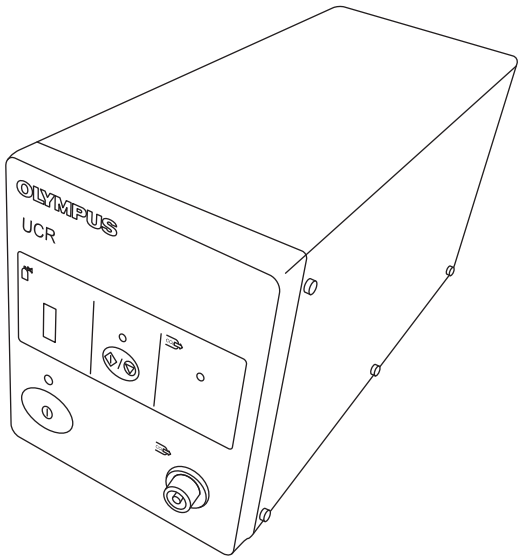
OLYMPUS®

INSTRUCTIONS

ENDOSCOPIC CO_2 REGULATION UNIT

OLYMPUS UCR



Labels and Symbols 1

Important Information — Please Read Before Use 5

Chapter 1 Checking the Package Contents 13

Chapter 2 Instrument Nomenclature 17

Chapter 3 Installation and Connection 25

Chapter 4 Inspection 35

Chapter 5 Operation 45

Chapter 6 Reprocessing, Storage, Disposal, and Transportation 53

Chapter 7 Troubleshooting 65

Appendix 67

CE 0197

Contents

Labels and Symbols **1**

Important Information — Please Read Before Use **5**

Intended use 5
Applicability of endoscopy, endoscopic treatment, and endoscopic surgery 5
Instruction manual 5
User qualifications 6
Instrument compatibility 6
Repair and modification 6
Signal words 7
Dangers, warnings, and cautions 7

Chapter 1 Checking the Package Contents 13

1.1 Checking the package contents 13

1.2 Optional items 14

Chapter 2 Instrument Nomenclature 17

2.1 Symbols and descriptions 17

2.2 Front panel 18

2.3 Rear panel 20

2.4 Gas tube (MAJ-1741) 22

2.5 Optional components 23

Chapter 3 Installation and Connection 25

3.1 Installation workflow 25

3.2 Installation of the endoscopic CO2 regulation unit 26

3.3 Connecting a CO2 gas cylinder 26

3.4 Connecting the medical gas pipeline adapter (MAJ-1084, MAJ-1085) 29

3.5 Connecting to an AC power supply 30

3.6 Connecting the Gas tube (MAJ-1741), Low flow gas tube (MAJ-1742), and Extra low flow gas tube (MAJ-1816) 32

3.7 Connecting the water container and endoscope 34

Chapter 4 Inspection 35

4.1 Inspection before use 35

4.2 Inspection workflow 36

4.3 Inspection of the cylinder hose (MAJ-1080, MAJ-1081, MAJ-1082) 37

4.4 Inspection of the medical gas pipeline adapter (MAJ-1084, MAJ-1085) 37

4.5 Inspection of the Gas tube (MAJ-1741), Low flow gas tube (MAJ-1742), and Extra

low flow gas tube (MAJ-1816) 38

4.6 Inspection of the endoscopic CO2 regulation unit 38
Inspection of the power supply 38
Inspection of the gas supply 39
Inspection of insufflation 40
Inspection of gas feeding at gas tube 41
Inspection of gas and water feeding 42
Power OFF 43

Chapter 5 Operation 45

5.1 Precaution for operation 45
5.2 Operation flow 46
5.3 Function setting before use 47
Turn the endoscopic CO2 regulation unit ON 47
Selecting the gas supply source 47
Timer setting 48
5.4 Gas supplying and water feeding 49
5.5 After use 50
Disconnecting the CO2 gas cylinder 50
Disconnecting the medical gas pipeline 51

Chapter 6 Reprocessing, Storage, Disposal, and Transportation ... 53

6.1 Reprocessing 53
6.2 Surface disinfectant cleaner 56
6.3 Signs of degradation from reprocessing 57
6.4 Preparing equipment for reprocessing 58
Equipment needed 58
6.5 Reprocessing the endoscopic CO2 regulation unit and accessories 59
6.6 Storage 62
6.7 Disposal 63
6.8 Transportation 63

Chapter 7 Troubleshooting 65

7.1 Troubleshooting guide 65
Endoscopic CO2 regulation unit (UCR) 65
7.2 Returning the endoscopic CO2 regulation unit for repair 66

Appendix 67

Combination equipment 67
System chart 67
Transportation, storage, and operating environments 69

Specifications **69**
EMC information **73**

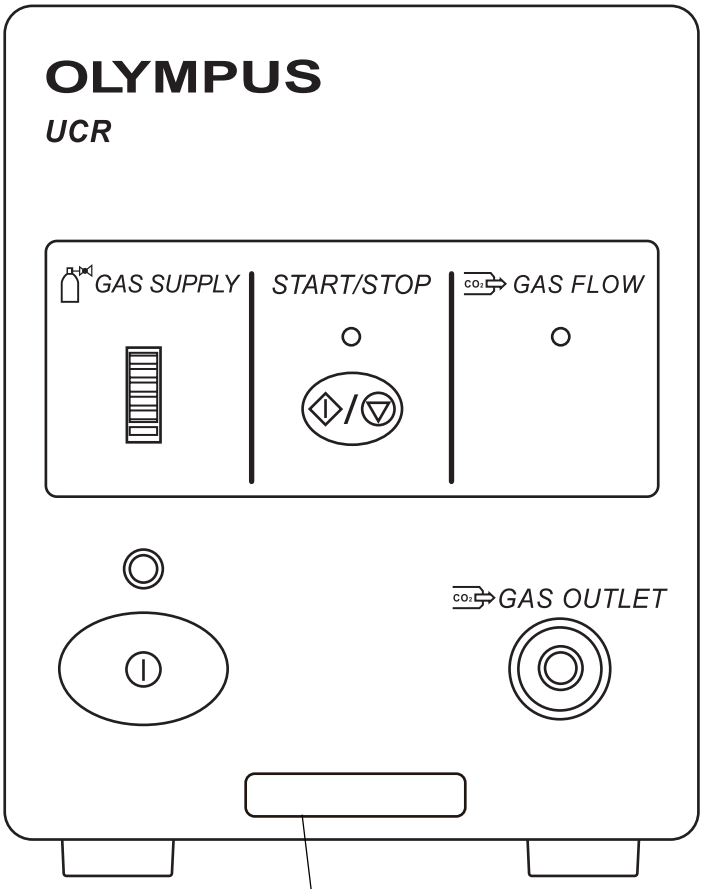
Contents

Labels and Symbols

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

UCR CO_2 regulation unit

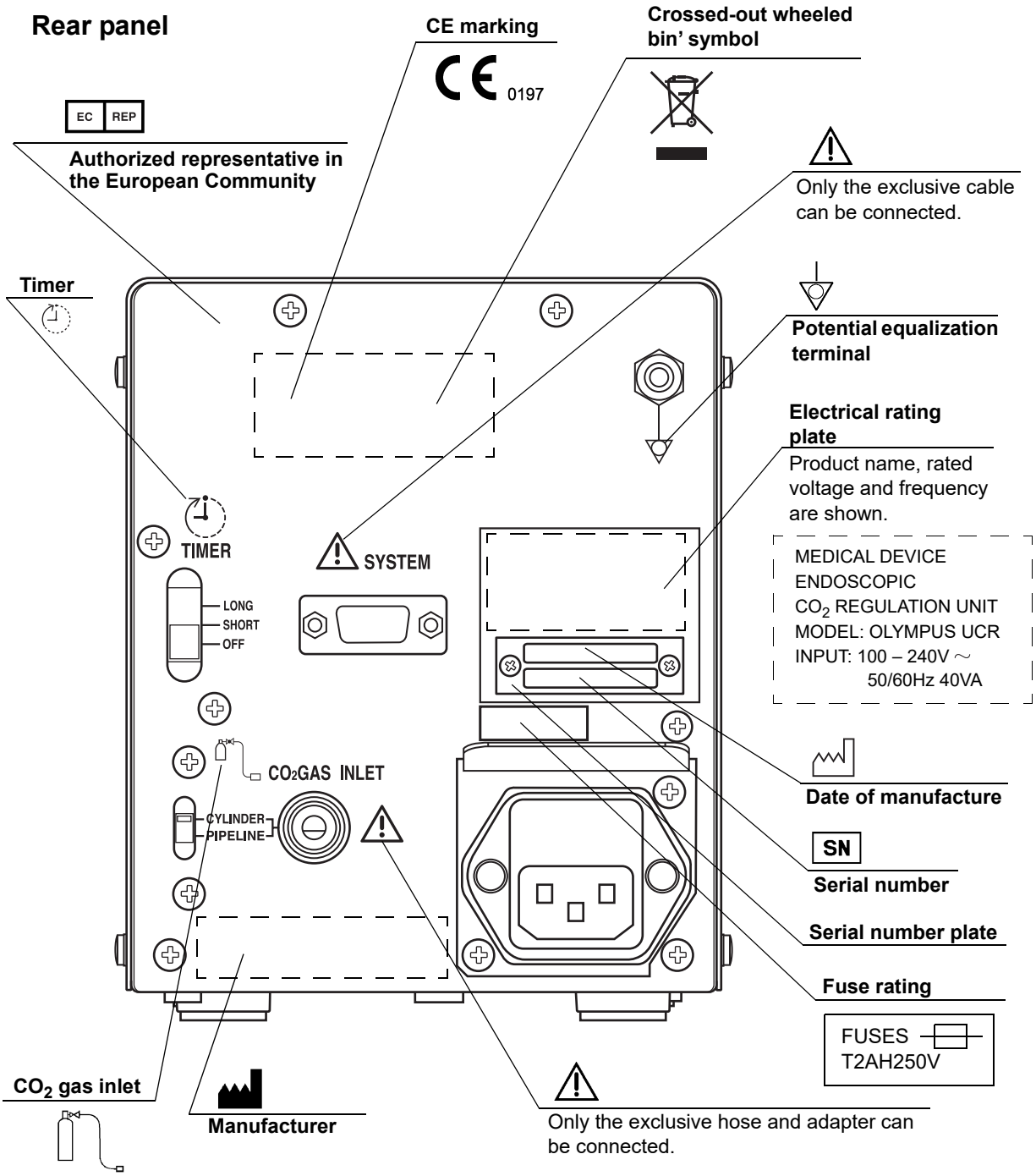
Front panel



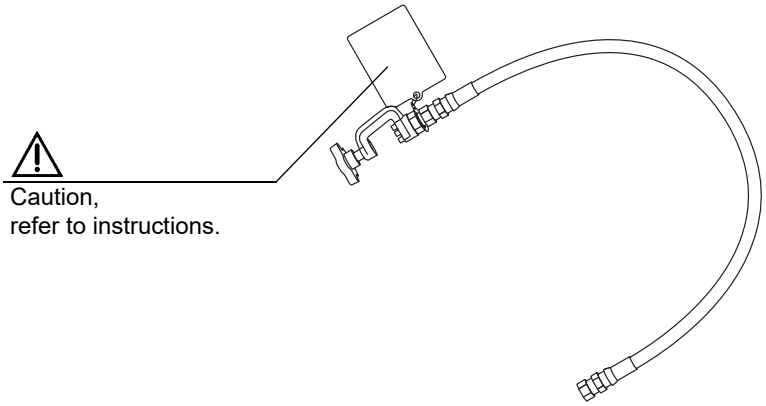
UDI label

The UDI label is required by some countries' regulations regarding the identification of a medical device also known as Unique Device Identification (UDI).

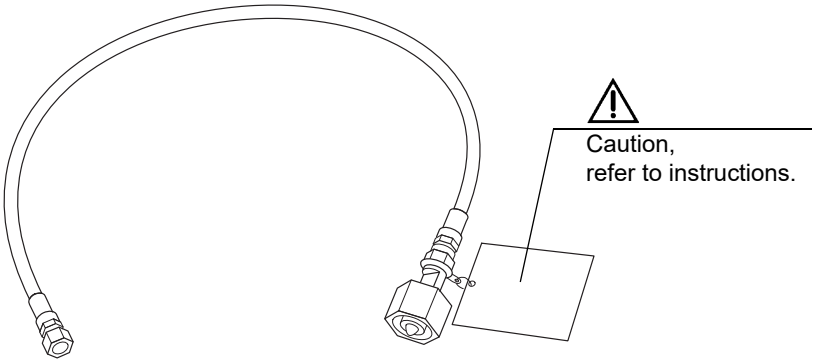
(01)xxxxxxxxxxxxxx
(11)xxxxxx(21)xxxxxxx


Rear panel
CE marking
0197
Crossed-out wheeled bin' symbol
EC REP
Authorized representative in the European Community
Only the exclusive cable can be connected.
Timer
Potential equalization terminal
Electrical rating plate
Product name, rated voltage and frequency are shown.
TIMER
SYSTEM
LONG
SHORT
OFF
MEDICAL DEVICE
ENDOSCOPIC
CO2 REGULATION UNIT
MODEL: OLYMPUS UCR
INPUT: 100 – 240V ~
50/60Hz 40VA
CO2GAS INLET
CYLINDER
PIPELINE
Date of manufacture
SN
Serial number
Serial number plate
Fuse rating
FUSES
T2AH250V
CO2 gas inlet
Manufacturer
Only the exclusive hose and adapter can be connected.

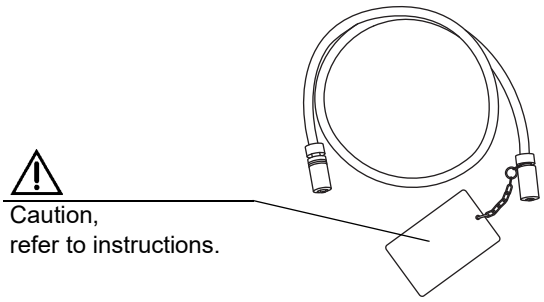
❍ Cylinder hose (PIN, MAJ-1080)



❍ Cylinder hose (DIN, MAJ-1081), Cylinder hose (ISO, MAJ-1082)



Gas tube (MAJ-1741), Low flow gas tube (MAJ-1742), Extra low flow gas tube (MAJ-1816)



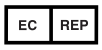
Gas tube ID indications on tags are shown as follows:

“HIGH” (MAJ-1741)

“MED” (MAJ-1742)

“LOW” (MAJ-1816)

Back cover of this instruction manual

Symbol	Description
	Manufacturer
	Authorized representative in the European Community
	Translation
	Importer (into European Union)

Important Information — Please Read Before Use

Intended use

The endoscopic CO_2 regulation unit has been designed to be used with Olympus gastrointestinal endoscopes, lens cleaning sheath for surgical endoscope and ancillary equipment for CO_2 gas and water feeding. Do not use the endoscopic CO_2 regulation unit for any purpose other than its intended use.

Applicability of endoscopy, endoscopic treatment, and endoscopic surgery

If there are official standards on the applicability of endoscopy, endoscopic treatment, and endoscopic surgery that is defined by the hospital's administration or other official institutions such as academic societies on endoscopy or endoscopic surgery, follow that standard.
Before starting endoscopy, endoscopic treatment, and endoscopic surgery, thoroughly evaluate its properties, purposes, effects, and possible risks (their natures, extent and probability). Perform endoscopy, endoscopic treatment, and endoscopic surgery only when its potential benefits are greater than its risks.
Fully explain to the patient the potential benefits and risks of the endoscopy, endoscopic treatment, and endoscopic surgery as well as any examination/treatment/surgery methods that can be performed in its place, and perform the endoscopy, endoscopic treatment, and endoscopic surgery only after obtaining the consent of the patient.
Even after starting the endoscopy, endoscopic treatment, and endoscopic surgery, continue to evaluate the potential benefits and risks, and immediately stop the endoscopy/treatment/surgery and take proper measures if the risks to the patient become greater than the potential benefits.

Instruction manual

This instruction manual contains essential information on using this instrument safely and effectively. Before use, thoroughly review this manual and the manuals for all equipment that will be used during the procedure and use the instruments 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, contact Olympus.

