MiroCam

MiroCam Capsule Endoscope

User Manual

Smallest Capsule & Highest Resolution

Discovering Medical Innovations

IntroMedic
Capsule Endoscope

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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.

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Safety Information

1. SAFETY INFORMATION

1.1 Warnings

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

MiroCam® 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.

IEC 348: Notice for the user to pay special attention to the following details

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

1.3 Function Symbols

1.3.1 MiroView™ Function Symbols

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

Symbol	Description	Symbol	Description
	Connect to the receiver and open receiver control screen.		Open the report screen to create a patient capsule endoscopy report.
	Open the patient data screen.		Open screen to export (save externally) selected image data for a specific patient.
	Open screen to review for a specific patient		Open screen to backup image data for a specific patient.
	Select and save an image being reviewed.		Place a landmark in an image being reviewed.
	Move to the previous image.		Move to the next image.
	Move to the previous captured image.		Move to the next captured image.
	Play images in sequential order.		Play images in reverse order.
	Stop playback of images.		Show images in full screen
	Show images in a single screen.		Show images in the dual screen.

Symbol	Description	Symbol	Description
	Show images in the quad screen.		Play all images.
	Play the selected images only. View images via Quick Mode function.		SGIB - Play the images captured via Suspected GI Bleeding function.
	Show images in the Capture Box by group.		Show all images in the Capture Box.
	When editing the captured image in the report mode, add a circle on the captured image.		When editing the captured image in the report mode, add an arrow on the captured image.
	Erase the circle or arrow displayed in an image when a report is created.		Select a color to use in an image when a report is created.
	Cancel the last action applied to an image when a report is created.		Re-apply the cancelled changes when a report is created.
	Indicate that a report for the selected patient is being created.		Indicate that a report for the selected patient has been created.
	Indicate that image data for the selected patient has been exported.		Indicate that image data for the selected patient has been backed up.
Log out	User logs out from MiroView™.	Whole list	Show the complete list of patients

1.3.2 Receiver Function Symbols

Symbol		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 Receiver Unit Green : Receiver is initialized Yellow : Receiver is not initialized
BAT		Battery Status Green : Fully charged Yellow : Not charged

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 cables. Take care to guard them against mechanical stress (e.g. wheels or heels)!
- The sensor pads, receiver, data cables, and capsules 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 or data cable 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 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 procedure in areas with high vibrations or in environments where high electro-magnetic 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 voltage supplied from the power receptacle matches with the voltage the system requires. Check Voltage and Frequency on the AC/DC adaptor.
- CAUTION: Verify that all connection terminals are securely connected to the system.
- 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.
- CAUTION: Discard the battery according to the regulations of industrial waste. DO NOT discard with general waste.
- DO NOT carry out the 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 receiver while the receiver's data cable and sensor pads are still connected

- DO NOT charge the receiver while the receiver's data cable and sensor pads are still connected.
- Connect USB cable to 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 capsule is disposable and should not be reused.
- The capsule and sensor pads are medical waste, and should be disposed of according to local regulations or WEEE directive on waste disposal.
- Only use the capsule, receiver, data cables and sensor pads in the medical environment condition.
- All products connected with the MiroCam® Endoscope system must be compliant with requirements of IEC60950-1 or UL certifications.

1.4.1 Environmental Conditions for Operation

- Temperature : +10 ℃ - +40℃
- Relative humidity : 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 capsule and 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 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.

CAUTION DO NOT use the 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 have an effect on other products or be effected by other products.
- Follow your doctor’s instructions and abide by the guidelines in the User Manual.
- DO NOT try to upload the data while the data cables are still connected to the receiver.
- DO NOT charge the rechargeable battery in the receiver while the data cable and sensor pads are still connected to the 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 endoscope 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 capsule endoscope procedure, please notify your doctor.
- Always check the connection between the receiver and the data cable.
- Always check that the battery in the receiver is fully charged before use.
- DO NOT use the capsule if the package is unsealed.
- After ingesting the capsule, always check whether the capsule has been excreted.
- Prior to undergoing the 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 procedure. The patient must fast for 11 hours prior to ingesting the capsule.
- If recommended by the physician, the patient may take a laxative prior to the procedure.
- DO NOT smoke for at least 12 hours prior to the capsule endoscope procedure.
- DO NOT apply body lotion before the procedure.
- DO NOT bite the capsule.
- Avoid excessive physical activity during the capsule endoscope procedure.
- 2 hours after ingesting the capsule, patients may drink water, and after 4 hours, patients may have liquid food.

- When undergoing the capsule endoscope procedure, DO NOT make physical contact with another person undergoing the same procedure.
- During operation of the receiver, DO NOT touch the receiver, or get the receiver wet.
- Only use the provided batteries, and never remove the battery from the receiver during the procedure.
- During upload of the data recorded in the receiver to the PC, avoid disconnecting the USB. This may damage the patient's data.
- Always confirm that the USB is connected by checking the Receiver screen on the MiroView™ software.
- Always check the AC Power range before use the workstation.
- DO NOT touch AC Power code with wet hands.
- DO NOT open the receiver bag or touch receiver outside of the hospital.
- This device is intended for patient over the age of 18.

WARNING The Capsule takes a picture for 11 hours and gets naturally excreted in about 24 hours under normal conditions. If the 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 moving the system, always make sure to disconnect the monitor from the main system, and then safely move the main system and monitor separately. Connect the main system and monitor only after the hardware is fully installed, secure and stable.

1.4.3 Cleaning and Maintenance

- 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, MiroCam® receiver, 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™), 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 procedure by a Physician.
- Not intended for patients with pacemakers and/or defibrillators.
- This device is intended for patient over the age of 18.

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

3

Performing Capsule Endoscopy

3. PERFORMING CAPSULE ENDOSCOPY

3.1 General Comments

- This chapter describes how to operate and control 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 MiroCam® capsule endoscope system.

CAUTION In case the system has been brought from cold environment (stock room or airfreight) into a warm room, you should 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) should be connected to 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 Receiver turns yellow after ingesting the capsule, immediately contact the physician.

CAUTION If SIG indictor of the Receiver does not turn green when the patient holds the capsule by the gold bands, immediately stop the procedure.

NOTE If images of the small bowel are not captured during the procedure, ensure the 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 receiver and register patient data for the capsule endoscopy procedure. For more information see section 4.2.

3.3.1 Start System

- Turn on power of MiroCam® workstation.
- Click icon to start the MiroView™ software program.
- Insert the ID and password and click icon.

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

3.3.2 Initialize the Receiver

- Connect the smaller connector of USB Cable to Receiver unit.
- Connect normal connector of USB cable to workstation.
- Turn on the power of the Receiver unit.
- Click icon in MiroView™.
- Click icon in the top right of MiroView™ screen.
- After end of formatting of MiroCam® Receiver unit, complete patient information and click button.

Note Before clicking the icon in MiroView™, connect USB cable to MiroCam® Receiver unit.

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

3.3.3 Receiver Preparation

- Connect battery to the receiver unit.
  - Insert pins on back side of the receiver unit in the slots on the battery.
  - Press battery to receiver until clasp locks battery in place.
- Turn on power switch of receiver unit.
- Check battery indicator (BAT) of upper side of receiver unit. If battery is fully charged, light will be green. If light is not green, charge the battery.
- Check initialization indicator (INI) of upper side of receiver unit. Prior to beginning a procedure, this light must be green.
- Connect data cable to receiver unit.

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 Receiver Unit Green : Receiver is initialized Yellow : Receiver is not initialized
BAT		Battery Status Green : Fully charged Yellow : Not charged

WARNING DO NOT do begin procedure when receiver unit's battery indicator is not green. This indicates battery is not fully charge or out of order, and patient data may be lost.

3.4 Patient Preparation

Provide the patient with the following instructions to prepare for the capsule endoscope procedure.

3.4.1 Patient Preparation

- One day prior to the capsule endoscope procedure

  - Lunch: Patient can have a normal mean around noon, followed by a liquid diet as instructed by the physician.
  - The patient should fast for at least 12 hours prior to the 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 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 capsule endoscope procedure, and should not ingest any medicine at least 2 hours prior to the 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 procedure.
  - On the day of the capsule endoscope test, the patient should wear comfortable and loose cloths. One-piece clothing should not be worn.
  - Prior to the procedure, do not apply any lotions or perfumes.

- On the day of capsule endoscope 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 taking any food or drink two hours after ingesting the MiroCam® capsule endoscope. Water is permitted after two hours.

