# Contents

1 **SAFETY** ............................................................................................................................. 2  
   1.1 Warnings ......................................................................................................................... 2  
   1.2 Symbols for Safety .......................................................................................................... 3  
   1.3 Function Symbols ........................................................................................................... 4  
   1.4 Remarks for Safe Use .................................................................................................... 6  

2 **Overview** ........................................................................................................................... 12  
   2.1 Description of MiroCam Capsule Endoscope System .................................................... 12  
   2.2 System Overview ........................................................................................................... 13  
   2.3 Feature of MiroCam Capsule Endoscope System ......................................................... 14  
   2.4 Function Explanation .................................................................................................... 15  
   2.5 Intended Purposes and Side Effect ............................................................................... 18  

3 **Product** .............................................................................................................................. 19  
   3.1 Pictures .......................................................................................................................... 19  
   3.2 Supply Items .................................................................................................................. 21  

4 **Installation** ......................................................................................................................... 22  
   4.1 Installation ...................................................................................................................... 22  

5 **Technical Data** .................................................................................................................... 24  
   5.1 Overview ......................................................................................................................... 24  
   5.2 Hardware ......................................................................................................................... 24  
   5.3 Software .......................................................................................................................... 25  
   5.4 COMPLIANCE/APPROVALS ............................................................................................ 25  

6 **Environment condition for storage and transport.** .......................................................... 27  
   6.1 Safety environment condition for storage .................................................................... 27  
   6.2 Environment condition for transport ........................................................................... 27  

7 **Troubleshooting** ................................................................................................................... 28  
   7.1 Introduction ..................................................................................................................... 28  
   7.2 Who should perform repairs .......................................................................................... 28  
   7.3 Obtain replacement parts ............................................................................................... 28  
   7.4 Troubleshooting guide ................................................................................................. 28
1 SAFETY

1.1 Warnings

The MiroCam® has been manufactured to conform to 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. The MiroCam® has been manufactured to conform Medical Equipment with respect to electric shock fire and mechanical hazard only CAN/CSA C22.2 NO.601.1.

To guarantee safety and reliability of the equipment, special attention should be paid to all the precautions directed throughout this manual, such as "⚠️ WARNING", "⚠️ CAUTION", and "⚠️ NOTE". Also, to prevent incorrect operations and a failure in maintenance, it is essential that you should be familiar with the functions, operation and maintenance instructions by thoroughly reading this manual before operating the equipment.

⚠️ WARNING

"WARNING" is used to alert the user of a potential serious hazard that may lead to death or serious injury of patients and personnel.

⚠️ CAUTION

"CAUTION" is used to indicate information the user should know to avoid a hazard that may lead to device malfunction, device failure, damage to the device, or damage to other property.

⚠️ NOTE

"NOTE" is used to indicate important information on installation, operation, or maintenance which you should to know for the safe and effective use of the equipment.
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 Date of Manufacture Address

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

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

EN 980: Denotes serial number

IEC 417-5031: Denotes DC (Direct Current)

IEC 417-5032: Denotes AC (Alternating Current)

