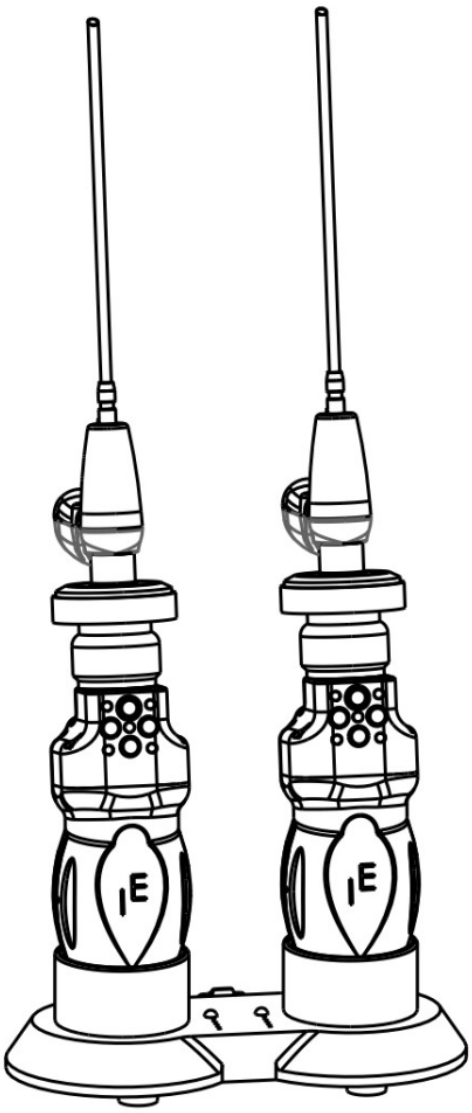
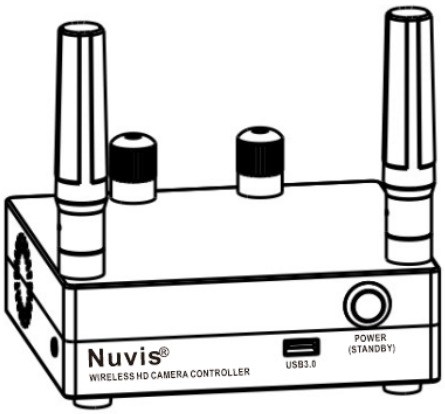
integrated endoscopy

Nuvis® Wireless HD Camera System

Model: Nuvis-2K



nuvis®



CE

Instructions for Use (English)

Before operating the unit, please read this manual thoroughly and retain it for future reference.
Integrated Endoscopy. All Rights reserved.

Rx ONLY
Caution Federal law (United States of America) restricts this device to sale by or on the order of a physician or licensed medical practitioner.

EC REP

Emergo Europe
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

Product description

The Integrated Endoscopy (“IE”)’s Nuvis Wireless HD Camera System (or “System” or “Nuvis-2K”) is a sterile wireless HD reusable camera head that is paired to a Wireless Base Station. When attached to an arthroscope/light source and a clinic supplied video system, arthroscopic examinations can be viewed and pertinent data recorded.

The IE Nuvis Wireless HD Camera System (“System” or “Nuvis-2K”) delivers uncompressed 2K/60fps full HD video content between the camera head and wireless base station wirelessly. The System can transmit uncompressed video content to 5 meters (16 feet) LOS (line of sight) with no perceptible latency.

The System is provided with two camera heads, a wireless base station. A camera charging station, HDMI cable, C-mount coupler are also provided.

The camera head is connected to the Arthroscope with a C-mount coupler (“Coupler”). The camera head communicates with the wireless base station by means of a wireless connectivity.

The wireless base station is intended to store still images and record HD video transmitted from the camera head. The wireless base station also manages both the patient’s image and video data, and system settings. The wireless base station saves recorded images and videos to an internal hard disk drive which can be copied to a portable USB drive.

Indications for Use

The Nuvis Wireless HD 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.

Clinical Benefits

Wireless capability removes risks related to cables that drape over the patient found in conventional arthroscopic procedures. The camera cord is eliminated which

- Removes a possible trip hazard
- Removes camera cord reprocessing

Notice to User and/or patient

Any serious incidents that have occurred in relation to the device should be reported to IE and the competent authority of the Member State in which the user and/or patient is established.

Symbols used

Follow instructions for use

Medical device

Manufacturing date

Manufacture

EC REP **European authorized representative**

Model number

Lot number

Serial number

Unique device identifier

Storage and transport temperature

Storage and transport humidity

Storage and transport pressure

WIFI capability
Wi-Fi capability indicator

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)

Important EMC notices for use in medical environment

- Nuvis-2K needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the instructions for use.
- Nuvis-2K is intended for use in a professional healthcare facility environment.
- Portable and mobile RF communications equipment, such as cellular phones, can affect the Nuvis-2K.
- Nuvis-2K may interfere with 5.8GHz 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 5.8GHz band.

Warning

- 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 of the Nuvis-2K.

Contraindications

- There are no known contraindications regarding the use of Nuvis-2K.

Warning

Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Note

This equipment 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. This equipment 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 this equipment 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:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- 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 20cm between the radiator & y our body. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Declaration of conformity

Nuvis® camera head,

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

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.

EN 55022 Information technology equipment----

Radio disturbance characteristics--- Limits and methods of measurement

EN 61000-3-2 Electromagnetic compatibility (EMC)---

Part 3-2: Limits---Limits for harmonic current emissions (equipment input current up to and including 16 A per phase)

EN 61000-3-3 Electromagnetic compatibility (EMC)---

Part 3: Limits---Section 3: Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≦16 A per phase and not subject to conditional connection

EN 55024 Information technology equipment----

Equipment---Immunity characteristics---Limits and methods of measurement

EN 301 489-1

Electromagnetic compatibility and Radio spectrum Matters (ERM); Electro Magnetic Compatibility (EMC) standard for radio equipment and services;

Part 1: Common technical requirements

EN 301 489-17

Electromagnetic compatibility and Radio spectrum Matters (ERM); Electromagnetic Compatibility (EMC) standard for radio equipment;

Part 17: Specific conditions for 2,4 GHz wide-band transmission systems, 5GHz high performance RLAN equipment and 5,8 GHz Broadband Transmitting Systems

EN 60065 Video and similar electronic apparatus—Safety requirements

TRADEMARK INFORMATION

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

Special Notice

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

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

Nuvis-2K operates in the following channels:

5190 MHz,5230 MHz, 5755 MHz, 5795 MHz

Nuvis-2K cannot operate in the following channels:

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

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Ordering Information

Nuvis® Wireless HD Camera System
Model: Nuvis-2K

Components and product No.

Nuvis® camera head	IE-CH1000
Nuvis® camera head charging station	IE-CS1000
Nuvis® wireless base station	IE-BS1000
Nuvis® sterilization tray	IE-ST1000
Nuvis® camera head plasma vent	IE-PV1000
Nuvis® connection APP	NuvisCon
Nuvis® C-mount coupler	IE20CMT

Nuvis® camera head charging station power supply adapter	IE-HA1000
Nuvis® wireless base station power supply adapter	IE-BA1000
Nuvis® HDMI cable	IE-HC1000
Nuvis® USB cable	IE-UC1000
Nuvis® instruction manual	IE-IM1000

Philips HDMI/DVI converter	IE-MO3000
Logi Mouse (2.4GHz wireless)	IE-WM1000

Nuvis® Wireless HD camera system packing	IE-PK1000

Technical Support
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INTEGRATED ENDOSCOPY
16 Technology Drive, Suite 165 Irvine, CA 92618, USA
www.iescope.com

Read first

Please take time to read the whole user instruction manual before using the Nuvis-2K. It contains important information about the system operation. In addition, read all user safety information provided with any accessories (such as Arthroscope and Light source) and/or energized devices.

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

CAUTIONS

- [Power] of the wireless base station should be turned off before connecting the wireless base station and the display with HDMI cable
- Power outlet: Make sure to use system provided power supply adapters.
- Power cord: Be sure the power cord is routed so that it will not be stepped on or pinched by heavy items
- Power overloading: Avoid overloading electrical outlets
- Lightning: Disconnect the system from the wall power source if it is left unattended for a long period of time, protect the system from lightning

WARNINGS

- The wireless base station and charging station should not be exposed to dripping or splashing
- Object entry: Unless indicated, never stick anything into the wireless base station slots on the case or remove the cover
- Place the wireless base station and charging station on a flat, hard and stable surface
- Do not block the ventilation slots on the wireless base station
- Water exposure: Do not expose the wireless base station and the charging station to rain or moisture

- This system is for medical professionals and intended for use in medical environments, such as clinics, laboratory rooms and operating rooms
- The camera head is non autoclavable
- Do not open the camera head nor the wireless base station

- Copyright

When using this unit for video recording, it may require the permission of the copyright holder of the video. To protect copyright, carefully observe laws relating to copyright when connecting a recording device to this and recording video. Without the permission of the copyright holder, the showing or distribution of video material of which the copyright is held by a third party is prohibited by law. Under copyright law, you may not use recorded video other than for your personal use 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, or the improper management of passwords on this equipment, for any reason. Your use of this product is subject to these conditions.

For absolute data security, please always keep the data in the base station empty at the end of each surgery.

- Deletion of the data when disposing of the unit

Before disposing of the unit, you first must delete patient data and other confidential information that is stored therein. Failure to delete stored data before disposing of the unit can expose confidential information to third parties.

- On security

We set a password for access to [Patient data and system setting]. We designed authorization for any wired or wireless access to the wireless base station.

Authorization can be terminated at any time. Please strictly follow the security requirements when operating the system.

- Condensation, temperature and humidity, vibrations and shocks precautions

If condensation occurs, turn off the wireless base station and wait until the condensation clears. Use and store the unit only in locations where the specified temperature and humidity ranges are not exceeded. (Be sure to use the unit that conforms fully to the specifications of this unit.) Protect from vibrations and shocks.

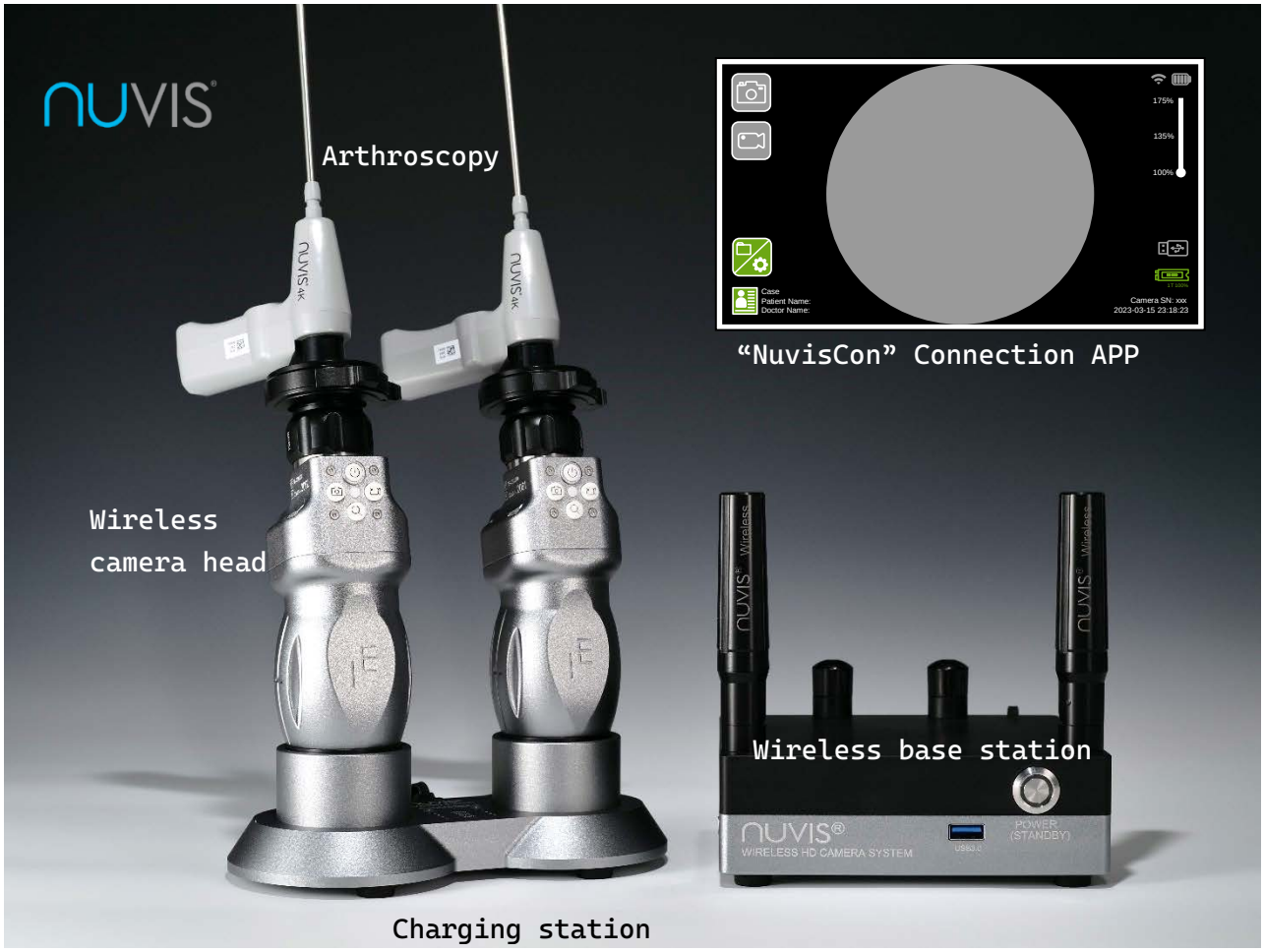
Usage Notes

- Do not cover the wireless base station while operating
- Do not block the wireless base station vents to prevent overheating
- Do not block the camera head transmitter antenna cover, the black part of the camera head, as the wireless signal may be weakened
- Press and hold the [Power] (ON/Standby) switch on the wireless base station and the camera head for more than 8 seconds to turn them OFF. Disconnect the AC adapter for the wireless base station and charging station, if the system will not be used for a long period of time
- Pack the system in the shipping cartoon for transportation by truck, ship, or air
- Clean in accordance with instructions
- Contact IE if you should experience problems with the system
- Before each use or after a change of viewing modes / settings, the OPERATOR should check to ensure the view provides a live image (rather than a stored one) and has the correct image orientation

1 Overview

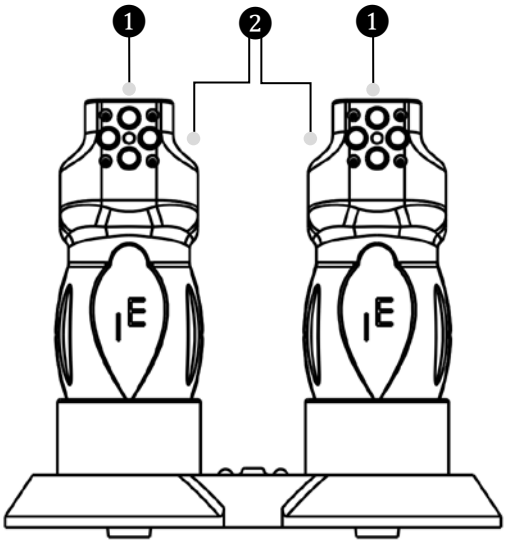
System features

- Wireless live HD video, communication & control automatically built between camera head and wireless base station
- System wireless and with multiple available controls, e.g. camera head, mouse
- Up to 8 wireless camera heads can be paired to an individual wireless base station
- Each camera head contains built in rechargeable batteries that ensures over 3.5 hours's operation time
- Internal 1T storage capacity PCIE M2 built in storage for reliable, long time, initial data backup
- Up to 110 hours (about one month) of high quality 2K@60fps HD video data backup recording
- A front panel external USB storage port especially designed for easy patient data copy
- Up to 300M/s high speed data copy using the rear panel USB port for internal storage and large data transfer
- Dual HDMI outputs available for a clinical display and live video sharing up to the cloud or head mounted OLED display
- Secured patient data management and system settings
- Fail safe operation especially designed for surgical procedures
- Camera heads can be cleaned. Sterile procedures can be conducted using a sterile camera head covering (drape) or sterilizing the camera heads using low temperature plasma.

