OLYMPUS®

INSTRUCTIONS

HEAT PROBE UNIT

HPU-20

USA: CAUTION: Federal law restricts this device to sale by or on the order of a physician.

Contents

Labels and Symbols ***1***

Important Information — Please Read Before Use ***3***

Intended Use 3
Instruction Manual 3
User Qualifications 3
Instrument Compatibility 4
Reprocessing and Storage 4
Repair and Modification 4
Signal Words 5
Dangers, Warnings and Cautions 5

Chapter 1 Checking the Package Contents ***7***

1.1 Checking the Package Contents 7

Chapter 2 Instrument Nomenclature ***8***

2.1 Front and Side Panels 8
2.2 Rear Panel 9
2.3 HPU-20 Accessories 10

Chapter 3 Installation and Connection ***12***

3.1 Installation of the HEAT PROBE UNIT 12
3.2 Connection of the Water Container (MAJ-526) 13
3.3 Connection of the Water Pump (MAJ-527) 14
3.4 Connection of the HEAT PROBE (CD-110, CD-120) 16
3.5 Connection of the Foot Switch (MAJ-528) 18
3.6 Connection of the Power Cord 18

Chapter 4 Inspection ***20***

4.1 Inspection the Power Supply 21
4.2 Inspection the Energy Level Settings 23
4.3 Inspection the Water Feed Settings 24
4.4 Inspection the HEAT PROBE (CD-110, CD-120) 25
4.5 Inspection the Water Feed Function 26

Chapter 5 Operation 28

5.1 Turn the Power ON 28
5.2 Set the Energy Level 29
5.3 Set the Water Feed Level 29
5.4 Insert the HEAT PROBE (CD-110, CD-120) 30
5.5 Coagulating Tissue 30

Chapter 6 Care, Storage and Disposal 32

6.1 Reprocessing: General Policy 32
6.2 Compatible Reprocessing Methods and Chemical Agents 33
6.3 Required Reprocessing Equipment 35
6.4 Care and Storage of the HEAT PROBE (CD-110, CD-120) 37
6.5 Care and Storage of the Water Pump (MAJ-527) 38
6.6 Care and Storage of the Water Container (MAJ-526) 41
6.7 Care and Storage of the Foot Switch (MAJ-528) 43
6.8 Care and Storage of the HEAT PROBE UNIT (HPU-20) 44
6.9 Disposal 45

Chapter 7 Troubleshooting 46

7.1 Troubleshooting Guide 46
7.2 Returning the HEAT PROBE UNIT for Repair 49

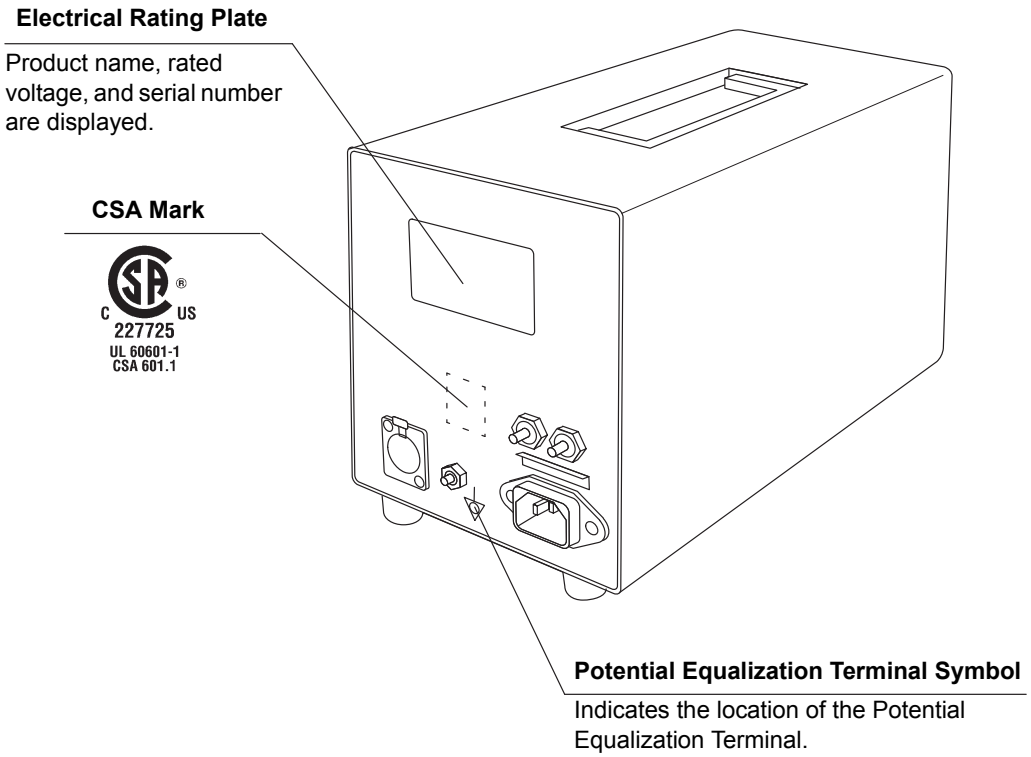
Appendix 50

System Chart 50
Operating Environment 52
Transportation and Storage Environment 52
Specifications 52

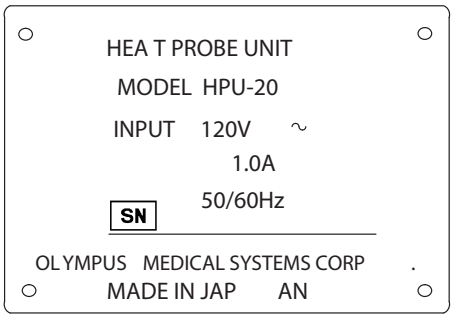
Labels and Symbols

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

❍ Rear side



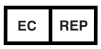
Electrical Rating Plate



❍ Back cover of this instruction manual



Manufacturer



Authorized representative in the European Community

Important Information — Please Read Before Use

Intended Use

This instrument has been designed to be used with an Olympus HEAT PROBE (CD-110, CD-120) for thermal cauterization at a bleeding point. Do not use this instrument for any purpose other than its intended use.

Instruction Manual

This instruction manual contains essential information on using this instrument safely and effectively. Before use, thoroughly review this manual and the manuals of all equipment which 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, please contact Olympus.

❍ Terms Used in This Manual

Wall Mains Outlet

An electrical outlet that has a terminal used exclusively for grounding.

User Qualifications

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

Instrument Compatibility

Refer to the “System Chart” in Appendix to confirm that this instrument is compatible with the ancillary equipment being used. Using incompatible equipment can result in patient or equipment damage.

Reprocessing and Storage

The HEAT PROBE, Water Pump and Water Container used in combination with HEAT PROBE UNIT were not disinfected or sterilized before shipment. Before using these instruments for the first time, reprocess them as instructed in this manual.
After using these instruments, reprocess and store them following the instructions given in this manual. Improper and/or incomplete reprocessing or storage can present an infection control risk and/or cause tissue inflammation.

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. Problems that appear not to be malfunctions may be correctable by referring to Chapter 7, “Troubleshooting”.
If the problem cannot be resolved using the information in Chapter 7, please contact Olympus.

Signal Words

The following signal words are used throughout this manual:

DANGER

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

WARNING

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

CAUTION

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

NOTE

Indicates additional helpful information.

Dangers, Warnings and Cautions

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

DANGER

- As a Type BF applied part, this instrument must never be applied directly to the heart and must not be used in procedures involving cardiac observation or surgery. Leakage current from Type BF applied parts may cause ventricular fibrillation or otherwise seriously affect the cardiac function of the patient. Always adhere to the following precautions, and never apply a HEAT PROBE connected to this instrument to the heart or any area near the heart.
- Pay close attention to the precautions listed below. Failure to do so may put the patient and medical personnel in danger of receiving an electric shock.

- When using this equipment, make sure that the metal parts of the endoscope or HEAT PROBE do not come in contact with metal in the area or in other system components. Metal-to-metal contact can create an electrical connection and cause current to flow unintentionally to the patient.
- Keep liquids away from all electrical equipment. If spilled fluids enter the unit, immediately stop operation of the equipment and contact Olympus.
- Do not prepare, inspect or use the equipment with wet hands.

- Never use the instrument in an environment containing flammable liquids or gases or a high concentration of oxygen and keep all flammable gases and liquids away from the instrument while it is being used. Otherwise, explosion or fire may result because the instrument is not designed to be explosion-proof.

WARNING

- In the event of instrument failure or malfunction, always have another HEAT PROBE UNIT, Water Container, Foot Switch and Water Pump available for immediate use.
- The system should be establish with equipment complied with relevant EMC standards for safety reason.
- Equipment which do not comply with EMC standard may cause interference and its function or performance may be affected.
- Portable or mobile phones may influence the medical electrical equipment by their emitting energy.

CAUTION

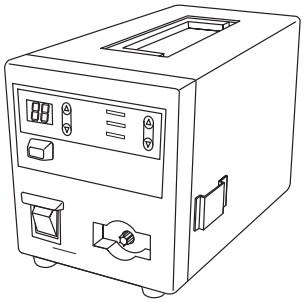
- Do not use pointed or hard objects to press the switches on the front panel of the HEAT PROBE UNIT. Doing so may damage the switches.
- Do not apply excessive force to any connector or touch its electrical contacts. Doing so may damage or corrode the contacts, which could lead to contact failure and/or instrument malfunction.
- Do not connect the power cord of the HPU-20 to a different voltage electrical outlet. Fire and smoke may result.

Chapter 1 Checking the Package Contents

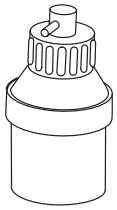
1.1 Checking the Package Contents

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.

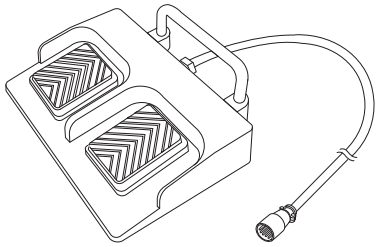
This instrument was not disinfected or sterilized before shipment. Before using this instrument for the first time, reprocess it according to the instructions in Chapter 6, “Care, Storage and Disposal”.



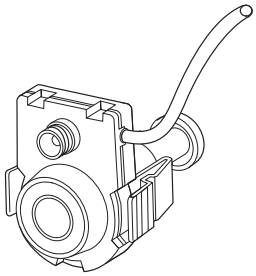
HEAT PROBE UNIT (HPU-20)



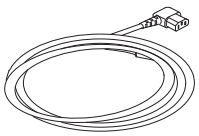
Water Container for Model HPU-20 (MAJ-526)



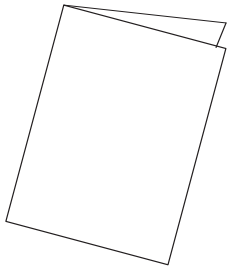
Foot Switch for Model HPU-20 (MAJ-528)



Water Pump for Model HPU-20 (MAJ-527)



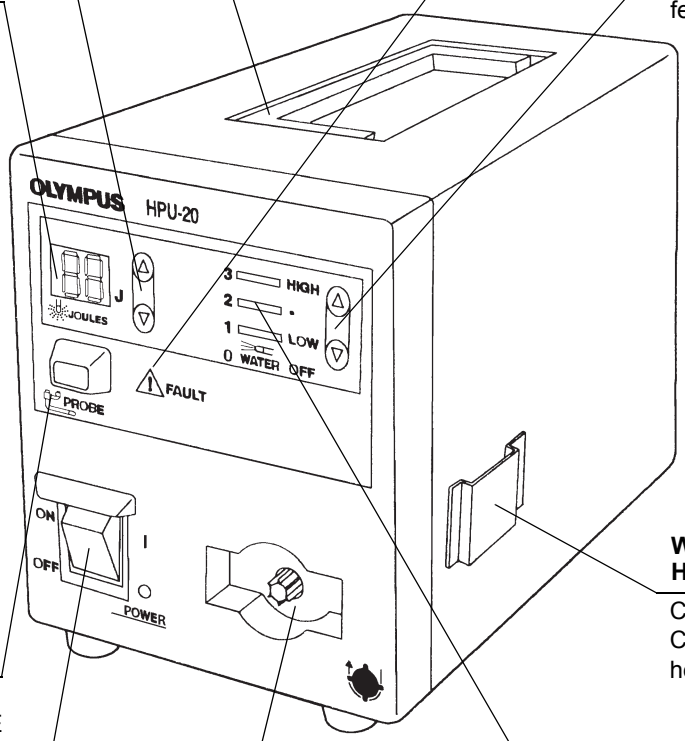
Power Cord



Instruction Manual

Chapter 2 Instrument Nomenclature

2.1 Front and Side Panels



Energy Setting Switches

Used to set the energy level of the HEAT PROBE.

