

MiroCam®

MiroCam Capsule Endoscope

User Manual



Smallest Capsule & Highest Resolution

Discovering
Medical
Innovations

 **IntroMedic**
Capsule Endoscope

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To validate the warranty, please complete product registration with the local authorized IntroMedic distributor.

Warranty

Exclusive warranty service

The warranty service provided hereby is applicable exclusively to the purchaser of the product. IntroMedic will only warranty the product for purposes and usage as defined in this User Manual. Any usage not heeding the warnings, cautions and recommended usages as defined in this manual will nullify the warranty.

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IntroMedic Customer Service

TEL: 82-2-801-9300
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E-mail: helpdesk@intromedic.com

Safety

Non-compliance with the user's manual, unauthorized modifications of the product or replacement of parts, and/or opening of the product casing is prohibited and may be hazardous.

Declaration on translation of labeling

Based on buyer's request, IntroMedic will provide the labeling, such as ID label, Instruction for use and other promotional materials, which is translated into the national language(s) of European countries. And it will be evaluated by the local language expert, and will be confirmed by the native speaker of the local language.

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1

Safety Information

1. SAFETY INFORMATION

1.1 Warnings

MiroCam® Capsule Endoscope System has been manufactured to conform with the International Standard for Medical Electrical Equipment: IEC 60601-1, together with the Collateral Standard for Electromagnetic Compatibility Requirement and Tests IEC 60601-1-2.

MiroCam® Capsule Endoscope System has been manufactured to conform to the electric shock, fire and mechanical hazard standards as defined in CAN/CSA C22.2 NO.601.1.

Based on request of the buyer, IntroMedic will provide the labeling, such as ID labels, and the User Manual in the national language(s) of European countries. Translated documents will be evaluated by a local language expert, and will be confirmed by a native speaker of the respective national language.

Safety Symbols: The User Manual incorporates various safety symbols to ensure safe and correct use of the product and to prevent any personal injury or property damage. These symbols are defined in the following table:

| | |
|---|---|
|  | WARNING WARNING indicates a potential hazard that, if not avoided, could result in serious personal injury or damage to the product. |
|  | CAUTION CAUTION indicates a potential hazard that, if not avoided, could result in minor personal injury or damage to the product. |
|  | NOTE NOTE does not indicate potential hazards as in Caution or Warning, but contains important information regarding the installation, operation or maintenance of the product. |

1.2 Symbols for Safety

This section describes a set of symbols that the IEC (International Electrotechnical Commission) has established for medical electronic equipment to classify connections and warnings of any potential hazards.



EN980: Attention. See instruction manual for use.



IEC 878-02-03: Indicates that this is classified into Type BF equipment



EN 980: Denotes Date of Manufacture



EN 980: Denotes Address of Manufacture



IEC60601, ANNEX D: Denotes "ON" status of main power switch



IEC60601, ANNEX D: Denotes "OFF" status of main power switch

SN

EN 980: Denotes serial number



IEC 417-5031: Denotes DC (Direct Current)



IEC 417-5032: Denotes AC (Alternating Current)

A

Denotes Ampere, the unit of current

V

Denotes Volt, the unit of Voltage

Hz

Denote Hertz, the unit of Frequency



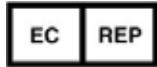
IEC 417-5021: Denotes potential equalization terminal



Single Use Only



Use by date



EN980: Authorized representative in the European community

IPX

Protected against the effects of continuous immersion in water

1.3 Function Symbols

1.3.1 MiroView™ Software Function Symbols

The following table describes symbols or icons used in the MiroView™ Software.

1.3.1.1 MiroView™ Client

| Symbol | Description | Symbol | Description |
|--------|---|--------|---|
| | Open the patient data screen. | | Open screen to review a specific patient |
| | Open the report screen to create a patient capsule endoscopy report. | | Open screen to export (save externally) selected image data for a specific patient. |
| | Print the selected report on the List. | | Delete the selected case on the List. |
| | Add a new review for the selected case on the List. | | Delete the selected review on the List. |
| | Open the Recycle Bin dialog. | | Find the Item from the list with the keyword typed in the search box. |
| | Show all the items on the List. | | Open the Position Window |
| | Show images in the Single View. | | Show images in the Dual View. |
| | Show images in the Quad View. | | Show images in the Range View. |
| | Show images in the Map View. | | Play all images. |
| | Play the selected images only. View images via Express Play function. | | SGIB - Play the images captured via Suspected GI Bleeding function. |

| Symbol | Description | Symbol | Description |
|--------|--|--------|---|
| | Move to the first image in the video. | | Move to the previous captured image. |
| | Play images in reverse order. | | Stop playback of images. |
| | Play | | Play images in sequential order. |
| | Move to the next captured image. | | Move to the final image in the video. |
| | Open the Comparison Window | | Expand/Shrink Capture Box |
| | Indicating the current Capture Box / Finding Summary Box / Drag Bag status is Capture Box. Click this icon to change the status to 'Finding Summary box' | | Indicating the current Capture Box / Finding Summary Box / Drag Bag status is Finding Summary Box. Click this icon to change the status to 'Drag Bag' |
| | Indicating the current Capture Box / Finding Summary Box / Drag Bag status is Drag Bag. Click this icon to change the status to 'Capture Box' | | Show Circumference Markers |
| | Add a Circle on the image | | Add a Line on the image |
| | Delete selected Circle / Line | | Color Palette |
| | Undo the action | | Redo the action |

| Symbol | Description | Symbol | Description |
|---|---|---|--|
|  | Check the selected captured images |  | Uncheck the selected captured images |
|  | Print |  | Preview |
|  | Save as PDF |  | Export Review |
|  | Open PACS function (Registered User Only) |  | Export Captured Images with EXMIF |
|  | Export Captured Images as Image / Video / MiroVideo |  | Export Segments as Image / Video / MiroVideo |
|  | Export Case as Video / MiroVideo |  | Select the area as a Segment |
|  | Deselect the area from Segment | | |

1.3.1.2 MiroView™ Operator

| Symbol | Description | Symbol | Description |
|---|---|---|---|
|  | Open the patient data screen. |  | Connect to the MiroCam® Receiver and open MiroCam® Receiver control screen. |
|  | Print the selected report on the List. |  | Delete the selected case on the List. |
|  | Open the Recycle Bin dialog. |  | Export the case selected on the List. |
|  | Find the Item from the list with the keyword typed in the search box. |  | Show all the items on the List. |
|  | Upload the image data from the selected MiroCam® Receiver |  | Show / Edit the patient information for the selected MiroCam® Receiver |
|  | Initialize the selected MiroCam® Receiver | | |
|  | Unconnected |  | Unformatted the MiroCam® Receiver. |
|  | Empty the MiroCam® Receiver. |  | Prepared the MiroCam® Receiver. |
|  | Recorded the MiroCam® Receiver. |  | Uploaded the MiroCam® Receiver. |

1.3.2 MiroCam® Receiver Function Symbols

| Symbol | | Description |
|--------------|--|--|
| SIG | | Indicates status of signal from the MiroCam® Capsule. Green : Signal is being received from the MiroCam® Capsule. Yellow : Signal is not being received from the MiroCam® Capsule. |
| INI | | Initialization status of the MiroCam® Receiver Green : MiroCam® Receiver is initialized Yellow : MiroCam® Receiver is not initialized |
| BAT | | Battery Status Green : Fully charged Yellow : Not charged |
| Wi-Fi | | Wi-Fi Switch Status (LED) On : Enabled (LED) Off : Disabled |

1.4 Notes for Safe Use

- Follow the safety instructions included in this User Manual and clinical precautions advised by the medical professional.
- The manufacturer is not liable for harm or damage caused by improper, unauthorized, unprofessional or inexpert use of the device and/or product.
- IntroMedic Co., Ltd. is NOT responsible for physical harm or equipment problems caused by the user's careless operation or mismanagement of the device and/or product.
- Users MUST have read and understood the User Manual. ONLY trained and qualified medical professionals or authorized representatives of IntroMedic Co., Ltd. may operate the system.
- User Manual must ALWAYS be with the equipment. This is the USER'S RESPONSIBILITY.
- **CAUTION:** foreign substances including water, cleaning fluids, disinfecting cleanser and such substances may harm the equipment, and should not enter the equipment.
- ONLY authorized personnel may perform repairs. Never attempt to open covers, panels or casings.
- DO NOT crease, bend, fold or twist the data cable (or data belt). Take care to guard them against mechanical stress (e.g. wheels or heels)!
- The sensor pads, the MiroCam® Receiver, the data cable, the data belt and the capsule must not be exposed to mechanical shock (e.g. by dropping). Any damage caused that way will void the product warranty.
- **CAUTION:** Damage/injuries to the sensor pad, data cable or data belt may cause a safety hazard. Damaged items MUST be repaired IMMEDIATELY.
- DO NOT handle fluids in the vicinity of the system.

- When using a cart purchased elsewhere, ensure the brake or latch guard is in use to prevent the wheels from rolling.
- DO NOT USE in moist or damp places.
- DO NOT operate the equipment with wet hands.
- Avoid using the equipment in extreme temperatures or humid environments.
- DO NOT keep the equipment or carry out the MiroCam® Capsule endoscopy procedure in places such as areas exposed to direct sunlight, vicinity of heaters, vicinity of chemical materials or gases, areas moist/damp or dusty, or poorly ventilated areas.
- DO NOT disassemble or open the equipment without permission. This will invalidate the warranty.
- DO NOT carry out the MiroCam® Capsule endoscopy procedure in areas with high vibrations or in environments where high electromagnetic waves are generated.
- DO NOT pull out the power cord by grabbing the cable. When disconnecting the power cord, grasp the plug, and pull out. This prevents short-circuits, disconnection, or cord damage.
- **CAUTION:** Verify that the power rating supplied from the power receptacle matches with the voltage the system requires. Check Voltage and Frequency on the AC/DC adaptor.
- **CAUTION:** Turn off the power switch before connecting the sensor pad.
- DO NOT discard sensor pads, cables and connectors with general waste. Discard separately as industrial or medical waste.
- DO NOT carry out the MiroCam® Capsule endoscopy procedure simultaneously with other procedures using medical products or equipment.
- DO NOT use for purposes other than medical treatment.

- DO NOT connect the USB cable to the MiroCam® Receiver while the MiroCam® Receiver's data cable is still connected to sensor pads or data belt.
- DO NOT charge the MiroCam® Receiver while the MiroCam® Receiver's data cable is still connected to sensor pads or data belt while still attached to the human body.
- Connect USB cable to the MiroCam® Receiver only after mounting it on charger.
- DO NOT install any other programs onto the workstation utilized for review and diagnosis of patient image data (i.e computers with the MiroView™ Software).
- The MiroCam® Capsule is disposable and should not be reused.
- The sensor pads and data belt are medical waste, and should be disposed of according to local regulations or WEEE directive on waste disposal.
- Only use the capsule, the MiroCam® Receiver, the data cables, the sensor pads and the data belt in the medical environment condition.
- All products connected with the MiroCam® Endoscope system must be compliant with requirements of IEC60950-1 or UL certifications.
- Check the outer surface of the endoscope for rough surfaces, sharp edges, or protrusions which may cause a safety hazard.
- Please don't try to cut the label.

1.4.1 Environmental Conditions for Storage

- Temperature : -10 °C ~ 70 °C (Operating 0 °C ~ 40 °C)
- Relative humidity : 10 % ~ 80 % (Operating 45 % ~ 75 %)
- Atmospheric pressure : 700hPa to 1060hPa



WARNING DO NOT operate the equipment in the vicinity of generators, power stations, X-ray devices, and broadcasting stations where high levels of electro-magnetic waves are generated. The electro-magnetic waves can cause equipment malfunctions.



CAUTION If the equipment has been brought in from a cold environment (stock room, airfreight) into a warm room, initial activation should take place after a few hours, to allow for temperature adjustment and balance and evaporation of condensed humidity.



WARNING DO NOT operate the equipment in the vicinity of heat sources, strong electric or magnetic fields (close to a transformer), or near instruments generating high-frequency signals.



WARNING DO NOT use MiroCam® alongside or together with medical devices or procedures involving electrical currents.
DO NOT use MiroCam® with h.f. surgical equipment. It may result in burns at the site of the electrodes and possible damage to the MiroCam® Capsule and the MiroCam® Receiver.
DO NOT use the unit in close radius (within 1 m) of short wave or microwave therapy equipment. It may produce instability in the captured image.



WARNING This device is a Class B device according to EN60601-1-2 standards. This equipment can cause radio interference in residential areas. In this case, the owner (or operator) can be held responsible to take appropriate measures or take proper measures for compensation.

1.4.2 Safety Precaution



CAUTION

- Make sure the environment is without interference from electromagnetic fields.
 - Make sure the environment is without noise and vibration.
 - DO NOT carry out the MiroCam® Capsule endoscopy procedure while using other equipments, devices or products.
 - The instruction for use of the sensor pads MUST be observed.
 - DO NOT use on patients with pacemakers or defibrillators.
 - DO NOT use the MiroCam® Capsule if the package is unsealed.
-
- DO NOT reuse a used capsule.
 - To prevent unexpected accidents like fire or explosion, do not use any product near or in the presence of inflammable or ignitable substances.
 - DO NOT disassemble the equipment case nor open the cover. In case service is required, please contact IntroMedic customer support or local point of sale immediately.
 - Only the accessories authorized and designed by IntroMedic Co., Ltd. should be used with this equipment. Faults resulting from the usage of unapproved or inappropriate accessories are not guaranteed against.
 - This equipment may affect on other products or be affected by other products.
 - Follow your doctor's instructions and abide by the guidelines in the User Manual.
 - DO NOT try to upload the image data while the data cable or data belt is still connected to the MiroCam® Receiver.

- DO NOT change the rechargeable battery in the MiroCam® Receiver while the data cable or data belt is still connected to the MiroCam® Receiver.
- Stay away from high frequency radiation sites (such as high voltage, radar, installation power plants, MRI, CT or electric blankets etc.) during your capsule endoscopy procedure. (It may result in serious side effects requiring an emergency operation.)
- In case of any symptoms of abdominal pain, vomiting, fever, heart trouble, dizziness or seizure during or after the MiroCam® Capsule endoscopy procedure, please notify your doctor.
- Always check whether the data cable or data belt is connected to the MiroCam® Receiver.
- Always check that the battery in the MiroCam® Receiver is fully charged before use.
- DO NOT use the MiroCam® Capsule if the package is unsealed.
- After ingesting the capsule, always confirm whether the MiroCam® Capsule has been excreted. Excretion of the MiroCam® Capsule can be confirmed with an X-ray procedure.
- Prior to undergoing the MiroCam® Capsule endoscopy procedure, patients with diabetes must be informed via a medical professional regarding appropriate medication & dosage.
- For more accurate data and better analysis, patients can have solid food for lunch, but must have liquid food for dinner on the day prior to the MiroCam® Capsule endoscopy procedure. The patient must fast for 11 hours prior to ingesting the MiroCam® Capsule.
- If recommended by the physician, the patient may take a laxative prior to the MiroCam® Capsule endoscopy procedure.
- DO NOT smoke for at least 12 hours prior to the MiroCam® Capsule endoscopy procedure.

- DO NOT apply body lotion before the MiroCam® Capsule endoscopy procedure.
- DO NOT bite the capsule.
- Avoid excessive physical activity during the MiroCam® Capsule endoscopy procedure.
- 4 hours after ingesting the capsule, patients may have liquid food.
- It is recommended to drink mineral water (non-colored liquid) frequently, so that it may raise the possibility to take much better quality of the image.
- When undergoing the MiroCam® Capsule endoscopy procedure, DO NOT make physical contact with another person undergoing the same procedure.
- During the MiroCam® Capsule endoscopy procedure, DO NOT touch the MiroCam® Receiver, or get the MiroCam® Receiver wet.
- Only use the provided batteries, and never remove the battery from the MiroCam® Receiver during the MiroCam® Capsule endoscopy procedure.
- Avoid disconnecting the USB while uploading the image data from the MiroCam® Receiver to the workstation.
- Always confirm that the USB is connected by checking the MiroCam® Receiver screen on the MiroView™ Software.
- Always check the AC Power rating prior to using the workstation.
- DO NOT touch AC power cable with wet hands.
- DO NOT open the MiroCam® Receiver bag or touch the MiroCam® Receiver outside of the hospital.
- DO NOT use on patient with electrical implantable device.
- Magnetic controller must be stored in special storage box.
- If electrical risk is detected from the MiroCam® Receiver, remove the battery.

 **WARNING** The MiroCam® Capsule takes images for 12 hours and naturally excretes in about 24 hours under normal conditions. If the MiroCam® Capsule has not been excreted from the patient within 72 hours, patient should contact the physician. After examining, the physician may need to perform a surgical operation or treatment to remove the capsule.

 **WARNING** Before doing capsule endoscopy with MC1000-WM, always check whether the previous capsule is retained or not in human body. If the previous capsule is detected in human body, remove it by surgical treatment. When two MC1000-WM are existed in human body at the same time, those can stick to each other.

 **WARNING** Make sure the capsule had been excreted before going through an MRI, CT and etc. It may cause injury to the patient.

1.4.3 Cleaning and Maintenance

■ Capsule

The capsule is disposable and should not be reused.

■ System and accessories

- All products should be cleanly maintained. For cleaning, rub them lightly with a soft cloth wet with warm water at least once a week. DO NOT use organic solvents such as lacquer, thinner, ethylene and oxide because they can damage the equipment. Be careful that foreign substances do not enter the main system when cleaning.
- ALWAYS operate the equipment under sanitary environmental conditions. DO NOT use heat or gas for disinfection of the capsule.

■ Service Document

If required, or upon request, the local IntroMedic distributor (authorized IntroMedic representative) may provide block diagrams, lists of spare parts, descriptions, adjustment instructions or other related information which may help qualified technical personnel in repairing specified parts of the equipment which have been defined repairable by IntroMedic Co., Ltd. .

■ Moving the Equipment

- CAUTION when moving equipment.
- WARNING: Excessive impact/shock causes internal damage.
- If wiring is connected/disconnected when moving, check the exact wiring status after moving.
- If damage to the equipment is discovered after moving, immediately contact IntroMedic or local Distributor.

2

Overview & Intended Usage

2. SYSTEM OVERVIEW

MiroCam® is an orally ingested capsule endoscope designed to capture and wirelessly transmit images of the lining of the small intestine. Captured images are viewed via the MiroView™ Software for diagnosis of diseases related to the small intestine.

The MiroCam® Capsule Endoscope System consists of the MiroCam® Capsule, the MiroCam® Receiver, the MiroView™ Software, and accessories.

2.1 Intended Purpose

MiroCam® is intended for visualization of the small bowel mucosa as an adjunctive tool in the detection of abnormalities of the small bowel. The device captures images of the small bowel with a wireless camera contained in a capsule. This device includes an ingestible capsule (containing a light source, camera, transmitter, and battery), an electrode array, a receiving/recording unit, a data storage device, computer software to process the images (MiroView™ Software), and accessories.

2.1.1 Contraindications

- Not intended for patients with known or suspected gastrointestinal tract obstructions, perforations, strictures or fistular.
- Not intended for patients who have difficulty ingesting food or pills (dysphagia).
- Not intended for patients who have difficulty communicating.
- Not intended for patients with indigestion, or slow gastric emptying.
- Not intended for patients who may be affected by electromagnetic radiation, such as pregnant women, infants, and patients with heart disease or epilepsy.
- Not intended for patients with diverticulosis in the Small Bowel.
- Not intended for patients who are recommended against having the MiroCam® Capsule endoscopy procedure by a Physician.
- Not intended for patients with pacemakers and/or defibrillators.
- This device is intended for use in adults and children from two years of age. If a patient is younger than 18, the doctor should decide whether to perform the MiroCam® Capsule endoscopy procedure.

2.2 Observable Diseases

2.2.1 Obscure gastrointestinal bleeding (OGIB)

- Angioectasia
- Meckel diverticulum
- NSAIDs

2.2.2 Crohn's Disease

2.2.3 Small Bowel Tumors

- Polyps
- Peutz-Jeghers Syndrome
- Familial adenomatous polyposis
- Lymphoma
- Carcinoid
- Gastro-Intestinal Stromal Tumor (GIST)
- Lipoma
- Hemangioma

2.2.4 Inflammation

- Intestinal Tuberculosis
- Typhoid Fever
- Angeitis
- Amyloidosis
- Eosinophilic enteritis

2.2.5 Celiac Disease**2.2.6 Behcet's Disease****2.2.7 Cowden Disease****2.2.8 Cronkhite-Canada Syndrom**

2.3 Product Warranty Period

2.3.1 Maximum Storage Time of MiroCam® Capsule

- MC1000 : 1 Year
- MC1000-F : 1 Year
- MC1000-G : 1 Year
- MC1000-W : 1 Year
- MC1000-WG : 1 Year
- MC1000-WM : 1 Year
- MC1000-B : 1 Year
- MC1200 : 1 Year
- MC1200-B : 1 Year
- MC1200-G : 1 Year
- MC1200-M : 1 Year
- MC1600 : 1 Year
- MC1600-B : 1 Year
- MC1600-G : 1 Year
- MC1600-M : 1 Year

2.3.2 MiroCam® Receiver, MR1100

- MiroCam® Receiver: 1 Year
- MiroCam® Receiver Battery: 6 Months

2.4 Product Specification

2.4.1 MiroCam® Capsule

■ Component

| Component | Model Name | Quantity |
|---------------------|--|---------------------|
| Capsule | MC1000 MC1000-F MC1000-G MC1000-W MC1000-WG MC1000-WM MC1000-B MC1200 MC1200-B MC1200-G MC1200-M MC1600 MC1600-B MC1600-G MC1600-M | 1 Piece (Selection) |
| Sensor Pads | MC1000-S | 10 Piece |
| Magnetic Controller | MC1000-C | 1 Piece (Optional) |

■ Specification

| Item | Specification | |
|--|----------------------|------------------------------------|
| Capsule Unit (MC1000, MC1000-F, MC1000-G) | Size | 10.8 X 24 mm |
| | Weight | 3.25 ± 0.05 g (-F) 3.5 ± 0.05 g |
| | Frame Rate | 3 frame/sec |
| | Field of View | 150 degrees |
| | Battery Life | 12 hours |
| | Pixels | 102,400 |
| | Lighting | 6 LEDs |
| | Communication Method | Human Body Communication |
| Magnetic Controller (MC1000-C) | Length | 27.3 cm |

| Item | Specification |
|---|--|
| Capsule Unit (MC1000-W, MC1000-WG, MC1000-WM, MC1000-B) | Size 10.8 X 24.5 mm 10.8 X 25.5 mm (-WM) |
| | Weight $3.25 \pm 0.05\text{g}$ $4.75 \pm 0.05\text{g}$ (-WM) |
| | Frame Rate 3 frame/sec |
| | Field of View 170 degrees |
| | Battery Life 12 hours 8 hours (-WM) |
| | Pixels 102,400 |
| | Lighting 6 LEDs |
| Communication Method | Human Body Communication |

| Item | Specification |
|---|--|
| Capsule Unit (MC1200 MC1200-B MC1200-G, MC1200-M) | Size 10.8 X 24.5 mm |
| | Weight 3.2 ± 0.05 g 4.5 ± 0.05 g (-M) |
| | Frame Rate 3 frame/sec |
| | Field of View 170 degrees |
| | Battery Life 12 hours 8 hours (-M) |
| | Pixels 102,400 |
| | Lighting 6 LEDs |
| | Communication Method Human Body Communication |

| Item | Specification |
|---|--|
| Capsule Unit (MC1600 MC1600-B MC1600-G, MC1600-M) | Size 10.8 X 24.5 mm |
| | Weight 3.2 ± 0.05 g 4.5 ± 0.05 g (-M) |
| | Frame Rate 6 frame/sec |
| | Field of View 170 degrees |
| | Battery Life 12 hours 8 hours (-M) |
| | Pixels 102,400 |
| | Lighting 6 LEDs |
| | Communication Method Human Body Communication |

2.4.2 MiroCam® Receiver

■ Component

| Component | Model Name | Quantity |
|----------------------|-----------------------------|----------|
| Receiver | MR1100 | 1 piece |
| Battery Pack | MR1100-B | 2 piece |
| Data Cable | MR1000-D | 1 piece |
| Data Belt | MR1000-D(M), MR1000-D(L) | 1 piece |
| Receiver Bag | MR1000-G | 1 piece |
| System Carrying Case | MR1000-A | 1 piece |
| Battery Charger | MR1000-C | 1 piece |
| Adaptor | MR1000-T | 1 piece |
| Power Cable | MR1000-P | 1 piece |
| Measuring Tape | MR1000-M | 1 piece |
| USB Cable | MR1100-U | 1 piece |

■ Specification

| Item | Specification | |
|----------------------|---------------|--------------------------|
| Receiver (MR1100) | Battery Life | 12 Hours |
| | Size | 85 X 140 X 40 mm |
| | Weight | 350g (including Battery) |

| Item | Specification | |
|--|-----------------|--|
| Battery Pack (MR1100-B) | Type | Lithium-Ion storage cell |
| | Capacity | 10400 mA |
| | Voltage | 3.6 V |
| | Recharging Time | Approx. 4 hours |
| | Size | 73.8 X 84.3 X 21.4 mm |
| Data Cable (MR1000-D) | Channel | 9 |
| | Size | 700 x 900 x 110 mm |
| Data Belt (MR1000-D(M), MR1000-D(L)) | Channel | 9 |
| | Size | 1000 X 180 mm (M) 1500 X 180 mm (L) |
| Receiver Bag (MR1000-G) | Size | 100 X 190 X 55 mm |
| System Carrying Case(MR1000-A) | Size | 480 X 350 X 100 mm |
| Battery Charger (MR1000-C) | Power Source | Adaptor |
| | Size | 135 X 75 X 105 mm |
| | Weight | 285 g |
| Adaptor (MR1000-T) | Weight | 231g |
| | Power Rating | AC100~240V/ 50~60 Hz |

| Item | | Specification |
|------------------------------|--------|---------------|
| Power Cable (MR1000-P) | Length | 1.5 m |
| Measuring Tape (MR1000-M) | Length | 1.5 m |

2.4.3 MiroCam® Software

- Component

| Component | Model Name | Version |
|-------------------------|-------------------------|---------|
| MiroView™ Workstation | MiroView™ Software | 2.5 |
| MiroView™ RTV | MiroView™ RTV | 2.0 |
| Wireless MiroView™ RTVi | Wireless MiroView™ RTVi | 1.4 |

3

Performing Capsule Endoscopy

3. PERFORMING CAPSULE ENDOSCOPY

3.1 General Comments

- This chapter describes how to operate and control the MiroCam® Capsule Endoscope System.
- Installation and initial operation must be done by an Authorized IntroMedic Service Technician.

3.2 Safety Warnings

 **WARNING** Before turning on the system, check the environment condition for the MiroCam® Capsule Endoscope System.

 **WARNING** This device is intended for use in adults and children from two years of age. If a patient is younger than 18, the doctor should decide whether to perform the MiroCam® Capsule endoscopy procedure.

 **CAUTION** In case the system has been brought from cold environment (stock room or airfreight) into a warm room, first switch on it after some hours for temperature balance and removing of condensation humidity (Risk of leakage current).

 **CAUTION** For the electrical safety, make sure that peripheral equipments (external PC, Monitor, printer etc) are connected to a wall socket of independent power supply with a perfect ground. Particularly make sure whether or not those peripheral equipments should be authorized for medical usage.

 **CAUTION** DO NOT touch the dome of the capsule.

 **CAUTION** If SIG indicator of the MiroCam® Receiver turns yellow after ingesting the capsule, immediately contact the physician.

! **CAUTION** If SIG indictor of the MiroCam® Receiver does not turn green when the patient holds the MiroCam® Capsule by the gold bands, immediately stop the MiroCam® Capsule endoscopy procedure.

! **NOTE** If images of the small bowel are not captured during the MiroCam® Capsule endoscopy procedure, ensure the MiroCam® Capsule has been excreted by the patient and perform procedure again.

3.3 Examination Preparation

The following steps (3.3.1 to 3.3.4) explain the process to initialize the MiroCam® Receiver and register patient data for the MiroCam® Capsule endoscopy procedure. For more information, see section 4.2.

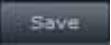
3.3.1 Start System

- Turn on the power of the workstation.
- Click the  to start the MiroView™ Operator.
- Type the ID and the password in each field, and then click the .



! **WARNING** Before starting the system, check the power rating for the workstation.

3.3.2 Initialize the MiroCam® Receiver

- Connect the smaller side of the USB Cable to the MiroCam® Receiver
- Connect the larger side of the USB cable to the workstation.
- Turn on the MiroCam® Receiver.
- Click the  in the MiroView™ Operator to initialize the MiroCam® Receiver.
- Click the  in the MiroView™ Operator to input patient information.
- After completing the required fields, click the  to save the patient information onto the MiroCam® Receiver.



WARNING If the MiroCam® Receiver is initialized, any patient data stored on the device will be deleted permanently.



NOTE During initialization with MR1100, it is not possible to cancel the process.

3.3.3 MiroCam® Receiver Preparation

- Connect the battery to the MiroCam® Receiver.
 - Insert pins and bumps on back side of the MiroCam® Receiver in the slots on the battery.
 - Press battery to the MiroCam® Receiver until clasp locks battery in place.
- Turn on the power switch of the MiroCam® Receiver.
- Check the battery indicator (BAT) of upper side of the MiroCam® Receiver. If the battery is fully charged, the LED light will be green. If the LED light is not green, charge the battery.

- Check the initialization indicator (INI) of upper side of the MiroCam® Receiver. Prior to beginning a procedure, this light must be green.
- Connect the data cable to the MiroCam® Receiver.

| Indicator | Description |
|--------------|---|
| SIG |  Indicates status of signal from capsule Green : Signal is being received from capsule Yellow : Signal is not being received from capsule |
| INI |  Initialization status of the MiroCam® Receiver Green : The MiroCam® Receiver is initialized Yellow : The MiroCam® Receiver is not initialized |
| BAT |  Battery Status Green : Fully charged Yellow : Not charged |
| Wi-Fi |  Wi-Fi Switch Status (LED) On : Enabled (LED) Off : Disabled |

- ⚠ WARNING** DO NOT do begin the MiroCam® Capsule endoscopy procedure when the MiroCam® Receiver's battery indicator is not green. This indicates battery is not fully charged or out of order, and patient data may be lost.
- ! CAUTION** Switch the MiroCam® Receiver off prior to connect the sensor pad.

3.4 Patient Preparation

Provide the patient with the following instructions to prepare for the MiroCam® Capsule endoscopy procedure.

3.4.1 Patient Preparation

- One day prior to the MiroCam® Capsule endoscopy procedure
 - Lunch: Patient can have a normal meal around noon, followed by a liquid diet as instructed by the physician.
 - The patient should fast for at least 12 hours prior to the MiroCam® Capsule endoscopy procedure. Patient may only drink water (no food or other beverages such as milk or coffee).
 - The patient should not take any medications two hours before ingesting the MiroCam® Capsule endoscope.
 - Male patients may need to shave area, as advised by physician or nurse.
 - Patient should stop taking iron supplements 1 week before the MiroCam® Capsule endoscopy procedure, and should not ingest any medicine at least 2 hours prior to the MiroCam® Capsule endoscopy procedure.
 - Diabetic patients need to follow any changes to insulin dosage as prescribed by the physician.
 - Physician is recommended to prescribe patient a laxative such as PEG or Sodium Phosphate. Patient should ingest laxative 12 hours prior to procedure.

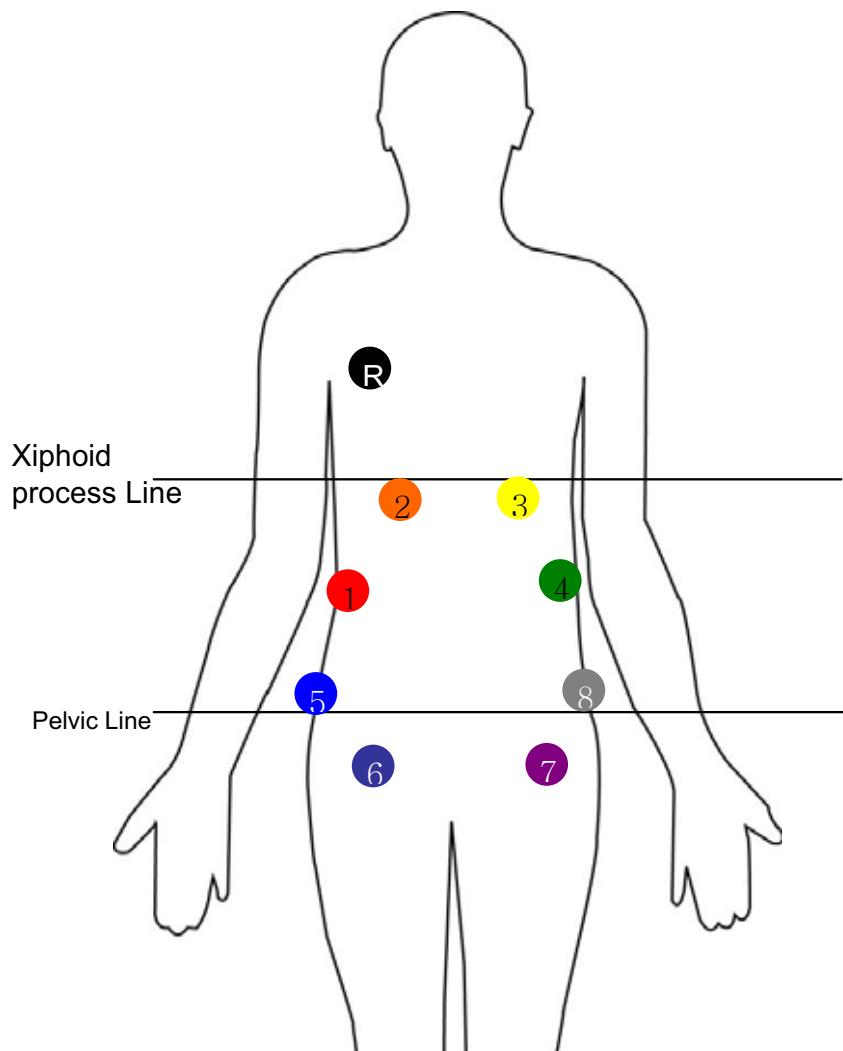
- Physician is recommended to prescribe patient an anti-foaming agent (such as simethicone), to reduce bubbles in the GI tract. This should be ingested after the laxative.
 - The patient should abstain from smoking 12 hours before the MiroCam® Capsule endoscopy procedure.
 - On the day of the MiroCam® Capsule endoscope test, the patient should wear comfortable and loose cloths. One-piece clothing should not be worn.
 - Prior to the MiroCam® Capsule endoscopy procedure, do not apply any lotions or perfumes.
- On the day of capsule endoscopy procedure
- After arriving in a hospital at the appointed time, the patient should submit an examination permission form and check in.
- After ingesting capsule endoscope
- The patient should refrain from ingesting any food or drink (except water) two hours after swallowing the MiroCam® Capsule endoscope.
 - Patient is recommended to drink water every half hour during the MiroCam® Capsule endoscopy procedure.
 - The patient can start with light food after 4 hours. When the examination is complete, the patient can start having normal meals.
 - In case of any abdominal pain, nausea or vomiting after ingesting the MiroCam® capsule, the patient should contact physician or nurse immediately.

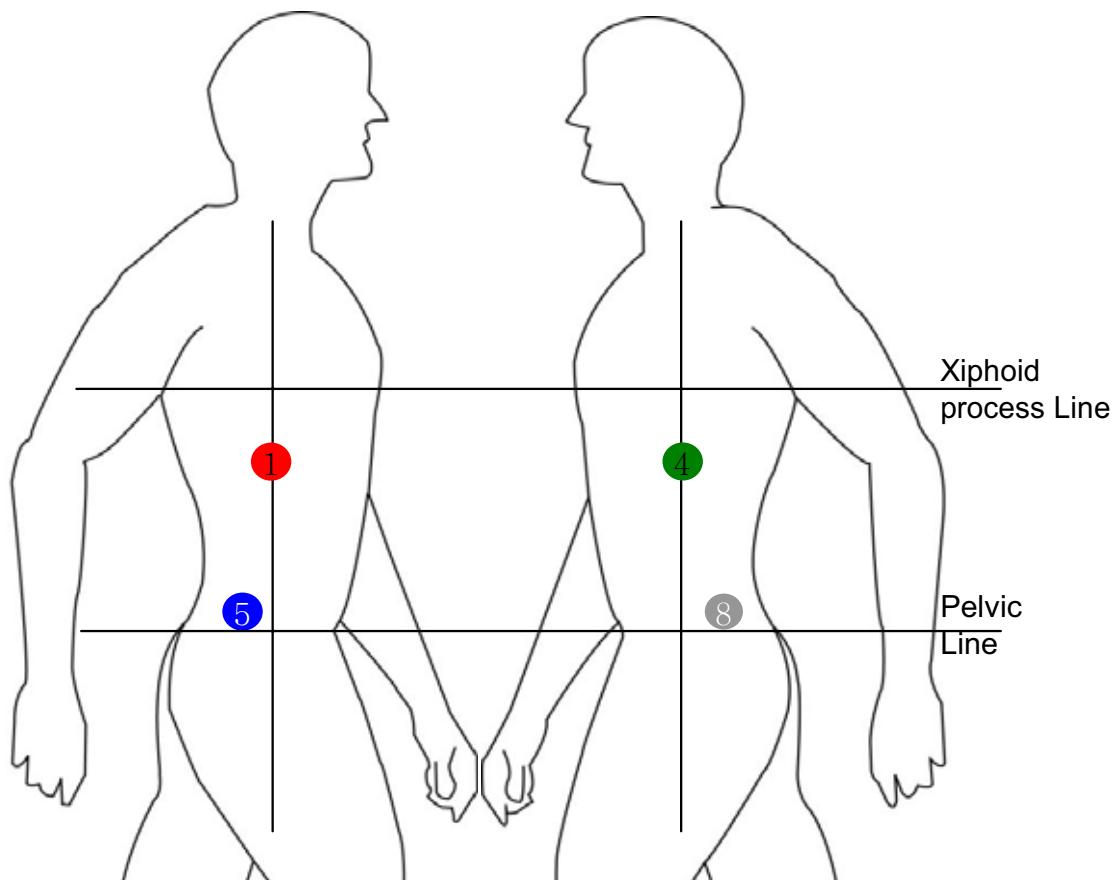
3.5 Sensor Placement & Capsule Ingestion

Following is the detailed procedure required to correctly administer the MiroCam® Capsule endoscopy procedure.

3.5.1 Connecting Sensor Pads

After attaching sensor pads to the data cables, attach the sensor pad correctly to each area as shown below.





- Attach sensor pads according to the number on the data cable.
 - Locate the center between the umbilical and the xiphoid process. From this center point, attach the sensor to the distal point on the right flank of the patient's body.
 - Place the sensor pad on the xiphoid process line, directly below the right clavicle.
 - Place the sensor pad on the xiphoid process line, directly below the left clavicle.
 - Locate the center between the umbilical and the xiphoid process. From this center point, attach the sensor to the distal point on the left flank of the patient's body.
 - Place the sensor pad on the right pelvic line, 2 cm behind sensor #1.

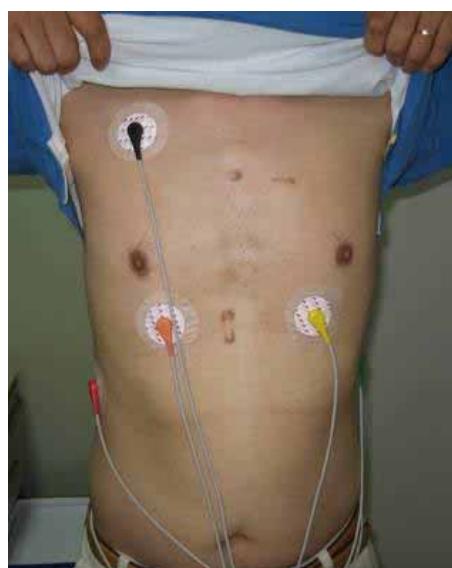
- Place the sensor on the right inguinal line, 2 cm to the outside of sensor #2.
- Place the sensor on the right inguinal line, 2 cm to the outside of sensor #3.
- Place the sensor pad on the right pelvic line, 2 cm behind sensor #4.
- Place the sensor directly below the right clavicle.

! **CAUTION** The numbering of the data cables and sensor pad must match the specified area. Please follow the numbering sequence appropriately.

! **CAUTION** To prevent entanglement of the data cables during procedure, organize cables and place appropriately in cable bag.

! **WARNING** Correct image signal may not be obtained if a sensor pad is not in direct, immediate contact with the skin. Ensure the sensor pads are in direct contact with the skin. Shaving may be required for male patients.

- The pictures below show the sensor pads attached in the correct locations.



3.5.3 Connecting Data Belt

- Attach stitched point on the belly button.
- Tighten the data belt around the waist with the velcro.
- Use the data belt as shown below.



! **CAUTION** Do not attach the Data belt above clothing

- After placing sensor pads on the patient, connect the cable to the MiroCam® Receiver as detailed in the following image.



3.5.4 Removing Capsule from Package

- While holding the case upside down, peel off the sterilized package cover.



3.5.5 Removing the Case

- Turn the package over, the MiroCam® case will slip out of the package.
While holding the case, open the lid.



3.5.6 Removing the Capsule

- Grip capsule with right hand, and remove from cast. DO NOT touch the dome of the capsule.



- Make sure that the MiroCam® Capsule packaging is not damaged in any way. When removed capsule from case, the MiroCam® Capsule should be flashing.

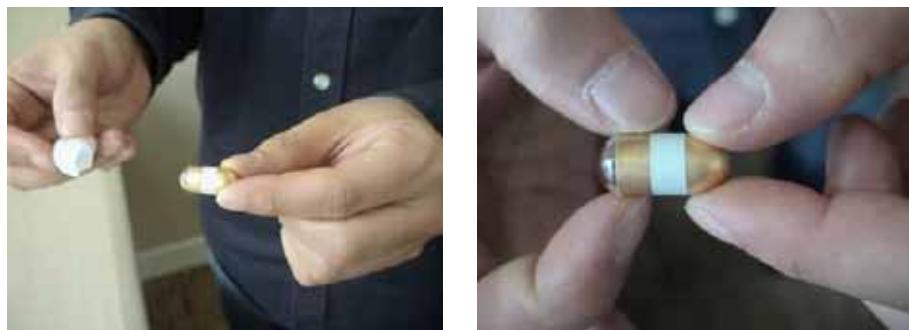
! **CAUTION** Do not use a MiroCam® Capsule Endoscope if the packaging or the MiroCam® Capsule is damaged.

! **CAUTION** Do not touch the dome of the MiroCam® Capsule. This may result in poor image quality.

- Check if the front of the MiroCam® Capsule is flashing when it is removed from the case



- After washing hands, patients should grip the gold section of the MiroCam® Capsule between the thumb and the forefinger of the both hands.



! CAUTION Initialize the MiroCam® Receiver prior to the MiroCam® Capsule Endoscopy Procedure. Once the MiroCam® Receiver confirms signal transmissions with a green SIG indicator, the receiver will start recording for 12 hours, even while the power switch of the MiroCam® Receiver is in the off position.

3.5.7 Checking Operation of the MiroCam® Receiver and Signal Reception

After the patient holds the MiroCam® Capsule as detailed above, the signal indicator on the MiroCam® Receiver is green and signal indication melody is generated. If signal indicator is yellow, there is no signal being received from the capsule.

- Switch on the MiroCam® Receiver.
- Check if the battery indicator (BAT) at the top of the MiroCam® Receiver shows that the battery is fully charged. The battery indicator on the MiroCam® Receiver should be green.
- Check if the initialize indicator (INI) at the top of the MiroCam® Receiver shows that initialization is complete. The INI indicator on the MiroCam® Receiver should be green.

- Connect the data cable to the MiroCam® Receiver.
- After patient grasps capsule by opposing gold bands (as detailed in picture above, check the SIG indicator on the MiroCam® Receiver is green and signal indication melody is generate.

