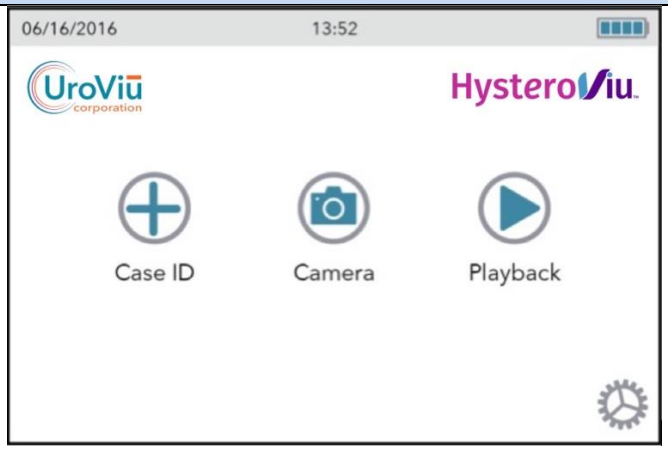
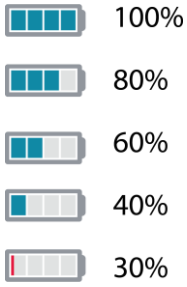
6.3. **PHOTO/VIDEO**

The PHOTO/VIDEO button (Figure 6) allows the user to save still images (PHOTO) or record video loops of the procedure. The image capture operations are described below.

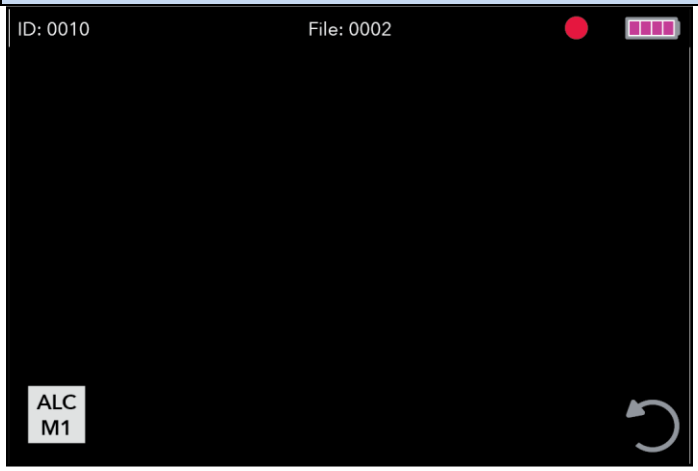
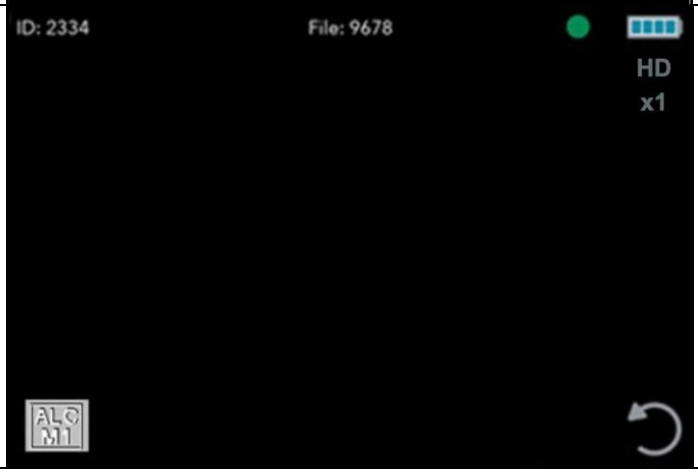
Figure 6. PHOTO/VIDEO Button on handle

