OLYMPUS®

INSTRUCTIONS

Ultrasonic Surgical System SonoSurg

SonoSurg Transducer
SonoSurg-T2L-GE
SonoSurg-T2L-GE-C

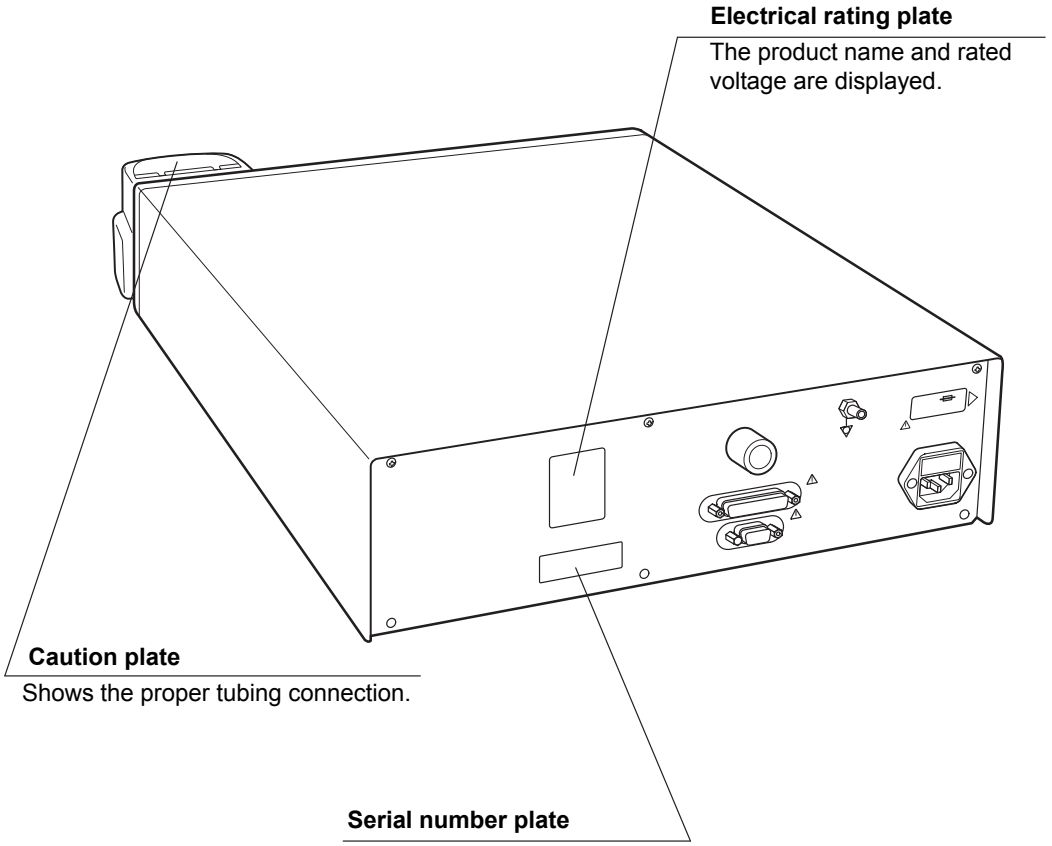
SonoSurg Irrigation Unit
SonoSurg-IU

USA: CAUTION: Federal law restricts this device to sale by or on the order of a physician.	CE 0197

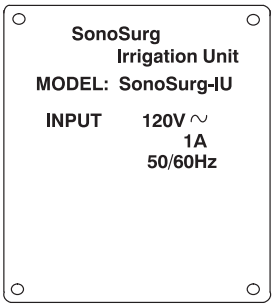
Contents

Labels and Symbols

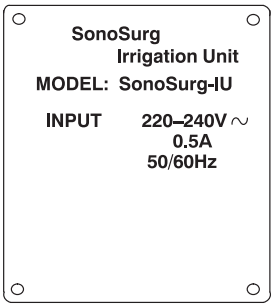
Safety-related labels and symbols are attached to the instrument at the locations shown below. If labels are missing or illegible, contact Olympus.



Electrical rating plate

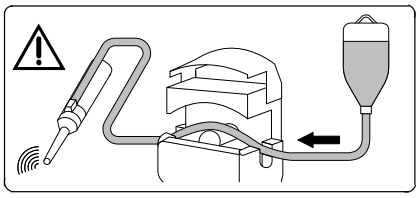


(120 V)



(220 – 240 V)

Caution plate



Back cover of this instruction manual

Manufacturer

Authorised representative in the European Community

Important Information — Please Read Before Use

Intended use

These devices have been designed to be used with the SonoSurg generator (SonoSurg-G2) and a separate surgical suction device to dissect, fragment, emulsify and aspirate tissue for general surgery, laparoscopic surgery, plastic and reconstructive surgery and urologic surgery. These devices may also be combined with electrosurgery using Olympus electrosurgical Units. Do not use these 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.

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 techniques. This manual, therefore, does not explain or discuss these techniques.

Instrument compatibility

Refer to the “System chart” in the Appendix to confirm that this instrument is compatible with the ancillary equipment being used. Using incompatible equipment can result in patient injury and/or equipment damage. If this instrument is used in combination with equipment manufactured by other companies, confirm their compatibility before use.
This instrument complies medical electrical equipment edition 2 (IEC 60601-1-2: 2001). However when connecting with a instrument complies with medical electrical equipment edition 1 (IEC 60601-1-2:1993), the whole system complies edition 1. (See “EMC compliance information” on page 136 for EMC compliance level.)

Reprocessing and storage

The transducer and ancillary components (e.g. probes and sheaths, which are sold separately) were not sterilized before shipment. Before using them for the first time, reprocess them according to the instructions given in Chapter 7, “Reprocessing and Storage”.
After using the instruments, reprocess and store them according to the instructions given in Chapter 7, “Reprocessing and Storage”.
Improper and/or incomplete reprocessing or storage can present an infection control risk, cause equipment damage or reduce performance.

Repair and modification

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

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

DANGER

- These devices are not explosion-proof. Do not use them where flammable gases or liquids or high concentrations of oxygen may be present. Otherwise, an explosion or fire may occur.
- These devices are not intended to be used for dissection, fragmentation, emulsification, or aspiration of fatty cells for liposuction.

WARNING

- Do not prepare or operate this instrument with wet hands. Otherwise, the user may receive an electric shock.
- Always have a defibrillator ready in case of a cardiac emergency. Before operating the defibrillator, remove the instrument and endoscope from the patient. Also make preparations for an abdominal operation if necessary.
- Use this instrument in an environment equipped to accommodate open surgery and have the hospitalization plan prepared in case any problem occurs that may not be resolved by form of endoscopic surgery.
- To ensure electrical safety, this instrument should not be used in conjunction with:
  - Electromedical equipment whose safety in combined use is not guaranteed.
  - Electromedical equipment whose safety against leakage current is not guaranteed.

When performing electrosurgery, special attention should be paid to the following:

DANGER

- Never apply this instrument directly to the heart in combination with a TYPE B/BF electrosurgical unit. Doing so may cause ventricular fibrillation, which could be fatal to the patient.
- The HF-equipment, when applied to a patient with a pacemaker implanted, may cause malfunctioning or failure of the pacemaker and may seriously affect the patient. Before proceeding, confirm with a cardiologist or the manufacturer of the pacemaker that it is safe to do so.

CAUTION

- Be sure not to bring and/or pile up this instrument too close to other instruments to avoid an electromagnetic interference from them.
- Electromagnetic interference may occur on this instrument near a portable device and a mobile RF communications equipment such as a cellphone marked with the following symbol:

CAUTION

- Never loop the A-cord or bundle it together with the cords belonging to other medical equipment (e.g. electrocardiograph, video camera for endoscopes, etc.). Otherwise, the high-frequency signals or spark discharge noise generated may interfere with the operation of the medical equipment during electrosurgery.
- If the intestines contain a flammable gas, replace this gas with a nonflammable gas such as CO_2 before the procedure to minimize the risk of fire or explosion.

WARNING

- The safety standard for electromedical equipment (IEC 60601-1) classifies equipment into TYPE CF (applicable to the whole human body including the heart) and TYPE B/BF (applicable to organs other than the heart). As the applicable region of the instruments varies depending on the classification of connected equipment, it is necessary that this classification first be checked by referring to the instruction manual of the electromedical equipment in use.

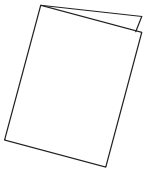
Symbol	Classification
	TYPE CF applied part
	TYPE BF applied part
	TYPE B applied part

- Exercise special care when electrosurgical output is applied in the vicinity of the heart. Current flowing through the heart or the low-frequency current generated by rectification during spark discharge may cause ventricular fibrillation, even when this instrument is used in combination with a TYPE CF electrosurgical unit.

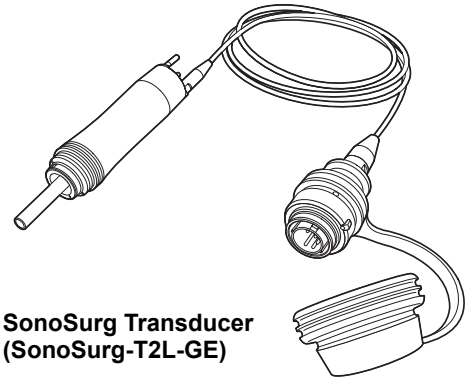
Chapter 1 Checking the Package Contents

Match all items in the package with the components shown below. Inspect each item for damage. If these instruments are damaged, a component is missing or you have any questions, do not use these instruments; immediately contact Olympus.
The transducer and ancillary components (e.g. probes and sheaths) were not sterilized before shipment. Before using them for the first time, reprocess them according to the instructions given in Chapter 7, “Reprocessing and Storage”.
This instruction manual is shipped with the SonoSurg Transducer (SonoSurg-T2L-GE/SonoSurg-T2L-GE-C) and the SonoSurg Irrigation Unit (SonoSurg-IU).

SonoSurg Transducer (SonoSurg-T2L-GE)

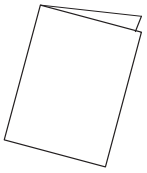


Instruction manual

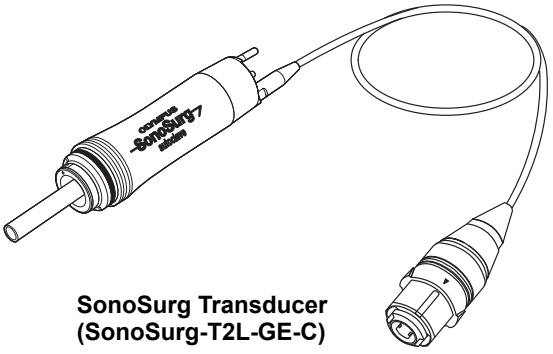


SonoSurg Transducer (SonoSurg-T2L-GE)

SonoSurg Transducer (SonoSurg-T2L-GE-C)

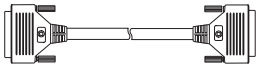


Instruction manual

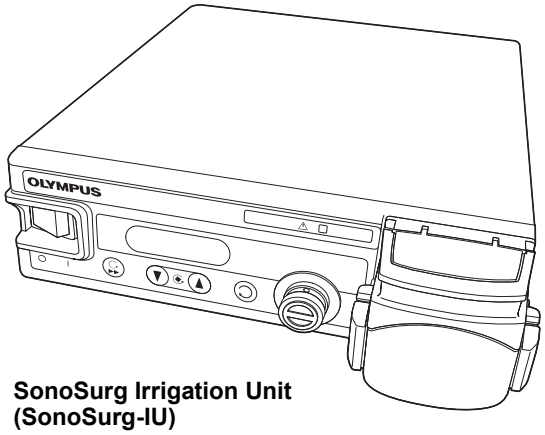


SonoSurg Transducer (SonoSurg-T2L-GE-C)

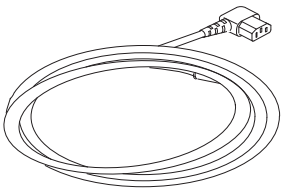
SonoSurg Irrigation Unit (SonoSurg-IU)



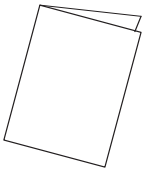
SonoSurg Communication Cable (MAJ-1103)



SonoSurg Irrigation Unit (SonoSurg-IU)



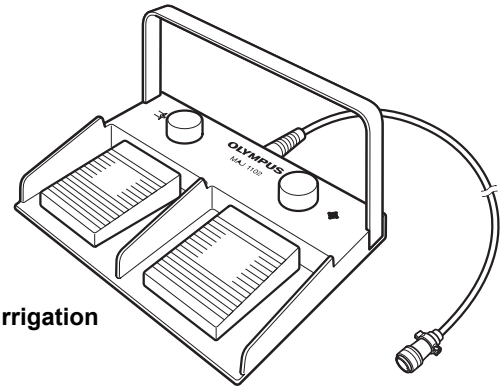
Power cord



Instruction manual

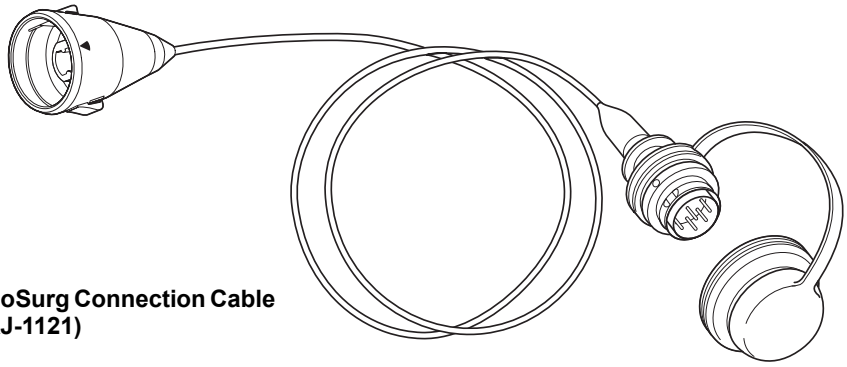
The following Olympus items are optional and may be purchased separately:

Foot Switch for SonoSurg Irrigation Unit (MAJ-1102)



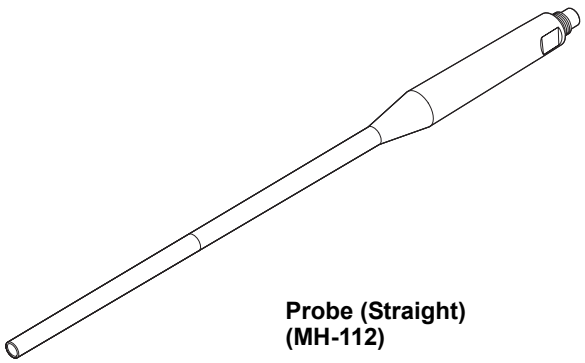
Foot Switch for SonoSurg Irrigation Unit (MAJ-1102)

SonoSurg Connection Cable (MAJ-1121)



SonoSurg Connection Cable (MAJ-1121)

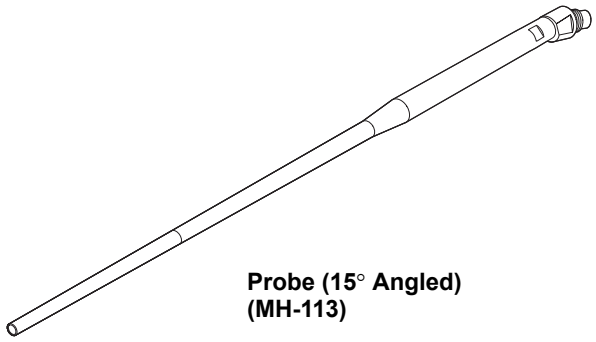
Probe (Straight) (MH-112)



Probe (Straight) (MH-112)

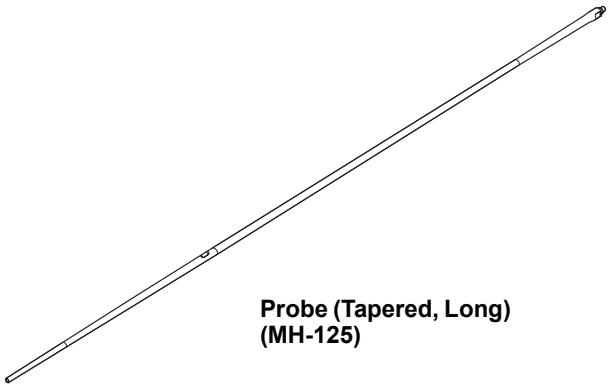
The following Olympus items are optional and may be purchased separately:

Probe (15° Angled) (MH-113)



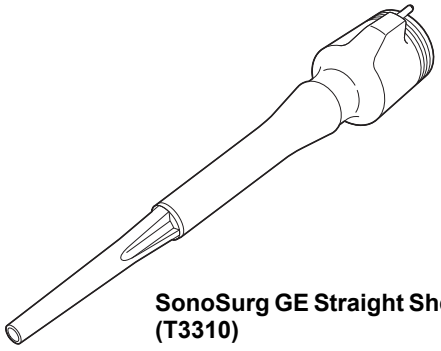
Probe (15° Angled)
(MH-113)

Probe (Tapered, Long) (MH-125)

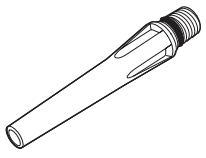


Probe (Tapered, Long)
(MH-125)

SonoSurg GE Straight Sheath (T3310)



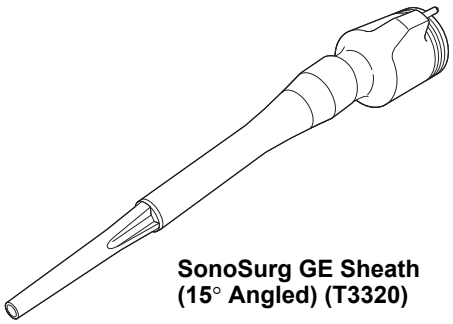
SonoSurg GE Straight Sheath
(T3310)



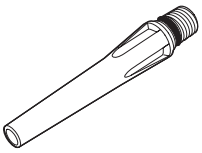
SonoSurg GE Sheath
Attachment (T3300), × 3

The following Olympus items are optional and may be purchased separately:

SonoSurg GE Sheath (15° Angled) (T3320)

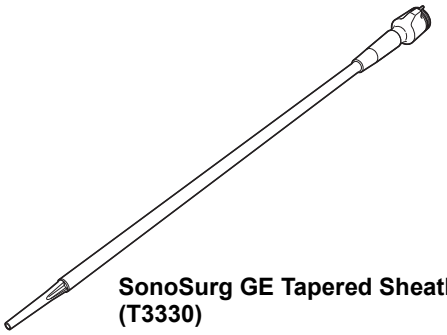


SonoSurg GE Sheath (15° Angled) (T3320)



SonoSurg GE Sheath Attachment (T3300), × 3

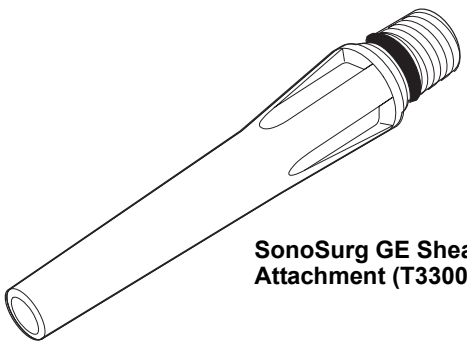
SonoSurg GE Tapered Sheath (T3330)



SonoSurg GE Tapered Sheath (T3330)