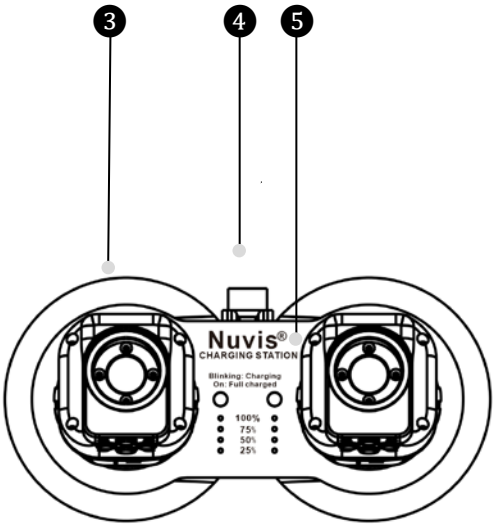


Parts names & functions

Camera heads (shown in charging station)



Front

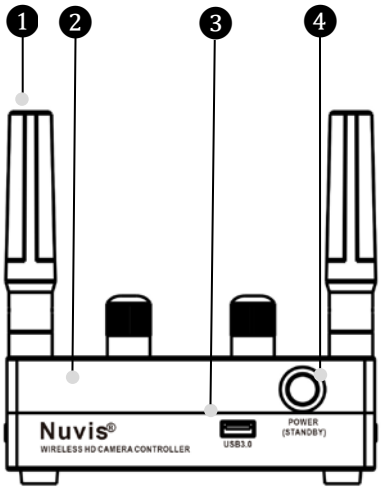


Above

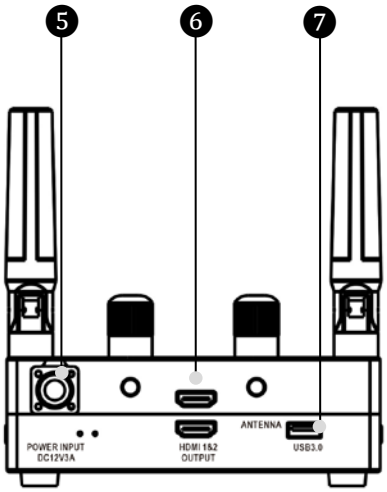
❶ Wireless camera heads
❷ Wireless communication & control buttons
❸ Charging station

❹ Charging station power input socket (Power input DC12V4A)
❺ Charging status LED display

Wireless base station



Front



Rear

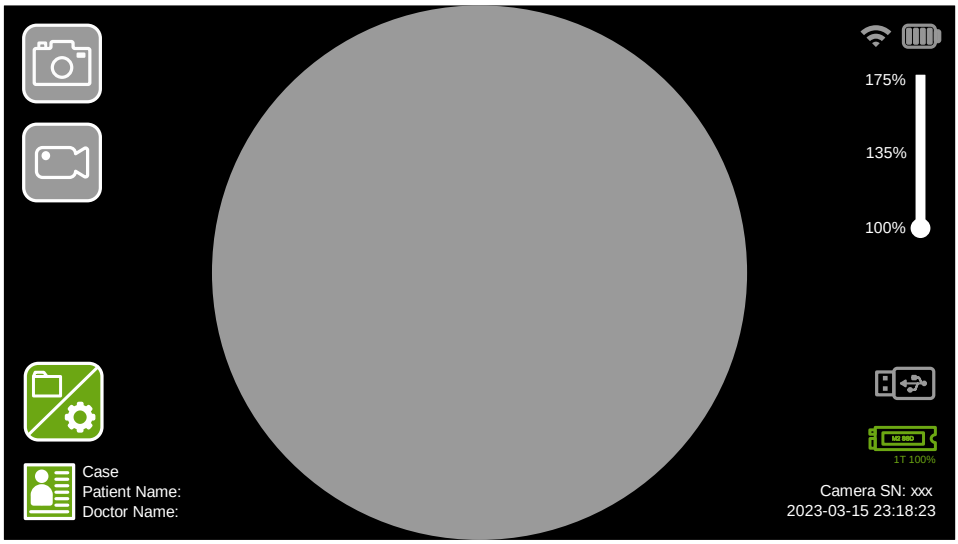
❶ Wireless control & communication antenna
❷ Wireless base station body
❸ Front panel USB3.0 port (For patient data copy and mouse)
❹ [Power] ON/OFF (standby)
❺ Power input socket (DC12V4A)

❻ HDMI OUTPUT 1for clinic display & HDMI 2 for live video sharing up to the cloud or head mounted OLED display

❼ Rear panel USB3.0 port (for mouse connection or for high-speed data copy)

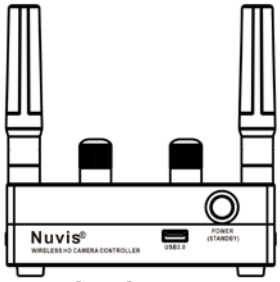
2 Preparation

Typical connections in the surgical operating room



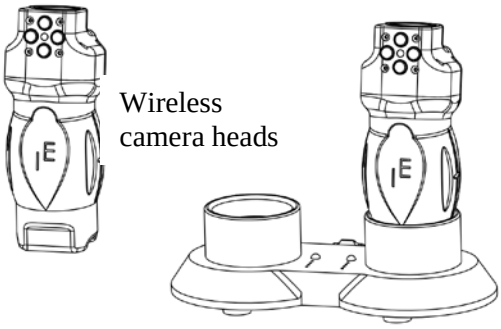
Clinic provided display

HD video from HDMI 1
cable output to clinical display



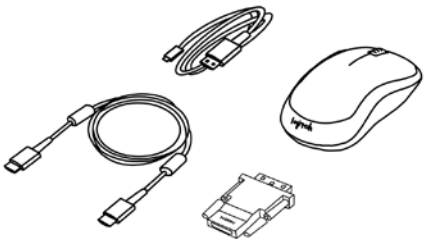
Wireless base station

Wireless HD video
communication and control



Wireless
camera heads

Charging station



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

Camera head button marks & display UI icons descriptions

Marks on the camera head control button		
Marks	Name	Description
	Power	• Camera head power ON/OFF
	☆Camera	• Take a picture • Start a case (multi-function)
	Video	• Video recording Start/stop
	☆Zoom	• Zoom in • White balance (multi-function)

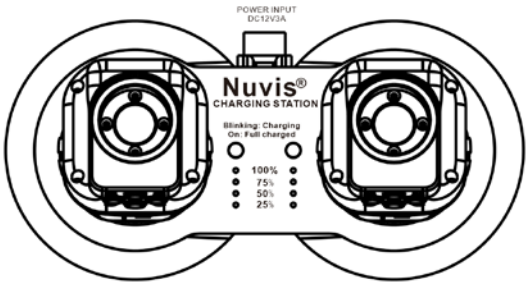
User interface icons on clinic provided display		
Icons	Name	Description
	◎Camera	• Take a picture
	◎Video	• Video recording Start/stop
	◎Data/system	• Patient data management & system setting
	☆◎Patient info	• Patient info input • Start a case (multi-function)
	Camera head battery	• Camera head battery level
M2 SSD	Internal storage	• Internal M2 storage (PCIE M2 SSD card)
	External storage	• External USB storage
W/B	Camera head W/B	• White balance automatic correction
	◎Data management	• Patient data management
	◎System setting	• System setting
	★Add a camera head into the system	• Wireless base station & camera head T/R pairing
	★Camera head setting	• Camera head manufacture setting

☆ Multi-function button: two functions are realized by short pressing and long pressing (more than 3 seconds).
◎ Icons can be used as button on monitor screen.
★ Icons are hidden from users, they are designed for maintenance and manufacturing settings.

Charging the camera head

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 IN connector on the rear of the charge dock and confirm plug has self-locked
- Plug the DC power cable to wall power.
- Each camera head has two built-in lithium-ion rechargeable cells
- Put the camera head into the charging station to charge the cameras
- Two camera heads can be charged at the same time
- Refer to chapter 5 for detailed cleaning instructions



NOTE

- The charging status LED and charge level percentage are displayed on the charging station
- There are two groups of LED displays that independently display charging status and charge level of each battery
- There are 3 charging status LED displays:

  Slow speed blinking (blink 1 time in 3 seconds): ready to charge

  Normal speed blinking (blink 1 time in 1 second): charging

  Constant illumination (LED on): fully charged

- 100% charge level + charging status LED normal speed blinking: the battery goes into trickle charging
- 25% charge level LED blinking + charging status LED normal speed blinking: the battery is undergoing fast charging

NOTE

- The camera head is 33% charged within about 30 minutes, for about 1.5 hours operation time
- The camera head is 66% charged within about 60 minutes, for about 2.5 hours operation time
- The camera head is 90% charged within about 90 minutes, for more than 3.5 hours operation time
- The newly factory delivered camera head can work up to 4 hours once fully charged
- Each camera head has an expected service life of 300 charge and discharge cycles

- Do not put camera heads that have not been cleaned in the charging station

- Put the cleaned camera heads into the cleaned charging station for charging
- Clean the charger when needed
- Refer to chapter 5 for detailed cleaning instructions

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℃, 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

- The camera head can be charged regardless 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 charge 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

TIP

- If the camera head meets 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

Wireless base station

Connect the DC power cable of the supplied AC adapter to the DC IN connector on the rear of the wireless base station

- The wireless base station has two HDMI signal output terminals for a clinical display and a video sharing display
- There are reminders and alert audio output in the HDMI

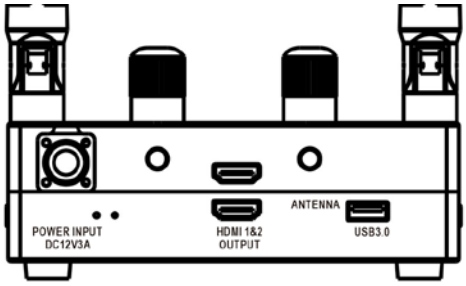
The audio in the upper HDMI 1 output, comes out from the speaker inside the wireless base station

- The audio in the lower HDMI 2 output, goes out to the attached monitor display

NOTE

- HDMI 2 has priority for audio output

(Wireless base station rear panel)



TIP

- In most cases the clinical display should be connected to the upper HDMI 1 terminal, otherwise there will be no audio alert coming out from the wireless base station speaker
- The audio in the lower HDMI 2 output comes out from audio output jack, for an HD OLED head mounted display when attached

Internal (PCIE M2 SSD card) and external storage

- Wireless base station built-in PCIE M2 SSD card 1T internal storage ensures the initial preservation of the patient's endoscope still images and video data
- External USB storage is used when a copy of the patient's data is desired
- The recommended port on the wireless base station for copying patient data is the USB port on the front panel
- You can select and copy the data from the internal storage (PCIE M2 SSD card) into the external USB storage
- The recommended capacity of the external USB storage is 16G, 32G, 64G, 128G, or above up to 1T (please confirm, when inserted the storage should be recognized and formatted and with capacity displayed on screen) (please refer to "Data saving time" on page 48). Use a USB storage formatted to FAT32 or NFTS
- PCIE M2 is recommended for faster data copy
- The front panel USB3.0 port data copy speed is around 30M/s
- The rear panel USB3.0 port data copy speed can be as high as 300M/s with PCIE M2 external storage

Precautions when using an external USB flash drive

- Check the format of newly purchased USB 3.0 Flash Drives before use. Only FAT32 or NFTS formatted drives can be used on the wireless base station.
- USB 3.0 Flash Drives with exFAT format must be formatted to NFTS or FAT32 format.

NOTE

- When the Flash Drive with NFTS or FAT32 format is inserted into the front panel USB port, it will be recognized and be configured further in the FAT32 format. The capacity and remaining percentage will be displayed on screen. This process will last 15 seconds, please wait until the remaining capacity and percentage is displayed on the screen.
- The wireless base station USB port will recognize whether it is a mouse or a USB flash drive attached.
- The wireless base station will not recognize the exFAT format USB flash drive.

