



Nuvis[®] Wireless 2K Camera System

Model: IE3000SYS-N1
Instructions for Use (IE-IM1000)



Rx only

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician or licensed medical practitioner.



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SECTION I: INTRODUCTION

WARNINGS

- Before operating the unit, please read this manual thoroughly and retain for future reference.
- Read and follow warnings from other tools used in the procedure.
- Do not confuse the displayed live image with a recorded image. Live images on the display will have additional control icons next to the image while a recorded image on the display will not.
- Before each use or after a change of viewing modes/settings, visually check that the viewed image is the correct image and image orientation.
- After taking an image or video, confirm that the image or video was recorded. During recording, if the Wireless Base Station power is turned off, or the power supply from the adapter lost power, the recorded data of the latest video will be lost.
- Clean and sterilize the equipment prior to and after use to minimize the potential for infection. Cleaning and sterilization instructions are provided in Section V.
- No modifications of this equipment are allowed.
- Perform white balance correction to assure that the image colors are balanced. White balance correction is recommended when a new endoscope or light source is used.
- Avoid overloading electrical outlets that supply power to the system.
- Multiple socket-outlets or extension cords should not be connected to the Wireless Base Station or camera Charging Station to prevent overloading the electrical outlets.
- The system cannot be connected to an IT Network. Do not attempt to connect devices not approved for use with the system.

Camera Head

- Do not block the Camera Head transmitter antenna cover (the black part of the Camera Head) as the wireless signal may be weakened.
- Periodically inspect the Camera Head and clean/sterilize if dirty.
- Clean the camera optics as needed.
- Use the camera cap to prevent damage to the camera optics during storage.
- The Camera Head is NOT autoclavable.

Wireless Base Station

- Place the Wireless Base Station and Charging Station on a flat, hard and stable surface to prevent damage.
- The Wireless Base Station should be placed in an area where there are no metal pillars or materials that could interfere with the signal from the Camera Head.
- Do not block the ventilation slots or cover the Wireless Base Station in operation as this may cause overheating.
- Use the system provided power supply adapters only.
- Route the power cord so that it will not be stepped on, pinched or damaged by heavy items.
- Unless indicated, never stick anything into the Wireless Base Station slots or remove the covers.
- The Wireless Base Station and camera Charging Station should not be exposed to dripping, splashing, moisture, shock, heat or damage.
- The Wireless Base Station should be turned OFF before connecting it to a display with the provided HDMI cable.

- Disconnect the system from the wall power source if it is left unattended for a long period of time to protect the system from electrical hazards.

Camera Head Charging Station

- Do not expose the Camera Head Charging Station to dripping, splashing or moisture.

To prevent an unacceptable risk if endoscopic equipment loses function:

- Always check the proper functioning of your system and endoscopic equipment prior to the start of the procedure.
- Always video record your imaging session and save the video so that the images viewed prior to the loss of endoscopic function can be re-played and assessed.
- Keep an Eye Coupler available for visualization in case there is a loss or degradation of display on the monitor.
- Note: If the imaging data is not displayed, check the camera battery power and all connections such as the C-mount Coupler, illumination source, and cables. Also, ensure that the coupler is correctly focused. If everything appears satisfactory, and the image is still not displaying, consider replacing the endoscope.

CAUTIONS

- Portable RF communications equipment should be used no closer than 20 cm (8 inches) to any part of the Nuvis Wireless 2K Camera System. Otherwise, degradation of the performance of this equipment can result. If the system will be used adjacent to or stacked with other equipment, normal operation of the system under such configurations should be verified via observation.
- Connect only items that have been specified as part of the system or that have been specified as being compatible with the system. The use of accessories and cables other than those specified, with the exception of replacement parts sold by IE, may result in increased emissions or decreased immunity for the system.
- The system has been designed, inspected and tested to comply with the safety requirements of IEC 60601-1 with respect to fire, shock and mechanical hazards, only if used as intended.
- Do not attempt to replace the Camera Head batteries. The rechargeable batteries are not intended to be replaced.
- Lightning: Disconnect the Wireless Base Station and camera Charging Station from the wall power source if the system will not be used for a long period of time to protect the system from lightning or electrical surges.
- Any changes or modifications not expressly approved by the grantee of this device can void the user's authority to operate the equipment.
- This equipment must be installed and operated in accordance with provided instructions.
- The Wireless Base Station antenna(s) used for receiving and transmitting must be placed to provide a separation distance of at least 20 cm from all persons and metal, and must not be co-located or operating in conjunction with any other antenna or transmitter.
- The user should periodically inspect the device for damage. Do not use if the device is damaged.
- Contact IE if you should experience problems with the system.

CONTRAINDICATIONS

There are no known contraindications associated with the use of this device.

INDICATIONS FOR USE

The Nuvis Wireless 2K Camera System is indicated for use in diagnostic and operative arthroscopic procedures, supplying visualization of an interior cavity of the body.

The users of the System include general surgeons and orthopedic surgeons. Some of the common arthroscopic procedures include arthroscopy of the knee, shoulder, elbow, and ankle.

Device Description

The Nuvis Wireless 2K Camera System (or “System”, “Nuvis-2K”, or “IE3000SYS-N1”) consists of two wireless 2K reusable Camera Heads that can be paired to a Wireless Base Station. When a Camera Head is attached to an arthroscope/light source (using a C-mount coupler) AND the Wireless Base Station is attached to a clinic supplied video system, arthroscopic examinations can be viewed and pertinent data recorded. A touch screen monitor or mouse can be connected to the Wireless Base Station to enter patient and case data.

The System can transmit uncompressed video content from the Camera Head to the Wireless Base Station up to 5 meters (15 feet) away.

Recorded video and pictures are wirelessly saved to an internal storage drive and managed in the Wireless Base Station. The recorded video and pictures can be moved or copied onto a configured USB Drive (FAT32 or NTFS configured).

The system includes:

Provided System components	Model/Re-order Number
Nuvis® Camera Head	IE-CH1000
Nuvis® Camera Charging Station	IE-CS1000
Nuvis® Wireless Base Station	IE-BS1000
Nuvis® Touch Monitor	IE-TC1000
Nuvis® C-mount Coupler	IE20CMT
Nuvis® Sterilization Tray	IE-ST1000
Nuvis® Wireless Base Station Power Supply Adapter	IE-BA1000
Nuvis® HDMI Cable	IE-HC1000
Nuvis® USB Cable	IE-UC1000
Nuvis® Instruction Manual	IE-IM1000
Nuvis® Wireless Mouse	IE-WM1000
Nuvis® DVI/HDMI Adapter	IE-MO3000

Wireless Base Station (WBS)

The Wireless Base Station receives live video transmitted from the Camera Head and transmits the images onto an attached clinic supplied video system (using HDMI cable) and/or other display monitors.

The Wireless Base Station is powered through a wall plug.

The Wireless Base Station internally stores (via a PCIE M2 SSD internal storage drive with 1T storage capacity) recorded video and still images transmitted from the Camera Head. Up to 110 hours of high quality 2K@60fps (2K resolution at 60 frames per second) video recording can be stored.

The stored video and still images can be moved or copied onto a configured USB Drive (FAT32 or NFTS configured).

The front panel USB3.0 port allows for convenient downloading of stored video and still images to the configured USB drive. The front panel USB3.0 port data copy speed is around 30Mb/s.

The back panel contains HDMI ports for two (2) signal outputs. One is for a clinic supplied video system. The second HDMI port, paired with the back panel USB3.0 port can be used to attach the Touch Monitor to the Wireless Base Station or for touch input to control high-speed downloading of stored video and still images.

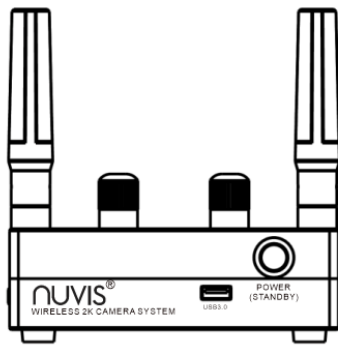


Figure 1 Front View of the Wireless Base Station

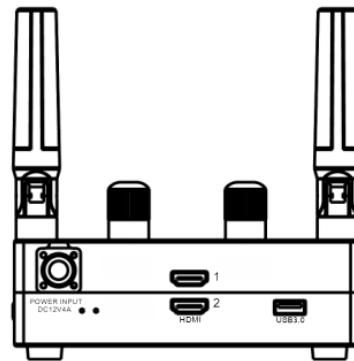


Figure 2 Back panel of the Wireless Base Station

Touch Monitor

The Touch Monitor can be attached to the Wireless Base Station to:

- Enter patient and case data
- Start/stop video recording and record image stills
- View data stored on the Wireless Base Station internal storage
- Facilitate the movement of data stored on the Wireless Base Station internal drive to an external USB drive
- Facilitate the removal of data stored on the Wireless Base Station internal storage
- View the status of the Camera Head batteries

The connection of the Touch Monitor to the Wireless Base Station can only be made using the provided USB to USB cable, and HDMI to HDMI cable. USB 3.0 port on the rear panel provides power supply and touch screen data communication to the touch screen controller.

All entered patient and case data is stored onto the Wireless Base Station internal storage. The Touch Monitor does not store any data.

The Touch Monitor cannot connect to the Internet nor to any wireless communications such as: Bluetooth, WIFI, 4G communications, SIM, etc.



Figure 3 Front and Side View of the touch screen controller

Camera Head

The Camera Head contains a CMOS camera, camera controls, a high-performance antenna, and rechargeable batteries. The Camera Head enclosure is anodized aluminum.

The camera sensor allows 2K @ 60 (frames/second) resolution and 1920(H) × 1080(V) pixel images.

Camera controls can allow the user to power the Camera Head ON/OFF, zoom, start/stop video recording, and snap still images. A White Balance correction can also be conducted.

Each Camera Head contains built in re-chargable batteries to ensure over 3 hours of operation time. Up to eight (8) Camera Heads can be configured to work with a single Wireless Base Station. However, the Wireless Base Station will only recognize one Camera Head at a time (the last one powered ON).

A wall powered camera Charging Station is included with the system. The Charging Station displays the Camera Head charging status and can accommodate two Camera Heads simultaneously. Charging will automatically stop when the Camera Head is fully charged. The wireless Camera Head signal is automatically cut off when the Camera Head is put into the Charging Station dock.

The Camera Head is not intended to contact the patient directly and is provided non-sterile. The Camera Head can be manually cleaned, disinfected, and sterilized as needed. The Camera Head and C-coupler can be sterilized (low temperature plasma/hydrogen peroxide) through the use of a provided sterilization tray. A commercially available sterile disposable sleeve/drape can be used to cover the Camera Head if desired.

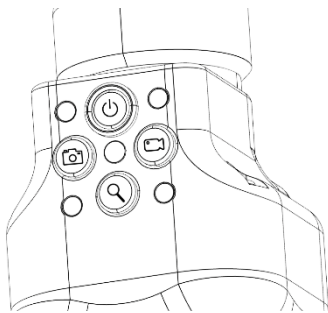






Figure 4 Camera Control Panel

Legend

Icon	Name	Input	Output
	Power	Short Press	Camera Head Power ON
		Short Press 2 times	Camera Head Reconnection
		Long Press	Camera Head Power OFF
	Camera	Short Press	Take a picture
		Long Press	Start a case
	Video	Press	Start and Stop Video
	Zoom	Press	Zoom In/Out Loop: 100% ->135% ->175% ->100%
		Long Press	Start white balance correction

Camera Head battery status

Camera Head battery icon on the display	Battery capacity percentage (as shown on the Charging Station)	Charging status LED	Estimated charging time until fully charged (minutes)	Estimated Operation time (hours)	LED light on the Camera Head control panel
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4 level (green)	100%	ON	120-150	3.5-4	Solid light
4 level (green)	75-100%	Blinking	90-120	3-3.5	
3 level (green)	50-75%	Blinking	60-90	2-3	
2 level (green)	25-50%	Blinking	30-60	1-2	Slow blinking
1 level (green)	0-25%	Fast Blinking	0-30	0-1	Fast blinking

* Camera Head battery status (timed and power remaining percentage are estimated. The figures in the table are measured under the following conditions: ambient temperature 25°C, new Camera Head. Charging and operation time is affected by ambient temperature and battery age and amount of use.)

Symbols Used



Follow instructions for use



Medical device



Manufacturing date



Manufacturer



Model number



Lot number



Serial number



Unique Device Identifier



Storage and transport temperature



Storage and transport humidity



Storage and transport pressure



Waste Electrical and Electronic Equipment Directive (WEEE Directive)



Keep dry

Indicates a medical device that needs to be protected from moisture.



