OLYMPUS®

INSTRUCTIONS

EndoCapsule
OLYMPUS CAPSULE ENDOSCOPE SYSTEM

OLYMPUS CAPSULE ENDOSCOPE SYSTEM

CE 0197

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 following symbols can be found on the equipment and its packaging.

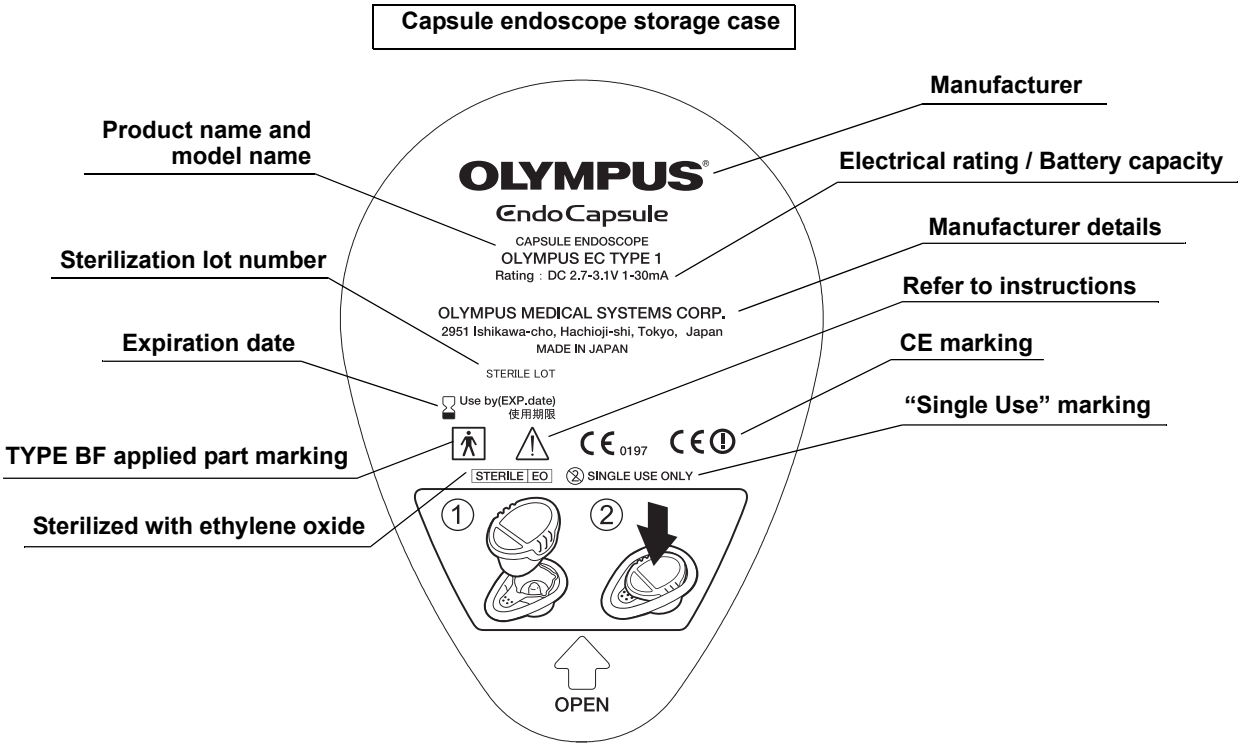
	Refer to instructions.
	TYPE BF applied part
	When in the proximity of this equipment or portable RF communication devices, electromagnetic interference may occur, affecting cardiac pacemakers. Users of cardiac pacemakers must maintain a sufficient distance from the equipment.
	Power switch (ON/OFF)
STERILE EO	Sterilized using ethylene oxide.
STERILE LOT	Sterilization lot number
LOT	Lot number
	Do not reuse.
RT VIEWER	Connector for connecting the viewer cable to the recorder unit
RECORDER U	Connector for connecting the viewer cable to the real time viewer
WORK STATION	Connector for connecting the cradle cable to the recorder unit cradle
UP	Top side of the viewer cable
	Maximum washing temperature 40°C normal process

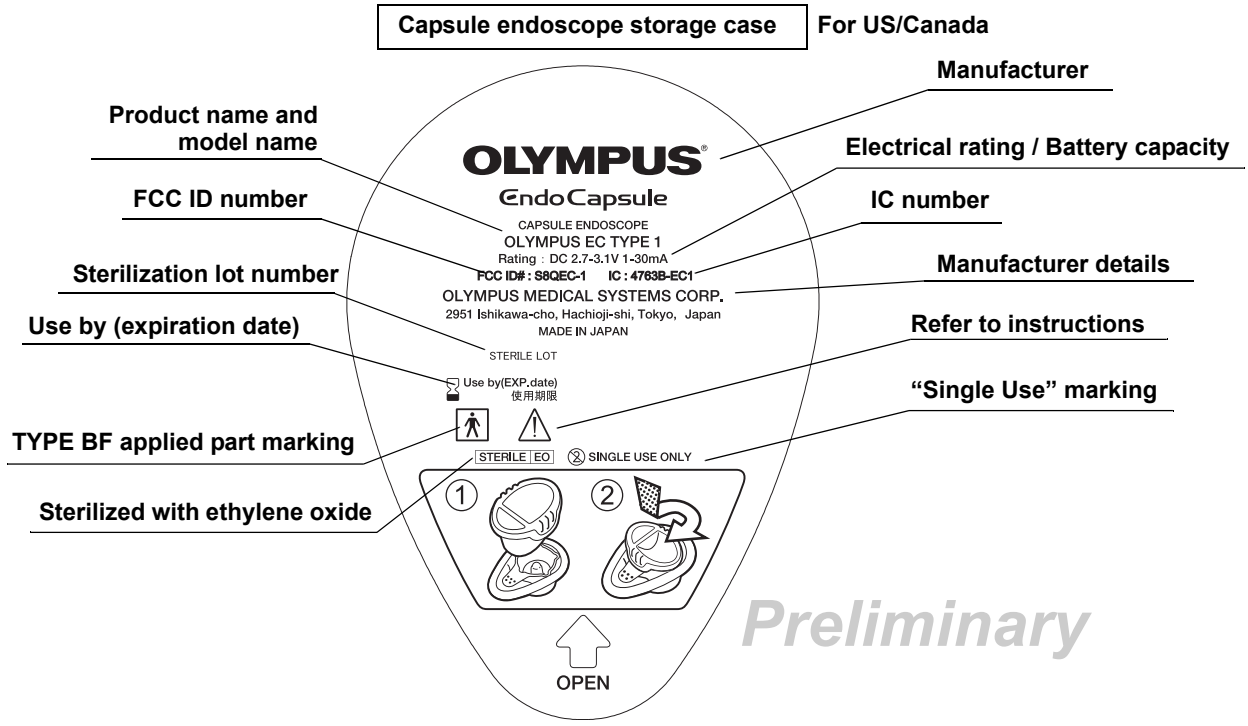
Do not iron.

Do not dry clean.