Denotes Ampere, the unit of current

Denotes Volt, the unit of Voltage

Denote Herz, the unit of Frequency

IEC 417-5021: Denotes potential equalization terminal

Single Use Only

The Available Period
### 1.3 Function Symbols

#### 1.3.1 Application Function Symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1" alt="Functions &amp; Windows for Receiver Unit" /></td>
<td>Functions &amp; Windows for Receiver Unit</td>
<td><img src="image2" alt="Functions &amp; Windows for Diagnosis Report" /></td>
<td>Functions &amp; Windows for Diagnosis Report</td>
</tr>
<tr>
<td><img src="image3" alt="Function &amp; Windows for Patient Database Listing" /></td>
<td>Function &amp; Windows for Patient Database Listing</td>
<td><img src="image4" alt="Function &amp; Windows for Export Patient Image Data" /></td>
<td>Function &amp; Windows for Export Patient Image Data</td>
</tr>
<tr>
<td><img src="image5" alt="Function &amp; Windows for Image Display and Diagnosis" /></td>
<td>Function &amp; Windows for Image Display and Diagnosis</td>
<td><img src="image6" alt="Function &amp; Windows for Backup Patient Image Data" /></td>
<td>Function &amp; Windows for Backup Patient Image Data</td>
</tr>
<tr>
<td><img src="image7" alt="Capturing current patient image to the thumbnail" /></td>
<td>Capturing current patient image to the thumbnail</td>
<td><img src="image8" alt="Landmark current time of patient image to the thumbnail" /></td>
<td>Landmark current time of patient image to the thumbnail</td>
</tr>
<tr>
<td><img src="image9" alt="Single previous image" /></td>
<td>Single previous image</td>
<td><img src="image10" alt="Single next image" /></td>
<td>Single next image</td>
</tr>
<tr>
<td><img src="image11" alt="Previous Selected image" /></td>
<td>Previous Selected image</td>
<td><img src="image12" alt="Next Selected image" /></td>
<td>Next Selected image</td>
</tr>
<tr>
<td><img src="image13" alt="Display image continuously" /></td>
<td>Display image continuously</td>
<td><img src="image14" alt="Display image continuously reverse direction" /></td>
<td>Display image continuously reverse direction</td>
</tr>
<tr>
<td><img src="image15" alt="Pause image display" /></td>
<td>Pause image display</td>
<td><img src="image16" alt="Enlarge image display" /></td>
<td>Enlarge image display</td>
</tr>
<tr>
<td><img src="image17" alt="Single image display mode" /></td>
<td>Single image display mode</td>
<td><img src="image18" alt="Dual image display mode" /></td>
<td>Dual image display mode</td>
</tr>
<tr>
<td><img src="image19" alt="Quad image display mode" /></td>
<td>Quad image display mode</td>
<td><img src="image20" alt="Display full image" /></td>
<td>Display full image</td>
</tr>
<tr>
<td><img src="image21" alt="Display selected image" /></td>
<td>Display selected image</td>
<td><img src="image22" alt="Display red image" /></td>
<td>Display red image</td>
</tr>
<tr>
<td><img src="image23" alt="Grouping image display in Thumbnail" /></td>
<td>Grouping image display in Thumbnail</td>
<td><img src="image24" alt="Single image display in Thumbnail" /></td>
<td>Single image display in Thumbnail</td>
</tr>
<tr>
<td><img src="image25" alt="Minimize application software" /></td>
<td>Minimize application software</td>
<td><img src="image26" alt="Close application software" /></td>
<td>Close application software</td>
</tr>
<tr>
<td><img src="image27" alt="Mark circle in current image" /></td>
<td>Mark circle in current image</td>
<td><img src="image28" alt="Mark arrow in current image" /></td>
<td>Mark arrow in current image</td>
</tr>
<tr>
<td><img src="image29" alt="Erase circle and arrow in current image" /></td>
<td>Erase circle and arrow in current image</td>
<td><img src="image30" alt="Select marker color" /></td>
<td>Select marker color</td>
</tr>
<tr>
<td>Symbol</td>
<td>Description</td>
<td>Symbol</td>
<td>Description</td>
</tr>
<tr>
<td>--------</td>
<td>-------------</td>
<td>--------</td>
<td>-------------</td>
</tr>
<tr>
<td><img src="#" alt="Undo" /></td>
<td>Undo mark in current image</td>
<td><img src="#" alt="Redo" /></td>
<td>Redo mark in current image</td>
</tr>
<tr>
<td><img src="#" alt="Login" /></td>
<td>Doctor login</td>
<td><img src="#" alt="Cancel" /></td>
<td>Cancel login</td>
</tr>
<tr>
<td><img src="#" alt="History" /></td>
<td>Patient's diagnosis history</td>
<td><img src="#" alt="Delete" /></td>
<td>Delete current patient information</td>
</tr>
<tr>
<td><img src="#" alt="Progress" /></td>
<td>Progress reporting current patient</td>
<td><img src="#" alt="Complete" /></td>
<td>Complete reporting current patient</td>
</tr>
<tr>
<td><img src="#" alt="Export" /></td>
<td>Complete Export current patient</td>
<td><img src="#" alt="Backup" /></td>
<td>Complete backup current patient</td>
</tr>
<tr>
<td><img src="#" alt="Logout" /></td>
<td>Doctor logout</td>
<td><img src="#" alt="List" /></td>
<td>Display full patient list</td>
</tr>
</tbody>
</table>

### 1.3.2 Receiver Function Symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
</table>
| SIG    | Status of capsule signal receiving  
  Green : Good  
  Yellow : Bad |
| INI    | Status of initialization of Receiver Unit  
  Green : Good  
  Yellow : Bad |
| BAT    | Status of Battery  
  Green : Full charged  
  Yellow : Not charged |
1.4 Remarks for Safe Use