Handle

Warning Lamp

Lights when an abnormality is detected.

Water Feed Setting Switches

Used to set the water feed level.

Energy Level Indicator

Shows the set energy level. Displays an error code if any abnormalities are detected.

Water Container Hanger

Connect the Water Container (MAJ-526) here.

Probe Electrical Connector

Connect the electrical plug of the HEAT PROBE (CD-110, CD-120) here.

Water Feed Level Indicators

Shows the set water feed level.

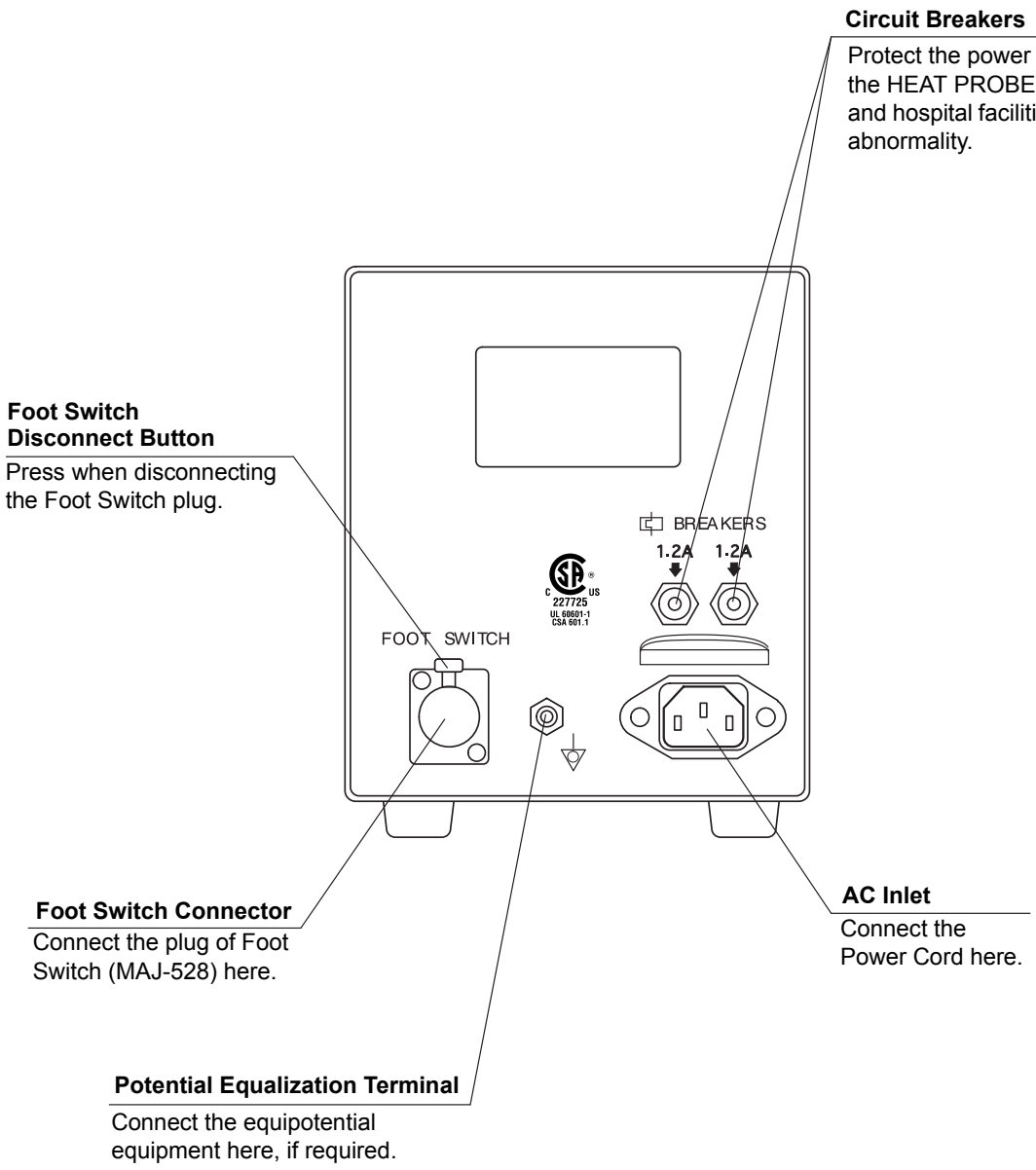
Power Switch

The switch is illuminated when the power is on.

Water Pump Connector

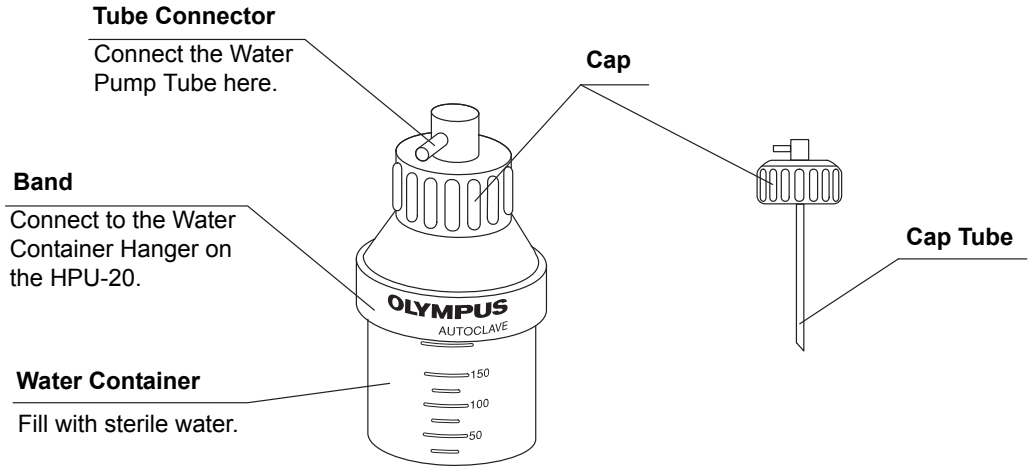
Connect the Water Pump (MAJ-527) here.

2.2 Rear Panel

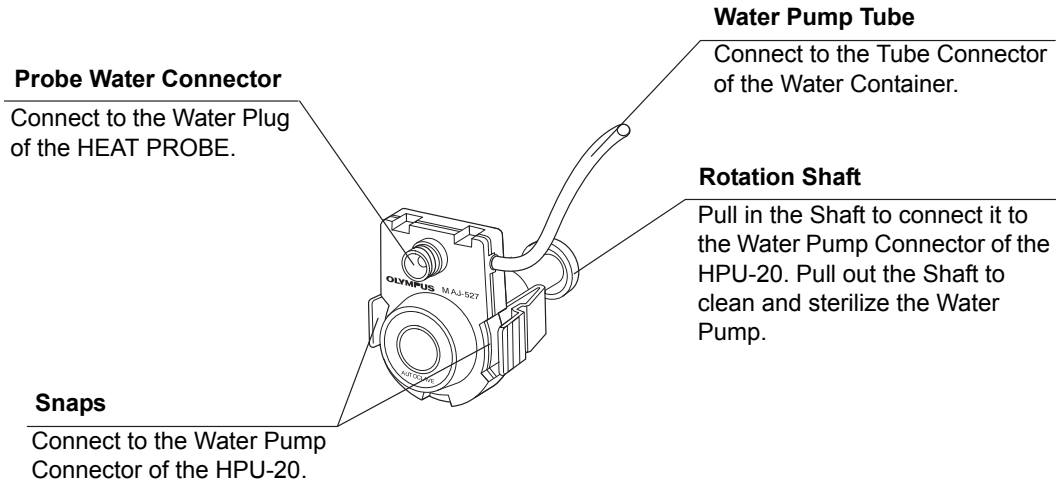


2.3 HPU-20 Accessories

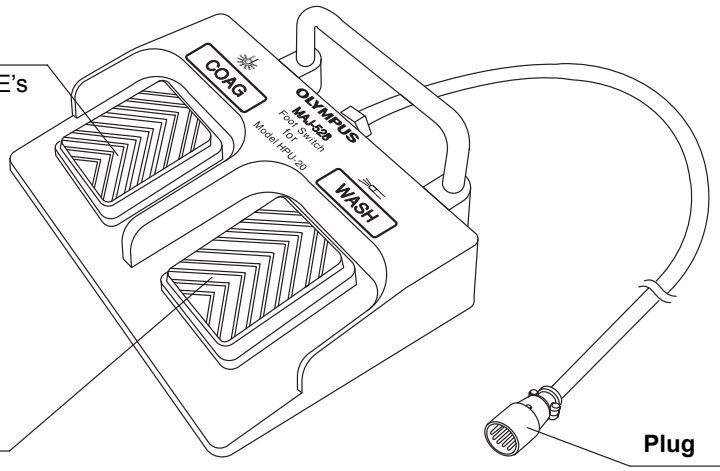
❍ Water Container (MAJ-526)



❍ Water Pump (MAJ-527)



❍ Foot Switch (MAJ-528)



COAG Pedal

To turn the HEAT PROBE's output ON.

WASH Pedal

To turn water feeding ON and OFF.

Plug

Connect to the Foot Switch Connector on the HPU-20.

Chapter 3 Installation and Connection

CAUTION

- Be sure to set the power switch of the HEAT PROBE UNIT to the OFF (“O”) position before connecting cords or equipment. Otherwise the equipment may be damaged.
- Do not connect the power cord of the HPU-20 to a different voltage electrical outlet. Fire and smoke may result.

Prepare the instrument and other equipment to be used with this instrument before each use according to the “System Chart” in Appendix and the instruction manuals for each piece of equipment. Install and connect all equipment as follows:

3.1 Installation of the HEAT PROBE UNIT

Place the HEAT PROBE UNIT on a stable, horizontal surface.

CAUTION

- Do not place the HEAT PROBE UNIT on its side or upside down. Otherwise the equipment may not function normally and could become damaged.
- Place the HEAT PROBE UNIT close enough to the endoscope so that there is sufficient slack in the HEAT PROBE’s cord when the HEAT PROBE is inserted into the endoscope. Otherwise the equipment may be damaged.

3.2 Connection of the Water Container (MAJ-526)

WARNING

- Sterilize the Water Container before connecting it. Otherwise infection or inflammation of tissue may result.
- Use only sterile water in the Water Container. Otherwise infection or inflammation of tissue may result.