General warning sign



Caution

Rx only

Prescription only



CE marking



Federal Communications Commission (FCC)



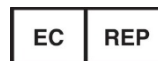
Class II device



Power (Stand-by)



Consult instructions for use




















European Authorized Representative



Non-sterile

Camera Head Button Marks & Display UI Icons Descriptions

Marks on the Camera Head control button			User interface icons appear on Touch Monitor and clinic provided display		
Marks	Name	Description	Icons	Name	Description
	Power	Camera Head power ON/OFF		◎ Camera	Take a picture
	☆ Camera	Take a picture Start a case (multi-function)		◎ Video	Video recording Start/stop
	Video	Video recording Start/stop		◎ Data/system	Patient data management & system setting
	☆ Zoom	Zoom in White balance (multi-function)		☆ ◎ Patient info	Patient info input Start a case (multi-function)
				Camera Head battery	Camera Head battery level
				Internal storage	Internal M2 storage (PCIe M2 SSD card)
				External storage	External USB storage
				Camera Head W/B	White balance automatic correction
				◎ Data management	Patient data management
				◎ System setting	System setting
				◎ Wireless Base Station & Touch Monitor connection	Wireless Base Station & Touch Monitor wired connection authorization management
				★ Add a Camera Head into the system	Wireless Base Station & Camera Head T/R pairing
				★ Camera Head setting	Camera Head manufacture setting

◎ Icons can be used as a button on Touch Monitor screen.

★ Icons are hidden from users, they are designed for maintenance and manufacturing settings.

☆ Multi-function button: two functions are realized by short pressing and long pressing (more than 3 seconds)

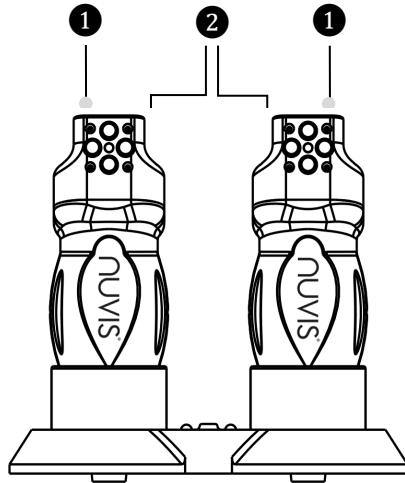
SECTION II: Setting Up the System

System Components

Check that you have all of the components in the description as well as those identified below:

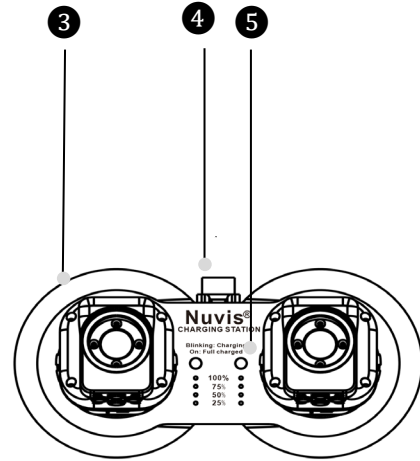
Parts Names & Functions

Camera Heads (shown in Charging Station)



Front

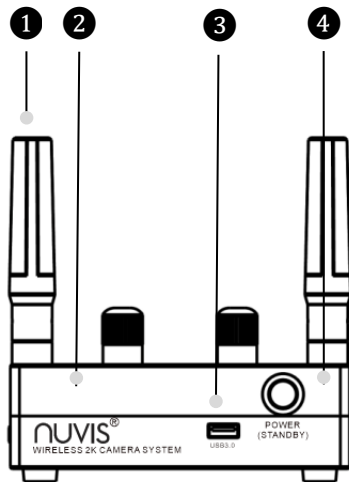
- ① Wireless Camera Heads
- ② Wireless communication & control buttons
- ③ Charging Station



Above

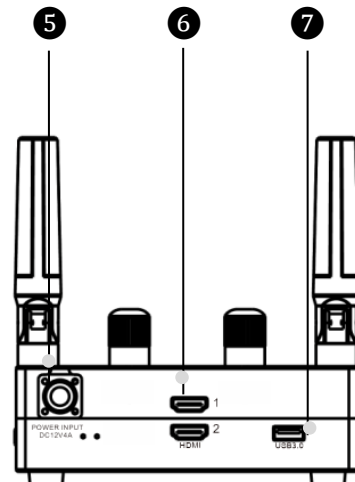
- ④ Charging Station power input socket (Power input DC12V4A)
- ⑤ Charging status LED display

Wireless Base Station



Front

- ① Wireless control and communication antenna
- ② Wireless Base Station housing
- ③ Front panel USB 3.0 port (for patient data copy and mouse connection)
- ④ [Power] button ON/OFF (standby)



Rear

- ⑤ Power input socket (DC 12V, 4A)
- ⑥ HDMI OUTPUT 1 for clinic display & HDMI 2 for live video streaming to the cloud or head-mounted OLED display
- ⑦ Rear panel USB 3.0 port (for touch screen power and data communication)

Procedure Components that are not included in the system

Required
Endoscope and light source (such as a Nuvis® battery endoscope which has an integrated light source)
Clinic supplied video monitor to view live images

Recommended Components that are not included in the system

Recommended
<p>External Storage:</p> <ul style="list-style-type: none"> • For data backup, use external USB storage connected to the front panel USB 3.0 port. • You may transfer data from the internal SSD to external USB storage. • Recommended external storage: <ol style="list-style-type: none"> 1) Minimum 128GB capacity (up to 1TB supported) 2) Must be formatted as FAT32 or NTFS 3) SSD-based USB drives recommended for faster transfers <p>Recommended Flash Drive Specifications:</p> <ul style="list-style-type: none"> • Brand/Model: SanDisk Extreme Pro (CZ880/CZ900) • Capacity Options: 256GB / 512GB / 1TB <p><u>Sterile Drape</u> if sterilization of Camera Heads is unavailable.</p>

Set Up the Camera Charging Station

Place the Charging Station onto a flat and stable surface to prevent damage. Plug the Charging Station into the wall power. Be sure the power cord is routed so that it will not be stepped on or pinched by heavy items. The Charging Station's LED's will illuminate.

Clean the Camera Head(s)

Clean using the procedure in Section V. **Note: The Camera Heads are supplied non-sterile.**

Charge the Camera Head(s)

For shipping and transportation safety, the cameras built-in battery will be almost completely discharged. So, when the camera is first used, please charge it for at least 2 hours.

Place the camera charger on a flat stable surface

Connect the DC power cable of the supplied AC adapter into the DC I Station and confirm plug has self-locked

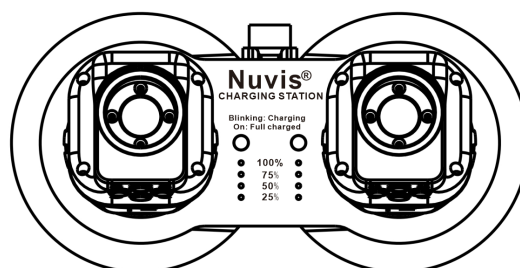
Plug the DC power cable to wall power. Be sure the power cord is not pinched by heavy items, causing damage.

Confirm the LEDs are blinking slowly (once every 3 seconds), indicating the Camera Head is being charged. Put the Camera Head into the Charging Station to charge the cameras.

Two Camera Heads can be charged at the same time

Charging status is indicated by three LED modes:

- Slow blink (once every 3 seconds): Ready to charge
- Normal blink (once per second): Charging



- Solid light (LED on): Fully charged
- At 100% charge with normal blinking: The battery enters trickle charge mode.
- 25% charge level with normal blinking: Fast charging in progress.

Camera Head battery status (timed and power remaining percentage are estimated. The figures in the table are measured under the following conditions: ambient temperature 25°C, new Camera Head.

Charging and operation time is affected by ambient temperature and number of cycles.)

Camera Head battery icon on the display	Battery capacity percentage on Charging Station	Charging status LED	Estimated total charging time (minutes)	Estimated operation time (hours)	LED alert on Camera Head
4 level (green)	100%	ON	90-190	3.5-4	2 to 4 hours, solid green LED
4 level (green)	75-90%	Blinking	65-90	3-3.5	
3 level (green)	50-75%	Blinking	50-65	2-3	
2 level (green)	25-50%	Blinking	25-50	1-2	Slow blinking
1 level (green)	0-25%	Fast blinking	0-25	0-1.0	Fast blinking

TIP

- The Camera Head can be charged regardless of position it is placed in the Charging Station dock
- Confirm that the Camera Head is fully seated in the charger
- Confirm that the charging status LED and battery level are displayed normally. If not, remove and place the Camera Head into the charging dock again
- The wireless Camera Head signal is automatically cut off when it is put into the charging dock
- When the Camera Head is fully charged, the charging automatically stops
- If the Camera Head short circuits, the Camera Head automatically turns [Power] off and locks
- To unlock the Camera Head, put it into the Charging Station for 3 seconds and take it out

Sterilize

Sterilize the Camera Head(s) and C-mount coupler(s) using the procedure described in Section V.

Set Up the Wireless Base Station

Place the Wireless Base Station onto a non-metallic flat surface. Do not block the cooling vents. The space between the Wireless Base Station and the wireless camera should be clear of metal pillars/posts and materials which could block the wireless signal.

The Wireless Base Station must be located with a separation distance of at least 20 cm from all persons and metal and must not be co-located or operating in conjunction with any other antenna or transmitter.

Connect the HDMI cable from the Wireless Base Station back panel to the clinic supplied video system (if used). Up to two HDMI devices may be connected to the Wireless Base Station.

Plug the Wireless Base Station power cord to the wall power.

Be sure the power cord is routed so that it will not be stepped on or pinched by heavy items, causing damage.

The power button light (on the front) will illuminate when pressed on.

Set Up the Touch Monitor

Connect the Touch Monitor to the Wireless Base Station using the provided USB-C cable and HDMI cable.

Turn on the Touch Monitor, and verify that the below interface appears on the screen.

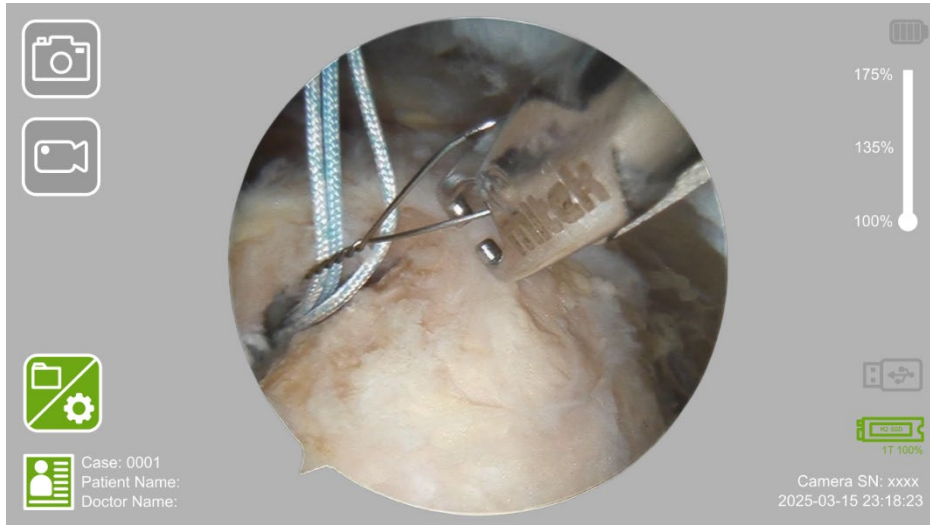


Figure 5 Main Interface

Set Up External Storage

USB Flash Drive Preparation:

- 1) Format Verification:
- 2) All new USB 3.0 flash drives must be pre-formatted to FAT32 or NTFS
- 3) exFAT-formatted drives must be reformatted to FAT32 or NTFS

Initialization Process:

When inserting a compatible drive:

- a. The system automatically detects and configures it as FAT32
- b. Capacity and available space display after 15-second initialization
- c. Wait until the capacity information appears before use

System Recognition:

The USB port automatically distinguishes between:

- a. Mouse devices
- b. Storage devices

Note: exFAT drives will not be recognized

USB Connection Guidelines:

1. Connection Behavior:
 - Older or loose USB drives may experience:
 - Extended recognition time
 - Possible failure to be recognized
 - Insertion Method:
 - Firmly insert USB 3.0 drives using both hands
 - Slow insertion may default to USB 2.0 mode
2. Operation Restrictions:

- Never remove or swap drives during:
 - Configuration (15-sec process)
 - Active data transfer
- Consequences of interruption:
 - Extended configuration time
 - Potential data loss
 - Drive recognition failure

Internal SSD Storage Alerts:

- Low Storage Warning (10% Remaining):
- Visual Indicators:
 - Red SSD icon
 - On-screen alert (1 minute duration):
"WARNING: Internal storage below 10% - Data may not save.
Transfer data to external USB immediately."

Internal Storage space is low and data may not be saving.
Download the internal storage data to an external USB
to assure that data is saved.

