



Endosee® Advance Direct Visualization System

Display Module, Docking Station and Cannula
Instructions for Use

CE 2797

Endosee® Advance Direct Visualization System - Instructions for Use

About This IFU

This IFU provides instructions on how to use the Endosee Advance Direct Visualization System with the single-use Cannula safely and effectively for its intended use. 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 for operating this device as indicated in this IFU.

Endosee Advance Display Module Part Number:

ES9000 – Contains Display Module, Docking Station, Power Supply (IEC Plug Type A), USB Cable and IFU

Endosee Advance Cannula Part Number:

ESPX5 – Cannula with endometrial suction Pipet Curet (Box of 5)

Endosee Convenience Kit Part Number:

ES-TRAY – Endosee Kit (Box of 5)

Spare Unit Part Numbers*:

ES-POWS: Power Supply Spare Unit

ES-USBC: USB Cable Spare Unit

* Must have previously purchased ES9000 System to order spare units

CooperSurgical®

95 Corporate Drive • Trumbull, CT, 06611 • USA

Phone: (800) 243-2974 • Fax: (800) 262-0105

International

Phone: +1 (203) 601-9818 • Fax: +1 (203) 601-4747

www.coopersurgical.com

Table of Contents

1	Glossary of Symbols	3
2	Product Description	4
2.1	Reusable Display Module	4
2.2	Docking Station	4
2.3	Sterile, Single-use Cannula	5
2.4	Clinical Benefits	6
2.5	Patient Population	6
2.6	Intended User	6
2.7	Indications for Use	6
2.8	Contraindications	6
3	Warning and Precautions	6
3.1	General	6
3.2	Battery and Power Supply	7
3.3	Environmental Requirements	7
3.4	Inspection, Use and Disposal	8
4	Instructions for Use	8
4.1	Unpacking and Inspection of System	8
4.2	Display Module Charging	9
4.3	Cannula Inspection	9
4.4	Display Module Attachment	9
4.5	Fluid Delivery System	10
4.6	Power Button Function	10
4.7	Image/Video Capture Button	11
4.8	Touch Screen	11
4.9	Procedure Start: Patient Examination	15
4.10	Procedure End: Removal of the Endosee Advance System	16
4.11	Disposal of Biohazardous Material	16
4.12	Battery Re-Charging	16
4.13	Stored Image Transfer	16
5	Device Maintenance	17
5.1	Cleaning/Disinfecting Instructions	17
5.2	Display Module Cleaning/Disinfecting Instructions	18
5.3	Disposable Cannula Handling/Care	18
5.4	Maintenance Intervals	18
6	EMC Compliance Information	19
6.1	Guidance and Manufacturer's Declaration - Electromagnetic Emissions	19
6.2	Guidance and Manufacturer's Declaration - Electromagnetic Immunity	19
7	Storage & Shipping	21
8	Troubleshooting Guide	21
9	Technical Assistance	22
10	Technical Specifications	22
11	Warranty	22

1 Glossary of Symbols

The following symbols are used in this IFU, and/or on the product labeling.

The symbols below are referenced in ISO-15223-1:2016

REF. #	Symbol	Title	Description
5.1.1		Manufacturer	Indicates the medical device manufacturer, as defined in EU Directive 90/385/EECV, 93/42/EEC and 98/79/EC.
5.1.3		Date of manufacture	Indicates the date when the medical device was manufactured.
5.1.4		Use-by Date	Indicates the date after which the medical device is not to be used.
5.1.5		Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
5.1.6		Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
5.1.7		Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
5.2.3		Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.
5.2.4		Do not re-use	Indicates a medical device that is intended for one use, or use on a single patient during a single procedure.
5.2.6		Do not re-sterilize	Indicates a medical device that is not to re-sterilize
5.2.7		Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.
5.1.2		Authorized representative in the European Community.	Indicates the authorized representative in the European Community
5.2.8		Do not use if package is damaged	Indicates a medical device that should not be used if the package has been broken or damaged.
5.4.4		Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.

Symbol not listed in ISO-15223-1:



MEDICAL EQUIPMENT WITH RESPECT TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARD ONLY IN ACCORDANCE WITH UL60601-1 AND CAN/CSA C22.2 No.601.1



Medical Device



Contains or presence of Phthalate.
This product contains DEHP.

2 Product Description

Endosee® Advance Direct Visualization System with Cannula is intended for use in viewing the cervical canal, uterine cavity, or female urinary tract, including the bladder, for the purpose of performing diagnostic and therapeutic procedures in an operating room, outpatient, or office setting.

The Endosee Advance System is a lightweight handheld battery operated portable system. The system consists of a single-use Cannula with a working channel, camera and light source at the distal end to illuminate the area for visualization, image and video capture. An LCD touch screen Display Module is mounted on the Cannula for viewing.

Note: The Endosee Advance System cannot be used with an external monitor.

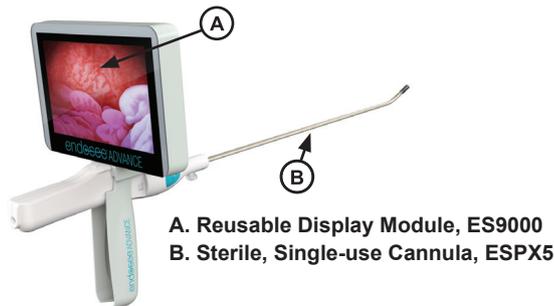


Figure 1: Fully assembled Display Module and Cannula

2.1 Reusable Display Module

The Display Module contains electronics including a power on/off button, a video processor, a display unit (LCD touch display), a rechargeable battery, battery management electronics, microcontrollers, storage for images and video, and firmware. The battery is charged when the Display Module is connected to the Docking Station and the Docking Station is plugged into a wall outlet. A power supply is provided with the device. Figure 2 shows the reusable Display Module. The detailed Battery Specifications are listed in Section 10.



A. LCD Touch Screen Display

B. Power On/Off Button

Figure 2: Reusable Display Module on Docking Station

2.2 Docking Station

The Docking Station has dual functions. It allows the battery to be charged using the power supply and allows video recordings and single frame photographs to be transferred via USB Cable from the internal memory of the Display Module to an external computer.