TIP

- We recommend the following Flash Drive:

Brand: SanDisk

Model: Ultra Flair 16GB 32GB 64GB 128GB 256GB 512GB USB 3.0 Flash Drive

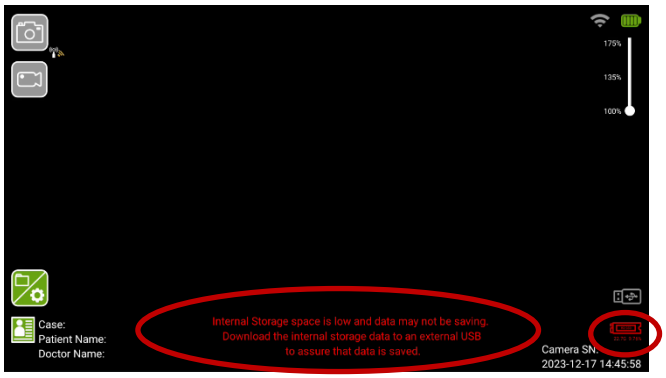
NOTE

- The Wireless base station could take a longer time to recognize old or loose fitting USB flash drives, or not recognize them at all.
- Do not remove the USB flash drive or insert an additional one during its process. Doing so can cause the configuration to take longer or prevent the wireless base station to recognize or store data onto the USB flash drive.
- Please insert a USB 3.0 flash drive quickly into the USB port on the Wireless base station with two hands, if inserted slowly, then the USB 3.0 Flash Drive will be recognized as a USB 2.0 Flash Drive. This can cause longer recognition and configuration time.

Precautions when using the internal PCIE M2 SSD card

When the internal storage (PCIE M2 SSD card) remaining is less than 10%, there will be an audio alert. The internal storage (PCIE M2 SSD card) icon color will change to red. The following message in red will also appear on the screen for one minute:

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.



NOTE

Remaining capacity10% to 5% can only ensure about 3 hours's video recording.

Lower than 5%, picture/video recording, new case start will be disabled.

When the internal storage (PCIE M2 SSD card) remaining is less than 5%, there will be an audio alert. The internal storage (PCIE M2 SSD card) icon color will stay red. The following message in red will also appear on the screen for one minute:

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.

At the same time, the picture video recording and case icons turn gray. The picture video recording and new case start will be kept disabled until the internal storage space has more than 5% remaining capacity.

Endoscope C-mount coupler

- The C-mount mechanical optical coupler (or “Coupler”) is placed between the camera and the Arthroscope.
- Refer to chapter 5 for detailed cleaning and sterilization instructions

Be sure to keep the coupler C-mount and camera head C-mount dry to prevent condensation prior to mounting together

TIP

- When the camera head is sent to cleaning, the C-mount coupler should keep on the camera head
- Refer to chapter 5 for detailed cleaning instructions

To prevent an unacceptable risk if endoscopic equipment loses function

1) Always check the proper functioning of your Nuvis system and endoscopic equipment prior to the start of the procedure.
2) 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.

NOTE

If the imaging data is not displayed, check the camera head battery power and all connections such as the C-mount Coupler, illumination source, and cables. If everything appears satisfactory, and the image is still not displaying, consider replacing the endoscope.

Turn ON the system power

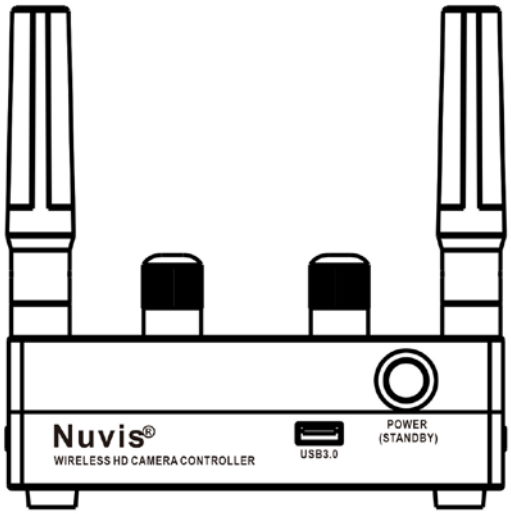
Long press (at least 8 seconds) the power switch to turn off power completely.

Short press (less than 2 seconds) of wireless base station [Power] button only turns off the HDMI 1& 2 outputs, it does not turn off the power. The wireless base station goes to [Standby] and video will continue to record if video is on.

Wireless base station front panel

Turn ON the wireless base station and camera head power for live video, picture taking and video recording

- Wait for 15-20 seconds for the camera head and wireless base station to build a live video transmission and receiving connection
- Confirm there is live video on the display and the image is correctly oriented
- Confirm the camera head SN number and case number appear on the display
- A White Balance correction may be performed
- At this point, the system preparation is complete
- You can now take pictures and record videos (See Quick Operation section)



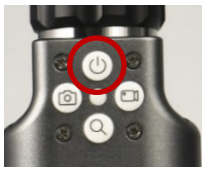
Read and follow warnings from other tools used in the procedure. Other tools can include but are not limited to insufflator, shavers, etc.

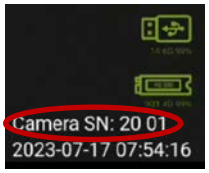
3 Quick Operation (the easiest and fastest operation steps)

The five steps described below can quickly and independently complete the basic operations of the system. This includes turning on the system power, displaying live video on the clinical display, taking pictures, recording videos, and saving data into internal storage (PCIE M2 SSD card).

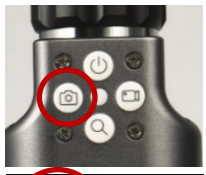
- Step 1 Turn ON [Power] of wireless base station and confirm the control UI is displayed on the screen
- Step 2 Turn ON [Power] of camera head and confirm the correct camera head SN number is displayed on the screen
- Step 3 Start a new case by long pressing (3 seconds hold) the [Camera] button, then confirm the case number on the screen. Confirm that the live image is displayed and correctly oriented
- Step 4 Take Pictures and record Videos from buttons on the camera head
- Step 5 Copy data from the control UI if desired or control the system from a mouse

- Turn wireless base station [Power] ON

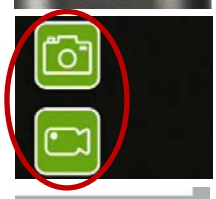


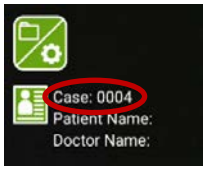


- Turn camera head [Power] ON, confirm camera head SN last 4-digit number “2001” (for example) appears on the screen, (in case the camera head power was turned on earlier than the wireless base station, double click the camera head power button)



- Start a new case (long press over 3 seconds the [Camera] button) confirm case number appears on the screen





- Confirm pictures and video icons are green on the display. Take pictures and videos by pressing the [Camera] and [Record] buttons

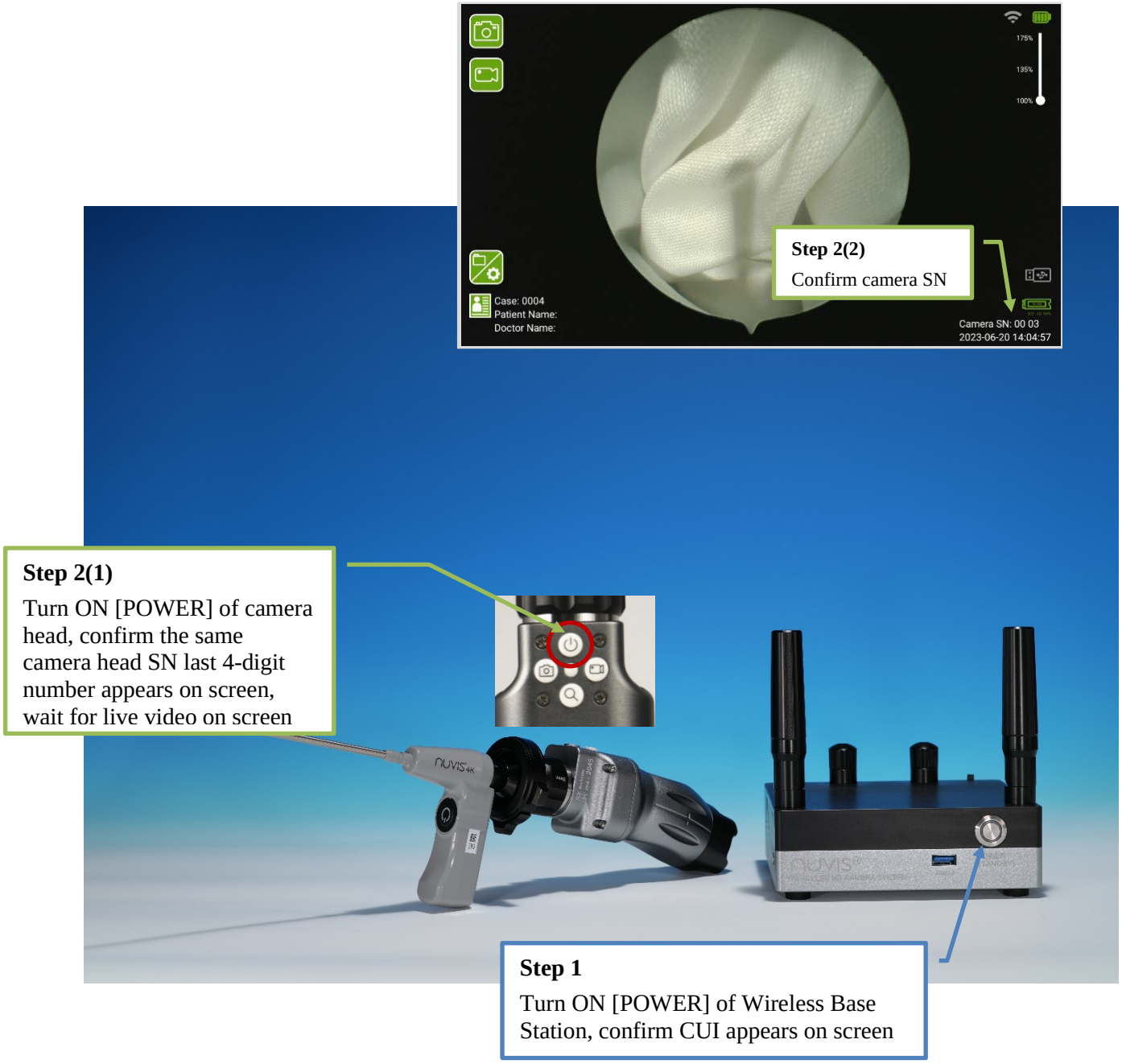
- Copy data to the external USB storage from control UI if desired

Quick Operation Steps

Nuvis Wireless HD Camera System

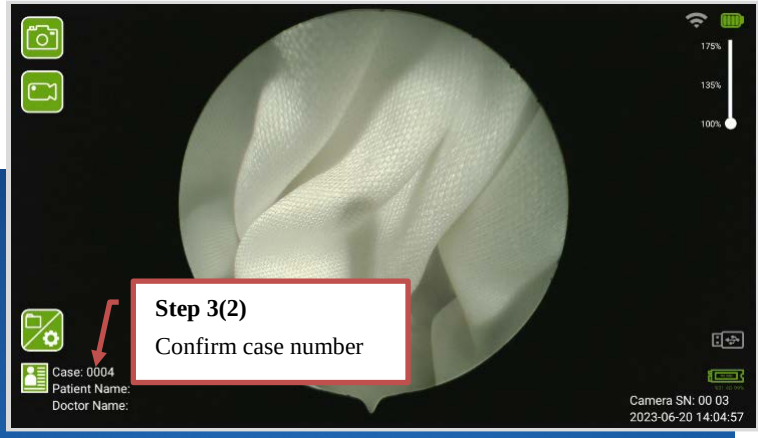
Step 1

Step 2



Step 3

Step 4

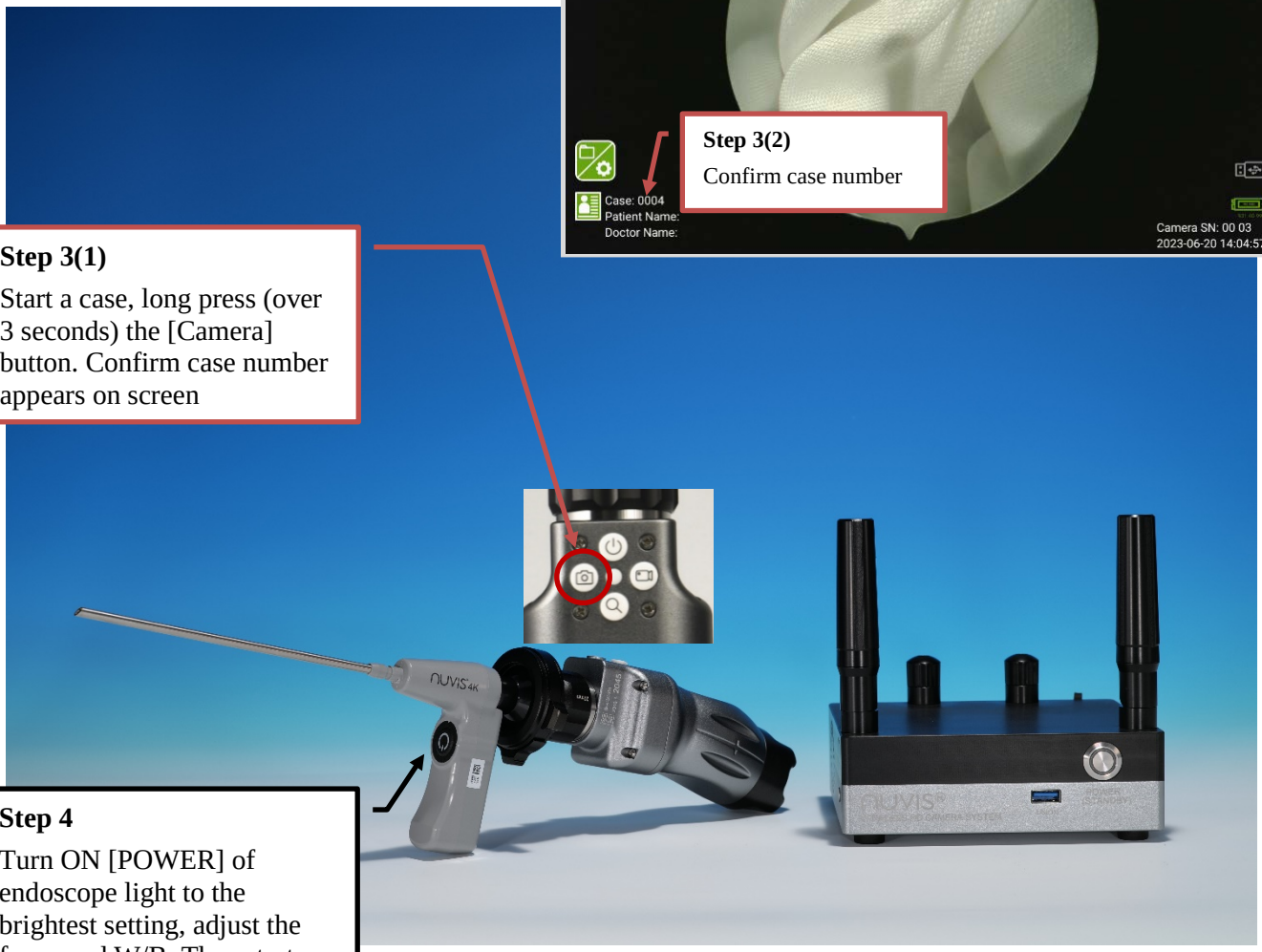


Step 3(2)

Confirm case number

Step 3(1)

Start a case, long press (over 3 seconds) the [Camera] button. Confirm case number appears on screen



Step 4

Turn ON [POWER] of endoscope light to the brightest setting, adjust the focus and W/B. Then start picture and video recording

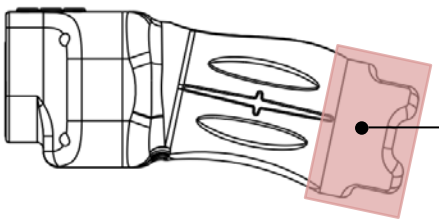
Camera exchanging

* Double click desired camera [POWER] button, to switch between the two powered-ON camera heads;
* Control the system with a mouse from the USB3.0 port on the front panel.

