MiroCam

MiroCam Capsule Endoscope

Service Manual

Smallest Capsule & Highest Resolution

Discovering Medical Innovations

IntroMedic Capsule Endoscope

Version 1.22

MM1100-0807
Date : 2008-07-01

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IntroMedic Customer Service

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FAX: 82-2-801-9330
http://www.intromedic.com
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.

Contents

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Safety Information

1. SYSTEM OVERVIEW

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 & Service 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 & Service 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 IEC (The International Electrotechnical Commission) has established for medical electronic equipment to classify a connection or warning 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 Herz, the unit of Frequency


IEC 417-5021: Denotes potential equalization terminal


Single Use Only


Use by date

1.3 Function Symbols

1.3.1 Application 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 of the MiroCam® system.		Open screen to export (save externally) selected image data for a specific patient.
	Opens screen to view MiroCam ® 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.		Zoom images.
	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.
	User logs out from MiroView™.		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 Remarks for Safe Use

- Follow the safety instructions included in this Service Manual and clinical precautions advised by medical professionals.
- 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: The equipment should not be exposed or come in contact with foreign substances including water, cleaning fluids, disinfecting cleanser; as such substances may harm 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 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, ensure the brake or latch guard is in use to prevent the cart 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 on the receiver before connecting the sensor pads.
- DO NOT discard 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.
- The capsule and sensor pads are medical waste, and should be disposed of according to local regulations or WEEE directive on waste disposal.
- 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.
- In the medical environment condition, only use the capsule, receiver, data cable and sensor pads.
- All products connected with the MiroCam® Endoscope system must be compliant with requirements of IEC60950-1 or UL certifications.

1.4.1 Environmental Condition 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 capsules.
- 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 the 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 emergency treatment.)
- In case of any symptoms of abdominal pain, vomiting, fever, heart trouble, dizziness or seizure during or after the capsule endoscope procedure, the patient should immediately notify the physician in charge.
- 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, ask patient to 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, follow the Patient Preparation as recommended in the User's Manual.
- Tell Patient not to bite the capsule before ingesting.
- Patient should avoid excessive physical activity during the capsule endoscope procedure.
- 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 the patients over the age of 18.

⚠ WARNING The Capsule takes images 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 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 wiring status after moving.
  - If damage to the equipment is discovered after moving, immediately contact IntroMedic or local Distributor.

2

System Overview

2. SYSTEM OVERVIEW

2.1 MiroCam® Overview

MiroCam® is an orally ingested capsule endoscope designed to capture images of the small intestine lining. Captured images are viewed via the MiroCam® software for diagnosis of diseases related to the small intestine. Generally, the capsule endoscope has been developed to provide a means to view the entire small bowel, with much higher diagnostic sensitivity than other radiological techniques. Further, the capsule endoscope avoids a great deal of discomfort associated with traditional endoscopy, while allowing the patient to maintain a normal schedule.

Additional methods for screening of the small bowel primarily include barium x-rays and enteroscopy, but the diagnostic value of these tests for a wide variety of specific lesions is low. Following is further description of the methods.

Enteroscopy is a method to perform direct visual inspection of the small bowel mucosa beyond the reach of standard upper endoscopes. The procedure can be accomplished of the small by examination with either push or sonde type endoscopes, or operative enteroscopy. Enteroscopy of the small intestine is difficult, requires a lengthy examination time, can only partially visualize the small intestine, is extremely uncomfortable, and is not performed on a widespread basis.

Barium X-rays of the small bowel are currently the primary radiographic means of diagnosing a small bowel neoplasm, and the best way to locate small bowel lesions. However, the procedure has limited sensitivity.

Sensitivity to diagnose small bowel neoplasms can be doubled by enteroclysis, which is extremely inconvenient for the patient and must be done only in a hospital set up by an expert. The sensitivity and specificity of the diagnosis of mucosal lesion (like AVM, for example) is close to zero.

Computed tomography (CT) of the abdomen is sometimes helpful in diagnosing and localizing of small bowel abnormalities, but it is unable to determine small intraluminal or mucosal lesions.

It is widely accepted that the aforementioned methods for diagnosing small bowel diseases and disorders are limited. Capsule Endoscopy is a great advancement, providing a much more thorough diagnostic method. IntroMedic's MiroCam Capsule Endoscope System is designed to aid the gastroenterologist in visualizing and diagnosing disease of the small bowel in an efficient, cost effective, and comfortable manner. .

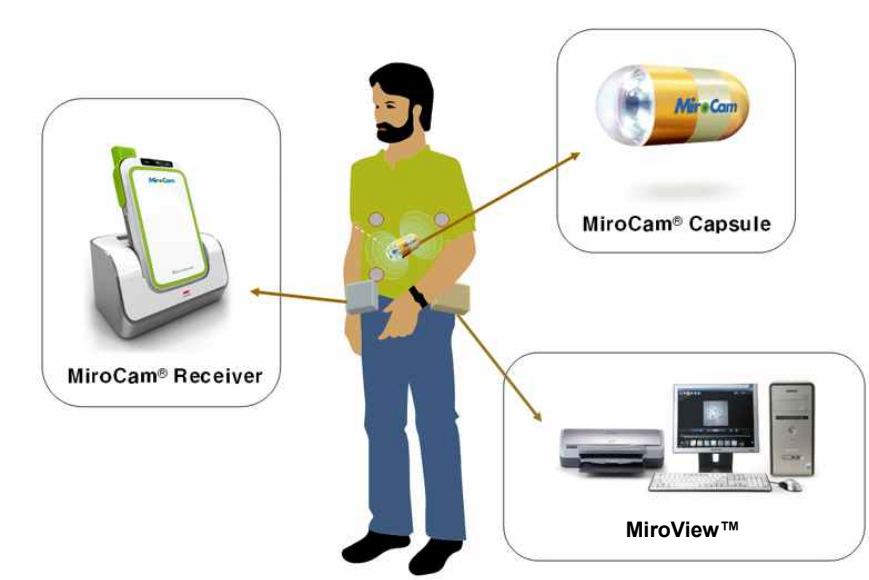
2.2 MiroCam System Main Components

- Capsule:The MiroCam Capsule moves slowly through the small intestine tract, capturing images of the entire small intestine at 3 frames/sec.
- Receiver:The MiroCam Receiver provides 9 receiving channels through which signals can be received. The pair of channels which have the best signal characteristics are selected and used for the receipt of the of image signals. The receive also connects to MiroView™ software to upload images taken of the patient's GI tract.
- MiroView™ Software: MiroView™ enables the gastorenterologist to perform a diagnostic reiview of the patient's small bowel, and

document the results in a printable report.

2.3 MiroCam® Method of Action

The following image displays the key components of the MiroCam capsule endoscope system.



To enable physicians to diagnose images of a patient's small bowel, the MiroCam method of action includes the following steps.

Step 1. Image Capturing: The MiroCam capsule uses a CMOS Image sensor built in the capsule to take the pictures through the front of the optical dome. The LED light flashes each time the picture is taken to brighten the dark digestive organ. The capsule captures 3 pictures per second and sends the images to the receiver immediately. For transmission, the images taken from the capsule are transformed to data that is possible to transmit to the receiver through the human body.

Step 2. Data transmission: The MiroCam capsule transmits the data from the capsule via E-Field Propagation. This communication method uses the human body as the medium to transmit signals from internally within the body (from the capsule) to external sensors (data cable sensor pads).

Step 3. Data Reception and Storage: To retrieve the signal emitted from the capsule, the MiroCam system needs to attach reception poles (sensors attached to data cables) on the exterior of the human body to retrieve the signal. The signal is then changed into a data format that is feasible for image processing, and stored onto the memory of the receiver.

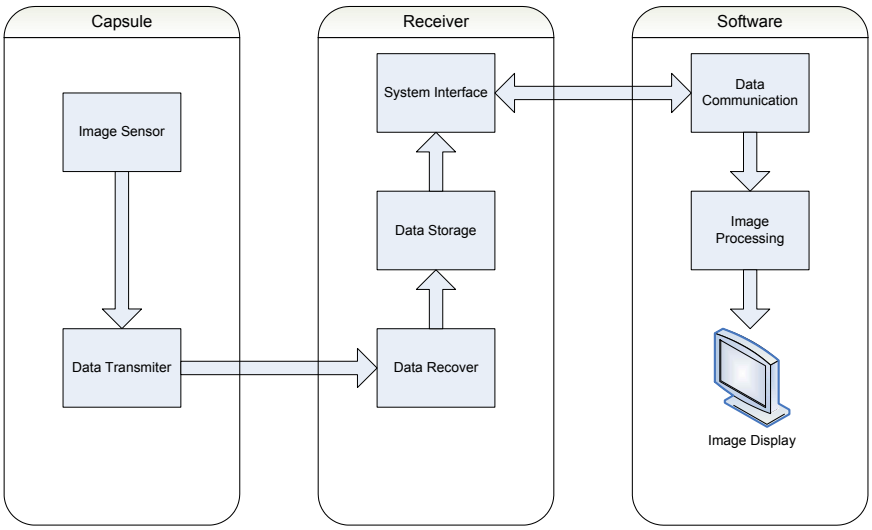
Step 4. Data Upload: The image data is uploaded from the receiver to the MiroView software (software on a PC workstation) via a standard USB data cable. This data is uploaded after the patient has completed the procedure (i.e. sensor pads / data cables are not attached to patient).

Step 5. Image Restoration & Display: After all stored image data in the receiver has been transferred to the image processing software (MiroView™), the software changes the transferred image data by using an image reconstruction algorithm to a RGB signal. The reconstructed image data is saved along with patient information, and viewed by the physician to diagnose diseases of the small bowel. MiroView™ can recall the saved data anytime, as the user desires to perform a diagnostic review of the patient images.

2.4 System Configuration

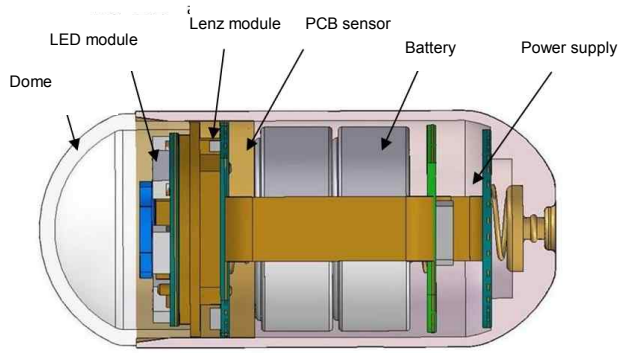
The MiroCam® System consists of an imaging capsule, signal receiver, and the MiroView™ software for image viewing. The overall system configuration is as follows:

MiroCam System Block Diagram



2.4.1 Capsule

The capsule consists of an optical dome, LED module, imaging & communication module, battery, power supply module, cage pin and cage. The capsule can operate inside a human body for more than 11 hours. This mechanical device is enclosed in a harmless plastic capsule. The dome and the capsule body are bonded with a medical grade adhesive. The surface of the plastic body is gold-plated for signal transmission.



<Capsule Structure>

CMOS Image Sensor Specifications

- Image size : 320 * 320 pixel
- Operation voltage : 3V
- Operation Frequency :12MHz
- Image Frame : 3 Frame / sec

2.4.2 Receiver

The MiroCam® Receiver consists of the data cable, signal input block, analog block, digital control block, data storage block and USB communication block. Following is some more information about the

individual components.

- Signal input block includes 9 channel connectors and a multiplexer
- Analog block has an amplifier and filter for analog to digital conversion. This converts the image data transmitted by the capsule.
- Digital control block includes a digital image processing unit and demodulation unit. This block also saves the data.
- All image data is saved to flash memory and transferred to image processing workstation by USB channel
- The receiver is divided into a restoration part that restores the actual data, and a transmitter part that transmits the image data to MiroView™. More specifically, the receiver can be divided into the receiving block, signal input block, analog block, digital block, storage block and USB transmission block. After processing the converted signals, the digital block demodulates image data and saves it. The saved data is then transferred to MiroView™ software (on a PC) via the USB transmission module.

Receiver Power Source: The MiroCam receiver operates via a battery, completely independent of any other power sources.

The receiver of the MiroCam® capsule endoscope system includes amplifier and filter components, which convert the image data transmitted by the capsule. The receiver is divided into a restoration part that restores the actual data, and a transmitter part that transmits the image data to MiroView™. More specifically, the receiver can be divided into the receiving block, signal input block, analog block, digital block, storage block and USB transmission

block. The signal input block is implemented with 9 signal lines and connectors while the analog block amplifies, filters and performs AD conversion. After processing the converted signals, the digital block demodulates image data and saves it. The saved data is then transferred to MiroView™ software (on a PC) via the USB transmission module.

2.4.3 MiroView™ (Software)

MiroView™, the application software for the MiroCam® capsule endoscope system, consists of an image-processing module that restores the received image data to actual images, and an output module for image output.

The recorded images can be viewed via a conventional PC or Notebook using IntroMedic's proprietary software. MiroView™ is compatible with Windows operating systems. Selected images can be edited and saved in a CD or DVD.

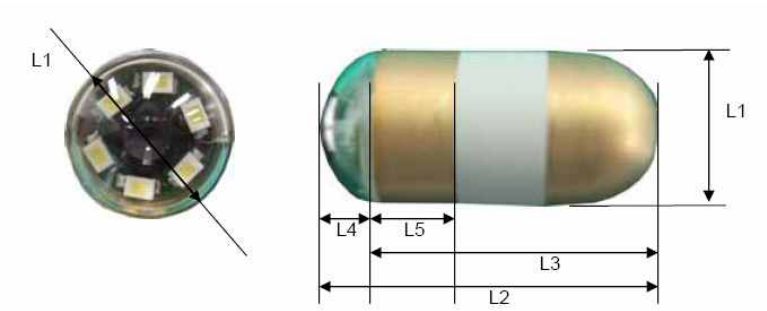
The software includes a number of features and functions to assist in the efficiency and sensitivity of the diagnosis.

2.5 Product Specifications

2.5.1 Capsule

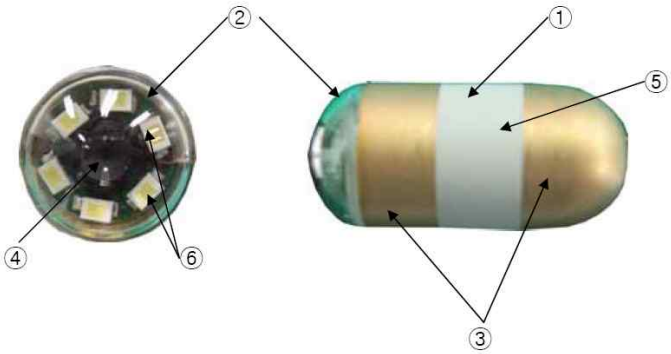
Capsule consists of the optical dome, lens, led lighting module, gold-band, battery, power module, case pin and case. The capsule operates for about 11 hours in the human body. The electrical components are enclosed by a plastic cage that is safe and does not harm the human body.

- Dimensions



Size(mm)	Weight(g)
10.8(L1) x 24(L2) x 19(L3) x 5(L4) x6(L5)	3.25

■ Description



No.	Title	Function
1	Main Body	- Main Device of MiroCam MC1000
2	Optical Dome	- This transmits light from the outside of Capsule and its transparency is over 98%. - Made from COC. - This transmits light source of image from the LED of inside of capsule.
3	Gold-Band	- Gold coating that transmits the image data from the capsule to the human body.
4	Lens	- The lens concentrates the light emitted by the LEDs, and focuses the image for the CMOS image sensor.
5	Cage	- Protects the interior capsule components. - Prevents entry of foreign materials into capsule. - Cage is composed of an FDA certified safe material, harmless to the human body.
6	White LED	- LED illuminates the dark spaces inside the human body GI tract. - The illumination enables images to be captured.

■ Specifications

- Size : 10.8 X 24mm
- Weight : 3.25g
- Material : Human Compliance Plastic
- Light : 6 white LED
- View Angle : 150°(In image)
- View Depth : 3 cm
- Enlargement Ratio : 1:8
- Detectable Range : under 0.1mm
- Sampling Ratio : 2.9 fps
- Operating time : 11 hours
- Mechanical Safety : Compatible ISO60601-1-1
- Biocompatibility Safety : Compatible ISO10993-4, ISO10993-5, ISO10993-10, ISO10993-11
- Chemical Safety : Safe in pH=2 ~ pH=8
- Battery Type : Silver Oxide Cell
- Operation Temperature : 20 ~ 40℃
- Storage Temperature : 0 ~ 50℃

2.5.2 Receiver

Receiver consists of the data cable, signal input block, analog block, digital control block, data storage block and USB communication block. Signal input block has 9 channel connectors and a multiplexer. Analog block has an amplifier and filter for analog to digital conversion. Digital control block has a digital image processing unit and demodulation unit. All image data are saved to flash memory and transferred to image processing workstation by USB channel.

■ Dimensions

Size(mm)	Weight(g)
140(H) x 85(W) x 40(L)	350

■ Description

No.	Title	Function
①	Main Body	- Main Device of MiroCam MR1000.
②	9-Channel Connector	- Durable connector to deliver the signal from the data cables to the receiver.
③	LED Display	- Display status of Receiver. - Signal display to indicate normal operation, including battery, initialization status and signal reception.
④	USB Connector	- USB Communication connector for image data transmission to Image processing workstation.
⑤	Power Switch	- Turn Main power of Receiver on or off.
⑥	Battery	- Rechargeable battery for MiroCam Receiver unit. - Output voltage : 3.7Vdc - Output Current : 8.8A

■ Specifications

- Operation System : Firmware
- Recording Time : 12 Hours
- Weight : 350g, include battery
- Operation Voltage : 3.7V, 0.45A
- Battery Type: Lithium Ion Battery (3.7V, 8.8A)
- Battery Weight : 215g
- Operation Temperature : 0 ~ 40℃
- Storage Temperature : 0 ~ 55℃
- Category : Type BF

2.5.3 MiroView™

Image processing workstation consists of image processing software (MiroView™) and hardware workstation. MiroView™ operates on windows XP, enabling viewing and saving of image data.

