OLYMPUS

OLYMPUS CONFIDENTIAL

SYSTEM MANUAL

INSTRUCTIONS

OLYMPUS CAPSULE ENDOSCOPE SYSTEM

CAPSULE ENDOSCOPE SYSTEM SET MAJ-Y0136

MAJ-Y0136

CAPSULE ENDOSCOPE

EC-Y0005

Refer to the companion manual, the “WORKSTATION MANUAL” and “Cautions for Capsule Endoscopy Patient” for operating information of the MAJ-Y0134.

USA:CAUTION: Investigational device. Limited by Federal (or United State) Law to investigational use.

Contents

Labels and Symbols

Safety-related labels and symbols are attached at the locations shown below. If labels or symbols are missing or illegible, contact Olympus.

Symbols

The meaning(s) of the symbol(s) shown on the package, the back cover of this instruction manual and/or this equipment are as follows:

Caution, refer to instructions.

Refer to instructions.

When this equipment is in the proximity of portable RF (Radio Frequency) communication devices, electromagnetic interference that affects cardiac pacemakers may occur. Users of cardiac pacemakers must maintain a sufficient distance from the equipment.

Power switch (ON/OFF)

TYPE BF applied part

Single use only

Use by (expiration date)

Sterilized using ethylene oxide

Non-sterile

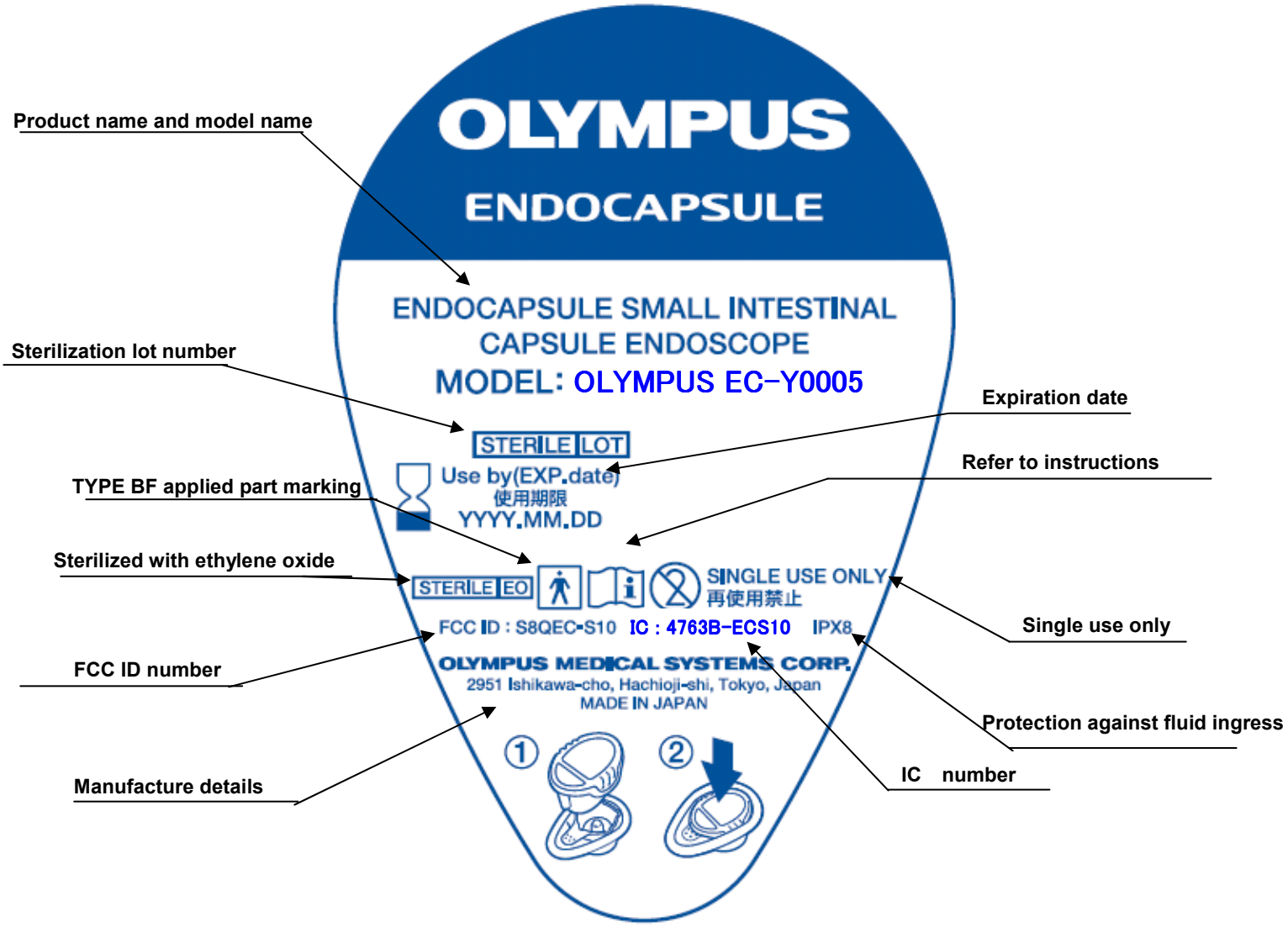
Manufacturer

Authorized representative in the European Community

Labels

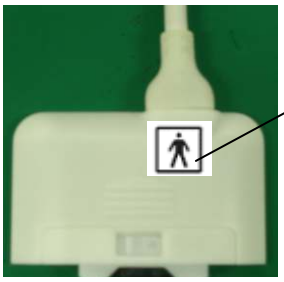
Capsule endoscope

Capsule endoscope storage case (**Label 1**)

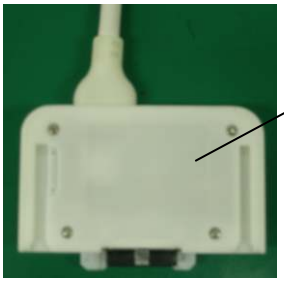


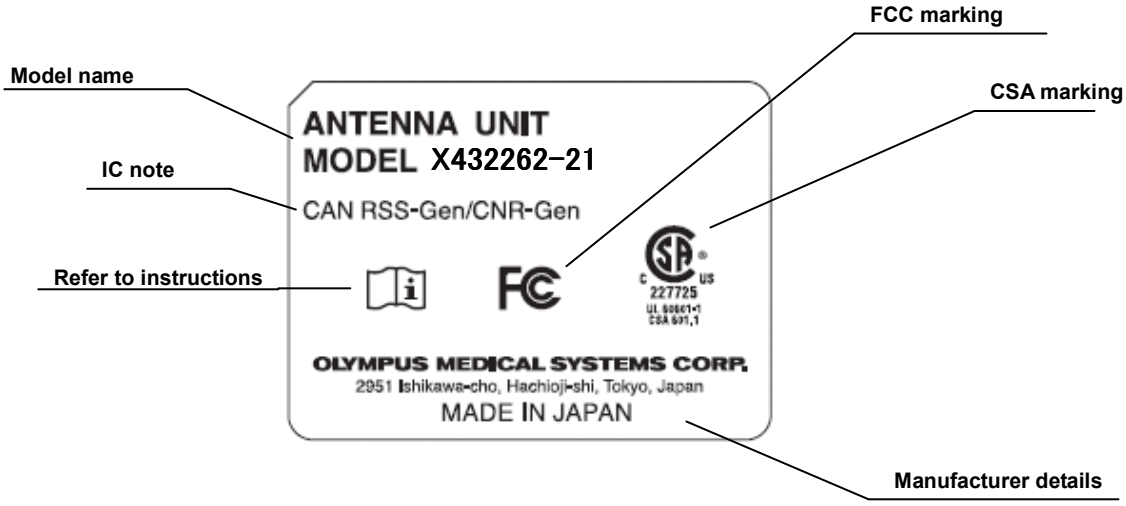
Antenna unit

Antenna Unit (front panel)



Antenna Unit (back panel)

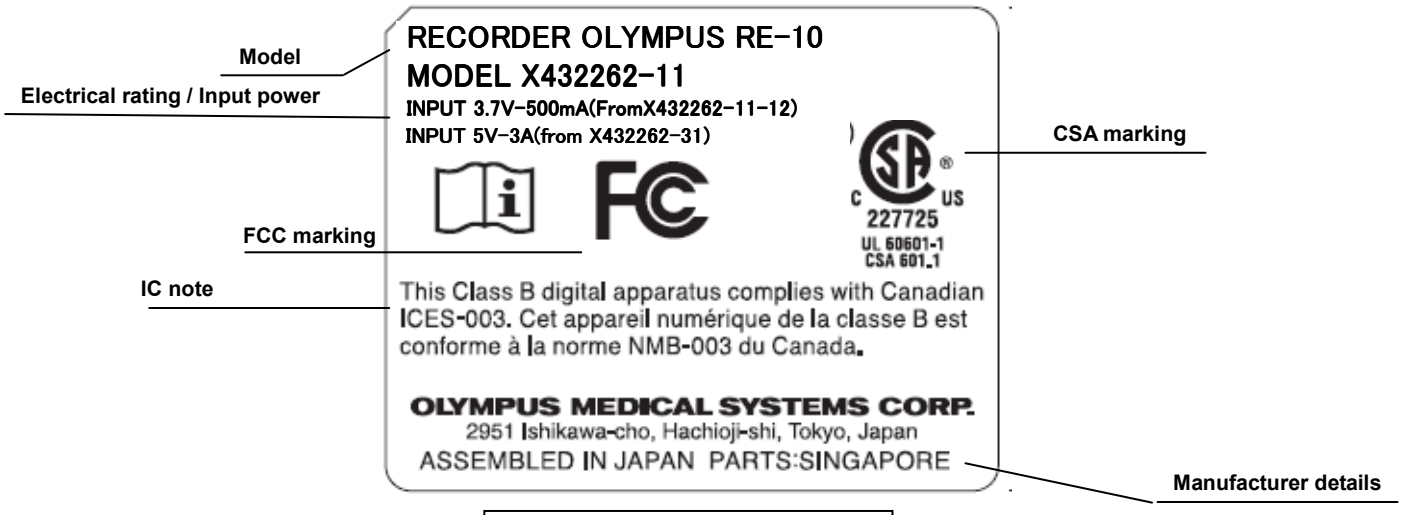




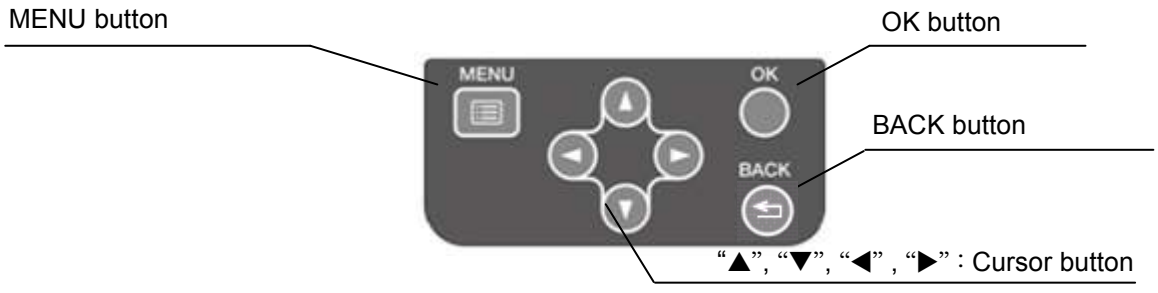
Recorder unit

Recorder unit (back panel)

Label

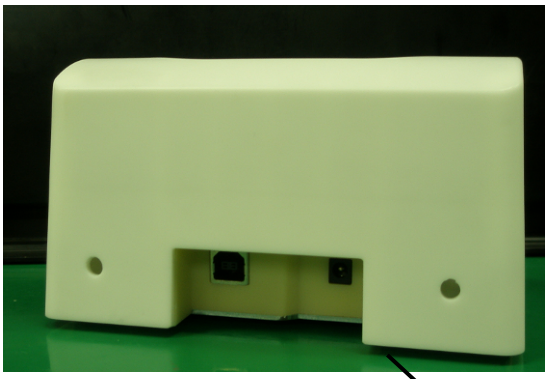


Recorder unit (front panel)



Recorder unit cradle

Recorder unit cradle (bottom panel)



Label

Model name

Refer to instructions

Electrical rating / Input power

CSA marking

FCC note

FCC marking

IC note

Manufacturer details

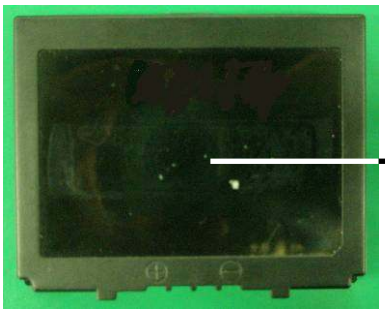
CRADLE
MODEL X432262-31
INPUT 5V⎓2.4A

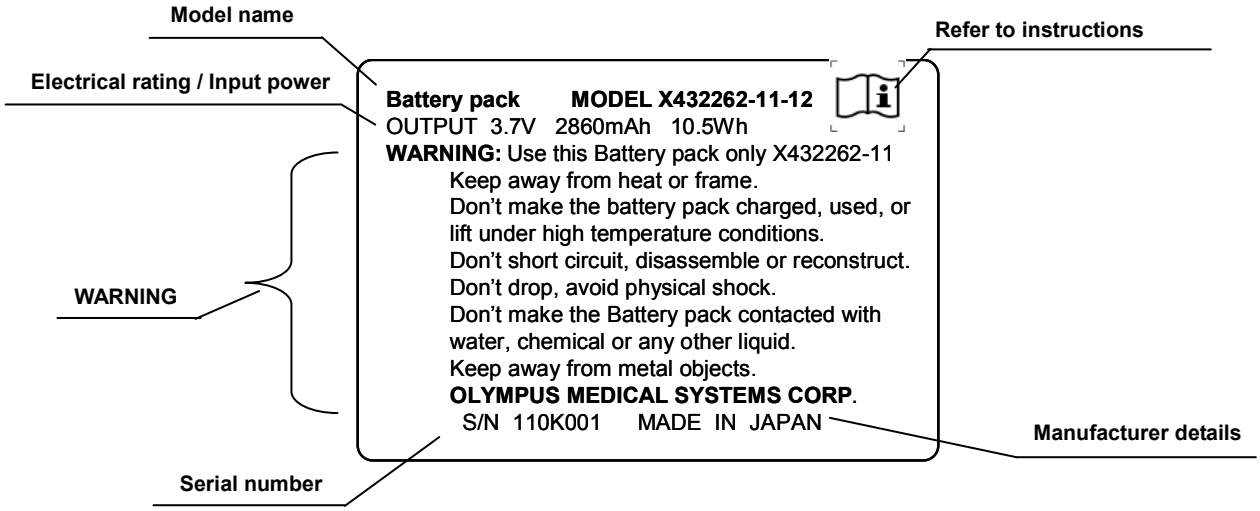
227725
UL 60601-1
CSA 601.1

This device complies with Part 15 of the FCC Rules.
Operation is subject to the following two condtions:
(1)This device may not cause harmful interference,and
(2)this device must accept any interference received,
Including interference that may cause undesired operation.
This Class B digital apparatus complies with Canadian
ICES-003. Cet appareil numérique de la Classe B est
conforme à la norme NMB-003 du Canada.

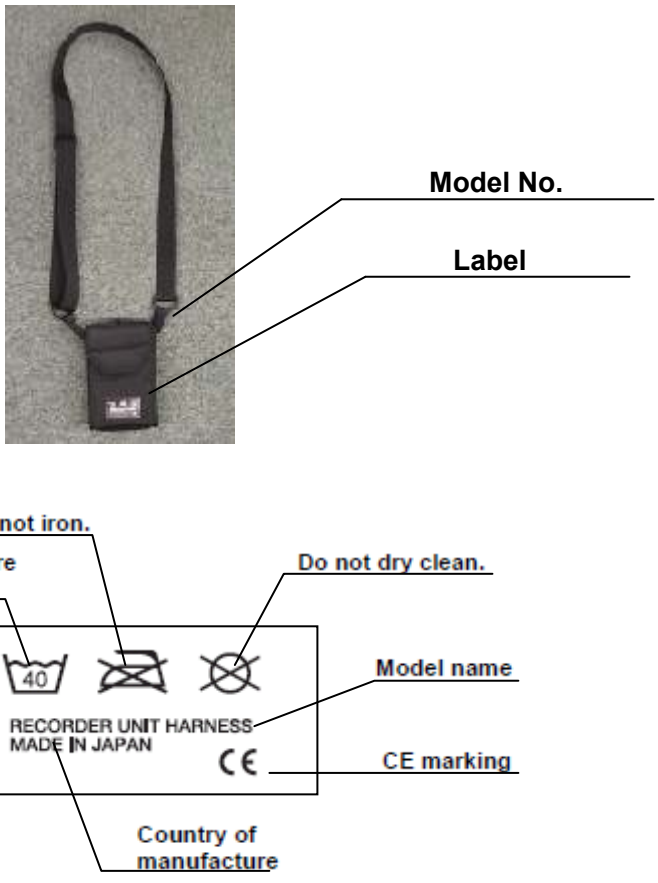
OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan
ASSEMBLED IN JAPAN PARTS:SINGAPORE

Battery pack

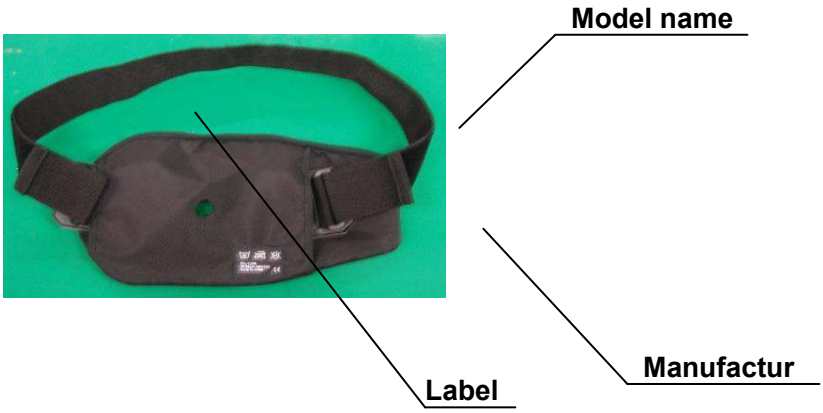


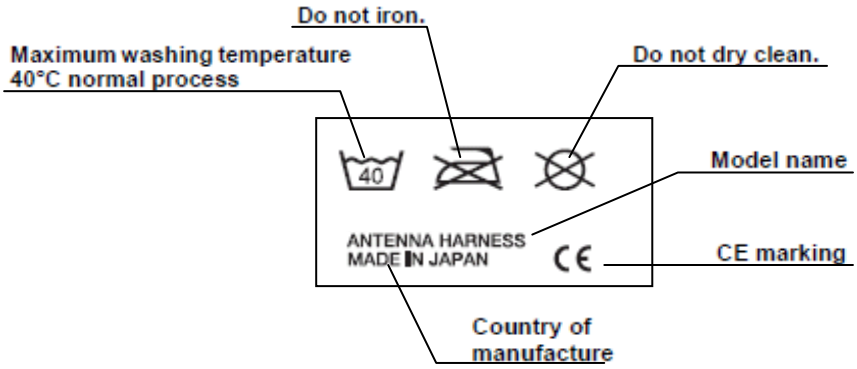


Recorder unit harness



Antenna harness





Important Information — Please Read Before Use

Intended use

The OLYMPUS CAPSULE ENDOSCOPE SYSTEM has been designed to be used for visualization of the small intestine mucosa. The Red Color Detection Function is intended to mark frames of the video suspected of containing blood or red areas. Do not use this system for any purpose other than its intended use.

Instruction manual

This instruction manual contains essential information on using the system safely and effectively. Before use, thoroughly review this manual and the manuals of all equipment that will be used during the procedures, and use the equipment as instructed.
Note that the complete instruction manual for this system consists of following parts: this manual, the “WORKSTATION MANUAL”, and the “Cautions for Capsule Endoscopy Patient”.
Keep this and all related instruction manuals in a safe, accessible location.
If you have any questions or comments about any information in this manual, please contact Olympus.

Terms used in this manual

DC magnetic field
Magnetic field formed by permanent magnets or electromagnets that are used in health devices and audio speakers.

RTC (Real time clock)
Refers to the recorder unit’s internal clock.

User qualifications

The operator of this instrument must be a physician or medical personnel under the supervision of a physician and must have received sufficient training in capsule endoscopy procedures. This manual, therefore, does not explain or discuss capsule endoscopy procedures.

Physicians performing capsule endoscopy should:

- Have completed a formal training program that includes training in the recognition and management of small intestinal diseases
- Have competency and privileges to perform gastrointestinal endoscopy
- Be familiar with the Endo Capsule hardware and software
- Have formal training in capsule endoscopy that includes hands-on training and supervised review of initial cases by a competent capsule endoscopist
- Meet pertinent local hospital/clinic requirements and professional society credentialing guidelines.

Instrument compatibility

Refer to the “System chart” in the Appendix to confirm that the system is compatible with the ancillary equipment being used. Using incompatible equipment can result in patient injury and/or equipment damage.

Repair and modification

This system does not contain any user-serviceable parts. Do not disassemble, modify or attempt to repair it. Doing so may result in patient or user injury and/or equipment damage.
Some problems that appear to be malfunctions may be correctable by referring to Chapter 5, “Troubleshooting”. If the problem cannot be resolved using the information in Chapter 5, contact Olympus.

Signal words

The following signal words are used throughout this manual.

DANGER

Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.

WARNING

Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION

Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.
It may also be used to alert against unsafe practices or potential equipment damage.

NOTE

Indicates additional helpful information.

Dangers, warnings and cautions

Follow the dangers, warnings and cautions given below when handling the system. This information is to be supplemented by the dangers, warnings and cautions given in each chapter.