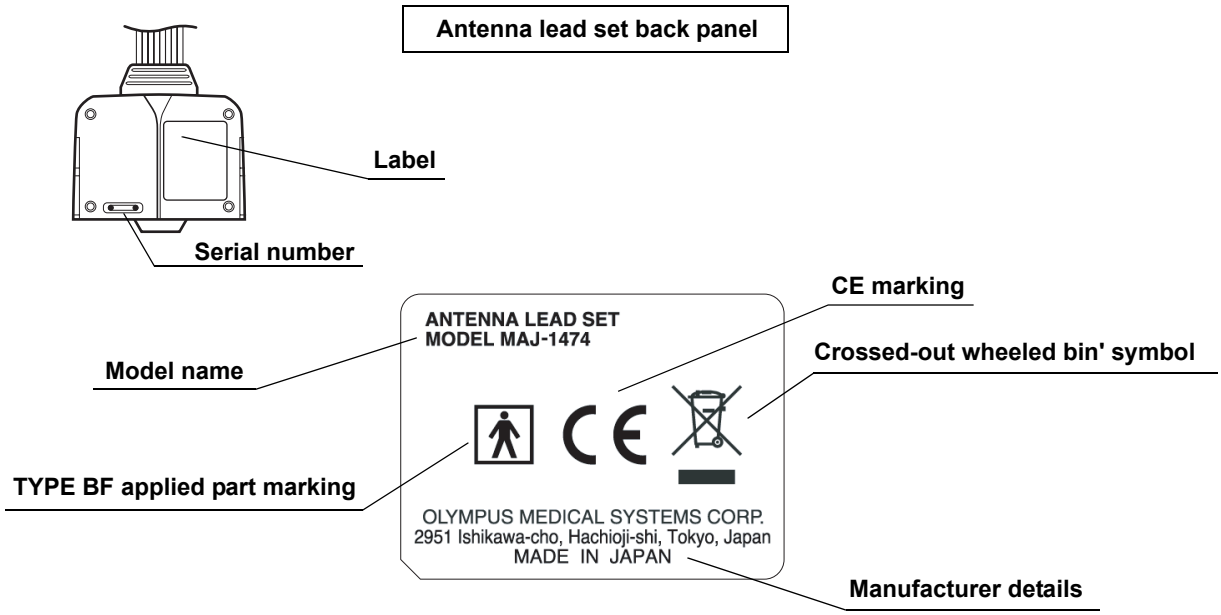
Labels

Capsule endoscope

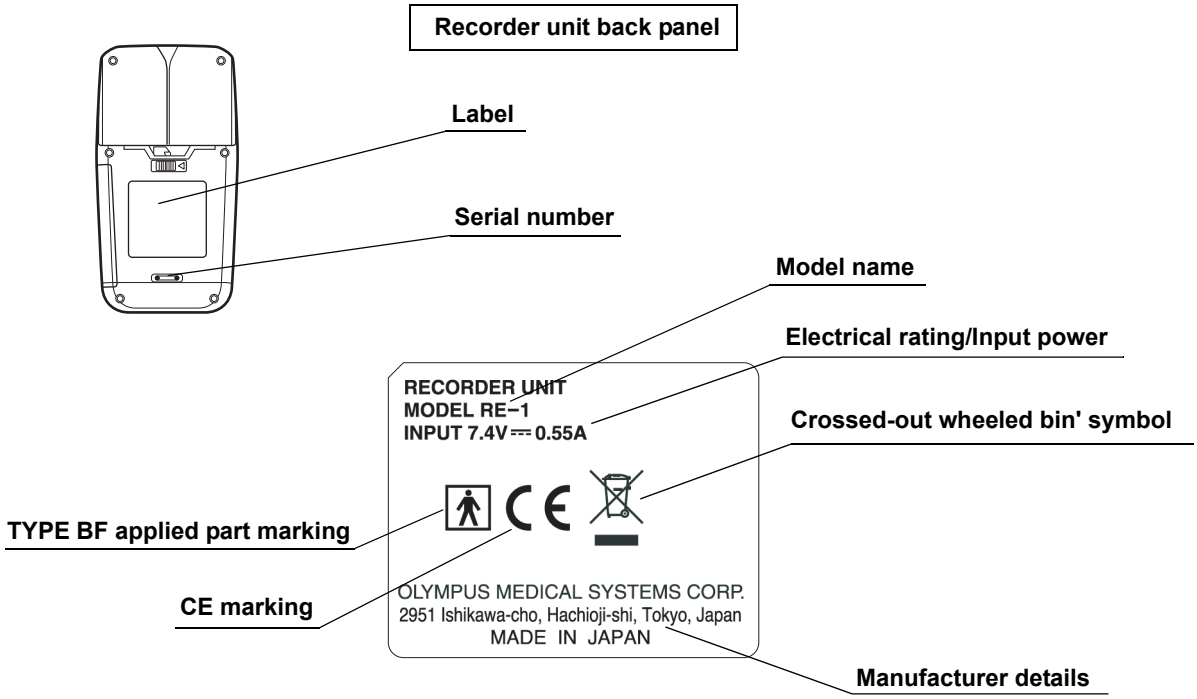




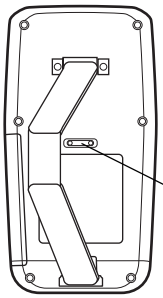
Antenna lead set



Recorder unit

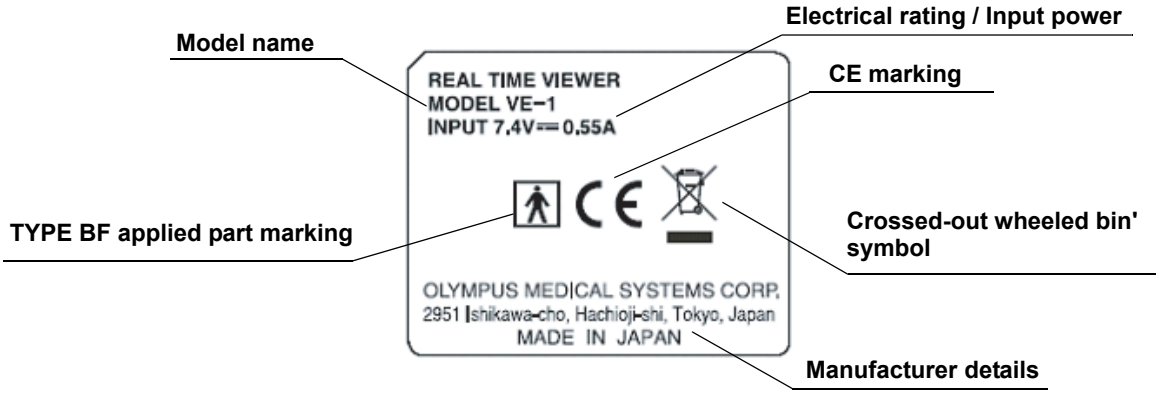


Real time viewer



Real time viewer back panel

Serial number



Recorder unit cradle

Recorder unit cradle bottom side

Label

Model name

Crossed-out wheeled bin' symbol

Electrical rating / Input power

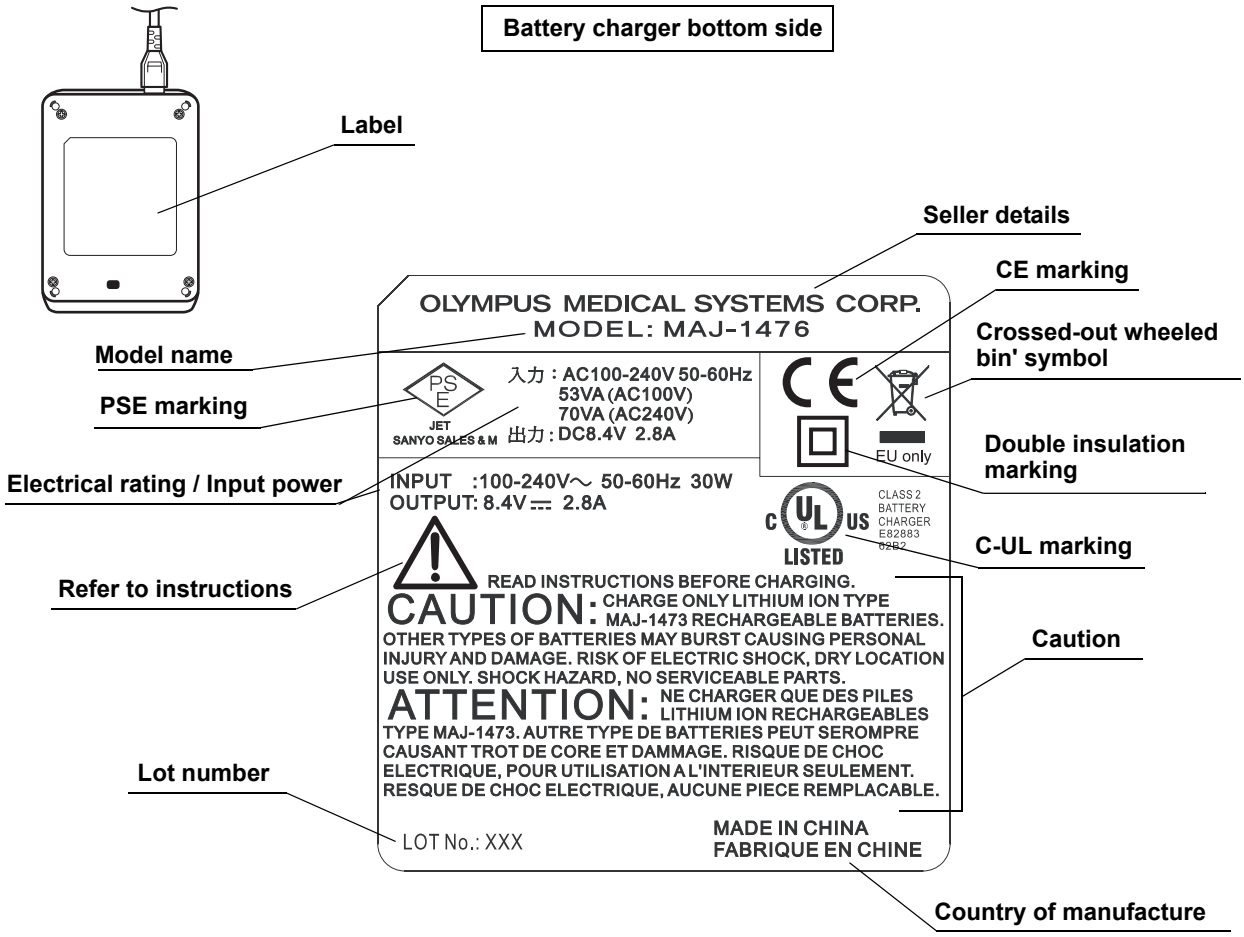
CE marking

RECORDER UNIT CRADLE
MODEL MAJ–1484
INPUT 9V ⎓ 2A

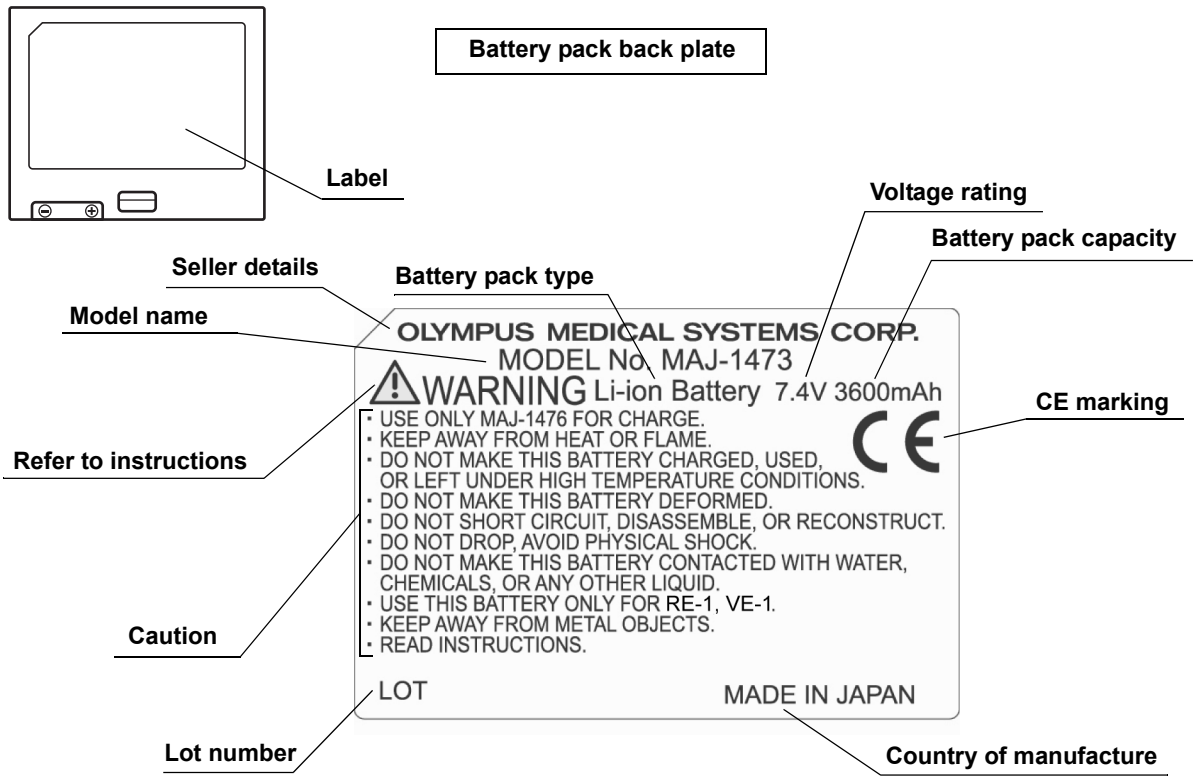
OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan
MADE IN JAPAN

Manufacturer details

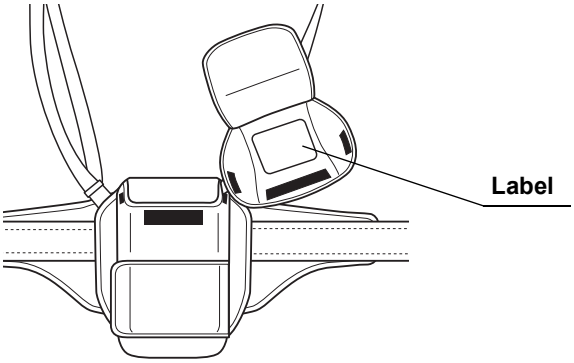
Battery charger

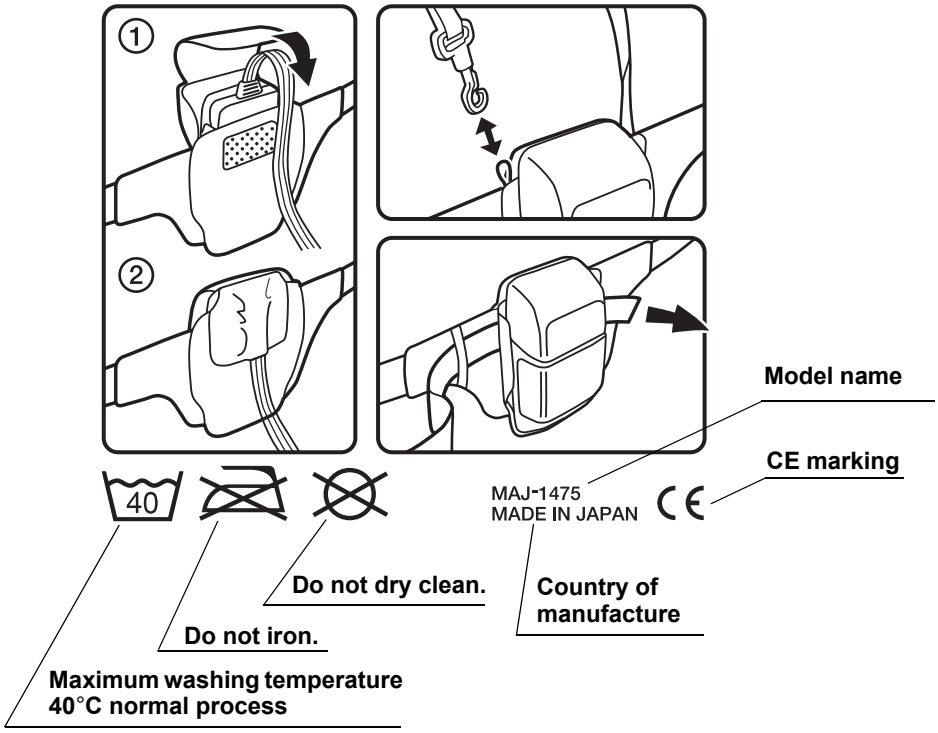


Battery pack



Recorder unit harness





Important Information - Please Read Before Use

Intended use

The capsule endoscope system has been designed to be used for endoscopic diagnosis of small bowel, consisting of capsule endoscope, recorder unit, real time viewer, workstation and other accessories. 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 which will be used during the procedures, and use the equipment as instructed.
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

Patient environment

Places that the patients have direct access to, such as medical wards and operating rooms.

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 internal clock.

 Workstation

A drive which contains examination data and thumbnail data.

Examination data

The image data created from the data downloaded from a recorder.

Report

A HTML file created from a thumbnail data.

Check out

The process in which a physician exports examination data from a workstation for observation on Endo Capsule software light.

Check in

The process in which a physician imports thumbnail data from a workstation after examination on Endo Capsule software light.

Thumbnail data

The data which contains thumbnails of the selected images and comments added by a physician.

Exclusion criteria

- Risk of capsule examination:
  The capsule endoscope is warranted for remaining within the body for up to 30 days. 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. For this reason, the following exclusion criteria have been set. Be sure to explain this risk to the patient and obtain his/her consent prior to the examination.
  - Patients who have not given the consent.
  - Patients who, as a result of X-ray examinations or past profiling examinations, have been determined to have a obstruction clear narrowing, adhesion, and/or diverticula in the gastrointestinal tract which may interfere with the passing capsule endoscope.
  - Patients who have had open abdominal surgery.
  - Patient is a non-surgical candidate.
  - Pregnant women.
  - Patients with serious gastrointestinal transit delay.
- The capsule endoscope may accidentally go down the trachea, if the patient has difficulties in swallowing.
- Patients using equipment that may be affected by radio transmission (i.e. cardiac pacemaker and other implanted electrical medical devices). The capsule endoscope has not been tested with such equipment for safety.

User qualifications

- The operator of this system must be a physician or medical personnel under the supervision of a physician and must have received sufficient training in endoscopic procedures. This manual, therefore, does not explain or discuss endoscopic procedures.
- Analysis of the captured endoscopic images require substantial training.

Instrument compatibility

Refer to the “System chart” in the Appendix to confirm that this instrument is compatible with the ancillary equipment being used.Using incompatible equipment can result in patient injury and/or equipment damage.
This instrument complies with the EMC standard for medical electrical equipment; edition 2 (IEC 60601-1-2:2001).

Repair and modification

This instrument does not contain any user-serviceable parts. Do not disassemble, modify or attempt to repair it; patient or user injury and/or equipment damage can result.
Some problems that appear to be malfunctions may be correctable by referring to Chapter 8, “Troubleshooting” on page 233. If the problem cannot be resolved using the information in Chapter 8, contact Olympus.

FCC warning

Changes or modifications not expressly approved by the party responsible for compliance could void the user’s authority to operate the equipment.

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.

NOTE

Indicates additional helpful information.

Danger, warnings and cautions

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

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. Otherwise, injury within the body cavity may occur.

WARNING

- The effect of the capsule endoscope on the safety of the patient's body has only been tested for a period of 30 days. If the excretion of the capsule endoscope has not been confirmed, conduct an X-ray examination in an attempt to locate the capsule endoscope within the patient's body. If the capsule endoscope is located within the body, it must be collected within 30 days from the date of ingestion.
- Regardless of the positive/negative result, one examination does not cover all of the small intestine. Continuous checkup is required.
- Avoid use under combustible environments, such as:
  - where the concentration of oxygen is high.
  - where oxidizing agents, such as nitrous oxide (N_2O), are contained in the atmosphere.
  - nearby a location using combustible anesthetic gases.

  The system is not explosion-proof, and may cause an explosion or a fire.
- 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.
- Do not attach the recorder unit to the recorder unit cradle while the antenna lead set is attached to the patient. Electric shock and burns may result in the worst case.
- The capsule endoscope is a sterilized single-use product. Do not reuse it. Doing so may result in an infection of the patient and/or medical personnel, as well as internal injury to the patient due to equipment damage.

- Do not use a capsule endoscope that has been dropped, bitten or subjected to excessive pressure. Using such endoscopes may result in internal injury to the patient due to equipment damage.
- Store the capsule endoscope in a safe location and out of the reach of children.
- The capsule endoscope must be ingested under the supervision of a physician, or medical personnel authorized by a physician. Clearly instruct the patient not to use the capsule endoscope on themselves or others without proper medical supervision.
- Instruct the patient to immediately consult a physician if he/she experiences abdominal pain, discomfort, or nausea after ingesting the capsule endoscope. If treatment is delayed, it may result in internal injury to the patient.
- When using the capsule endoscope, avoid using other electronic device simultaneously. The safety of the device in combination with other equipment cannot be guaranteed.
- Do not place the workstation and its peripherals (including the recorder unit cradle) in the patient environment. Electric shocks and burns may result.

CAUTION

- Do not use a capsule endoscope after its expiration date. An expired capsule endoscope may not perform a proper examination.
- To prevent the capsule endoscope battery from deteriorating, store the capsule endoscope under a temperature of 0 to 25°C (39 to 77°F). Do not store in a refrigerator or a freezer, as condensation may result.
- Keep the capsule endoscope away from magnets. 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, check that the surface of the capsule endoscope is clear of roughness, sharp edges, and projections. They may cause internal injury to the patient.

- Keep the recorder unit, antenna lead set, and real time viewer away from water, alcohol, and any other liquids. Liquids entering these components may damage them and/or result in equipment failure.
- Be sure to use only the specified cables for the 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 "Recorder unit error messages" of Chapter 8, "Troubleshooting" on page 235, 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 recorder unit cradle cable and/or the AC adapter. It may damage the recorder unit's internal memory.
- The examination cannot proceed if there is insufficient space on the recorder unit's internal memory. 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. The initialization may be interrupted.
- The examination cannot proceed if the battery pack is not fully charged. Use the battery charger to fully charge the battery pack in advance.
- 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 pack. If the indicator on the battery pack changes from to prior to the examination, recharge the battery pack, or replace with a fully-charged battery pack.
- Do not remove the battery pack while the receiver unit's power is ON. It may cause the recorder unit to break.
- Avoid prolonged use of the system at or below 0°C/32°F. The capsule endoscope may not be able to operate for 8 hours, and you may not be able to recharge the battery packs fully.
- Be sure to use the antenna covers when attaching the antennas. Failure to do so may prevent the proper reception of capsule endoscope images.
- Perform the examination with all 8 antenna pads attached to the patient. The examination may fail with even one antenna pad not properly attached.

- Do not allow the antenna cable to lay on or near the antenna pads. It may prevent the proper reception of capsule endoscope images.
- Do not use an antenna pad that has been completely folded. 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.
- Only one capsule endoscope should be ingested per examination. If the patient ingests more than one capsule endoscope simultaneously. It may cause the images to lost.
- Do not turn ON a capsule endoscope within 1 m/3.3 ft. of another patient already undergoing an examination with an ingested capsule endoscope. It may cause capsule endoscope images to become distorted.
- During the examination, have the patient stay away from radio-transmitting devices (i.e. keyless entry, home security, waitress call system, garage door remote, wireless headphones, ham radio, etc.).
- While downloading, do not remove the recorder unit from the recorder unit cradle, unplug the AC adapter, or turn the workstation or the recorder unit OFF. Doing so will interrupt the download, and require you to start the download again. In the worst case, loss of recorded data may result.
- Do not install other software onto the workstation. It may cause the system to malfunction.

NOTE

- This system is used to examine the small intestine by the patient's ingestion of a capsule endoscope, which continuously takes pictures as it moves down the gastrointestinal tract by peristalsis. The captured images are radio transmitted to the recorder unit, and can be observed using the workstation. After the examination, the capsule endoscope is excreted naturally.
- The duration of the capsule endoscope's presence within the stomach and the small intestine varies from patient to patient. There may also be other residual material within the gastrointestinal tract. For these reasons, it may not be possible to capture images of some parts of the small intestine.

- Have a spare capsule endoscope ready for use in case the primary device is determined to be unusable prior to patient ingestion.
- The recorder unit cradle cannot be used to recharge the battery pack. To recharge the battery pack, remove it from the recorder unit, and use the dedicated battery charger.
- After turning ON the capsule endoscope, bring it near the antenna lead set 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.
- If the real time viewer is displaying images passed via the recorder unit, an icon () indicating this will be displayed on the real time viewer's display panel.
- When the real time viewer is receiving capsule endoscope images directly, an icon ( ) is displayed on its display panel.
- The real time viewer is to be used within the hospital only, and is not to be given to the patient.