Shut down

* Press and hold over 3 seconds until the LED turn off to shut down the camera power;
* Press and hold over 8 seconds will shut down the wireless base station power;

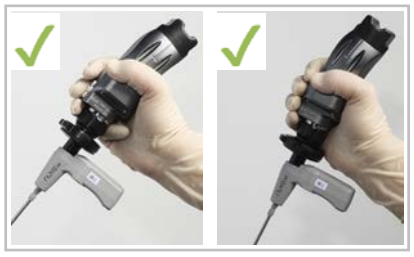
Camera antenna



Holding the black cover can block the antenna!

Do not fully block the camera head transmitter antenna cover (the black part of the camera head), as the wireless signal may be weakened.

Antenna



Not covered

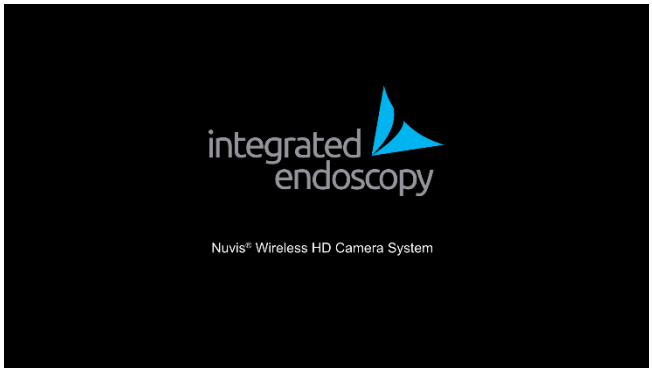
Partially covered

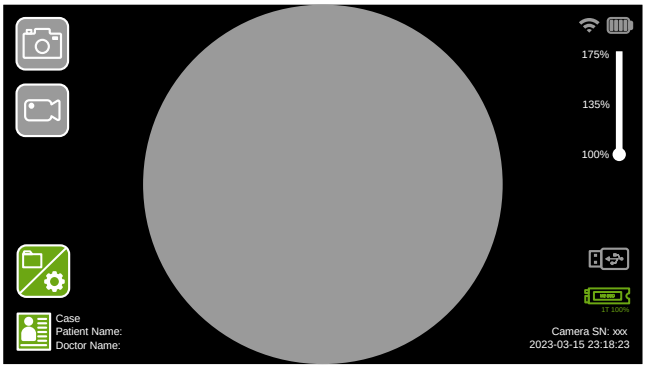
Totally covered

Quick and no fail workflow

Step 1 Turn ON [Power] of wireless base station and confirm the control user interface (“CUI”) on the screen

ur [Power] of wireless base station, confirm the wireless base station starts in about 10 seconds with control UI on the screen





NOTE

- Confirm that the HDMI cable is connected from HDMI 1 output (please refer to page 20 for more information on HDMI 1 and HDMI 2)

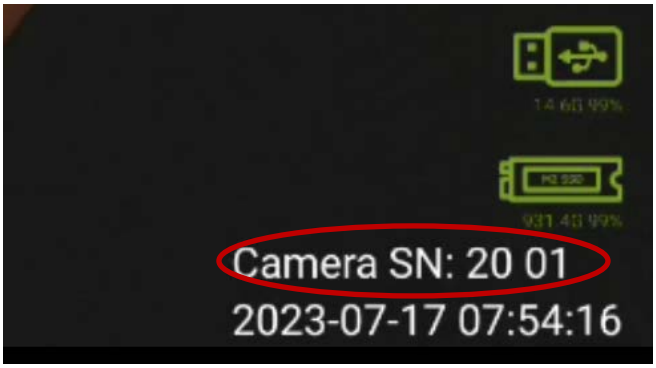
Step 2 Turn ON [Power] of camera head confirm the camera head SN last 4-digit number on the screen

- Attach the coupler and arthroscope
- Check the camera head’s battery level and estimate the operation time
- Turn ON [Power] of the camera head, confirm that this camera head SN appears on the screen immediately (camera head SN: 2001, for example)

- It will usually 15 to 20 seconds for the camera head to build HD video connection with the wireless base station
- Confirm the HD live video on the display

a) Patient information input

b) Patient data management and system setting



NOTE

Switching between camera heads:

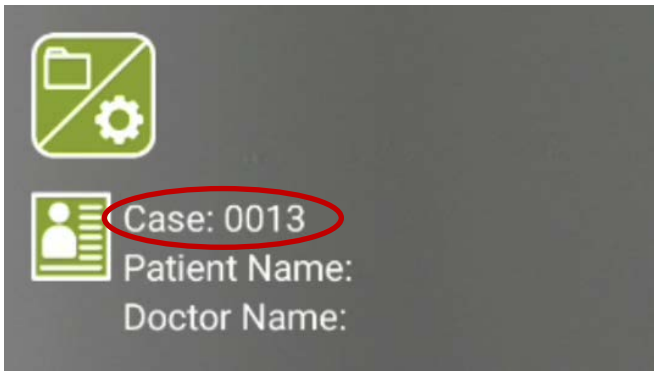
- Turn the previously used camera head's [Power] OFF and set it aside for cleaning
- Turn the replacement camera head's [Power] ON, the latest powered-ON camera head has the priority to build new video connection with the wireless base station

TIP

- In a typical hospital OR's WIFI environment, the time for HD video connection between the wireless base station and the camera head is about 10 to 20 seconds.
- In a WIFI environment where there is a multitude of competing signals, the HD video connection between the wireless base station and camera head takes up to 35 seconds.

Step 3 Start a new case by long pressing (3 seconds hold) the [Camera] picture taking button, confirm the case number on the screen

- Confirm camera head SN and live video display on the screen. Confirm that the image is correctly oriented.
- Long press the [Camera] picture taking button on the camera head to start a case
- Confirm the case number appeared and [Camera], picture taking and [Video], video recording button turned from gray to green



Start a new case

- Three seconds long pressing of the [Camera] button on the camera head starts a new case without patient information
- New case folder name generated as Case0001 (for example)

Step 4 Take Pictures and record Videos from control buttons on the camera head

- There are 4 buttons on the camera head, they are: [Power], [Camera], [Zoom] and [Video]
- Press the [Camera] button to take a picture
- Press the [Video] button to start the video recording
- Press the [Video] button again to stop the video recording and save data

NOTE

Picture files will be named in the following manner. (examples below)

- Case0001_20230313_181239_William.jpg
- Case0001_20230313_181239.jpg
- When more than one pictures is taken in one second
- Case0001_20230313_181239_William_1.jpg
- Case0001_20230313_181239_1.jpg

Video files will be named in the following manner

- Case0001_20230313_181239_William.MP4
- Case0001_20230313_181239.mp4

Step 5 Copy data for patient from control UI

- To copy the data insert an External USB Storage into the USB port on the front panel
- This USB port in the front panel is designed only for patient data copy
- Copy patient data from [Data/system], in the data management page, press [Copy] button for one way copy directly to external USB storage on the front panel

- If a USB storage is inserted, the user will be reminded on the screen: “The external USB storage will be formatted within 10 seconds” and if not taken away within 10 seconds the inserted external USB storage will be formatted and data stored on the USB storage may be lost
- USB external storage icon on the screen turns from gray to green, with 31.5G and 99% total capacity for example
- Photos and videos or folders can be copied into the external storage
- When [Power] button on the wireless base station front panel is long pressed (over 8 seconds), the wireless base station power will be turned off

4 System Operation Instructions

Display control UI icons description

[camera] icon: take a picture

- Gray: not ready (no camera head SN number or no case number)
- Green: ready (camera head SN number and case number confirmed on the screen)

TIP

- Each time you turn ON the power of the wireless base station, you will find that the [Camera] icon is gray. After confirming the camera head SN number and case number on the screen, the camera icon will turn green.
- As long as the camera head power is on, camera head SN number appears on the screen and a new case is started, this [Camera] icon will turn green, enable you to take pictures.
- There is a zoom out of the picture taken, this picture is saved into the internal storage (PCIE M2 SSD card).

TIP

- In order to take a good picture, just take as you take a picture on a digital camera. Half press the

[Camera] button, continue pressing until you feel a click, a better picture might be taken without any blur.

- The camera head system is always equipped with enough illumination, the automatic electronic shutter speed will usually be shorter than 1/500s, so even if you press the [Camera] button directly without care of the half/half press, the picture would be in focus.
- 3 pictures can be taken in 1 second (even shutter pressed more than 3 times). During recording, 2 pictures can be taken (even if shutter is pressed more than 2 times)

[Video] icon: record a video

- Gray: not ready
- Green: ready
- During video recording the red dot in the icon begins to blink, the recording time appears on the right side of the icon
- When video recording stops, the data will be saved in about 1 second
- The icon will be gray when one of the following occurs:

a) There is no camera head SN number on the screen

b) There is no case number (folder is no ready for data saving

- The icon will be green when both the above settings are done

TIP

- Each time you turn ON the [Power] of the wireless base station, you will find the [Video] icon gray. The [Video] icon turns green once you start a new case.
- As long as a new case is started, this [Video] icon stays green, this will enable you to take videos
- When the video is being saved on to the storage (PCIE M2 SSD card), the [Video] icon turns to static green

[Patient info] icon: input patient information and start a new case

Patient information input can be done from GUI APP, after inputting the patient information, start a new case with folder name of [Case0001]

Case 0001
Patient Name:
Doctor Name:

- The new case name will remain, as long as you do not turn the wireless base station [Power] off, or if you do not start a new case
- Always remember to start a new case with a new case number folder for a new patient to save data
- Each time you turn ON the wireless base station [Power], there is no case number until you start a case
- Long press of [Camera] button, will automatically generate a new case named Case0001, without any patient information entered
- After inputing the patient information, you can start a new case with the new case number, Case0001
- Enter the information including: Patient name, patient birthday, gender, patient ID number, doctor name, memo

[Patient data/system setting] icon (access needs password)

- If you press [Data/system] icon, there will be a reminder for password input
- When [Data/system] icon is pressed, the picture/video recording will not function
- [Data management] icon: Patient data list, file and folder sorting and select, copy to external storage and delete
- [System setting]: photo and video format selection, audio embed video recording selection, date and time setting, audio alert volume adjustments, etc.
- Inside the [Data/System setting]: [Camera wireless pairing/adding a camera head] and [Camera setting/menu setting] are designed only for manufacturer

Camera head battery level Icon

- For shipping and transportation safety, the cameras built-in battery will be almost completely discharged. So, when the camera is first used, please check and charge it for 2 hours to fully charge the battery
- Camera head battery level display
- Capacity remains 100-75%, 75-50%, 50-25%, 25-0%
- When under 25%, 1 level red battery icon will start blinking and will give off warning audio alert (“beep, beep”)

[Zoom] icon: zoom in

- One press: zoom in/out in the loop of 100%→135%→175% (full screen) →100%
- Long press over three seconds: camera head white balance automatically corrected

W/B icon: camera head white balance automatic correction

- With over a 3-second-long press of [Zoom] button on the camera head, W/B icon appears on the screen. The camera starts W/B automatic correction for about 5 seconds
- After about 5 seconds, the correction will finish and the icon disappears

Internal storage (PCIE M2 SSD card) Icon

- Gray: no storage
- When a PCIE M2 SSD card is installed in factory, this icon turns green with total capacity and percentage of remaining capacity
- When the remaining percentage is under 10%, the icon color will turn red

External storage Icon

- Gray: no storage
- Each time a USB stick is inserted, formatting is reminded and the USB stick is automatically formatted in 10 seconds
- Once formatted, a green icon is shown with total capacity and percentage of remaining
- When the remaining percentage is under 10%, the icon color will turn red

System Control from camera head

System basic operation including camera head SN number input, starting a case, picture taking, video recording.

Camera head control marks and buttons

[Power] mark: power ON/OFF Button

- Short press [Power] button turns on the camera head power, at the same time the camera head starts to build the HD video connection with the wireless base station, and the camera head SN number will also be read by the wireless base station
- Press and hold [Power] button for over 3 seconds, the LED light in the middle of the buttons will turn off. Release the [Power] button, and the camera head power turns off
- When camera head power is on, double click the [Power] button to start the HD video connection again and send the camera head SN number to the wireless base station

NOTE

Any misoperation on power button (accidental operation even more than 2 times short press) on any 4 buttons on the camera head will not turn the camera live video off;

Any misoperation on power button (accidental operation even more than 2 times short press) will not lead to catastrophic consequences, such as the loss of live video T/R, such as the loss of video recording, such as data not recorded, etc.

Long press the power button for 3 seconds until the LED light goes off, the camera head power will be turned off, if the base station is recording, then the live video on the screen will become black with no live video, but GUI (graphic user interface) will always be there, and the recording will always be continuing.