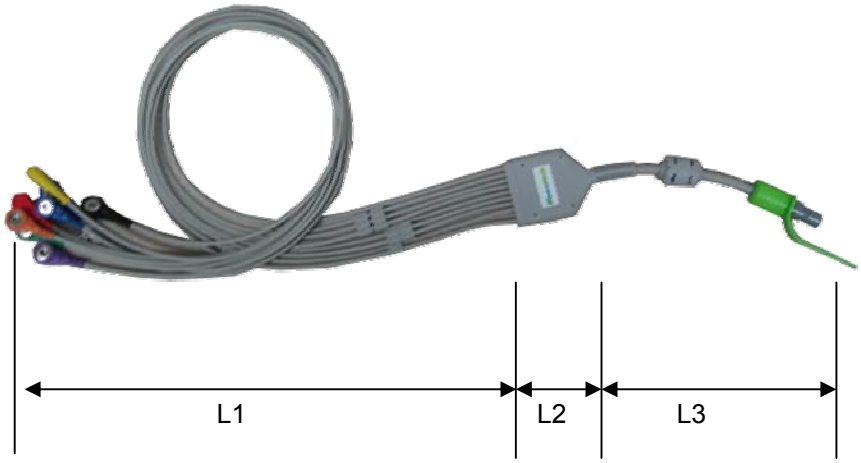
- Software Version : MiroView™ Version 1.00
- Operating System : Windows XP Professional
- Language : English
- Data Export : JPEG Image, AVI Video Clip, PDF Data Report
- Data Display : Single or Multi Image, Time Bar, Diagnosis Data
- Event Marker : Small Image and comments
- Display Ratio : 5 ~ 30 fps
- Display Mode : Single View, Dual View, Quad View
- Running Mode : Normal View, Quick View, Blood View

2.5.4 Recommended Workstation Specifications

- Operating System : Windows XP Professional
- CPU : Core 2 Duo E6300(1.86GHz/2M)
- Memory : DDR II 1GByte(667MHz)
- Display Adaptor : Geforce 7600GT 256MB
- Hard Disk : SATA II 160GB, SATA II 320GB
- ODD : DVD-RW
- Monitor Resolution : 1280 X 1024
- Monitor Contrast : 700 : 1
- Printer Resolution : 4800 X 1200 dpi
- Printer Paper : A4

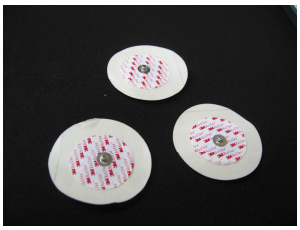
2.5.5 Accessories

- Data Cable



Part No.	Description	Size(mm)	Weight(g)
MR1000-D	Image data receiving cable	700(L1) x 90(L2) x 110(L3)	155

- Sensor Pads

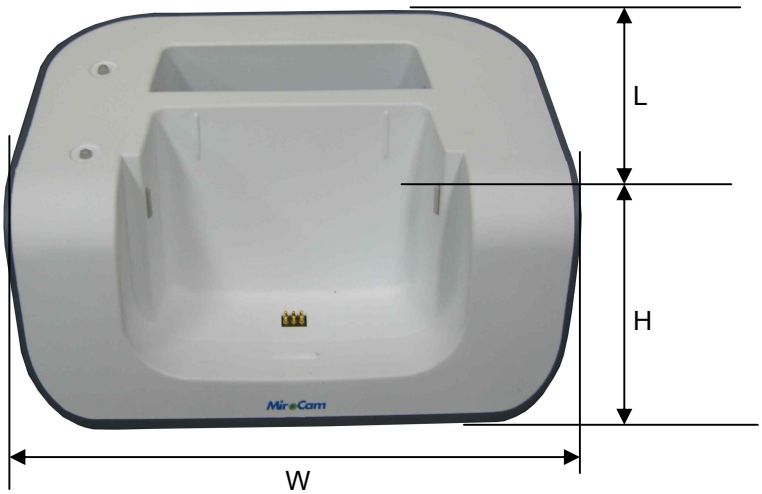


Part No.	Description	Size(mm)	Weight(g)
MR1000-S	Image data receiving sensors	60	5

■ USB Cable

Part No.	Description	Size(mm)	Weight(g)
MR1000-U	Image data uploading cable	1500	50

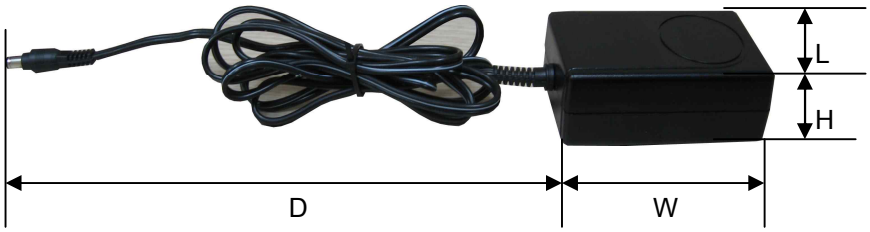
■ Battery Charger



Part No.	Description	Size(mm)	Weight(g)
MR1000-C	Receiver Battery Charger	135(H) x 105(L) x 150(W)	350

- Input Specification : 9Vdc, 3A
- Output Specification : 4.2Vdc, 4A

■ Adaptor



Part No.	Description	Size(mm)	Weight(g)
MR1000-T	Receiver Battery Charging Adaptor	95(W) x 55(L) x 30(H) x 750(D)	240

- Input Specification : 110~220Vac, 50~60/Hz
- Output Specification : 9Vdc, 3A
- Compliance with requirements of IEC601-1

2.6 Component List

The components of the MiroCam® System are as follows:

No.	Product Name	Model Name	Q'ty	Description	Note
1	Capsule Endoscope	MC1000	1 ea	Capsule for imaging	
2	Receiver	MR1000-R	1 ea	Receiver for data storage	
3	Battery Pack	MR1000-B	2 ea	Batteries for receiver	
4	Receiver Bag	MR1000-G	1 ea	Portable receiver bag	
5	Data Cable	MR1000-D	1 ea	Data cable	
6	Battery Charger	MR1000-C	1 ea	Battery Charger	
7	Adapter	MR1000-T	1 ea	Adaptor for charging	
8	USB Cable	MW1000-U	1 ea	Communication cable for workstation	
9	Measuring Tape	MR1000-M	1 ea		
10	Sensor Pad	MR1000-S	1 pk	Signal-receiving pad	
11	Software	MW1000-SV1.0	1 ea	Software for image diagnosis	
12	User Manual	MM1000	1 ea	Instruction for use	
13	Service Manual	MM1100	1 ea	Instruction for service	

<Table 1> List of Component

3

Product Installation

3. PRODUCT INSTALLATION

Installation and initial operation of the system should be performed by authorized IntroMedic service personnel. .

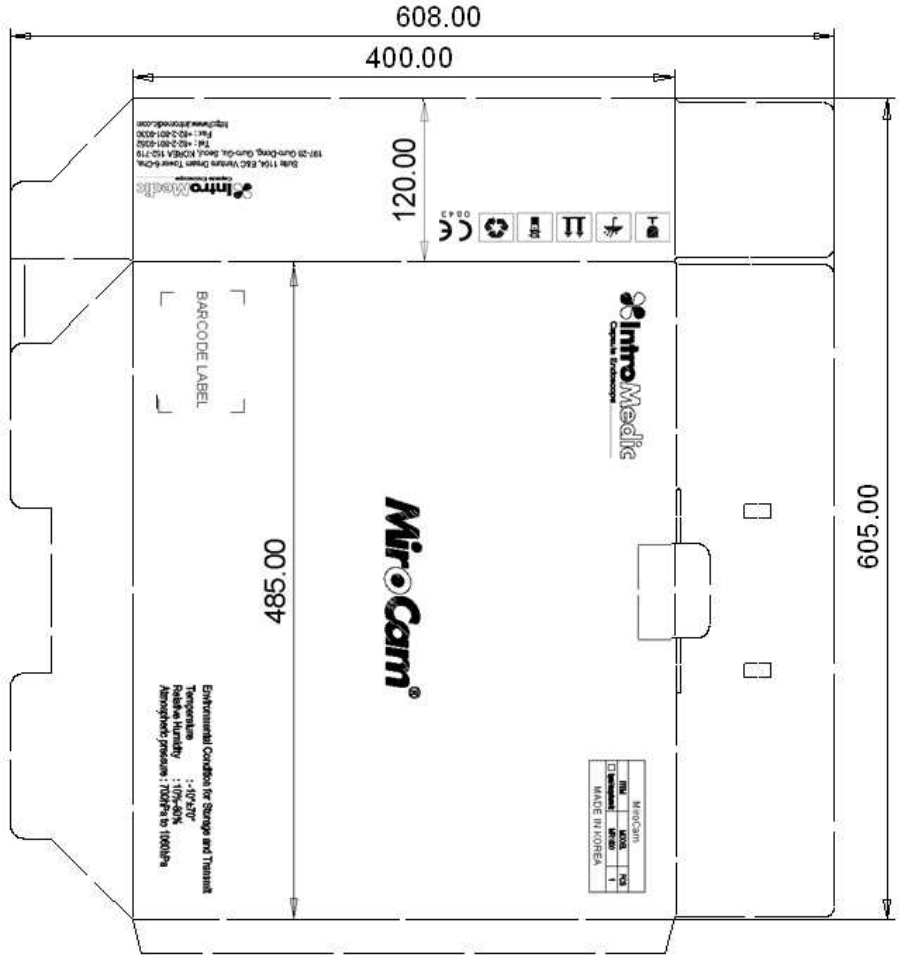
The following component list should be rechecked prior to product installation.

3.1 Component Check List

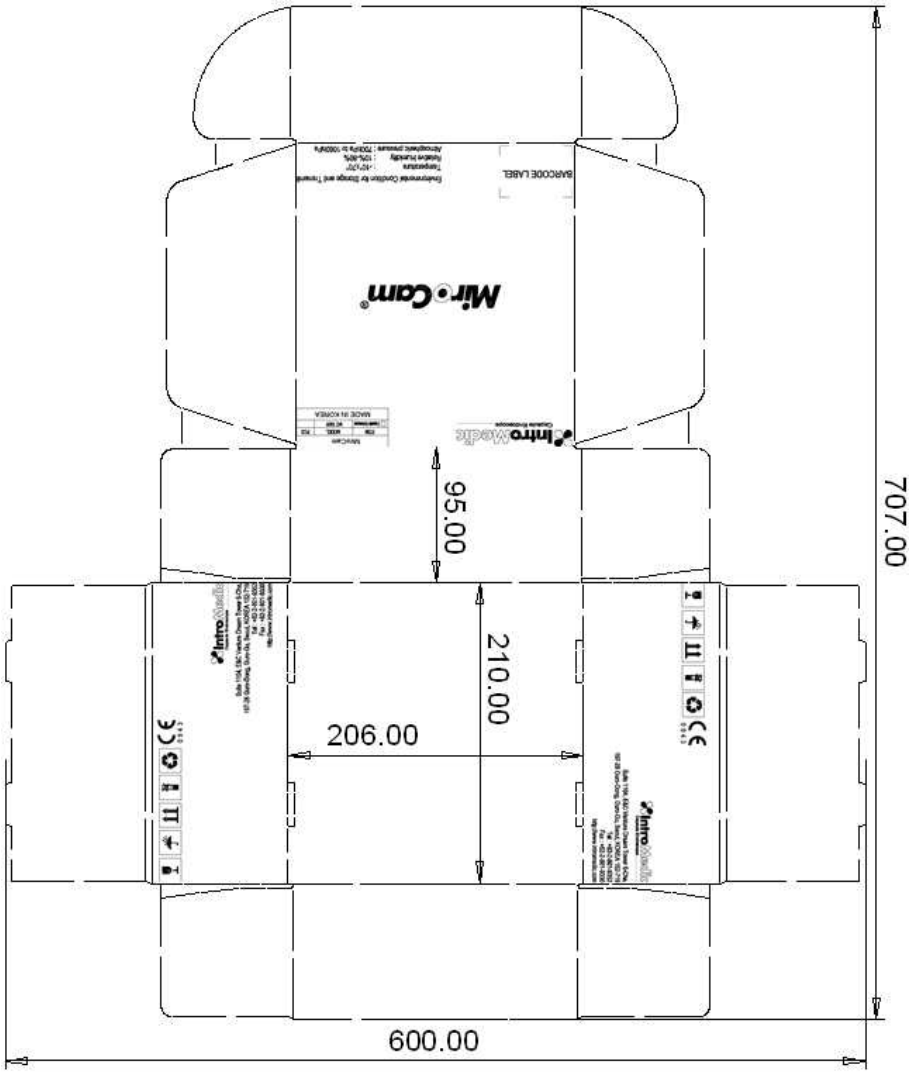
No.	Product Name	Model Name	Q'ty	Description	Note
1	Capsule Endoscope	MC1000	1 ea	Capsule for imaging	
2	Receiver	MR1000-R	1 ea	Receiver for data storage	
3	Battery Pack	MR1000-B	2 ea	Batteries for receiver	
4	Receiver Bag	MR1000-G	1 ea	Portable receiver bag	
5	Data Cable	MR1000-D	1 ea	Data cable	
6	Battery Charger	MR1000-C	1 ea	Battery Charger	
7	Adapter	MR1000-T	1 ea	Adaptor for charging	
8	USB Cable	MW1000-U	1 ea	Communication cable for workstation	
9	Measuring Tape	MR1000-M	1 ea		
10	Sensor Pad	MR1000-S	1 pk	Signal-receiving pad	
11	Software	MW1000-SV1.0	1 ea	Software for image diagnosis	
12	User Manual	MM1000	1 ea	Instruction for use	
13	Service Manual	MM1100	1 ea	Instruction for service	

3.2 Packaging Specifications

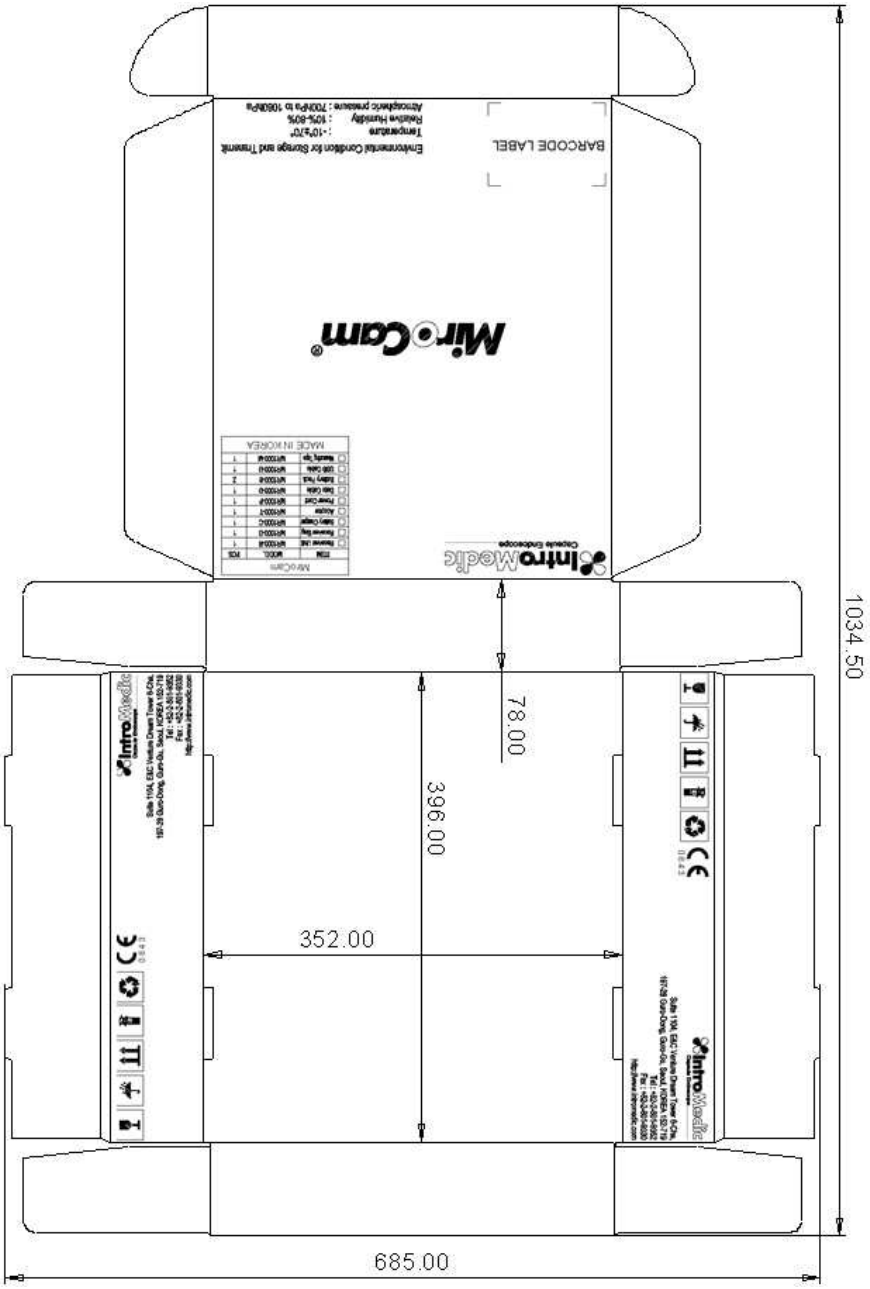
3.2.1 Capsule Endoscope Receiver set Box : 485 X 120 X 400 mm



3.2.2 Capsule Endoscope Box : 210 X 206 X 95 mm



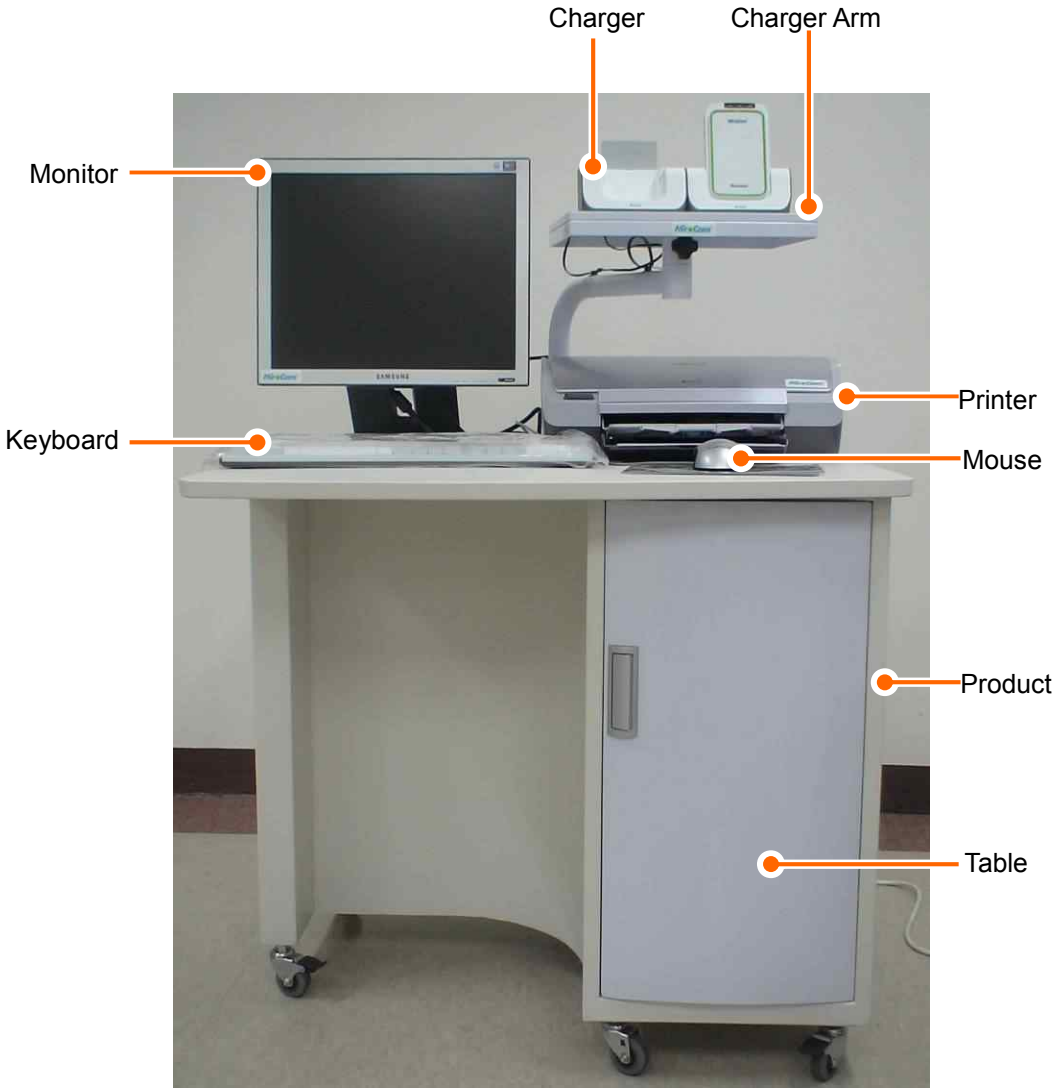
3.2.3 Accessory Box : 352 X 396 X 78 mm



3.3 Installation Diagram

The recommended configuration of the MiroCam® Capsule Endoscope System is as follows:

Note: configuration may change.