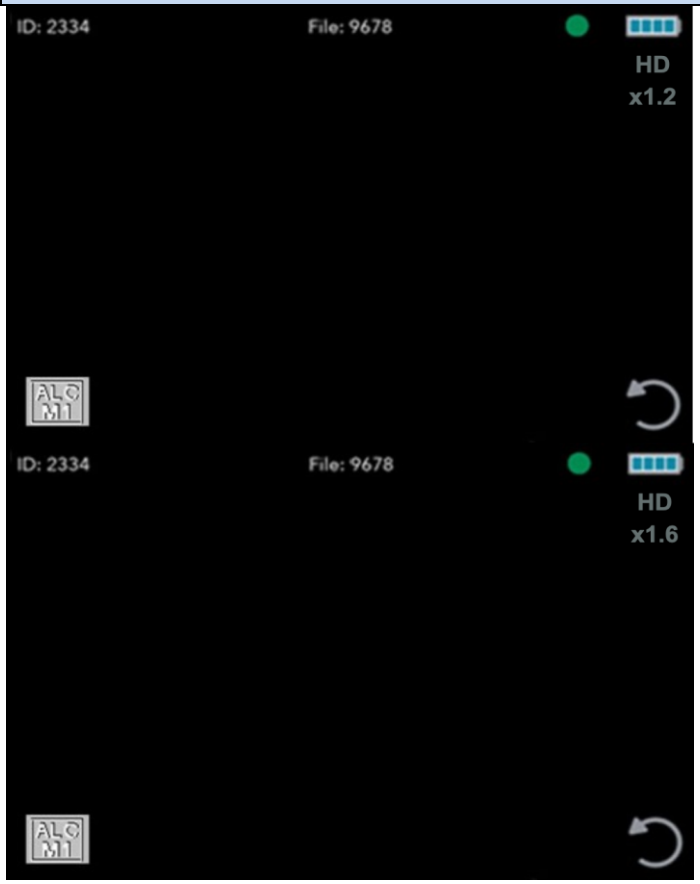
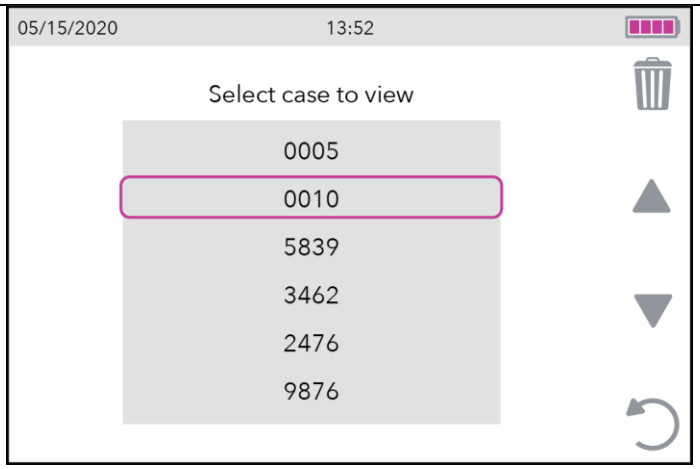
PHOTO/VIDEO Function	Action
Capture Still Image	Press and Hold: 1 second
Begin Video Recording	Press and Hold: 3 seconds
End Video Recording	During Video Recording, press button to stop recording.