- Follow these safety instructions and the clinically adopted precautions.
- The manufacturer is not liable for harm or damage caused by improper, unauthorized, unprofessional or inexpert use of the device.
- IntroMedic.Co.Ltd., is NOT responsible for physical harm or equipment problems caused by the user’s careless operation or mismanagement.
- The user MUST have read and understood the user's manual. ONLY trained and qualified persons may operate the system.
- The user's manual must ALWAYS be with the equipment. It is the USER’S RESPONSIBILITY to ensure this!
- CAUTION is advised that the foreign substances, ironware or fluids, such as water or disinfecting fluid, not enter the equipment.
- ONLY authorized personnel may perform any type of repair. Never attempt to open the covers, panels or casings.
- DO NOT crease, bend, fold or twist the probe cables and take care to guard them against mechanical stress (e.g. wheels or heels)!
- The probes must not be exposed to mechanical shock (e.g. by dropping). Any damage caused that way invalidates the warranty.
- CAUTION: Damage/injuries to the probe or cable may lead to safety hazard. It is HIGHLY advised to have them repaired IMMEDIATELY.
- DO NOT handle fluids in the vicinity of the system.
- When using a cart purchased elsewhere, implement the latch guard method 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. The free repair warranty will be automatically invalidated.
- 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, grab the plug and then 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 probe.

DO NOT discard probes, cables and connectors with general waste. Separately discard as industrial waste 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 carry out the procedure on patients with pacemakers and/or defibrillators.

DO NOT use for purposes other than medical treatment.

DO NOT connect the USB cable to the receiver while the receiver’s patch probes are still connected.

DO NOT charge the receiver while the receiver’s patch probes 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.

DO NOT carry out the procedure on patients with known or suspected gastrointestinal tract obstruction, perforation, stricture or fistular.

DO NOT carry out the procedure on patients who have difficulty swallowing food or pills (dysphagia).

DO NOT carry out the procedure on patient who have difficulty communicating.

DO NOT carry out the procedure on patient with indigestion or delay in gastric emptying.

DO NOT carry out the procedure on patient who may be affected by electromagnetic radiation, such as pregnant women, infants, and patients with heart disease or epileptics.

DO NOT carry out the procedure on patients with diverticulosis in the Small Bowel.

DO NOT carry out the procedure on patients who are recommended against having the procedure by a Physician.

The capsule is disposable and should not be reused.
1.4.1 Environmental Conditions for Operation

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

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

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

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

⚠️ WARNING
- Do not use this device when the output contains d.c. components.
- Do not use the unit 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 Precautions

⚠️ 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 probes MUST be observed.
- DO NOT use on patients with pacemakers or defibrillators.

⚠️ NOTE This device has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of U.S. FCC Rules.

⚠️ CAUTION EQUIPOTENTIAL BONDING:
In hospital, doctors and patients are subjected to dangerous, uncontrollable compensating currents. These currents are due to the potential differences between connected equipment and touchable conducting parts as found in medical rooms. The safest solution to the problem is consistent equipotential bonding. Medical equipment is connected with connecting leads made up with angle sockets to the equipotential bonding network in medical rooms.

⚠️ CAUTION DO NOT use the capsule if the package is unsealed. If capsule package is unsealed, it can be infected.

- DO NOT reuse a used capsule.
- To prevent unexpected accidents like fire or explosion, do not use it near or in the presence of inflammable or ignitable substances.
- DO NOT disassemble the equipment case nor open the cover. In case of problems in equipment or need for other service, please contact our head office or a customer support staff immediately.
- Only the accessories authorized and designed by our company 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 them.
- Follow your doctor’s instructions and abide by the guidelines in the user manual.
- DO NOT try to upload the data while the patch probes are still connected to the receiver.
- DO NOT charge the rechargeable battery in the receiver while the patch probes 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 patch probes.
- 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 control their insulin doses.
- For more accurate data and better analysis, patients can have solid food for lunch, but must have liquid food as dinner on the day before the procedure and need to fast for 12 hours before the procedure.
- 12 hours before the procedure, take a laxative such as Sodium phosphate or PEG solution.
- DO NOT smoke for 12 hours prior to the capsule endoscope procedure.
- DO NOT apply body lotion to your body before the procedure.
- DO NOT bite the capsule before swallowing.
- Avoid excessive physical activity during the capsule endoscope procedure.
- 2 hours after swallowing the capsule, patients may drink water, and after 4 hours, patients may have liquid food.
- When undergoing the capsule endoscope procedure, DO NOT makes physical contact with another person undergoing this same procedure.
- During operation of the receiver, DO NOT touches it or gets it wet.
- Use the provided batteries only and never take it out of the receiver body during the procedure.
- During upload of the data recorded in the receiver to the PC, avoid disconnecting the USB (it may damage the patient's data).
- Always confirm that the USB is connected by checking on the screen of the MiroCam application program.
1.4.3 Cleaning and maintenance