Danger, warnings 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 and/or may interfere with the examination. Please provide the patient with the separate “Caution for Capsule Endoscopy Patients”.

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 capsule endoscope is warranted for remaining within the body for up to 30 days. 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. For this reason, the following exclusion criteria have been set. Be sure to explain this risk to the patient and obtain his/her consent prior to the examination.

CAUTION

- Reddening or irritation of the skin may sometimes be caused by the adhesive on the antenna lead cover. Instruct the patient to consult a physician immediately if such symptom is observed on a patient, consult a physician immediately.
- 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.

- 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 procedure. 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 lead set, or remove an antenna pad during the examination. Failure to follow instructions may interfere with the examination.
- Antenna cables must be connected from the antenna pads on the abdomen to the recorder unit worn outside the clothing. Instruct the patient to avoid wearing one-piece-suit; a shirt and pants or skirt must be worn to ensure proper placement of the recorder unit and antenna cables.
- Instruct the patient to stay away from radio-transmitting devices (i.e. keyless entry, home security, waitress call system, garage door remote, wireless headphones, ham radio, etc.) while the capsule endoscope is within his/her body.
- Instruct the patient to keep the recorder unit, antenna lead set, and real time viewer away from water, alcohol, and any other liquids. Liquids entering these components may damage them and/or result in equipment 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 your emergency contact number for the patient on the "Caution for Capsule Endoscopy Patients", included in the capsule endoscope set A (MAJ-1469).

Expiration date of the capsule endoscope

The battery inside the capsule endoscope actually consumes gradually during long term storage. This higher storage environment over 25°C may cause the battery inside the capsule endoscope consume rapidly. The consumption of the battery inside the capsule endoscope may shorten the operation time (continuous record and transmission of the images) of the capsule endoscope. The capsule endoscope is designed to keep 8 continuous hours by the expiration date printed on the package of the blister pack of the capsule endoscope if stored in the normal storage environment (0 to 25°C (39 to 77°F)).

CAUTION

- The storage environment of the capsule endoscope is restricted between 0 to 25°C (39 to 77°F). The severe storage environment over 25°C may cause the battery inside the capsule endoscope consume rapidly, and then the consumption of the battery inside the capsule endoscope may shorten the operation time of the capsule endoscope. In such a case, the capsule endoscope may not operate for 8 continuous hours.
- The rapid temperature change between inside and outside of the refrigerator or the freezer may cause the condensation inside the capsule endoscope. And this may cause the battery inside the capsule endoscope consume rapidly or severe damage and failure in the image.
- Do not use the expired capsule endoscope. The expired capsule endoscope may not operate for the assured operation time (8 hours).
- The peristalsis movement differs among patients. The capsule endoscope does not pass to the cecum within 8 hours after a patient swallows it in every case. The capsule endoscope typically operates for 8 continuous hours, and it is not assured for operation for 8 continuous hours for observation for whole small bowel in every case.
- Please the capsule endoscope be swallowed by a patient soon after the capsule endoscope turned on to avoid consumption of the battery before examination.

Battery charger

WARNING

- This recorder unit is only to be used with battery pack MAJ-1473. Do not use the battery charger to charge other battery packs or batteries. Excessive charging, or recharging at abnormal current may occur if the battery charger is used improperly, causing unexpected chemical reactions within the battery, which may result in excessive heat, release of smoke, explosion, and/or a fire.
- Be sure to align the battery pack terminals (+ / –) correctly.
- Do not disassemble or modify the battery charger. It may result in excessive heat, release of smoke, explosion, and/or a fire while charging the battery pack.
- Do not leave the battery charger plugged in for a prolonged period. It may result in excessive heat, release of smoke, explosion, and/or a fire.
- Keep the battery charger away from water, alcohol, and any other liquids.
- Keep the battery charger away from flames.
- Remove the battery pack from the battery charger before storage.

NOTE

- The battery charger will not charge the battery if the temperature of the battery pack is below 0°C/32°F. In this case, the charge lamp will blink in yellow at 1.5 second intervals.
- The battery charger will not charge the battery if the battery pack or the battery charger is damaged. In this case, the charge lamp will blink in yellow at 0.5 second intervals.

About the recharger's power cord

For use in America and Canada

The following Power Cord should be used for this battery charger.
Type SPT-2, 2C/18AWG, UL Listed and CSA Certified cord set with non-polarized plug, 125V, 10A

For use in Europe

The following Power Cord should be used for this battery charger.
Type H03VVH2-F~0.75mm^2, Europe Approved cord set with non-polarized plug, 250V, 2.5A

For use in England

The following Power Cord should be used for this battery charger.
Type H03VVH2-F~0.75mm^2, BSI certified cord set with non-polarized plug, 250V, 3A

Battery pack

WARNING

- 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 (+) and (-) 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.
- 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 battery chargers (MAJ-1476) under the specified recharging conditions. Recharging under conditions other than those specified (temperature outside the specified range, excessively high voltage/current, use of modified battery charger, etc.) 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.

- 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 you notice leaking 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 you notice an abnormal odor, excessive heat, change of color, deformation, or other abnormalities during use, recharging, or storage of the battery pack, immediately remove it from the equipment or battery charger, 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

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

NOTE

- When disposing of the battery pack, follow the classification and recycling guidelines provided by your country, local government, or the facility.
- The life span of a battery pack is approximately 1 year from the date of purchase, or 320 recharging cycles, whichever is first. When the battery pack approaches its end-of-life, the recorder unit will prompt for replacement. Order a new battery pack and replace.

EMC (Electromagnetic Compatibility)

- In order to provide the intended functionality, the system must emit RF energy while in operation. This may affect electrical devices in the vicinity.

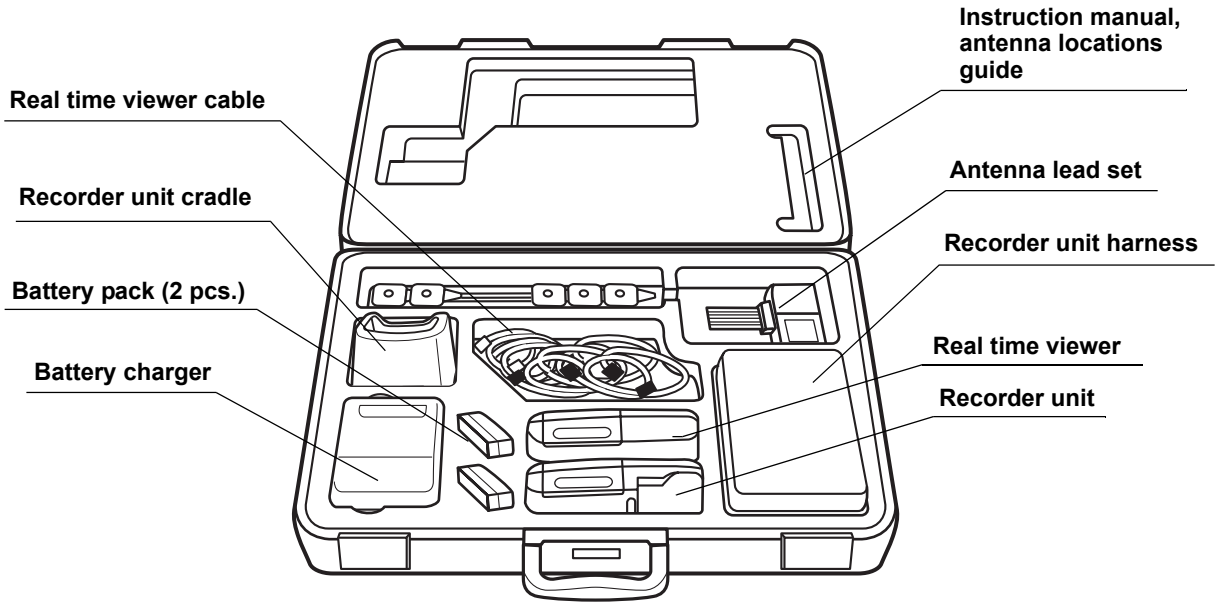
- The system is equipped with a function for device identification via radio transmission, and is thus subject to electrostatic interference from other equipment in the vicinity.

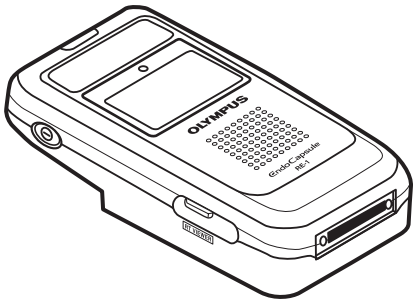
Receiver (recorder unit, real time viewer, antenna lead set)	Frequency range of possible interference: 426.8 to 440.8MHz	Frequency range of possible interference: 306 to 322MHz (for US/Canada)
Transmitter (capsule endoscope)	Central frequency: 433.8MHz Required bandwidth: 7MHz Modulation method: Minimum shift keying (MSK) High frequency output: +37dBμV/m (when inside body) phantom	Central frequency: 315MHz Required bandwidth: 7MHz Modulation method: Minimum shift keying (MSK) High frequency output: +37dBμV/m (when inside body) phantom

Chapter 1 Checking the Package Contents

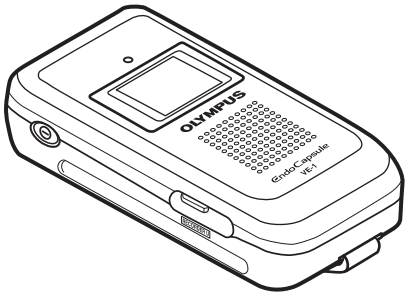
Match all items in the package with the components shown in this chapter. Inspect each item for damage. If the instrument is damaged, a component is missing or you have any questions, do not use the instrument; immediately contact Olympus.

1.1 Capsule endoscope system set A (MAJ-1467)

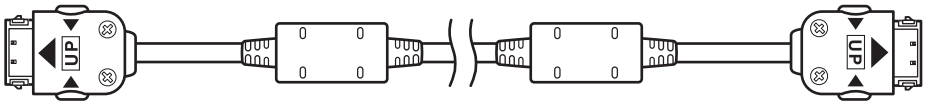




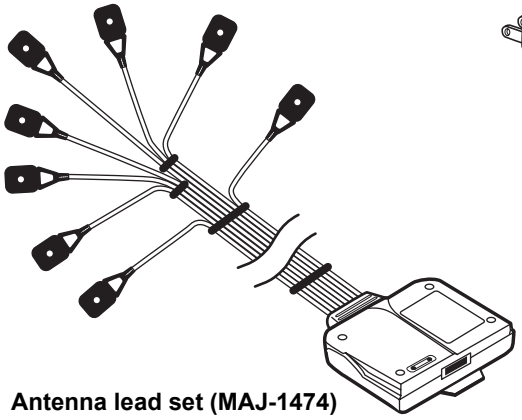
Recorder unit (OLYMPUS RE-1)



Real time viewer (OLYMPUS VE-1)

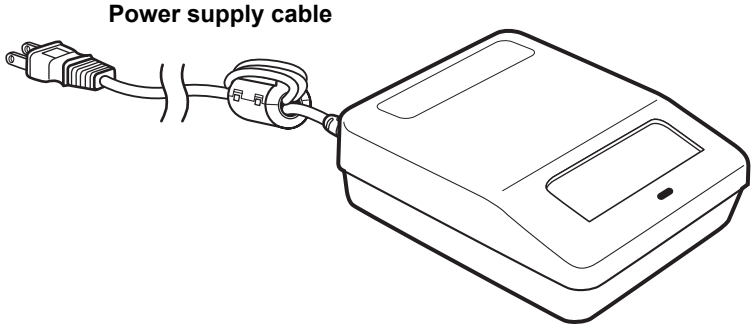


Real time viewer cable (MAJ-1485)

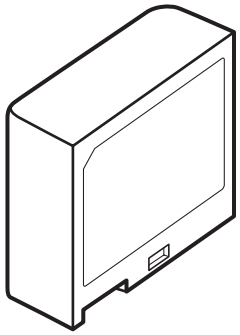


Antenna lead set (MAJ-1474)

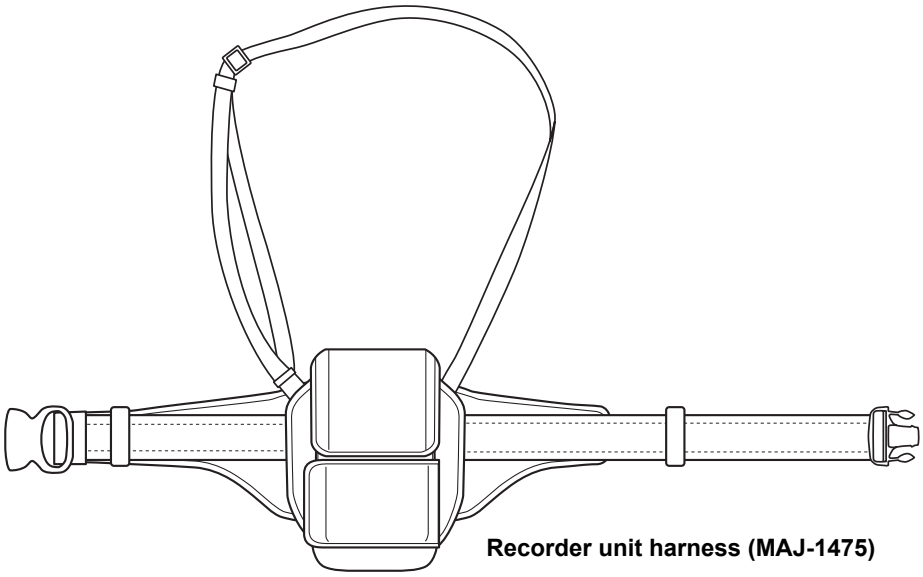
Power supply cable



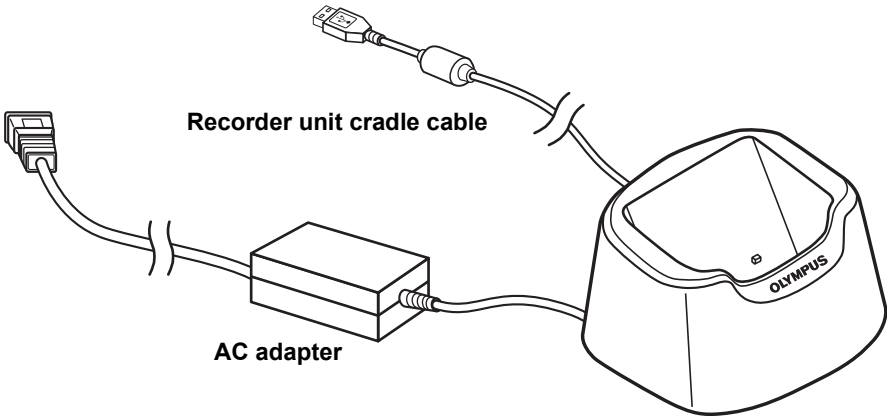
Battery charger (MAJ-1476)



Battery pack (MAJ-1473) x 2



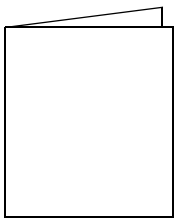
Recorder unit harness (MAJ-1475)



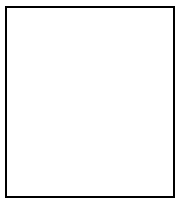
Recorder unit cradle cable

AC adapter

Recorder unit cradle (MAJ-1484)



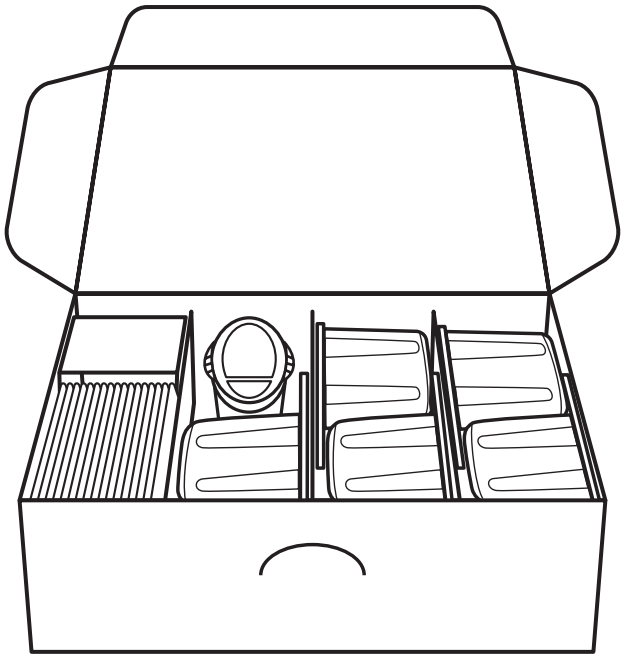
Instruction manual

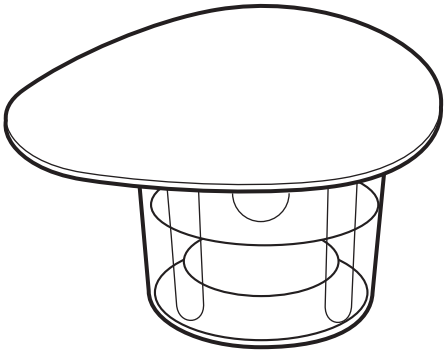


Antenna locations guide

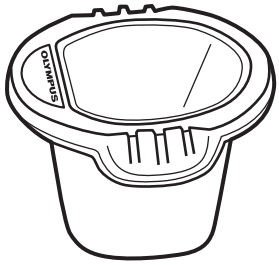
1.2 Capsule endoscope set A (MAJ-1469)

The capsule endoscope set A includes 5 capsule endoscopes, 1 capsule activator (reusable), and 50 antenna lead cover (disposable). For a single examination, 1 capsule endoscope, 1 capsule activator, and 10 antenna lead cover (including 2 spare) are used.

