# 5000WEU Display Handle

Instructions for Use

UroViu corporation

| CAUTION | |
|---|---|
| ⚠ | SALE AND USE<br>Federal law (USA) restricts this device to sale by or on the order of a physician.<br><br>INCIDENT REPORT<br>Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established. |

# Notice

UroViu Endoscopy Display Handle

Model Number:  Handle REF: 5000EUW

Basic UDI-DI: 0850051518UV5000EU7P



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# Trademark and Patent Information



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# About this document

This Instruction for Use (IFU) provides instructions on how to use the UroViu Handle 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

1.4. Clinical benefits

1.4.1. In conjunction with a compatible single-use UroViu cannula, the UV5000 Handle provides visualization and inspection of urethra and bladder or cervical canal and uterine cavity in the body.

# 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**

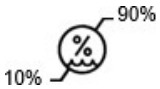
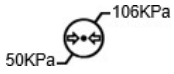
The following symbol conventions are used in this manual, and/or on the UroViu Endoscope product labeling.

| 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 system (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 system 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 system. Do not use the system if indications of external damage are observed.

2.2.6. Do not operate the Endoscopic system if any shipping damage or other defects to the equipment are noted during inspection. Immediately notify UroViu Customer Service if any defect is found.

2.2.7. Follow all disinfecting procedures provided for the Endoscopic system handle: See Section 9.

2.2.8. The Endoscopic system image can only be viewed with the LCD display on the handle and synchronously displayed on an external monitor through the provided Wireless Relay.

2.2.9. Use only the battery charger 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.

2.2.13. Do not position the Wireless Relay within the sterile field.

2.2.14. The handle is the primary image displayer, doctor-in-charge who perform the endoscopy diagnosis or therapy should always primarily view the imaging displayed with the handle screen. External monitor introduced by the Wireless Relay is the secondary image displayer, which provide real time image display for patients or other medical staffs.

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. Lower battery warning appears when one bar left in the battery icon, which indicates 30% battery and maximum 30min operating time. The battery should be charged 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. 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 system 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 5000 Handle ships with one AC Adaptor, one USB-A to USB-C cable, and one connector socket rubber cap. The UroViu Wireless Relay ships with one AC Adaptor and one HDMI to DVI adapter. The UroViu handle and the UroViu Wireless Relay are packaged separate inner boxes but within the same outer box.

- Packing Materials. Save the packing materials for potential future transportation and storage of the UroViu Handle.
- 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.

- Connect the AC adapter with cable to the Type-C port at the bottom of the handle.
- 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 Handle is ready for use.

**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. 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 60601-1-2:2014 + A1:2020<br>EN 60601-1-2:2015 + A1:2021<br>Clause 4 | General requirements | Per Clause 4 | Review | Complies |
| IEC 60601-1-2:2014 + A1:2020<br>EN 60601-1-2:2015 + A1:2021<br>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 Handle is intended for use in the electromagnetic environment specified below. The customer or the user of the Handle should assure that it is used in such an environment.

| Emission Test | Compliance Level | Electromagnetic Environment Guidance |
|---|---|---|
| RF Emissions CISPR 11 | Group 1 | The system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF Emissions CISPR 11 | Class A | The system is suitable for use in all establishments other than domestic and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purpose. |
| Harmonic Emissions IEC 61000-3- 2 | Class A | |
| Voltage Fluctuations/Flicker Emissions IEC 61000-3-3 | Complies | |

### 3.3.4. Guidance and Manufacturer's Declaration—Electromagnetic Immunity

The 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 | IEC 60601-1-2 Test Level | Compliance Level | Electromagnetic Environment Guidance |
|---|---|---|---|
| Electrostatic<br><br>Discharge (ESD)<br><br>IEC 61000-4-2 | ± 8 kV contact<br>Discharge<br>± 2, 4, 8, 15 kV air discharge | ± 8 kV contact<br>Discharge<br>± 2, 4, 8, 15 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 RF<br><br>Immunity<br><br>IEC 61000-4-3 | 3 V/m 80 MHz - 2.7 GHz<br><br>80% AM at 1 kHz | 3 V/m 80 MHz - 2700 MHz<br>80% AM at 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.<br>Recommended separation distance:<br>$d=1.17\sqrt{P}$<br>$d=1.17\sqrt{P}$ (80 MHz to 800 MHz)<br>$d = 2.33\sqrt{P}$<br>(800 MHz to 2.7 GHz)<br>*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 RF Immunity<br><br>IEC 61000-4-6 | 3 V RMS<br>0,15 MHz – 80 MHz<br>6 V RMS<br>in ISM bands<br>80 % AM at 1 kHz | 3 V RMS<br>0,15 MHz – 80 MHz<br>6 V RMS<br>in ISM bands<br>80 % AM at 1 kHz | |

| IMMUNITY TEST SUMMARY | | | |
|---|---|---|---|
| Test Type | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment Guidance |
| | | | 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/ Bursts IEC 61000-4-4 | ±2 kV AC Mains I/O ports 100 kHz repetition | ±2 kV AC Mains I/O ports 100 kHz repetition | Mains power quality should be that of a typical commercial or hospital environment. |
| Surges IEC 61000-4-5 | ±0.5, ±1 kV Line to Line ±2 kV Line to Ground | ±0.5, ±1 kV Line to Line ±2 kV Line to Ground | Mains power quality should be that of a typical commercial or hospital environment. |
| Power frequency magnetic fields IEC 61000-4-8 | 30 A/m at 50/60 Hz | 30 A/m at 50/60 Hz | Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment. |
| Voltage Dips & Interruptions IEC 61000-4-11 | Voltage Dip: Dip to 0 % for 1 cycle @ 0° phase angle Dip to 70 % for 25/30 cycles @ 0° phase angle Dropout to 0 % for 0.5 cycle @ 0°, 45°, 90°, 135°, 180°, 225°, 270° & 315° phase angles Voltage interruption: 0 % for 250/300 cycles | Voltage Dip: Dip to 0 % for 1 cycle @ 0° phase angle Dip to 70 % for 25/30 cycles @ 0° phase angle Dropout to 0 % for 0.5 cycle @ 0°, 45°, 90°, 135°, 180°, 225°, 270° & 315° phase angles Voltage interruption: 0 % for 250/300 cycles | 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 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**