! **CAUTION** If the battery indicator on the MiroCam® Receiver shows that the battery is not fully charged, do not start the endoscopy procedure. The battery may be depleted during the MiroCam® Capsule endoscopy procedure and images may not be saved properly.

! **CAUTION** Please be noticed to confirm the shape and the direction of the connector when you connecting the data cable to the MiroCam® Receiver, since it may cause cable damage problem.

3.5.8 Ingesting the Capsule

After checking if the signal indicator on the MiroCam® Receiver is green, ingest the MiroCam® Capsule with water.



! **CAUTION** DO NOT bite the MiroCam® Capsule while ingesting.

! **NOTE** To increase the effectiveness of the MiroCam® Capsule endoscopy procedure, please be sure to drink water on a regular basis.

**WARNING**

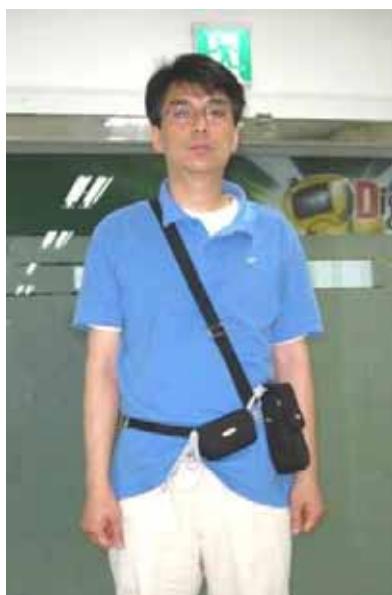
The MiroCam® Capsule should enter the stomach. Make sure to always check that the MiroCam® Capsule enter the stomach by checking the images on the MiroView™ RTV (or the Wireless MiroView™ RTVi) and color of SIG indicator on the MiroCam® Receiver turns green right after ingesting the capsule.

**WARNING**

DO NOT USE a MiroCam® Capsule that has been dropped or coughed up by a patient. New MiroCam® Capsule must be used. Take note of the new MiroCam® Capsule number. The MiroCam® Receiver does not need to be initialized again prior to swallowing the MiroCam® Capsule.

3.5.9 Checking and Wearing the MiroCam® Receiver

- After ingesting the capsule, make sure that the SIG indicator is green.
- Place the MiroCam® Receiver in the bag.
- Organize the contents of the bag so that the cables are not entangled.
- Adjust cables, and place excess in cable bag.
- Adjust the bag strap as needed.



- The MiroCam® Capsule endoscopy procedure will be complete after 12 hours.

! **CAUTION** Patient should not touch the MiroCam® Receiver during the MiroCam® Capsule endoscopy procedure. This may lead to loss of image data.

! **CAUTION** During the MiroCam® Capsule endoscopy procedure the SIG indicator should be green.
In this case, check data cable to ensure it is securely inserted and check the sensor pads to ensure these are fixed to the body.

3.5.10 During the Procedure

- After ingesting the MiroCam® Capsule Endoscope instruct the patient to:
 - Immediately report any episodes of abdominal pain, nausea or vomiting, to the Nurse or Physician in charge.
 - After ingesting the MiroCam® Capsule you may ingest water, and only water. At least 250ml of water should be ingested per hour.
 - Four hours after swallowing the MiroCam® Capsule, you will be permitted to resume a clear liquid diet. A clear liquid diet includes water, clear broth, Jell-O, Sprite, apple juice, and popsicles. No solid foods, milk or milk products, or dark-colored liquids are allowed. A light diet (e.g. applesauce, cereal, toast) can be resumed six hours after the MiroCam® Capsule was swallowed.
 - Do not touch or disturb the MiroCam® Receiver or get them wet for the duration of the procedure. The MiroCam® Receiver and sensors must remain on the body for a period of 12 hours after ingestion of the MiroCam® Capsule.

- If a sensor pad or cable is removed during the procedure, the patient can replace the sensor pad or cable and take a note of the time of the occurrence.
- Patient should not exercise or lift heavy items
- Daily activities, aside from strenuous activities are permitted for the patient.
- Please refrain from bathing or showering while sensor pads and MiroCam® Receiver are attached to your body.
- Patient must Avoid MRI rooms at the hospital and radio transmission towers.
- Patient should not use electric blankets or electric heating pads.
- Use of computers, radios, cell phones are permitted
- Keep away from other patients who are undergoing the MiroCam® Capsule endoscopy procedure.
- Once the patient has ingested a MiroCam® Capsule, the patient may leave the clinic.

**WARNING**

Patient should not open the MiroCam® Receiver bag. The safety of ESD (electrostatic discharge) when the patient leaves the clinic is not published.

**WARNING**

Patient should not contact any electric device to the patient abdomen directly. This may lead to loss of image data.

**CAUTION**

Tell the patient to notify the nurse or physician of symptoms of abdominal pain, or vomiting during or after the MiroCam® Capsule endoscopy procedure.

**CAUTION**

Tell the patient to avoid excessive physical activity during the MiroCam® Capsule endoscopy procedure.

**CAUTION**

4 hours after ingesting the MiroCam® Capsule patients may resume a liquid diet.

! **CAUTION** When undergoing the MiroCam® Capsule endoscopy procedure, DO NOT make physical contact with another person undergoing the same procedure.

3.5.11 Completion of the Procedure

- The MiroCam® Receiver set, sensor pad and cables can be removed by the patient 12 hours after ingestion of the MiroCam® Capsule.
- Hospital or clinic is to arrange the time for the patient to return the MiroCam® Receiver set.

3.5.12 After the Procedure

- Inform the patient that:

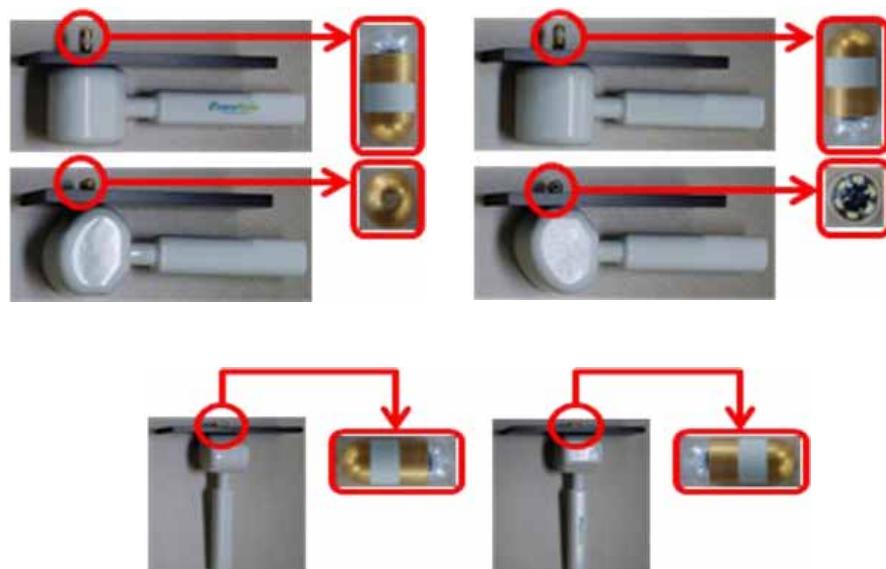
- The MiroCam® Capsule will be naturally excreted.
- Instruct patient to contact nurse or physician if the patient feels acute or continuing abdominal pain.
- Meals: eat as usual.
- The day following the MiroCam® Capsule endoscopy procedure the patient may resume all usual activities.
- MRI examinations: patient should avoid MRI examinations prior to excretion of the MiroCam® Capsule.

! **WARNING** After ingesting the MiroCam® Capsule, always check whether the MiroCam® Capsule has been excreted. The MiroCam® Capsule captures images for up to 12 hours and gets naturally excreted in about 24 hours under normal conditions. If the MiroCam® Capsule has not been excreted from the patient within 72 hours, patient should contact the physician. If examination confirms retention of the MiroCam® Capsule, surgical or medical treatment to remove the MiroCam® Capsule may be necessary.

! **NOTE** The MiroCam® Capsule and sensor pads are medical waste, and should be disposed of according to local regulations or Waste Electrical and Electronic Equipment (WEEE) directive on waste disposal.

3.6 Using Magnetic Controller

- After ingesting the capsule, make sure that the SIG indicator is green.
- Connect to the MiroView™ RTV or Wireless MiroView™ RTVi and then confirm current location of capsule.
- Control the direction of the MiroCam® Capsule in human body with the magnetic controller like following pictures.



- Lead the MiroCam® Capsule into the duodenum with magnetic controller by checking the images on the MiroView™ RTV or the Wireless MiroView™ RTVi.

! CAUTION If the patient feels pain during doctor controls a magnetic capsule with magnetic controller, carry out conventional endoscopy.

! CAUTION DO NOT put any steel or magnetic materials within 1m radius during the MiroCam® Capsule endoscopy procedure.

3.7 Uploading Image Data

Once the MiroCam® Capsule endoscopy procedure is complete, upload the image data from the MiroCam® Receiver to the workstation and start diagnosis of the data using MiroView™ Software.

3.7.1 Transferring and Checking image data

- Switch on the workstation.
- Connect the smaller end of the USB cable to the MiroCam® Receiver
- Click the  on the desktop to launch MiroView™ Operator.
- When the login window appears, enter the user ID and password, and then click the .
- Connect the smaller end of the USB cable to the MiroCam® Receiver.
- Connect the other end of the USB cable to the workstation.
- Click the  in MiroView™ Operator.
- After the image data in the MiroCam® Receiver has been successfully uploaded, execute MiroView™ Client to review and report on the patient file.

 **WARNING** For more information on using MiroView™ Software please refer to ***Chapter 4. Using MiroView™ Software.***

3.8 MiroCam® Receiver Management – Post Procedure

3.8.1 Cleaning

- Remove data cable (or data belt) from the MiroCam® Receiver .
- Capsule, data belt and sensor pads should not be reused.
- To clean the MiroCam® Receiver and the workstation, dampen a soft cloth with warm water or with a commercial, nonabrasive cleaner (or a mild soap or detergent solution) and wipe the exterior surface lightly. DO NOT allow any liquids to come in contact with the power connector, cable connector or switches. DO NOT allow any liquids to penetrate connectors or openings in the system cover. Cleaning of the system and accessories should be conducted at least once a week.



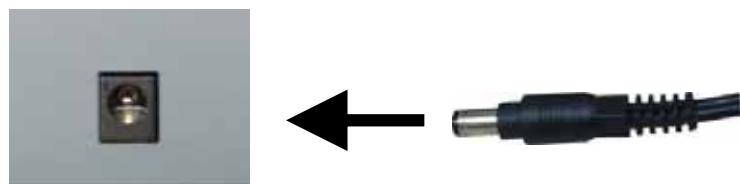
CAUTION DO NOT immerse the MiroCam® Capsule Endoscope System or its accessories in liquid or clean with caustic or abrasive cleaners. DO NOT spray or pour any liquid on the system or its accessories. DO NOT use the organic solvents such as a lacquer, thinner, ethylene and oxide because they can damage the equipment. When cleaning the data cable, do not use the cleaning tools such as brush and sandpaper.

3.8.2 Charging Battery

- Battery must be recharged after every procedure.
- Battery can be individually recharged using the battery charger or while attached to the MiroCam® Receiver.
- Battery must be recharged in the battery charger.
- If two batteries are inserted in charger, the batteries will automatically consecutively charge (not simultaneous).



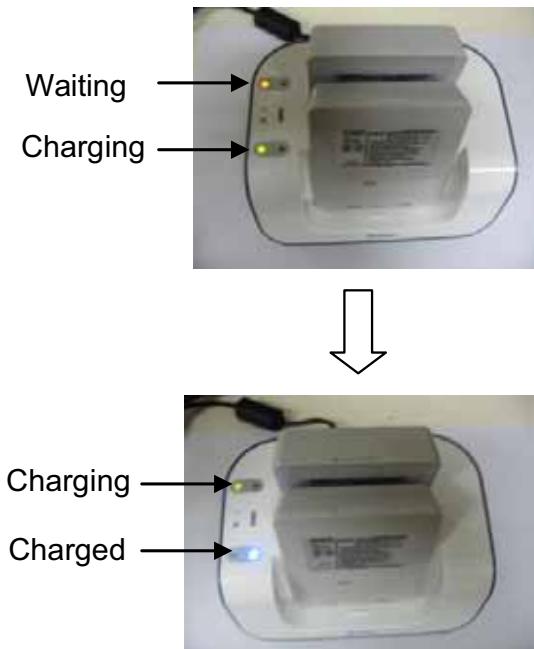
- Connect adapter DC cable to battery charger.



- Connect AC power cable to adaptor.
- Connect AC power cable to AC outlet or multi-tap.
- Battery charger indicator lights:
 - Battery is charging when green light is blinking
 - Battery is fully charged when light is solid blue
 - Battery is not-charging if light is yellow



NOTE Second Battery in charger will automatically begin charging once first battery is fully charged.



-  **WARNING** If the indicator on the battery charger is blinking yellow there is a bad connection. Please disconnect the battery from the battery charger and try again.
-  **WARNING** Only use batteries provided by IntroMedic. Usage of inappropriate batteries can cause serious damage to the MiroCam® Receiver.
-  **WARNING** Recharge the batteries with the adaptor and the battery charger only from IntroMedic. Improper adaptors and battery chargers cause serious damage.
-  **WARNING** Try not to contact the metallic terminal board of batteries with conductive objects or human body. It can cause an electric shock or damage and/or breakage of the batteries.
-  **WARNING** DO NOT use the batteries with visible surface damage on. Usage of damaged batteries can result in leakage of contents of the batteries.
-  **WARNING** To avoid the risk of explosion, keep batteries away from fire.
-  **WARNING** Treat the batteries carefully from serious impact or shock. This can cause serious damage to the batteries.
-  **WARNING** DO NOT expose the batteries to liquids. This can cause serious damage.



4

Using MiroView™ Software

4. USING MIROVIEW™ SOFTWARE

The MiroView™ Software is a computer software program that aids in diagnosis of disease of the small bowel via displaying images obtained from the MiroCam® Capsule.

Following is a list of new & updated features:

- User Interface
 - ❖ The MiroView™ Software enables adjustable resolution, to appropriately fit to the screen size.
 - ❖ The MiroView™ Software has been designed with a dark background to reduce eye strain.
 - ❖ The MiroView™ Software provides intuitive and unified icons so that the user can adapt quickly.
- Reporting Tool
- Express Play
- SGIB Play
- Range View
- Map View
- Network Support
- Account Management
- Multi-Review / Report Generation
- Multi-Receiver Management
- Multi-Data Path
- Customizing Print Dialog
- Data Multi-Language
- ODF Report
- Drag Bag
- Finding Setting (Custom Finding)

The workstation where the MiroView™ Software is installed properly has icons for four applications on the Desktop folder: MiroView™ Client, MiroView™ Operator, MiroView™ Server, and MiroView™ Viewer. However this manual will not explain details on how to use the MiroView™ Viewer. For additional information for MiroView™ Viewer, please refer to the MiroView™ Viewer Instruction Manual. To get the installation procedure for MiroView™ Software, refer to the MiroCam® Service Manual.

**MiroView™ Client****MiroView™ Operator****MiroView™ Server****MiroView™ Viewer**

This program is used for reviewing the images from the MiroCam® Capsule and generating a patient report. The MiroView™ Server should be started prior to starting the MiroView™ Client.

This program is used for managing the MiroCam® Receivers (initialize, upload etc.) and managing user accounts. The MiroView™ Server should be started prior to starting MiroView™ Operator.

The server stores the patient data files. Start the MiroView™ Server prior to starting MiroView™ Software or MiroView™ Operator.

The MiroView™ Viewer is used for reviewing, editing and creating the images exported from the MiroView™ Software; EXMIF or JPEG images.

Functions:

- List Mode
- Review Mode
- Report Mode
- Export Mode
- Image Atlas
- SGIB
(Suspected
GI Bleeding)
- Express Play
- Position Window
- Network connectivity
- Multi-Review
- Range View
- Map View
- GI Dictionary
- Finding / Diagnosis Information
- Drag Bag

Functions:

- Input Patient Information
- Receiver Initialization
- Upload Image Data from Receiver
- Data Backup
- Account Management
- Patient Manager
- Network connectivity

Functions:

- DB, Mass storage
- Network connectivity
- Multiple Data Path

Functions:

- Study Information
- Image Information
- Show Findings / Diagnosis

4.1 H/W Specifications for MiroView™ Software

4.1.1 MiroView™ Server

■ Minimum Hardware Requirements

- OS: Windows XP (32 bit, 64 bit),
Windows Vista Business (32 bit, 64 bit),
Windows 7 (32 bit, 64 bit)
- CPU: > Core 2 Duo E6300
- Memory: > DDR II 4GByte
- Video Card: Windows Compatible
- HDD: SATA 500GB
- ODD: DVD+-RW
- Monitor Resolution: 1024x768

■ Recommended Hardware Requirements

- OS: Windows XP (32 bit, 64 bit),
Windows Vista Business (32 bit, 64 bit),
Windows 7 (32 bit, 64 bit)
- CPU: > Core 2 Duo E6300
- Memory: > DDR II 4GByte
- Video Card: Windows Compatible
- HDD: SATAII RAID 1TB
- ODD: DVD+-RW
- Monitor Resolution: 1680x1050, 1280 x 1024

4.1.2 MiroView™ Client

■ Minimum Hardware Requirements

- OS: Windows XP (32 bit, 64 bit),
Vista or Windows7 (32 bit, 64 bit)
- CPU: Pentium4 2GHz
- Memory: 1GB
- Video Card: Geforce 7600GT 128MB
- HDD: SATA 160GB
- ODD: DVD+-RW
- Monitor Resolution: 1024x768
- Sound Card / Mike / Speaker

■ Recommended Hardware Requirements

- OS: Windows XP (32 bit, 64 bit),
Vista or Windows7 (32 bit, 64 bit)
- CPU: > Core 2 Duo E6300
- Memory: > DDR II 2GByte
- Video Card: > Geforce 7600GT 128MB
- HDD: SATA II 500 GB
- ODD: DVD+-RW
- Monitor Resolution: 1680x1050
- Sound Card / Mike / Speaker

4.1.3 MiroView™ Operator

■ Minimum Hardware Requirements

- OS: Windows XP (32 bit, 64 bit),
Vista or Windows7 (32 bit, 64 bit)
- CPU: Pentium4 2GHz
- Memory: 1GB
- Video Card: Windows Compatible
- HDD: SATA 160GB
- ODD: DVD+-RW
- Monitor Resolution: 1024x768

■ Recommended Hardware Requirements

- OS: Windows XP (32 bit, 64 bit),
Vista or Windows7 (32 bit, 64 bit)
- CPU: > Core 2 Duo E6300
- Memory: 1GB
- Video Card: Windows Compatible
- HDD: SATA 160GB
- ODD: DVD+-RW
- Monitor Resolution: 1680x1050

4.1.4 MiroView™ Viewer

■ Hardware Requirements

- OS: Windows XP (32 bit, 64 bit),
Vista or Windows7 (32 bit, 64 bit)
- CPU: Pentium4 2GHz
- Memory: 1GB
- Video Card: Windows Compatible
- HDD: SATA 160GB
- ODD: DVD+-RW
- Monitor Resolution: 1024x768

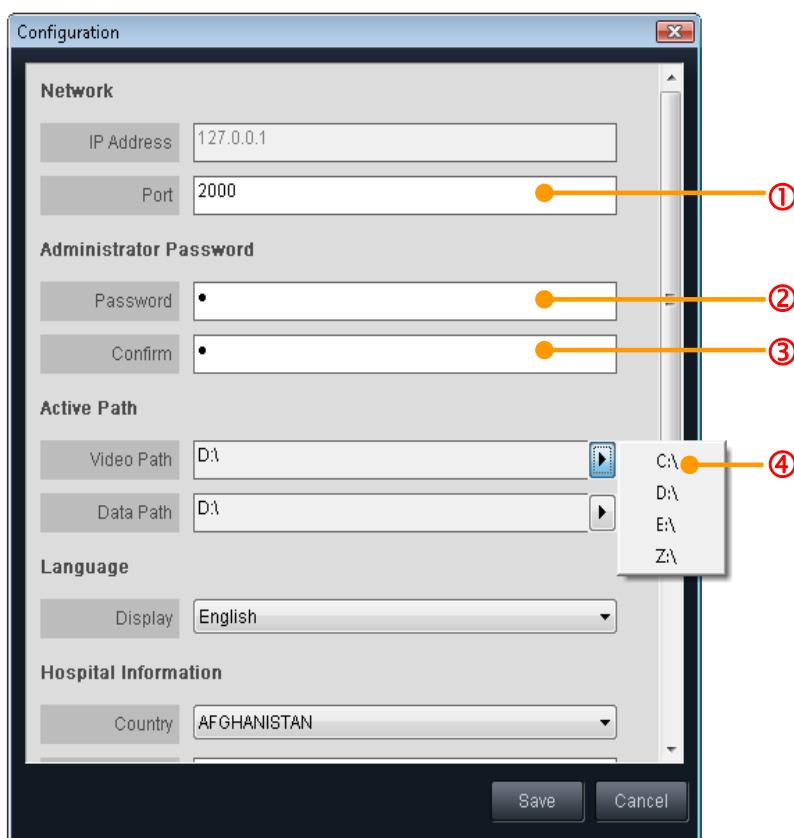
 **CAUTION** The MiroView™ Software cannot be viewed on a monitor with a resolution under 1024x768.

 **NOTE** The GUI is best viewed on a wide monitor of 19" or larger.

4.2 Overview – MiroView™ Server

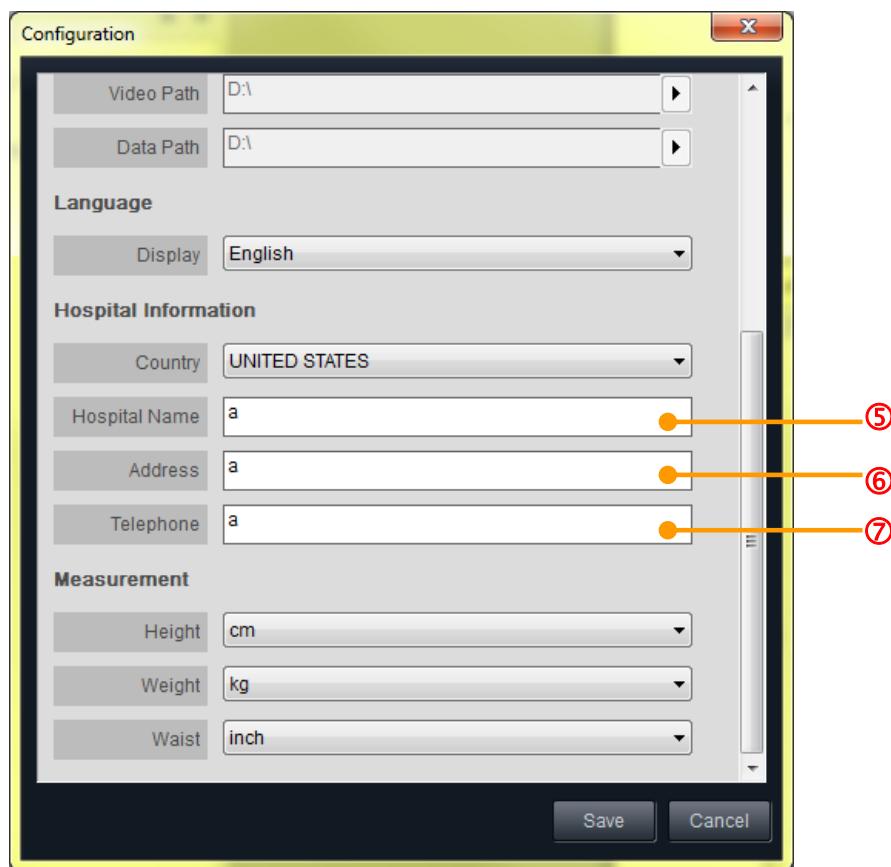
The MiroView™ Server software is intended to be used as a system administrative managing tool. The MiroView™ Server manages file systems and database systems.

When switching the workstation on, the MiroView™ Server will start automatically. When the following window appears, set up the configuration and press the **Save** to continue.



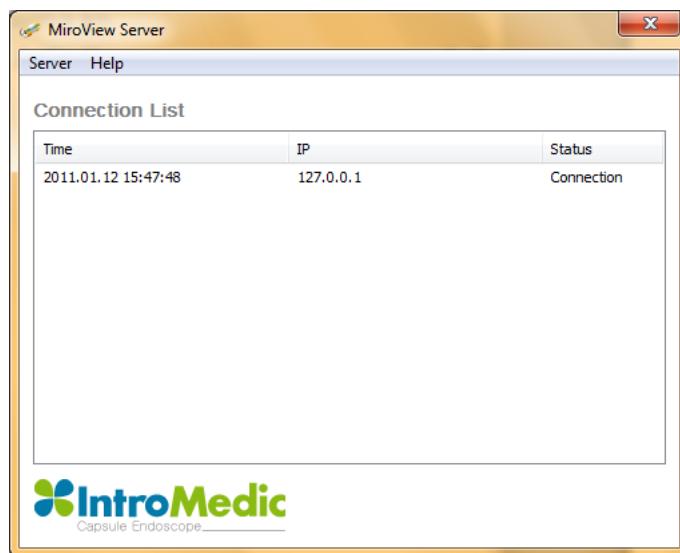
- ① Set the port number for the Network. If unknown, please leave the field as '2000'. This field should be managed by a Network Administrator at the hospital.

- ② Set the password for ‘Administrator’ account. Additional accounts can be made via Account Manager function after logging in the MiroView™ Operator as ‘Administrator’.
- ③ Confirm the password.
- ④ Set the Active Path; Video Path and Data Path as the desirable path. Select one of multiple paths from the paths list for the active path. The paths list can be modified via Server Menu → Multi Data Path on the MiroView™ Server running.



- ⑤ Input the Hospital’s Name in this field.
- ⑥ Input the Hospital’s Address in this field.
- ⑦ Input the Hospital’s Telephone number in this field.

- After setting up the Configuration Windows, the MiroView™ Server window above will appear. Click the  to hide the window.



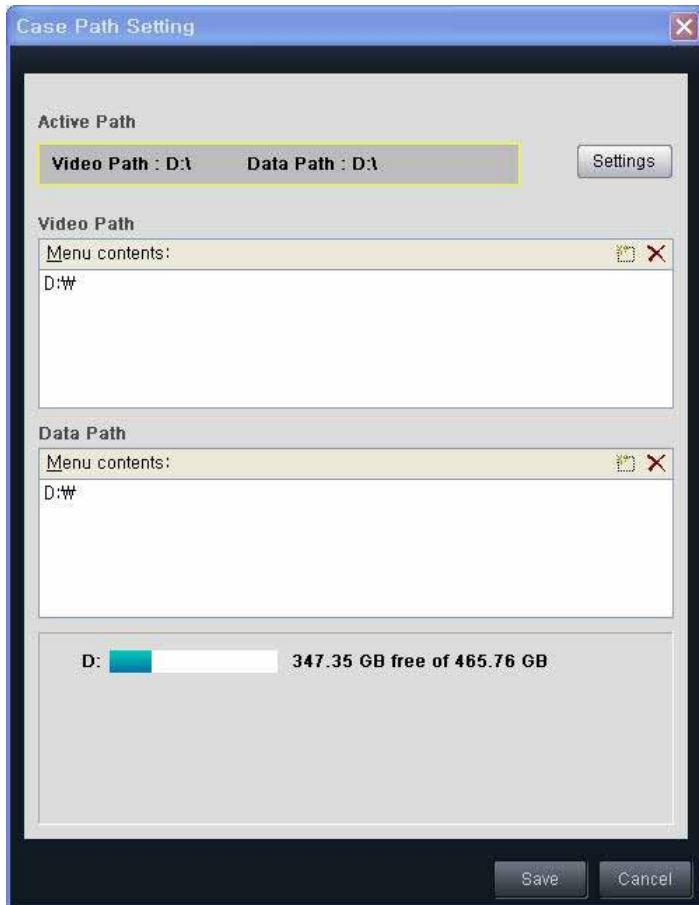
- The Video Path list and the Data Path list for the Active Paths can be modified via Server Menu → Multi Data Path on the MiroView™ Server running.



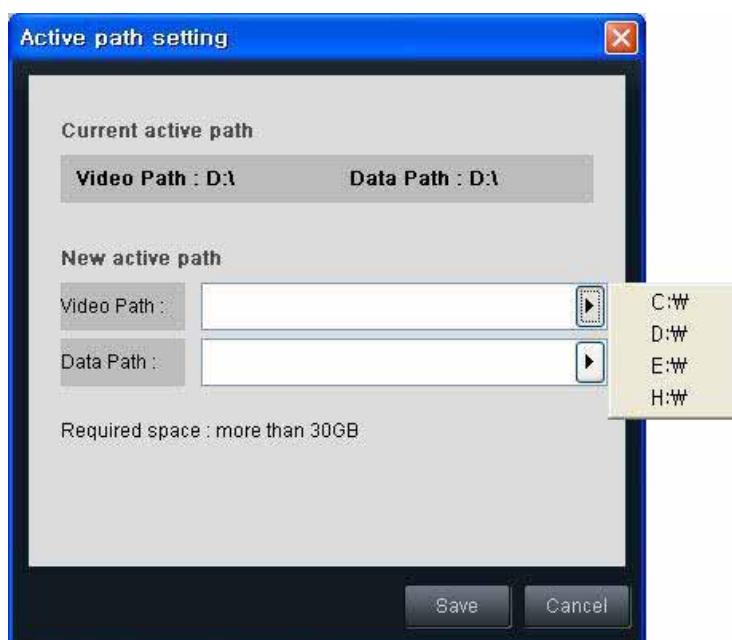
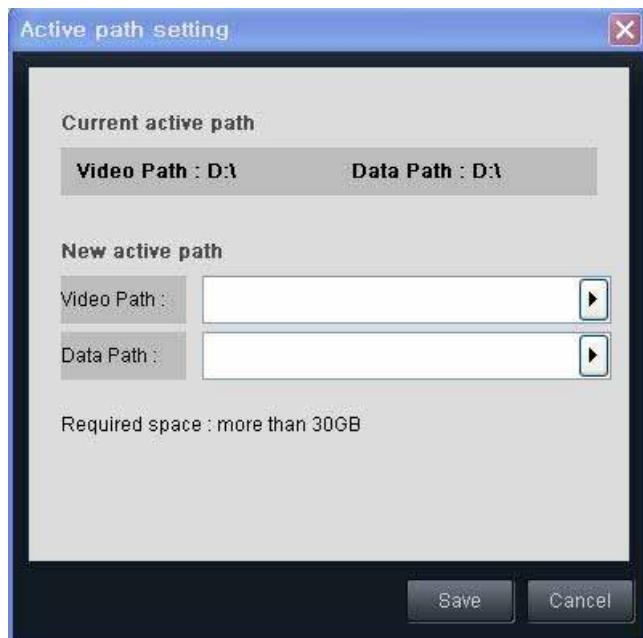
- Login window will appear. Input the password for the Administrator account.

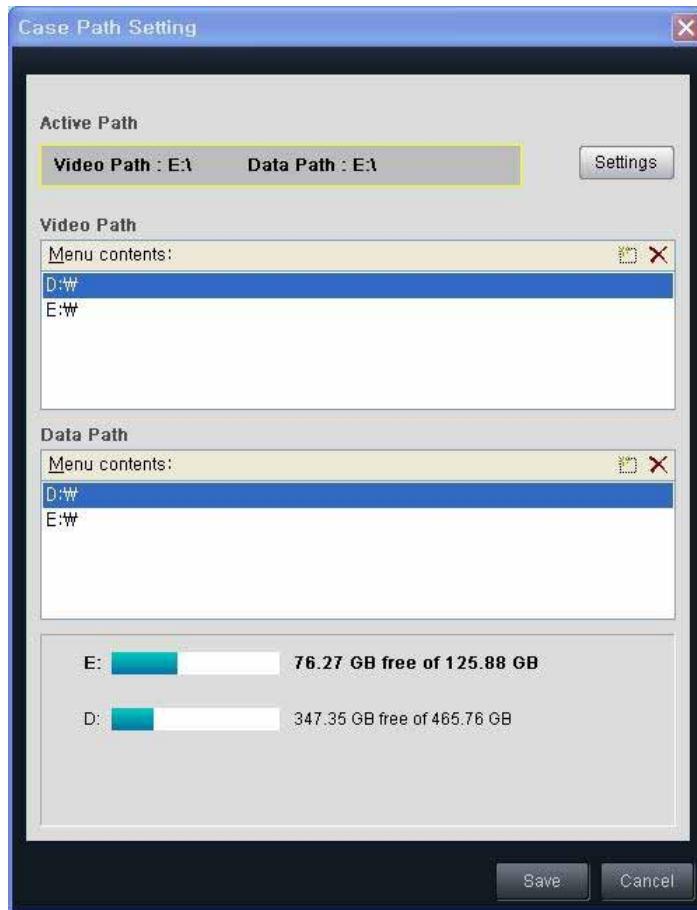


- Case Path Setting will appear. Click the  to show the Active Path Setting.



- Click the  to set the path for the Video Path and the Data Path respectively.





- The user can modify the Video Path and Menu Path using the (add path) and (remove path) as well.
- If the Active Path' memory becomes insufficient to use (below 10GBytes), set the path as new one larger than 30 GB.

**NOTE**

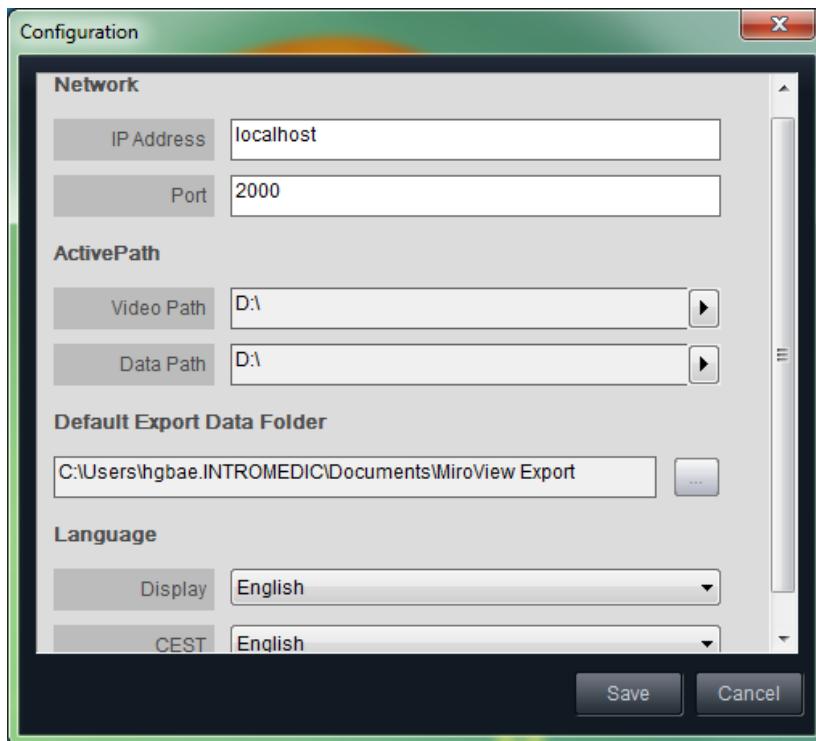
The MiroView™ Server provides the task manager to show the activating status on the server. The MiroView™ Server offers the case list and the analysis function as well.

4.3 Overview - MiroView™ Operator

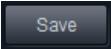
The MiroView™ Operator software is intended to be used for administrative purposes, including the Account Manager, the Patient Manager and the MiroCam® Receiver management functionality.

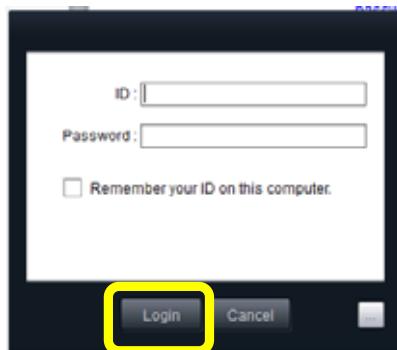
4.3.1 Start MiroView™ Operator

- Double-click the  to run the MiroView™ Operator. When executed for the first time, the following window will appear.

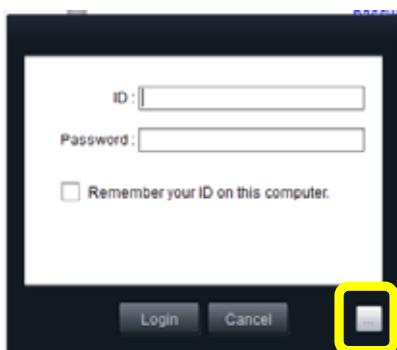


- Input “127.0.0.1” for the IP Address and “2000” for the Port.
 - ※ If the MiroView™ Server is installed on the network, input the workstation’s IP on which the MiroView™ Server is installed for this field, and the port which the MiroView™ Server is using, referring to the IT engineer in the hospital to point the operator to the MiroView™ Server.

- Set the Active Path; Video Path and Data Path as the desirable path. Select one of multiple paths from the paths list for the active path.
- Direct the Default Export Data Folder.
- Choose the preferred Language settings and press  to access the MiroView™ Operator.
- After the MiroView™ Operator has launched, the Log-in window will appear.
- Input ‘Administrator’ for ID and designated password. Then press the .



- Press the  to change the IP address the MiroView™ Server is using.



- After clicking the  the window will appear like the above.

Type the MiroView™ Server IP address and port. Then press the  after inputting ID and password.



! **CAUTION** DO NOT forget the ID and password after they are encrypted.

! **CAUTION** Before the MiroView™ Operator is launched, a password for the administrator account should be created. When running the MiroView™ Server for the very first time, a password for the administrator account should be created.

! **NOTE** Create new and edit existing accounts by using the 'Account Manager' menu in MiroView™ Operator.

- The following subsections describe the main interfaces and functions of the MiroView™ Operator.

4.3.2 List Mode

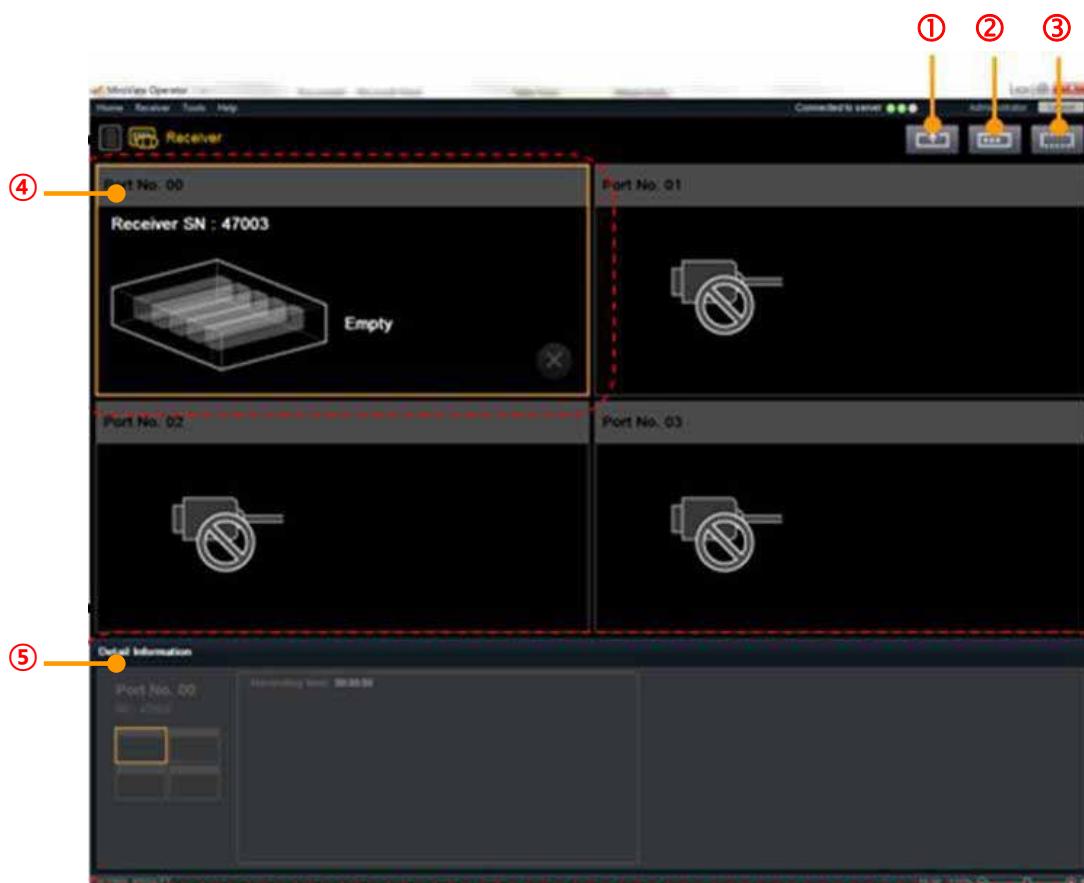


| | | |
|---|---------------|---|
| ① | List Mode | Opens List Mode |
| ② | Receiver Mode | Opens Receiver Mode |
| ③ | Print Report | Print out the selected Report |
| ④ | Delete Case | Delete the selected Cases |
| ⑤ | Recycle Bin | Open Recycle Bin Window |
| ⑥ | Export | Export the selected Report |
| ⑦ | Search | Search Cases and/or Reviews by keyword |
| ⑧ | Show all | Refresh and Show all the Cases and Review on the List |

NOTE Right click the mouse at the list item to use the context menu functionality, for example the Backup function.

4.3.3 Receiver Mode

Screen enables administration and status display for up to four MiroCam® Receivers.



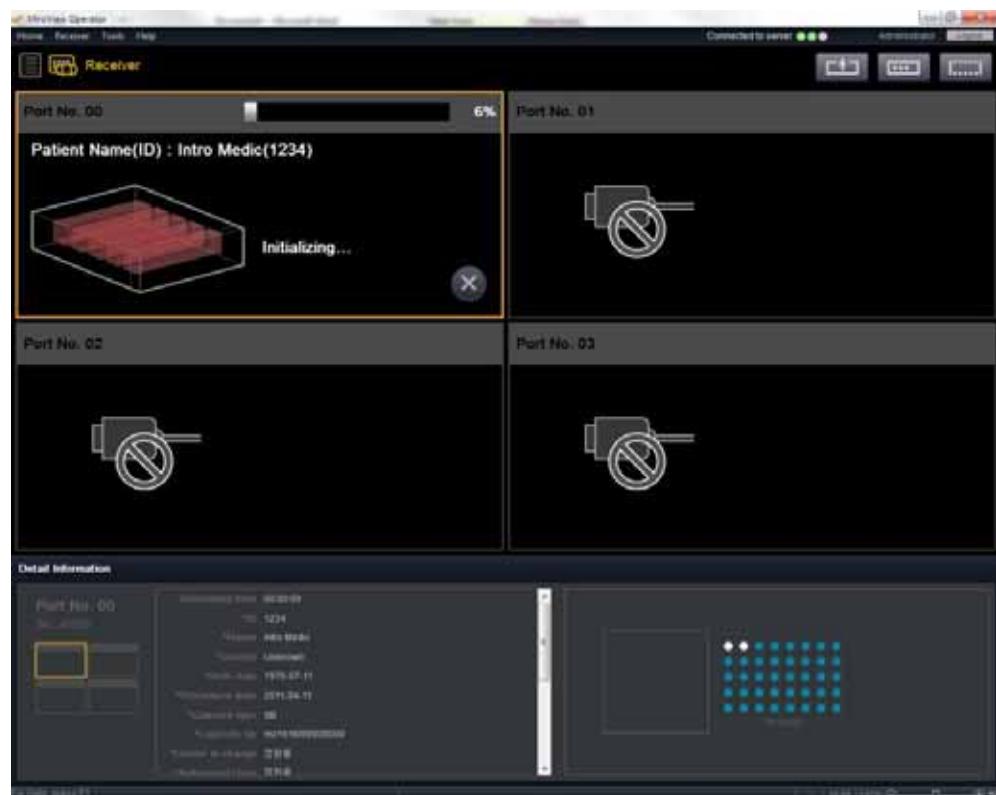
| | | |
|---|-----------------------------|--|
| ① | Upload | Upload image data in the MiroCam® Receiver to the server |
| ② | Input Patient's Information | Input Patient's Information to the selected Receiver |
| ③ | Initialization | Delete all data from the MiroCam® Receiver and/or prepare the MiroCam® Receiver for the next patient |
| ④ | Receiver Port | Shows the status of the connected the MiroCam® Receiver for each of the four ports |
| ⑤ | Detail Information | Shows the patient's information for the selected Receiver |



CAUTION When running MiroView™ Operator on a 64bits OS, Do not turn off or disconnect the MiroCam® Receiver while uploading a patient file.