DANGER

- This system is contraindicated to patients with the following conditions.
  - Patients with cardiac pacemakers or other implanted electronic devices (e.g., defibrillators)
    (Cardiac pacemakers or other implanted electronic devices may malfunction due to the RF (radio frequency) interference.)
  - Patients with known intestinal strictures, adhesions, diverticulum, obstruction, or fistulas that may block the passage of the capsule endoscope
    (Patients with these physical features risk retention of the capsule endoscope.)
  - Patients with known dysphagia
    (Patients with dysphagia may have a risk of aspiration into the tracheal branches and could have difficulty ingesting the capsule endoscope.)
  - Patients with significant difficulty in swallowing a tablet as large as capsule endoscope
    (Patients that may have difficulty ingesting a capsule as large as the capsule endoscope risk getting the capsule lodged in their throat.)
  - Patients who are nonsurgical candidates
    Open surgery is required if the capsule endoscope is retained in the patient's body.
  - Patients who are pregnant
    Use of the capsule endoscope has not yet been proven to be safe on pregnant patients.
  - Patients with significant gastrointestinal tract delay
    Long-term retention of the capsule endoscope may be observed in patients with known radiation enteritis due to intestinal strictures or adhesions.
  - Patients diagnosed with radiation enteritis
    Long-term retention of the capsule endoscope may be observed in patients with known radiation enteritis due to intestinal strictures or adhesions.

DANGER

- Instruct of the patient to stay away from equipment that generates strong electromagnetic fields (such as MRI equipment), between ingestion and excretion of the capsule endoscope. Otherwise, injury within the body cavity may occur. If the excretion of the capsule endoscope has not been confirmed, within 2 weeks after ingestion, attempt to locate the capsule endoscope within the patient's body by X-ray examination.

WARNING

- Safety of the Capsule Endoscope has been confirmed by durability and biocompatibility testing for a patient retention period of 30 days. Patient safety has not been verified if the capsule endoscope remains within the patient's body for a period of 30 days or more. If excretion of the capsule endoscope has not been confirmed within 30 days after ingestion, conduct an X-ray examination in an attempt to locate the capsule endoscope. Once found, remove the capsule endoscope. First of all, perform procedure except for surgical intervention. For methods to remove the capsule endoscope, please follow the respective guidelines in your country.
- This system is contraindicated to patients with the following conditions.
  − Patients who have an obstruction in their digestive tract as a result of past digestive bypass surgery
  A patient who has undergone bypass surgery in the digestive tract usually has an obstruction that could result in retention of the capsule endoscope.
  − Patients with instruments that could interfere with the capsule endoscope's passage in the digestive tract such as a stent in the digestive tract
  A patient with an instrument in their digestive tract (such as a stent) may have sections that are too narrow for the capsule endoscope to pass through.
- Prior to the examination, the physician should explain to the patient the risks of capsule endoscope retention and obtain the patient's informed consent.

WARNING

- Prior to using the capsule endoscope, the physician should consider performing a contrasted X-ray series in patients with the following conditions. Patients with suspected intestinal strictures, adhesions, diverticulum, obstructions, fistulas that may block the passage of the capsule endoscope, and patients with suspected gastrointestinal tract delay.
  - − Patients with a history of ileus or small intestinal strictures
  - − Patients diagnosed with, or suspected to have, Crohn's disease in small intestine
  - − Patients with any history of abdominal surgery, pelvic surgery, and/or radiological treatment
- The physician should confirm that the contrast medium reaches the ileocecal valve and should continuously observe/trace the entire small-intestine during the contrasted X-ray series. Do not use the capsule endoscope on the patient if any of the following conditions is observed during the contrast X-ray series.
  - − Patients with known intestinal strictures, adhesions, diverticulum, obstructions, or fistulas that may block the passage of the capsule endoscope.
  - − Patients with significant gastrointestinal tract delay.
- The peristaltic motion in the small intestine varies among individuals. Therefore, the recording time in the small intestine may differ among patients. Though this system is designed to obtain the images for 12 hours, image recording in a patient with slower peristaltic motion may finish before the capsule endoscope reaches the patient's large intestine.
- In order to implement the examination smoothly, the physician should hand the "Cautions for capsule endoscopy patient" that comes packed with the capsule endoscope (EC-Y0005) to the patient at least one day before the examination and verify that the patient understands it thoroughly.
- The physician should explain to the patient the risks of retention in the examination and obtain the patient's informed consent before the examination. The capsule endoscope may cause unexpected intestinal obstruction that may require surgery.
- Write your emergency contact number in the "Please provide your emergency contact number" section on the back page of the "Cautions for capsule endoscopy patient" that is packed with the capsule endoscope (EC-Y0005), hand it to the patient and instruct him/her to immediately contact the number if he/she feels abdominal pain, discomfort, or nausea after ingesting the capsule endoscope. If treatment is delayed, patient injury may result.

WARNING

- A negative or normal result obtained by the imaging capsule does not exclude the presence of pathology and if symptoms persist, further evaluation should be performed.
- The capsule endoscope must be ingested under the supervision of the physician or medical personnel authorized by the physician.
- Never install and/or operate this system in locations where:
  − Concentration of oxygen is high.
  − Oxidizing agents (such as nitrous oxide (N_2O)) are present in the atmosphere.
  − Flammable anesthetics are present in the atmosphere.
  Otherwise, explosion or fire may result because this system Is not explosion-proof.
- The capsule endoscope is a TYPE BF applied part, which means that application to the heart is prohibited. Do not use it for the purpose of observing or treating the heart.
- The capsule endoscope is a sterilized single-use product. Reusing a capsule endoscope may cause infection to the patient and/or medical personnel and internal injury to the patient. Also, severe equipment malfunctions may occur. Never reuse a capsule endoscope.
- Do not use a capsule endoscope that has been dropped, bitten, or subjected to excessive pressure. Doing so may result in internal injury to the patient.
- When using the capsule endoscope, avoid using other medical electrical devices simultaneously. The safety of the use of the capsule endoscope in combination with other medical electrical devices has not been verified.
- The capsule endoscope may accidentally enter the trachea. Before the examination, check whether the patient is able to swallow the capsule endoscope safely. If accidental entry occurs, immediately remove the capsule endoscope from the trachea.
- Do not disassemble or modify the battery pack. The battery pack is equipped with a safety circuit and a protective circuit. Disabling either or both of these circuits may result in excessive heat, release of smoke, explosion, and/or a fire.
- Do not connect the positive (+) and negative (–) terminals of the battery pack using pieces of metal. In addition, do not store or transport the battery pack alongside other metallic objects. The battery pack may be short-circuited, causing an overflow of current, resulting in excessive heat, release of smoke, explosion, and/or a fire from the battery, or excessive heating of the metallic item.

WARNING

• Do not heat the battery pack or bring it in contact with fire. The insulating material may melt, gas could be released, the safety circuit may be damaged, and electrolytic solution may be ignited, causing excessive heat, release of smoke, explosion, and/or a fire.
• Do not use or store the battery pack near flames or a source of high temperature (over 80°C (176°F)) such as a stove. If the plastic separator is damaged by heat, the battery pack will be short-circuited internally, causing excessive heat, release of smoke, explosion, and/or a fire.
• Keep the battery pack away from water or any other liquids. If the internal protective circuit becomes wet and/or damaged, it may result in excessive heat, release of smoke, explosion, and/or a fire.
• Do not recharge the battery pack near an open flame, or under direct sunlight. The protective circuit is activated under high heat, and may prevent proper recharging. If the protection circuit fails, recharging may occur at abnormal current and/or voltage, causing unexpected chemical reactions within the battery pack, which may result in excessive heat, release of smoke, explosion, and/or a fire.
• When recharging the battery pack, use only the provided Recorder unit cradle (X432262-31) under the specified recharging conditions. Recharging under conditions other than those specified (temperature outside the specified range) may cause abnormalities or overcharging, causing unexpected chemical reactions within the battery pack, which may result in excessive heat, release of smoke, explosion, and/or a fire.
• Do not strike, pierce, drop, or step on the battery pack. A ruptured or damaged battery pack may be short-circuited internally, which could cause excessive heat, release of smoke, explosion, and/or a fire.
• Do not apply strong shocks to the battery pack. They could cause the battery pack to leak, generate excessive heat, release smoke, explode, or ignite. If the protection circuit fails, recharging may occur at abnormal current and/or voltage, causing unexpected chemical reactions within the battery pack, which may result in excessive heat, release of smoke, explosion, and/or a fire.
• Do not use a battery pack that is visibly damaged or deformed. Excessive heat, release of smoke, explosion, and/or a fire may result.
• Use the battery pack only for this equipment. Using the battery pack in other equipment could cause its performance to deteriorate rapidly, or, depending on the equipment, cause damage from overcurrent, excessive heat, release of smoke, explosion, and/or a fire.

WARNING

• If a battery pack is leaking, take care that the liquid does not come in contact with your skin or eyes. If liquid enters the eye, do not rub it; immediately rinse with clean water, then consult a physician. Failure to take appropriate action may result in injury.
• If recharging is not completed after the given recharging time, do not continue recharging. Excessive heat, release of smoke, explosion, and/or a fire may result.
• Do not place the battery pack in a microwave or a high-pressure cooker. Rapid heating or breaking of the battery pack's seal may result in excessive heat, release of smoke, explosion, and/or a fire. In this case, the battery pack may be damaged. Do not use this battery pack and replace it with a new one.
• If the operator notices a leak or an abnormal odor from the battery pack, immediately remove it from any heat source in the vicinity. The electrolytic solution may ignite, causing release of smoke, explosion, and/or a fire. Do not use this battery pack, and replace it with a new one.
• If the operator notices an abnormal odor, excessive heat, change of color, deformation, or other abnormalities during use, recharging, or storage of the battery pack, immediately remove the battery pack from the recorder unit, and do not use the battery pack. Continued use of the battery pack may result in excessive heat, release of smoke, explosion, and/or a fire. Use a new battery pack instead.

CAUTION

• Any ancillary diagnostic tests or examinations (e.g. upper GI endoscopy and colonoscopy) required prior to or in conjunction with this device should be performed at the physician's discretion.
• Do not use the capsule endoscope after its expiration date because the life of the battery may be insufficient to perform the entire exam. The expiration date is placed on the label of the capsule endoscope storage case (see page 2).
• To prevent the capsule endoscope battery from deteriorating, store the capsule endoscope within a temperature range of 0 – 25°C (32 – 77°F). Do not store the capsule endoscope in a refrigerator or a freezer because condensation may occur inside the cover dome.
•Avoid long term use or storage at temperatures exceeding 40°C (104°F). Battery pack performance may deteriorate rapidly under these conditions.
•Avoid long term use at temperatures below 0°C (32°F). In case of long term use at temperatures below 0°C (32°F), you should not start the examination.

CAUTION

- Keep the capsule endoscope away from permanent magnets or electromagnets. Magnets can turn the capsule endoscope ON, resulting in the consumption of battery power.
- Keep the capsule activator away from implant devices, such as cardiac pacemakers, defibrillators, nerve stimulators, and other equipment that may be affected by DC magnetic fields.
- Before use, ensure that there are no rough or sharp edges and/or projections on the surface of the capsule endoscope. If the surface of the capsule endoscope is not smooth, patient injury may occur.
- Keep the recorder unit, antenna unit, and recorder unit cradle from water, alcohol, and any other liquids.Liquids entering these components may damage them and/or result in the system failure.
- Connect the cables according to the “System chart” on page 103. Be sure to use only the specified cables for the proper connection of system components.
- Before using the recorder unit, check that no error icon is displayed on the recorder unit’s display panel. If an error icon is displayed, refer to the “Recorder unit error messages” section in Chapter 5, “Troubleshooting”, to evaluate and attempt to correct the problem.
- While initializing the recorder unit, do not remove the recorder unit from the recorder unit cradle or unplug the USB cable and/or the AC adapter. Doing so may damage the recorder unit’s internal memory.
- The examination cannot proceed if there is insufficient space on the recorder unit’s internal memory and “Download” icon is indicated. Use the workstation to initialize the recorder unit in advance.
- While initializing the recorder unit, do not turn OFF the workstation or the recorder unit. Doing so will interrupt initialization.
- Prior to the examination, use the recorder unit cradle to fully charge the battery pack in the recorder unit. The examination cannot proceed if the battery pack is not fully charged.
- Do not remove the battery pack while the receiver unit’s power is ON. Doing so may damage the recorder unit.
- Avoid prolonged use of the system at or below 0°C (32°F). In such temperatures, the capsule endoscope may not be able to operate for 12 hours, and the battery packs may not be fully recharged.
- Do not use an antenna sheet of the antenna unit that has been completely folded or creased. Its reception performance may be degraded, causing noise to appear in the transmitted images.
- The capsule endoscope should only be ingested with water. Use of other liquids may interfere with the examination.
- Do not make a diagnosis using images displayed on the recorder unit.

CAUTION

- If more than one capsule endoscope is ingested at the same time, image recording may fail because of radio interference. Before use, the physician has to ensure that the patient has not swallowed any other capsule endoscope. Do not use the capsule endoscope with any other swallowable diagnostic devices because the safety of concomitant use has not been verified.
- Do not turn ON a capsule endoscope near another patient already undergoing an examination with an ingested capsule endoscope. Also do not allow patients undergoing such examination sit next to each other. It may cause capsule endoscope images to become distorted.
- While downloading, do not remove either the recorder unit or the USB cable and/or AC adapter from the recorder unit cradle. Doing so will result in loss of image data. If you do remove the recorder or the USB cable and AC adapter, connect the recorder to the workstation through the recorder unit cradle and the USB cable and restart the workstation before downloading again.
- Do not drop or strike either product. Equipment damage may occur.
- During the capsule endoscope exam instruct the patient to stay away from generators of strong electromagnetic fields (such as MRI equipment, amateur (ham) radio, etc.) otherwise image recording may not occur due to radio interference.
- Please advise the patients not to use radio transmitting devices such as keyless entry devices (frequency range of possible interference: 306 - 322 MHz) or stay in an area where other persons may use them frequently, in order to reduce the possibility of dropped video frames caused by the use of these devices.
- Since the capsule endoscope is a radio-transmitting device, it could interfere or experience interference with other radio-transmitting devices (e.g., telemetry, keyless entry devices).
- On rare occasions, interference may result in the need to repeat the capsule endoscope procedure. In this case, the physician should advise the patient to stay within the premises of the medical facility during the examination to prevent this problem from reoccurring.
- The capsule endoscope contains a radio transmitter; therefore, the patient cannot fly in an airplane until the examination is over.
- In rare cases, the interference could occur due to the military use of the frequency band in the USA.
- This device has not been authorized as required by the rules of the Federal Communications Comission. This device is not, and may not be, offerd for sale or lease, or sold or leased, until authorization is obtained.

NOTE

- This system is used to examine the small intestine by the patient’s ingestion of a capsule endoscope, that continuously takes pictures as it moves down the gastrointestinal tract by peristalsis. The captured images are radio transmitted to the recorder unit, and are observed using the workstation. After the examination, the capsule endoscope is excreted naturally.
- Have a spare capsule endoscope ready for use in case the primary device is determined to be unusable prior to patient ingestion.
- After turning ON the capsule endoscope, bring it near the antenna unit on the patient, and confirm that the radio reception indicator lamp blinks in green. If the indicator does not blink, the capsule endoscope and/or the recorder unit may be malfunctioning.
- You can check for proper operation of the equipment by periodically inspecting the status of the indicator lamp.

Danger, warning and cautions for patients

Provide the following information to the patients at least one day before the examination, so that the examination may be performed properly.
Failure to follow these instructions may result in injury to the patient and/or may interfere with the examination. Please provide the patient with the separate "Caution for Capsule Endoscopy Patient" packed with the capsule endoscope (EC-Y0005).

DANGER

•Instruct the patient to stay away from generators of strong electromagnetic fields (such as MRI equipment), between ingestion and excretion of the capsule endoscope. Failure to follow instructions may result in injury to the body cavity.

WARNING

• Instruct the patient to consult a physician immediately if abdominal pain, discomfort, or nausea is experienced after ingesting the capsule endoscope. If treatment for these symptoms is delayed, it may result in injury to the body cavity.
• The safety of the patient has not been verified if the capsule endoscope remains within his/her body for a period of 30 days or more. If the capsule endoscope is not excreted from the body, it must be collected using an endoscope or by surgery, within 30 days from the date of ingestion. To determine the location of the capsule endoscope within the patient's body, an X-ray examination may be required. Be sure to explain this risk of endoscopic or other surgical operation for collection to the patient.

CAUTION

• Instruct the patient to abstain from eating, beginning 8 hours before the examination until 4 hours after ingesting the capsule endoscope. If necessary, small quantities of water may be consumed. Failure to follow instructions may interfere with the examination.
• Instruct the patient to handle the external equipment attached to his/her body with care, and to avoid sudden movements. Failure to follow instructions may interfere with the examination.

CAUTION

• Patients who are currently taking medication must not take any medication during the period beginning two hours before and ending two hours after the beginning of the examination. If the medication must be taken on a set schedule, instruct the patient to consult the prescribing physician about shifting the schedule. Failure to follow instructions may interfere with the examination.

• Instruct the patient not to turn the recorder unit's power OFF, remove the battery pack from the recorder unit, disconnect the antenna unit, nor remove the antenna harness during the examination. Failure to follow instructions may interfere with the examination.

• During the examination, the patient puts on the antenna harness from the clothes of the thin nature material. In consideration of the examination situation, please appoint the clothes of the patient on the examination day before.

• During the examination of the capsule endoscope, stay away from generators of strong electromagnetic fields (such as MRI equipment, amateur-radio, etc.) and avoid pointing radio-transmitting devices such as keyless entry at the antenna leads. Otherwise, images may not be taken due to radio interference. As the capsule endoscope contains a radio transmitter, you cannot take an airplane until the examination is completed.

• Instruct the patient to keep the recorder unit, and the antenna unit, from water, alcohol, and any other liquids. Liquids entering these components may damage them and/or result in system failure.

• Instruct the patient to avoid using the recorder unit at or below 0°C (32°F). Failure to follow instructions may cause the battery pack to deteriorate rapidly, resulting in the examination ending prematurely.

• Provide the physician's emergency contact number for the patient on the "Caution for Capsule Endoscopy Patient" packed with the capsule endoscope system set MAJ-Y0136 (MAJ-Y0136).

Expiration date of the capsule endoscope

The battery inside the capsule endoscope gradually loses life during long term storage. A storage environment with temperatures over 25°C (77°F) may cause the capsule's battery to deplete rapidly. Loss of battery life may shorten the operation time (continuously recording and transmitting the images) of the capsule endoscope. If stored in the recommended storage environment (0 – 25°C (32 – 77°F)) the capsule endoscope is designed to record 12 continuous hours by the expiration date printed on the package.

CAUTION

- The storage environment of the capsule endoscope is restricted to between 0 – 25°C (32 – 77°F). Storage of the capsule endoscope in temperatures over 25°C (77°F) may cause the battery to lose life. As a result, the capsule endoscope may not operate for 12 continuous hours.
- Never store the capsule endoscope in a refrigerator or freezer. The rapid temperature change that occurs when the capsule endoscope is removed from the refrigerator or freezer may cause condensation on the inside the capsule endoscope. Such condensation may cause the battery to lose life and lead to severe equipment damage.
- Do not use the expired capsule endoscope. The expired capsule endoscope may not operate for the assured operation time (12 hours).
- The capsule endoscope typically operates for 12 continuous hours. Its passage to the cecum depends on the peristalsis movement of the patient. If peristalsis is slower than normal, the capsule endoscope may not reach the ileocecal valve before the 12 hours are up. Therefore, not every case is guaranteed to view the entire small intestine.
- To maximize operation time, the capsule endoscope should be swallowed by the patient immediately after the capsule endoscope is turned on.

Color Tone of the Capsule Endoscope Image

Images photographed by the CMOS incorporated in the capsule endoscope (EC-Y0005) are wirelessly transmitted to the antenna harness attached to the patient and then recorded on the recorder unit . The images stored in the recorder unit can be played on the workstation for observation. Once the capsule endoscope is dispensed to the patient, it cannot be controlled from outside of the patient. The capsule endoscope's images may be interfered or unusual with depending on the operating environment or the settings of the devices used in conjunction with the capsule endoscope system. The following are foreseeable image interference cases and unusual image cases and the corresponding preventative methods or solutions.

CAUTION

• If the capsule endoscope gets close to the object rapidly, halation will occur. As a result, the image may whiteout. In this case, refer to the images before and after the whiteout image. Compare Figure 1 (halation) and Figure 2 (normal).

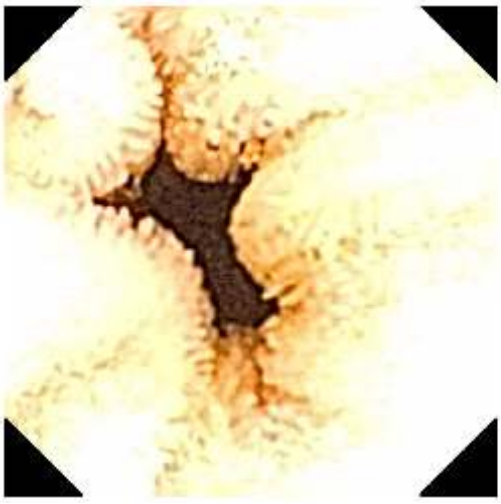


Figure 1

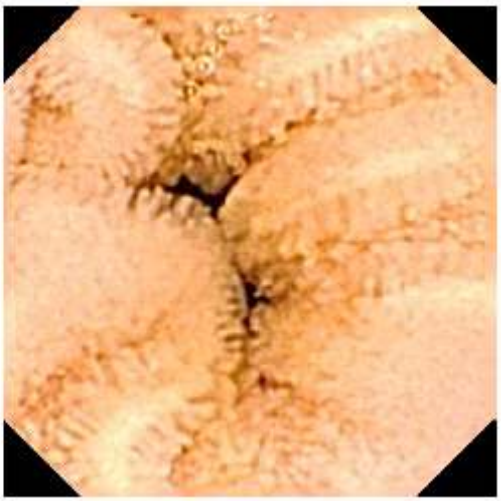


Figure 2

CAUTION

- Since the capsule endoscope transmits images by radio, noise may appear in the recorded images depending on the surrounding electromagnetic environment (see Figure 3 (an example of the noise is indicated by the arrow)). If an image with noise is displayed, observe the image carefully.

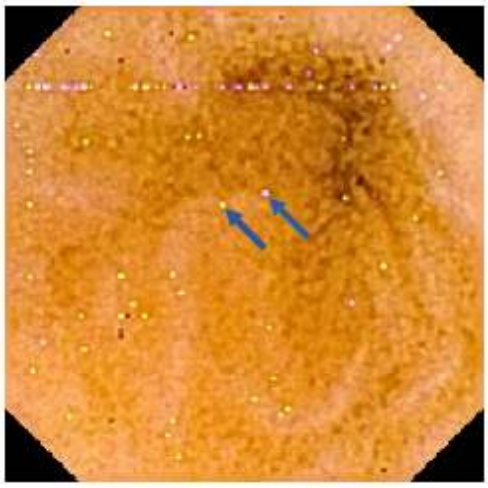


Figure 3

- Some debris in the small intestine may look like bleeding in color and shape (see Figure 4 (in the circle)). To determine if the image is debris or bleeding, observe the surrounding condition and the images before and after the image in question.