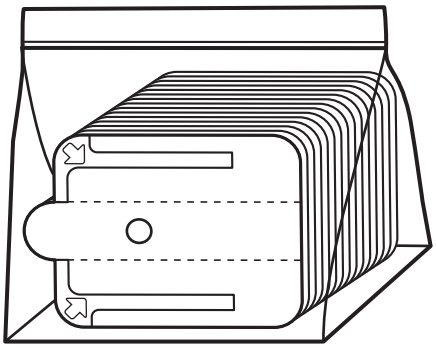




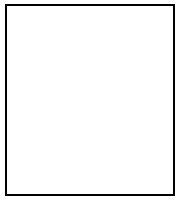
Capsule endoscope (in sterile container)
(OLYMPUS EC TYPE 1) x 5



Capsule activator (reusable)
(MAJ-1478)



Antenna lead cover (set of 50 pcs., disposable)
(MAJ-1470)



Caution for capsule endoscopy patients x 5

1.3 Workstation (OLYMPUS WS-1)

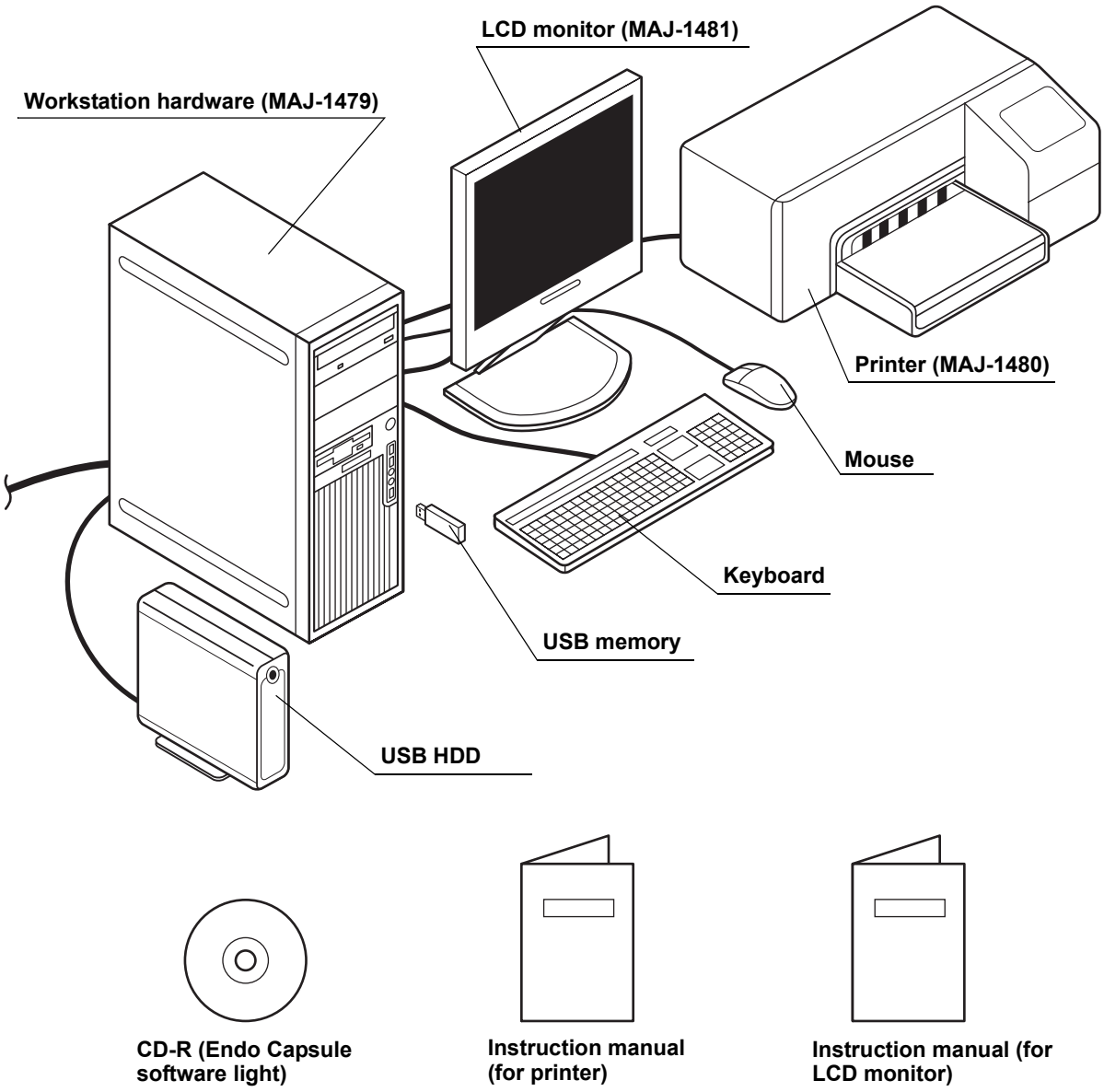


Figure 1.1

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

Product Name	Model	Contents
Capsule endoscope system set A	MAJ-1467	Recorder unit, real time viewer, antenna lead set, 2 battery packs, battery charger, recorder unit harness, real time viewer cable, and recorder unit cradle
Capsule endoscope set A	MAJ-1469	Set of 5 pcs., with 50 antenna lead cover and an capsule activator
Capsule activator	MAJ-1478	1 pc.
Recorder unit	OLYMPUS RE-1	1 pc., with 1 battery pack
Antenna lead set	MAJ-1474	1 pc.
Real time viewer	OLYMPUS VE-1	1 pc., with 1 battery pack, real time viewer cable
Battery pack	MAJ-1473	1 pc.
Battery charger	MAJ-1476	1 pc., with power supply cable
Recorder unit harness	MAJ-1475	1 pc.
Real time viewer cable	MAJ-1485	1 pc.
Recorder unit cradle	MAJ-1484	1 pc., with AC adapter, recorder unit cradle cable
Workstation	OLYMPUS WS-1	Workstation hardware, LCD monitor, and printer
Workstation hardware	MAJ-1479	Workstation main body, keyboard, mouse, USB memory (2GB), conversion cable, and Endo Capsule software light CD-R
LCD monitor	MAJ-1481	1 pc., power cable, monitor cable
Printer	MAJ-1480	1 pc., with printer cable, AC adapter, power cable, ink cartridges (black, cyan, magenta, yellow), print head (black, cyan, magenta, yellow)
Antenna lead cover	MAJ-1470	Set of 50 pcs.

NOTE

For the articles of consumption, refer to the instruction manual for printer.

The following items are optional third-party products that may be purchased separately:

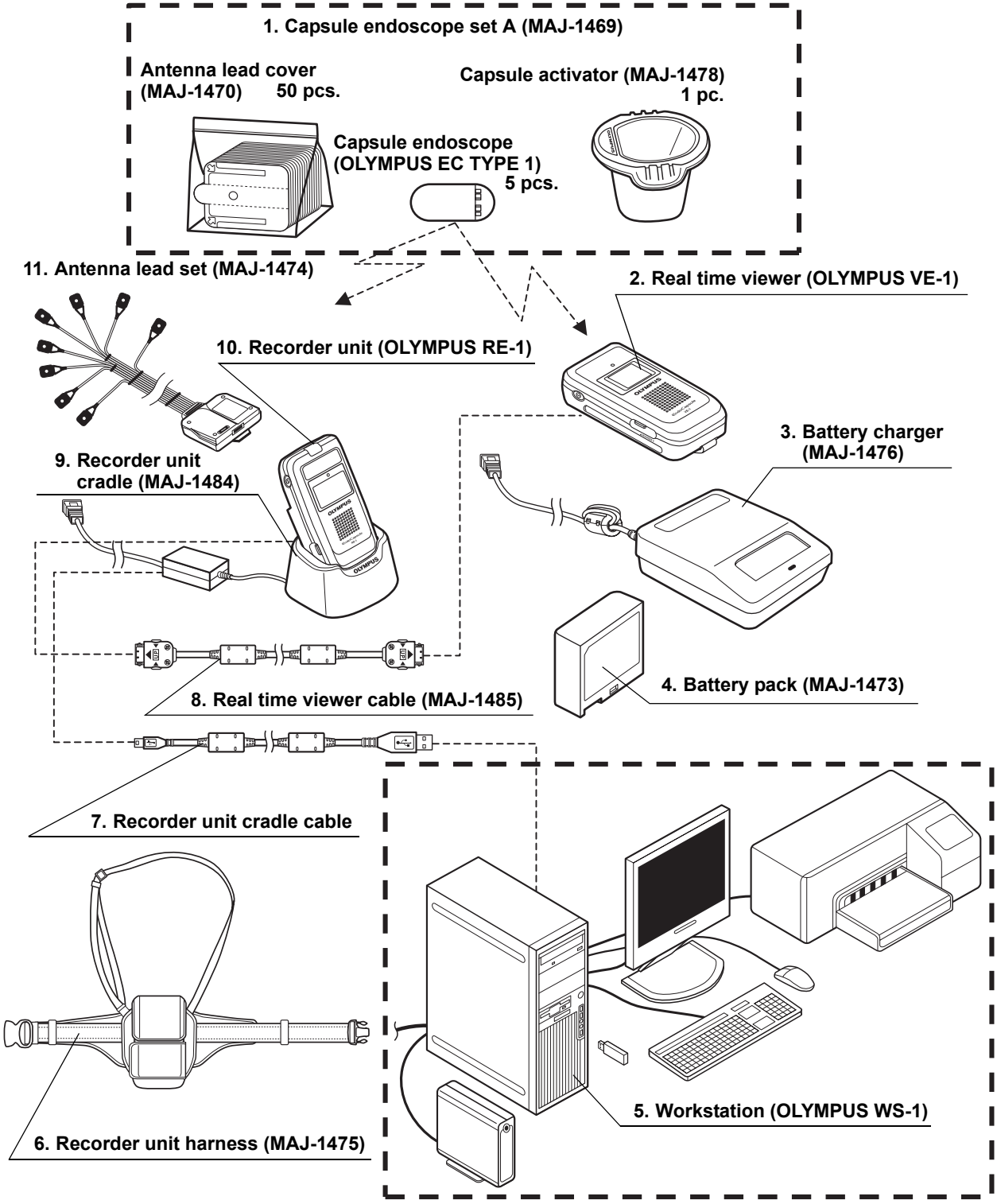
USB HDD: MAXTOR E30G300 (320GB)

NOTE

For further information, please contact Olympus.

Chapter 2 Nomenclature and functions

2.1 System components



1. **Capsule endoscope set A (MAJ-1469)**
   Takes endoscopic pictures of the gastrointestinal tract, and transmits the image data by radio transmission.

   Consists of:

   - Capsule endoscope (OLYMPUS EC TYPE 1) 5 pcs.
   - Capsule activator 1 pc.
   - Antenna lead cover 50 pcs.

2. **Real time viewer (OLYMPUS VE-1)**
   Monitors the operation of the capsule endoscope before and during the examination. Also, by using the real time viewer cable to connect the real time viewer to the recorder unit, the endoscopic images can be viewed in real-time.

3. **Battery charger (MAJ-1476)**
   Recharges battery packs.

4. **Battery pack (MAJ-1473)**
   The power supply for the recorder unit and the real time viewer.

5. **Workstation (OLYMPUS WS-1)**
   Registers patient information and patient ID onto the recorder unit. Also used to download the endoscopic images from the recorder unit for observation, diagnosis, and reporting.

6. **Recorder unit harness (MAJ-1475)**
   Holds the recorder unit during the examination.

7. **Recorder unit cradle cable**
   Connects the recorder unit cradle to the workstation for transmission of patient ID, image data, etc.

8. **Real time viewer cable (MAJ-1485)**
   Connects the real time viewer to the recorder unit, allowing images from the recorder unit to be transferred to the real time viewer for real-time viewing.

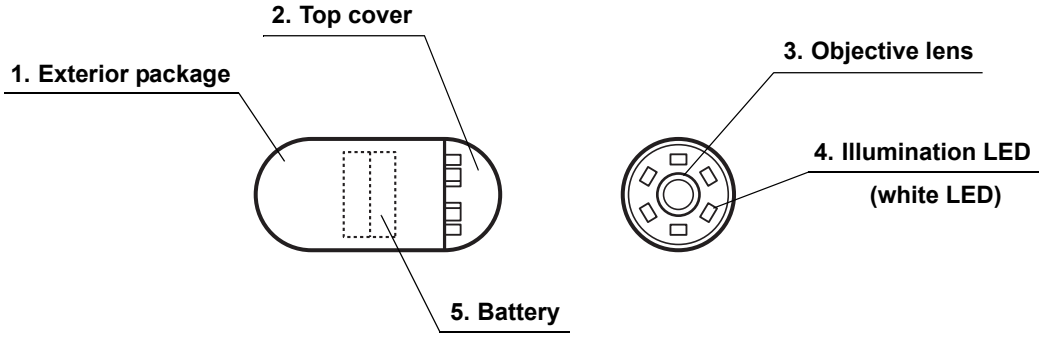
9. **Recorder unit cradle (MAJ-1484)**
   Holds the recorder unit while connecting to the workstation, for initialization of the recorder unit, registration of the patient ID, and downloading of image data.

10. **Recorder unit (OLYMPUS RE-1)**
    Records the image data transmitted by the capsule endoscope via the antenna lead set.

11. **Antenna lead set (MAJ-1474)**
    Receives transmissions from the capsule endoscope, and transfers the image data to the recorder unit.

2.2 Capsule endoscope set A (MAJ-1469)

Capsule endoscope (OLYMPUS EC TYPE1)



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

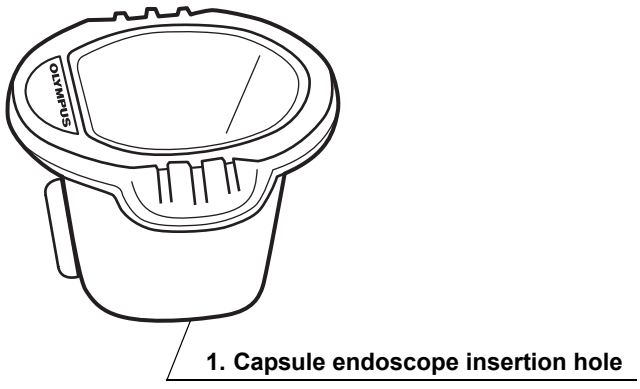
2. **Top cover**
A transparent observation port covering the objective lens and illumination LED.