■ *User qualifications*

If there is an official standard on user qualifications to perform endoscopy, endoscopic treatment, and endoscopic surgery that is defined by the medical administration or other official institutions, such as academic societies on endoscopy or endoscopic surgery, follow that standard. If there is no official qualification standard, the operator of this instrument must be a physician approved by the medical safety manager of the hospital or person in charge of the department (department of internal medicine, etc.).
The physician should be capable of safely performing the planned endoscopy, endoscopic treatment, and endoscopic surgery following guidelines set by the academic societies on endoscopy or endoscopic surgery, etc., and considering the difficulty of endoscopy, endoscopic treatment, and endoscopic surgery. This manual does not explain or discuss endoscopic procedures.

■ *Instrument compatibility*

Refer to the "■ System chart" on page 67 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 4 (IEC 60601-1-2: 2014).
When connecting to an instrument that complies with a previous edition of the EMC standard for medical electrical equipment edition, the EMC characteristics could be vulnerable.

■ *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 7, "Troubleshooting".
If the problem cannot be resolved using the information in Chapter 7, 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 and warnings given below when handling this instrument.
This information is to be supplemented by the dangers and warnings given in each chapter.

DANGER

- As a TYPE BF applied part, this endoscopic CO_2 regulation unit must never be applied directly to the heart and must not be used in procedures involving cardiac observation or surgery.
  Leakage current from the TYPE BF applied part may be dangerous and cause ventricular fibrillation or otherwise seriously affect the cardiac function of the patient.
  Accordingly, always adhere to the following points:
  - Never apply the endoscope connected to this endoscopic CO_2 regulation unit to the heart or any area near the heart.
  - Never allow the hand instruments or another endoscope applied to or near the heart to come in contact with an endoscope connected to this endoscopic CO_2 regulation unit.

DANGER

- Strictly observe the following precautions. Failure to do so may place the patient and medical personnel in danger of an electric shock.
  - When the endoscopic CO_2 regulation unit is used to examine a patient, do not allow metal parts of the endoscope or its accessories to touch metal parts of other system components. Such contact may cause unintended current flow to the patient.
  - Keep fluids away from all electrical equipment. If fluids are spilled on or into the endoscopic CO_2 regulation unit, stop operation of the unit immediately and contact Olympus.
  - Do not prepare, inspect or use this CO_2 regulation unit with wet hands.
- Never install and operate the endoscopic CO_2 regulation unit in the following locations. An explosion or fire may result because the endoscopic CO_2 regulation unit is not explosion-proof.
  - The concentration of oxygen is high.
  - Oxidizing agents (such as nitrous oxide (N_2O)) are present in the atmosphere.
  - Flammable gases are present in the atmosphere.
  - Flammable liquids are nearby.
- Supply medical grade CO_2 gas only. Never use other kinds of gas. Using gases other than CO_2 gas may result in fire, poisoning, complications, etc.

WARNING

- If the endoscopic CO_2 regulation unit is used with the upper/lower gastrointestinal endoscopes, use it only for CO_2 gas/water feeding within the upper/lower digestive tract. If the endoscopic CO_2 regulation unit is used with the lens cleaning sheath, use it only for CO_2 gas feeding/spraying toward the objective lens of the endoscope within the thoracic and abdominal cavities including female reproductive organs.
- If the endoscopic CO_2 regulation unit is used with the lens cleaning sheath, do not feed spray/CO_2 gas to an open vessel directly. Do not use the lens cleaning sheath near an open vessel or do not press the distal tip of the lens cleaning sheath against tissues. Otherwise, gas embolism may result.

WARNING

- To prevent electrical shock hazards, the housing of the endoscopic CO_2 regulation unit must be grounded. Always connect the power cord plug to a properly grounded hospital grade AC outlet (wall mains outlet).

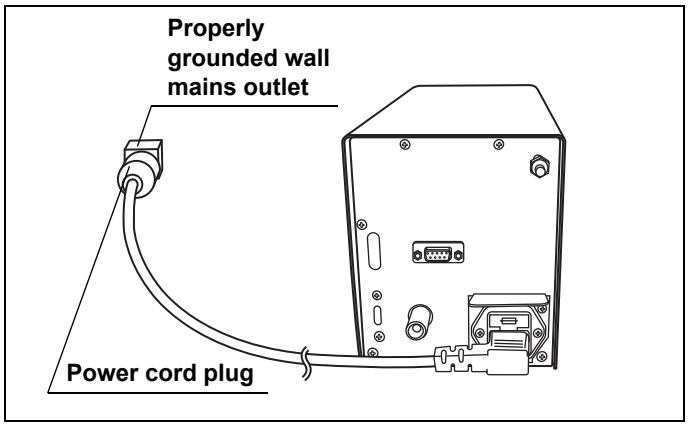


Figure 1

- To ensure electrical safety, do not use this instrument with any of the following medical electrical equipment.
  - Medical electrical equipment that has not been approved for safe use in combination with this instrument.
  - Medical electrical equipment that has not been verified to be safe with respect to leakage current, etc.
- To ensure that the operation can be completed without complication in case of a malfunction, prepare a spare endoscopic CO_2 regulation unit as a backup.

WARNING

- Occurrences of hypercapnemia through CO_2 absorption have been reported in medical literature, primarily during laparoscopic surgery. Careful clinical review prior to the procedure should be undertaken by trained medical personnel to eliminate this potential risk. To avoid complications, monitor patient parameters such as PCO_2, electrocardiogram, body temperature, etc., while using the endoscopic CO_2 regulation unit.
  - Reference
    1) Norman J, Atkinson SA: The effect of cardiac sympathetic blockade on the relationship between cardiac output and carbon dioxide tension in the anesthetized dog. Br J Anaesth 42: 592 – 602, 1970
    2) Scott, D. B. and Julian, D. G.: Observations on cardiac arrhythmias during laparoscopy.
       Br. Med. J.,1: 411 – 413, 1972.
    3) Smith, I., Benzie, R. J., Gordon, N. L. M., et al.: Cardiovascular effects of peritoneal insufflation of carbon dioxide for laparoscopy. Br. Med. J., 3: 410 – 411, 1971.
    4) Lenz, R. J., Thomas, T. A. and Wilkins, D. G.: Cardiovascular changes during laparoscopy: Studies of stroke volume and cardiac output using impedance cardiography. Anaesthesia, 31: 4 – 12, 1976.
    5) Ishizaki, Y., Bandai, Y., Shimomura, K., et al.: Safe intra-abdominal pressure of carbon dioxide pneumoperitoneum during laparoscopic surgery. Surgery, 114: 549 – 554, 1993.
- The endoscopic CO_2 regulation unit has no function of intraluminal pressure measurement and automatic control.
- Always use the provided power cord with the endoscopic CO_2 regulation unit. Using another power cord may result in equipment failure or power cord burns. The provided power cord has been designed exclusively for the endoscopic CO_2 regulation unit and should not be used with other equipment.
- Be sure to turn the endoscopic CO_2 regulation unit OFF after use. If it is left ON after examination/operation, an accidental contact with the start/stop switch may start gas supply. This will not only empty the CO_2 gas cylinder but may also increase the CO_2 concentration in the environment.
- Use the endoscopic CO_2 regulation unit only under the conditions described in “Transportation, storage, and operating environments” on page 69. Use under other conditions may not only impair the normal performance, but may also result in equipment damage.
- Prepare spare CO_2 gas cylinders for quick replacement if the cylinder used during the procedure should run out.

WARNING

- Be sure that this instrument is not used adjacent to or stacked with other equipment (other than the components of this instrument or system) to avoid electromagnetic interference.
- Electromagnetic interference may occur on this instrument near equipment marked with the following symbol or other portable and mobile RF (Radio Frequency) communications equipment such as cellular phones. If electromagnetic interference occurs, mitigation measures may be necessary, such as reorienting or relocating this instrument, or shielding the location.

CAUTION

- Do not use a pointed or hard object to press the buttons on the front panel. This may damage the instrument.
- To prevent equipment damage, do not use it in a dusty environment.

Use in combination with the upper/lower gastrointestinal endoscope

WARNING

- Over-insufflating the lumen may cause patient pain, injury, bleeding, gas embolism and/or perforation.
- Anytime you observe an irregularity in the endoscopic CO_2 regulation unit, immediately stop using the endoscopic CO_2 regulation unit and withdraw the endoscope from the patient slowly as described in the endoscope's instruction manual.
- The CO_2 gas is normally emitted through the small hole in the endoscope's air/water valve. Persons in the operating room may be affected if the CO_2 concentration in the operating room increases. Be sure to ensure ventilation of the room.
- During use, always stop the device like light source from supplying air. If "Stop" is not selected, a mixture of air and CO_2 may be supplied into the patient body.
- To prevent the water in the water feed tank from flowing into this unit through the gas tube, install this unit in a position as high as possible compared to the water feed tank.

Use in combination with the lens cleaning sheath

WARNING

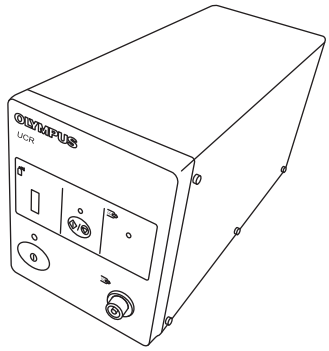
- Anytime you observe an irregularity in the endoscopic CO_2 regulation unit, immediately stop using the endoscopic CO_2 regulation unit and withdraw the endoscope from the patient slowly as described in the instruction manual for the lens cleaning sheath.
- To prevent gas embolism caused by intra-abdominal over-pressurization from the combined use of the lens cleaning sheath and a laser device, argon-enhanced coagulator, or other gas supply devices, carefully read and understand the following before using in case the insufflator is used in operation:
  - When performing endoscopic operation using a lens cleaning sheath and a laser device, argon-enhanced coagulator, or other gas supply devices simultaneously, both instruments become a source of supply for gas. Accordingly, the desired pressure in the abdomen is reached in a shorter time than when a lens cleaning sheath is used alone. In these cases, be careful that the cavity does not become over-pressurized. The laser device, argon-enhanced coagulator, and other gas supply devices are not equipped to monitor the cavity pressure (automatic termination of insufflation, warning light or alarm). Although the insufflator is equipped with these functions, it does not always prevent gas embolism inasmuch as this depends on the patient and the condition of the infected area. We ask that the physicians make a suitable judgment from a professional standpoint himself.
  - If the insufflator emits a caution (caution light or alarm) for cavity over-pressurization, quickly open the stopcock or valve of the trocar. Then, reduce the amount of outflow from the laser device, argon-enhanced coagulator, or other gas supply device. If use is continued while the alarm sounds, there is a risk of gas embolism due to cavity over-pressurization.
- Be careful not to feed CO_2 too much during CO_2 gas feed or spraying. Excessive CO_2 gas feed/spraying may cause pain to the patient and/or gas embolism. Reduce the use of CO_2 gas feed and spraying at the requisite minimum level.
- In case the insufflator is used in operation, open the trocar cannula stopcock if the pressure in the abdomen exceeds the set pressure by more than 5 mmHg.
- Do not attempt to insufflate the abdominal cavity using the lens cleaning sheath. Otherwise, patient injury and/or gas embolism may result.
- Do not use the endoscopic CO_2 regulation unit in combination with other than the compatible lens cleaning sheath (with the MAJ-1345, MAJ-1537, or MAJ-659, for example). Otherwise, CO_2 gas is fed continuously and patient pain and gas embolism can result.

Chapter 1 Checking the Package Contents

1.1 Checking the package contents

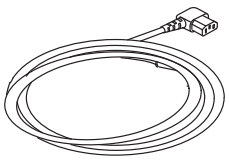
Match all items in the package with the components shown below. Inspect each item for damage. If the instrument is damaged, a component is missing or you have any questions, do not use the instrument; immediately contact Olympus.

❍ Endoscopic CO_2 regulation unit (UCR)

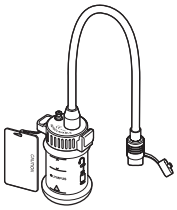


Endoscopic CO_2 regulation unit (UCR)

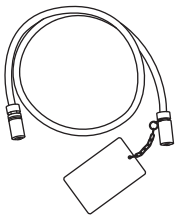
❍ Accessories



Power cord

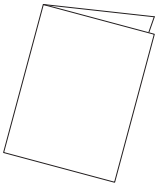


Water container (MAJ-902)[*1]



Gas tube (MAJ-1741)[*1]

Nut cover



Instruction manual

*1 When the endoscopic CO_2 regulation unit is combined with the lens cleaning sheath, the water container (MAJ-902) and Gas tube (MAJ-1741) are not used.

1.2 Optional items

The following Olympus items are optional items, which may be purchased separately according to the examination technique and/or patient condition.

- Low flow gas tube (MAJ-1742)
- Extra low flow gas tube (MAJ-1816)

The following Olympus items are optional items, which may also be purchased separately.

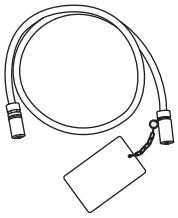
- Cylinder hose for UHI-3 (PIN, MAJ-1080)
- Cylinder hose for UHI-3 (DIN, MAJ-1081)
- Cylinder hose for UHI-3 (ISO, MAJ-1082)
- Medical gas pipeline adapter for UHI-3 (NIST, MAJ-1084)
- Medical gas pipeline adapter for UHI-3 (DISS, MAJ-1085)

The following non-Olympus item may also be purchased separately.

- Medical gas pipeline hose

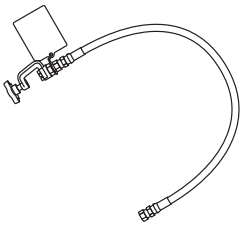
For other equipment combinations, refer to the “■ System chart” on page 67.

❍ Low flow gas tube (MAJ-1742), Extra low flow gas tube (MAJ-1816)



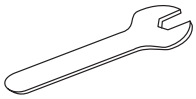
Low flow gas tube (MAJ-1742), Extra low flow gas tube (MAJ-1816)

❍ Cylinder hose for UHI-3 (PIN, MAJ-1080)*1

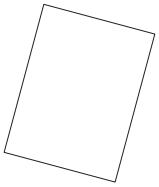


Hose for cylinder

Cap



Wrench

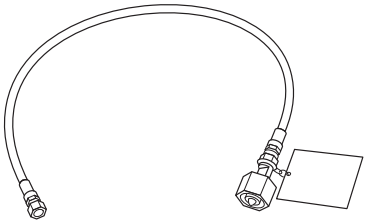


Replacement procedure for packing (O-ring)

*1 The endoscopic CO_2 regulation unit is compatible with the cylinder hose for UHI-3 (MAJ-1080).

The wrench is supplied for installation of the unit by an Olympus sales representative or service engineer only.
The wrench should be returned to Olympus directly after installation.

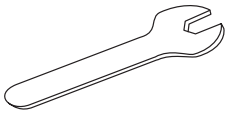
❍ Cylinder hose for UHI-3 (DIN, MAJ-1081), Cylinder hose for UHI-3 (ISO, MAJ-1082)*1



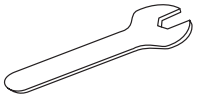
Hose for cylinder

Cap1

Cap2



Wrench (large)

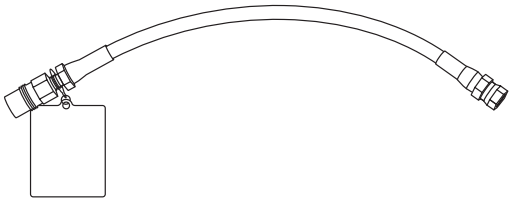


Wrench (small)

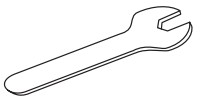
*1 The endoscopic CO_2 regulation unit is compatible with the cylinder hose for UHI-3 (MAJ-1081, MAJ-1082).

The wrench (small) is supplied for installation of the unit by an Olympus sales representative or service engineer only.
The wrench (small) should be returned to Olympus directly after installation.