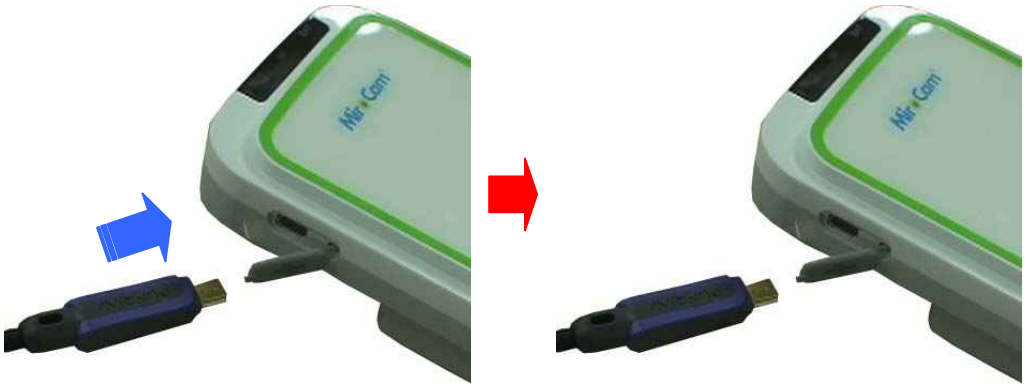
3.4 System Installation & Connection

3.4.1 Connect data cable

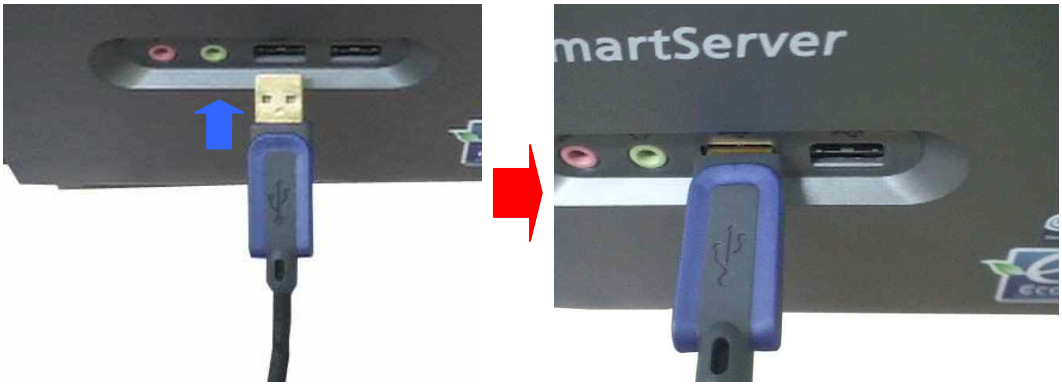
- Check the data cable's direction.
- Hold green cover of data cable and insert into the receiver.

3.4.2 Connect USB cable

- Hold small side of USB cable and insert into the receiver.



- Hold large side of USB cable and insert into the workstation.



WARNING DO NOT connect the USB cable to the receiver while the receiver's sensor pads and data cable are still connected.

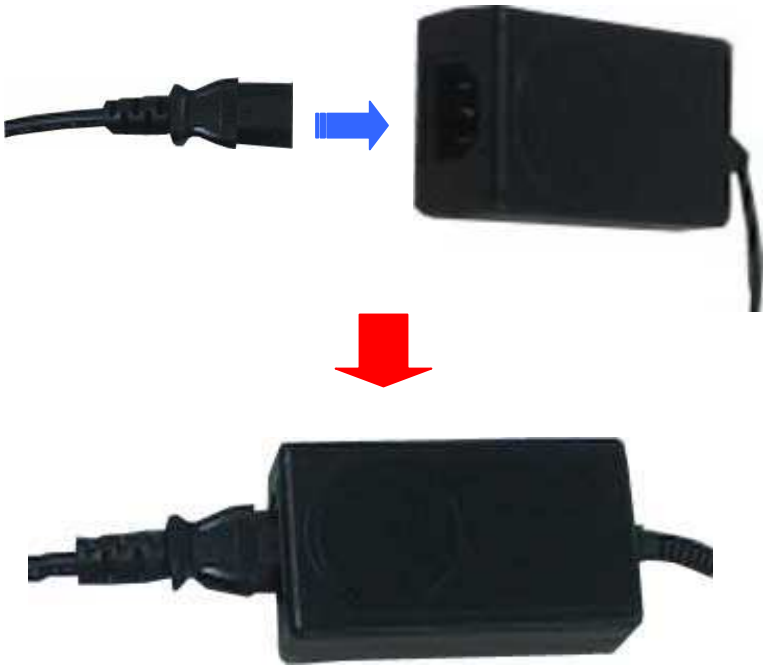
WARNING Connect USB cable to receiver only after mounting it on charger.

3.4.3 Connect battery charger

- Battery charger connection diagram.

- Insert dc-jack of adaptor into battery charger.

- Insert power-jack of power cord into adaptor.



- Connect power plug of power cord into AC consent.

WARNING Always check the AC Power range before connect power plug into AC consent.

WARNING DO NOT touch AC power code with wet hand.

3.5 MiroView™ Installation

For installation and operation of MiroView™ application software, the workstation must be prepared. Recommended workstation specifications are provided to the local IntroMedic Representative, who will install the system and software.

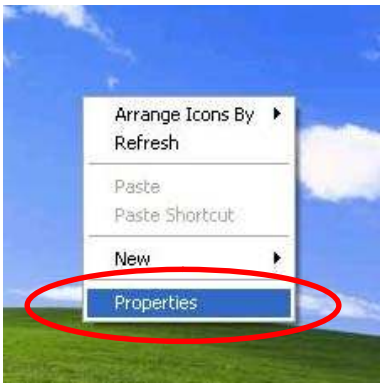
3.5.1 Preparation(Prior to Installing MiroView Software)

- Setup hard disk drive

  - This process should be done by the hardware vendor
  - HDD must have three partitions : C, D and E drive
  - C drive should have larger space than 150GB for database
  - D drive should have larger space than 50GB for MiroView™
  - E drive should have larger space than 250GB for patient data.

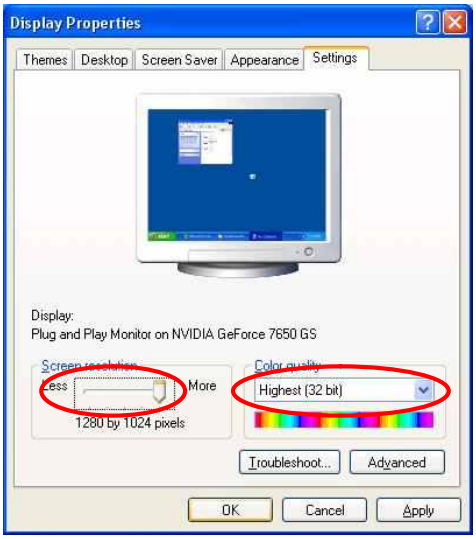
■ Setup graphic resolution

- Click mouse right button.
- Click properties in command list.

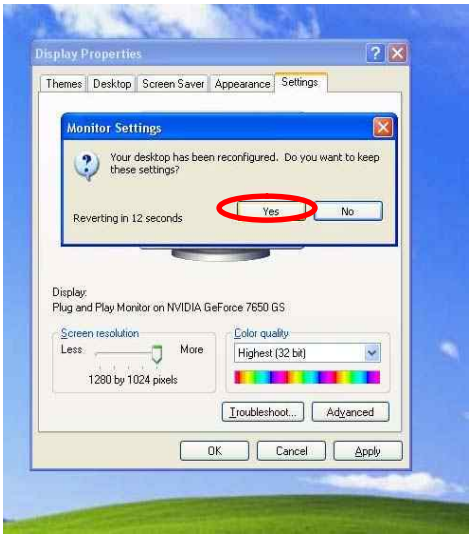


- In display properties window click settings tab.

- Setting screen resolution by 1280 * 1024 and color quality by Highest(32 bit).

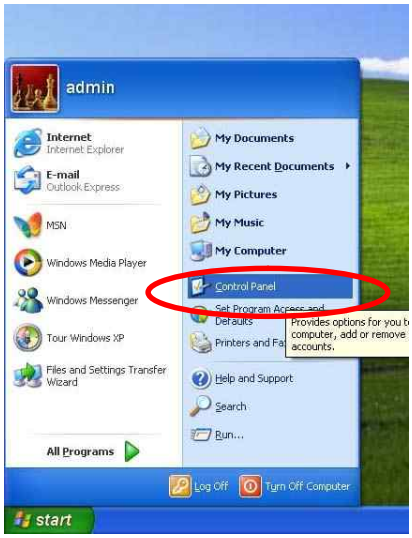


- Click OK button.
- Confirm monitor setting by clicking Yes button.

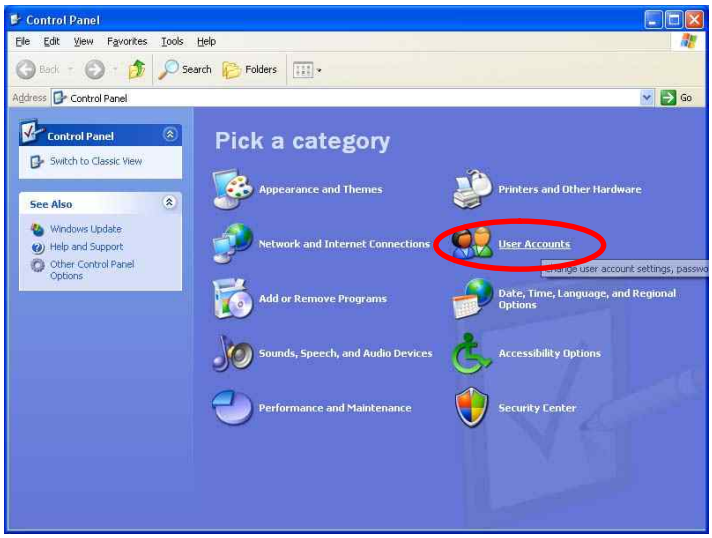


■ Setup windows account

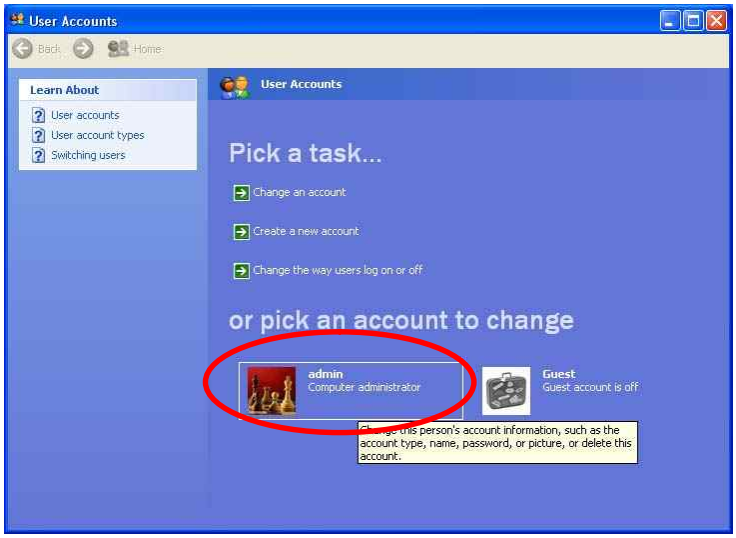
- Click  button and select ‘Control Panel’.



- Select ‘User Account’.

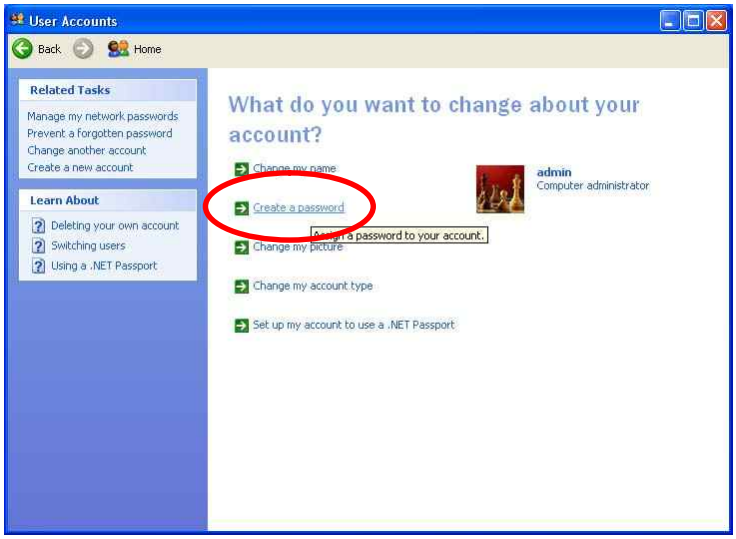


- Select “Admin” account.



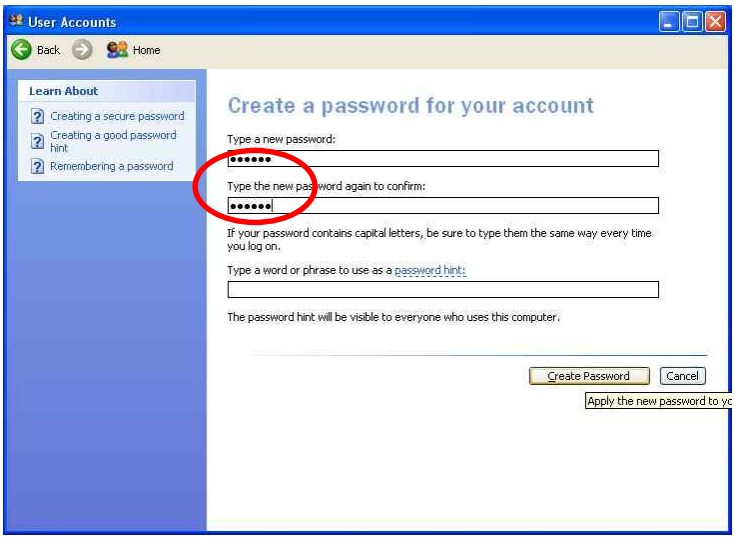
NOTE If you can’t see admin account, create admin account by select “Create a new account”.

- Select ‘Create a password’.

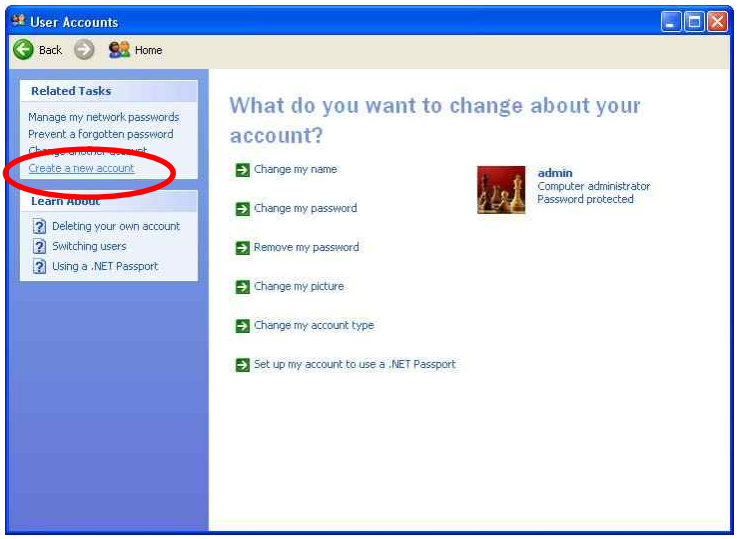


- Enter new password **miro06** and click 

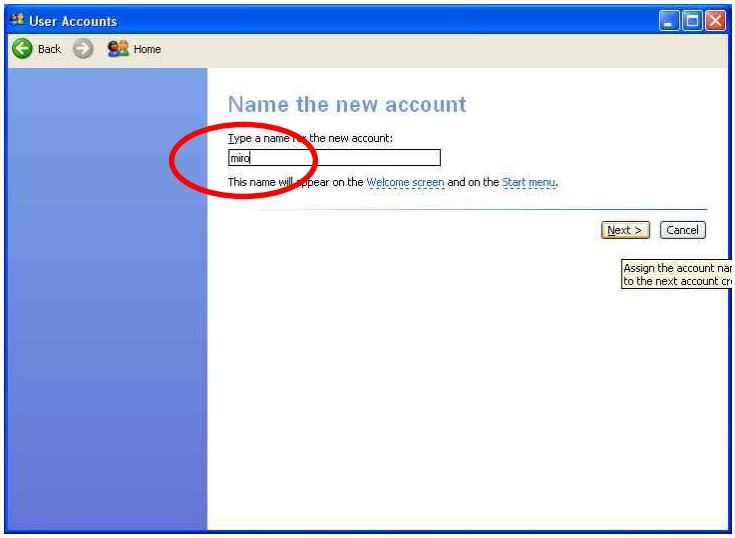
button



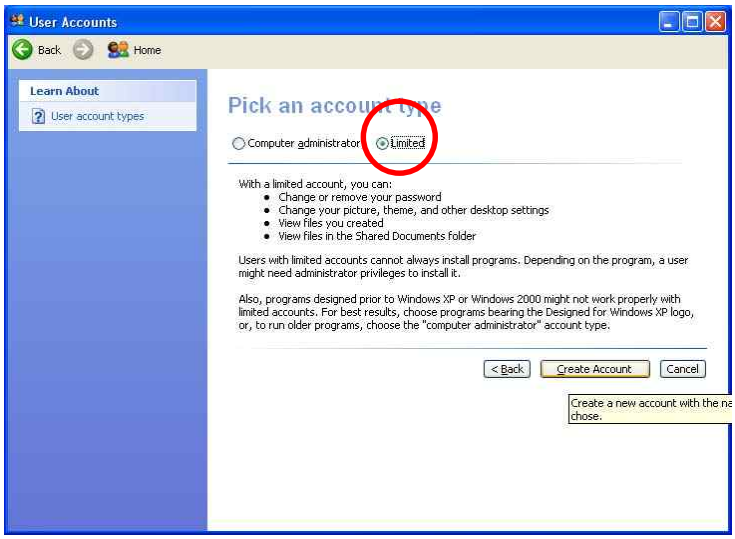
- Select ‘Create a new account’.