1.4.3.1 System and accessories

- Other units and accessories 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. Please maintain the probe according to the disinfection instructions.
- The vaginal manometry probe must not be cleaned with a wet towel before usage. Use the vaginal probe ONLY after putting a disposable latex condom on it, and then discard only the condom after use.
- The patch probe for abdominal attachment must not be rubbed or wiped.
- ALWAYS operate the equipment under sanitary environmental conditions. DO NOT use heat or gas for the disinfection of the probes and cables.
- CLEAN vaginal probes, anal probes, patch probes and vaginal manometry probe should ALWAYS be used.

1.4.3.2 Service documents

If required, or upon request, the supplier may provide block diagrams, list 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 the manufacturer.

1.4.3.3 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 found out after moving, immediately contact the company or dealer.

⚠️ 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 moving is finished and the systems structure is settled and stabilized.
2 Overview

2.1 Description of MiroCam Capsule Endoscope System

MiroCam is Capsule Endoscope Systems and accessories to be used to diagnosis of patients. It consists of the capsule and receiver.

2.1.1 Photos

2.1.1.1 Capsule

2.1.1.2 Receiver

2.1.1.3 Accessory
2.2 System Overview

MiroCam Capsule Endoscope Systems consist of Capsule Receiver and Image Processing Workstation (Software).

MiroCam System Block Diagram

2.2.1 Capsule

MiroCam Capsule Endoscope System's Capsule Unit consists of optical dome, white LED, image sensor, lens and gold courted cage.

2.2.2 Receiver

MiroCam Capsule Endoscope System's Receiver unit consist of 8 channel connector, differential amplifier, filter, data demodulator, data storage memory and USB communication channel.

2.2.3 IPW

MiroCam Capsule Endoscope System's Software is running on the Microsoft Windows XP using the IBM compatible PC platform and provide easy-to-use icon menu. It consist of Image reconstruction part and Image display part.
2.3 Feature of MiroCam Capsule Endoscope System

2.3.1 Main Feature

- **Capsule**
  - High Resolution Image (320 X 320)
  - Wide Field of view (150 degrees)
  - Smallest Capsule size (11 X 24mm)
  - Longest operation time

- **Receiver**
  - Built-in circuit protection functions
  - Small, light and easy to carry around

- **IPW**
  - User Friendly software feature
  - Red Color Detection
  - Color of images are virtually natural
  - Dual and quad image views

- **System**
  - Over Intel P4 3.0GHz
  - Over 1G Byte Memory
  - Over 100GByte Hard Disk
2.4 Function Explanation

2.4.1 Display flow

2.4.2 Function of Control and Display of Signal

- All operations start after completing or selecting the patient registration on the default screen.
- If select Patient in Patient List for data review and press button, Review window is displayed.
- Press button for playing image data.
2.4.3 Sequence of Operation

- **Initialize Receiver Unit**
  1. Connect USB Cable between Receiver unit with Workstation → 2. Click button
  3. Click button 4. Click button 
  5. Input 
  6. Click button

- **Upload Image Data**
  1. Connect USB Cable between Receiver unit with Workstation → 2. Click button
  3. Click button

- **Display Image Data and Diagnosis**
  1. Select Patient in Patient List for data review → 2. Click button → 3. Click button

- **Print Diagnosis Data**
  1. Select Patient in Patient List for data review → 2. Click button → 3. Input diagnosis result → 4. Insert diagnosis point in patient image data
### 2.4.4 Connection and Disconnection