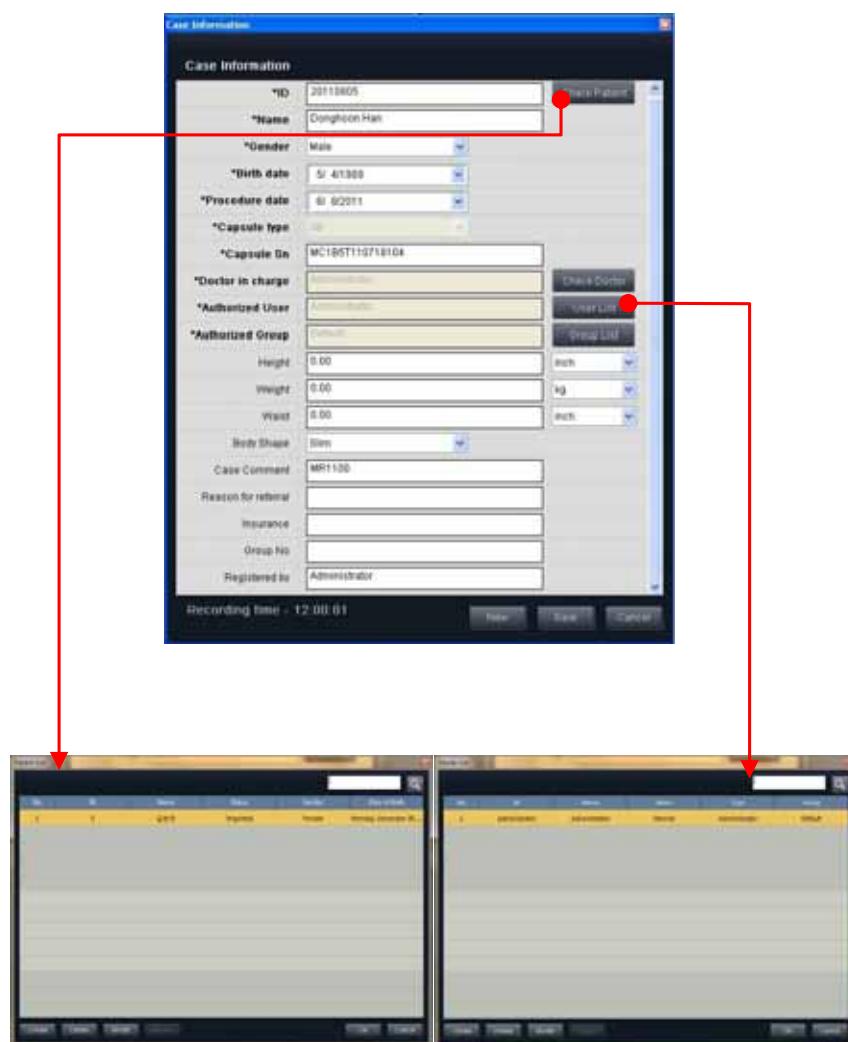
4.3.4 Receiver Initialization

Click the to initialize the selected Receiver.



4.3.5 Inputting Patient Information

Click the  to enter the patient information. After completing the required fields, click the  to save the patient information onto the MiroCam® Receiver. The fields in the patient information are editable and additional fields can be added. This can be accessed via Tools → Preferences → Receiver → Set → Add / Modify. (The field, “Reason for referral” is newly added on the MiroView™ Software version.)



* indicates required fields.

4.3.6 Image Data Upload

After the MiroCam® Capsule endoscopy procedure, upload the image data from the MiroCam® Receiver to the MiroCam® system via the MiroView™ Operator. Click the  to upload the image data from the MiroCam® Receiver.

After the image data in the MiroCam® Receiver has been successfully uploaded, enter the List Mode and check if the new Case has been created.

- Double-click the  to run the MiroView™ Client.
- Select the newly uploaded image data and enter the Review Mode.
- Play the case to check the uploaded image data.

**CAUTION**

If uploading of the image data failed, disconnect the USB cable from the workstation, turn off the MiroCam® Receiver and back on. Reconnect the USB cable to the workstation and try uploading once more. If the problem continues, please contact the local IntroMedic distributor.

**NOTE**

Make sure the patient's name has been inputted properly prior to uploading the image data. If the image data is uploaded with the wrong patient name, it could result in misdiagnosis or delay in diagnosis.

**NOTE**

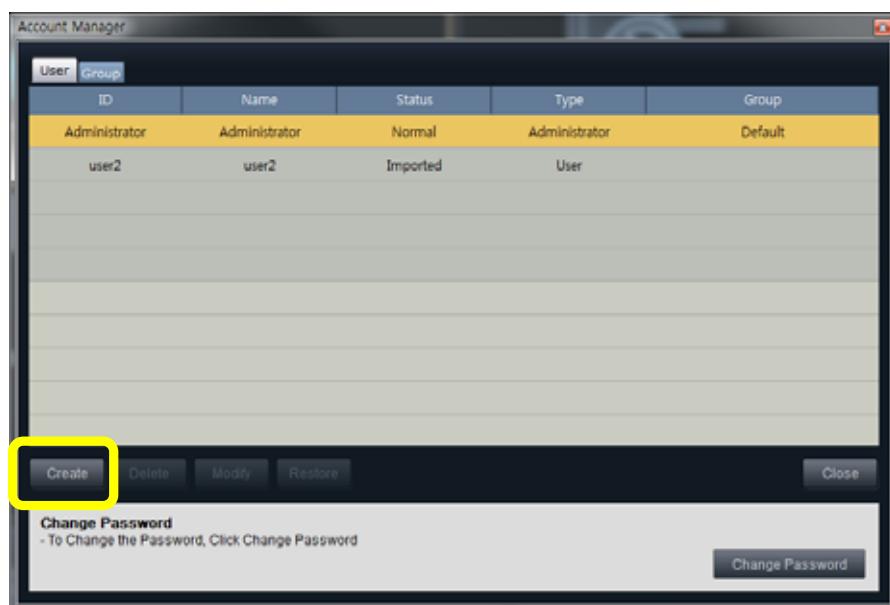
If the user uploads an image data which has been uploaded before, an error message 'Data has been previously uploaded. Would you like to upload again?' will appear.

**NOTE**

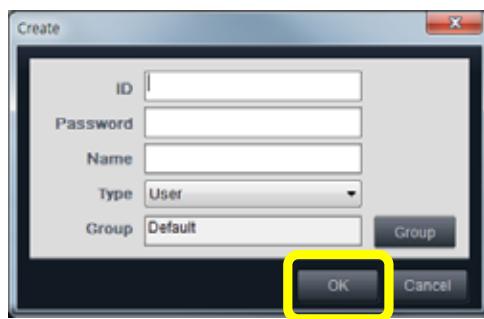
The user can stop the uploading of the image data while uploading process file by clicking the .

4.3.7 User Account Management

The MiroView™ Operator enables management of multiple users & Groups. Users can be organized into Groups to readily control access. The following screen can be accessed by Tools → Account Manager.



- Click the **Create** button to show the window as displayed below to create a new user ID.



ID: User ID

Password: Password

Name: User Name

Type: User type.

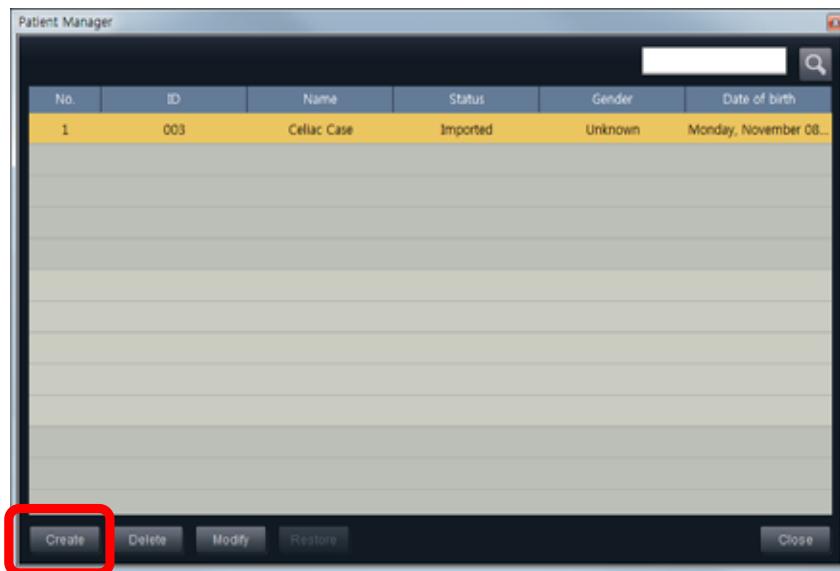
- User: can access own reviews and all the reviews in the Group of the User's only.
 - Super User: can access all the reviews in the System
 - Operator: can log in via the MiroView™ Operator S/W only.
- ※ Administrator account can log in via both the MiroView™ Client and the MiroView™ Operator.

Group: Set of users in the same Clinic or Laboratory.

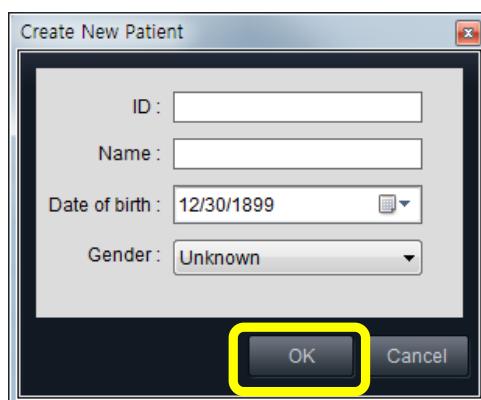
- Click the **Delete** button to delete the selected account

4.3.8 Patient Manager

The MiroView™ Operator enables management of Patient. The following screen can be accessed by Tools → Patient Manager



- Click the **Create** to show the window as displayed below to create a patient's ID.



ID: ID for the new patient.

Name: Patient's name.

Date of birth: The date of birth for the patient which will appear on the report

Gender: The patient's gender

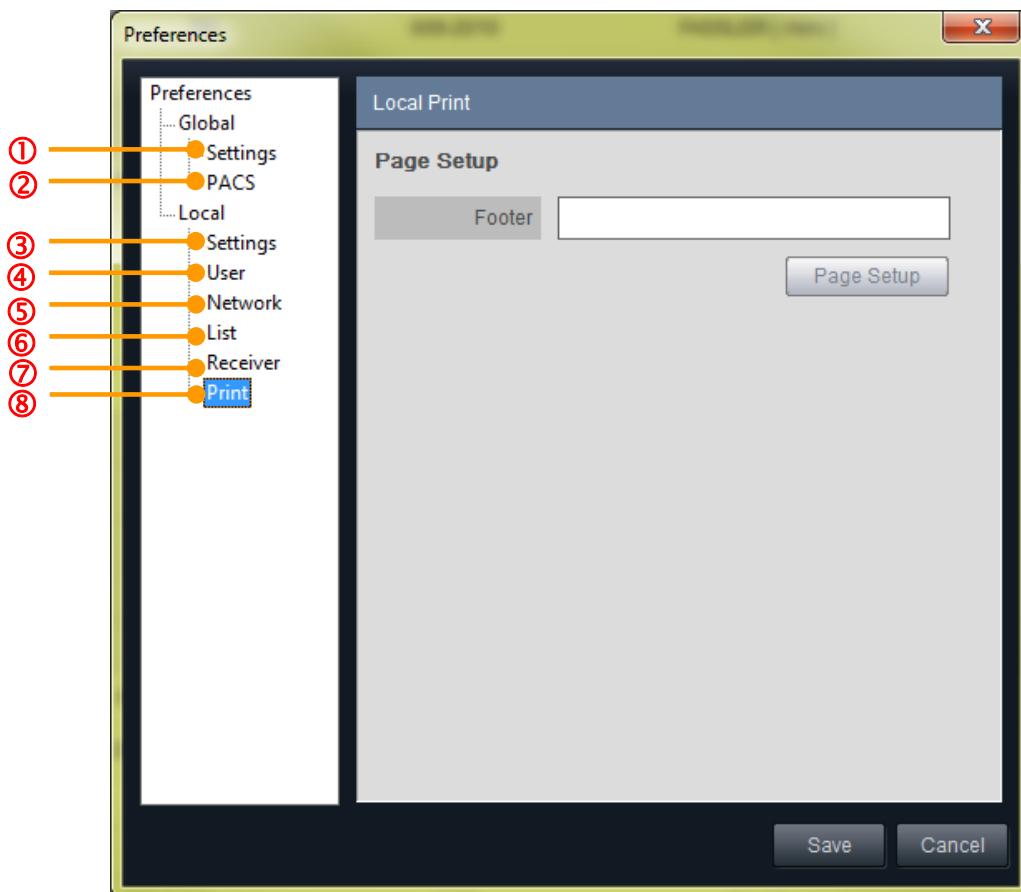
4.3.9 Preferences

To set and/or change the settings for the MiroView™ Operator, access Preferences via Tools → Preferences.

Preferences for the MiroView™ Operator falls into two categories: Global and Local.

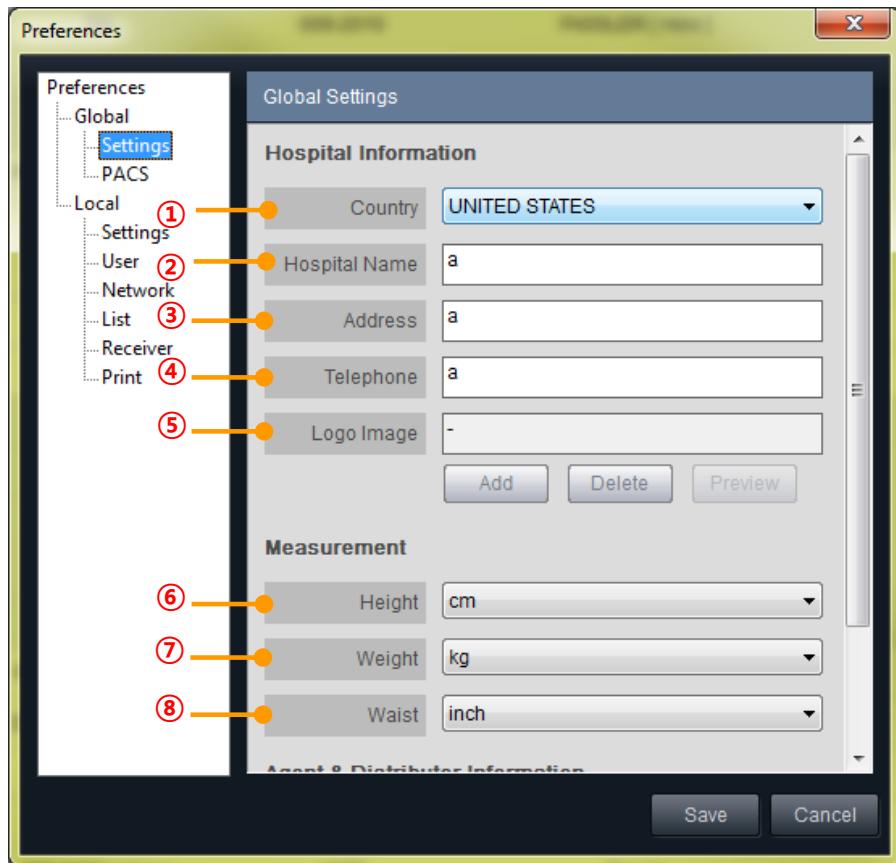
Global preference is saved on the MiroView™ Server and has in effect for all the users using the MiroView™ Server.

Local preference is saved on the workstation on which the MiroView™ Operator is installed and has in effect for the workstation only.



| | | | |
|--------|---|----------|--|
| Global | ① | Settings | - Hospital Information - Measurement - Agent & Distributor Information |
| | ② | PACS | - PACS Registration - Technical Settings |
| Local | ③ | Settings | - Language - GI Tract Color Reference - Free Hard Disk - Display - Default Export Data Folder - Finding Setting |
| | ④ | User | - User's Information - Change Password |
| | ⑤ | Network | - MiroView™ Server - Server Manager |
| | ⑥ | List | - Display – Show/Hide Columns |
| | ⑦ | Receiver | - Patient Information Configuration - Multiple Upload |
| | ⑧ | Print | - Page Setup |

1) Global Settings

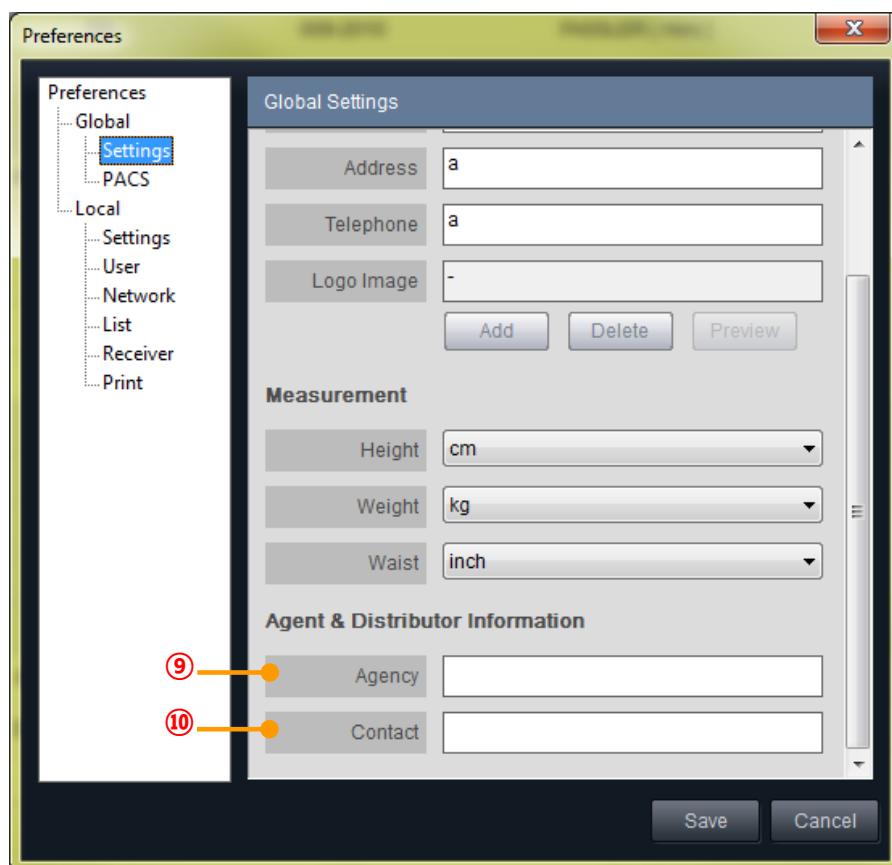


i. Hospital Information

- ① Country – Choose the Country where the hospital is located.
- ② Hospital Name – Input the Hospital's Name in this field.
- ③ Address – Input the Hospital's Address in this field.
- ④ Telephone – Input the Hospital's Telephone number in this field.
- ⑤ Logo Image – Add the Logo Image
※ These information will be applied and shown on the final report.

ii. Measurement

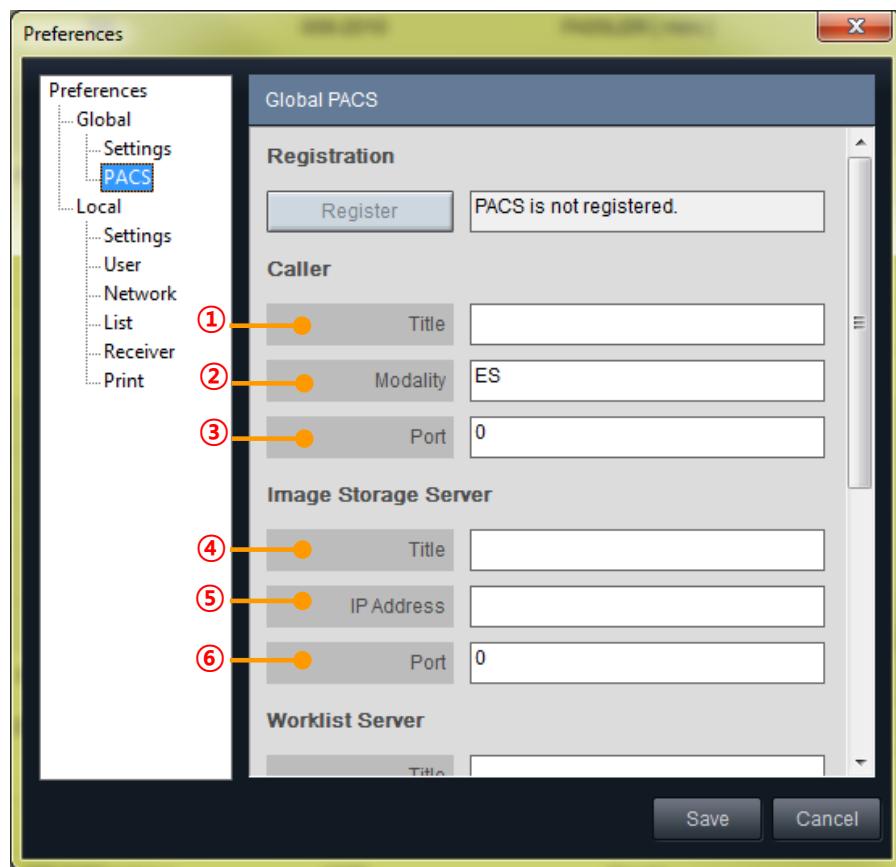
- ⑥ Height – Choose the measurement unit for patient's height.
 - ⑦ Weight - Choose the measurement unit for patient's weight.
 - ⑧ Waist - Choose the measurement unit for patient's waist.
- * These information will be applied and shown on the case information and patient information



iii. Agent & Distributor Information

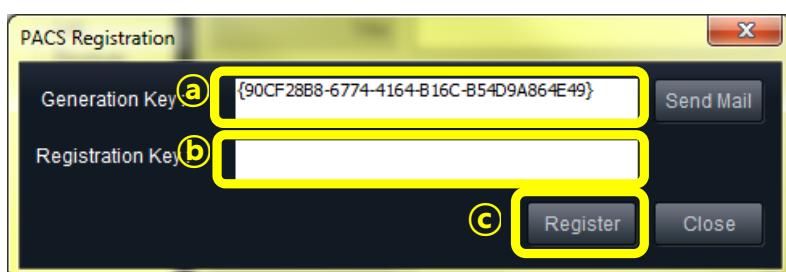
- ⑨ Agency: Input the Agency's information in this field.
- ⑩ Contact: Input the contact information for the agency.

2) Global PACS



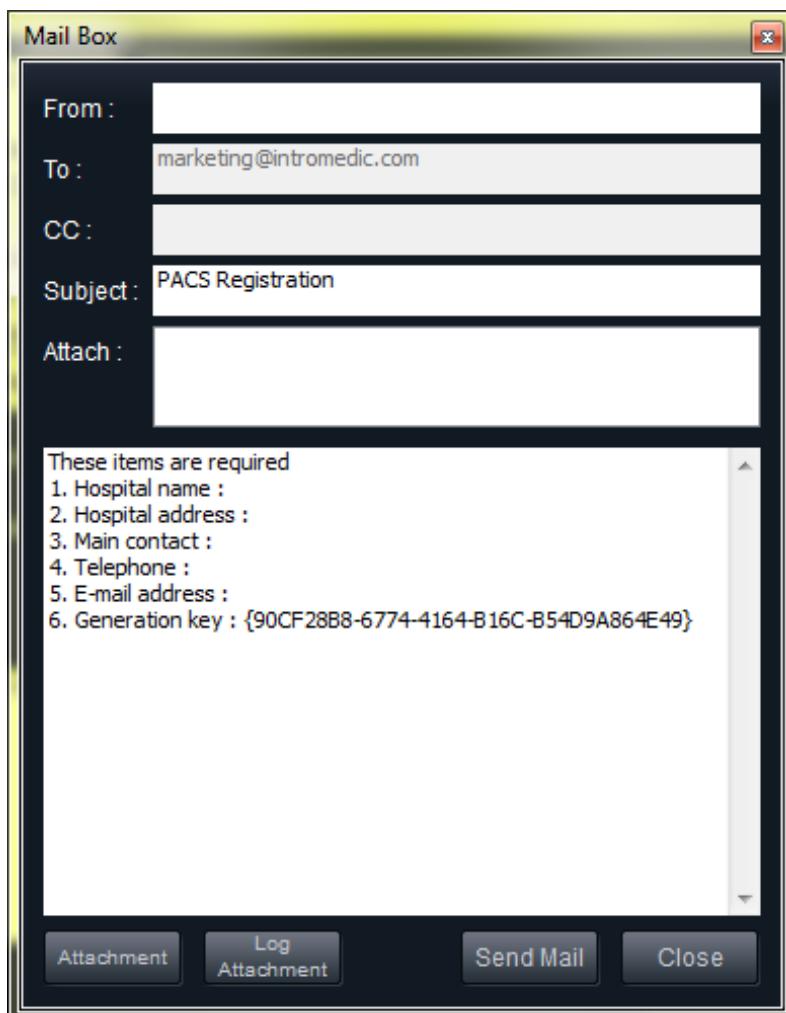
i. Registration: Process to enable the PACS related functionalities.

- Click the **Register**. PACS registration window will appear like the below.
- Carry out in alphabetical order like following picture.



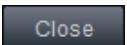
NOTE Generation key is a key that unlocks the PACS function on the MiroCam® workstation.

- Generation key will be generated automatically. Click the **Send Mail** to send the Generation key to IntroMedic. Mail Box window will appear like below.



- Input the e-mail address of the hospital administrator in the 'From' field. Input all the required information to send to IntroMedic: Hospital name, Hospital address, Main contact, Telephone, E-mail address and Generation key.
- Click the **Send Mail** to send the information to IntroMedic. IntroMedic will reply with the Registration Key to the

e-mail address typed in ‘From’ field. It will take time to receive the reply.

- Click the  to close the Mail Box window.
- After receiving the Registration Key, input the Key in the Registration Key field on PACS registration window.

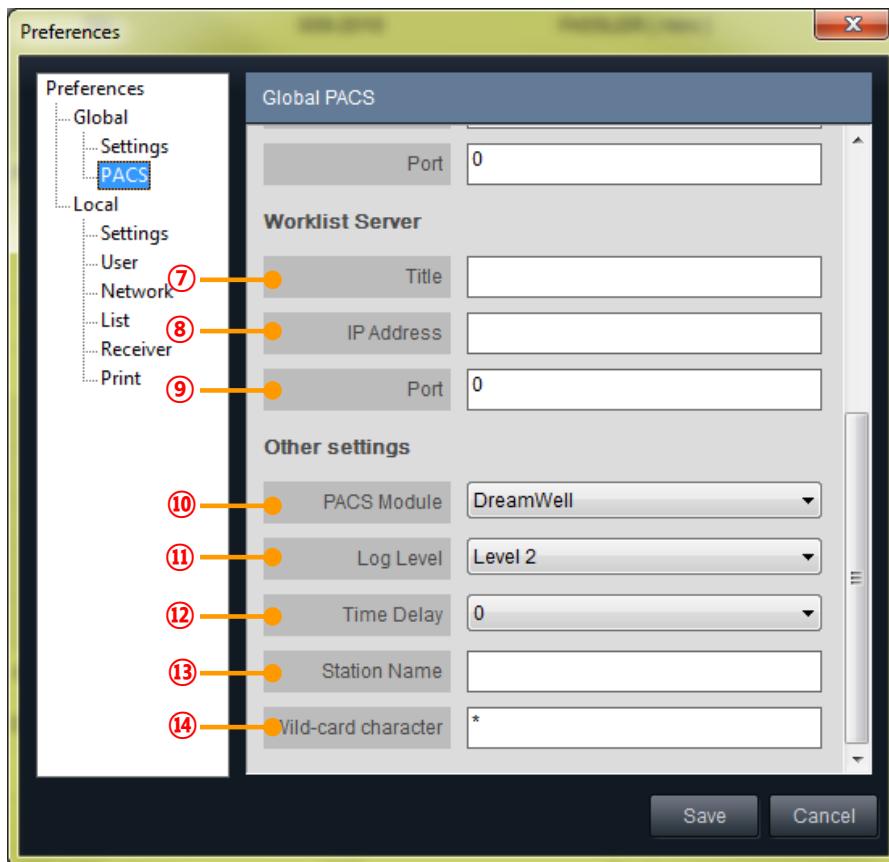
Click the  to finalize the registration process.

ii. Caller: Technical properties for Caller.

- ① Title: Input the Title for Caller.
- ② Modality: Input the Modality for Caller.
- ③ Port: Input the port number to use for Caller.

iii. Image Storage Server: Technical properties for Image Storage.

- ④ Title: Input the title for Image Storage Server.
- ⑤ IP Address: Input the IP Address for Image Storage Server.
- ⑥ Port: Input the port number to connect to Image Storage Server.



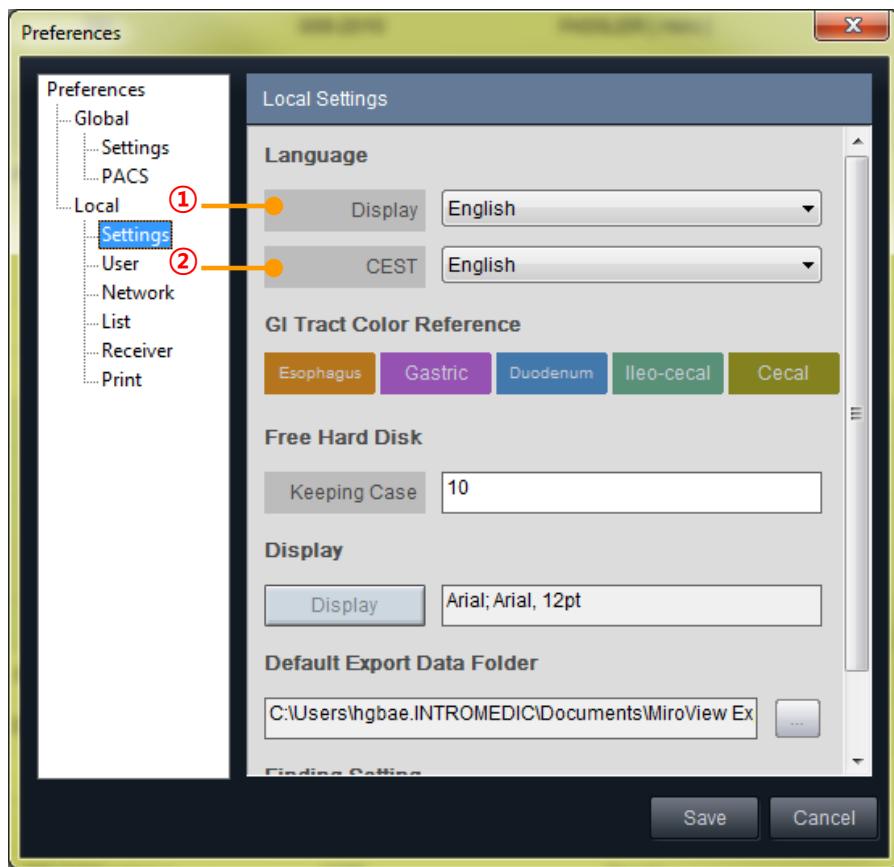
iv. Work list Server: Technical property for Work list Server.

- ⑦ Title: Input the Title for Work list Server.
- ⑧ IP Address: Input the IP Address for Work list Server.
- ⑨ Port: Input the port number to connect to Work list Server.

v. Other Settings: Technical properties for PACS setting.

- ⑩ PACS Module: Choose the appropriate PACS Module, DreamWell or Viewworks.
- ⑪ Log Level: Choose the appropriate Log Level for the PACS functionality: Level 0, Level 1 and Level 2.
- ⑫ Time Delay
Choose the Time delay from 0 to 9 seconds.
- ⑬ Station Name
- ⑭ Wild-card character

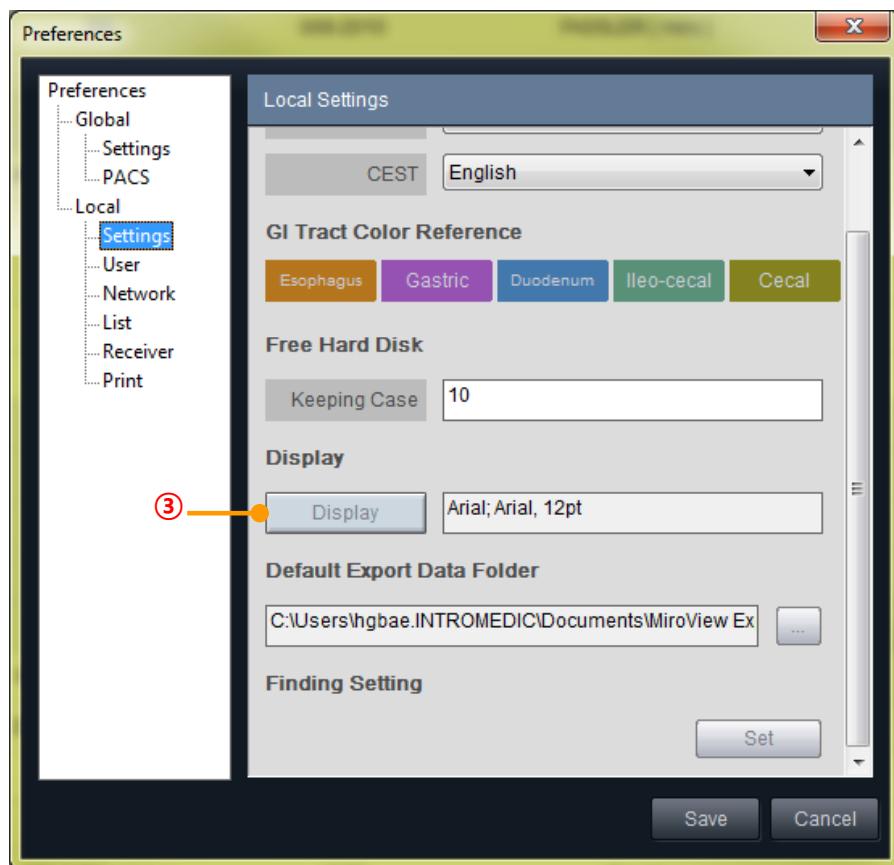
3) Local Settings



- i. Language
 - ① Display: Choose the display language.
 - ② CEST: Choose the CEST language.
- ii. GI Tract Color Reference: Show the color references for the GI Tract.
Free Hard Disk: Decide the number of cases on the local drive.



NOTE If the number of cases saved from the Server is more than the number of Keeping Case, it will automatically delete the oldest cases from the local drive.



iv. Display

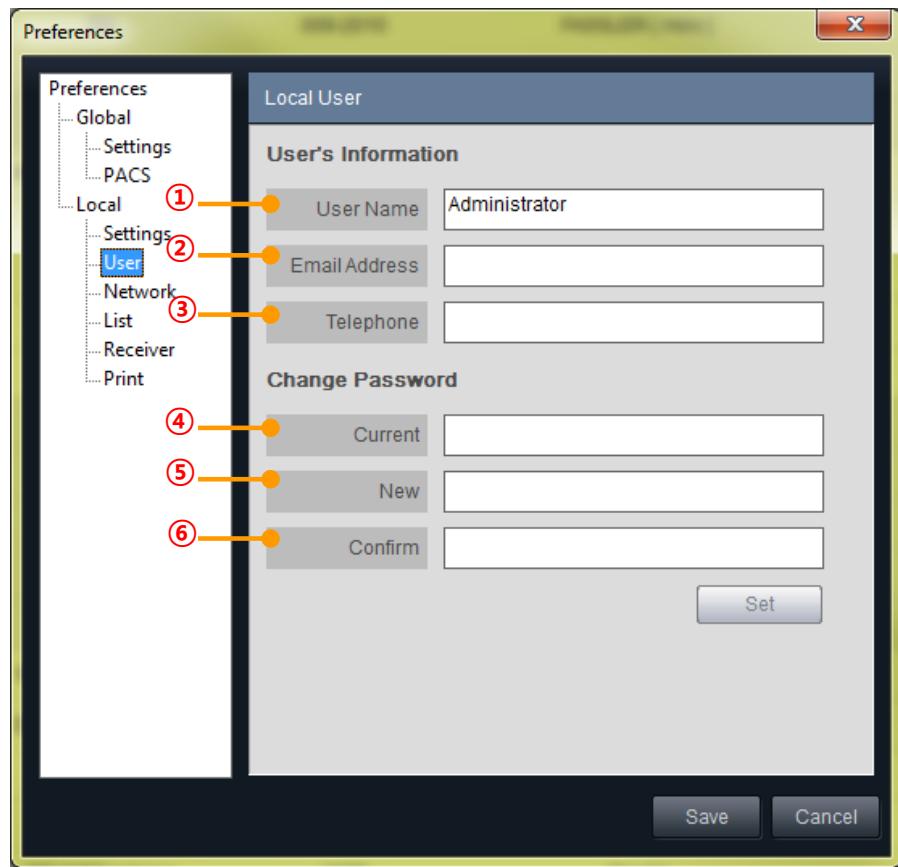
③ Display: Font setting to display.

v. Default Export Data Folder: Direct the folder for exporting

data. Click the to open the browser.

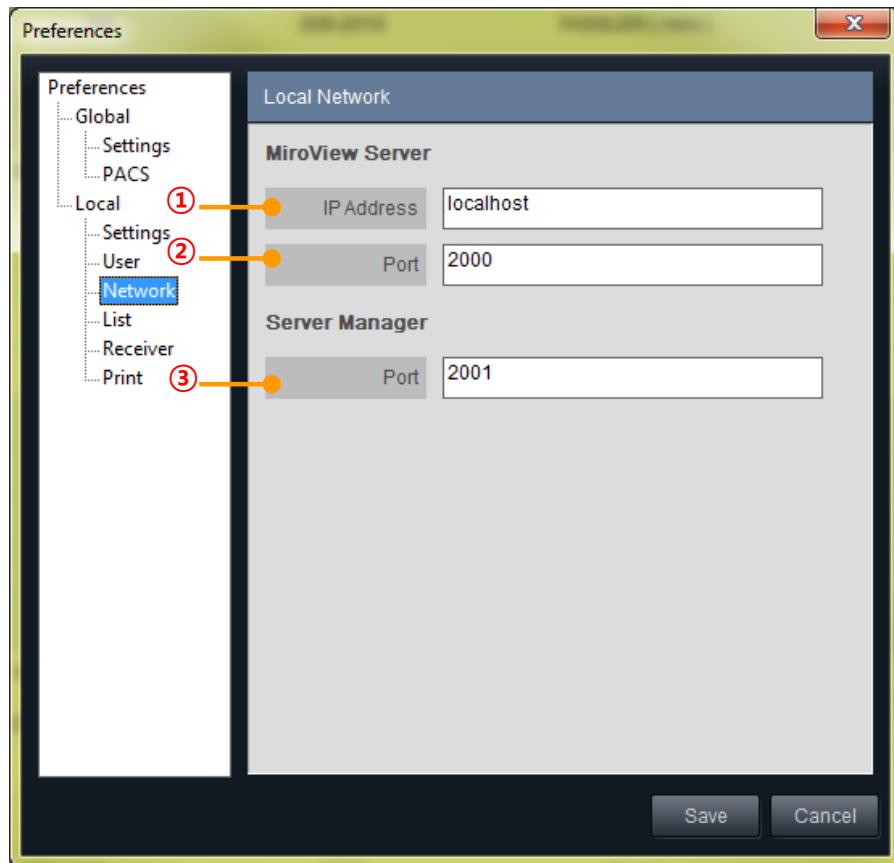
vi. Finding Setting: Configure the finding setting. Click the to open the configuration dialogue.

4) Local User



- i. User's Information: Set/modify the information for the user.
 - ① User Name: Input User Name which will be used for log-in ID.
 - ② Email Address: Type in the e-mail address here.
 - ③ Telephone: Type in the telephone number here.
- ii. Change Password
 - ④ Current: Input the current password
 - ⑤ New: Input the desired password to use.
 - ⑥ Confirm: Input the desired password again.

5) Local Network



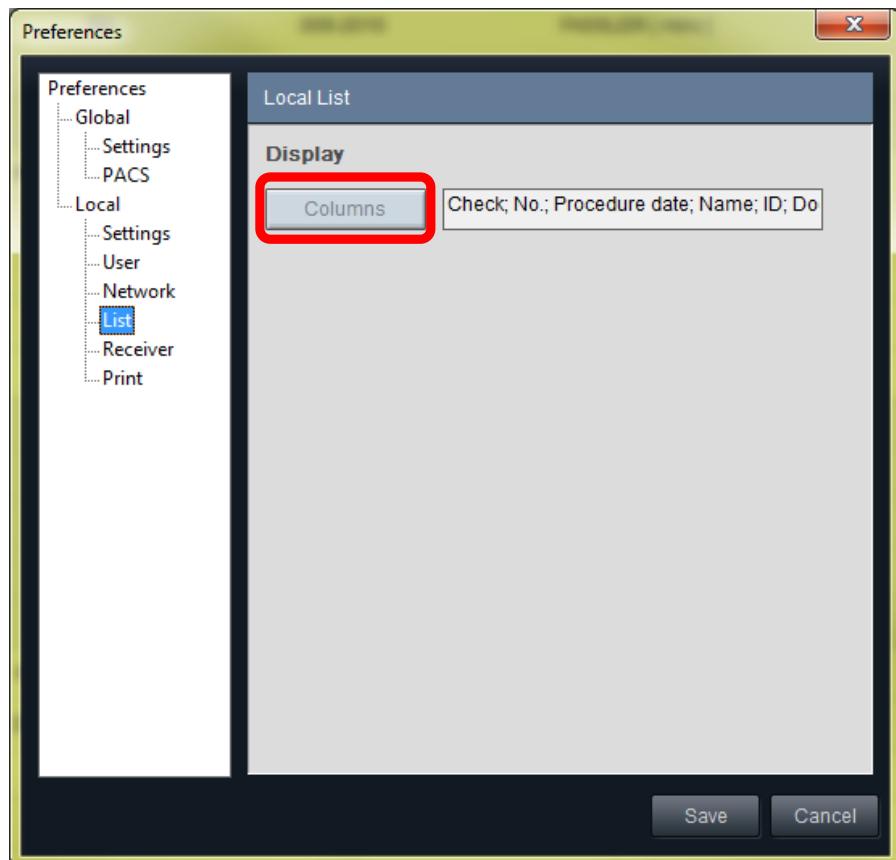
i. MiroView™ Server

- ① IP Address: Input the IP Address where the MiroView™ Server is installed.
- ② Port: Input the port number to connect with MiroView™ Server.

ii. Server Manager

- ③ Port: Input the port number for connection between the Server Manager and the MiroView™ Server.