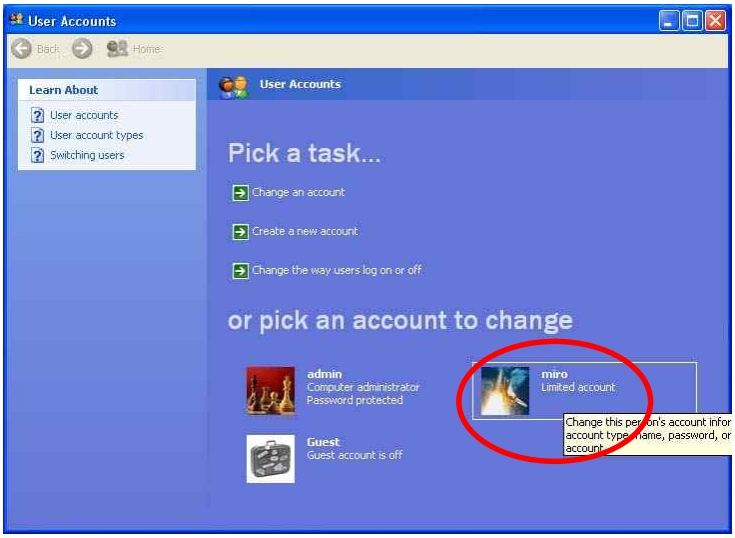
- Enter new account name **miro** and click Next > button



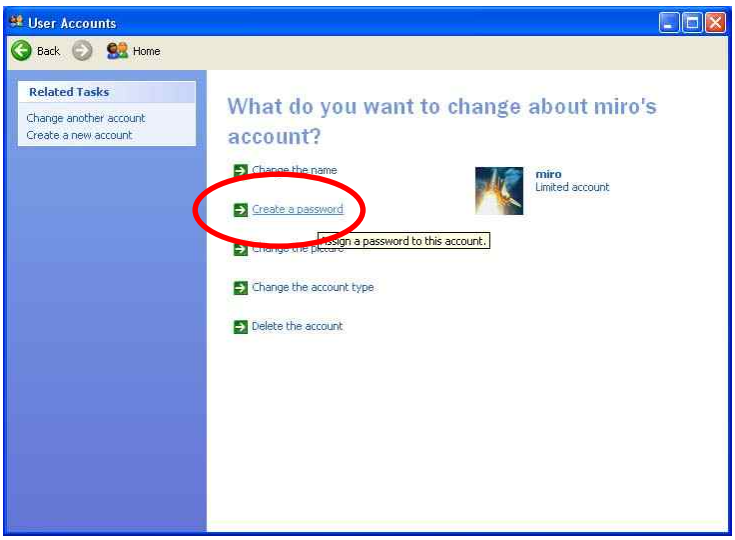
- Check account type by 'limited' and click Create Account button.



- Select “miro” account

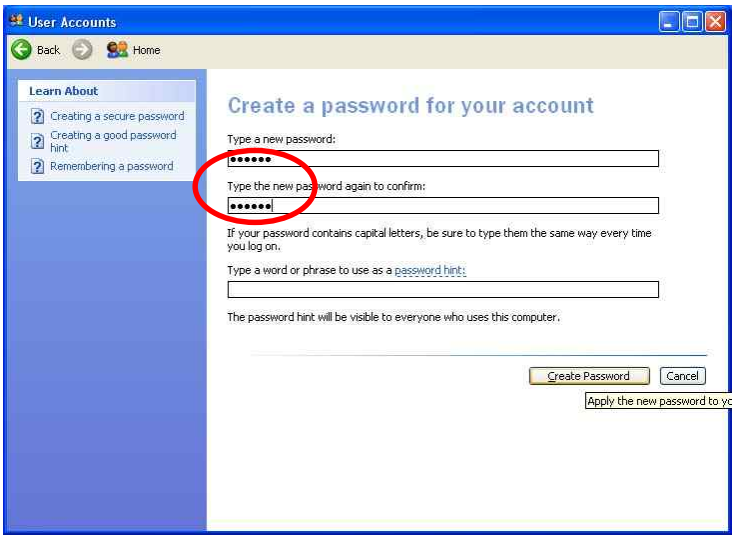


- Select ‘Create a password’.



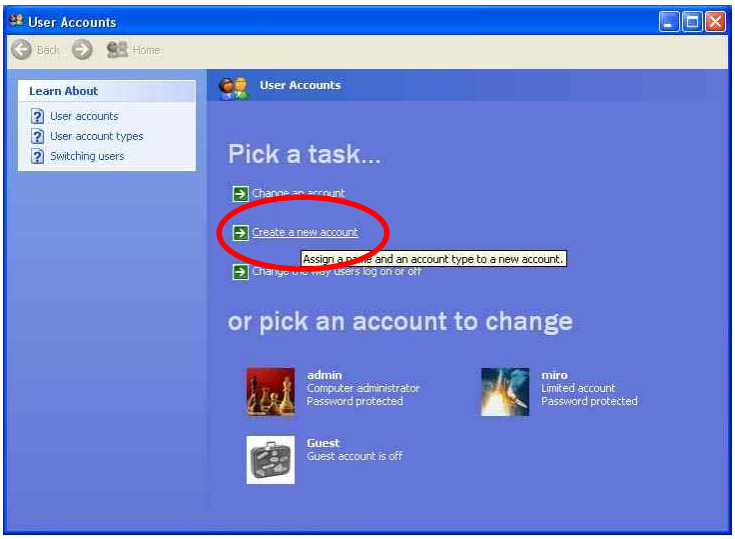
- Enter new password **miro06** and click 

button

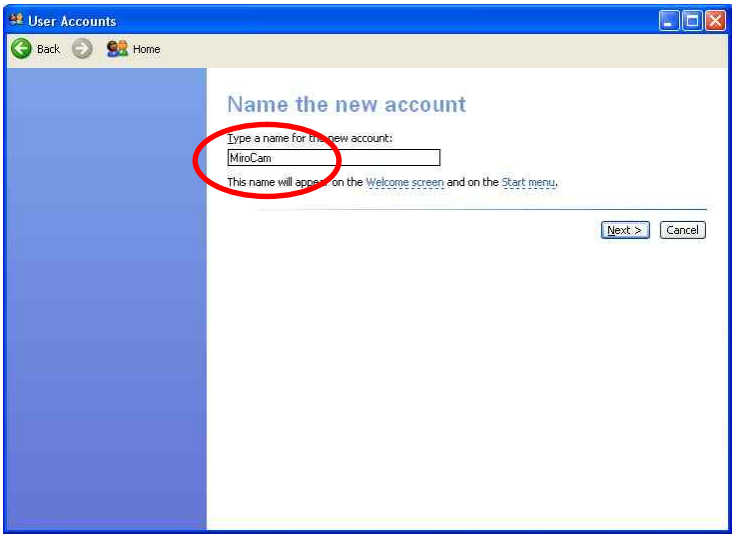


- Click 

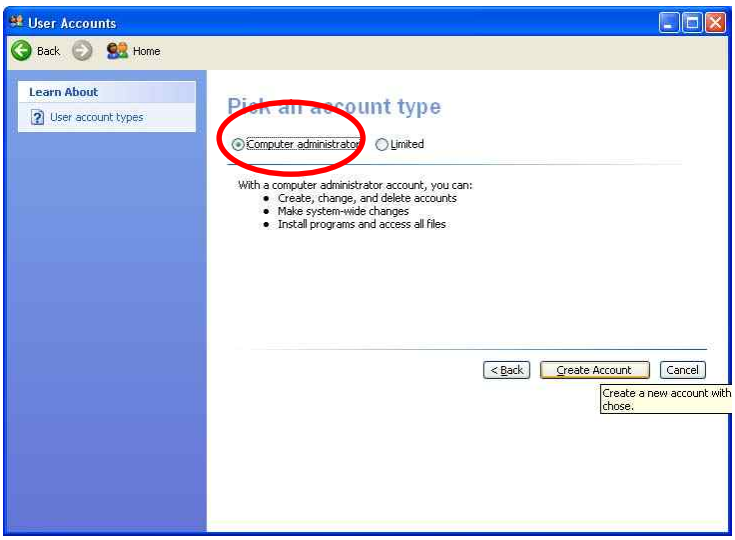
button
- Select ‘Create a new account’.



- Enter new account name **MiroCam** and click Next > button

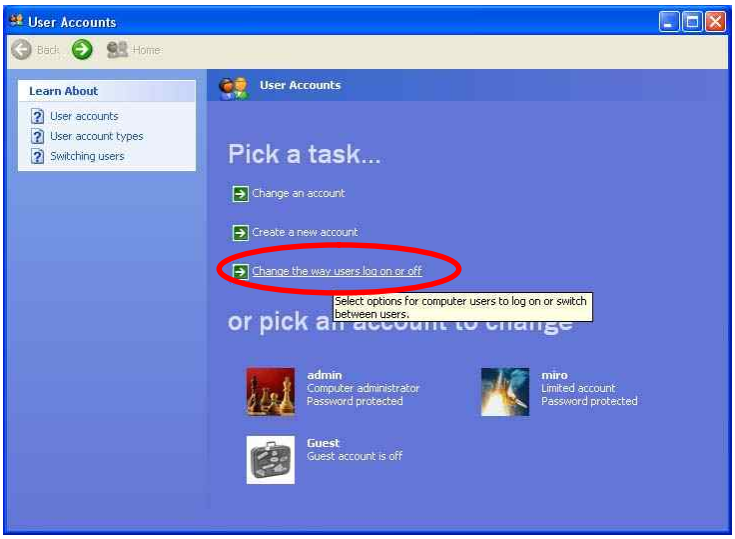


- Check account type by 'Computer administrator' and click Create Account button.

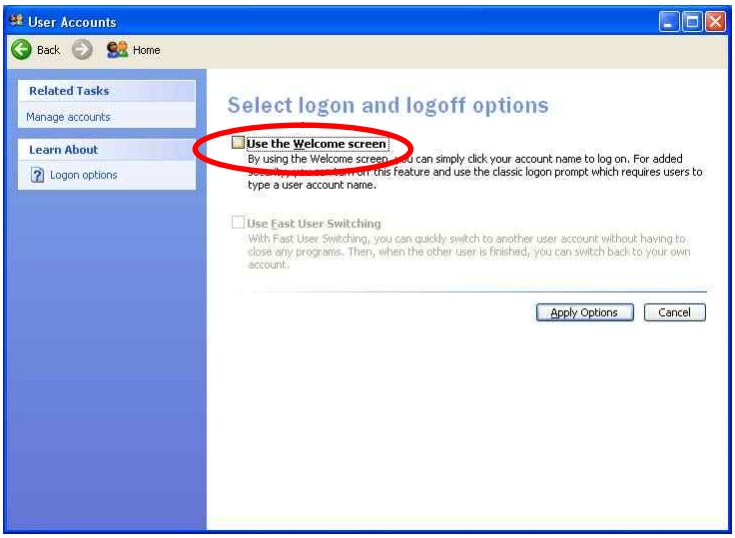


■ Autonomous log-on for the user

- Select ‘Change the way users log on or off’

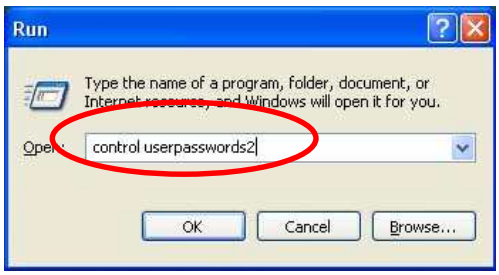


- Uncheck ‘Use the Welcome screen’ and click Apply Options button.

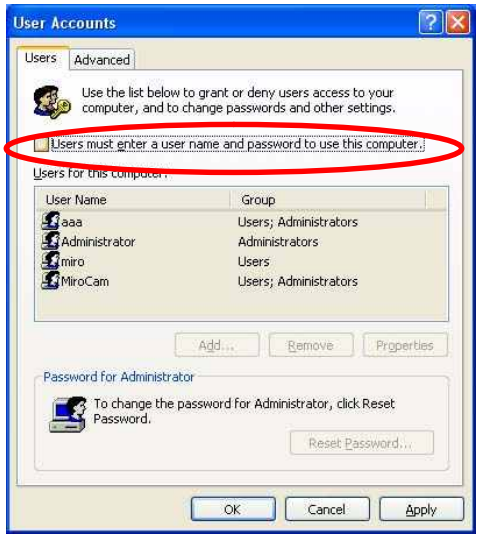


- Click start button and select 'Run'.

- Enter **control userpasswords2** and click OK button



- Uncheck ‘User must enter user name and password to use this computer’ and click OK button

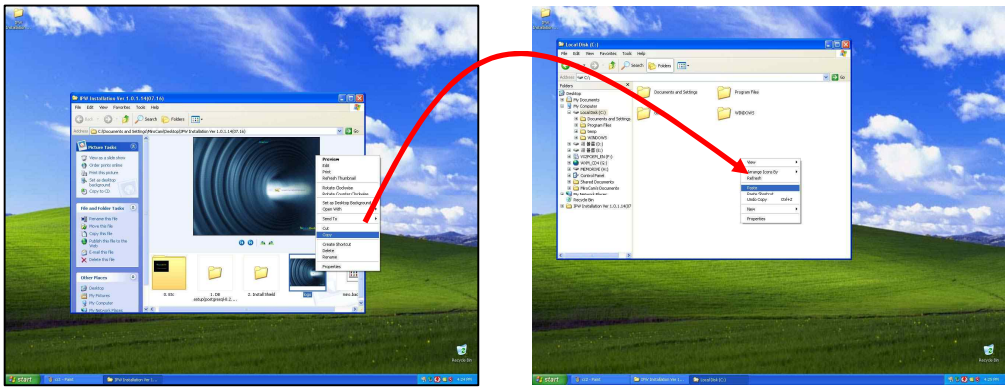


- Change User name to **MiroCam** instead of Administrator and click OK button.

- Log-off and Log-on with using ‘MiroCam’ account.

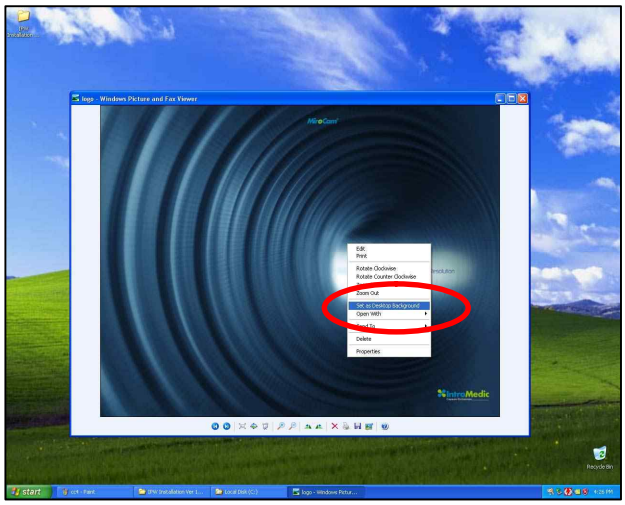
■ Setup wallpaper

- Copy ‘IPW Installation Ver 1.0.1.x (2007.x.x)’ from the IPW installation CD to desktop.
- Copy ‘Logo.jpg’ file to ‘C:\logo.jpg’



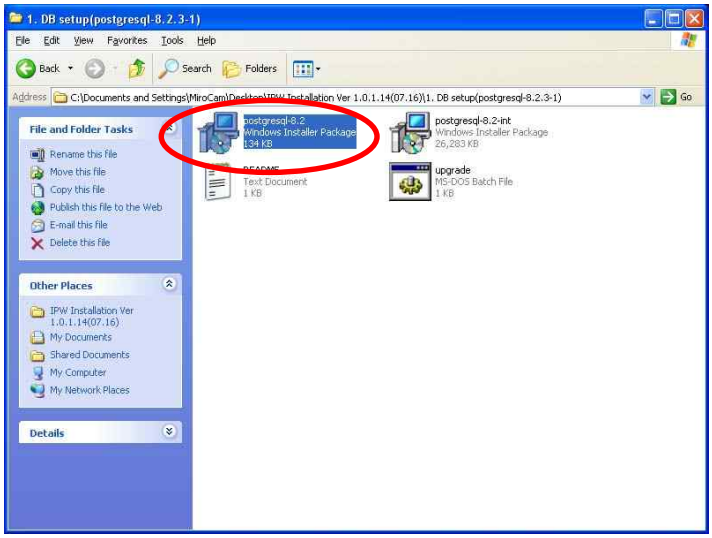
<Copy> <Paste>

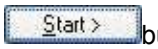
- Double click ‘logo.jpg’ file to execute Windows Fixture and Fax Viewer.
- Move the mouse pointer to center of the picture and click the right button on the mouse and click ‘Set as Desktop Background’



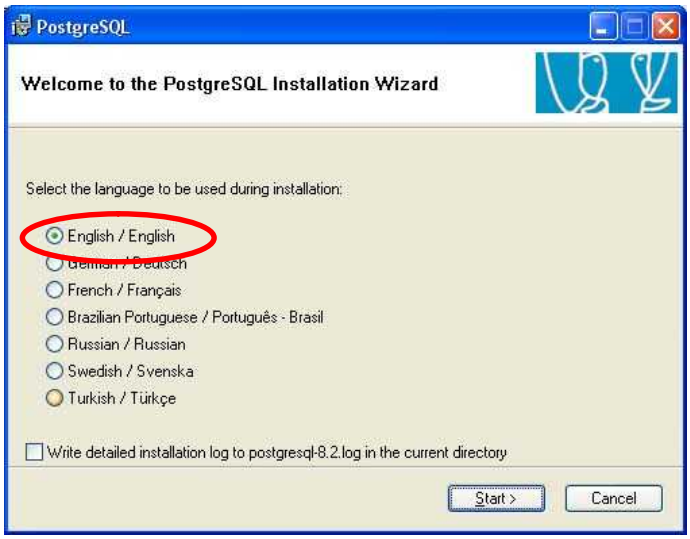
3.5.2 Database setup

- Open ‘1. DB Setup (postgresql-8.2.3-1)’ folder.
- Double click ‘postgresql-8.2.smi’ file to execute.