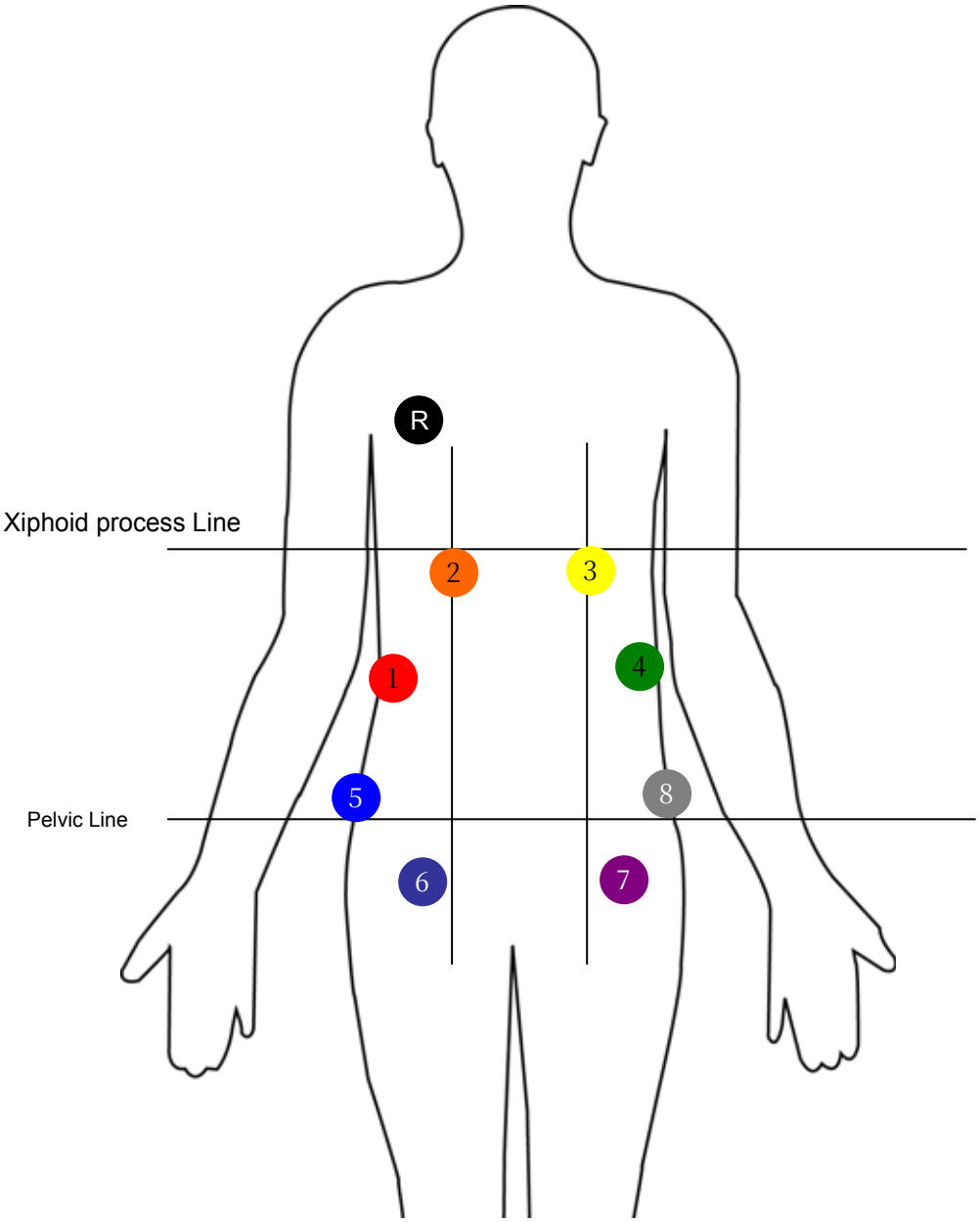
- The patient can start with light food after 4 hours. When the examination is complete, the patient can start having normal meals.
- In case of any abdominal pain, nausea or vomiting after ingesting the MiroCam® capsule, the patient should contact physician or nurse immediately.

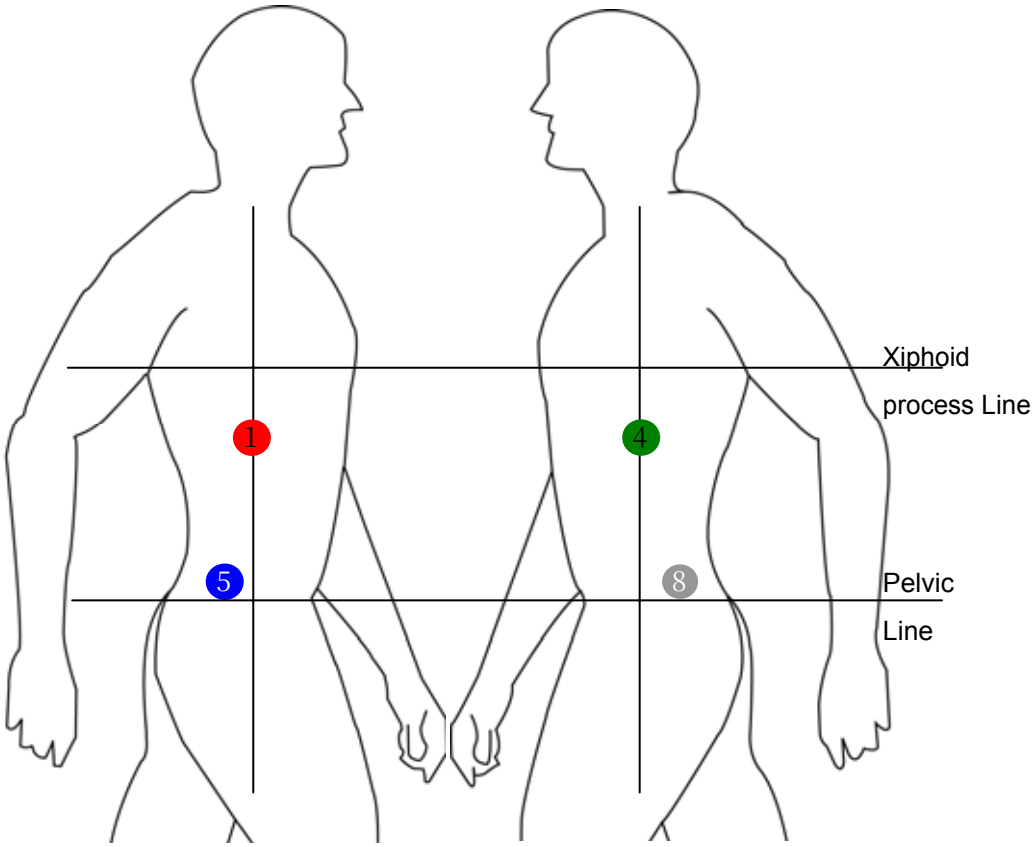
3.5 Sensor Placement & Capsule Ingestion

Following is the detailed procedure required to correctly administer the capsule endoscope 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 Removing Capsule from Packaging

While holding the MiroCam® upside down, peel off the sterilized packaging cover.

3.5.4 Removing the Case

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

3.5.5 Removing the Capsule

Grip capsule with right hand, and remove from cast. Do not touch the dome of the capsule.

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

CAUTION Do not use a capsule endoscope when the packaging or the capsule is damaged.

- Check if the front of the capsule is flashing when it is removed from the case

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

3.5.6 Checking Operation of the Receiver and Signal Reception

After the patient holds the capsule as detailed above, the signal indicator on the 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 receiver.
- Check if the battery indicator (BAT) at the top of the receiver shows that the battery is fully charged. The battery indicator on the

receiver should be green.

- Check if the initialize indicator (INI) at the top of the receiver shows that initialization is complete. The INI indicator on the 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 receiver is green and signal indication melody is generate.

CAUTION If the battery indicator on the receiver shows that the battery is not fully charged, do not start the endoscopy procedure. The battery may be depleted during the procedure and images may not be saved properly.

3.5.7 Ingesting the Capsule

After checking if the signal indicator on the receiver is green, ingest the capsule with water.

CAUTION Do NOT bite the capsule while ingesting.

3.5.8 Checking and Wearing the Receiver

- After ingesting the capsule, make sure that the SIG indicator is green.
- Place the 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.

- Capsule endoscopy procedure will be complete after 11 hours.

CAUTION Patient should not touch receiver during the procedure. This may lead to loss of image data.

3.6 Uploading Images

Once the capsule endoscopy procedure is complete, upload image data from the receiver to the workstation and start diagnosis of the data using MiroView™.

3.6.1 Transferring and Checking image data

- Switch on the workstation.
- Click the icon on the desktop to launch MiroView™.
- When the login window appears, enter the user ID and password, and then click the

button.
- Connect the smaller end of the USB cable to the receiver.
- Connect the other end of the USB cable to the workstation.
- Click the

button in MiroView™.
- Click the

button in the upper right corner of MiroView™.
- When the image data in the MiroCam® receiver is successfully uploaded, click the button in the upper left corner of MiroView™.
- Select the patient image data and click the icon to review patient images.

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

3.7 Receiver Management – Post Procedure

3.7.1 Cleaning

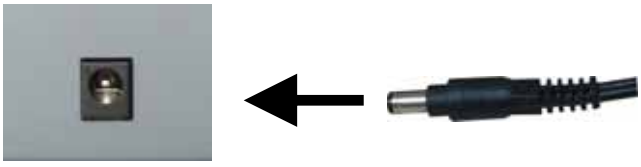
- Remove data cable from receiver unit.
- Capsule and sensor pads should not be reused.
- To clean the MiroCam® Receiver unit and Workstation, dampen a soft cloth with warm water or with a commercial, nonabrasive cleaner (or a mild soap or detergent solution) and wipe the exterior surface lightly. Do 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 cables, do not use the cleaning tools such as brush and sandpaper.

3.7.2 Charging Battery

- Battery must be recharged after every procedure.
- Battery can be individually recharged or with receiver unit.
- Battery must be recharged in 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 code to adaptor.
- Connect AC power code to AC consent 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 receiver.