❍ Medical gas pipeline adapter for UHI-3 (NIST, MAJ-1084), Medical gas pipeline adapter for UHI-3 (DISS, MAJ-1085)*1



Adapter for medical gas pipeline



Wrench

*1 The endoscopic CO_2 regulation unit is compatible with the medical gas pipeline adapter for UHI-3 (MAJ-1084, MAJ-1085).

The wrench is supplied for installation of the unit by an Olympus sales representative or service engineer only.
The wrench should be returned to Olympus directly after installation.

Chapter 2 Instrument Nomenclature

2.1 Symbols and descriptions

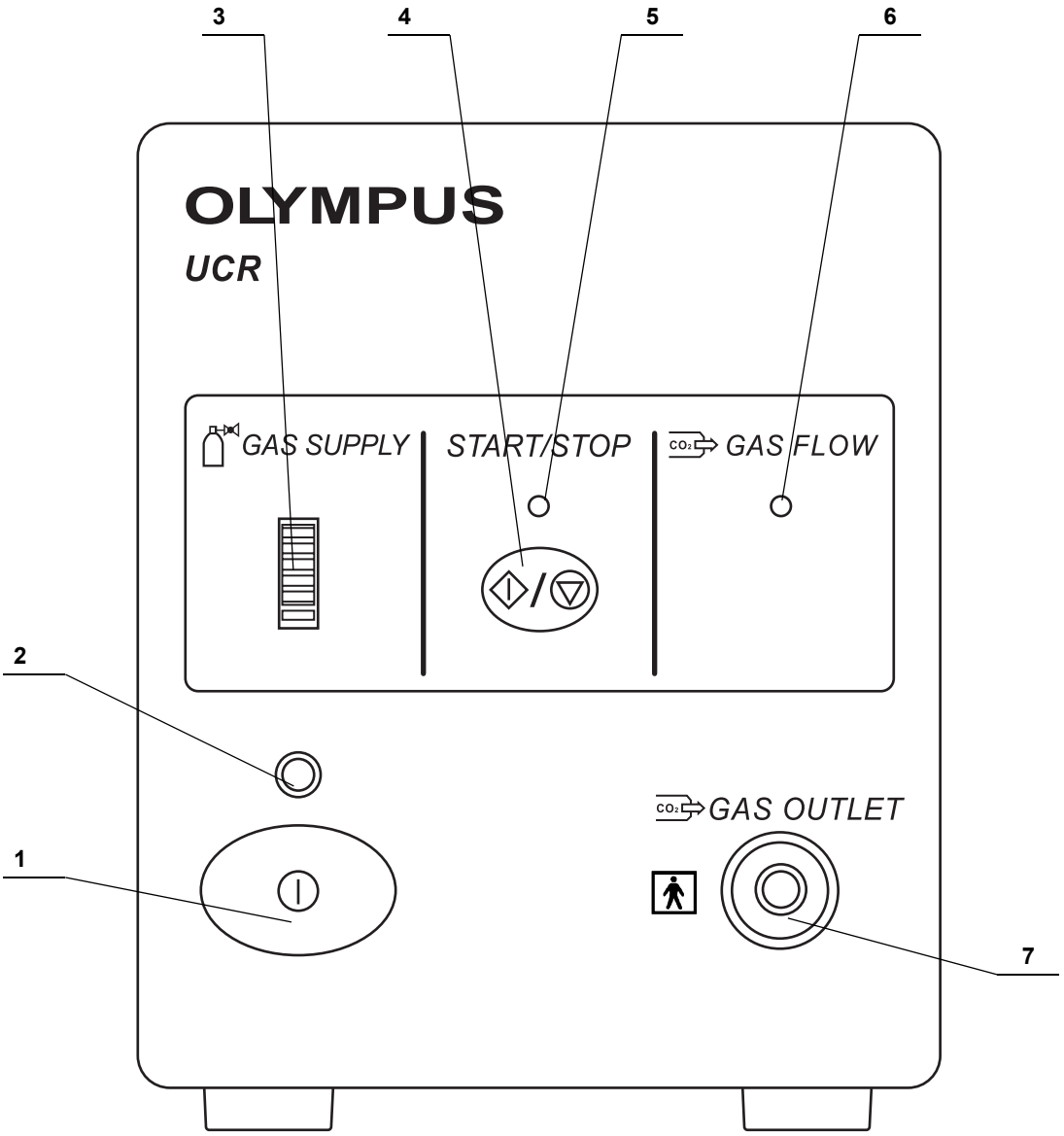
Front panel

Symbol	Description	Symbol	Description
	Power ON/OFF		Gas source pressure
	Start		CO_2 gas outlet
	Stop		Type BF applied part

Rear panel

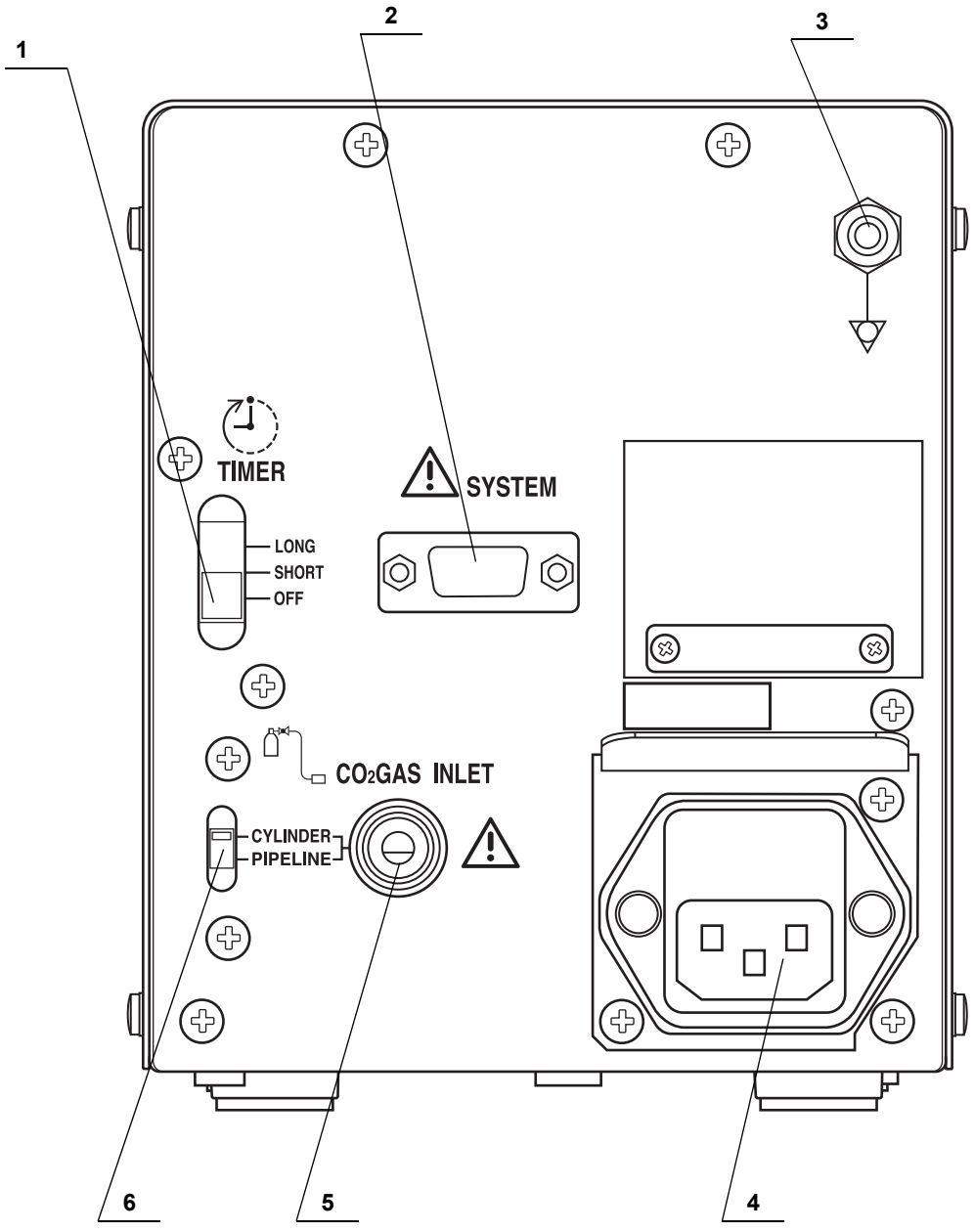
Symbol	Description	Symbol	Description
	CO_2 gas inlet		Timer
	Serial number		Potential equalization terminal
	Fuse		Alternating current
	Caution, refer to instructions.		

2.2 Front panel



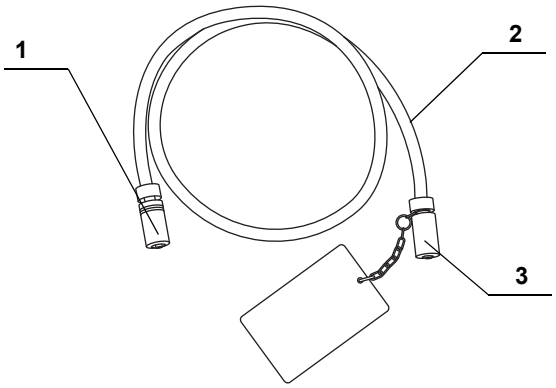
No.	Nomenclature	Description
1	Power switch	This switch is pressed to turn the endoscopic CO_2 regulation unit ON or OFF.
2	Power indicator	Lights up when the endoscopic CO_2 regulation unit is ON.
3	Gas pressure display	In the “Cylinder” mode, the gas pressure display indicates the supply pressure level of the connected CO_2 cylinder. The red LED at the bottom is illuminated when the gas supply is unavailable due to a drop of the supply pressure. In the “Pipeline” mode, the top green LED is illuminated.
4	Start/stop switch	Press the start/stop switch in the “Stop” mode to light up the start indicator and start the gas supply. Pressing the switch during gas supply extinguishes the start indicator and stops the gas flow.
5	Start indicator	The indicator blinks when the timer is set to “LONG” or “SHORT”, and illuminates steadily when the timer is “OFF”. The indicator is not illuminated in the stop mode regardless of timer ON/OFF.
6	Gas flow indicator	The gas flow indicator illuminates green when CO_2 gas is supplied, and is extinguished when no gas is supplied. The red LED lights give an alarm warning.
7	CO_2 gas outlet	Connect the gas supply tube or UCR connector of the lens cleaning sheath here.

2.3 Rear panel



No.	Nomenclature	Description
1	Timer switch	Select the timer period “LONG”, “SHORT”, or “OFF”.
2	System connector	This terminal is reserved for future system expansion.
3	Potential equalization terminal	In case of equipotential, connect this terminal to a potential equalization busbar of the electrical installation.
4	AC power inlet	Connect the power cord here.
5	CO_2 gas inlet	Connect the cylinder hose (MAJ-1080, MAJ-1081, MAJ-1082) or medical gas pipeline adapter (MAJ-1084, MAJ-1085) here.
6	Gas source selection switch	Select the gas supply source “Cylinder” mode or “Pipeline” mode.

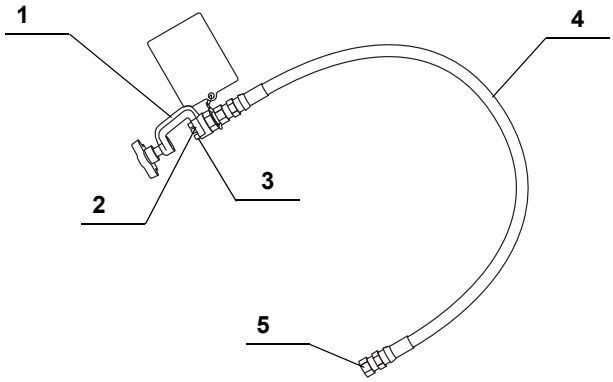
2.4 Gas tube (MAJ-1741)



No.	Nomenclature	Description
1	Instrument-side connector	Connect to the CO_2 gas outlet on the front panel of the endoscopic CO_2 regulation unit.
2	Tube	–
3	Water container-side connector	Connect to the water container.

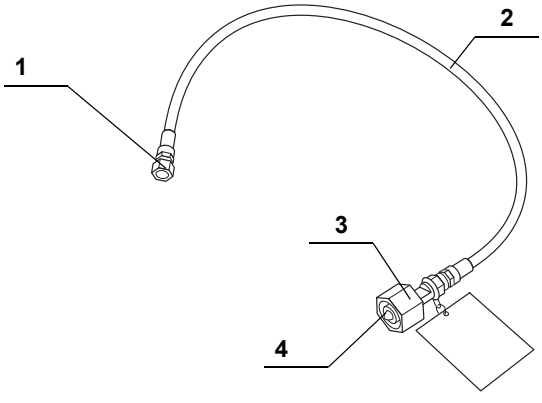
2.5 Optional components

Cylinder hose (PIN, MAJ-1080)



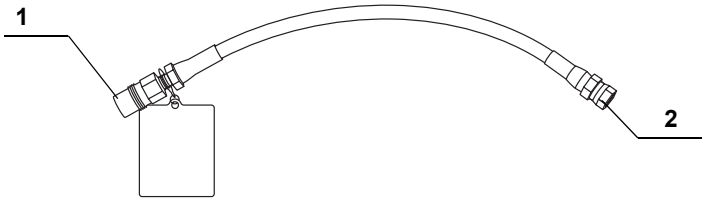
No.	Nomenclature	Description
1	Clamp	This clamp connects the cylinder hose to the gas cylinder.
2	Packing	This packing prevents the leak of CO_2 gas between the gas cylinder and cylinder hose.
3	Pin	Insert to the guide hole of the adapter of the CO_2 gas cylinder.
4	Hose	–
5	Connector	Use the supplied wrench to connect this connector to the CO_2 gas inlet on the rear panel of the endoscopic CO_2 regulation unit.

Cylinder hose (DIN, MAJ-1081), Cylinder hose (ISO, MAJ-1082)



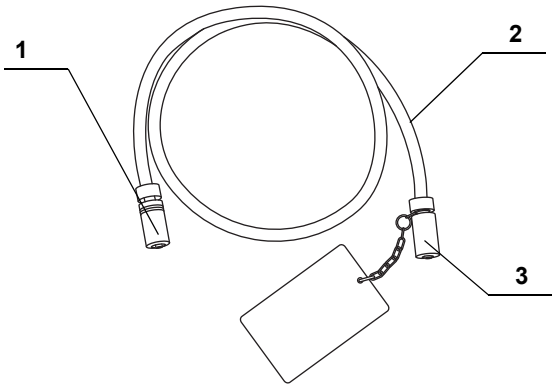
No.	Nomenclature	Description
1	Connector	Refer to Section 3.3.
2	Hose	–
3	Cylinder adapter	Use the supplied wrench (large) to connect to cylinder.
4	Packing (MAJ-1081)	This packing prevents the leak of CO_2 gas between the gas cylinder and cylinder hose.

Medical gas pipeline adapter (NIST, MAJ-1084), Medical gas pipeline adapter (DISS, MAJ-1085)



No.	Nomenclature	Description
1	Connector	Connect the medical gas pipeline hose here.
2	Connector	Use the supplied wrench to connect this connector to the CO_2 gas inlet on the rear panel of the endoscopic CO_2 regulation unit.

Low flow gas tube (MAJ-1742), Extra low flow gas tube (MAJ-1816)



No.	Nomenclature	Description
1	Instrument-side connector	Connect to the CO_2 gas outlet on the front panel of the endoscopic CO_2 regulation unit.
2	Tube	–
3	Water container-side connector	Connect to the water container.

Chapter 3 Installation and Connection

Prepare the instrument and other compatible equipment (shown in the "■ System chart" on page 67) before each use.
Refer to the instruction manuals for each piece of equipment. Install and connect all equipment as follows:

When the endoscopic CO_2 regulation unit is combined with the lens cleaning sheath, refer to the instruction manual for the lens cleaning sheath before installing and connecting this instrument.

3.1 Installation workflow

See the installation workflow in Figure 3.1 below. Follow each step of the workflow before using the endoscopic CO_2 regulation unit.