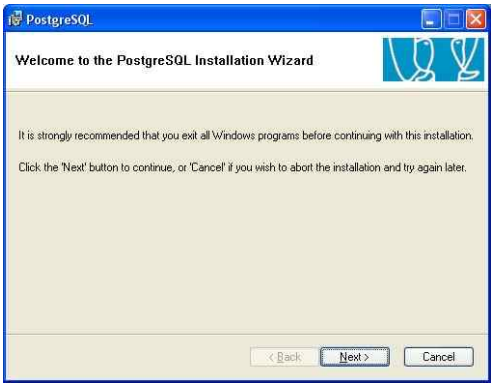


- Check English/English and click 

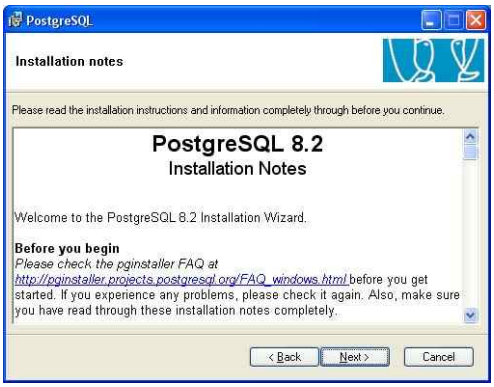
button.



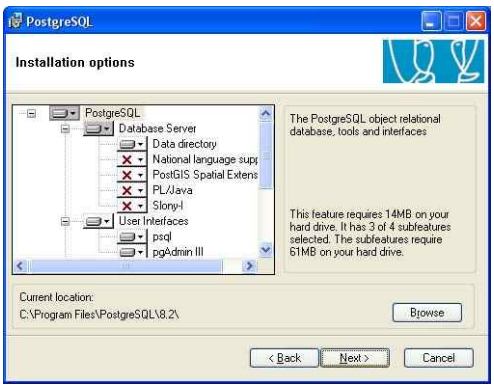
- Click Next > button.



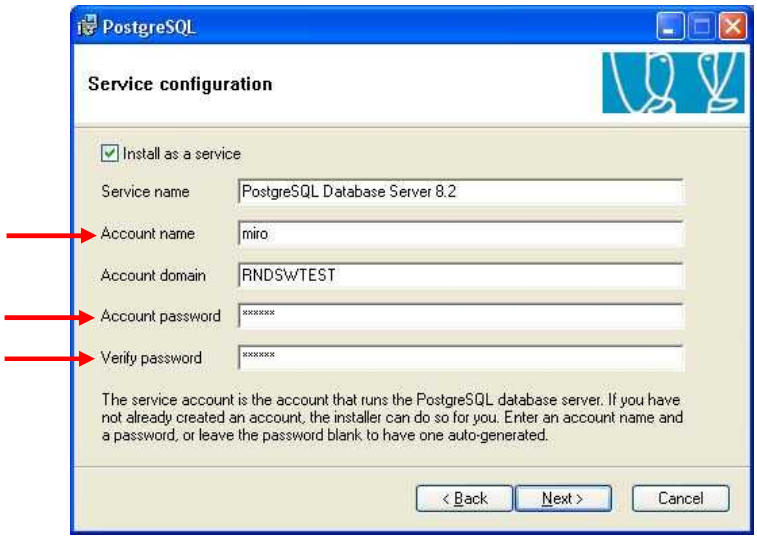
- Click Next > button.



- Click Next > button.



- Change ‘Account name’ to **miro** and enter **miro06** for ‘Account password’ and ‘Verify password’. Click Next > button.

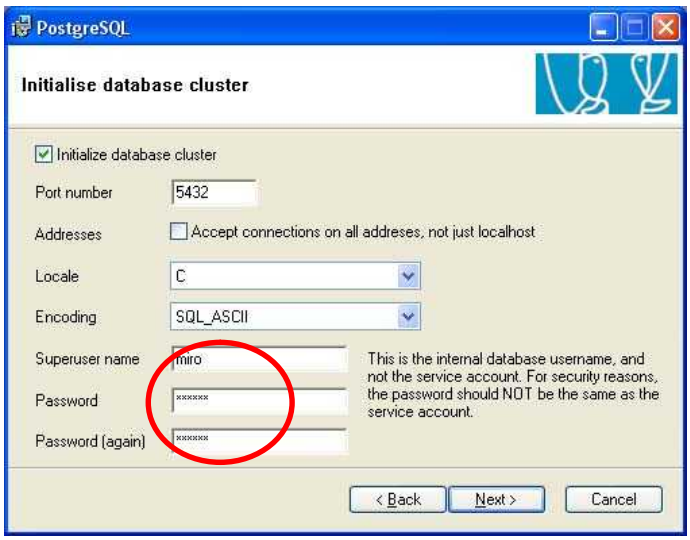


WARNING There is a default value for the ‘Account Domain’. This should NOT be changed, although it may be different than detailed in the image above.

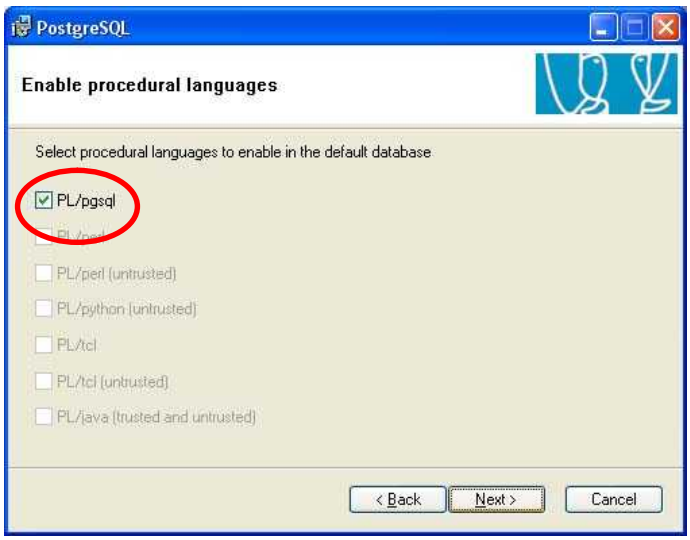
- Click Yes button.

- Click OK button.

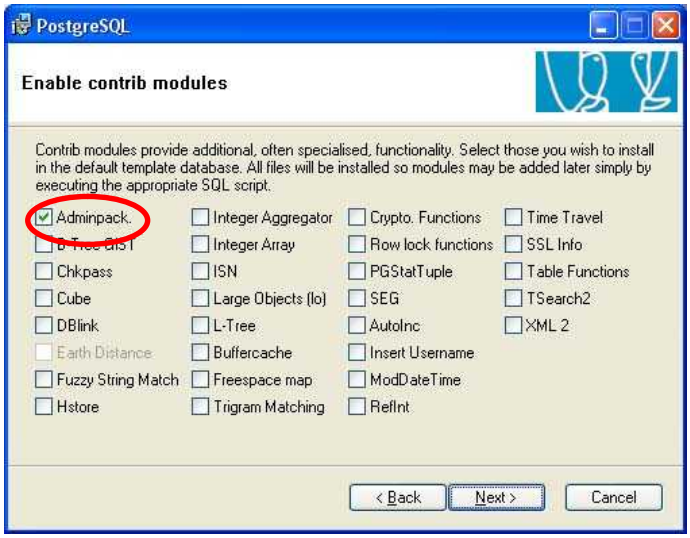
- Enter **miro** for 'Superuser name' and enter **miro06** for 'Password' and 'Password (again)'. Click Next > button.



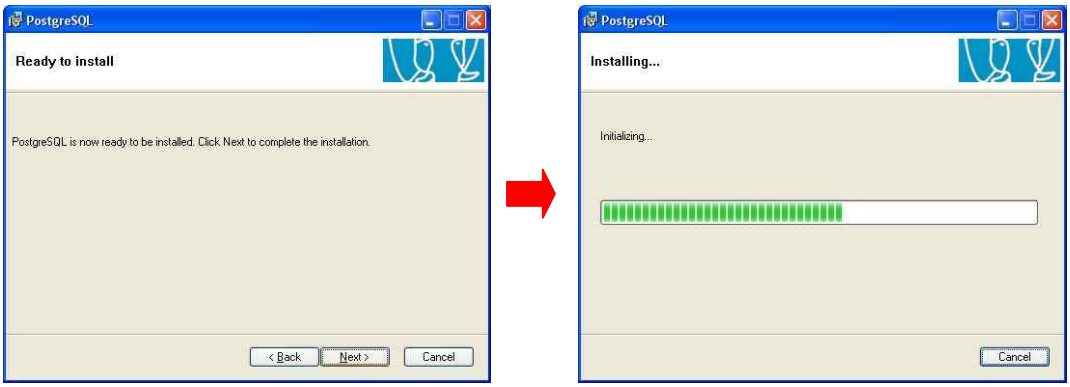
- Check 'PL/pgsql' and click Next > button.



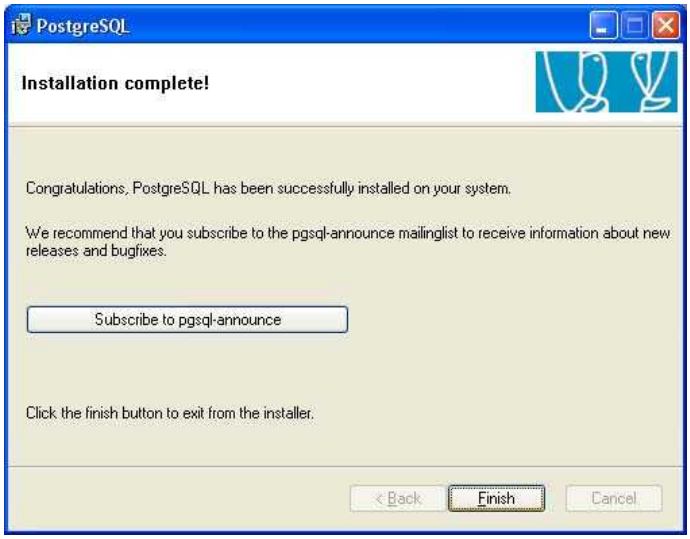
■ Check ‘Adminpack’ and click Next > button.



■ Click Next > button.



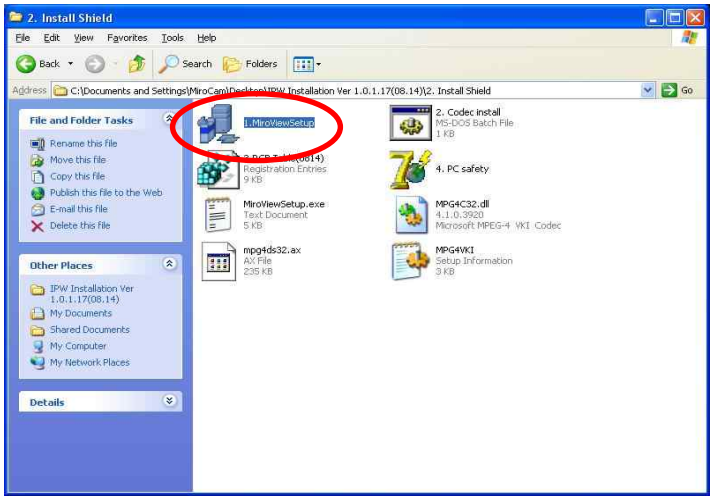
- Click Finish button.



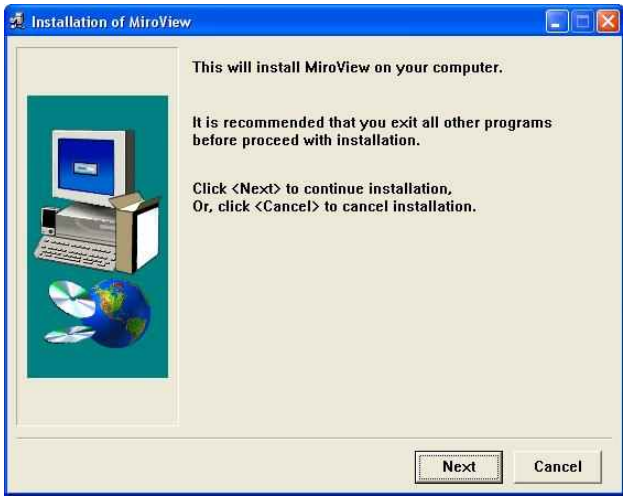
3.5.3 Software installation

■ MiroView™ application software installation.

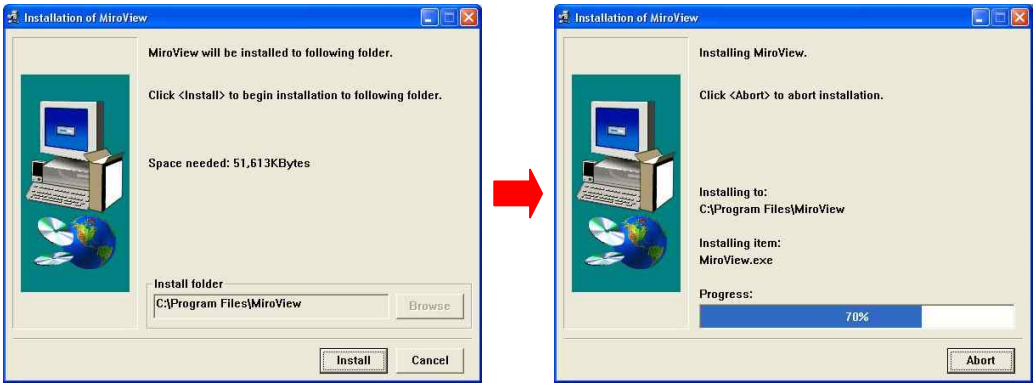
- Open ‘Installshield’ folder and double click ‘1. MiroViewSetup’



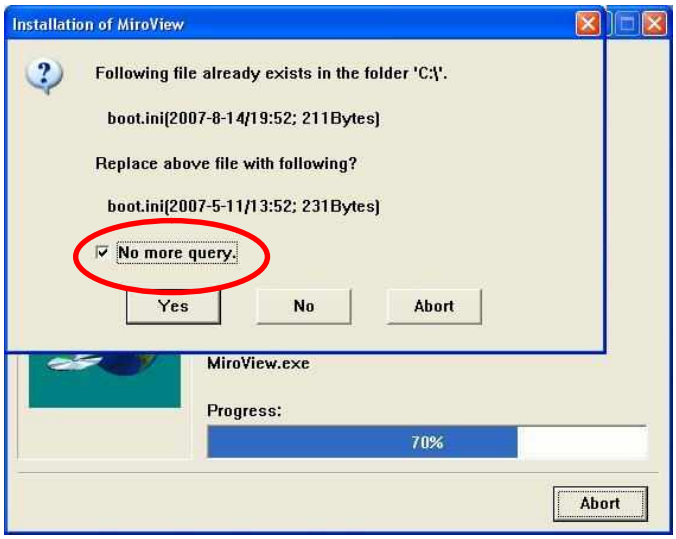
- Click  button



- Click Install button.

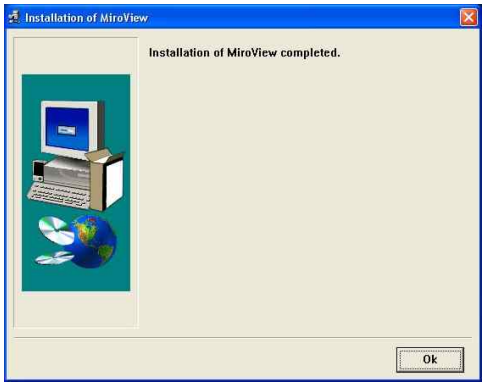


- Check 'No more query' and click Yes button.

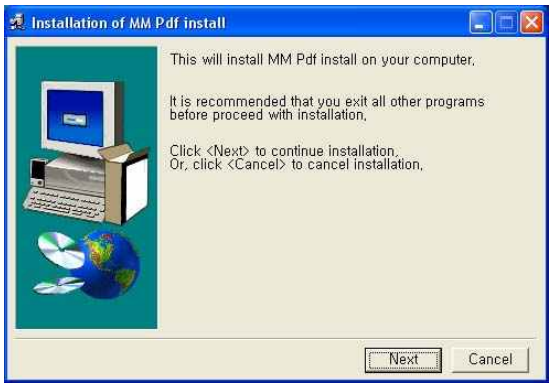


- Click Yes button.

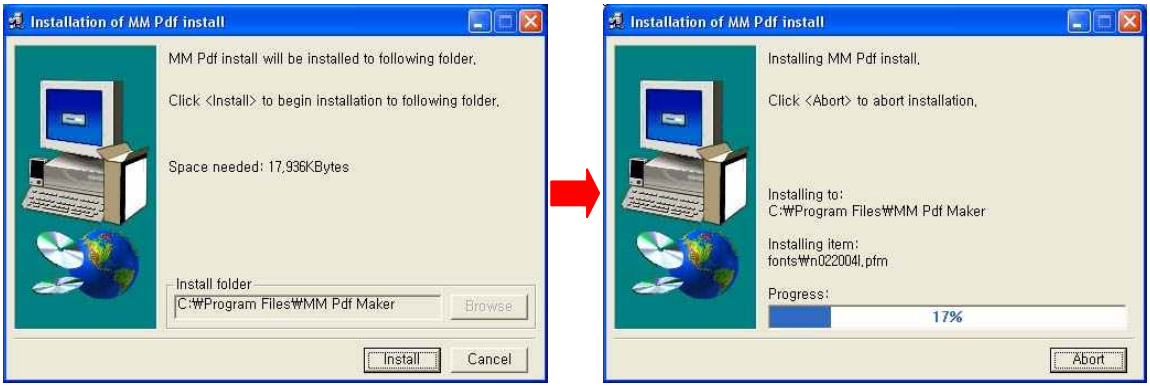
- Click Ok button.