The handle contains electronics, including a power on/off button, a video capture button, an image enhancement button, a video processor, a display unit (LCD display), a rechargeable battery, battery management electronics, microcontrollers, and firmware. The device uses a 4.2V rechargeable Lithium ion battery that can last more than 2 hours of continuous use. The battery is charged with a AC Adaptor. Full battery charge requires approximately 4 hours to complete. Charge the battery after each use will ensure handle is ready for the next procedure. Figure 1 shows the reusable handle. The screen has touch screen function for user interaction.

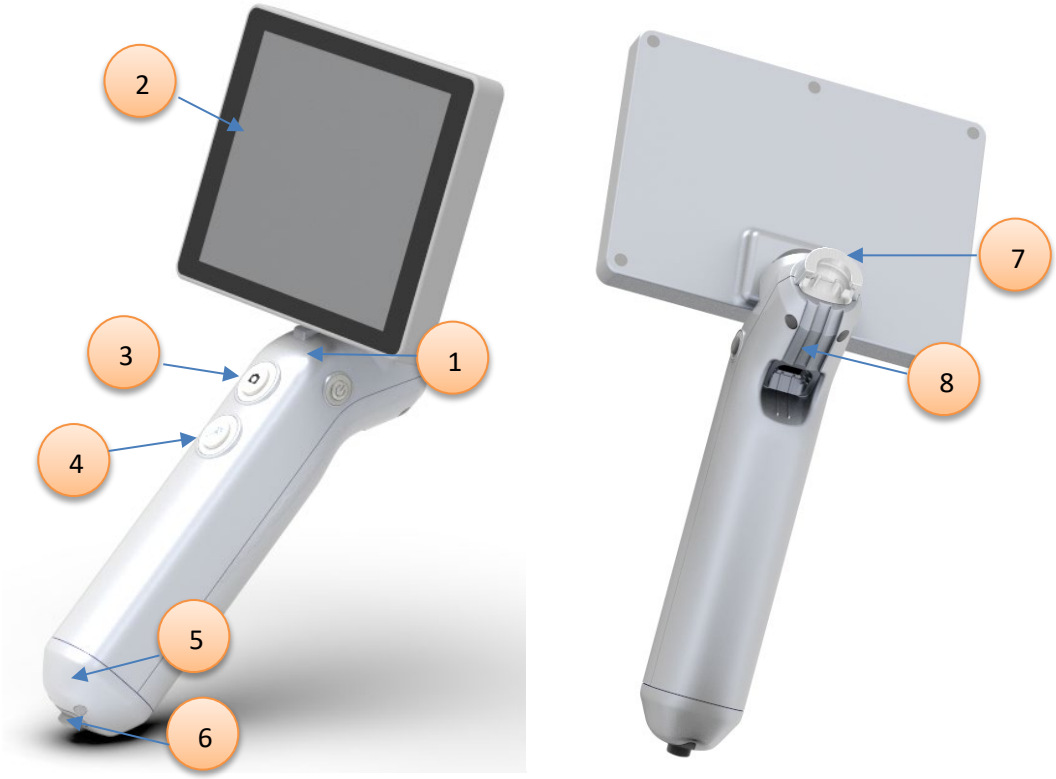



*Figure 1. UroViu 5000 Handle*

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

4.2. **Reusable Wireless Relay**

The WIFI Relay contains electronics, including antennae, an image size switch, a video processor, microcontrollers, and firmware. The Wireless Relay start once plugged in. The Wireless Relay has a HDMI port which can connect to external monitor for video/ photo display.

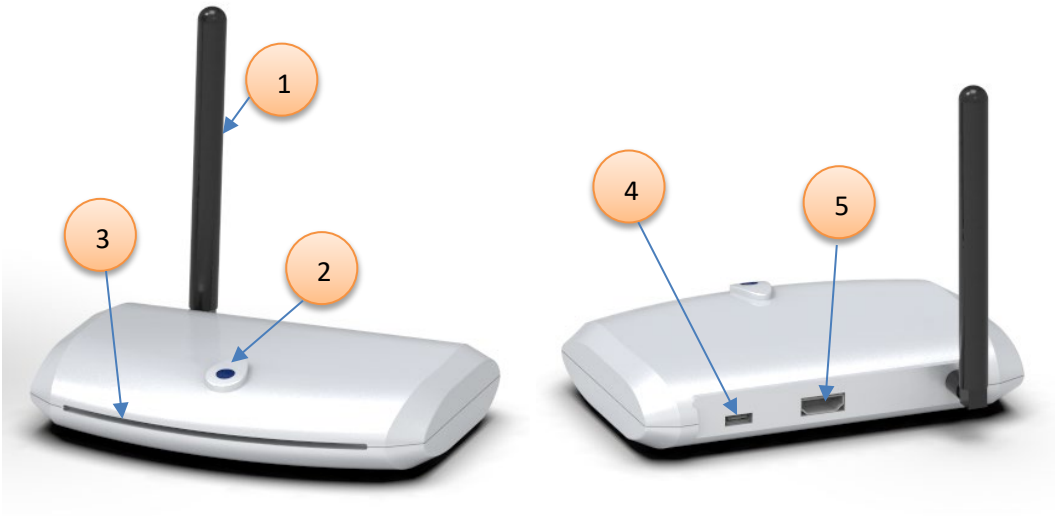



*Figure 2. UroViu Wireless Relay*

1. *Antennae*
2. *Image size switch*
3. *LED light*
4. *Charging port*
5. *HDMI port*