<table>
<thead>
<tr>
<th>Part</th>
<th>Where</th>
<th>When</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patch Probe</td>
<td>Connector of upper side of receiver unit</td>
<td>Before process capsule endoscope</td>
<td>Connection: Hold the connector on the end of the receiver’s patch probe and put it into the socket of the top of the patch. Disconnection: Hold the connector on the end of the receiver’s patch probe and pull it out by hands.</td>
</tr>
<tr>
<td>USB Cable</td>
<td>USB Connector of left side of receiver unit</td>
<td>After process capsule endoscope</td>
<td>Connection: Hold the USB cable connector and push it into the USB connector on the side of the receiver. Disconnection: Hold the connector on the tip of the USB cable and pull it out by hands.</td>
</tr>
<tr>
<td>Cradle</td>
<td>Lower side of receiver unit</td>
<td>After process capsule endoscope</td>
<td>Connection: Place down the receiver into the Cradle as its slot. Disconnection: Pull out the receiver from the Cradle vertically.</td>
</tr>
<tr>
<td>Adaptor</td>
<td>Rear side of cradle</td>
<td>System Installation</td>
<td>Connection: Put the DC cable of the charger into the DC jack of the Cradle. Disconnection: Pull out the connector of the DC cable of the charger by hands.</td>
</tr>
</tbody>
</table>
2.5 Intended Purpose and Side Effect

2.5.1 Intended Purpose

- **MiroCam** is intended for the detection of pathologies as an adjunctive tool in the diagnosis of small bowel gastrointestinal disorders and diseases.
3 Product
3.1 Pictures
3.1.1 Main Device

- Capsule

- Receiver
3.1.2 Accessories

- **Patch Cable**
  - Model: 21-1-19-1, 10P
  - Manufacturer: Mednis

- **USB Cable**
  - Model: AV22201-06
  - Manufacturer: BELKIN

- **Cradle**
  - Model: MR1000-C
  - Manufacturer: JEC Korea

- **Adaptor**
  - Model: JMW128KAXXXXNXX (Compliance with requirements of IEC601-1)
  - Manufacturer: JEC Korea
3.2 Supply Items

3.2.1 Basic Supply Item

<table>
<thead>
<tr>
<th>No.</th>
<th>Model</th>
<th>MiroCam Product Code</th>
<th>Quantity</th>
<th>Description</th>
<th>Replace Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Capsule</td>
<td>MR1000-C</td>
<td>1 ea</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Receiver</td>
<td>MR1000-R</td>
<td>1 ea</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Cradle</td>
<td>MR1000-C</td>
<td>1 ea</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Adaptor</td>
<td>MR1000-A</td>
<td>1 ea</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Power Code</td>
<td>MR1000-P</td>
<td>1 ea</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Patch Probe</td>
<td>MR1000-S</td>
<td>1 pk</td>
<td>Single use</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Ground Pad</td>
<td>MR1000-E</td>
<td>1 ea</td>
<td>Single use</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Patch Cable</td>
<td>MR1000-D</td>
<td>1 ea</td>
<td>6 month</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Software</td>
<td>MR1000-S</td>
<td>1 ea</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Sack</td>
<td>MR1000-K</td>
<td>1 ea</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>PC</td>
<td>MR1000-P</td>
<td>1 ea</td>
<td></td>
<td></td>
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<tr>
<td>12</td>
<td>Monitor</td>
<td>MR1000-L</td>
<td>1 ea</td>
<td></td>
<td></td>
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<tr>
<td>13</td>
<td>Printer</td>
<td>MR1000-I</td>
<td>1 ea</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>Keyboard</td>
<td>MR1000-K</td>
<td>1 ea</td>
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3.2.2 Optional Supply Item

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<tr>
<th>No.</th>
<th>Model</th>
<th>MiroCam Product Code</th>
<th>Quantity</th>
<th>Description</th>
<th>Replace Period</th>
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<tr>
<td>1</td>
<td>Battery</td>
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<td>1 ea</td>
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<td>6 month</td>
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</table>
4 Installation
4.1 Installation
4.1.1 Specification of packing

- MiroCam Capsule Endoscope System Box

- MiroCam Capsule Endoscope Receiver Set Box
- **MiroCam Capsule Endoscope Battery Charger Box**

<table>
<thead>
<tr>
<th>ITEM</th>
<th>N/S</th>
<th>MODEL</th>
<th>BARCODE LABEL</th>
</tr>
</thead>
<tbody>
<tr>
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<td>MiroCam</td>
<td>MADE IN KOREA</td>
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</table>

- **MiroCam Capsule Endoscope Accessory Box**

<table>
<thead>
<tr>
<th>ITEM</th>
<th>N/S</th>
<th>MODEL</th>
<th>BARCODE LABEL</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>MiroCam</td>
<td>MADE IN KOREA</td>
</tr>
<tr>
<td></td>
<td></td>
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</table>
5 Technical Data

5.1 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.