1 **Install the instrument.**
→Section 3.2 on page 26

2 **Connect the instruments to a CO_2 gas cylinder or the medical gas pipeline adapter.**
- CO_2 gas cylinder→Section 3.3 on page 26
- Medical gas pipeline adapter→Section 3.4 on page 29

3 **Connect the instruments to the power source.**
→Section 3.5 on page 30

4 **Connect the instruments to the gas tube.*1**
→Section 3.6 on page 32

5 **Connect the water container and endoscope.*1**
→Section 3.7 on page 34

*1 When the lens cleaning sheath is used, do not connect the gas tube/water container to the endoscope.

3.2 Installation of the endoscopic CO_2 regulation unit

CAUTION

- Never place the endoscopic CO_2 regulation unit on its side or upside down.
- If the endoscopic CO_2 regulation unit is to be placed on a mobile workstation, the mobile workstation must be of adequate strength and size to safely hold it.
- Do not place any object on top of the instruments. Otherwise, equipment deformation and/or damage can result.
- Clean and vacuum dust the ventilation grills using a vacuum cleaner. Otherwise, the endoscopic CO_2 regulation unit may break down from overheating.

1. Make sure that the operation of the instrument will take place according to the conditions described in “Transportation, storage, and operating environments” on page 69.
2. Place the endoscopic CO_2 regulation unit on a level, stable surface.

3.3 Connecting a CO_2 gas cylinder

The optional cylinder hose (MAJ-1080, MAJ-1081, MAJ-1082) is required for connection of the CO_2 cylinder.

DANGER

Using other gases than medical grade CO_2 may result in fire, poisoning, complications, etc. In addition, oil, impurities, etc., may penetrate the interior of the endoscopic CO_2 regulation unit and impede proper CO_2 gas insufflation.

CAUTION

- If the cylinder hose is damaged, replace it with a new one.
- Always keep the gas cylinder in the upright position. Fasten the cylinder to a wall or another stable structure to prevent it from toppling. If the gas cylinder is placed horizontally or in an inclined position, liquefied CO_2 may enter the insufflation channel inside the endoscopic CO_2 regulation unit and normal insufflation may become impossible.
- Olympus is not liable for any injury or damage due to improper cylinder connection.

CAUTION

- If a significant gas leak is noticed from within the endoscopic CO_2 regulation unit, stop using the endoscopic CO_2 regulation unit immediately and contact Olympus.

NOTE

Attach the CO_2 cylinder holder (MAJ-188, MAJ-1614) to the Olympus mobile workstation (WM-NP1 or WM-WP1), and attach the CO_2 cylinder to the holder.

The cylinder hose must be attached to the endoscopic CO_2 regulation unit by Olympus personnel during installation. The enclosed nut cover will be fixed during the installation when the cylinder hose and the endoscopic CO_2 regulation unit are connected by Olympus personnel.

1 Inspect the cylinder hose for the endoscopic CO_2 regulation unit for damage, cracks, and other irregularities.

2 Set the gas source selection switch on the rear panel to the “Cylinder” mode.

3 Use the supplied wrench to attach the cylinder hose to the CO_2 gas inlet on the rear panel of the endoscopic CO_2 regulation unit and securely tighten it with a force of about 24.5 N·m (2.5 kgf/m) clockwise.

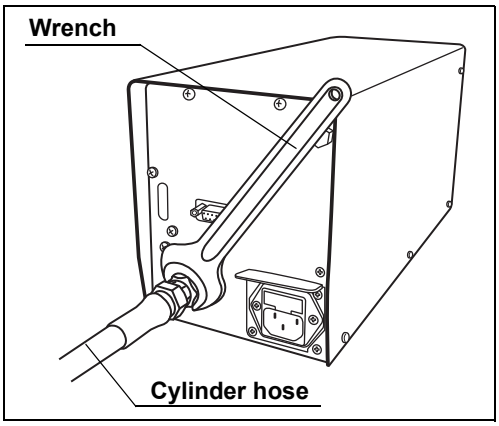


Figure 3.1

4 When using the cylinder hose (PIN, MAJ-1080), attach the clamp to a gas cylinder filled with CO_2 gas. Attach the clamp to the adapter by placing the pin of the clamp into the guide hole of the cylinder, and tighten the handle with a force of about 17.2 N·m (1.8 kgf/m).

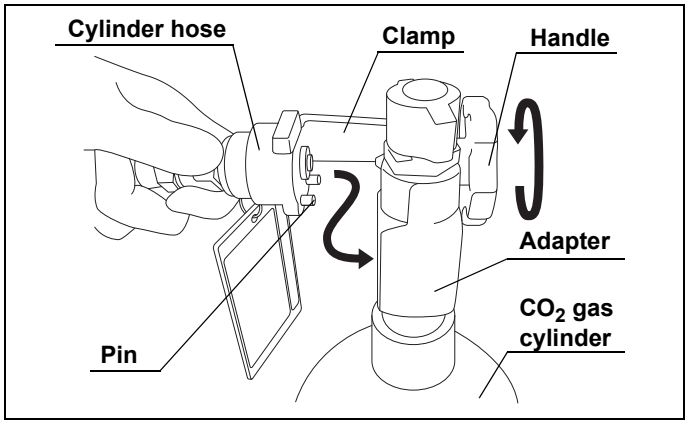


Figure 3.2

5 When using the cylinder hose (MAJ-1081, MAJ-1082), use the supplied wrench to attach the cylinder hose's adapter to a gas cylinder filled with CO_2 gas.

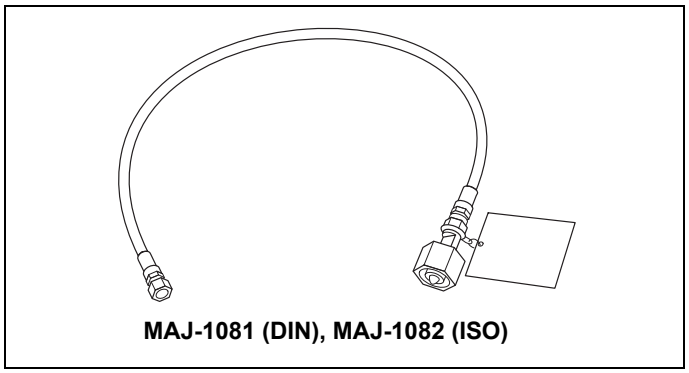


Figure 3.3

6 Confirm that the endoscopic CO_2 regulation unit and the CO_2 gas cylinder are correctly connected and open the gas cylinder valve by turning it counterclockwise.

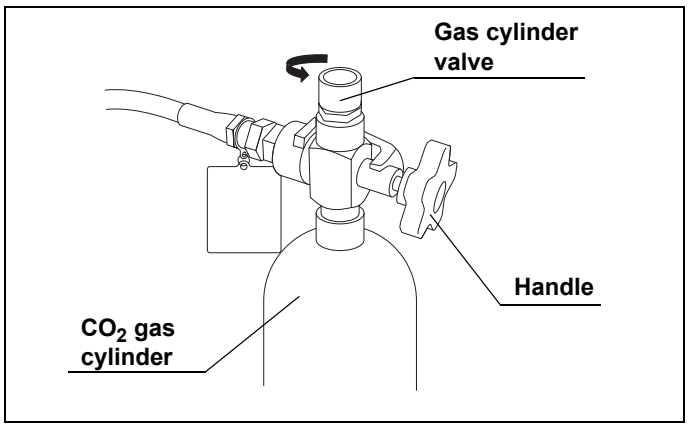


Figure 3.4

3.4 Connecting the medical gas pipeline adapter (MAJ-1084, MAJ-1085)

The optional medical gas pipeline adapter (MAJ-1084 or MAJ-1085) is required for connection to the medical gas pipeline.

DANGER

Using gases other than medical grade CO_2 may result in fire, poisoning, complications, etc. In addition, oil, impurities, etc., may penetrate the interior of the endoscopic CO_2 regulation unit and impede proper CO_2 gas insufflation.

CAUTION

- If the medical gas pipeline adapter is damaged, replace it with a new one.
- Connect the gas supply hose to the endoscopic CO_2 regulation unit before connecting it to the CO_2 gas connector. Otherwise, there is a danger of significant gas leakage.
- For proper insufflation of the CO_2 gas, confirm that the pressure of the medical gas pipeline is more than 343.2 kPa (3.5 kgf/cm^2) and below the upper limit given in ISO 7396 (1400 kPa).
- Use MAJ-1084 for NIST type fittings, and MAJ-1085 for DISS type fittings. Do not use any other hoses than those specified.

NOTE

Olympus does not sell medical gas pipeline hoses. Use an appropriate hose for the medical gas pipeline being used.

The medical gas pipeline adapter must be attached to the endoscopic CO_2 regulation unit by Olympus personnel during installation. The enclosed nut cover will be fixed during the installation when the cylinder hose and the endoscopic CO_2 regulation unit are connected by Olympus personnel.

1. Inspect the medical gas pipeline adapter for the endoscopic CO_2 regulation unit for damage, cracks, and irregularities.
2. Set the gas source selection switch on the rear panel to the “Pipeline” mode.
3. Use the supplied wrench to attach the medical gas pipeline adapter for the endoscopic CO_2 regulation unit to the CO_2 gas inlet on the rear panel of the endoscopic CO_2 regulation unit and securely tighten it. Tighten with a force of about 24.5 N·m (2.5 kgf/m). (See Figure 3.1)

4 Connect the medical gas pipeline adapter to the medical gas pipeline hose and tighten the adapter manually with a force (about 5 N·m (0.5 kgf/m)) until the position where the connector is stopped. (See Figure 3.5)

5 Connect the hose to the CO_2 gas connector of the medical gas pipeline.

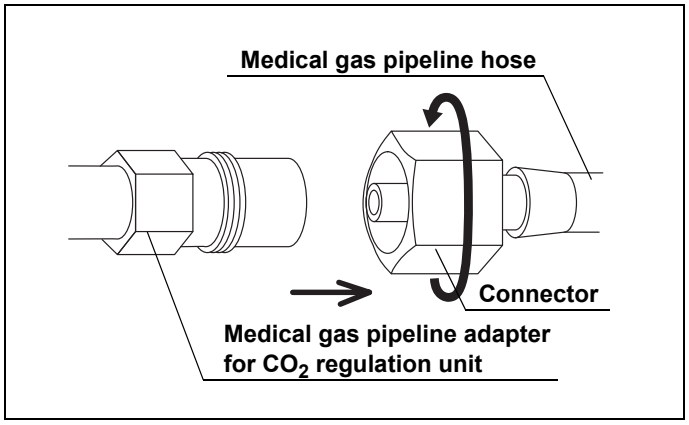


Figure 3.5

3.5 Connecting to an AC power supply

DANGER

- Be sure to connect the power plug of the power cord directly to a grounded wall mains outlet. If the endoscopic CO_2 regulation unit is not grounded properly, it can cause an electric shock and/or fire.
- Do not connect the power plug to the 2-pole power circuit with a 3-pole to 2-pole adapter. It can prevent proper grounding and cause an electric shock.
- Do not connect the power plug using an extension cord. It can prevent proper grounding and cause an electric shock.

CAUTION

- Always keep the power plug dry. A wet power plug may cause electric shocks.
- Confirm that the hospital grade wall mains outlet to which this instrument is connected has adequate electrical capacity that is larger than the total power consumption of all connected equipment. If the capacity is insufficient, fire can result or a circuit breaker may trip and turn OFF this instrument and all other equipment connected to the same power circuit.
- Do not bend, pull or twist the power cord. Equipment damage including separation of the power plug and disconnection of the cord wire as well as fire or electric shock can result.

CAUTION

- Be sure to connect the power plug securely to prevent erroneous unplugging during use. Otherwise, the equipment will not function.
- Do not extend a single wall mains outlet into multiple outlets for connecting the power cords of both the endoscopic CO_2 regulation unit and electrosurgical unit. Otherwise, malfunction of the equipment may result.

1 Confirm that the endoscopic CO_2 regulation unit is OFF.

2 Connect the power cord of the endoscopic CO_2 regulation unit to the AC power inlet.

3 Connect the power cord plug directly to a 3-pin hospital grade AC outlet (wall mains outlet) that meets the power requirements indicated on the electrical rating plate on the rear panel of the endoscopic CO_2 regulation unit.

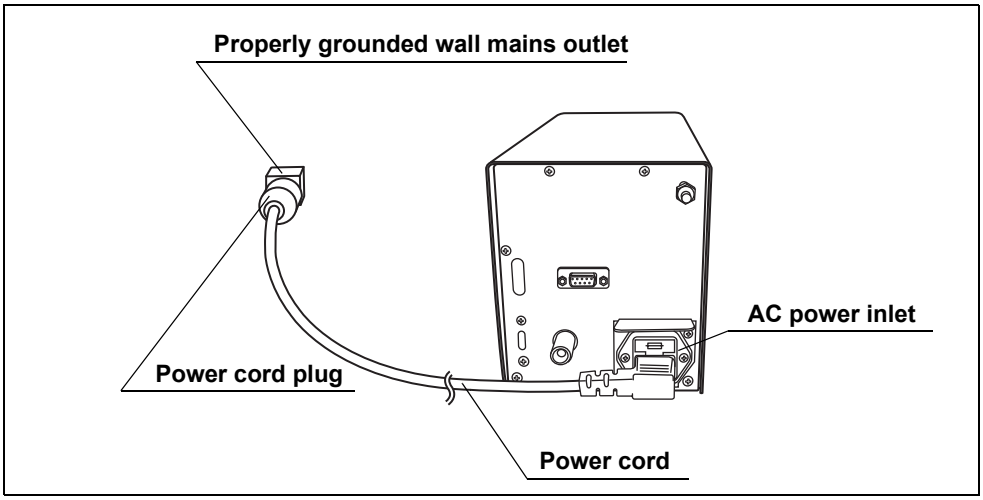


Figure 3.6

3.6 Connecting the Gas tube (MAJ-1741), Low flow gas tube (MAJ-1742), and Extra low flow gas tube (MAJ-1816)

WARNING

- Make sure the inside of the tube is clean. Using a dirty tube can cause infections in the patient. If it is dirty, dispose of it according to the instructions in Chapter 6, “Reprocessing, Storage, Disposal, and Transportation” and replace it with a new one.
- Connect the gas tube (MAJ-1741, MAJ-1742, MAJ-1816) to the equipment as described below.
- Connect the water container (MAJ-902) to the water container-side connector. Do not connect anything other than the water container (such as intravenous sets, a trocar, veress needle, etc.).
- Always use the provided gas tube (MAJ-1741, MAJ-1742, MAJ-1816). Non-Olympus tubes may impair the performance and lead to incorrect operation.
- Never attempt to alter the tube by cutting, splicing, connecting several tubes, etc.
- If the tube is damaged, replace it with a new tube.
- Water drops remaining on/inside the tube may cause damage to internal sensors (e.g., short circuit) or cause an electric shock. Dry the tube thoroughly before use.

NOTE

- The Low flow gas tube (MAJ-1742) and the Extra low flow gas tube (MAJ-1816) are optional items.
- Use the Gas tube (MAJ-1741), Low flow gas tube (MAJ-1742), and Extra low flow gas tube (MAJ-1816) according to the examination technique and/or patient condition.

1 Connect the instrument-side connector end of the gas tube to the CO_2 gas outlet of the endoscopic CO_2 regulation unit by turning it clockwise.