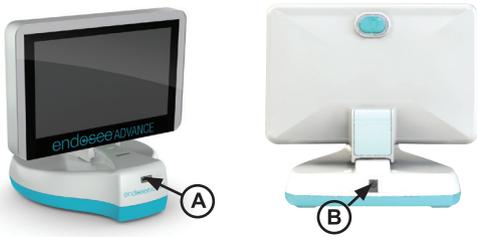
WARNING: Use only the power supply provided with the device. Use of other chargers may damage the device and will void the warranty.



WARNING: Charge the battery at room temperature.



WARNING: Do not charge the battery near a heat source.



A. USB Port

B. Power Cable Port

Figure 3: Display Module on Docking Station

Note: The Endosee Advance System cannot be used with an external monitor.



WARNING: The Endosee Advance System contains no user-serviceable components within the enclosure. To avoid electrical shock or damage, the unit must not be disassembled. Doing so will void the warranty.



CAUTION: Do not operate the Endosee Advance System if any shipping damage or other defects to the equipment are noted during inspection. Immediately notify CooperSurgical, Inc. Customer Service (800) 243-2974 if any defect is found.

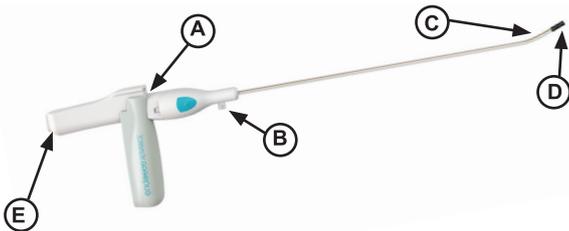
2.3 Sterile, Single-use Cannula

The Cannula contains a miniature camera and LED illumination at the tip. The Cannula connects to the Display Module through an electrical connector. The Cannula has an inner channel for the infusion of fluid. Fluid infusion is achieved by attaching either a pre-filled syringe or a pressurized bag of distending medium to the inflow port through an extension tube or a tubing set. The outflow port is at the distal tip of the Cannula and empties out around the tip to infuse fluid into the uterine cavity or female bladder. The Cannula has a pre-curved tip section at an angle of $20^{\circ} \pm 5^{\circ}$. The Cannula tip section should not be altered. The Cannula maximum temperature will not exceed 41°C . **Figure 4** shows the Cannula.

The Cannula allows the introduction of standard endoscopic instruments to the uterine or bladder cavity if desired.

Instruments within the following dimensions are compatible with the Endosee Advance Cannula:

- Maximum outer diameter: 1.67 mm (5 Fr)
- Minimum working length: 455 mm



A. Display Module Connector

B. Fluid Infusion Port

C. Tip Section

D. Camera & LED Illumination Module

E. Working Channel

Figure 4: Cannula

Do not use the Cannula if the package has been damaged or the expiration date on the label has passed.



CAUTION: For single use only. Do not reuse, reprocess, or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or re-sterilization may create a risk of contamination of the device and/or cause patient infection or crossinfection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.



WARNING: The used cannula must be disposed of as biohazardous waste according to the safety guidelines of user facility/institution.

2.4 Clinical Benefits

Allows the physician to perform diagnostic or therapeutic procedures related to the cervical canal and uterine cavity as well as the female urinary tract, including the bladder.

2.5 Patient Population

The devices can be used in adult female.

2.6 Intended User

The Endosee Advance Display Module is for use only by physicians with adequate training in hysteroscopy and/or cystoscopy.

2.7 Indications for Use

The Endosee Advance System is used to permit viewing of the adult cervical canal and uterine cavity for the purpose of performing diagnostic and therapeutic procedures. The types of procedures where the Endosee Advance System could offer visualization include:

- Abnormal bleeding
- Infertility and pregnancy wastage
- Evaluation of abnormal hysterosalpingogram
- Intrauterine foreign body
- Amenorrhea
- Pelvic pain
- Directed Biopsy
- Removal of Fibroids and Polyps
- Transection of Intrauterine Adhesions
- Transection of Intrauterine Septa

The Endosee Advance System can also be used to permit viewing of the female adult urinary bladder through a minimally invasive approach by utilizing natural orifices for the purpose of performing diagnostic and therapeutic procedures.

2.8 Contraindications

Hysteroscopy is contraindicated in patients with known or suspected acute pelvic inflammatory disease. Hysteroscopy may be contraindicated by the following conditions depending on their severity or extent:

- Inability to distend the uterus
- Cervical stenosis
- Cervical/Vaginal infection
- Uterine bleeding or menses
- Known pregnancy
- Invasive carcinoma of the cervix
- Recent uterine perforation
- Medical contraindication or intolerance to anesthesia

Cystoscopy is contraindicated in febrile patients with urinary tract infection (UTIs) and those with severe coagulopathy.

3 Warnings and Precautions

This section contains important safety information related to use of the Endosee Advance Display Module and the Cannula. Other important safety information is provided throughout this IFU in sections that relate specifically to the precautionary information.

Read all text surrounding all warning and precautionary information prior to performing any procedures with this equipment.

3.1 General

R_xOnly CAUTION: *Federal Law (USA) restricts the device to sale by or on the order of a physician.*

The Endosee Advance System is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

The Endosee Advance System is for use only by physicians with adequate training in hysteroscopy and/or cystoscopy.

This product contains DEHP - data derived from animal and epidemiological studies outlines the following risks including, but not limited to: adverse effects on fetal development, kidney and liver toxicity, negative impact on fertility. Special attention on the application of phthalate products should be given for the following patient populations: pediatrics, pregnant and nursing women.

When a liquid distension medium is used, strict fluid intake and output surveillance should be maintained. Intrauterine instillation exceeding 1 liter should be followed with great care to reduce the possibility of fluid overload.

Potential complications of continuous flow hysteroscopy:

- Hyponatremia
- Hypothermia
- Uterine perforation resulting in possible injury to bowel, bladder, major blood vessels and ureter
- Pulmonary edema
- Cerebral edema
- Infection
- Bleeding
- Pain

The use of sterile saline as a distending medium, and limiting the infused volume to less than 1000 mL is recommended to decrease the risk of the above complications.

Intrauterine distension can usually be accomplished with pressures in the range of 35 - 75 mmHg. Unless the systemic blood pressure is excessive, it is seldom necessary to use pressures greater than 75-80 mmHg.

Vaginal ultrasonography before hysteroscopy may identify clinical conditions that will alter patient management.

Since most urological endoscopy procedures utilize irrigation fluids, it is important that the correct fluid be chosen and that the volumes of inflow and outflow be strictly observed. Appropriate measures should be undertaken to prevent the possibility of fluid overload of the patient.