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

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

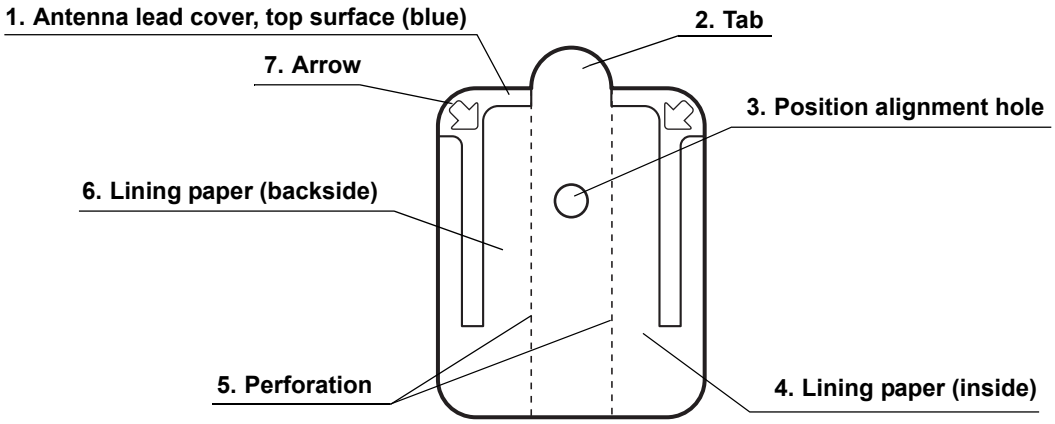
5. **Battery**
Internal battery for operating the capsule endoscope.

Capsule activator (MAJ-1478)



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

Antenna lead cover (MAJ-1470)



1. **Antenna lead cover, top surface (blue)**
Insert the antenna so that its color tag is aligned with the blue surface of the antenna lead cover.

2. **Tab**
Remove the antenna lead cover by pulling the tab to tear off the perforated section.

3. **Position alignment hole**
Use to align the antenna lead cover and the antenna.

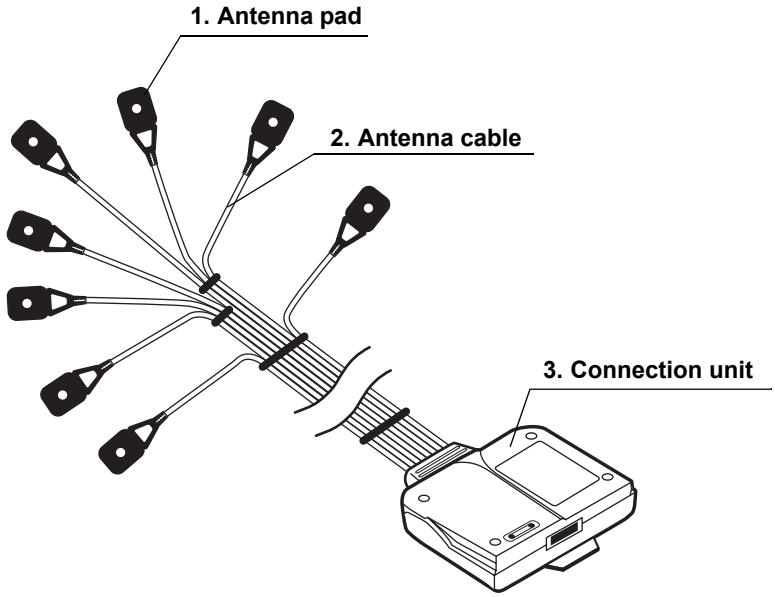
4. **Lining paper (inside)**
Peel off the lining paper to adhere the antenna lead cover onto the antenna lead set.

5. **Perforation**
Tear off this perforated section to remove the antenna lead cover from the antenna.

6. **Lining paper (backside)**
Peel off the lining paper to attach the antenna pad to the patient.

7. **Arrow**
When removing the lining paper from the antenna lead cover, or when removing the antenna lead cover from the patient, start peeling at the position marked by the arrow.

2.3 Antenna lead set (MAJ-1474)

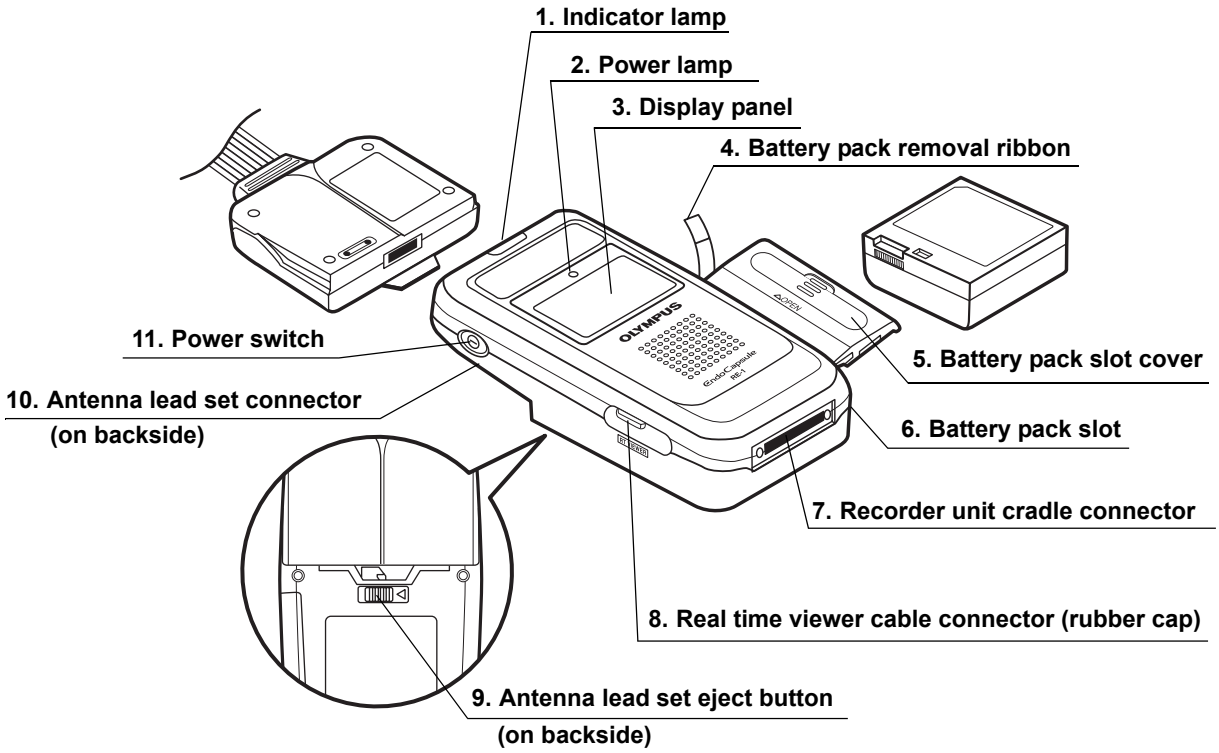


1. **Antenna pad**
Receives signals from the capsule endoscope.

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

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

2.4 Recorder unit (OLYMPUS RE-1)



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 pack removal ribbon**
Used for removing the battery pack. With the battery pack removal ribbon hanging out of the battery pack slot, insert the battery pack into the battery slot.

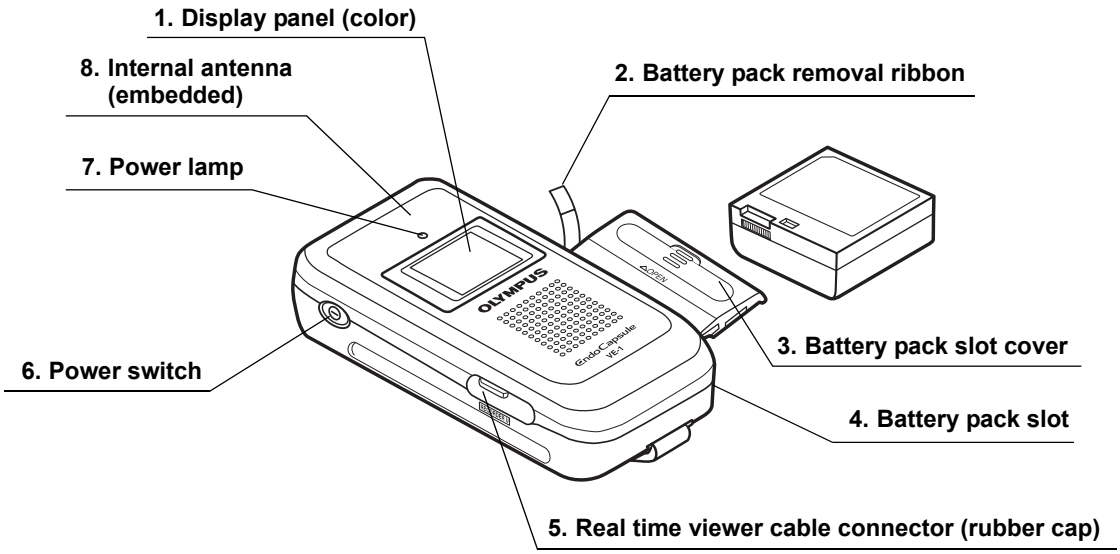
5. **Battery pack slot cover**
Cover for the battery pack slot to hold the battery pack.

6. **Battery pack slot**
Insert the battery pack here. To remove the battery pack, pull the ribbon located inside the slot.

7. **Recorder unit cradle connector**
Inserted into the recorder unit connector on the recorder unit cradle.

8. **Real time viewer cable connector (rubber cap)**
   Connect the real time viewer cable here.
   The rubber cap is provided for the protection of the viewer unit connector. Attach the rubber cap when the real time viewer cable connector is not in use.
9. **Antenna lead set eject button**
   Slide the button located on the backside of the recorder unit to disconnect the antenna lead set.
10. **Antenna lead set connector**
    Attach the antenna lead set here.
11. **Power switch**
    Turn the recorder unit ON by holding down the switch for 1 seconds or more. Turn the recorder unit OFF by holding down the switch for 2 seconds or more.

2.5 Real time viewer (OLYMPUS VE-1)



1. **Display panel (color)**
Displays endoscopic images sent by the capsule endoscope or the recorder unit, as well as information such as battery pack level.

2. **Battery pack removal ribbon**
Used for removing the battery pack. With the battery pack removal ribbon hanging out of the battery pack slot, insert the battery pack into the battery slot.

3. **Battery pack slot cover**
Cover for the battery pack slot to hold the battery pack.

4. **Battery pack slot**
Insert the battery pack here. To remove the battery pack, pull the ribbon located inside the slot.

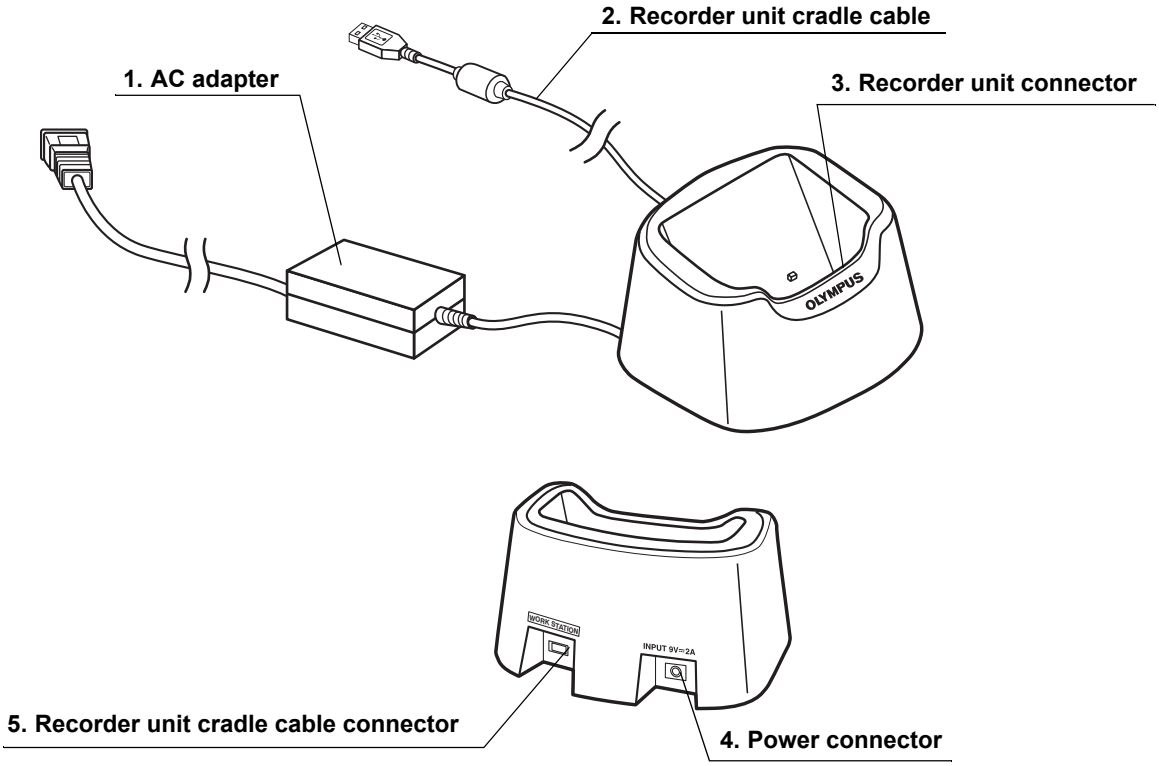
5. **Real time viewer cable connector (rubber cap)**
Connect the real time viewer cable here. By connecting the real time viewer to the recorder unit, the operation of the recorder unit can be checked, and the endoscopic images can be viewed in real-time.
The rubber cap is provided for the protection of the viewer unit connector. Attach the rubber cap when the real time viewer cable connector is not in use.

6. **Power switch**
Turn the real time viewer ON by holding down the switch for 1 second or more. Turn the real time viewer OFF by holding down the switch again for 1 second or more.

7. **Power lamp**
Illuminates green when the real time viewer is turned ON.

8. **Internal antenna (embedded)**
Receives signals from the capsule endoscope in proximity.

2.6 Recorder unit cradle (MAJ-1484)



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

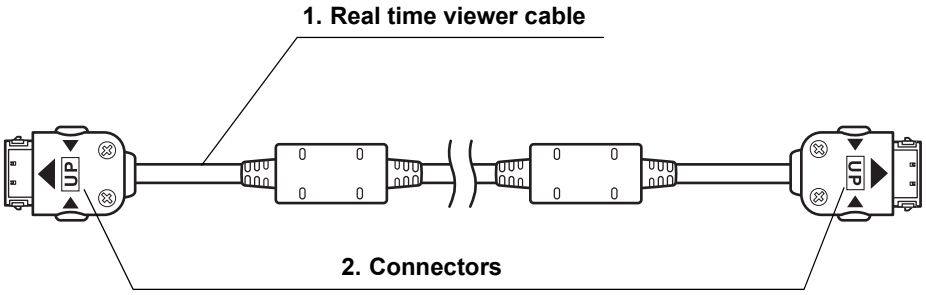
2. **Recorder unit cradle cable**
Connected to the recorder unit cradle cable connector. Connects the recorder unit to the workstation.

3. **Recorder unit connector**
Connects the recorder unit securely. When the recorder unit is connected to the recorder unit cradle, the recorder unit's power is automatically turned ON. Remove the antenna lead set from the recorder unit before attaching the recorder unit to the recorder unit cradle.

4. **Power connector**
Connect the power supply cable here.

5. **Recorder unit cradle cable connector**
Connect the recorder unit cradle cable here.