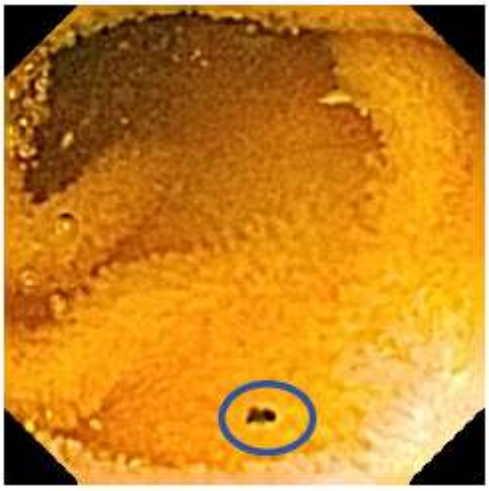


Figure 4

- Avoid touching the top cover of the capsule endoscope. Do not wipe with gauze or other clothes. Doing so may damage the top cover and interrupt observation.

CAUTION

- Do not change the color setting of **Windows®** installed in the workstation. Doing so may change the color tone of the image.
- Connect the LCD monitor and the workstation hardware securely. If the connection is loose, the images may not be displayed properly.
- Use monitors designated by Olympus for observation of the capsule endoscopic images. Non-designated monitors may display the images in different color tones.
- Due to the characteristics of an LCD monitor, color tones may look different depending on the angle of observation. When observing capsule endoscopic images, look straight in the LCD monitor.
- Some of the pixels on the LCD monitor display can be lost due to gradual deterioration of the monitor. The portion of the monitor that has lost pixels may appear as white or black. Before starting the observation, make sure that the color tone of the color bar is appropriate, refer to “Color Settings” in the Chapter 8 of the workstation MAJ-Y0134 instruction manual.
- Do not observe the image in sunlight whether direct or indirect since the color tone may look different because of the LCD monitor.

EMC (Electromagnetic Compatibility)

• In order to provide the intended functionality, the system emits RF (Radio Frequency) energy while in operation. This may affect electrical devices in the vicinity.

• The system is equipped with a function for device identification via radio transmission, and is thus subject to electromagnetic interference from other equipment in the vicinity.

Receiver (recorder unit, antenna unit)	**Frequency range of possible interference**	306 – 322 MHz
Transmitter (capsule endoscope)	**Central frequency**	315 MHz
	Required bandwidth	7 MHz
	Modulation method	Minimum Shift Keying (MSK)
	Effective radiated power	0.5 nW (when inside body)
	High-frequency output	+37 dBμV/m at 3 m (when inside body)

Limits of the technology

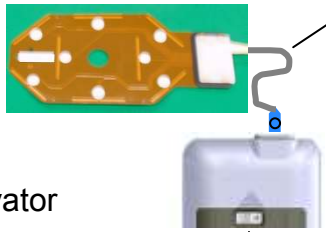
• Effect of the capsule endoscope on the body is unknown when it remains in the patient for over 30 days.
• Even if a full 12 hours of images are recorded, there is no guarantee that the whole small intestine is photographed.
• Since the capsule endoscope is a radio-transmitting device, it could interfere/ or experience interference with other radio-transmitting devices (e.g., telemetry, keyless entry devices).
• For some patients, there is a possibility that the capsule endoscope may remain in the stomach for a longer period of time. Therefore, Olympus recommends using the real time viewer to confirm that the capsule endoscope has passed completely through the stomach.
• A normal diagnosis does not exclude a clinically important abnormality in the small bowel.

Chapter 1 Checking the Package Contents

Match all items in the package with the components shown in this chapter. Inspect each item for damage. If the instrument is damaged, a component is missing or you have any questions, do not use the system; immediately contact Olympus.

1.1 Capsule endoscope system MAJ-Y0136 (MAJ-Y0136)

Antenna Unit（X432262-21）

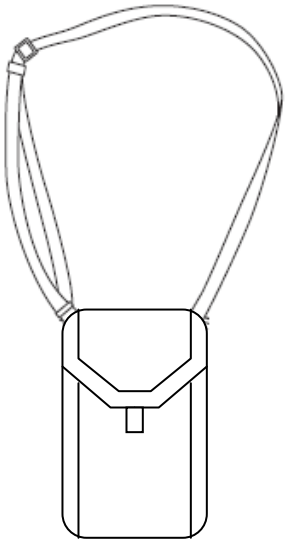


Antenna harness (X432252-51)

Capsule Activator
(MAJ-1478)

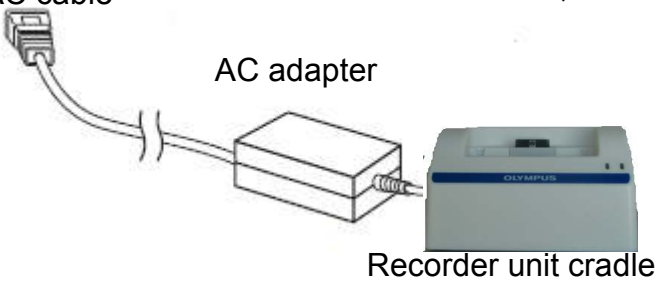
Battery pack
(X432262-11-12)

Recorder unit（X432262-11）



Recorder unit harness (X432251-40)

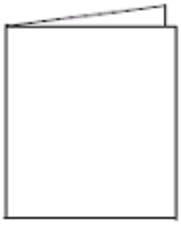
AC cable



AC adapter

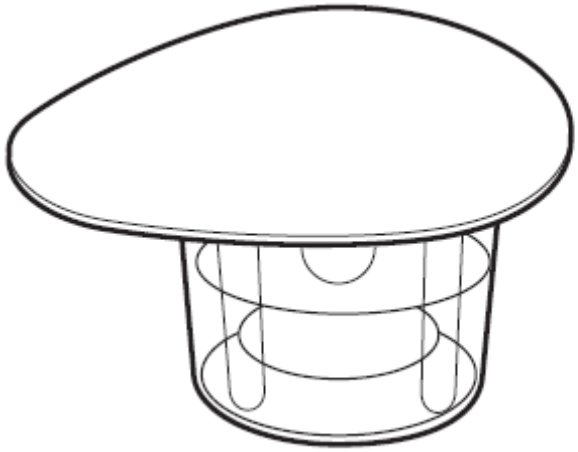
Recorder unit cradle
(X432262-31)

USB cable

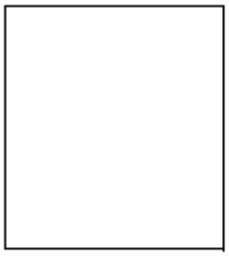


Instruction manual

1.2 Capsule endoscope (EC-Y0005)



Capsule endoscope (in sterile container)



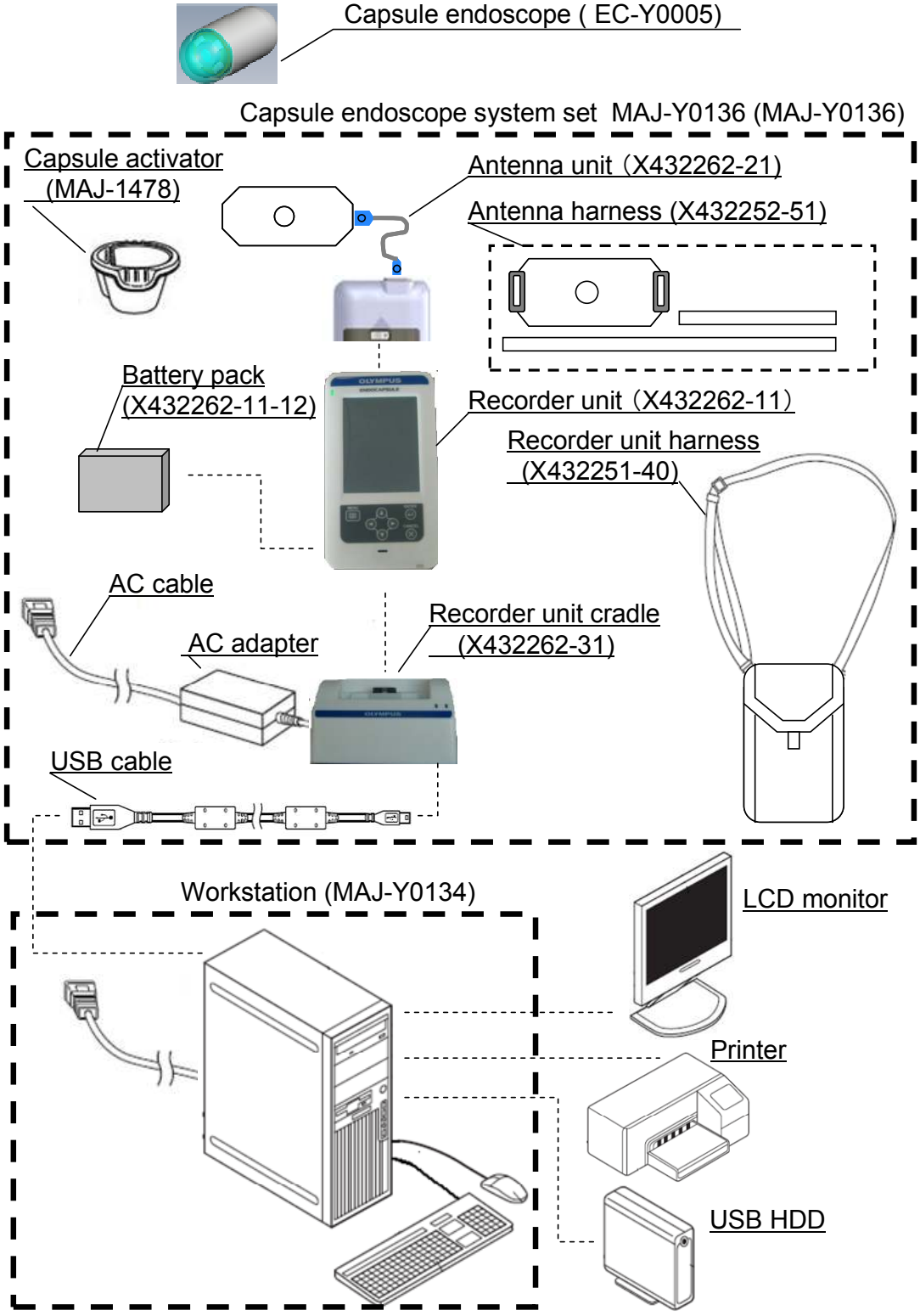
Caution for capsule endoscopy patient

The product model of each item and its content are as follows:

Product name	Model	Comments
Capsule endoscope system set MAJ-Y0136	MAJ-Y0136	Recorder unit, antenna unit, battery pack, recorder unit harness, recorder unit cradle, antenna harness, AC adapter, AC cable ,USB cable, capsule activator
Capsule endoscope	EC-Y0005	1 pc.
Capsule activator	MAJ-1478	1 pc.
Recorder unit	X432262-11	1 pc., with 1 battery pack
Antenna unit	X432262-21	1 pc.
Recorder unit cradle	X432262-31	1 pc., with 1 AC adapter and 1 AC cable
Antenna harness	X432252-51	1 pc.
Recorder unit harness	X432251-40	1 pc.

Chapter 2 Nomenclature and Functions

2.1 System components



1. Capsule endoscope (EC-Y0005)
Takes endoscopic pictures of the gastrointestinal tract and transmits the image data by radio transmission.

2. Antenna unit (X432262-21)
Receives transmissions from the capsule endoscope, and transfers the image data to the recorder unit.

3. Recorder unit (X432262-11)
Records the image data transmitted by the capsule endoscope via the antenna unit.

4. Battery pack (X432262-11-12)
The power supply for the recorder unit.

5. Recorder unit cradle (X432262-31)
Holds the recorder unit while connecting to the workstation. Used for initialization of the recorder unit, registration of the patient ID, and downloading of image data.

6. Antenna harness (X432252-51)
Holds the Antenna unit during the examination.

7. Recorder unit harness (X432251-40)
Holds the recorder unit during the examination.

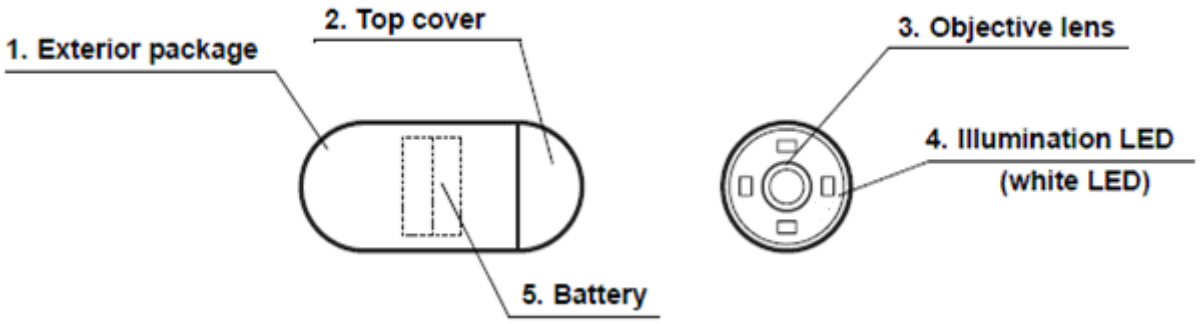
8. Capsule Activator (MAJ-1478)
Holds the recorder unit during the examination.

9. USB cable
Connects the recorder unit cradle to the workstation for transmission of patient ID, image data, etc.

10. Workstation (MAJ-Y0134)
Registers patient information and patient IDs onto the recorder unit. Also used to download the endoscopic images from the recorder unit for observation, diagnosis, and reporting (refer to the “WORKSTATION MANUAL”).

2.2 Capsule endoscope (EC-Y0005)

Capsule endoscope (EC-Y0005)



1. **Exterior package**
Exterior package of the capsule endoscope.

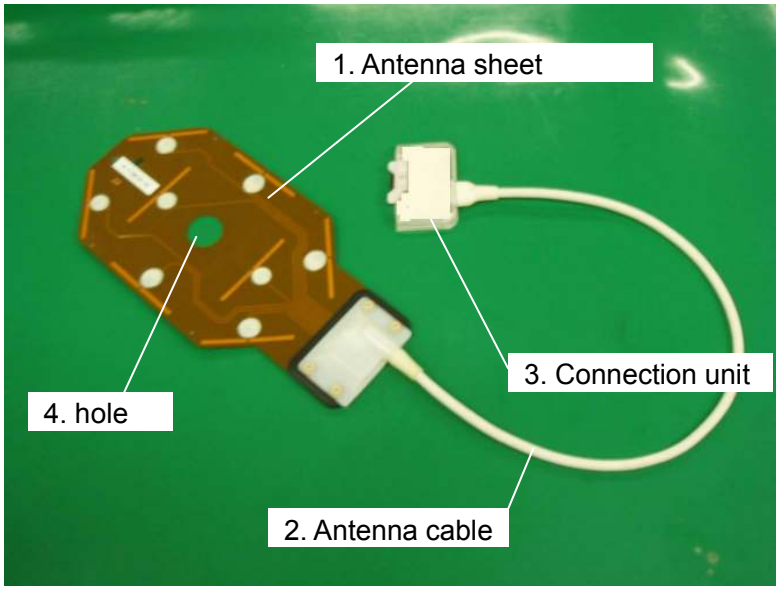
2. **Top cover**
A transparent observation port covering the objective lens and illumination light emitting diode (LED).

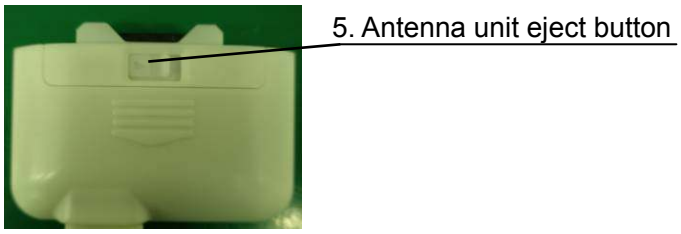
3. **Objective lens**
Lens for endoscopic observation.

4. **Illumination LED**
Illuminates the area being observed.

5. **Battery**
Internal battery for operating the capsule endoscope.

2.3 Antenna unit (X432262-21)





1. **Antenna sheet**
Receives signals from the capsule endoscope.

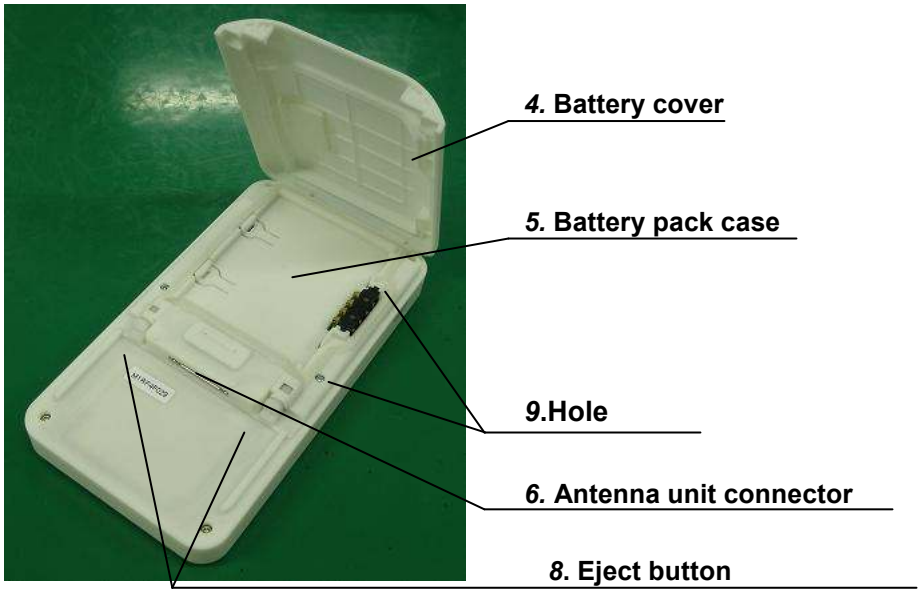
2. **Antenna cable**
Transfers the received signals to the connection unit.

3. **Connection unit**
Connects to the recorder unit.

4. **Hole**
Use it for alining the antenna sheet.

5. **Antenna unit eject button**
Slide the button located on the backside of the recorder unit to disconnect the antenna unit.

2.4 Recorder unit (X432262-11)



1. **Indicator lamp**

Indicates the reception/communication status with the capsule endoscope and the workstation.

2. **Power lamp**

Illuminates green when the recorder unit is turned ON.

3. **Display panel**

Displays patient ID, battery pack level, etc.

4. **Battery cover**

Covers the battery pack and holds the battery pack in place.

5. **Battery pack case**

Insert the battery pack here.

6. **Antenna unit connector**

Attach the antenna unit here.

Connect to the recorder unit cradle.

7. **Power switch**

Turn the recorder unit ON by holding down the switch for 1 second or more.

Turn the recorder unit OFF by holding down the switch for 2 seconds or more.

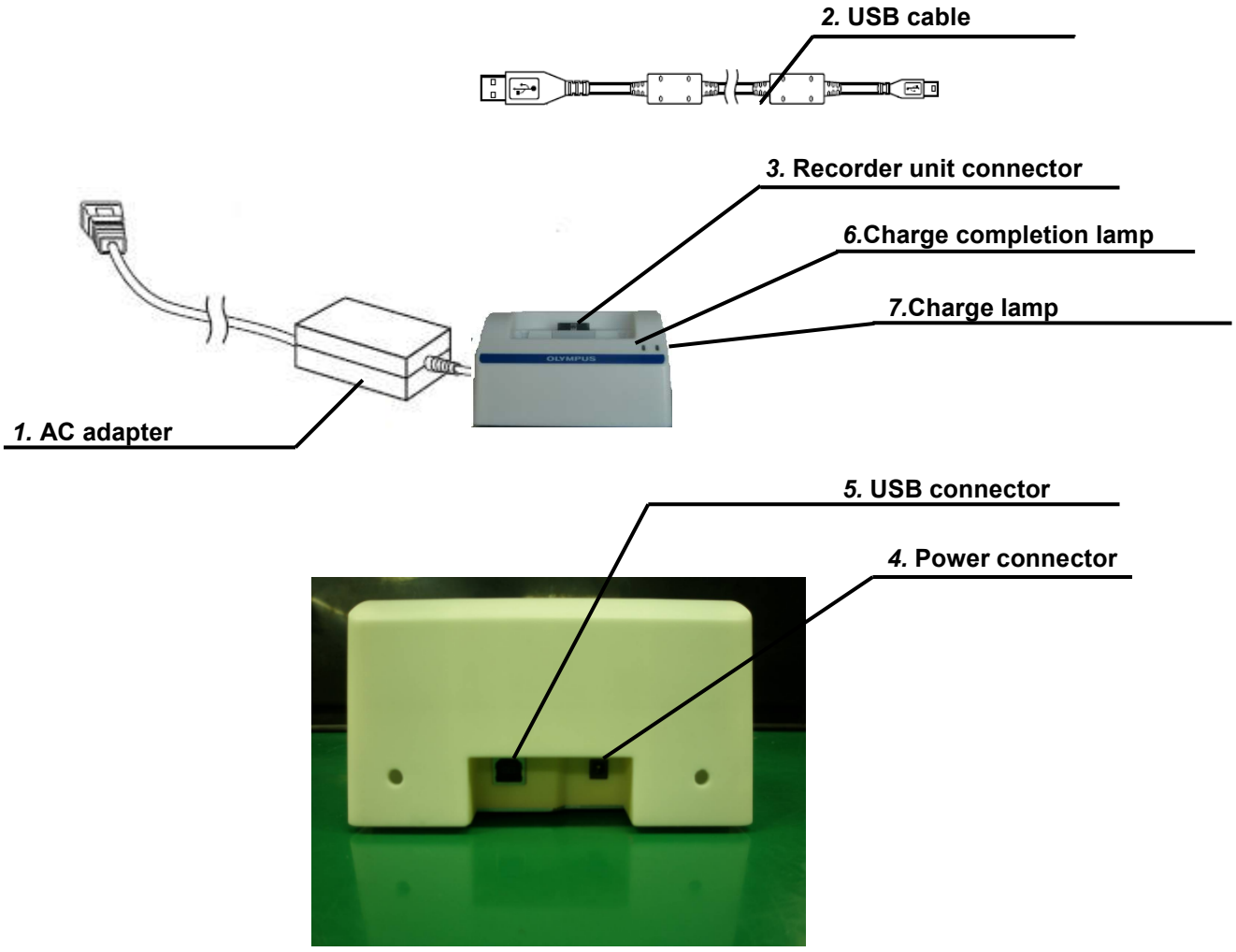
8. Battery cover eject button

Push it to remove the battery cover

9. **Hole**

Insert the nail of the battery pack into this hole when inserting the battery pack into the battery pack case.