3.2 Battery and Power Supply

Comply with the following to prevent damage to the battery:

- Use only the power supply provided with the device. Use of other chargers may damage the device and will void the warranty.
- Charge the battery at room temperature.
- Do not charge the battery near a heat source.
- Do not disassemble or alter the battery in any way.
- Battery is not replaceable.
- The Display Module should be fully charged before use. A fully charged battery will provide at least 1 hour of continuous operating time under normal operating conditions.
- Fully charge the Display Module after each procedure. An LED indicator located on the Docking Station will display a steady green light when the unit is fully charged.
- Refer to battery power indicator on the touch screen Display Module to determine remaining battery power.
- Do not attempt to use any power source or battery not directly provided by CooperSurgical, Inc.

Comply with the following to reduce the risk of burns, fire, electric shock, or injury to persons:

- Do not operate the power supply if it has a damaged cord or plug, if it is not working properly, or if it has fallen into water.
- Do not charge the battery where oxygen is being administered.
- Do not unplug power supply by pulling on the cord. To unplug, pull on the plug, not the cord.

PLEASE NOTE: If a serious incident is suspected from using the Endosee Advance Display Module System, report the details of the incident to CooperSurgical via phone number +1 203-601-5200 Ext 3100 or by email at ProductSurveillance@coopersurgical.com and to the local Health Authority in your country. A serious incident may have caused or contributed to a death, a delay in a procedure which resulted in death or serious injury, or a malfunction that could have caused an adverse event.

3.3 Environmental Requirements

Failure to ensure that all of these environmental requirements are met may result in improper performance or damage to the electronic components within the Endosee Advance System.

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

See Section 6 - EMC Compliance Information.

The Endosee Advance System is not designed for use in environments in which strong Electromagnetic interference (EMI) may impact the performance of the equipment.

The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as re-locating or re-orienting the equipment.

If this occurs, the site of use should be surveyed to determine the source of this disruption, and the following actions may be taken to eliminate the source:

- Remove, re-orient or re-locate the interfering equipment.
- Increase the separation between the interfering equipment and the Endosee Advance System.
- Incrementally turn off equipment in the vicinity to identify the interfering device.

This product is intended for indoor use only.



WARNING: All of the environmental requirements listed in the Warnings and Precautions section must be met in the location where the Endosee Advance System is intended to be operated for patient use. If ANY of these environmental parameters are present the Endosee Advance System should not be operated until modifications to the environmental conditions are met.

3.4 Inspection, Use and Disposal

- Inspect the integrity of the unit and condition before powering-on the fully assembled Endosee Advance System. Do not use the system if indications of external damage are observed.
- The Endosee Advance System contains no operator serviceable components within the enclosure. To avoid electrical shock or damage, the unit must not be disassembled. Doing so will void the warranty.
- Do not operate the Endosee Advance System if any shipping damage or other defects to the equipment are noted during inspection. Immediately notify CooperSurgical, Inc. Customer Service (800) 243-2974 or +1 (203) 601-9818 if any defect is found.
- Do not use the Cannula if the package has been damaged or the expiration date on the label has passed.
- The Cannula is single-use only. Do not re-use or re-sterilize the Cannula.
- The Cannula must be disposed of as biohazardous waste according to the safety guidelines of user facility/institution.
- Follow all cleaning procedures provided for the re-usable Display Module.
- The Endosee Advance System can only be used with the LCD touch screen display on the Display Module. A separate video monitor cannot be used.
- Do not allow any fluids or substances to be spilled into or around the cannula connector on the Display Module, as damage to the electronics may occur.
- Do not mis-align the connectors between the removable cannula and the Display Module during assembly, as damage may occur.
- When detaching the cannula from the Display Module, be sure that fluid does not contact the connector in the Display Module. Do not rotate or twist the cannula while removing.
- Do not alter the shape of the distal end of the cannula.
- No portion of the Endosee Advance System should be opened for cleaning or disinfecting.
- Do not pour water or any cleaning solution directly onto Display Module during cleaning or disinfection. Doing so may damage electronic components and reduce product life.
- Do not immerse any component of the Display Module into solutions during the cleaning or disinfecting processes, as damage to the electronic components may occur.



WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.



WARNING: Use of accessories other than those provided by CooperSurgical, Inc. could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

4 Instructions for Use



WARNING: The Endosee Advance System is for use only by physicians with adequate training in hysteroscopy/cystoscopy.

4.1 Unpacking and Inspection of System

Unpack and inspect all components for damage during shipment, or discrepancies upon arrival. Ensure there are no unintended rough surfaces, sharp edges or protrusions which may cause harm.

NOTE: Do not dispose of protective box or any other shipping materials. These items should be retained for future storage or transport of the equipment.

4.2 Display Module Charging

The Endosee Advance System operates on DC voltage, from an internal battery source. The Display Module must be fully charged before the initial use.

Connect the Display Module to the Docking Station, as shown below:

1. Attach power supply cord to the Docking Station.
2. Plug the power supply to a wall outlet.
3. Continue to charge until the LED indicator on the Docking Station displays a steady green light, indicating the Display Module is fully charged. Once it is charged, the Display Module is ready for use.

Note: When first received, the Display Module will not turn ON until it is connected to the Docking Station to take the unit out of Ship Mode. Once charged the Display Module will present the Language Screen.



Figure 5: Display Module connected to Docking Station.

4.3 Cannula Inspection

Each single-use Cannula comes sealed in a pouch (**Figure 6**) and is Ethylene Oxide (EO) sterilized. ESPX5 contains an individually wrapped Cannula and an individually pouched endometrial suction Pipet Curet.

- Check that the expiration date has not passed before use.
- Check that the pouch's sterile seal is intact.
- Check that the device is not damaged prior to use.



Figure 6: Disposable Cannula and Pipet in pouch

4.4 Display Module Attachment

1. Peel apart the chevron end of the pouch near the handle and remove the sterile cannula.
2. Open cannula handle to the "Down" position as shown in Figure 7.



Figure 7: Opening the Cannula Handle

Note: The Display Module will not connect to the cannula unless the handle is in the "Down" position.



Figure 8: Cannula and Display Module Attachment

- Align the slot at the bottom of the Display Module with the 'rail' on the top of the Cannula and slide the Display Module towards the back end of the Cannula to connect (see red arrow in Figure 8). There will be tactile and auditory clicks when the two components are properly connected.