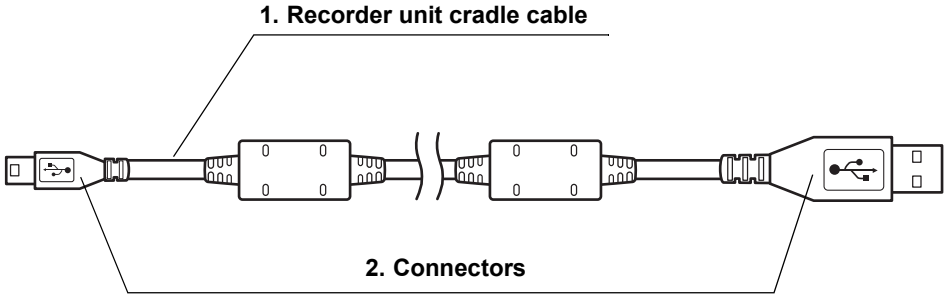
2.7 Real time viewer cable (MAJ-1485)



1. **Real time viewer cable**
Connects the real time viewer to the recorder unit, and transfers image signals between them.

2. **Connectors**
Connect to the real time viewer cable connectors on the recorder unit and the real time viewer. To disconnect, push in the buttons on the side.

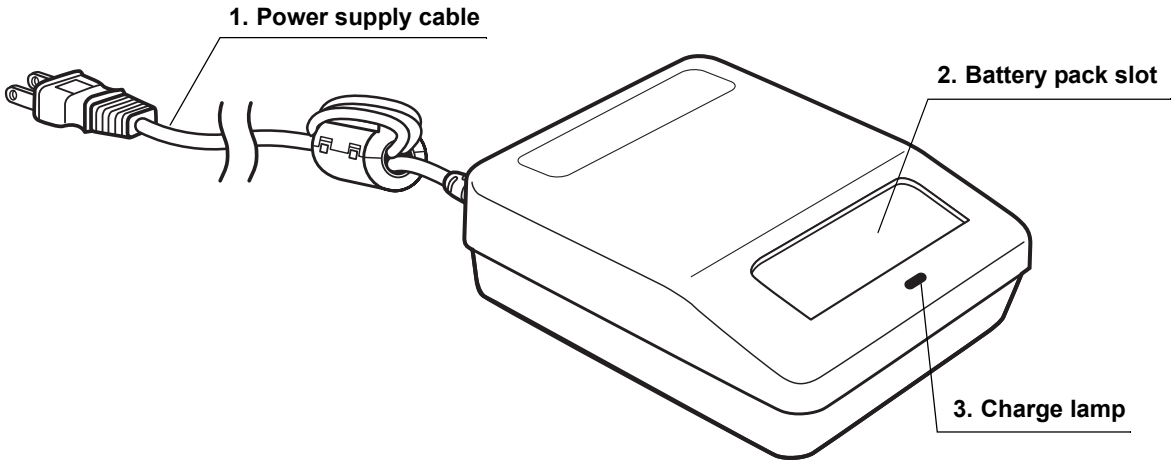
2.8 Recorder unit cradle cable



1. **Recorder unit cradle cable**
Connects the recorder unit cradle to the workstation, and transfers data between the recorder unit and the workstation.

2. **Connectors**
Connect to the USB connector on the workstation, and to the recorder unit cradle cable connector on the recorder unit cradle.

2.9 Battery charger (MAJ-1476)

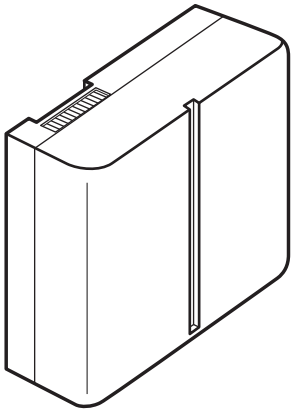


1. **Power supply cable**
Connects the battery charger to an AC power source.

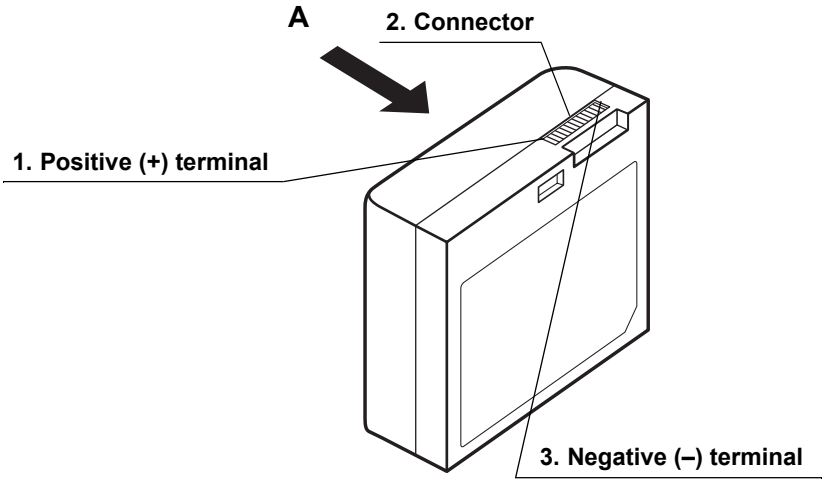
2. **Battery pack slot**
Place the battery pack in this slot.

3. **Charge lamp**
Illuminates yellow when the battery pack begins charging. Illuminates green when charging is completed.

2.10 Battery pack (MAJ-1473)

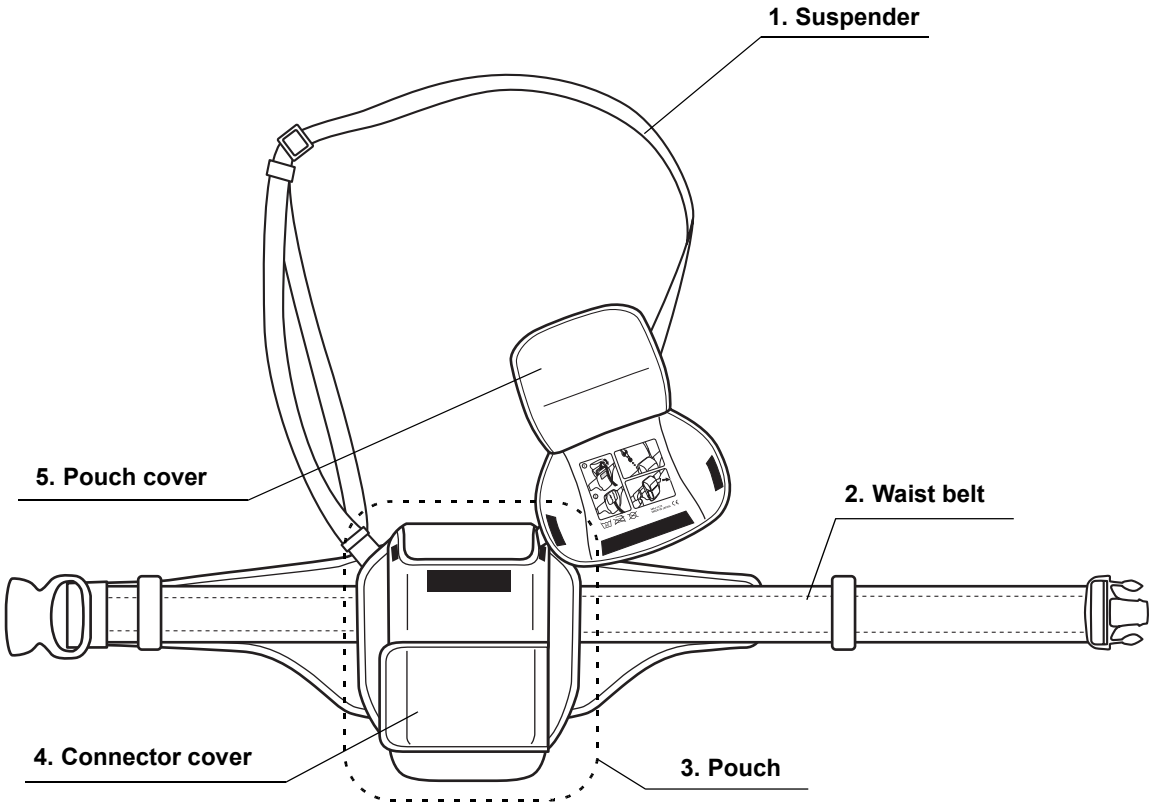


(as seen from "A")



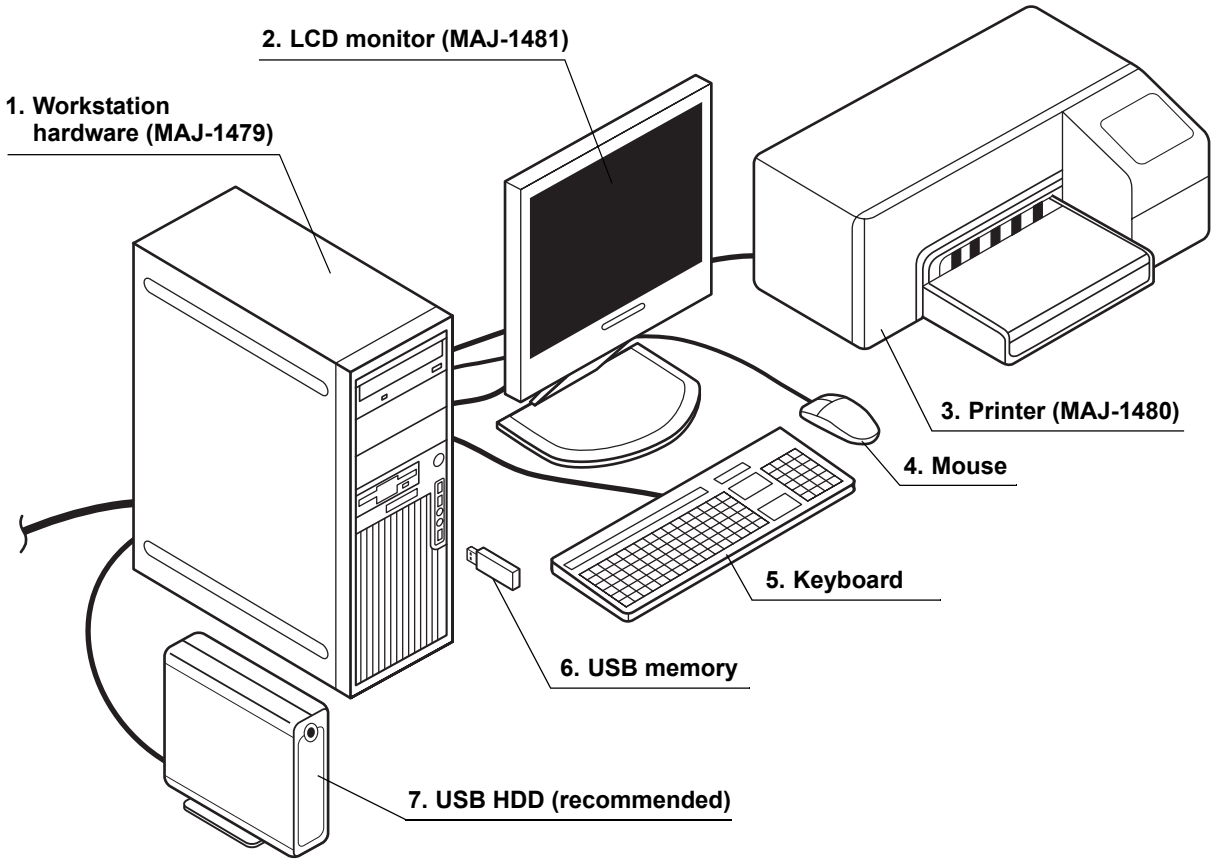
1. **Positive (+) terminal**
   Outputs positive voltage.
2. **Connector**
   Connects to the connector in the battery pack slot of the receiver/real time viewer. Also connected to the connector in the battery pack slot of the recharger.
3. **Negative (–) terminal**
   Outputs negative voltage.

2.11 Recorder unit harness (MAJ-1475)



1. **Suspender**
   Adjust the length according to the patient's physique.
2. **Waist belt**
   Holds the recorder unit during the examination.
   Adjust the length according to the patient's physique.
3. **Pouch**
   Stores the recorder unit during the examination.
4. **Connector cover**
   Covers the connector on the recorder unit to which the real time viewer cable is connected.
5. **Pouch cover**
   Secures the recorder unit and the antenna cables to the pouch.

2.12 Workstation (OLYMPUS WS-1)



1. **Workstation hardware (MAJ-1479)**
   Contains the processing unit. Also used to store data onto the CD/DVD for backup.
2. **LCD monitor (MAJ-1481)**
   Displays images captured by the capsule endoscope.
3. **Printer (MAJ-1480)**
   Used for printing. Refer to the included manual for replacement and ordering of ink and paper.
4. **Mouse**
   For screen operation.
5. **Keyboard**
   For data input.
6. **USB memory**
   Used for data storage. 2GB capacity.
7. **USB HDD (recommended)**
   Used for data backup. If unavailable, please contact Olympus.

NOTE

OLYMPUS WS-1 contains workstation hardware (MAJ-1479), LCD monitor (MAJ-1481) and printer (MAJ-1480).

Chapter 3 Installation and Connection of the Workstation

WARNING

- Use the workstation in the configuration shown in the “System chart” on page 244. Use of a workstation in any other configuration may cause patient and/or operator injury or equipment damage, and may impair the functionality of the system.
- Before use, thoroughly review chapters 3 and 4 of this instruction manual, as well as the instruction manuals provided with the peripherals. If the equipment is not properly prepared before each use, equipment damage, patient and operator injury, and/or fire may result.
- Do not place the workstation and its peripherals (including the recorder unit cradle) in the patient environment. Electric shocks and, burns may result.

CAUTION

- Avoid placing the equipment in locations with the following conditions. Failure to do so may result in malfunction of and/or damage to equipment.
  - Exposure to water.
  - Exposure to rapid changes in temperature.
  - Exposure to direct sunlight.
  - Proximity to heat sources.
  - Proximity to equipment that generates high frequency waves.
  - Exposure to high humidity.
  - Exposure to significant vibration, or dust, lampblack, or smoke.
- Use in a combustible atmosphere is prohibited.
  The system is not explosion-proof, and may cause an explosion or a fire.
- When turning the system OFF, follow the proper shutdown procedure.
  Failure to do so may result in equipment damage.

- Installing applications not recommended by Olympus on the workstation, or upgrading the Operating System (OS) are prohibited.
- Use only the dedicated cables. Use of other cables may result in malfunction and/or equipment damage.
- The cables should not be sharply bent, pulled, twisted, or crushed. Doing so may result in damage to the cables.
- Only use the system under the conditions described in the “Operating / Storage environment” on page 243.
  Failure to do so may result in malfunction of and/or equipment damage.

3.1 Installation of workstation and peripherals

Place the workstation, keyboard, mouse, monitor, recorder unit cradle, and printer on a level surface, such as a desk. When doing so, be sure not to tangle the cables or trap them under any equipment. Also, be sure not to block the ventilation grills on the workstation and the printer.

3.2 Connection of equipment

WARNING

- Never allow the power plug to become wet. It may result in an electric shock.
- Confirm that the wall power outlet has adequate capacity. Failure to do so may cause a fire, or a power failure to all equipment connected to the same power supply.
- Do not bend, pull, or twist the power supply cable. Equipment damage, including separation of the power plug and disconnection of the cable wire, fire or electric shock may result.
- Do not use extension power supply cables. A fire or electric shock may result. If the extension of power supply cables is necessary, please contact Olympus.
- Do not place the power strip on the floor.
  Exposure to water and/or dust may cause fire or electric shock.

CAUTION

- Use only the provided cables. Otherwise, equipment malfunction may result.
- Be sure to connect the power plug securely. Failure to do so may prevent the equipment from functioning.
- Use of a power supply with insufficient electrical capacity may cause the equipment to malfunction.