2.5 Recorder unit cradle (X432262-31)



1. **AC adapter**
Connects to an AC power supply.

2. **USB cable**
Connects between the USB connector and the workstation.

3. **Recorder unit connector**
Connect to the recorder unit.

4. **Power connector**
Connect to the AC adapter.

5. **USB connector**
Connect to USB cable.

6.Charge completion lamp
Show the status that battery is charged completely..

7. **Charge lamp**
Show the status that battery is charging.

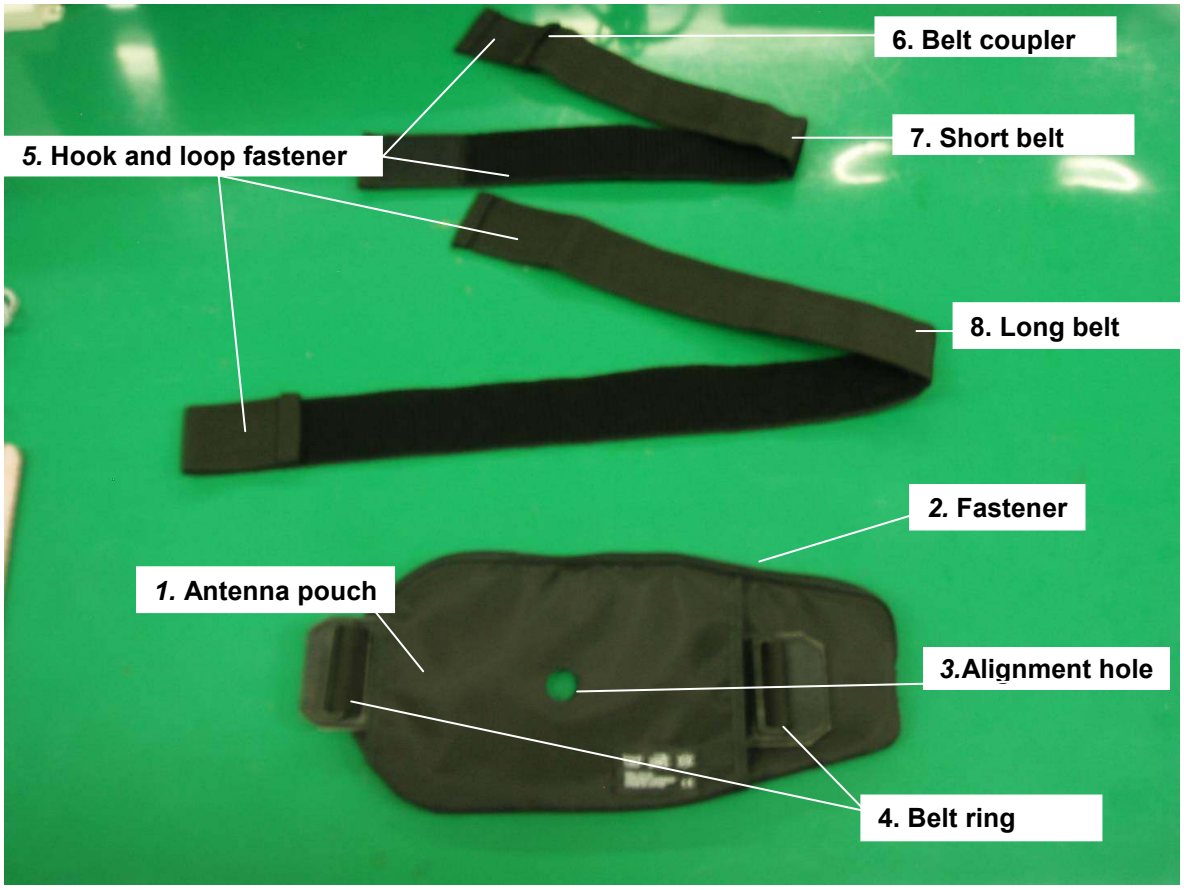
2.6 Recorder unit harness (X432251-40)

1. **Suspender**
Adjusts the length according to the patient's physique.

2. **Pouch**
Stores the recorder unit during the examination.

3. **Pouch cover**
Secures the recorder unit and the antenna cables to the pouch.

2.7 Antenna harness (X432252-51)



***1.*Antenna pouch**
Housing the antenna sheet..

2. Fastener
Zip up to fix the antenna sheet..

3. Alignment hole
Adjust this hole to the umbilical position.

4. Belt ring
Through a belt, and fix the hook and loop fastener..

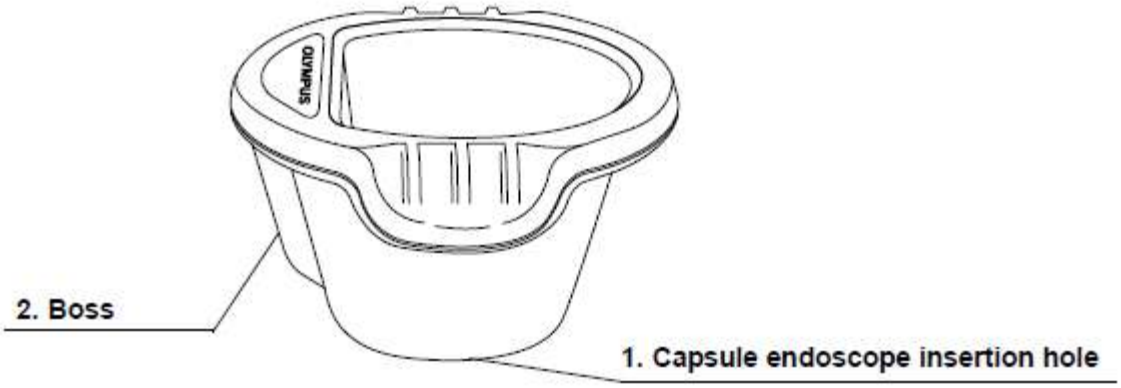
5. Hook and loop fastener
Connect the both ends of the belt.

6. Belt coupler
Please use it to connect the long belt and the short belt.

7. Short belt
It fixes the antenna pouch to the patient's body.
If necessary, connect to the long belt.

8. Long belt
It fixes the antenna pouch to the patient's body.
If necessary, connect to the short belt.

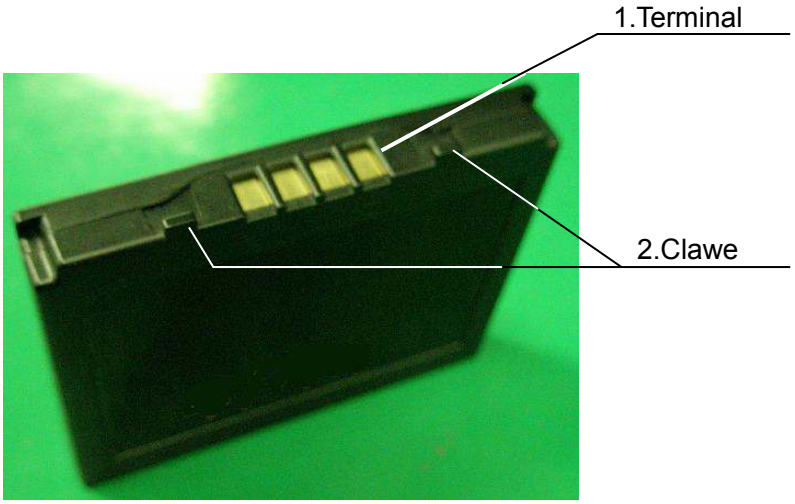
2.8 Capsule activator (MAJ-1478)



1. **Capsule endoscope insertion hole**
To turn ON the capsule endoscope, insert it into this hole.

2. **Boss**
Projected portion that indicates direction of the activator.
It is like a guide when inserting the activator.

2.9 Battery pack (X432262-11-12)



1. **Terminal**
Connects to the connector in the battery case of the recorder unit.

2. **Clawe**
Insert this nail into the hole of the recorder unit when inserting the battery pack into the battery pack case.

2.10 Workstation (MAJ-Y0134)

For a diagram of the workstation configuration, please refer to the "WORKSTATION MANUAL"

Chapter 3 Installation and Connection

3.1 Preparation

The following items are required for the capsule endoscope examination.
Inspect them the day before the examination as described in this chapter.

Equipment	Quantity
Capsule endoscope	2 (Including 1 spare)
Antenna unit	1
Recorder unit	1
Battery pack	1
Recorder unit cradle	1
USB cable	1
Recorder unit harness	1
Workstation	1
Capsule activator	1
Antenna harness	1
Drinking water	As required
Gauze	As required
Ethyl or isopropyl alcohol	As required

Table 3.1

3.2 Exterior

CAUTION

Do not use if the equipment exterior is abnormal.It may result in failure of the examination.

Inspect the equipment as described in Table 3.2 below.

Equipment	Description
Antenna unit	Check that the unit is free of cracks, deterioration, deformation, And other damage.
Recorder unit	Check that the unit is free of cracks, deterioration, deformation, And other damage.
Recorder unit cradle	Check that the unit is free of cracks, deterioration, deformation, and other damage.
AC adapter	Check that the unit is free of cracks, deterioration, deformation, And other damage. Check the power supply cable for scratches and bends,. Check the connectors for cracks, deterioration, deformation, and other damage.
USB cable	Check the cable for scratches and bends. Check the connectors for cracks, deterioration, deformation, and otherdamage.
Battery pack	Check that the unit is free of cracks, deterioration, deformation, and other damage.

Table 3.2

3.3 Capsule endoscope

WARNING

Perform the following inspections before use. Should any irregularity be observed, do not use this system. Damage to or irregularity of this system may cause malfunction or patient injury.

1. Confirm that the expiration date has not passed.
2. Check the sterile package for ruptures, damage to the seal or water that might have entered the sterile package.
3. Before removing the capsule endoscope from the sterile package, inspect the capsule's surface for cracks, deterioration, deformation, and other damage.

3.4 Preparation of the recorder unit

Attaching the battery pack

1. Open the battery cover by pressing the battery cover eject button.

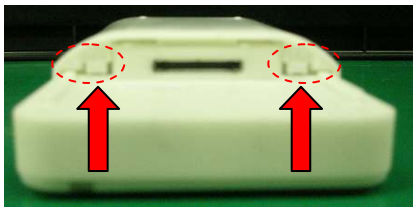


Figure 3.1

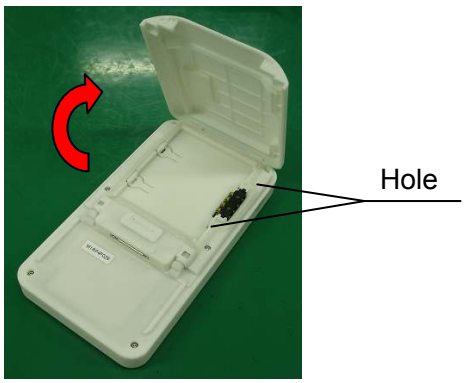


Figure 3.2

2. Align the two claws on the battery pack with the hole in the battery pack case, and insert the battery pack to the battery pack case.

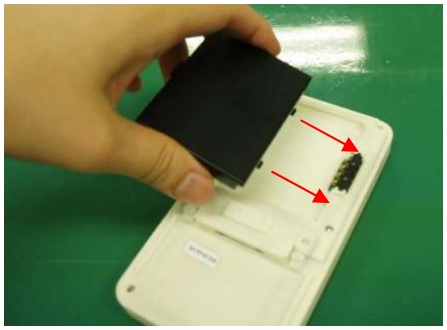


figure 3.3

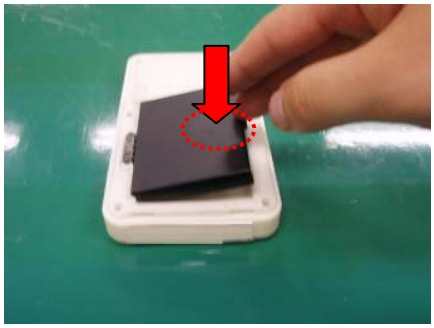


Figure 3.4

3. Close the battery cover by pressing it down over the battery pack until the battery cover is locked. (Refer Figure 3.5)

Figure 3.5

CAUTION

Don’t use the recorder unit if there are cracks, deterioration, deformation, and other damage. It may interfere with the examination.

NOTE

• The battery pack is not charged when it is shipped. Charge it before use.

• To remove the battery pack, remove the battery cover for reference ‘1’ of “Attaching the Battery pack” of the previous page. And lift the edge of the battery pack which is surrounded with the dotted line of the figure below.

Figure 3.6

3.5 Preparation of the recorder unit cradle

1. Connect the AC adapter to the power connector.

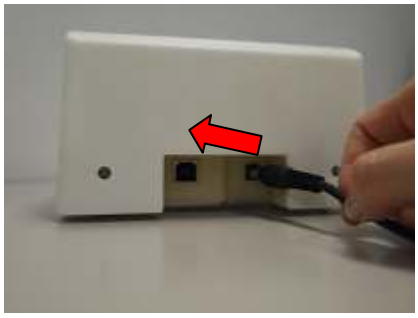


Figure 3.7

2. Connect the USB cable to the USB connector.

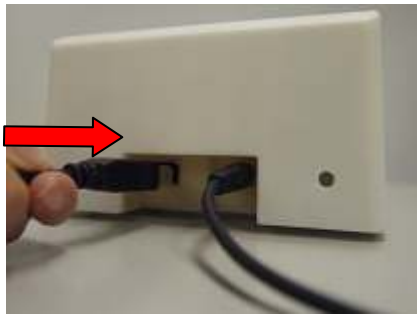


Figure 3.8

3. Connect the AC cable to the AC Adapter.

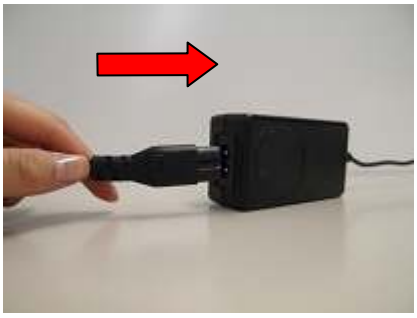


Figure 3.9

4. Connect the AC cable to the AC power supply.

5. Connect the USB cable to the USB connector on the workstation. Refer to “Workstation manual”.

Chapter 4 Operation

4.1 Preparation and Inspection before examination

Before starting an examination, be sure to read and clearly understand the information in this instruction manual.

DANGER

Instruct the patient to stay away from equipment that generates strong electromagnetic fields (such as MRI equipment), between ingestion and excretion of the capsule endoscope. Otherwise, injury within the body cavity may occur. If the excretion of the capsule endoscope has not been confirmed 30 days after ingestion, attempt to locate the capsule endoscope within the patient's body by X-ray examination.

WARNING

Instruct the patient to consult their physician immediately if symptoms such as abdominal pain, discomfort, or nausea are experienced after ingesting the capsule endoscope. Injury to the patient may result if treatment for such symptoms is delayed.

CAUTION

- Instruct the patient not to turn the recorder unit's power OFF, push any buttons on the recorder unit, disconnect the antenna unit, or remove an antenna harness during the examination. Failure to follow the instructions may interfere with the examination.
- During the capsule endoscope exam instruct the patient to stay away from generators of strong electromagnetic fields (such as MRI equipment, amateur (ham) radio, etc.), otherwise image recording may not occur due to radio interference.

- Please advise the patients not to use radio transmitting devices such as keyless entry devices (frequency range of possible interference: 306 - 322 MHz) or stay in an area where other persons may use them frequently, in order to reduce the possibility of dropped video frames caused by the use of these devices.
- Since the capsule endoscope is a radio-transmitting device, it could interfere/ or experience interference with other radio-transmitting devices (e.g., telemetry, keyless entry devices).

CAUTION

- On rare occasions, interference may result in the need to repeat the capsule endoscope procedure. In this case, the physician should advise the patient to stay within the premises of the medical facility during the examination to prevent this problem from reoccurring.
- The capsule endoscope contains a radio transmitter; therefore, the patient cannot fly in an airplane until the examination is over.
- The life span of a battery pack is approximately 1 year from the date of purchase. When the battery pack approaches its end-of-life, the recorder unit will prompt for replacement. Order a new battery pack and replace. Otherwise the recorder unit may not be able to operate for 12 hours.

Exterior

Inspect the equipment as described in Table 4.1 below.

Equipment	Description
Antenna unit	Check that the Antenna unit is free of cracks, deterioration, deformation, and other damage.
Recorder unit	Check that the recorder unit is free of cracks, deterioration, deformation, and other damage.
Recorder unit cradle	Check that the recorder unit cradle is free of cracks, deterioration, deformation, and other damage.
AC adapter	Check that the AC adapter is free of cracks, deterioration, deformation, and other damage. Check the power supply cable for scratches and bends,. Check the connectors for cracks, deterioration, deformation, and other damage.
USB cable	Check the cable for scratches and bends. Check the connectors for cracks, deterioration, deformation, and other damage.
Antenna harness	Check that the Antenna harness is free of rips, deterioration, and other damage.
Recorder unit harness	Check that the recorder unit harness is free of rips, deterioration, and other damage.

Recharging

Fully recharge the battery packs to prevent low battery charge, which could cause the examination to end prematurely. In preparation for the examination, recharge the battery packs on the previous day.

CAUTION

The battery pack can not be recharged at temperatures below 0℃.

1. Check that the recorder unit is off and the display panel is blank.

2. Suppress the recorder unit cradle by hand, and insert the recorder unit to the recorder unit cradle as shown in Figure 4.1. The recorder unit is turned on, and displays starting screen as shown in Figure 4.2 on the display panel.

Figure 4.1

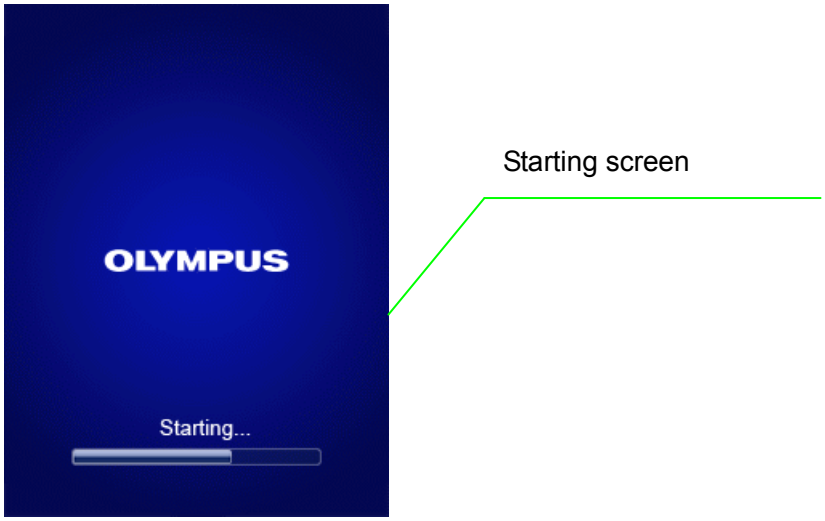


Figure 4.2

NOTE When the antenna unit is connected to the recorder unit, the recorder unit cannot be connected to the recorder unit cradle. Remove the antenna unit from the recorder unit to insert the recorder unit to the recorder unit cradle.

3. Wait a few seconds, and check that the charge lamp illuminates and Battery charge screen as shown in Figure 4.4 is displayed on the display panel. The recharging time is approximately 2 hours.

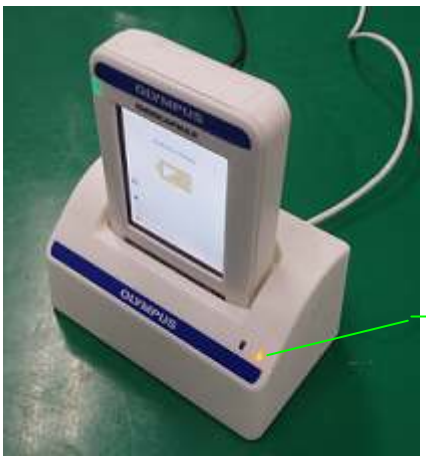


Figure 4.3

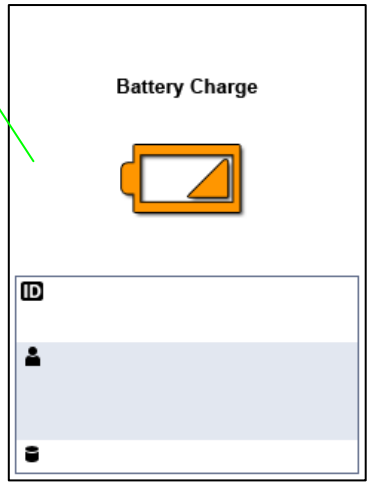


Figure 4.4

4. When recharging is complete, the charge lamp goes off, the charge completion lamp illuminates and Battery full screen as shown in Figure 4.6 is displayed on the display panel.

Figure 4.5

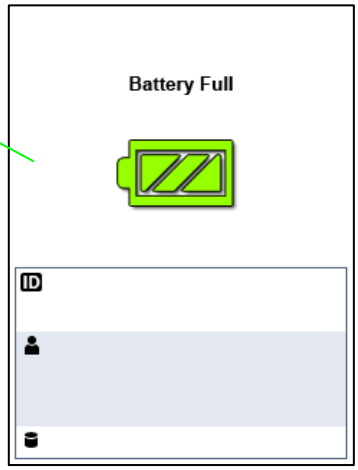


Figure 4.6

Initial setup of the recorder unit

NOTE

Before initializing, to complete the connection and setup of the Workstation, refer to the “WORKSTATION MANUAL”.

The recorder unit is connected to the workstation via the recorder unit cradle.