CAUTION

- Do not drop or apply shock to the Water Container. Otherwise it may become damaged.
- Do not fill the Water Container with more than 250 cm^3 of sterile water (e.g., not higher than the top of the Band). Otherwise, water may overflow and cause equipment damage.

1. Ensure that the Water Container is not cracked or otherwise damaged.
2. Fill the Water Container with sterile water and close the Cap.
3. Connect the Water Container to the Water Container Hanger on the HEAT PROBE UNIT (see Figure 3.1).
4. Remove the Water Container from the HEAT PROBE UNIT and fill with sterile water as necessary.

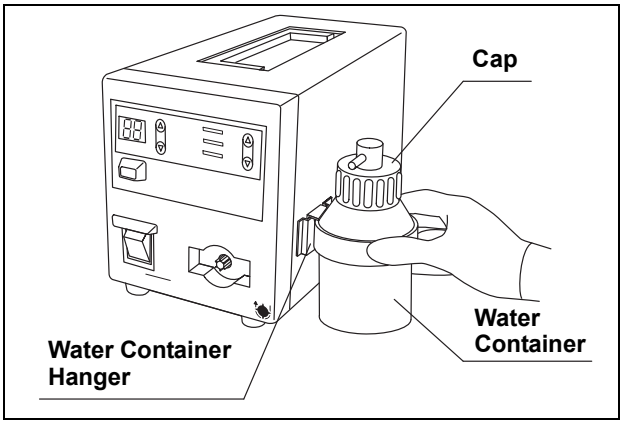


Figure 3.1

3.3 Connection of the Water Pump (MAJ-527)

WARNING

Sterilize the Water Pump before connecting it. Otherwise infection or inflammation of tissue may result.

CAUTION

- Do not drop or apply shock to the Water Pump. Otherwise it may become damaged or malfunction.
- Be sure to connect the Water Pump securely according to the following procedures. Otherwise the equipment may become damaged or function improperly.

1. Ensure that the Water Pump is not cracked or otherwise damaged.
2. Push in the Rotation Shaft of the Water Pump straightforward until it stops (see Figure 3.2). If not, pull out the shaft and push it in again.

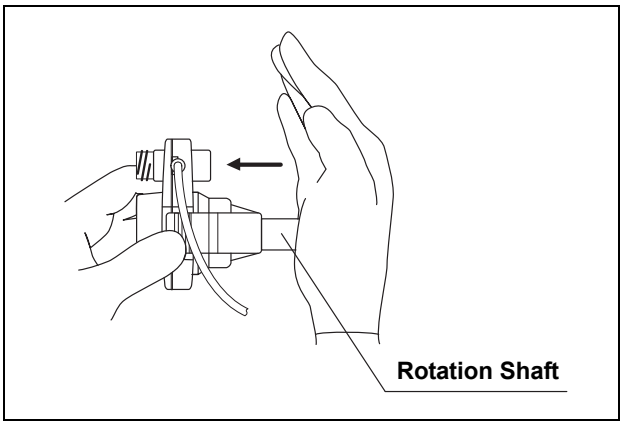


Figure 3.2

3. While holding the Snaps on the left and right sides of the Water Pump, insert the Pump into the Water Pump Connector of the HEAT PROBE UNIT until it stops (see Figure 3.3). To disconnect the Water Pump, pull it while holding the Snaps.

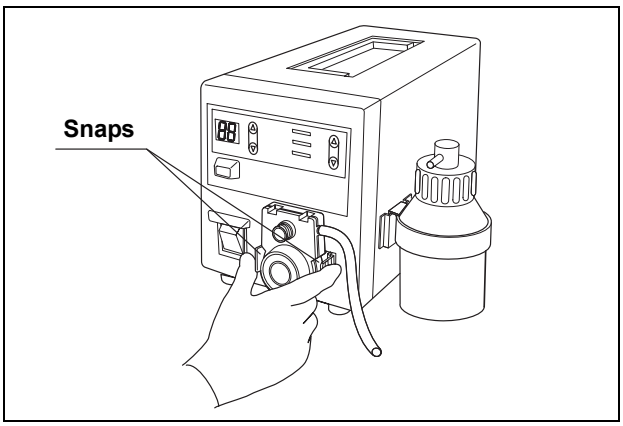


Figure 3.3

4. To ensure connection of the Water Pump, push it into the HEAT PROBE UNIT with both hands (see Figure 3.4).

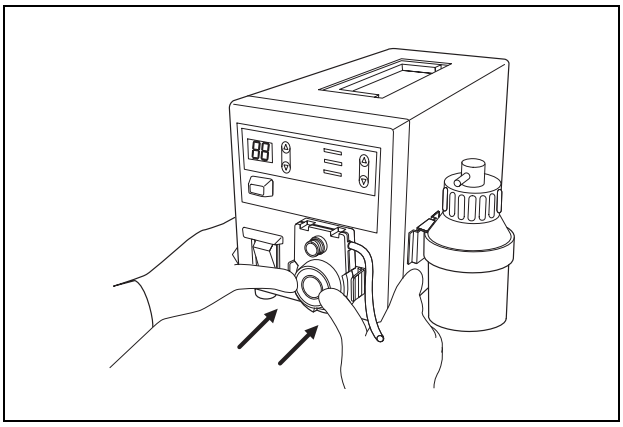


Figure 3.4

5. Push the Water Pump Tube onto the Tube Connector of the Water Container until it stops (see Figure 3.5). Otherwise, water may not be supplied properly.

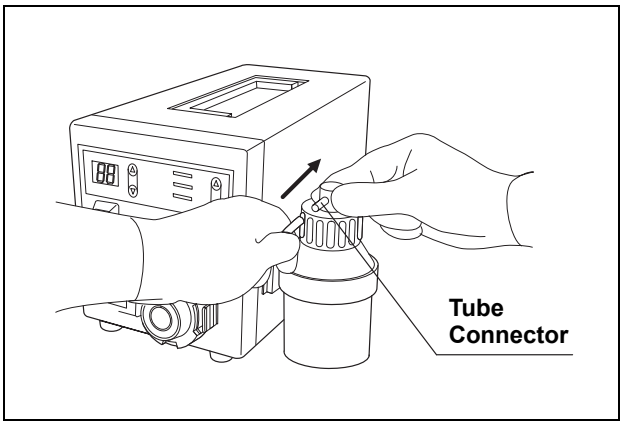


Figure 3.5

3.4 Connection of the HEAT PROBE (CD-110, CD-120)

WARNING

- Be sure to read the instruction manual provided with the HEAT PROBE before using it.
- Sterilize the HEAT PROBE before connecting it. Otherwise infection or inflammation of tissue may result.
- Do not connect the HEAT PROBE to any equipment except the HPU-20. Otherwise, electric shock may result.

CAUTION

- Do not connect Heat Probes other than the CD-110 or CD-120 to the Probe Water Connector. Otherwise the equipment may be damaged.
- Hold the HEAT PROBE by its connector when connecting or disconnecting it, otherwise the HEAT PROBE may be damaged.

NOTE

The Probe Water Connector is a Luer-lock connector.

1. Connect the Water Plug of the HEAT PROBE to the Probe Water Connector on the Water Pump by turning the plug clockwise (see Figure 3.6). To disconnect the plug, turn it counterclockwise.

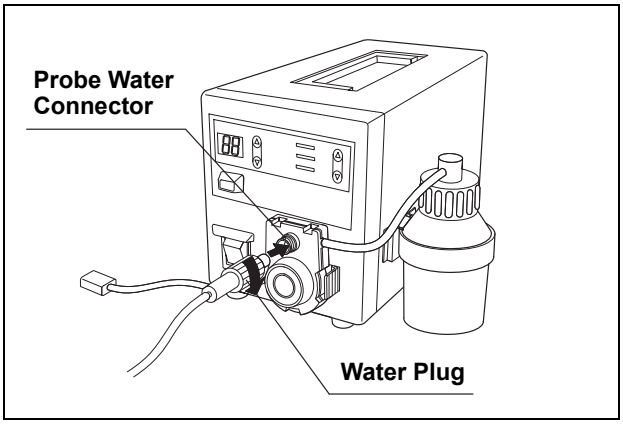


Figure 3.6

2. Connect the HEAT PROBE's Electrical Plug to the Probe Electrical Connector of the HEAT PROBE UNIT (see Figure 3.7). To disconnect the plug, pull it out.

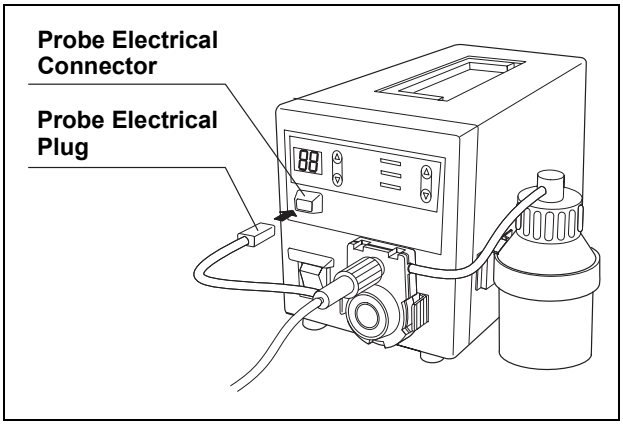


Figure 3.7

3.5 Connection of the Foot Switch (MAJ-528)

Hold the plug of the Foot Switch so that the arrow is on the top, and insert the plug into the Foot Switch Connector on the rear panel of the HEAT PROBE UNIT until it clicks (see Figure 3.8). To disconnect the plug, press the Foot Switch Disconnect Button and pull the plug out.

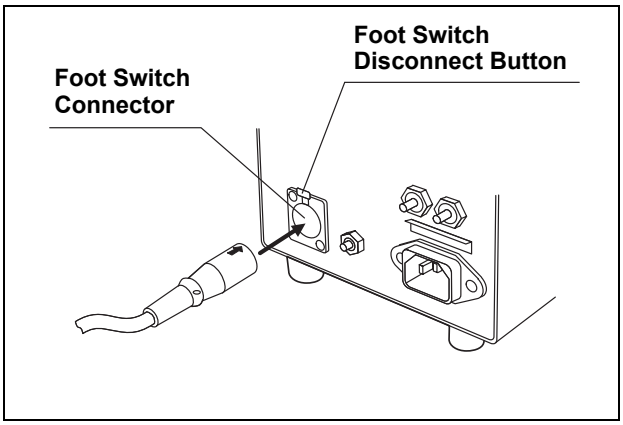


Figure 3.8

3.6 Connection of the Power Cord

DANGER

- Always connect the Power Cord of the HEAT PROBE UNIT directly into a Wall Mains Outlet. If the HEAT PROBE UNIT is not connected directly to a Wall Mains Outlet, the HEAT PROBE UNIT cannot be grounded through the Power Cord, and an electric shock or fire hazard may result.
- Do not use any Cord other than the dedicated Power Cord. Doing so may cause a electric shock or fire.

WARNING

- Never moisten the Power Cord. Otherwise an electrical shock may result.
- Ensure that the Wall Mains Outlet has a higher capacity than the total current consumption of all connected equipment, including the HEAT PROBE UNIT. If the power capacity is lower than the total current consumption, a fire hazard may occur, or, when the circuit breaker of the medical facility is activated, the power of the HEAT PROBE UNIT and all equipment connected to the same power source may be shut off.

- Do not apply excessive force to the Power Cord by bending, pulling, twisting or crushing it. Otherwise the Power Cord's wires may be disconnected and a fire hazard or electric shock may result.