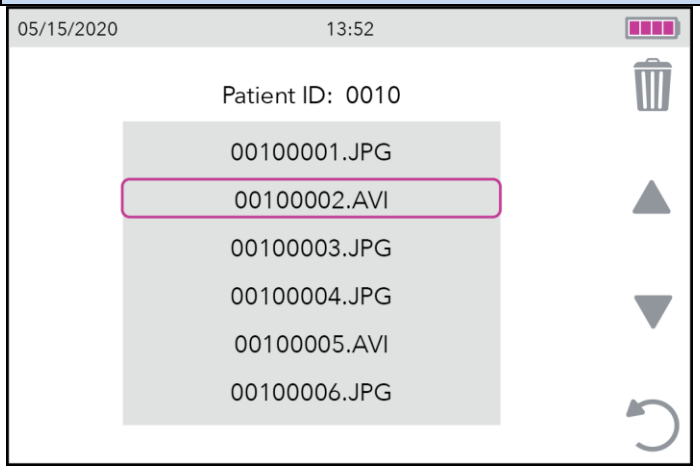
6.4. **Touch Screen Functions**

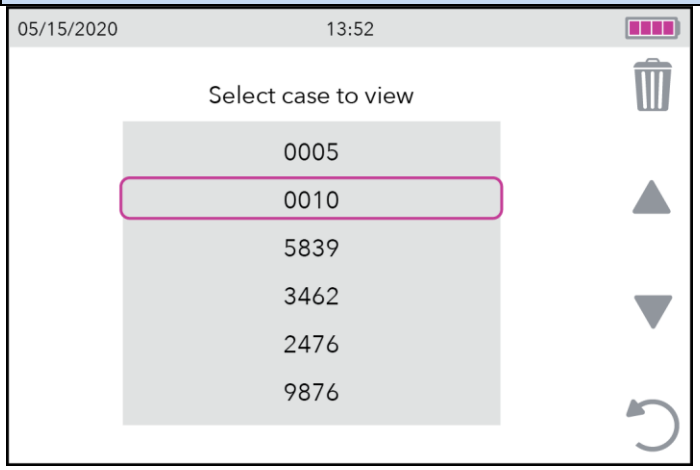
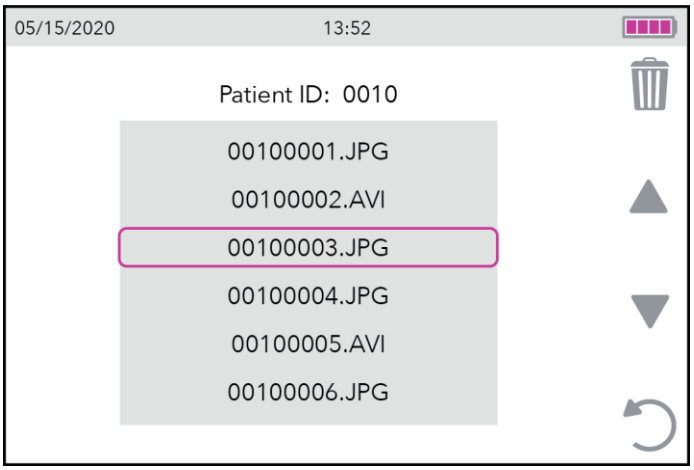
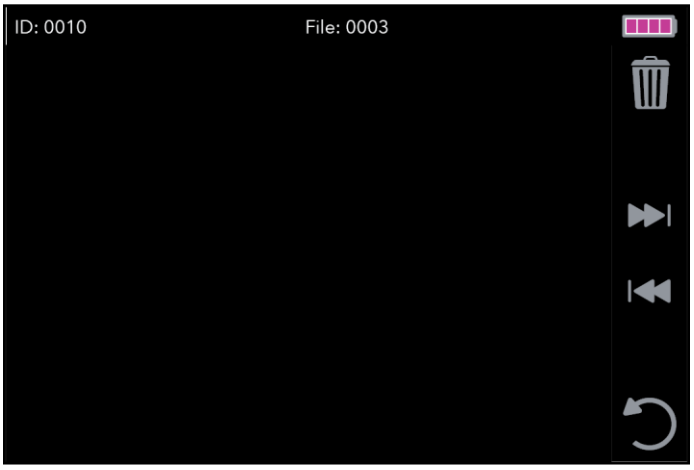
Touch Screen Description/Action	Touch Screen
Home Menu The Home Menu shows the date, time, and battery power usage at the top of the screen. The screen has four soft buttons, each allowing a discrete function. Pressing each soft button enters a sub menu that provides a separate menu for a specific function. The instructions for each touch screen user menu are described in this section.	
Battery Power Usage Indicator Battery usage indicator provides the battery power usage status. *When battery power usage reaches 30%, the user should charge the handle.*	