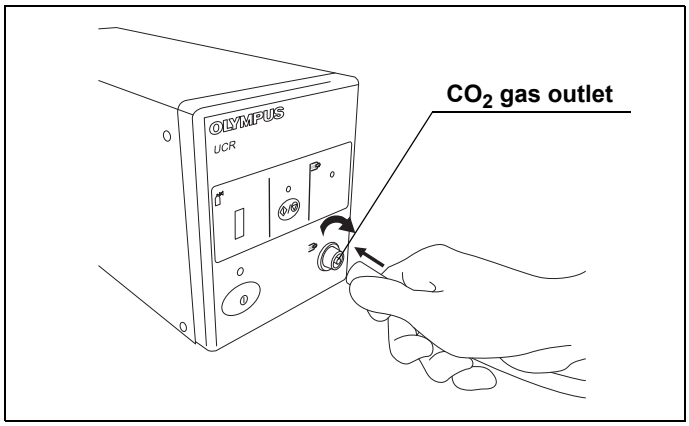


Figure 3.7

2 Connect the other connector of the gas tube to the connector of the water container (MAJ-902) by turning it clockwise.

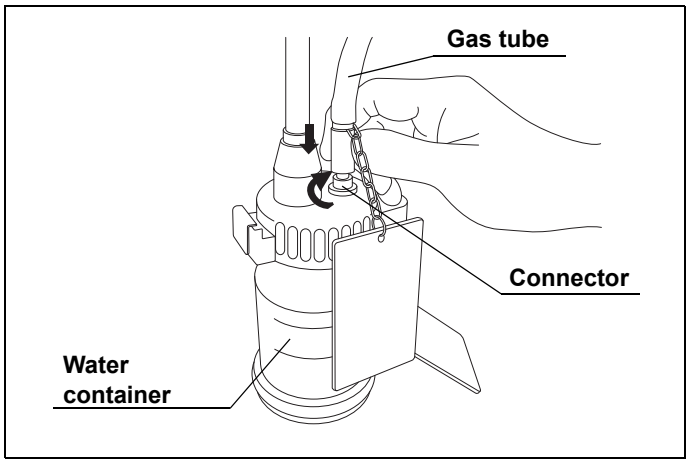


Figure 3.8

3.7 Connecting the water container and endoscope

Connect the equipment, such as the water container (MAJ-902) and endoscope, as described in their instruction manuals.

Chapter 4 Inspection

4.1 Inspection before use

WARNING

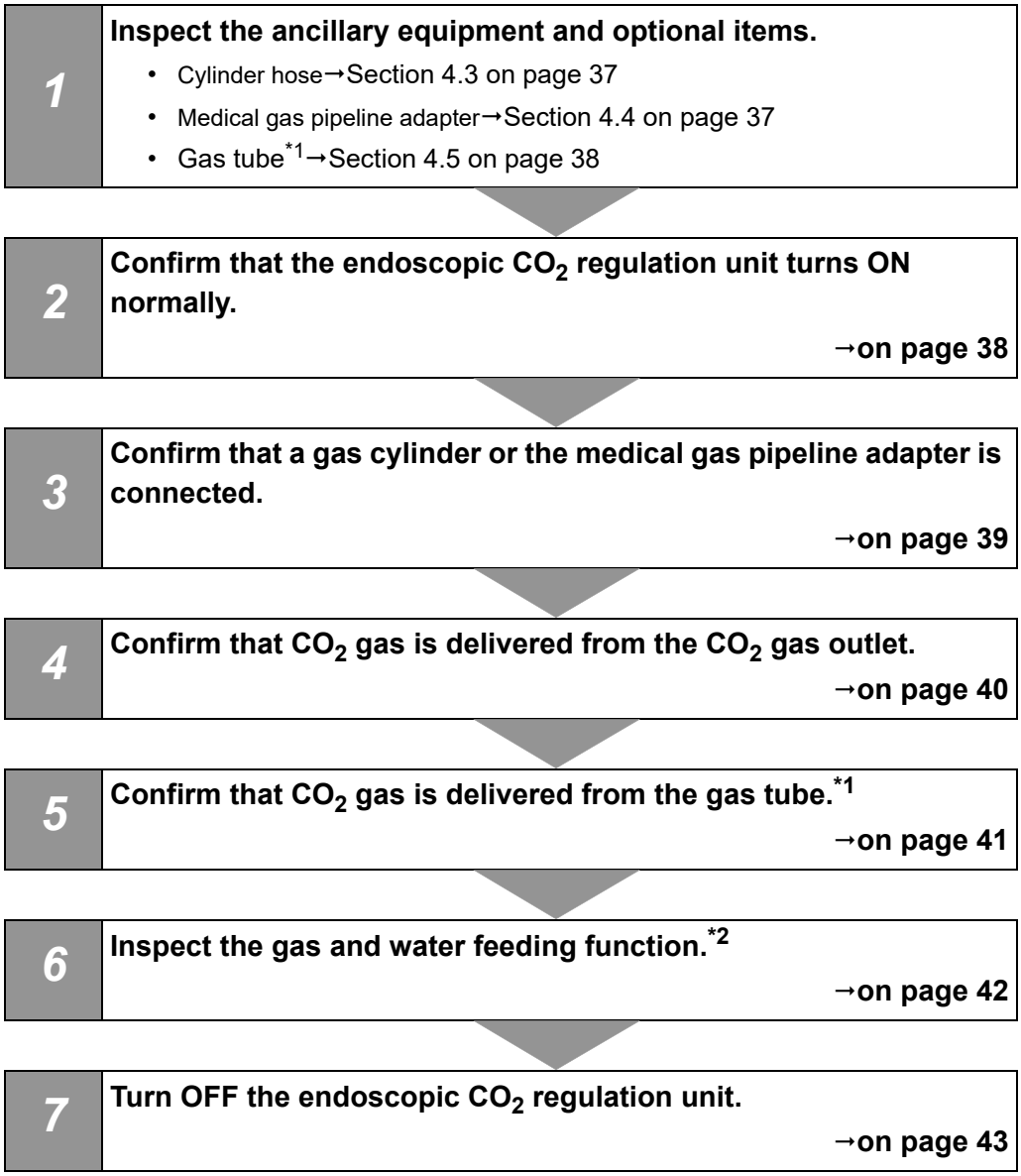
- Review Chapter 3, “Installation and Connection” thoroughly, and prepare the instruments properly before inspection. If the equipment is not properly prepared before each use, equipment damage, patient and operator injury can result.
- Before each case, inspect this instrument as instructed below. Inspect other equipment to be used with this instrument as instructed in their respective instruction manuals. Should any irregularity be observed, do not use the instrument and refer to Chapter 7, “Troubleshooting”. If the irregularity is still observed after consulting Chapter 7, contact Olympus. Damage or irregularity may compromise patient or user safety and may result in more severe equipment damage.

Inspect the endoscopic CO_2 regulation unit and other equipment to be used with the endoscopic CO_2 regulation unit. Refer to the respective instruction manuals for each piece of equipment.

When the endoscopic CO_2 regulation unit is combined with the lens cleaning sheath, the user does not need to comply with all of the instructions given in this chapter, as the instructions that must be followed are defined in the instruction manual for the lens cleaning sheath. Read the instructions before inspecting this instrument.

4.2 Inspection workflow

See the inspection workflow in Figure 4.1 below. Follow each step of the workflow for inspection of the endoscopic CO_2 regulation unit before use.



*1 When the lens cleaning sheath is used, the gas tube is not used so it therefore does not need inspection.

*2 When the lens cleaning sheath is used, the gas and water feeding functions should be inspected by following the instruction manual for the lens cleaning sheath.

4.3 Inspection of the cylinder hose (MAJ-1080, MAJ-1081, MAJ-1082)

WARNING

- If the cylinder hose is damaged, replace it with a new one.
- If the packing is damaged, replace it with a new one or replace the cylinder hose with a new one.
- For information on how to replace the packing, refer to the leaflet “Replacement procedure for packing (O-ring)”, which is included with the cylinder hose for UHI-3 (MAJ-1080).

1 Inspect the cylinder hose for scratches, cracks, or other damage.

2 Inspect the packing inside the clamp for scratches, cracks or other damage.

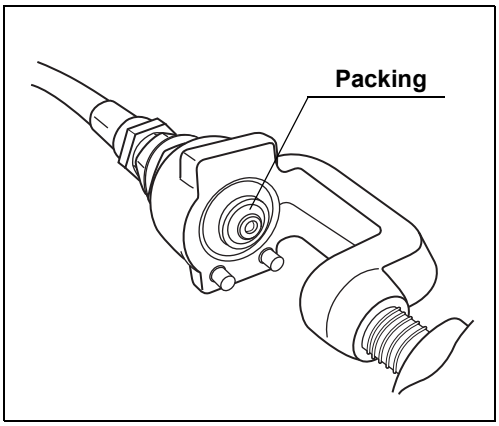


Figure 4.1

4.4 Inspection of the medical gas pipeline adapter (MAJ-1084, MAJ-1085)

WARNING

If the medical gas pipeline adapter is damaged, replace it with a new one.

Inspect the packing inside the clamp for scratches, cracks or other damage.

4.5 Inspection of the Gas tube (MAJ-1741), Low flow gas tube (MAJ-1742), and Extra low flow gas tube (MAJ-1816)

WARNING

- If the gas tube is damaged, replace it with a new tube.
- Water drops remaining on or inside the tube could cause damage to internal sensors (e.g., short circuit) or cause an electric shock. Dry the tubes thoroughly before use.
- Make sure the inside of the tube is clean. Using a dirty tube can cause infections in the patient. If it is dirty, dispose of it according to the instructions in Chapter 6, “Reprocessing, Storage, Disposal, and Transportation” and replace it with a new one.

1. Check the gas tube ID on the tag and confirm that the gas tube matches the selected flow rate.
2. Inspect the tube and connector for scratches, cracks, or other damage. Discard and replace any damaged equipment.
3. Confirm that the tube and the connector are dry.

4.6 Inspection of the endoscopic CO_2 regulation unit

■ Inspection of the power supply

CAUTION

If the power indicator does not light up, the instrument may be damaged. Immediately turn the endoscopic CO_2 regulation unit OFF, disconnect the power plug from the hospital grade receptacle (wall mains outlet) and contact Olympus.

1. Press the power switch to turn the endoscopic CO_2 regulation unit ON.
2. Confirm that the power indicator lights up.

■ *Inspection of the gas supply*

❍ When a gas cylinder is connected

1 Confirm that the “Cylinder” mode is selected using the gas source selection switch on the rear panel and that the gas pressure display indicates at least three green LED bars.

2 Close the gas cylinder valve and confirm that the supply pressure remains unchanged.

CAUTION

- The gas pressure display displays not the remaining amount of the CO_2 gas but the supply pressure. Always have a CO_2 gas cylinder available in case the supply pressure drops down.
- If the supply pressure drops down, gas is leaking. Check the connection of the cylinder hose again. If the supply pressure continues to move down, stop operating and immediately contact Olympus.

3 Disconnect the gas tube from the CO_2 gas outlet of the endoscopic CO_2 regulation unit.

4 Press the start/stop switch to start gas supply.

5 While insufflation is performed, confirm that the gas pressure display moves down. When the red LED illuminates, confirm that the insufflation stops and the alarm sounds.

6 Connect the gas tube to the endoscopic CO_2 regulation unit as described in Section 3.6, “Connecting the Gas tube (MAJ-1741), Low flow gas tube (MAJ-1742), and Extra low flow gas tube (MAJ-1816)” and open the gas cylinder valve after inspection.

CAUTION

If the gas flow indicator lights red, the gas cylinder valve is not open or the CO_2 gas volume in the cylinder is insufficient. If the warning alarm continues even if the gas cylinder valve is open, the CO_2 gas volume in the cylinder is insufficient. In this case, replace it with a new cylinder, as described in Section 3.3, “Connecting a CO_2 gas cylinder”. Always have a spare CO_2 gas cylinder available.

When the medical gas pipeline adapter is connected

1. Confirm that the “Pipeline” mode is selected using the gas source selection switch on the rear panel and that the top green LED in the gas pressure display is lit.
2. Press the start/stop switch to confirm that the gas supply is activated. If gas supply is stopped, check the connections of the hose, the endoscopic CO_2 regulation unit and the medical gas pipeline adapter, and inspect the medical gas pipeline system to confirm that the supply pressure is at the specified level.
3. Press the start/stop switch to stop the gas supply.

Inspection of insufflation

1. Disconnect the gas tube from the CO_2 gas outlet of the endoscopic CO_2 regulation unit.
2. Press the start/stop switch to start gas supply.
3. Confirm that CO_2 gas is supplied from the CO_2 gas outlet and the start indicator and the gas flow indicator illuminate green.
4. Press the start/stop switch to stop the gas supply, and confirm that the gas flow indicator is OFF. If the red LED is illuminated, an irregularity is observed with the instrument. Immediately stop using it and contact Olympus.
5. Connect the gas tube to the endoscopic CO_2 regulation unit as described in Section 3.6, “Connecting the Gas tube (MAJ-1741), Low flow gas tube (MAJ-1742), and Extra low flow gas tube (MAJ-1816)” after inspection.

CAUTION

If no CO_2 gas is supplied, immediately stop using the instrument and contact Olympus.

■ *Inspection of gas feeding at gas tube*

1 Connect the instrument-side connector end of the gas tube to the CO_2 gas outlet of the endoscopic CO_2 regulation unit.

2 Disconnect the gas tube from the connector of the water container.

3 Press the start/stop switch to start gas supply.

4 Confirm that CO_2 gas is supplied from the water container-side connector and that the start indicator and the gas flow indicator illuminate green.

CAUTION

If no CO_2 gas supplied, the gas tube may be clogged. Replace the gas tube with a new one.

5 Cover the port on the water container-side connector of the gas tube with a clean fingertip and confirm that the gas flow indicator is OFF. Then, straighten the gas tube and confirm that gas cannot be heard leaking and that the gas flow indicator remains extinguished.

CAUTION

If the gas can be heard leaking, or the gas flow indicator illuminates, the gas tube may be damaged. Replace the gas tube with a new one.

6 Connect the gas tube to the endoscopic CO_2 regulation unit as described in Section 3.6, “Connecting the Gas tube (MAJ-1741), Low flow gas tube (MAJ-1742), and Extra low flow gas tube (MAJ-1816)” after inspection.

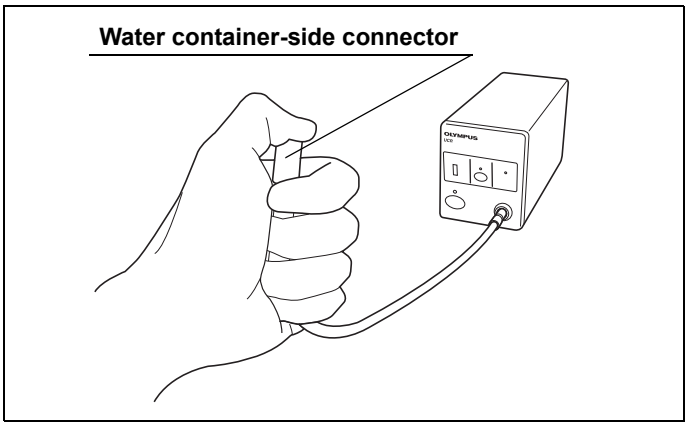


Figure 4.2

■ *Inspection of gas and water feeding*

When using a water container to feed water from the endoscope, inspect the air and water feeding function as follows:

1 Confirm that the light source stops supplying air.

2 Press the start/stop switch to start gas supply.

3 Immerse the distal end of the connected endoscope in sterile water and operate the endoscope's insufflation function following the instructions given in the endoscope's instruction manual.

4 Cover the hole of the air/water valve of the endoscope, and press it so that air bubbles are emitted. Press the start/stop switch and confirm that the air bubbles from the air/water nozzle stop. (See Figure 4.3)

5 Remove the distal end of the endoscope from the sterile water and press the start/stop switch. Operate the endoscope's water feeding function following the instructions given in the endoscope's instruction manual. Confirm that water is emitted from the air/water nozzle.

WARNING

If gas feeding cannot be stopped using the air/water valve, press the start/stop switch to stop the gas supply and then replace it with a new valve.

NOTE

The gas flow indicator is OFF when water feeding has been continued for a certain period. Even if the gas flow indicator illuminates again after the water supply has stopped, it is not a malfunction.

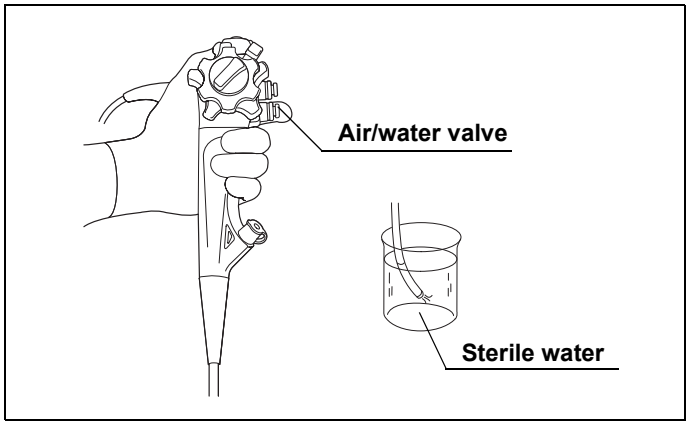


Figure 4.3

■ *Power OFF*

1 Press the power switch to turn the endoscopic CO_2 regulation unit OFF.

2 The power indicator goes OFF after the power switch is pressed.

CAUTION

If the power indicator remains lit after this instrument has been turned OFF, do not use this instrument, unplug the power cord from the power outlet and contact Olympus.