SonoSurg GE Sheath Attachment (T3300), × 3

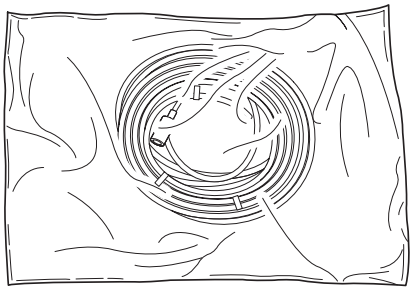
SonoSurg GE Sheath Attachment (T3300)



SonoSurg GE Sheath Attachment (T3300), × 3

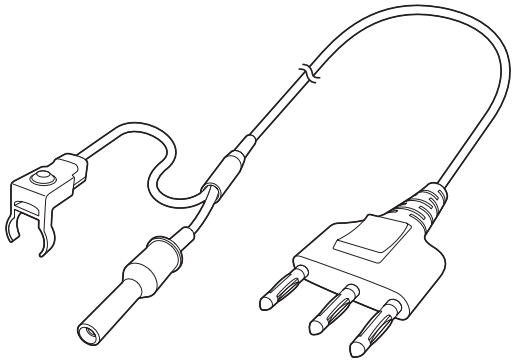
The following Olympus items are optional and may be purchased separately:

Irrigation/Suction Tube for SonoSurg (MAJ-1099) (disposable, sterile)



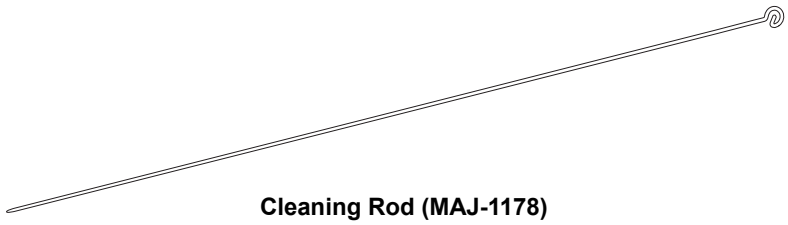
SonoSurg Irrigation/Suction Tube for SonoSurg (MAJ-1099), × 6

SonoSurg GE Hand Switch (MAJ-1100)



SonoSurg GE hand switch (MAJ-1100)

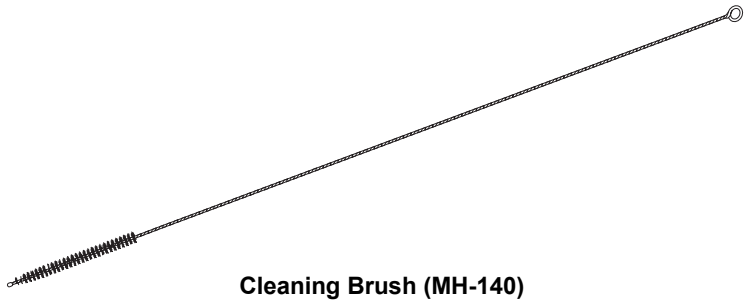
Cleaning Rod (MAJ-1178)



Cleaning Rod (MAJ-1178)

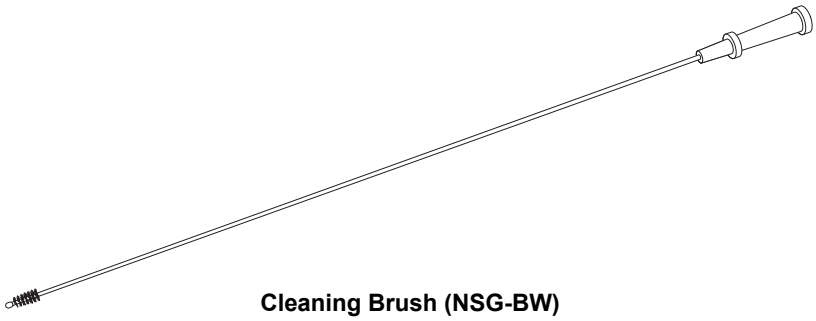
The following Olympus items are optional and may be purchased separately:

Cleaning Brush (MH-140)



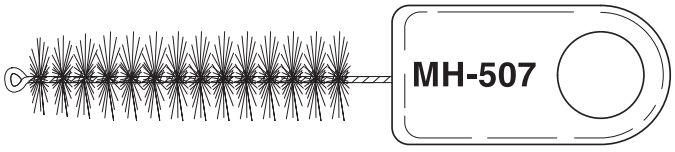
Cleaning Brush (MH-140)

Cleaning Brush (NSG-BW)



Cleaning Brush (NSG-BW)

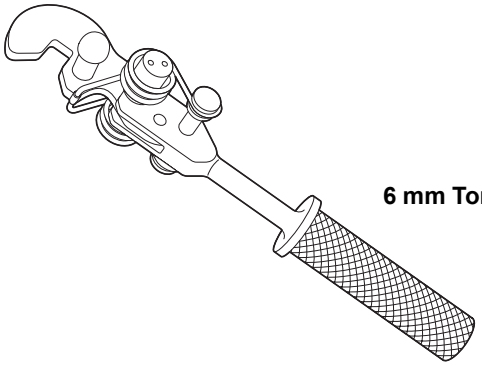
Brush (MH-507)



Brush (MH-507)

The following Olympus items are optional and may be purchased separately:

6 mm Torque Wrench (MAJ-1117)



6 mm Torque Wrench (MAJ-1117)

Chapter 2 Instrument Nomenclature

Symbols and Descriptions

Warning section

COMM.	Communication error

Power switch

○	Power OFF
|	Power ON

Front panel

	Flush
	Irrigation
	Suction mode select
	Normal suction
	Laparoscopic suction

Rear panel

SN	Serial number
	Fuse
	Potential equalization terminal
	Foot Switch

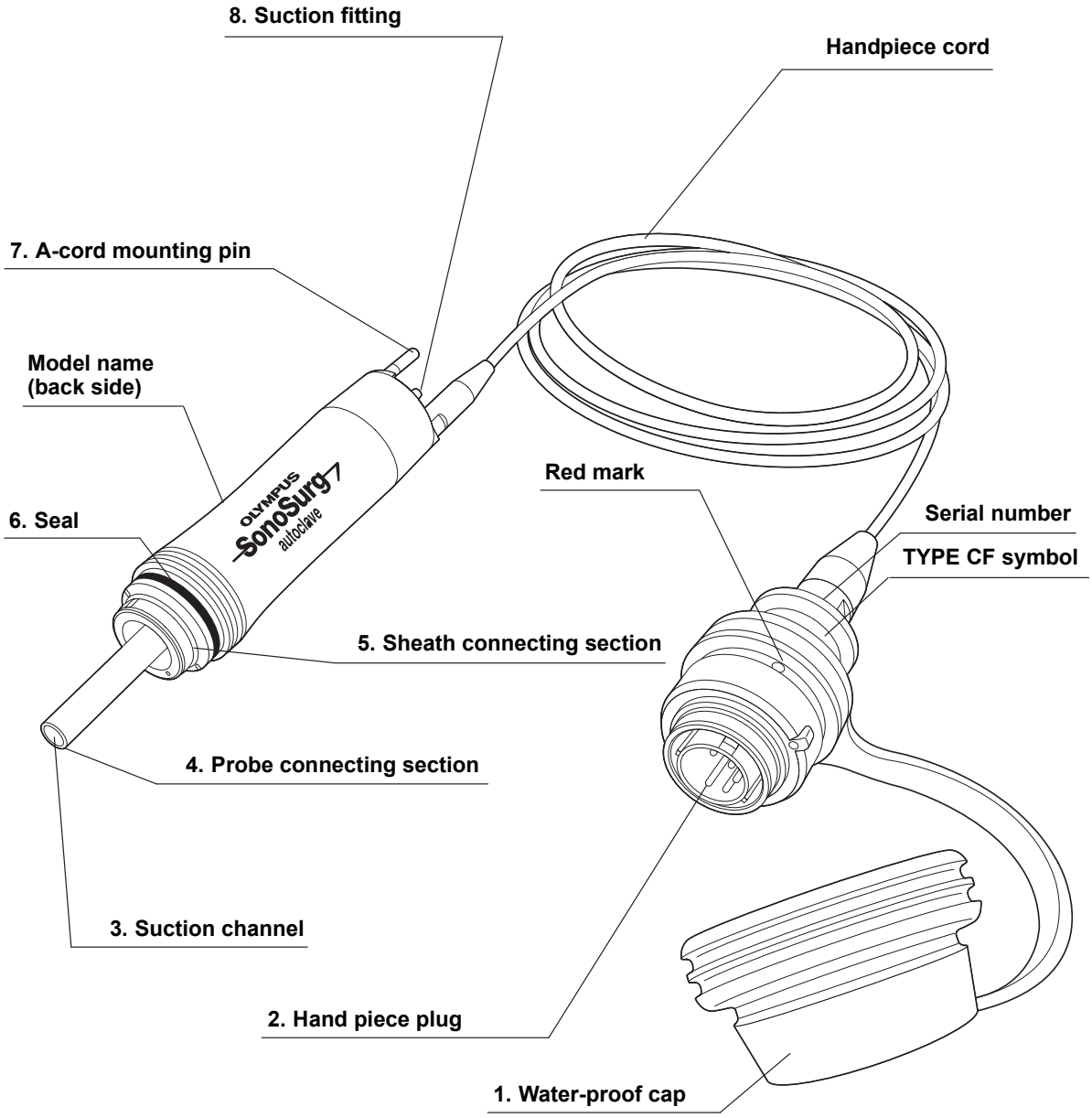
Foot switch

	Ultrasonic output
	Variable steps
	Maximum output level
	Irrigation
	Suction

Irrigation/suction tube package

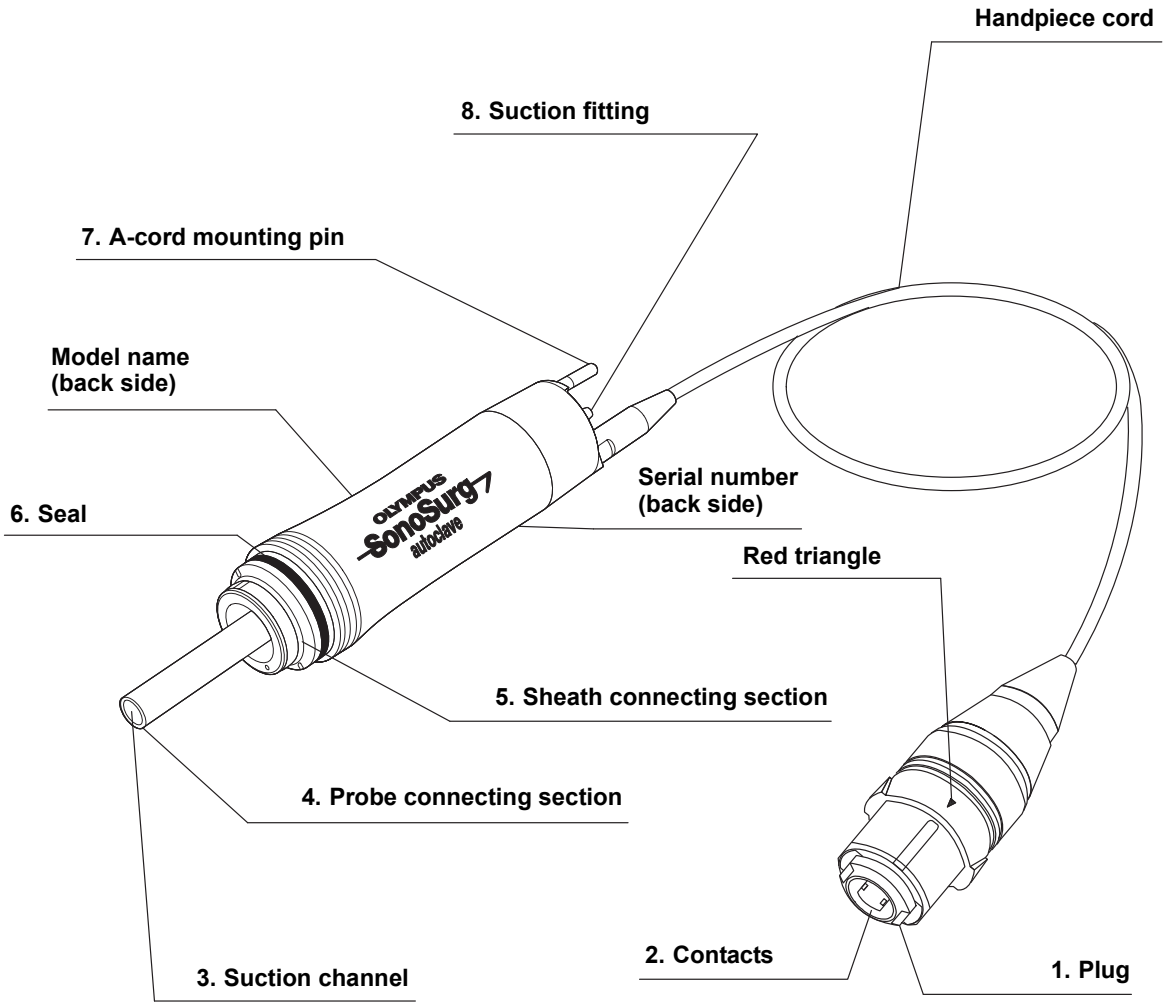
	Refer to instructions.
	Single use only
	Use by (expiration date)
STERILE EO	Sterilized using ethylene oxide
STERILE LOT	Sterilization lot number
LOT	Lot number
	Keep away from sunlight
	Keep dry

SonoSurg Transducer (SonoSurg-T2L-GE)



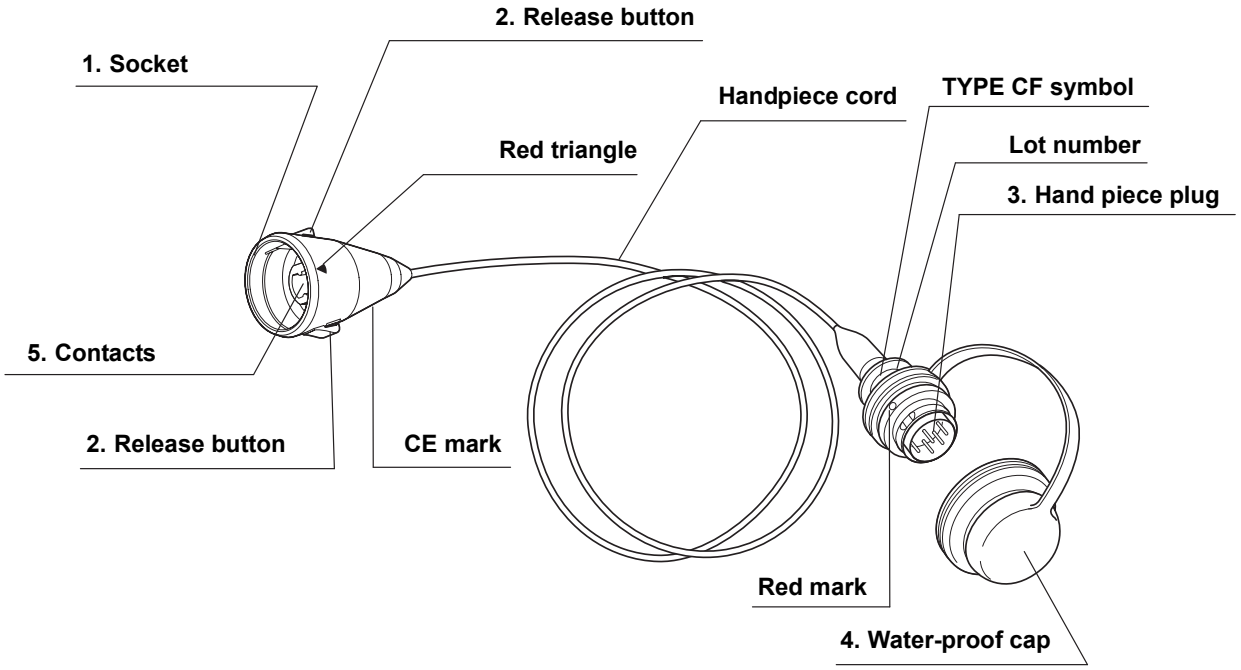
1. **Water-proof cap**
   When cleaning, the hand piece plug is covered with the water-proof cap to prevent water from entering the plug.
2. **Hand piece plug**
   The hand piece plug is connected to the hand piece connector of the SonoSurg generator (SonoSurg-G2).
3. **Suction channel**
   Emulsified tissue is aspirated through the channel.
4. **Probe connecting section**
   The probe connecting section is connected to the probe.
5. **Sheath connecting section**
   The sheath connecting section is connected to the sheath.
6. **Seal**
   Prevents leakage of irrigation fluid.
7. **A-cord mounting pin**
   The A-cord mounting pin is connected to the active cord (A-cord), which is connected to the electrosurgical unit.
8. **Suction fitting**
   Connects to the suction tube of the irrigation/suction tube for SonoSurg (MAJ-1099).

SonoSurg Transducer (SonoSurg-T2L-GE-C)



1. **Plug**
   The plug is connected to the socket of the connection cable (MAJ-1121).
2. **Contacts**
   The contacts conduct the ultrasonic drive current.
3. **Suction channel**
   Emulsified tissue is aspirated through the channel.
4. **Probe connecting section**
   The probe connecting section is connected to the probe.
5. **Sheath connecting section**
   The sheath connecting section is connected to the sheath.
6. **Seal**
   Prevents leakage of irrigation fluid.
7. **A-cord mounting pin**
   The A-cord mounting pin is connected to the active cord (A-cord), which is connected to the electrosurgical unit.
8. **Suction fitting**
   Connects to the suction tube of the irrigation/suction tube for SonoSurg (MAJ-1099).

SonoSurg Connection Cable (MAJ-1121)



1. **Socket**
The socket is connected to the plug of the SonoSurg transducer (SonoSurg-T2L-GE-C).

2. **Release button**
Press the button to remove the transducer.