CAUTION While setting up the recorder unit, do not remove the recorder unit from the recorder unit cradle or remove the USB cable and/or AC adapter. Doing so may result in failure of the examination. If the recorder unit is taken off the recorder unit cradle, or the USB cable and/or AC adapter is disconnected, reconnect the recorder unit to the workstation by placing it on the recorder unit cradle or by reattaching the USB cable and AC adapter. Restart the workstation before setting up the recorder unit again.

1. The workstation is used to initialize the recorder unit and to enter patient information.

   For more information on the initialization procedure and entering patient information, refer to the “WORKSTATION MANUAL”.

NOTE

During the initial setup, recorder unit is displayed Initializing screen as shown in Figure 4.7 on the display panel, and the recorder unit’s indicator lamp illuminates orange.

Figure 4.7

2. When initialization is completed, patient ID and the patient's name are displayed on the Battery full screen as shown in Figure 4.8 on the display panel and the recorder unit's indicator lamp change green.

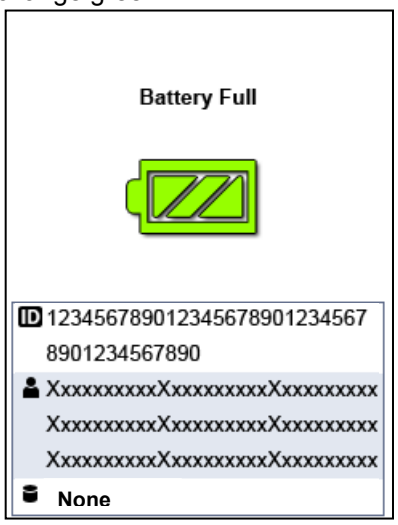


Figure 4.8

3. While holding the recorder unit cradle with one hand, lift the recorder unit up with your other hand to remove it from the recorder unit cradle. The recorder unit is turned OFF automatically.

4.2 Attaching the equipment to the patient

Patient confirmation

Before attaching the antenna unit to the patient, confirm the patient's identity. Also confirm that the patient has not eaten or drunk for at least 8 hours before the examination.

Inserting the antenna sheet

CAUTION •When inserting the antenna sheet to the antenna harness, take care not to bend the antenna sheet. Otherwise, receiving sensitivity of the antenna sheet may decrease so that noise may appear in the images or the images may not be transmitted properly.
• Do not reverse the antenna sheet upside down, left to right, and inside out when inserting it to the antenna harness. If antenna sheet is inserted to antenna harness improperly, the recorder unit may not be able to receive accurate data from the capsule endoscope.
• In case of accidental drop of the recorder unit, push the power button to restart the recorder unit, and confirm if the error message is displayed or not. The examination can be continued unless the error message is displayed.

1. Open the fastener of the antenna harness and insert the antenna sheet in the antenna harness as shown in the figure 4.9.
2. Zip up the fastener of the antenna harness.

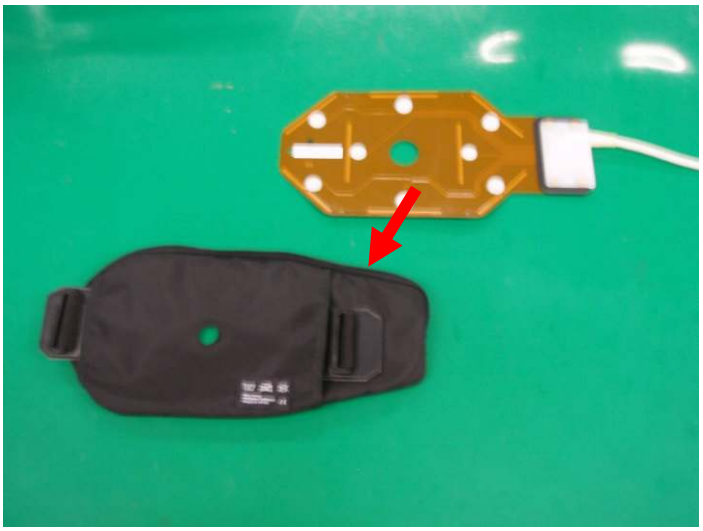


Figure 4.9

NOTE

Please insert the antenna unit in the antenna harness so that the brown aspect of the antenna unit and the label of the antenna harness are the same side.

Preparation of antenna unit harness

Select the appropriate belt to fit the body form of the patient.
If it is necessary, connect two belts in the following procedures. (Refer to figure 4.10, figure 4.11)

1. Turn down a belt in a belt coupler of the short belt. And close a hook and loop fastener.

Figure 4.10

Figure 4.11

2. Put the end of the long belt through the belt coupler of the short belt like figure 4.12.

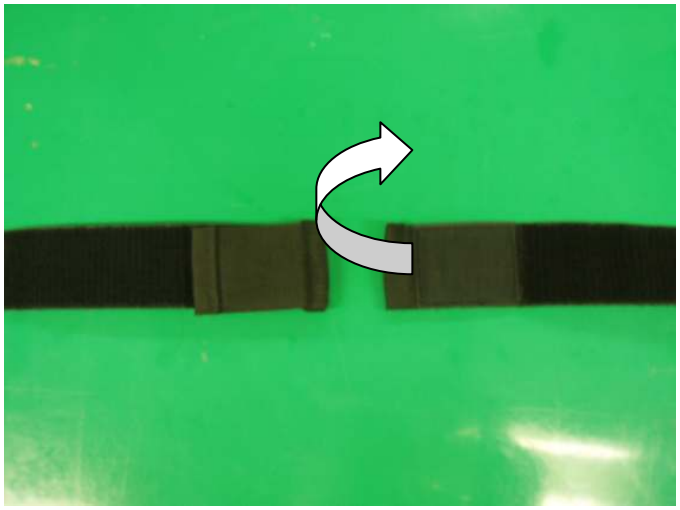


Figure 4.12

3. Close the hook and loop fastener of the long belt. (Refer to figure 4.13)

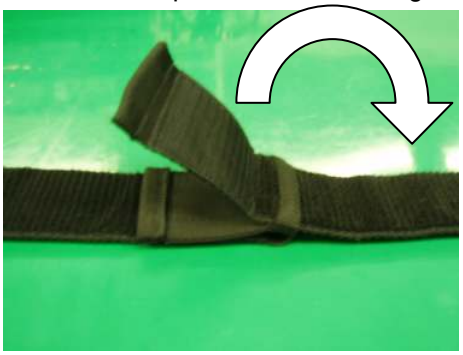


Figure 4.13

Attaching the antenna unit

CAUTION

• Refer to the following information to attach the antenna unit to the patent's body. Otherwise, noise may appear in the images or the images may not be transmitted properly.
• Allow only a thin clothing of natural materials to be placed between the body and the antenna harness.
• Do not tuck metals, such as buckle of belt, between the antenna unit and surfaces of the body. Otherwise, noise may appear in the images or the images may not be transmitted properly.
• Attach the antenna unit and the recorder unit so that antenna cable is not caught on things such as a knob of a door. Otherwise it may damage the antenna unit and/or the recorder unit and may result in failure of the examination.
• Attach the antenna unit and the recorder unit so that antenna cable is not laid on or near the antenna sheet. It may prevent the reception of images so that noise may appear in the images or the images may not be transmitted properly.

1. Instruct the patient to wear only a thin piece of clothing around abdominal area.
2. Put the belt through the belt ring. And fix the belt to the belt ring of the porch with a hook and loop fastener. Set a porch to the abdomen so that a mesh side becomes the patient side and so that an antenna cable comes to the left side of the patient's body.

Figure 4.14

3. Let the other end of the belt into a belt ring. Pull out the both ends of the belt in right and left to attach antenna harness to the patient. (Refer to figure 4.16)

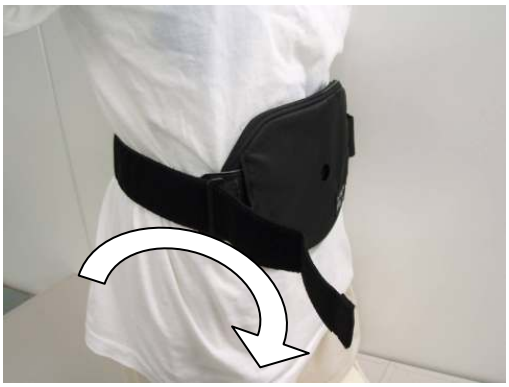


Figure 4.15

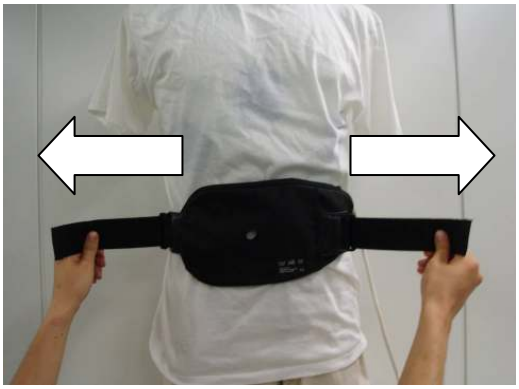


Figure 4.16

4. Adjust the position of the antenna harness so that the alignment hole of the antenna harness to the umbilical position of the patient.(Refer to figure 4.17)

Figure 4.17

5. Reattach the antenna harness in the case such as follows when the patient walks and/or sits down.
   - A patient feels unpleasantness.
   - The antenna harness move or is separate from the patient's body

CAUTION

・ Tighten the belt so that the antenna harness is not separate from the surface of the patient's body, and so that the antenna harness is believed not to move from the attached position. Otherwise, noise may appear in the images, or the images may not be transmitted properly.

CAUTION

- Instruct the patient to be careful so that the antenna harness does not move from the attached position and so that the antenna harness is not separated from the surface of the patient's body. Otherwise, noise may appear in the images, or the images may not be transmitted properly.
- Instruct the patient to be careful so that the antenna cable is not caught on things such as knob of doors.

NOTE

Instruct the patient to confirm that the position of the antenna harness is same as it's attached position after going to a restroom.

Attaching the recorder unit harness

Attach the recorder unit harness as shown in the figure 4.18.

Figure 4.18

Connecting the recorder unit and the antenna unit

1. Connect the antenna unit to the recorder unit by inserting the connection unit into the recorder unit until they click (Refer to Figure 4.19).

Figure 4.19

2. Hold down the recorder unit's power switch for at least 1 second to turn ON the recorder unit (Refer to 4.20). The starting screen is displayed as shown in Figure 4.21 on the display panel.

3. After the starting screen is displayed, The ID view screen is displayed as shown in Figure on the display panel. Check that battery icon is green. (Refer to Figure4.21, Figure 4.22)

Figure 4.20

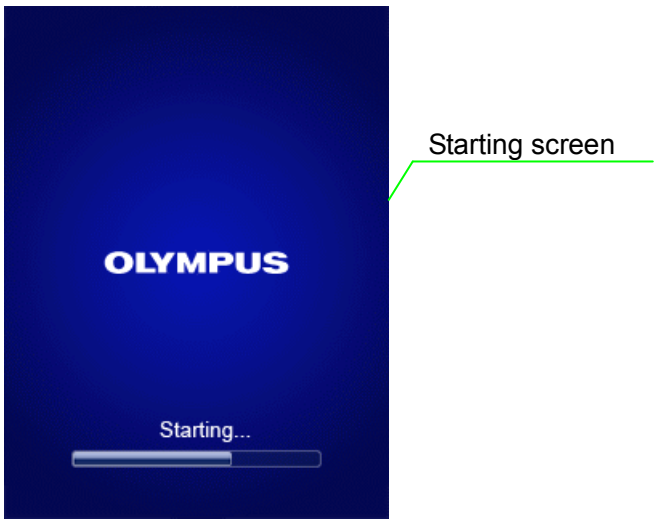


Figure 4.21

4. Confirm the patient's identity with the patient ID and the patient's name displayed on the recorder unit (Refer to Fig 4.22).

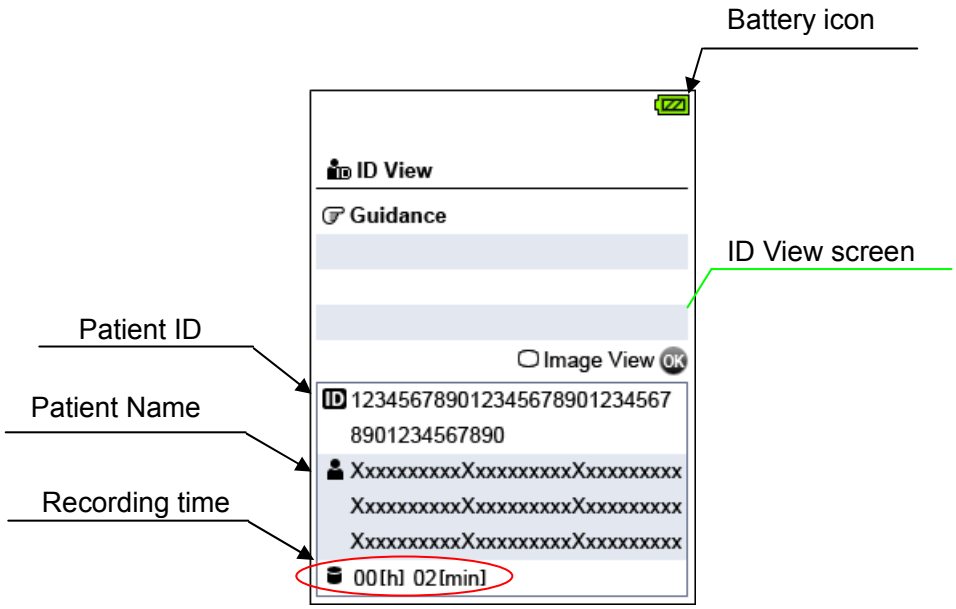


Figure 4.22

CAUTION

• If the Battery icon is orange, the battery may run out before 12 hour. Recharge the battery pack, or replace with a fully-charged battery pack.

• Start the examination immediately after turning the recorder unit ON. Failure to do so may result in premature termination of the examination due to an empty or low battery.

• If any of error messages are appeared on the display panel, refer to “Troubleshooting”.

• The recording time is displayed at the lower left of the display panel. Recording time is displayed when data are remained without being downloaded. Download such data and initialize the recorder unit if necessary.

Inserting the Recorder Unit in the Recorder Unit Harness

CAUTION

• Attach the antenna unit and the recorder unit so that antenna cable is not caught on things such as a knob of a door. Otherwise it may damage the antenna unit and/or the recorder unit and may result in failure of the examination.
• Attach the antenna unit and the recorder unit so that antenna cable is not laid on or near the antenna sheet. It may prevent the proper reception of images.

1. Insert the recorder unit into the pouch of recorder unit harness and close the pouch cover. (Refer to Figure 4.23) Please attach them so that an antenna cable is between the body of the patient and the suspenders of the recorder unit.

Figure 4.23

4.3 Preparing the capsule endoscope

WARNING

• Do not use capsule endoscopes that have been dropped, bitten, or been subjected to excessive pressure. Doing so may result in an infection control risk as well as cause injury to the patient due to damage to the capsule endoscope.

CAUTION

• Inspect the sterile package before you open it. If it is already opened or damaged, the sterility of the capsule endoscope may have been compromised. Use a new capsule endoscope instead.
• To prevent the capsule endoscope battery from deteriorating, store the capsule endoscope under a temperature of 0 – 25°C (32 – 77°F). Do not store in a refrigerator or a freezer, as condensation inside of the top cover may result.

Turning the power ON

1. Check the expiration date.

2. Slowly remove the sealing paper and take care that the capsule endoscope does not fall out of the container.

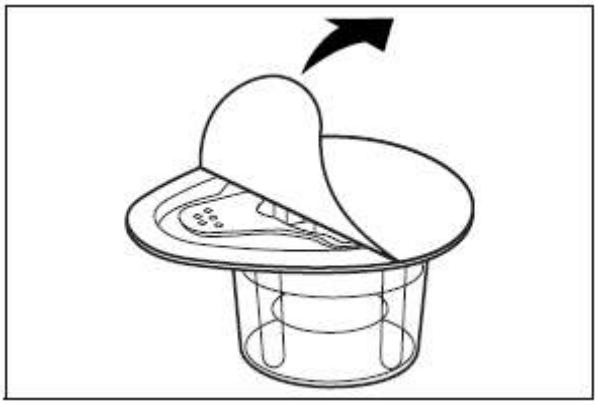


Figure 4.24

3. Hold the sterile container, taking care not to squeeze it. Adjust the direction of the activator's boss to the closest groove to the handle of the inner lid of the sterile container. Insert the capsule activator straight along with the groove. The capsule endoscope will turn ON (see Figure 4.25). When the capsule endoscope is turned ON, the LED illuminates.

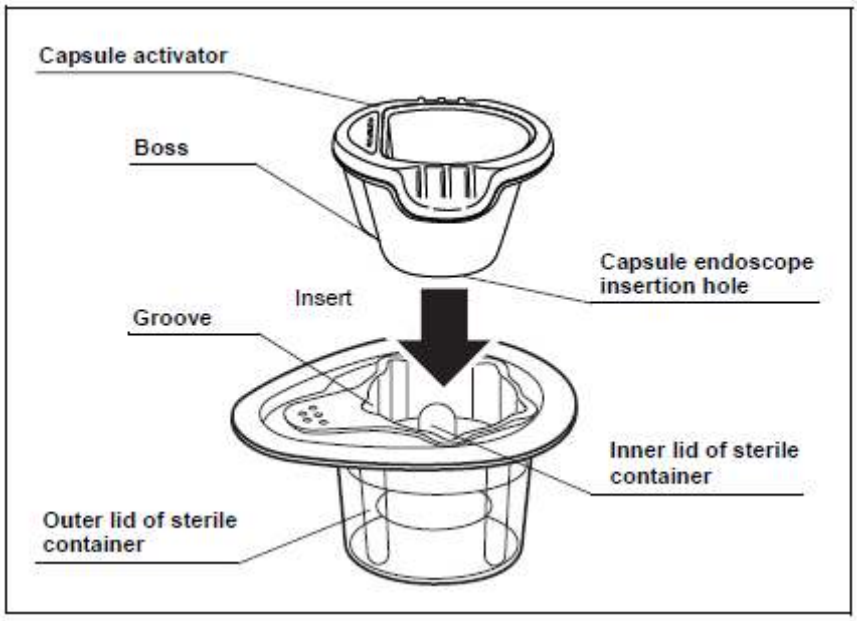


Figure 4.25

CAUTION

• The capsule activator is not sterilized. Do not allow the capsule endoscope to touch the activator.
• Keep the capsule endoscope away from DC magnetic fields such as magnets. Magnets can turn the capsule endoscope ON, resulting in the consumption of battery power.
• Do not look directly at the capsule endoscope's LED for a prolonged duration. You may feel dizzy due to the afterimage.

NOTE

Inserting the capsule activator again will turn the capsule endoscope OFF.

Confirming Operation

Confirm the operation of the capsule endoscope according to the following steps.

1. Bring the capsule endoscope in the sterile container close to the antenna sheet (the patient's abdomen).

2. Confirm that the receiving lamp of the recorder unit blinks green.

Confirming image

You can confirm if the image transmitted from capsule endoscope by Image View screen.

1. Push the “MENU” button to display the Menu screen.

2.Choose the “Image View” by pushing “Cursor” button, and push “OK” button.(Refer to Figure 4.26)

The capsule endoscope image is displayed on the Image View screen. (Refer to Figure 4.27)

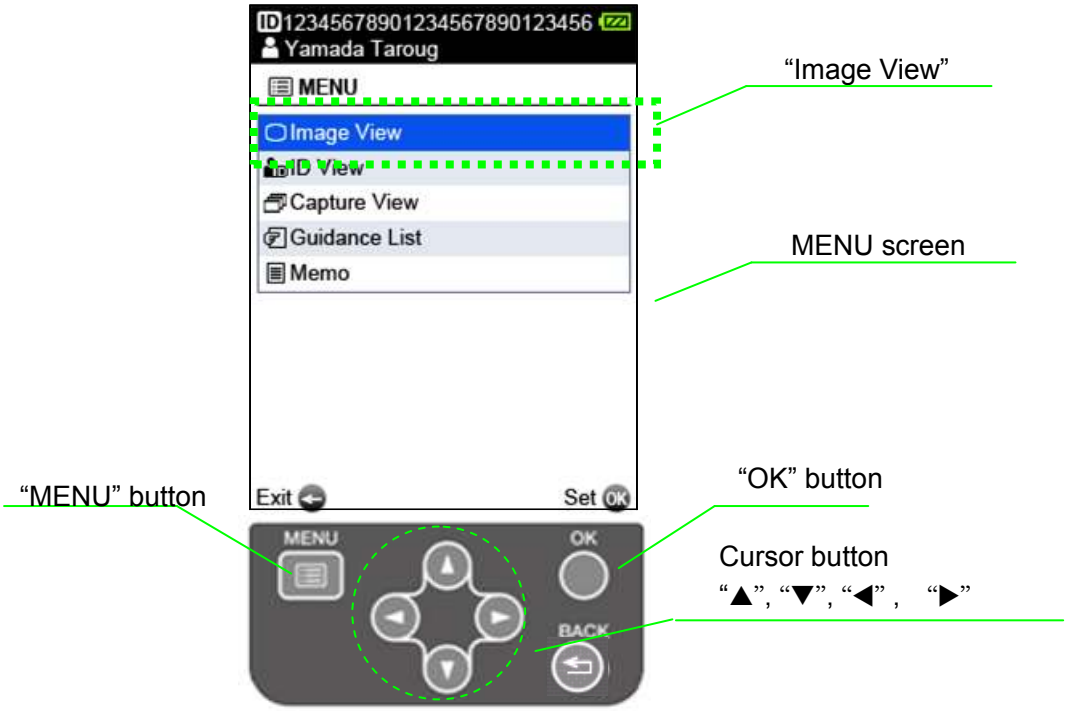


Fig 4.26

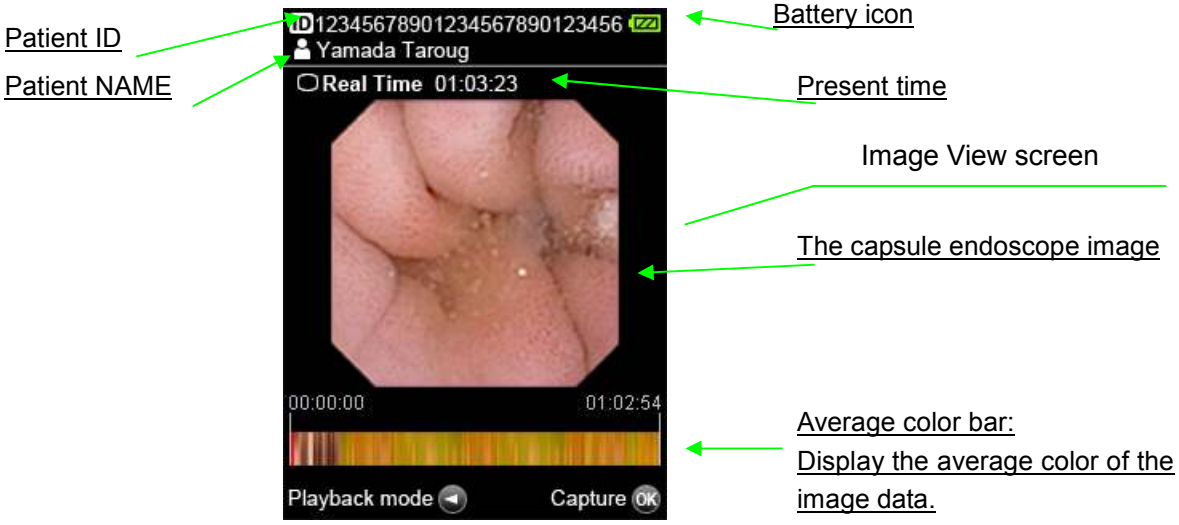


Fig 4.27

NOTE

When the ID View screen with Image View icon (Refer to Figure 4.28) is displayed, Image View screen can be displayed with the pushing “OK” button.