**Warning:** Do not position the Reusable Wireless Relay within the sterile field

4.3. **Wireless Relay Shelf (Optional, supplied separately)**

UroViu proposed an optional shelf for the Wireless Relay, the outer width of the two metal legs is 8.3cm, which could be mounted on external monitor with a VESA interface of FDMI MIS-D/E/F (i.e. caliber equal to or greater than 100mm×100mm). Similar shelf could be used as replacement.

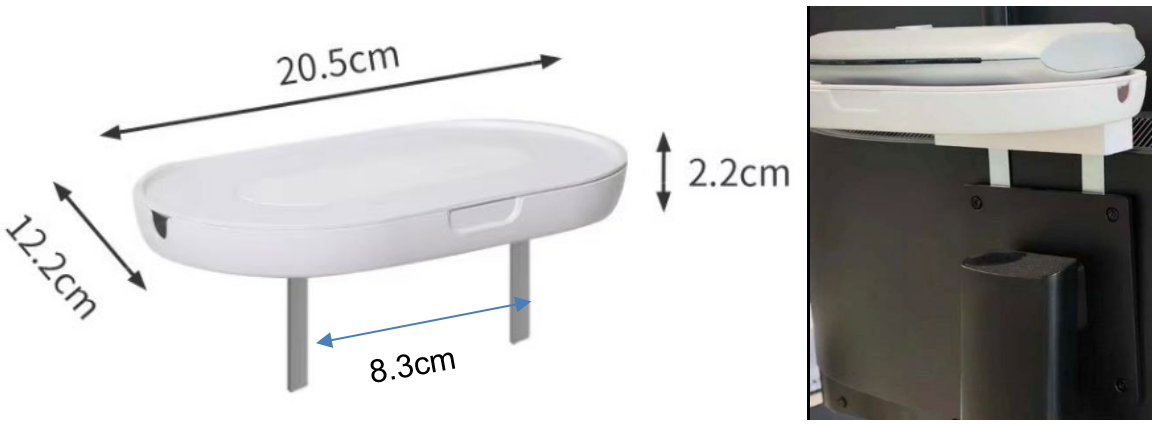



*Figure 3. Wireless Relay shelf*

4.4. **Charger and USB cable**

4.4.1. The Handle is charged with the provided AC Adapter. The UroViu Handle and the UroViu Wireless Relay are equipped with separate AC adapter, but the same mode. The USB-A to USB-C cable equipped with the handle is used for video recordings and images transfer 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 |

*Figure 4. AC Adopter*

# 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 | 143.4mm±2mm |
| Diameter | 119.8mm±2mm |
| Weight | 345 g |
| | |
| LCD Touch Screen Display Panel | |
| Diagonal Size of Display Area | 5in |
| Horizontal | 125.4mm±2mm |
| Height | 91.4mm±2mm |
| | |
| AC Adapter Requirements | |
| Input Power Range | 100-240V 0.8A Max. |
| Frequency | 50/60Hz |
| Output | 5.0V/ 3.0A |
| | |
| Battery Specifications | |
| Battery Type | 21700 Lithium Ion Rechargeable |
| Capacity | 4900 mAh |
| Maximum Voltage of fully charged battery | 3.63V power rating 4900 mAh |
| Full Charge Time | 4 hours |
| Operating time | 2 hours |
| | |
| Internal Storage | |
| SD-Card | 32GB |
| | |
| Site Requirements – Operating conditions | |
| Operating Temperature | 5°C to 40 °C |
| Operating Humidity | 10% - 90% |
| Air Pressure | 50 KPa – 106 KPa |
| | |
| Transport and Storage | |
| Temperature | -10°C to 55°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

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 5, 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 5, right image)

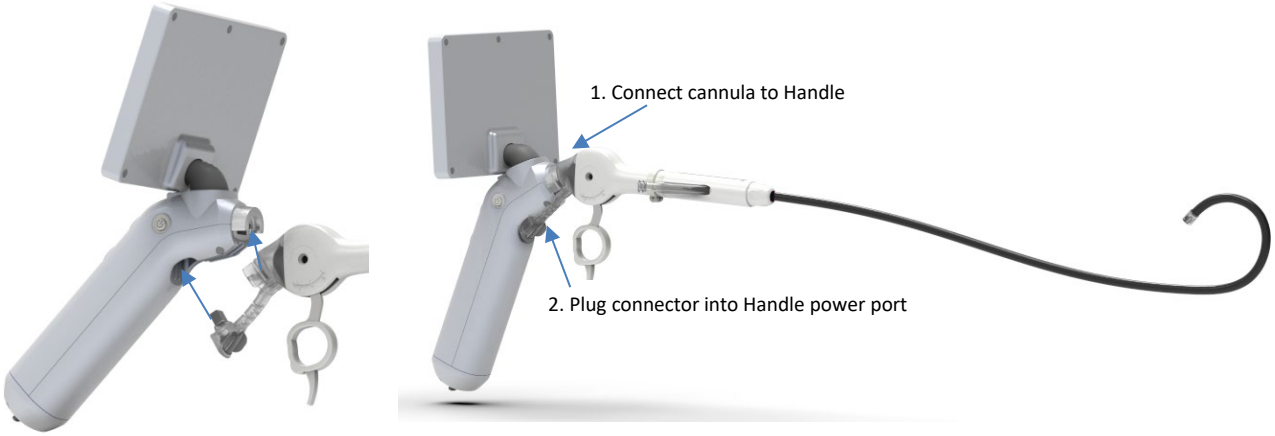



*Figure 5. Attach Cannula to Handle*

6.2. **Power Button Function** – Press and hold Power Button (Figure 6) for 1 second to turn handle on or off.