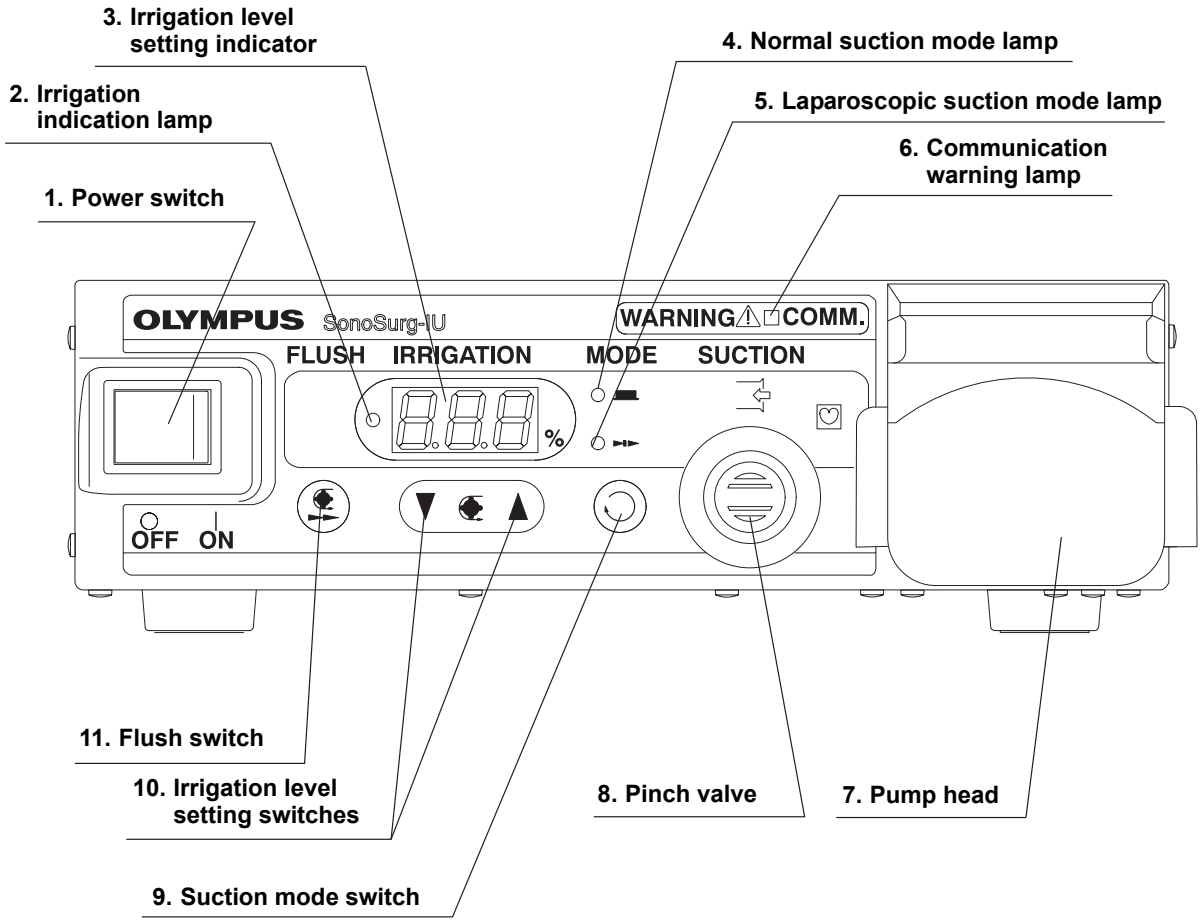
3. **Hand piece plug**
The hand piece plug is connected to the hand piece connector of the SonoSurg generator (SonoSurg-G2).

4. **Water-proof cap**
When cleaning, the hand piece plug is covered with the water-proof cap to prevent water entering the plug.

5. **Contacts**
The contacts conduct the ultrasonic energy from generator to the probe tip.

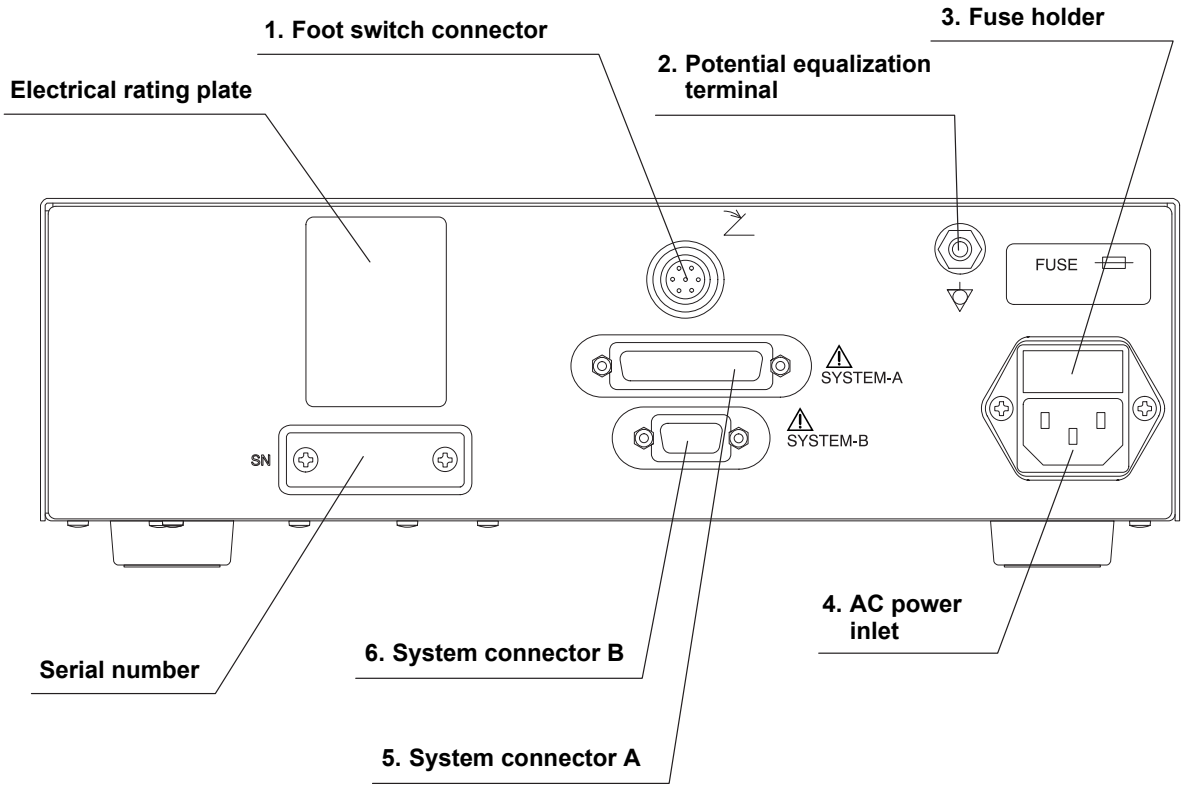
SonoSurg Irrigation Unit (SonoSurg-IU)

❍ Front panel



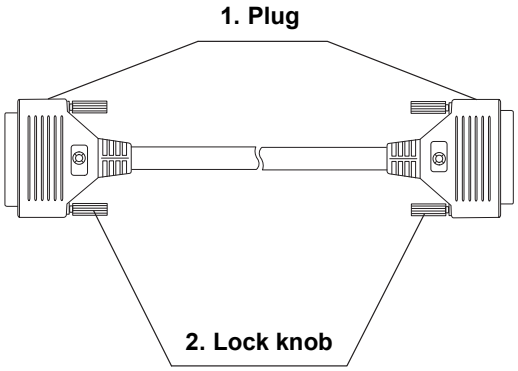
1. **Power switch**
   Press this switch to turn the instrument ON. The switch lights up when the power is ON.
2. **Irrigation indication lamp**
   While irrigation is performed, this indication lamp lights up.
3. **Irrigation level setting indicator**
   The irrigation level setting indicator displays the irrigation level set with the irrigation level setting switches. If an abnormality is detected, the indicator displays an error code to provide further information.
4. **Normal suction mode lamp**
   When the normal suction mode is selected, this lamp lights up.
5. **Laparoscopic suction mode lamp**
   When the laparoscopic suction mode is selected, this lamp lights up.
   The laparoscopic suction mode provides suction flow only while the ultrasonic output is activating. In particular, this mode will help maintain the selected pressure such as the laparoscopic operation.
6. **Communication warning lamp**
   The communication warning lamp lights up if the communication cable is not properly connected to the SonoSurg generator (SonoSurg-G2) and the SonoSurg irrigation unit (SonoSurg-IU). If the lamp is lit, the SonoSurg irrigation unit cannot be interlocked with the SonoSurg generator.
7. **Pump head**
   When the irrigation/suction tube is connected, the pump head facilitates the flow of irrigation fluid.
8. **Pinch valve**
   When the laparoscopic suction mode is selected, the pinch valve controls the suction flow.
9. **Suction mode switch**
   Press to alternate between normal and laparoscopic suction modes.
10. **Irrigation level setting switches**
    Press "▲" to increase the irrigation level setting, and press "▼" to decrease the irrigation level setting.
11. **Flush switch**
    When pressed, irrigation fluid is supplied to the irrigation/suction tube.

Rear panel


1. Foot switch connector
3. Fuse holder
2. Potential equalization terminal
Electrical rating plate
FUSE
SYSTEM-A
SYSTEM-B
SN
4. AC power inlet
6. System connector B
Serial number
5. System connector A

1. **Foot switch connector**
   Connect the foot switch plug (MAJ-1102) here to control ultrasonic output, irrigation and suction.
2. **Potential equalization terminal**
   In case of an equipotential, connect this terminal to a potential equalization busbar of the electrical installation.
3. **Fuse holder**
   The fuses contained here protect the equipment from electrical surges.
4. **AC power inlet**
   The AC power inlet accepts the power cord.
5. **System connector A**
   Accepts a 25-pin type system connector for system expansion.
6. **System connector B**
   Accepts a 9-pin type system connector for system expansion.

SonoSurg Communication Cable (MAJ-1103)



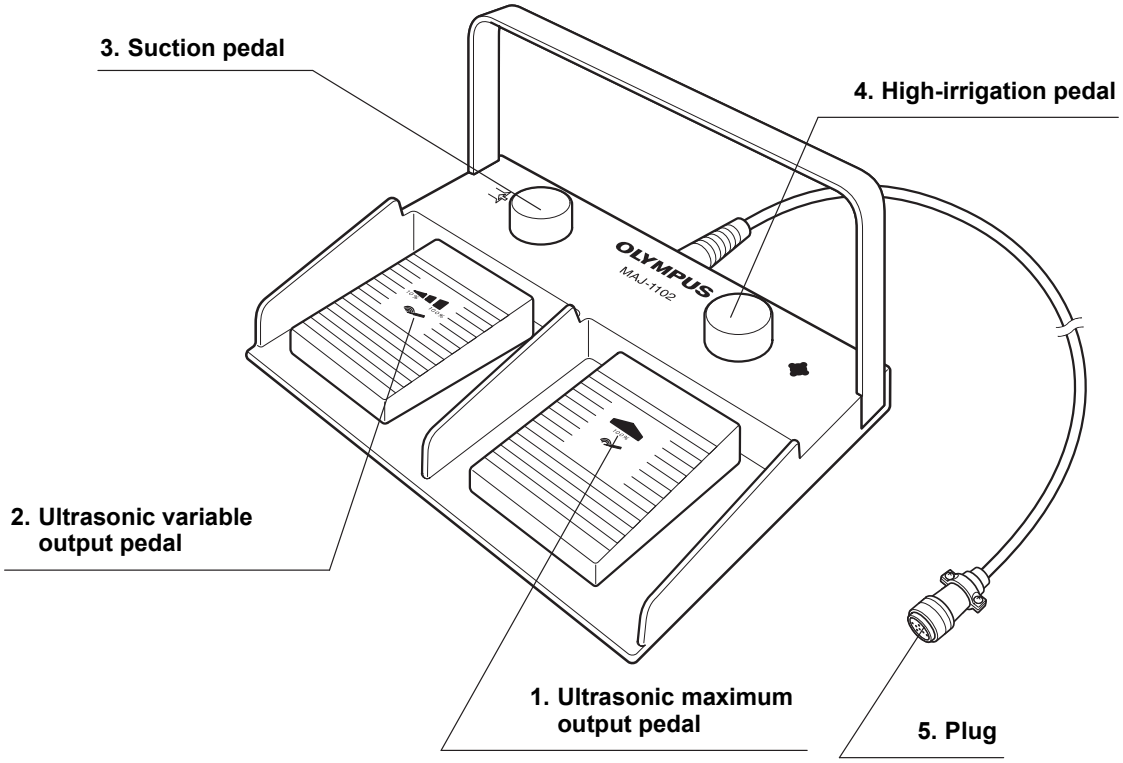
1. **Plug**

The plugs are connected to system connector B of the SonoSurg generator and the SonoSurg irrigation unit.

2. **Lock knob**

Secure the plugs into the connectors of the SonoSurg generator and the SonoSurg irrigation unit.

Foot Switch for SonoSurg Irrigation Unit (MAJ-1102)



1. **Ultrasonic maximum output pedal**
The ultrasonic maximum output pedal applies ultrasonic output of 100% regardless of the level set on the SonoSurg generator. This pedal does not function when the SonoSurg-T2L-GE/SonoSurg-T2L-GE-C transducers are used.

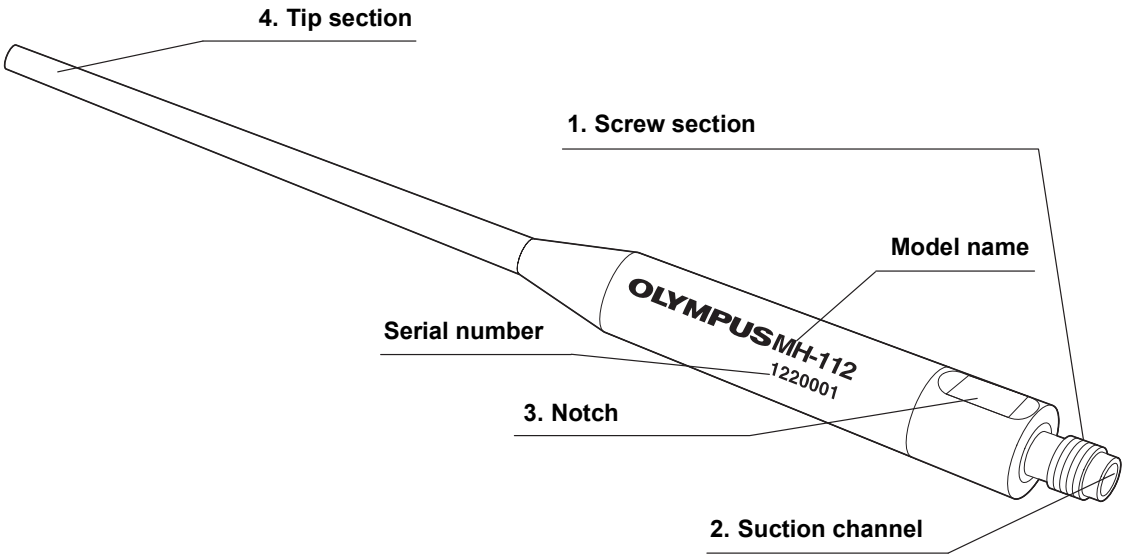
2. **Ultrasonic variable output pedal**
The ultrasonic variable output pedal applies ultrasonic output equal to the level displayed on the ultrasonic output setting indicator of the SonoSurg generator (SonoSurg-G2).

3. **Suction pedal**
The suction pedal opens/closes the pinch valve of the SonoSurg irrigation unit (NOTE: this function is only available in laparoscopic suction model).

4. **High-irrigation pedal**
The high-irrigation pedal applies the maximum irrigation output from the SonoSurg irrigation unit (SonoSurg-IU).

5. **Plug**
The plug is connected to the SonoSurg irrigation unit (SonoSurg-IU).

Probe (Straight) (MH-112)
Probe (15° Angled) (MH-113)
Probe (Tapered, Long) (MH-125)



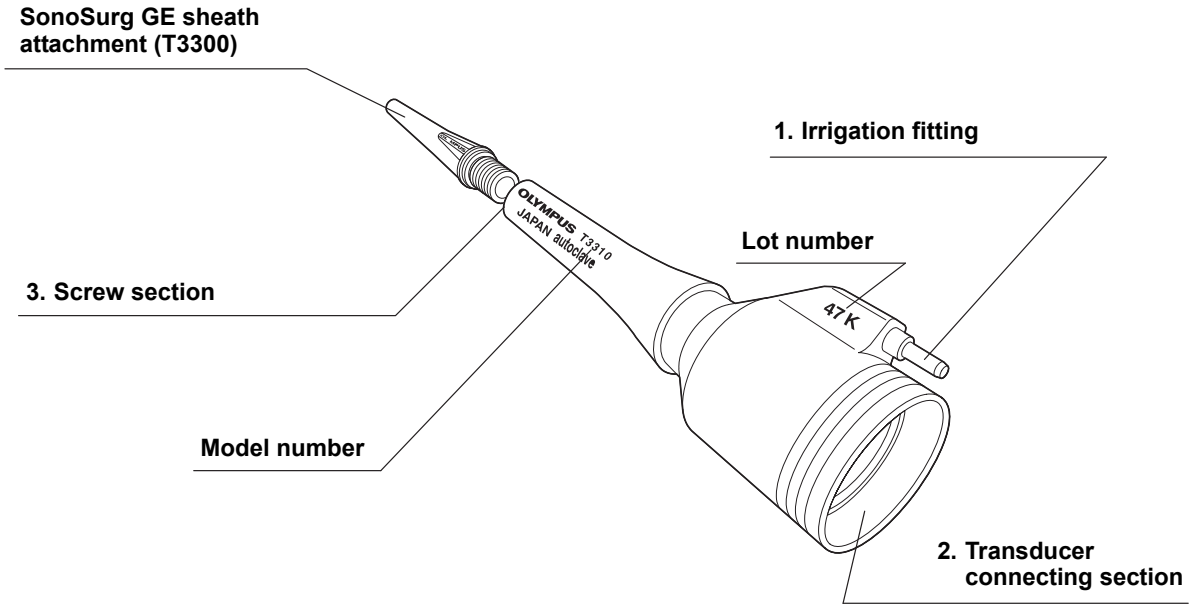
1. **Screw section**
The screw section is connected to the SonoSurg transducer (SonoSurg-T2L-GE/SonoSurg-T2L-GE-C).

2. **Suction channel**
Emulsified tissue is aspirated through the channel.

3. **Notch**
When connecting the probe to the transducer, the torque wrench (MAJ-1117) is attached here.

4. **Tip section**
Emulsified tissue is aspirated through the channel.

SonoSurg GE Straight Sheath (T3310)
SonoSurg GE Sheath (15° Angled) (T3320)
SonoSurg GE Tapered Sheath (T3330)

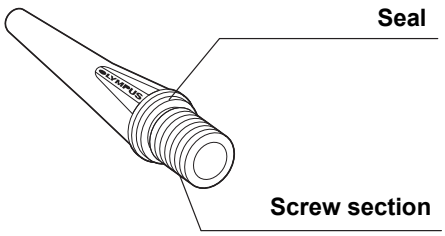


1. **Irrigation fitting**
Connects to the irrigation tube of the irrigation/suction tube for SonoSurg (MAJ-1099).

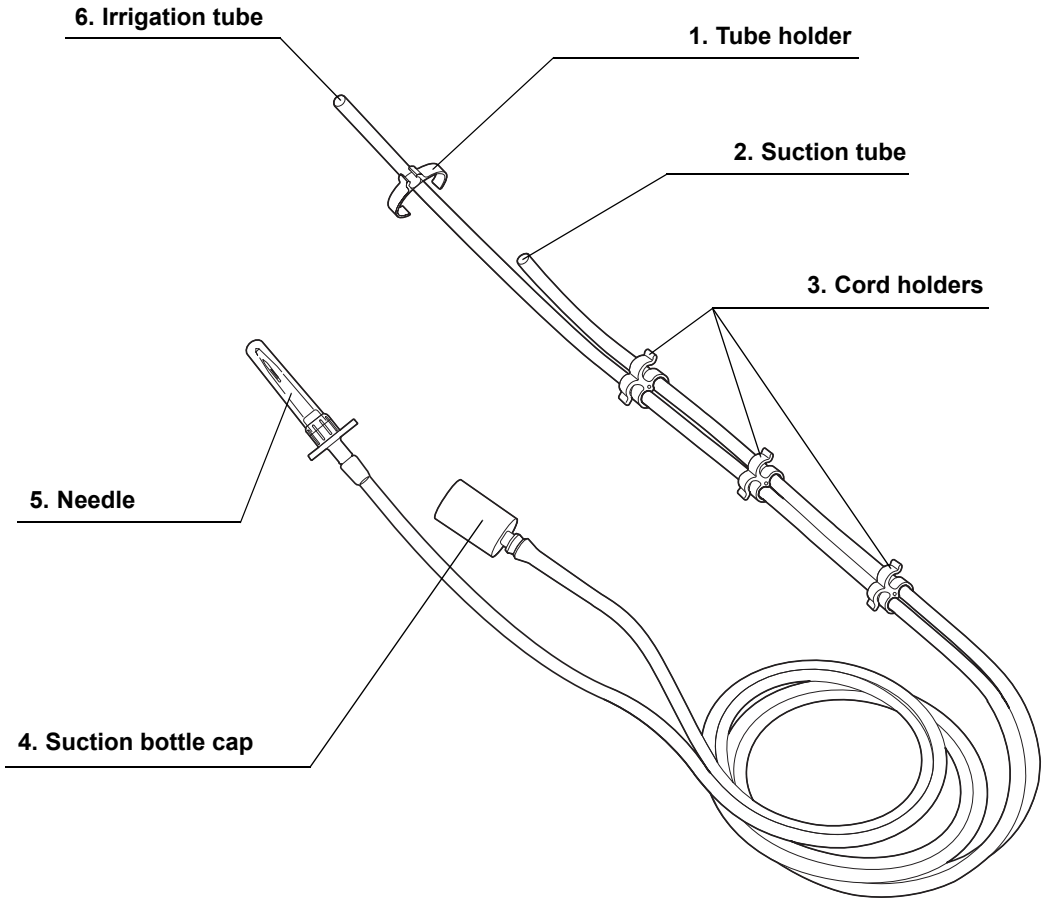
2. **Transducer connecting section**
The SonoSurg transducer (SonoSurg-T2L-GE/SonoSurg-T2L-GE-C) is inserted here.