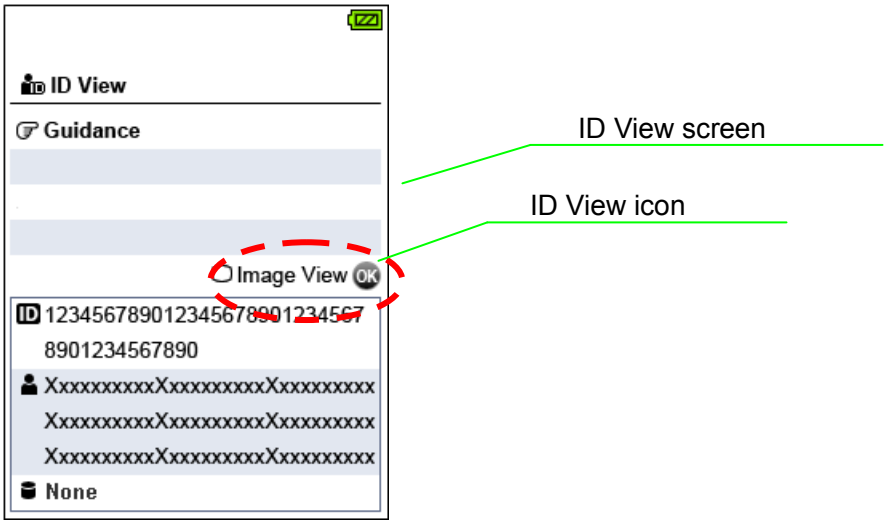


Figure 4.28

NOTE

• When approximately two minutes pass, the display panel of the recorder unit turn off.

• When “MENU” button is pushed, the MENU screen is displayed.

• When “Back” button is pushed, the previous screen is displayed.

• You can capture a displaying image with the pushing the “OK” button. Refer to the “Capture of the image”.

• Do not touch the display panel with Image View screen. You may not operate the recorder unit normally.

Confirming the recorded image

You can display recorded images on Playback mode of the Image View screen.
1. Push the “MENU” button to display the Menu screen.
Choose the “Image View” by pushing “Cursor” button, and push “OK” button.
The capsule endoscope image is displayed by Image View screen.
2. Push the ”◀” on Image View screen shown below. (See Figure 4.29)
As shown figure 4.30, a stored image is displayed by playback screen.

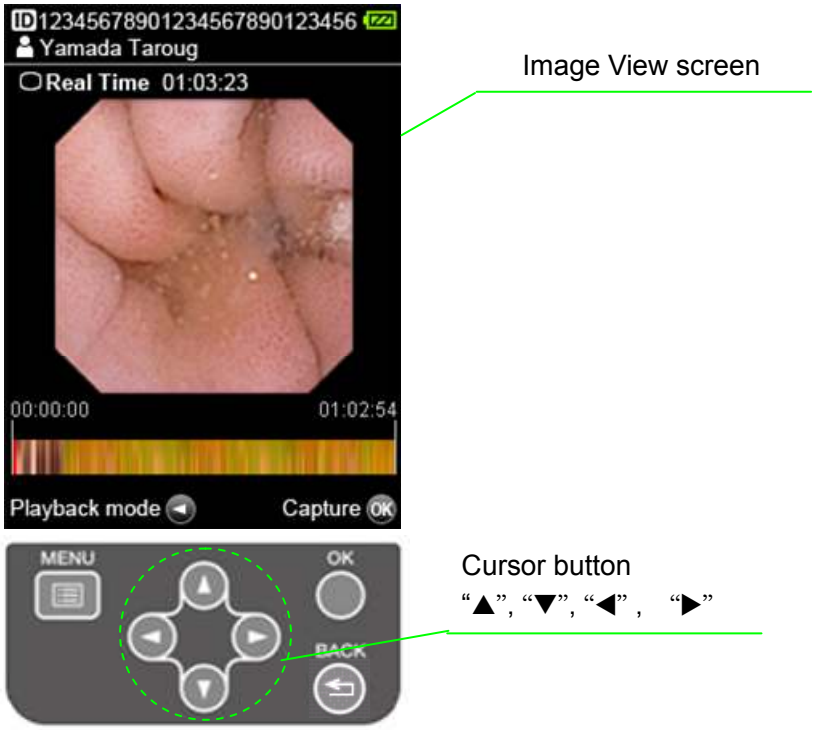


Fig 4.29

3. You can confirm the image after one piece by pushing ”◀” one piece ago by pushing ”▶”.

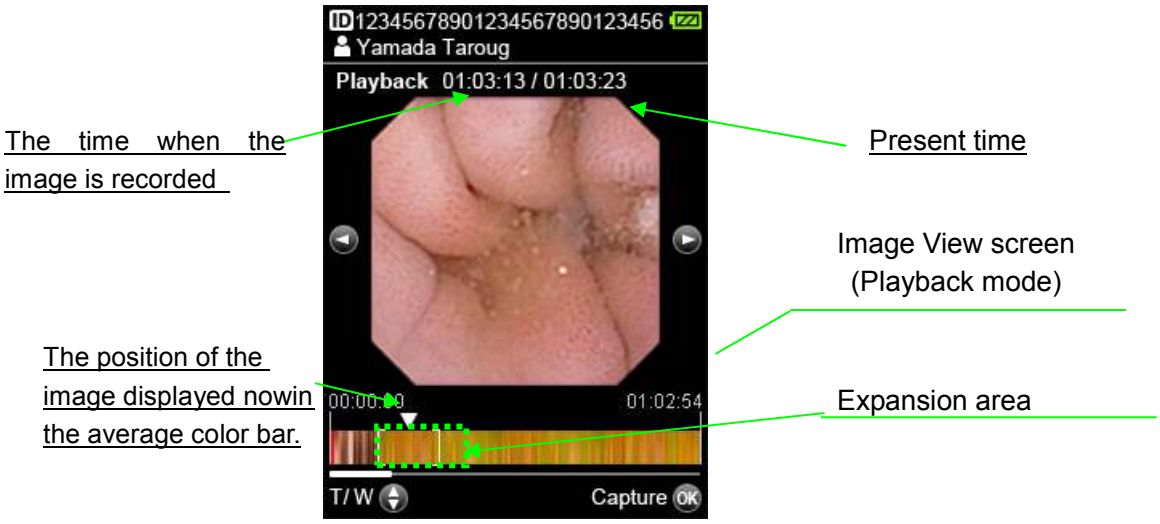


Fig4.30

NOTE

• Expansion and the reduction of the average color bar are possible by pushing “▲”or ”▼”.
The average color bar can display three following conditions.
— All mode displays the average color bar of all images which are stored.
— 1hour mode displays 30 minutes before and after an image chosen. (Displays average color bar of 1 hour.)
— 10 minutes mode displays 5 minutes before and after an image chosen. (Displays average color bar of 10 minutes.)

• You can choose 30 minutes before and after image by pushing the “◀” or“▶” in all mode.

• You can choose 5 minutes before and after image by pushing in the“◀” or“▶” in 1 hour mode.

• You can choose 5 minutes before and after image by pushing in the“◀” or“▶” in 10 minutes mode.

•You can rewind or fast forward when keep pushing in the“◀” or“▶” in 10 minutes mode.

• “[]” shows the spreading range in average color bar.

• When approximately two minutes pass, the display panel of the recorder unit turn off.

• When “MENU” button is pushed, the MENU screen is displayed.

• When “Back” button is pushed, the previous screen is displayed.

• You can capture a displaying image with the pushing the “OK” button. Refer to the “Capture of the image”.

• Do not touch the display panel with Image View screen. You may not operate the recorder unit normally.

Capture of the image

During Image View screen is displayed, you can capture the image shown on the screen.
1. Push “OK” button when the image to be captured is displayed.
Such screen as in the Figure 4.31 is displayed. Set icon and Cancel icon are displayed in the screen.

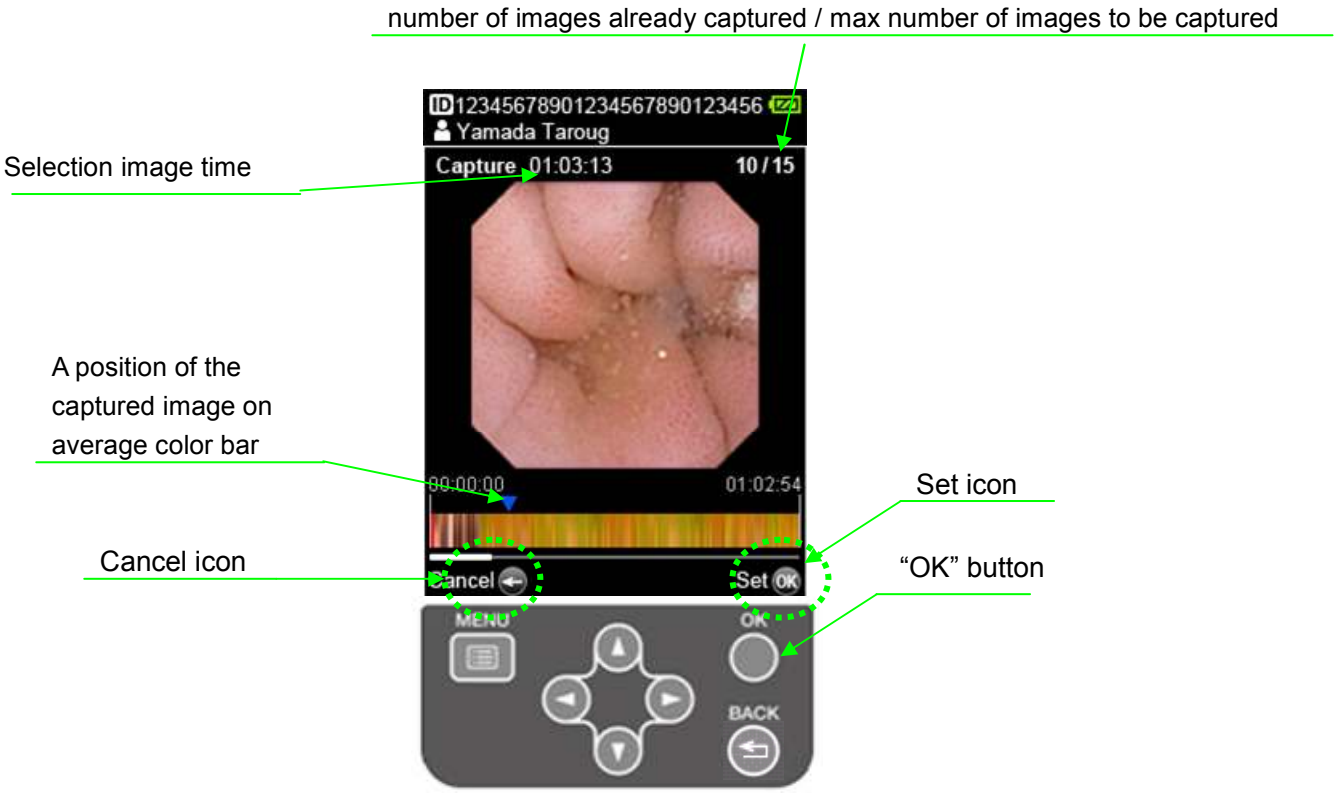


Figure 4.31

2. Push “OK” button to capture images. When you do not capture it, push “BACK” button.
After operation, the recorder unit displays Image View screen.

NOTE

• The display panel of the recorder unit turns off approximately two minutes after the last operation.

・When “MENU” button is pushed, the MENU screen is displayed.

・When “Back” button is pushed, the previous screen is displayed.

・Max 15 images are captured.

NOTE

・When number of the capture image exceeds 15, Figure 4.32 is displayed. Choose “Capture cancel” to stop capturing image or “Erase others” to capture more image by ”◀”,”▶” and “OK” button.

・When you choose “Erase others”, Capture list is displayed. Please refer to cancellation method “capture for the later operation.”

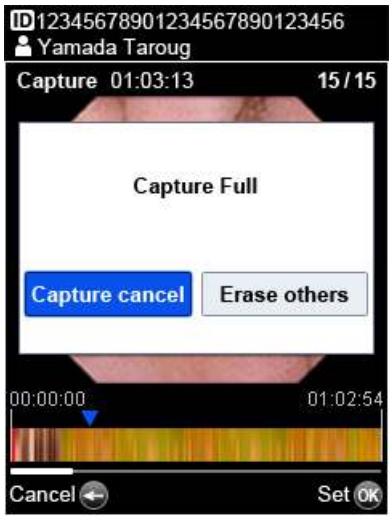


Figure 4.32

• Do not touch the display panel with Image View screen. You may not operate the recorder unit normally.

Confirming capture image

You can confirm the image which is captured by following operation from Capture list.

1. Push “MENU” button to display Menu screen.

2. Choose “Capture View” and push “OK” button on MENU screen.

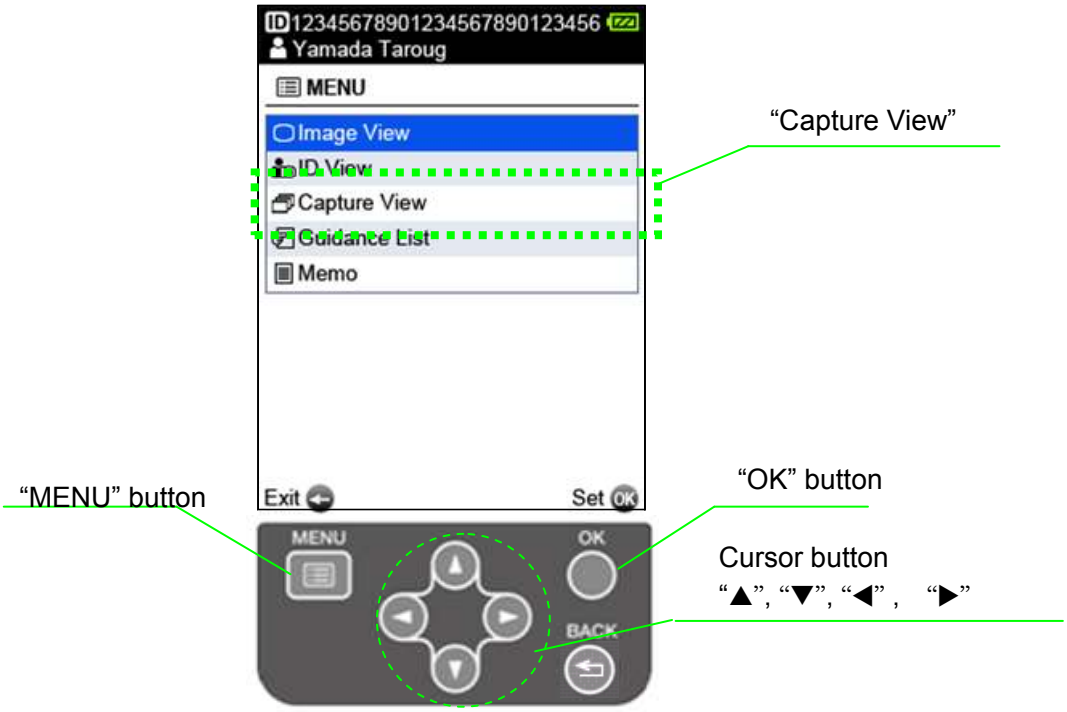


Figure 4.33

3. The images which are captured are displayed. The chosen image is surrounded in a blue line.(Refer to Figure 4.34)
Choose an image using Cursor button.

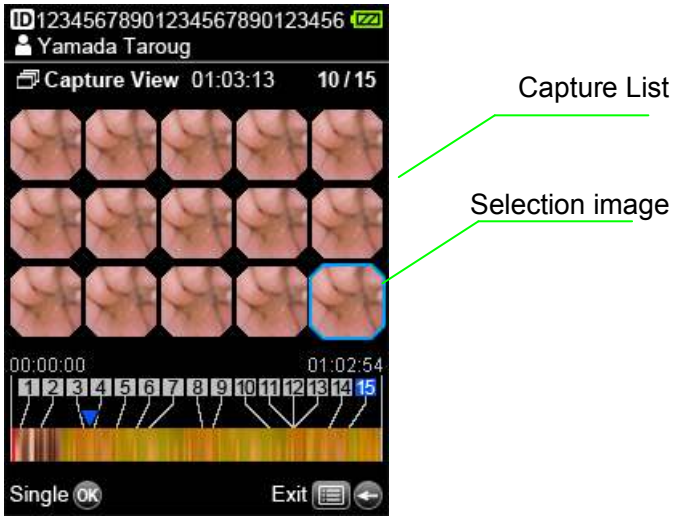


Figure 4.34

4. The image which you choose is displayed when push “OK” button. (Refer to Figure4.35)
You can display previous and following images by pushing a “◀”, ”▶”.

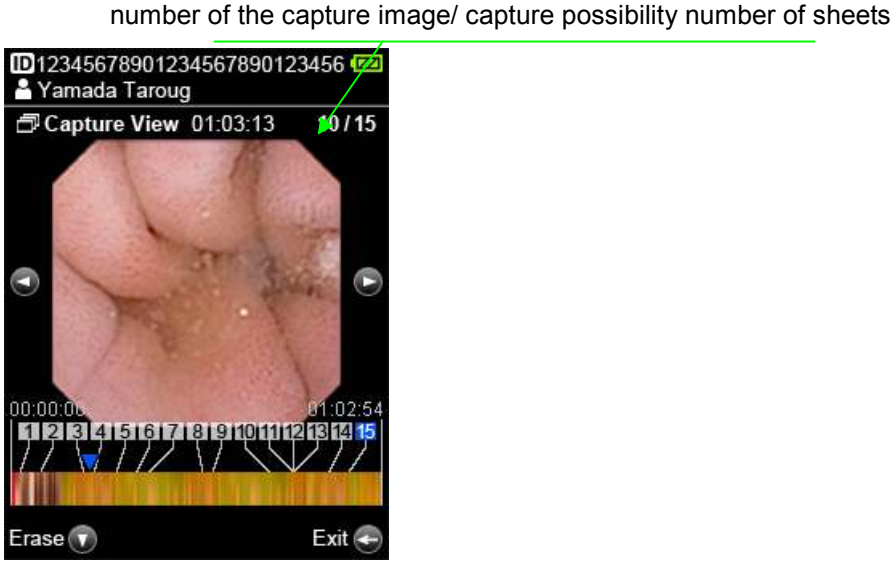


Figure 4.35

NOTE

・The display panel of the recorder unit turn off approximately two minutes after the last operation.

・When “MENU” button is pushed, the MENU screen is displayed.

・When “Back” button is pushed, the previous screen is displayed.

- Image capture is cancelled by pushing with screen ”▼” on the screen of the Figure 4.35. Please refer to “Cancellation of the capture”.

- You can view the image which is captured by the recorder unit on Workstation.

Cancellation of the captured image

By the following operation, cancellation of the capture is possible.

1. Choose an image to erase from Capture list and push "OK" button.
2. Push ”▼” when the captured image which you choose is displayed on the screen.

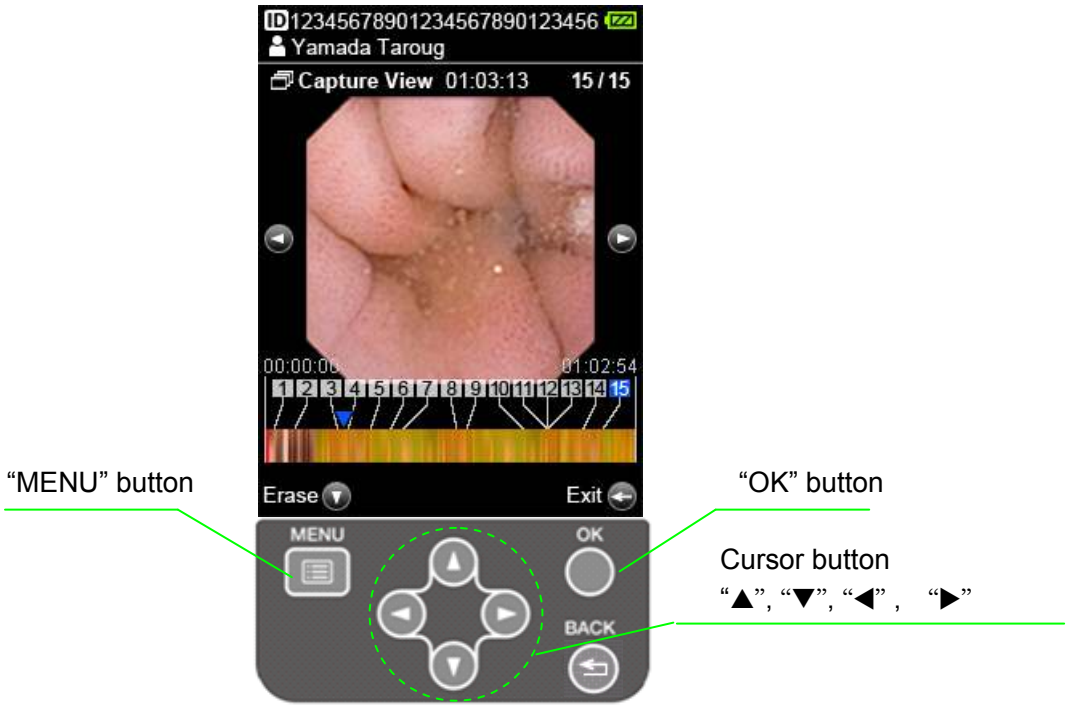


Fig 4.36

3. Choose "Yes" and push "OK" button on the following screen. (Refer to Figure 4.37)

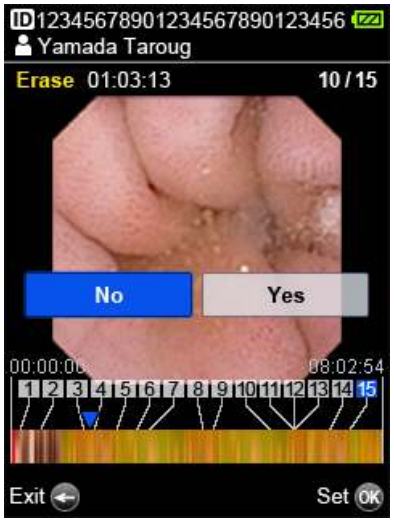


Figure 4.37

NOTE

・The display panel of the recorder unit turn off approximately two minutes after the last operation.