CAUTION

Do not connect the power cord of the HPU-20 to a different voltage electrical outlet. Fire and smoke may result.

1. Ensure that the Power Switch of the HEAT PROBE UNIT is set to the OFF "O" position (see Figure 3.9).

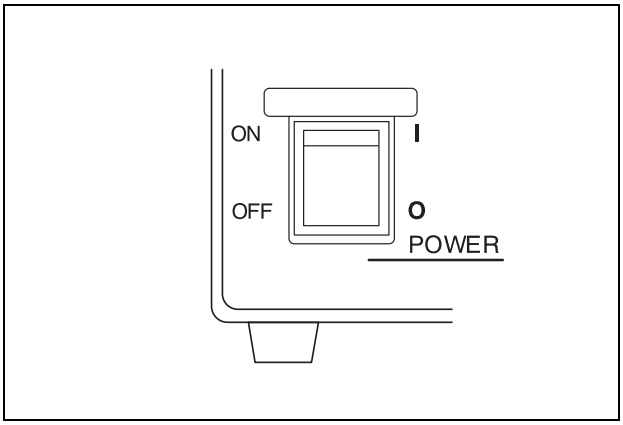


Figure 3.9

2. Insert the AC inlet end of the Power Cord into the AC Inlet of the HEAT PROBE UNIT until it stops (see Figure 3.10).
3. Insert the Power Plug of the Power Cord directly into a Wall Mains Outlet at the medical facility (see Figure 3.10).

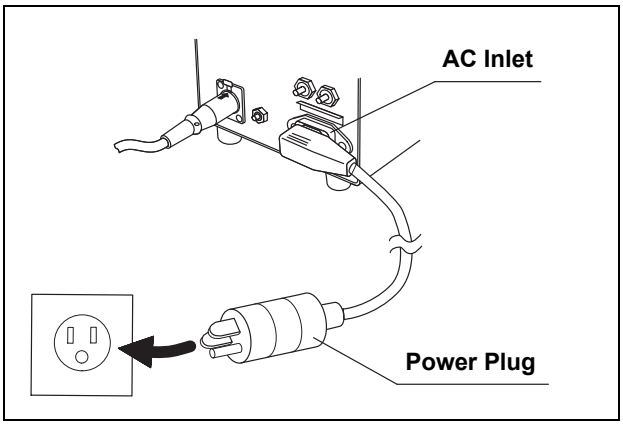


Figure 3.10

Chapter 4 Inspection

WARNING

- Before each case, prepare and inspect this instrument as instructed below. Inspect other equipment to be used with this instrument as instructed in their respective instruction manuals. Should the slightest irregularity be suspected, do not use the instrument and see Chapter 7, “Troubleshooting”. If the irregularity is still suspected after consulting Chapter 7, contact Olympus.
  Damage or irregularity may compromise patient or user safety and may result in more severe equipment damage. Do not use the HEAT PROBE UNIT if you suspect an abnormality.
- This instrument was not sterilized before shipment. Before using this instrument for the first time, reprocess it according to the instructions in Chapter 6, “Care, Storage and Disposal”.

According to the “System Chart” in Appendix, prepare this instrument, other equipment that are used with this instrument, paper towels, basin, gauze and protective equipment, such as eye wear, a face mask, moisture-resistant clothing and chemical-resistant gloves, for the procedure. Refer to respective instruction manuals for each item.

4.1 Inspection the Power Supply

Turn the Power Switch to the ON (“ | ”) position and ensure that power is supplied to the unit by checking the following: The Power Switch should be illuminated green, three different tones should be produced; and the front panel display and lamps should blink for about 2 seconds, after which they will remain lit (see Figure 4.1).

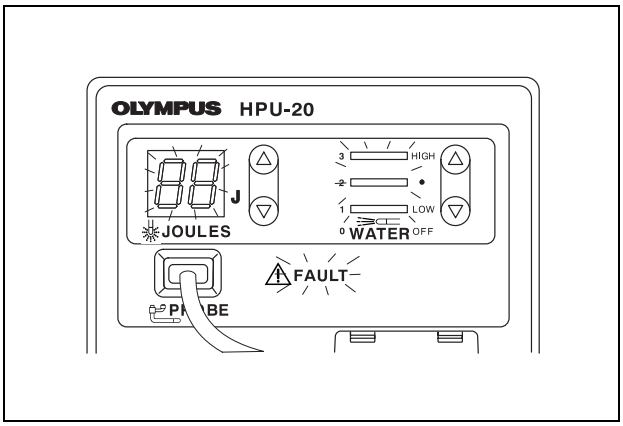


Figure 4.1

❍ If no Power is Supplied

If the power is not supplied to the HEAT PROBE UNIT, inspect the equipment using the following procedure:

1. Ensure that the Power Cord is connected securely to the AC Inlet of the HEAT PROBE UNIT and the Wall Mains Outlet.
2. Ensure that the circuit breakers have not tripped. If one or both circuit breakers have tripped, reset them as described in Steps 3. and 4. below.

WARNING

Reset the circuit breaker(s) only once. If power is still not supplied, immediately turn off the Power Switch (“O”), unplug the Power Cord from the Wall Mains Outlet and contact Olympus. The HEAT PROBE UNIT may be abnormal or faulty and continued attempts to use it may result in a fire hazard or electric shock.

CAUTION

When the circuit breaker is activated, do not immediately reset it. Turn off the Power Switch (“O”) and wait for at least 15 seconds before resetting it. Otherwise the circuit breaker may malfunction.

3. Turn off the Power Switch (“O”). Remove the Power Plug from the Wall Mains Outlet and push in the circuit breaker button until it clicks (see Figure 4.2).

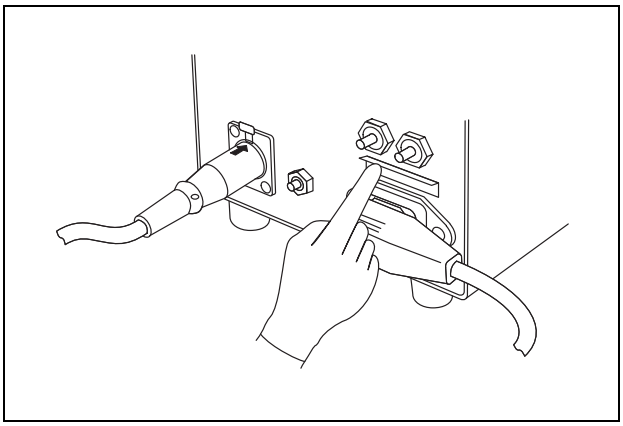


Figure 4.2

4. After pushing the circuit breaker button in, connect the Power Plug again. Then turn the Power Switch to ON (“ | ”) and confirm that power is supplied to the unit.

❍ If the red FAULT Indicator Lights and an Alarm Tone is Generated

If the red FAULT indicator lamp on the front panel of the HEAT PROBE UNIT lights up and an alarm tone is generated when the HEAT PROBE UNIT is turned ON, inspect it following the procedures described in Chapter 7, “Troubleshooting”.

4.2 Inspection the Energy Level Settings

Before inspecting the Energy Level settings, connect all ancillary equipment following the procedures described in Chapter 3, “Installation and Connection” and turn the Power Switch ON (“ | ”).

Press the Energy Setting Switches (“▲” and “▼”) on the front panel and ensure that the Energy Level Indicator can be changed in 6 successive steps to 5, 10, 15, 20, 25 and 30 joules [J], respectively (see Figure 4.3). A short beep is generated at each step.

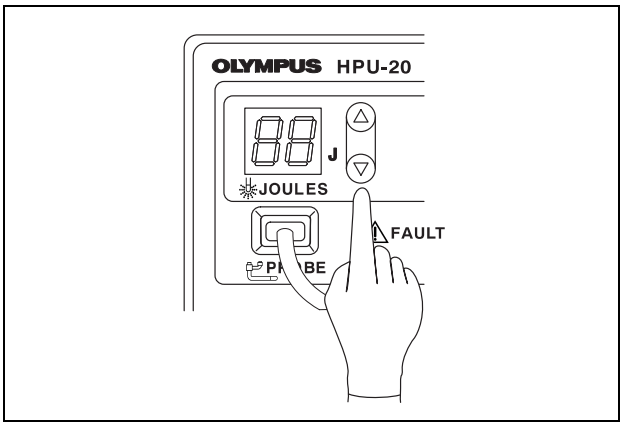


Figure 4.3

NOTE

Inspect the HEAT PROBE as described in Section 4.4, “Inspection the HEAT PROBE (CD-110, CD-120)”.

4.3 Inspection the Water Feed Settings

Before inspecting the water feed settings, connect all ancillary equipment following the procedures described in Chapter 3, “Installation and Connection” and turn the Power Switch ON (“ | ”).

Press the Water Feed Indicator setting switches (“▲” and “▼”) on the front panel and confirm that the Water Feed Indicator can be changed in 4 successive steps to “HIGH”, “•”, “LOW” and “OFF”, respectively (see Figure 4.4). A short beep is generated at each step.

NOTE

- The Water Feed Level Indicators are not illuminated when the water feed level is set to “OFF”.
- The step “•” means a level between “HIGH” and “LOW”.

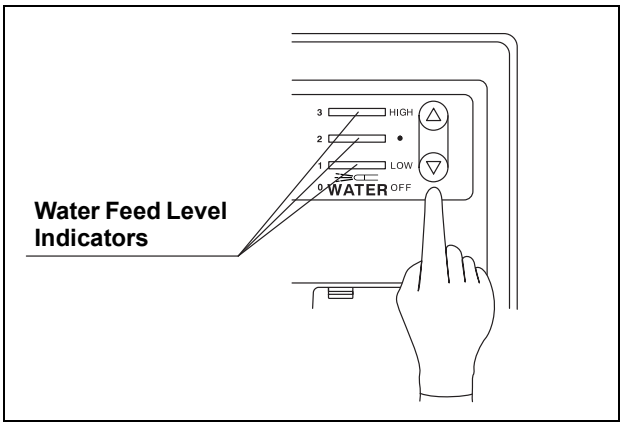


Figure 4.4

4.4 Inspection the HEAT PROBE (CD-110, CD-120)

Before inspecting the HEAT PROBE, connect all ancillary equipment following the procedures described in Chapter 3, “Installation and Connection” and turn the Power Switch ON (“ | ”).

CAUTION

- If the red FAULT indicator lamp on the front panel of the HEAT PROBE UNIT lights up and an alarm tone is generated during inspection of the HEAT PROBE, inspect the HEAT PROBE UNIT as described in Section 7.1, “Troubleshooting Guide”.
- Do not touch the tip of the HEAT PROBE with your finger during this inspection. Otherwise you may burn your finger.
- Do not activate the HEAT PROBE unless it is submerged in liquid. Otherwise the HEAT PROBE may malfunction.

1. Press the Energy Setting Switches (“▲” and “▼”) to set the energy level to 20 J (see Figure 4.5).
2. Fill a sterile container such as a beaker with sterile water and immerse the tip of the HEAT PROBE in the water.
3. Press the “COAG” pedal on the Foot Switch.
4. Ensure that the output buzzer beeps, the Energy Level Indicator on the front panel blinks and then lights steadily.