- Operational Impact:
 - Approximately 3 hours recording time remaining

Critical Storage Warning (5% Remaining):

- Visual Indicators:
 - Persistent red SSD icon
 - On-screen alert (1 minute duration):
"CRITICAL: Internal storage below 5% - Recording disabled.
Transfer or delete files to enable recording."
- Functional Restrictions:
 - Grayed-out recording/case icons
 - All recording functions suspended
 - New case creation blocked
- Reactivation Requirements:
 - Must achieve >5% available space

Internal Storage is extremely low and picture/video taking is closed.
Download the internal storage data to an external USB
or delete files to free up internal storage space.

Critical Safety Notices:

Data Loss Prevention

- The 10-second countdown cannot be canceled
- Remove USB immediately if containing valuable data
- Recommended practice: Use empty dedicated USB drives

Transfer Integrity

- Never interrupt power during data copy
- Verify successful transfer before device removal
- SSD drives recommended for large video files

Technical Specifications:

- Port Type: USB 3.0 SuperSpeed (blue connector)
- File System: FAT32/NTFS only (exFAT unsupported)
- Minimum Capacity: 128GB
- Optimal Performance: USB 3.1 Gen2 SSD drives

Technical Notes:

-
- Write speed: $\geq 800\text{MB/s}$ (SSD recommended)
- Supported formats: JPEG/H.264 with metadata
- Data integrity checks run automatically

Data saving time

H.265	Bitrate	20M kbps	Wireless Base Station built-in internal HI speed storage (PCIe M2 SSD card)
	Size of 2K video recorded data for 1 hour	9GB/1hour	
	Size of a still 2K picture data	0.5M	
	Internal 1T PCIe M.2 SSD SSD storage total saving time	About 111 hours*	Recommended external USB storage for patient
	External 64GB USB storage total saving time	About 7 hours	
	External 32GB USB storage total saving time	About 3.5 hours	

Note: A loose USB drive connection to the Wireless Base Station may increase the time needed for the Wireless Base Station to recognize the USB flash drive. In some cases, the USB may not be recognized.

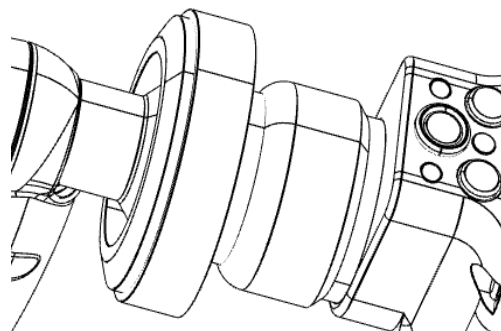
Note: Removing and reinserting the USB drive from the Wireless Base Station during formatting may increase the time needed for the Wireless Base Station to recognize the USB flash drive. In some cases, the USB may not be recognized.

Note: Slowly inserting the USB drive into the Wireless Base Station may increase the time needed for the Wireless Base Station to recognize the USB flash drive.

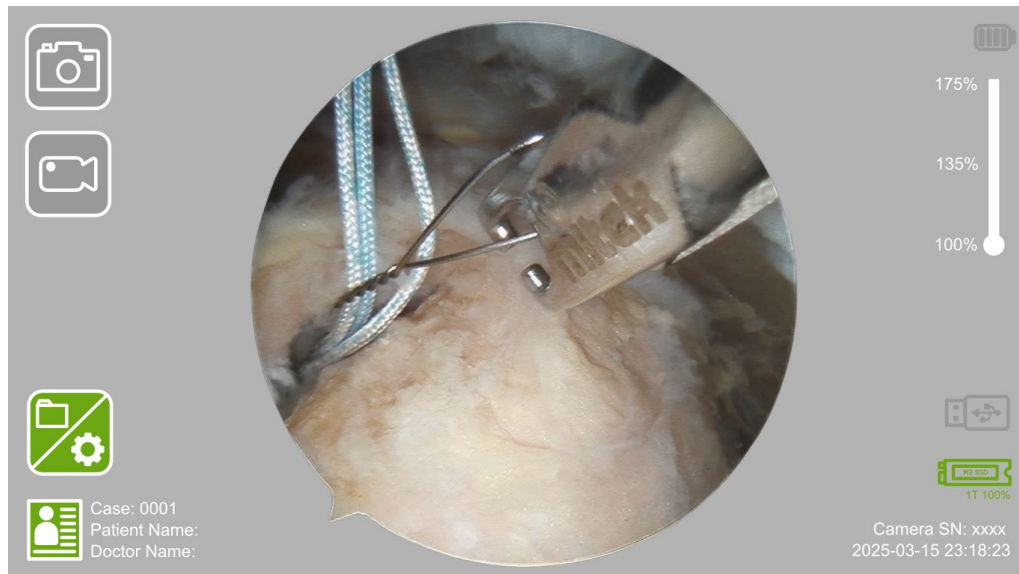
Mounting an Endoscope to C-Mount Coupler

Description & Placement

- The C-mount mechanical optical coupler ("Coupler") serves as the interface between the camera and arthroscope.
- Ensure both the coupler's C-mount and Camera Head's C-mount are completely dry before assembly to prevent condensation.
- Pull back the lever on the coupler to allow the arthroscope to enter.
- Insert arthroscope by eye cup, and release the lever.
- Ensure the arthroscope is fully seated.



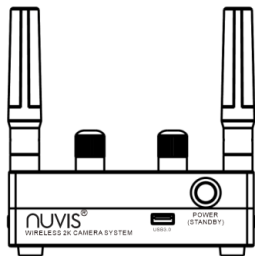
System Standard Configuration



Clinic provided display

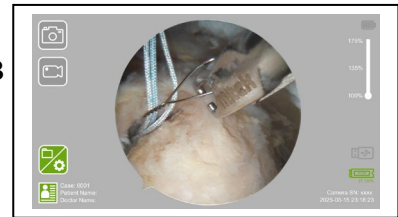
2K video from HDMI 1
cable output to clinical display

System standard configuration



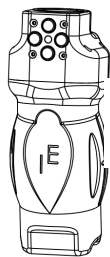
Wireless base station

2K video communication and
control through HDMI 2/USB
cable connected touch screen

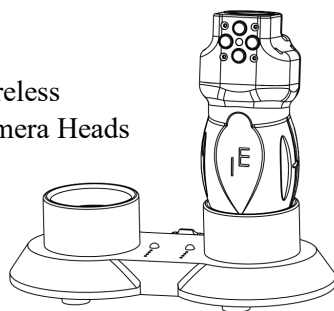


Touch screen controller

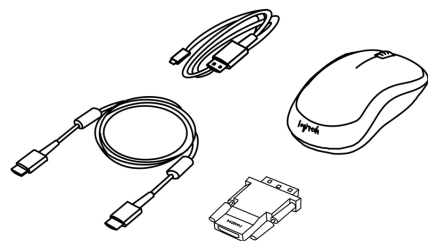
Wireless 2K video
communication and control



Wireless
Camera Heads




Charging station



HDMI cable, USB cable, wireless
mouse, HDMI/DVI converter

Initial Password Set-Up

Select  to access the **Data/System Setting** screen shown below. A password must be set to access patient information and settings. These features will be restricted until a password is set.

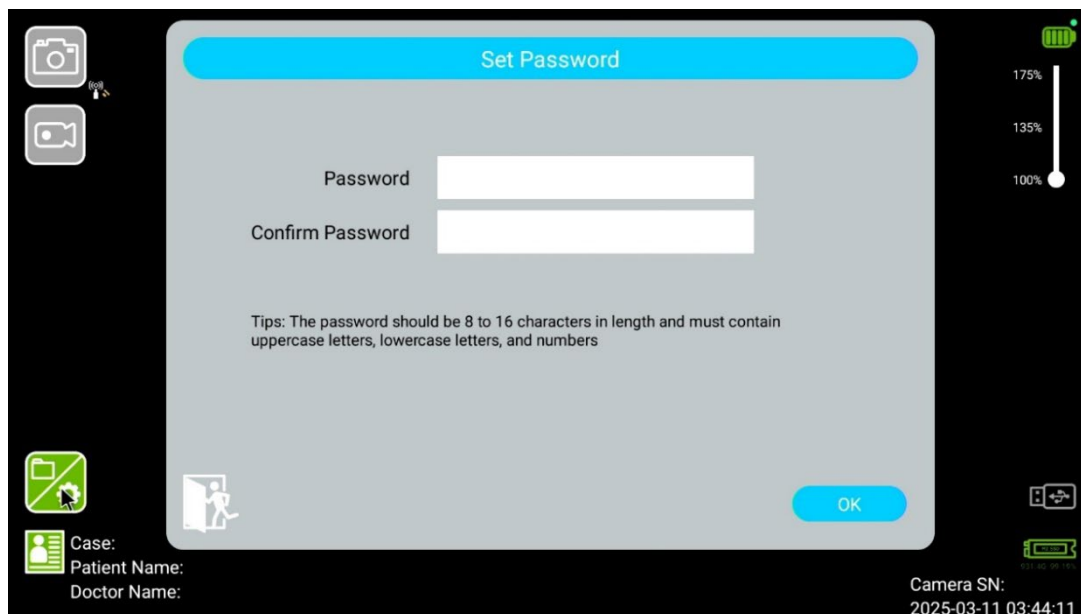


Figure 4 Data/System Setting on top of the Main Operating Screen

Follow on screen prompts to set a password, ensuring that the password meets the system's security requirements (e.g., minimum length, inclusion of numbers or special characters).

For security purposes, ensure the password is strong, kept confidential, and managed responsibly. If a password is lost, it will have to be reset by IE personnel.

Password Recovery

Follow these steps to retrieve a temporary password:

1. Contact the manufacturer to obtain a 5-minute valid temporary password.
2. Provide the base station's serial number and the current time when prompted.
3. Enter the temporary password into the system when prompted.

Once the temporary password is accepted, the system will prompt you to reset your password. Follow the steps below to set a new password:

1. Enter a new password in the designated field.
2. Confirm the new password by re-entering it.
3. Save the new password as instructed.

Note: The temporary password is valid for only 5 minutes. If it expires, the process will have to be repeated.

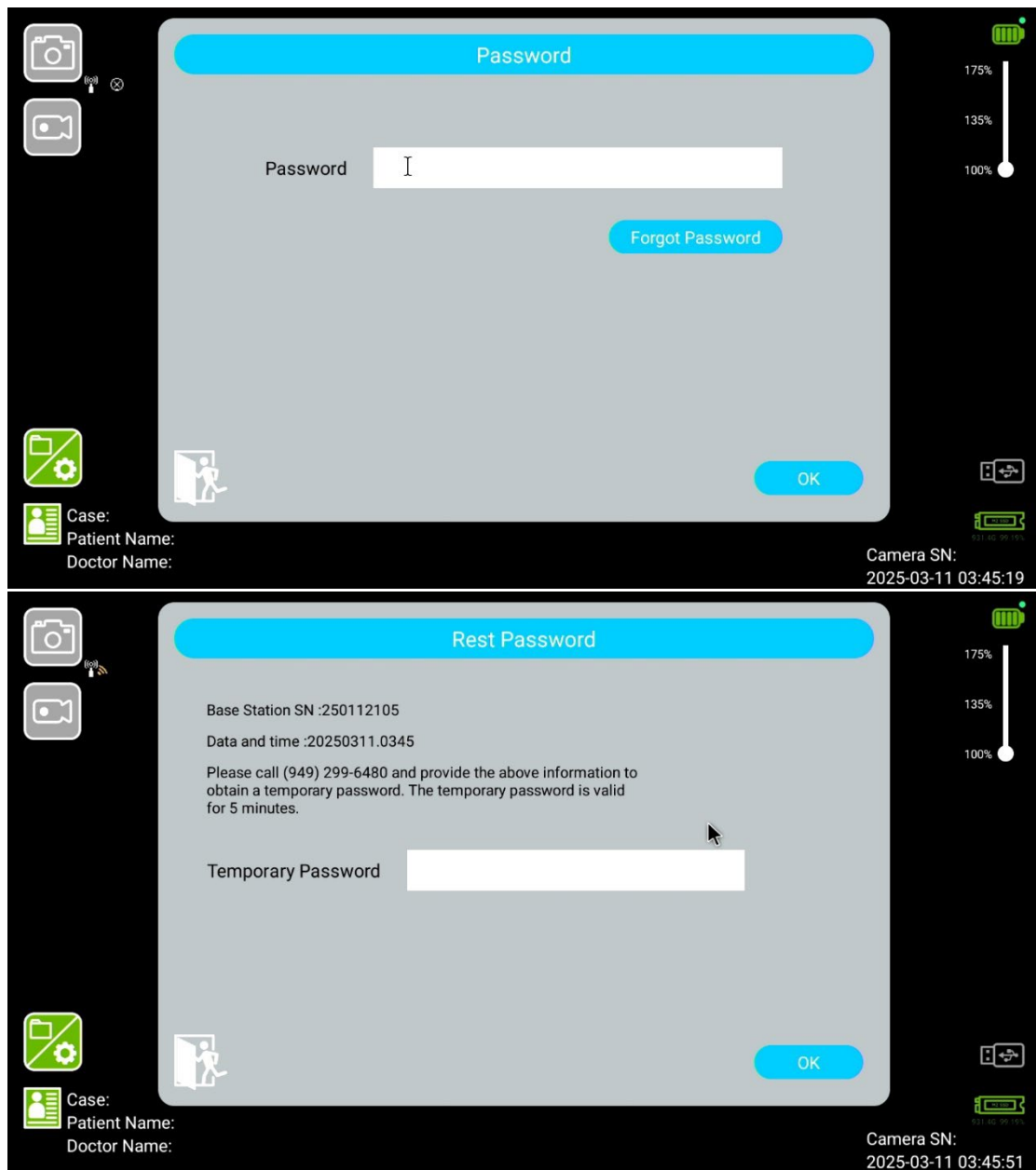


Figure 7 Forgot Password Screen

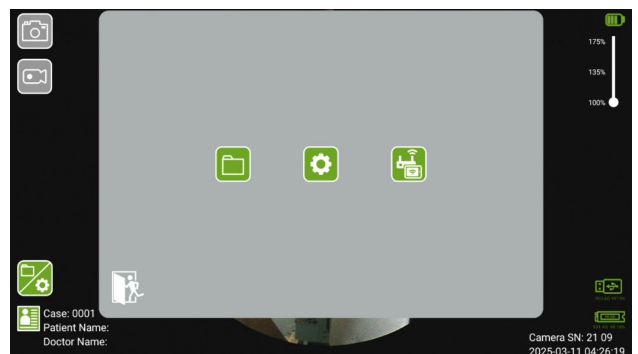
Add Camera Head Communication Number in the System Settings