CAUTION: Do not mis-align the connectors between the Cannula and the Display Module during assembly, as damage may occur.

4.5 Fluid Delivery System

Fluid infusion is achieved by attaching either a pre-filled syringe or a pressurized bag of distending medium to the inflow port of the cannula through an extension tube or a tubing set as shown in Figure 9.



Figure 9: Fluid Inflow Port



WARNING: When a liquid medium is used, strict fluid intake and output surveillance should be maintained. Intrauterine instillation exceeding 1 liter should be followed with great care to reduce the possibility of fluid overload.



WARNING: Potential complications of Continuous Flow Hysteroscopy include:

- Hyponatremia
- Hypothermia
- Uterine perforation resulting in possible injury to bowel, bladder, major blood vessels and ureter
- Pulmonary edema
- Cerebral edema
- Infection
- Bleeding
- Pain

The use of sterile saline as a distending medium, and limiting the infused volume to less than 1000 mL is recommended to decrease the risk of the above complications. Intrauterine distension can usually be accomplished with pressures in the range of 35-75 mmHg. Unless the systemic blood pressure is excessive, it is seldom necessary.



CAUTION: Do not allow any fluids or substances to be spilled in or around the cannula connector on the Display Module, as damage to the electronics may occur.

4.6 Power Button Function

The function of the Display Module Power Button is described below.



WARNING: Inspect the integrity of the unit and its condition before powering-on the fully assembled unit. Do not use the system if visual signs of external damage are observed.

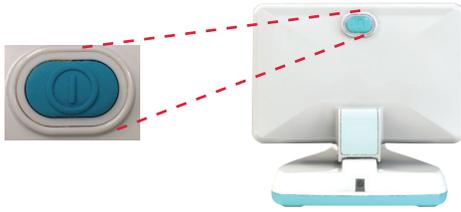


Figure 10: Power Button

Touch Function	Action
Power On	Press-and-Release; Endosee splash screen will appear
Power Off	Press-and-Hold until audible beeps occur (approximately 1 second); Endosee Advance splash screen will appear and indicate unit is shutting down.

4.7 Image/Video Capture Button

The image/video capture buttons, located on both sides of the cannula, allow the user to capture/save still images and video images. The image capture operations are described below.

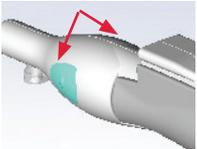


Figure 11: Pictures (Single Frame) or Video Button

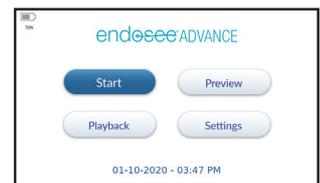
Video/Single frame Touch Function	Action
Capture Still Image	Press-and-Release
Capture Video Clip	Press-and-Hold: 1 second
Capture Still Image while Video is Recording	Press-and-Release while video is recording
Stop Video Capture	While system is capturing video, press and hold button one more time

4.8 Touch Screen

Touch Screen Description/Touch Screen Action

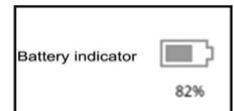
4.8.1 Start Screen

Start Screen has a battery power usage indicator and four (4) touch buttons each allowing a discrete function. Pressing each touch button takes user to a sub screen for a specific function. This section describes the sequences of screens that will appear with each selection.



Battery Power Usage Indicator

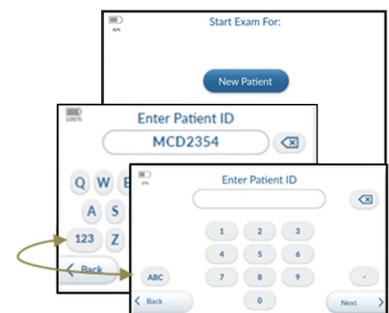
Battery usage indicator provides the battery power usage status. When battery power usage reaches 12% the system will prompt user to charge the Display Module. When battery power usage reaches 0%, the system will automatically shut down.



4.8.2 Patient Select Screen and Patient ID Screen

On **Start Screen**, press the *Start* touch button to enter the **Patient Select Screen**. The user has a choice of entering Exam mode for a *New Patient* or *Saved Patient*.

Select *New Patient* button to enter **Patient ID Screen**. Touch the desired numbers and/or letters to enter Patient ID.



The numbers are displayed on the first screen. If letters are desired, select the touch button labeled “ABC” on the left side of the screen. User may enter up to twelve (12) characters.

If an error is made when entering Patient ID press the delete touch button to back space.

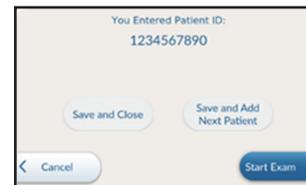
- Touch *Next* to confirm Patient ID.
- Touch *Back* to return to **Patient Select Screen**.



4.8.3 Patient Confirmation and Start Exam Screen

Verify the Patient ID is correct. Select from the following four touch options:

1. *Start Exam*: Opens the **Exam Screen** - The newly created Patient ID will be displayed on the left side of the **Exam Screen**.
2. *Cancel*: The display returns you to the **Patient ID Screen** without saving the Patient ID.
3. *Save and Close*: Saves this Patient ID and returns user to **Patient Select Screen**.
4. *Save and Add Next Patient*: Saves the entered ID and brings user back to **Patient ID Screen**.

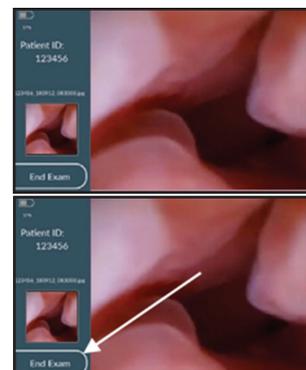


4.8.4 Exam Screen and Image Capture

Press *Start Exam* and verify the **Display Module screen** displays a live image in the correct orientation.

To record/save individual images or video visualized on the display screen, press the capture button(s) – follow guidance laid out in Section 4.7. A thumbnail of the previous image/video recorded will appear on the left side of the **Exam Screen**.

To exit Exam mode, touch *End Exam* on the bottom left of the **Exam Screen**. The user will be returned to the **Start Screen**.