WARNING Recharge the MiroCam® receiver 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™

4. USING MIROVIEW™

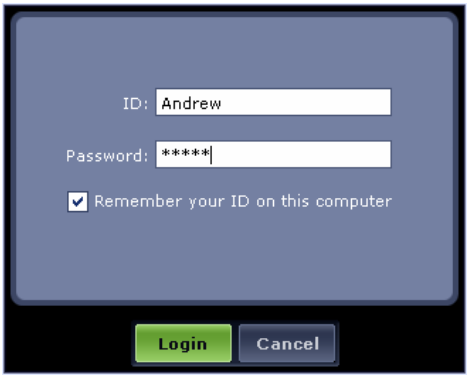
MiroView™ is a computer software program that aids in diagnosis of disease of the small bowel via displaying images obtained from the MiroCam® capsule.

4.1 Before Using MiroView™

MiroView™ will be pre-installed on workstations. Click the corresponding icon on the desktop to launch MiroView™.

4.1.1 Starting MiroView™

- Switch on the workstation.
- Click the icon on the desktop to launch MiroView™.



- When the login screen appears, enter your user ID and password and press the button to access MiroView™.

CAUTION Before starting the system, check the power rating for the workstation.

NOTE If you have forgotten your password, contact your system administrator or local IntroMedic representative.

4.1.2 MiroView™ Icons

Symbol	Description	Symbol	Description
	Connect to the receiver and open receiver control screen.		Open the report screen to create a patient capsule endoscopy report.
	Open the patient data screen of the MiroCam® system.		Open screen to export (save externally) selected image data for a specific patient.
	Open screen to review for a specific patient		Open screen to backup image data for a specific patient.
	Select and save an image being reviewed.		Place a landmark in an image being reviewed.
	Move to the previous image.		Move to the next image.
	Move to the previous captured image.		Move to the next captured image.
	Play images in sequential order.		Play images in reverse order.
	Stop playback of images.		Show images in full screen
	Show images in a single screen.		Show images in the dual screen.
	Show images in the quad screen.		Play all images.

Symbol	Description	Symbol	Description
	View images via Quick Mode function.		SGIB - Play the images captured via Suspected GI Bleeding function.
	Show images in the Capture Box by group.		Show all images in the Capture Box.
	When editing the captured image in the report mode, add a circle on the captured image.		When editing the captured image in the report mode, add an arrow on the captured image.
	Erase the circle or arrow displayed in an image when a report is created.		Select a color to use in an image when a report is created.
	Cancel the last action applied to an image when a report is created.		Re-apply the cancelled changes when a report is created.
	Indicate that a report for the selected patient is being created.		Indicate that a report for the selected patient has been created.
	Indicate that image data for the selected patient has been exported.		Indicate that image data for the selected patient has been backed up.
	User logs out from MiroView™.		Show the complete list of patients

4.1.3 MiroView™ Menus

File Menu	
Save	Save changes (captured images, comments etc.) to Database
Backup…	Backup patient information and image data file (complete file)
Restore…	Restore patient information and image data file into MiroView (from backup file)
Export	Save captured images, videos and/or patient report to a designated storage space (USB etc.)
Export for MiroView Express…	Export patient information and image data file for MiroView Express
Import for MiroView Express…	Import patient information and image data file from MiroView Express
Preview…	Preview of printing image
Print Report	Print current patient report
Save as PDF File	Convert the report to a PDF file
Print check list	Print system and/or patient check list
Printer options	Printer settings
Close	Close MiroView™ Software

Tools Menu	
Settings…	Setting MiroView™ Software
View history of changes…	View history of changes
View personal info…	Display patient information
Delete	Delete the selected file from the list
Reload	Refresh the list of patient files
Play mode	Change the play mode
Show compare window	Show comparison window
Show position window	Show positioning window

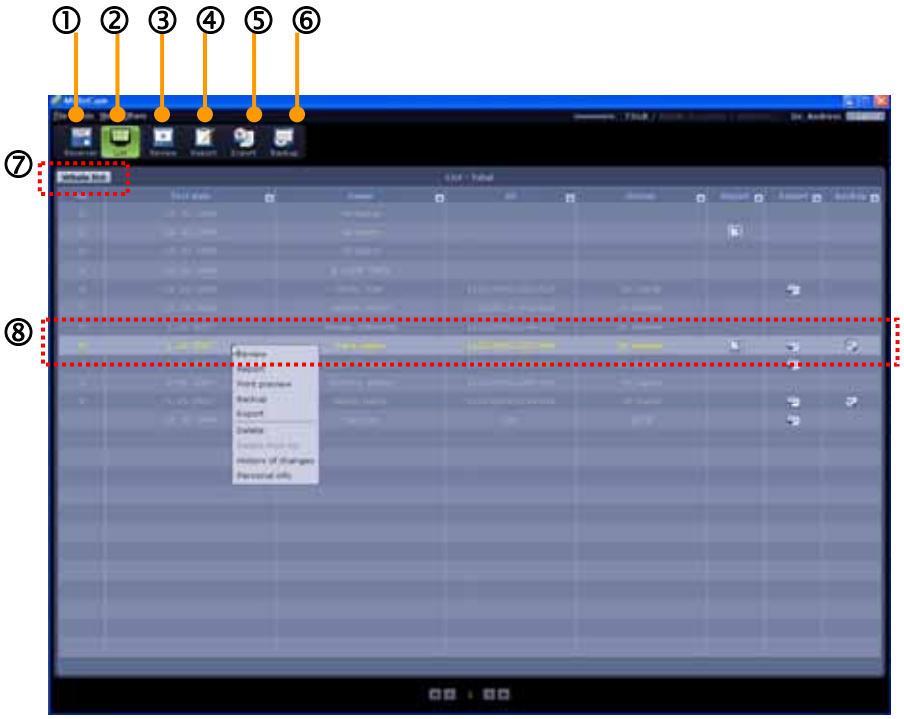
4.1.4 MiroView™ Keyboard shortcuts

List Screen	
<<F5>>	Refresh List
↑↓ or Mouse Wheel	Move the cursor up / down the list
<<Enter>>	Select a file from the list to review
<<Home>>	Go to first page of patient files
<<END>>	Go to last page of patient files
<< PGUP>>	Move 1 page in direction of older files
<<PGDN>>	Move 1 page in direction of newer files
<<CTRL>> + << PGUP>>	Move 10 pages in direction of older files
<<CTRL>> + <<PGDN>>	Move 10 pages in direction of newer files

Review Screen	
<<Space>> (While Playing)	Start / Pause video while in play mode
↑	Increase Frame-rate
↓	Decrease Frame-rate
Mouse Wheel	Move forward / backward frame by frame
<<CTRL>> + <<PGUP/PGDN>>	Skip forward / backward to next ten captured images.
<<CTRL>> + <<direction arrows>> or <<CTRL>>+ mouse wheel	Move to previous / next captured image
<<LShift>> ←/ → (LShift+ wheel up/dn)	Move to the previous/next sub-captured image
<<CTRL>>+<<+>>	Expand to display all sub-captured images.
<<CTRL>>+<<->>	Hide all sub-captured images.

Drawing Tool (Used in Comparison Window & Report Mode)	
<<Delete>> (After selecting a or more diagram)	Delete a selected arrow or circle
<<CTRL>> + <<Delete>>	Delete all arrows / circles
<<CTRL>> + <<z>>	Undo
<<CTRL>> + <<LSHIFT>> +<<z>>	Redo

4.1.5 Basic Screen Layout



①	Receiver	Connect to the receiver and switch to the control screen.
②	List	Switch to the patient data screen of the MiroCam® system.
③	Review	Switch to the screen where images for the selected patient can be reviewed.
④	Report	Switch to the screen where a report for the selected patient can be created.
⑤	Export	Switch to the screen where image data for the selected patient can be exported.
⑥	Backup	Switch to the screen where image data for the selected patient can be backed up.
⑦	Whole List	Show the complete list of patients contained on the workstation.
⑧	Active Item	In the complete list of patients, the patients in yellow are the ones being diagnosed and the items in grey are the ones deleted.

NOTE In the complete list of patients screen, use the review, report or backup function by clicking the right mouse button.

① Review View

② Report View

4.1.6 Basic Procedure

- In the patient list, select a desired patient and press the button to review data for the selected patient.
- Press the button to play the images.
- Press the button to stop playback of the images.
- Press the button to save the current image in the Capture Box.
- Press the button to create and print a report for the patient being diagnosed.
- Press the button to upload the data from the receiver or to initialize the receiver.

4.2 Administering and Initializing Patients

Before performing capsule endoscopy, run MiroView™ to check in (administer) and initialize the receiver for a patient.

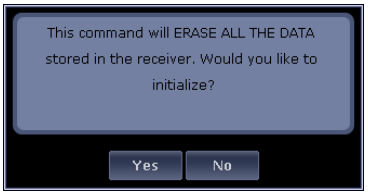
4.2.1 Sequence of Operation

- Initialize the receiver unit
  - Press the button.

  - Connect the receiver's USB cable to the receiver.

- Press the **Initialize** button to continue.

- The initialization screen will appear.



- Click the **Yes** button to initialize.
- When the progress bar is full and the 'complete' message appears, the initialization is complete.