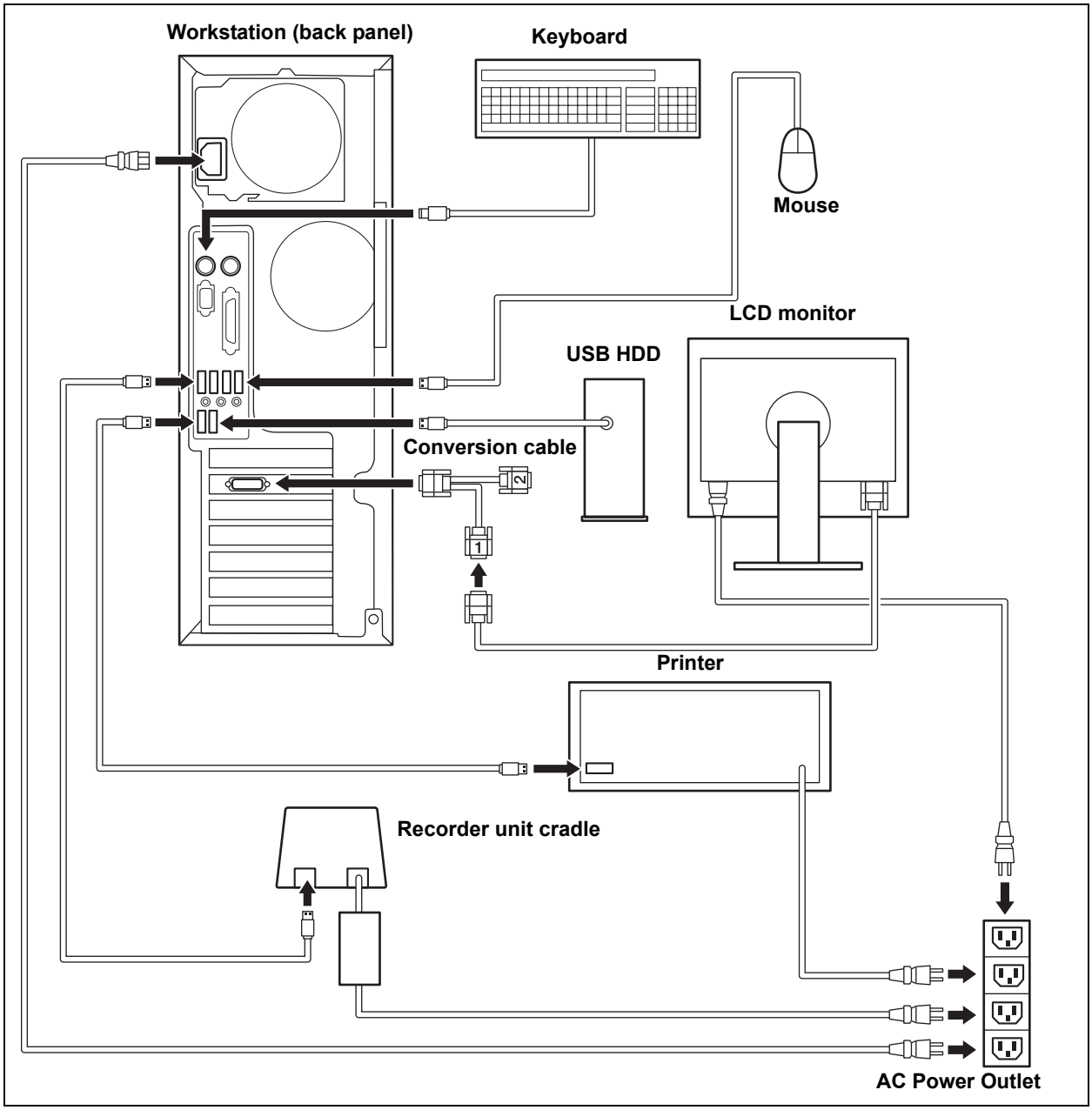


Figure 3.1

1. Connect the LCD monitor to the workstation.
2. Connect the keyboard and the mouse to the corresponding cable connector on the back panel of the workstation (see Figure 3.1).
3. Connect the printer to the workstation.
4. Prepare the printer according to the instruction manual of the printer.
5. Connect the power supply cables for the workstation, LCD monitor, printer, USB HDD, and recorder unit cradle.

6. Connect the recorder unit cradle to the workstation.
   Connect the recorder unit cradle cable to the recorder unit cradle's cable connector, then connect the other end of the recorder unit cradle cable to the USB connector on the workstation.
7. Confirm that the workstation, the LCD monitor, and the printer are turned OFF.
8. Connect the power cables for all equipment to wall power outlets.

NOTE

The conversion cable is equipped with two connectors on the monitor end, but only one of them can be used. Connect the monitor cable to the connector labeled "1".

3.3 Installation of Endo Capsule software light

CAUTION

Be sure to back up your data before installing Endo Capsule software light, as a software conflict may occur, requiring you to reinstall the OS.

System requirements

Operating system	**Windows XP Professional (SP1 or SP2)** **Windows XP Home Edition (SP1 or SP2)**
Processor	**1.3GHz or higher (SSE2 required)** **Intel Pentium M family or equivalent processor**
RAM	**512MB or more**
Hard disk	**10GB of available hard disk space**
Color quality settings	**Highest (32bit)**
Screen resolution	**Over XGA**

Main menu

The following software can be installed from the Main menu:

1. Endo Capsule software light

   Used to display the capsule endoscope images and to create reports.

2. WMV CODEC

   Used to export the capsule endoscope images as movies.

❍ Installation Endo Capsule software light

1. Insert the installation CD into the CD-ROM drive. The CD will auto-run, and the Main menu is displayed.
2. On the Main menu, click “Install Endo Capsule Software Light”.
3. The installer will be launched. Follow the instructions on the screen to install the software.

NOTE

Product ID: d2Ht-mx9e-weVz-Kr7b

Installation WMV CODEC

1. Insert the installation CD into the CD-ROM drive. The CD will auto-run, and the Main menu is displayed.
2. On the Main menu, click “Install WMV CODEC”.
3. The installer will be launched. Follow the instructions on the screen to install the software.

Uninstalling

1. Select [Start] > [Control Panel]. The control panel is displayed.
2. In the control panel, double-click “Add or Remove Programs”. The “Add or Remove Programs” screen is displayed.
3. In the “Change or Remove Programs” tab, select the Endo Capsule software light.
4. Click the “Change/Remove” button and follow the instructions on the screen.

Chapter 4 Workstation Access and Setup

This section describes the login and logoff processes for the workstation, as well as the initial workstation setup procedures.

CAUTION

- If you forget your user ID and password, you will lose access to your workstation. Be sure to manage your user ID and password well.
- The password should only be given to those who require its use. Otherwise, it could lead to unauthorized viewing and/or alteration of data.
- Using a user ID and password that are provided by default or are easy to guess may allow an unauthorized third person to use the workstation.
- Turn OFF the workstation when it is not in use.
- Remove the USB devices from the workstation and restart the workstation when it does not work properly. Then connect the removed USB devices again.

4.1 Login

NOTE

- The “Login” function is not available in Endo Capsule software light.
- You need to change a language in some languages other than English when you input alphabets. Please right-click on the text box and select “Language” and then “English” from the context menu.

1. Turn ON the monitor and the workstation. The system starts automatically, and the login screen is displayed (see Figure 4.1).

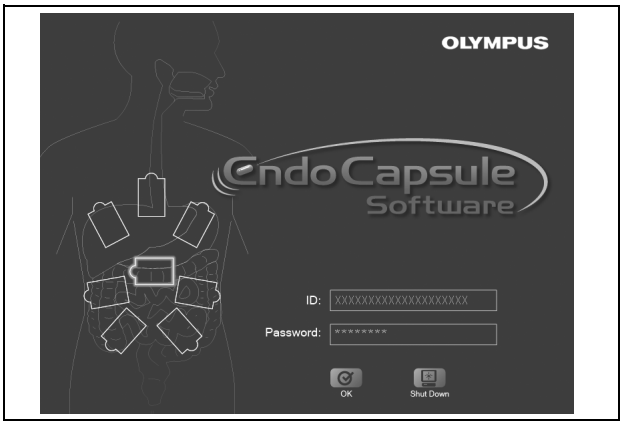


Figure 4.1

2. Enter your user ID and password (see).

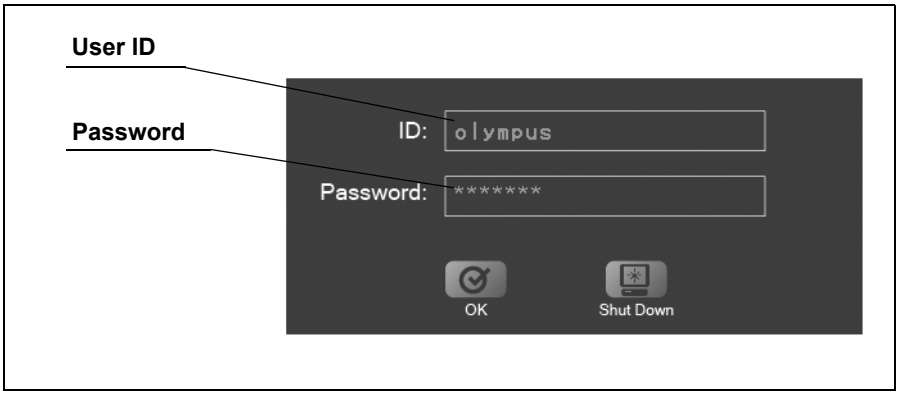


Figure 4.2

NOTE

- When logging in for the first time, enter “olympus” as the user ID and password. After you log in, add a user in the user settings.
- Characters that can be used for user IDs and passwords are shown in Table 4.1:

Table 4.1

Uppercase	A B C D E F G H I J K L M N O P Q R S T U V W X Y Z
Lowercase	a b c d e f g h i j k l m n o p q r s t u v w x y z
Numbers	0 1 2 3 4 5 6 7 8 9
Symbols	` ~ ! @ # $ % ^ & * ( ) _ + – = { } | [ ] ¥ : " ; ' < > ? , . /

- User IDs and passwords are case sensitive.
- When entering a password, the entered characters will be displayed as asterisks (∗) for security.

3. Click the [OK] button (see Figure 4.3).

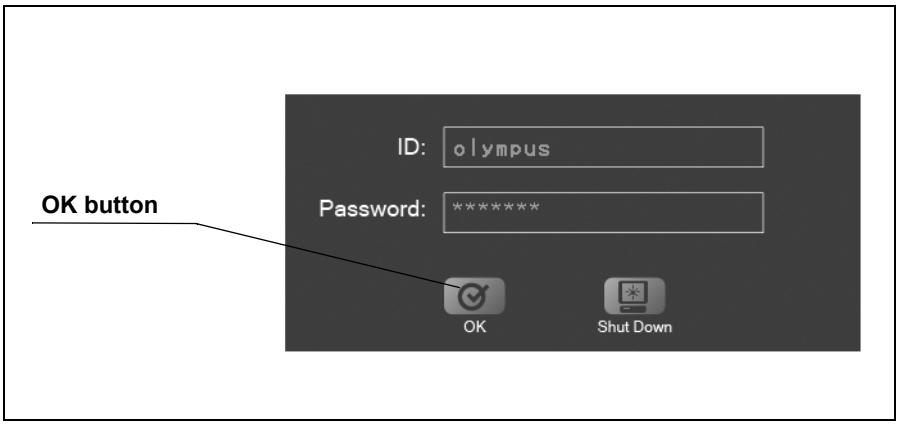


Figure 4.3

NOTE

- Click the [Shutdown] button to turn OFF the workstation.
- If the message in Figure 4.4 is displayed, the user ID or password is incorrect. Click the [OK] button, and then check and re-enter the user ID and password.

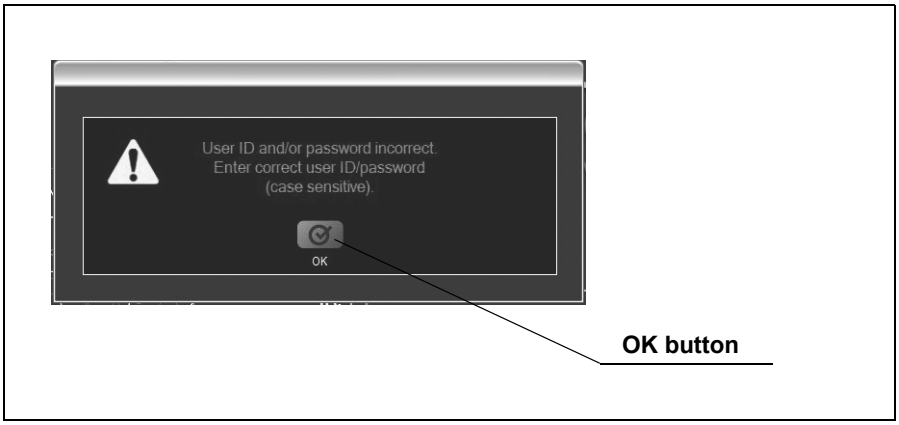


Figure 4.4

4. If the user ID and password are correct, a confirmation screen for the user name and system time is displayed. Confirm the user name and system time (see Figure 4.5).

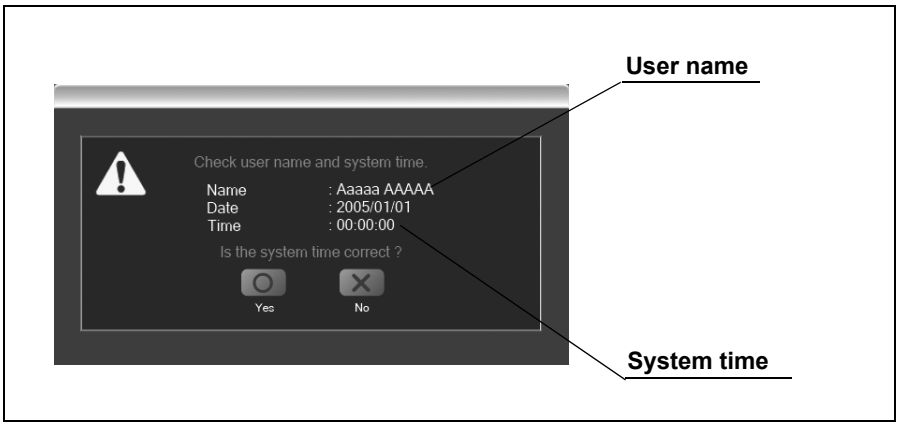


Figure 4.5

5. To change the system time, click the [No] button.

NOTE

If you do not need to change the system time, click the [Yes] button. The main screen is displayed.

6. Set the correct date and time.

Figure 4.6

7. Click the [OK] button. A confirmation screen for the user name and system time appears and the system time has changed.

NOTE

If you wish to cancel changing the system time, click the [Cancel] button.

8. On the confirmation screen for the user name and system time, click the [Yes] button. The observation screen is displayed.

4.2 Start-up of Endo Capsule software light

1. Double-click the icon of Endo Capsule Software Light on the desktop. Endo Capsule Software Light runs and the user name screen is displayed.

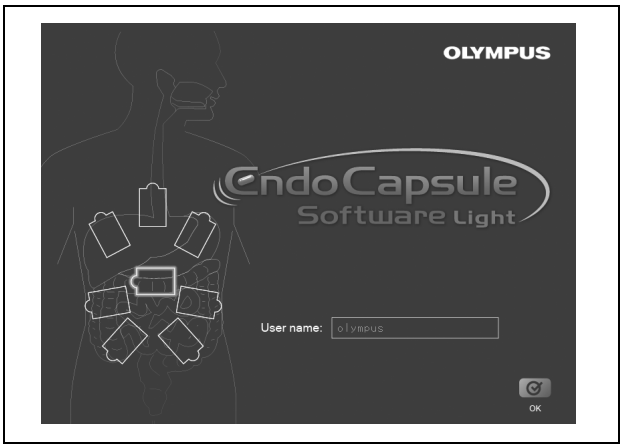


Figure 4.7

2. Enter the user name and click [OK] button.

Figure 4.8

NOTE

Entering the use name is necessary.