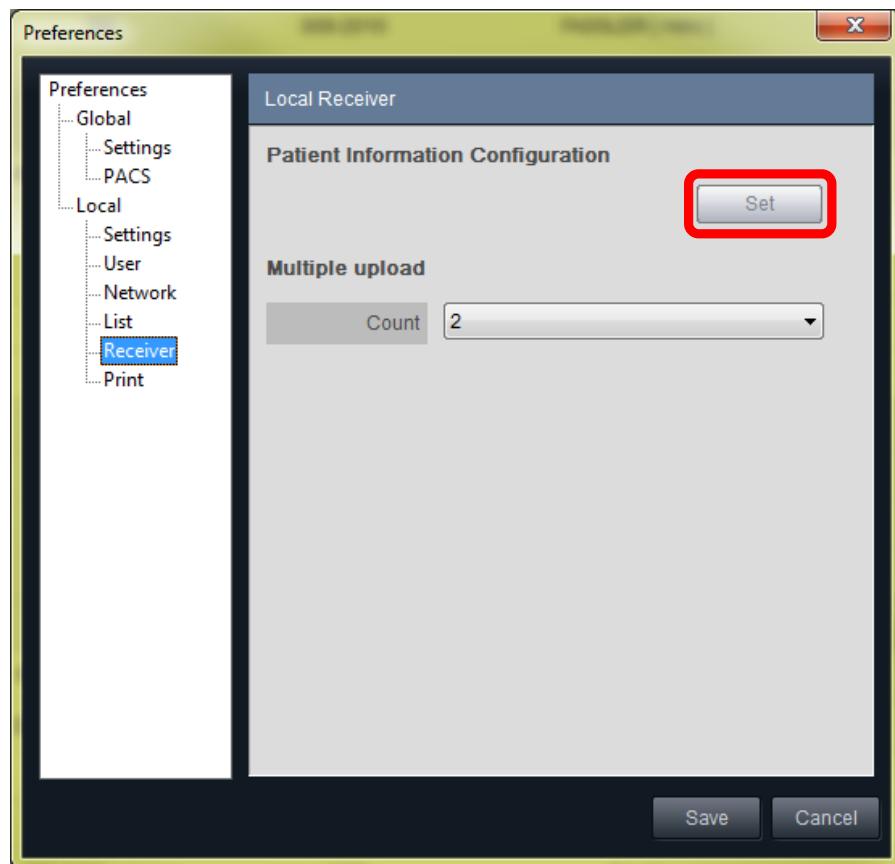
6) Local List



i. Display

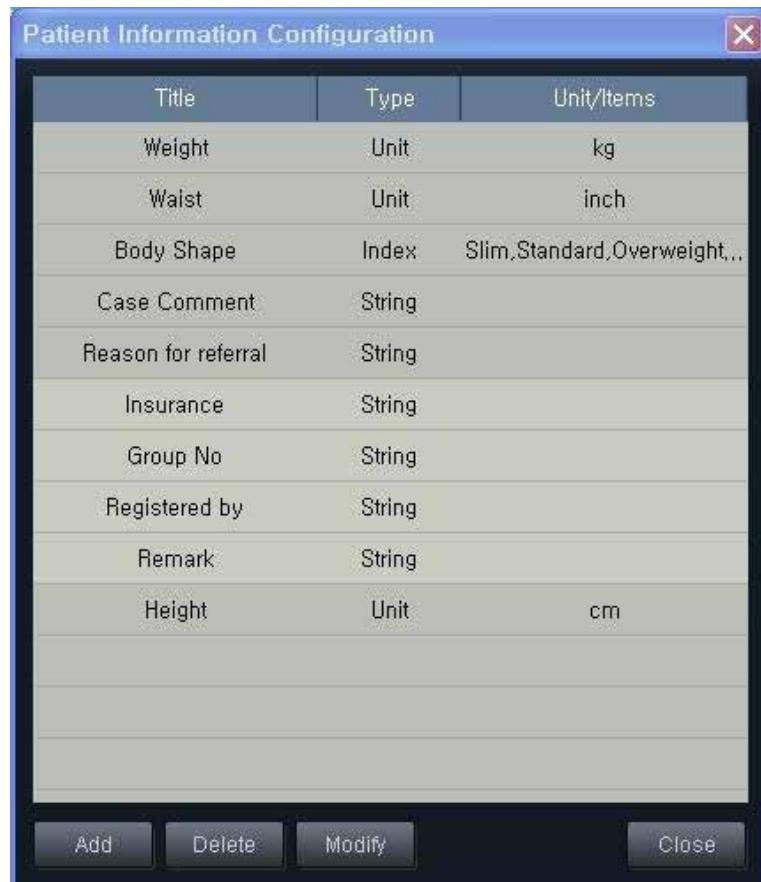
Columns: Configure the columns which will appear on List.

7) Local Receiver



- i. Patient Information Configuration: Configure the items shown on Patient Information after initializing the MiroCam® Receiver.

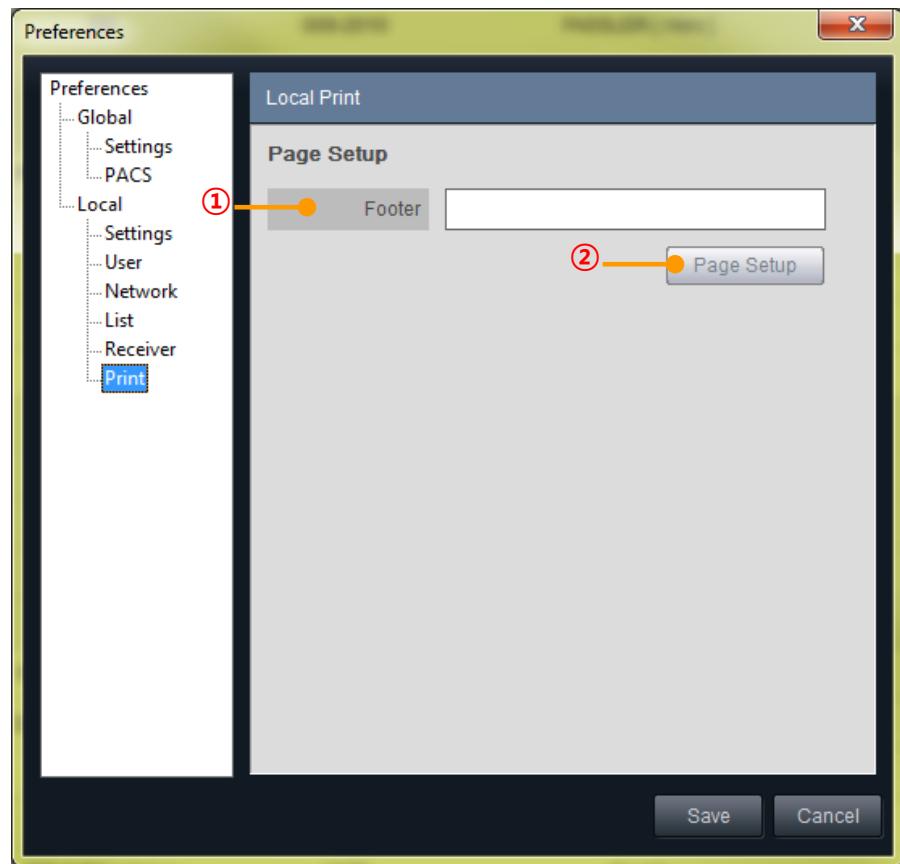
- Click the  to show the Patient Information Configuration window.



- Add/Delete/Modify the items. After completing the tasks, click the  to close the window.

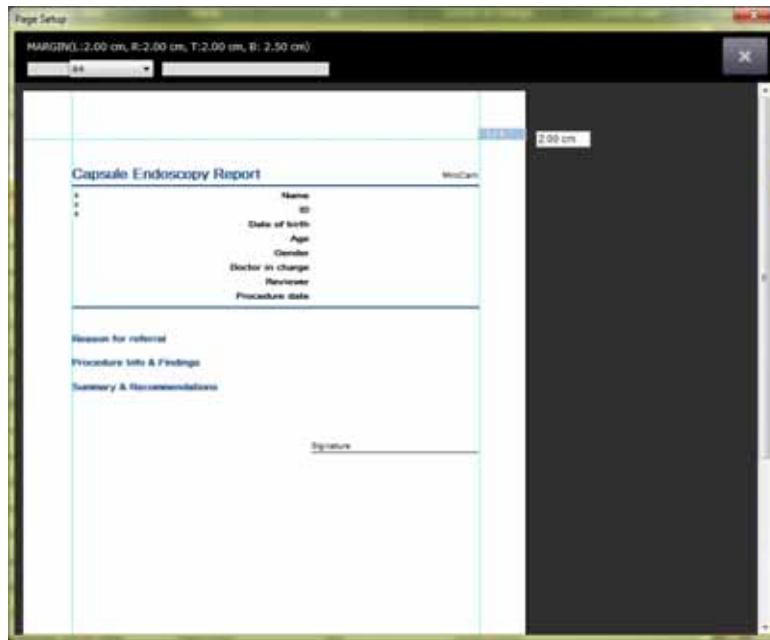
ii. Multiple Upload

Count: Set the number of MiroCam® Receivers to upload to the MiroView™ Operator at once. Choose a number, 1 to 4.

8) Local Print**i. Page Setup**

- ① Footer: Type in the string for footer which will appear on the final report.
- ② Page Setup: Edit the layout of the report.

- Click the  to show the Page Setup window.

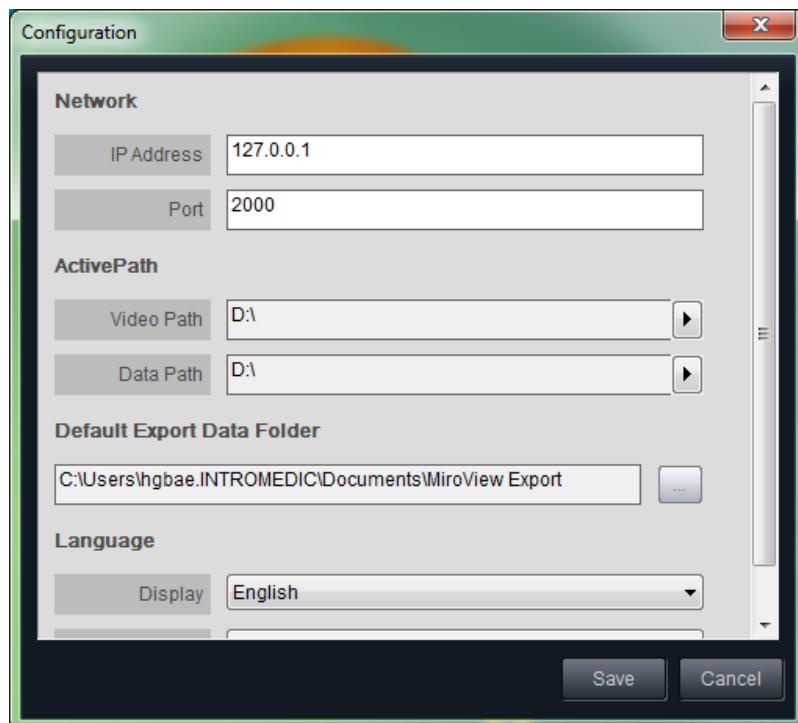


- Choose the paper type; A4 or Letter and adjust the margins for Header, Footer, Right and Left.

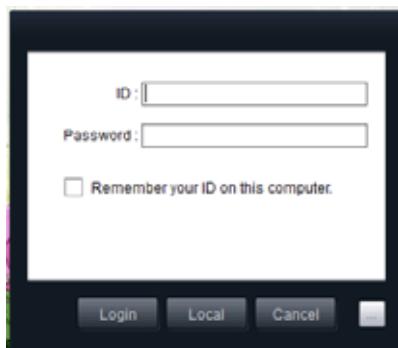
4.4 Overview - MiroView™ Client

4.4.1 Start MiroView™ Client

- The MiroView™ Client is used to review images from the MiroCam® Capsule procedure and generating a patient report. Other functions included In MiroView™ Client are Network Connectivity, List Mode, Review Mode, Report Mode, Export Mode, Image Atlas, Multi-Review, SGIB(Suspected GI Bleeding)Play, Express View, Range View, Map View, Positioning Window, GI Dictionary, and Finding / Diagnosis Information.
- Double-click the  to run the MiroView™ Client. When executed for the first time, the following window will appear.



- Input “127.0.0.1” for the IP Address and “2000” for the Port.
If the MiroView™ Server is installed on the network, input the workstation’s IP on which the MiroView™ Server is installed for this field, and the port which the MiroView™ Server is using, referring to the IT engineer in the hospital.
- Direct the “Active Path” to the caching folder.
- Direct the Default Export Data Folder.
- Choose the preferred Language settings and press  to access the MiroView™ Client.
- After the MiroView™ Client has launched, the Log-in window will appear.



- Input ‘Administrator’ for ID and password already typed in. Then press the .
- Press the  to change the IP address the MiroView™ Server is using.



- After clicking the  the window will appear as the above. Type the MiroView™ Server IP address and port. Then press the  after inputting ID and password.
(Use the  to change the port number for the Server Manager, which is used to manage the server availability)

 **CAUTION** ID and password are encrypted. DO NOT forget the ID and password.

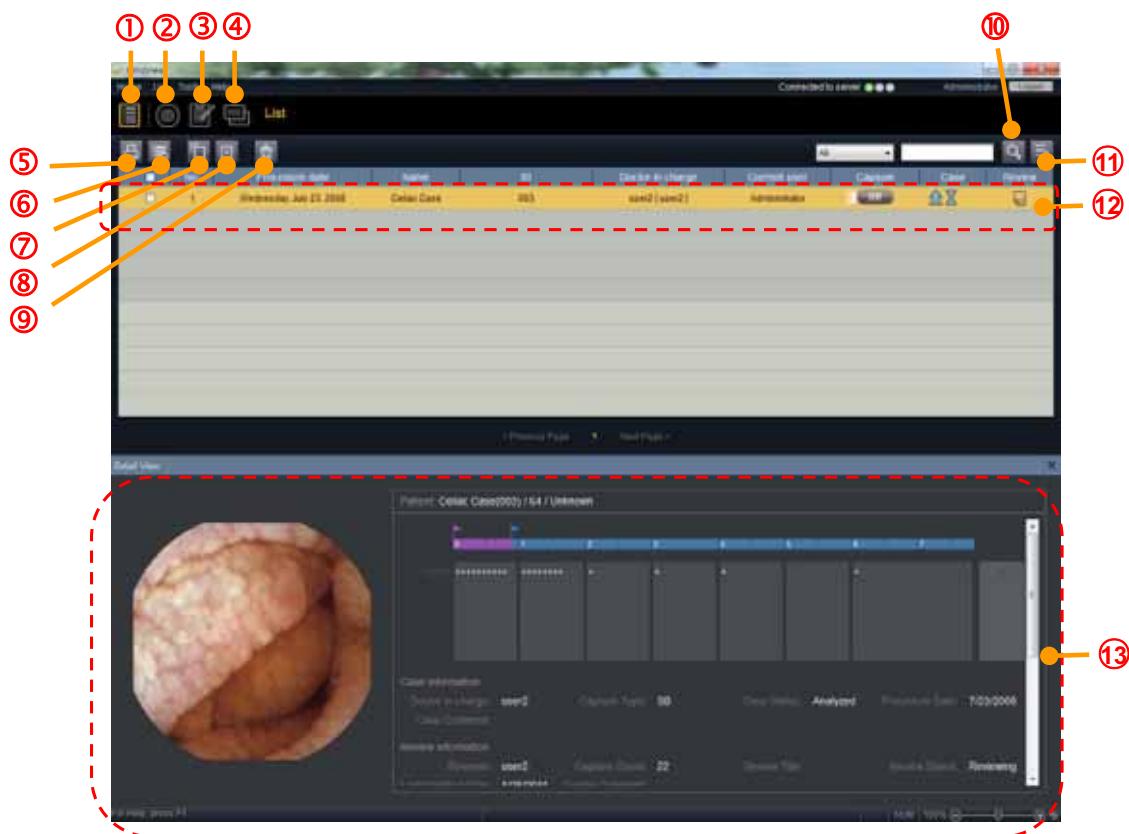
 **CAUTION** Before the MiroView™ Client has launched, a password for the administrator account should be created. When running the MiroView™ Server for the first time, a password for the administrator account should be created.

 **NOTE** Create new and edit new or existing accounts by using the Account Management tool on the MiroView™ Operator.

 **NOTE** Access to the MiroView™ Client at Local Mode by clicking the  to use the MiroView™ Client without connecting to the MiroView™ Server.

4.4.2 List Mode

■ List

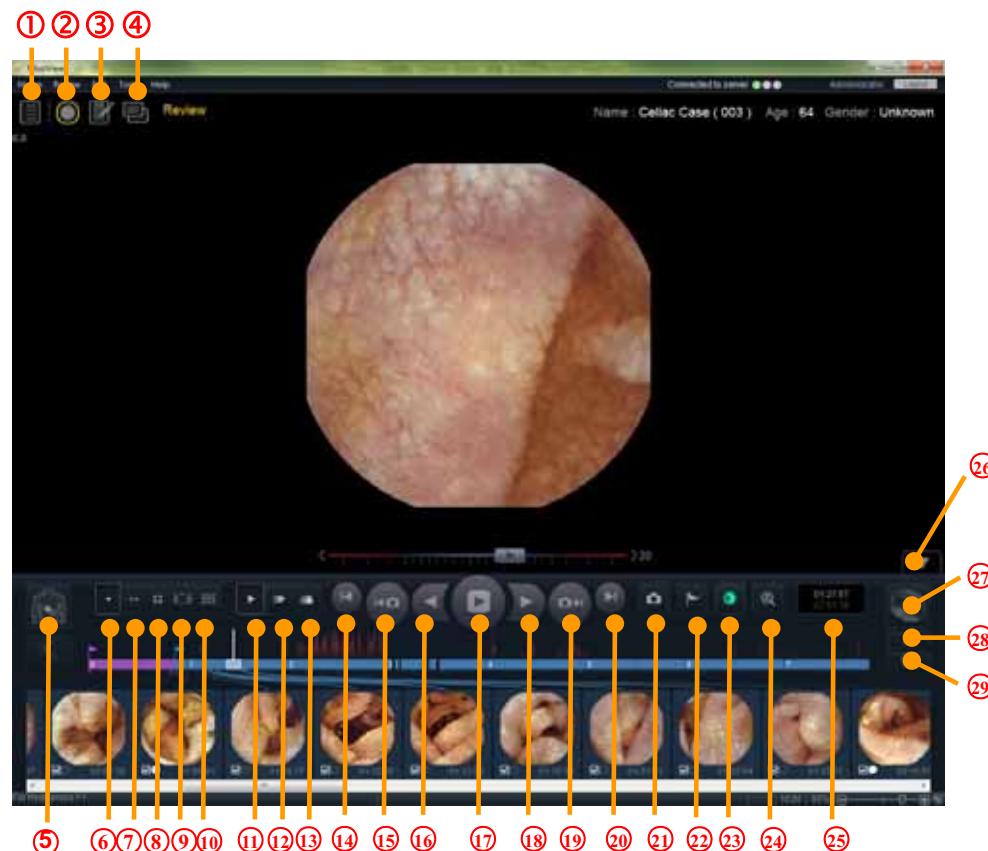


| | | |
|---|---------------|---|
| ① | List Mode | Open List Mode |
| ② | Review Mode | Open Review Mode |
| ③ | Report Mode | Open Report Mode |
| ④ | Export Mode | Open Export Mode |
| ⑤ | Print Report | Print selected Report |
| ⑥ | Delete Case | Delete Selected Case |
| ⑦ | Add a Review | Add a Review for the Selected Case |
| ⑧ | Delete Review | Delete selected Review |
| ⑨ | Recycle Bin | Open Recycle Bin |
| ⑩ | Search | Search Cases and/or Reviews by key word |
| ⑪ | Show all | Refresh and Show all the Cases/Reviews on the List |
| ⑫ | Selection Bar | A rectangular area to show selected item |
| ⑬ | Detail View | Show Detail Information for selected Case or Review |

4.4.3 Review Mode

Select a case to review on the List Mode and click the  to enter the Review Mode.

■ Capture Box Mode



| | | |
|---|-----------------|--|
| ① | List Mode | Open List Mode |
| ② | Review Mode | Open Review Mode |
| ③ | Report Mode | Open Report Mode |
| ④ | Export Mode | Open Export Mode |
| ⑤ | Position Window | Current position of the MiroCam® Capsule in 2D |
| ⑥ | Single View | Change to Single View |
| ⑦ | Dual View | Change to Dual View |
| ⑧ | Quad View | Change to Quad View |

| | | |
|---|-------------------------|---|
| ⑨ | Range View | Change to Range View |
| ⑩ | Map View | Change to Map View |
| ⑪ | Normal Play | Show all images. |
| ⑫ | Express Play | This mode actively removes images based upon similarity; effectively reducing the number of images for review. This mode is recommended to review the patient file but not to diagnose the patient symptoms. |
| ⑬ | SGIB Play | Shows the images that have a high possibility of bleeding and / or blood. This mode may assist in finding areas of suspected bleeding; however, it is NOT 100% reliable, and should only be used as an adjunctive tool to assist in reviewing the images. |
| ⑭ | First Frame | Go to the First Image Frame |
| ⑮ | Previous Captured Image | Go to Previous Captured Image Frame |
| ⑯ | Play in reverse | Play in reverse |
| ⑰ | Play / Pause | Play / Pause |
| ⑱ | Play | Play Forward |
| ⑲ | Next Captured Image | Go to the Next Captured Image |
| ⑳ | Last Frame | Go to the final Image Frame |
| ㉑ | Capture Image | Image capture button. |
| ㉒ | Set landmark | Landmark button. Use this to set landmarks for transition points in the GI tract. |
| ㉓ | Image Enhancement | Show the Image Enhancement window |
| ㉔ | Full Screen Mode | Fit image to full screen |
| ㉕ | Time Display | Display the time duration of the MiroCam® Capsule from procedure start. |
| ㉖ | Annotation Box Handle | Expand / Shrink the control panel (Show / Hide the Capture Box) The video image area may widen by Annotation Box Handle. |

| | | |
|------|--|---|
| (27) | Comparison Window | Display the image selected from the Image Atlas |
| (28) | Thumbnail Extension | Extend the Capture Box to display all captured images. (Hide the Video area) |
| (29) | Capture Box / Finding Summary Box / Drag Bag Toggle Icon | Replace the Capture Box with Finding Summary Box or Drag Bag. |

■ Finding Summary Box



| | | |
|------|---------------------|---|
| (30) | Finding Summary Box | <p>Displays Capture Box, Thumbnail and Finding Summary Box.</p> <p>This is changed by clicking the . When new findings are added in Report mode, new information for captured image will be shown in Finding Summary Box.</p> |
|------|---------------------|---|

- Choose a section of Summary Box to show the thumbnails.

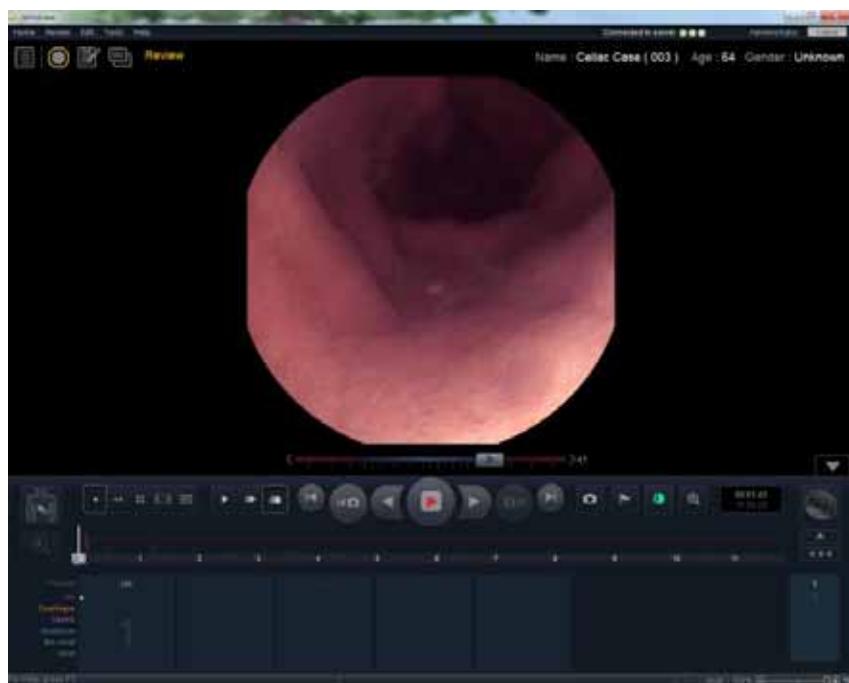
When a section of Summary Box is selected, the thumbnails

will be shown in the screen. Click the  to close the thumbnail mode.



■ Drag Bag

- Choose a section of Drag Bag to show the captured images.

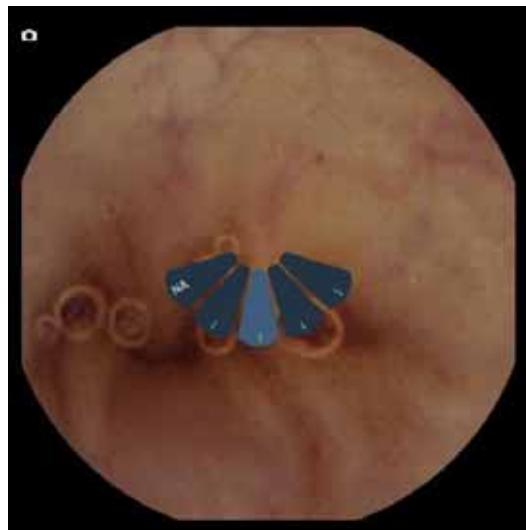


- There are two ways to set the captured image, the drag bag: set the main image to a drag directly and capture the main image first and set the image to a drag bag via the pop-up menu.

- i. Left click the mouse and drag the mouse downwards.

Fan shaped Drag Bags will appear like below.

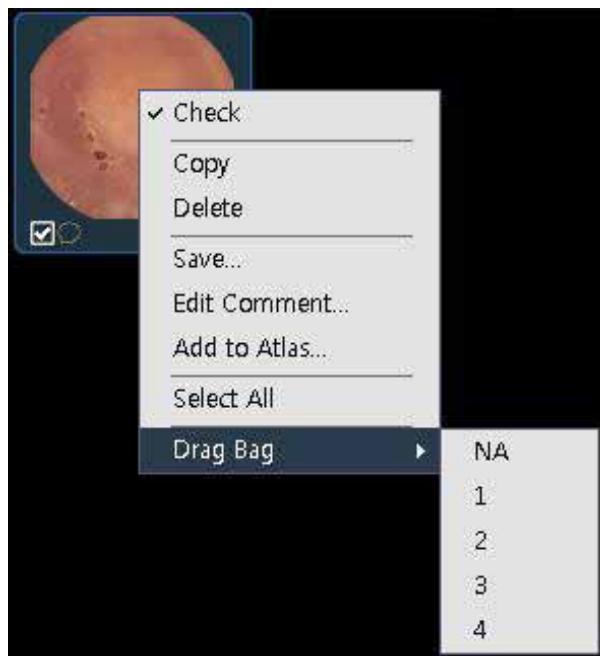
Release the mouse in one of them.



- ii. Left click the mouse and drag to upper direction. Fan shapes for Landmarks will appear like below. Release the mouse on one of them.



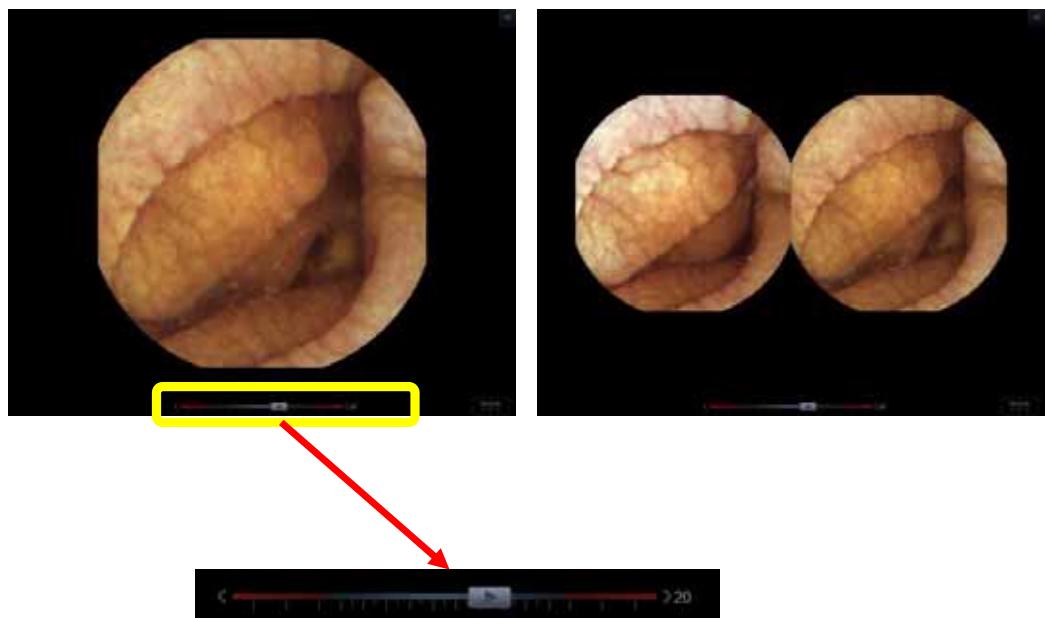
- iii. Right click the mouse on a captured image and then set the image to a Drag Bag.



■ Mode Control

- Full Screen Mode

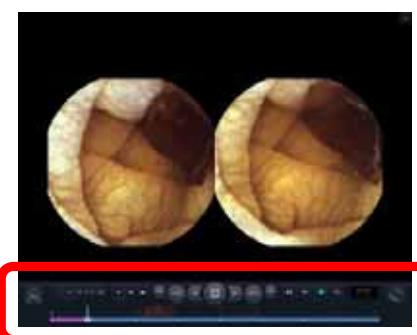
Click the  to change to Zoom View mode



NOTE Play Slide Control is available on the Full Screen Mode to set playing direction, playing speed and playing status: Play and Pause.



NOTE Move the cursor away from the bottom of the screen and the Play Control will appear.



- Viewing Modes

Select one of the  for preferred Viewing Mode.



Single View



Dual View



Quad View



Range View



NOTE Range View has been designed to assist in readily finding transition points in the GI tract. The display will show 9 images before and 9 images after the current position. The 9 images are defaulted to 10 minutes apart, resulting in an overview of 90 minutes prior to, and 90 minutes after the current position. The number of images displayed is set at 9, and is not configurable. The 90 minute duration is configurable and can be adjusted by dragging the side line in blue on the Time Bar and dragging the mouse icon on the time boundary. It can also be adjusted by going to Tools -> Preference -> Review.



Map View

- Use the wheel of the mouse to zoom in/out the map.
- Double-click the desired image to capture. Right click the mouse for the desirable image to capture or set landmark.
- Click the desirable image and press <Space> to play the adjacent image frames.



NOTE Map view has been designed to assist in reviewing the patient file by showing all the images on the same page to assist in readily identifying landmarks and potential bleeding areas.
Move the cursor on the designated image to see the original image in detail.

- The  will change to playing Mode, as below.



Normal Play

Express Play



SGIB Play

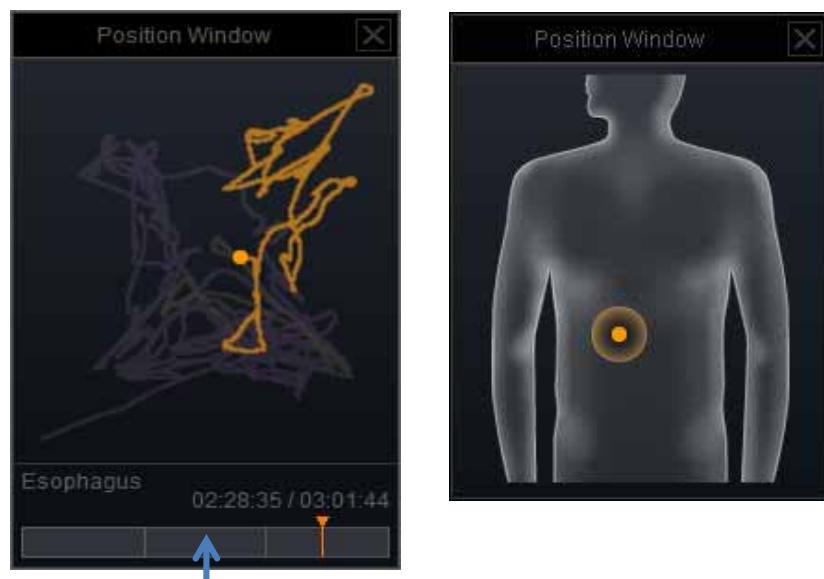
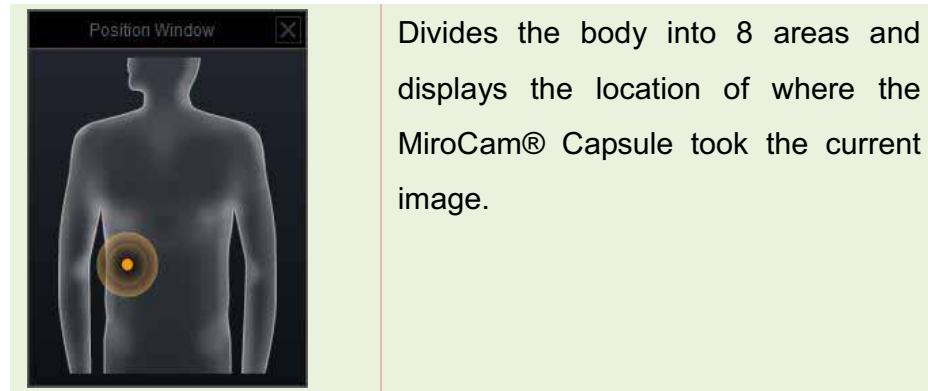


NOTE The Express Play shows the meaningful images only so that the user can review the whole video for the patient quickly. When entering the Express Play, the MiroView™ Software will show the message, The Express Play is not intended to detect abnormalities and should not be used as a substitute for reviewing the entire video.



NOTE The SGIB Play shows the images in red or the obscure bleeding images. IntroMedic does not guarantee the performance and/or accuracy. Thus, use this function for reference only.

■ Position Window



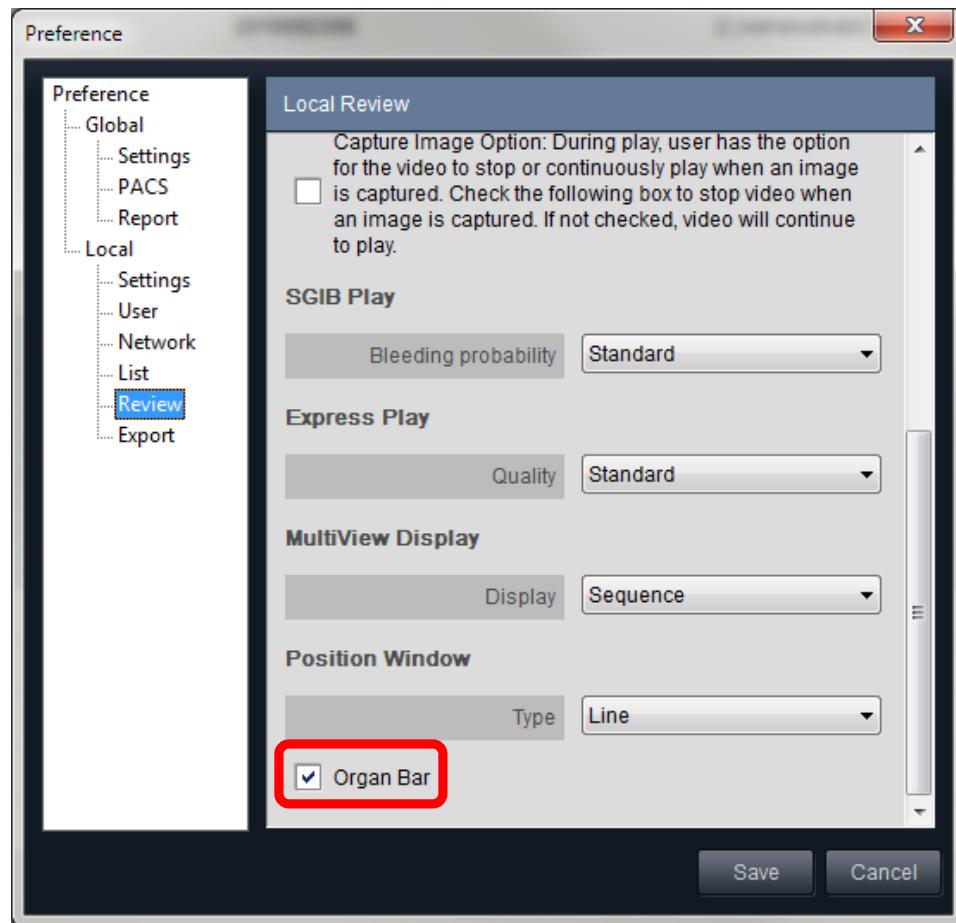
Organ Bar



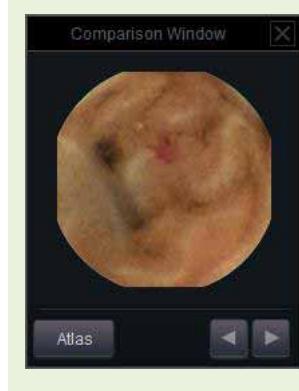
NOTE User is able to choose the option of selecting the type of Position Window between line and region.



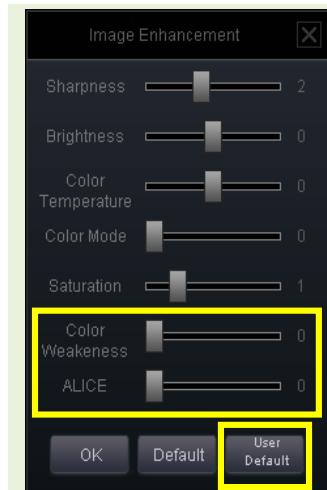
NOTE User is able to change the Position Window Setting via Tools -> Preference



NOTE User can now choose the Organ bar option. This organ bar also displays the entire trajectory of the MiroCam® Capsule in the GI track.

■ Comparison Window

Displays the image shown from the Image Atlas lastly.

■ Image Enhancement Window

Alter images characteristics (ie. color, saturation etc.) to assist in identifying abnormalities:

- Color Weakness
 - : Image adjustment for the reviewer who has color blindness.
- ALICE
 - : Image adjustment as NBI(Narrow Band Image)

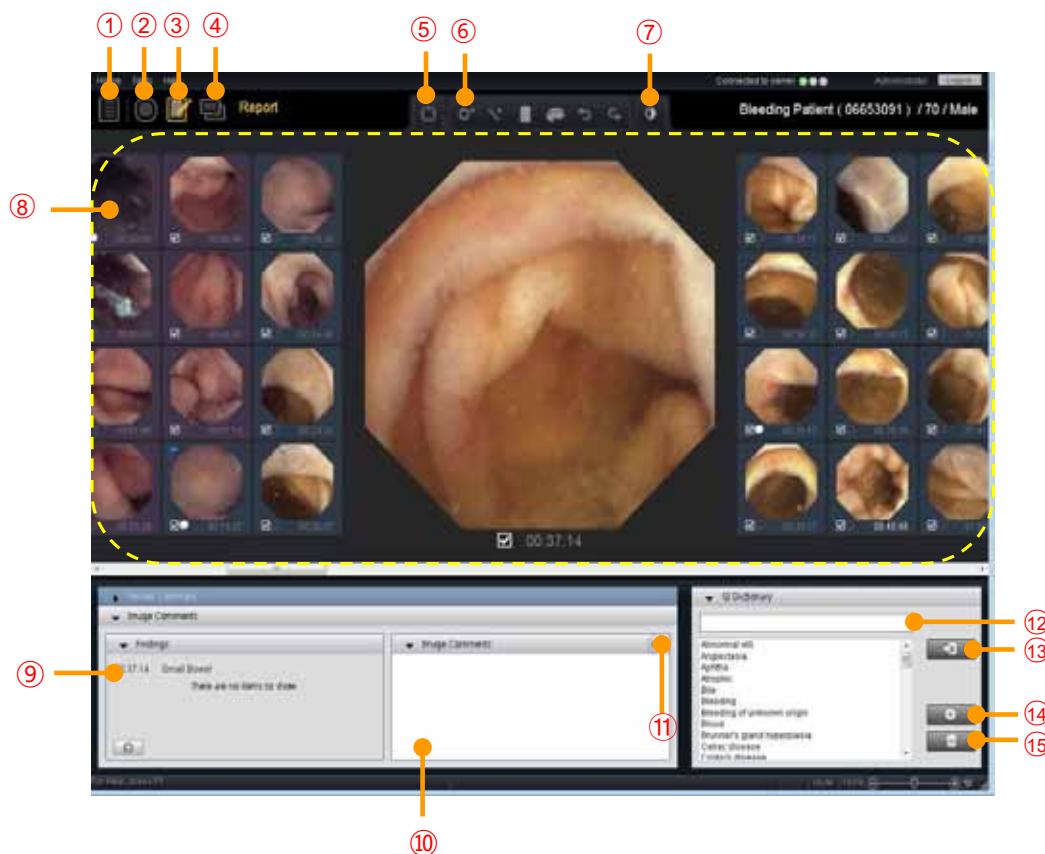
4.4.4 Report Mode

Select the desired review for the Case from the List Mode and click the



to move to the Report Mode.

■ Report Mode



| | | |
|---|--------------------------------|---|
| ① | List Mode | Open List Mode |
| ② | Review Mode | Open Review Mode |
| ③ | Report Mode | Open Report Mode |
| ④ | Export Mode | Open Export Mode |
| ⑤ | Circumference markers | Opens graduated scale for display on the image |
| ⑥ | Drawing Tools | Enables users to include annotations for the image. |
| ⑦ | Image Enhancement | Alter images characteristics (ie. color, saturation etc.) to assist in identifying abnormalities. |
| ⑧ | Thumbnail Area | Show the adjacent captured images so that the user can select/deselect the captured images to export. |
| ⑨ | Image Comments | Write comments for the Capture on the main display and the report. (Image Comments, Reason for Referral, Procedure info & findings, Summary & Recommendation) |
| ⑩ | Diagnosis | Provides the Level of certainty of diagnosis. |
| ⑪ | Audio Comment | Record voice comment (The user can record the voice, from 3 seconds to 180 seconds for each captured image) |
| ⑫ | GI Dictionary | Provides the frequently-used-words to search. |
| ⑬ | Input Selected Word | Input the selected word into the text editor. |
| ⑭ | Add Word to Dictionary | Add the typed word into the Dictionary. |
| ⑮ | Remove word from Dictionary | Delete selected word from the Dictionary. |



NOTE User is able to change the Panel Layout like following pictures via Tools -> Preference -> Local -> Report



NOTE Comments can be completed automatically by pressing <Ctrl+ Space Bar> or <Ctrl + Enter> on the keyboard.

Refer to **4.6.4 Review (MiroView™ Client)** for more information.