・When “MENU” button is pushed, the MENU screen is displayed.

・When “Back” button is pushed, the previous screen is displayed.

Confirming the guidance

The recorder unit gives guidance to a patient during the examination by registering patient and examination data in Workstation.
By the following operation, guidance to a patient is displayed.

1. Push “MENU” button to display MENU screen.

2. Choose the “Guidance List” by the Cursor button, and push “OK” button. (Refer to Figure 4.38)

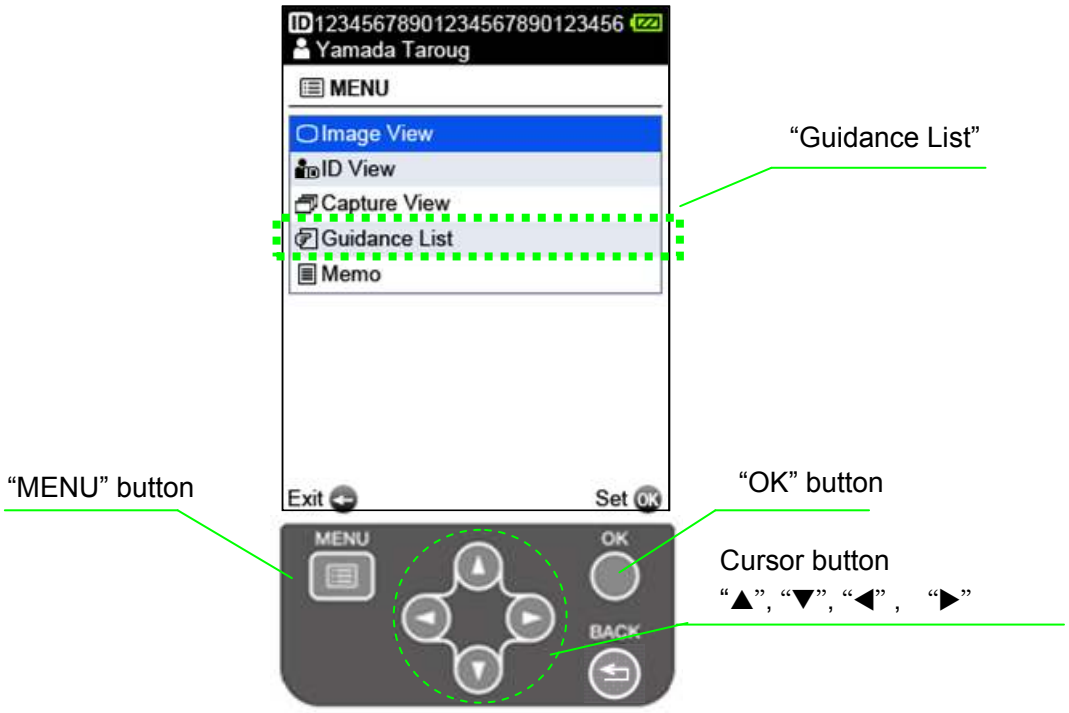


Figure 4.38

3. Guidance List is displayed. (Refer to Figure 4.39)

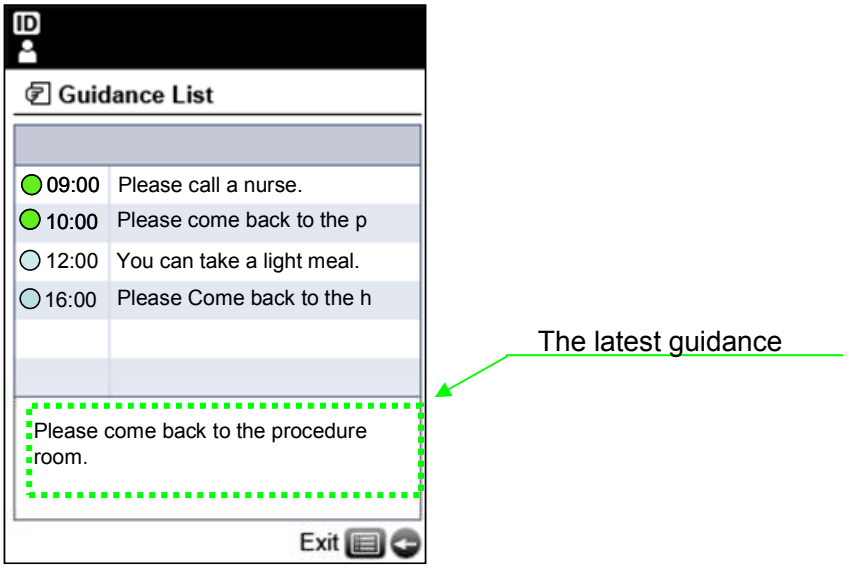


Figure 4.39

NOTE

・If the guidance has already been given, the icon shown beside the time green from white.
・The latest guidance is displayed in the lower part of the screen. （Refer to Figure 4.39）

・When “MENU” button is pushed, the MENU screen is displayed.

・When “Back” button is pushed, the previous screen is displayed.

・The display panel of the recorder unit turn off approximately two minutes after the last operation.

Handling the recorder unit when guidance is given

CAUTION

- Instuct the patient not to operate the recorder unit other than guidance occurs and to stop beep and vibration.
- Instruct a flow of the examination to the patient to patient cope even if a patient does not notice guidance.

1. Instruct a patient how to stop beep and vibration of guidance by pushing “OK” button when guidance is given.

2. ID View screen is displayed when guidance is given. Instruct patient to confirm the guidance after stopping beep and vibration.

NOTE

- The beep and vibration of the guidance stop automatically 30 seconds later.

- The latest guidance information is displayed on the ID View screen. (Refer to figure 4.40)

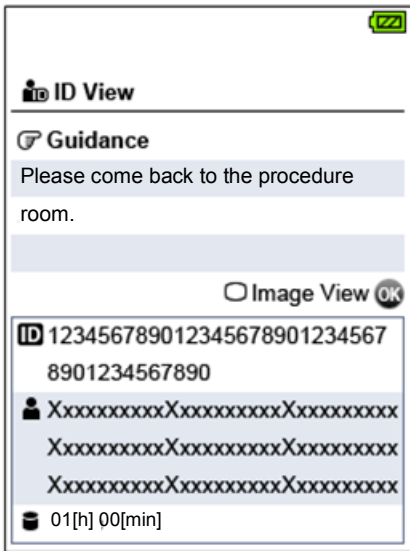


Figure 4.40

Confirmation of the memo

You can confirm the memo which is inputted in the recorder unit.

1. Push the “MENU” button.
2. Choose “Memo” by the Cursor button and push “OK” button. (Refer to Figure 4.41)

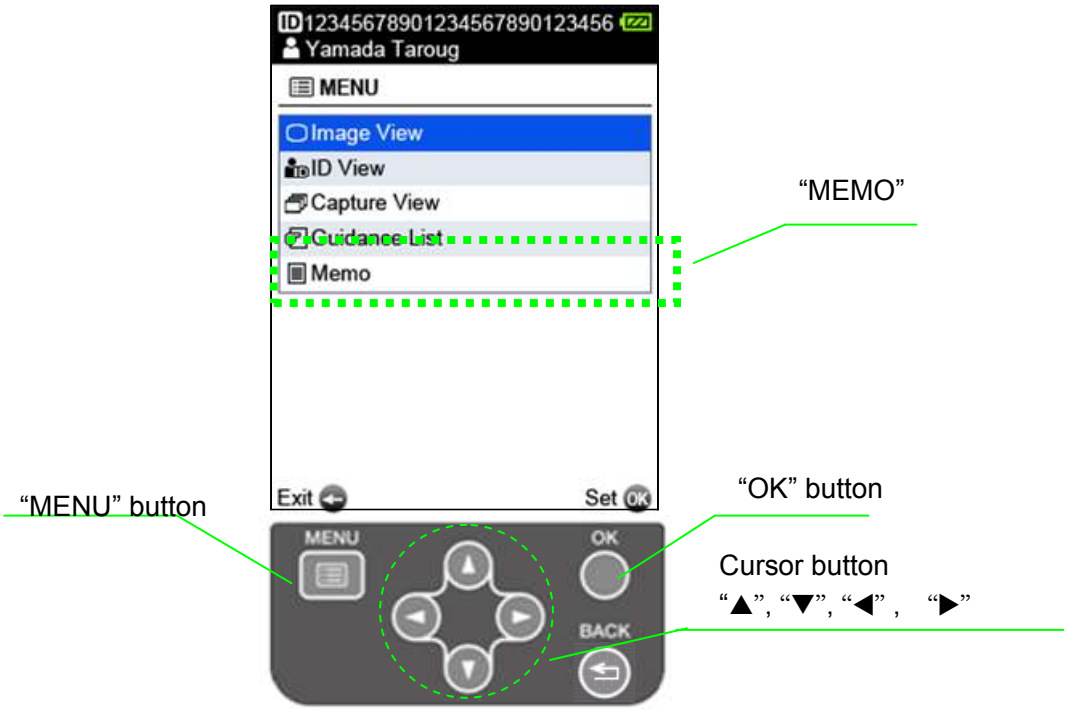


Figure 4.41

3. Such screen as figure 4.42 is displayed so that you can read the memo.

Figure 4.42

NOTE

・The display panel of the recorder unit turn off approximately two minutes after the last operation.

・When “MENU” button is pushed, the MENU screen is displayed.
・When “Back” button is pushed, the previous screen is displayed.

Editing of the memo

You can edit the memo into a recorder unit.

1. Choose the inputting position on the Memo screen by Cursor button.
2. Input a letter by touching it with a keyboard displayed on the screen.

Figure 4.43

Button	Function
▲	Press to move cursor up in input.
▼	Press to move cursor down in input.
◀	Press to move cursor left in input.
▶	Press to move cursor right in input.
OK	Save and Exit to Menu screen.
BACK	Exit to Menu screen, Memo not saved.
MENU	Exit to Menu screen, Memo not saved.

NOTE

・When “MENU” button is pushed, the MENU screen is displayed.

・You can confirm the memo which is inputted with the recorder unit only. You can not confirm it in Workstation.

4.4 Starting the examination

CAUTION

Even when the guidance function is used, explain the patient how the examination is performed, so that the examination can proceed if the patient fails to be aware of the guidance.

Ingesting capsule endoscope

CAUTION

・The capsule endoscope should only be ingested with water.
Use of other liquids may interfere with the examination.
・Avoid touching the top cover (LED side) of the capsule endoscope. Do not wipe with gauze or other cloths.

1. Prepare a glass of water

2. Remove the inner case, and hand it to the patient.

3. Confirm that the capsule endoscope's LED is blinking.

4. Instruct the patient to take the capsule endoscope out of the inner case without touching the top cover.

5. Instruct the patient to carefully ingest the capsule endoscope with a sip of water.

Confirming Passage

1. If necessary, you can confirm on the Image view screen that the capsule endoscope has passed through the esophagus and entered the stomach. To display the Image View screen, follow the instruction of "Confirming image."

2. If necessary, you can confirm on the Image view screen that the capsule endoscope has passed through the stomach and entered the duodenum by using the recorder unit If it takes too long for the capsule endoscope to pass to the duodenum, the battery may run out before the capsule goes through the entire small intestine.

NOTE

The passage of the capsule endoscope can be confirmed on the Image View screen. To display the Image View screen, follow the instruction of "Confirming image."

4.5 During the examination

Familiarize the patient with the following warnings and cautions.

DANGER

Instruct the patient to stay away from equipment that generates strong electromagnetic fields (such as MRI equipment), between ingestion and excretion of the capsule endoscope. Otherwise, injury within the body cavity may occur. If the excretion of the capsule endoscope has not been confirmed within 2 weeks from the time of ingestion, attempt to locate the capsule endoscope within the patient's body by X-ray examination.

WARNING

Instruct the patient to consult their physician immediately if symptoms such as abdominal pain, discomfort, or nausea are experienced after ingesting the capsule endoscope. If treatment of such symptoms is delayed, patient injury may result.

CAUTION

- Patients with allergies may experience reddening or irritation of the skin caused by the adhesive on the antenna unit covers.
- Instruct the patient not to turn the recorder unit's power OFF, to push any buttons on the recorder unit, disconnect the antenna unit, or remove an antenna harness during the examination. Failure to follow the instructions may interfere with the examination.
- During the capsule endoscope exam instruct the patient to stay away from generators of strong electromagnetic fields (such as MRI equipment, amateur (ham) radio, etc.) otherwise image recording may not occur due to radio interference.
- Please advise the patients not to use radio transmitting devices such as keyless entry devices (frequency range of possible interference: 306 - 322 MHz) or stay in an area where other persons may use them frequently, in order to reduce the possibility of dropped video frames caused by the use of these devices.

CAUTION

- Since the capsule endoscope is a radio-transmitting device, it could interfere/ or experience interference with other radio-transmitting devices (e.g., telemetry, keyless entry devices).
- On rare occasions, interference may result in the need to repeat the capsule endoscope procedure. In this case, the physician should advise the patient to stay within the premises of the medical facility during the examination to prevent this problem from reoccurring.
- The capsule endoscope contains a radio transmitter; therefore, the patient cannot fly in an airplane until the examination is over.
- Do not make a diagnosis using images displayed on the Image View screen.
- Instruct the patient not to operate the recorder unit other than guidance occurs and to stop beep and vibration.
- Instruct the patient to be careful so that the antenna cable is not caught on a knob and the lever of the door.
- Instruct a flow of the examination to the patient to patient cope even if a patient does not notice guidance.
- Instruct the patient to contact the physician or medical personnel, when the patient dropped the recorder unit during the examination. After having received the recorder unit, physician or medical personnel push the power button to restart the recorder unit, and confirm the error message is not displayed. If error message is not displayed, please continue the examination.
- Please attach the antenna unit to the body firmly, and set the alignment hole of the antenna harness to the umbilical position. Otherwise, noise may appear in the images, or the images may not be transmitted properly.

4.6 Ending the examination

Removing equipment

1. About 8 hours after the start of the examination, check that the recorder unit's indicator lamp has stopped blinking, and end the examination.
   If the indicator lamp is blinking, confirm the image view screen and determine whether to continue or stop the examination.

2. Take the recorder unit out of the pouch of the recorder unit harness.

CAUTION

In order to prevent damage to the antenna unit and/or the recorder unit, be sure to hold the connection unit when disconnecting the antenna unit. Do not disconnect the antenna unit while holding only the antenna cable.

3. Hold down the recorder unit's power switch for 2 seconds or more to turn OFF the recorder unit (see Figure4.44), then disconnect the antenna unit. Slide the antenna unit eject button on the backside of the recorder unit, and disconnect the connection unit by sliding it in the direction of the arrow (Refer to Figure4.45).

Figure 4.44

Figure 4.45

4. Remove the recorder unit harness from the patient.
5. Remove the antenna unit from the patient.

Downloading image data

Download the image data from the recorder unit to the workstation according to the following procedure:

CAUTION

• While downloading, do not remove the recorder unit from the recorder unit cradle or turn OFF the workstation. Doing so may result in loss of image data.
• While downloading, do not unplug the power cable. Doing so may result in loss of image data.
• While downloading, do not turn OFF the recorder unit. Doing so will interrupt the download, and require you to start the download again from the beginning.
• While downloading, do not remove the recorder unit from the recorder cradle or remove the USB cable and/or AC adapter. Doing so may result in loss of image data. If the recorder unit or cradle are disconnected from the workstation, ensure that the USB cable and AC adapter is connected to the workstation and reconnect the recorder unit to the workstation through the recorder unit cradle. Restart the workstation before downloading again.

1. Check that the recorder unit cradle is connected to the workstation using the USB cable.

2.Turn the workstation ON and log in, as described in “WORKSTATION MANUAL”.

3. Insert the recorder unit into the recorder unit cradle. The recorder unit will be turned ON automatically.

4. The patient's ID and name are displayed on the recorder unit's display panel.

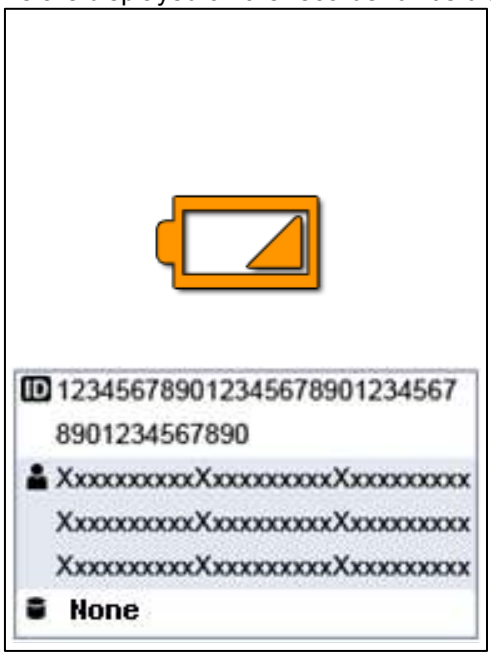


Figure 4.46

NOTE

If an error is detected on the recorder unit, the indicator lamp will blink yellow. To troubleshoot, refer to Chapter 6, "Troubleshooting".

5. The workstation is used to download image data. For specific information on downloading image data, refer to the "WORKSTATION MANUAL".

NOTE

• While downloading the image data, the indicator lamp on the recorder unit turns from green to yellow and blinks once every second. The recorder unit will be turned OFF when the download is complete.
• While downloading the image data, the icon in Figure 4.47 is displayed on the recorder unit's display panel.

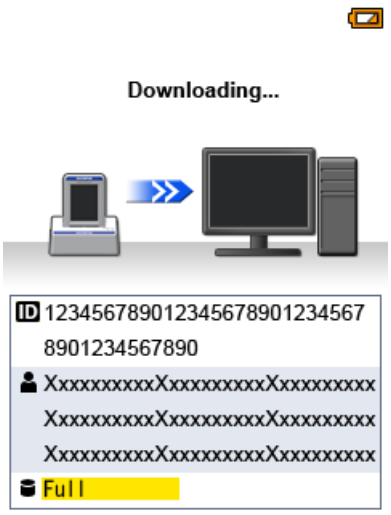

Downloading...
ID 12345678901234567890123456789012345678901234567890
XxxxxxxxxXxxxxxxxxxXxxxxxxxxx
XxxxxxxxxXxxxxxxxxxXxxxxxxxxx
XxxxxxxxxXxxxxxxxxxXxxxxxxxxx
Full

Figure 4.47

Confirming excretion of the capsule endoscope

Familiarize the patient with the following danger.

DANGER

Instruct the patient to stay away from equipment that generates strong electromagnetic fields (such as MRI equipment), between ingestion and excretion of the capsule endoscope. Otherwise, injury within the body cavity may occur. If the excretion of the capsule endoscope has not been confirmed within 2 weeks after ingestion, attempt to locate the capsule endoscope within the patient's body by X-ray examination.

1. The capsule endoscope will be excreted with the patient's feces.
2. Contact the patient to ensure that the patient observes the capsule endoscope in his/her feces.

Cleaning and storing the equipment

For instructions on cleaning and storing the equipment, refer to Chapter 4, "Care, Storage and Disposal".

Chapter 5 Care, Storage and Disposal

5.1 Care

After using the system, immediately perform the following cleaning procedure.

WARNING

- After wiping with a piece of moistened gauze, dry this system thoroughly before using it again. If it is used while still wet, there is the risk of an electric shock.
- During cleaning, wear appropriate personal protective equipment, such as eye wear, face mask, moisture-resistant clothing and chemical-resistant gloves that fit properly and are long enough so that the operator's skin is not exposed. Blood, mucous and other potentially infectious material adhering to this system could pose an infection control risk.

CAUTION

- Do not soak the system components in water, or sterilize them using autoclave or gas. Doing so will damage the system.
- Do not wipe the external surfaces with hard or abrasive wiping material. Doing so will scratch the surface.
- Do not wipe the connector of the recorder unit cradle with wet gauze. A terminal becomes short and defective, and the charging the recorder unit and downloading the data may not be possible.

1. Remove dust, dirt, and other stains on the surface of the antenna unit using a piece of gauze moistened with a neutral detergent, then wipe the surfaces using a piece of gauze moistened with70% ethyl or isopropyl alcohol.

2. Remove dust, dirt, and other stains on the surface of the following equipment using a piece of gauze moistened with a neutral detergent, then wipe the surfaces using a piece of gauze moistened with 70% ethyl or isopropyl alcohol. After doing so, dry them thoroughly.

- Recorder unit
- Recorder unit cradle
- USB cable
- Antenna harness
- Recorder unit harness
- Capsule activator

NOTE

Do not soak the equipment in any liquid.
It may damage the equipment.

CAUTION

・Do not iron or dry clean and do not use a bleach for the recorder unit harness and antenna harness. Doing so will damage the surface.

NOTE

Note that machine-washing may cause the recorder unit harness to shrink slightly.

3. If the recorder unit harness becomes wet, be sure to dry it completely.

5.2 Storage

After cleaning the equipment according to the procedure given in Section 4.1, “Care”, be sure to dry it off thoroughly. When the equipment is dry, place it into its designated positions in the carrying cases for storage.
Store the carrying cases in a clean and dry location.
For details on storage environment, refer to “Transportation, storage, and operation environment” on page 99 in the Appendix.