Chapter 5 Operation

5.1 Precaution for operation

This chapter explains the workflow of endoscopic observation using the endoscopic CO_2 regulation unit.
The operator of the endoscopic CO_2 regulation unit must be a physician or medical personnel under the supervision of a physician and must have received sufficient training in clinical endoscopic technique. This manual, therefore, does not explain or discuss clinical endoscopic procedures. It only describes basic operation and precautions related to the operation of the endoscopic CO_2 regulation unit.

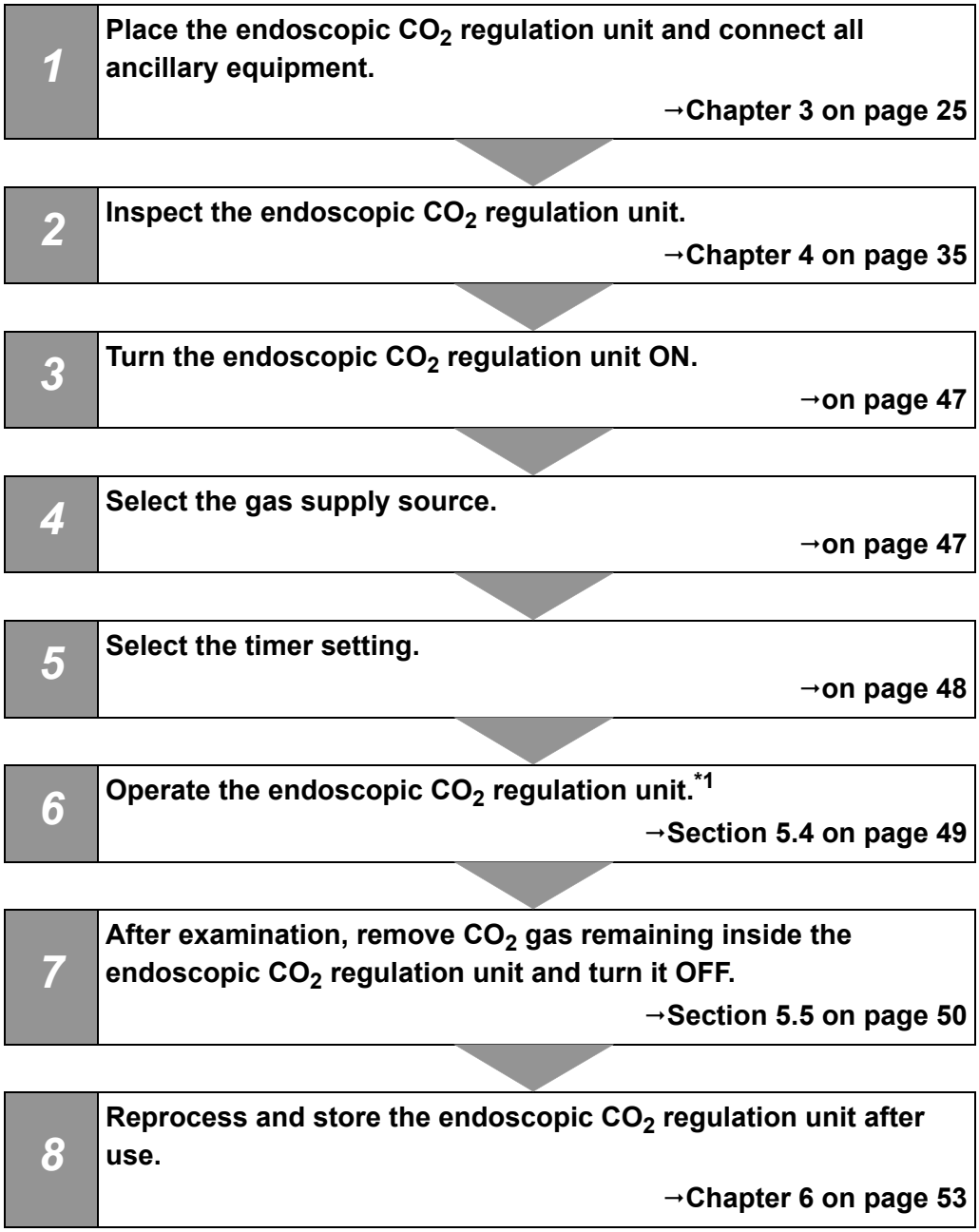
When using the lens cleaning sheath, follow the instructions given in the manual for the lens cleaning sheath.

WARNING

- The CO_2 gas is normally emitted through the small hole in the endoscope's air/water valve. Persons in the operating room may be affected if the CO_2 concentration in the operating room increases. Be sure to ensure ventilation of the room.
- If an irregularity is observed or the gas flow indicator illuminates red, immediately stop using the endoscopic CO_2 regulation unit and take the following actions:
  - Close the gas cylinder valve.
  - Withdraw the endoscope from the patient slowly as described in the endoscope's instruction manual.
- During use, always stop the device like light source from supplying air. If "Stop" is not selected, a mixture of air and CO_2 may be supplied into the patient body.
- After an examination is completed, turn OFF the endoscopic CO_2 regulation unit. If the unit is not turned OFF after an examination, the unit may continue to supply gas when the gas supply button is pressed by mistake. In such a case, the CO_2 gas cylinder may be emptied, and the ambient CO_2 concentration may increase.

5.2 Operation flow

See the operation workflow in Figure 5.1 below. Follow each step of the workflow for using the endoscopic CO_2 regulation unit.



*1 When using the lens cleaning sheath, follow the instructions given in the manual for the lens cleaning sheath.

5.3 Function setting before use

■ Turn the endoscopic CO_2 regulation unit ON

Press the power switch to turn the endoscopic CO_2 regulation unit ON. The power indicator lights up.

■ Selecting the gas supply source

❍ Connected to a gas cylinder

1 Set the gas source selection switch on the rear panel to the “Cylinder” mode. (See Figure 5.1)

2 The gas pressure display shows the gas supply pressure of the CO_2 cylinder. If the supply pressure drops below the minimum required level, an alarm tone is generated, the red LED is illuminated and the instrument stops automatically.

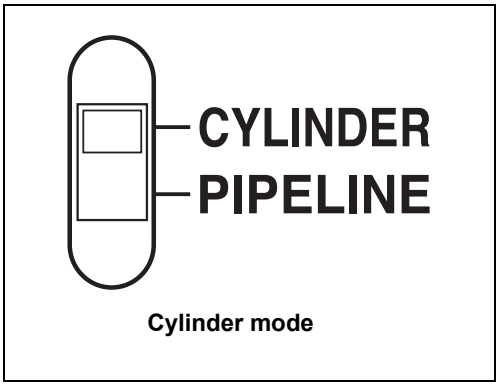


Figure 5.1

❍ Connected to the medical gas supply of the hospital

1 Set the gas source selection switch on the rear panel to the “Pipeline” mode.

2 A green LED in the gas pressure display illuminates. The gas supply operation described on the previous page is not available in this mode.

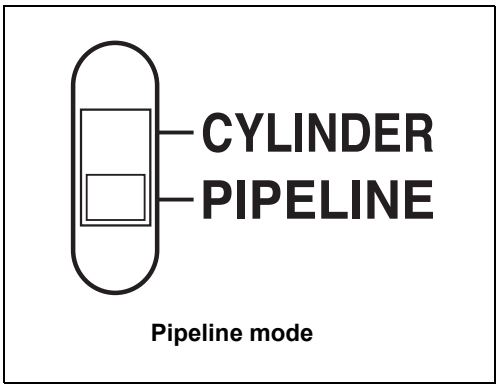


Figure 5.2

■ *Timer setting*

The endoscopic CO_2 regulation unit has a timer built in, and will automatically stop feeding gas as the set time elapses.

NOTE

See below the available timer settings.
Select OFF to negate the automatic gas function.

Timer setting	Time before gas stop
LONG	**About 30 minutes**
SHORT	**About 15 minutes**
OFF	**The automatic stop function is turned off.**

Table 5.1

Slide the timer switch to select the timer setting.

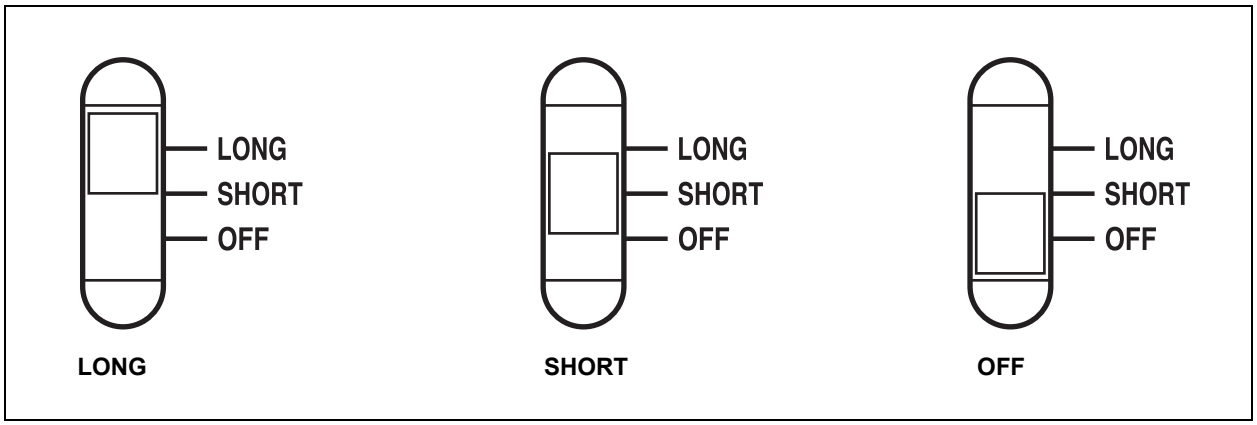


Figure 5.3

5.4 Gas supplying and water feeding

1. Confirm that the gas tube is properly connected according to Section 3.6, “Connecting the Gas tube (MAJ-1741), Low flow gas tube (MAJ-1742), and Extra low flow gas tube (MAJ-1816)”.
2. Press the start/stop switch to start gas supply.
3. The gas supply indicator illuminates and the endoscopic CO_2 regulation unit starts supplying gas.
4. Supply gas or water according to the instruction manual for the endoscope.
5. After the examination, press the start/stop switch again to stop the gas supply.

WARNING

If the gas supply from the endoscopic CO_2 regulation unit cannot be stopped by pressing the start/stop switch, stop the gas supply by turning the valve of the CO_2 gas cylinder clockwise.

CAUTION

Be sure to stop the gas supply from the endoscopic CO_2 regulation unit before disconnecting any gas tubes, water container, endoscope, or lens cleaning sheath. As the gas supply is not designed to automatically stop when disconnection takes place, replacing the endoscope without stopping the gas flow will not only empty the CO_2 gas cylinder but may also increase the CO_2 concentration in the environment.

NOTE

When the endoscopic CO_2 regulation unit is combined with the Gas tube (MAJ-1741), the Low flow gas tube (MAJ-1742), or Extra low flow gas tube (MAJ-1816), the gas flow rate is approximately equivalent to that when the airflow pressure level setting of the light source is set to “High”, “Medium”, and “Low”. For the standard gas flow rate with different types of endoscopes, refer to the endoscope’s instruction manual.

5.5 After use

WARNING

When disconnecting the high-pressure hose from the gas supply port on the rear panel and the CO_2 cylinder, be sure to close the CO_2 cylinder valve and exhaust CO_2 remaining in the instrument. Otherwise, a large amount of gas will jet out of the instrument.
When disconnecting the endoscopic CO_2 regulation unit's cylinder hose from the CO_2 gas inlet and CO_2 gas cylinder, ensure that the CO_2 gas cylinder' valve is closed, then release any residual CO_2 gas remaining inside the endoscopic CO_2 regulation unit. The gushed high-concentration CO_2 is hazardous and may cause difficulty in breathing if inhaled.

■ Disconnecting the CO_2 gas cylinder

1 Close the gas cylinder valve by turning it clockwise.

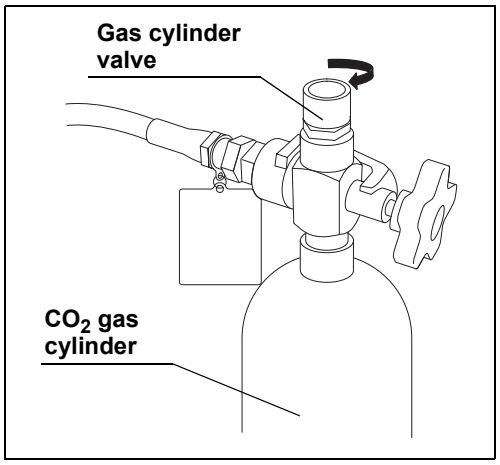


Figure 5.4

2 Disconnect the water container-side connector of the gas tube from the gas tube connector on the water container (MAJ-902).

3 Disconnect the Gas tube (MAJ-1741), Low flow gas tube (MAJ-1742), or Extra low flow gas tube (MAJ-1816) from the CO_2 gas outlet of the endoscopic CO_2 regulation unit.

4 Press the start/stop switch of this instrument to start the gas insufflation for removing CO_2 gas remaining inside the endoscopic CO_2 regulation unit.

5 After the endoscopic CO_2 regulation unit has entered the stop mode, turn it OFF.

6 Disconnect the power cord plug from the hospital grade AC outlet (wall mains outlet).

■ *Disconnecting the medical gas pipeline*

1. Disconnect the hose from the CO_2 gas connector of the medical gas pipeline.
2. Disconnect the water container-side connector of the gas tube from the gas tube connector on the water container (MAJ-902).
3. Disconnect the Gas tube (MAJ-1741), Low flow gas tube (MAJ-1742), or Extra low flow gas tube (MAJ-1816) from the CO_2 gas outlet of this instrument.
4. Press the start/stop switch of the endoscopic CO_2 regulation unit to start the gas insufflation for removing CO_2 gas remaining inside the instrument.
5. After the endoscopic CO_2 regulation unit has entered the stop mode, turn it OFF.
6. Disconnect the power cord plug from the hospital grade AC outlet (wall mains outlet).

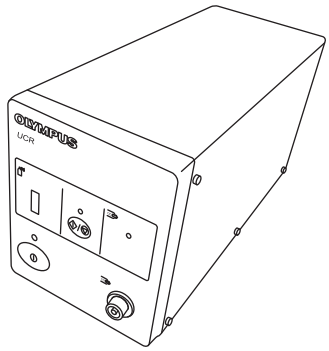
Chapter 6 Reprocessing, Storage, Disposal, and Transportation

6.1 Reprocessing

This section describes the method of reprocessing for the endoscopic CO_2 regulation unit and accessories below.

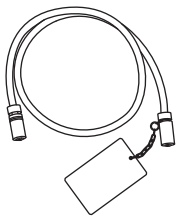
This section is based on the requirements of ISO 17664.

❍ Endoscopic CO_2 regulation unit

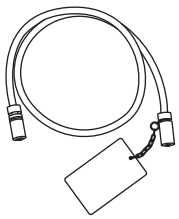


Endoscopic CO_2 regulation unit (UCR)

❍ Accessories



Gas tube (MAJ-1741)



Low flow gas tube (MAJ-1742),
Extra low flow gas tube (MAJ-1816)

NOTE

Reprocess the water container (MAJ-902) as described in the instruction manual for the water container.