NOTE Additional tabs in the report can be created or modified via Tools -> Preferences -> Report



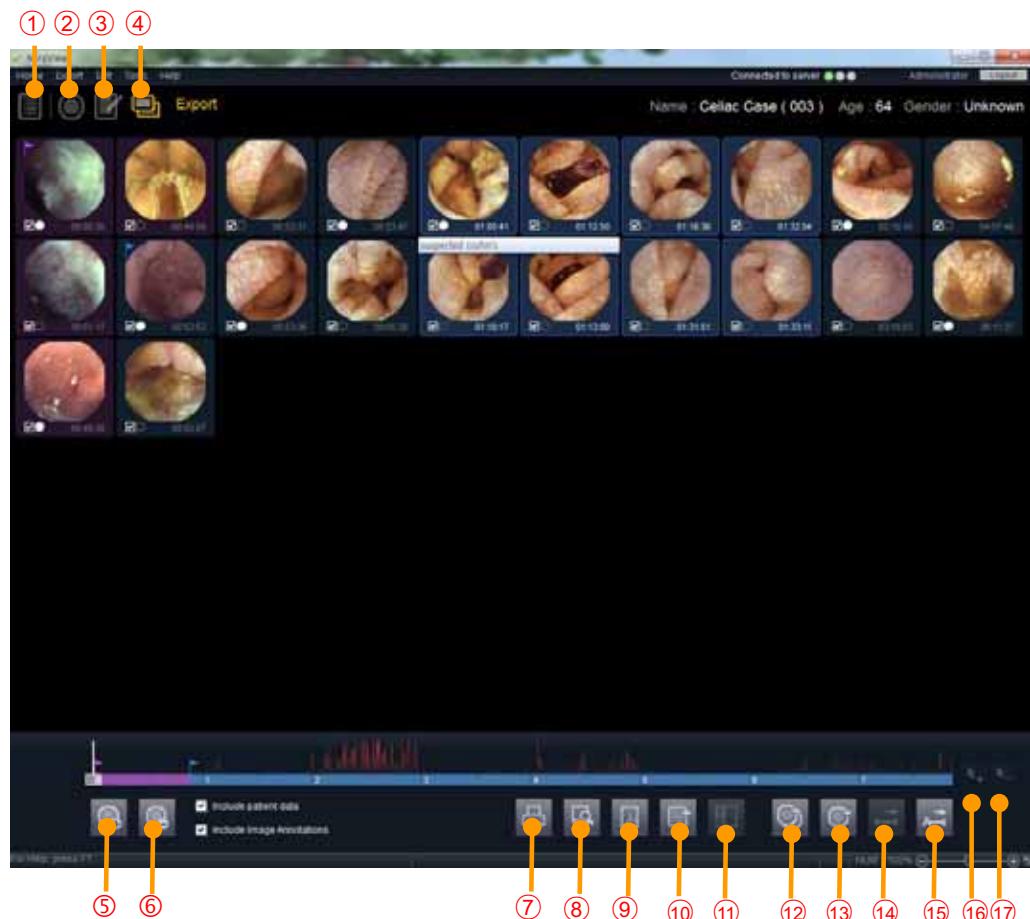
NOTE Right click the mouse on Text Comments area to use Annotations.

Refer to **4.6.4 Review (MiroView™ Client)** for more information.



NOTE Patient information, including the reason for referral, is registered in the MiroCam® Receiver via MiroView™ Operator

4.4.5 Export Mode



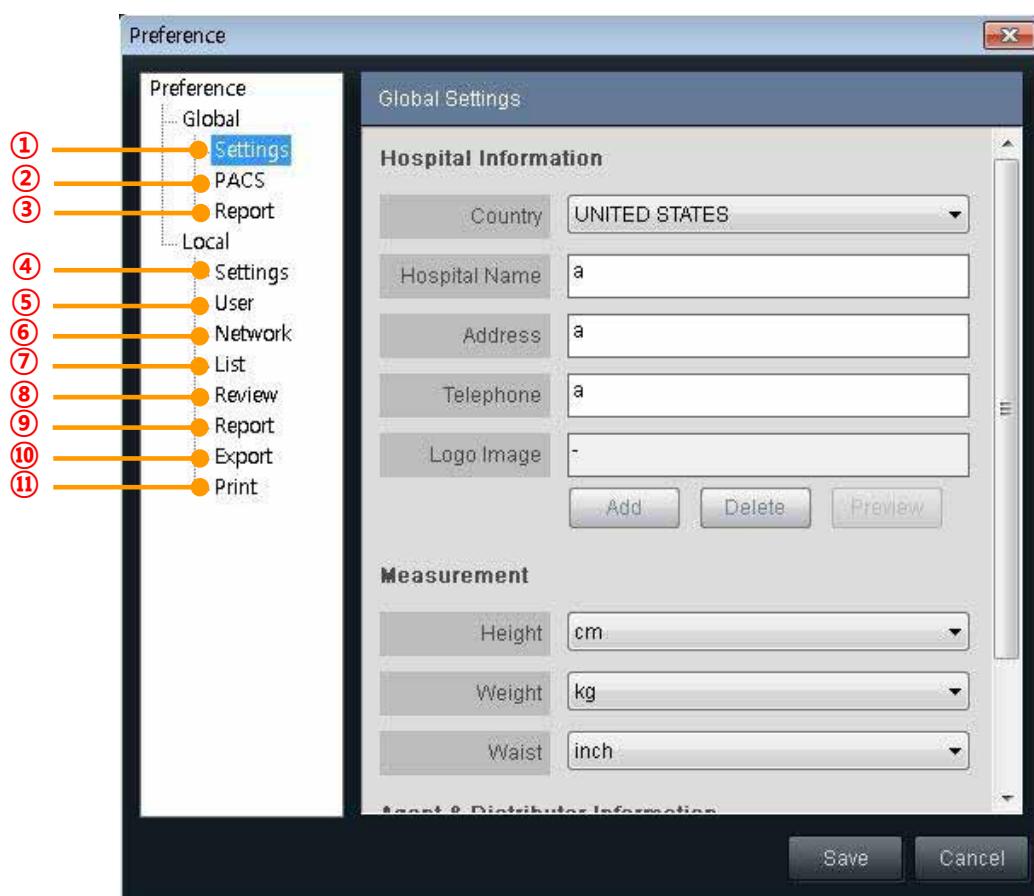
| | | |
|---|------------------------|--|
| ① | List Mode | Open List Mode |
| ② | Review Mode | Open Review Mode |
| ③ | Report Mode | Open Report Mode |
| ④ | Export Mode | Open Export Mode |
| ⑤ | Check Captured Image | Select Captured image and add to the list to print/export. |
| ⑥ | Uncheck Captured Image | Deselect Captured image and remove from the candidate list to print/export. |
| ⑦ | Print | Print out the report for the Review. |
| ⑧ | Preview | Preview the report |
| ⑨ | Save as PDF | Save the report as a PDF file. |
| ⑩ | Export Review | Export Review data only without the Video. Review data is the own format of the MiroView™ Software, which contains Captured Images and Comments by the user. |
| ⑪ | Send to PACS | Send selected captured images to PACS system via DICOM Sender |
| ⑫ | Export EXMIF | Export Captured Images as EXMIF <u>E</u> Xchangeable <u>M</u> edical <u>I</u> nformation <u>F</u> ormat) |
| ⑬ | Export Images | Export Captured Images as Image, Video, or MiroVideo. MiroVideo is the own video format for the MiroView™ Software. |
| ⑭ | Export Segment | Export segment as Video, MiroVideo |
| ⑮ | Export Entire | Export entire file as Video, MiroVideo |
| ⑯ | Add segments | Add the selected range as segments |
| ⑰ | Remove segments | Remove the selected range from segments. |

4.4.6 Preferences

Preferences for the MiroView™ Client falls into two categories: Global and Local.

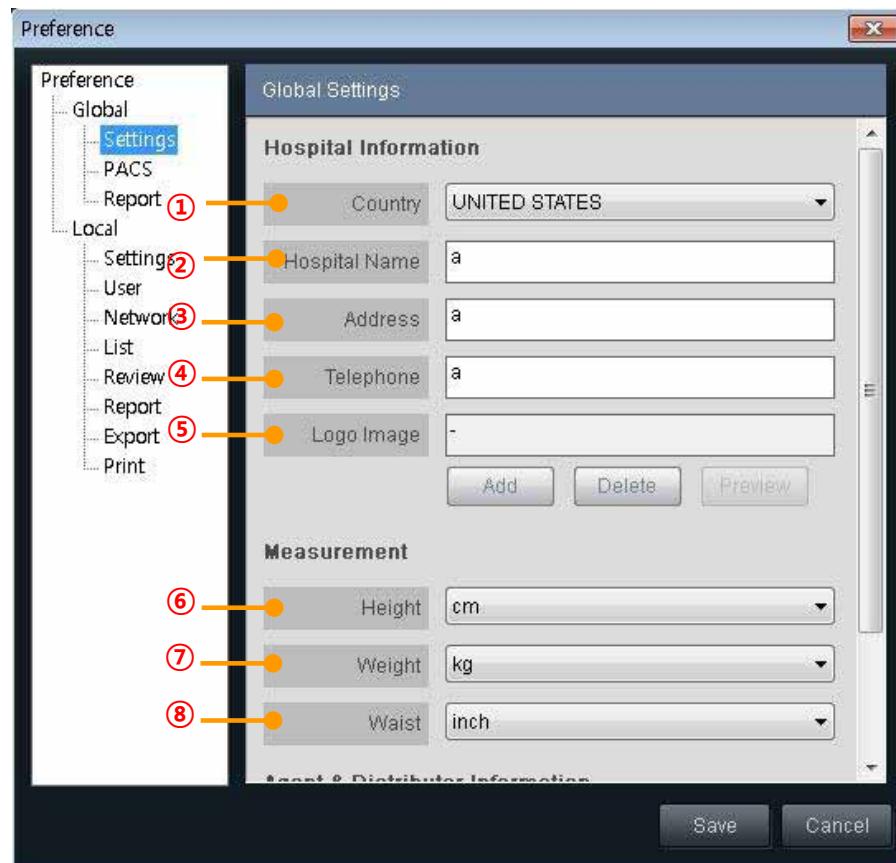
Global preference is saved on the MiroView™ Server and has in effect for all the users using the MiroView™ Server.

Local preference is saved on the workstation on which the MiroView™ Client is installed and has in effect for the workstation only.



| | | | |
|--------|---|----------|--|
| Global | ① | Settings | - Hospital Information - Measurement - Agent & Distributor Information |
| | ② | PACS | - PACS Registration - Technical Settings |
| | ③ | Report | - User added comment tab |
| Local | ④ | Settings | - Language - GI Tract Color Reference - Captured Image Box - Free Hard Disk - Display - Default Export Data Folder - Auto Recover Information - Finding Setting |
| | ⑤ | User | - User's Information - Change Password |
| | ⑥ | Network | - MiroView™ Server - Server Manager |
| | ⑦ | List | - Display – Show/Hide Columns |
| | ⑧ | Review | - Range View - Summary Control - Capture - Captured Image Box - Drag Bag - SGIB Play - Express Play - Position Window |
| | ⑨ | Report | - Panel Layout |
| | ⑩ | Export | - Export AVI (captured images) |
| | ⑪ | Print | - Page Setup |

1) Global Settings

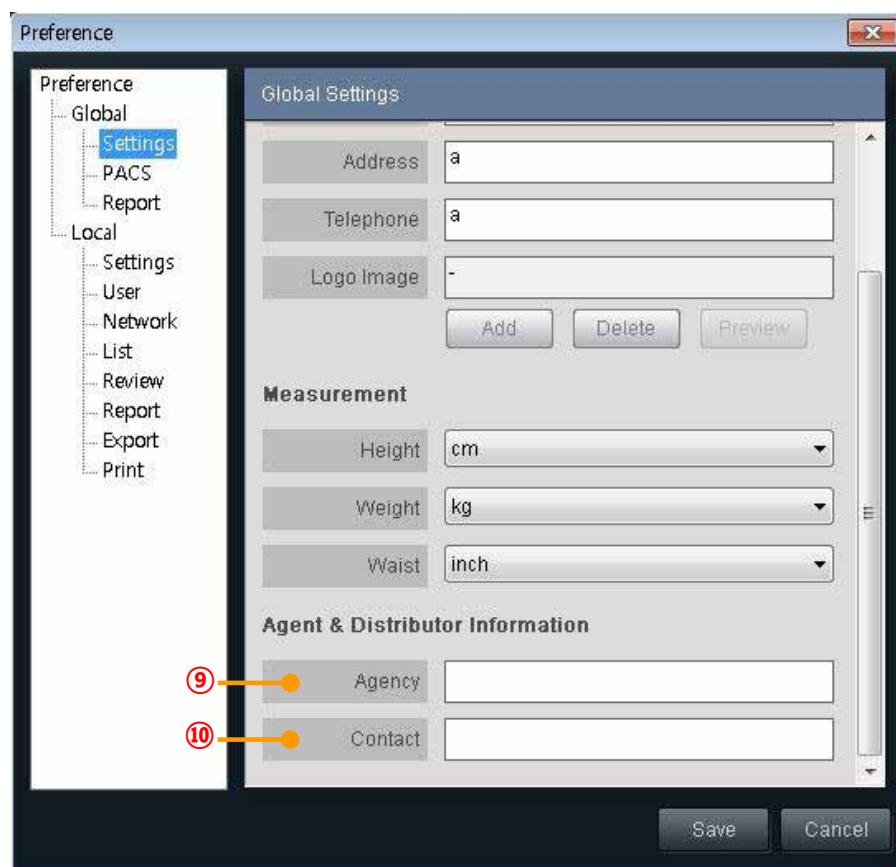


i. Hospital Information

- ① Country – Choose the Country where the hospital is located.
- ② Hospital Name – Input the Hospital's Name in this field.
- ③ Address – Input the Hospital's Address in this field.
- ④ Telephone – Input the Hospital's Telephone number in this field.
- ⑤ Logo Image – Add the Logo Image
 - * These information will be applied and shown on the final report.

ii. Measurement

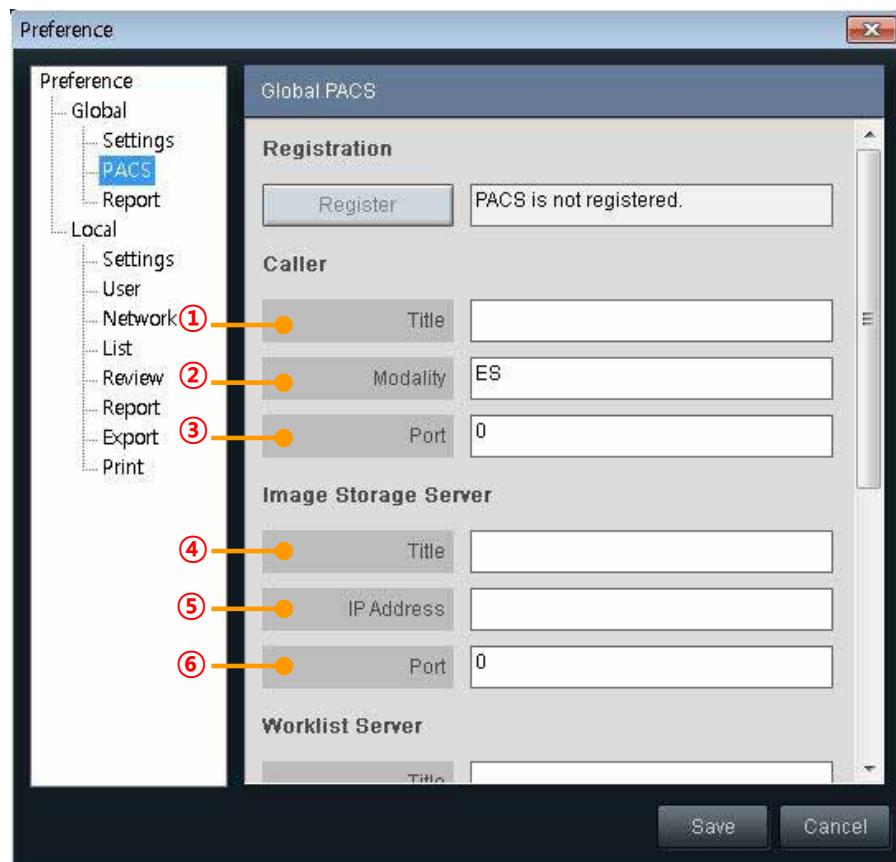
- ⑥ Height – Choose the measurement unit for patient's height.
 - ⑦ Weight - Choose the measurement unit for patient's weight.
 - ⑧ Waist - Choose the measurement unit for patient's waist.
- * These information will be applied and shown on the case information and patient information



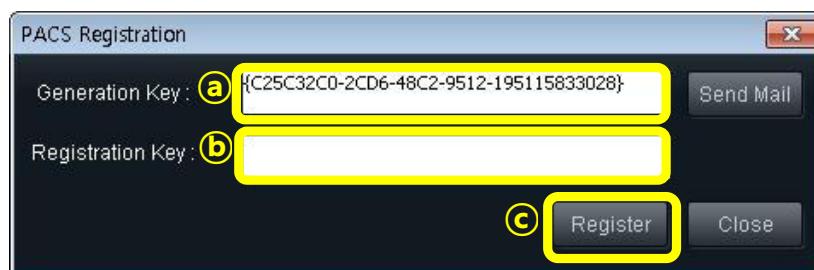
iii. Agent & Distributor Information

- ⑨ Agency: Input the Agency's information in this field.
- ⑩ Contact: Input the contact information for the agency.

2) Global PACS

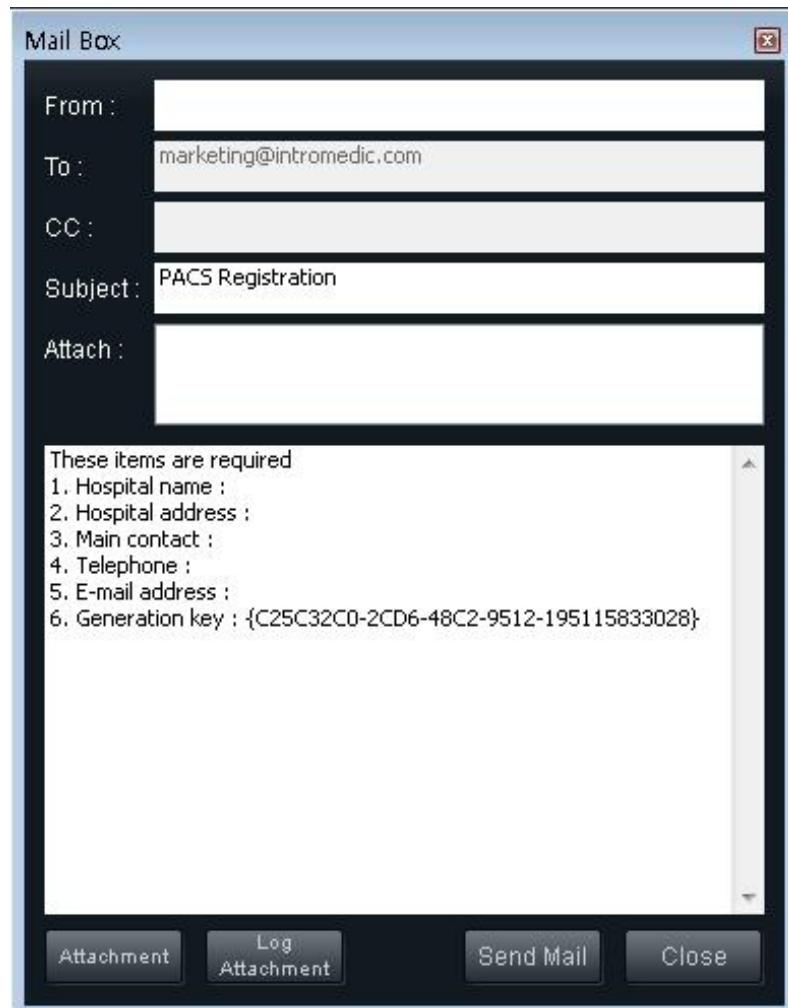


- i. Registration: Process to enable the PACS related functionalities.
- Click the **Register** button. PACS registration window will appear like below.

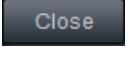


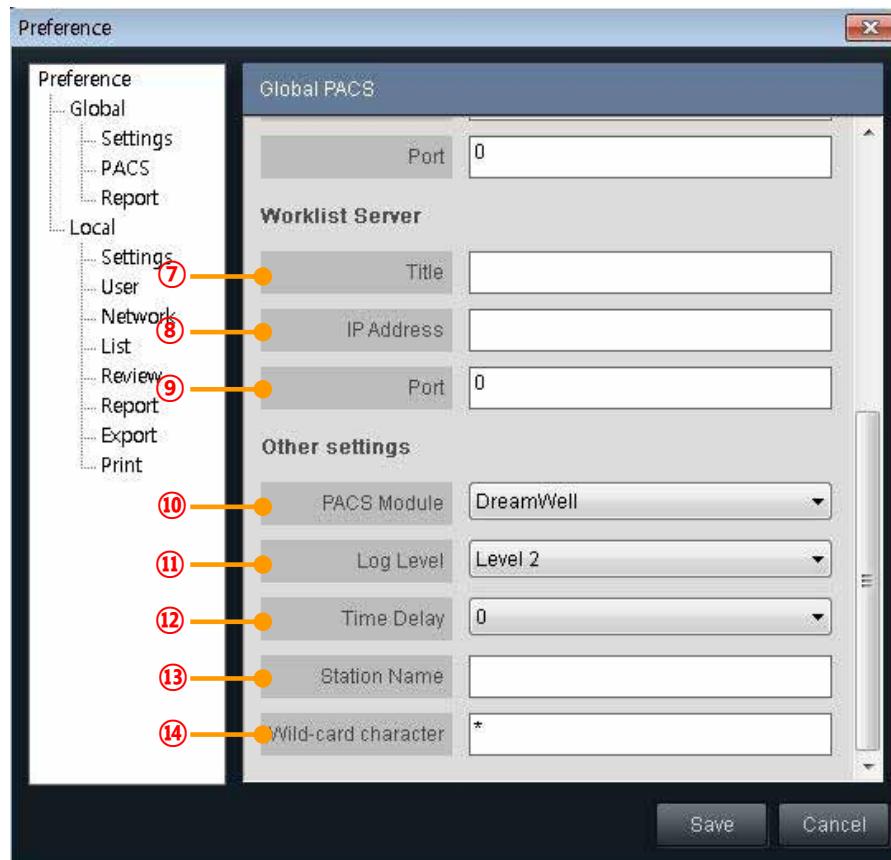
- Generation key will be generated automatically.

Click the **Send Mail** to send the generation key to IntroMedic. Mail Box window will appear like below.



- Input the e-mail address in the field 'From' for receiving the Registration Key. Fill in the information for the items in the text box: Hospital name, Hospital address, Main contact, Telephone, E-mail address and Generation key.
- Click the **Send Mail** to send the information to IntroMedic. IntroMedic will reply with the Registration Key to the e-mail address typed in 'From' field. It will take time to receive the reply.

- Click the  to close the Mail Box window.
 - After receiving the Registration Key, input the Key in the Registration Key field on PACS registration window.
Click the  to finalize the registration process.
- ii. Caller: Technical properties for Caller.
- ① Title: Input the Title for Caller.
 - ② Modality: Input the Modality for Caller.
 - ③ Port: Input the port number to use for Caller.
- iii. Image Storage Server: Technical properties for Image Storage.
- ④ Title: Input the title for Image Storage Server.
 - ⑤ IP Address: Input the IP Address for Image Storage Server.
 - ⑥ Port: Input the port number to connect to Image Storage Server.



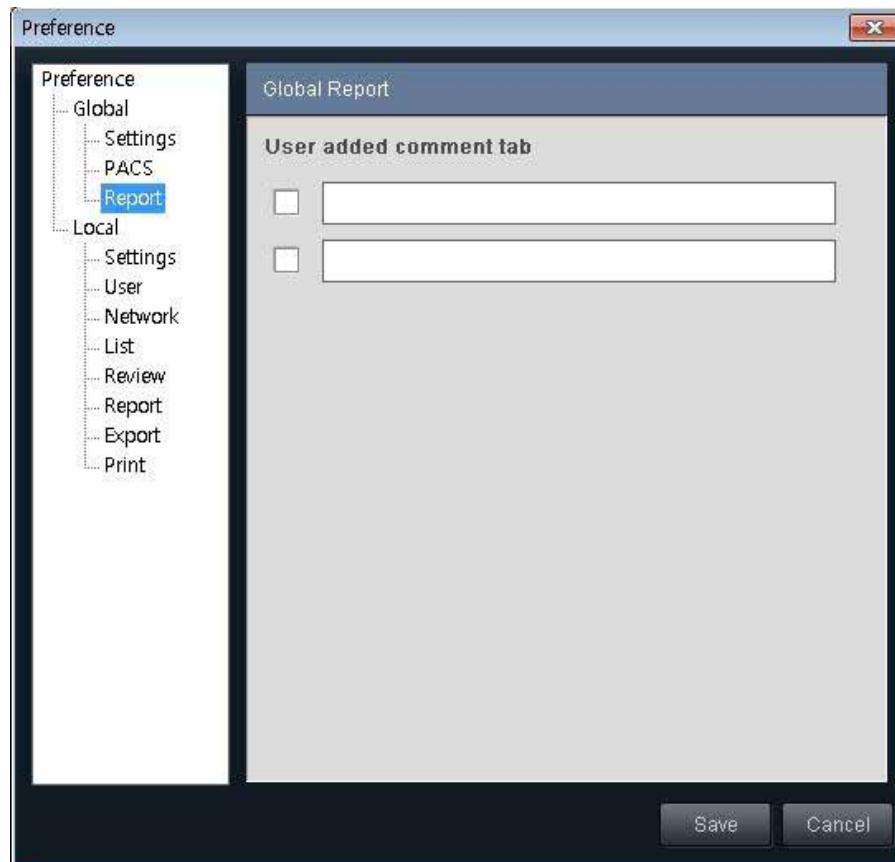
iv. Worklist Server: Technical property for Worklist Server.

- ⑦ Title: Input the Title for Worklist Server.
- ⑧ IP Address: Input the IP Address for Worklist Server.
- ⑨ Port: Input the port number to connect to Worklist Server.

v. Other Settings: Technical properties for PACS setting.

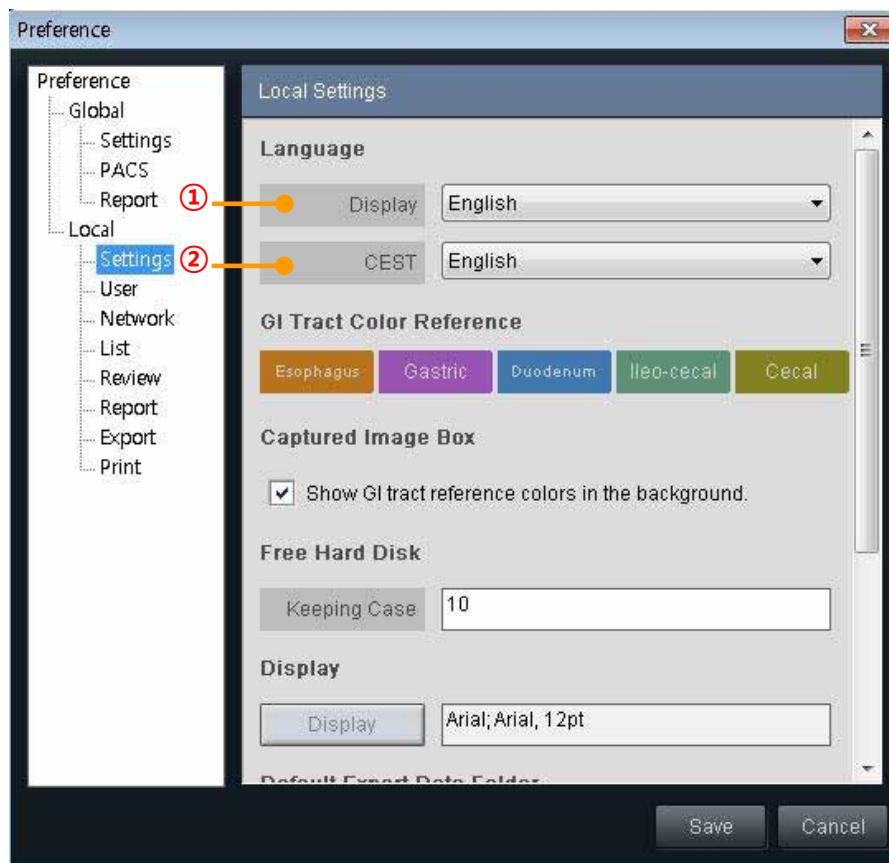
- ⑩ PACS Module: Choose the appropriate PACS Module of DreamWell or Viewworks.
- ⑪ Log Level: Choose the appropriate Log Level for the PACS functionality: Level 0, Level 1 and Level 2.
- ⑫ Time Delay: Choose the Time delay from 0 to 9 seconds.
- ⑬ Station Name
- ⑭ Wild-card character

3) Global Report

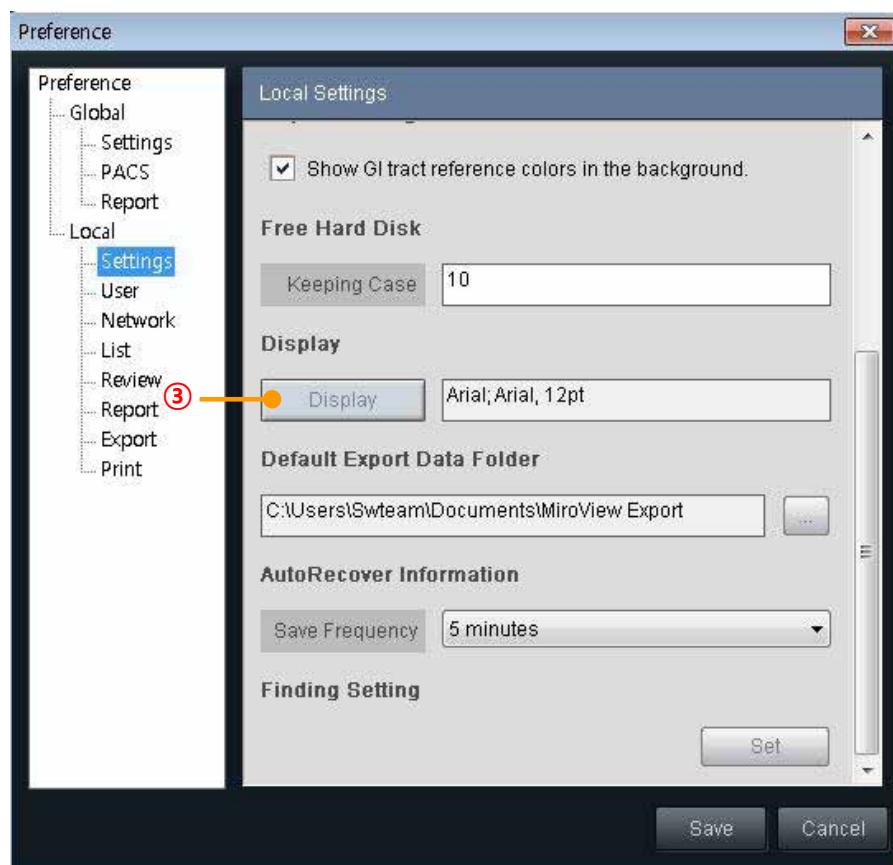


- i. User added comment tab: If checking on the checkbox and typing the desired string into the textbox, a comment tab will be added on the Report Mode. To apply the change, click **Save**.

4) Local Settings



- i. Language
 - ① Display: Choose the display language.
 - ② CEST: Choose the CEST language.
 - ③ GI Tract Color Reference: Show the color references for the GI Tract.
- ii. Captured Image Box: Check the check box to show GI tract reference colors in the background of Captured Image Box.



iii. Free Hard Disk

Keep the number of cases on the local drive. If the cases are cached from the Server more than the configured number, the oldest case on the local drive will be freed up.

iv. Display

Display: Font setting to display.

v. Default Export Data Folder: Direct the folder for exporting

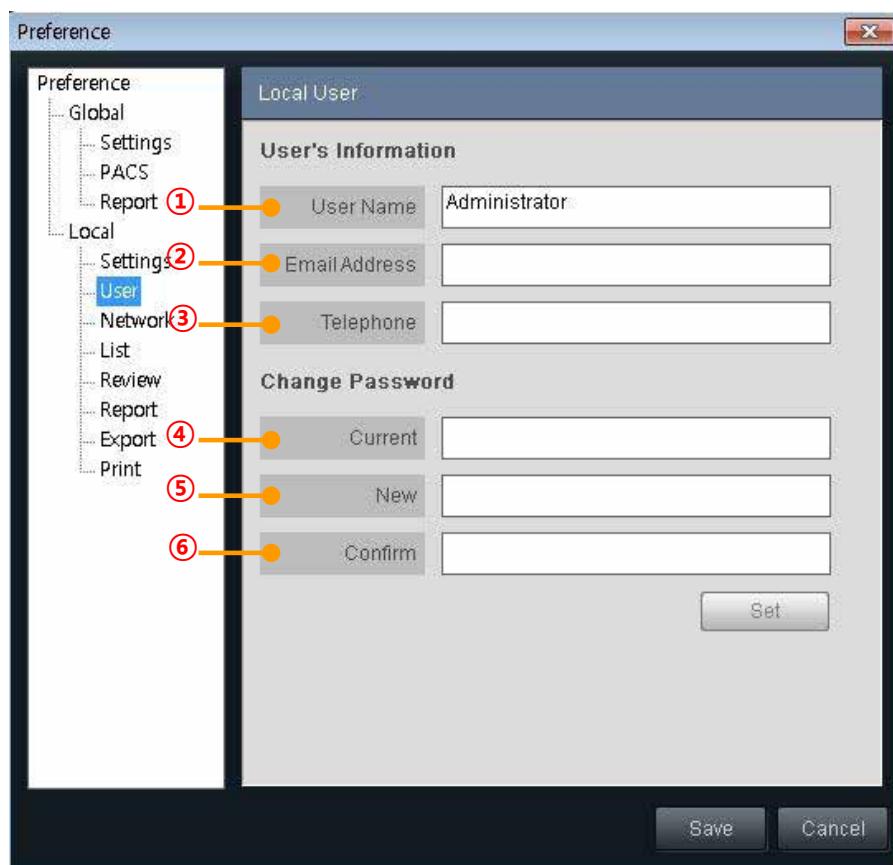
data. Click the to open the browser.

vi. AutoRecover Information

Save Frequency: The MiroView™ Client saves the auto recovery information while the user is reviewing the patient file, periodically. Choose the period to save the auto recovery information from 0 to 60 minutes.

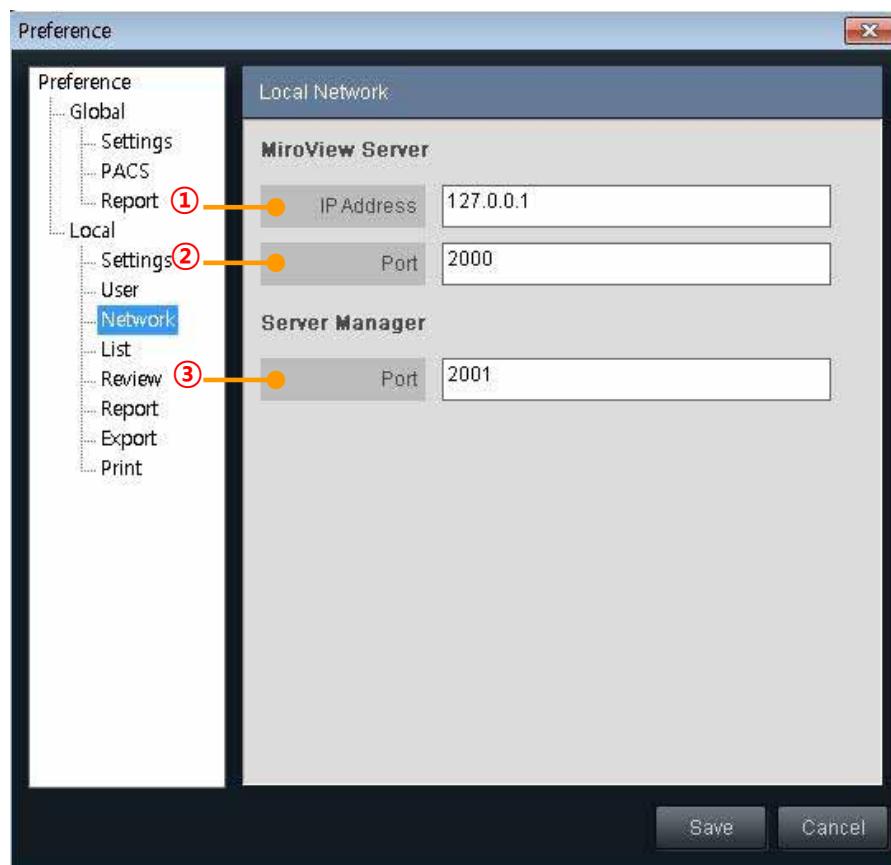
- vii. Finding Setting: Configure the finding setting. Click the  to open the configuration dialogue.

5) Local User



- i. User's Information: Set/modify the information for the user.
- ① User Name: Input User Name which will be used for log-in ID.
 - ② Email Address: Type in the e-mail address here.
 - ③ Telephone: Type in the telephone number here.
- ii. Change Password
- ④ Current: Input the current password
 - ⑤ New: Input the desired password to use.
 - ⑥ Confirm: Input the desired password again.

6) Local Network



i. MiroView™ Server

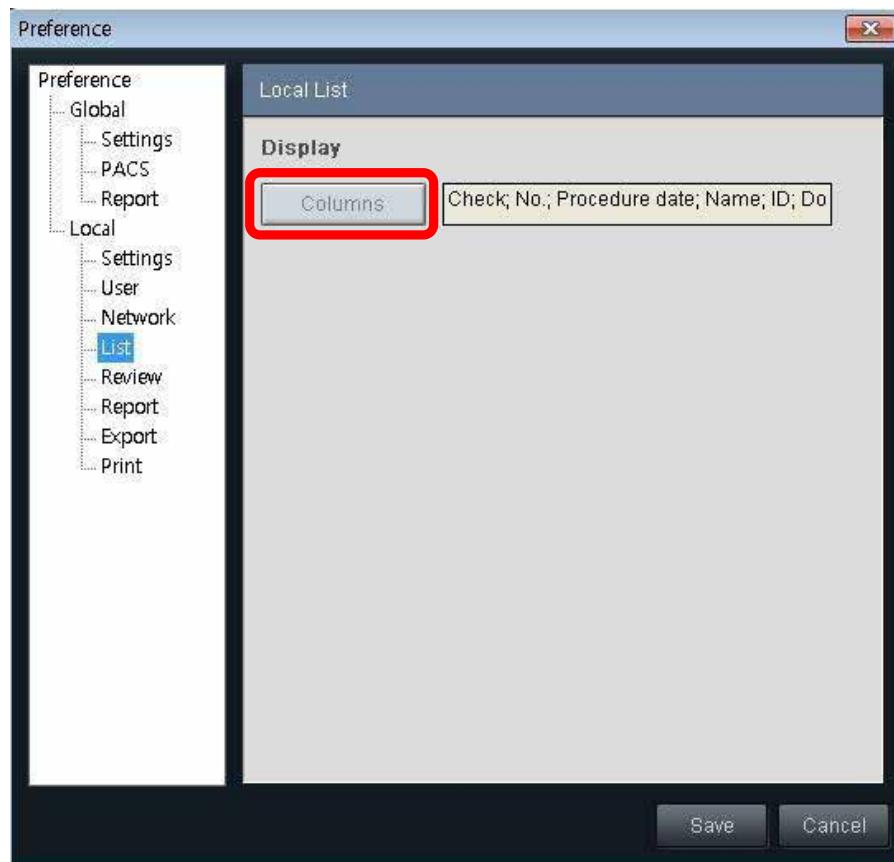
① IP Address: Input the IP Address where the MiroView™ Server is installed.

② Port: Input the port number to connect with the MiroView™ Server.

ii. Server Manager: Utility to manage the MiroView™ Server remotely.

③ Port: Input the port number for connection between Server Manager and the MiroView™ Server.

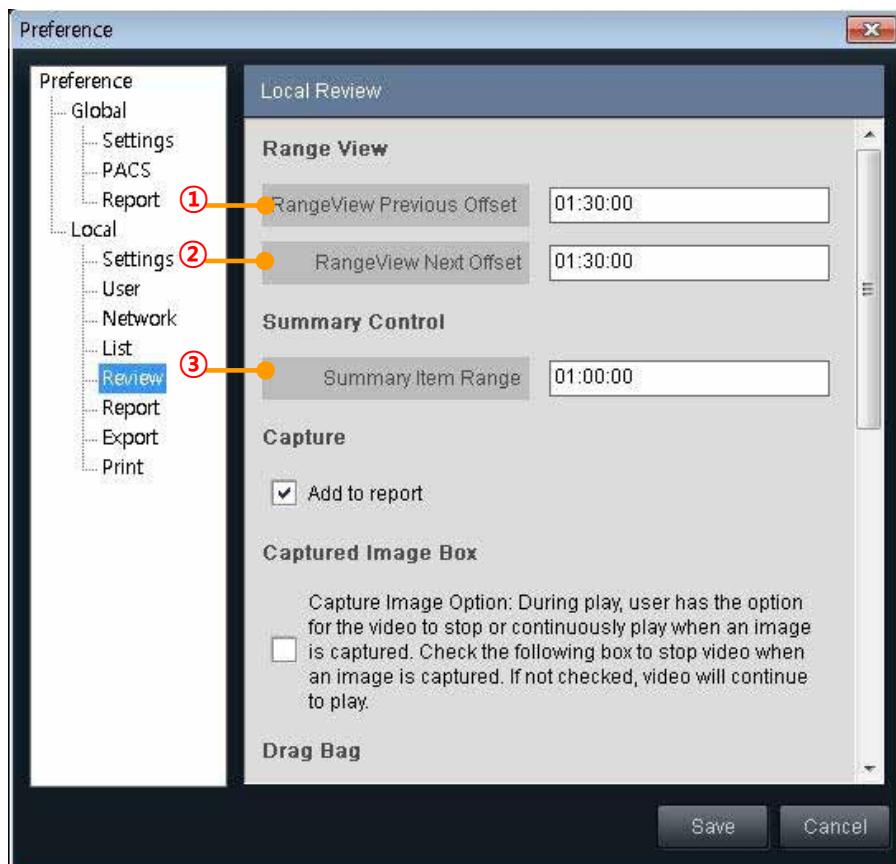
7) Local List



i. Display

Columns: Configure the columns which will appear on List.

8) Review



i. Range View

- ① Range View Previous Offset: Set the range for range view.
- ② Range View Next Offset: Set the range for range view.

ii. Summary Control

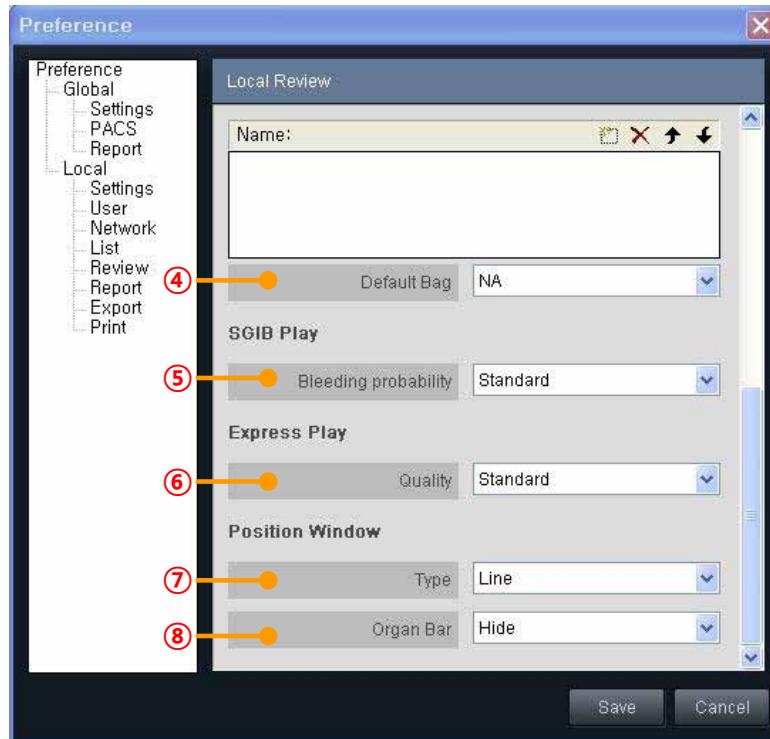
- ③ Summary Item Range: Set the period of one item on the Finding Summary Box.

iii. Capture

Add to report: If the checkbox is checked, the captured images will be shown on Report Mode and added to the final report. The added captured image can be removed from the Report Mode.

iv. Captured Image Box

Captured Image Option: If the checkbox is checked, the video will stop when capturing an image on Review Mode.



v. Drag Bag: Drag Bag related setting. Add/Remove the Drag Bags and set a Bag to Default Bag by choosing one from the combo list. The Bags will be applied for the reviews added newly. If the user makes a new review for a case or open a case not reviewed and choose finding box for the captured image box, the drag bags which are modified on this preference will be shown.