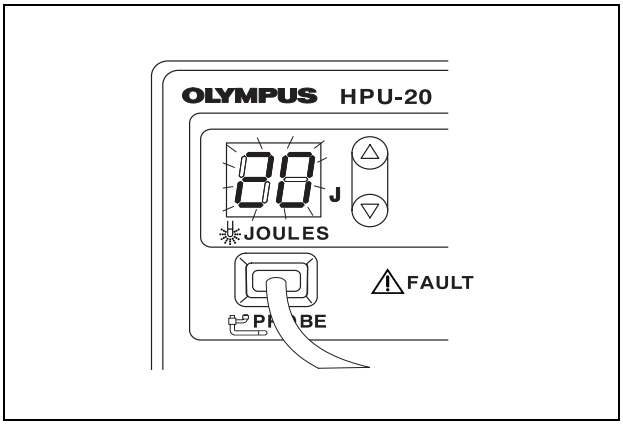


Figure 4.5

4.5 Inspection the Water Feed Function

Inspect the Water Feed Function to check if water is properly supplied. Before inspecting the water feed, connect all ancillary equipment following the procedures described in Chapter 3, “Installation and Connection” and turn the Power Switch ON (“ | ”).

DANGER

Do not place anything under this equipment.
The Water Pump is a consumable product.
The Water leakage caused by the exceeded number of the usage may hinder operations. Replace the Water Pump after using it in approximately 40 clinical cases.

WARNING

Do not allow the equipment to become wet. Otherwise an electric shock or equipment damage may occur.

CAUTION

Do not insert your fingers into the Water Pump Connector when the motor shaft is rotated. This may result in injury.

1. Confirm that the Water Container is filled with sterile water.
2. Set the water feed level to “Low” (see Figure 4.6).
3. Place the tip of the HEAT PROBE in a breaker or other container to retrieve the fed water.
4. Prime the HEAT PROBE by pressing the “WASH” pedal of the Foot Switch until water comes out of the tip of the HEAT PROBE.

NOTE

- Priming water means supplying water to the tube so that it can be fed steadily from the tip of the HEAT PROBE.
- We recommend that you release the pedal as soon as water comes out of the tip of the HEAT PROBE. Priming more water than necessary will shorten the service life of the Water Pump.

5. Change the water feed level to "•" then "HIGH", and confirm that the water feed level from the tip of the HEAT PROBE changes accordingly (see Figure 4.6).

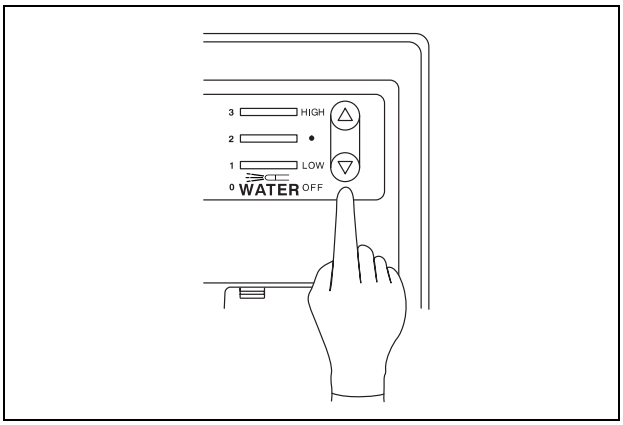


Figure 4.6

Chapter 5 Operation

The operator of this instrument must be a physician or medical personnel under the supervision of a physician and must have received sufficient training in 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 this instrument.

WARNING

- Use personal protective equipment to guard against dangerous chemicals and infectious material. During operation, wear appropriate protective equipment, such as eye wear, a face mask, moisture-resistant clothing and chemical-resistant gloves that fit properly and are long enough so that your skin is not exposed.
- If you suspect an irregularity or malfunction when attempting to operate this instrument, turn OFF the power switch and follow the instructions given in Chapter 7, “Troubleshooting”. If the irregularity or malfunction persists after you have referred to Chapter 7, do not use the instrument and contact Olympus. Using an instrument that is not working properly may cause the unit to malfunction and could also lead to electric shock, burns or fire hazard.

5.1 Turn the Power ON

Connect all ancillary equipment following the procedures described in Chapter 3, “Installation and Connection” and turn the Power Switch of the HEAT PROBE UNIT ON (“ | ”) (see Figure 5.1).

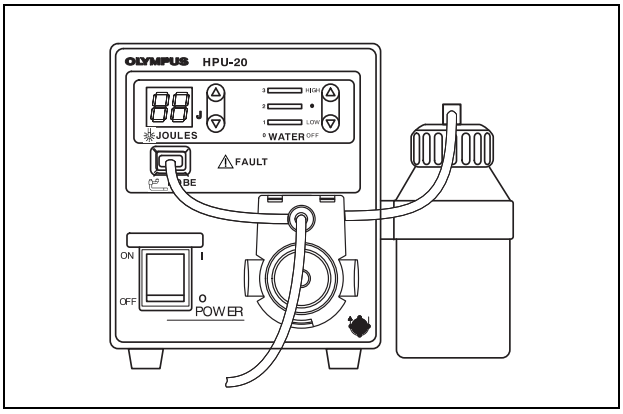


Figure 5.1

5.2 Set the Energy Level

Set the energy level from the HEAT PROBE by pressing the Energy Setting Switches (“▲”and “▼”) on the front panel (see Figure 5.2).

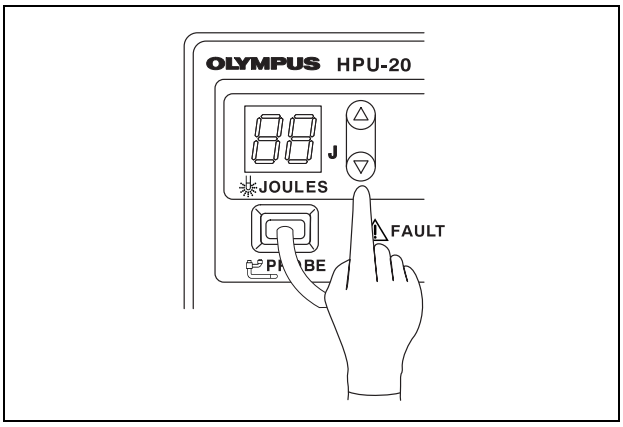


Figure 5.2

5.3 Set the Water Feed Level

Set the water feed level by pressing the Water Feed Setting Switches (“▲”and “▼”) on the front panel (see Figure 5.3).

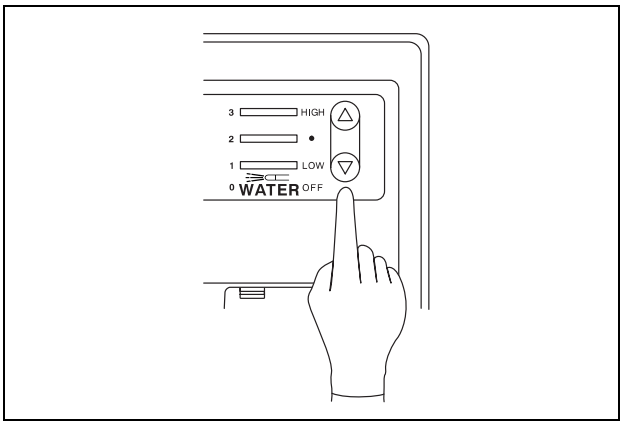


Figure 5.3

5.4 Insert the HEAT PROBE (CD-110, CD-120)

Following the instruction manuals for HEAT PROBE.

Insert the HEAT PROBE slowly into the biopsy valve of the endoscope (see Figure 5.4).

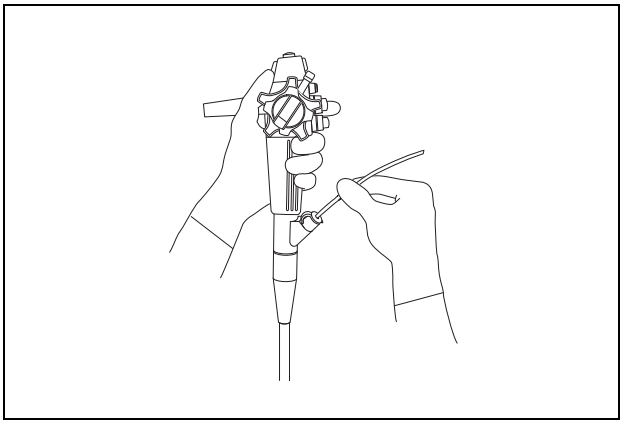


Figure 5.4

5.5 Coagulating Tissue

DANGER

- To stop tissue coagulation, remove the HEAT PROBE from the tissue or turn the Power Switch of the HEAT PROBE UNIT OFF (“O”) to prevent an accident or patient injury.
- Do not press the tip of the HEAT PROBE against the tissue with excessive force. Doing so may injure the tissue.
- Be careful not to press the foot switch of other instrument.

WARNING

Do not allow the Distal End of the endoscope and the tip of HEAT PROBE to come in contact with each other. If heat is generated while the HEAT PROBE is in contact with the endoscope, the endoscope may be damaged.

CAUTION

- If the red FAULT indicator lamp on the front panel lights up and an alarm is generated during operation, inspect the HEAT PROBE UNIT as described in Section 7.1, “Troubleshooting Guide”.
- If any abnormalities occur, e.g. water feeding does not stop, follow the instructions given in Chapter 7, “Troubleshooting”.
- Do not feed water to the HEAT PROBE if it is bent. This may result in equipment damage.

1. Ensure that the tip of the HEAT PROBE is completely visible in the endoscopic field of view and is not in contact with non-target tissue.
2. Depress the “WASH” pedal of the Foot Switch to feed water through the HEAT PROBE and wash blood away from the target site.
3. Apply the tip of the HEAT PROBE to the target site.
4. Press the “COAG” pedal of the Foot Switch. The buzzer sounds continuously, the Energy Level Indicator on the front panel blinks, and the tip of the HEAT PROBE generates heat to coagulate the tissue.

NOTE

The “COAG” pedal does not have to be held down. Once the pedal is pressed, the HEAT PROBE generates the set energy level automatically, then stops.

5. If more heat is required after the initial output has stopped, press the “COAG” pedal again.
6. After confirming hemostasis, depress the “WASH” pedal of the Foot Switch to feed water for a second or two to cool the tip of the HEAT PROBE.
7. Slowly withdraw the HEAT PROBE from the endoscope. If you are using an endoscope with a forceps elevator, first lower the elevator, then withdraw the HEAT PROBE slowly.

CAUTION

Do not withdraw the HEAT PROBE immediately after heat generation. Otherwise the endoscope may be damaged by the heat from the HEAT PROBE.

Chapter 6 Care, Storage and Disposal

6.1 Reprocessing: General Policy

- This chapter describe recommended procedures for the cleaning and sterilization this instrument.
- If you have any questions or comments about any information in this manual or if a problem that cannot be solved occurs while you are using the instrument, contact Olympus.
- The medical literature reports incidents of patient cross contamination resulting from improper cleaning and sterilization. It is strongly recommended that reprocessing personnel have a thorough understanding of and follow all national and local hospital guidelines and policies. It is highly desirable that a trained backup be available should the primary reprocessing individual(s) be absent.
- All individuals responsible for reprocessing should thoroughly understand:
    - your institution’s reprocessing procedures
    - occupational health and safety regulations
    - national and local hospital guidelines and policies
    - the instructions in this manual
    - pertinent germicide labeling

WARNING

- Failure to properly clean and sterilize the equipment after each examination can compromise patient safety. During use, the equipment normally comes in contact with intact mucous membranes. To minimize the risk of transmitting diseases from one patient to another, after each examination the equipment must undergo thorough manual cleaning followed by sterilization.
- If the equipment is not cleaned meticulously, effective sterilization cannot be obtained. Clean the equipment thoroughly before sterilization to remove microorganisms or organic material that could reduce the efficacy of sterilization.