[Camera] mark: take a picture and start a new case button

- Short press takes a picture and saves a file into the designated folder
- Over three seconds long press of [Camera] button starts a new case directly

[Video] mark: record a video button

- Short press starts video recording
- Another short press stops video recording and saves a file into the designated folder

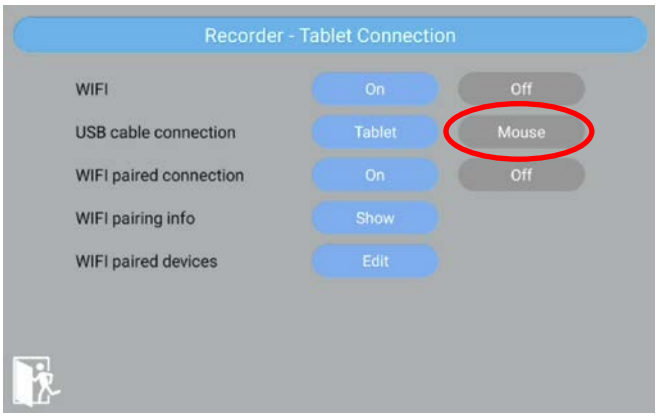
[Zoom] mark: zoom & (W/B) button

- One short press, zoom in from 100% to 135%
- Another one short press, zoom in from 135% to 175% (full screen)
- Another one short press, zoom out back to 100%
- Three seconds long press [Zoom] button, camera head white balance correction executed

System control from a mouse

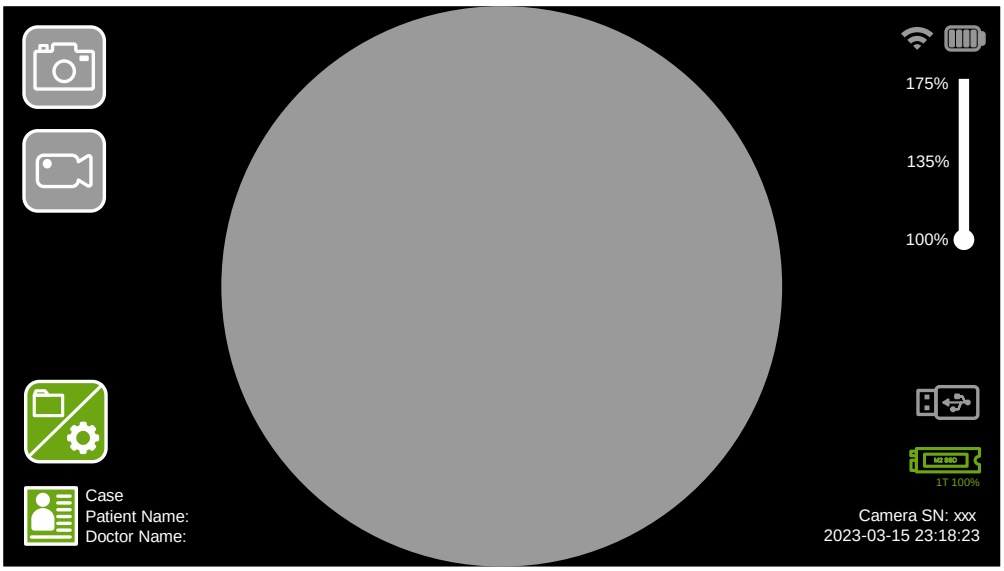
A mouse can operate all of the functions on the CUI.

- If you want to control the wireless base station by a mouse, change to [Mouse]
- A mouse can be inserted into the USB port on the rear panel to operate the wireless base station
- Both the 2.4GHz wireless mouse and the cabled mouse can be used for the control
- Bluetooth mouse cannot be used



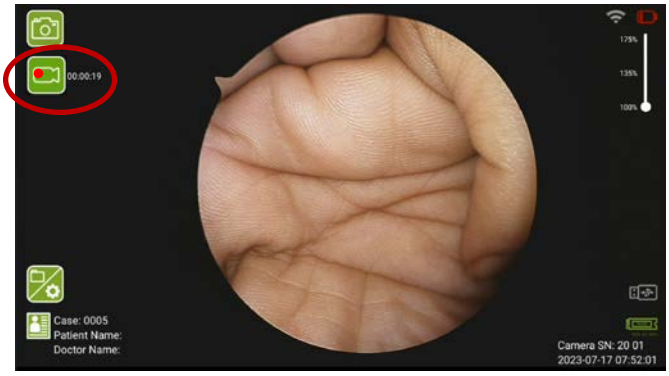
Icons operation detailed explanation

The following operations can be done from a mouse though the USB port on the front panel.



[Camera] icon: take a picture

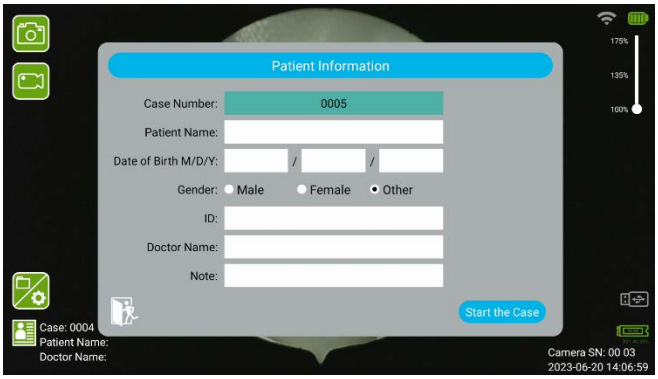
- Short press takes a picture and saves a still image
- Jpeg file into the designated “Case 0005” folder



[Video] icon: record a video

- Short press starts video recording, during recording the dot in the video icon will turn red and start blinking with the recorded time will appear on the right side in the display
- Another short press stops video recording and saves a video mp4 file into the designated “Case 0005”(for example) folder, the icon will return to static green

[Patient info] icon: patient information input and start a new case

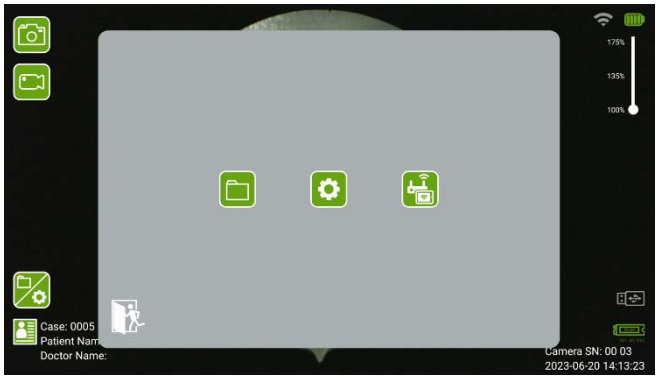


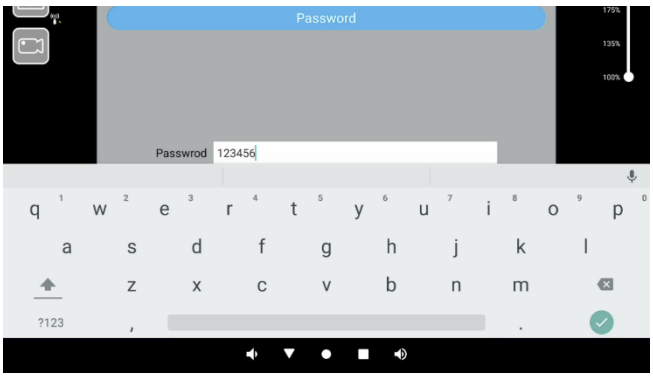
[Data/system] icon

3 icons inside the [Data/system]

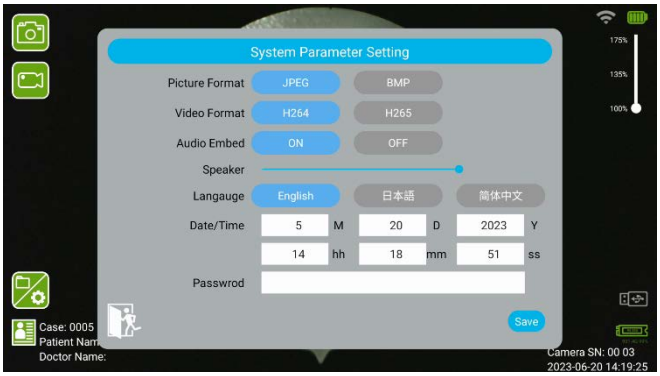
a) [Data], access needs password

b) [System setting], access needs password





- System parameter setting

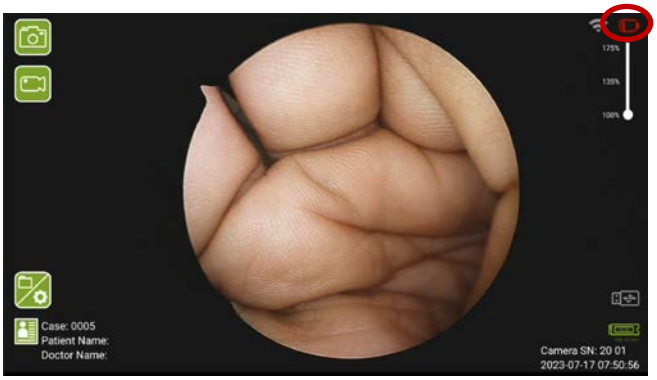


NOTE

Picture Format, Video Format, Audio Embed, Language are set by default to JPEG, H.264, ON, English

Camera head battery level icon

- Battery level is real time displayed on the screen



Camera head battery status (timed and percentage are estimated)

Camera head battery icon on the display	Battery capacity percentage on charging station	LED color when charging	Total charging time (minutes)	Operation time (hours)	LED alert on camera head
4 level (green)	100%	Solid green	120-150	3.5-4	2 to 4 hours, solid green LED stays on
4 level (green)	75-90%	Green blinking	90-120	3-3.5	
3 level (green)	50-75%	Green blinking	60-90	2-3	
2 level (green)	25-50%	Green blinking	30-60	1-2	Slow blinking
1 level (green)	0-25%	Green (fast) blinking	0-30	0-1.0	Fast blinking

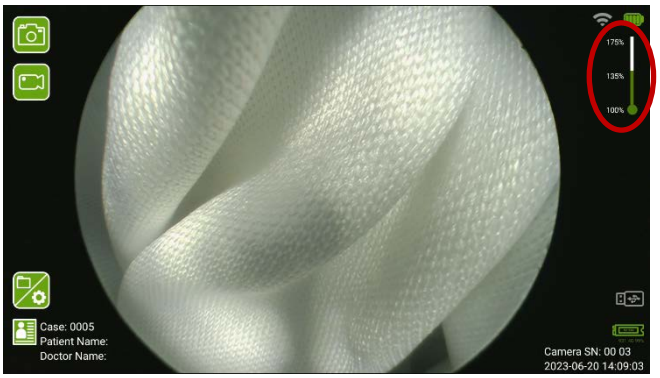
Zoom icon: zoom in

a) One short press, zoom in from 100% to 135%

b) Another one short press, zoom in from 135% to 175% (full screen)

c) Another one short press, zoom out back from full screen to 100%

- white medical gauze could be used for White Balance automatic correction

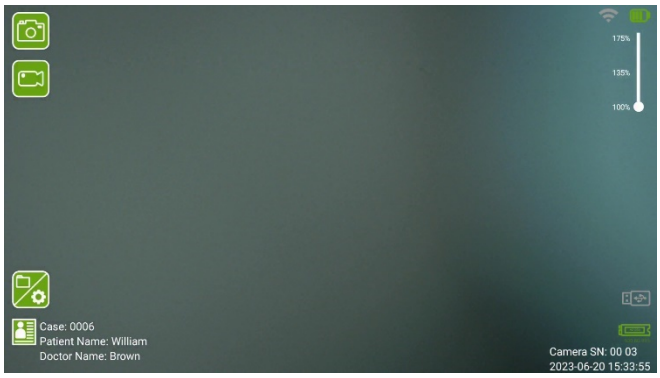


W/B icon: white balance automatic correction

a) Point the endoscope to get a full screen live video of white material such as white gauze or a white medical sponge

b) Long press the [Zoom] button on the camera head for over 3 seconds until the W/B icon appears on the screen

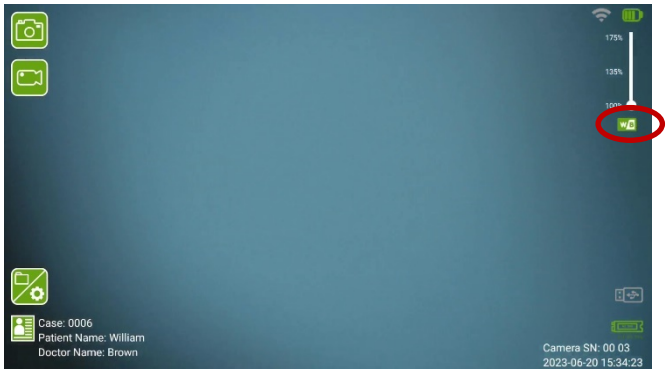
c) Release the button and continue pointing the endoscope on the white material for another 3 seconds to let the camera head to perform automatic white balance correction



d) The W/B will disappear after the white balance correction is completed.

NOTE

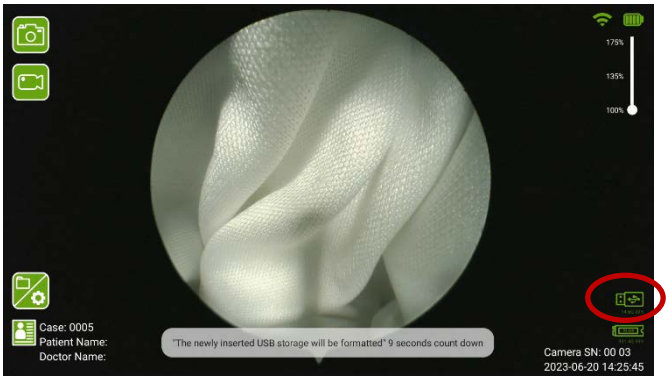
White balance correction of the camera head is required only if a new endoscope from a different manufacturer is used, or if the endoscope light source is new.