*Figure 6. 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.

6.2.2 Real-time display on external monitor

Enter Wireless Relay ID in Setting Menu and press WIFI button on Home Menu of the Handle, then the Handle could pair with the Wireless Relay if the Wireless Relay is plugged in. Real-time imaging on handle screen could be displayed on external monitor if connecting the monitor to the Wireless Relay with an HDMI cable.

The Handle remembers the ID of the latest paired Wireless Relay and requires no re-entering.

If the handle cannot connect with the Wireless Relay or the connection is interrupted, press and hold the button on top of the Wireless Relay for 3 seconds to restart the Wireless Relay and reconnect with the Handle.

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 7. PHOTO/VIDEO Button on handle*

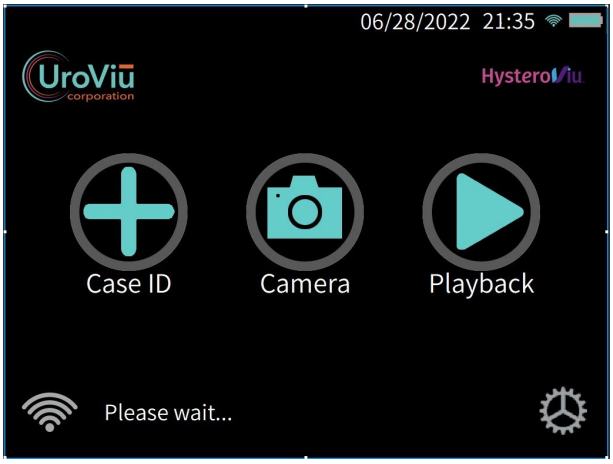
| **PHOTO/VIDEO Function** | **Action** |
|---|---|
| Capture Still Image | Press and Hold: 1 second |
| Begin Video Recording | Press and Hold: 3 seconds |
| End Video Recording | During Video Recording, press button to stop recording. |

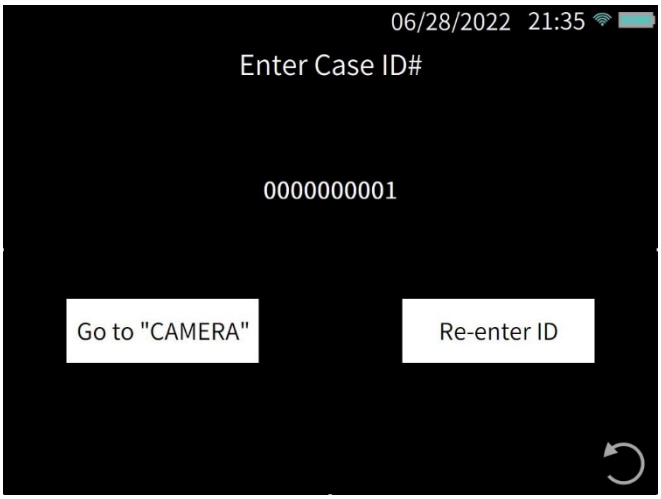
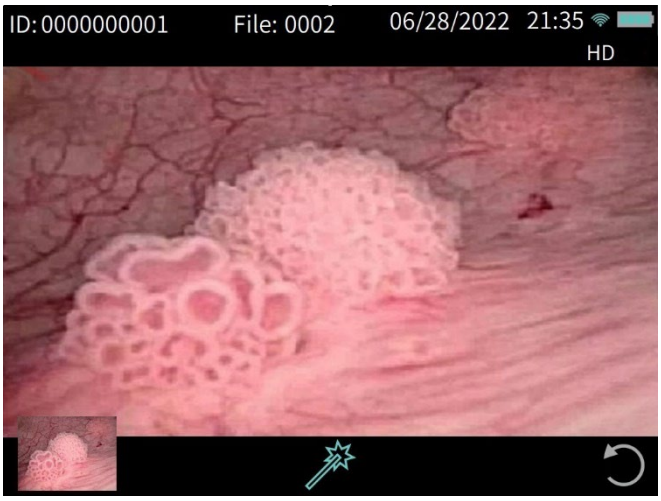
6.4. **Image Enhancement**