WARNING

- If patient debris directly or indirectly adheres to this instrument, disinfection has to be performed within 1 hour after the patient procedure. Patient debris will begin to dry and solidify, hindering effective removal and reprocessing efficacy.
- After wiping with a piece of moistened lint-free cloth, dry the endoscopic CO_2 regulation unit and accessories thoroughly before using it again. If it is used while still wet, there is the risk of an electric shock.
- When caring the endoscopic CO_2 regulation unit and/or accessories, always wear appropriate personal protection equipment such as eye wear, face mask, moisture-resistant clothing, and chemical-resistant gloves that fit properly and are long enough so that your skin is not exposed. Blood, mucus, and other potentially infectious material adhering to the endoscopic CO_2 regulation unit could pose an infection control risk.
- Do not apply spray-type medical agents such as rubbing alcohol directly to the endoscopic CO_2 regulation unit and accessories. Medical agents may enter the endoscopic CO_2 regulation unit and accessories through the ventilation grills and/or the gaps and may cause a fire and/or equipment damage.
- Use a surface disinfectant cleaner cleared/approved by your national or local regulatory agencies. Furthermore, surface disinfectant cleaner should have an antiseptic solution that allows them to apply to medical products. Using an unauthorized surface disinfectant cleaner may result in insufficient disinfecting effect.
- As for the use of chemicals, be sure to follow instructions of chemicals manufacturer. Failure to follow manufacturer's instructions may result in insufficient cleaning and disinfecting effects.
- When residual organic debris attached to this product, residual organic debris will begin to dry and solidify, hindering effective removal and reprocessing efficacy.
- Wipe remaining surface disinfectant cleaner according to instructions of surface disinfectant cleaner manufacturer. Failure to do may adversely affect the human body or this instrument.
- When patient debris enters the hole or gap of this instrument, contact Olympus without using it. If you try to disinfect by force, the medicine will get inside this instrument, causing fire and malfunction of this instrument.

CAUTION

- Do not reprocessing the AC mains power inlet. Reprocessing them can deform or corrode the contacts, which could damage the endoscopic CO_2 regulation unit.
- Do not soak in water and autoclave, the endoscopic CO_2 regulation unit and accessories. These methods will damage them.
- Do not wipe the external surface with hard or abrasive wiping material. The surface will be scratched.
- When patient debris enters a hole or gap of the endoscopic CO_2 regulation unit, contact Olympus without disinfecting it. If you try to disinfect by force, the disinfectant solution will get inside the endoscopic CO_2 regulation unit causing fire and malfunction of the endoscopic CO_2 regulation unit.

6.2 Surface disinfectant cleaner

Use a medical-grade hydrogen peroxide surface disinfectant cleaner with properties as shown in Table 6.1.

NOTE

- Use the surface disinfectant cleaner cleared/approved by your national regulatory agency.

Surface disinfectant cleaner	Hydrogen peroxide
Percentage solution	Undiluted solution
Disinfectant concentration	Hydrogen peroxide 1.5g/100g
Component	Hydrogen peroxide, Glycolic acid
Others	Acting as disinfectant and cleaner No rinsing required

Table 6.1 Hydrogen peroxide surface disinfectant cleaner with properties

Follow the surface disinfectant cleaner manufacturer's instructions regarding concentration, drying, temperature, contact time, use life, and expiration date. The surface disinfectant cleaner shown in Table 6.2 was used for validation.

Trade name	Type	Manufacture
Incidin™ OxyForm S	Hydrogen Peroxide	ECOLAB

Table 6.2 Surface disinfectant cleaner used for validation

6.3 Signs of degradation from reprocessing

CAUTION

- Improper reprocessing may significantly reduce the service life of the endoscopic CO_2 regulation unit and accessories.
  - Do not reprocessing without observing the instructions of the manufacturer.

UCR

If you spot any of these signs of deterioration or notice any other evidence of deterioration, contact Olympus.

- Crack appears on the panel or the Power switch.
- Discoloration on the panel or the top cover.
- Peeling of the labels on the panel.

Accessory (MAJ-1741, MAJ-1742, MAJ-1816)

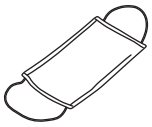
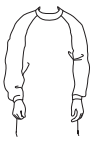
If you spot any of these signs of deterioration or notice any other evidence of deterioration, dispose of the accessory.

- Crack appears on the tubing or the connector.
- Discoloration on the tubing or the connector.

6.4 Preparing equipment for reprocessing

■ Equipment needed

❍ Personal protective equipment

			
Eyewear	**Face mask**	**Moisture-resistant cloth**	**Chemical-resistant gloves[*1]**

❍ Chemicals used for reprocessing

- **Surface disinfectant cleaner**
  (Refer to Section 6.2, “Surface disinfectant cleaner”on page 56)

❍ Other

- **Clean lint-free cloths[*2]**

Table 6.3 Equipment needed

*1 Long sleeve gloves are recommended to prevent skin exposure.

*2 Lint-free cloths are recommended for reprocessing to prevent lint or cloth fibers from lodging or being trapped in the instrument’s components.

6.5 Reprocessing the endoscopic CO_2 regulation unit and accessories

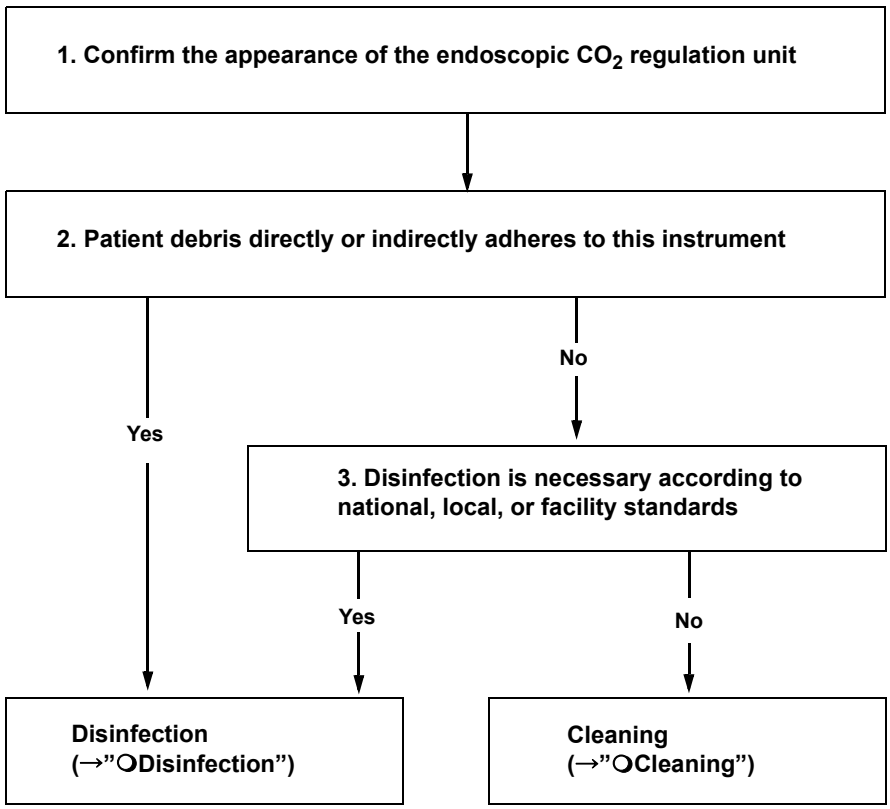
❍ Reprocessing workflow for the endoscopic CO_2 regulation unit and accessories

This chapter describes the workflow for reprocessing the endoscopic CO_2 regulation unit and accessories.

1 Confirm the appearance of the endoscopic CO_2 regulation unit and accessories.

2 If patient debris directly or indirectly adheres to this instrument and accessories, refer to "❍ Disinfection" on page 60. Otherwise, be sure to follow the next step.

3 If disinfection is necessary according to national, local, or facility standards, refer to "❍ Disinfection" on page 60. Otherwise, refer to "❍ Cleaning" on page 61.



❍ Disinfection

WARNING

Follow the usage (temperature, contact time, use life) and amount (concentration) provided by surface disinfectant cleaner manufacturer. Failure to follow manufacturer's instructions may result in insufficient cleaning and disinfection effect.

CAUTION

- Wipe off remaining surface disinfectant cleaner solution according to instructions of surface disinfectant cleaner manufacturer. Failure to do so may adversely affect the human body or this instrument.
- After wiping with a moistened lint-free cloth, dry the endoscopic CO_2 regulation unit and accessories thoroughly before using it again. If it is used while still wet, there is the risk of an electric shock.

1 Turn OFF the endoscopic CO_2 regulation unit and disconnect the power cord from the hospital grade wall mains outlet.

2 Prepare a lint-free cloth moistened with the surface disinfectant cleaner.

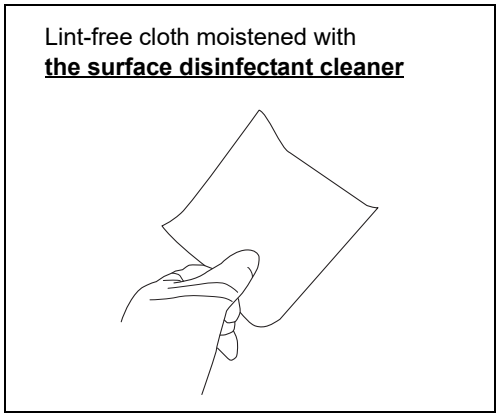


Figure 6.1

3 Wipe off all patient debris from the endoscopic CO_2 regulation unit and accessories this instrument using the moistened lint-free cloth.

4 Prepare another lint-free cloth moistened with the surface disinfectant cleaner.

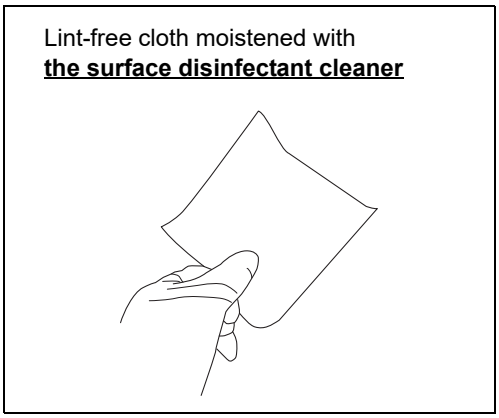


Figure 6.2

5 Disinfect the surfaces that previously contained patient debris (see Step 3) by wiping with the moistened lint-free cloth.

6 Ensure that the surfaces are completely wet for the contact time instructed by the surface disinfectant cleaner manufacturer.

7 If any surface of the endoscopic CO_2 regulation unit and accessories remains wet, wipe it with a dry lint-free cloth and let it dry thoroughly.

❍ Cleaning

CAUTION

After wiping with a moistened lint-free cloth, dry the endoscopic CO_2 regulation unit thoroughly before using it again. If it is used while still wet, there is the risk of an electric shock.

1 Turn the endoscopic CO_2 regulation unit OFF and disconnect the power cord from the hospital grade wall mains outlet.

2 Wipe with a dry lint-free cloth or a moistened lint-free cloth with water until dust and dirt are removed.

3 If the surface of the instruments is wet, wipe it with a dry lint-free cloth and let it dry thoroughly.

6.6 Storage

WARNING

Store the endoscopic CO_2 regulation unit and accessories in a proper storage cabinet, following the policies at your institution, applicable national laws and standards, and professional society guidelines and recommended practices.

CAUTION

Do not store the endoscopic CO_2 regulation unit in a location exposed to direct sunlight, X-rays, radio activity, or strong electromagnetic radiation (e.g., near microwave medical treatment equipment, short-wave medical treatment equipment, MRI, radio equipment, or cellular phones). Damage to the endoscopic CO_2 regulation unit may result.

1. Turn the endoscopic CO_2 regulation unit OFF and disconnect the power cord from the hospital grade power outlet.
2. Store the endoscopic CO_2 regulation unit properly in a clean, dustless place in compliance with the environmental conditions given in “Specifications” on page 69.

6.7 Disposal

CAUTION

When disposing of the endoscopic CO_2 regulation unit or any of its components (such as fuses), be sure to observe your national and local laws and guidelines.

6.8 Transportation

When transporting the endoscopic CO_2 regulation unit and accessories, follow the policies at your institution.

Chapter 7 Troubleshooting

If the endoscopic CO_2 regulation unit is visibly damaged, does not function as expected or is found to have other irregularities during the inspection described in Chapter 3, “Installation and Connection” and Chapter 4, “Inspection”, or the use described in Chapter 5, “Operation”, do not use the endoscopic CO_2 regulation unit; contact Olympus. Some problems that appear to be malfunctions may be correctable by referring to Section 7.1, “Troubleshooting guide”. If the problem cannot be resolved by the described remedial action, stop using the instrument and contact Olympus.

7.1 Troubleshooting guide

■ Endoscopic CO_2 regulation unit (UCR)

Irregularity description	Possible cause	Solution
UCR is not supplied with power.	The power cord plug is not connected.	Connect the power cord plug.
	The power switch is not set to ON.	Set the power switch to ON.
The indicators on the front panel do not light.	The power cord plug is not connected.	Connect the power cord plug.
	The power switch is not set to ON.	Set the power switch to ON.
Insufflation is not possible.	The start/stop switch is not pressed.	Confirm that the green LED on the start/stop switch is lit. If it is not lit, press the start/stop switch.
	The gas cylinder valve is closed.	Open the valve.
	The cylinder hose for UCR is not connected.	Connect the cylinder hose correctly.
	The medical gas pipeline hose is not connected.	Connect the medical gas pipeline hose correctly.
	The medical gas pipeline pressure is too low.	Check the pressure of the gas supply source.
	The gas tube is not connected.	Connect the gas tube.
	The gas tube is collapsed.	Correct the collapsed area.
	A hole is in the gas tube.	Replace the tube with a new one.
	The gas cylinder is not in an upright position.	Place the gas cylinder in an upright position. Turn the endoscopic CO_2 regulation unit on and wait 5 minutes or more before operating.

Irregularity description	Possible cause	Solution
Supply pressure warning is generated continuously.*1	The valve of the CO_2 gas cylinder is closed.	Open the valve.
	The CO_2 cylinder is running out of gas.	Replace the cylinder with a new one.
	The cylinder hose or the medical gas pipeline adapter is not connected.	Connect the hose/adapter properly.

*1 If the red LED in the gas pressure display is illuminated, an alarm tone is generated and the gas supply is stopped during operation using the CO_2 cylinder, the valve of the CO_2 cylinder may be closed or the CO_2 cylinder may be empty. If the green LED in the gas pressure display is not illuminated even when the valve of the CO_2 cylinder is open, replace the cylinder with a new one as described in Section 3.3, “Connecting a CO_2 gas cylinder”.

7.2 Returning the endoscopic CO_2 regulation unit for repair

When returning the endoscopic CO_2 regulation unit for repair, include a description of the endoscopic CO_2 regulation unit malfunction or damage and the name and telephone number of the individual at your location who is most familiar with the endoscopic CO_2 regulation unit problem. Include a repair purchase order.

CAUTION

Olympus is not liable for any injury or damage that occurs because of repairs attempted by non-Olympus personnel.