- ④ Default Bag: Set a Bag to Default Bag by choosing one from the combo list on Drag Bag mode.



vi. SGIB Play

- ⑤ Bleeding probability: Choose the Bleeding probability to play on SGIB Play. Set this value as Low to show many images on SGIB Play or set high to show little images.

vii. Express Play

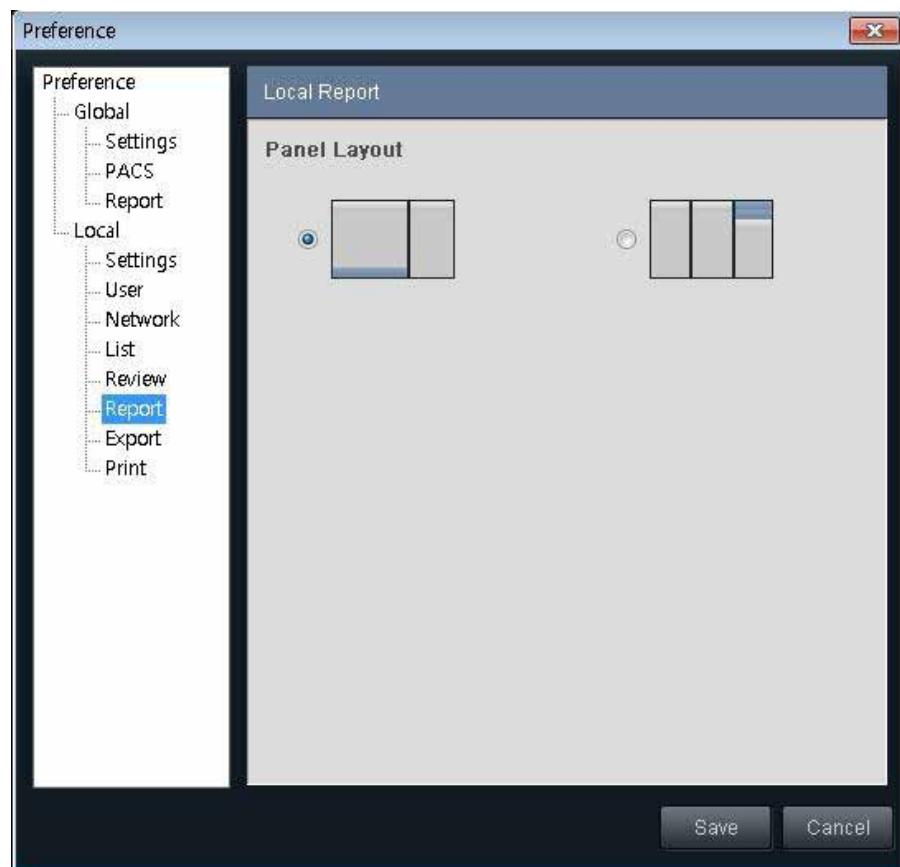
- ⑥ Quality: Choose the Quality to play on Express Play. Set this value as Low to skip more images on Express Play than High.

viii. Position Window

- ⑦ Type: Choose the type for the Position Window. If Line is chosen, the trace of the MiroCam® Capsule will be displayed in line. If Region is chosen, the position of the MiroCam® Capsule will be displayed on region segmented.

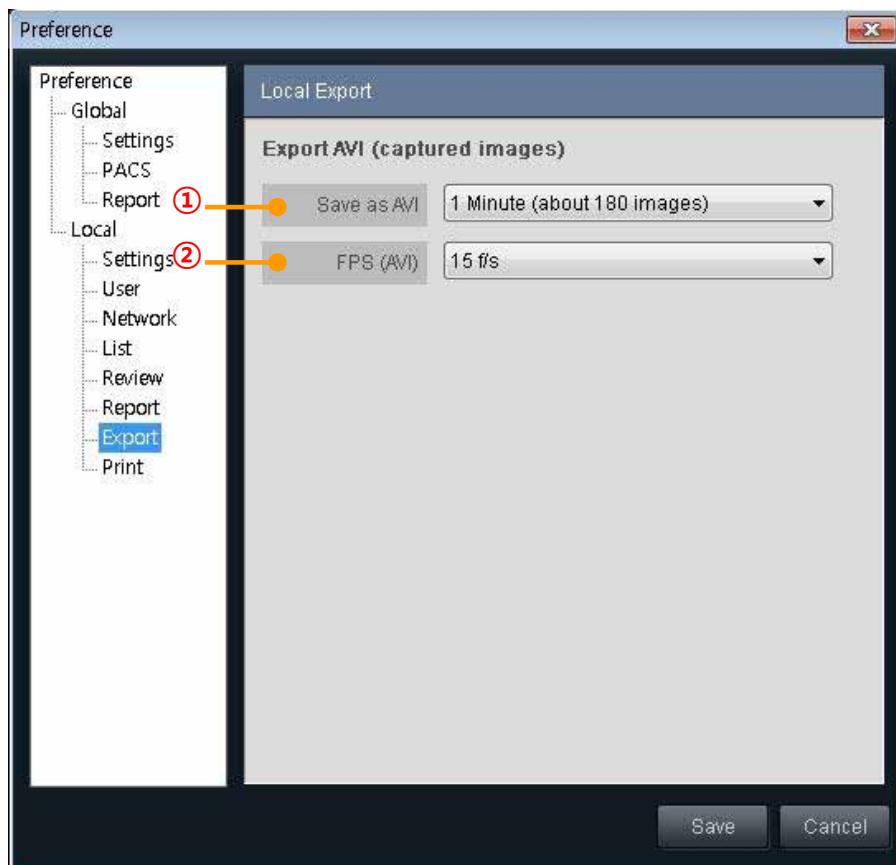
- ⑧ Organ Bar: Choose the Organ Bar status. If Show is chosen, the Organ Bar will appear on the Position Window.

9) Local Report



- i. Panel Layout: Choose the Panel Layout. The Panel Layout will be shown as per the choice.

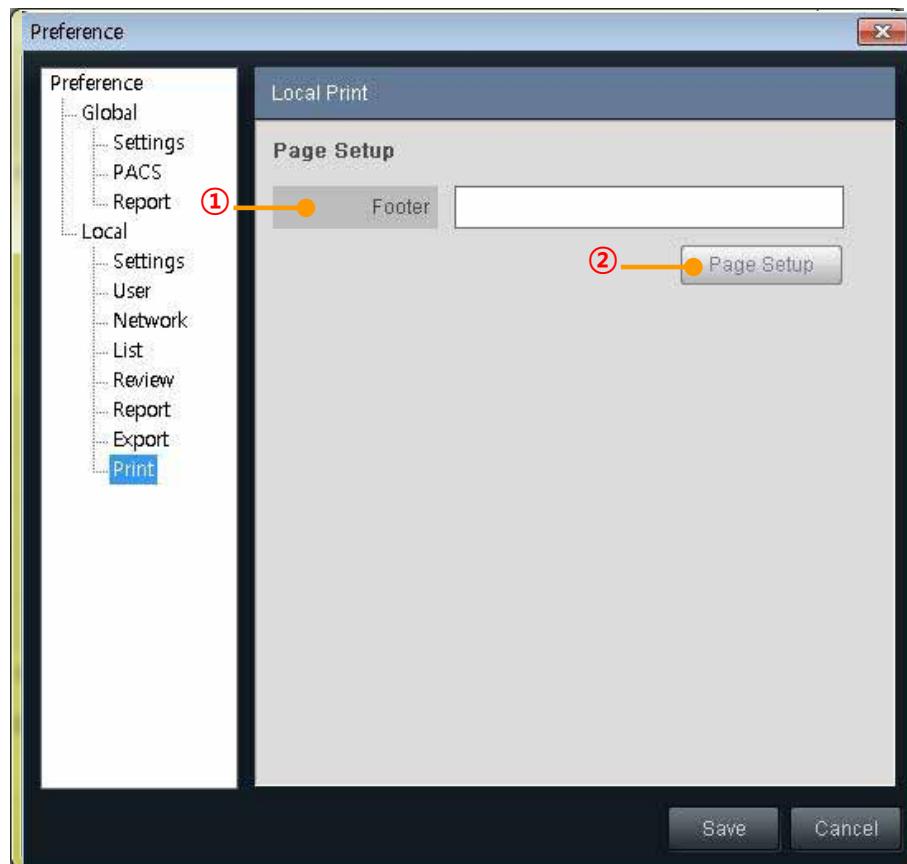
10) Export



i. Export AVI

- ① Save as AVI: Set the length of the AVI to export.
- ② FPS (AVI): Set the frame rate of the AVI to export.

11) Local Print

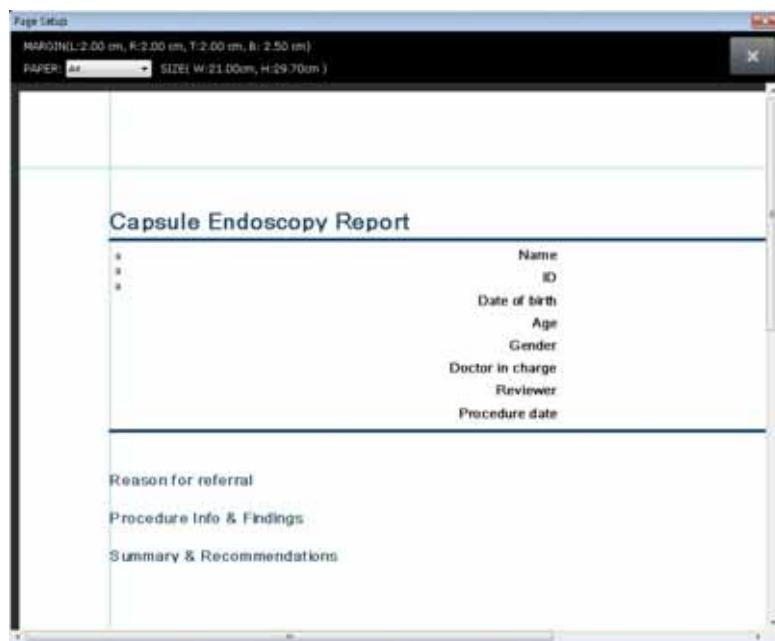


ii. Page Setup

- ① Footer: Type in the string for footer which will appear on the final report.

② Page Setup: Edit the layout of the report.

- Click the **Page Setup** to show the Page Setup window.

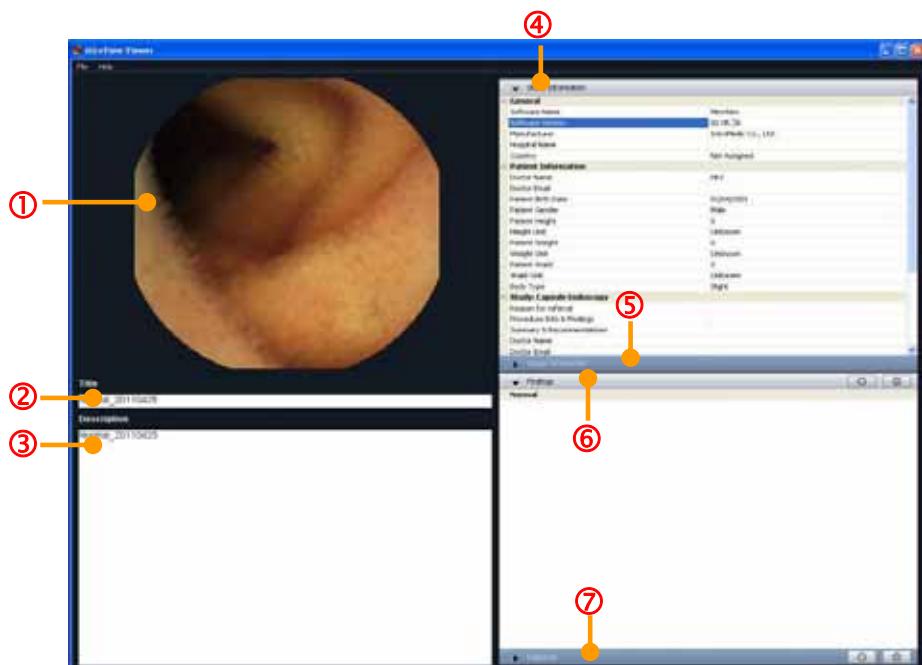


- Choose the paper type; A4 or Letter and adjust the margins for Header, Footer, Right and Left.

4.5 Overview - MiroView™ Viewer

4.5.1 Start MiroView™ Viewer

- Double-click the  to run the MiroView™ Viewer. Open an Image File (EXMIF-Exchangeable Medical Image Format data or JPEG) via 'File -> Open' function.



| | | |
|---|-------------------|---|
| ① | Image Display | Image Display Area (EXMIF or JPEG) |
| ② | Title | Title for the image in the Image Display |
| ③ | Description | Description for the image in the Image Display |
| ④ | Study Information | General Information (Software / Manufacturer / Hospital Information), Patient Information (Doctor, Patient Body Shape) and Study Information (Doctor, Receiver, Capsule and Procedure Information) for the image in the Image Display |
| ⑤ | Image Information | Creator Information and/or Finding Comments for the image in the Image Display |
| ⑥ | Findings | Findings information the creator captured and commented before for the image in the Image Display. |
| ⑦ | Diagnosis | Diagnosis information the creator captured and commented on for the image in the Image Display. |

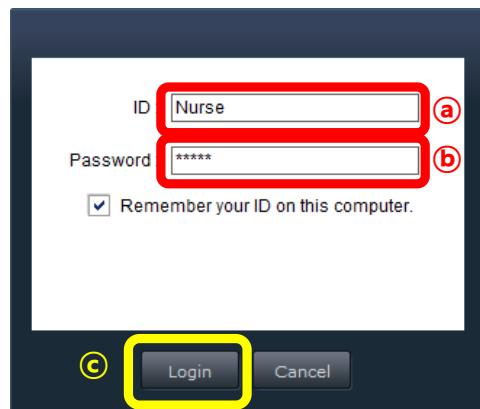
4.6 Performing Capsule Endoscopy

4.6.1 Initializing Receiver

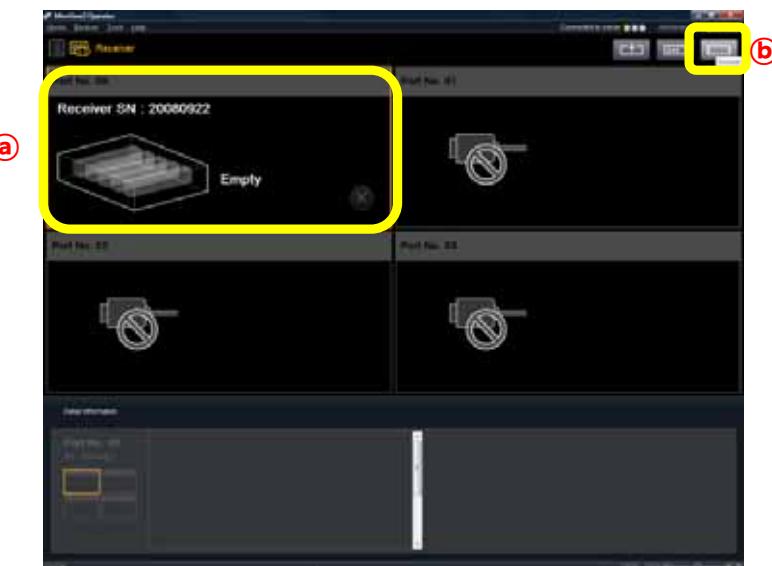
- Connect the MiroCam® Receiver to the workstation via USB port.

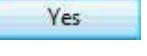


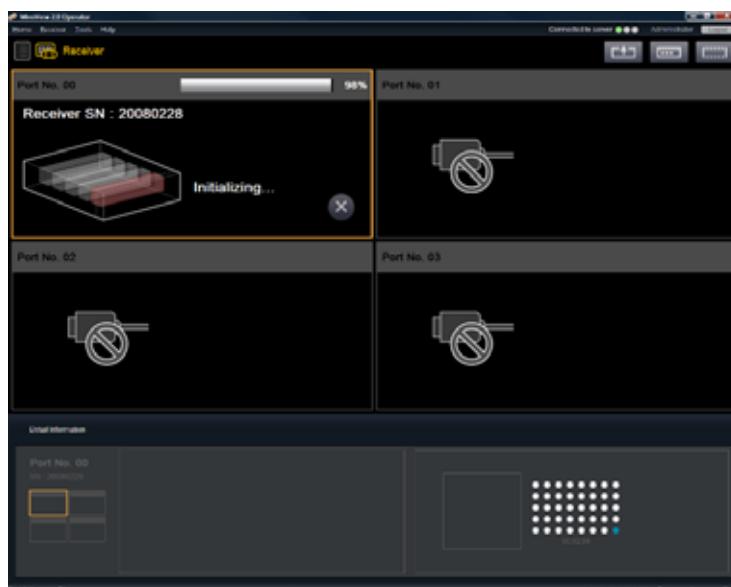
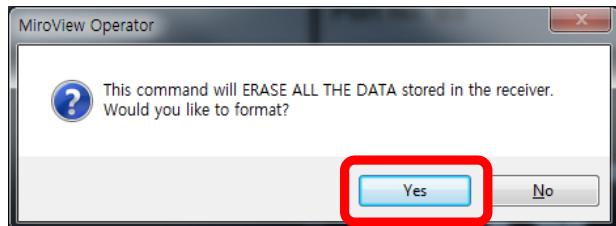
- Run the MiroView™ Operator by double-clicking the  on the desktop or from the Windows Start-up menu. Log in.
- Carry out in alphabetical order like following picture.



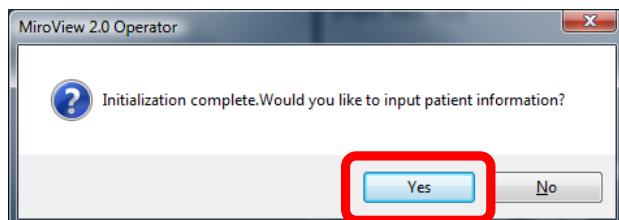
- Enter the MiroCam® Receiver mode and select the MiroCam® Receiver port to initialize and click the .



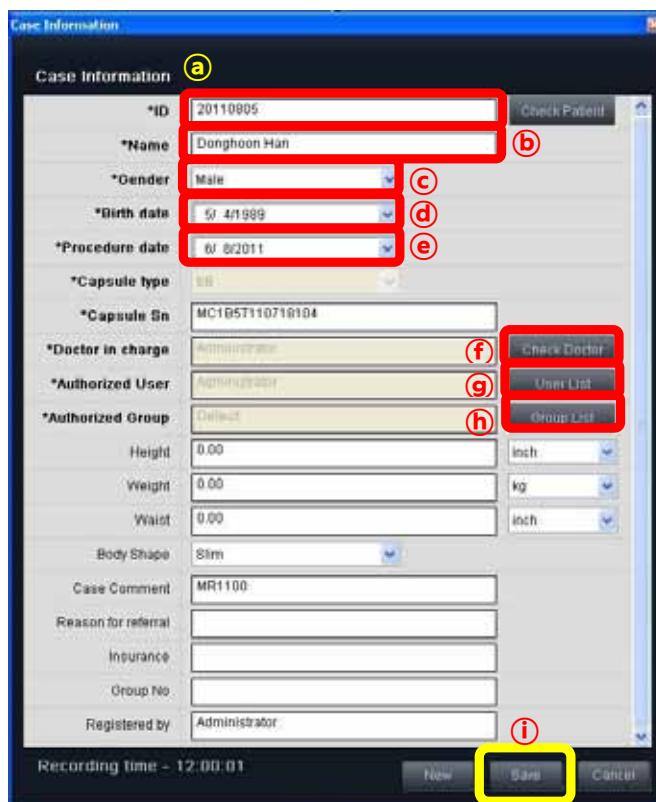
- When following message will appear, click the  to start the initializing process.



- After the initializing process is complete, the following message will appear.



- Click the **Yes** and the Patient Information window will appear. Input the patient information for each field.
- Click the **Check Patient** to input the patient name and then click the **Check Doctor** to input the doctor name.
(Type in the patient's name and the ID into the appropriate fields directly.)
- Carry out in alphabetical order like following picture.



(The fields marked with * is required.)

- Click the **Save** button to save the Case Information to the MiroCam® Receiver. The MiroCam® Receiver is now ready for the MiroCam® Capsule endoscopy procedure.



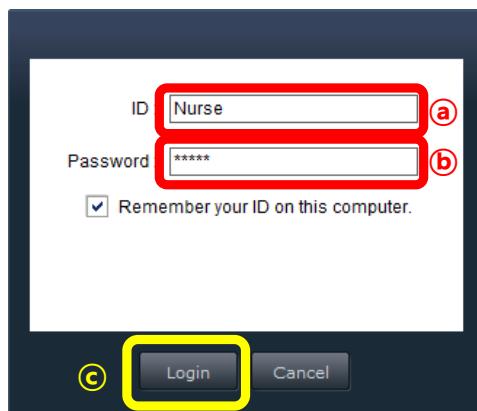
NOTE The fields in the Case Information are editable, and additional fields can be added. This can be accessed via Tools → Preferences → Receiver → Set → Add / Modify.

4.6.2 Upload Image Data (MiroView™ Operator)

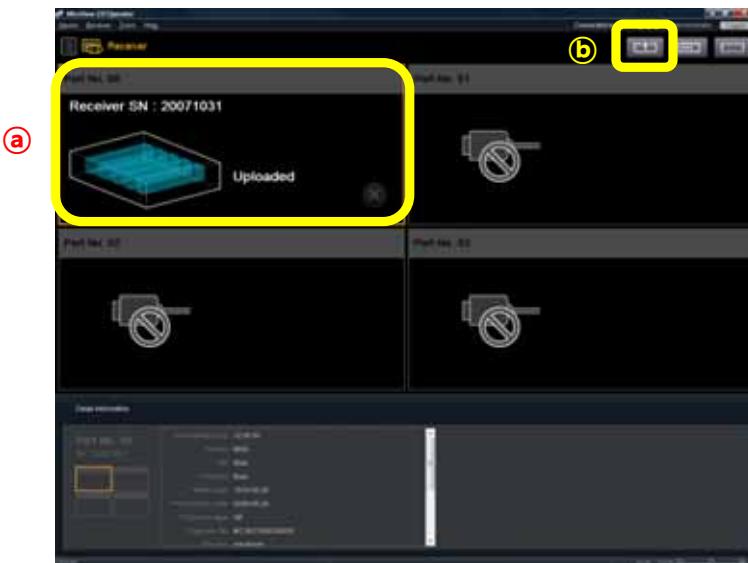
- Connect the MiroCam® Receiver to the workstation via USB port.



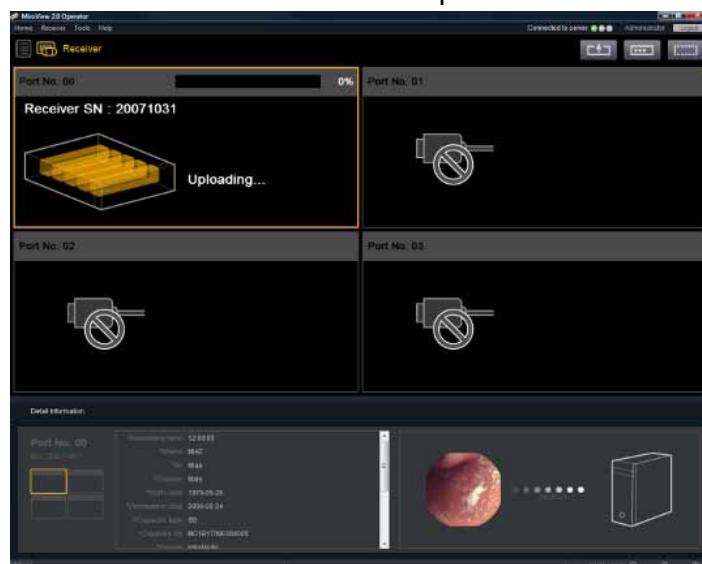
- Run the MiroView™ Operator by double-clicking the  on the desktop or from the Windows Start-up menu. Log in.
- Carry out in alphabetical order like following picture.



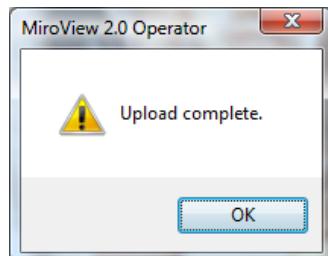
- After switching the MiroCam® Receiver on, enter the MiroCam® Receiver mode and select the proper the MiroCam® Receiver port to upload the image data.
- Carry out in alphabetical order like following picture.



- Click the to start the Upload.



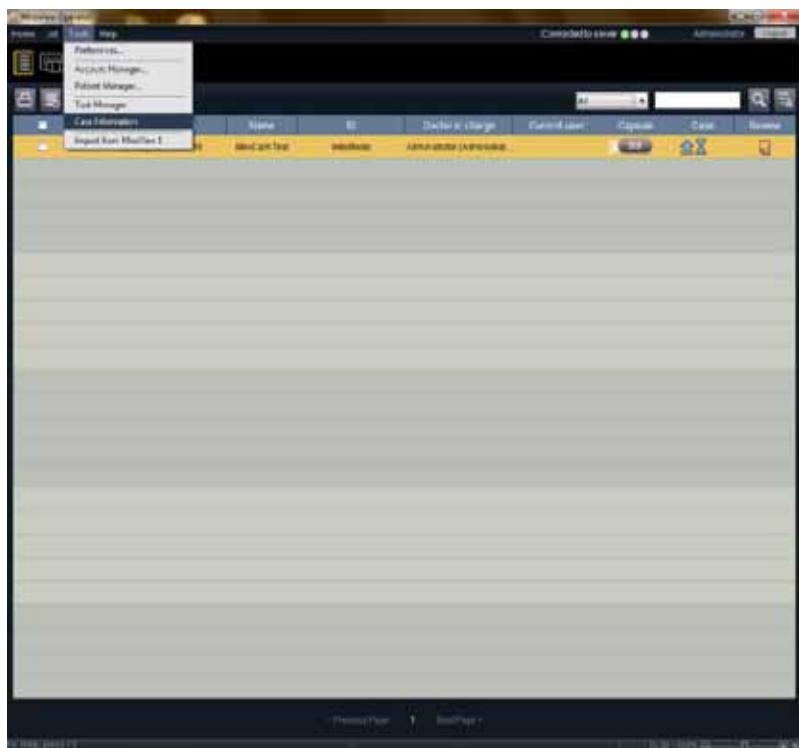
- After completing the Upload, the following message will appear.



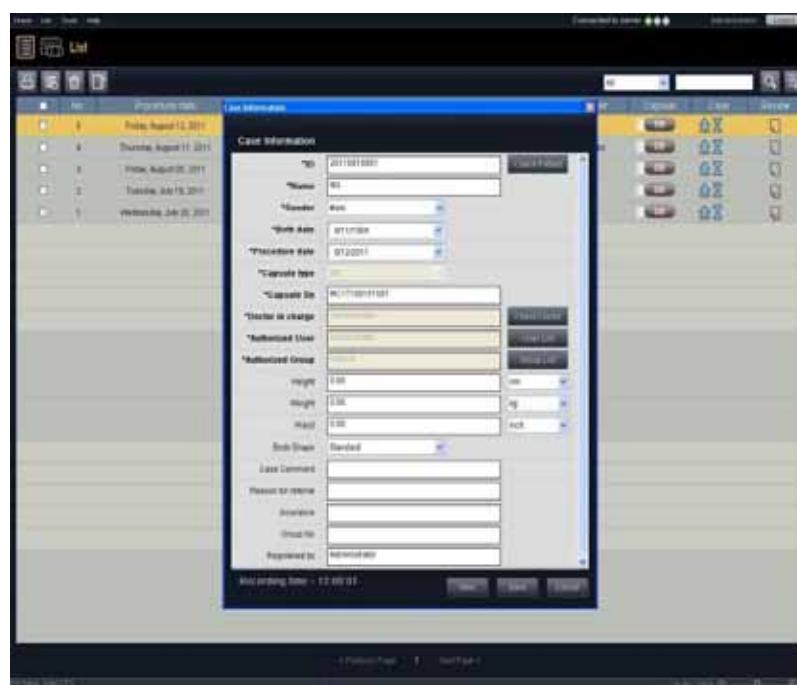
CAUTION When the MiroView™ Operator is running on a 64bits OS, Do not turn off or disconnect any MiroCam® Receivers connected to the workstation while uploading.

4.6.3 Change Patient Information After uploading the Image Data (Optional)

- From the MiroView™ Operator, under 'Tools' -> Select 'Case Information'.



- Then ‘Case Information’ dialog box will pops up. Change the patient information and click the **Save**.

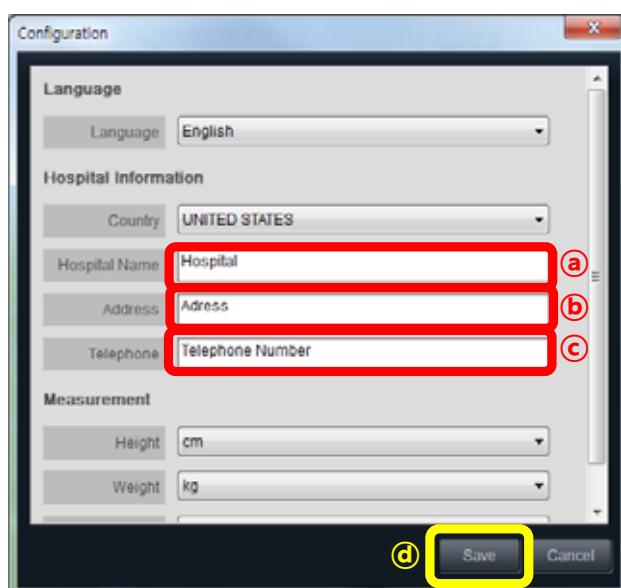


4.6.4 Review (MiroView™ Client)

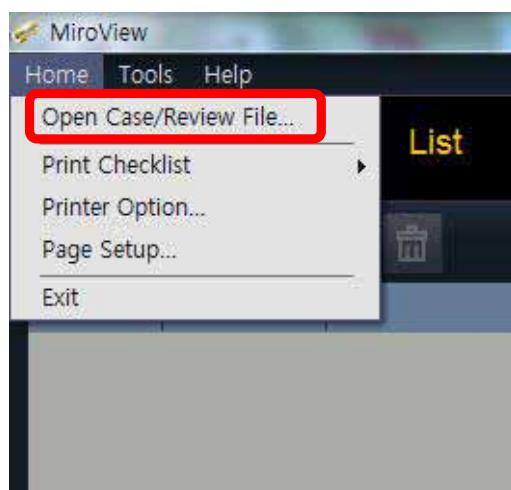
- Run the MiroView™ Client by double-clicking the  on the desktop or from the Windows Start-up menu. Log in.
- Carry out in alphabetical order like following picture.



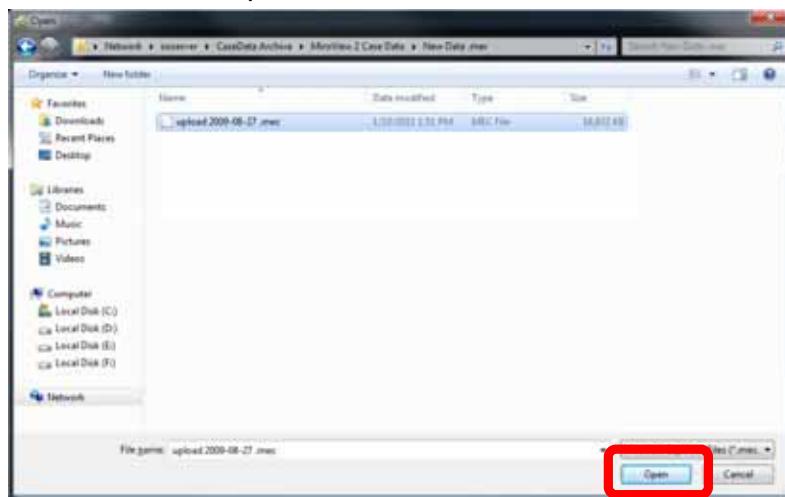
- Click the  on the Log-in screen to run the MiroView™ client as Local Mode. (See **4.7.4 Using MiroView™ Client at Local PC without connecting to MiroView™ Server** for details.)
 - At the first running of 'Local Mode', the window will appear like below. Input the appropriate values in to the empty fields and click the  to proceed.
 - Carry out in alphabetical order like following picture.



- Open the Case/Review via Menu → Home → Open Case/Review file... .

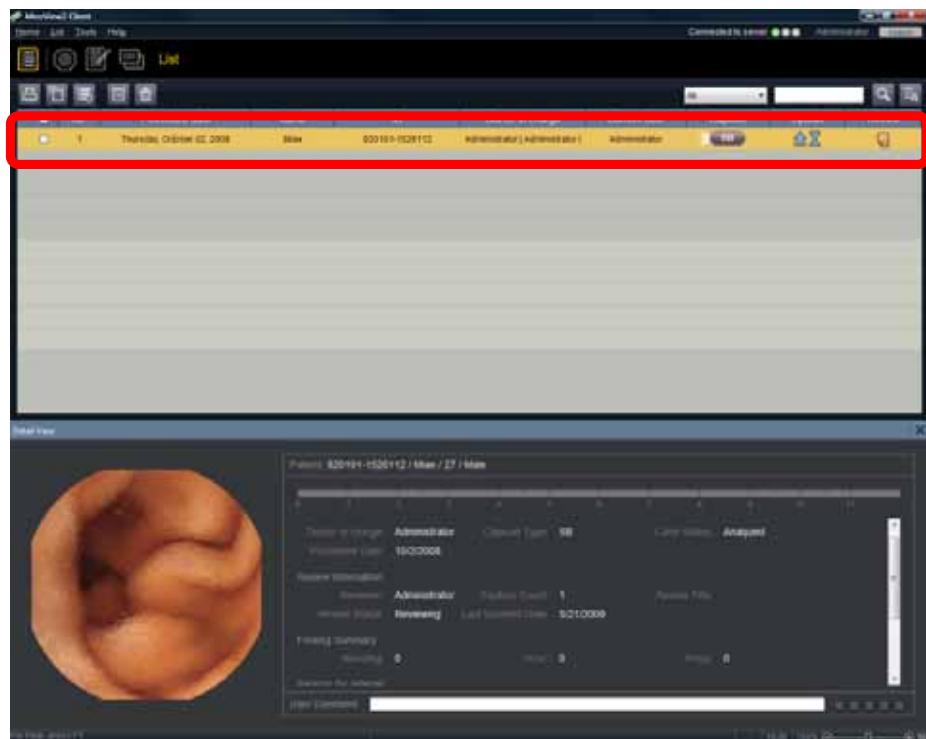


- Choose a file to open and click the **Open**.

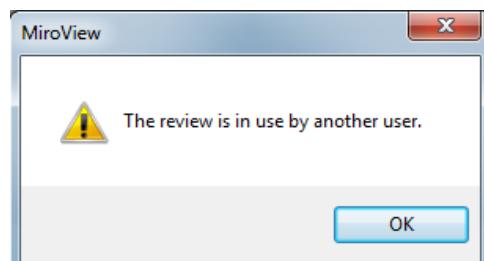


- After completely reviewing the file, save the review via **Menu → Home → Save Active Review** so that the user can import the edited review file on the MiroView™ Server in the future.

- Select the Patient Video Data on the List Mode
 - Select a patient video data to review from the List Mode and click the  to enter the Review Mode.
 - Check to see if another user is reviewing the patient file on the Current User column in the List Mode.



- If the patient file is being reviewed by another user, a message will appear.



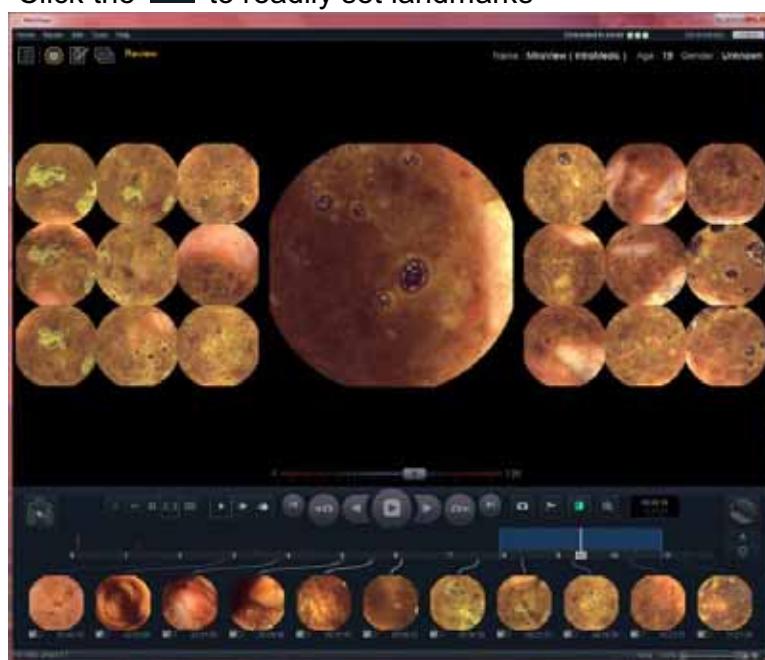
■ Review the Patient Video on the Review Mode



NOTE When using network connection between the MiroView™ Server and the MiroView™ Client, for efficient video playback the video is cached locally in the server. During this buffering process, the video may be reviewed.



– Click the to readily set landmarks



- Use the Range View and Map View to find all the landmarks.



NOTE Click the and select landmark type:
Esophagus, Gastric, Duodenum, Ileo-cecal, Cecal
and User landmark.

- After marking the necessary landmarks, play the video via the Express Play and capture abnormalities and / or suspected disease pathologies in the small bowel.





NOTE The user can press ‘Enter’ key to capture the image.

- To identify abnormalities and/or disease pathology more easily, use the Image Enhancement function to adjust preferred image settings. Click the to open the Image Enhancement window.

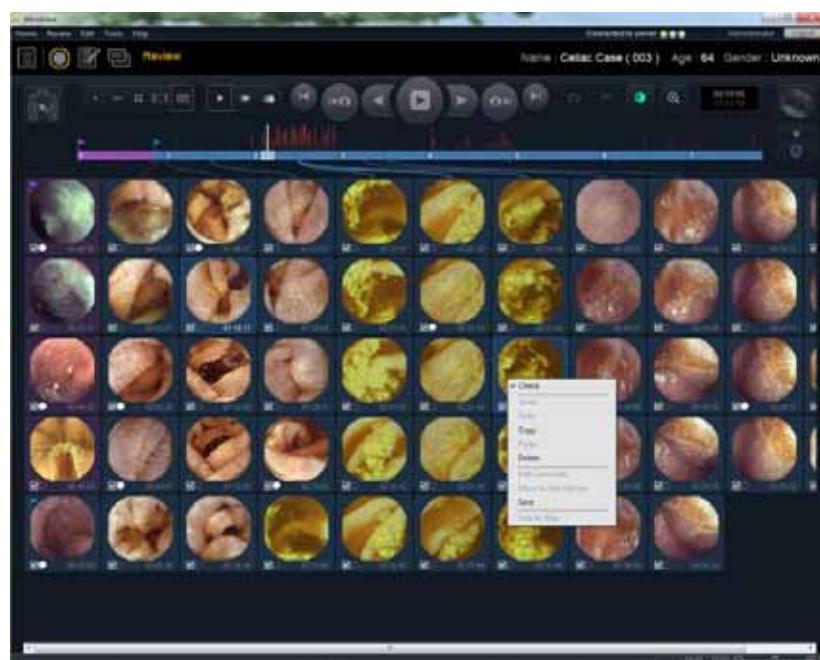


■ Converting AVI File

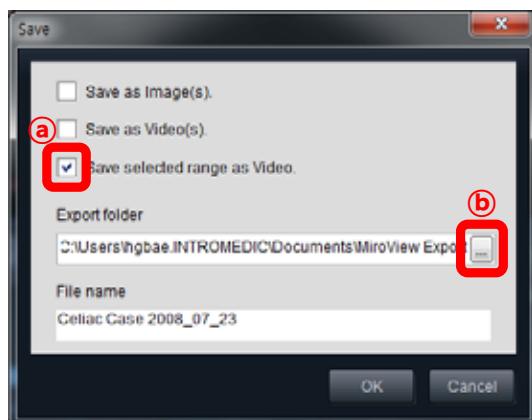
- Click two images (the first image and the last image) while holding the < Ctrl > key among the to convert the segment to an AVI file.



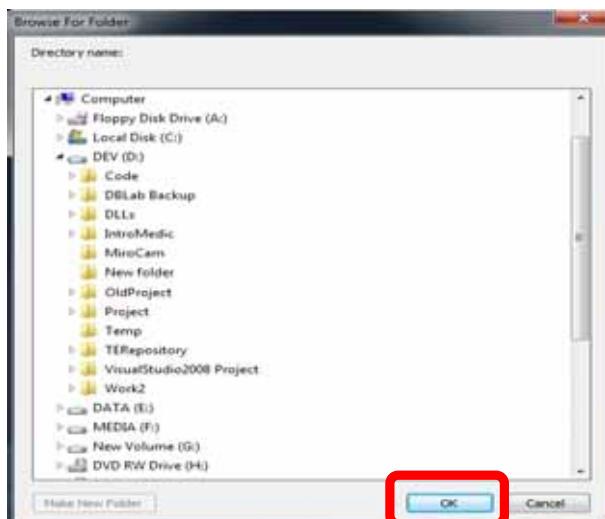
- Right mouse click and select 'Save' from dialog box.



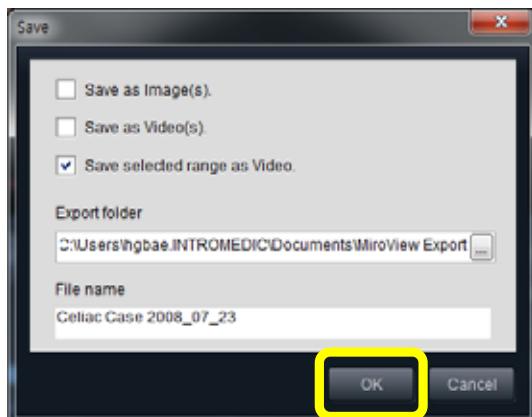
- Only check 'Save selected range as Video.'
- Carry out in alphabetical order like following picture.



- Choose the location you want to save this file and click the **OK**.



- Click the **OK** to save selected range as Video.



■ Composing the Report on the Report Mode

- After capturing images of suspected disease in the Review Mode pathology, click the  to enter the Report Mode.



- Use the auto complete dictionary slide and choose available disease pathology from the list.
 - The user can use hot key, 'Ctrl + Space' or 'Ctrl + Enter' to use auto complete function while composing comments. Select a word from the list after pressing the hot key.



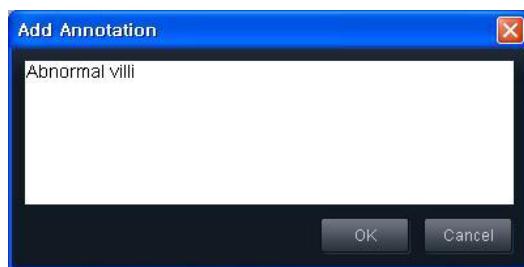
- The user can add the word shown on the GI Dictionary into the text comment by double-clicking the appropriate word or clicking the .
 - The user can prepare Annotations for use by right clicking the mouse in the comments area.
 - Click 'Edit Annotation'.



- Click the  .



- Input annotation and then click the OK



- Completing the report:
 - Complete image comments for captured images (as required)
 - Complete the following tabs: Reason for referral; Procedure Info & Findings; and Summary & Recommendations
 - After completing the report, enter the Export Mode to print out the complete report and/or export the MiroView™ Software data.



NOTE The GI Dictionary tab and findings tab allow the user to adjust the findings and the level of severity. The user can use the GUI easily.



CAUTION DO NOT detach and/or attach the Microphone from/to the workstation while recording the audio comment.



CAUTION Sound Card Driver must be installed prior to using the Recording function.