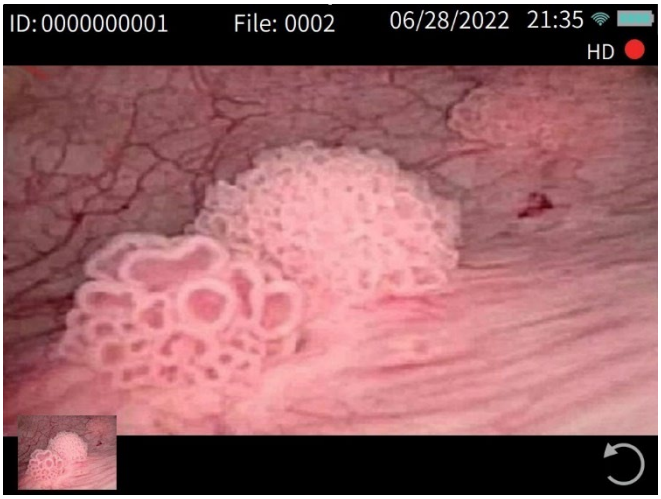
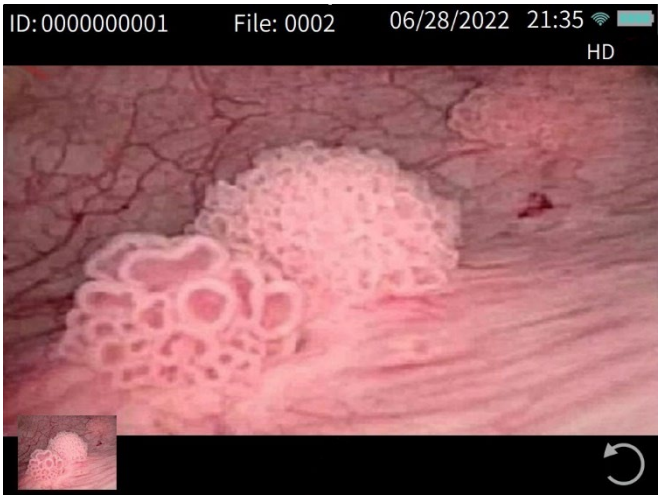
Press and hold the Image Enhancement button (Figure 8) for 1 second to turn standard image to enhanced image.

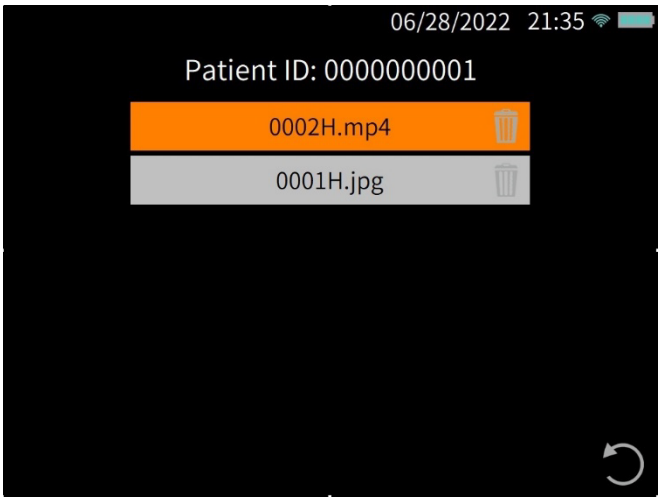
*Figure 8. Image Enhancement Button on handle*

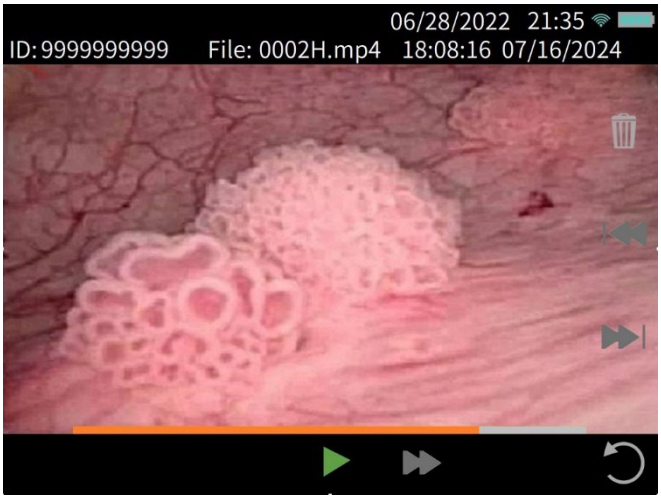
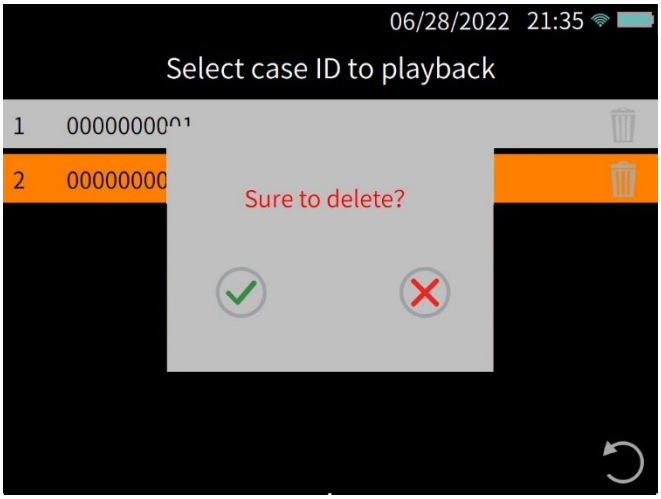
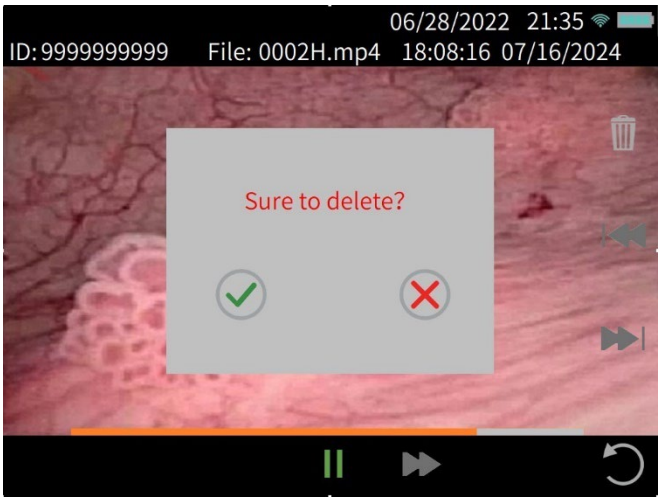
### 6.5. **Touch Screen Functions**