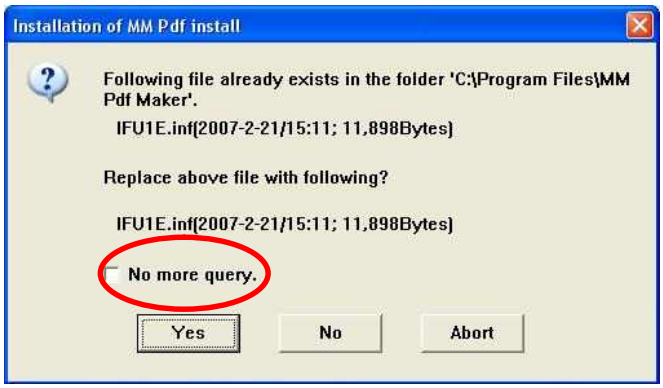
- Click Next button.



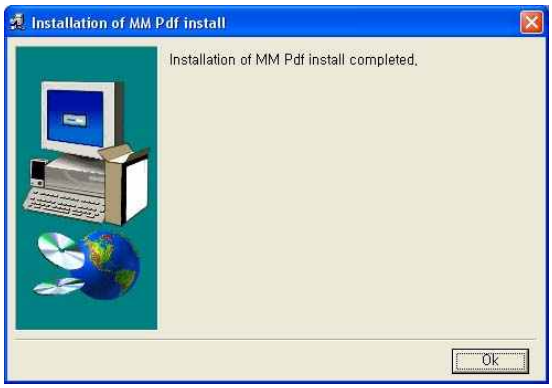
- Click Install button.



- Uncheck 'No more query' and click Yes button,

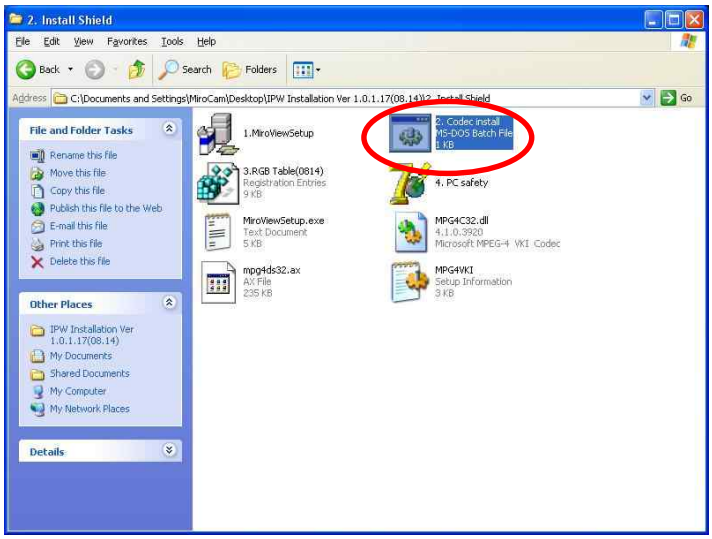


- Click Ok button.



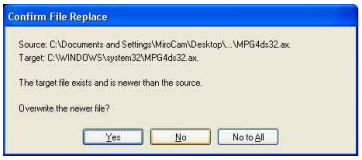
■ Codec Installation.

- Open ‘Install shield’ folder and double click ‘2. Codec Install’



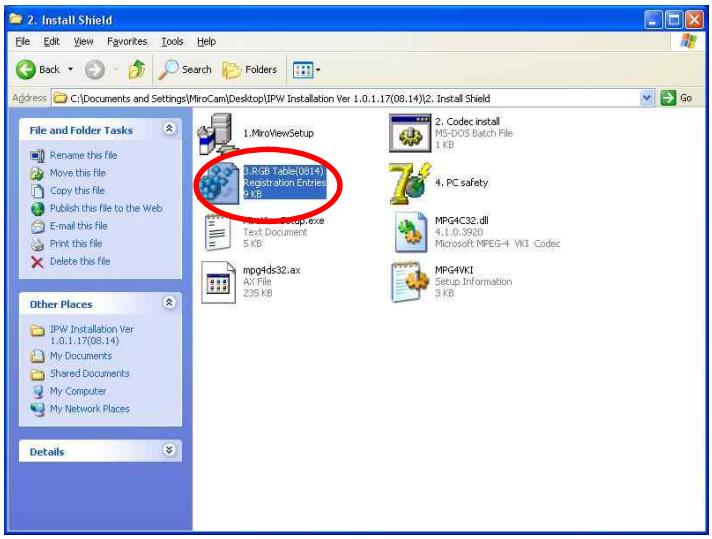
- If this window appear, click Continue Anyway button

- Click Yes button



■ Registry Installation.

- Open ‘Install shield’ folder and double click ‘3. RGB Table(0814)’.



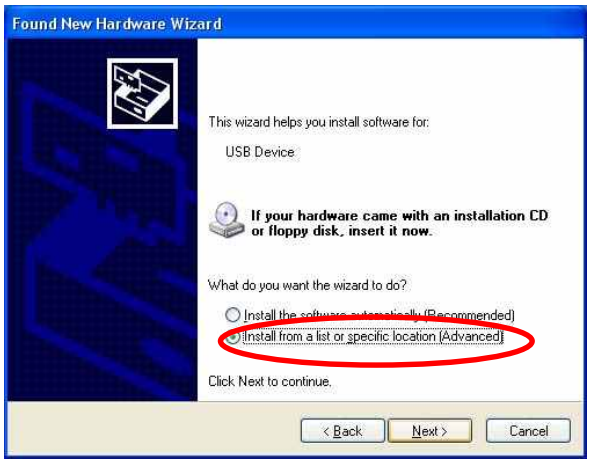
- Click Yes button.

- Click OK button.

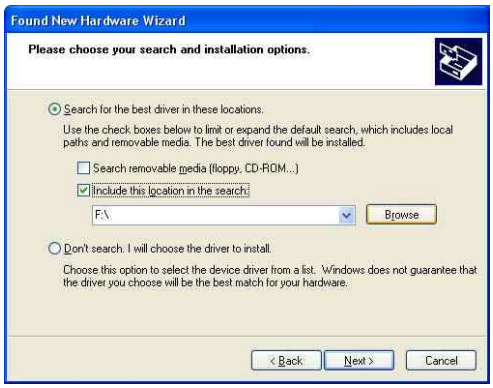
3.5.4 Device driver installation

- Connect a receiver with the PC via USB port
- Check 'Yes, now and every time I connect a device' and click Next > button.

- Check 'Install from list or specific location (Advanced)' and click Next > button.

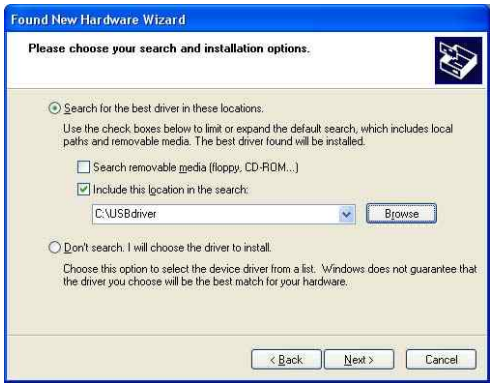


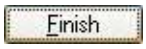
■ Click Browse button.



■ Select 'C:\USB Driver' folder and click OK button.

■ Click Next > button.

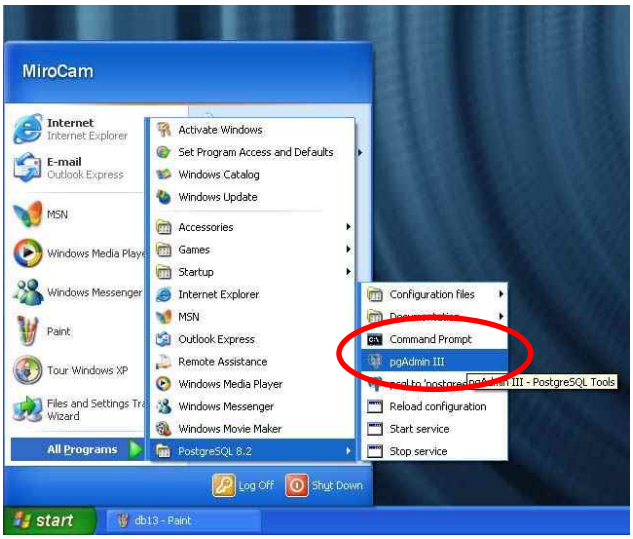


■ Click  button.

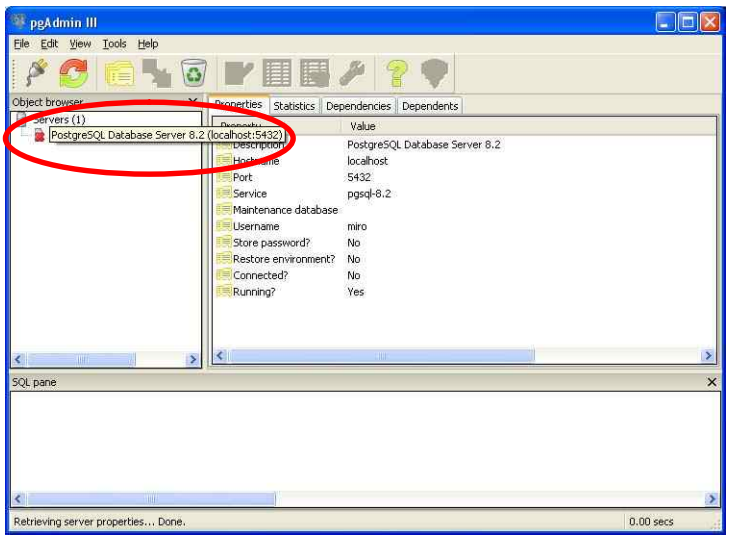
NOTE USB driver installation process should be undergone for every USB port to to be used for uploading the receiver data. If you connect the receiver via a different USB port from the one with the installed the driver with, then the driver must be set up again.

3.5.5 Make the tables on the database

- Click  button and select ‘All program → postgreSQL 8.2’.
- Select ‘pgAdmin III’

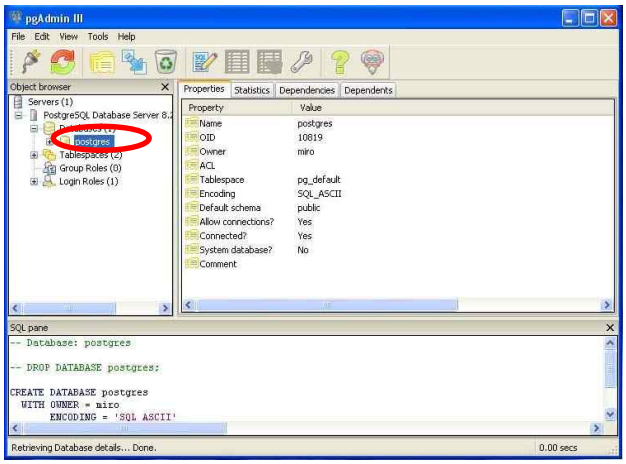


- Double click ‘PostgreSQL Database Server 8.2 (Localhost : 5432)’



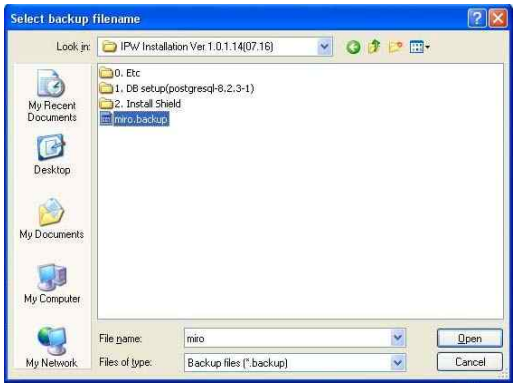
- Enter **miro06**.

- Select ‘postgres’ and click the right button on the mouse and run ‘Restore’ in the pop-up menu.



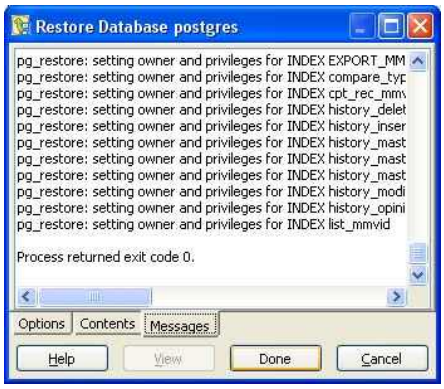
- Click  button and look for ‘miro.backup’ in the installation folder on desktop.

- Click Open button.



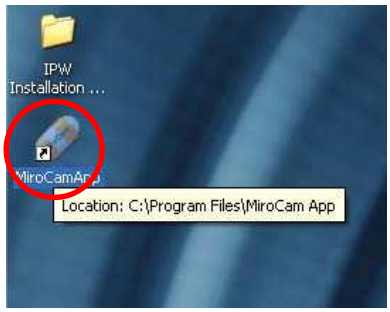
- Click OK button.

- If you see done button, the restoration is successfully complete. Click done button.



3.5.6 Finalize

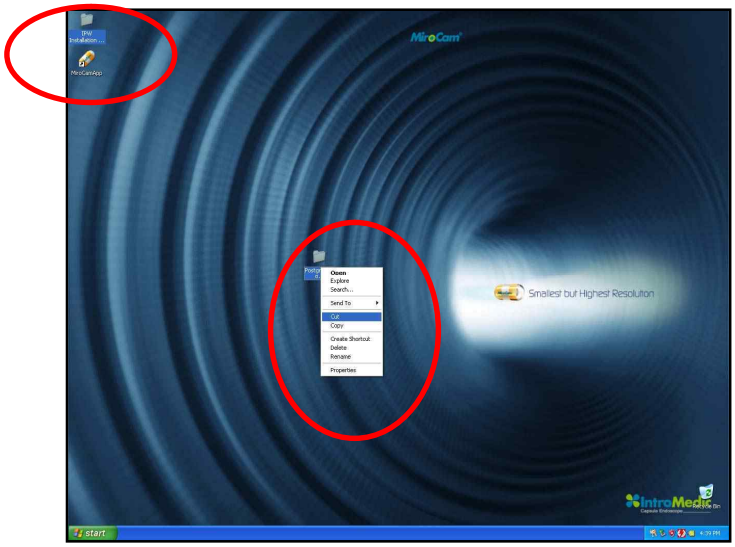
- Execute MiroView™ Software by double-clicking  icon.



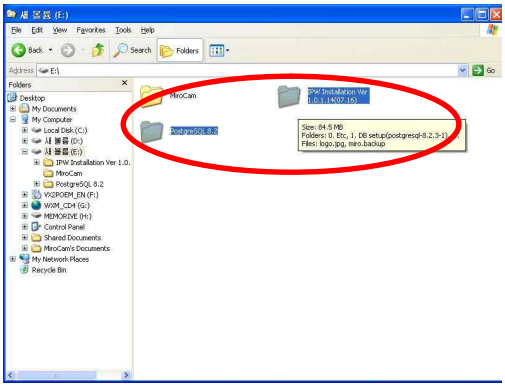
- If the form for registration appears, setting up the MiroView™ is successfully complete.

- Move this folder with pushing the left button on the mouse and dragging to the desktop.

- Cut two folders; ‘IPW Installation……’ and ‘Postgres……’.

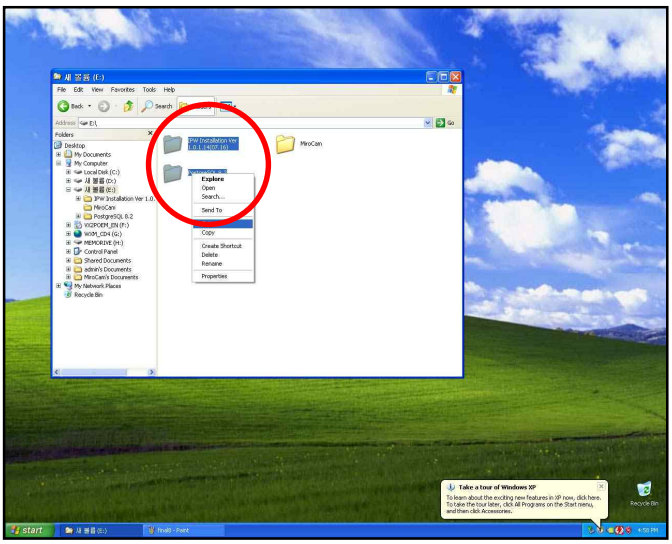


- Paste to the E drive.

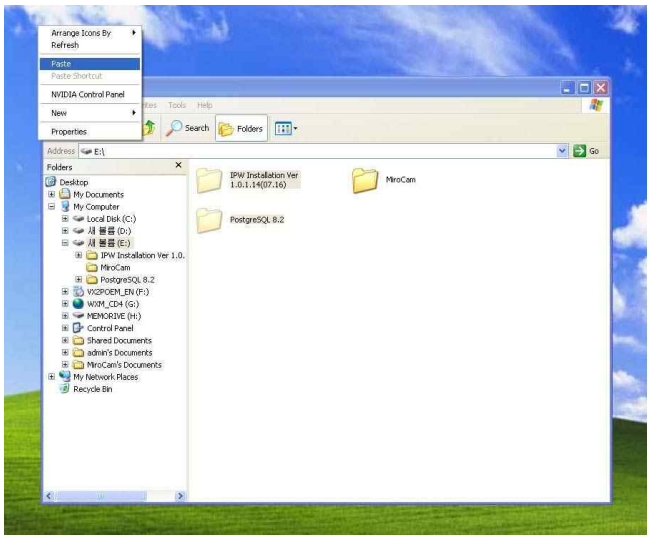


- Log off and log on whit ‘admin’ account.

- Cut two folders; ‘IPW Installation……’ and ‘Postgres……’ from E drive.

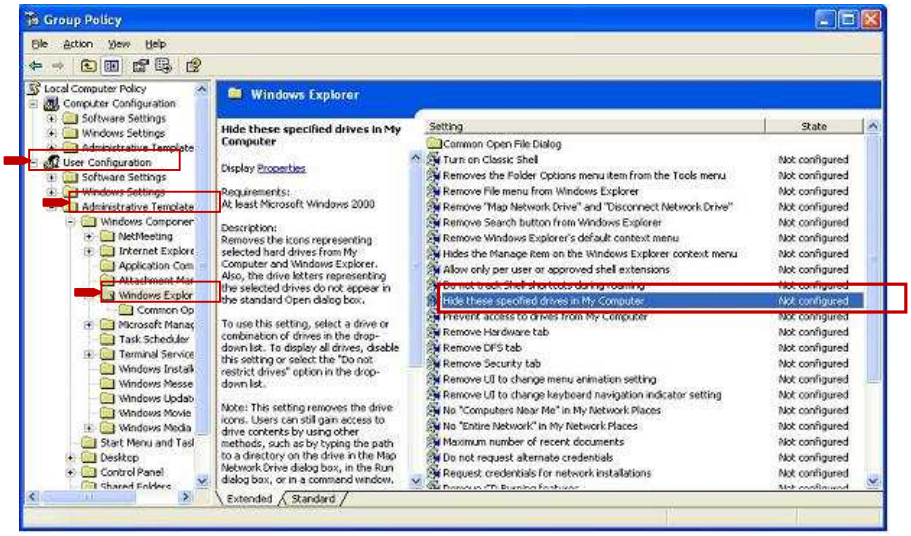


- Paste to the desktop.