Internal storage (M2 PCIE SSD card) icon always green

External storage icon

- Gray: no external storage
- Green: external storage inserted and ready for use



Camera head SN number & date/time

- The camera head serial number is one of the two prerequisites for picture and video data saving
- The other prerequisites for picture and video data saving is the case number (case folder for data saving)
- After turning on the power of the camera head, the camera head will be registered into the wireless base station, and the camera head serial number will appear on the screen
- The wireless base station only receives controls from registered camera head
- Date and time can be set from [System setting]

HD video wireless transmission & receiving

Live video T/R automatically built

- Turn ON the [Power] of wireless base station and camera head, the live HD video connection is built in 15-20 seconds
- Within a radius of 5m (15 feet), the wireless base station and camera head can establish a stable real time HD video connection
- The live video displayed on the screen has no perceptible latency
- The camera head that is turned on latest has the priority to connect the wireless base station. It stops the previously connected live video and builds its own connection

Live video with no perceptible latency

- Stable and no-delay real-time high-definition live video transmitted and displayed on the screen, can help doctors perform surgery.

Storage preparation, data saving and protection

Internal storage (PCIE M2 SSD card)

- Internal PCIE M2 SSD storage is factory installed and formatted
- Internal PCIE M2 SSD storage is for initial data saving, green with total capacity and remaining percentage displayed on the screen

When internal storage remaining is under 10%, the icon turns red, audio alert will be given out, at the same time, the following message will also appear on the screen: **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.**

When internal storage remaining under 5%, icon's color stays red + alert sound + message appear on screen in red for one minute: **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 and video recording and case icons turn gray.

External USB storage

- External USB storage usually used for copying of the picture/video data and for removing it from the wireless base station.
- The [Copy] is designed only in one direction, internal storage to external storage
- The USB port on the front panel is designed for USB patient external storage

- The recommended capacity of the external USB storage for patient is 16G, 32G, 64G, 128G, or above up to 1T (please confirm, when inserted the storage should be recognized and formatted and with capacity displayed on screen) (please refer to "Data saving time" on page 48). Find those USB storage available in the market which can be formatted and used

- Insert a USB external storage on the front panel USB port. "The newly inserted USB storage will be formatted" + 10 seconds count down. If the USB storage is not removed it will be configured after 10 seconds count down has finished
- Wait for a few seconds, USB external storage icon on the screen turns from gray to green. With 16G (for example) Free100% for example (Total capacity and remaining percentage)

- After data copy, do not forget to remove the external USB storage

NOTE

- End user should prepare the standard or high-speed storage (PCIE M2 SSD card)
- Before inserted into the wireless base station USB port, the storage should be formatted by a PC in FAT32 or NFTS format

USB storage will be configured after each insertion

- To prevent a different patients data being saved on the same storage drive, each time a USB storage drive is inserted into the wireless base station front panel USB port, the USB storage drive will be configured.

Internal storage

- The wireless base station is equipped with a PCIE M2 SSD 1T internal storage
- It cannot be removed from the wireless base station unless done so by maintenance personnel
- Every patients information, picture and video data must and will be saved in this internal storage first
- The USB external storage is designed to copy data when needed

- “Insert USB storage”, “copy patient data”, “remove USB storage” are the complete copy of the data operation 3 steps and procedures
- Never forget to remove the external USB storage after patient data copy

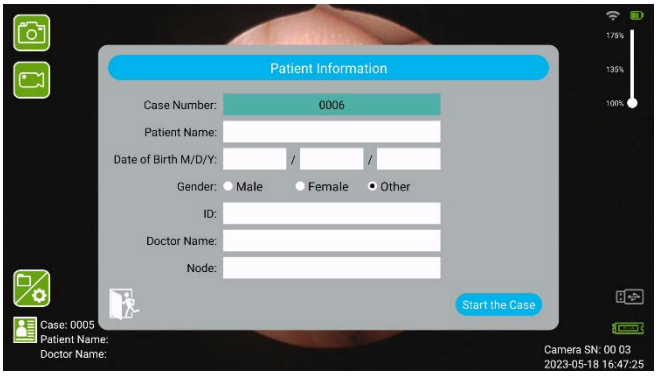
Data saving time

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

Patient information registration

Patient information input

- Patient information and doctor information can be input with a mouse from [Patient info]
- The patient's name will be used as part of the picture and video file name
- The file name with the patient's name can be more easily found in file sorting and searches
- In the patient information input page, you will find the "start the case" icon. Press it and start a new case
- Patient information is saved in a txt file together with the still image and video files. Txt file can be read on a PC



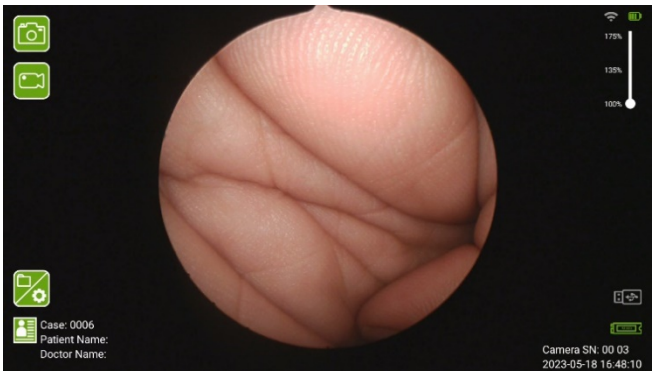
Start a new case and find the case number on the screen

- When a new case is started, the case number, patient name and doctor name appear on the screen
- You can also start a new case by long pressing (over 3 seconds) the [Camera] button, in this case, only the case number appears on the screen

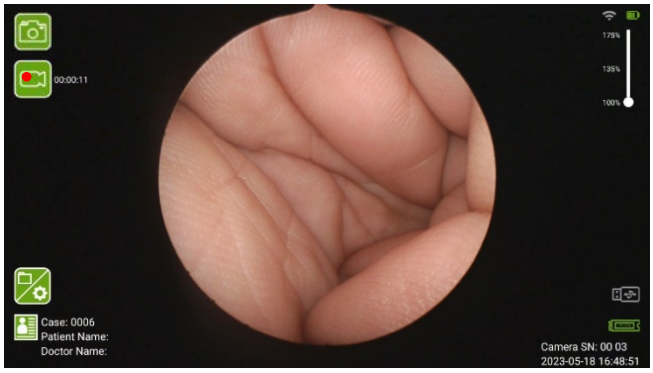
Picture taking & video recording

Take a picture

- A picture can be taken from camera head body [Camera] button
- One short press of the camera head body [Camera] button or a [Camera] icon can take and save a picture
- There should be about half a second time interval between the taking of two pictures



Record a video



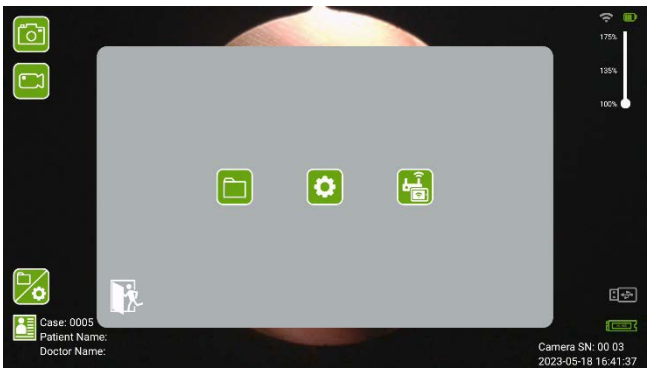
- A video recording can be started from camera head body [Video] button
- A video recording can be ended from camera head body [Video] button
- One short press of the camera head body [Video] button
- [Video] icon starts a video recording
- Another short press of the camera head body [Video] button ends and saves a video recording
- Video data saving takes a few seconds. The [Video] icon on the screen turns from blinking to static green
- When the [Video] icon on the screen turns green, you can start recording another video

NOTE

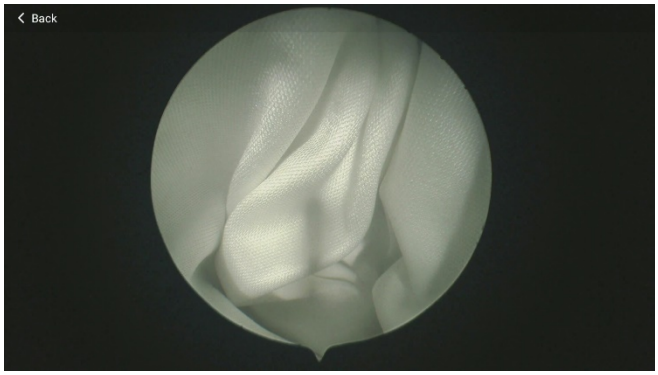
- During recording, if the wireless base station power is turned off, or the power supply from the adapter is stopped, the recorded data of the latest episode will got lost

Patient data management

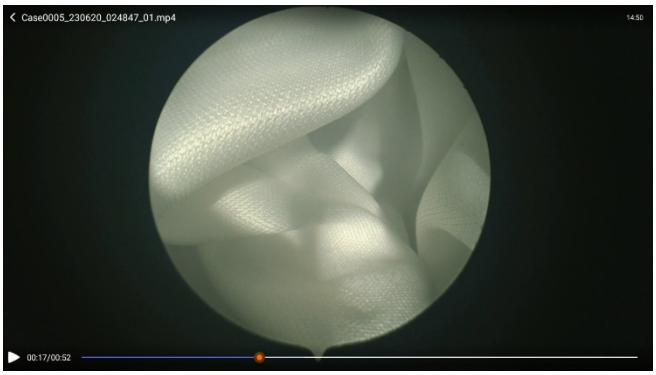
Accessing the [Patient data] requires passwords



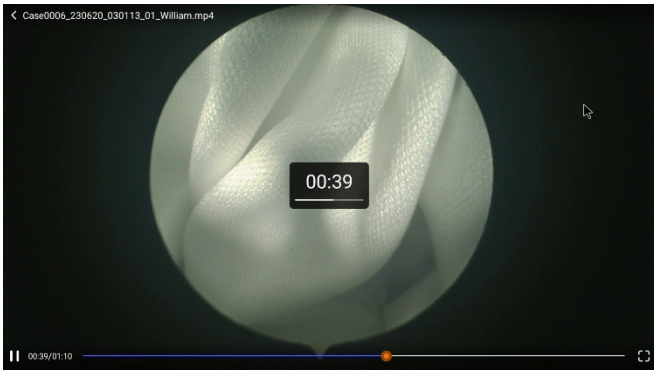
Review pictures



Play videos



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



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

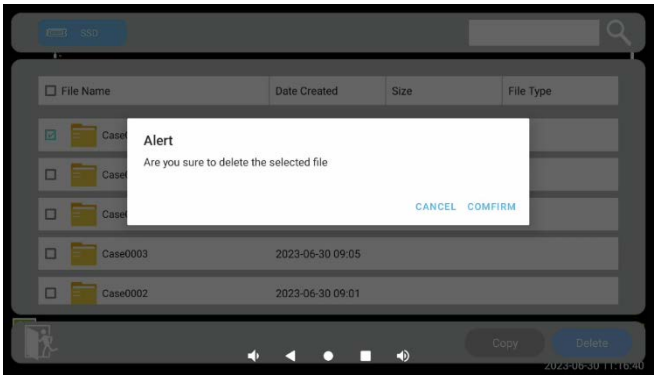
Sorting & finding

- The following terms can be used for sorting and finding the file
  a) Patient name: William
  b) The case number, for example: Case0001 (Note that C is capitalized)
  c) Date in the file name, “Case0001_20230313_181239_William.jpg (for example)”: 20230313

Select & delete data

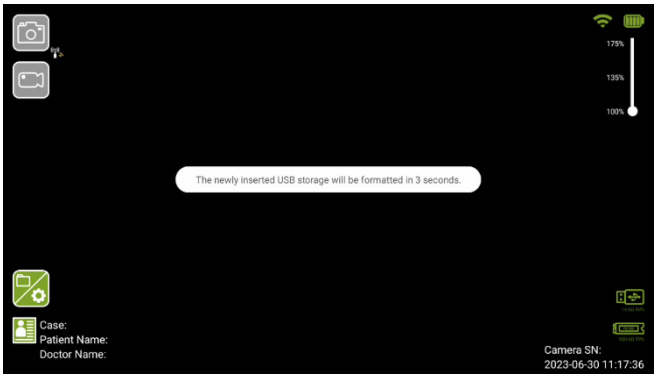
Go to internal or external storage, select the files to be deleted. Confirm the [Delete] button is blue

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



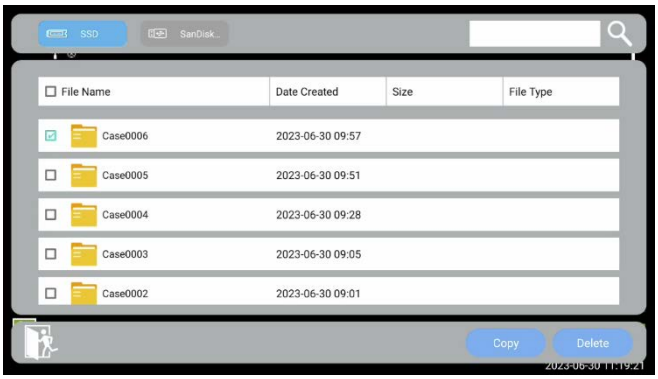
Select & copy data to external storage

Insert USB storage into the USB port on the wireless base station front panel



After USB configuring, confirm external USB storage icon green

In [Data management], confirm that the external USB icon appears in gray color. Also confirm that [Copy] and [Delete] button is blue

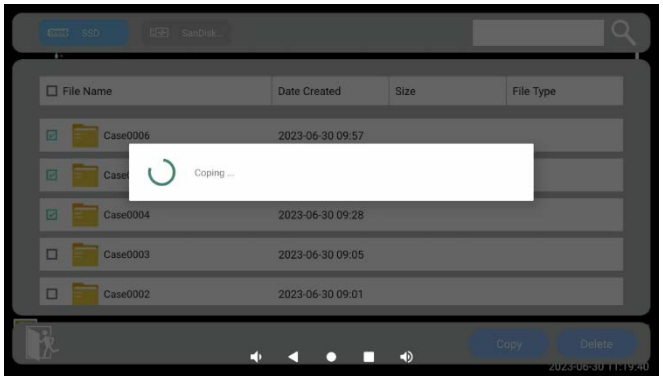


Select the file to be copied, press [Copy], there will be the following reminder messages appear on the screen:

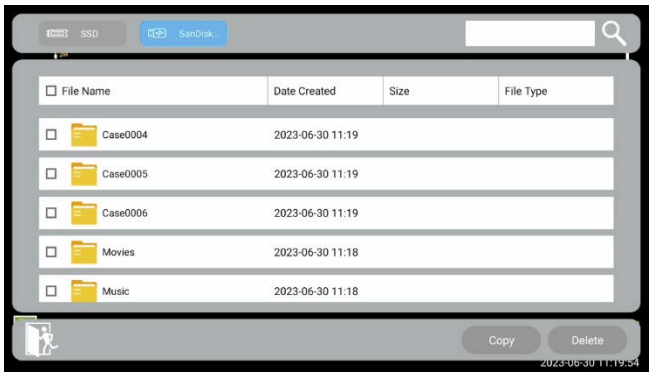
- “This file is being copied, please be patient.”
- “It takes approximately 00:03:20 to complete, …”

if the data selected to be copied with the bigger size than the external USB storage, then,

- “The disk space not enough”



Confirm the selected files copied in external storage (USB). Press the external storage icon, icon color will change from gray to blue with recorded data displayed.