5.2 Hardware

5.2.1 Capsule

- 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: Over 11 Hours
- Mechanical Safety: Compatible I5060601-1-1
- Chemical Safety: Safe in pH2 ~ pH8
- Battery Type: Silver Oxide Cell (3Vdc, 70mA)
- Operation Temperature: 20 ~ 40°C
- Storage Temperature: 0 ~ 50°C

5.2.2 Receiver

- Operation System: Firmware
- Recording Time: 11 Hours
- Weight: 350g, include battery
- Operation Voltage: 3.7Vdc, 0.45A
- Battery Type: Lithium Ion Battery (3.7Vdc, 8.8A)
- Battery Weight: 215g
- Operation Temperature: 0 ~ 40°C
- Storage Temperature: 0 ~ 55°C
- Category: Type BF

5.2.3 Image Workstation

- Operating System: Windows XP Professional
5.2.4 Cradle
- Input Voltage: 110-220VAC
- Input Current: 3A
- Output Voltage: 4.2VDC
- Output Current: 4A
- Operation Display: LED Display

5.3 Software
5.3.1 Version
- MiroCam Application Software Version 1.00

5.3.2 Specification
- Language: English
- Data Export: JPEG Image, AV Video Clip, PDF Data Report
- Data Display: Single or Multi Image, Time Bar, Color 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 Mode, Fast Mode

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

5.4 COMPLIANCE/APPROVALS
The MiroCam capsule endoscope system and accessories complies with the Medical Device Directive 93/42/EEC (CE0843).
In addition, the product complies with
- EN 60601-1-2
- EN 10993-1
- EN 10993-10

The possibility of hazards arising from software errors was minimized in compliance with EN1441 and EN60601-1-4.

5.4.1 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 Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation, which can be determined by turning the equipment off and on, the user is encourage to try to correct the interference by one or more of the following measures:

  - Reorient or relocate the receiving antenna.
  - Increase the separation between the equipment and receiver.
  - Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
  - Consult the dealer or an experienced radio/TV technician for help.
6 Environment condition for storage and transport.

6.1 Safety environment condition for storage

6.1.1 Receiver unit

- Environment condition for storage
  - Temperature: -10°C - +70°C
  - Relative humidity: 10%–80%
  - Atmospheric pressure: 700hPa to 1060hPa

- Keep in the place which is not contacted with water.
- Keep in the place where the direct light dose not shines.
- Keep in the place which is not contacted with something that is a hazardous to the human body.
- Keep in the place which the kid’s hand dose not closes.
- Don’t keep it in the (storing) place for chemicals or near gas.
- When you clean up the outside of the product, only use gauze with water. Other liquid like alcohol should not be allowed.
- When you charge the battery, please use the cradle.
- If you don’t use this product for so long, please separate the battery from the body of it.

6.1.2 Image Workstation

- Treat this based upon the way how to handle a general PC

6.2 Environment condition for transport

- Temperature: -10°C - +70°C
- Relative humidity: 10%–80%
- Atmospheric pressure: 700hPa to 1060hPa
7 Troubleshooting

7.1 Introduction

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

7.2 Who should perform repairs

Only qualified service personnel should open the HMT2100 housing, remove and replace components, or make adjustments.

7.3 Obtain replacement parts

IntroMedic Technical Services 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 Section 3.2, Supply Items.

7.4 Troubleshooting guide

<table>
<thead>
<tr>
<th>Condition</th>
<th>Recommended Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The MiroCam capsule endoscope system workstation fails to power-up when the I/O power switch is on.</td>
<td>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..</td>
</tr>
<tr>
<td>2. The MiroCam capsule endoscope system receiver unit fails to power-up when the I/O power switch is on.</td>
<td>1. Recharging battery of receiver unit. 2. Replacement battery of receiver unit. 3. If the condition persists, contact IntroMedic Co.,Ltd..</td>
</tr>
<tr>
<td>3. It’s not blinking when it’s out of the case.</td>
<td>1. DO NOT use this capsule and retry another capsule. 2. Contact IntroMedic Co.,Ltd. for replacement capsule.</td>
</tr>
<tr>
<td>4. INI LED, on receiver unit, is lighted as yellow.</td>
<td>1. Initialization receiver unit in MiroCam application software. 2. If the condition persists, contact IntroMedic Co.,Ltd..</td>
</tr>
<tr>
<td>5. BAT LED, on receiver unit, is lighted as yellow.</td>
<td>1. Recharging battery of receiver unit. 2. Replacement battery of receiver unit. 3. If the condition persists, contact IntroMedic Co.,Ltd..</td>
</tr>
</tbody>
</table>