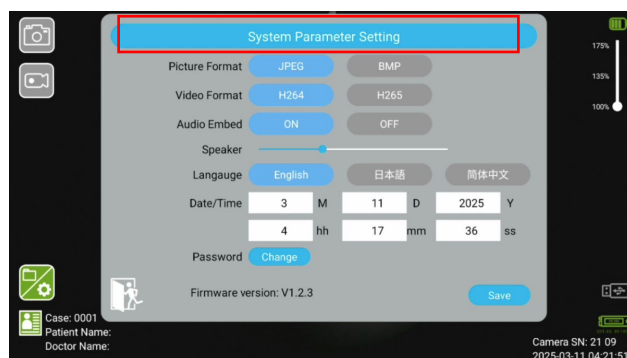
Go to **[Patient Data & System Settings]** in the Graphical User Interface (GUI).



Select **[System Settings]**

Long press the **[System Parameter Setting]** bar for 3 seconds, until the **[Add camera]** and **[Camera menu setting]** comes out

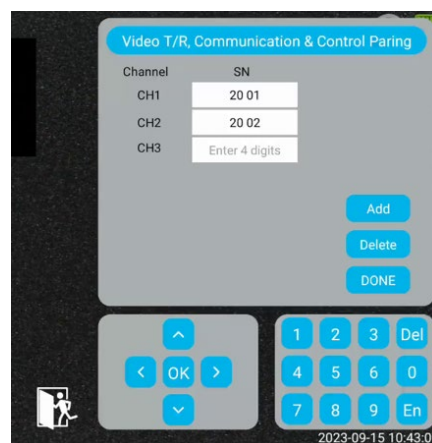




Adding Camera Head to the system steps



1. Before adding camera operation, confirm that the camera power is OFF
2. Press the above icon [Add a Camera Head in to the system], up to 8 Camera Heads can be added
3. Press [Add] button
4. Input the camera SN number from the smaller number into the CH1 position
5. Press [DONE] button
6. Add the second larger SN (serial number) camera to the system by:
 - 1) Press “Add”
 - 2) Adding the Camera Head using the last four digits of the SN SN number on the camera body
 - 3) Press “DONE”
 - 4) Confirm that the SNs are arranged from smallest to largest across Channel 1 (CH1) to Channel 3 (CH3)






System Button Presses and Touch Monitor Icon Colors Overview

A short button press (less than 2 seconds) is used to enable most functions.

A long button press (more than 3 seconds or 8 seconds) is used in these scenarios:

Camera Head:

- Long button Press (more than 3 seconds)  (camera) to initiate a new Case.
- Long button Press (more than 3 seconds)  (Power) to turn OFF the Camera Head power. Note: the middle LED light will turn OFF.
- Long button Press (more than 3 seconds)  (Zoom) to enable the White Balance Correction (WB) feature.

Wireless Base Station:

- Long button Press the Power (Standby) button (more than 8 seconds) to turn OFF the Wireless Base Station power.

Display Icons:

Icons will be colored gray if they are not enabled and green if they are enabled.

Main Operating Screen Display

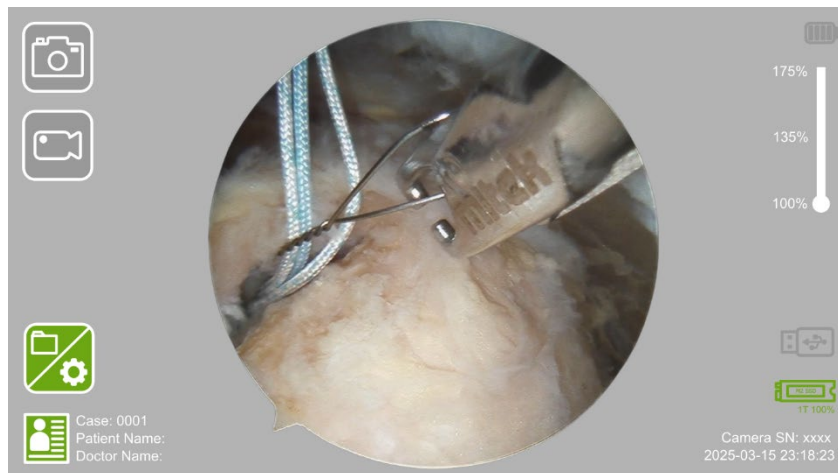


Figure 8 Main Operating Screen (note: The Camera Head serial number and date appear in the lower right corner.)

Displayed Camera Controls

Camera images		Video images		Camera Head battery power	
	Ready to snap images		Ready to record video		Camera Head battery level 100%
	No Camera Head connection or no case number		Recording video		Camera Head battery level less than 100%
			No Camera Head connection or no case number		Camera Head battery level less than 25%.


Other Displayed Information

	Link to the Main Menu
	Patient Information. If entered, Input data displayed.

Wireless Base Station Information


Internal Storage		External Storage	
	Internal Storage Ready		Formatted USB Storage inserted and ready
	Less than 10% Internal Storage remaining		No USB Storage inserted
			USB Storage inserted but under 10% storage space is available

Camera Stills and Video Information

Short press the  button, then further press until you feel a click to minimize potential image blurring.

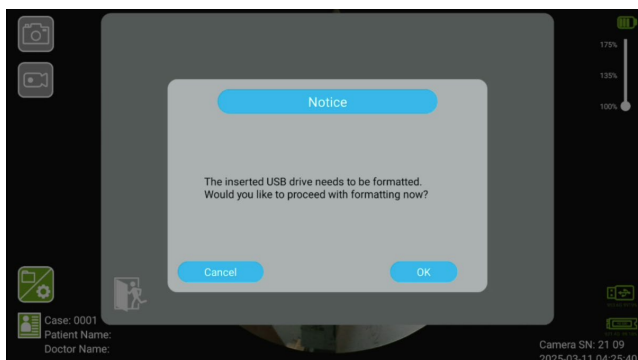
Note: A maximum of 3 pictures can be snapped in 1 second even if the shutter is pressed more than 3 times). During video recording, 2 pictures can be snapped even if the shutter is pressed more than 2 times.

Camera Reconnection to Base Station

In case of unexpected Camera Head disconnection from the base station, short press the  button twice, quickly.

Wireless Base Station Firmware Upgrade

1. An Integrated Endoscopy representative will contact its customers to let them know a software upgrade is available, and provide a link for download or a USB drive for IT personnel.
2. Insert the USB drive into the front or rear USB port of the Base Station.
3. When prompted to format, select "Cancel."



4. Navigate to the USB drive, locate the latest update file, and execute the update.
5. The update will complete in a few seconds. Afterward, you will need to set a new password, similar to the initial setup of a new device.
6. After the APP update, the 1TB internal storage of the Base Station will remain intact, and all data, including patient data stored in the built-in 1T storage, all settings, and passwords, will remain unchanged and will be preserved exactly as they are.

SECTION III: Preparing for a Case

Confirm that the Camera Head is sufficiently charged.

Confirm that the Camera Head and C-Coupler are cleaned and sterilized or draped.

Turn ON the Wireless Base Station by pressing the front panel Power button. The button should illuminate and the control UI is displayed on the clinic supplied monitor screen (within 10 seconds).

Turn ON the clinic supplied display system.

Turn ON the Camera Head by pressing the camera control display power icon. Confirm the correct Camera Head SN number is displayed on the clinic supplied monitor screen (about 15-20 seconds).

Attach the Endoscope using the C-coupler to the Camera Head.

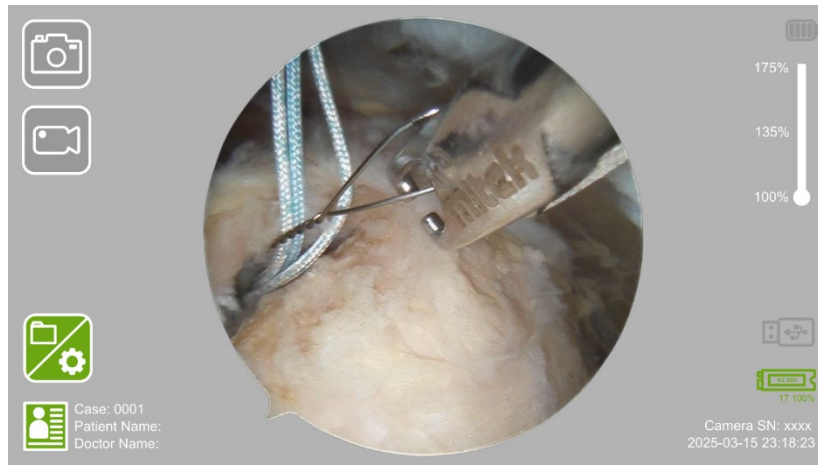


Figure 9 Main Operating Screen

Select  to access the Data/System Setting screen shown below:

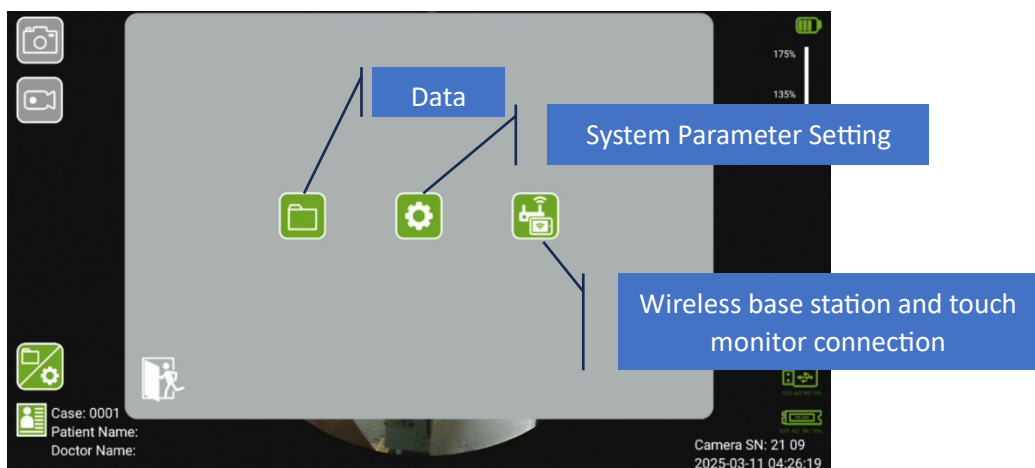


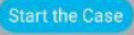
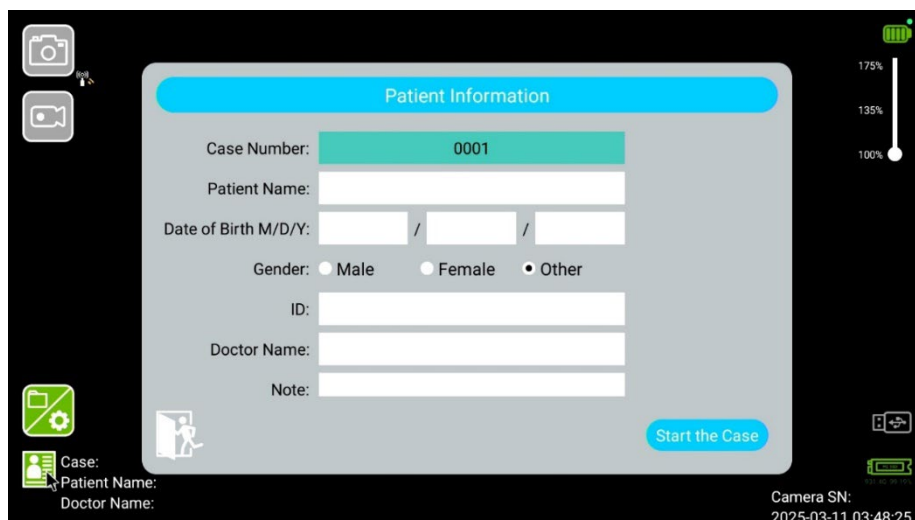


Figure 10 Data/System Setting Screen

Enter Patient Information

Select  **Data** setting or  , to input the patient data. Select  to start the case. Note: after any power interruptions or completion of the case, the patient information (or presets) will reset and will need to be re-entered. The addition of specific patient information is optional. The case number can be used to reference a specific patient to a case.