- Click the **Personal Info** button and enter basic information for the patient.

- Complete all fields and click Save button. Receiver is ready for use.

■ Upload image data for patient

- Press the button.

- Connect the receiver's USB cable to the receiver.

- Press the Upload button, and wait until the following screen appears.

- When the progress bar is full and the 'complete' message appears, the upload is complete.

■ Play and diagnose image data for a patient

- Select the desired patient from the patient list.
- Press the button.
- Press the button to play and diagnose image data.

■ Printing Patient Report

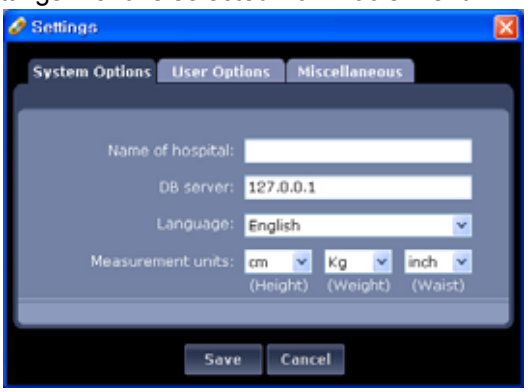
- Press the button.
- Create a report.
- Print the report

CAUTION The installation and initial operation of the system should be performed by authorized service personnel from IntroMedic. Follow the steps in the Service Manual.

CAUTION Before starting the procedure, ensure the environmental conditions are suitable, as described in the User Manual. ,

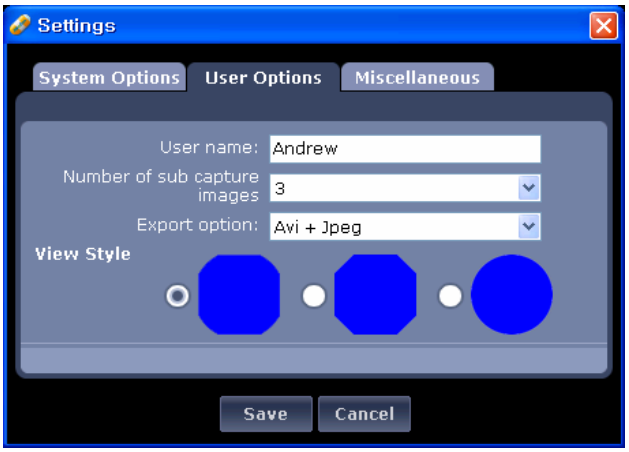
4.2.2 MiroView™ Setting

- Settings Menu is selected from Tools Menu



- Name of hospital: Input the hospital name
- DB server: IP address for using a DB (PostGreSql server). Consult with IT staff to properly use this option.
- Language: Select preferred language.
- Measurement units: Choose preferred measurement units.

- User Option Tab within Settings Menu

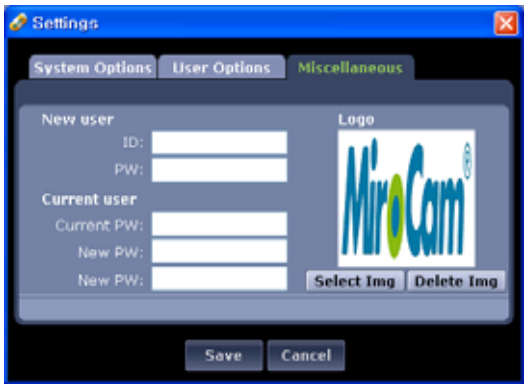


- User Name: Change the name of doctor which appears in the top right of the MiroView program.
- Number of sub-capture images: Select the number of sub-captured images (from 0 to 9).
- Export option: Select type of report files to be exported: avi +

jpeg, avi only, jpeg only, avi + jpeg. Selecting 'All' includes all files (both included and not-included in report).

- View Style: Select preferred viewing style.

■ Miscellaneous Tab within Setting Menu

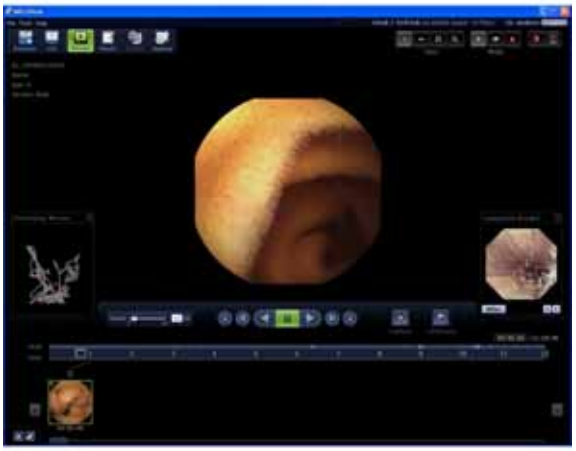


- New User: Create a new ID. Only the master user can use this function.
- Current User: Change the password of the current user.
- Select Image: Save a logo image to insert into the report. Appropriate image file size should be used.
- Delete Image: Delete logo image.

NOTE To apply the changes from the Settings menu, the user must close and re-start the MiroView program.

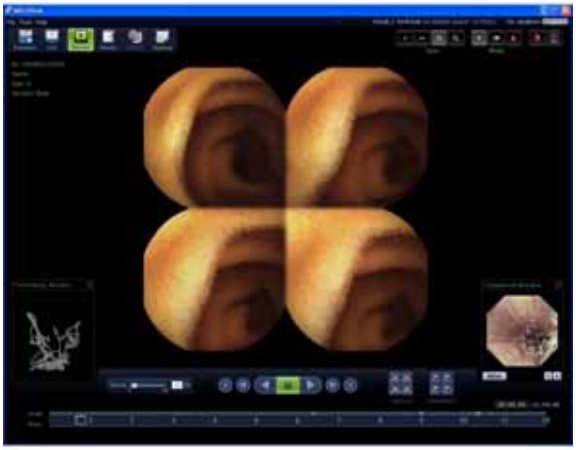
4.3 Viewing Setting

- Single view
  - Click the icon in the upper right corner of MiroView™.
  - The Single View screen will appear, allowing viewing of a single image.



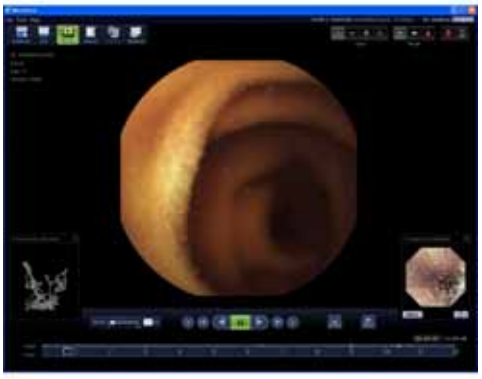
- Dual view
  - Click the icon in the upper right corner of MiroView™.
  - The Dual View screen will appear, allowing viewing of two images at a time.
  - In this screen, images are displayed alternately in each pane.

- Quad view
  - Click the icon in the upper right corner of MiroView™.
  - The Quad View screen will appear, allowing viewing of four images at a time.
  - In this screen, images are displayed alternately in each pane.



CAUTION Because the playback speed varies depending on the view type, use the view that is most comfortable and appropriate for diagnosis.
Do not be confused due to odd image on the center. The S/W distorts center of an image to fill out.

- Zoom
  - Click the icon in the upper right corner of MiroView™.
  - The Zoom screen will appear, allowing viewing of zooming image at a time



4.3.1 Viewing Mode Setting

- Click the icon in the upper right corner of MiroView™ to view images in normal playback mode, in which all images are displayed.
- Click the icon in the upper right corner of MiroView™ to view images in brief playback mode, in which the selected images are displayed based on their similarities. This mode will skip images which are the same.

CAUTION Quick View mode does not display all images, so it is not intended for diagnosis. Use normal playback mode for diagnosis.

- Click the icon in the upper right corner of MiroView™ to use the SGIB (Suspected GI Bleeding) function to view images containing suspected bleeding.

CAUTION Because SGIB mode only display images selected by software, it is possible that there are some images or areas of GI bleeding not detected by the software.

- Use the image playback speed bar in the center of the MiroView™ screen to adjust the playback speed for images. The playback speed is measured in the number of images displayed per second.
- Use the control icon in the center of the MiroView™ screen to specify how images are displayed.

Image displayed by following capsule progress.

Image displayed by reverse capsule progress.

Stop image display.

Display next frame image

Display previous frame image

Display next captured image

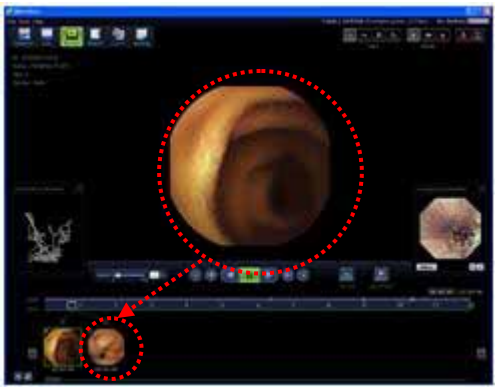
Display previous captured image

4.3.2 Setting and Using Capture Box

- Save data in capture box

Clicking the button in the upper right corner of MiroView™ displays the area corresponding to the current image in the time bar and saves the image group for the area in the Capture Box.

Use the capture ( ) button to save images. Images will be displayed in the Capture Box.