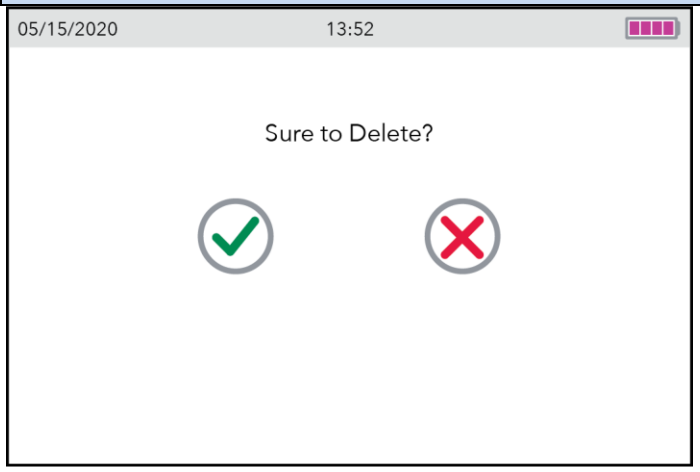
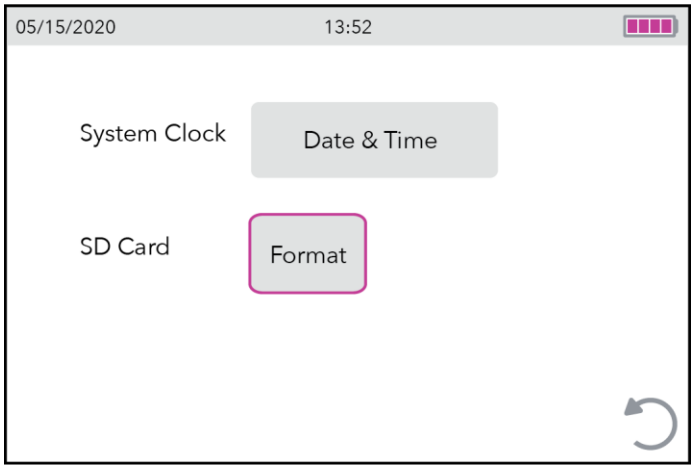
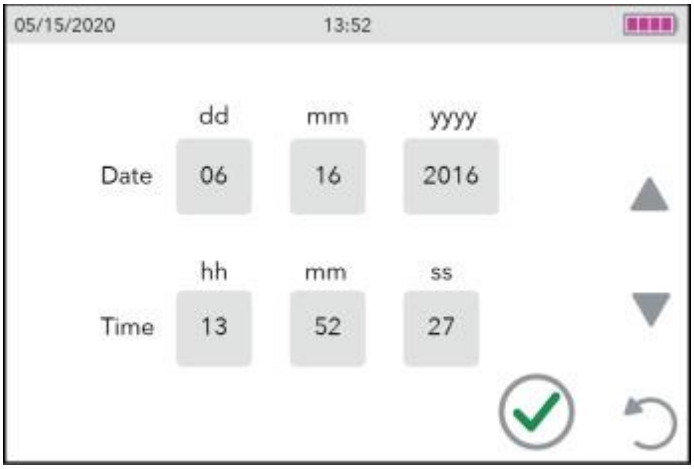
Touch Screen Description/Action	Touch Screen
Add Case Menu ■ To add a new Case ID, Press the ⊕ button on the Home Menu. ■ Enter the appropriate numbers to create the case ID. The number is displayed above the number keypad. ■ Press ↺ to return to the Home Menu and no Case ID is entered. ■ Press C to clear the previously entered number. ■ Press ✓ to confirm the keyed in Case ID . If the Case ID already exists, an error message "ID exists/re-enter ID" will display. Following the steps above, use the keypad to enter a different Case ID. ■ If the Case ID is accepted, system will enter the next screen. Tap "Go to Camera" will go into Camera mode. Tap "Reenter ID" to go to "Enter Case ID#" screen.	
Camera Mode and Menu ■ In "Camera" Mode, real-time video will display on the screen. A green dot appears in the header next to the battery usage icon. ■ The ALC/M1/M2/Off button is for controlling the brightness and exposure. ALC/M1 is automated light control level 1, ALC/M2 is automated light control level 2, and ALC/Off turns off ALC and system is in fixed manual mode.	

Touch Screen Description/Action	Touch Screen
To start recording: ■ On the ***UroViu Handle***, press and hold the PHOTO/Video button for 3 seconds (refer to figure 6 for button's physical location). ■ On the ***touch display***, the dot next to battery icon will flash Red while recording is in progress. ***To stop recording:*** ■ On the ***UroViu Handle***, briefly press the PHOTO/Video button	
To take a still photo: ■ On the ***UroViu Handle*** press the PHOTO/Video button on the handle for 1 second ■ On the ***touch display***, the dot next to battery icon will flash Red for ~1 second. ■ To take still photo during video recording, briefly press the PHOTO/Video button to exit video recording and then press the PHOTO/Video button on the handle for 1 second.	
Digital Zoom (Only with Uro-GHD Cannula SKU 1588-1 and only applies to the 4500 Handle with SW Version 4.1.001 and above.) The symbol 'HD' will be displayed under the battery symbol.	

Touch Screen Description/Action	Touch Screen
(Only with Uro-GHD Cannula SKU 1588-1 and only applies to the 4500 Handle with SW Version 4.1.001 and above.) ***Zooming in and out*** ▪ Swipe the screen up. One swipe: 120% zoom in, two swipe: 160% zoom in. ▪ Swipe down to zoom out back to 100% (normal image "HD x1").	
Playback Menu ***To select video for playback:*** ▪ Press ▶ button from the Home Menu. ▪ Select the desired Case ID to playback by using the ▲ and ▼ arrows.	