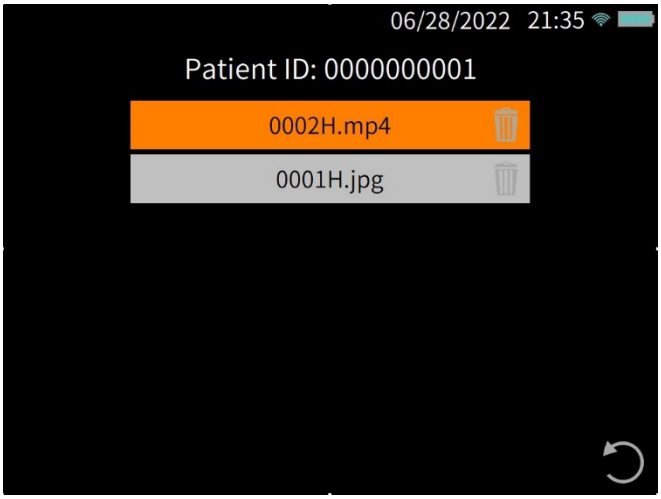
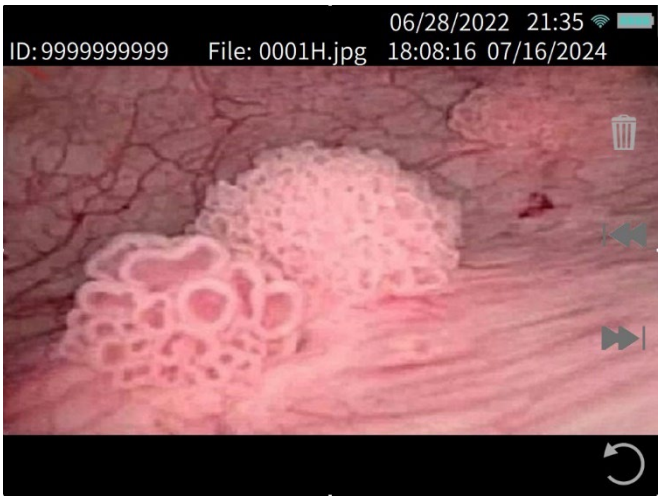
| Touch Screen Description/Action | Touch Screen |
|---|---|
| **Home Menu**<br><br>The Home Menu shows the date, time, WIFI and battery power usage at the top of the screen. The screen has five soft buttons, each allowing a discrete function. Except the WIFI button, pressing each of other soft button 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.<br><br>Note: all the Touch Screen illustrations in the right column were made with wireless connection on. |  |
| **Battery Power Usage Indicator**<br><br>Battery usage indicator provides the battery power usage status.<br><br>*When battery power usage reaches 30%, the user should charge the handle.* |  30%<br>  40%<br>  60%<br>  80%<br>  100% |

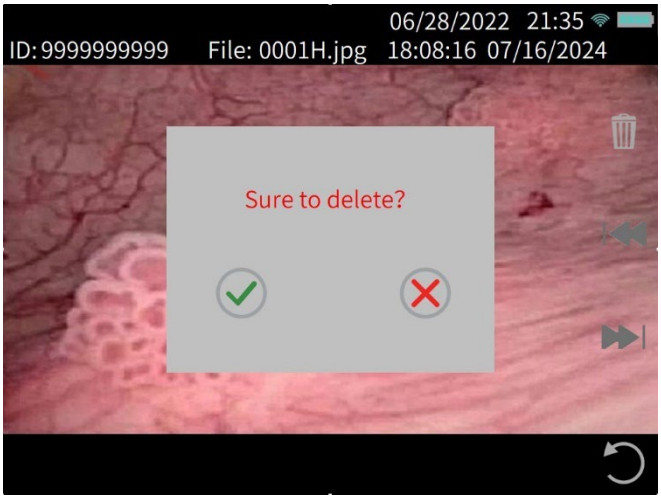
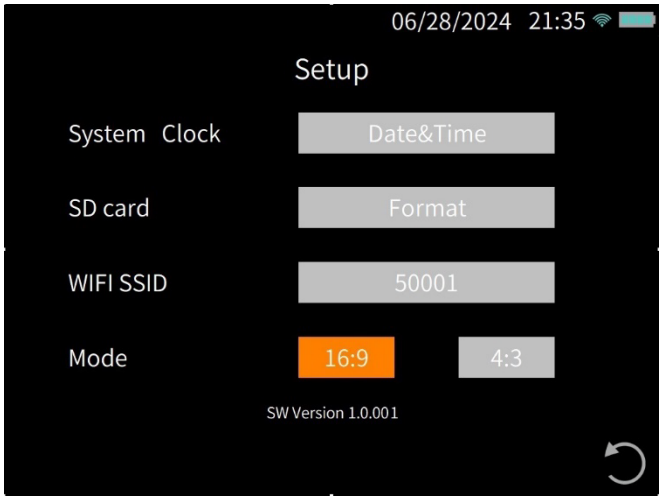
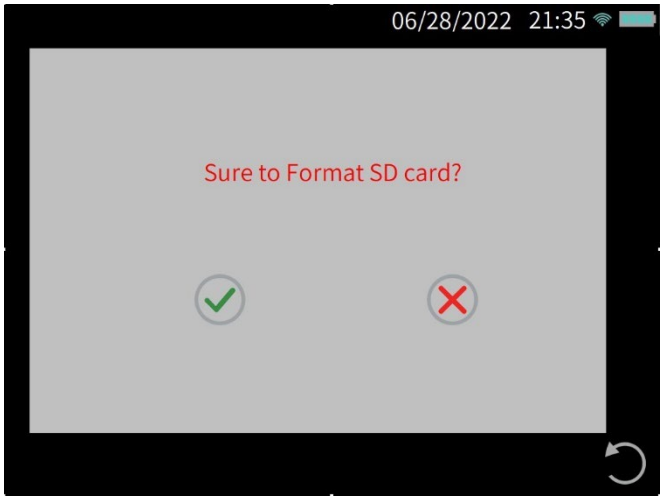
| Touch Screen Description/Action | Touch Screen |
|---|---|
| **Add Case Menu**<br><br>■ To add a new Case ID, Press the ⊕ button on the Home Menu.<br>■ Enter the appropriate numbers to create the case ID. The number is displayed above the number keypad.<br>■ Press ↺ to return to the Home Menu and no Case ID is entered.<br>■ Press C to clear the previously entered number.<br>■ 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.<br>■ If the Case ID is accepted, system will enter the next screen. Tap "Go to Camera" will go into Camera mode. Tap "Re-enter ID" to go to "Enter Case ID#" screen. |  <br>  |
| **Camera Mode and Menu**<br>In "Camera" Mode, real-time imaging will display on the screen.<br><br>If connect with Uro-G HD cannula, HD text appears under the battery usage icon.<br><br>If press the image enhancement button (refer to figure 1 for button's physical location), the image quality will be enhanced and  appears on bottom of the screen. |  |