- Save data in capture box

  Click the icon in the center of the MiroView™ screen to specify the start point of each area of the GI tract. Images for each area of the GI tract are displayed in the time bar and are saved in the Capture Box.

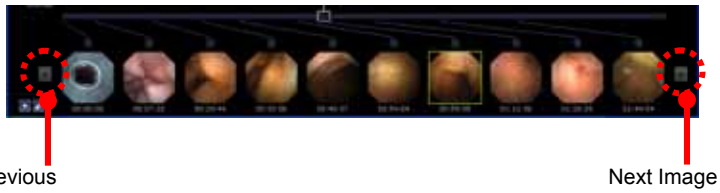
- Specify playback position

  Drag and drop the position control bar in the time bar to place an image to display in the center of the screen.

- View saved images

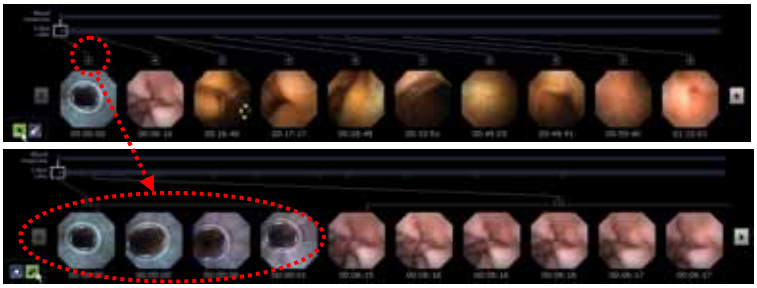
  The captured images group and landmarked images can be viewed in the Capture Box. Captured images cannot be viewed in the Quad View screen.

  Use the left or right arrow to view the saved images from start to finish.



NOTE **Using the Mouse Wheel**
When paused, move the mouse wheel down to view the 'next image' and move it up to view the 'previous image.' During playback, you can display the previous or next images by using the mouse wheel.

Click the + icon to display the all captured images in the group. A group consists of between 2 to 9 neighboring images before and after a captured image.



Use the SGIB (Suspected GI Bleeding) detection bar at the top of the time bar to retrieve images with suspected bleeding.

4.3.3 Setting and Using Tracking Function

- Click the Positioning Window button in the lower center of the screen.

- The route taken by a capsule will be displayed in 2D based on actual human anatomy.

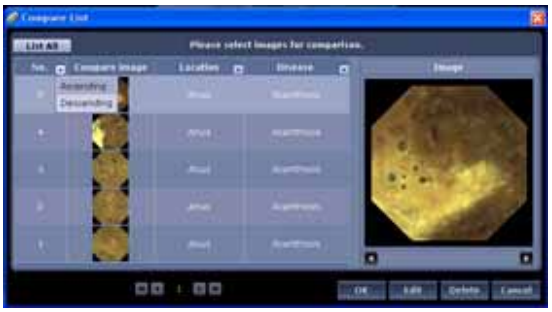
4.3.4 Setting and Using Comparison Window

The current image can be compared with existing images of other patients in the Compare window to readily identify disease pathologies or abmormalities.

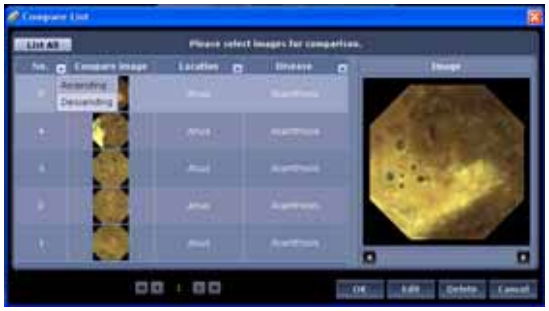
- Click the Compare window button in the right side of the screen.

- Click the List button in the Compare window.

- Image data that will be displayed in the Compare window can be selected and sorted.



- The Edit function can be used in the Compare window.



- In the Compare window, circle or arrow marks can be placed or removed to highlight a specific area.

4.4 Creating a Report

After reviewing images, a diagnostic report can be created for the patient. Access via the icon.

4.4.1 Editing Report

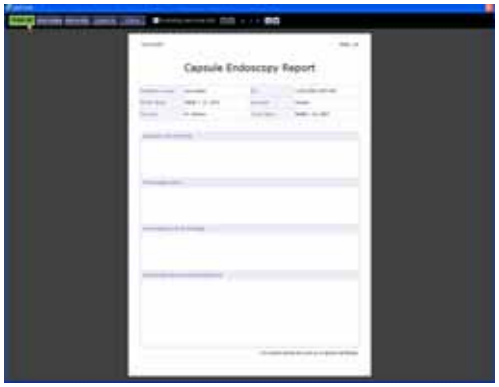
- Click icon in the upper left corner of MiroView™.
- Enter patient information, and procedure findings in the appropriate text boxes; choose a desired text box from the tab. The tab is editable. Click the icon to add and name a text box onto the tab.

- A specific image can be selected, and related comments entered in the text box. Double-click the left mouse button to select desired image.
- If needed, place a mark on disease pathology in the captured image.

	Add circle mark
	Add arrow mark
	Delete added mark
	Change marker color
	Undo last action
	Redo last undo action

- Check the Final Approval option in the lower right corner.

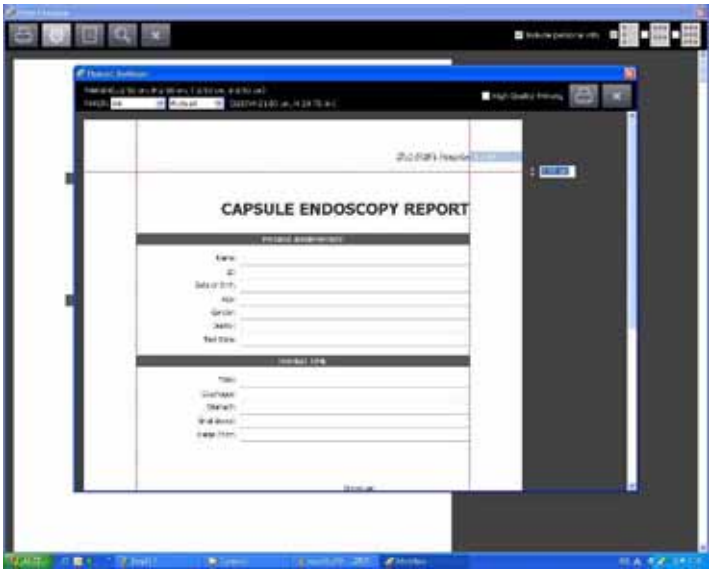
- Press the Save button to save the created report.
- Press the Print button to print a report for the selected patient.



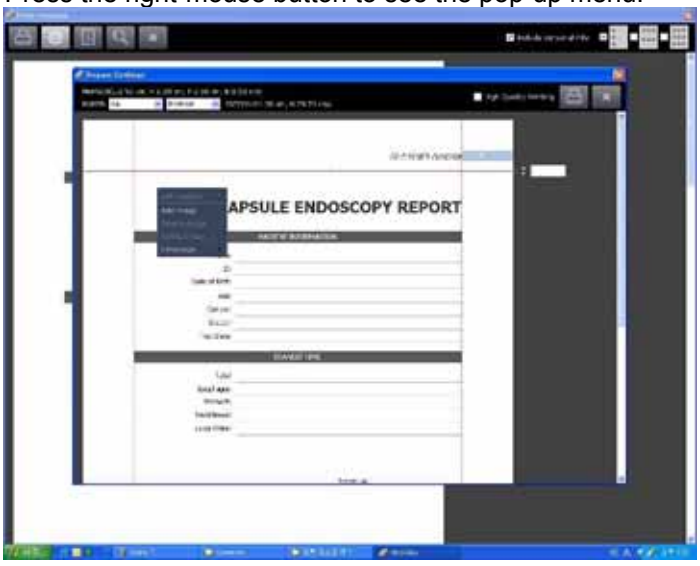
CAUTION If Final Approval is not checked, a report cannot be used as a medical examination certificate. However, if it is checked, the report becomes a finalized medical examination certificate that is not editable.

4.4.2 Settings

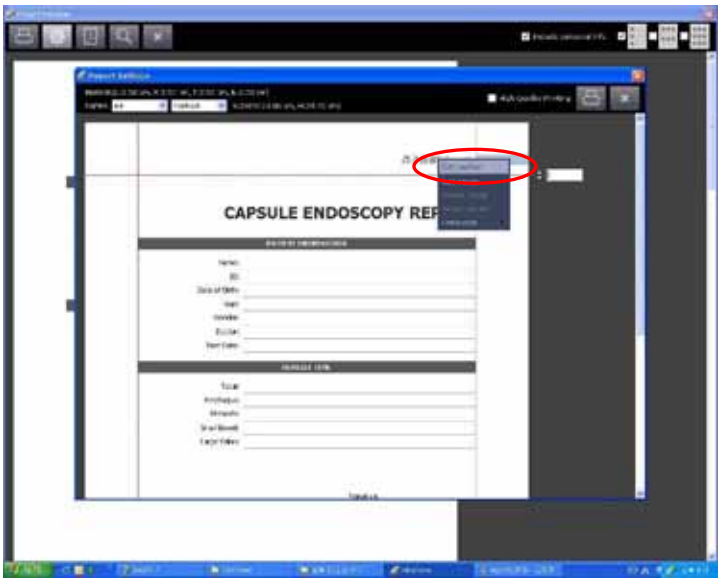
■ Press the button to change settings.