Touch Screen Description/Action	Touch Screen
▪ Tap the selected recorded video .AVI file to review the video for the selected ID.	
Video Playback Control Fast Forward button Fast Rewind button Play/Pause Button Play the next file Play the previous file	
To delete a case or video: ▪ Select the desired Case ID or video file. Click , a confirmation screen is displayed. On the confirmation screen choose to confirm delete or to cancel deletion and return to the previous screen. ▪ Press the Button to return to the previous screen.	

Touch Screen Description/Action	Touch Screen
To select photo to display: ■ Press ▶ from the Home Menu. ■ Select the desired Case ID to playback by using the ▲ and ▼ arrows.	
■ Tap the selected saved.JPG file to review the recorded photo for the selected ID.	
Photo display ⏭ Display next file ⏮ Display previous file	

Touch Screen Description/Action	Touch Screen
To delete a photo: ■ Select the desired Case ID or jpg file. Click , a confirmation screen is displayed. On the confirmation screen choose to confirm delete or to cancel deletion and return to the previous screen. ■ Press the Button to return to the previous screen	
Settings Menu ■ Use the icons on the touch display to: ***Change the Date and Time*** – Tap the Date and Time button to update the system date and time settings. ***Format the SD Card*** – Tap the Format button to delete all contents on the SD card. A confirmation screen will display allowing user to confirm or cancel SD Card format.	
Date and Time ■ To change the Date and Time, use the [up and down arrows] to enter the appropriate information. ■ Once entered, select to update the system date and time. ■ Or, select the to cancel action and return to the settings menu.	

7. Patient Examination Procedure

7.1. **PRIOR TO THE EXAMINATION**

7.1.1. Ensure that the UroViu Handle has been reprocessed (cleaned and disinfected), using the procedures as described in Section 9, prior to use.

- DO NOT use if the UroViu Handle has not been reprocessed.

7.1.2. Ensure that the UroViu Handle is fully charged. (Refer to section 3.2 for additional details).

7.1.3. Please refer to section 6.1 before proceeding with opening the pouch and connecting the cannula to the Handle

- DO NOT use if there is damage to the sterile packaging of the cannula. If there is damage to the sterile packaging, obtain a replacement sterile cannula for use.

7.2. **POST THE EXAMINATION**

7.2.1. Cannula is for single use only. DO NOT reprocess/reuse.

7.2.2. Turn off the 4500 Handle.

7.3. **CHARGING THE BATTERY**

Docking the reusable handle in the charging cradle between uses and when not in use will ensure handle is ready for the next procedure. To fully recharge the battery, follow steps as described in Section 3.2.

8. External Interface Information.

8.1. Downloading Stored images/video

The UroViu Handle videos and images may be downloaded by using the USB cable provided with the charging cradle.

WARNING

⚠**WARNING** Do not connect the UroViu Handle to an insecure host computer (i.e., a computer lacking proper cybersecurity measures).

Download to a PC	Download to a Mac
1. Plug cradle charge cable to handle. 2. Connect cradle USB cable to computer. 3. Turn on handle power. 4. Boot-up computer. 5. Click “Start” and then click “My Computer.” 6. The handle shows up as a remote disk on the “My computer” window. 7. Left-click on that removable disk icon to find a folder with patient ID. 8. Click on the patient ID folder of interest. 9. Click on the sub-folder with the exam date of interest. 10. The files in the exam date folder are recorded pictures, with their names ending in “jpg.” 11. Copy those files by selecting them and copying them. The keyboard short-cut (control-A) marks all the photos in a folder and the keyboard short-cut. 12. Navigate to the folder on your PC where you want to save patient pictures and paste (control-V) the photos into that folder. 13. After you copy files or folders from the handle onto the PC’s hard drive, it is useful to view the hard drive to confirm that the files were copied. 14. Do not erase photos from the handle until you are certain that you have saved them onto the PC’s hard drive. NOTE: follow this same procedure for any videos of interest.	1. Plug cradle charge cable to handle. 2. Connect cradle USB cable to computer. 3. Turn on handle power. 4. Boot-up computer. 5. Click “Finder” on the application dock of the Mac computer. 6. The handle shows up as a removable disk under “Devices”. 7. Left-click on that removable disk icon to find a folder with patient ID. 8. The files in that folder are recorded pictures, with their names ending in “jpg.” 9. Copy those files by selecting them and copying them. The keyboard short-cut (command-A) marks all the photos in a folder and the keyboard short-cut (command-C) copies them to the computer’s clipboard. 10. Navigate to the folder on your Mac where you want to save patient pictures and paste (command-V) the photos into that folder. 11. After you copy files or folders from the handle onto the Mac’s hard drive, it is useful to view the hard drive to confirm that the files were copied. 12. Do not erase photos from the handle until you are certain that you have saved them onto the Mac’s hard drive. NOTE: follow this same procedure for any videos of interest.