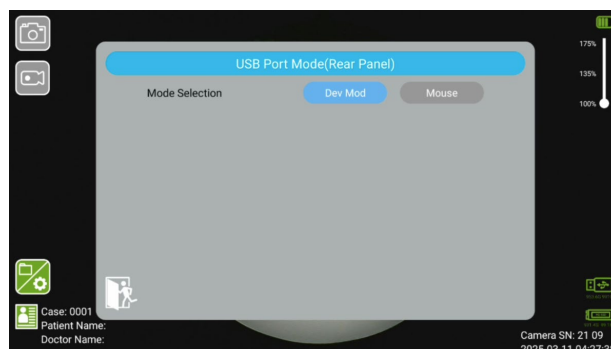
The screenshot shows the 'Patient Information' screen. It features a central form with the following fields: 'Case Number' (0001), 'Patient Name' (empty), 'Date of Birth M/D/Y' (empty), 'Gender' (radio buttons for Male, Female, and Other), 'ID' (empty), 'Doctor Name' (empty), and 'Note' (empty). A 'Start the Case' button is at the bottom right. The screen also includes a battery level indicator (100%) on the right, a 'Case:' label with a person icon on the bottom left, and a 'Camera SN: 2025-03-11 03:48:25' timestamp at the bottom right.

Figure 11 Patient Information Screen

NOTE

The two USB ports on the Wireless Base Station are multi-function designed for Touch Monitor/mouse control, USB data storage, or software upgrades:

- Mode Selection should always be set to “Mouse” mode.
- When in “Mouse” mode, a Touch Monitor, 2.4GHz mouse, or wired mouse can be used to control the Wireless Base Station software. A Bluetooth mouse cannot be used.
- When in “Mouse” mode, an external USB storage device can be used to store data.
- When in “Dev Mod”, software updates can be performed by IE personnel.



White Balance Correction (W/B)

To perform a white balance correction, point the endoscope to a white background (e.g. white medical gauze or a medical sponge). Long press [Zoom] button on the Camera Head until the W/B icon appears on the screen:





Release the [Zoom] button and continue to point the endoscope to the white background.

The white balance correction will take about 5 seconds. When complete, the W/B icon will disappear from the screen. Note: White balance correction is only required when a new endoscope or light source is used.

SECTION IV: Performing a Case

Starting A New Case, Two Options:

Using Camera Head-  Long Press the Camera Head icon on the Camera Head (3 seconds). Confirm that a new case number is displayed. Confirm that the live image is displayed and correctly oriented. This will start a case with an automatically generated case number and no patient information.

Touch Monitor or Mouse Option- Start a new case by selecting the patient information icon , input pertinent information and select the “Start the Case” button. Start a new case by selecting the patient information icon, input pertinent information and select the “Start the Case” button.

Confirm the case number (lower left) and the camera serial number (lower right) appears on the Touch Monitor Main Operating screen. Confirm the picture and recording icons are green. Confirm that the live image is displayed and correctly oriented.

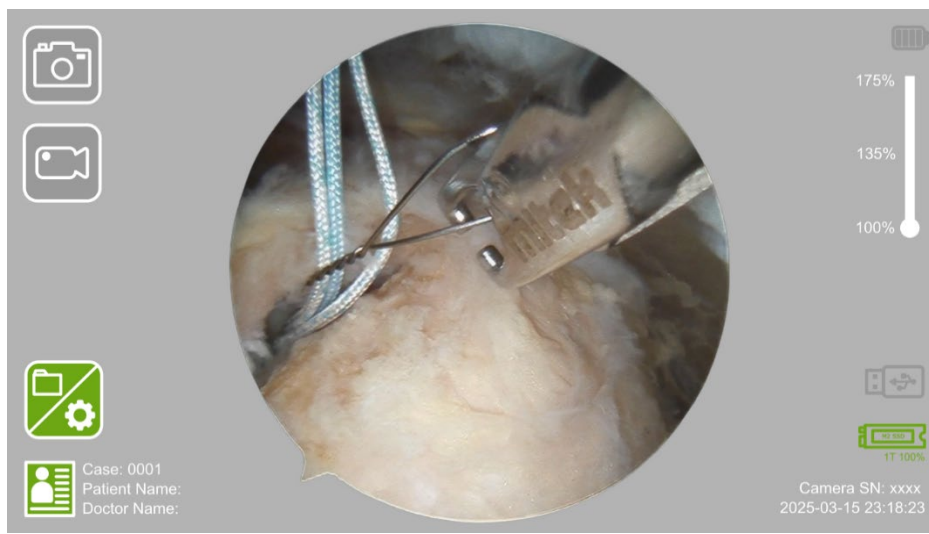




Figure 12 Main Operating Screen




Select  to record a still image or  to start a video recording. This can be done on the Camera Head, Touch Monitor, or with a mouse.

Note: Carefully hold the Camera Head so that the antenna in the Camera Head (the black part of the Camera Head) is not fully covered. The antenna is located at the base of the Camera Head.



Figure 50 Holding Camera

Pictures/Videos Can Also Be Recorded from Control Buttons on Camera Head.

- Press the  [Camera} button to take a picture
- Press the  [Video] button to start and stop the video recording
- Press the  button to zoom in from 100% to 135%, 135% to 175%, and return to 100%

Switching to a new Camera Head

To switch from Camera Head A to Camera Head B (replacement Camera Head), turn the power OFF (long press) on Camera Head A. Power ON Camera Head B. It will take about 15-20 seconds for camera B to be recognized by the Wireless Base Station. Once recognized, the camera B Serial number will be displayed on the video monitor. Alternatively, if both cameras are on, double click the power button on the desired Camera Head to switch to that one.

Copy data from the Touch Monitor control UI

Insert the configured USB drive into the front USB port of the Wireless Base Station. A notification will appear on the Touch Monitor screen: “The newly inserted USB drive needs to be formatted, would you like to proceed with formatting now?”. Do not remove the external USB during formatting. The USB external storage icon on the Touch Monitor screen turns from gray to green when formatting is complete.

Patient data such as photos and videos or folders can then be copied into the external USB storage. They can also be viewed by clicking on the case file.

Copy patient data from [Data/system], in the data management page, press [Copy] button for one way copy directly to external USB storage.

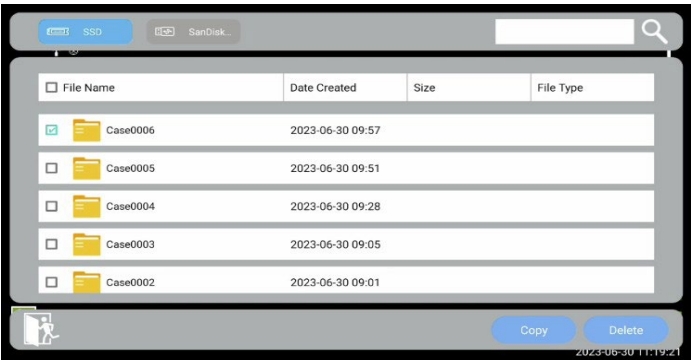


Figure 63 Storage Screen

Select the file to be copied, press [Copy]

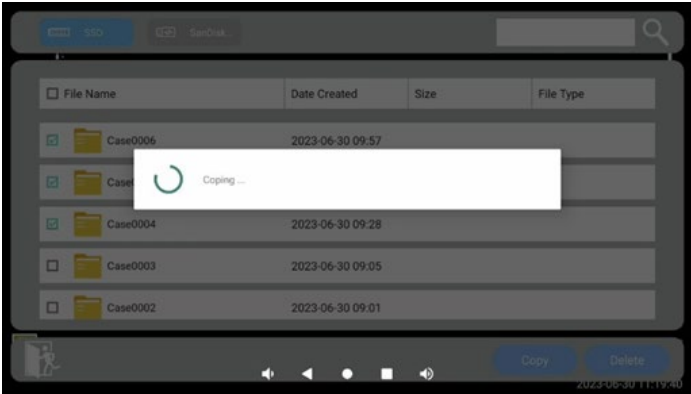


Figure 74 Copying Screen

Confirm the selected files are copied in external storage.

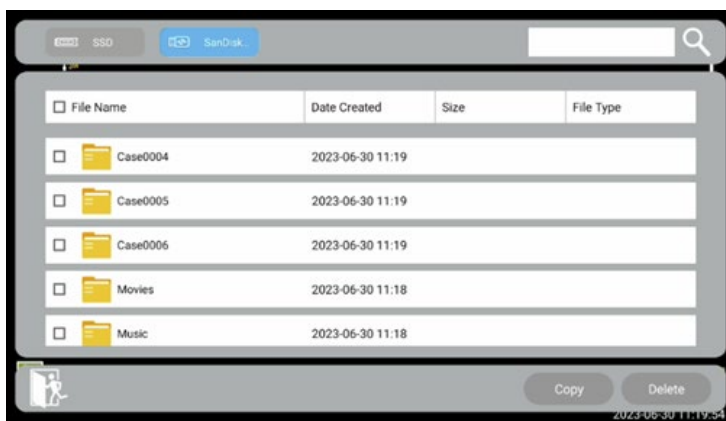


Figure 85 File Storage Screen

Note: Examples of file names are:

Case0001_20230313_181239_William.jpg (if patient name of “William” is entered)

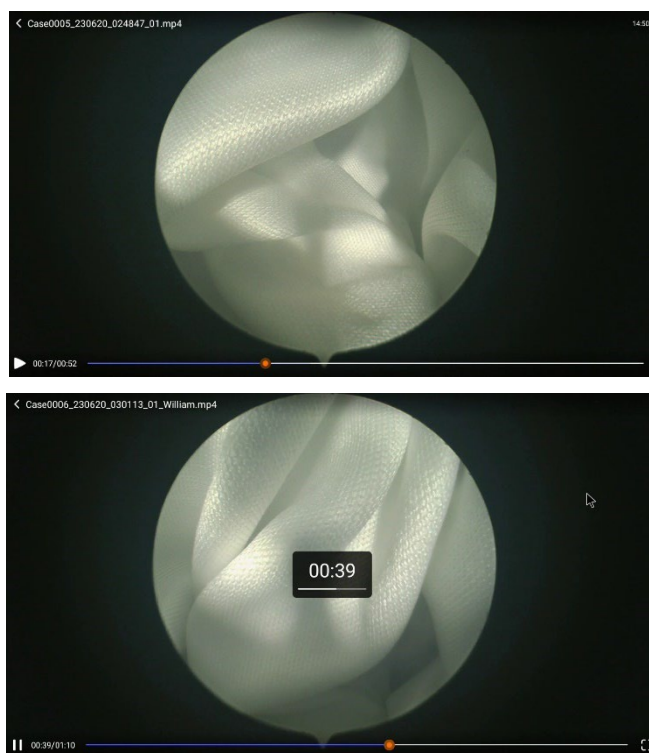
Case0001_20230313_181239.jpg (for a still photo and no patient name is entered)

Case0001_20230313_181239.mov (for a video and no patient name is entered)

Play videos

The next and previous buttons can select the next or previous video to play

Swiping left or right on the screen can fast forward or rewind the video play



Finishing the Procedure/ Shutdown Procedure

⏻ Turn OFF the Camera Head (long press 3+ seconds). Confirm that the center Camera Head LED light is OFF.

Remove the external USB storage. Store the external USB drive in a safe place to mitigate the potential for data theft or loss.

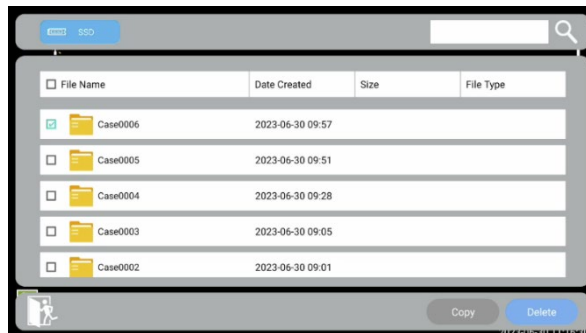
Turn OFF (long press 8+ seconds) the Wireless Base Station.

Turn OFF both monitors.