4.8.5 Start Screen Additional Options

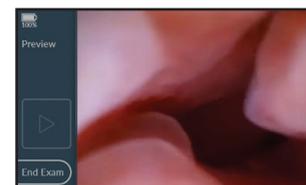
4.8.5.1 Preview Screen

From the **Start Screen**, press the *Preview* touch button to display a real-time image without entering a Patient ID.

Verify the **Display Module Screen** displays a live image in the correct orientation.

Note: While in preview mode the device will capture images by date/time only, stored in a file named *Preview*. No Patient ID will be associated with these files.

Press the *End Exam* touch button to return to the **Start Screen**.



4.8.5.2 Playback Screen

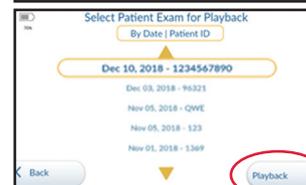
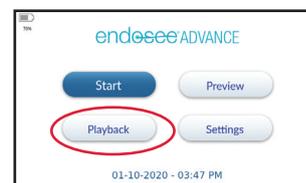
To review or playback the images/videos previously captured, press the *Playback* touch button in the lower left corner of the display.

On the Select Patient Exam for **Playback Screen**:

Scroll through the list to select the appropriate file by Date and Patient ID. This can be done by using the gold up and down arrows or by a single finger touch.

Once the appropriate image file is selected, touch the *Playback* button in the lower right corner of the display to review the procedure images and/or video.

- In the **Playback Screen**, the Patient ID will be displayed in the bar on the left side of the screen.
- Upon first entering the **Playback Screen**, the last image or video taken during the procedure will be displayed first.



To review the images and videos recorded during a procedure use the gold *right* and *left* arrows or a single finger touch to swipe.

To play a video, touch the icon at the bottom center of the screen. Touch it again to pause/restart the video.

Press the *Back* touch button on the bottom left of the screen to return to the **Playback Screen**, and touch the *Back* touch button again to return to **Start Screen**.



Note: As in all systems, proper care must be taken to ensure the privacy and security of Patient data.



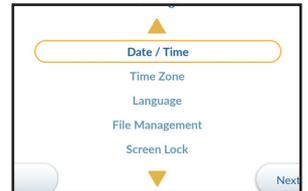
WARNING: The Endosee Advance can store images and videos of exams. If you enter a name or ID for the patient, this field will also be stored with the image or video. This information is HIPAA protected.

4.8.5.3 Settings Screen

From the **Start Screen**, press the Settings touch button on the display.

There are five options in the **Settings Screen**:

- Date/ Time
- Time Zone
- Language
- File Management
- Screen Lock



Use the gold *up* and *down* arrows or a single finger touch to select the desired Settings.

4.8.5.3.1 Date/Time

Select *Date/Time* on the **Settings Screen**. Press *Next* in the bottom right corner of the display to go to **Date/Time Screen**. Select *Date/Time* format preferences (MM/DD/YYYY or DD/MM/YYYY; 12-hr or 24-hr clock).

Use the up and down arrows to set the date and time.

Press *AM* or *PM* to complete the time of day setting, if applicable.

Press the *Save* touch button in the bottom right corner of the screen once the date and time are correct.

Press the *Back* touch button on the bottom left of the screen to return to **Start Screen**.



4.8.5.3.2 Time Zone

Select *Time Zone* on the **Settings Screen**. Press *Next* in the bottom right corner of the display to go to the **Time Zone Screen**. Use the gold up and down arrows or a single finger touch to select the desired time zone. Press the *Save* button to set the selected time zone.



4.8.5.3.3 Language

Select *Language* on the **Settings Screen**. Press *Next* in the bottom right corner of the display to go to the **Language Screen**. Use the gold up and down arrows or a single finger touch to select the desired language. Press the *Save* button to set the selected language preference on the display module.



4.8.5.3.4 File Management

Select *File Management* on the **Settings Screen**. Press *Next* in the bottom right corner of the display to go to **File Management Screen**.

In addition to the removal of files via USB and PC, patient files can be removed from the Endosee Display through the **File Management Screen**:

1. Delete Files By Exam
2. Delete All Files

Use the gold up and down arrows or a single finger touch to select desired file management action.



Use the up and down arrows or a single finger touch select the desired file for deletion. Once the file is selected press the *Delete* button. A message will appear asking to confirmation the deletion of the file selected.

In the **Delete All Files** screen, there is an option to erase all files and their content from the Display Module. Press the *Delete All Files* touch button to permanently delete all files. A message will appear asking to confirm your actions.

Note: All data should be transferred and stored prior to the deletion of any or all files from the memory, refer to Section 4.13 for Transfer Image to PC.

4.8.5.3.5 Screen Lock

The Endosee Advance provides the option to enable a screen lock to the display module. In the **Settings Screen**, use the gold up and down arrows or a single finger touch to select **Screen Lock**, then press *Next*.



The screen lock default setting is disabled. To enable screen lock, select the text, *Enabled*. The display module will automatically require a 4-digit numeric passcode be set and confirmed.



To enable lock on inactivity, select the text, *Enabled*. The inactivity timer can be set between 5 – 60 minutes, in one-minute increments. This feature will automatically lock the display module after the set time of inactivity is achieved.



If lock on inactivity is disabled, the display module can be forced into a locked state by a short press on the Power On/Off button.

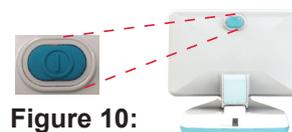


Figure 10: Power Button

When the display module is in a locked state, the screen will display the **Passcode Entry Screen**.

When the correct 4-digit numeric passcode is entered the display module will automatically unlock and display the **Home Screen**.

If the passcode is forgotten, press the *Forgot Passcode* touch button. The display will prompt further instructions on how to reset the passcode.



To transfer images and video, the connection from the display module to the PC must be made while the display module is in an unlocked state.

Screen lock will remain enabled between power on/off cycles.

4.8.5.3.6 Service Screen

The **Service Screen** is for use by CooperSurgical staff only.



4.8.6 Patient Select Screen Additional Option

From the **Start Screen**, press the *Start* touch button to go to the **Patient Select Screen**.