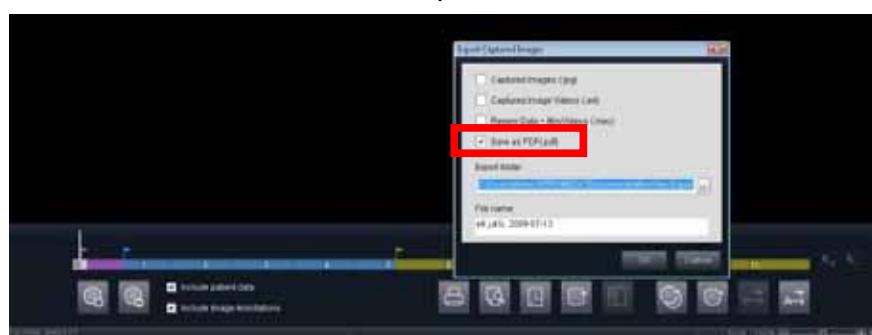


CAUTION Prior to recording the comments, close all the applications using the Sound Card such as music/video player.

■ Print report, create file and export the Review on the Export Mode.

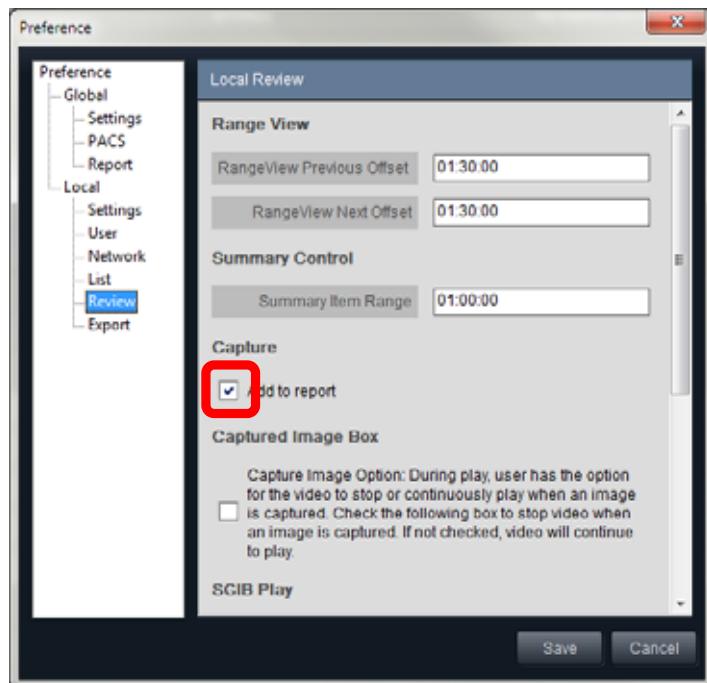


- Select the images to select and click the and add the selected captured images to the candidate list to export. (Remove the selected images from the candidate list using the)
- The 'Save as PDF' function is updated

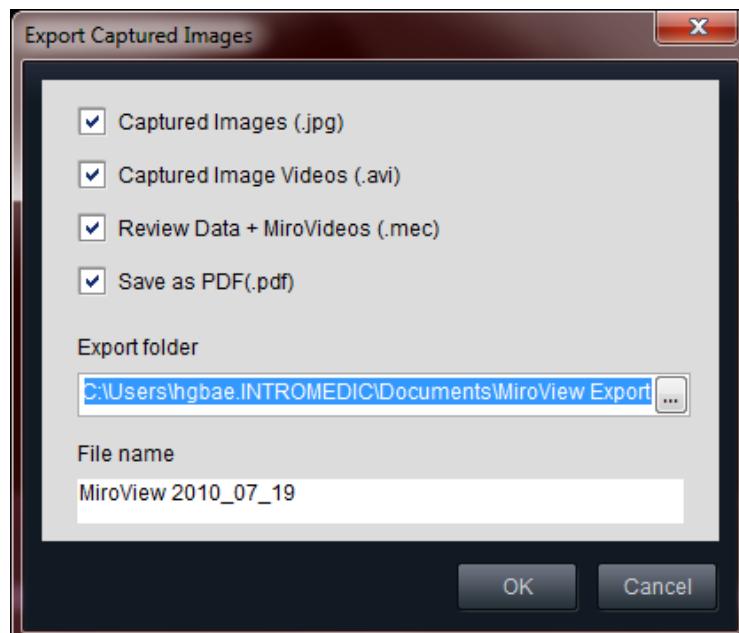


NOTE User is able to change default settings on whether or not to add the images on the report via Tools -> Preference -> Review.

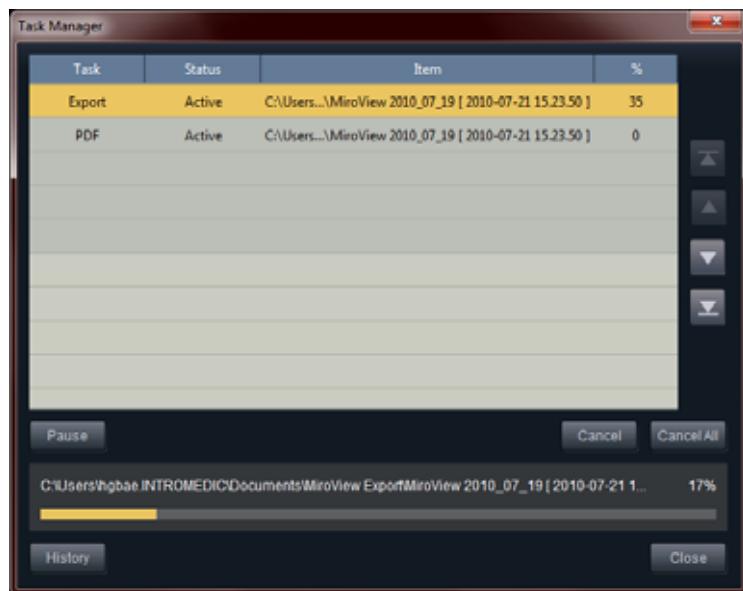
- Check to include on the report when capturing the image.
- Uncheck to not include the images on the report.



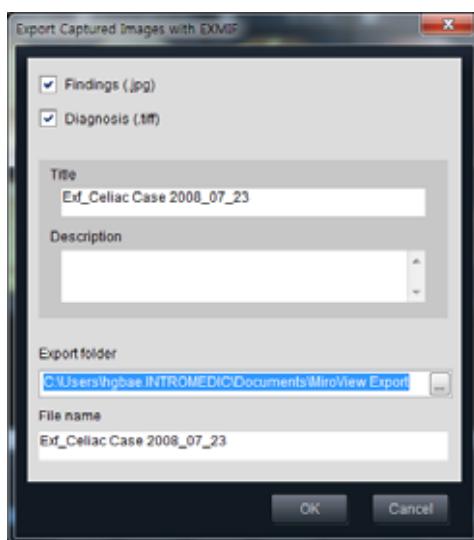
- Click the to use export function. A window will appear like below.



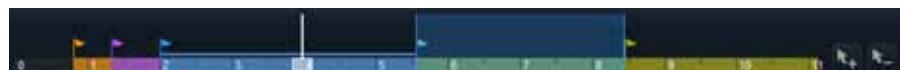
- Select the File Type to export and change the desired file location on the Selected Folder and click the **OK**. A window will appear with a progress bar.



- The user can use the  for EXMIF. When clicking the , the window will appear like below. The user can configure the EXMIF properties: title and description. Findings will be saved as the JPEG file format(.jpg) and diagnosis images will be saved as the multiple image file format(.tiff)



- The user can use the  for Segment Export (Video / Miro Video) and the  for Export Case function.



NOTE Select the segments on the Timebar to export by selecting two captured images to set as the start point and the end point respectively, or by clicking the landmark flag. If no segment is selected, the  to export segments would be disabled.



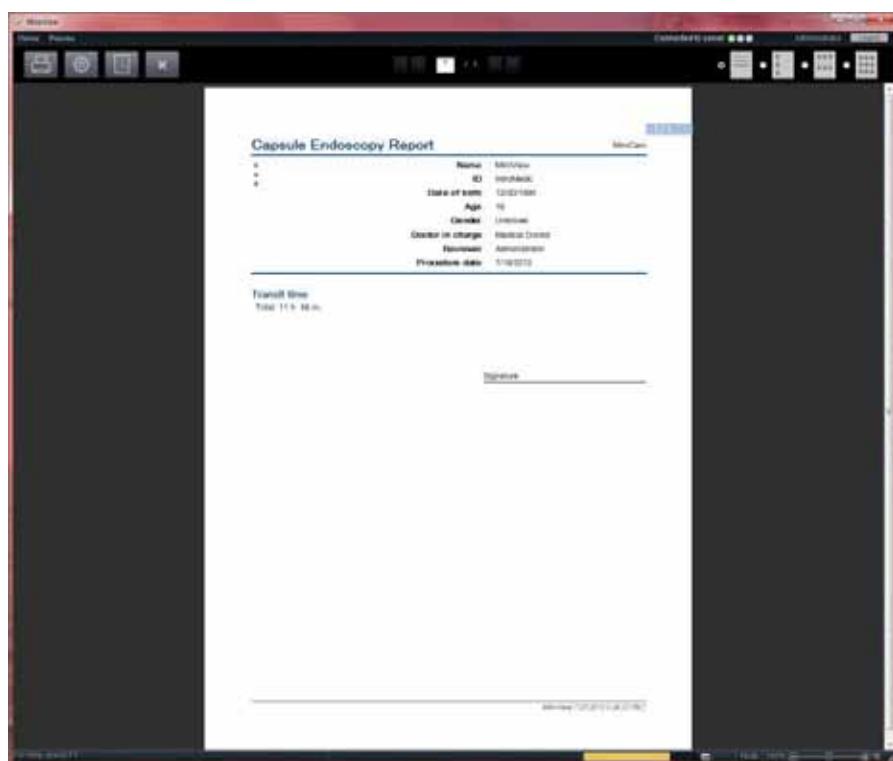
NOTE MiroVideo includes selected Segments so that the user can confirm the contents and edit from 'Open Case / Review file...', 'Import Case / Review file...' main menu.



CAUTION

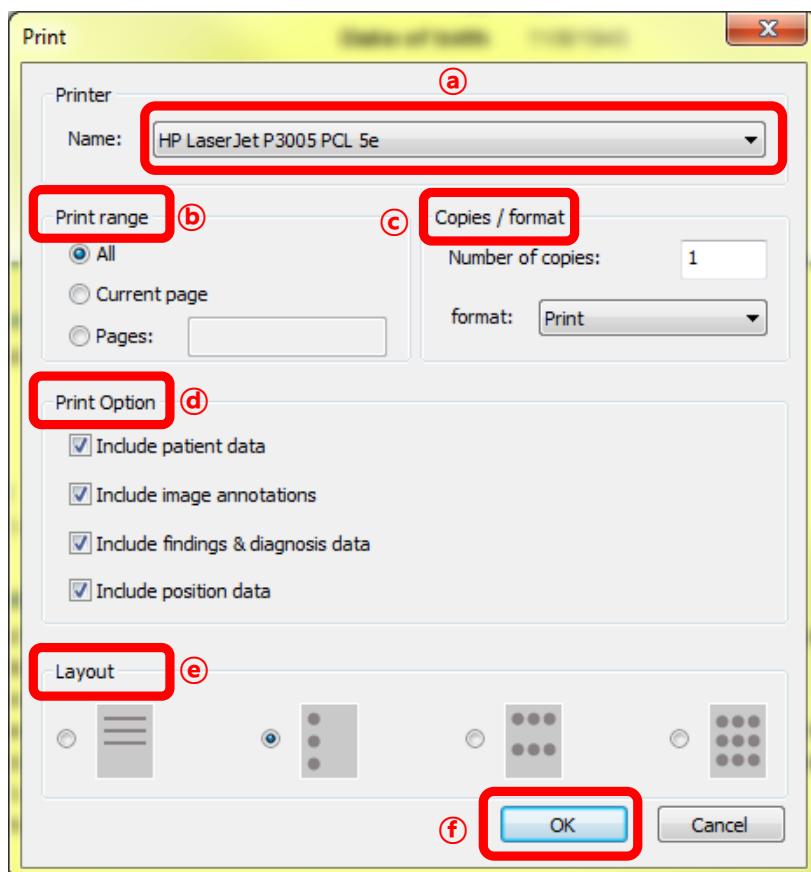
It is highly recommended to constantly back up patient data through export function in order to prevent the data loss.

- Print Report and save the report as PDF on the Report Preview
 - Click the  to print reports and/or click the  to save the report as PDF.
 - Show report preview on the screen. The user can include or exclude findings/diagnosis data on the final report via **Menu → Preview → Including findings & diagnosis data.**



- The user can print out the report and save the report to PDF file in this screen.
- If the user selects the 9 images per page mode, the message 'If you proceed with the current Layout mode, image comments may be omitted and not printed. Please select 3 images per page mode to include all comments in the report.' will appear. This will be defaulted during the next use in that the workstation for all users.
- If the user selects the Draft report, no captured images will be included in the final report.

- Click the  to print the report, the Print window will appear.
- Choose the desirable Printer, Print Range, Copies/format, Print Option and Layout.
- Carry out in alphabetical order like following picture.



- The MiroView™ Software provides the ODF for the soft copy of the report so that the user can open the ODF report in other word processors; MS Word and Haansoft; ODF is available for 3 images layout only.



NOTE The previous software version (MiroView™ Software 1.0) did not support the draft report style.

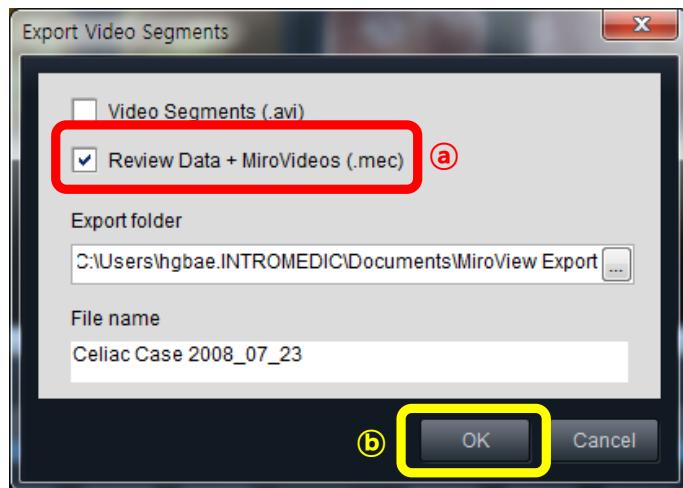
- Back up the segment
 - If a hospital wants only back up small bowel section, they can use this feature. From 'Export' mode, select the range and click the  to add segment first.



- Click the , Export Segments as Video/MiroVideo.



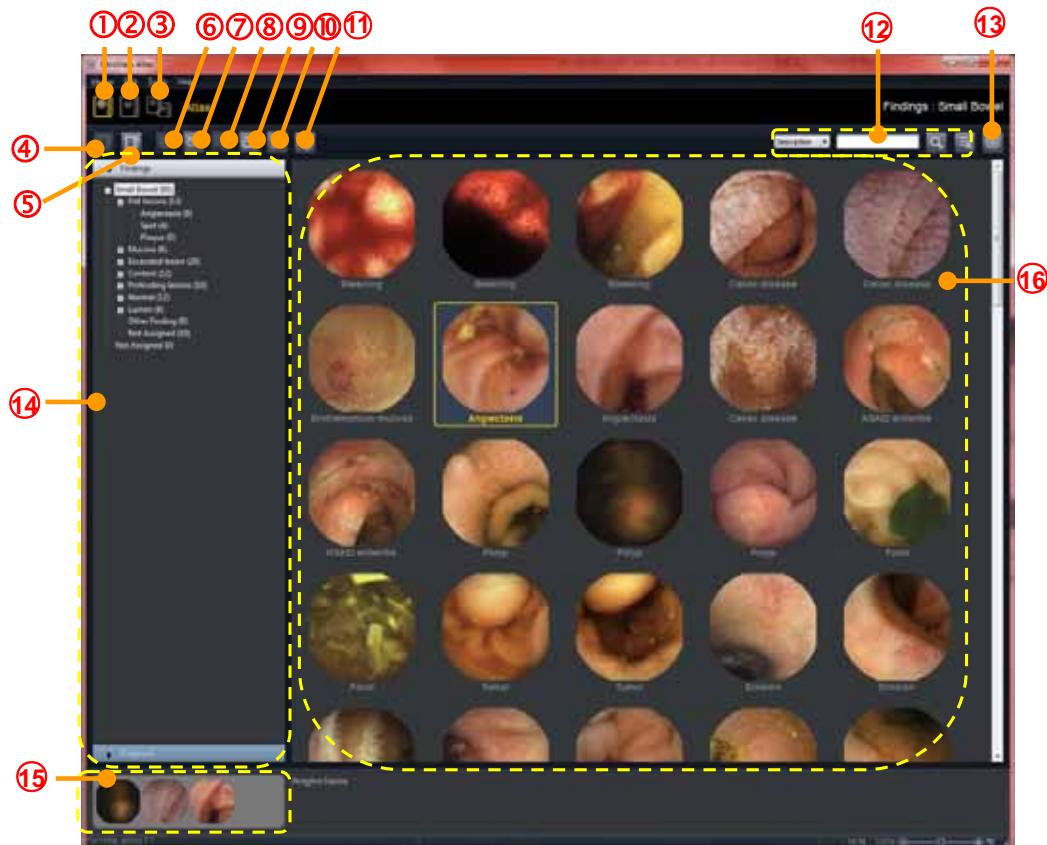
- Select 'Review Data+MiroVideos(.mec)' and click the **OK**.
- Carry out in alphabetical order like following picture.



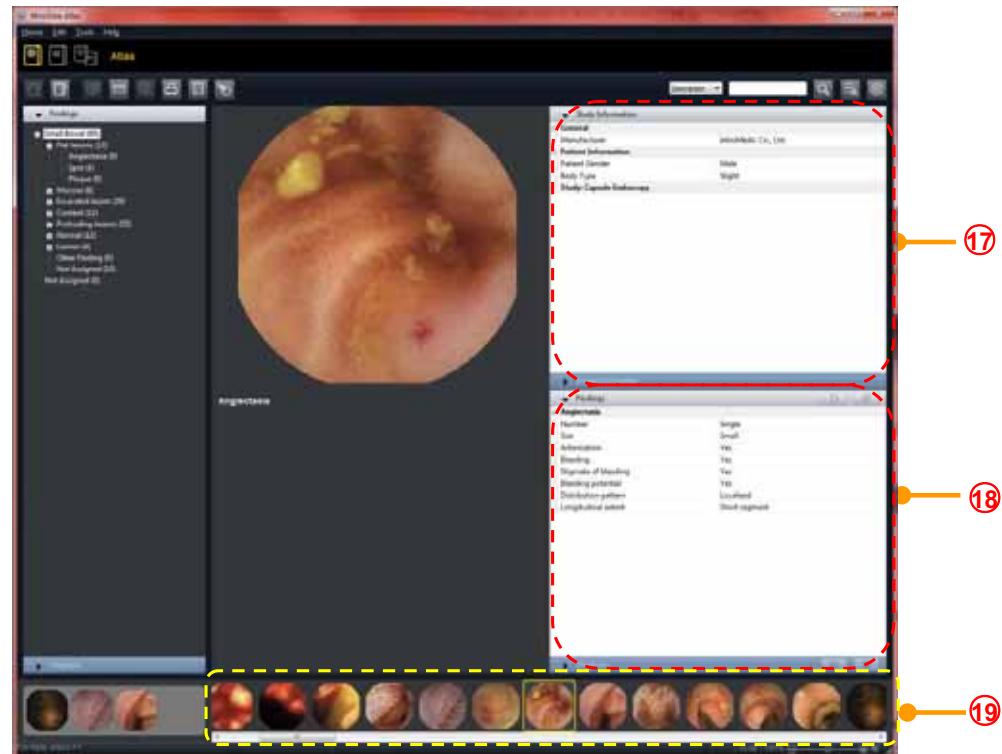
4.6.5 Image Atlas

■ Atlas

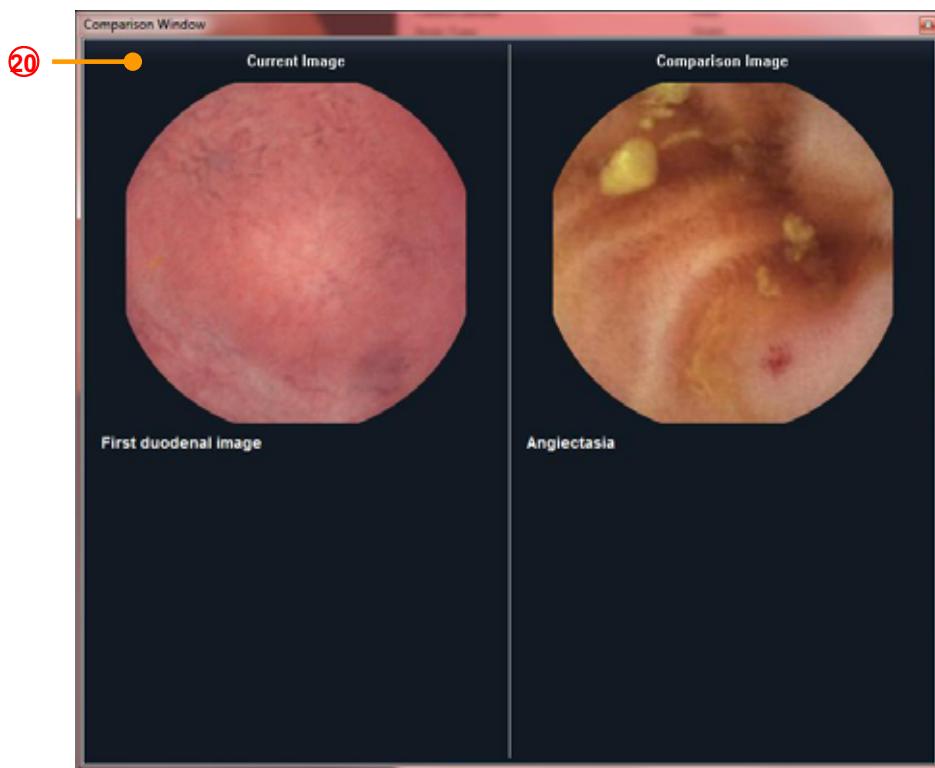
The following picture show via **Help → Atlas**



| | | |
|---|-----------------------------------|--|
| ① | Atlas | Default Atlas Images |
| ② | My Atlas | Atlas Images configured by the user |
| ③ | Atlas + My Atlas | Show Atlas Images and My Atlas Images at once. |
| ④ | Import Atlas Images from file | Import Atlas Images from file; BMP, JPEG, GIF, EMF, WMF, TIFF and PNG file format. |
| ⑤ | Export Atlas Images to file(s) | Export Atlas Images to file; BMP, JPEG, GIF, EMF, WMF, TIFF and PNG file format. |
| ⑥ | Edit Information | Edit the Information of the selected Atlas Image. |
| ⑦ | Export Atlas Image(s) to E-mail | Export selected Atlas Image(s) and send it / them to another doctor via E-mail. |
| ⑧ | Delete Atlas Image(s) | Delete the selected Atlas Image(s) |
| ⑨ | Print Atlas Image(s) | Print the selected Atlas image(s) |
| ⑩ | Save as PDF | Save the selected Atlas Image(s) as PDF |
| ⑪ | Show/Hide Marks | Show / Hide Marks on the Atlas Image(s) |
| ⑫ | Search | Search the Atlas Image |
| ⑬ | Comparison Window | Show the Comparison Window |
| ⑭ | Browser Tab(Findings / Diagnosis) | Area to select the Category of the Atlas Image and to see the selected image. |
| ⑮ | Recent Images | Images the user saw on the Comparison Window |
| ⑯ | Atlas Thumbnail Area | Area to select the Atlas Image. Double-click the Atlas Image to see the Image Information. |

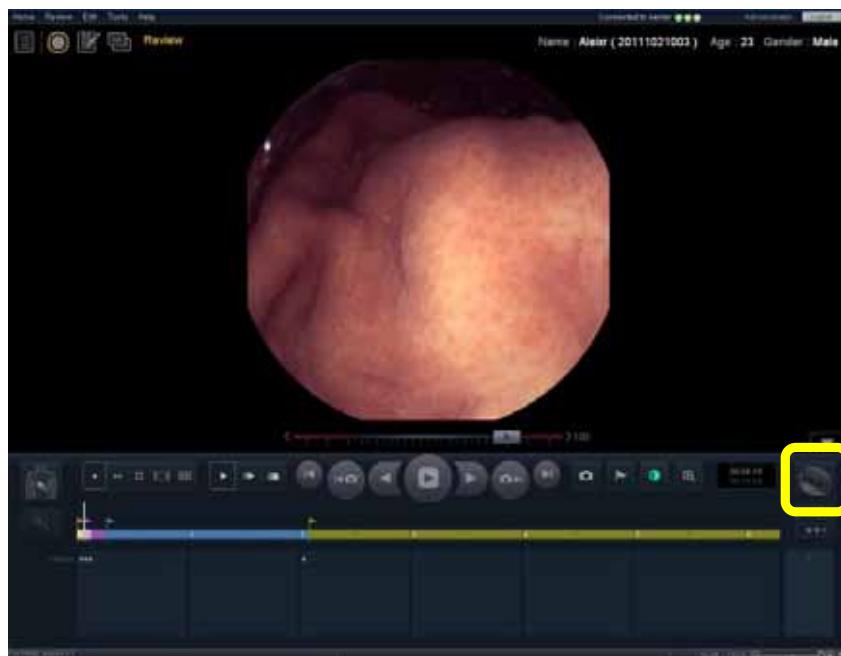


| | | |
|------|--|---|
| (17) | Study Information / Image Information | Show the Information of the Atlas Image |
| (18) | Findings / Diagnosis | Show the Findings / Diagnosis Information |
| (19) | Atlas Thumbnail Area(2) | Search the Atlas Image |

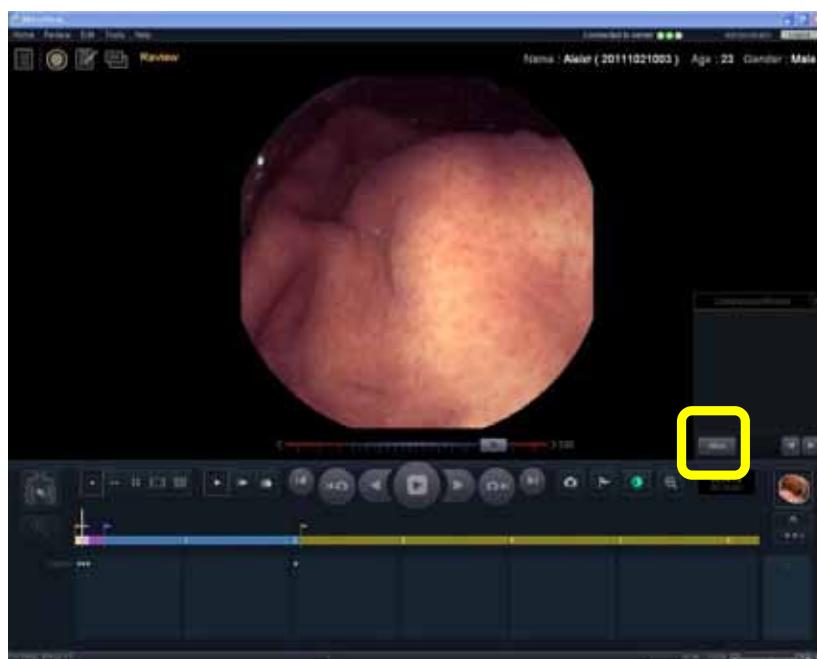


| | | |
|----|-------------------|--|
| ②0 | Comparison Window | Show the Current Image and Comparison Image at once. |
|----|-------------------|--|

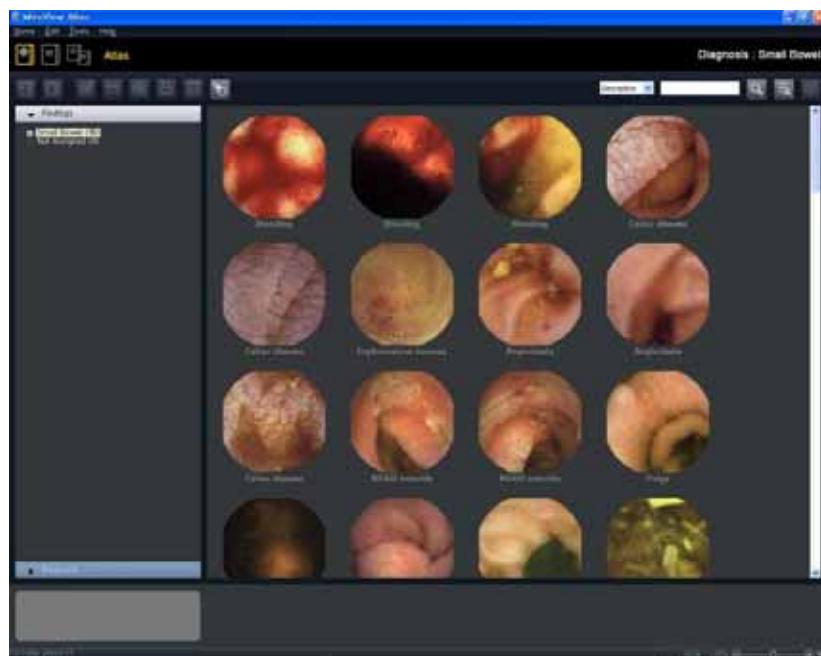
- To compare a captured image with ATLAS image, click the  (Optional).



- Select an image from MiroView™ Atlas to compare the atlas image with the captured image for a side by side comparison. (Option)



- Double-click an ATLAS image for selection.



- To show the ATLAS image on the comparison window, click the on the ATLAS mode.



- The comparison windows will appear. Figure out the current image and comparison image.



- Import Atlas Images from file(s)

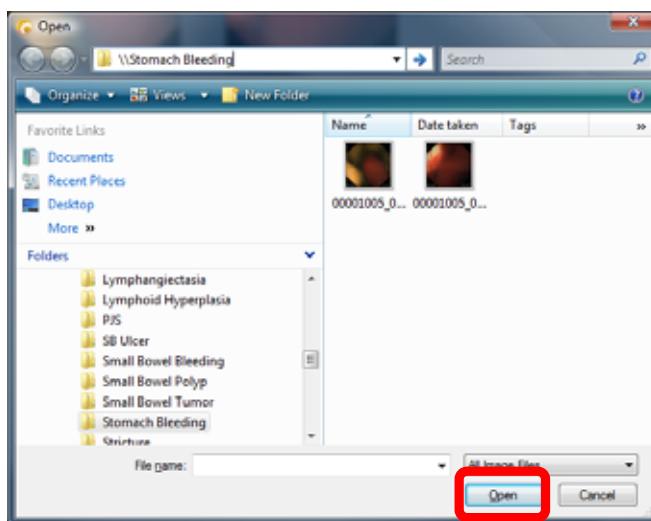
The MiroView™ Software allows the user to import image files for personal purpose.

- Click the to open the 'Open' Browser to look for the files to import.

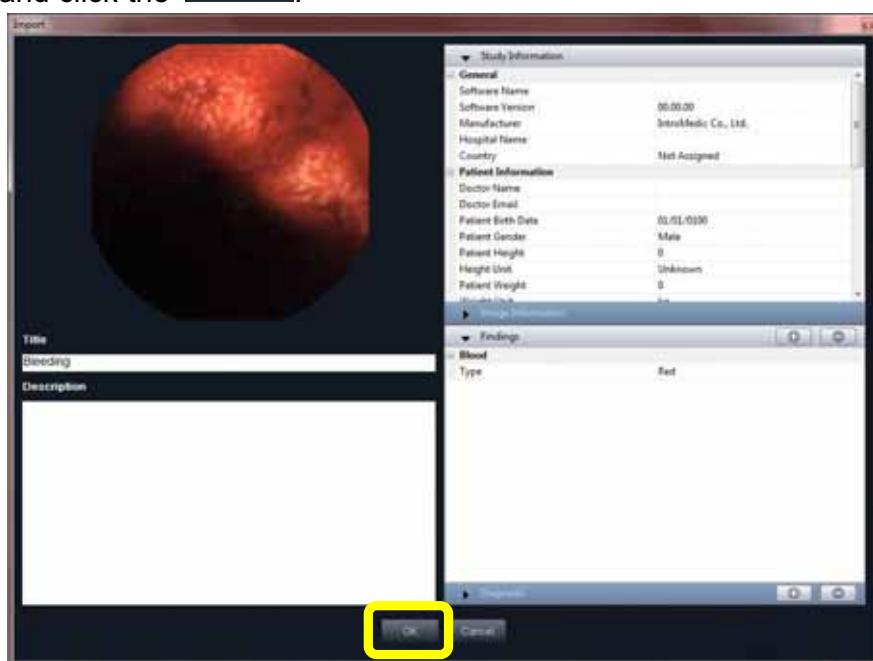
- Import Atlas Images from file(s)

The MiroView™ Software allows the user to import image files for personal purpose.

- Click the  to open the 'Open' Browser to look for the files to import.
- Select the file to import and click the .



- Complete the 'Title', 'Description' and 'Image Information' fields and click the .



4.7 How to import MiroView™ Software 1.0 Files

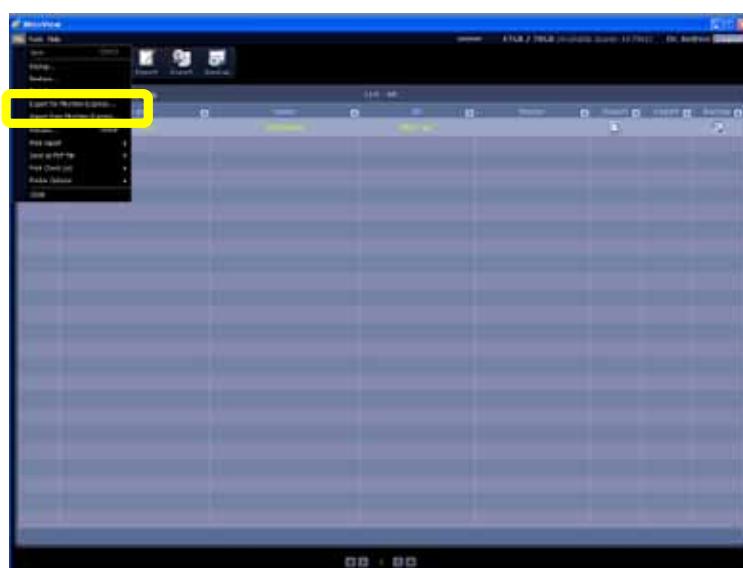
4.7.1 Preparing files for import

- Run the MiroView™ Software 1.0
- Export files by clicking 'Export for the MiroView™ Express' function or back up files by using Backup Mode on the MiroView™ Software 1.0. Before using the Export to the MiroView™ Express function, insert DVD media to the DVD writer or connect the external hard disk or USB flash memory to the workstation via USB port.

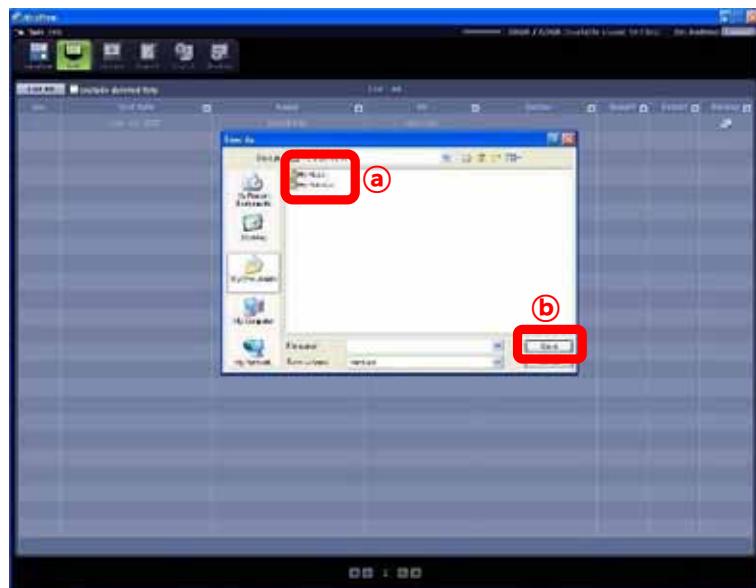


NOTE The MiroView™ Software supports the MiroView™ Software Case / Review files, the MiroView™ 1.0 express files (the MiroCam® Capsule Endoscope System companying with .MMV) and the MiroView™ Software 1.0 backup files(.ifo companying with .ict and .frg files) to import.

- Select a patient file from the list to export to the MiroView™ Express.
- Execute 'Export to the MiroView™ Express...' on the main menu



- If the form, ‘Save As’ appears like below, select the location to export and fill in the ‘File name’ field and click ‘Save’.
- Carry out in alphabetical order like following picture.

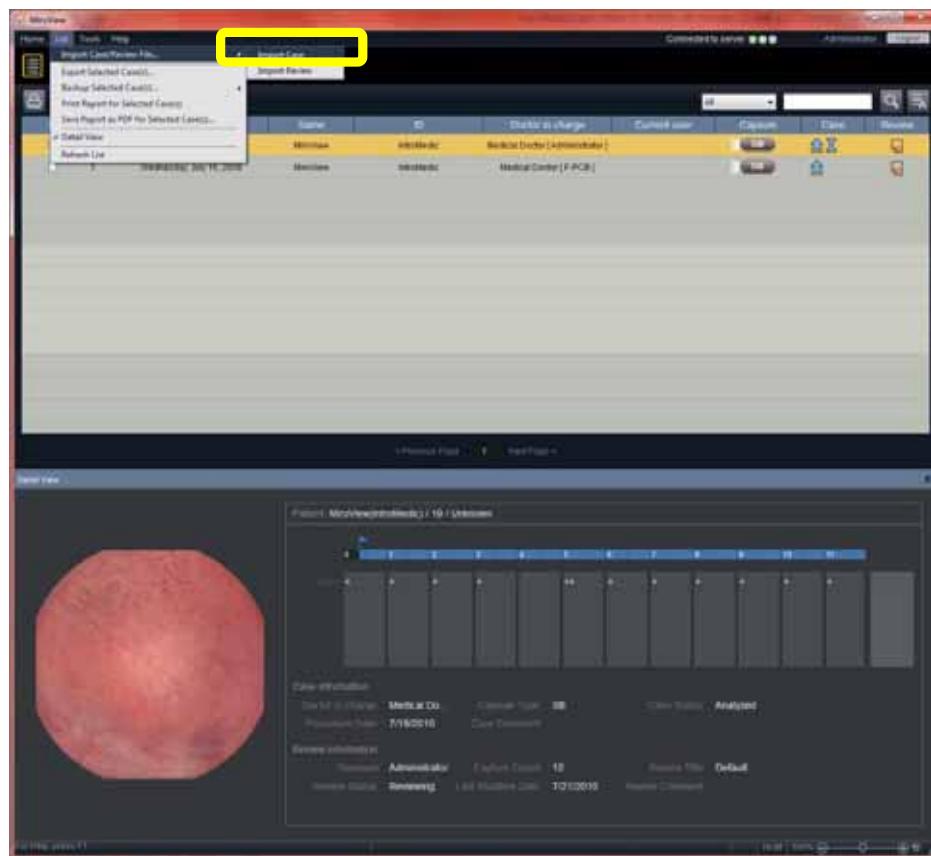


- A window will appear like below and if the function ends successfully A message will appear, “Exporting has been completed.”

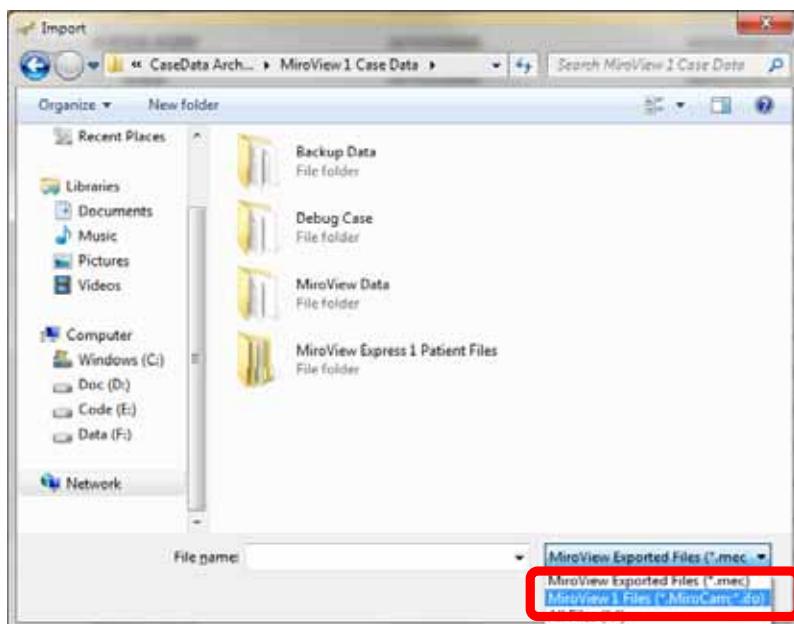


4.7.2 Import MiroView™ Software 1.0 files

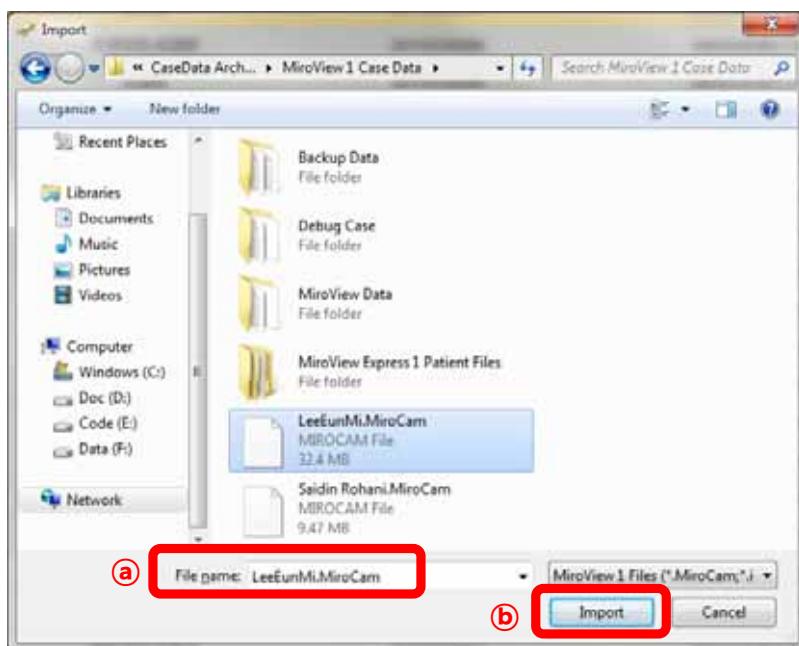
- Run the MiroView™ Operator or MiroView™ Client.
 - Execute the 'Import Case / Review File... -> Import Case' in the 'List' menu



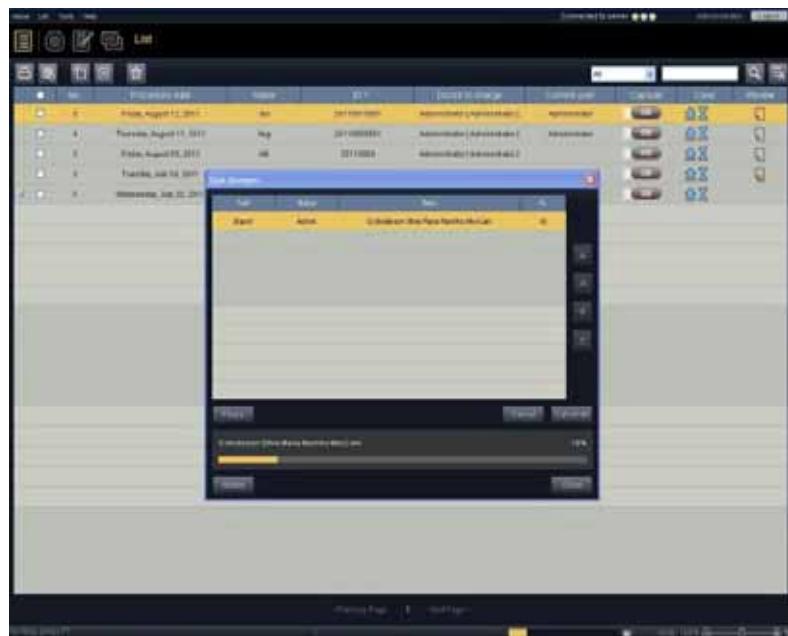
- Select the MiroView™ Software 1.0 files from the file extension drop-down box and look for the file to upgrade



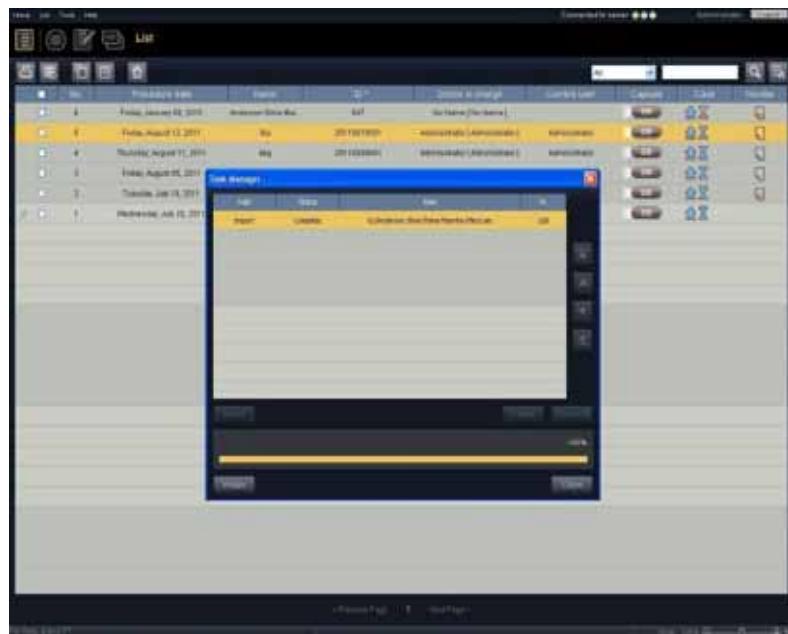
- Look for the File with extension '.MiroCam' and click 'Import'.
- Carry out in alphabetical order like following picture.