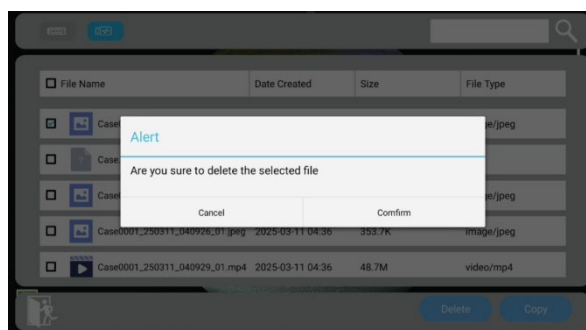
Clean the Camera Head(s) (see Section V) prior to returning the Camera Head(s) to the camera Charging Station.

Select & delete data

Go to internal or external storage, select the files to be deleted. Confirm the [Delete] button is blue



Press the [Delete] button, “Are you sure to delete the selected file?” confirm to delete



All patient data will be permanently erased via secure multi-pass deletion, guaranteeing irreversible destruction beyond any recovery method.

Always keep the external storage drives in a secure location when not in use.

Patient data should always be deleted from the base station at the end of each surgery.

Quick Operation Instructions

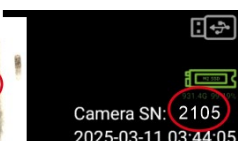
STEP 1: System Initialization

- Press **[Power]** button on Wireless Base Station
- Verify:
 - GUI appears on display within 15-20 seconds
 - Status LEDs illuminate normally



STEP 2: Camera Activation

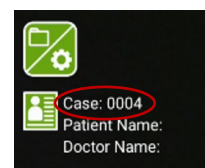
- Press **[Power]** button on Camera Head
- Confirm:
 - Camera serial number displays on screen
 - Wireless connection indicator shows stable link



STEP 3: Case Creation

• Long-press (3 sec) **[Camera]** button to:

- Generate new case number
- Initialize recording system
 - Verify:
 - Live video feed appears
 - Correct anatomical orientation
 - Case number displays prominently

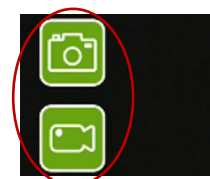
**STEP 4: Media Capture**

Use Camera Head controls for:

• **Still Images:**

- Single-press **[Camera]** button
- Confirm capture sound/visual feedback
- **Video Recording:**

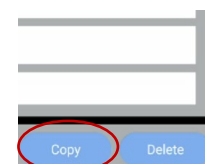
- Press **[Record]** button (toggle start/stop)
- Observe recording indicator on GUI

**STEP 5: Data Management**

Optional post-procedure actions:

• **Touch Screen Controller:**

- Access file management GUI
- Initiate data transfers
- **Mouse Control:**
- Navigate system menus
- Select files for external backup



SECTION V: Cleaning, Disinfection and Sterilization

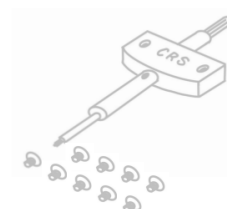
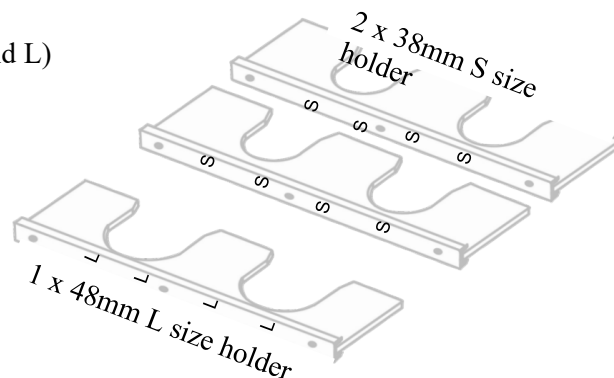
Sterilization Tray Assembly

Included Parts:

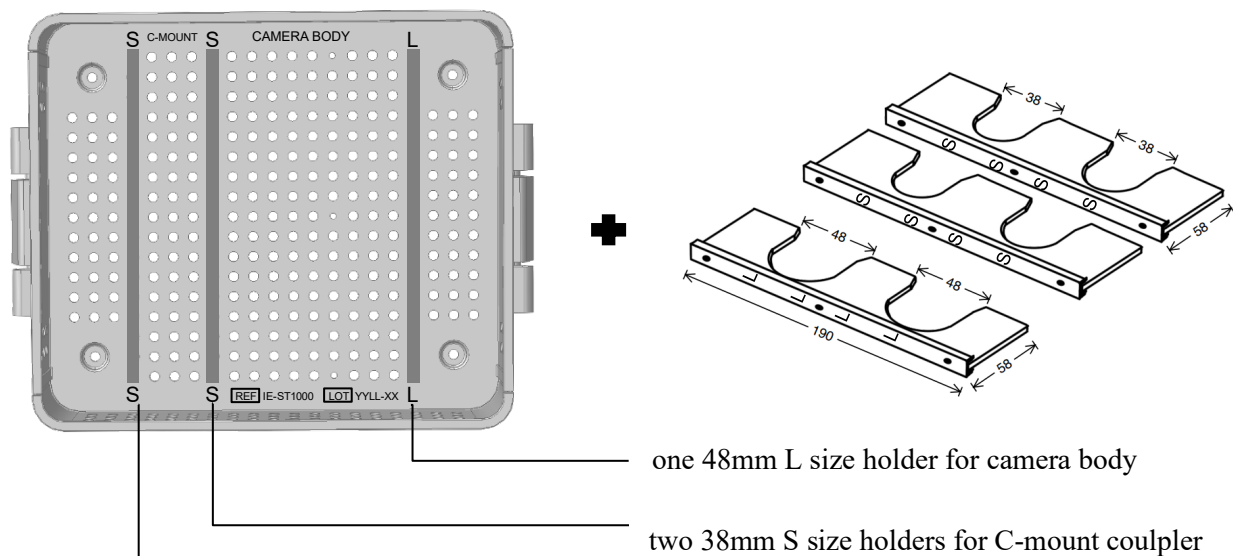
- Sterilization tray
- Sterilization tray cover
- 3 pcs of camera and C-mount coupler holders (size S and L)
- 9 screws
- 1 screw driver

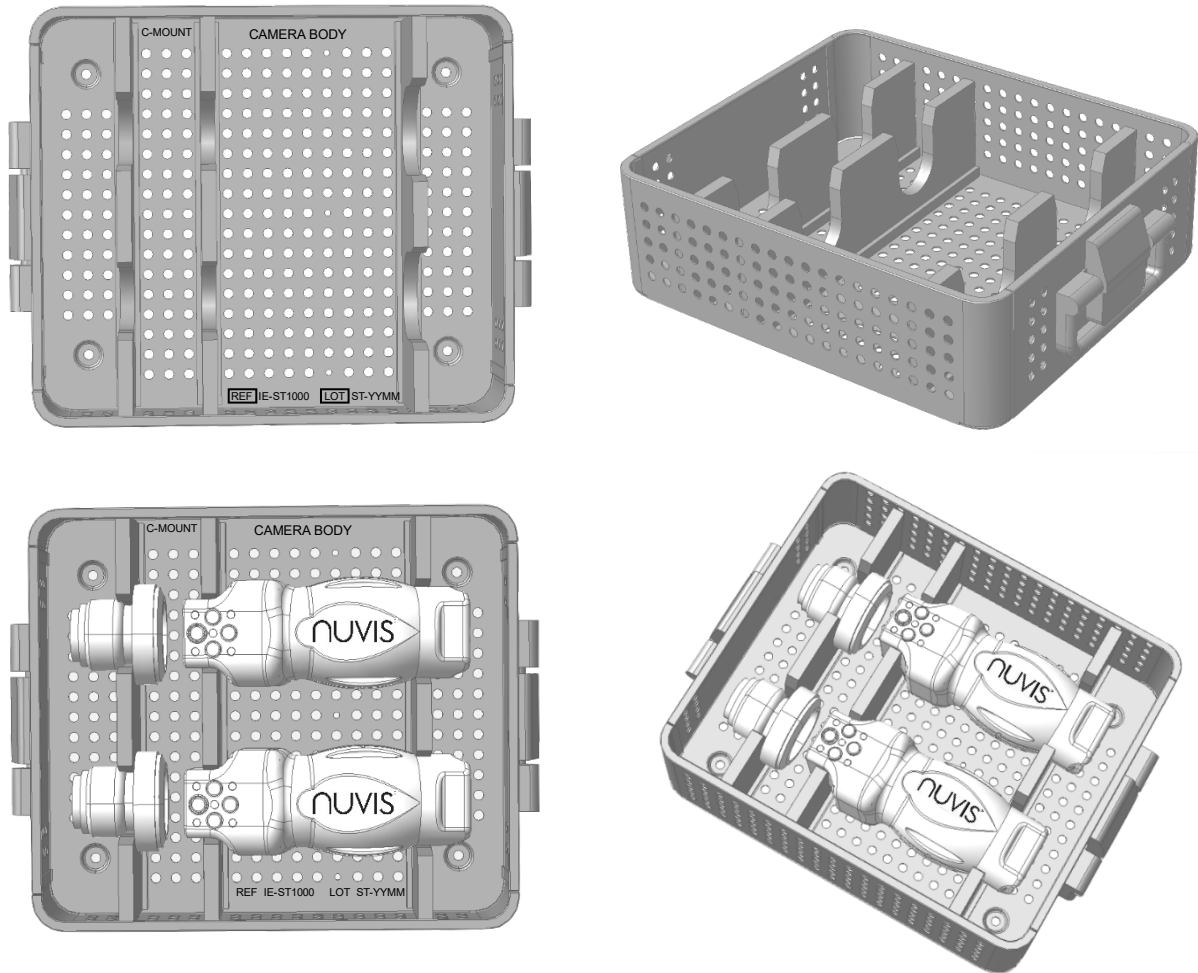
Please install the 3 pcs of C-mount coupler and Camera body holders into the tray bottom:

- Install the two S size holders in the tray position S
- Install the one L size holders in the tray position L

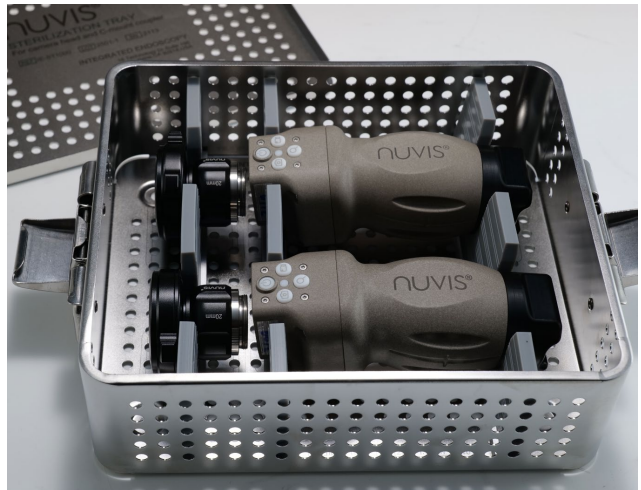


C-mount coupler and camera body holders mounting positions inside the sterilization tray bottom.





The C-mount couplers can sit on the holders in both directions.



Cleaning and Sterilization

The cleaning and sterilization instructions in this manual are made in accordance with Guidance for Industry and Food and Drug Administration Staff, Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling (2017). The following instructions have been validated and must be followed in their entirety.

Follow the instructions in the following section to clean and sterilize the Camera Head(s) and C-mount coupler(s).

As the Camera Head Charging Station and Wireless Base Station are not located in the immediate surgical area, use the instructions to clean the Camera Head Charging Station and the Wireless Base Station.



WARNING: Always follow the cleaning instructions in this manual. Any deviation may damage the device and/or create health hazards for the patient, clinician, or user.



WARNING: Do not place any component of the System in a moist heat sterilizer (autoclave). Temperatures in these units may cause damage to sensitive electronics or the lithium-ion cell inside the Camera Head and, in turn, put the patient, clinician, or user at risk of serious injury.



WARNING: Any visibly soiled articles should be re-cleaned and sterilized prior to use with a patient.

CAUTION: Do not immerse any system component in liquid. Doing so may irreparably damage the Component. Note: Sterile disposable drape covers may be used to minimize equipment contamination.

CAUTION: System components may be damaged by the use of harsh oxidizing chemicals or the use of improper cleaning techniques or tools.

Cleaning instructions: Camera Head(s) and C-mount coupler(s).

These cleaning, assembly, and sterilization instructions are made available in accordance with AAMI TIR30:2011/(R) 2016, A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices. These instructions are validated by the manufacturer and must be followed in their entirety to thoroughly clean the device(es).

- **Moisten.** Keep the C-mount coupler on the Camera Head. Spray purified water onto the Camera Head and C-mount coupler surface and wrap the device with a soft and lint-free cloth soaked with purified water. Or simply wrap the Camera Head and C-mount coupler with a soft and lint-free cloth soaked with purified water to keep it moist.