3. **Screw section**
The screw section is connected to the SonoSurg GE sheath attachment (T3300).

SonoSurg GE Sheath Attachment (T3300)



Irrigation/Suction Tube for SonoSurg (MAJ-1099)



1. **Tube holder**
The tube holder is used to attach the tube to the body of the SonoSurg transducer (SonoSurg-T2L-GE/SonoSurg-T2L-GE-C).

2. **Suction tube**
Connects to the suction fitting of the transducer.

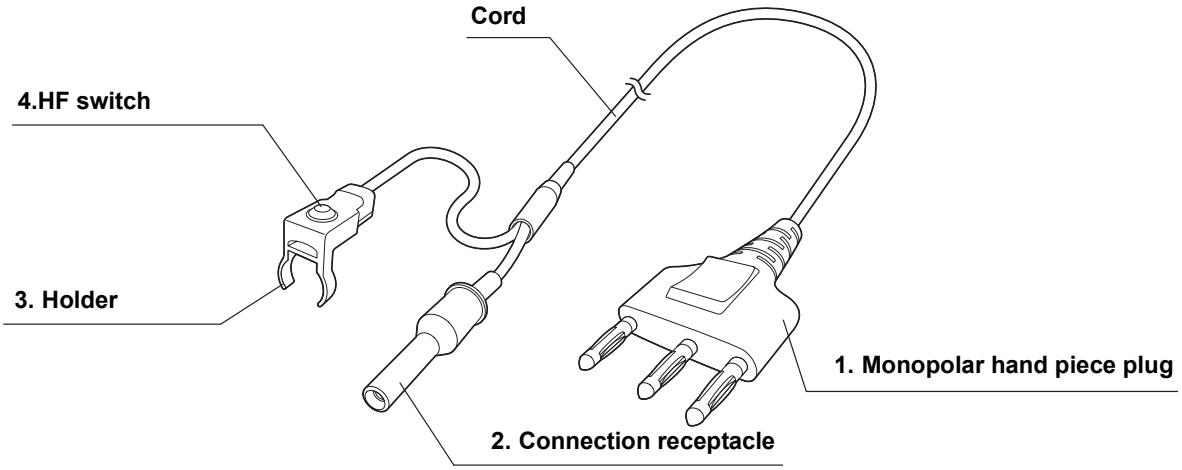
3. **Cord holders**
The hand piece cord of the transducer is attached to those clips.

4. **Suction bottle cap**
The suction bottle cap is attached to the “PATIENT” fitting of a suction bottle.

5. **Needle**
Used to pierce a saline solution bag.

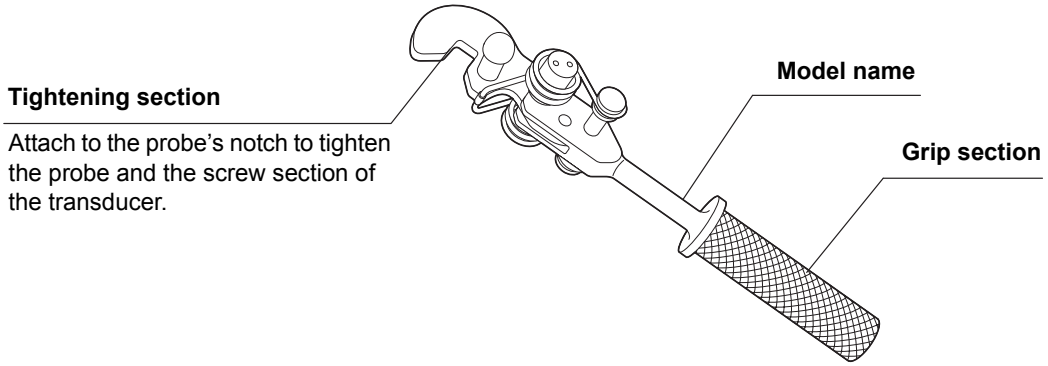
6. **Irrigation tube**
Connects to the irrigation fitting of the transducer.

SonoSurg GE Hand Switch (MAJ-1100)



1. **Monopolar hand piece plug**
   This plug is attached to the 3-pins jack of the electrosurgical unit.
2. **Connection receptacle**
   Connect the transducer's A-cord mounting pin here.
3. **Holder**
   The sheath can be attached to this holder.
4. **HF switch**
   This switch applies to the coagulation output from the electrosurgical unit.

6 mm Torque Wrench (MAJ-1117)



Chapter 3 Preparation and Inspection of the SonoSurg Irrigation Unit

Before each case, prepare and inspect the SonoSurg irrigation unit as instructed below. Should the slightest irregularity be suspected, do not use the equipment and see Chapter 8, “Troubleshooting”. If the irregularity is still suspected after consulting Chapter 8, contact Olympus.
Prepare and inspect other equipment to be used with the unit as instructed in their respective instruction manuals.

3.1 Preparation of equipment

Prepare the SonoSurg irrigation unit and compatible equipment (shown in the “System chart” in the Appendix) before each use and refer to the instruction manuals of each system component.

WARNING

- Damage or irregularity may compromise patient or operator safety and may result in more-severe equipment damage.
- Never apply excessive force to connections. Doing so can cause equipment damage.
- Only use the unit in an operating environment whose conditions are within the ranges given in “Environment” in the Appendix. Conditions outside these ranges may impair performance and/or cause equipment damage.
- The housing of the unit must be properly grounded to ensure safe operation. To reduce the risk of an electric shock, be sure to connect the power cord to a properly grounded hospital grade 3-pin receptacle.
- The hospital grade 3-pin receptacle to which the unit is connected should have sufficient power capacity to handle all equipment connected to it. If the power capacity is insufficient, a fire hazard may occur or the circuit breaker of the medical facility may be tripped, cutting the power supply to all equipment connected to the same power source.

CAUTION

- If the unit is placed on a cart, the cart must be of adequate strength and size to hold the unit securely.
- Never place the unit on its side or upside down.
- Do not lift and/or carry the unit while holding the pump head. Do not subject the unit to strong impacts such as hitting the pump head. Product functionality may be impaired if the pump head is subject to strong impacts.

3.2 Installation of the SonoSurg irrigation unit

NOTE

Please keep this instruction manual near the unit or in another easily accessible location.

1. Confirm that the conditions in which the unit will be used correspond to those specified in “Environment” in the Appendix.
2. Install the unit on a stable bench or cart.
3. Install the SonoSurg generator (SonoSurg-G2) on top of the irrigation unit. If they are placed on a cart, take proper measures to ensure that the unit will not fall.

3.3 Power connection for the SonoSurg irrigation unit

CAUTION

- Securely connect the plug of the power cord so that it will not be accidentally dislodged during the operation.
- Never apply excessive force to the cord by bending, straining, twisting, or pressing it. Doing so can damage the cord, which increases the risk of an electric shock.
- Use only the cord that was shipped with the unit. Do not use another cord or attempt to modify the cord, as doing so may cause equipment damage.

1. Confirm that the irrigation unit is turned OFF (see Figure 3.1).

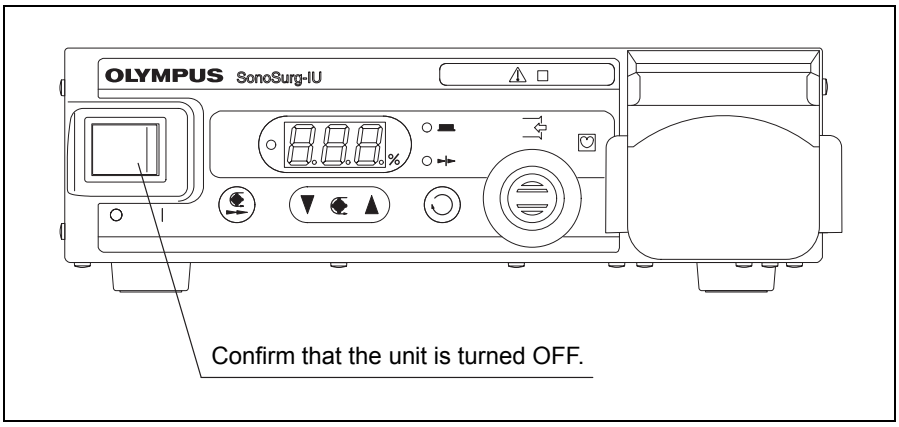


Figure 3.1

2. Connect the power cord to the AC power inlet on the unit's rear panel.
3. Connect the cord to a hospital grade 3-pin receptacle that meets the power requirements indicated on the electrical rating plate.

3.4 Connection of the foot switch

CAUTION

When connecting/disconnecting the foot switch plug, always hold the plug firmly, and do not apply excessive force to the cable. Otherwise, disconnection or other damage could occur.

NOTE

The SonoSurg generator's foot switch cannot be connected to the SonoSurg irrigation unit.

❍ How to connect the foot switch

1. Before connecting, confirm that both the cable and the foot switch plug are free from scratches and cracks.
2. Step on each pedal, and confirm that they operate smoothly.
3. With the indicator on the plug facing upward, align the plug with the foot switch connector on the rear panel of the SonoSurg irrigation unit (see Figure 3.2).
4. Insert the plug into the connector until it clicks.

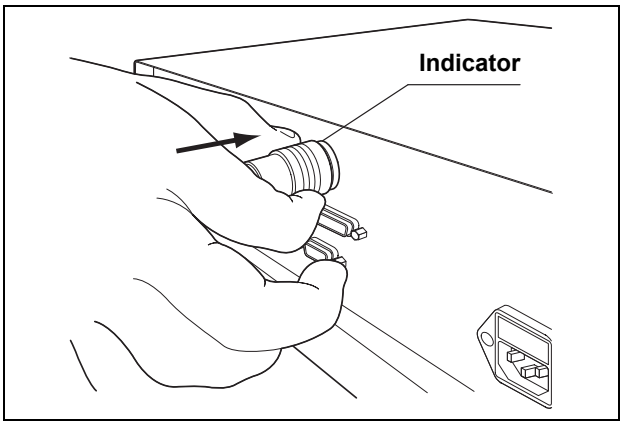


Figure 3.2

How to disconnect the foot switch

Pull out the ring on the foot switch plug, and disconnect the plug from the foot switch connector (see Figure 3.3).

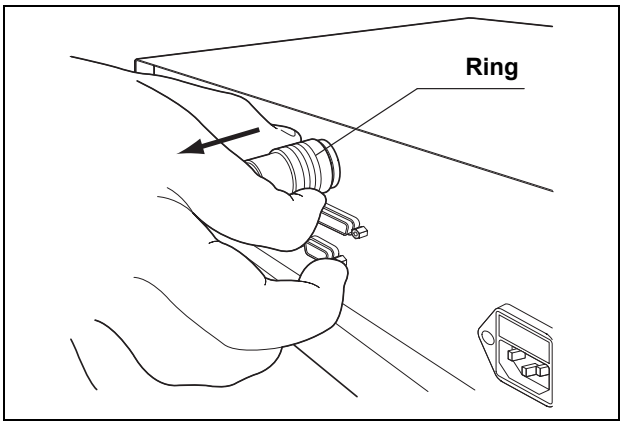


Figure 3.3

3.5 Connection to the SonoSurg generator (SonoSurg-G2)

When operating in laparoscopic suction mode with the SonoSurg generator (SonoSurg-G2), the SonoSurg irrigation unit (SonoSurg-IU) can irrigate cooling water and control suction.

CAUTION

- For more details on the functionality, also refer to the instruction manual for the SonoSurg generator set (SonoSurg-G2 Set).
- For more details on connecting the SonoSurg generator with other equipment, refer to the instruction manual for the SonoSurg generator.

Connect the SonoSurg communication cable (MAJ-1103) to system connector B of both the SonoSurg generator and the SonoSurg irrigation unit. Secure the lock knobs tightly (see Figure 3.4).

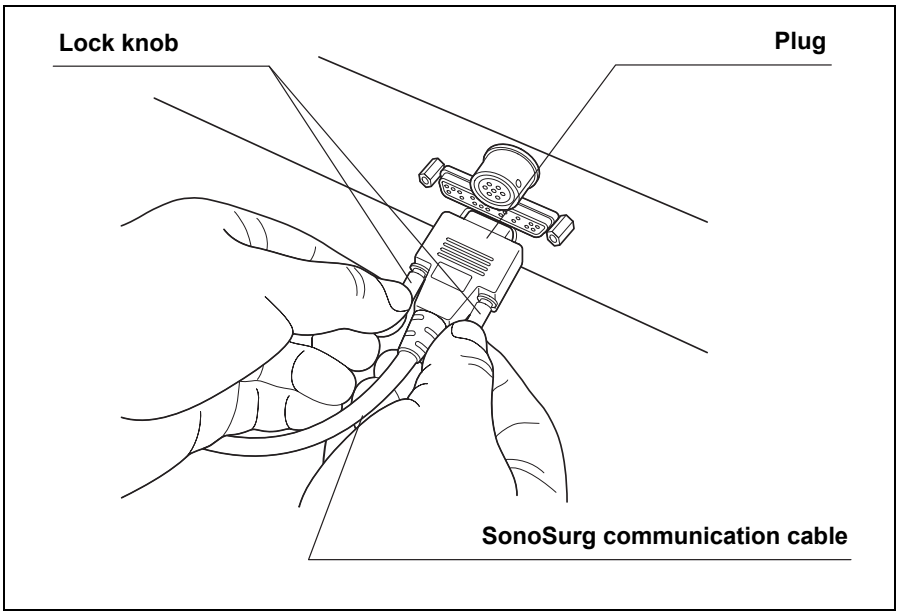


Figure 3.4

3.6 Inspection of the power supply

CAUTION

- If an alarm sounds and an error code (E0.5/E0.A/E0.C) is shown on the irrigation level setting indicator when the SonoSurg irrigation unit is turned ON, refer to Chapter 8, “Troubleshooting”.
- For instructions on inspecting the power supply to the SonoSurg generator, refer to its instruction manual.
- If the SonoSurg irrigation unit is not supplied with power, the fuses may have blown. Do not replace or attempt to repair the fuses; contact Olympus. Otherwise, patient or user injury and/or equipment damage can result.
- For additional information on the SonoSurg generator’s stand-by mode, refer to Section 4.2, “Inspection of the hand piece and stand-by mode” in the generator’s instruction manual.
- While the communication warning lamp is lit, the operation of the SonoSurg irrigation unit cannot be with that of the SonoSurg generator.
- If “Irr” (either steadily lit or flashing) is shown on the irrigation level setting indicator, the operation of the SonoSurg irrigation unit cannot be with that of the SonoSurg generator.
- If “OPE” is shown on the irrigation level setting indicator, the pump head’s cover may be open. Irrigation is not possible in this condition because the safety mechanism is activated when the cover is open. Check and close the cover firmly before attempting irrigation.
- SonoSurg generators with ROM version 1.02 cannot be combined with the irrigation unit. If such a combination is attempted, the communication warning lamp will light up. In this case, contact Olympus.

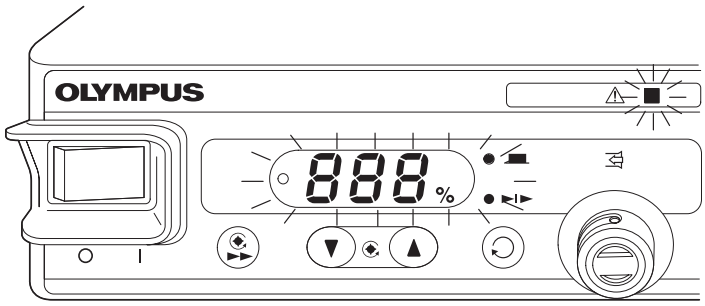
NOTE

Operations of the SonoSurg irrigation unit can be with those of the SonoSurg generator when the irrigation unit and generator are connected by the SonoSurg communication cable (MAJ-1103).

1. Turn the SonoSurg generator ON, then inspect the generator’s operation as described in its instruction manual.

2. After confirming that there are no abnormalities in the operation of the generator, turn the SonoSurg irrigation unit ON. Then perform the following inspection to confirm that power supply is normal.

   - The power switch lamp lights up.
   - All indicator lamps (irrigation level setting indicator, irrigation indication lamp, communication warning lamp, normal suction mode lamp, laparoscopic suction mode lamp) light for about 2 seconds (see Figure 3.5).
   - A confirmation tone will sound in 3 pitches (high, medium, low).



All indicators should light.

Figure 3.5

If an alarm sounds and an error code appears on the irrigation level setting indicator when the SonoSurg irrigation unit is turned ON, one of the following conditions may exist:

- E0.5:

  The safety circuit has been activated, because either a foot switch pedal is being pressed, or there is a short-circuit of some kind.

- E0.A or E0.C:

  The safety circuit has been activated, because of an error in the pump drive system.

If any of these conditions exists, refer to Chapter 8, “Troubleshooting”. If the problem cannot be solved using the information in Chapter 8, contact Olympus.

When no hand piece is connected to the SonoSurg generator

Confirm that “Irr” is shown on the irrigation level setting indicator (see Figure 3.6).

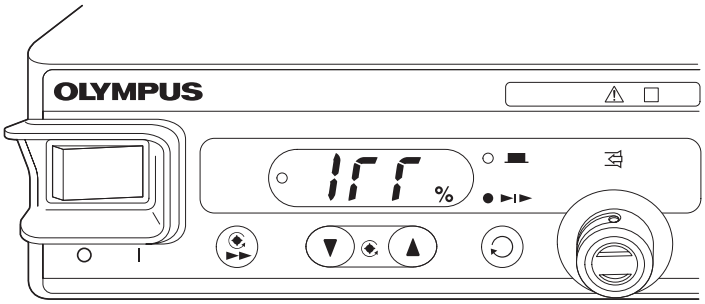
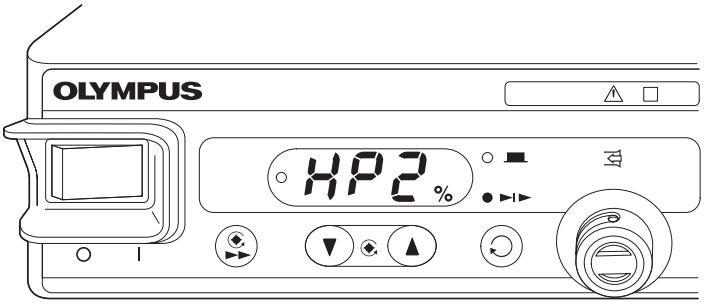


Figure 3.6

When a hand piece is connected to the SonoSurg generator

1. Confirm that the irrigation level setting indicator displays the type of transducer, which is connected to the SonoSurg generator (see Figure 3.7).