| Touch Screen Description/Action | Touch Screen |
|---|---|
| ***To start recording:***<br>■ On the ***UroViu 5000 Handle***, press and hold the PHOTO/Video button for 3 seconds (refer to figure 1 for button's physical location).<br>■ On the ***touch display***, a red dot appears under the battery usage icon and will flash Red while recording is in progress.<br><br>***To stop recording:***<br>■ On the ***UroViu 5000 Handle***, press and hold the PHOTO/Video button for 3 seconds |  |
| ***To take a still photo:***<br>■ On the ***UroViu 5000 Handle*** press the PHOTO/Video button on the handle for 1 second |  |

| Touch Screen Description/Action | Touch Screen |
|---|---|
| **Playback Menu**<br><br>***To select video for playback:***<br>■ Press button from the Home Menu.<br>■ Select the desired Case ID to playback.<br>■ Tap the selected recorded video .MP4 file to review the video for the selected ID. |  <br>  |

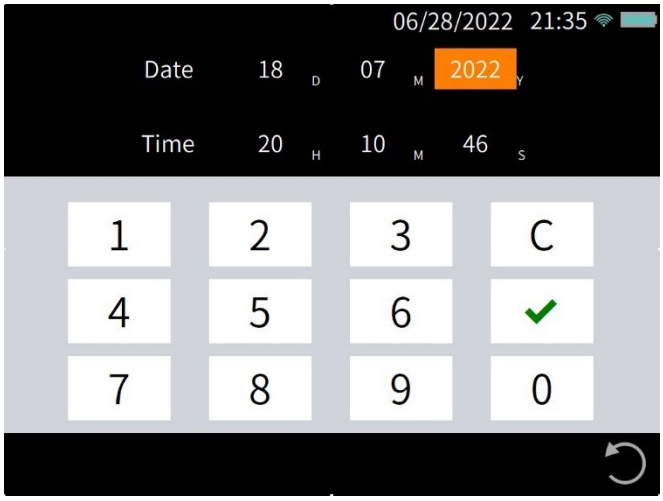
| Touch Screen Description/Action | Touch Screen |
|---|---|
| ***Video Playback Control***<br><br>Play/Pause Button<br>Play the next file<br>Play the previous file<br>Fast forward button<br><br>***To delete a case or video:***<br>■ Select the desired Case ID or video file. Click , a confirmation screen is displayed. On the confirmation screen choose to confirm delete or to cancel deletion and return to the previous screen.<br><br>■ Press the Button to return to the previous screen. |  <br>  <br>  |

| Touch Screen Description/Action | Touch Screen |
|---|---|
| ***To select photo to display:***<br><br>■ Press from the Home Menu.<br>■ Select the desired Case ID to playback. |  |
| ■ Tap the selected saved.JPG file to review the recorded photo for the selected ID. |  |
| ***Photo display***<br><br>Play the next file<br>Play the previous file |  |

| Touch Screen Description/Action | Touch Screen |
|---|---|
| ***To delete a photo:***<br>■ 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.<br>■ Press the Button to return to the previous screen |  |
| **Settings Menu**<br>■ Use the icons on the touch display to:<br>***Change the Date and Time*** – Tap the Date and Time button to update the system date and time settings.<br>***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.<br>***WIFI SSID*** – Tap the WIFI SSID button to enter wireless Relay ID.<br>***Mode*** – If connect with Uro-G HD cannula, tap the display mode of 4:3 to realize full screen display; if connect with other cannulas, the mode is fixed as 16:9 and no mode button. |  <br>  |

**Date and Time**

- To enter appropriate information to change the Date and Time.
- Once input, select ✔ to update the system date and time.
- Or, select the ↺ to cancel action and return to the settings menu.