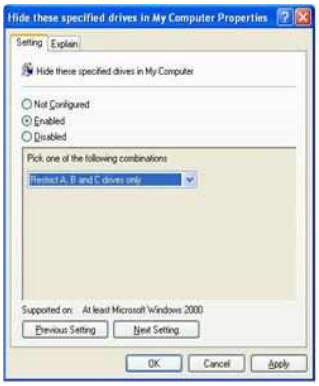


■ Click start button and select ‘Run’ and type “gpedit.msc” into the form and Enter.

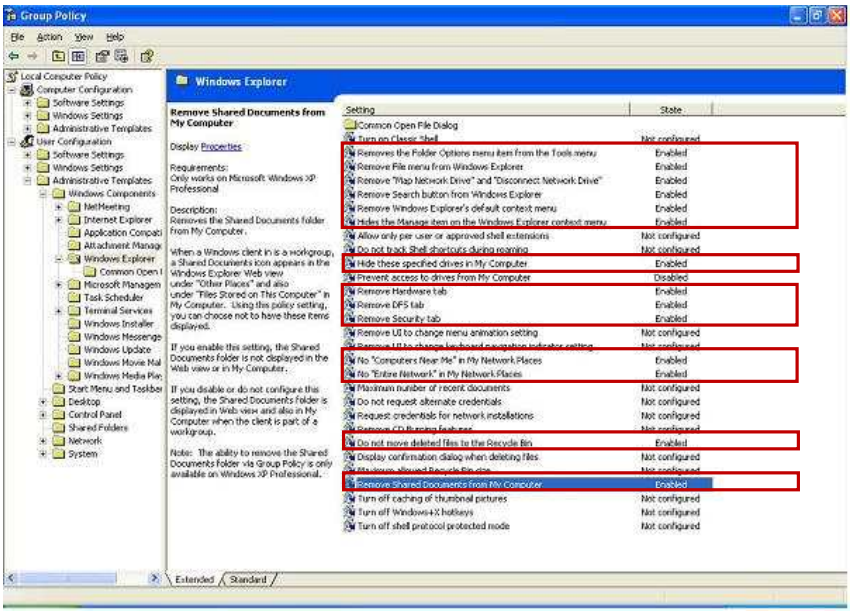
■ Select ‘User Configuration → Administrative Template → Windows Components → Windows Explorer’ on the left side of the window and double click ‘Hide these specified drives in My Computer’.



- If a form appears like below, check on ‘Enabled’ and select “Restrict A, B and C drives only” and OK.



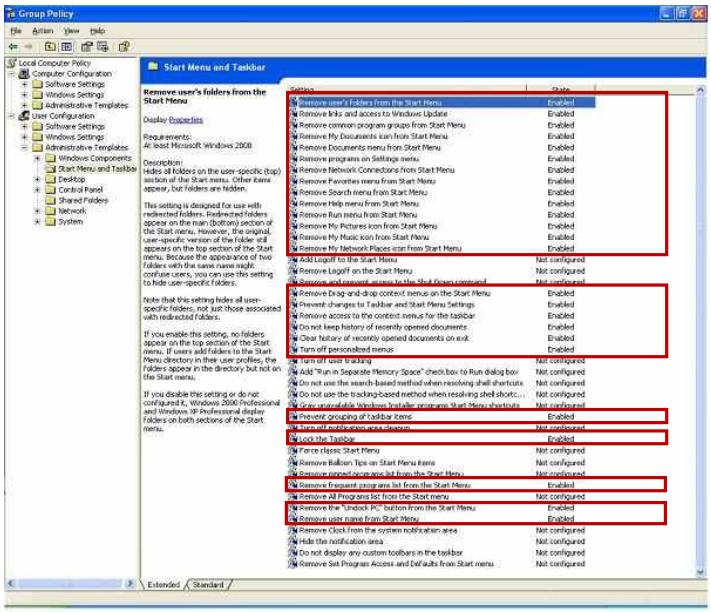
- Double clicked the specified items like below and get them to “Enabled”.



- Enabled item list

Line	Description
2	Remove the folder Options menu item from the Tools manu
3	Remove File menu from the Windows Explorer
4	Remove “Map Network Drive” and “Disconnect Network Drive”
5	Remove search button from Windows Explorer
6	Remove Windows Explorer’s default context menu
7	Hide the Manage item on the Windows Explorer context memu
10	Hide these specified drives in My Computer
12	Remove Hardware tab
13	Remove DFS tab
14	Remove Security tab
17	No “Computer Near Me” in my Network Places
18	No “Entire Network” in My Network Places
23	Do not move deleted files to the Recycled bin
26	Remove Shared Documents from My Computer

■ Select ‘User Configuration → Administrative Template → Start Menu and Taskbar on the left side of the window and set items to “Enabled” like below.

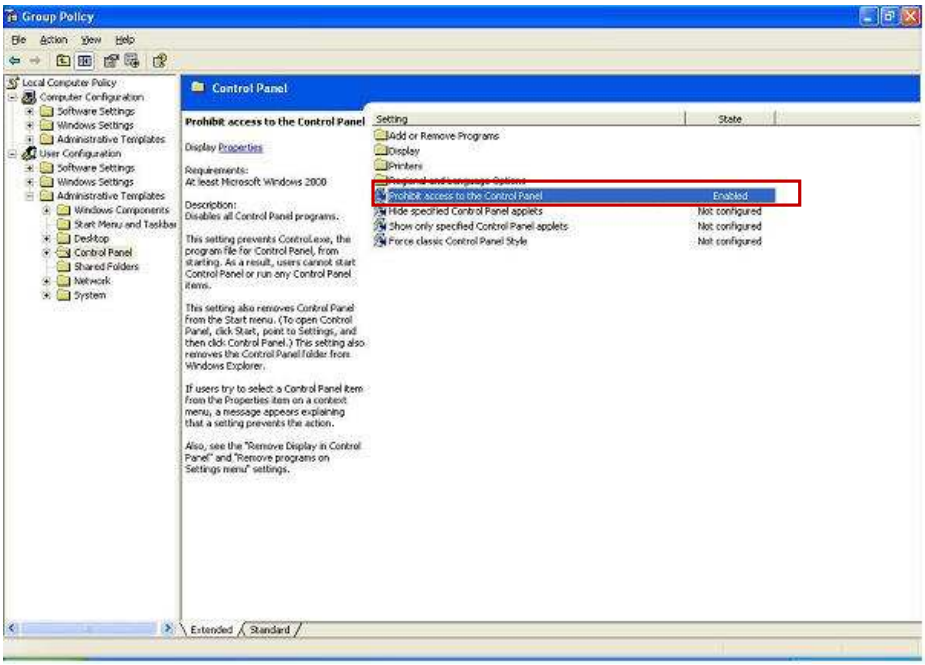


- Enabled item list

Line	Description
1	Remove user’s folders from the Start Menu
2	Remove links and access to Windows Update
3	Remove common program groups from Start Menu.
4	Remove My Document icon from Start Menu
5	Remove programs on Setting menu
6	Remove Network Connections from start menu
7	Remove Favorites menu from Start menu
8	Remove Search menu from Start menu

Line	Description
9	Remove Help menu from Start menu
10	Remove Run menu from Start menu
11	Remove My Pictures icon from Start menu
12	Remove My Music icon from Start menu
13	Remove My Network Places icon from Start menu
17	Remove Drag-and-drop context menus on the Start menu
18	Prevent changes to taskbar and Start Menu Settings
19	Remove access to the context menus for the taskbar
20	Do not keep history of recently opened documents
21	Clear history of recently opened documents on exit
22	Turn off personalized menus
28	Prevent grouping of taskbar items
30	Lock the Taskbar
34	Remove frequent programs list from the Start menu
36	Remove the “Unlock PC” button from the Start menu
37	Remove user name from Start menu

- Select ‘User Configuration → Administrative Template → Control Panel’ on the left side of the window and set ‘Prohibit access to the Control Panel’ to “Enabled” like below.



■ Installation is finished.

4

Technical Data

4. TECHNICAL DATA

4.1 Overview

- Product Name: MiroCam Capsule Endoscope System
- Model Name: MiroCam
- Serial Number: Refer to the label which is attaching in the reverse side of the product.
- Manufacturer: IntroMedic. Co., Ltd.
- Manufacturer Address

  Suite 1104, E&C Venture Dream Tower 6-Cha

  197-28 Guro-Dong, Guro-Gu, Seoul, KOREA 152-719

  Tel : +82-2-801-9300

  Fax : +82-2-801-9330

  http://www.intromedic.com

  e-mail : help@intromedic.com

4.2 Classification of Equipment

4.2.1 According to the type of protection against electric shock
: Internally Powered Equipment

4.2.2 According to the degree of protection against electric shock
: Type BF Applied Part

4.2.3 According to the degree of protection against ingress of water
: IPX0

4.2.4 According to the method of sterilization or disinfection
: Equipment not usable sterilization & disinfection

4.2.5 According to the degree of safety of application in the presence of a FLAMMABLE ANAESTHETIC MIXYURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE
: Equipment not suitable for use in the presence of a

FLAMMABLE ANAESTHETIC MIXYURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE

4.2.6 According to the mode of operation
: Continuous Operation with Short-Time Loading Equipment

4.3 Hardware

4.3.1 Capsule (Model: MC1000-C)

- Size: 10.8 X 24mm
- Weight: 3.25g
- Material: Human Compliance Plastic
- Light: 6 white LED
- View Angle: 150°(In image)
- View Depth: 3 cm
- Enlargement Ratio: 1:8
- Detectable Range: under 0.1mm
- Sampling Ratio: 2.9 fps
- Working time: 11 hours
- Mechanical Safety: Compatible ISO60601-1-1
- Biocompatibility Safety: Compatible ISO10993-4, ISO10993-5, ISO10993-10, ISO10993-11
- Chemical Safety: Safe in pH=2 ~ pH=8
- Battery Type: Silver Oxide Cell
- Operation Temperature: 20 ~ 40℃
- Storage Temperature: 0 ~ 50℃
- Recommended Maximum Storage Time: 1 Year

4.3.2 Receiver(Model: MR1000-R, MR2000-R)

- Operation System: Firmware
- Recording Time: 12 Hours
- Weight: 350g, include battery
- Operation Voltage: 3.7V, 0.45A
- Battery Type:
  - MR1000: Lithium Ion Battery (3.7V, 8.8A)
  - MR2000: Lithium Ion Battery (3.7V, 10.4A)
- Battery Weight: 215g
- Operation Temperature: 0 ~ 40℃
- Storage Temperature: 0 ~ 55℃
- Category: Type BF
- Life Time: 4.62 Year

4.3.3 Battery Charger(MR1000-C)

- Input Voltage: 9VDC
- Input Current: 3A
- Output Voltage: 4.2VDC
- Output Current: 4A
- Operation Display: LED Display
- Adaptor Manufacturer: BridgePower Corporation(JEC Korea)
- Adaptor Model: JMW128XA0902F02

4.3.4 Recommended Image Workstation

- Operating System: Windows XP Professional
- CPU: Core 2 Duo E6300(1.86GHz/2M)
- Memory: DDR II 1GByte(667MHz)

- Display Adaptor: Geforce 7600GT 256MB
- Hard Disk: SATA II 160GB, SATA II 320GB
- ODD: DVD-RW
- Monitor Resolution: 1280 X 1024
- Monitor Contrast: 700 : 1
- Printer Resolution: 4800 X 1200 dpi
- Printer Paper: A4

4.4 Software

4.4.1 Version

- MiroView Version 1.1.5

4.4.2 Specification

- Monitor Contrast: 700 : 1
- Language: English
- Data Export: JPEG Image, AVI Video Clip, PDF Data Report
- Data Display: Single or Multi Image, Time Bar, Diagnosis Data
- Event Marker: Small Image with Explanation
- Display Ratio: 5 ~ 30 fps
- Display Mode: Single View, Dual View, Quad View
- Running Mode: Normal View, Quick View, Blood View
- Error Ratio: Under 100 image continuously

4.4.3 Feature

- Language: English

- Color status Display
- User Friendly software feature
- Automated detection of GI tract bleeding
- Color of images are virtually natural

4.5 Compliance / Approvals

The MiroCam capsule endoscope system and accessories complies with the Medical Device Directive 93/42/EEC (CE_{0843}).
In addition, the product complies with

IEC 60601-1:1988 + A1:1991 + A2:1995 (EN 60601-1:1990 + A1:1992 + A2:1995)	Medical Electrical Equipment, Part 1 : General requirement for safety
EN 60601-1-1:2001	Medical Electrical Equipment, Part 1 : General requirement for safety Collateral Standard : Medical Electrical System
EN 60601-1-2:2001	Medical Electrical Equipment, Part 1 : General requirement for safety Collateral Standard : Electromagnetic compatibility
EN 60601-1-4:1998	Medical Electrical Equipment, Part 1 : General requirement for safety Collateral Standard : Programmable Electrical Medical System
EN60601-2-18:1996	Medical Electrical Equipment, Part 2 : Particular requirement for the safety of endoscope equipment
EN 10993-1:2003	Biological evaluation of medical devices, Part 1: Evaluation and Testing Third Edition

4.5.1 FCC Statement

- This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
- CAUTION: Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
- NOTE: This equipment has been tested and found to comply with the limit for a Cass B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation, 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.

5

Storage & Transportation

5. Storage & Transportation

5.1 Safe Storage Conditions

- Environmental condition for storage
  - Temperature : -10℃ - +70℃
  - Relative humidity : 10% - 80%
  - Atmospheric pressure : 700hPa to 1060hPa
- Keep in the place that is not in contact with water
- Keep in the place out of direct light
- Keep away from hazardous materials for the human body.
- Keep away from children.
- Do not store with chemicals.
- For cleaning, only use gauze with water. Other liquid like alcohol should not be used.
- Use the provided battery charger for charging.
- If product is not used for an extensive period of time, please separate the battery from the receiver unit.

5.2 Safety Transportion Conditions

- Temperature : -10℃ - +70℃
- Relative humidity : 10% - 80%
- Atmospheric pressure : 700hPa to 1060hPa
- Product MUST be handled with care, and not dropped.

6

Troubleshooting

6. TROUBLESHOOTING

6.1 Introduction

This chapter explains how to troubleshoot the MiroCam® capsule endoscope system if problems arise. Tables are supplied that list possible difficulties, probable cause, and recommended actions to correct.

6.2 Who should perform repairs

Only qualified service personnel should open the MiroCam® Capsule Endoscope System housing, remove and replace components, or make adjustments.

6.3 Obtain replacement parts

IntroMedic Technical Service provides technical assistance information and replacement parts. To obtain replacement parts, contact IntroMedic Co., Ltd. or your local representative. Refer to part names and part numbers listed on Chapter 2.6, *Component List.*

6.4 Troubleshooting Guide

Condition	Recommended Action
The MiroCam capsule endoscope system workstation fails to power-up when the I/O power switch is on.	1. Ensure that the MiroCam capsule endoscope workstation main system is plugged into an operational AC outlet in accordance with the input specification rated on the side panel of the workstation main system. 2. If the condition persists, contact IntroMedic Co., Ltd. or local representative.
The MiroCam capsule endoscope system receiver unit fails to power-up when the I/O power switch is on.	1. Recharge battery of receiver unit. 2. Replace battery of receiver unit. 3. If the condition persists, contact IntroMedic Co., Ltd or local representative.
Capsule is not blinking when taken out of the case.	1. DO NOT use the capsule. Use an alternate capsule. 2. Contact IntroMedic Co., Ltd. for replacement of capsule.
INI LED on receiver unit is yellow, and does not turn green when held appropriately by patient.	1. Initialize receiver unit via MiroView™ software. 2. If the condition persists, contact IntroMedic Co., Ltd.
BAT LED, on receiver unit is yellow.	1. Recharge battery of receiver unit. 2. Replace battery of receiver unit. 3. If the condition persists, contact IntroMedic Co., Ltd.

If you see following message when you use MiroView™ software, check possible cause and action before contacting IntroMedic.

	Error Message	Possible cause	Action
1	The selected drive does not support CD/DVD burning.	The CD/DVD drive does not support CD/DVD burning.	Exchange the CD/DVD drive for DVD multi or DVD writable drive.
2	The selected drive does not support CD/DVD burning.	User selected wrong drive.	Select the DVD writable drive and try again.
3	BACKUP or EXPORT is not yet complete. Wait for process to finish and try again.	The user executed BACKUP or EXPORT function while the burning process is operating.	Wait until the process has stopped and try again.
4	The selected capture cannot be added.	MiroView™ software installation problem.	Contact to IntroMedic.
5	The selected landmark cannot be added.	MiroView™ software installation problem.	Contact to IntroMedic.
6	Failed to save.	MiroView™ software installation problem.	Contact to IntroMedic.

7	An error arose while trying to export. Please try again.	Improper export destination selected.	Check the drive to export. Check if the drive has sufficient space.
8	An error arose while trying to export. Please try again.	MiroView™ software installation problem.	Contact IntroMedic.
9	There is no data to export.	There is no data to export.	If you did not capture any image, then this is not an error. If persists, contact IntroMedic.
10	Failed to make a video file because Microsoft MPEG4-V2 codec does not exist.	MiroView™ software Installation problem	Contact IntroMedic
11	Not enough memory.	The system resources are not sufficient to support MiroView™	Reboot.
12	The file buffer size is over the limit.	The system resources are not sufficient to support MiroView™.	Reboot.

13	Failed to create the file.	The disk space is not enough.	Delete data (patient files) from the List Mode.
14	Not enough storage space.	The disk space is not enough.	Delete data (patient files) from the List Mode..
15	Failed to find the file.	Synchronization error between files and list	Contact IntroMedic
16	The file type does not match.	File version error.	Contact IntroMedic
17	Database error	Failed to access the DB server.	Reboot.
18	The printer driver is not installed.	A printer driver (MM PDF Maker) is not installed.	Contact IntroMedic
19	The PDF converting module is not installed.	Cannot create the report PDF file because PDF converting module is not installed.	Contact IntroMedic
20	Receiver is disconnected while uploading	Cannot continue to upload because receiver has become disconnected.	Check the connection between the receiver and the PC.
21	Cannot upload because receiver is not connected.	Improper connection between the receiver and the PC	Check the connection between the receiver and the PC

22	Cannot upload because receiver is not connected.	The receiver is turned off.	Turn on the receiver and try again.
23	Fill out all the required fields.	There are the fields which you did not enter the contents into.	Make sure all require fields are filled.
24	Failed to upload data from receiver.	Connection error between the receiver and the PC	Check the connection between the receiver and the PC
25	Failed to complete restoration.	MiroView™ software installation problem.	Contact to IntroMedic
26	Failed to complete restoration due to some missing files.	Backup error	Back up the data and restore again
27	Please insert disk number ##.	The user inserted wrong disk while restoring the data	Insert disk with number ##.
28	Wrong disk. Please insert a disk of the same original file.	The user inserted wrong disk while restoring the data	Insert the disk of the same original file.
29	The backup disk info is incorrect.	Backup error	Back up the data and restore again

Warnning If the problem arises again, contact to IntroMedic Service center.