This example shows the indicator when a SonoSurg-T2L-GE/SonoSurg-T2L-GE-C transducer is connected.

Figure 3.7

Also confirm that the display correctly shows the type of hand piece you have connected:

Type of hand piece	Display on the irrigation level setting indicator
SonoSurg-T2L-MS	After “HP1” is displayed, “Irr” is blinking.
SonoSurg-T2L-GE SonoSurg-T2L-GE-C	After “HP2” is displayed, “Irr” is blinking.
MAJ-336	After “HP3” is displayed, “Irr” lights steadily.
SonoSurg-T2L-T	After “HP4” is displayed, “Irr” lights steadily.
SonoSurg-T2H SonoSurg-T2H-C	After “HP5” is displayed, “Irr” lights steadily.

2. When the SonoSurg generator is in stand-by mode, the ultrasonic output and setting operations cannot be controlled. When the SonoSurg irrigation unit is connected to the generator, it also goes into stand-by mode when the generator in stand-by mode. Confirm that “– – –” is displayed on the irrigation level setting indicator (see Figure 3.8).

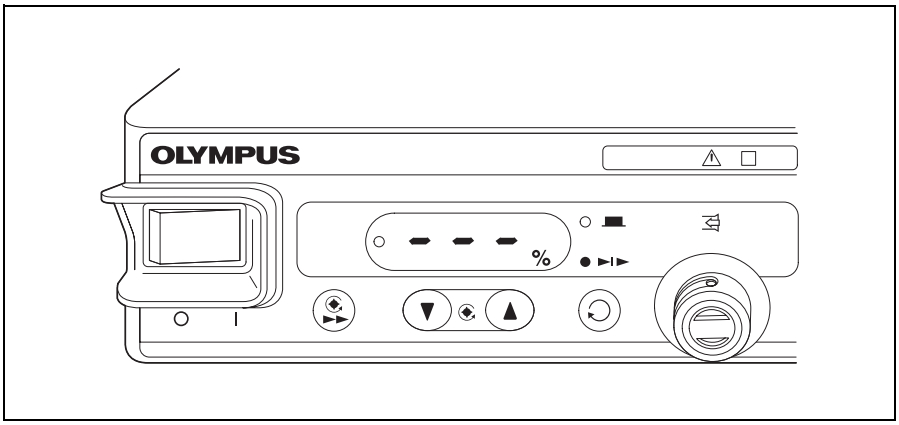


Figure 3.8

NOTE

When the socket of the SonoSurg connection cable (MAJ-1121) and the transducer plug (SonoSurg-T2L-GE-C) are not connected, the generator is still in stand-by mode and ultrasonic output and the setting operations are disabled, even if the plug of the cable is connected to the SonoSurg generator.

3.7 Inspection of the suction mode

NOTE

- The roller will not rotate if the pump head cover is not closed securely.
- The laparoscopic suction mode provides suction flow only while the ultrasonic output is activating. In particular, this mode will help maintain the selected pressure such as the laparoscopic operation.

1. Press the suction mode switch several times. Confirm that the normal suction mode lamp and the laparoscopic suction mode lamp light up alternately, and that the pinch valve opens and closes alternately (see Figure 3.9).

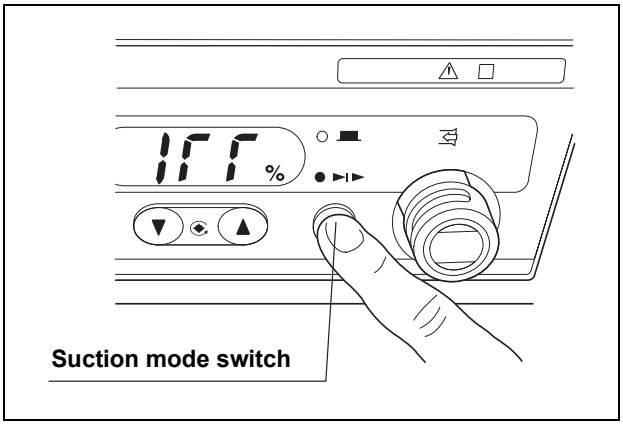


Figure 3.9

2. Press the irrigation pedal of the foot switch (MAJ-1102), and confirm that the pump head roller rotates and the pinch valve closes. The suction setting mode is set to the normal suction mode (indicated by illumination of the normal suction mode lamp), and the pinch valve is closed.

Chapter 4 Preparation, Inspection and Connection of the Handpiece

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 this instrument and see Chapter 8, “Troubleshooting”.
If the irregularity is still suspected after consulting Chapter 8, contact Olympus. Damage or irregularity may compromise patient or operator safety and may result in more severe equipment damage.

WARNING

- The transducer and ancillary components (e.g. probes and sheaths, which are sold separately) were not sterilized before shipment. Before using them for the first time, reprocess them according to the instructions given in Chapter 7, “Reprocessing and Storage”.
- If the contacts inside of the transducer’s plug or the connection cable’s socket turn black, replace both the transducer and the connection cable. Otherwise, the equipment could short-circuit and damage the generator.
- When inspecting or using the equipment, always wear appropriate personal 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. Otherwise, blood, mucus and other potentially infectious material from the patient could pose an infection control risk.

CAUTION

- Do not apply excessive force when assembling or disassembling this instrument. If the instrument is difficult to assemble, do not forcibly bend or strike any components. Instead, disassemble the instrument and attempt to reassemble it. If difficulties persist, examine the instrument and its components thoroughly for irregularities. If you observe or suspect a problem with the instrument or any of its components, do not use the instrument and contact Olympus.
- The distal ends of the probe and the sheath are subject to wear, due to ultrasonic and high-frequency output. Inspect them before and after each use to prevent damage or reduced performance.
- Prepare a spare probe, sheath and transducer for use in case of damage and/or malfunction.
- Check the equipment for damage before and after each use. If damage is observed or suspected; dispose of the equipment and use new items.

4.1 Preparation of the equipment

Prepare this instrument, the SonoSurg generator (SonoSurg-G2), the SonoSurg irrigation unit (SonoSurg-IU), compatible ancillary equipment (shown in the “System chart” in the Appendix) and other equipment to be used with this instrument (e.g. paper towels, a basin, lint-free cloth and personal protective equipment, such as eye wear, a face mask, moisture-resistant clothing and chemical-resistant gloves) for the particular case. Refer to the respective instruction manuals for each piece of equipment.

WARNING

The suction device combined with this instrument may cause hazardous situations under certain operating conditions. Be sure to check the safety at the overall system level before use. The suction pressure during the procedure should be set within the range shown below. If the suction pressure is not set within the range shown below, it will not be possible to cool the probe sufficiently, and patient burns or probe damage may result.
Suction pressure range: −8 to −85 kPa

CAUTION

- Prepare the equipment shown in the “System chart” in the Appendix.
- Equipment used simultaneously with this equipment (e.g. endoscope, microscope, suction device, electrosurgical unit, light source unit, video camera, etc.) should be handled and used as described in their respective instruction manuals.
- For more details on the SonoSurg generator and its ancillary equipment, refer to the instruction manual for the SonoSurg generator set (SonoSurg-G2 set).

4.2 Inspection and connection of the transducer, probe and sheath

Inspection

WARNING

- If the suction fitting of the SonoSurg transducer (SonoSurg-T2L-GE/SonoSurg-T2L-GE-C) is damaged, do not use the transducer and contact Olympus.
- If the transducer's seal is damaged, do not use the transducer and contact Olympus. Otherwise, insufficient cooling due to a leakage of irrigation fluid may cause patient burns or probe damage.
- If the sheath connecting section of the transducer (SonoSurg-T2L-GE/SonoSurg-T2L-GE-C) is deformed or damaged, do not use the transducer and contact Olympus. If the connection between the transducer and the sheath is not complete, connect them securely. Otherwise, insufficient cooling due to a leakage of irrigation fluid may cause patient burns or probe damage. Moreover, when high frequency output is performed through this instrument, unintended leakage current may cause operator or patient burns.
- If the hand piece cord of the transducer (SonoSurg-T2L-GE/SonoSurg-T2L-GE-C) or the connection cable (MAJ-1121) is damaged or broken, leakage current may cause operator or patient burns. If the cord is damaged, stop using it and contact Olympus.
- If the contacts inside of the plug and/or the socket turns black, replace the transducer (SonoSurg-T2L-GE/SonoSurg-T2L-GE-C) and/or the connection cable (MAJ-1121). Otherwise, it could cause a short-circuit and/or cause equipment damage.
- If the irrigation fitting of the sheath has been damaged, replace the sheath with a spare one. Otherwise, insufficient cooling may cause patient burns and/or probe damage.
- If the SonoSurg GE sheath attachment (T3300) is damaged (e.g. cracks, deformation or damage to the seal), replace it with a spare one. Otherwise, insufficient cooling due to leakage of irrigation fluid may cause patient burns or further probe damage.

WARNING

- Be sure to connect the SonoSurg GE sheath attachment (T3300) to the sheath. If it is not attached, patient burns or other injuries or probe damage could occur.
- The transducer and ancillary components (e.g. probes and sheaths, which are sold separately) were not sterilized before shipment. Before using them for the first time, reprocess them following the instructions in Chapter 7, “Reprocessing and Storage”.
- Check the probe tip for any coating peeling, scars, flaws or deformities. If irregularities are observed or suspected, do not use the probe. Otherwise, abnormal output and/or detachment of the tip may result.

CAUTION

- If the sheath connecting section of the transducer (SonoSurg-T2L-GE/SonoSurg-T2L-GE-C) is deformed or damaged, never connect it to the sheath. Otherwise, it may be impossible to remove the sheath from the transducer.
- Never touch the contacts of the plug and/or the socket. Static electricity accumulated during autoclaving may result in an electric shock.
- Ultrasonic output cannot be activated if liquid or foreign substances are inside the plug and/or the socket. Remove them.
- Do not attempt to clean the contacts inside the plug or the socket with a sharp object, such as the tip of a pair of tweezers. Otherwise, the contacts may become deformed or damaged, and ultrasonic output may not be activated.
- Be sure to connect the plug and the socket securely. If the connection is not secure, the SonoSurg connection cable (MAJ-1121) may be unplugged, which will disable ultrasonic output.
- When connecting and/or disconnecting the plug and the socket, always hold both the plug and the socket. Pulling the cord could damage the cord or the wires inside.
- If a component becomes damaged or deformed, do not use it. Even if you can restore its original shape, the durability of the component has been diminished. Continued use may cause more-severe equipment damage and/or makes it impossible to remove it from the trocar tube.

NOTE

Repeatedly connecting and disconnecting the socket and the plug helps to remove substances adhering to the contacts. This is a positive cleaning action, to be undertaken when a foreign substance has hardened on the contacts.

1. Confirm that the transducer (SonoSurg-T2L-GE/SonoSurg-T2L-GE-C) and the connection cable (MAJ-1121) are free from rust, dislocation, cracks rattling or looseness, and that the hand piece cord is not damaged. If the contacts inside of the transducer's plug or the connection cable's socket are black, replace both the transducer and the connection cable.
2. Check to see if any foreign substance or liquid is adhering inside the plug. If a liquid is adhering, point the plug downward and wipe the liquid away with a piece of dry gauze. If a foreign substance is adhering inside the plug, clean it using a brush such as the MH-507 (this item is sold separately). Never try to push or rub the contacts with the metallic tip of the brush. Inspect and clean the inside of the socket in the same manner.
   After cleaning, connect and disconnect the socket and the plug about 10 times.
3. Confirm that the probe, the sheath and the SonoSurg GE sheath attachment are free from rust, dislocation, cracks, looseness, dents or bends.
4. If the transducer's seal is damaged or broken, do not use the transducer and contact Olympus (see Figure 4.1).

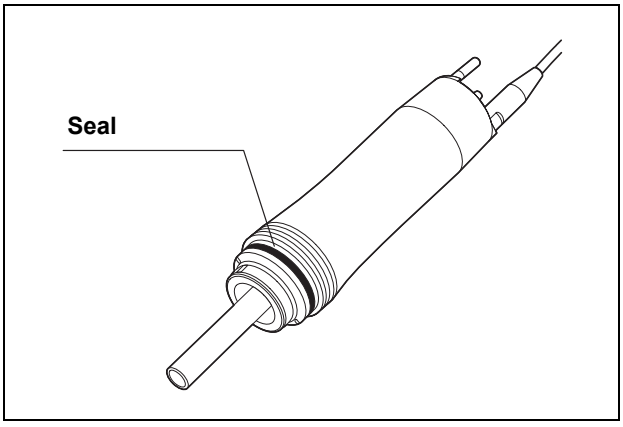


Figure 4.1

❍ Connecting the probe to the transducer

WARNING

Be sure to connect the transducer, the probe and the sheath in the order specified below. Otherwise, there is a possibility of patient burns or other injury, equipment damage.

CAUTION

- Ensure that the probe and the transducer are securely connected. Otherwise, ultrasonic output cannot be transmitted from the SonoSurg generator through the probe, the probe may be damaged, or the surface of the transducer may become hot.
- Use only the torque wrench (MAJ-1117) to loosen/tighten the probe. Otherwise, the probe and/or the transducer could be damaged.
- If the probe cannot be rotated smoothly, disconnect and reattach the sections, then screw them together again without using excessive force. Screwing the section together with excessive force may damage the probe and/or the transducer.
- Do not hold the front part of the torque wrench's grip section and do not place your finger on it. Doing so could be the reason that the connection is too tight or too loose.
- Stop turning the torque wrench when the head stops and the arm moves. Applying further force could cause damage to the probe and the transducer.

1. Insert the screw section of the probe into the probe connecting section of the transducer. Then, rotate the probe with your fingers until it stops (see Figure 4.2).

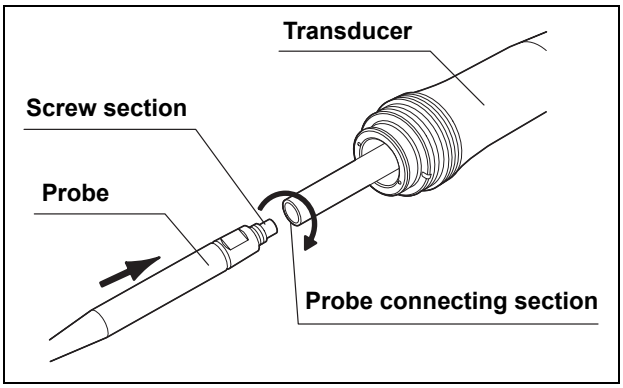


Figure 4.2

2. Attach the torque wrench (marked with “This side up”) to the notch of the probe (see Figure 4.3). Then turn the torque wrench by holding it on the grip section until the head stops and the arm moves. When the head stops lower tension is felt (see Figure 4.4).

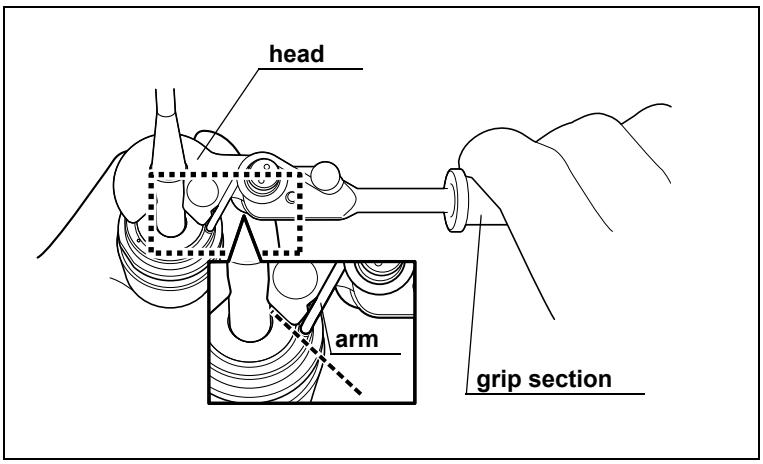


Figure 4.3

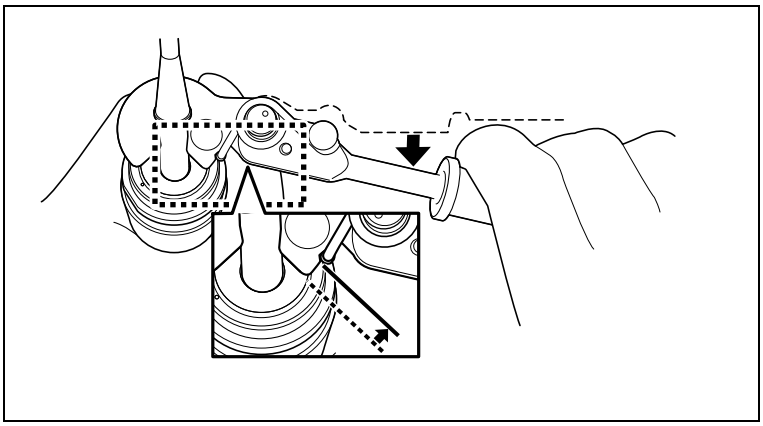


Figure 4.4

3. When the transducer must be replaced during a procedure, inspect the new transducer as described in this section, and connect the new transducer to the probe as described in steps 1. and 2. above.

Connecting the sheath to the transducer

WARNING

Be sure to align the sheath and the probe properly. In particular, when using the GE sheath (15° Angled) (T3320), the tip of the sheath (the GE sheath attachment) may come in contact with the probe, and heat generated by the friction between the two could cause patient burns and/or equipment damage.

CAUTION

- When attaching the SonoSurg GE sheath attachment to the sheath, screw them together carefully. There is a possibility of damaging the attachment and/or the sheath.
- When tightening the screw section of the SonoSurg GE sheath attachment to the sheath, rotate it gently with your fingers. Using excessive force may damage the attachment and/or the sheath.
- If the attachment and the sheath cannot be rotated smoothly, disconnect and reattach the screw section, then screw them together again. Screwing the sections together with excessive force may damage the attachment and/or the sheath.
- If the attachment and the sheath are not properly aligned, they could become damaged.
- Insert the transducer to which the probe is attached into the sheath from the proximal end and push it all the way in until it stops. Otherwise, abnormal flow of cooling water may cause insufficient probe cooling, which in turn could cause burns and/or further equipment damage.

1. Insert the screw section of the SonoSurg GE sheath attachment (T3300) into the screw section of the sheath. Then, rotate the attachment counterclockwise with your fingers until it stops (see Figure 4.5).

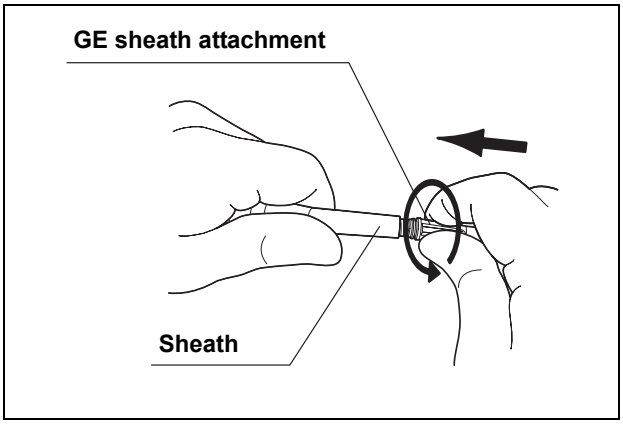


Figure 4.5

2. Insert the transducer to which the probe is attached into the proximal end of the sheath and push it all the way in until it stops (see Figure 4.6).