3. The main screen is displayed.

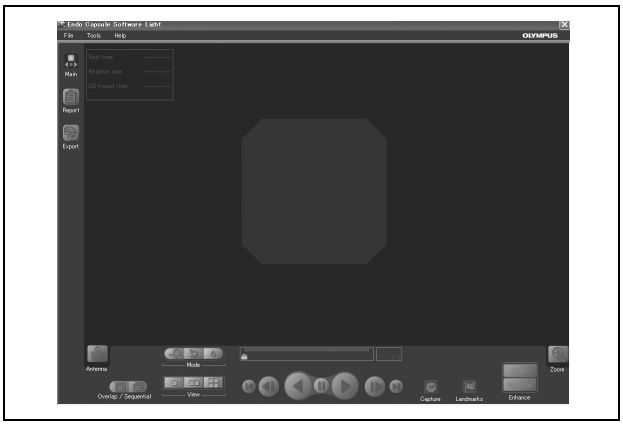


Figure 4.9

CAUTION

Other software installed on the workstation may cause a software conflict, and prevent Endo Capsule software light from functioning properly.

4.3 Nomenclature and functions of the main screen

The following screen is displayed after login, and is used for observing images downloaded from the recorder unit.

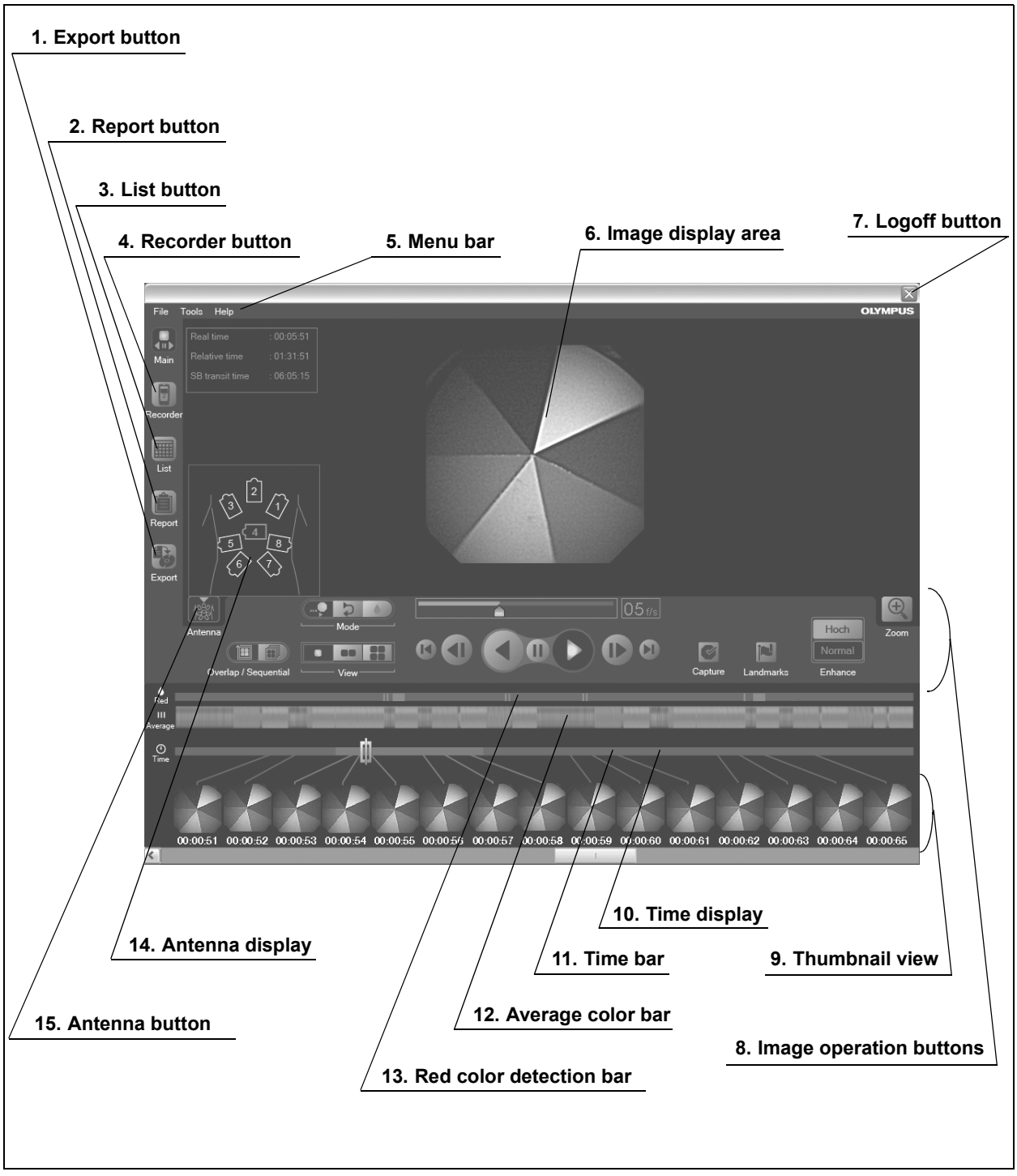


Figure 4.10

1. **Export button**
   Displays the export screen.
2. **Report button**
   Displays the report screen.
3. **List button**
   Displays the examination list screen.
4. **Recorder button**
   Displays the recorder management screen.
5. **Menu bar**
   Contains the “File”, “Tools” and “Help”. For more information, refer to “Menus” on page 72.
6. **Image display area**
   Displays the image data.
7. **Logoff button**
   Quits the application and displays the login screen.
8. **Image operation buttons**
   Plays back image data. For more information, refer to Figure 4.11 on page 70.
9. **Thumbnail view**
   Displays thumbnails.
10. **Time display**
    Displays the time associated with a thumbnail.
11. **Time bar**
    Indicates the time position of the currently displayed image.
12. **Average color bar**
    Displays the average color of the image data.
13. **Red color detection bar**
    Indicates positions of red-color detected image data.
14. **Antenna display**
    Displays the antenna with the best signal reception.
15. **Antenna button**
    Shows/hides the antenna display.

Image operation buttons

NOTE

- Red color detection function
  Detects red color in images and indicates the position of red-color detected image data.

- Auto review speed adjustment function
  Adjusts the review speed automatically during the playback or the reverse playback.

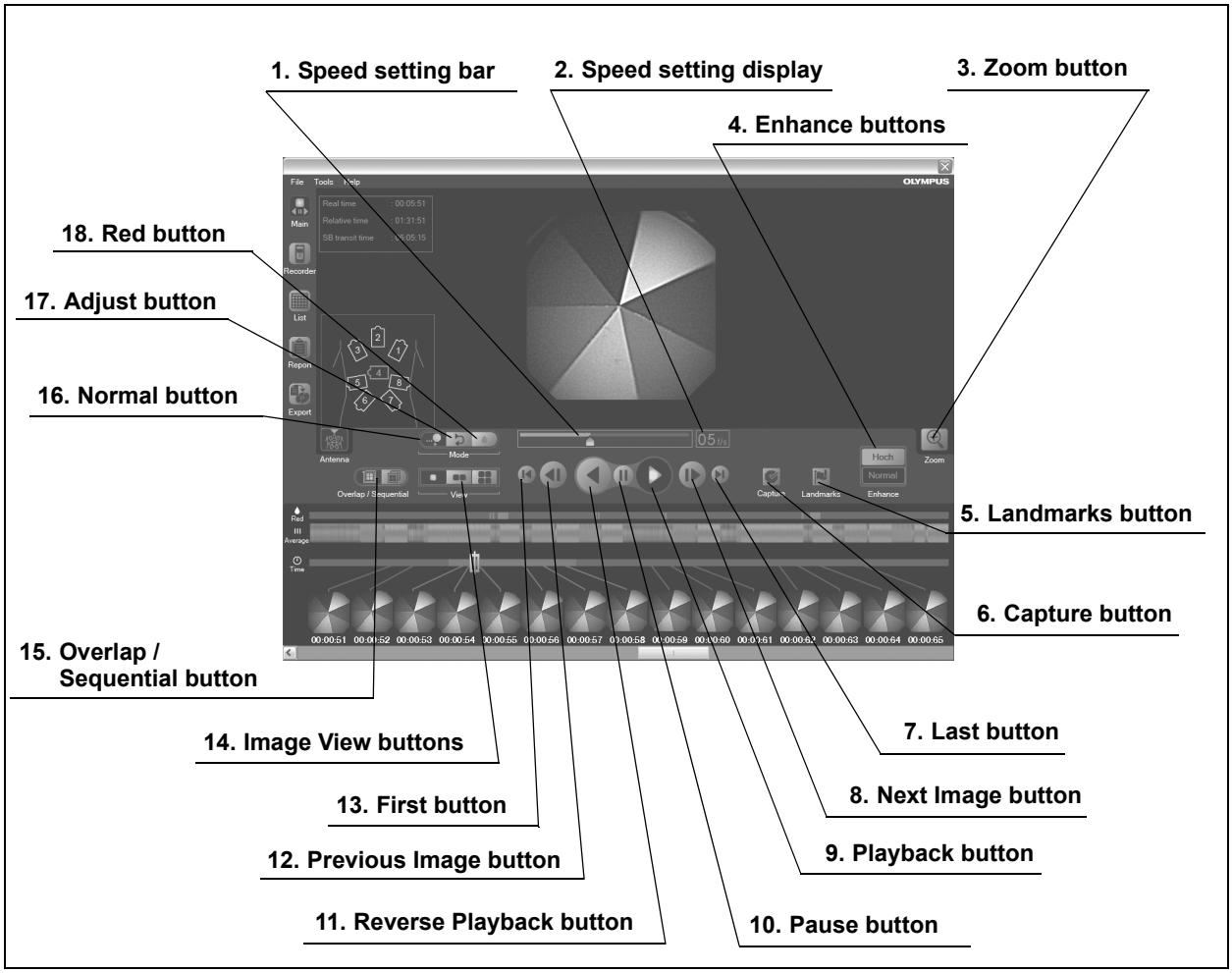


Figure 4.11

1. **Speed setting bar**
   Sets the review speed.
2. **Speed setting display**
   Displays the review speed.
3. **Zoom button**
   Enlarges the image(s) displayed in the image display area.
4. **Enhance buttons**
   Sets the level of structure enhancement.
5. **Landmarks button**
   Displays the feature setting screen for setting the feature for thumbnails.
6. **Capture button**
   Makes a thumbnail in the image display area.
7. **Last button**
   Displays the last image data.

8. **Next Image button**
   Displays the next image.
9. **Playback button**
   Plays back the image data.
10. **Pause button**
    Pauses the playback or reverse playback of the image data.
11. **Reverse Playback button**
    Plays back the image data in reverse order.
12. **Previous Image button**
    Displays the previous image.
13. **First button**
    Displays the first image data.
14. **Image View buttons**
    Switches the number of images displayed (1, 2, or 4).
15. **Overlap / Sequential button**
    Changes the image update mode how the image data is updated during playback.
16. **Normal button**
    Plays back images at the speed set by a user.
17. **Adjust button**
    Automatically adjusts the review speed during the playback.
18. **Red button**
    Plays back only the image data detected by the red detection function.

Menus

File menu

This menu is displayed by clicking “File” on the menu bar (see Figure 4.12).

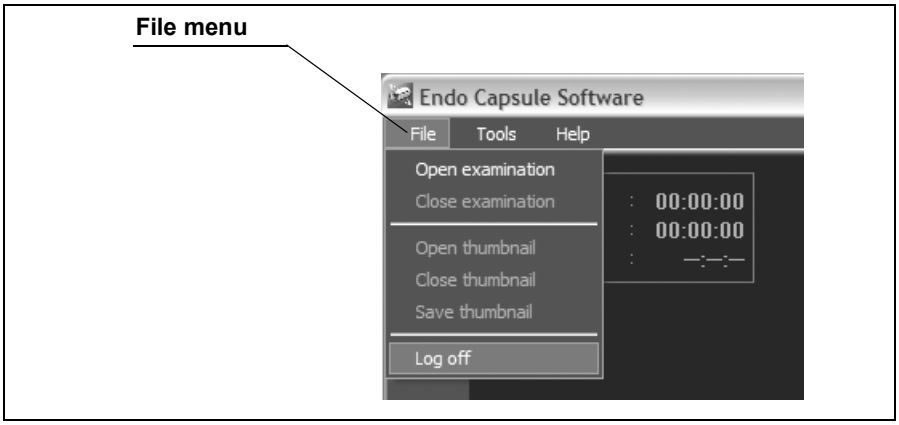


Figure 4.12

Open examination

Opens examination data.

Close examination

Closes examination data.

Open thumbnail

Opens thumbnail data.

Close thumbnail

Closes thumbnail data.

Save thumbnail

Saves thumbnail data.

Log off

Displays the login screen.

Tools menu

This menu is displayed by clicking “Tools” on the menu bar (see Figure 4.13).

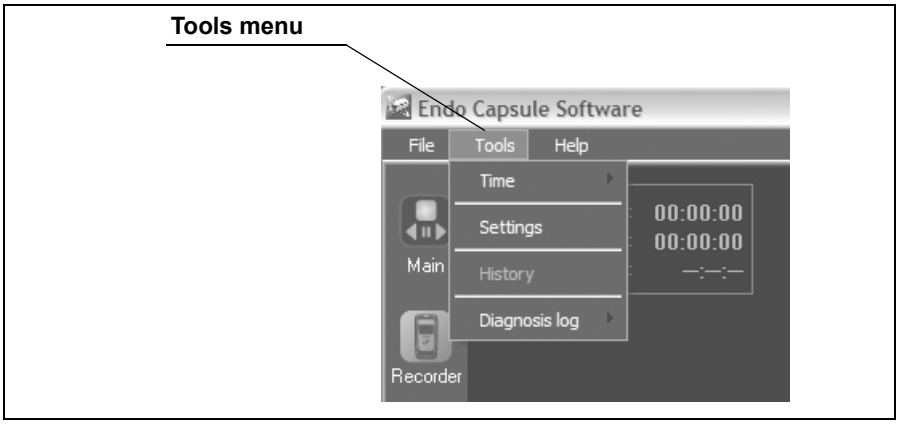


Figure 4.13

Time

Sets up the time display on the thumbnail. Select from “Real Time” or “Relative Time”.

Settings

Displays the settings screen.

History

Displays the history display screen.

Diagnosis log

Displays the diagnosis log. Select from “view” or “export”.

Help menu

This menu is displayed by clicking “Help” on the menu bar (see Figure 4.14).

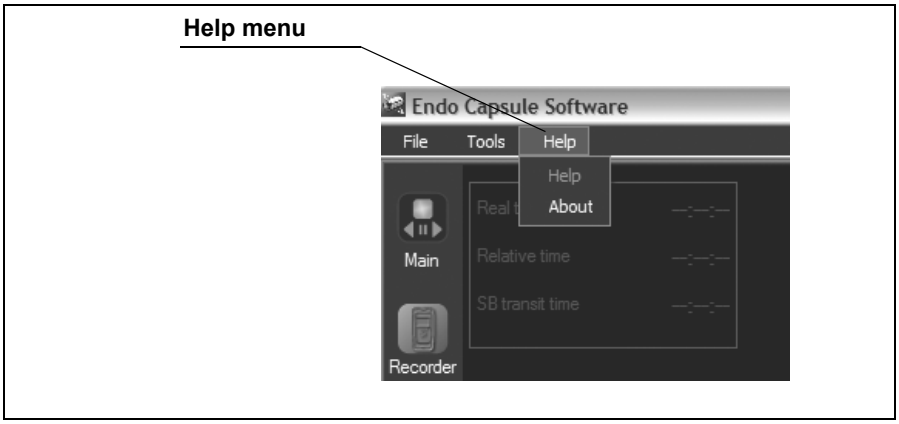


Figure 4.14

Help

Displays the help.

About

Displays the version information of the system.