- **Prepare Cleaning Solution**

Cleaning solution: ALCONOX (Powder). Prepare a fresh 1% cleaning solution (2 1/2 Tbsp/Gal, 4 oz/Gal or 10g/L) in cold, warm, or hot water. If available, use warm water. Use cold water for blood stains.

- **Wipe the surfaces** for at least 3 minutes with a soft, lint-free cloth soaked with the cleaning solution. Pay close attention to the vent, button, and screw areas.

- **Scrub.** Separate the C-mount coupler from the Camera Head. Pay close attention to threaded mating surfaces where soil may have accumulated. Use a nylon brush to thoroughly scrub the Camera Head and C-mount coupler under running purified water for at least 2 minutes. Pay close attention to the vent, button, and screw areas.
- **Final Rinsing.** Rinse the Camera Head and C-mount coupler for at least 1 minute under running purified water until any visible soil and cleaning solution are completely removed. Repeat any cleaning and rinsing steps as needed.
- **Dry.** Dry each part thoroughly inside and out using a clean, soft, lint-free single use cloth or using micro filtered forced air. Using a syringe (100 mL or greater) as a vacuum, suction out any visible fluid from the Camera Head. Pay close attention to the vent, button, and screw areas. Allow the Camera Head to air dry (at least 10 minutes) before proceeding to sterilization.

Point of Use Processing

- Keep the C-mount coupler on the Camera Head.
- Spray purified water onto the Camera Head and C-mount coupler surface and wrap the device with a soft and lint-free cloth soaked with purified water. Or simply wrap the Camera Head and C-mount coupler with a soft and lint-free cloth soaked with purified water to keep it moist.

Note: Cleaning Instructions were validated per ANSI/AAMI ST98:2022: Cleaning Validation of healthcare products -requirements for validation and revalidation of a cleaning process for medical devices

Disinfection instructions: Camera Head and C-mount Coupler

- **Wipe.** Use a clean wipe saturated with Ethyl or isopropyl alcohol (70-90%), to wipe all surfaces. Wait at least 1 minute before rinsing. (1 minute or greater exposure time as recommended by the CDC for smooth hard surfaces.)
- **Rinse.** Use a clean wipe saturated with sterile water, filtered water (commonly used with AERs) or tap water (i.e., high-quality potable water that meets federal clean water standards at the point of use). Do not submerge the Camera Head.
- **Dry:** Allow the Camera Head and coupler to air dry before storage.
- **Store:** Store the Camera Head and coupler in a way that prevents recontamination and promotes drying (e.g. store Camera Head in the Camera Head charger).

Sterilization instructions: Camera Head and C-mount Coupler

Prior to placing the Camera Head(s) and C-mount Coupler(s) into the sterilization tray:

Confirm that the Camera Head(s) and C-mount Coupler(s) have been thoroughly cleaned using the instructions above.

Ensure every part of the Camera Head and C-mount are completely dried. Pay close attention to the vent, button, and screw areas on Camera Head.

Inspect the sterilization tray to ensure all components are present, including device holders. The tray should be assembled per the below image. The holders are labeled with A and B marks, which correspond to their positioning on the tray.

Place the Camera Head(s) and C-mount coupler(s) into the sterilization tray in the locations indicated by the image in the base of the sterilization tray.



Figure 96 Loaded Sterilization Tray

Wrap the sterilization tray in a double layer of sterilization wrap (FDA-cleared or legally marketed wrap, pouch such as Halyard H300 Sterilization Wrap).

Use a pre-existing, low-temperature hydrogen peroxide plasma sterilization system on its standard cycle setting.




The Sterrad® 100NX Standard Cycle below has been validated per ISO 22441: 2022 Sterilization of health care products-Low temperature vaporized hydrogen peroxide-Requirements for the development, validation and routine control of a sterilization process for medical devices. Use of any other cycle, equipment, or parameters must be validated independently by the end user.

Cleaning instructions: Camera Head Charging Station and Wireless Base Station

- Unplug the component prior to cleaning. Carefully wipe the outer surfaces with a soft cloth saturated with IPA alcohol isopropyl alcohol (70-90%), to remove any visible debris. Allow to air dry before use. Do not immerse the devices in any fluids.
- Periodically inspect each item for signs of damage or wear that may impair operation. If damaged or worn, discontinue use and contact IE for replacement.

SECTION VI: Reminders, Quality of Service, Troubleshooting, Maintenance, Service and Disposal

Reminders

No.	Situation	Audio alert	Text reminder	LED and icons
1	2K video T/R connecting			
	searching for a Camera Head			 4 levels looping
	connecting a Camera Head			
	Camera Head connected			 HDMI CH9 1080p
	Camera Head not found			
2	Camera Head battery remain			
	Remaining operation time from 4 hours to 2 hours			LED solid green static/battery level 4 to 3 (green)
	Remaining operation time from 2 hours to 1 hours			LED green fast blinking /battery level 2 (green)
	Remining operation time under 1 hour	Alert audio		LED green fast blinking /battery level 1 (red)
3	Camera Head white balance correction			W/B icon appears for 3 seconds
4	Picture taken/saved	Reminder 1		
5	Video recording start/stop	Reminder 2		
6	Access the [Patient Data]			Password needed
7	Access the [System Setting]			Password needed
8	Newly inserted external USB storage		“The newly inserted USB drive needs to be formatted, would you like to proceed with formatting now?”	External USB storage icon color turns from gray to green with total capacity and remaining capacity percentage

9	Internal storage under 10%	Alert audio	“Internal Storage space is low and data may not be saving. Download the internal storage data to an external USB to assure that data is saved.”	Icon color changes from green to red
11	Internal storage under 5%	Alert audio	“Internal Storage is extremely low and picture/video recording is closed. Download the internal storage data to an external USB or delete files to free up internal storage space.”	Icon color stays red. Picture, video recording and case icons turn gray.
12	External storage under 10%	Alert audio		Icon color changes from green to red
13	Delete data from internal storage	Alert audio	“Are you sure to delete the selected file?” “CANCEL” or “CONFIRM”	
14	Delete data from external storage	Alert audio	“Are you sure to delete the selected file?” “CANCEL” or “CONFIRM”	
15	Copy the data		“This file is being copied, please be patient.”, “It takes approximately 00:03:20 to complete, ...”, if the data selected to be copied with the bigger size than the external USB storage, then, “The disk space not enough”	

- There are three types of audio alerts: Reminder 1, Reminder 2, and Alert.
- The volume of reminders and alerts is adjustable and can be turned off in the system settings.
- When HDMI 2 is connected to a monitor, ensure that the monitor has built-in speakers and that the volume is sufficient.

Audio Output Behavior:

- If the **Wireless Base Station** is connected **only** to the clinical display, audio alerts will play through the **Wireless Base Station speaker**.
- If the **Wireless Base Station** is connected to a **touchscreen display**, audio alerts will play through the **touchscreen speaker**.

Quality of Service

The system uses 5.1 GHz wireless LAN (16QAM modulation) and 5.8 GHz spread-spectrum communication (5725–5850 MHz, 5150–5250 MHz) to transmit uncompressed 2K video and control signals. Acceptable QoS is defined as:

- **Data Integrity:** No frame loss ($\text{FLR} \leq 0.05\%$) to ensure reliable video streaming.
- **Data Latency:** System latency ≤ 130 ms for real-time visualization; channel switching ≤ 220 ms post-interference.
- **Throughput:** Sustained 60 fps at 2K resolution (minimum 144 Mbps) to support uncompressed video.
- **Network Accessibility/Signal Priority:** The Wireless Base Station operates as a dedicated access point (AP) with six discrete channels, automatically selecting the least-interfered channel (priority over coexisting WiFi/LTE signals). It does not rely on clinic-supplied routers, ensuring standalone operation.

Troubleshooting

Symptom	Potential Cause	Solution
Loss/degradation of function/performance characterized as: <ul style="list-style-type: none"> • Image does not display • Image stops displaying after doing so previously • Image displays poor resolution • Image is grainy • Camera Head does not connect to base station 	EM disturbance	<ul style="list-style-type: none"> • Maintain a separation distance of at least 20 cm from other wireless devices or metallic objects. • Ensure black transmitter antenna cover is not blocked • Ensure device is kept away from high-powered industrial equipment, MRI scanners, and close-proximity wireless routers. • Place Camera Head in the Charging Station for 10 seconds. Remove Camera Head and power the Camera Head ON. • Relocate to a lower-EMI environment if significant interference occurs.
Video recording stops	Patient Icon is clicked while recording	Restart video recording
Camera Head locks	The Camera Head has experienced an electrical short.	Place Camera Head in the Charging Station for 10 seconds. Remove Camera Head and power the Camera Head ON.
Live display stops	The Camera Head to Wireless Base Station signal is interrupted.	Double click the power button on the Camera Head to start the 2K video connection again. Increase the distance between the Camera Head and the Wireless Base Station.
Live video displays intermittent horizontal dashed line interference for several seconds, especially at the start of a	1) Busy 5.8 GHz WIFI environment; 2) The Camera Head body black cover part was held or completely held; and/or	1) Avoid use of system in areas with high interference. If a router must be on in the area, set it to 2.4GHz. 2) Do not hold or completely hold the black cover part of the Camera Head;

new live video connection.	3) Wireless Base Station and Camera Head LOS (line of sight) distance is more than 5 meters (15 feet)	3)Keep the Wireless Base Station and Camera Head LOS (line of sight) within 5 meters (~16 feet)
Not all items in the image are in view.	The system is in “Zoom” mode.	Click on the Zoom Camera Head button to adjust the image size.
During stable image transmission and display, some noise occurs and then returns to a normal and stable receiving	The Camera Head body black cover part was partially covered or completely covered.	Do not hold or completely hold the black cover part of the Camera Head.
The USB external storage cannot be recognized by the Wireless Base Station	The USB external storage is not formatted with NTFS or FAT32.	Replace the USB external storage drive with one that is NTFS or FAT32 configured.
Touch Monitor display does not show the Wireless Base Station UI.	The USB cable between the rear panel USB port or HDMI has been disconnected or are not compatible.	1)Use the supplied (data and power) USB cable and HDMI cable; Do not use the USB cable (which is only for power charging)
Wireless Base Station [Power] button (on the front panel) does not turn the power OFF	A short press was used instead of a long press, causing the system to go into Standby instead of turn off.	Long Press (over 8 seconds) the power button.
Condensation	The unit was not stored within the specified temperature and humidity ranges; not protected from vibrations and shocks.	Turn off the Wireless Base Station and wait until the condensation clears.
The reminder and alert audio in the Wireless Base Station disappear.	<ul style="list-style-type: none"> • The Wireless Base Station speaker volume is set too low. • HDMI 2 output (which has priority for audio output) is connected to a monitor that either has no speakers or has the speaker volume set too low. 	<ol style="list-style-type: none"> 1. Increase the volume of the Wireless Base Station speaker. 2. Ensure that the HDMI 2-connected monitor has speakers and that the speaker volume is turned up.
The live video suddenly flickers and disappears for about 3 seconds.	Electrostatic discharge may cause interference or interruption in the live video transmission from the Camera Head to the Wireless Base Station. The connection will automatically be restored after approximately 3 seconds.	<ol style="list-style-type: none"> 1. Medical personnel in the operating room should regularly perform electrostatic discharge procedures to minimize static electricity buildup. 2. Ensure that the operating room ground is properly grounded. 3. Floors, walls, and instruments in the operating room should be cleaned regularly to remove dust and dirt that may contribute to static electricity. 4. Avoid excessive gathering of people in the operating room to reduce static electricity accumulation and release.

Maintenance

- Periodically inspect the Camera Head, Wireless Base Station, and Touch Monitor for damage. Do not use if damaged.
- Replace the Camera Head if the batteries are no longer charging, cannot hold a charge, or require an excessive amount of time to charge. This can be assessed by observing the charger indicator lights while the Camera Head(s) are charging. Note: the batteries are not replaceable.
- Periodically inspect all cables for wear. Inspect shielding and filtering components for wear or damage. Verify the integrity of connectors and cables to minimize EMI risks.
- Visually inspect the items for dirt and debris. Clean, disinfect and sterilize as needed.
- Check Internal storage capacity for availability. Remove internal data and store onto an external drive as needed. (See Section IV, Removing Data from the wireless base Internal Storage)

Service

The system must be returned to Integrated Endoscopy for Service. Contact Integrated Endoscopy for packaging and shipping instructions.

Prior to Return:

- Unplug all items from power.
- Clean and disinfect the items to be returned (as per Section V)

Disposal

Before disposing of the unit, you delete ALL patient data and other confidential information that is stored in the Wireless Base Station. Failure to delete stored data before disposing of the unit can expose confidential information to third parties.

Dispose of all equipment according to local and regional Regulations.

SECTION VII: Compliance Statements and Technical Specifications

Important EMC Notices For Use in Medical Environment

• Nuvis-2K is intended for use in a professional healthcare facility environment. NOTE 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 relocating or re-orienting the equipment.