Appendix

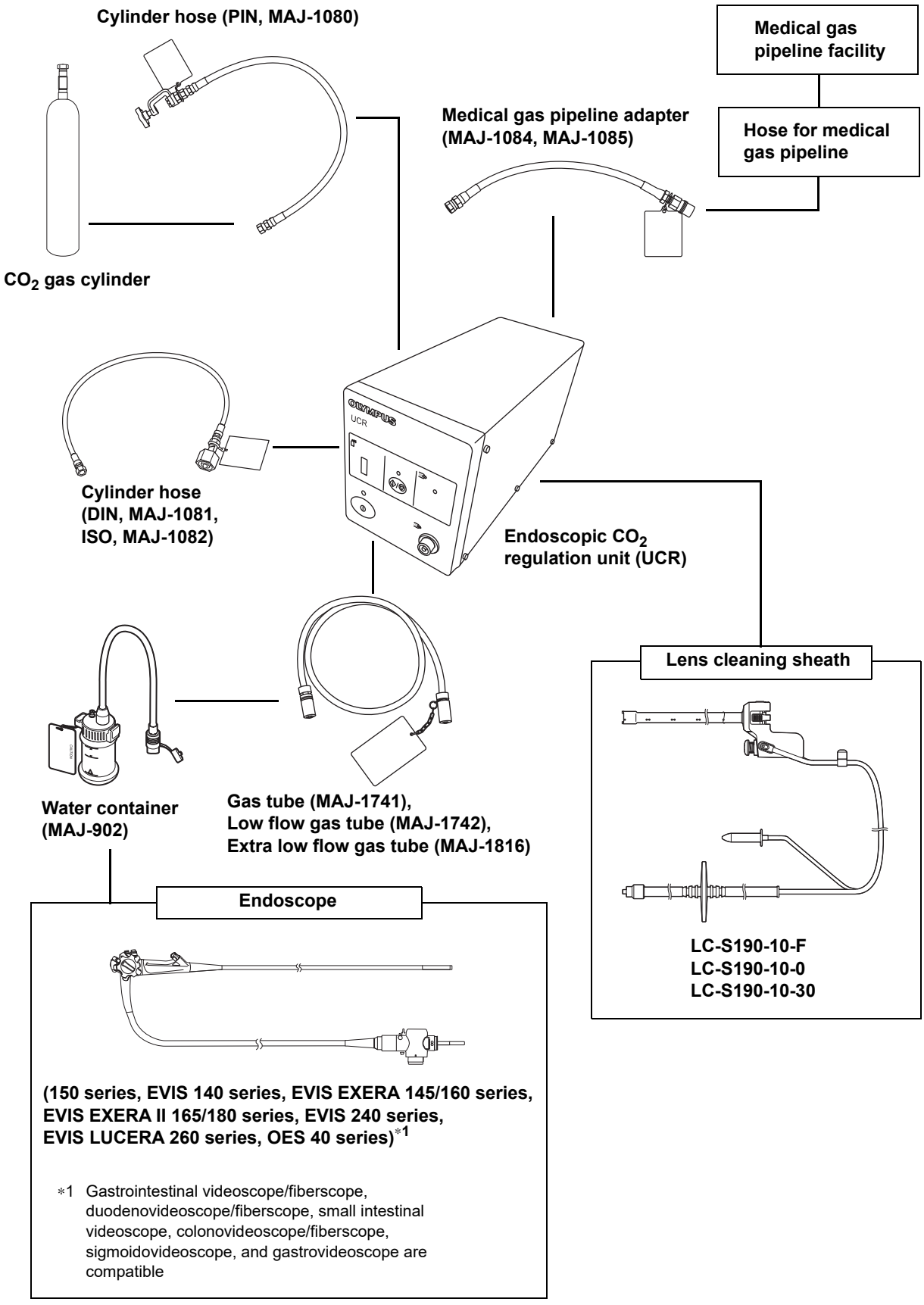
Combination equipment

■ System chart

The recommended combinations of equipment that can be used with this endoscopic CO_2 regulation unit are listed below. New products released after the introduction of the endoscopic CO_2 regulation unit may also be compatible for use in combination with it. For further details, contact Olympus.

WARNING

If combinations of equipment other than those shown below are used, the full responsibility should be assumed by the medical treatment facility. Such combinations do not only not allow the equipment to manifest their full functionality but may also compromise the safety of the patient and medical personnel. In addition, the endurance of the endoscopic CO_2 regulation unit and ancillary equipment is not guaranteed. Troubles caused in this case are not covered by free-of-charge repair. Be sure to use the equipment in one of the recommended combinations.



*1 Gastrointestinal videoscope/fiberscope, duodenovideoscope/fiberscope, small intestinal videoscope, colonovideoscope/fiberscope, sigmoidovideoscope, and gastrovideoscope are compatible

Transportation, storage, and operating environments

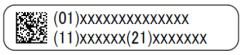
Operating environment	**Ambient temperature**	10 – 40°C (50 – 104°F)
	Relative humidity	30 – 85%
	Atmospheric pressure	700 – 1060 hPa
Transportation and storage environment	**Ambient temperature**	–25 to 70°C (–13 to 158°F)
	Relative humidity	10 – 90%
	Atmospheric pressure	700 – 1060 hPa

Specifications

❍ Endoscopic CO_2 regulation unit

Item		Specification
Power supply	**Voltage**	100 – 240 V AC
	Voltage fluctuation	Within ±10%
	Frequency	50/60 Hz
	Frequency fluctuation	Within ±1 Hz
	Input	40 VA
	Fuse rating	2 A, 250 V
	Fuse size	ø 5 × 20 mm
Size	**Dimensions**	130 (W) × 156(H) × 334 (D) mm (housing dimensions)
	Weight	4.9 kg
Applicable gas		• CO_2 gas for medical use. • Connection to gas cylinder via the Olympus cylinder hose (optional; three hose types available to fit the specific CO_2 gas cylinders used: MAJ-1080 (PIN), MAJ-1081 (DIN), MAJ-1082 (ISO)) • Connection to medical gas pipeline via the Olympus medical gas pipeline adapter (MAJ-1084 (NIST), MAJ-1085 (DISS)) • Pressure range of medical gas pipeline – upper limit: according to ISO 7396 (1400 kPa) – lower limit: 343.2 kPa (3.5 kgf/cm^2) • Hose for medical gas pipeline is required to comply with ISO 5359 (NIST or DISS)

Item		Specification
Supply pressure indications		• Five steps by LEDs. 5: above 4.5 MPa 4: 3.3 – 4.5 MPa 3: 2.3 – 3.3 MPa 2: 1.3 – 2.3 MPa 1: 0.3 – 1.3 MPa • When the cylinder pressure drops below 0.3 MPa, the cylinder pressure indicator will light red.
Start/stop		• When the start/stop switch is pressed, the gas supply indicator illuminates and the unit starts supplying the gas. • When the start/stop switch is pressed again, the indicator goes out and the unit stops supplying the gas.
Gas feeding pressure	**Maximum pressure feed**	45 kPa
Timer		Timer setting: After the set time elapses, the gas supply stops.
Classification (electromedical equipment)	**Type of protection against electric shock**	Class I (3-pin power cord)
	Degree of protection against electrical shock of applied part	Type BF applied part: Gas tube (MAJ-1741) Low flow gas tube (MAJ-1742) Extra low flow gas tube (MAJ-1816)
EMC	**Applied standard**	IEC 60601-1-2: 2001 IEC 60601-1-2: 2007 IEC 60601-1-2: 2014 • This instrument complies with the EMC standard for medical electrical equipment, edition 4 (IEC 60601-1-2: 2014). When connecting to an instrument that complies with a previous edition of the EMC standard for medical electrical equipment edition, the EMC characteristics could be vulnerable. • CISPR 11 of emission: Group 1, Class B
Year of manufacture		The last digit of the year of manufacture is the second digit of the serial number. In this example, the year is 2006. Ex. 7612345 (serial number)
Medical Devices Directive		CE 0197 This device complies with the requirements of Directive 93/42/EEC connecting medical devices. Classification: Class II a

Item		Specification
WEEE Directive		 In accordance with European Directive 2002/96/EC on Waste Electrical and Electric Equipment, this symbol indicates that the product must not be disposed of as unsorted municipal waste, but should be collected separately. Refer to your local Olympus distributor for return and/or collection systems available in your country.
UDI label	**Indication**	 The UDI label is required by some countries' regulations regarding the identification of a medical device also known as Unique Device Identification (UDI). The following information is being coded in the 2-dimensional barcode (GS1 Data Matrix): - (01) 14-digit GS1 Global Trade Item Number; - (11) 6-digit date of manufacture; - (21) 7-digit serial number.

❍ Cylinder hose (PIN, MAJ-1080)

Item	Specification
Hose length	1000 mm
Compatible cylinder connector	Pin-index (ISO 407)
Life time	5 years

Cylinder hose (DIN, MAJ-1081), Cylinder hose (ISO, MAJ-1082)

Item		Specification
Hose length		1000 mm
Compatible cylinder connector	**MAJ-1081**	DIN (DIN 477 Anschl. No. 6, W21. 8-14)
	MAJ-1082	ISO (ISO 5145 W27 16-16)
Life time		5 years

Gas tube (MAJ-1741)

Item	Specification
Tube length	1000 mm
Tube external diameter	9 mm
Flow rate	Using this tube, the gas flow rate is approximately equivalent to the airflow pressure level “High” of the light source.

Low flow gas tube (MAJ-1742)

Item	Specification
Tube length	1000 mm
Tube external diameter	9 mm
Flow rate	Using this tube, the gas flow rate is approximately equivalent to the airflow pressure level “Medium” of the light source.

Extra low flow gas tube (MAJ-1816)

Item	Specification
Tube length	1000 mm
Tube external diameter	9 mm
Flow rate	Using this tube, the gas flow rate is approximately equivalent to the airflow pressure level “Low” of the light source.

EMC information

Guidance and manufacturer's declaration — Electromagnetic emissions

This model is intended for use by medical personnel in hospital environments and for use in the electromagnetic environment specified below. The customer or the user of this model should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment — 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 B	This instrument's RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Main terminal conducted emissions CISPR 11		
Harmonic emissions IEC 61000-3-2	Class A	This instrument's harmonic emissions are low and are not likely to cause any problem in the typical commercial power supply connected to this instrument.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	This instrument stabilizes its own radio variability and has no effect such as flicker in lighting apparatus.

Guidance and manufacturer's declaration — Electromagnetic immunity

This model is intended for use by medical personnel in hospital environments and for use in the electromagnetic environment specified below. The customer or the user of this model should assure that it is used in such an environment.
This instrument can be used with the high-frequency electrosurgical equipment that designated by Olympus.

Immunity test	IEC 60601-1-2 (2014) test level	IEC 60601-1-2 (2007, 2001) test level	Compliance level	IEC 60601-1-2 (2007, 2001) Electromagnetic environment — Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	Contact: ±8 kV Air: ±2, ±4, ±8, ±15 kV	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	±2 kV for power supply lines ±1 kV for input/output lines	Same as left	Mains power quality should be that of a typical commercial (original condition feeding the facilities) or hospital environment.
Surge IEC 61000-4-5	Differential mode: ±0.5, ±1 kV Common mode: ±0.5, ±1, ±2 kV for signal input/ output lines: ±2 kV	Differential mode: ±0.5, ±1 kV Common mode: ±0.5, ±1, ±2 kV	Same as left	Mains power quality should be that of a typical commercial or hospital environment.

Immunity test	IEC 60601-1-2 (2014) test level	IEC 60601-1-2 (2007, 2001) test level	Compliance level	IEC 60601-1-2 (2007, 2001) Electromagnetic environment — Guidance
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	0% U_T (100% dip in U_T) for 0.5 cycle/1 cycle	< 5% U_T (> 95% dip in U_T) for 0.5 cycle	Same as left	Mains power quality should be that of a typical commercial or hospital environment. If the user of this instrument requires continued operation during power mains interruptions, it is recommended that this instrument be powered from an uninterruptible power supply or a battery.
	–	40% U_T (60% dip in U_T) for 5 cycle		
	70% U_T (30% dip in U_T) for 25 cycle (50 Hz)/ 30 cycle (60 Hz) Phase angle causing voltage dips: 0°	70% U_T (30% dip in U_T) for 25 cycle		
	0% U_T (100% dip in U_T) for 250 cycle (50 Hz)/ 300 cycle (60 Hz)	< 5% U_T (> 95% dip in U_T) for 5 seconds		
	U_T is the a.c. mains voltage prior to application of the test level.			
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m (50 Hz or 60 Hz)	3 A/m (50 Hz, 60 Hz)	Same as left	It is recommended to use this instrument by maintaining enough distance from any equipment that operates with high current.

Immunity test	IEC 60601-1-2 (2014) test level	IEC 60601-1-2 (2007, 2001) test level	Compliance level	IEC 60601-1-2 (2007, 2001) Electromagnetic environment — Guidance
Conducted RF IEC 61000-4-6	3V (150 kHz – 80 MHz)	3V (V_1) (150 kHz – 80 MHz)	Same as left	Recommended separation distance $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$ 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].
	6V (ISM band of 150 kHz – 80 MHz)	–	Same as left	
	ISM (industry, science, and medical care) band of 6.765 MHz – 6.795 MHz, 13.553 MHz – 13.567 MHz, 26.957 MHz – 27.283 MHz, and 40.66 MHz – 40.70 MHz between 0.15 MHz and 80 MHz			
Radiated RF IEC 61000-4-3	3V/m (80 MHz – 2.7 GHz)	3V/m (E_1) (80 MHz – 2.5 GHz)	Same as left	Recommended separation distance $d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$ 80 MHz – 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz – 2.5 GHz 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].
Proximity magnetic field from RF communication equipment IEC 61000-4-3	Refer to the table of the next page.	–	Same as left	

NOTE

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
- Electromagnetic interference may occur in the vicinity of high-frequency electrosurgical equipment and/or other equipment marked with the following symbol:

NOTE

- Field strength from fixed RF transmitters as determined by an electromagnetic site survey[a)] should be less than the compliance level in each frequency range[b)].

  a) Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which this model is used exceeds the applicable RF compliance level above, this model should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating this model.

  b) Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m.

Test frequency [MHz]	Band [MHz]	Modulation*1	Maximum power [W]	Immunity test level [V/m]
385	380 – 390	Pulse modulation*1 18 Hz	1.8	27
450	430 – 470	FM ±5 kHz deviation 1 kHz sine	2	28
710	704 – 787	Pulse modulation*1 217 Hz	0.2	9
745				
780				
810	800 – 960	Pulse modulation*1 18 Hz	2	28
870				
930				
1720	1700 – 1990	Pulse modulation*1 217 Hz	2	28
1845				
1970				
2450	2400 – 2570	Pulse modulation*1 217 Hz	2	28
5240	5100 – 5800	Pulse modulation*1 217 Hz	0.2	9
5500				
5785				

*1 The carrier shall be modulated using a 50% duty cycle square wave signal.

WARNING

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of this instrument, including cables specified by Olympus. Otherwise, degradation of the performance of this equipment could result.

OLYMPUS

Manufactured by

OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507, Japan
Fax: (042)646-2429 Telephone: (042)642-2111

Distributed by

OLYMPUS AMERICA INC.
3500 Corporate Parkway, P.O. Box 610, Center Valley, PA
18034-0610, U.S.A.
Fax: (484)896-7128 Telephone: (484)896-5000

OLYMPUS LATIN AMERICA, INC.
5301 Blue Lagoon Drive, Suite 290 Miami, FL 33126-2097, U.S.A.
Fax: (305)261-4421 Telephone: (305)266-2332

EC REP **OLYMPUS EUROPA SE & CO. KG**
(Premises/Goods delivery) Wendenstrasse 20, 20097 Hamburg, Germany
(Letters) Postfach 10 49 08, 20034 Hamburg, Germany
Fax: (040)23773-4656 Telephone: (040)23773-0

KEYMED (MEDICAL & INDUSTRIAL EQUIPMENT) LTD.
KeyMed House, Stock Road, Southend-on-Sea, Essex SS2 5QH, United Kingdom
Fax: (01702)465677 Telephone: (01702)616333

OLYMPUS MOSCOW LIMITED LIABILITY COMPANY
Elektrozavodskaya str. 27 bld.8, 107023 Moscow, Russia
Fax: (7)495-926-7072 Telephone: (7)495-926-7077

OLYMPUS (BEIJING) SALES & SERVICE CO., LTD.
A8F, Ping An International Financial Center, No. 1-3, Xinyuan South Road,
Chaoyang District, Beijing, 100027 P.R.C.
Fax: (86)10-5976-1299 Telephone: (86)10-5819-9000

OLYMPUS KOREA CO., LTD.
(Seocho-dong, Majestar City Tower One), 2F & 3F, 12, Seocho-daero 38-gil, Seocho-gu,
Seoul, 06655, Republic of Korea
Fax: (02)6255-3210 Telephone: 1544-3200

OLYMPUS SINGAPORE PTE LTD
438B Alexandra Road #03-07/12, Alexandra Technopark Blk B, Singapore 119968
Fax: 6834-2438 Telephone: 6834-0010

OLYMPUS AUSTRALIA PTY LTD
3 Acacia Place, Notting Hill, VIC 3168, Australia
Fax: (03)9543-1350 Telephone: (03)9265-5400

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