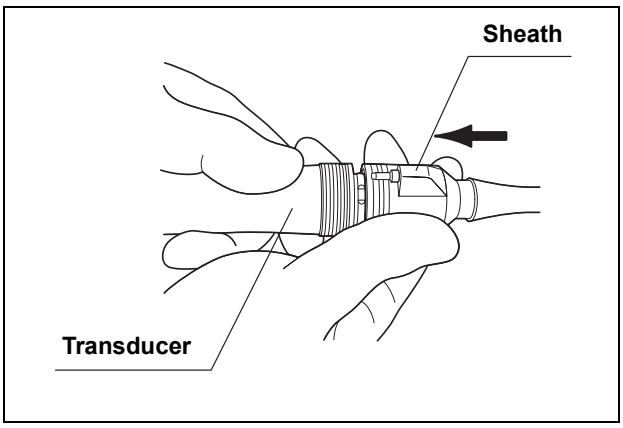


Figure 4.6

3. Before inserting the transducer, align the angled portions of the probe and sheath. After insertion, adjust the relative positioning between the probe tip and the sheath by rotating the sheath with respect to the transducer so that the sheath and probe are not in contact (see Figure 4.7).

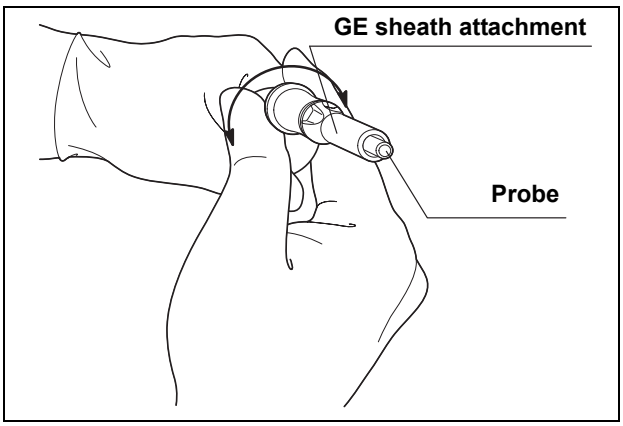


Figure 4.7

4. If the transducer must be replaced during the procedure, insert the probe with the new transducer into the sheath as described in steps 2. and 3. above.

Connect the connection cable to the transducer

1. Align the red triangle on the plug of the transducer with the red triangle on the socket (see Figure 4.8).

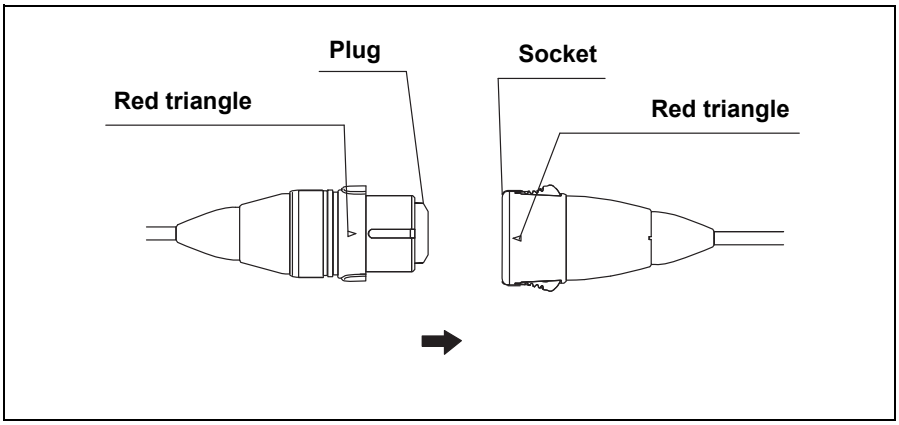


Figure 4.8

2. Insert the plug into the socket until it clicks.

4.3 Inspection and connection of the irrigation/suction tube for SonoSurg (MAJ-1099)

WARNING

- The irrigation/suction tube for SonoSurg (MAJ-1099) is a disposable item, that should never be reused. Doing so may result in infection, tissue inflammation and/or equipment damage.
- Do not attempt to sterilize the irrigation/suction tube for SonoSurg (MAJ-1099). This could pose an infection control risk, cause equipment damage or impair its functionality.
- Do not store the sterile package containing the irrigation/suction tube for SonoSurg (MAJ-1099) in places where it could become damaged, wet or improperly sealed. Otherwise, the sterility of the tube may be compromised, which could pose an infection control risk.
- Do not use the irrigation/suction tube for SonoSurg (MAJ-1099) after the expiration date displayed on the sterile package. Otherwise, the sterility of the tube may be compromised, which could pose an infection control risk.
- Do not use the irrigation/suction tube for SonoSurg (MAJ-1099) if the tube is crushed, excessively bent or damaged, or if the tube clip, cord clip, needle or suction connector is deformed or damaged. Otherwise, abnormal cooling water flow and/or abnormal suction may impair sufficient probe cooling and cause burns or probe damage. In addition, if cooling water or aspirated fluid leaks from the tube, current may be conducted through it during the procedure and cause burns.
- Connect all parts securely. If the irrigation/suction tube is not connected properly, abnormal cooling water flow or abnormal suction may impair sufficient probe cooling and cause burns or probe damage. In addition, if cooling water or aspirated fluid leaks from the tube, current may be conducted through it during the procedure and cause burns.
- Never use any tubing with this instrument other than the irrigation/suction tube for SonoSurg (MAJ-1099). Otherwise, the normal functionality of the product cannot be maintained and burns or equipment damage may result.

WARNING

- Connect the irrigation/suction tube securely as described in the following procedure. If it is not connected properly, abnormal cooling water flow or abnormal suction may impede sufficient probe cooling and may cause burns or probe damage.
- Never open the sterile package containing the irrigation/suction tube until immediately before use. Otherwise, the sterility of the tube may be compromised and pose an infection control risk.
- Never uncap the needle until immediately before inserting it into a saline solution bag, and never touch the tip of the needle after uncapping it. Otherwise, the sterility of the tube may be compromised and could pose an infection control risk.

CAUTION

- Always keep a spare one of the irrigation/suction tube for SonoSurg (MAJ-1099) to use in case of a malfunction.
- Be sure to attach the cord clip securely and in the correct position. Otherwise, the tubing may become bent during use, making normal suction impossible.
- When connecting the irrigation/suction tube to the irrigation fitting, always hold the sheath. Otherwise, the sheath may fall and could be damaged.
- Do not apply excessive force to the hand piece cord and/or irrigation/suction tube while connecting them, as it may result in disconnection, water leakage, breakage or other damage. If it is anticipated that the hand piece cord and the irrigation/suction tube will be subjected to excessive force, reposition the SonoSurg generator (SonoSurg-G2) and SonoSurg irrigation unit (SonoSurg-IU) to minimize the forces on the tubing.
- When fixing the irrigation/suction tube to an operating table, etc., do not clamp it using forceps. Otherwise, the hand piece cord may be damaged and/or its wires disconnected.

Inspection of the irrigation/suction tube

1. Confirm that the sterilized package is not broken, unsealed or wet. If any abnormality is found, do not use the package because its sterile condition may have been compromised.
2. Confirm that the irrigation/suction tube is not crushed, excessively bent or damaged.
3. Confirm that the tube clip, cord clip, needle and suction connector are not deformed or damaged. Also make sure that the needle is capped.

Connecting the irrigation/suction tube to the transducer

1. When connecting the irrigation tube of the irrigation/suction tube for SonoSurg (MAJ-1099) to the sheath, always hold the sheath firmly. Make sure to push the tube completely over the irrigation fitting (see Figure 4.9).

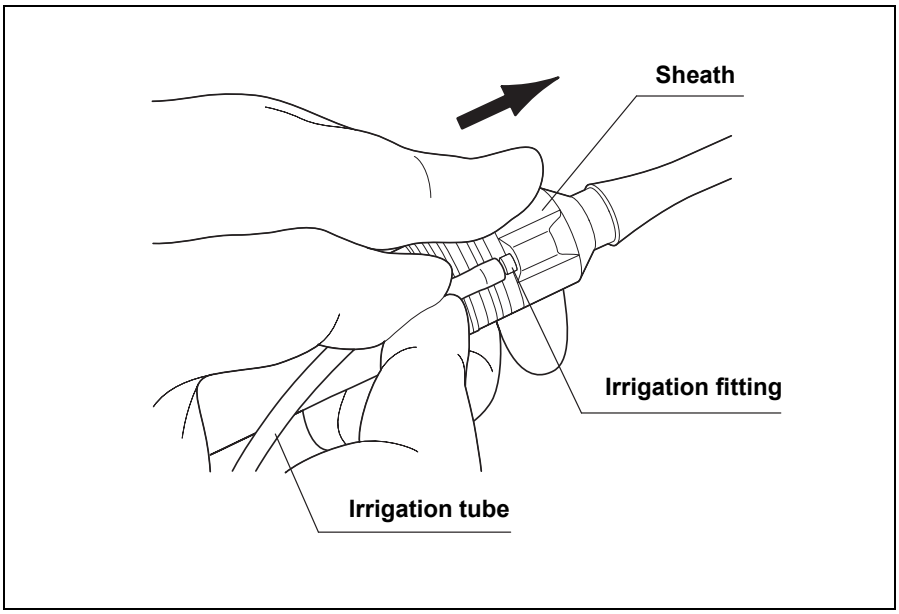


Figure 4.9

2. Attach the tube holder of the irrigation/suction tube of the transducer (see Figure 4.10).

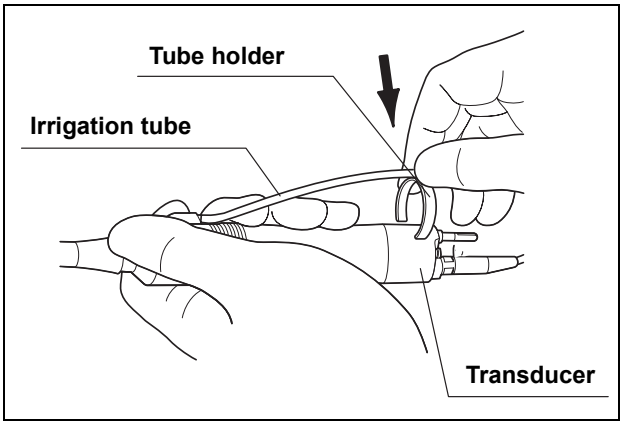


Figure 4.10

3. When connecting the suction tube of the irrigation/suction tube to the transducer, push the tube on until it covers the two ridges of the suction fitting (see Figure 4.11).

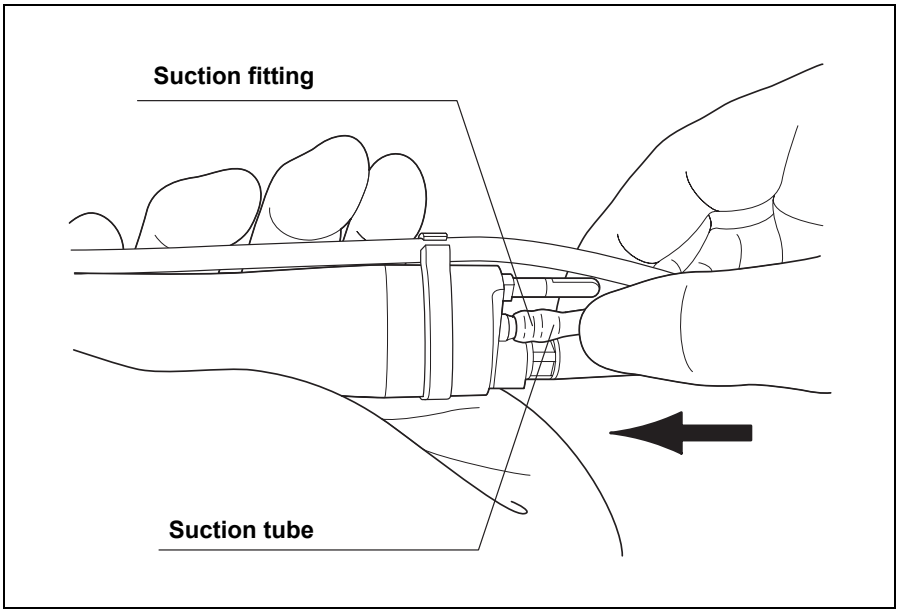


Figure 4.11

4. Attach the cord holder on the irrigation/suction tube to the hand piece cord. Be careful not to twist or bend the cord or the tube while doing so (see Figure 4.12).

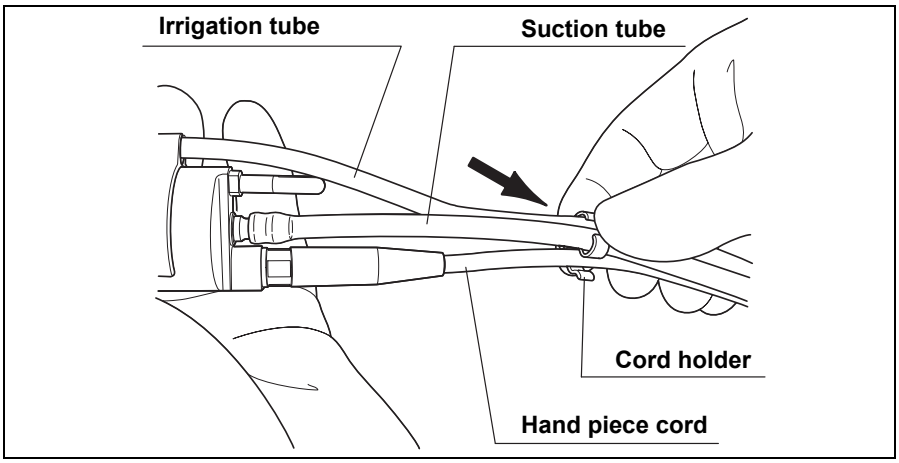


Figure 4.12

❍ Attaching the irrigation/suction tube to the pump head

WARNING

- Securely attach the irrigation tube of the irrigation/suction tube for SonoSurg (MAJ-1099) to the pump head. If the irrigation tube is not attached properly to the pump head, abnormal cooling water flow may not cool the probe sufficiently and may cause burns.
- Be sure to secure the irrigation tube in the guide grooves on either side of the pump head's roller. Otherwise, abnormal cooling water flow may not cool the probe sufficiently and may cause burns. In addition, the tube could become damaged.
- The water-supply tubing must be attached to this instrument in a specific orientation. If this tubing is not attached properly, abnormal cooling water flow may not cool the probe sufficiently and may cause burns.
- Take care that the pump head cover does not pinch the irrigation tube. Otherwise, the cooling water flow will be impaired, which could lead to in sufficient cooling of the probe and cause burns. In addition, the irrigation tube could become damaged.

CAUTION

- Before hooking the tube to the pump head, be sure to properly align the position of the roller. Otherwise, an insufficient quantity of water may be supplied.
- Before closing the pump head cover, confirm that the irrigation tube is not too loose and take care not to close the cover while pulling the irrigation tube. If the cover is closed while the tube is extended, abnormal irrigation may occur, which could lead to insufficient cooling of the probe and could cause burns.
- Be careful not to close your hand in the pump head cover.

NOTE

- The irrigation tube is indicated by a blue line on its side.
- The method of attaching the irrigation tube to the pump head is also indicated on the pump head cover.
- When the pump head cover is not closed securely, a safety mechanism prevents operation of the pump. In this case, the irrigation level setting indicator of the SonoSurg irrigation unit displays “OPE”.

1. Rotate the pump head cover upward to open the head cover (see Figure 4.13).

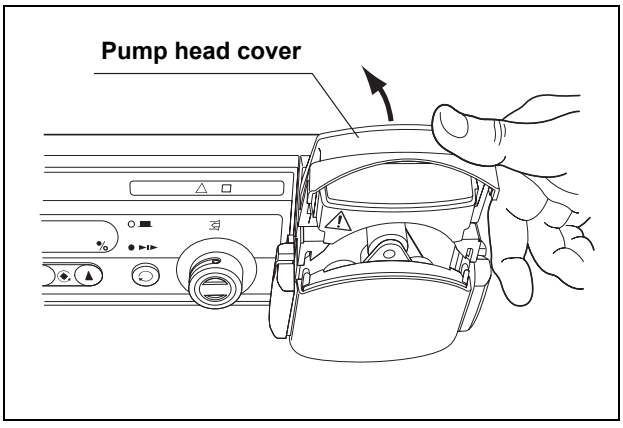


Figure 4.13

2. Manually rotate the roller to align it properly. Then, place the irrigation tube of the irrigation/suction tube for SonoSurg (MAJ-1099) on the roller, and push it into both guide grooves (see Figure 4.14).

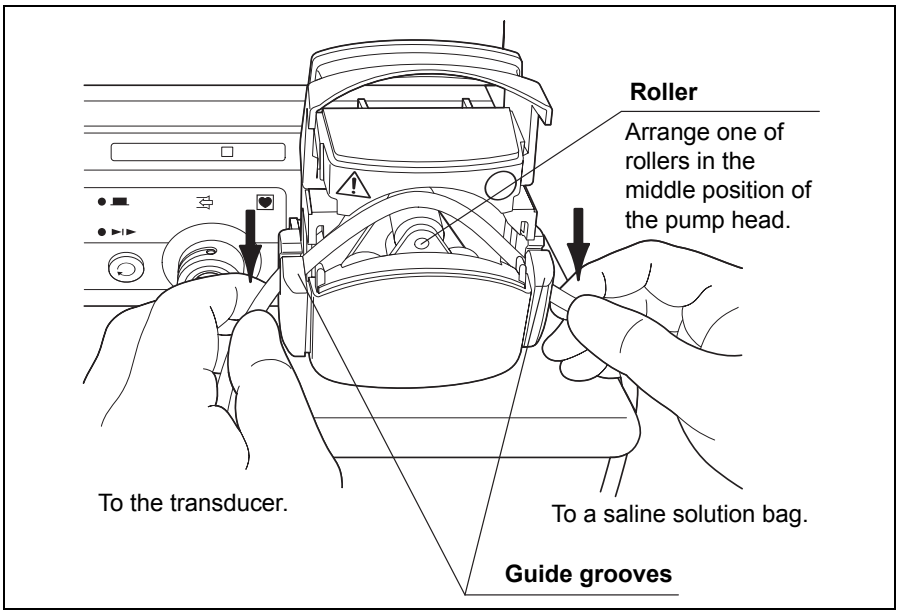


Figure 4.14

3. Confirm that the irrigation tube is in both guide grooves of the pump head, then close the pump head cover (see Figure 4.15).

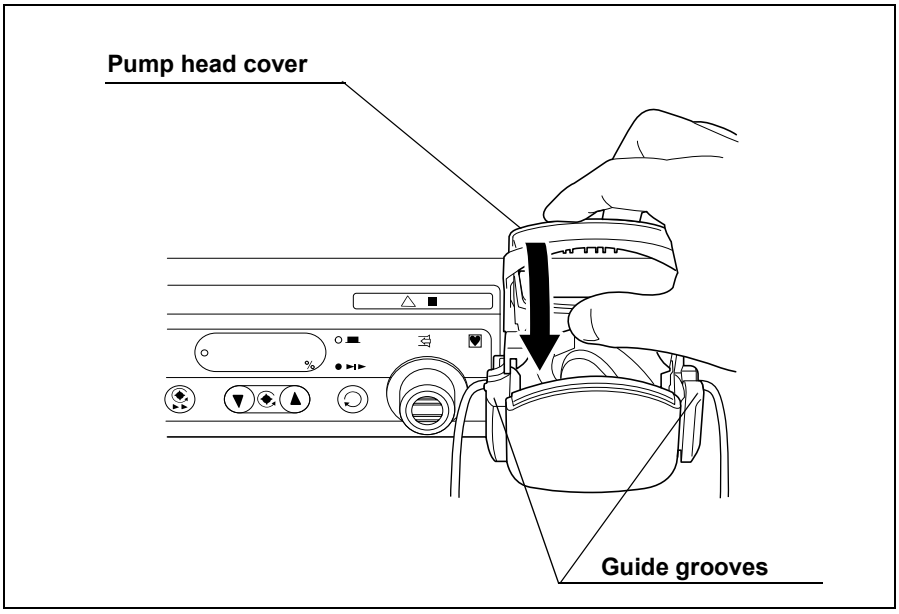


Figure 4.15

❍ Attaching the irrigation/suction tube to a saline solution bag.