- Portable and mobile RF communications equipment, such as cellular phones, can affect the Nuvis-2K.
- Nuvis-2K may interfere with 5.8 GHz wireless devices, such as routers or other wireless devices. Therefore, if you have an 802.11n router, configure it to the 2.4 GHz band rather than the 5.8 GHz band.

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.

Portable RF communications equipment should be used no closer than 20 cm (8 inches) to any part of the Nuvis-2K. Otherwise, degradation of the performance of this equipment can result. For optimal performance, maintain a minimum distance of 2 meters from any interference source operating on the same frequency as this device.

If the system will be used adjacent to or stacked with other equipment, normal operation of the system under such configurations should be verified via observation.

Shielded cables must be used with this unit to ensure compliance with the Class B FCC limits.

The use of accessories and cables other than those specified, with the exception of replacement parts sold by Integrated Endoscopy, may result in increased emissions or decreased immunity of the system.

Precautions Regarding Electromagnetic Energy Sources

- The device is not tested for environments exceeding 10 V/m RF fields.
- Emissions near MRI equipment may interfere with device performance.

Guidance And Manufacturer's Declaration – Electromagnetic Emissions		
Emissions tests	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	Nuvis Wireless 2K Camera System, Model Nuvis-2K (IE3000SYS-N1) 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	Nuvis Wireless 2K Camera System, Model Nuvis-2K (IE3000SYS-N1) is suitable for use in all establishments, including domestic establishments 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	

Guidance And Manufacturer's Declaration – Electromagnetic Immunity			
Nuvis Wireless 2K Camera System, Model Nuvis-2K (IE3000SYS-N1) is intended for use in the electromagnetic environment specified below. The customer or the user of the Unit should assure that it is used in such an environment.			
Immunity test	Basic EMC standard	IEC/EN 60601 test level	Compliance level
Electrostatic discharge (ESD)	IEC 61000-4-2	Contact: $\pm 8\text{kV}$ Air: $\pm 2\text{ kV}$, $\pm 4\text{ kV}$, $\pm 8\text{ kV}$, ± 15	Contact: $\pm 8\text{kV}$ Air: $\pm 2\text{ kV}$, $\pm 4\text{ kV}$, $\pm 8\text{ kV}$, ± 15
Electrical fast transient/burst	IEC 61000-4-4	$\pm 2\text{kV}$ 100kHz repetition frequency	$\pm 2\text{kV}$ 100kHz repetition frequency
Surge	IEC 61000-4-5	$\pm 0.5\text{ kV}$, $\pm 1\text{ kV}$ line-to-line; $\pm 0.5\text{ kV}$, $\pm 1\text{ kV}$ and $\pm 2\text{ kV}$ line-to-ground;	$\pm 0.5\text{ kV}$, $\pm 1\text{ kV}$ line-to-line; $\pm 0.5\text{ kV}$, $\pm 1\text{ kV}$ and $\pm 2\text{ kV}$ line-to-ground;
Voltage dips	IEC 61000-4-11	0%UT; 1cycle and 70%UT; 30cycles Single phase: at 0°	0%UT; 1cycle and 70%UT; 30cycles Single phase: at 0°
Voltage interruptions	IEC 61000-4-11	0%UT; 300cycles	0%UT; 300cycles
Rated power frequency magnetic fields	IEC 61000-4-8	30A/m 50/60Hz	30A/m 60Hz
Conducted RF	IEC 61000-4-6	3 Vrms 6 V in ISM bands: 6.765 - 6.795, 13.553 - 13.567, 26.957 - 27.283, 40.66 - 40.70 0.15MHz~80MHz 80%AM at 1kHz	3 Vrms 6 V in ISM bands: 6.765 - 6.795, 13.553 - 13.567, 26.957 - 27.283, 40.66 - 40.70 0.15MHz~80MHz 80%AM at 1kHz
Radiated RF	IEC 61000-4-3	3V/m 80MHz~2.7GHz 80%AM at 1kHz	3V/m 80MHz~2.7GHz 80%AM at 1kHz

Test specification for enclosure port immunity to RF wireless communications equipment					
Test frequency (MHz)	Band ^{a)} (MHz)	Service ^{a)}	Modulation ^{b)}	TEST LEVEL(V/m)	Compliance level
385	380-390	TETRA 400	Pulse modulation ^{b)} 18Hz	27	27
450	430-470	GMRS 460, FRS 460	FM ^{c)} ±5 kHz deviation 1kHz sine	28	28
710	704-787	LTE Band 13, 17	Pulse modulation ^{b)} 217Hz	9	9
745					
780					
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation ^{b)} 18Hz	28	28
870					
930					
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation ^{b)} 217Hz	28	28
1845					
1970					
2450	2400-2570	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation ^{b)} 217Hz	28	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation ^{b)} 217Hz	9	9
5500					
5785					
		NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1m. The 1m test distance is permitted by IEC 61000-4-3.			
		^{a)} For some services, only the uplink frequencies are included. ^{b)} The carrier shall be modulated using a 50 % duty cycle square wave signal. ^{c)} As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.			

Special Notice

Use of this product in the following locations may result in abnormal video and audio output (noise, blocked image... etc.).

- Product installed in concrete walls
- Product situated near refrigerator or metal fitment
- A cluttered room where the wireless signals may be blocked

This product has been tested and manufactured to comply with each country's safety rules. However, there is no guarantee that interference will not occur in some installation scenario. If the interference happens, increase the distance between the Wireless Base Station and Camera Head.

Nuvis-2K may interfere with 5.8 GHz wireless devices, such as routers or other wireless devices. Therefore, if you have an 802.11n router, configure it to the 2.4 GHz band rather than the 5.8 GHz band. If devices must use the 5.8 GHz band, limit their transmission power to below 20 dBm, and maintain a minimum distance of 2 meters from Nuvis-2K.

Maximum range between Nuvis-2K Wireless Base Station and Camera Head is within 5 meters (~16 feet).

FCC INTERFERENCE STATEMENT

FEDERAL COMMUNICATIONS COMMISSION(FCC)

The equipment (FCC ID: 2BEMN-IEBS1000) has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. The System generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications.

However, there is no guarantee that interference will not occur in a particular installation. If the System does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- a) Reorient or relocate the receiving antenna
- b) Increase the separation between the equipment (Camera Head) and receiver (Wireless Base Station).
- c) Connect the equipment into an outlet on a circuit different from that to which the receiver (Wireless Base Station) is connected.
- d) Consult the dealer or an experienced radio/TV technician for help.

Note: This equipment (FCC ID: 2BEMN-IEBS1000) complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with a minimum distance of 20 cm between the radiator and your body. The transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Declaration of conformity (FCC Part 15)

Nuvis® Camera Head, MODEL: IE-CH1000

FCC ID: 2BEMN-IECH1000

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- (1) This device may not cause harmful interference, and
- (2) This device must accept any interference received, including interference that may cause undesired operation.

Nuvis® Wireless Base Station, MODEL: IE-BS1000

FCC ID: 2BEMN-IEBS1000

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- (1) This device may not cause harmful interference, and
- (2) This device must accept any interference received, including interference that may cause undesired operation.

Nuvis® Touch Monitor: IE-TC1000

This device complies with Part 15 of the FCC Rules when used as described in this user manual.

Note: “Harmful interference” is defined in 47 CFR § 2.1 by the FCC as follows: interference which endangers the functioning of a radio navigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the [ITU] Radio Regulations.

CYBERSECURITY

The HIPPA Compliance Officer is required to do the following:

- Create the hospital password for the Nuvis Wireless Base Station following the HIPPA COMPLIANCE GUIDELINES.
- The HIPPA Compliance Officer must store password in a safe place. If password is lost/misplaced, it must be manually reset by IE personnel. Refer to Section II for Password Recovery information.

To prevent loss of patient data, always keep USB drives (with patient data) in a secure location.

Use the case number to reference a specific patient to a case and do not input specific patient identifying information into the file.

Caution: Using the System in the US

Any changes or modifications not expressly approved by the grantee of this device can void the user's authority to operate the equipment.

This equipment must be installed and operated in accordance with the provided instructions.

The Wireless Base Station should not be put on metal platform.

The Wireless Base Station antenna(s) used for receiving and transmitting must be installed to provide a separation distance of at least 20 cm from all persons and metal and must not be co-located or operating in conjunction with any other antenna or transmitter.

End-users and installers must be provided with antenna installation instructions and transmitter operating conditions for satisfying RF exposure compliance.

The System operates on the following channels:

5190 MHz, 5230 MHz, 5755 MHz, 5795 MHz

The System cannot operate on the following channels:

5270 MHz, 5310 MHz, 5510 MHz, 5550 MHz, 5590 MHz, 5630 MHz, 5670 MHz, 5835 MHz

Transmission Power Limitation: Any wireless device used in the operating room must not exceed a transmission power of 20 dBm and must maintain a minimum distance of 2 meters from the wireless endoscope's transmitter and receiver.

Channel Conflict: If other devices in the operating room use the dedicated channels of the wireless camera system (Channels 38, 46, 151, and 159), it may cause connection interruptions or delays for the camera system. Therefore, it is essential to ensure that these channels are not occupied by other devices.

Real-Time Monitoring: Operating room staff are advised to regularly use spectrum analysis software to monitor the usage of the 5GHz band, ensuring that the wireless endoscope's dedicated channels remain interference-free.

TRADEMARK INFORMATION

HDMI, the HDMI Logo and High-Definition Multimedia Interface are trademarks of HDMI Licensing LLC.

WARRANTY INFORMATION

Our limited warranty applies when the system is handled properly for intended use, in accordance with its operation instruction. However, the warranty may be void in the following cases:

- Repair, product modification or alteration have been performed by unauthorized personnel
- Damages caused by accidents, including but not limited to lightning, water, fire, or moisture
- Use of an AC adapter not compatible with the product and it's voltage rating

Copyright







When using this unit for video and/or audio recording, it may require the permission of the copyright holder of the video or audio. To protect copyright, carefully observe laws relating to copyright when connecting a recording device to this and recording video or audio. Without the permission of the copyright holder, the showing or distribution of video or audio material of which the copyright is held by a third party is prohibited by law. Under copyright law, you may not use recorded video or audio other than for your personal enjoyment without the permission of the copyright holder.

Disclaimer of Liability for Recorded data

“Integrated Endoscopy” does not accept any liability whatsoever for any problems arising from a failure to record, or from damage or erasure of recorded content on this equipment, for any reason. Your use of this product is subject to these conditions.

TECHNICAL SPECIFICATIONS

System	
Transmission Distance	Max 5 meters (15 feet)
Transmission to receiver Latency	Not perceivable
Video resolution	2K@60 fps
Effective Pixel	1920(H) × 1080(V)
Operational Conditions	Temperature: 59°F to 86°F (15°C to 30°C),

	Pressure: 700-1060hPa, Humidity: 15-85%, non-condensing
Long Term Storage and Temperature	 Temperature: -4°F to 104°F (-20°C to 40°C),  Pressure: 700-1060hPa,  Humidity: 15-85%, non-condensing
Short Term Storage and Transport	 Temperature: -4°F to 140°F (-20°C to 60°C),  Pressure: 500-1060hPa,  Humidity: 15-85%, non-condensing

Camera Head	
Camera Head Battery	Rechargeable 3500mAh*2 cells
Enclosure waterproof grade	IP67
Continuous working time	>= 3.5 hours on a full charge
Power Consumption	5W (average)
Dimensions	133(L) × 50(W) × 52(H)mm +/- 10%
Weight	2 lbs (907 grams) +/- 10%

Camera Head Charger	
Power Input	DC12V4A
Dimensions	180(L) × 90(W) × 50(D)mm +/- 10%
Weight	1 lb +/- 10% (454g)

Wireless Base Station	
Video Storage	1 Terabyte internal storage
Power Input	100-240 VAC; 50/60 Hz, DC12V4A
Dimensions	148 mm long; 134 mm wide and 49.5 mm high (without antenna)
Weight	no greater than 2 lbs (900 grams)
Operating System	Android 12
HDMI Ports	2
USB Ports	2

Touch Screen Monitor	
Display spec	Size: 7 inches
	Resolution: 1920(H) x 1080(V)
	TFT Active Area: 154.6 x 87mm
	Technology Type: IPS
	Pixel Configuration: R.G.B Vertical Stripe
	Display Mode: SFT

Touch Screen Monitor	
	Surface Treatment: HC
	Viewing Direction: All directions
	LCM (W x H x D) 177.2 x 111 x 18mm
Mechanical characteristics	334g
Weight	Luminance min 1200 cd/m ² max 2000 cd/m ²
Optical characteristics	Contrast Ratio 1000:1
	NTSC Typ 55 %
	Viewing Angle 88/88/88/88 degree
	Color Depth 16.7 million color
Electrical characteristics	Power supply: USB on the base station rear panel
	Power Consumption: 10.5W
Storage temperature	-30°C to 80°C
Operating temperature	-20°C to 70°C



Emergo Europe
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands



MedEnvoy Switzerland
Gotthardstrasse 28
6302 Zug
Switzerland