CAUTION

- To prevent the capsule endoscope battery from deteriorating, store the capsule endoscope within the temperature range of 0 – 25°C (32 – 77°F). Do not store the capsule endoscope in a refrigerator or a freezer.

・Avoid long term use or storage at temperatures exceeding 40°C (104°F). Battery pack performance may deteriorate rapidly under these conditions.

- Keep water and any other liquid away from this system and components. It may cause damage to the system and components.
- Do not store the system in a location exposed to direct sunlight, UV rays, X-rays, radio activity, or strong electromagnetic radiation (e.g. near microwave therapy equipment, shortwave therapy equipment, MRI equipment, radios, or mobile phones). Doing so may damage the system.
- Do not store the system in a location where it may be subjected to impacts or excessive vibrations. Doing so may damage the system.
- Do not store the capsule endoscope in a location where it may be accessed and/or accidentally swallowed by children.

5.3 Disposal

When disposing of any item, follow all applicable national and local laws and guidelines.
The capsule endoscope is excreted naturally through the patient’s feces.

Chapter 6 Troubleshooting

If, during the inspections described in Chapter3, “Installation and connection” and Chapter4 “Operation, the system or any of its components appears to have problems,refer to Section 6.1, “Troubleshooting” to correct the problem.If the problem persists, stop using the system, and refer to Section 6.2,“Returning the system for repair” to correct the situation. If the problem cannot be resolved by these countermeasures, contact Olympus.

WARNING

Never use the system if any abnormality is observed.
Damage to the system or irregularities with the system not only cause equipment malfunction, but may also cause injury to the patient’s body cavity.

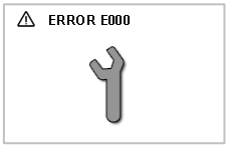
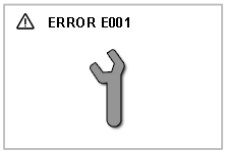
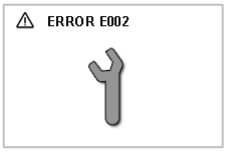
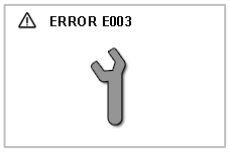
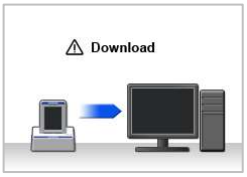
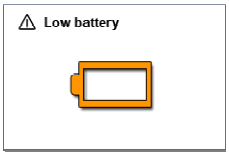
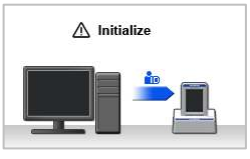
6.1 Troubleshooting

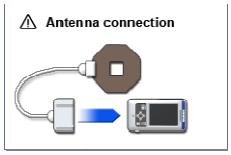
The following table lists the possible causes of and countermeasures for problems that may occur due to equipment setting errors or to the deterioration of replaceable parts. For more information, refer to “Recorder unit error messages”.
Problems or failures other than those listed in the following table require repair. Since repairs performed by persons who are not qualified by Olympus could cause further damage to the equipment and result in operator and/or user injury, be sure to contact Olympus for repair (refer to Section 6.2).

Irregularity	Possible cause	Solution
Capsule endoscope’s LED fails to illuminate.	The power is not turned ON.	Use the capsule activator to turn the power ON.
	The capsule endoscope is broken.	Use a new capsule endoscope.
Recorder unit’s power fails to come ON.	The battery pack is missing.	Insert a charged battery pack.
	The battery pack is low.	Recharge the battery pack.
Recorder unit’s power lamp fails to illuminate.	The recorder unit is broken.	Try turning on the recorder unit power again. If the problem persists, contact Olympus.

Irregularity	Possible cause	Solution
Images from the capsule endoscope are not displayed by the Image View screen.	The recorder unit is broken.	Contact Olympus.
	The capsule endoscope is broken.	Use a new capsule endoscope.
	The antenna cable is broken.	Contact Olympus.
	The antenna unit is not connected to the recorder unit.	Connect the antenna unit to the recorder unit properly.
	The antenna unit is too far from the capsule endoscope.	Reduce the distance between the antenna and the capsule endoscope.
The recorder unit fails to turn OFF.	The power switch is not held down long enough.	Hold down the power switch for 2 seconds or more.
Display layout is out of place.	The PC's DPI setting is not set to 96DPI or 120DPI.	Right-click on the desktop and select [Properties]. Select [Settings]. Click on the [Advanced] button. Set [DPI setting] to either [96DPI] or [120DPI].
You can not operate the recorder unit by pushing any button.	Troubles occur in software of the recorder unit.	Remove the battery pack from the recorder unit, and attach it again. Then turn ON the recorder unit by pushing the power button.
WS does not recognize the recorder unit	USB cable or AC adapter is not connected normally.	Connect USB cable and AC adapter once again.
	The USB cable or AC adapter is broken.	Contact Olympus

Recorder unit error messages

Error code on recorder Unit's display panel	Possible cause	Solution
	System error	1. Restart the system. 2. If the error persists, contact Olympus.
	Internal memory error	Contact Olympus.
	RTC error	1. Connect the recorder unit to the workstation, and perform initialization. 2. If error persists after initialization, contact Olympus.
	Communication error with the battery pack	1. Replace the battery pack again. 2. Replace with a new battery pack.
	Internal memory full	Connect the recorder unit to the workstation, and download the data from the recorder unit.
	Uncharged battery pack	Recharge the battery pack, or replace it with a charged battery pack.
	Patient Information not registered	Connect the recorder unit to the workstation, and perform initialization.
	Low battery pack	Recharge the battery pack.

Error code on recorder Unit's display panel	Possible cause	Solution
	Time to replace battery pack∗1	Order a new battery pack from Olympus, and replace it after the new battery pack arrives. The recorder unit may not be able to operate for 12 hours
	Antenna unit disconnected	Connect the antenna unit to the recorder unit.

∗1 The expiration of a battery pack is approximately 1 year from the date of purchase When the battery pack approaches its end-of-life, the recorder unit will prompt for replacement. Order a new battery pack and replace.

The battery pack is configured to provide more than 12 continuous hours of power. Recorder unit does not function with an expired battery pack.

6.2 Returning the system for repair

CAUTION

Olympus is not liable for any injury or damage occurring as a result of repairs attempted by non-Olympus personnel.

Before sending the system for repair, contact Olympus. With the system, include a description of malfunction or damage and the name and telephone number of the individual at your location who is most familiar with the problem.

NOTE

Refer to Labels Section in Chapter 1 to easily locate the model name and serial number when sending equipment to Olympus for repair.
To purchase accessories and consumables, contact Olympus.

Appendix

Transportation, storage, and operation environment

Capsule endoscope

Transportation and storage environment	**Ambient temperature**	0 – 25°C (32 – 77°F)∗1
	Relative humidity	30 – 85%∗2
	Barometric pressure	700 – 1060 hPa (10.2 – 15.4 psia)
Operation environment	**Ambient temperature**	10 – 40°C (50 – 104°F)
	Relative humidity	N/A
	Barometric pressure	700 – 1060 hPa (10.2 – 15.4 psia)

∗1 Storage outside the storage environment range may cause condensation and/or deterioration of the battery.

∗2 No condensation (inside the capsule endoscope)

Antenna unit

Transportation and storage environment	**Ambient temperature**	–20 to +70°C (–4 to +158°F)
	Relative humidity	10 – 95%∗1
	Barometric pressure	700 – 1060 hPa (10.2 – 15.4 psia)
Operation environment	**Ambient temperature**	0 – 50°C (32 – 122°F)
	Relative humidity	30 – 90%∗1
	Barometric pressure	700 – 1060 hPa (10.2 – 15.4 psia)

∗1 No condensation

Recorder unit

Transportation and storage environment	**Ambient temperature**	–20 to +70°C (–4 to +158°F)
	Relative humidity	10 – 95%∗1
	Barometric pressure	700 – 1060 hPa (10.2 – 15.4 psia)
Operation environment	**Ambient temperature**	0 – 50°C (32 – 122°F)
	Relative humidity	30 – 90%∗1
	Barometric pressure	700 – 1060 hPa (10.2 – 15.4 psia)

∗1 No condensation

Recorder unit cradle

Transportation and storage environment	**Ambient temperature**	–20 to +70°C (–4 to +158°F)
	Relative humidity	10 – 95%∗1
	Barometric pressure	700 – 1060 hPa (10.2 – 15.4 psia)
Operation environment	**Ambient temperature**	10 – 40°C (50 – 104°F)
	Relative humidity	30 – 85%∗1
	Barometric pressure	700 – 1060 hPa (10.2 – 15.4 psia)

∗1 No condensation

Battery pack

Transportation and storage environment	**Ambient temperature**	0 – 50°C (32 – 122°F) Avoid prolonged storage at temperatures exceeding 40°C (104°F).
	Relative humidity	10 – 95%∗1
	Barometric pressure	700 – 1060 hPa (10.2 – 15.4 psia)
Operation environment	**Ambient temperature**	0 – 50°C (32 – 122°F) Recharging: 0 – 40°C (32 – 104°F) Discharging: 0 to +50°C (32 to +122°F)
	Relative humidity	30 – 90%∗1
	Barometric pressure	700 – 1060 hPa (10.2 – 15.4 psia)

∗1 No condensation

Recorder unit harness

Transportation and storage environment	**Ambient temperature**	–20 to +70°C (–4 to +158°F)
	Relative humidity	10 – 95%
	Barometric pressure	700 – 1060 hPa (10.2 – 15.4 psia)
Operation environment	**Ambient temperature**	0 – 50°C (32 – 122°F)
	Relative humidity	30 – 90%
	Barometric pressure	700 – 1060 hPa (10.2 – 15.4 psia)

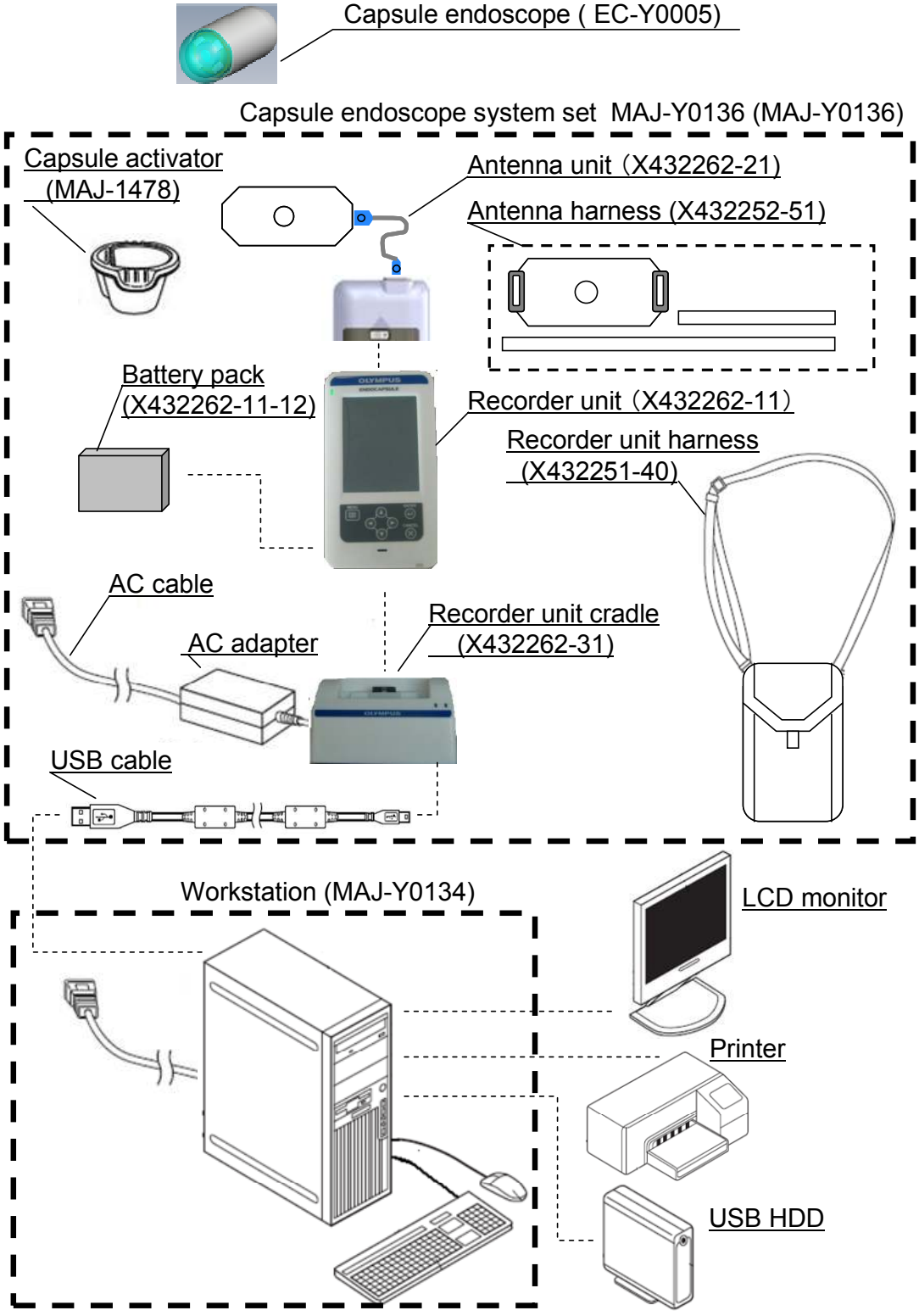
∗1 No condensation

Antenna harness

Transportation and storage environment	**Ambient temperature**	–20 to +70°C (–4 to +158°F)
	Relative humidity	10 – 95%
	Barometric pressure	700 – 1060 hPa (10.2 – 15.4 psia)
Operation environment	**Ambient temperature**	0 – 50°C (32 – 122°F)
	Relative humidity	30 – 90%
	Barometric pressure	700 – 1060 hPa (10.2 – 15.4 psia)

Specifications

System chart



The system (components within the bold dotted line) is IEC 60601-1 certified in a configuration that includes the capsule endoscope, antenna unit, and recorder unit. The recorder unit cradle, and USB cable, are IEC 60950-1 certified.

WARNING

- In order to provide the intended functionality, the system emits RF energy while in operation. This may affect electrical devices in the vicinity. The patient should keep a distance from such devices.
- Before the examination, the capsule endoscope is turned on before it is ingested. This could interfere with other nearby electrical equipment. To prevent problems, keep the capsule endoscope away from equipment that is susceptible to RF interference prior to ingestion.
- This system conducts weak radio communication. Images may be lost or distorted when operating in an environment affected by electromagnetic transmissions (such as that of portable RF (Radio Frequency) communication devices). Avoid use in such environments.

FCC (for recorder unit , antenna unit, and Recorder unit cradle)

NOTE

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

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

Capsule endoscope

Product name		Capsule endoscope (EC-Y0005)
Optics	**Field of view (maximum)**	160°
	Depth of field	0 – 20 mm
Sampling rate		2 fps
Power supply	**Power source**	Internal battery
Battery life		12 hours
Size	**Dimensions**	ø 11 (diameter) × 26 (length) mm
Classification as medical electrical equipment	**Type of protection against electric shock**	Internal power supply
	Degree of protection against electric shock	TYPE BF
	Degree of protection against explosion	Use under combustible atmosphere prohibited.
Protection against fluid ingress		IEC 60529 IPX-8
EMC	**Applied standard; IEC 60601-1-2:2001**	This instrument complies with the standards listed in the left column. CISPR 11 of emission: Group 1, Class A
Year of manufacturer	**1712345**	The year of manufacture is indicated by the second digit of the serial number.
The year of manufacture indicates the serial number of EC-Y0005.		
FCC ID	**:S8QEC-S10**	This device comlies 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.
IC	**:4763B-ECS10**	This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference , including interference that may cause undesired operation of the device.

Recorder unit

Product name		Recorder unit (X432262-11)
Power supply	**Power source**	Battery pack (X432262-11-12)
	Voltage	3.7 V
	Current	500 mA
Battery life		12 hours or longer
Size	**Weight**	282 g
	Dimensions	83 (W) × 151 (H) × 32 (D) mm
Classification as medical electrical equipment	**Type of protection against electric shock**	Internal power supply
	Degree of protection against explosion	Use under combustible atmosphere prohibited.
Year of manufacture	**1712345**	The year of manufacture is indicated by the second digit of the serial number.
EMC	**Applied standard; IEC 60601-1-2:2001**	This instrument complies with the standards listed in the left column. CISPR 11 of emission: Group 1, Class A

Recorder unit cradle

Product name		Recorder unit cradle (X432262-31)
Power supply	**Voltage**	DC 5V
	Current	3 A
Size	**Weight**	Main body: 345 g (AC Adapter: 175 g)
	Dimensions	133 (W) × 79 (H) × 84 (D) mm
Classification as medical electrical equipment	**Type of protection against electric shock**	Class Ⅰ
	Degree of protection against explosion	Use under combustible atmosphere prohibited.
Year of manufacture	**1712345**	The year of manufacture is indicated by the second digit of the serial number.
EMC	**Applied standard; IEC 60950-1:2005**	This instrument complies with the standards listed in the left column. CISPR 22 of emission: Group 1, Class A

Battery pack

Product name		Battery pack (X432262-11-12)
Type		Lithium-Ion storage cell
Capacity		2860 mAh
Voltage		3.7 V
Recharging time		Approx. 2 hours
Size	**Weight**	70 g
	Dimensions	70.4 (W) × 10.2 (H) × 55.2 (D) mm

Antenna unit

Product name		Antenna unit (X432262-21)
Size	**Weight**	140 g
	Dimensions	83 (W) × 50 (H) × 13 (D) mm
	The number of antennas	8
Classification as medical electrical equipment	**Degree of protection against electric shock**	TYPE BF
	Degree of protection against explosion	Use under combustible atmosphere prohibited.
EMC	**Applied standards; IEC 60601-1-2: 2001**	This instrument complies with the standards listed in the left column. CISPR 11 of emission: Group 1, Class A

Recorder unit harness

	Product name	Recorder unit harness (X432251-40)
Size	**Weight**	70 g
	Dimensions	100 (W) × 160 (H) × 37 (D) mm

Antenna harness

	Product name	Antenna harness (X432252-51)
Size	**Weight**	180 g
	Dimensions	pouch 350(W)×160(H)mm Long belt 90(W)×50(H)mm Short belt 60(W)×50(H)mm

EMC information

○ Magnetic emission compliance information and recommended electromagnetic environments

The system (components within the bold dotted line of “System chart” on page 103) is designed for use under the following electromagnetic environment.

Emission standard	Compliance	Guidance
RF emissions CISPR 11	Group 1	This instrument uses RF (Radio Frequency) 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.
Radiated emissions CISPR 11	Class A	This product is suitable for use in all buildings besides the residence.
Main terminal conducted emissions CISPR 11		
Harmonic emissions IEC 61000-3-2	Not applicable	The system is not powered by a commercial power source.
Voltage fluctuations/flicker emissions IEC 61000-3-3		

○ Electromagnetic immunity compliance information and recommended electromagnetic environments

The system (components within the bold dotted solid line of “System chart” on page 103) is designed for use under the following electromagnetic environment.

Immunity test	IEC 60601-1-2 test level	Compliance level	Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	Contact: ±2, ±4, ±6 kV Air: ±2, ±4, ±8 kV	Same as left	Floors should be made of wood, concrete, or ceramic tile that hardly produces static. If floors are covered with synthetic material that tends to produce static, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable	The system does not have a cable for this signal.
Surge IEC 61000-4-5	Differential mode: ±0.5, ±1 kV Common mode: ±0.5, ±1, ±2 kV	Not applicable	The system is not powered by a commercial power source.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% UT (> 95% dip in UT) for 0.5 cycle	Not applicable	The system is not powered by a commercial power source.
	40% UT (60% dip in UT) for 5 cycle		
	70% UT (30% dip in UT) for 25 cycle		
	< 5% UT (> 95% dip in UT) for 5 seconds		
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Same as left	It is recommended to use this instrument by maintaining enough distance from any equipment that operates with high current.

NOTE

U_T is the AC mains power supply prior to application of the test level.

○ Cautions and recommended electromagnetic environment regarding portable and mobile RF communications equipment such as cellular phones

Immunity test	IEC 60601-1-2 test level	Compliance level	Guidance
Conducted RF IEC 61000-4-6	3 Vrms (150 kHz – 80 MHz)	not applicable	The system does not have a cable for this signal.
Radiated RF IEC 61000-4-3	3 V/m (80 MHz – 2.5 GHz)	3 V/m (E_1)	Formula for recommended separation distance (V_1=E_1=3 according to the compliance level) $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz – 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz – 2.5 GHz

NOTE

- 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).
- This instrument complies with the requirements of IEC 60601-1-2: 2001. However, under electromagnetic environment that exceeds its noise level, electromagnetic interference may occur on this instrument.
- Electromagnetic interference may occur on this instrument near a high-frequency electrosurgical equipment and/or other equipment marked with the following symbol:

○ Recommended separation distance between portable and mobile RF communications equipment and this instrument

Rated maximum output power of transmitter P (W)	Separation distance according to frequency of transmitter (m) (calculated as V1=3 and E1=3)		
	150 kHz – 80 MHz	80 MHz – 800 MHz	800 MHz – 2.5 GHz
	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

NOTE

The guidance may not apply in some situations.
Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
Portable and mobile RF communications equipment such as cellular phones should be used no closer to any part of this instrument, including cables than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

FCC WARNING(for the USA)

Change or modifications not expressly approved by the party responsible for Compliance could void the user's authority to operate the equipment.
The shielded interface cable recommended in this manual must be used with this equipment in order to comply with the limits for a digital device pursuant to Subpart B of Part 15 of FCC Rules.

Declation of Conformity

Trade Name: OLYMPUS MEDICAL SYSTEMS

Model: X432262-11, X432262-21, X432262-31

Responsible Party: OLYMPUS AMERICA INC.

Address: 3500 Corporate Parkway, P.O. Box 610 Center Valley.
PA 18034-0610, U.S.A
Telephone Number: (484)896-5000

FCC notice

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.

IC notice

This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de

To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (e.i.r.p.) is not more than that permitted for successful communication.

Afin de réduire le risque d'interférence aux autres utilisateurs, il faut choisir le type d'antenne et son gain de façon à ce que la puissance isotrope rayonnée équivalente (p.i.r.e.) ne soit pas supérieure au niveau requis pour l'obtention d'une communication satisfaisante.

OLYMPUS®

Manufactured by

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