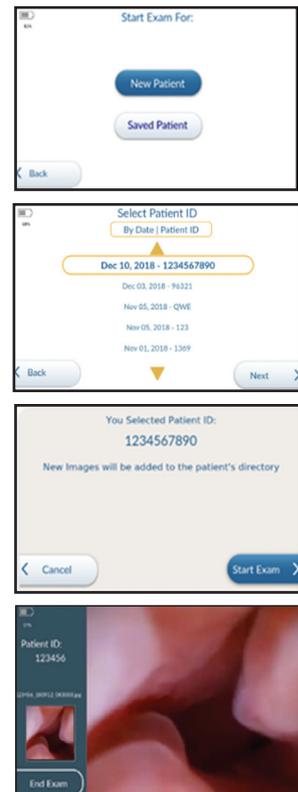
Press the *Saved Patient* touch button to access previously stored Patient file(s) organized by dates and associated Patient IDs. To scroll through this list, touch the gold up or down arrows or a single finger touch.

Once the desired Patient ID is selected, touch the *Next* button to verify Patient ID and then *Start Exam*. The selected Patient ID will be displayed on the top of the **Patient Confirmation Screen**. Touch *Start Exam* button and open the **Exam Screen**.

To record images or video, follow instructions laid out in Section 4.7.

The left side of the **Exam Screen** will display a thumbnail of the previous image/video recorded.

To exit Exam mode, touch *End Exam* on the bottom left of the **Exam Screen**. The user will be returned to the **Start Screen**.



4.9 Procedure Start: Patient Examination

The following steps describe the process for using the Endosee Advance System.



CAUTION: A fully charged battery will provide at least 1 hour of continuous operating time under normal operating conditions. The Display Module should be fully charged before initial use and should be recharged after each procedure.



CAUTION: Refer to battery power indicator on the touch screen Display Module to determine remaining battery power.

Ensure that the Display Module is thoroughly cleaned and disinfected using the procedures, as described in Section 5.1.

Ensure that the Display Module is charged, as described in Section 4.2.

- Press and Release POWER ON/OFF button on Display Module, Section 4.6.
- Press Start and select New Patient or Saved Patient via the **Patient Select Screen**. Section 4.8.2
- Enter Patient ID per Section 4.8.2
- Press Start Exam.

Before removing Cannula from sterile pouch, ensure cervical canal patency.

Once cervical patency has been established, remove the sterile Cannula from the pouch.

- Inspect the Cannula as described in Section 4.3.
- Attach the Cannula to the Display Module using the procedures, as described in Section 4.4.
- Check light source is illuminated at the distal tip of the Cannula. If the tip of the Cannula does not illuminate, system hardware troubleshooting procedures should be performed, as described in Section 8.
- Verify the Display Module Screen displays a live image (rather than a stored one) in the correct orientation. If the image displayed is not live or not in the correct orientation, system hardware troubleshooting procedures should be performed, as described in Section 8.
- Attach the fluid tubing to the Cannula, as described in Section 4.5.
- Flush the fluid through the Cannula until all air bubbles have cleared from the tubing.

The Cannula is inserted through the cervical canal or urethra, with fluid flowing, while viewing the image, as is standard procedure for introduction of a hysteroscope or cystoscope.

The Endosee Advance System is now ready for use.

4.9.1 Use of Cannula Working Channel

Follow the instructions below to introduce the instrument into the Endosee Advance Cannula Working Channel, reference Section 2.

1. The instrument tip must remain in its closed (non-working) configuration during insertion through the Cannula Working Channel.
2. Prior to engaging the instrument, verify that the instrument tip is fully inserted beyond the far end of the Cannula. Ensure the tip opens & closes fully using direct visualization on the Display Module screen.
3. Complete the procedure, ensure the instrument tip is closed prior to removing the instrument from the Working Channel. See Section 2.3 - Sterile, Single-use Cannula.

4.10 Procedure End: Removal of the Endosee Advance System

After the procedure is completed, press and hold the Display Module POWER ON/OFF button, and remove the Cannula.

- Hold the Display Module such that the Cannula tip is pointed towards the floor.
- With one hand support the Display Module which will be pushed off the Cannula.
- While holding the Cannula handle and using the thumb to gently press against the bottom of the center of the Endosee logo move the Display Module away from the Cannula.
- The Cannula will detach from the Display Module

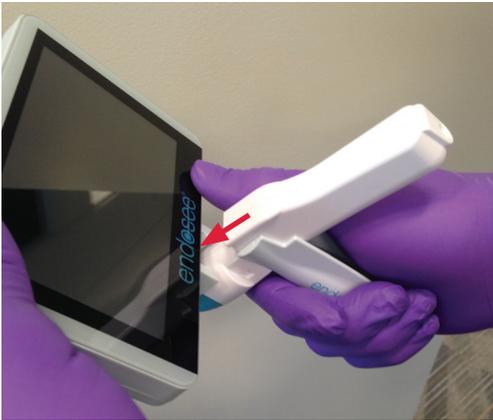


Figure 12: Detach Cannula



CAUTION: When detaching the Cannula from the Display Module, be sure that fluid does not contact the connector in the Display Module.

4.11 Disposal of Biohazardous Material



WARNING: The used Cannula must be disposed of as biohazardous waste according to the safety guidelines of user facility/institution.

4.12 Battery Re-charging

The Endosee Advance System has an internal battery that powers the unit during use. A fully charged battery will provide at least 1 hour of continuous operating time under normal operating conditions. Slide Display Module directly onto the Docking Station after each use to recharge battery.

To recharge the battery, follow the procedure in Section 4.2.

4.13 Stored Image Transfer

The Docking Station provides the capability for battery charging and image uploading.



Figure 13: Display Module on the Docking Station

Note: The unit should be kept in a secure location in order to ensure patient privacy.

4.13.1 Transfer Image(s) to a PC via Docking Station

1. Plug the power cord into the Docking Station Power Port. Slide the Display Module into position on the Docking Station. See Section 2.2 - Docking Station.
2. Connect the USB cable to the computer and to the Docking Station.
3. Turn on Display Module.
4. Boot up computer.
5. Click *Start*, and then click *My Computer*.
6. The Endosee Advance device shows up as a removable disk in “My Computer.” Open the ENDOSEE folder to find files named with a Date/Time/Patient ID.
7. These files are the recorded images and for still images the JPEG image ends in “.jpg”; for Video Clips “.avi”.
8. Click the file named with the desired Date/Time/Patient ID.
9. If a Patient ID folder was not created, select folder named *Preview*. The files in the *Preview* folder are named by the date/time. See Section 4.8.5.1 - Preview Screen.
10. Copy those files by selecting them and copying them. The keyboard shortcut (control-A) marks all the photos in a folder and the keyboard shortcut (control-C) copies them to the computer’s clipboard.
11. Navigate to the folder where you want to save Patient pictures and paste (control-V) your photos into place.
12. After you copy files or folders to the hard drive, it is useful to view the hard drive to confirm that the files are copied.
13. Do not erase photos or videos from your Display Module until you have confirmed that you saved them on the hard drive.