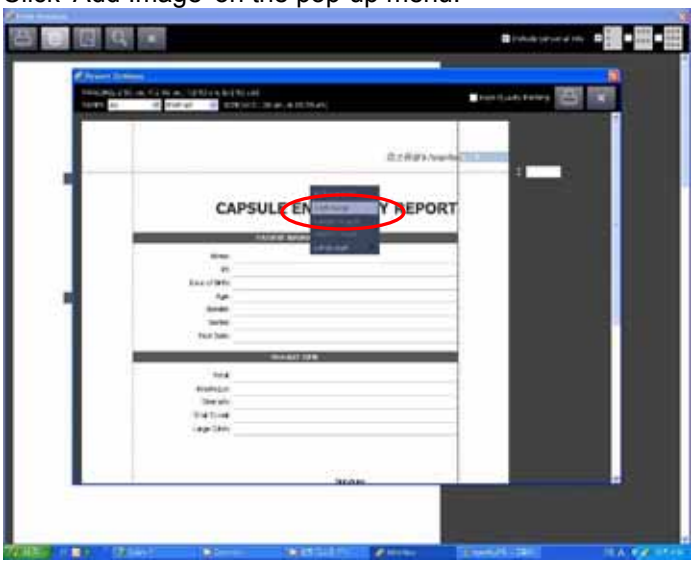
■ Press the right-mouse button to see the pop-up menu.



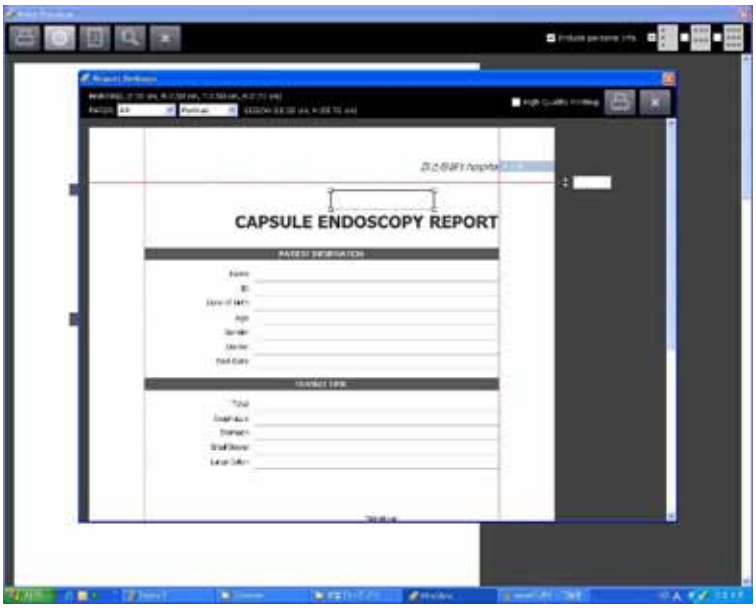
- Press the right-mouse button on the desired text line to edit.
  Pop-up menu will appear and select ‘Edit Caption’ to change text.



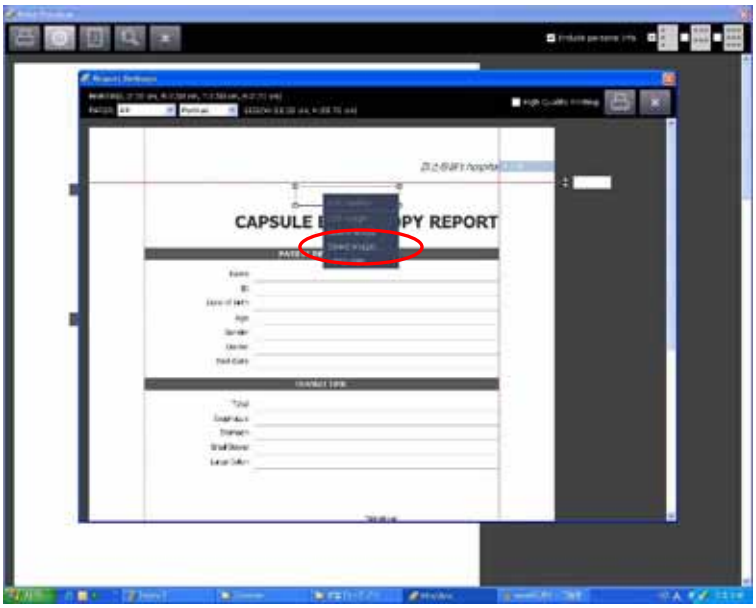
- Add images or logos to report:
  - Click ‘Add Image’ on the pop-up menu.



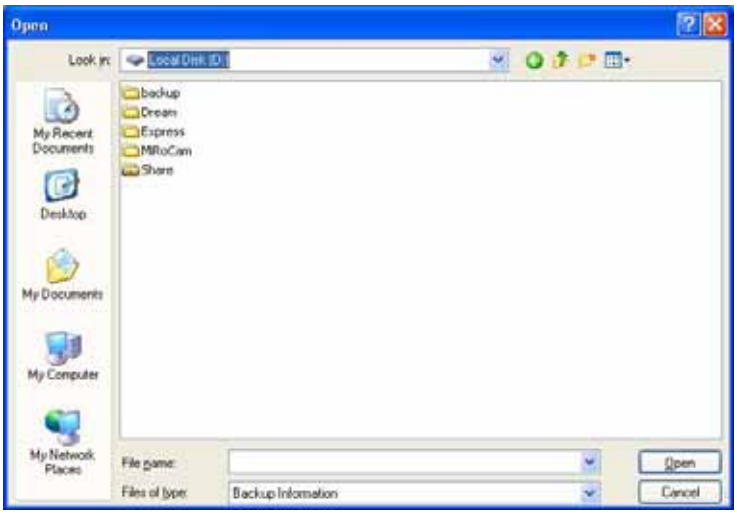
o Rectangular area appears.



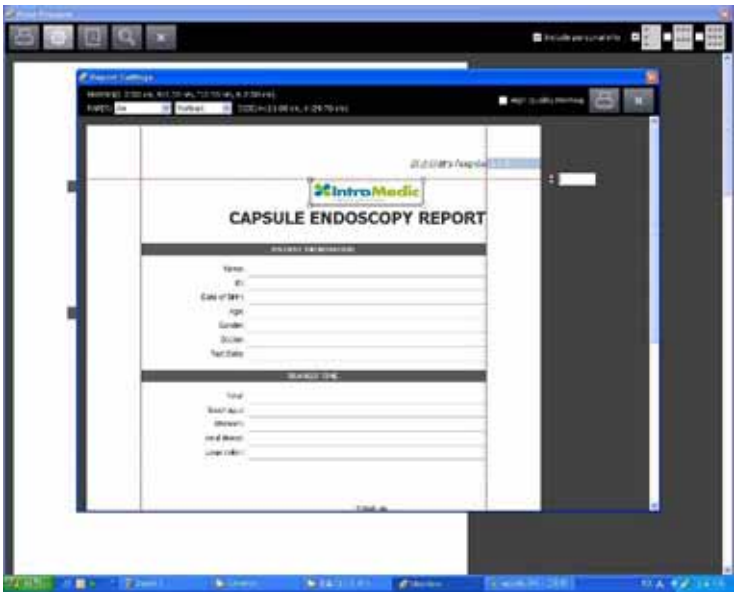
o Click the right-mouse button on the rectangular area.
Click ‘Select Image’.



o Select the desired image or logo to insert.



o Image box can be resized and moved to the desired location.

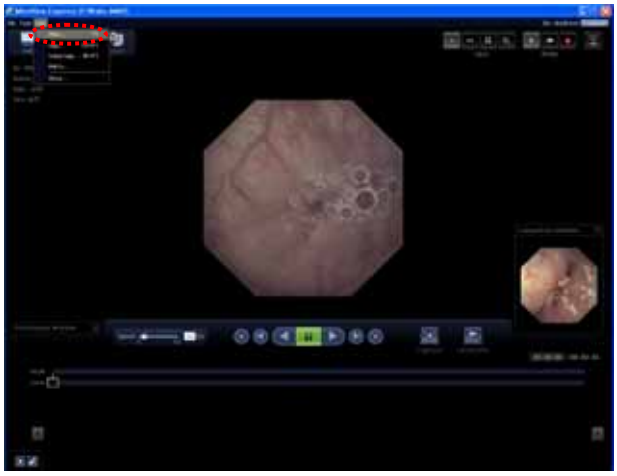


4.5 Atlas

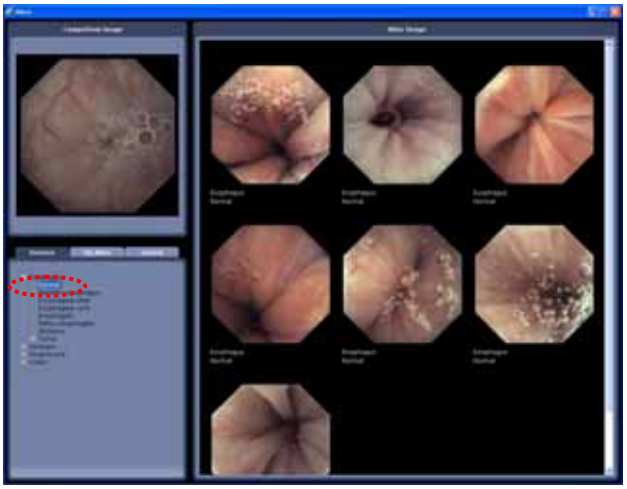
For reference, the MiroCam® Image Atlas provides an extensive image library of disease pathology and normal anatomy. Users can access the Atlas DB via 'Atlas' function on the Help menu.