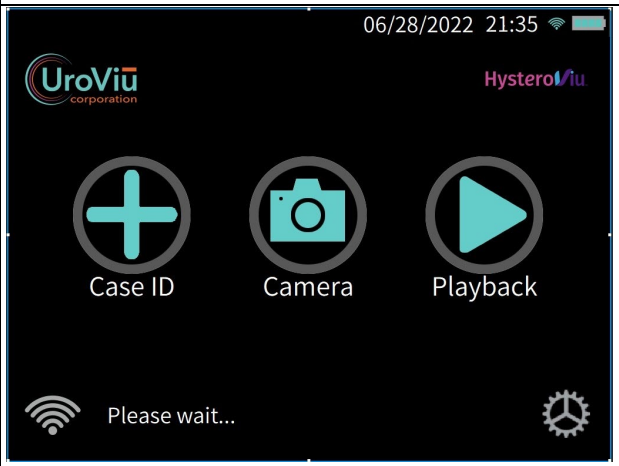



**WIFI SSID**

- To enter the wireless Relay ID, the ID could be found on down cover of the Relay.
- Once input, select ✔ to confirm the ID.
- Or, select the ↺ to cancel action and return to the settings menu.


**Real-time display on external monitor**

- Press  from the home menu to initiate the WIFI, it takes a few seconds. After WIFI function is ready,  appears on the left of the battery icon.
- Plug in power for the Wireless Relay, the handle pair with the wireless Relay automatically.
- Connect the Wireless Relay to external monitor with a HMDI cable. Then real-time imaging of handle screen is displayed on external monitor.



# 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 UroViu 5000 Handle.

7.3. **CHARGING THE BATTERY**

Charge the UroViu 5000 handle after use to ensure it 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 provided USB cable.

**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 USB cable to handle.<br>2. Connect USB cable to computer.<br>3. Turn on handle power.<br>4. Boot-up computer.<br>5. Click “Start” and then click “My Computer.”<br>6. The handle shows up as a remote disk on the “My computer” window.<br>7. Left-click on that removable disk icon to find a folder with patient ID.<br>8. Click on the patient ID folder of interest.<br>9. Click on the sub-folder with the exam date of interest.<br>10. The files in the exam date folder are recorded pictures, with their names ending in “jpg.”<br>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.<br>12. Navigate to the folder on your PC where you want to save patient pictures and paste (control-V) the photos into that folder.<br>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.<br>14. Do not erase photos from the handle until you are certain that you have saved them onto the PC’s hard drive.<br><br>NOTE: follow this same procedure for any videos of interest. | 1. Plug USB cable to handle.<br>2. Connect USB cable to computer.<br>3. Turn on handle power.<br>4. Boot-up computer.<br>5. Click “Finder” on the application dock of the Mac computer.<br>6. The handle shows up as a removable disk under “Devices”.<br>7. Left-click on that removable disk icon to find a folder with patient ID.<br>8. The files in that folder are recorded pictures, with their names ending in “jpg.”<br>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.<br>10. Navigate to the folder on your Mac where you want to save patient pictures and paste (command-V) the photos into that folder.<br>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.<br>12. Do not erase photos from the handle until you are certain that you have saved them onto the Mac’s hard drive.<br><br>NOTE: follow this same procedure for any videos of interest. |

# 9. Maintenance

## 9.1. Cleaning procedure

9.1.1 Power off and unplug all electronic connections. Ensure that the supplied rubber cap is plugged into the electrical port of the handle.

9.1.2 Prepare or dilute and enzymatic cleaner solution such as Enzol™, in accordance with manufacturer's instructions. Wet a sterile pad with the prepared solution and wipe all exposed surfaces of the device. The handle and LCD display should each be wiped for not less than 2 minutes.

9.1.3 Allow the unit to dry, then wet a sterile pad with sterile water and wipe all exposed surfaces of the device until any residue is removed.

**CAUTION**

⚠CAUTION 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.

⚠CAUTION 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.

⚠CAUTION Do not immerse any component of the handle into solutions during the cleaning or disinfecting processes, as damage to the electronic components may occur.

## 9.2. Disinfection Procedure

9.2.1. Disinfection must follow cleaning.

9.2.2. Wipe the device with a disinfectant solution, such as Cidex OPA™, or use a pre-moistened wipe, such as CaviWipes™, and allow to dry for 20 minutes.

9.2.3. Wet a sterile pad with sterile water and wipe all exposed surfaces of the device. Intermediate disinfection may be carried out by wiping the handle LCD display.

## 9.3. Maintenance

9.3.1. 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.

## 9.4. Maintenance Intervals

9.4.1. 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.

9.4.2. 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**
**4546 El Camino Real, Suite 214**
**Los Altos, CA 94022**
**+1 (650) 878-6686 phone**
**email: CS@uroviu.com**

## 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<br>If **YES**, contact UroViu Customer Care |
| Poor picture quality | | Clean cannula tip with a sterile, clean, soft wipe.<br>Ensure that both the cannula and the connector are fully inserted into the handle ports.<br><br>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.<br><br>If this does not correct the picture quality, contact UroViu Customer Care. |
| Loose component or poorly fitting connection | | Do NOT use device<br><br>Contact UroViu Customer Care for return. |
| Battery does not keep a charge. | | Do not use device<br><br>Contact UroViu Customer Care for return. |

## 13. Federal Communications Commission ID

TBD

## 14. Cybersecurity

The whole system of the device is of medium security risk (according to NIST, Common Vulnerability Scoring System (CVSS) Calculator) as:

- The device does not allow any input from external devices;
- Essential functionality is secured in case of network problems.

Software Bill of Material (SBOM)

| Title | Version | Used for |
|---|---|---|
| FlyThings IDE | Version: Developer 1.6.9-SNAPSHOT | Flything is used for the graphical user interface (GUI). |

| | | |
|---|---|---|
| Linux | Linux Kernel version 4.9.227 | The embedded Linux kernel is built custom by UroViu |
| Sigmstar SDK | m6_Tiramisu_DLS00 V011 | The SDK for camera drivers, LCD driver and ISP process. |