- Use protective equipment to guard against dangerous chemicals and infection material. During cleaning and sterilization, wear appropriate protective equipment, such as eye wear, a face mask, moisture-resistant clothing, and chemical-resistant gloves that fit properly and are long enough so that your skin is not exposed. Always remove contaminated protective clothing before leaving the cleaning area.
- The sterilization room must be adequately ventilated. Adequate ventilation protects against the buildup of toxic chemical fumes.
- Use 70% ethyl or isopropyl alcohol as directed on container labels. Store alcohol in an air-tight container. Alcohol stored in an open container may cause fires and will lose its efficacy due to evaporation.

6.2 Compatible Reprocessing Methods and Chemical Agents

❍ Compatibility Summary

The equipment is compatible with several methods of reprocessing. Certain methods, however, are not compatible with some components and can cause equipment damage. For appropriate reprocessing methods, refer to the Table below and the recommendations of your infection control committee and national and local hospital guidelines and policies.

HPU-20 Water Container and Water Pump are compatible with 2.0% to 3.2% glutaraldehyde solution. However, routine biological monitoring is not feasible with glutaraldehyde and, therefore, it should not be used to sterilize reusable medical devices that are compatible with other methods of sterilization that can be biologically monitored, such as steam sterilization.

CAUTION

- Endo-Therapy Accessories and other items which are marked by the words “AUTOCLAVE” or “AUTOCLAVABLE” are compatible with autoclaving.
- Endo-Therapy Accessories and other items which are marked with a green band or yellow-green marking are compatible with autoclaving.

		MAJ-526	MAJ-527
Cleaning	Ultrasonic	■	
	Solutions	■	■
Sterilization	Steam Sterilization (Autoclave)	■	■
	Ethylene Oxide Gas Sterilization		

■ **applicable** □ **not applicable**

❍ Rinsing Water

Once removed from the disinfectant solution, the instrument must be thoroughly rinsed with sterile water to remove any disinfectant residue. If sterile water is not available, clean potable tap water or water which has processed (e.g. filtered) to improve its microbiological quality may be used.

When non-sterile water is used after manual or automated disinfection, rinse the equipment with 70% ethyl or isopropyl alcohol, then are-dry all the equipment to inhibit the growth of residual bacteria.

Do not reuse rinsing water.

❍ Steam Sterilization (Autoclaving) of the Accessories

Steam sterilize (autoclave) the equipment within the parameters given in the Table below. When autoclaving, follow the hospital's protocol and the sterilization equipment manufacturer's instructions.

WARNING

Use biological indicators as recommended by your hospital's policy and follow the manufacturer's instructions, all national and local hospital guidelines and policies.

CAUTION

- Endo-Therapy Accessories and other items which are marked by the words "AUTOCLAVE" or "AUTOCLAVABLE" are compatible with autoclaving.
- Endo-Therapy Accessories and other items which are marked with a green band or yellow-green marking are compatible with autoclaving.

	Temperature	Exposure Time
Prevacuum	132 – 134°C (270 – 274°F)	5 minutes

- Autoclaving the equipment under conditions other than specified above may damage the equipment.

6.3 Required Reprocessing Equipment

		MAJ-526	
		cleaning	**sterilization**
Ultrasonic Cleaner	Use a medical grade Ultrasonic cleaner with a frequency range 40 kHz or higher, and with a depth and a diameter large enough to allow complete immersion of the equipment. Compatible ultrasonic cleaners include OLYMPUS ULTRASONIC CLEANER KS-2.	○	
A basin for drainage	Use a beaker or other container.	○	
Syringe	Use a 30 cm^3 syringe or larger.	○	
Packages for Steam sterilization	Use packages compatible with steam sterilization (autoclaving). The package should be large enough to accommodate the equipment.		○
Sealing Device for Packages	Sealing the packages may require a device such as a heat sealer. Prepare an appropriate sealing device according to the packages to be used.		○
Autoclave	Use an autoclave that will operate at the conditions specified in Section 6.2, “Compatible Reprocessing Methods and Chemical Agents”.		○

		MAJ-527	
		cleaning	**sterilization**
A Tube for cleaning and disinfection	Use the HEAT PROBE (CD-110, CD-120) or a Tube with a Luer-lock connector.	○	
A basin for drainage	Use a beaker or other container.	○	
Syringe	Use a 30 cm^3 syringe or larger.	○	
Packages for Steam sterilization	Use packages compatible with steam sterilization (autoclaving). The package should be large enough to accommodate the equipment.		○
Sealing Device for Packages	Sealing the packages may require a device such as a heat sealer. Prepare an appropriate sealing device according to the packages to be used.		○
Autoclave	Use an autoclave that will operate at the conditions specified in Section 6.2, “Compatible Reprocessing Methods and Chemical Agents”.		○

6.4 Care and Storage of the HEAT PROBE (CD-110, CD-120)

1. Remove the Water Pump Tube from the Tube Connector of the Water Container (see Figure 6.1).

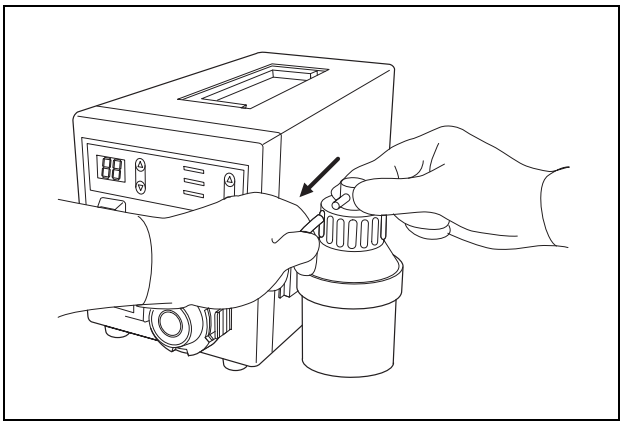


Figure 6.1

2. Place the tip of the HEAT PROBE in a beaker or other container, then drain the water remaining in the tube (see Figure 6.2).
3. Depress the “WASH” pedal of the Foot Switch until no water comes out of the tip of the HEAT PROBE.

NOTE

We recommend that you release the pedal as soon as water stops coming out of the tip of the HEAT PROBE. Operating the Water Pump without running water through it will shorten the service life of the Water Pump.

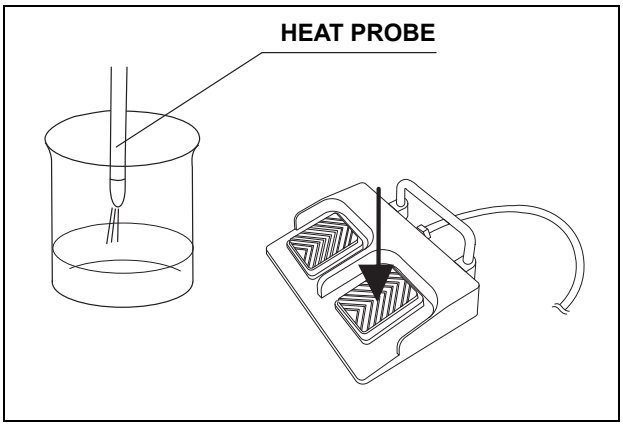


Figure 6.2

4. Disconnect the HEAT PROBE from the HEAT PROBE UNIT. Maintain and store the HEAT PROBE as described its instruction manual.

6.5 Care and Storage of the Water Pump (MAJ-527)

WARNING

- Each time the HPU-20 is used, clean and disinfect (or sterilize) the Water Pump according to the following procedure. An improperly maintained Water Pump can pose an infection control risk.
- Make sure to pull out the Rotation Shaft. Failure to do this may damage the Water Pump and may pose an infection control risk.

❍ Cleaning

1. Disconnect the Water Pump from the HEAT PROBE UNIT by holding the snaps on the Water Pump and pull out the Rotation Shaft from the pump until it stops (see Figure 6.3).

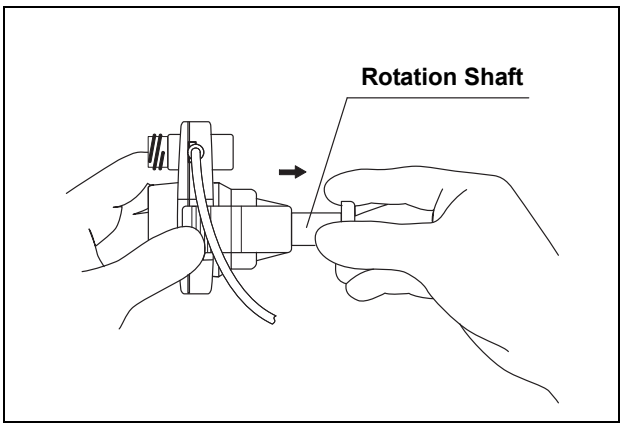


Figure 6.3

2. Wipe the external surfaces of the Water Pump using a piece of gauze moistened with 70% ethyl or isopropyl alcohol.

CAUTION

Do not immerse or soak the Water Pump. Doing so may damage the Water Pump.

3. Attach the HEAT PROBE (or a Tube with a Luer-lock connector) to the Probe Water Connector of the Water Pump and place the other end of the HEAT PROBE (or Tube) in a beaker or other container.

4. Fill a 30 cm^3 or larger syringe with detergent solution, connect it to the Water Pump Tube and inject the solution (see Figure 6.4).

5. Repeat Step 2. to inject the solution a total of 120 cm^3 (4 times) or over.

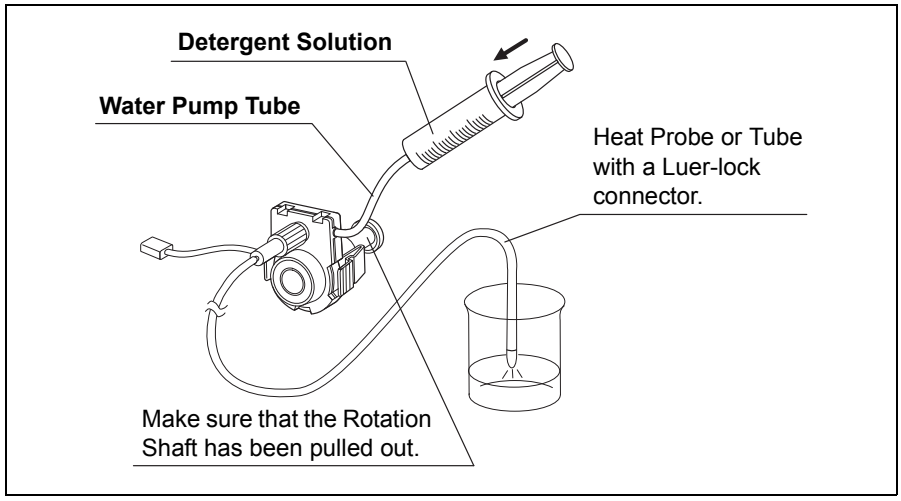


Figure 6.4

6. Disconnect the syringe, fill it with rinsing water, reconnect it to the Water Pump Tube with the water of a total of 120 cm^3 (4 times) or more.

7. Disconnect the syringe, fill it with air, reconnect it to the Water Pump Tube with air to remove the water (see Figure 6.5).