4.5.1 Accessing Atlas

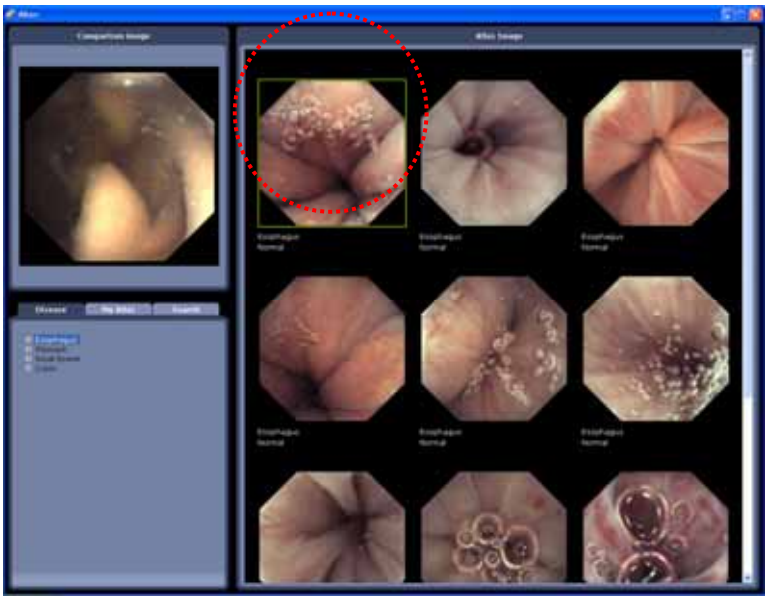
- Execute 'Atlas' from the Help menu



- Select image from categories in the bottom left.



- Click on an image from the Image Atlas to add to the Comparison Window in Review Mode

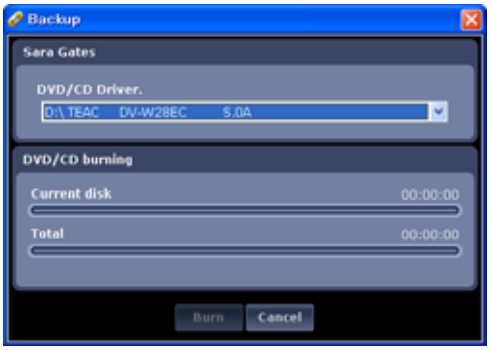


CAUTION My Atlas DB is not available in MiroView™ Express but only in MiroView™.

4.6 Backing up Patient Data

4.6.1 Backing up Image Data

- The entire image data for the selected patient can be backed up onto a DVD, an external HDD or a USB flash memory.
- Select a patient to back up from the patient list in MiroView™ and click the icon.



- Click the

icon and then move and save image data onto a DVD. If needed, insert an additional DVD and continue to save the data.

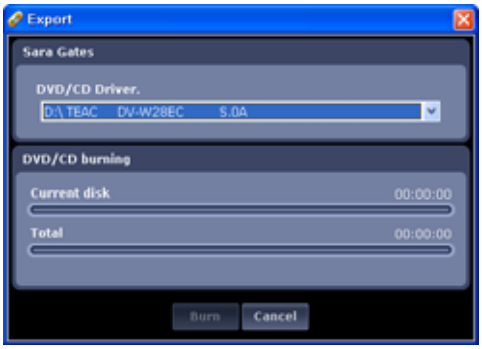
CAUTION The number of DVDs required for backup is displayed. Check the number of DVDs available and click the

icon.

NOTE A 4.7G DVD is recommended for optimal backup results.

4.6.2 Exporting Image Data

- Selected images and report files for a patient can be exported to a CD/DVD, an external HDD or a USB flash memory.
- Select a patient to back up from the patient list in MiroView™ and click the icon.



- Click the Burn icon and then move and save the image data onto a DVD.
- If needed, insert an additional DVD or CD and continue to save the data.

CAUTION The number of DVDs or CDs required for exporting is displayed. Check the number of DVDs or CDs available and click the Burn icon.

CAUTION The same type of CD or DVD should be used for a backup. If backup fails, it should be started again from the beginning.

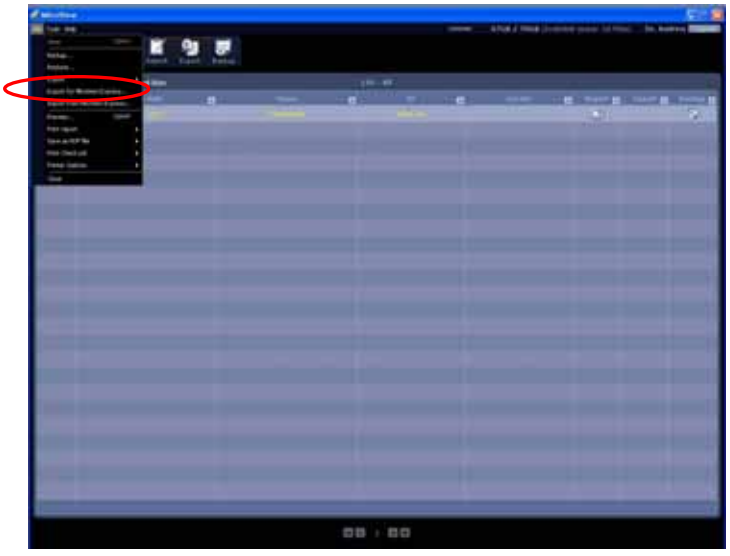
4.6.3 Exporting Image Data for MiroView™ Express

- MiroView™ Express Overview

  MiroView™ Express software is a 'light' version of the MiroView™ software, which can be installed on laptops or a PC (at home or the office), and is designed to enable Physicians to more readily review patient files. To view a patient file with MiroView™ Express, it is necessary to export the desired patient file from the MiroView™ workstation (via the *Export for Express* function). The file can be exported to external storage devices, including USB flash memory or USB external hard drive.

Before using the 'Export to MiroView Express…' function, insert or connect the external storage device (external hard disk or USB flash memory). The storage device must have a minimum of 4GB free space to export a file for MiroView™ Express (exact requirement will vary).

- Select 'Export for MiroView Express…' from the File tab in MiroView™.



- Select the location of the storage device and complete the ‘File name’ field.

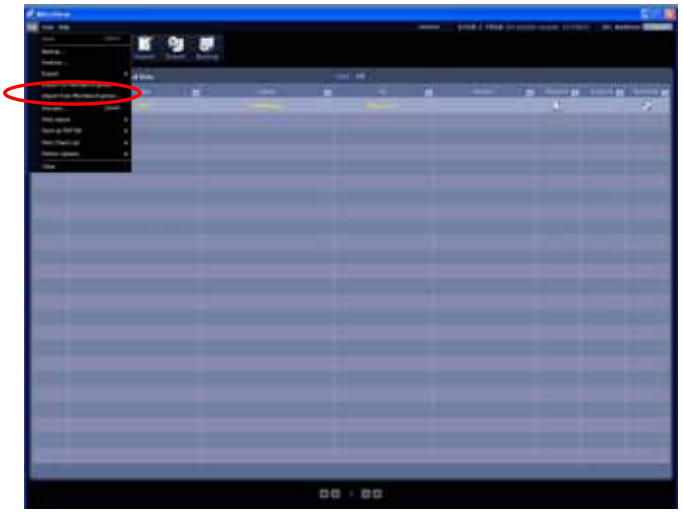
- A progress bar will appear.

- When complete, the following message “Exporting has been completed.” will appear.

4.6.4 Importing Image Data for MiroView™ Express

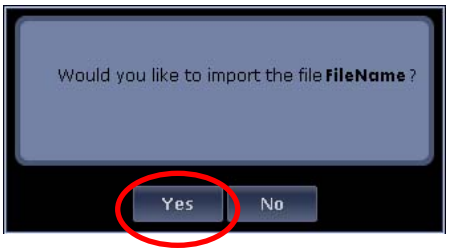
After reviewing the patient file with MiroView Express, the changed data (i.e. saved images, comments, reports etc.) can be synchronized with the patient file in the MiroView workstation via the 'Import from MiroView Express' function.

- Select 'Import from MiroView Express' from the File tab in MiroView™.



- Select the patient file to import (from the external storage device with the patient file).

- Confirm file by click Yes Button.



- A progress bar will appear.

- When import is complete, following message “Import from MiroView Express is complete.” will appear.

CAUTION For further information about MiroView™ Express, please refer to the MiroView™ Express User Guide included with the installation CD, and/or contact your local IntroMedic Representative for assistance.