7

Packing for shipment

7. PACKING FOR SHIPMENT

To ship the MiroCam® Capsule Endoscope System for any reason, follow the instructions in this chapter.

7.1 General Introduction

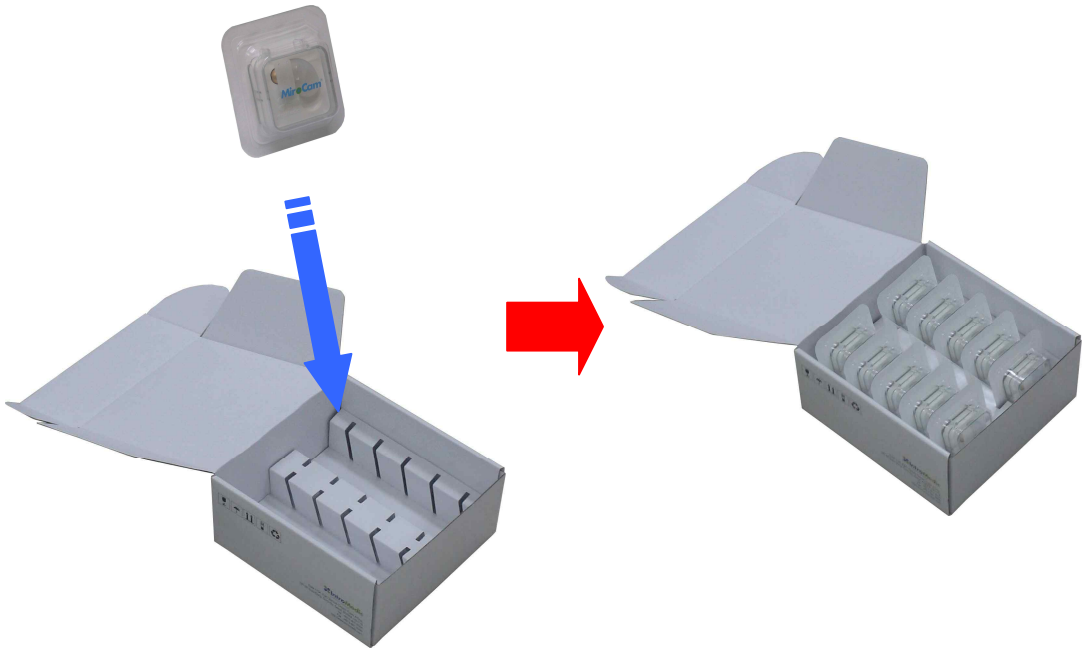
Pack the MiroCam capsule endoscope system carefully. Failure to follow the instructions in this chapter may result in loss or damage not covered by the IntroMedic Co., Ltd. warranty. If the original shipping box is not available, use another suitable box. Return the product with a detailed, written description of the problem.

7.2 Repacking in Original Packing Box

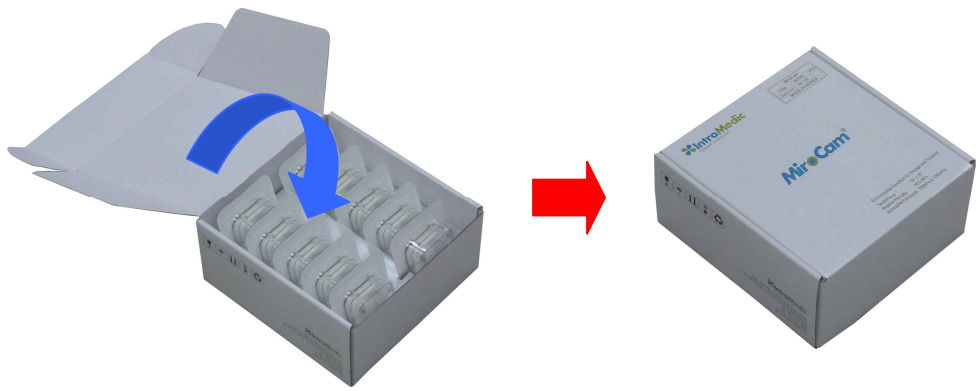
If available, use the original packing box and packing materials as illustrated figures in below.

■ Repacking MiroCam® capsule

- Insert capsule storage case into capsule box.



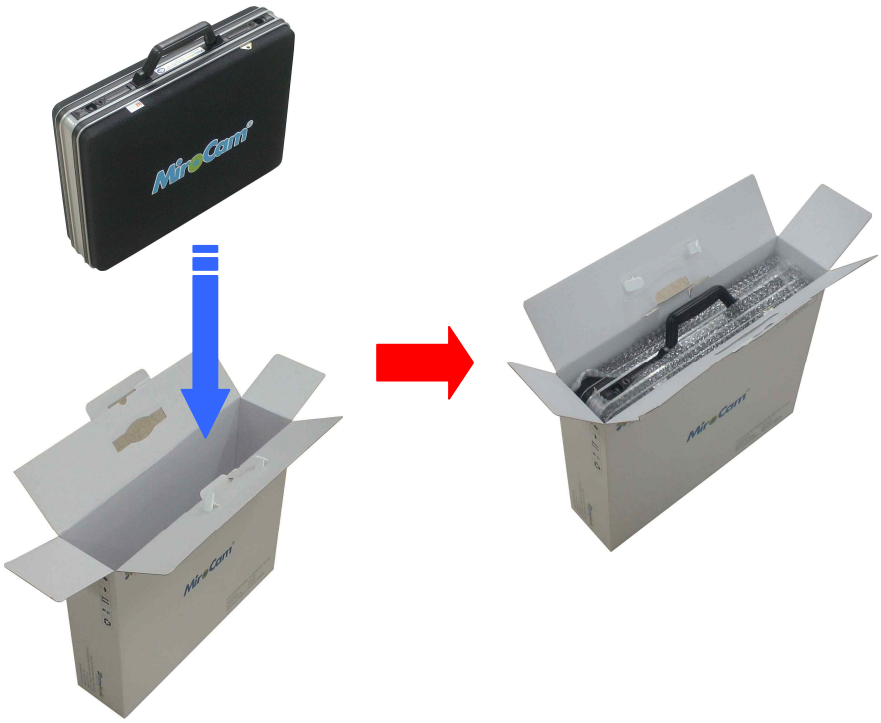
- Close capsule box.



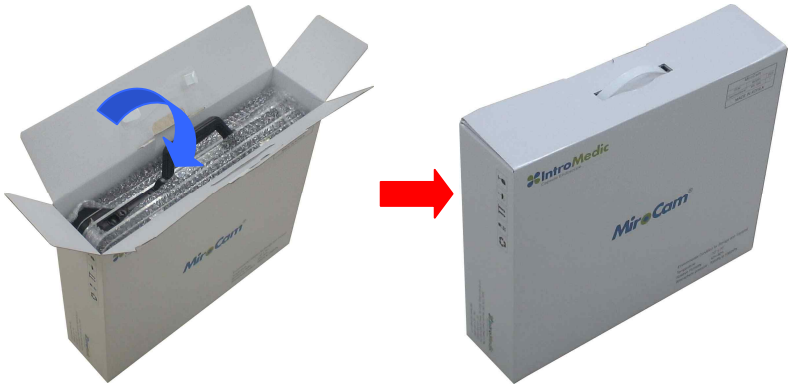
■ Repacking MiroCam® receiver unit

- Insert receiver unit into system carry case.

- Insert system carry case into receiver unit box.

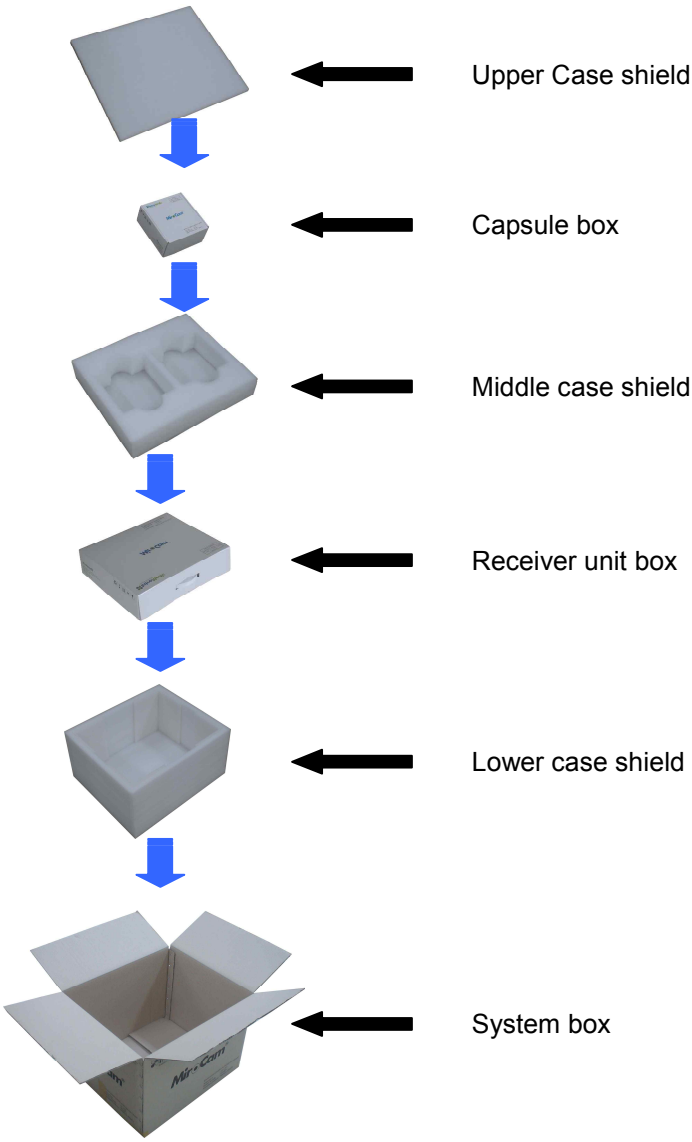


- Close receiver unit box.

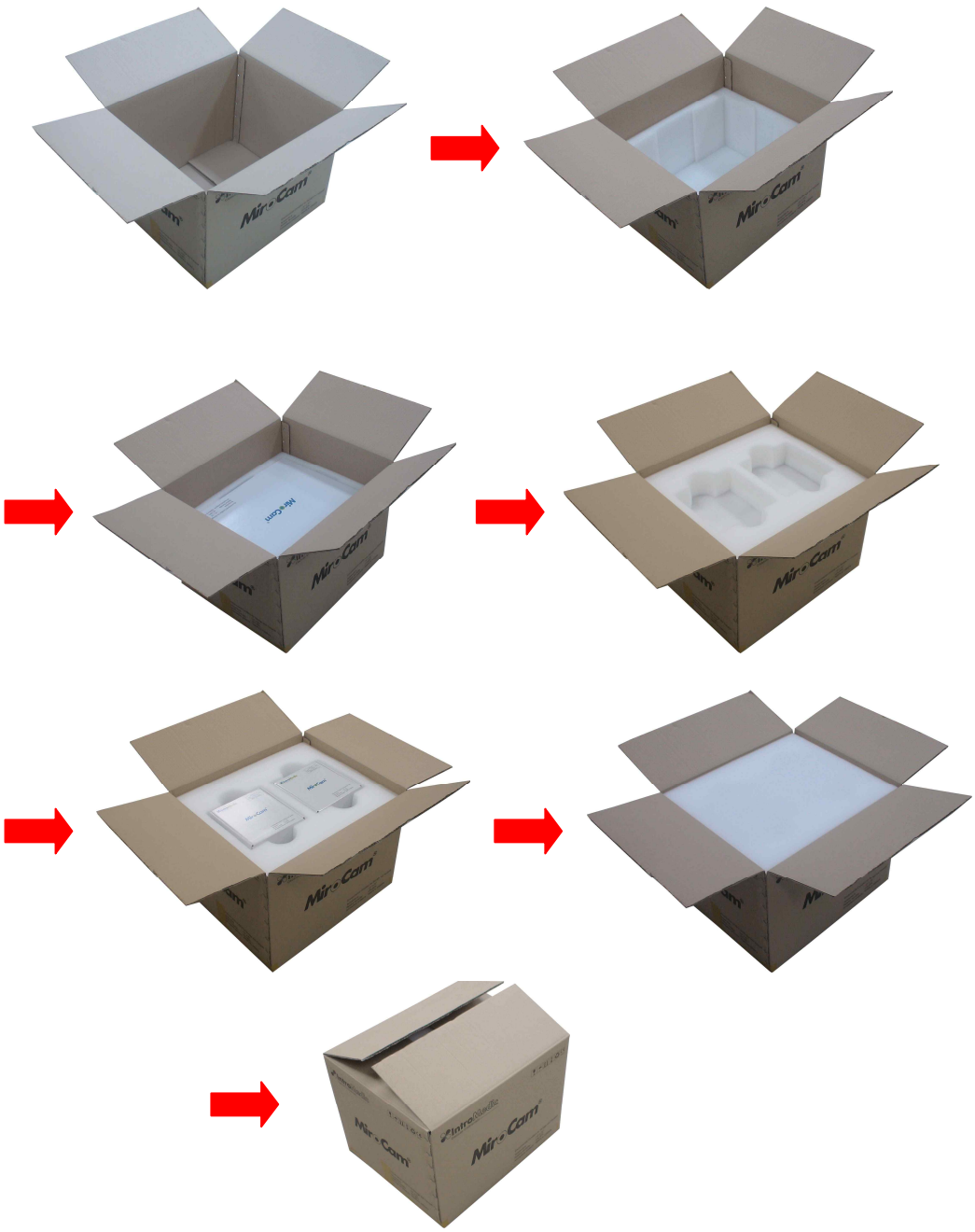


■ Repacking MiroCam® capsule endoscope system.

- System repacking diagram.



- System repacking procedure.



7.3 Repacking in Different Packing Box

If the original packing box is not available:

- Place the MiroCam capsule endoscope system in a plastic bag.
- Locate a corrugated cardboard shipping box with at least 200 pounds per square inch (psi) bursting strength.
- Fill the bottom of the box with at least 2 inches of packing material.
- Place the bagged unit on the layer of packing material and fill the box completely with packing material.
- Seal the packaging box with packing tape.
- Label packing box with shipping address, return address, and the written description.

8

EMC Information

8. EMC INFORMATION

8.1 Guidance and manufacturer's declaration - electromagnetic emissions

The EUT is intended for use in the electromagnetic environment specified below. The customer or the user of the EUT should assure that it is used in such an environment.		
Immunity test	**Compliance**	**Electromagnetic environment - guidance**
RF Emissions CISPR 11	Group 1	The EUT uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
RF Emissions CISPR 11	Class B	The EUT is suitable for use in ail establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

8.2 Guidance and manufacturer's declaration - electromagnetic immunity

The EUT is intended for use in the electromagnetic environment specified below. The customer or the user of the EUT should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV Contact ±8kV air	±6kV Contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ± 1kV for input/output lines	±2kV for power supply lines ± 1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode ±2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5cycle 40% U_T (60% dip in U_T) for 5 cycle 70% U_T (30% dip in U_T) for 25 cycle <5% U_T (<95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5cycle 40% U_T (60% dip in U_T) for 5 cycle 70% U_T (30% dip in U_T) for 25 cycle <5% U_T (<95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the EUT image intensifier requires continued operation during power mains interruptions, it is recommended that the EUT image intensifier be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity

8.3 Guidance and manufacturer's declaration - electromagnetic immunity

The EUT is intended for use in the electromagnetic environment specified below.

The customer or the user of the EUT should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance Level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80MHz	3 Vrms 150 kHz to 80MHz	Portable and mobile RF communications equipment should be used no closer to any part of the EUT, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5GHz	3 V/m 80MHz to 2.5GHz	**Recommended separation distance** $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{3,5}{E_1}]\sqrt{P}$ 80MHz to 800MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800MHz to 2.5GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as deter-mined by an electromagnetic site

			survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following 
NOTE 1) At 80MHz and 800MHz, the higher frequency range applies. NOTE 2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the EUT is used exceeds the applicable RF compliance level above, the EUT should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the EUT. [b] Over the frequency range 150kHz to 80MHz, field strengths should be less than [V_1] V/m.			

8.4 Recommended separation distances between portable and mobile RF communications equipment and the EUT

Intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the EUT can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the EUT as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter [W]	Separation distance according to frequency of transmitter[m]		
	150kHz to 80MHz $d = [\frac{3,5}{V_1}]\sqrt{P}$	80MHz to 800MHz $d = [\frac{3,5}{E_1}]\sqrt{P}$	800MHz to 2.5GHz $d = [\frac{7}{E_1}]\sqrt{P}$
	V_1=3Vrms	E_1=3V/m	E_1=3V/m
0.01	0.116	0.1166	0.2333
0.1	0.368	0.3687	0.7378
1	1.166	1.1660	2.3333
10	3.687	3.6872	7.3785
100	11.660	11.6600	23.333

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m)can be estimated using the equation applicable to the frequency of the transmitter, where *p* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1) At 80MHz and 800MHz, the separation distance for the higher frequency range applies.

NOTE 2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

8.5 Immunity and Compliance Level

Immunity test	IEC 60601 Test Level	Actual Immunity Level	Compliance Level
Conducted RF IEC 61000-4-6	3Vrms 150kHz to 80MHz	3Vrms	3Vrms
Radiated RF IEC 61000-4-3	3Vrms 80MHz to 2.5GHz	3V/m	3V/m

8.6 Guidance and manufacturer's declaration - electromagnetic immunity

The EUT is intended for use in the electromagnetic environment specified below.

The customer or the user of the EUT should assure that it is used in such an electromagnetic environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC61000-4-6	3 Vrms 150 kHz to 80MHz	3 Vrms 150 kHz to 80MHz	The EUT must be used only in a shielded location with a minimum RF shielding effectiveness and, for each cable that enters the shielded location with a minimum RF shielding effectiveness and, for each cable that enters the shielded location
Radiated RF IEC61000-4-3	3 V/m 80 MHz to 2.5GHz	3 V/m 80MHz to 2.5GHz	Field strengths outside the shielded location from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than 3V/m.[a] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. NOTE 2) It is essential that the actual shielding effectiveness and filter attenuation of the shielded location be verified to assure that they meet the minimum specification.
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength outside the shielded location in which the EUT is used exceeds 3V/m, the EUT should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as relocating the EUT or using a shielded location with a higher RF shielding effectiveness and filter attenuation.

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