WARNING

- When inserting the needle into a saline solution bag, never touch the tip of the needle and/or the insertion section of the bag. Otherwise, the sterility of the items may be compromised, which could pose an infection control risk.
- Use sterile saline solutions as cooling water. Other fluids may pose an infection control risk, impair equipment functionality or cause the equipment damage.

CAUTION

- Place the saline solution bag at the proper height, in order to ensure sufficient fluid flow. Closely monitor the fluid level in the bag.
- When using a saline solution bottle instead of a bag to supply cooling water, attach a venting needle in order to ensure sufficient fluid flow. An insufficient flow of cooling water may lead to insufficient cooling of the probe and cause burns.
- Use saline solution at a temperature of 25 degrees C (77 degrees F) or less. Otherwise, the probe may not be cooled sufficiently and could cause burns.
- When connecting the irrigation tube to a saline solution bag, take care not to stretch the tube. Otherwise, the needle may slip out of the bag. If this happens, reconnect the tube as described in Section 4.3, “Inspection and connection of the irrigation/suction tube for SonoSurg (MAJ-1099)”.
- Prepare a sufficient quantity of cooling water. If the cooling water is depleted, an insufficiently cooled probe could cause burns. When the quantity of cooling water is likely to be insufficient, prepare additional water prior to the procedure.

1. Adjust the height of the IV pole to position the saline solution bag as shown in Figure 4.16 below.

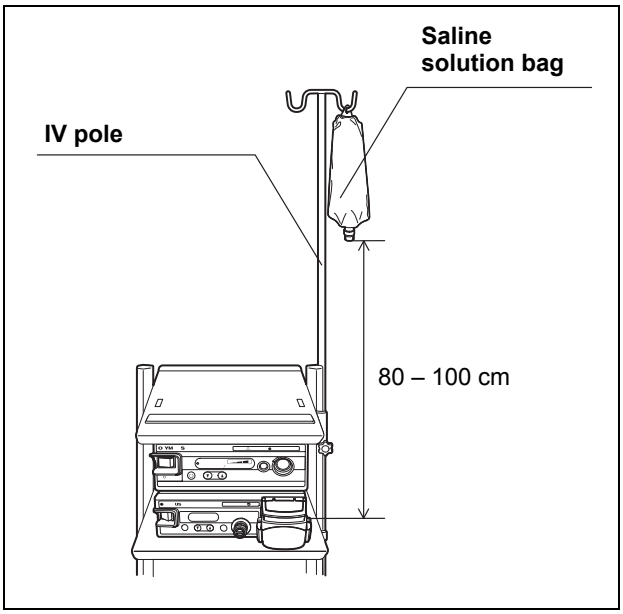


Figure 4.16

2. Remove the seal from a saline solution bag, remove the cap from the needle of the irrigation/suction tube and insert it into the bag (see Figure 4.17).

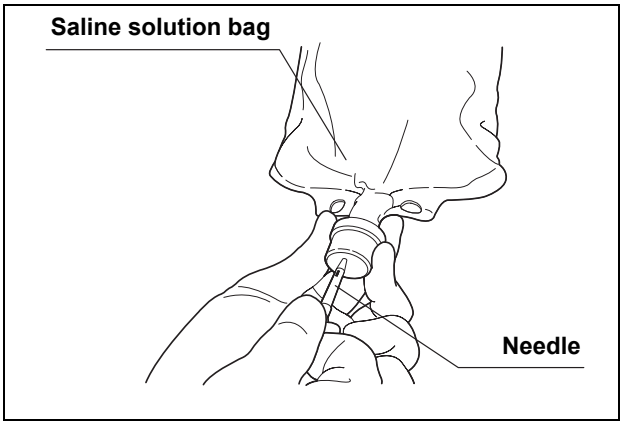


Figure 4.17

❍ Attaching the irrigation/suction tube to the pinch valve

CAUTION

Always attach the suction tube side of the irrigation/suction tube for SonoSurg (MAJ-1099) to the pinch valve of the irrigation unit. Particularly if the laparoscopic suction mode does not function properly during insufflation in laparoscopic procedures, reduced insufflation pressure may obstruct the operator's vision and/or deplete the cooling water during high-irrigation.

NOTE

in order to distinguish the suction tube from the irrigation/suction tube, observe that the suction tube does not have a blue line on its side.

1. Confirm that the pinch valve is open. If it is closed, press the suction mode switch to select the normal suction mode. This will open the pinch valve.
2. Attach the suction tube of the irrigation/suction tube to the pinch valve (see Figure 4.18).

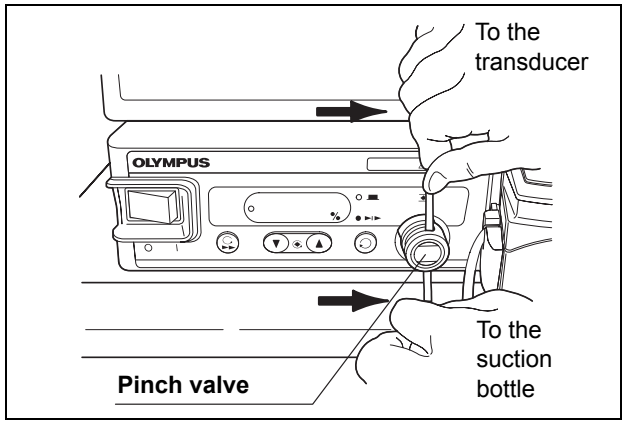


Figure 4.18

❍ Attaching the irrigation/suction tube to a suction device

WARNING

Connect the suction equipment securely so that the suction fluid does not leak. Otherwise, fluid leakage may pose an infection control risk.

CAUTION

- Be sure to inspect the suction equipment before connection as described in its instruction manual. Abnormal suction can cause insufficient probe cooling, which could cause burns.
- Prior to the procedure, estimate the amount of fluid that will be aspirated. Prepare a canister that is large enough to accommodate the estimated amount of fluid. If the canister is overfilled while in use, the probe may be insufficiently cooled, and could cause burns. If you observe during a procedure that a canister is about to become filled up, switch to an empty canister.

Connect the bottle cap of the irrigation/suction tube for SonoSurg (MAJ-1099) to the “PATIENT” fitting of a suction bottle (see Figure 4.19).

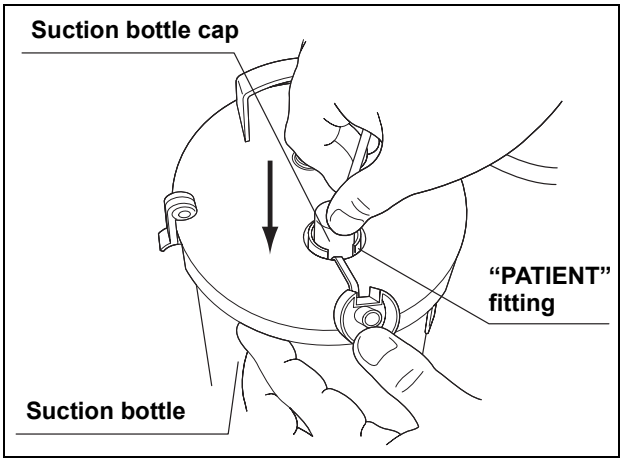


Figure 4.19

4.4 Connection of the hand piece plug

CAUTION

- Never touch the pins in the hand piece plug after sterilizing. Otherwise, static discharge accumulated during sterilization may cause an electrical shock.
- Confirm that the pins on the hand piece plug are fully dry before connecting.
- Hold the hand piece plug of the transducer firmly when connecting/disconnecting the transducer. Holding any other part of the transducer may cause equipment damage.
- Never pull the hand piece cord in order to unplug it from the generator (SonoSurg-G2) or to detach the water-proof cap. Otherwise, the cord or the wires inside of it may be damaged.

1. Detach the waterproof cap from the transducer plug (SonoSurg-T2L-GE) or the plug of the connection cable (MAJ-1121).
2. Align the red mark on the transducer plug with that on the hand piece connector of the generator (see Figure 4.20).
3. Insert the plug into the hand piece connector until it clicks.

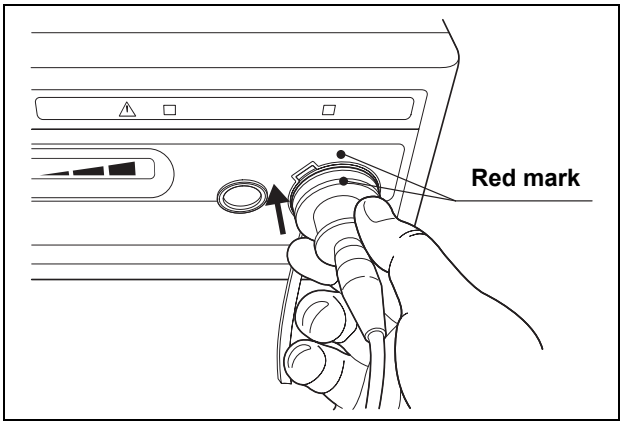


Figure 4.20

❍ How to disconnect the hand piece plug

Hold the plug firmly and pull it out of the generator's hand piece connector.

4.5 Preparation and inspection of the electrosurgical unit

WARNING

- This instrument should be used in combination with Olympus electrosurgical unit UES-40. It has been tested and found to be safe in combination with the instrument. Generally, since an electrosurgical unit can be hazardous, its safety should be checked.
- If this instrument will be used in combination with an electrosurgical unit that is not listed in the “System chart” in the Appendix, you have to confirm the safety of the system before use. Moreover, use only type BF/CF electrosurgical units whose applied parts are insulated from HF earth currents in accordance with IEC 60601-2-2. Otherwise, the unit may cause burns and/or other equipment damage.

❍ Preparation and inspection of the electrosurgical unit

Prepare and inspect the electrosurgical unit as described in its instruction manual. Should the slightest abnormality be suspected, do not use it, and contact Olympus.

❍ Preparation of the patient plate

CAUTION

To prevent patient burns, keep the patient away from metallic parts of the operating table or other devices. Otherwise, it may cause patient burns.

Prepare and inspect the patient plate as described in the instruction manual of the electrosurgical unit. Then attach the plate to the patient’s thigh or place it under the patient’s buttocks.

Preparation and inspection of the active cord (A-cord)

CAUTION

- Only A-cords A0335 and A0358 are compatible with this instrument. Do not use any other A-cord, as their safety in combination with this instrument is not guaranteed.
- Securely attach the A-cord to the A-cord mounting pin of the transducer (SonoSurg-T2L-GE/SonoSurg-T2L-GE-C). If the A-cord is not attached securely and output is generated, operator and/or patient burns could result.
- Never use an A-cord that can be easily removed from the A-cord mounting pin of the transducer. The A-cord or the mounting pin may have been deformed and/or damaged, which may cause operator and/or patient burns.
- Never use the A-cord if scratches, cracks, or peeling are observed on its insulation. A damaged A-cord may discharge electricity during high-frequency cauterization, which may cause patient and/or operator burns.
- Never connect the A-cord while either the A-cord or the A-cord mounting pin is wet, which could result in an electric shock. Otherwise, operator and/or patient burns may occur.
- Never attempt to grasp or fix the A-cord or the hand piece cord using a forceps or a similar tool. If the A-cord's insulation is damaged, it may affect the connection and/or cause current leakage.

1. Confirm that the A-cord's connector is free of scratches and cracks.
2. Attach the A-cord (A0355, A0358) to the A-cord mounting pin on the transducer (SonoSurg-T2L-GE/SonoSurg-T2L-GE-C), and confirm that it is secure (see Figure 4.21).

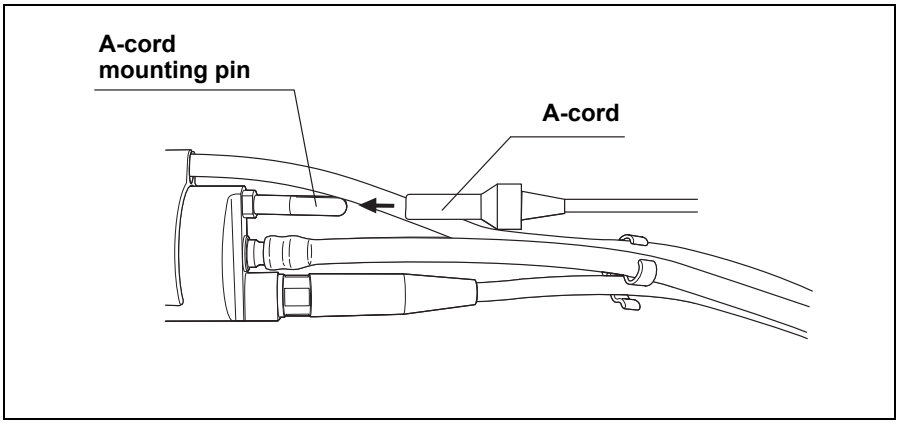


Figure 4.21

❍ Preparation and inspection of the SonoSurg GE hand switch (MAJ-1100)

CAUTION

- To prevent malfunction, do not apply excessive force to the connector sections when attaching this switch.
- Securely attach the A-cord mounting pin to the connection receptacle of the GE hand switch.
- Never use the GE hand switch that can be easily detached from the A-cord mounting pin of the transducer. The cord or the mounting pin may have been deformed and/or damaged, which may cause operator and/or patient burns.
- Never use the GE hand switch if scratches, cracks, or peeling are observed on the A-cord's insulation. A damaged switch or A-cord may discharge electricity during coagulation, which may cause operator and/or patient burns.
- Never attach the A-cord mounting pin to the connection receptacle while either of them is wet, which could result in an electric shock. Otherwise, patient and/or operator burns could occur.
- Never attempt to grasp or fix the cord using a forceps or a similar tool. If the cord's insulation is damaged, it may affect the connection and/or cause current leakage.

1. Confirm that the GE hand switch is free from rust, dislocation, cracks and rattles or looseness, and that the cord is not damaged.
2. Confirm that no foreign substances or liquids are adhering inside the plug and the receptacle. If a foreign substance and/or liquid is present, point the plug downward and wipe the inside with a clean, lint-free cloth.

3. Attach the A-cord mounting pin of the transducer into the connection receptacle of the GE hand switch (see Figure 4.22).

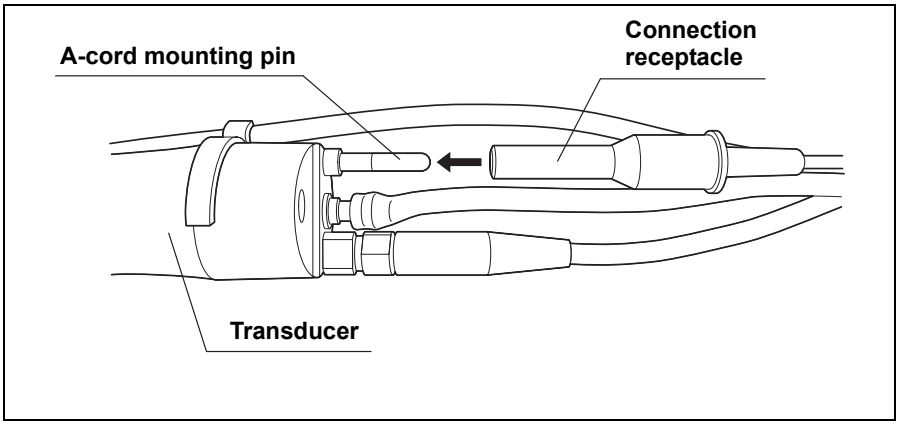


Figure 4.22

4. Fit the holder onto the sheath (see Figure 4.23).

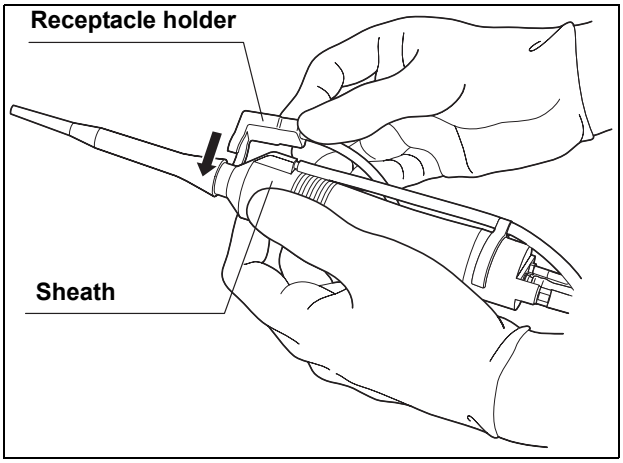


Figure 4.23

5. Attach the cord holder of the irrigation/suction tube (MAJ-1099) to the cord of the GE hand switch. Take care not to twist or bend the cord or the tube while doing this (see Figure 4.24).

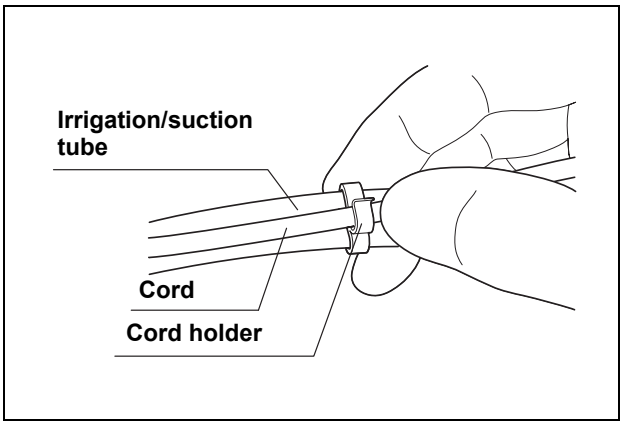


Figure 4.24

6. Attach the monopolar hand piece plug to the hand piece connector of the electrosurgical unit.

4.6 Inspection of compatibility with the trocar tube

CAUTION

- Only the probe (tapered, long) (MH-125) and the SonoSurg GE tapered sheath (T3330) are compatible with the trocar.
- The outer diameter of the insertion section of this instrument is 10 mm. Use a trocar tube with a corresponding size. It is recommended to assemble the instrument and the trocar tube before use to confirm that they fit together properly.
- Never use an instrument which has been dropped or subjected to a strong shock. Even if the instrument appears undamaged, it may become stuck in the trocar tube.

1. Carefully insert the insertion section of the instrument into the trocar tube.
2. Confirm that the sheath tip and the probe extend from the distal end of the trocar tube.
3. Make sure that the insertion section of the sheath moves smoothly in the trocar tube.
4. After inspecting the compatibility, carefully remove the insertion section from the trocar tube.

Chapter 5 Inspection of the System

CAUTION

During this inspection, also refer to the instruction manual of the SonoSurg generator (SonoSurg-G2).