System setting

Accessing the [Data/system] requires password

System setting

Picture Format, Video Format, Audio Embed (There is no audio input feature), Language defaults are JPEG, H.264, ON, English (operator cannot modify defaults at this time)

- Speaker: adjust the wireless base station speaker audio alert volume
- Date & time setting
- Password default setting, set, clear and reset

a) Factory default password setting is without password

b) The first time you receive the wireless base station there is no password

e) Set the password, the first time: enter 6 digits of numbers into password column and save

f) If you forget the password, there is an administrative password, use this administrative password (please confirm with IE) to come into the [System setting], and set the password and save it again

- Do not forget [Save] before exiting the system setting

Text reminder & audio alert

Text reminder appears on screen

- HD video T/R connecting (searching and connecting a camera head, camera head connected, camera head not found)
- The newly inserted external USB storage will be formatted in 10 seconds

"The newly inserted USB storage will be formatted" + 10 seconds count down

- Internal storage remaining under 10%, icon's color turns red + alert sound + message (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.) appear on screen
- Internal storage remaining under 5%, icon's color stays red + alert sound + message (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.) appear on screen. Icon color stays red. Picture and video recording and case icons turn gray.
- Delete data from internal storage, alert sound + reminder message "Are you sure to delete the selected file?" "CANCEL" or "CONFIRM"

Password needed

- Access the Data needs password
- Access the System Setting needs password

Camera head LED light alert

- In the middle of the camera head buttons there is green LED light which reminds remaining operation hours
- LED green static: remaining operation time from 4 hours to 2 hours
- LED green slow blinking: remaining operation time under 2 hours
- LED green fast blinking: remaining operation time under 1 hour
- When the camera battery capacity is under about 25%, when the remaining operation time is under 1 hour, the green LED will turn to fast blinking, at the same time, on the CUI display screen, the battery icon will turn to one level red, and gives off warning audio alert ("beep, beep")

Icons blinking & change color alert

- Camera head white balance is automatically correcting, W/B icon blinking for three seconds
- Camera head operation time is under 1 hour (new camera head), camera head battery level icon turns to be one level red and stays blinking until camera head runs out of power

Audio alert

- The wireless base station can give off 2 reminders and an alert sound
- Reminder and warning alert sound volume can be adjusted or turned off in system setting
- Picture taken/saved reminder sound 1
- Video recording start/stop reminder sound 2
- Camera head operation time under 1-hour, alert sound
- Internal and external storage remain under 10%, icon’s color turns red + alert sound
- Internal storage remaining under 10%, icon’s color turns red + alert sound + message (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.) appear on screen
- Internal storage remaining under 5%, icon’s color stays red + alert sound + message (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.) appear on screen. Icon color stays red. Picture and video recording and case icons turn gray.
- Delete data from internal storage, alert sound + reminder message “Are you sure to delete the selected file?” “CANCEL” or “CONFIRM”

Text reminder, audio alert, … system security management:

No.	Situation	Audio alert	Text reminder	LED and icons
1	HD video T/R connecting			
	searching for a camera head			4 levels looping
	connecting a camera head			
	camera head connected			
	camera head not found			
2	No device!			
	There is no connection between the wireless base station			
3	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)
4	Camera head white balance correction			W/B icon appears for 3 seconds
5	Picture taken/saved	Reminder 1		
6	Video recording start/stop	Reminder 2		
7	Access the [Patient Data]			Password needed
8	Access the [System Setting]			Password needed
9	Newly inserted external USB storage		“The newly inserted USB storage will be formatted” + 10 seconds count down	External USB storage icon color turns from gray to green with total capacity and

				remaining capacity percentage
10	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 (PCIE M2 SSD card)	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 3 types of audio alerts: reminder 1, reminder 2 and alert

*The reminder and alert audio volume is adjustable and can be turned off in system setting

*When HDMI 2 is connected to a monitor, confirm that there are speakers in the monitor and the volume is loud enough

TIP

*The audio alert comes out from wireless base station speaker when wireless base station is only connected with the clinical display

System data & cyber security management

Password designed for patient data access and system setting

- Password with maximum administrative privileges designed
- Easy way of wireless base station password setting and resetting (no need of mail and phone confirmation)
- Password required when accessing the [Data/system]

“One way copy” route designed for patient data copy

- Internal storage (PCIE M2 SSD card) saves all initial data, accessing needs password. Data delete gives off “warning alert” audio and need confirmation
- Data for patient if needed can be copied from internal storage through the only “One way copy” route, to the external storage USB port on the front panel

Text and audio alerts protect the patient data

- Each time the external USB storage inserted into the wireless base station front panel port, storage will be formatted in 10 seconds, in order to copy new patient data on an empty storage
- Each time “delete the patient data” is attempted an audio alert and “Are you sure to delete the selected file? ” “CANCEL”, “CONFIRM” message reminder appears on the screen, confirmation needed
- When the internal storage remaining is under 10%, alert audio will be given our and the following message will also be displayed on the screen: “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.”
- Internal storage remaining under 5%, icon’s color stays red + alert sound + message (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.) appear on screen. Icon color stays red. Picture and video recording and case icons turn gray.

CUI icon color change red gives alert to low battery and low storage

- When camera battery remains one level capacity (about one-hour remaining operation time), the icon will change to red and starts blinking
- When the internal storage remaining goes down to 10%, the icon will change to red
- When the external storage remaining is less than the selected file to be copied, then no data will be copied.

5 Cleaning, disinfection, sterilization and disposal

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 heads and C-mount couplers.

As the camera head charging station and wireless base station are not located in the surgical areas, follow the following 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: 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.

Cleaning instruction

These cleaning, assembly, and sterilization instructions are made available in accordance with AAMI TIR30: 2011(R) 2016. A compendium of processed, 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. These instructions include how to clean and sterilize the camera heads and C-mount couplers. These instructions also include how to clean the wireless base station and the camera head charging station.

CAUTIONS:

- System components may be damaged by the use of harsh oxidizing chemicals or the use of improper cleaning techniques or tools.
- Do not immerse any Nuvis system components in liquid. Doing so may irreparably damage the component. To ensure proper cleaning of the system components, always use a recommended cleaning agent.

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

Camera head and C-mount coupler cleaning instructions:

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.

Validated Cleaner:

ALCONOX (Powder). Prepare a fresh 1% cleaning solution (21 /2 Tbsp/Gal, 11 /4 oz/Gal or 10g/L) in cold, warm, or hot water. If available, use warm water. Use cold water for blood stains.

Wipe:

Wipe the surfaces of the Camera Head and C-mount coupler 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.

Note:

Cleaning validation was validated per ANSI/AAMI ST98:2022: Cleaning validation of healthcare products – requirements for validation and revalidation of a cleaning process for medical devices.

Disinfection

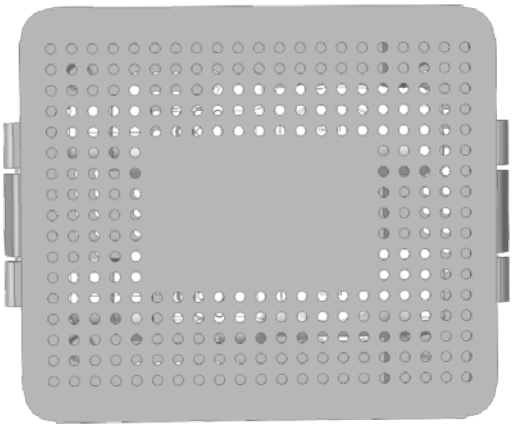
With the cleaning caps on, use a clean wipe saturated with Ethyl or isopropyl alcohol (70-90%), to wipe all surfaces. Wait at least 1 minute before rinsing. (1 minute or greater exposure time as recommended by the CDC for smooth hard surfaces.)

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

Camera head and C-mount coupler sterilization instructions

Sterilization Tray

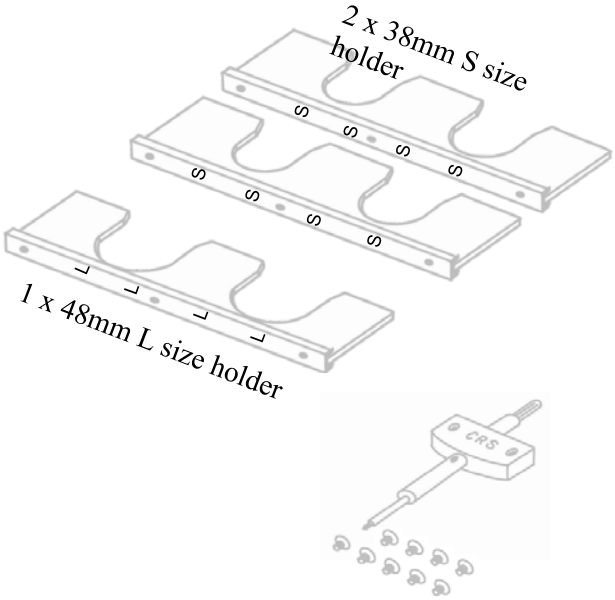
- Wireless Camera System - Standard, includes a plasma sterilization tray.
- Wireless Camera System – Basic, does not include any plasma sterilization tray.
- For the standard system, when shipped, the camera heads are packed in the Sterilization Tray.



Install the sterilization tray

Please find the follow items from the packing:

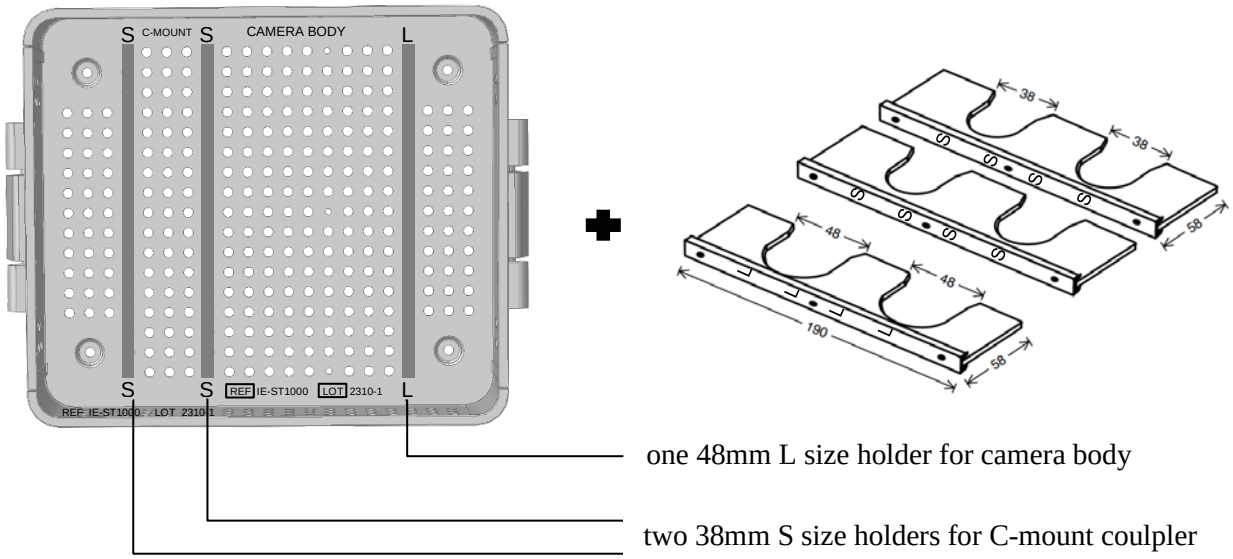
- Sterilization tray
- Sterilization tray cover
- 3 pcs of camera and C-mount coupler holders (size S and L)
- 9 screws
- 1 screw driver

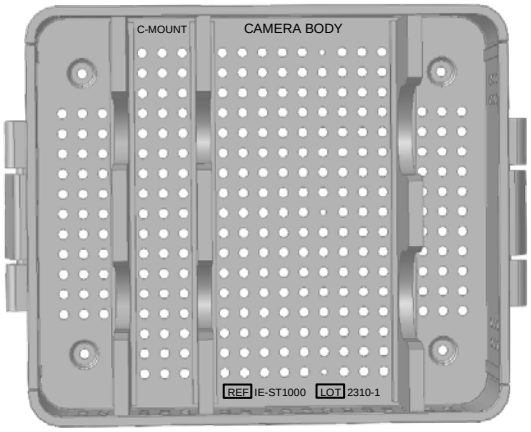


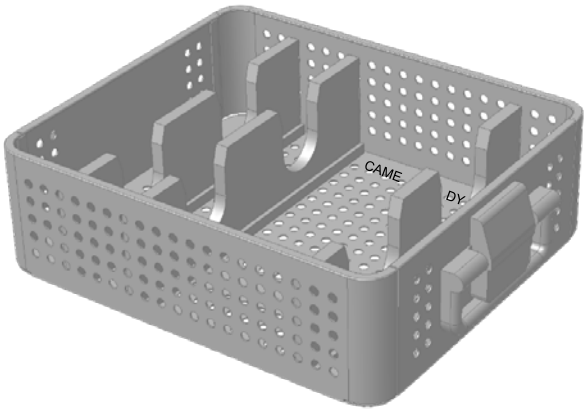
Please install the 3 pcs of C-mount coupler and Camera body holders into the tray bottom:

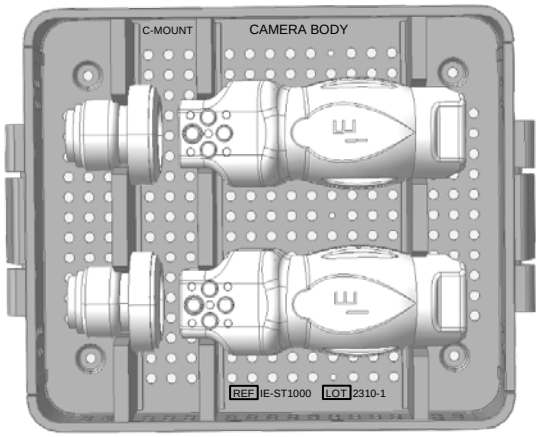
- Install the two S size holders in the tray position S
- Install the one L size holders in the tray position L

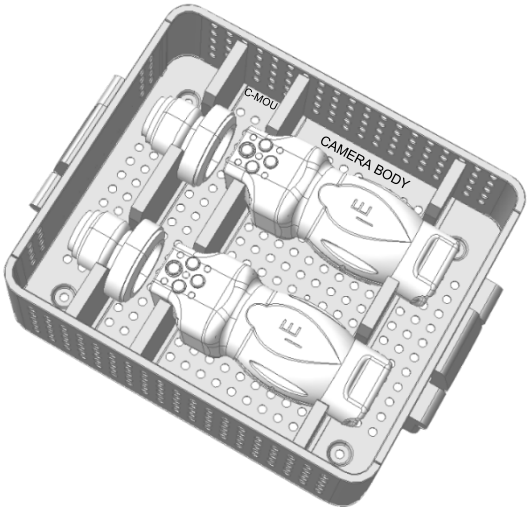
C-mount coupler and camera body holders mounting positions inside the sterilization tray bottom.