- Task Manager will appear and will proceed with importation of the file.
- Progress bar will appear.

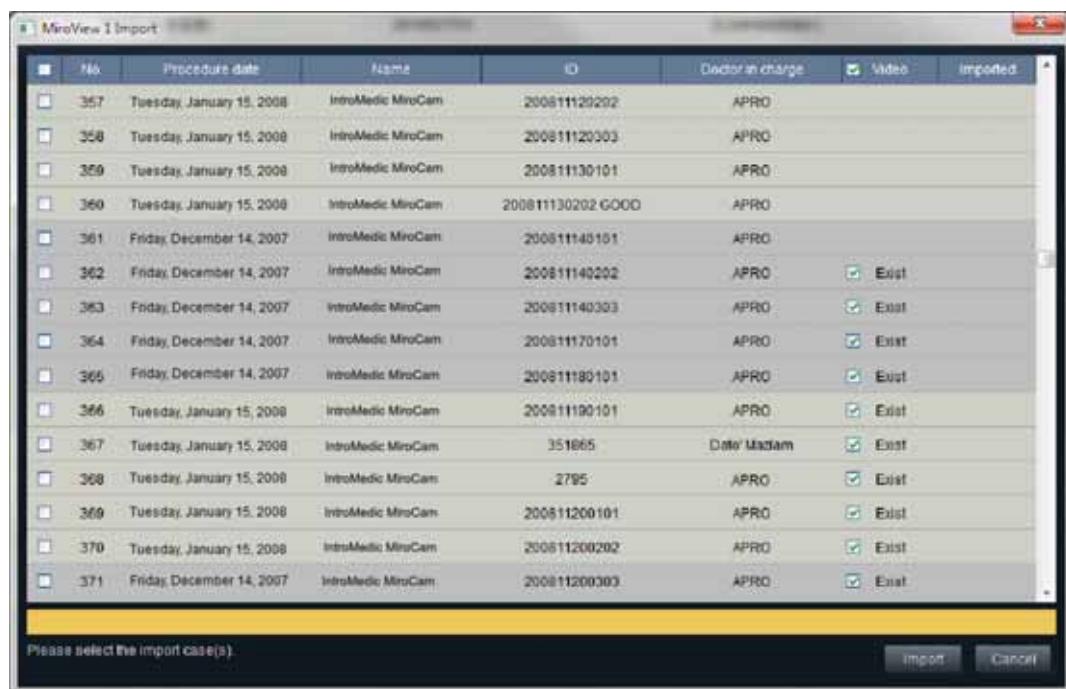


- Upgrading the MiroView™ Software 1.0 file to the MiroView™ Software file will be completed.



4.7.3 MiroView™ Software 1.0 files Batch Import

- If the MiroView™ Software 1.0 is already installed on the workstation, user can use the MiroView™ Software 1.0 files Batch Import function via <Menu -> Tools -> Import from the MiroView™ Software 1.0> in MiroView™ Operator (or <Menu -> Home -> Import from the MiroView™ Software 1.0> in the MiroView™ Client) so that MiroView™ can use the imported cases. Choose the cases to import and click the **Import**.

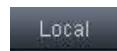


- To import cases without video file, uncheck the check box on the Video column.

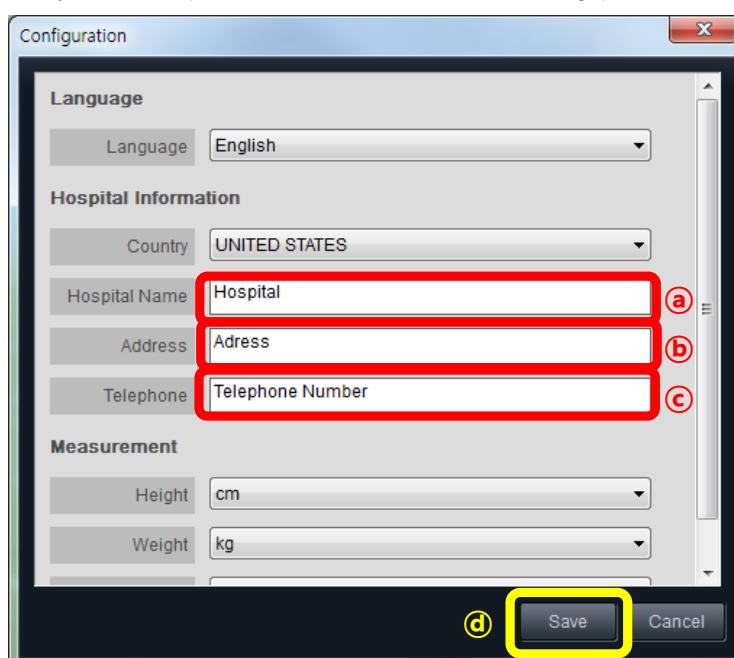
4.7.4 Using MiroView™ Client at Local PC without connecting to MiroView™ Server

- Run the MiroView™ Client by double-clicking the  on the desktop or from the Windows Start-up menu. Log in.
- Carry out in alphabetical order like following picture.

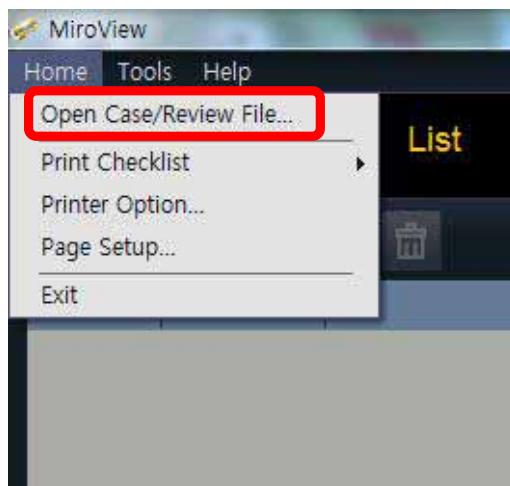


*If running the MiroView™ Client as Local Mode, click the  on the Log-in screen.

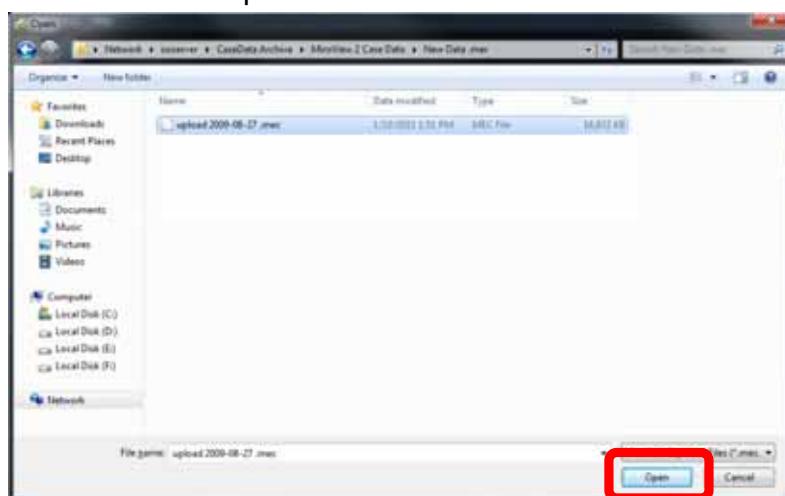
- At the first running of 'Local Mode', the window will appear like below. Input the appropriate values in to the empty fields and click the  to proceed.
- Carry out in alphabetical order like following picture.



- Open the Case/Review via Menu → Home → Open Case/Review file...



- Choose a file to open and click the **Open**.



- After completely reviewing the file, save the review via **Menu → Home → Save Active Review** so that the user can import the edited review file on the MiroView™ Server in the future.



5

Using MiroView™ RTV

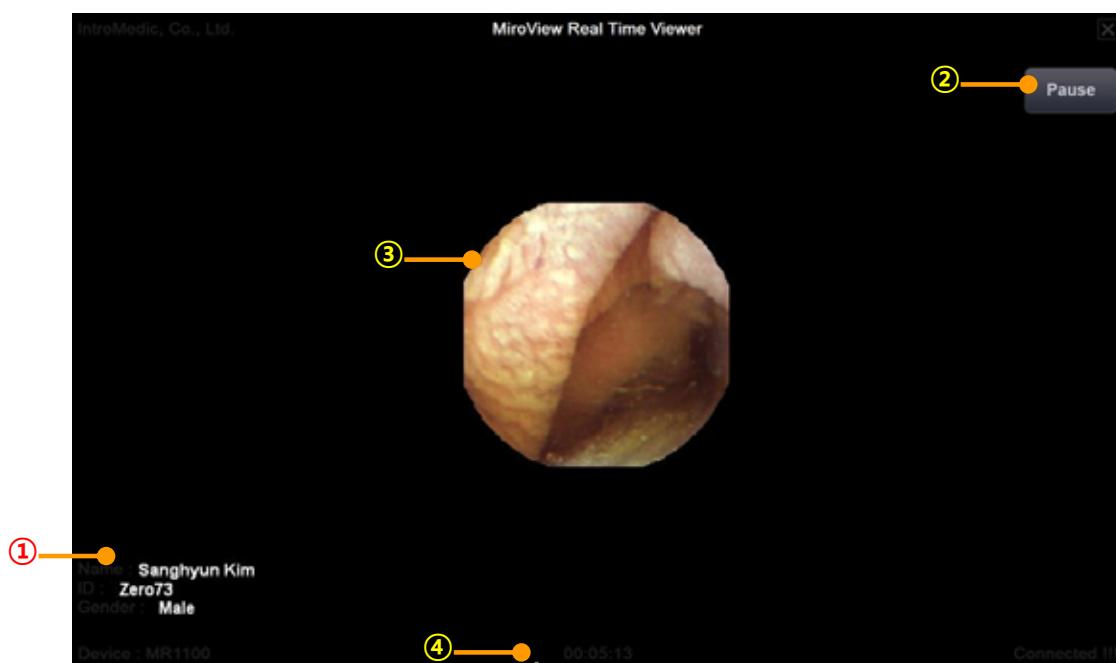
5. USING MIROVIEW™ RTV

The MiroView™ RTV, a software application of the MiroCam® System Real-time Viewer, consist of a data transmission module that directly receives the image data from the MiroCam® Receiver and an output module for image display.

5.1 Overview

The MiroView™ RTV software can be installed on any mobile platform. Click the corresponding icon on the desktop to launch the MiroView™ RTV.

Basic Screen Layout



| | | |
|---|---------------------|--|
| ① | Patient Information | Display patient name, ID, gender and age |
| ② | Operation Button | Change the MiroView™ RTV operation status between start, pause and resume. |
| ③ | Main Display | Display captured image. |
| ④ | Time Display | Indicates the MiroCam® Capsule endoscopy procedure time. |

Recommended Hardware Specification

- OS: Windows Vista (32 bit), Windows XP (32 bit),
Windows7 (32 bit)
- CPU: Atom N450(1.66GHz) or higher
- Memory: 1GB or higher
- Display Adaptor: Windows Compatible
- Hard Disk: 80GB memory space available
- Monitor Resolution: 1024 X 600 or higher
- Monitor Contrast : Windows Compatible
- In compliance with IEC60950-1 or IEC60601-1

5.2 Using MiroView™ RTV

5.2.1 Before Using MiroView™ RTV

- Installing the MiroView™ RTV software on a mobile PC.

! WARNING Only recharge the Mobile PC batteries when MiroCam® Receiver does not connect to the Mobile PC.

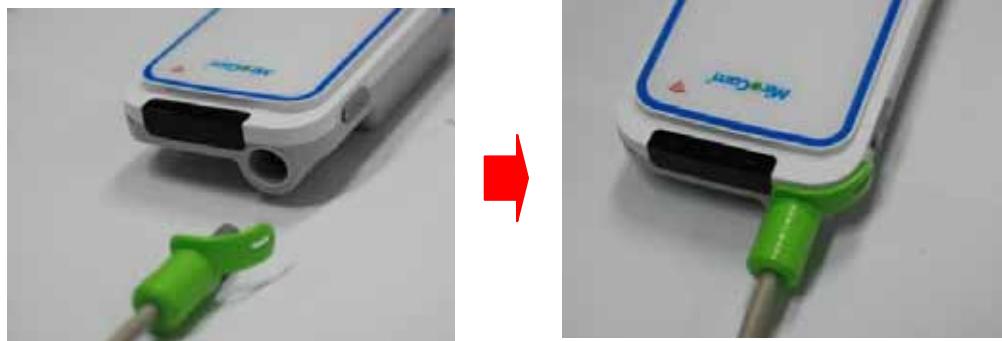
! WARNING For safe use of the Mobile PC, please refer to the Mobile PC User Manual.

! WARNING DO NOT use the MiroView™ RTV software and the Mobile PC before upgrading MR1000.

! WARNING DO NOT upgrade MiroCam® Receiver during the MiroCam® Capsule endoscopy procedure, it may result loss of image data.

! WARNING Use the MiroView™ RTV Software to check if the MiroCam® Capsule entered to the duodenum, small bowl; during a capsule endoscopy procedure. Thus, prior to running the MiroView™ RTV software, please make sure that the MiroCam® Capsule endoscopy procedure has been undergone.

- Connect the data cable of the Real-time Viewer to the MiroCam® Receiver.



! NOTE The data cable for the MiroView™ RTV has no cover for the USB port on the MiroCam® Receiver.

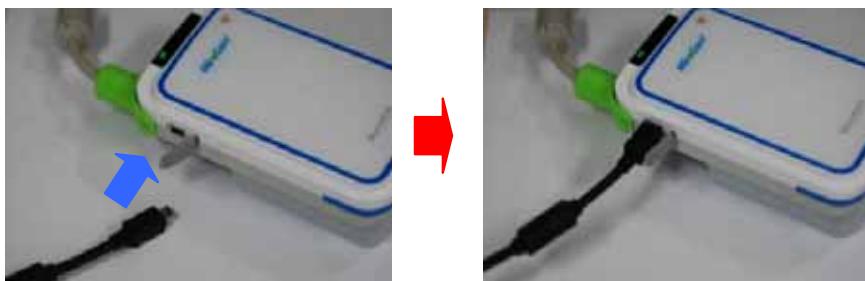
- Follow the MiroCam® Capsule endoscopy procedure.



NOTE For more information on the MiroCam® Capsule endoscopy procedure, please refer to **Chapter 3, Performing Capsule Endoscopy**.

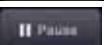
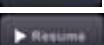
5.2.2 Starting MiroView™ RTV

- Switch on the Mobile PC.
- Click the  on the screen to launch the MiroView™ RTV.
- Connect the small side of the USB cable to the MiroCam® Receiver.



- Connect the large side of the USB cable to the Mobile PC.



- Click the  to start image display
- Click the  to stop image display
- Click the  to restart image display
- Click the  on the top-right to close the MiroView™ RTV.



NOTE To Start, Pause, and Resume use the same button. The function (Start, Pause or Resume) changes based upon the status of the MiroView™ RTV software.



CAUTION DO NOT disconnect the MiroCam® Receiver while the RTV software is running. If the MiroCam® Receiver is disconnected during use, the software may need to be restarted.



NOTE If an error message appears while using the MiroView™ RTV, reconnect the USB cable between the MiroCam® Receiver and the Mobile PC

5.2.3 After Using MiroView™ RTV

- Disconnect USB cable between the MiroCam® Receiver and the Mobile PC.
- Continue MiroCam® Capsule endoscopy procedure.

6

Using Wireless MiroView™ RTVi

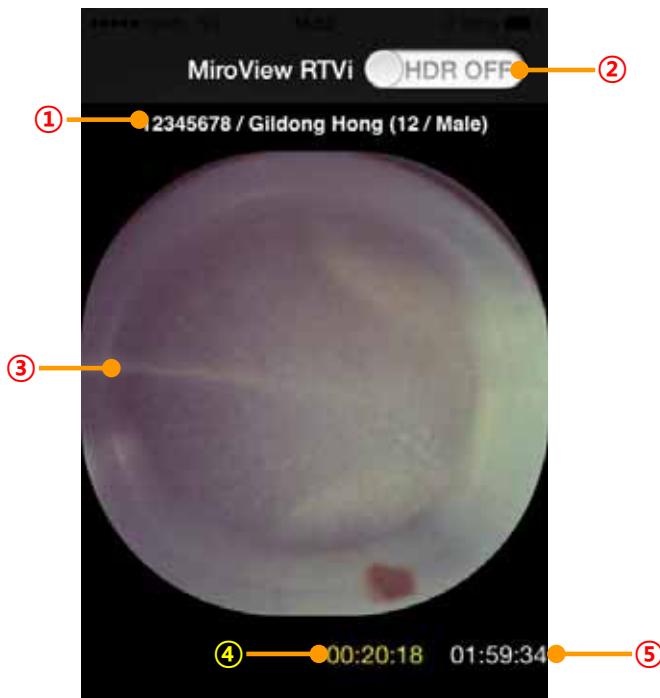
6. USING WIRELESS MIROVIEW™ RTVi

The Wireless MiroView™ RTVi, a software application of MiroCam® System Real-time Viewer, consist of a data transmission module that directly receives the image data from the MiroCam® Receiver and an output module for image display. The Wireless MiroView™ RTVi receives image data via Wi-Fi channel.

6.1 Overview

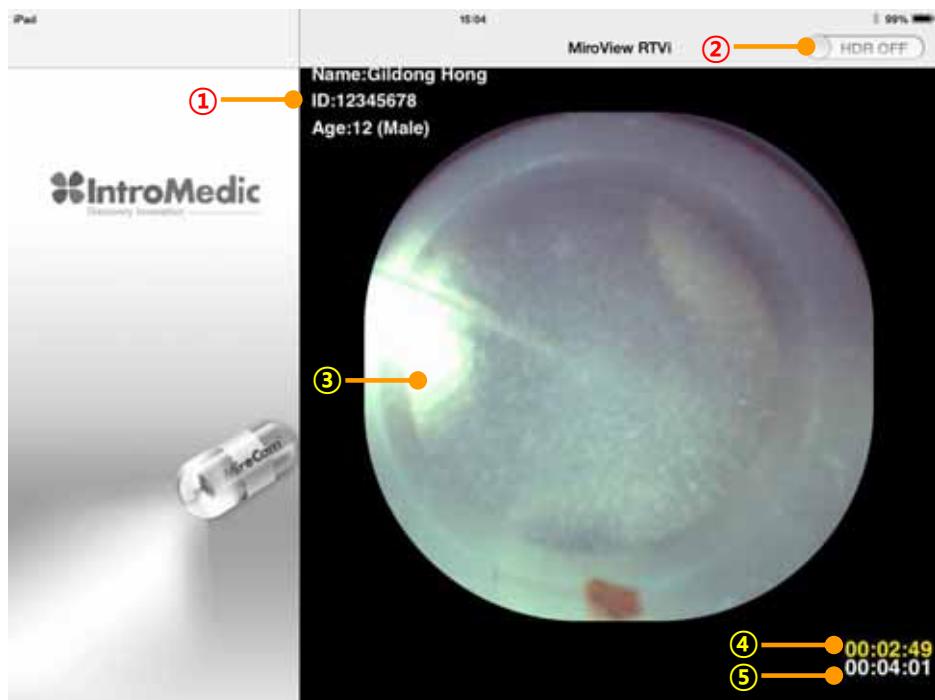
The Wireless MiroView™ RTVi software can be installed on iOS running on iPad / iPhone. Click the corresponding on the desktop to launch the Wireless MiroView™ RTVi.

6.1.1 Basic Screen Layout – iPhone



| | | |
|---|----------------------|--|
| ① | Patient Information | Display patient name, ID, gender and age |
| ② | HDR Button | High Dynamic Range Image Button |
| ③ | Main Display | Display captured image. |
| ④ | Wi-Fi Operation Time | Indicates the MiroCam® Wi-Fi operation time |
| ⑤ | Recording time | Indicates the MiroCam® Capsule recording time. |

6.1.2 Basic Screen Layout – iPad



| | | |
|---|----------------------|--|
| ① | Patient Information | Display patient name, ID, gender and age |
| ② | HDR Button | High Dynamic Range Image Button |
| ③ | Main Display | Display captured image. |
| ④ | Wi-Fi Operation Time | Indicates the MiroCam® Wi-Fi operation time |
| ⑤ | Recording time | Indicates the MiroCam® Capsule recording time. |



NOTE If turning the iPad upright as Portrait View, the MiroCam® Receiver List will disappear from the Main Display to be enlarged.

6.1.3 Recommended Hardware Platform

- iPhone 3G, 3GS, 4, 4S, 5
- iPad I, II (with only Wi-Fi)

6.2 Using Wireless MiroView™ RTVi

6.2.1 Before Using Wireless MiroView™ RTVi

- Installing the Wireless MiroView™ RTVi software on iOS on iPhone or iPad.
- The effective distance between the MiroCam® Receiver and iPhone or iPad is within 3m.

⚠ WARNING Use the Wireless MiroView™ RTVi Software to check if the MiroCam® Capsule entered to the duodenum and small bowel during a capsule endoscopy procedure. Thus, prior to running the Wireless MiroView™ RTVi software, please make sure that the MiroCam® Capsule endoscopy procedure has been undergone.

- ! NOTE** For more information on the MiroCam® Capsule endoscopy procedure, please refer to ***Chapter 3, Performing Capsule Endoscopy***.
- ! NOTE** When the Wireless MiroView™ RTVi run at first, network configuration for iPhone or iPad is required.

6.2.2 Turn on the Wi-Fi function of the MiroCam® Receiver.

- Press the Wi-Fi switch of MiroCam® Receiver.



- Keep pressing it until the buzzer sounds.

! WARNING DO NOT press the Wi-Fi switch when the buzzer sounds. It can cause the lost of captured images.

! WARNING The Wi-Fi switch of MiroCam® Receiver can be turned on involuntarily. Therefore, be careful it is not turned on.

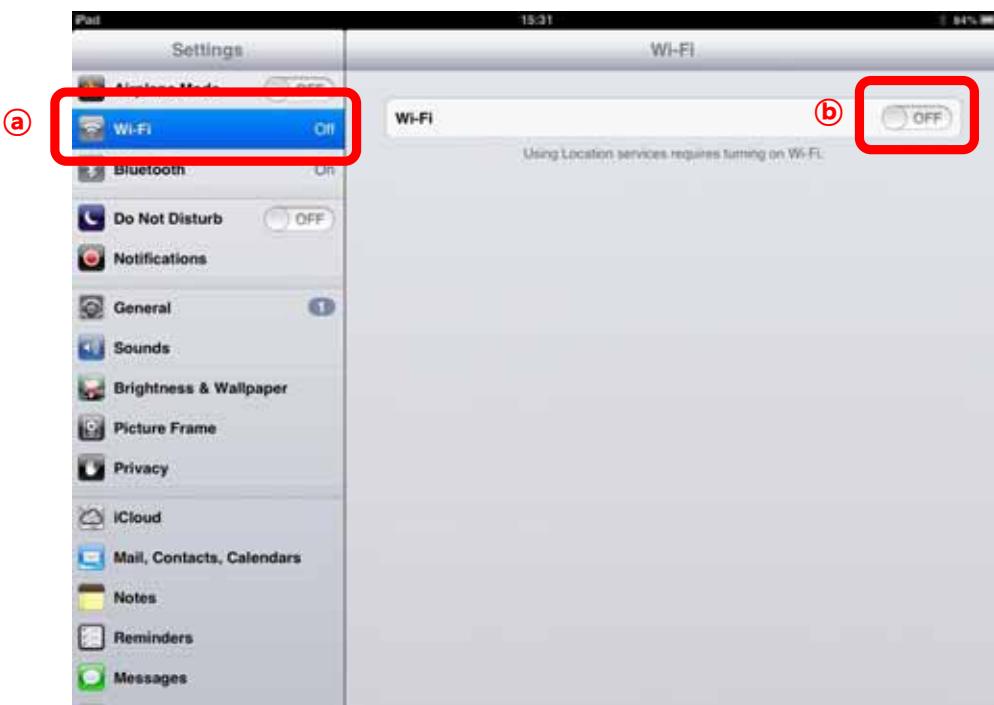
! WARNING The MiroView™ RTVi application can only be used for a total of 30 minutes during the entire MiroCam® Capsule Endoscopy Procedure.

6.2.3 Wireless MiroView™ RTVi.

- Run the Settings for the iOS.

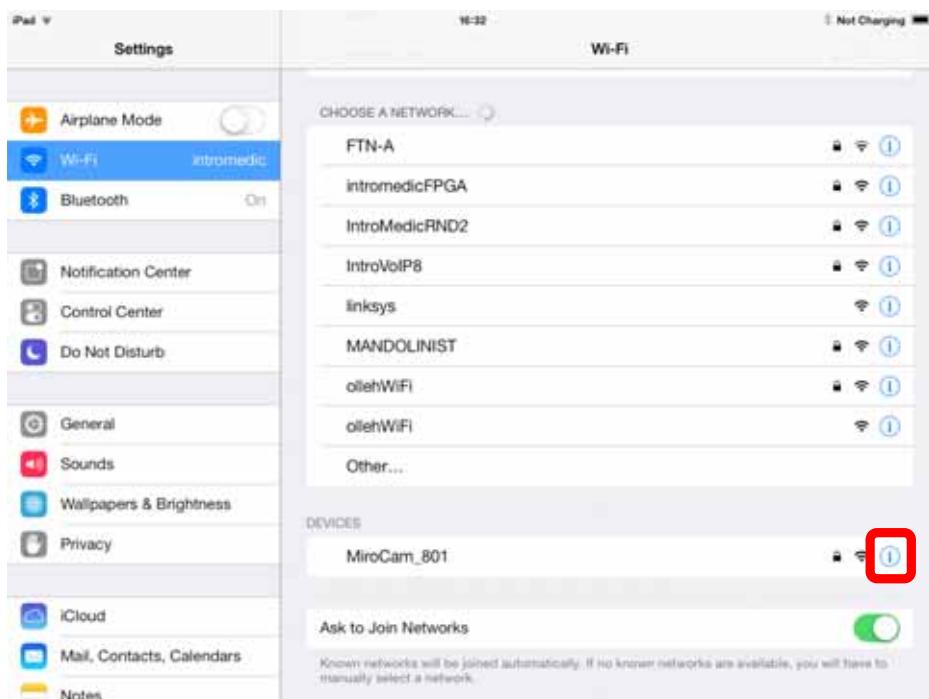


- Turn on the Wi-Fi. If Wi-Fi is already turned on, please turn it off and turn it back on. Carry out in alphabetical order like following picture.



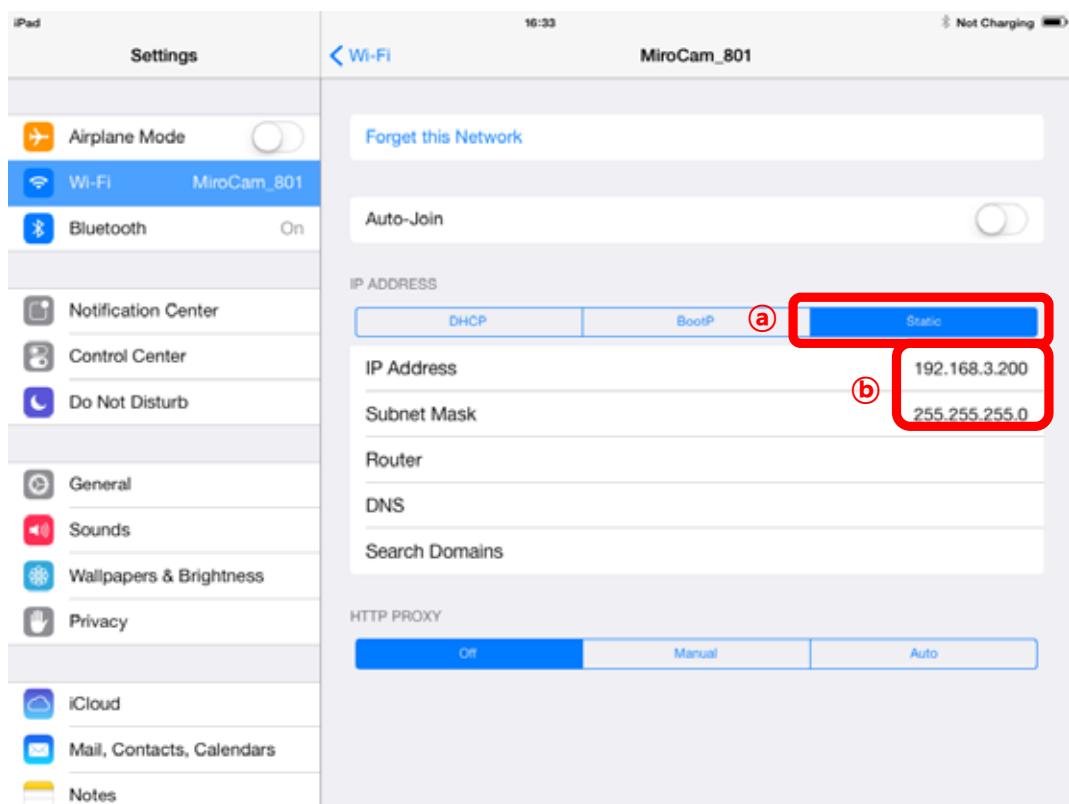
6.2.4 TCP/IP Configuration (for the first time to connect a MiroCam® Receiver access point: AP)

- Check a network with SSID of MiroCam_xxx in the network list.
- Click the  on the SSID (MiroCam_xxx).

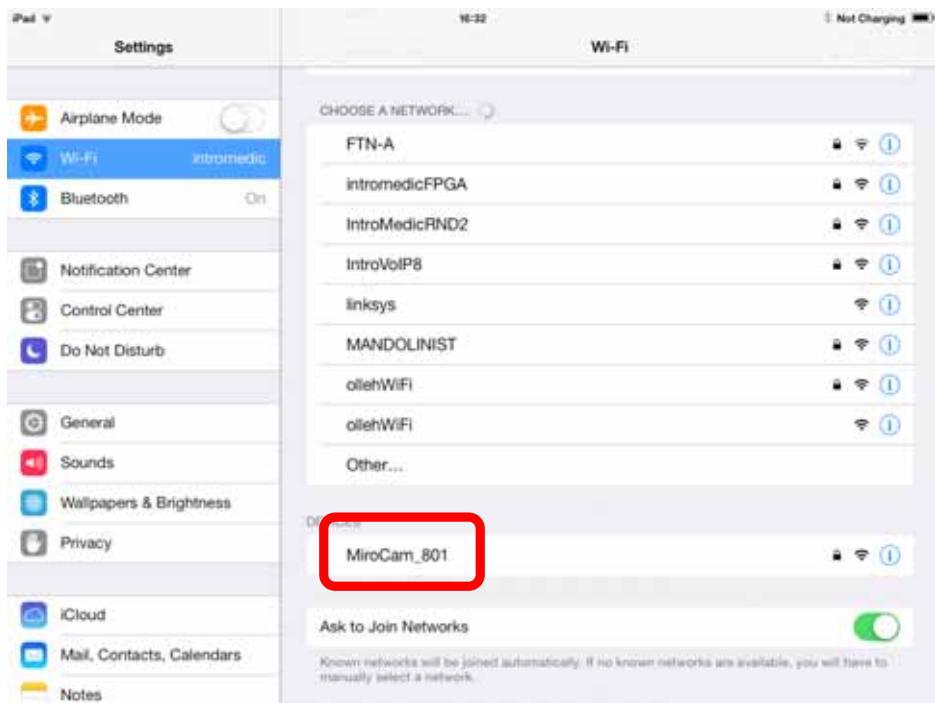


NOTE TCP/IP configuration is needed once at first.

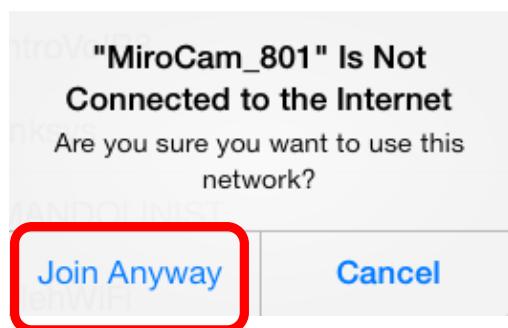
- Click the **Static**
- Click the **< Wi-Fi** on the top-left after entering the IP Address and Subnet Mask. (Setup as Static; IP Address: 192.168.3.200, Subnet Mask:255.255.255.0)
- Carry out in alphabetical order like following picture.



- Click the SSID.



- Click the [Join Anyway](#).



- Enter the password '1234567890' in the field with instruction of system. Afterward, click the **Join**.Carry out in alphabetical order like following picture.



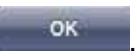
- Press home button when network connection finished.

6.2.5 Running Wireless MiroView™ RTVi

- Click the  on the desktop to launch the Wireless MiroView™ RTVi.

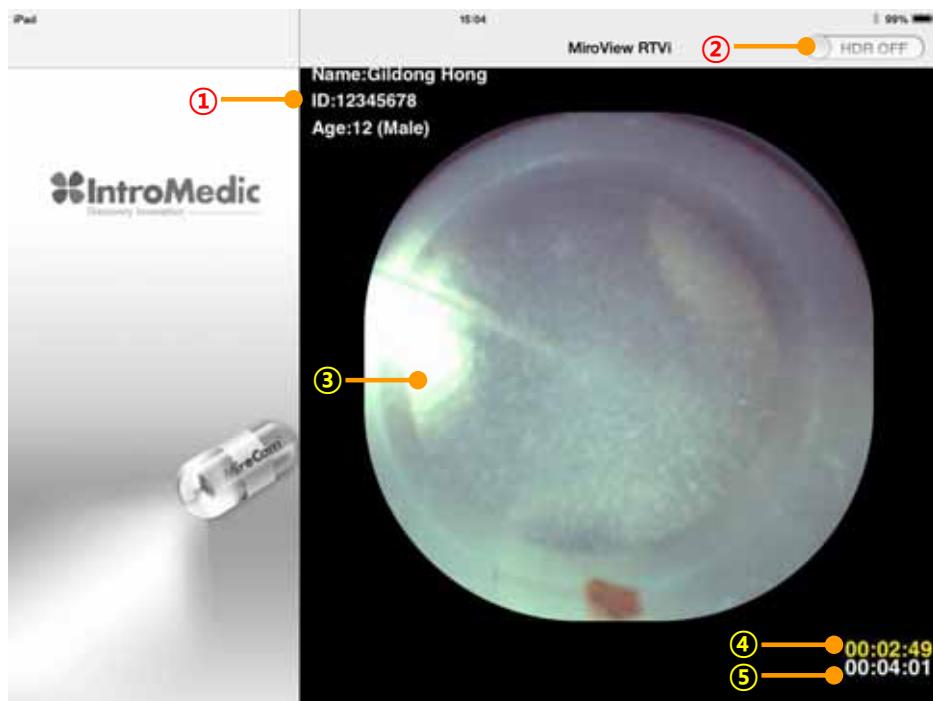


- The Splash window will appear for a while and then will disappear.

- Enter the password '1234567890' in the field with instruction of system. Afterward, click the  . Carry out in alphabetical order like following picture.



- Check whether Patient Information, MiroCam® Receiver Scan Button, Main Display, Wi-Fi Operation Time and Recording time are displayed normally.



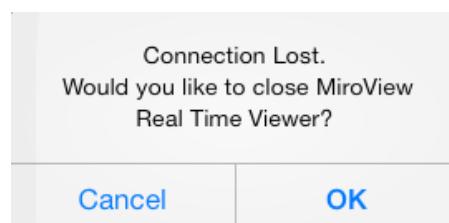
| | | |
|---|----------------------|--|
| ① | Patient Information | Display patient name, ID, gender and age |
| ② | HDR Button | High Dynamic Range Image Button |
| ③ | Main Display | Display captured image. |
| ④ | Wi-Fi Operation Time | Indicates the MiroCam® Wi-Fi operation time |
| ⑤ | Recording time | Indicates the MiroCam® Capsule recording time. |

6.2.6 After Using Wireless MiroView™ RTVi

- To close the Wireless MiroView™ RTVi, press the home button and then check whether the Wi-Fi light of the MiroCam® Receiver is off.



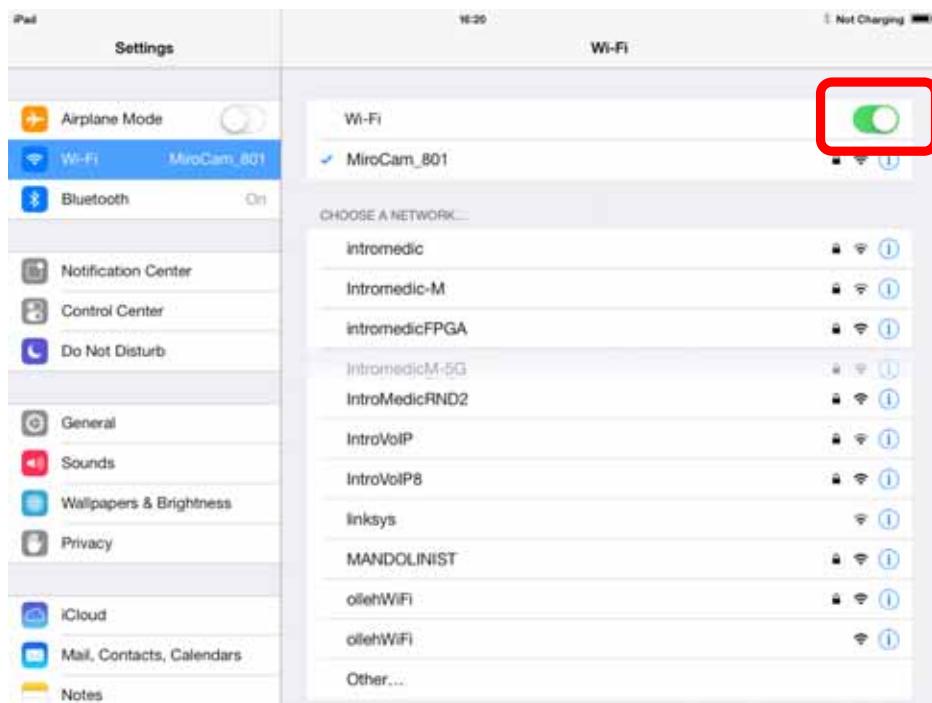
NOTE If MiroCam® Receiver is turned off, following window will appear after about 10 seconds. To Close this window, click the **OK**.

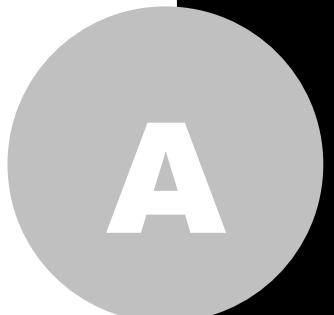


- Run the Settings for the iOS.



- Turn Wi-Fi off and turn it back on.





A

Appendix

Case Form Report

Case Form Report

Trial ID :

Version No. : 1.0 : 30/07/2007

CASE REPORT FORM

| | | |
|---------------------------|--------------------|-------------|
| Subject No.: | Subject Initials : | Center No.: |
| Principal Investigator | : | |
| Center Name | : | |
| Address | : | |
| Telephone No. | : | |
| Fax No. | : | |
| E-mail | : | |

CONFIDENTIAL

Trial ID :

Version No. : 1.0 :

30/07/2007

Screening

| | | |
|--------------|--------------------|-------------|
| Subject No.: | Subject Initials : | Center No.: |
|--------------|--------------------|-------------|

Date of Informed consent signed

| | | | | | | | |
|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|
| <input type="text"/> |
| D | M | M | Y | Y | Y | Y | Y |

Inclusion Criteria

| | Yes | No | N/A |
|--|--------------------------|--------------------------|--------------------------|
| 1. Informed consent form voluntarily signed | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Male / Female subject of age 19 years~70 years. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

If there is one or more mark of 'No', you shall be contradicted for this clinical test.

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Case Form Report

Trial ID :

Version No. : 1.0 : 30/07/2007

Screening

| | | |
|-----------------|--------------------|---|
| Subject No.: | Subject Initials : | Center No.: |
| Date of visit : | | <input type="text"/> |
| | | D M M Y Y Y Y |

Exclusion Criteria

| | Yes | No | N/A |
|---|--------------------------|--------------------------|--------------------------|
| 1. Do you have a gastrointestinal disorder (suspected malignant lesions or gastrointestinal obstructive disorders, perforation, stenosis or fistula)? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Do you have a cardiovascular disorder (dysrhythmia, trouble with cardiac conduction system, hypertension (high blood pressure) or ischemic heart disease)? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Have you been diagnosed of cardiac insufficiency, angina pectoris or cardiac arrest (heart attack) in recent 6 months? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Are you with (or implanted) medical devices such as cardiac pacemaker or defibrillator? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. Do you have a swallowing disorder? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. Do you have delayed gastric emptying or serious gastric disorder? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. Are you a pregnant or nursing woman, or a woman of child bearing potential? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. Are you an infant or epileptic? Are you easily affected by electronic waves? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. Do you have several small bowel diverticulum? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. Did you fail to obtain a voluntary agreement? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 11. Are you judged unqualified for this test by doctors or nurses? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| If there is one or more mark of 'Yes', you shall be contradicted for this clinical test. | | | |

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Case Form Report

EC Representative

SeDa S.p.A

20090 Trezzano sul Naviglio(MI),
Via Toistoi, 7 Italy
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Mobile: +39-02-48424290



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CAUTION: Federal (U.S.A) law restricts this device to sale by or on
the order of a physician.

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The device complies with Part 15 of the FCC Rules. Operation is subject to the condition that this device does not cause harmful interference.

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 instruction, may cause harmful interference to radio communication. However, there is no guarantee that interference will not occur in a particular installation. If this equipment dose 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.

Caution

Any changes or modifications (including the antenna) made to this device that are not expressly approved by the manufacturer may void the user's authority to operate the equipmen



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