Note: *It is recommended to save the last month of cases in two storage locations, as a backup.*

Note: *If screen lock is enabled on the display module, the display must be in an unlocked state upon connection to a PC in order to transfer images and videos.*

4.13.2 Download to a Mac via Docking Station

1. Plug the power cord into the Docking Station Power Port. Slide the Display Module into position on the Docking Station. See Section 2.2.
2. Connect the USB cable to the computer and Docking Station.
3. Turn on Display Module.
4. Boot up computer.
5. Click the Finder on the application dock.
6. The Endosee Advance device shows up as a removable device. Open the Endosee Advance device to find a folder named with a Patient ID.
7. These files are the recorded images and for still images the JPEG image ends in “.jpg”; for Video Clips “.avi”.
8. Click the file named with the desired Date/Time/Patient ID.
9. If a Patient ID folder was not created, select folder named *Preview*. The files in the *Preview* folder are named by the date/time. See Section 4.8.5.1. Preview Section.
10. Copy those files by selecting them and copying them. The keyboard shortcut (command-A) marks all the photos in a folder and the keyboard shortcut (command-C) copies them to the computer’s clipboard.
11. Navigate to the folder where you want to save Patient pictures and paste (command-V) your photos into place.
12. After you copy files or folders to the hard drive, it is useful to view the hard drive to confirm that the files are copied.
13. Do not erase images or videos from your Display Module until you have confirmed that you saved them on the hard drive. It is recommended to back up file to another device.

Note: *It is recommended to save the last month of cases in two storage locations, as a backup.*

5 Device Maintenance

5.1 Cleaning / Disinfecting Instructions

After each Patient use, follow the combined cleaning/ disinfecting instructions provided below for the Display Module.



WARNING: *Follow all cleaning procedures provided.*



CAUTION: *No portion of the Display Module should be opened for cleaning or disinfecting.*

5.2 Display Module Cleaning/Disinfecting Instructions

After each Patient use, power off.

Place Display Module on a clean, dry, disinfected or sterile basin or surface.

Before starting the cleaning and disinfection, wear Personal Protective Equipment (i.e. gloves, protective glasses, etc.).



CAUTION: Throughout the cleaning/ disinfection process, orient the connector in a manner that prevents liquid from entering the electrical connection area of the connector (e.g., with the opening to the electrical connections facing upward). Do not wet the opening or inside of the connector housing the electrical connection components.



CAUTION: When cleaning/disinfecting the LCD screen of the Display Module, pay careful attention to the seams around the edge of the display and the back of the unit, including seam around Power ON/OFF Button.

Follow the instructions below to clean and disinfect the Display Module. These instructions were validated using CaviWipes®, DisCide®, SaniCloth®, and Clorox Healthcare® sanitizing wipes. If you choose a wipe not listed here, you must validate it before use.

- Using a fresh, moist disinfectant wipe, thoroughly wipe the front and back of the LCD screen of the Display Module until entire device is wetted. Discard the wipe.
- Repeat with a fresh wipe for a minimum of thirty (30) seconds. Discard the wipe.
- Using a fresh, moist wipe, thoroughly wipe the seams of the Display Module:
 - With CaviWipes and DisCide for one (1) minute.
 - With SaniCloth for two (2) minutes.
 - With Clorox Healthcare for three (3) minutes.
- Using a fresh, moist wipe, thoroughly wipe all surfaces of the Display Module for a minimum of ten (10) seconds. Discard the wipe.
- Allow the wiped and wetted Display Module to stand for a minimum of three (3) minutes.
- At the end of the three (3) minutes, use a sterile, lint-free wipe saturated with sterile 70% IPA to thoroughly wipe the entire Display Module for a minimum of thirty (30) seconds.
- Allow the device to air dry. Once dry, visually inspect the Display Module for any residual soil. Repeat cleaning/ disinfection instructions if visible soil is present.
- Place the cleaned/disinfected device in an appropriate dry storage area.

5.3 Disposable Cannula Handling/Care

The Cannula is provided sterile and is a single-use, item. As such, no formal cleaning or disinfection procedures apply to the Cannula.

5.4 Maintenance Intervals

Basic preventive maintenance of the Endosee Advance System is an important function that should be performed on schedule to ensure safe and effective operation.

If the integrity or performance of any portion of the Endosee Advance System is in doubt, the system should NOT be used until the issue is resolved.

The following maintenance intervals are recommended:

Maintenance Type	Interval	Personnel
General Inspection: Check the device has not been damaged, no rough surfaces, sharp edges or protrusions; the unit turns on and the display screens are responsive and readable.	Before use with each Patient	Users
Safety Label Integrity	Not required – Labels are Direct Marked	All

Note: The Endosee Advance System requires no calibration or service in the field. All electronics are tested and validated for performance at the manufacturer.

6 EMC Compliance Information

6.1 Guidance and Manufacturer's Declaration – Electromagnetic Emissions

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

Professional Healthcare Facility Environment

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Endosee Advance 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	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

6.2 Guidance and Manufacturer's Declaration – Electromagnetic Immunity

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

Professional Healthcare Facility Environment

Immunity Test	IEC60601 Test and Compliance	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/- 15 kV air	
Radiated RF EM Fields IEC 61000-4-3	Professional Health Care 3V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz	
Proximity fields from RF wireless communications equipment IEC 61000-4-3	9 V/m 710,745,780 MHz Pulse modulation 217 Hz 9 V/m 5240,5500, 5785 MHz Pulse modulation 217 Hz 27 V/m 385 MHz Pulse modulation 18Hz 28 V/m 450 MHz	WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Endosee Advance System, including cables specified by the manufacturer.