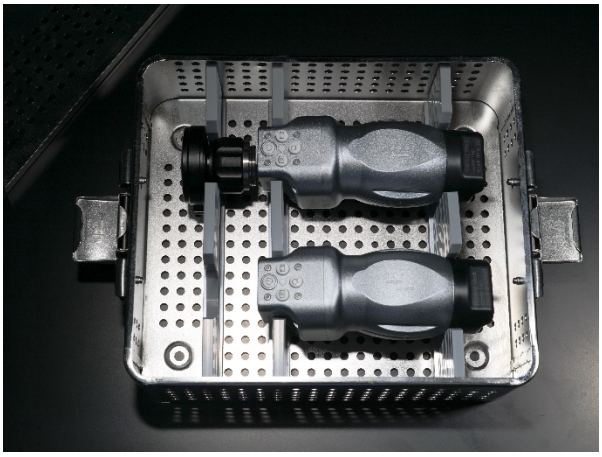








- The C-mount couplers can sit on the holders in both directions.



Sterilize the camera heads and C-mount coupler

- Ensure every part of the camera and C-mount coupler 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.
- Place the camera heads into the sterilization tray in the locations visually indicated by the image in the base of the sterilization tray.
- Place the C-mount coupler into the sterilization tray in the locations visually indicated by the image in the base of the sterilization tray.
- Wrap the sterilization tray in a double layer of sterilization wrap.
- Use a pre-existing, low-temperature hydrogen peroxide plasma sterilization system on its standard cycle setting.
- IE recommends use of the Sterrad® 100NX Standard Cycle. Use of any other cycle, equipment, or parameters must be validated independently by the end user.

Camera head charging station and wireless base station cleaning instruction

The components should be visually examined after every use and cleaned as needed per instructions below.

Cleaning and maintenance

- 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
- Clean and disinfect as needed

Disposal

Dispose of all equipment according to local and regional Regulations.

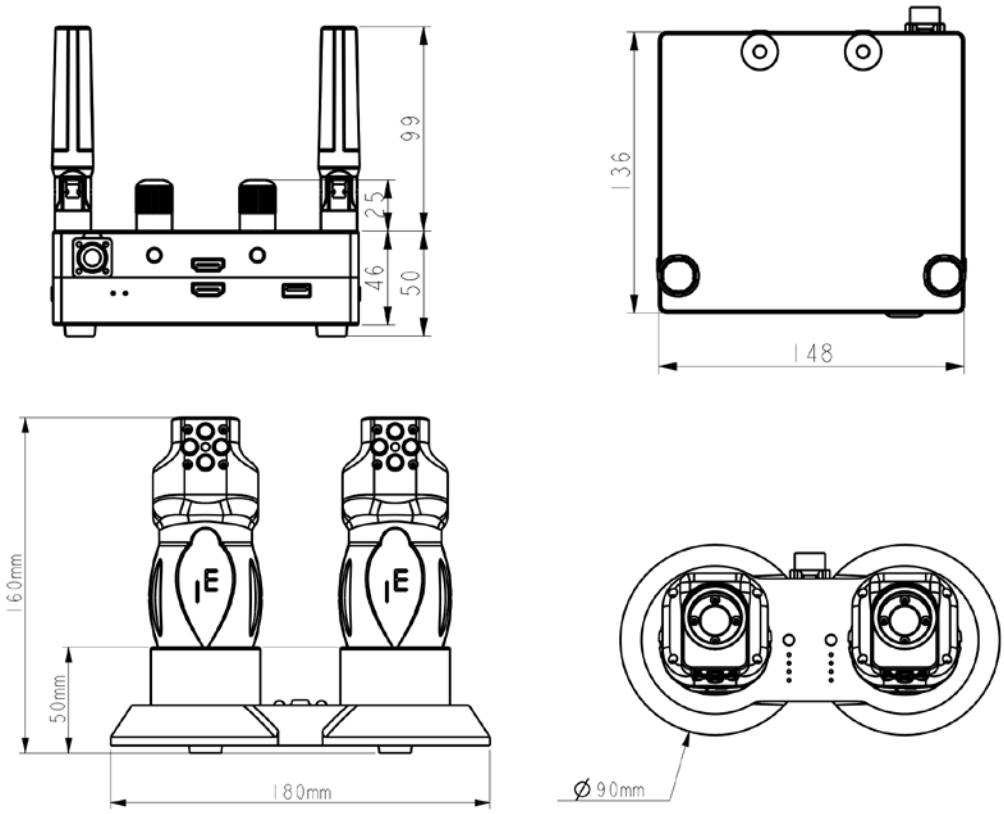
6 Specifications

Nuvis® Wireless HD Camera System		
Camera head (with internal Transmitter)		
Camera head Sensor	Image Sensor	1/2.5’ Progressive CMOS (approx. 2.1 mega)
	Scanning System	16:9 Progressive
	Effective Pixel	1920(H) × 1080(V)
	Horizontal Resolution	1,000TVL
	Video Output	2K@60fps
Wireless Camera head	Video Resolution	2K@60fps
	Transmission Distance	Max 5 meters (16 feet)
	T/R Latency	No perceptible latency
	Antenna	High performance internal antennas
	Camera head Buttons	[Power]Power ON/OFF, [Camera]Picture Taking/start a new case, [Video]Recording Start/Stop, [Zoom]Zoom/White Balance automatic correction)
	Wireless Connection	Wireless connection between the wireless base station and the camera head is done automatically when the wireless base station and camera head power on
	Remaining Power	Power on, LED static green (100%~50%), slow blinking (50%-25%), fast blinking (under 25%, 60mins)
	Built-in Battery	Rechargeable 3500mAh*2 cells
	Power Consumption	Average 5W
	Continuously Working Time	>/= 3.5 hours
	Enclosure Waterproof Grade	IP67
	Dimensions	133(L) ×50(W) × 52(H)mm +/-10%
	Net Weight	345g +/-10%
Charging station		
Charging station	Charging Position	2 charging positions for 2 camera heads charging independently at the same time
	Charging Indications	LED on the charging dock display the charging status (standby, charging, full charged and level)
	Dimensions	180(L) ×90(W) × 50(D)mm +/-10%
	Net weight	458g +/-10%
	Charging station Power Input	DC12V4A UL certified power supply
Wireless base station		
Wireless base station	Data Receiving and Saving	
	Video Resolution	1920×1080p@60fps
	Receiving Distance	Max 5 meters (16 feet)
	System Latency	From camera head to wireless base station operation and live video to display with no perceptible latency
	Antenna	High performance surface fix installed antennas ×4
	Encoding	Still image: JPEG file (.jpeg) Dimensions 1920×1080, 2K Resolution H96dpi and V96dpi Bit depth 24

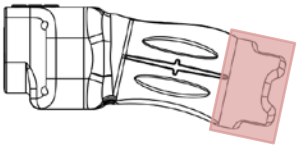
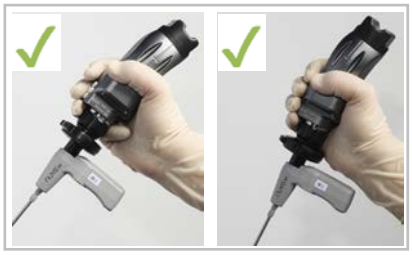
		Video: H265 MP4 file (.mp4) Bitrate 20Mkbs Frame rate 60 frames/second
		Data saving: 150M/minute
	Video I/O	HDMI output×2 (for clinical display and live video sharing)
	Recording Input	2K60fps
	WIFI	802.11 b/g/n/ac wireless (2.4Ghz WIFI)
	Camera head Auto Wireless Connection	Camera head builds the wireless connection with the wireless base station automatically when [Power] is turned on
	Recordable Devices	Videos & images can be initially saved in internal PCIE M2 SSD
	Front panel USB3.0 port	For one way patient data copy and mouse. The storage which can be used includes USB flash drive and PCIE M2 SSD with the capacity of 16G,32G, 64G, 128G, and above
	Rear panel USB3.0 port	For high-speed internal storage (PCIE M2 SSD card) data copy (moving) and NuvisCon APP connection or mouse connection. The storage which can be used includes USB flash drive and PCIE M2 SSD with the capacity of 16G,32G, 64G, 128G, and above
	Approximate Recording Time	1T internal PCIe M2 SSD, High quality 2K/60fps video 110 hours (about one month) recording time
	Wireless base station and Camera head Wireless Pairing	
	Streaming	Support live video streaming
	Camera head Registered and Paired into System	Camera heads should be registered and paired into the system
	Number of Camera head Pairing	up to 8 camera heads can be paired to a wireless base station
	General	
	Power Input	DC12V4A power supply
	Power Consumption	Max 36W (average 15W)
	Dimensions	148(L) ×134(W)×49.5(H)mm (without antenna)
	Net Weight	623g +/-10%
General		
Working Environment	Operational Conditions	Temperature 59°F to 86°F (15℃ to 30℃), Pressure 700-1060hPa, Humidity 15-85%, non-condensing
	Long Term Storage & Transportation	Temperature -4°F to 104°F (-20℃ to 40℃), Pressure 700-1060hPa, Humidity 15-85%, non-condensing
	Short Term Storage & Transportation	Temperature -4°F to 140°F (-20℃ to 60℃), Pressure 500-1060hPa, Humidity 15-85%, non-condensing

* All appearance and parameters are subject to change without notice.

- Size (mm):



7 Trouble shooting

No.	symptom	Analyze	Work out
1	Live video has “intermittent horizontal dashed line interference for several seconds” especially at the beginning of a new live video connection	This phenomenon occurs in the following conditions or combination of conditions: 1) Busy 5.8GHz WIFI environment; 2) The camera head interior antenna, camera head body black cover part was held or completely held; 3) Wireless base station and camera head LOS (line of sight) distance is more than 5 meters (16 feet)	1) Do not hold or completely hold the black cover part of the camera head; 2) Keep the wireless base station and camera head LOS within 5 meters (16 feet) 3) Set the router to 2.4GHz
2	During stable image transmission and display, some noise occurs and then return to a normal and stable receiving	 When a hand accidentally totally covers the black antenna cover of the camera, some noise may appear on the screen	1) Do not block the camera head transmitter antenna cover, the black part of the camera head, as the wireless signal may be weakened 2) Holding the black cover can block the antenna!
Antenna  Not covered Partially covered Totally covered			
3	The reminder and alert audio in the wireless base station disappears	This phenomenon occurs in the following conditions: 1) The wireless base station speaker volume is too low; 2) HDMI 2 output (has priority for audio output) is connected to a monitor, that has no speaker or the speaker volume is too low	1) Turn the wireless base station speaker volume louder; 2) Confirm that the HDMI 2 connected monitor has speaker and speaker volume is set louder

4	The USB external storage cannot be recognized by the base station	• The newly purchased USB external storage which will be used on the wireless base station should be formatted with NTFS or FAT32 format which could be recognized by the base station. exFAT format cannot be recognized by the base station. • Before press [Copy] button in the file management page, after insert an external USB storage, please wait enough time for base station to formate and configure. Unless the external USB storage icon on the file management page turns green, please do not press [Copy] button. • The USB ports on the base station are multi-function designed, they can both be used for external USB storage. When two external USB storages inserted into the base station, only the last inserted can be recognized.	1) Every new USB external storage format should be checked before it is used on the base station. If the format is exFAT, then it should be formatted into NTFS or FAT32 2) Every time insert an external USB storage, please wait another 5 seconds after the 10 seconds formatting count down finished, to confirm that the icon on the display right corner turns green → gray → green. 3) Please do not insert 2 USB external storages in the base station, (both the front and the rear panel) at the same time.
5	Short press (less than 8 seconds) of the [Power] button on the front panel does not turn the power off	• To prevent accidental shutdown caused by touching the [Power] switch, we designed press and hold more than 8 seconds to turn OFF the Power; • Short press the [Power button] will only turn off the HDMI output; One more time short press the [Power button] will turn on the HDMI output.	Press and hold more than 8 seconds until the power of the wireless base station is turned off

6	The live video suddenly flickered and disappeared for about 3 seconds	1) Due to electrostatic discharge, the live video from the camera head to the wireless base station might be disturbed or even interrupted, and the live video connection will be automatically rebuilt after about 3 seconds;	• Medical personnel in the operating room should perform electrostatic discharge regularly to reduce the accumulation of static electricity. • The ground in the operating room should be well grounded. • The floors, walls, and instruments in the operating room should be cleaned regularly to remove dust and dirt that can cause static electricity • Excessive gathering of people should be avoided in the operating room to reduce the accumulation and release of static electricity.

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IE-BH0510-EN-01
Nuvis wireless HD camera system user manual
IE-IM1000

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