5

Using MiroView™ RTV

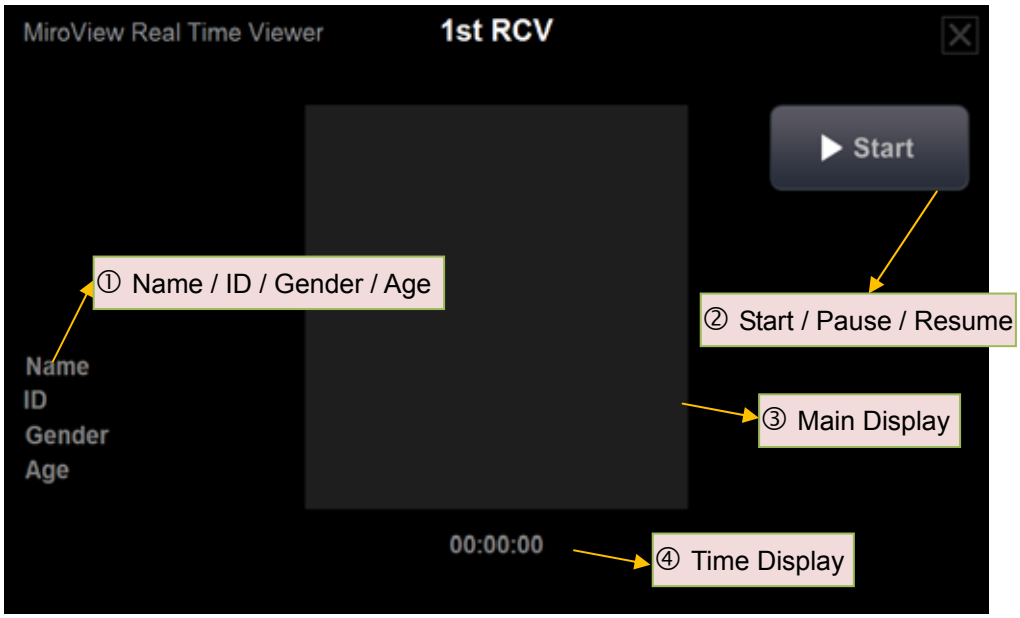
5. USING MIROVIEW™ RTV

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

5.1 Overview

MiroView™ RTV will be pre-installed on UMPC(Ultra-Mobile PC) that provided by IntroMedic. Click the corresponding icon on the desktop to launch the MiroView™ RTV.

5.1.1 Basic Screen Layout



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

5.1.2 Basic UMPC Layout

①	USB Port	USB Port for connect with MiroCam® Receiver
②	DC-Jack	Connector for UMPC Charger
③	Power Switch	UMPC Power on switch.

WARNING Only use UMPC provided by IntroMedic. Usage of inappropriate UMPC can cause serious harm to the patient.

WARNING Only recharge the UMPC batteries with the adaptor from IntroMedic. Use of the improper adaptor can cause serious damage to patient and UMPC.

WARNING For safe use of UMPC, please refer to UMPC User Manual.

5.2 Using MiroView™ RTV with MiroCam® Receiver MR1000

5.2.1 Before Using MiroView™ RTV

- The MiroView™ RTV software is pre-install on UMPC provided by IntroMedic.

WARNING Do not use MiroView™ RTV software and UMPC before upgrading the MiroCam® receiver.

WARNING Do not upgrade MiroCam® receiver during the MiroCam® capsule endoscopy procedure, it may result in loss if image data .

- Connect the data cable for the Real-time Viewer to the MiroCam® receiver.

NOTE The data cable for MiroView™ RTV has no cover for the USB port on the receiver.

- Fallow the MiroCam® capsule endoscopy procedure.

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

5.2.2 Starting MiroView™ RTV

- Switch on the UMPC.
- Click the icon on the desktop to launch MiroView™ RTV.
- Connect the small side of the USB cable to the receiver.

- Connect the large side of the USB cable to the UMPC.

- Click the ▶ Start button to start image display
- Click the ⏸ Pause button to stop image display
- Click the ▶ Resume button to restart image display
- Click the button on the top-right to close the MiroView™ RTV.

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

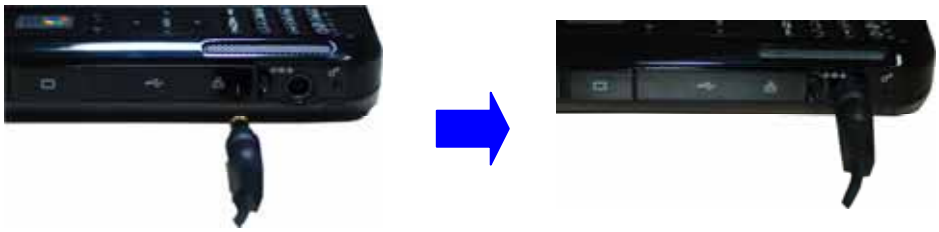
CAUTION MiroView™ RTV is not software for to be used for diagnostic purposes. Use the MiroView™ software for viewing the patient images for diagnostic purposes.

CAUTION Do not disconnect the receiver while the RTV is in use. If the receiver is disconnected during use, the software may need to be restarted.

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

5.2.3 After Using MiroView™ RTV

- Disconnect USB cable from MiroCam® Receiver and UMPC.
- Charge the UMPC by using the adaptor provided by IntroMedic.



- Continue MiroCam® capsule endoscope procedure.

5.3 Using MiroView™ RTV with MiroCam® Receiver MR2000

5.3.1 Before Using MiroView™ RTV

- The MiroView™ RTV software is pre-install on UMPC provided by IntroMedic.
- Fallow the MiroCam® capsule endoscopy procedure.

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

5.3.2 Starting MiroView™ RTV

- Switch on the UMPC.
- Click the icon on the desktop to launch MiroView™ RTV.
- Connect the small side of the USB cable to the receiver.

- Connect the large side of the USB cable to the UMPC.

- Click the ▶ Start button to start image display
- Click the ⏸ Pause button to stop image display
- Click the ▶ Resume button to restart image display
- Click the button on the top-right to close the MiroView™ RTV.

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

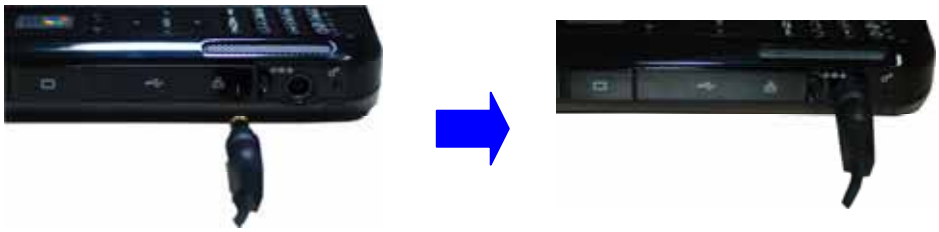
CAUTION MiroView™ RTV is not software for to be used for diagnostic purposes. Use the MiroView™ software for viewing the patient images for diagnostic purposes.

CAUTION Do not disconnect the receiver while the RTV is in use. If the receiver is disconnected during use, the software may need to be restarted.

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

5.3.3 After Using MiroView™ RTV

- Disconnect USB cable from MiroCam® Receiver and UMPC.
- Charge the UMPC by using the adaptor provided by IntroMedic.



- Continue MiroCam® capsule endoscope procedure.

A

Appendix

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 ☐☐☐☐☐☐☐☐
D M M Y Y Y Y

Inclusion Criteria

	Yes	No	N/A
1. Informed consent form voluntarily signed	☐	☐	☐
2. Male / Female subject of age 19 years~70 years.	☐	☐	☐
	☐	☐	☐
	☐	☐	☐

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

CONFIDENTIAL

Trial ID :

Version No. : 1.0 : 30/07/2007

Screening

Subject No.:	Subject Initials :	Center No.:

Date of visit : ☐☐☐☐☐☐☐☐ (D M M Y Y Y Y)

Exclusion Criteria

	Yes	No	N/A
1. Do you have a gastrointestinal disorder (suspected malignantlesions or gastrointestinal obstructive disorders, perforation, stenosis or fistula)?	☐	☐	☐
2. Do you have a cardiovascular disorder (dysrhythemia, trouble with cardiac conduction system, hypertension(high blood pressure) or ischemic heart disease)?	☐	☐	☐
3. Have you been diagnosed of cardiac insufficiency, angina pectoris or cardiac arrest (heart attack) in recent 6 months?	☐	☐	☐
4. Are you with (or implanted) medical devices such as cardiac pacemaker or defibrillator?	☐	☐	☐
5. Do you have a swallowing disorder?	☐	☐	☐
6. Do you have delayed gastric emptying or serious gastric disorder?	☐	☐	☐
7. Are you a pregnant or nursing woman, or a woman of child bearing potential?	☐	☐	☐
8. Are you an infant or epileptic? Are you easily affected by electronic waves?	☐	☐	☐
9. Do you have several small bowel diverticulums ?	☐	☐	☐
10. Did you fail to obtain a voluntary agreement?	☐	☐	☐
11. Are you judged unqualified for this test by doctors or nurses?	☐	☐	☐

If there is one or more mark of 'Yes', you shall be contradicted for this clinical test.

CONFIDENTIAL

EC Representative
NanoMedical

Largo do Sequeira 7 G3 P.E.

1100-587 Lisboa Portugal

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Email: nuno.nicola@nano-medical.org

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