9. Maintenance

9.1. Disinfection Procedure

9.1.1. The UroViu Handle should be disinfected prior to its first use and after each subsequent use. Perform the following steps:

CAUTION

⚠CAUTION No portion of the UroViu Handle should be opened for disinfecting.

Step 1 - Power off handle and unplug all electronic connections.

Step 2 - Ensure that the supplied rubber cap (see figure 9) is plugged into the electrical port of the handle so that moisture does not come into contact with internal device components.

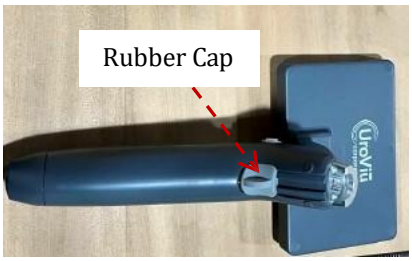


Figure 9. Rubber Cap

Step 3 - Start by using a CaviWipes towelette to wipe all exposed surfaces of the device handle and LCD display to remove any visible contaminants. Additional wipes may be used until any dried-on materials are removed.

- Be sure to include wiping of all creases and seams on the handle, the handle neck, and the screen.

Step 4 – Using a NEW CaviWipes towelette, wipe the handle external surfaces again to ensure they remain visibly wet for 6 minutes. Additional wipes may be used as needed to ensure the appropriate contact time.

Step 5 - Allow the handle to air dry.

9.2. Maintenance

9.2.1. The UroViu Handle requires no calibration or service in the field as all electronics are tested and validated for performance at the factory. If the performance of the UroViu Handle is in doubt, contact UroViu Customer Care.

9.3. Maintenance Intervals

9.3.1. Basic preventive maintenance of the UroViu Handle is an important function that should be performed on a schedule to ensure safe and effective operation. Preventive maintenance includes, but is not limited to:

- Schedule: minimum, once every 365 days (annually)
- LCD Display: Turning on the handle to ensure the LCD display contains the elements of section 6.4.
- Battery: fully charge battery and test if the battery holds a charge for at least 1 hour
- Checking the handle for visible damage to the connection ports, neck, LCD screen and battery door.

9.3.2. If the integrity or performance of any portion of the UroViu Handle is in doubt, the system should NOT be used until the issue is resolved.

10. Storage and Shipping

10.1. The UroViu Handle is shipped in protective packaging. Do not dispose of the protective packaging or any other shipping materials. These items should be retained for future storage or transport of the equipment.

11. Technical Assistance

For technical information or assistance, contact UroViu Corporation Customer Care or your local UroViu Corporation representative.

Information regarding system serial number and current software version is available from Customer Care.

UroViu Corporation
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Los Altos, CA 94022
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12. Troubleshooting Guide

The information in this section is intended to provide simple steps that can be performed by a user for identifying the primary cause, and possible simple solutions that can be resolved on-site, to basic problems that may be encountered while operating the UroViu Handle & UroViu Endoscope.

Any issues determined to be beyond the scope of the basic user troubleshooting steps provided in these Instructions for Use should be communicated to the UroViu Corporation Customer Care department as mentioned in Section 12.

Problem	Test	Action
When handle is powered ON, there is no image on screen	Is the cannula tip LED illuminated?	If **NO**, change to new cannula If **YES**, contact UroViu Customer Care
Poor picture quality		Clean cannula tip with a sterile, clean, soft wipe. Ensure that both the cannula and the connector are fully inserted into the handle ports. If the steps above to do not correct the picture quality, contact UroViu Customer Care.
Image on screen flickers or has lines across it		Ensure that both the cannula and the connector are fully inserted into the handle ports. If this does not correct the picture quality, contact UroViu Customer Care.
Loose component or poorly fitting connection		Do NOT use device Contact UroViu Customer Care for return.
Battery does not keep a charge.		Do not use device Contact UroViu Customer Care for return.