	<p>FM +/- 5 kHz deviation; 1 kHz sine</p> <p>28 V/m 810, 870, 930 MHz Pulse modulation 18 Hz</p> <p>28 V/m 1720, 1845, 1970, 2450 MHz Pulse modulation 217 Hz</p>	<p>Otherwise, degradation of the performance of this equipment could result.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
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Professional Healthcare Facility Environment

Immunity Test	IEC60601 Test and Compliance	Electromagnetic environment – guidance
Electrical Fast Transient/Burst IEC 61000-4-4	+/- 2 kV for ac power supply lines +/- 1 kV for input/output lines 100 kHz repetition frequency	
Surge IEC 61000-4-5	+/- 0.5, 1 kV line(s) to line(s) +/- 0.5, 1, 2 kV line(s) to earth	
Conducted disturbances induced by RF fields IEC 61000-4-6	Professional Health Care 3V 0.15-80 MHz 6V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1kHz	
Voltage dips IEC 61000-4-11	0 % U_T for 0.5 cycle 0, 45, 90, 135, 180, 225, 270 and 315° 0 % U_T for 1 cycle 0° 70 % U_T for 25/30 cycles 0°	
Voltage Interruptions IEC 61000-4-11	0 % U_T for 250/300 cycles 0°	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 or 60 Hz	

NOTE U_T is the a.c. mains voltage prior to application of the test level.

7 Storage & Shipping

The Endosee Advance System is shipped in a protective box.

Note: Do not dispose of protective box or any other shipping materials. These items should be retained for future storage or transport of the equipment.



CAUTION: Do not attempt to transport or ship the Endosee Advance System without using proper packaging to protect the product. Store at room temperature.

8 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 Endosee Advance System.

Any issues determined to be beyond the scope of the basic user troubleshooting steps provided in this IFU should be communicated to the CooperSurgical, Inc. Customer Support department.



WARNING: The Endosee Advance System contains no user-serviceable components within the enclosure. To avoid electrical shock or damage, the unit must not be disassembled. Doing so will void the warranty.



WARNING: Do not disassemble or alter the battery in any way.



WARNING: Battery is not replaceable.

Problem	Test	Action
When switched ON, there is no display on screen or dark image.	Is the Cannula tip LED illuminated?	<ul style="list-style-type: none"> If NO, first ensure Cannula is fully inserted in the Display Module. If still no illumination/screen display, switch to a new Cannula. If YES, contact CooperSurgical, Inc. Customer Service.
Poor picture quality	N/A	<ul style="list-style-type: none"> Clean Cannula tip with a sterile, clean, touch wipe. Ensure Cannula is fully inserted in the Display Module.
Image on screen flickers or has lines across it	N/A	<ul style="list-style-type: none"> Ensure Cannula is fully inserted in the Display Module.
Image displays on half of the screen	N/A	<ul style="list-style-type: none"> Disconnect and reconnect the Cannula.
Touchscreen is unresponsive	N/A	<ul style="list-style-type: none"> Press and hold the Power Button for 5 seconds and restart the unit.
No Data Transfer/File access over USB	N/A	<ul style="list-style-type: none"> Instruct hospital IT department to configure the computer to access files via USB 2.0.
Not viewing live image	N/A	<ul style="list-style-type: none"> Ensure display module is in Exam or Preview Mode not Playback Mode. Disconnect and reconnect the Cannula - enter Exam or Preview Mode. If issue persists, contact CooperSurgical Inc., Customer Support
Incorrect image orientation	N/A	<ul style="list-style-type: none"> Disconnect and reconnect the Cannula. Press and hold power button for 5 seconds and restart the unit. If issue persists, contact CooperSurgical Inc., Customer Support
Display not turning on while pressing the power button	N/A	<ul style="list-style-type: none"> Connect Display module to Docking Station to recharge. If issue persists, contact CooperSurgical Inc., Customer Support

9 Technical Assistance

For technical information, assistance or to order parts or IFU, contact CooperSurgical, Inc., Customer Support Department, or your local CooperSurgical, Inc. representative.

Information regarding system serial number is available from Customer Support.

CooperSurgical®

95 Corporate Drive • Trumbull, CT 06611 • USA

Phone: (800) 243-2974 • Fax: (800) 262-0105

International

Phone: +1 (203) 601-9818 • Fax: +1 (203) 601-4747

www.coopersurgical.com

10 Technical Specifications

DISPLAY MODULE

Diagonal Size of Display Area:	125 mm (4.9 in)
Thickness:	22 mm (0.9 in)
Horizontal:	136 mm (5.4 in)
Height:	91 mm (3.6 in)
Weight (cannula, display):	281 g (0.6 lbs)

STERILE, SINGLE-USE CANNULA

Cannula Working Length:	278 mm (11 in)
Tip Largest Outside Dimension:	4.3 mm (0.17 in)
Pre-fixed tip angle:	20° ± 5°

POWER ADAPTER REQUIREMENTS

Input Power Range:	100-240V AC/0.2-0.4A
Frequency:	50/60Hz
Output:	5.99V DC/2.0A
Cable Length:	4 ft.
Charging Connector:	AC Adapter incorporated into Docking Station

BATTERY SPECIFICATIONS

Battery Type:	Lithium-ion rechargeable battery
Capacity:	3.7V rating, 1320mAh
Maximum Voltage when Battery is fully charged:	4.2 V
Minimum working voltage is:	≤ 3.0V
Full Charge Time:	Approx. 2 hours
Operating Time:	1 hour

SITE REQUIREMENTS — OPERATING CONDITIONS

Operating Temperature:	Environmentally Controlled Room Temperature
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11 Warranty

CooperSurgical, Inc. warrants that the device(s) supplied is free from defects in materials or workmanship. This warranty is valid only if the product is supplied to the end user by a CooperSurgical, Inc. approved agent or distributor and has been maintained in accordance with procedures documented in the IFU. If failure occurs from manufacturing defects within 12 months of purchase, CooperSurgical, Inc. will repair or replace the defective item.

Endosee® Advance is a registered trademark of Coopersurgical, Inc.

CaviWipes® is a registered trademark of Metrex Research Corporation.

DisCide® is a registered trademark of AliMed, Inc.

Sani-Cloth® is a registered trademark of Professional Disposables International, Inc.

Clorox Healthcare® is a registered trademark of the Clorox Company.

Assembled in the USA

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CooperSurgical Distribution B.V.
Celsiusweg 35, 5928PR Venlo,
The Netherlands

 CooperSurgical, Inc. • 95 Corporate Drive • Trumbull, CT 06611 USA

CooperSurgical®

Phone: (800) 243-2974 • Fax: (800) 262-0105

International:

Phone: +1 (203) 601-9818 • Fax: +1 (203) 601-4747

www.coopersurgical.com