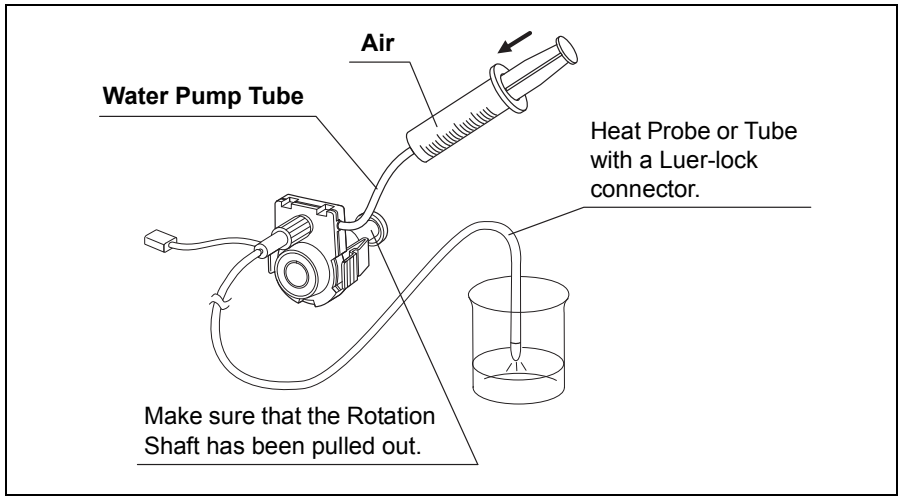


Figure 6.5

Steam Sterilizing (Autoclaving) the Water Pump

1. Pull out the Rotation Shaft of the Water Pump until it stops (see Figure 6.6).

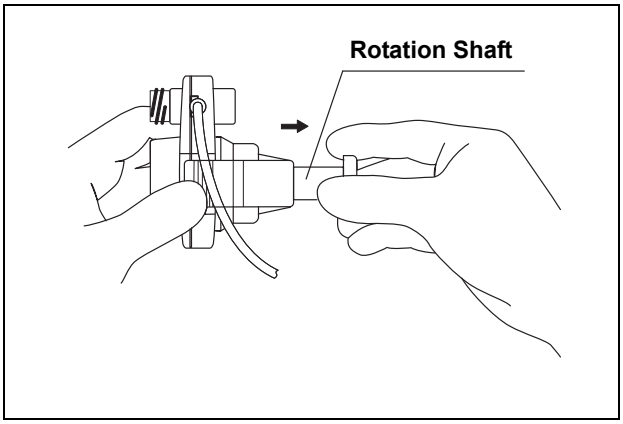


Figure 6.6

2. Seal the Water Pump in a package as shown in Figure 6.7 and place it in the autoclave. See Section 6.2, “Compatible Reprocessing Methods and Chemical Agents” for the recommended autoclaving conditions.

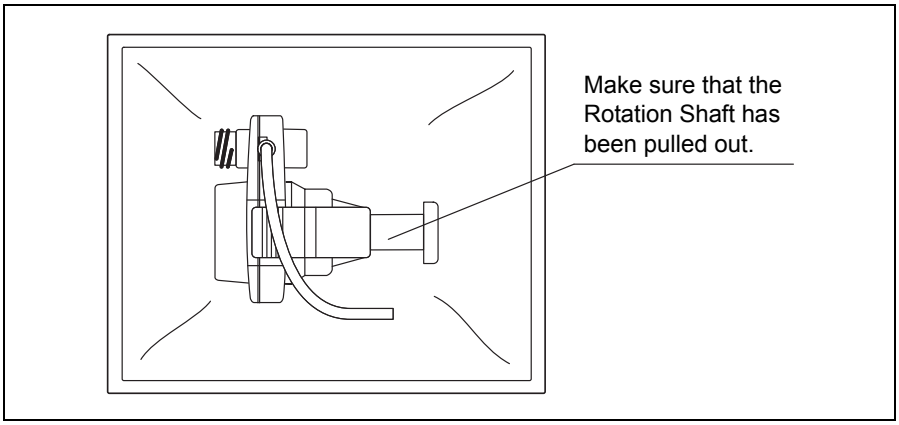


Figure 6.7

3. After autoclaving, store the Water Pump in the sealed sterile package.

WARNING

Do not store the sterile package in a place where it may become damaged or wet, otherwise the sterility of the Water Pump may not be maintained.

CAUTION

Do not store the Water Pump in direct sunlight. Doing so may damage the Water Pump.

6.6 Care and Storage of the Water Container (MAJ-526)

WARNING

Each time the HPU-20 is used, clean and disinfect (or sterilize) the Water Container according to the following procedure. An improperly maintained Water Container can pose an infection control risk.

❍ Cleaning

1. Disconnect the Water Container from the HEAT PROBE UNIT.
2. Use detergent solution, a brush and/or clean gauze to wash the Cap and both the inside and outside of the Water Container.
3. Put the Tube Connector in a container such as a beaker.
4. Fill a 30 cm^3 or larger syringe with detergent solution, connect it to the Cap Tube and inject the solution.
5. Repeat Step 4. to inject the detergent solution a total of 120 cm^3 (4 times) or over.
6. Disconnect the syringe, fill it with rinsing water, reconnect it to the cap tube and flush the tube with the water of a total of 120 cm^3 (4 times) or more.
7. Disconnect the syringe, fill it with air, reconnect it to the cap tube and flush the tube with air to remove the water.
8. If the Water Container should require further cleaning, first wash it again manually as described above, then perform ultrasonic cleaning for about 5 minutes using an ultrasonic cleaner with a frequency of 40 kHz or higher.
9. Rinse and dry the Water Container.

❍ Steam Sterilizing (Autoclaving) the Water Container

1. Remove the cap from the Water Container, seal them together in a package as shown in Figure 6.8, and place the package in an autoclave. See Section 6.2, “Compatible Reprocessing Methods and Chemical Agents” for the recommended autoclave parameters.

NOTE

The Band may come off of the Water Container due to expansion during autoclaving. However, since it returns to normal size when it cools down, attach it again after autoclaving.

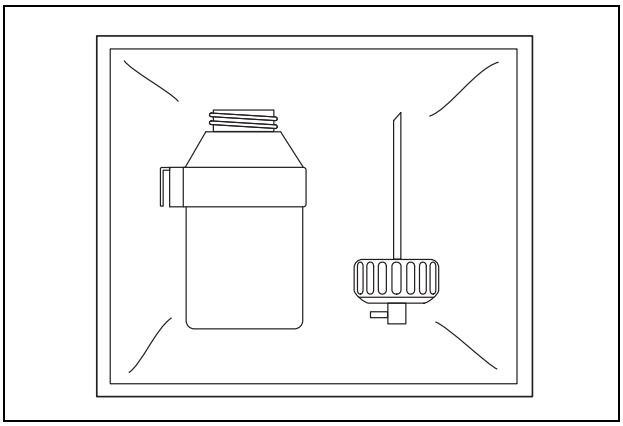


Figure 6.8

2. After autoclaving, store the Water Container sealed in the sterile package.

WARNING

Do not store the sterile package in a place where may become damaged or wet, otherwise an infection-control risk may result.

CAUTION

Do not store the Water Container in direct sunlight. Doing so may damage the Water Container.

6.7 Care and Storage of the Foot Switch (MAJ-528)

WARNING

Keep all liquids away from the Foot Switch plug. Otherwise a connection failure or malfunction of the HEAT PROBE UNIT may occur.

CAUTION

The Foot Switch cannot be disinfected by immersion, and it cannot be sterilized by ETO gas or steam sterilization (autoclaving). These processes will damage the Foot Switch.

Remove dirt and organic debris from the Foot Switch immediately after use as described below. Over time, organic debris may coagulate and become hard to remove. Also clean the Foot Switch on a regular basis.

1. Detach the Foot Switch from the HEAT PROBE UNIT.

NOTE

To disconnect the Foot Switch plug from the HEAT PROBE UNIT, press the Foot Switch Disconnect Button on the HEAT PROBE UNIT's rear panel.

2. Remove any dirt, dust or stains from the surface of the Foot Switch with a soft, dry cloth or brush, then wipe it down with a piece of gauze moistened with 70% ethyl or isopropyl alcohol.
3. To remove gross organic debris, wipe down the Foot Switch with a piece of gauze moistened with detergent solution, then wipe it with another piece of gauze moistened with 70% ethyl or isopropyl alcohol.
4. Coil the cord and store it near the HEAT PROBE UNIT in the clean environment.

6.8 Care and Storage of the HEAT PROBE UNIT (HPU-20)

WARNING

- When wiping the Power Switch, only use a dry piece of gauze. Using wet gauze may cause the switch to malfunction or cause an electric shock.
- If the HEAT PROBE UNIT has been wiped with a piece of gauze moistened with a detergent solution or 70% ethyl or isopropyl alcohol, dry the HEAT PROBE UNIT completely before its next use. Using the HEAT PROBE UNIT while it is wet may cause an electric shock.

CAUTION

- Do not touch the inside of any connector. Otherwise the HEAT PROBE UNIT may malfunction due to contact failure resulting from deformation or corrosion of the contacts.
- Do not disinfect or sterilize the HEAT PROBE UNIT using immersion in the disinfectant solution, steam (autoclave) or ETO gas. These processes will damage the HEAT PROBE UNIT or cause electrical shock.
- To prevent scratching the surface of the HEAT PROBE UNIT, only wipe it with a soft, lint-free cloth.

Remove dirt or organic debris from the HEAT PROBE UNIT immediately after use as described below. Over time, organic debris may coagulate and become hard to remove. Also clean the HEAT PROBE UNIT on a regular basis.

1. Turn the Power Switch of the HEAT PROBE UNIT OFF (“O”) and disconnect the Power Plug.
2. Remove any dirt, dust or stains from the surface of the unit with a soft, dry cloth or brush, then wipe it down with a piece of gauze moistened with 70% ethyl or isopropyl alcohol.
3. To remove gross organic debris, wipe down the HEAT PROBE UNIT with a piece of gauze moistened with detergent solution, then wipe it with another piece of gauze moistened with 70% ethyl or isopropyl alcohol.

4. Store the HEAT PROBE UNIT as shown in Figure 6.9 on a clean, stable, horizontal surface.

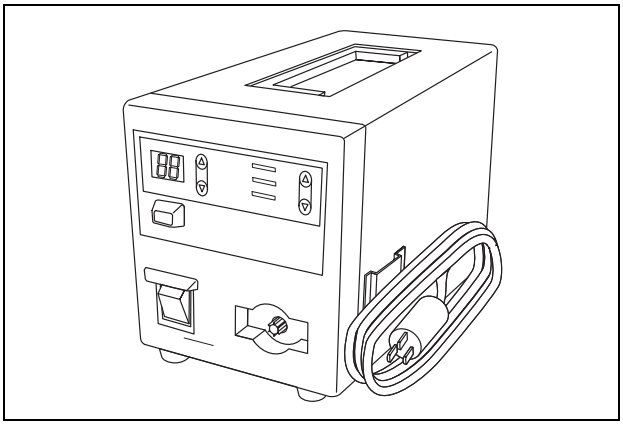


Figure 6.9

CAUTION

Do not store the HEAT PROBE UNIT in a place where it may be exposed to direct sunlight, X-rays, radiation or strong magnetic waves (for example, near microwave treatment equipment, shortwave treatment equipment, MRI, radio, etc.). Otherwise the HEAT PROBE UNIT may malfunction.

6.9 Disposal

When disposing of this instrument, or any of other components, follow all applicable national and local laws and guidelines.

Chapter 7 Troubleshooting

If the instrument is visibly damaged, does not function as expected or is found to have other irregularities during the inspections described in Chapter 3, “Installation and Connection”, and Chapter 4, “Inspection” do not use the instrument. Contact Olympus.
Problems that appear not to be malfunctions may be correctable by referring to Section 7.1, “Troubleshooting Guide”.
Should you fail to correct the problem even after taking the described remedial action, stop using the instrament and send it to Olympus for repair.
Olympus does not repair accessory parts. If an accessory part becomes damaged, please contact Olympus and purchase a replacement.

DANGER

If any abnormalities are suspected, do not use the HEAT PROBE UNIT. This could result in death or serious injury.

7.1 Troubleshooting Guide

This section addresses the possible causes and solutions of problems that may occur due to errors in equipment setup or deterioration of parts. Problems and malfunctions other than those listed below should be serviced by Olympus.

Error code

Error Code	Irregularity Description	Possible Cause	Solution
E1	Improper connection, damaged or disconnected wires, or HEAT PROBE short-circuit.	The HEAT PROBE is not connected properly.	Re-connect the Probe Electrical Plug to the HEAT PROBE UNIT.
		The life of the HEAT PROBE has expired.	Replace it with a new HEAT PROBE.
E2	The Water Pump's Rotation Shaft is locked.	The water pump is not connected properly to the HEAT PROBE UNIT.	Re-connect the Water Pump.
E3	Simultaneous occurrence of E1 and E2.	See E1 and E2.	See E1 and E2.
E4	The "WASH" output from the Foot Switch has been active for more than 3 min.	The "WASH" pedal is being held down.	Make sure that nothing is lying on the "WASH" pedal.
E5	A Foot Switch pedal is depressed when Power Switch is turned ON.	A Foot Switch pedal is being pressed.	Make sure that nothing is lying on the Foot Switch pedals.
E6	A control panel switch is depressed when Power Switch is turned ON.	A control panel switch is being depressed.	Confirm that nothing is pressing against the control panel switches.

HPU-20 Functions

Irregularity	Possible Cause	Solution
Power cannot be turned ON.	Power Plug is not connected.	Connect the Power Plug to a Wall Mains Outlet.
	Power Cord is not connected to the inlet of the HEAT PROBE UNIT.	Connect the Power Cord to the AC Inlet.
	Power Switch is not ON.	Turn the Power Switch ON (“ | ”).
	The circuit breaker has tripped.	Push in the circuit breaker button until it clicks, wait at least 15 seconds, then turn the Power Switch ON (“ | ”).
Control panel settings cannot be made.	The HEAT PROBE’s electrical connector is not properly connected.	Re-connect the HEAT PROBE’s electrical connector.
	HEAT PROBE failure.	Replace it with a new HEAT PROBE.
	Power Switch is not ON.	Turn the Power Switch ON (“ | ”).
	The circuit breaker has tripped.	Push in the circuit breaker button until it clicks, wait at least 15 seconds, then turn the Power Switch ON (“ | ”).
No heat can be generated by the HEAT PROBE.	The “COAG” pedal of the Foot Switch is being held down even after heat has been generated.	Make sure that nothing is lying on the Foot Switch pedal.
	The “WASH” pedal of the Foot Switch is being pressed.	Press the “COAG” pedal of the Foot Switch.
	The Foot Switch is not connected.	Connect the Foot Switch.
	Water is being supplied.	Stop feeding water and press the “COAG” pedal.

No water feed.	The water feed is set to “OFF”.	Set a water feed quantity.
	Connection failure.	Re-connect the Water Pump, the HEAT PROBE and the Water Container.
	Water Container is empty.	Fill the Water Container with sterile water.
	HEAT PROBE is damaged.	Replace it with a new HEAT PROBE.
	The “COAG” pedal of the Foot Switch is pressed.	Press the “WASH” pedal of the Foot Switch.
	The Foot Switch is disconnected.	Re-connect the Foot Switch to the HEAT PROBE UNIT.
	The life of the Water Pump has expired.	Replace it with a new Water Pump.
Water feed does not stop.	The “WASH” pedal of the Foot Switch is being pressed.	Make sure that nothing is lying on the Foot Switch pedal.
Water leakage.	Damage to the Water Pump	Replace it with a new Water Pump.
	The HEAT PROBE’s Water Plug is not connected properly.	Re-connect the Water Plug of the HEAT PROBE.

7.2 Returning the HEAT PROBE UNIT for Repair

WARNING

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

Before returning the HEAT PROBE UNIT for repair, contact Olympus. Include a description of the malfunction or damage and the name and telephone number of the individual at your location who is most familiar with the problem. Also include a repair purchase order.

Appendix

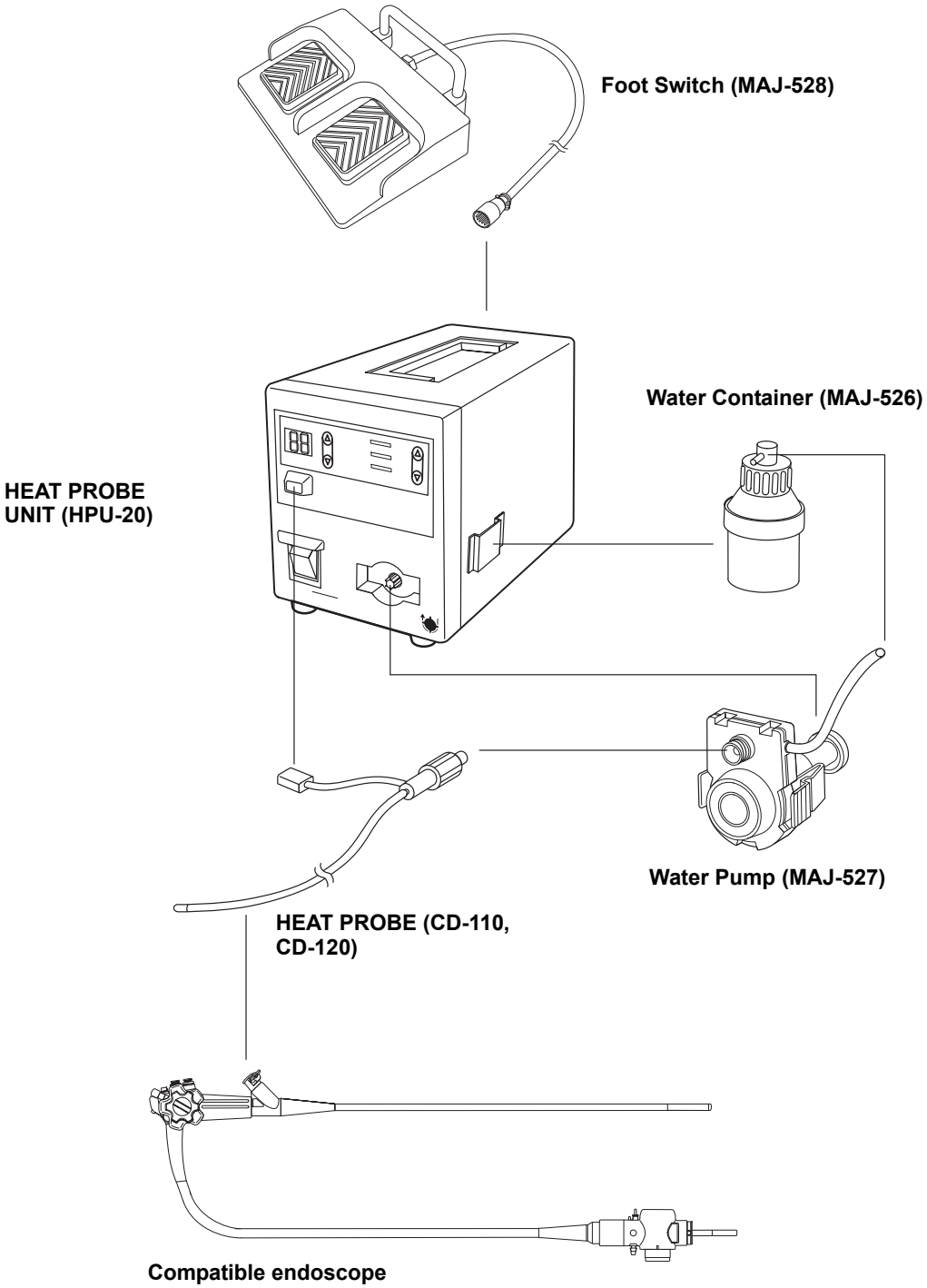
System Chart

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

WARNING

If combinations of equipment other than those shown below are used, the full responsibility is assumed by the medical treatment facility.

System Chart



Operating Environment

Operating Environment	**Ambient Temperature**	10 – 40°C (50 – 104°F)
	Relative Humidity	30 – 85%
	Air Pressure	700 – 1060 hPa (0.7 – 1.1 kgf/cm^2) (10.2 – 15.4 psia)

Transportation and Storage Environment

Transportation and Storage Environment	**Ambient Temperature**	–25 to +70°C (–13 to +158°F)
	Relative Humidity	10 – 90%
	Air Pressure	700 – 1060 hPa

Specifications

HEAT PROBE UNIT (HPU-20)

	Item	Specification
Power Supply	**Voltage**	120 V AC
	Input Current	1 A
	Voltage Fluctuation	Within ±10%
	Frequency	50/60 Hz
	Frequency Fluctuation	Within ±1 Hz
Size	**Dimensions**	150 (W) × 170 (H) × 300 (D) mm
	Dimensions (maximum)	155 (W) × 180 (H) × 320 (D) mm
	Weight	5.9 kg
Compatible Heat Probe		CD-110: Scope Channel ø 3.7 mm CD-120: Scope Channel ø 2.8 mm

Coagulation	**Energy Setting**	Can be set in 6 steps (5/10/15/20/25/30 Joules) using the Energy Setting Switches on the front panel.
	Output	Heat is generated by pressing the "COAG" pedal of the Foot Switch (MAJ-528).
		Once the Foot Switch pedal is pressed, heat is generated until the set energy value has been supplied.
Water Feeding	**Water Feed Setting**	Can be set in 4 steps ("High" "•" "Low" "OFF") using the Water Feed Setting Switches on the front panel.
	Output	Water is fed by depressing the "WASH" pedal of the Foot Switch (MAJ-528).

Item		**Specification**
Classification (Electro-medical equipment)	**Type of protection against electrical shock**	Class I equipment
	Degree of protection against electrical shock of applied part	Type BF Applied Part
	Degree of protection against explosion	Do not use the HEAT PROBE UNIT in areas in which there is a risk of exposure to flammable gases.
EMC		This device complies with the EMC requirements of IEC 60601-1-2: 1993 Emission: Class B of CISPR 11: 1997
Year of manufacture	**7812345**	The last digit of the year of manufacture is given in the second digit of the serial number.

Water Container (MAJ-526)

Item	Specification
Capacity	Standard: 200 cm^3
	Maximum: 250 cm^3
Disinfection and Sterilization Methods	Steam sterilization (autoclave)

Water Pump (MAJ-527)

Item	Specification
Pump Method	Tubing Pump
Connection to the HEAT PROBE UNIT	Spline shaft.
Connector system	Luer-lock connector for the CD-110, CD-120.
Disinfection and Sterilization Methods	Steam sterilization (autoclave)

Foot Switch (MAJ-528)

Item	Specification	
Pedals	"WASH" on the right, "COAG" on the left.	
Operation	Water feed:	Press to turn "ON", release to turn "OFF".
	Coagulation:	Press to turn "ON". (Coagulation will not be terminated until the selected energy level has been supplied.)
Length of Cord	4000 mm	
Dimensions	270 (W) × 62 (H) × 184 (D) mm	
Weight	3.2 kg	

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