5.1 Inspection of the generator and the irrigation unit

CAUTION

- After the transducer (SonoSurg-T2L-GE/SonoSurg-T2L-GE-C) has been connected to the generator (SonoSurg-G2) and the generator has been turned ON, “HP2” must be displayed on the ultrasonic output setting indicator of the generator. If this is not displayed, the generator and/or the transducer may not be working properly. In this case, immediately stop using the system, and contact Olympus.
- If “HP” flashes on the ultrasonic output setting indicator of the generator after the transducer (SonoSurg-T2L-GE/SonoSurg-T2L-GE-C) has been connected, the hand piece plug or the transducer’s plug may not be connected properly; reconnect them properly. If “HP” is still displayed after reconnection, perform the instructions given in Section 8.1, “Troubleshooting guide”.

1. Turn ON the SonoSurg generator (SonoSurg-G2) and the SonoSurg irrigation unit (SonoSurg-IU).
2. Confirm that “HP2” is displayed on the ultrasonic output setting indicator of the generator and the irrigation level setting indicator of the irrigation unit. After “HP2” has been displayed, the previous output setting is displayed (SonoSurg-G2) and “Irr” flashes (SonoSurg-IU) on the indicators of each unit (see Figure 5.1).

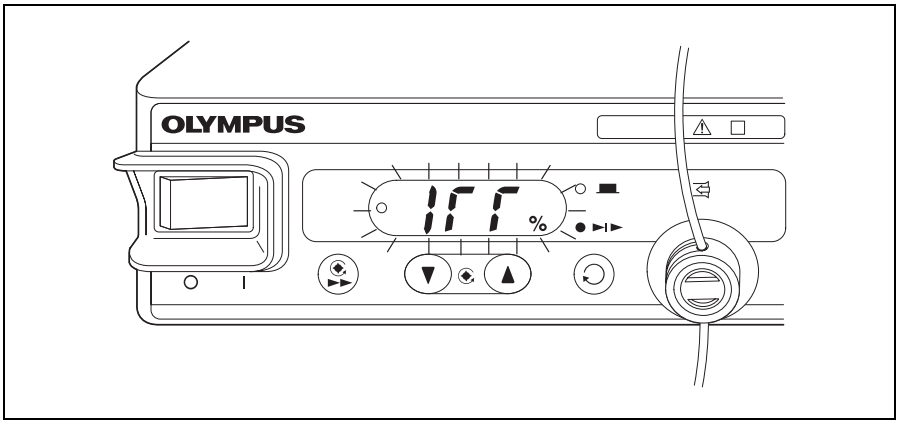


Figure 5.1

3. When the hand piece plug of the transducer (SonoSurg-T2L-GE/SonoSurg-T2L-GE-C) is not connected properly, “HP” flashes on the ultrasonic output setting indicator of the generator, and “Irr” is displayed on the irrigation level setting indicator of the irrigation unit (see Figure 5.2).

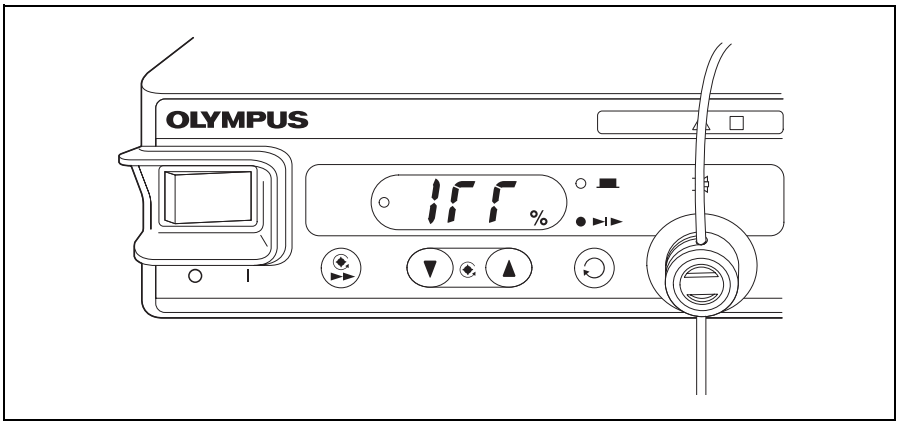


Figure 5.2

5.2 Inspection of the suction

CAUTION

- Confirm that suction pressure is applied at the probe's distal end. If this instrument is used without suction, it may not be cooled sufficiently, which could cause burns or probe damage.
- The suction pressure during the procedure should be set within the range shown below. If the suction pressure is set outside of this range, the safety of the procedure cannot be guaranteed. In particular, do not set a suction pressure below the minimum pressure given below. Otherwise, it will not be possible to cool the probe sufficiently, which could cause burns and/or probe damage.
  Suction pressure range: −8 to −85 kPa

1. Press the suction mode switch so that the normal suction mode lamp lights up (see Figure 5.3).

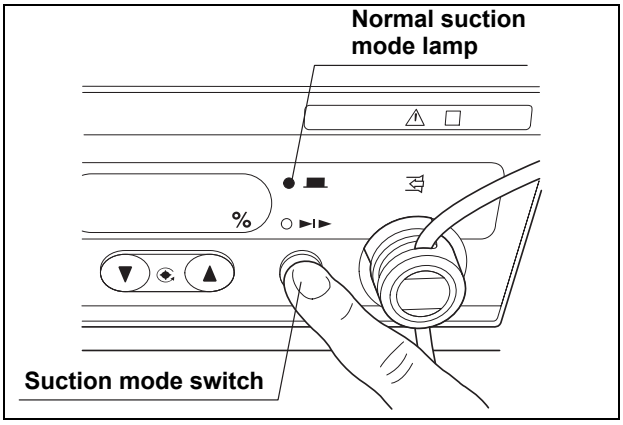


Figure 5.3

2. Activate the suction equipment, then aspirate saline solution as shown in Figure 5.4. Confirm that the suction pressure is applied at the probe's distal end.

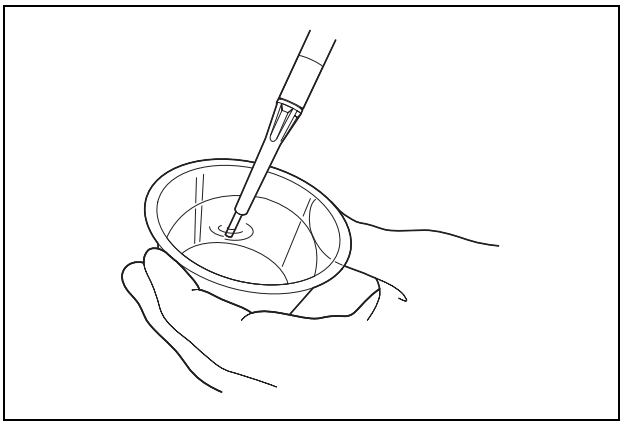


Figure 5.4

3. When the suction mode switch is pressed, the laparoscopic suction mode lamp lights up. In this mode, while depressing the suction pedal of the foot switch (MAJ-1102), confirm that the pinch valve of the irrigation unit opens and suction pressure is applied at the distal end of the probe.

5.3 Inspection of cooling water

WARNING

- Confirm that cooling water flows from the sheath tip. If cooling water does not flow, the connection or assembly may have been performed incorrectly. In this case, inspect the system and confirm the connections by referring to Chapter 3, "Preparation and Inspection of the SonoSurg Irrigation Unit" and Chapter 4, "Preparation, Inspection and Connection of the Handpiece". If the system is used without cooling water, insufficient cooling of the probe may cause burns.
- Confirm that no cooling water leaks from any part of the instrument. If the cooling water leaks, current may also be conducted through it during electrosurgical operation and could cause burns. In addition, the probe may not be cooled sufficiently and could cause burns.

1. Place the probe tip in a container or on a piece of gauze to collect cooling water (see Figure 5.5).

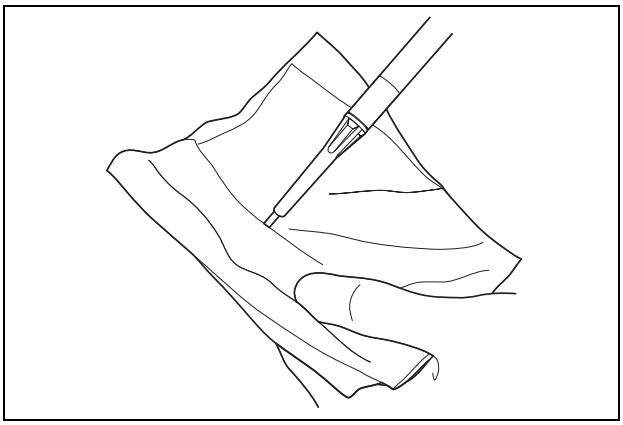


Figure 5.5

2. Press the flush switch of the irrigation unit and confirm that cooling water flows from the sheath tip. As it may take a few seconds before the cooling water flows, press and hold the switch until you observe water being discharged from the tip (see Figure 5.6). While “Irr” is flashing on the irrigation level setting indicator, the high-speed irrigation pedal does not function.

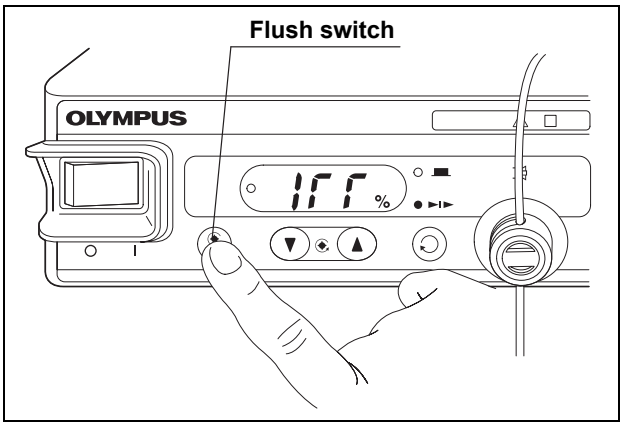


Figure 5.6

3. When the flush switch is pressed, the flashing “Irr” is illuminated continuously and the high-irrigation pedal of the foot switch (MAJ-1102) can be activated. Now press the high-irrigation pedal and confirm that cooling water flows out of the attachment on the sheath’s tip.

5.4 Inspection of ultrasonic output

WARNING

When inspecting the ultrasonic output, be sure to confirm that cooling water flows from the sheath tip. If ultrasonic output is activated while the inside of the sheath is not filled with cooling water, insufficient probe cooling may cause burns.

CAUTION

- Be sure to apply a suction pressure in the specified range during inspection of the ultrasonic output. If ultrasonic output is activated without suction, the probe may be cooled insufficiently and could cause burns.
- If a noise is emitted during ultrasonic output, the components of the GE hand piece may not have been connected properly. In this case, inspect the system and check that the connections are secure by referring to Chapter 4, “Preparation, Inspection and Connection of the Handpiece”. If you fail to solve the problem after taking remedial action, stop using the GE hand piece and replace it with a spare one.
- If the alarm tone continues during inspection, the probe may be fractured. In this case, immediately replace the probe with a spare one.
- During inspection, hold the probe so that its tip is below the horizontal. Otherwise, abnormal cooling water flow may cool the probe insufficiently and may cause burns.
- If the ultrasonic output tone is not heard from the irrigation unit when the output is activated, do not use the system and contact Olympus.

NOTE

The ultrasonic maximum output pedal of the foot switch (MAJ-1102) is disabled when a hand piece of type “HP1” or “HP2” is used. In this case, use the variable output pedal instead.

1. Ensure that the probe tip is not in contact with any other object. Make sure to orient the tip so that it is below the horizontal (see Figure 5.7).

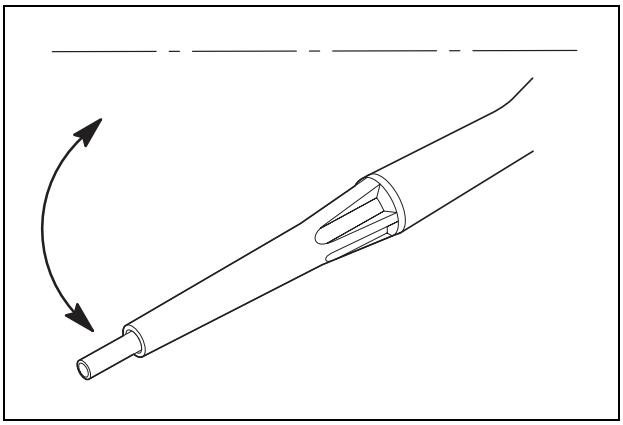


Figure 5.7

2. Set the output level to “10%” by pressing the ultrasonic output setting switches on the SonoSurg generator (see Figure 5.8).

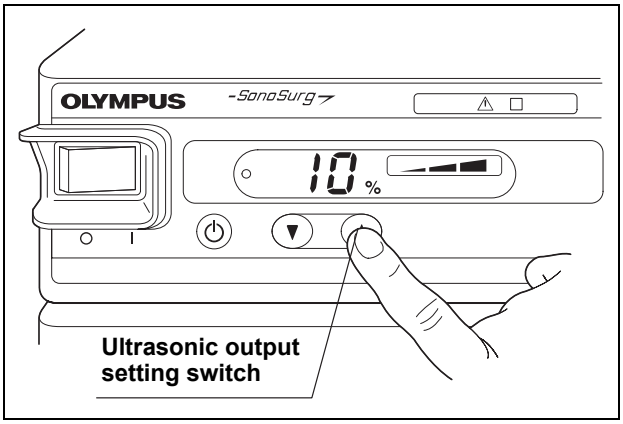


Figure 5.8

3. While stepping on the ultrasonic variable output pedal of the foot switch (MAJ-1102) as shown in Figure 5.9, activate the ultrasonic output and confirm that the irrigation unit generates an ultrasonic output sound and no abnormal noises. If the ultrasonic output warning lamp lights up, take proper measures as described in Chapter 8, “Troubleshooting”.

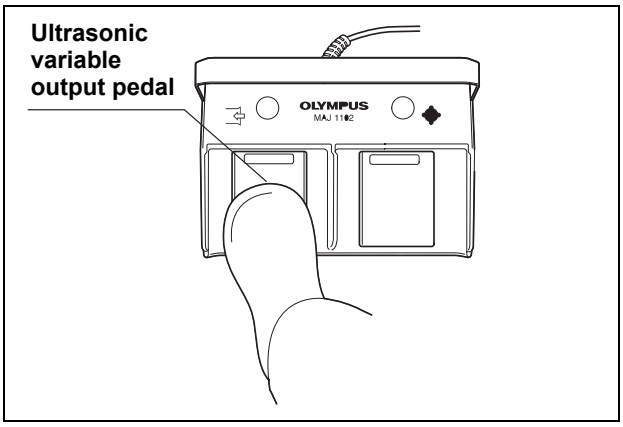


Figure 5.9

4. While stepping on the ultrasonic maximum output pedal of the foot switch (MAJ-1102) as shown in Figure 5.10, confirm that the warning tone is generated and the output is disabled.

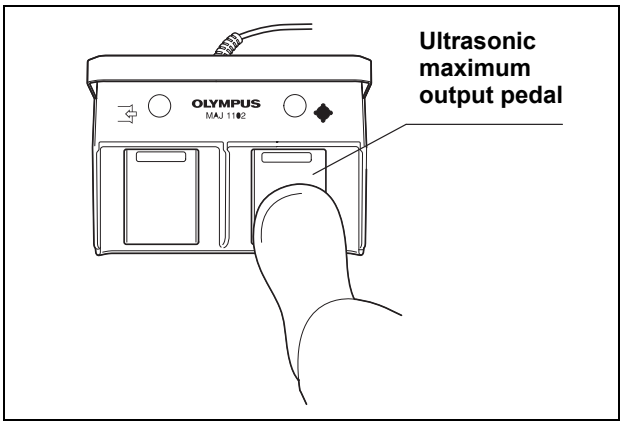


Figure 5.10

Chapter 6 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 techniques. This manual, therefore, does not explain or discuss clinical 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 potentially infectious material. During operation, wear appropriate protective 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.
- To ensure that the procedure can be completed without complications in case of a malfunction, prepare a spare instrument as a replacement.
- If abnormalities occur, immediately stop using the instrument and refer to Chapter 8, “Troubleshooting”. If the trouble persists or a malfunction is suspected, contact Olympus.
- Before activating output, be sure that the probe is not in contact with the surrounding tissue. Otherwise, ultrasonic output may cause perforation, bleeding, burns or tissue damage.
- Do not continue ultrasonic output with the sheath tip pressed against the tissue at the same point. In particular, never apply ultrasonic output if the sheath tip is in contact with the skin. Vibrations due to ultrasonic output may be conveyed via cooling water to the tissue in the vicinity of the sheath tip, and the heat generated by friction may cause burns to the surrounding tissues.
- When ultrasonic output is activated, ensure that the probe does not come in contact with any other surgical instruments. Doing so may cause equipment damage.

WARNING

- If the ultrasonic output stops during the procedure, the ultrasonic output warning lamp of the SonoSurg generator (SonoSurg-G2) will light up and a warning tone will sound. Immediately remove the insertion section of the SonoSurg GE hand piece from the patient, then inspect the system as described in Section 8.2, “When the ultrasonic output warning lamp is lit”. Otherwise, the probe may be scratched or broken and could drop into the body cavity during ultrasonic output.
- When the probe is contaminated with carbonized tissue, use a piece of moistened, soft gauze to remove the tissue. Never attempt to scrape it with a sharp object such as a scalpel. Otherwise, the probe may be scratched or broken and could drop into the body cavity during ultrasonic output.
- Never activate ultrasonic output if blood or saline solution is inside the plug or the socket. Otherwise, the component could short-circuit which, could damage the SonoSurg generator.
- If the contacts inside of the transducer’s plug or the connection cable’s socket turns black, replace both the transducer and the connection cable. Otherwise, the component could short-circuit and damage the SonoSurg generator.
- When replacing the hand piece, first remove the hand piece from the body cavity and detach the plug of the transducer from the connection cable. If the plug is removed and/or reattached while the hand piece is still within the body cavity, the probe or sheath tip may come in contact with tissue, and could cause injury.

CAUTION

- When inserting this instrument into or removing it from the trocar tube, gently hold the sheath. If the instrument is forcibly inserted or removed, the probe may become damaged, or it may become impossible to remove it from the trocar tube.
- Never drop the instrument or apply strong shock to it. Even if the instrument appears undamaged, its durability may have been impaired. If the instrument is dropped or subjected to a strong shock, do not use it, and replace it with a spare one.
- This instrument is delicate. Take care when inspecting, preparing and operating it.

CAUTION

- Only use this instrument under the conditions given in “Environment” in the Appendix.
- If all of the LEDs on the SonoSurg generator’s load indicator are lit, the probe is being subjected to an excessive load because it is in contact with a hard object such as a clip and/or another instrument, or the suction channel of the probe is clogged by large fragments or carbonized tissue. In this case, immediately reduce the load; operation of the instrument under these conditions could damage the probe.
- Before disconnecting the transducer’s plug, be sure to press the release buttons. If the plug is pulled without pressing the release buttons, the socket’s connection mechanism may be damaged or the sheath may accidentally become disconnected from the transducer.
- Do not press the release buttons while ultrasonic output is active. Doing so could disconnect the socket from the plug, which could stop ultrasonic output and cause insufficient coagulation.
- While the foot switch is pressed, do not connect or disconnect the transducer and cable.
- Never wipe the inside of the plug or the socket with gauze soaked with saline solution. If saline solution is adhering to the contacts inside the plug and/or the socket, ultrasonic output cannot be activated and/or the generator may be damaged.
- If the inside of the plug or socket is contaminated with blood, or other patient material during a procedure, rinse it with sterile water, then wipe it with a dry piece of gauze.
- If saline solution gets inside the plug or the socket during a procedure, wipe it away with a clean, lint-free cloth.
- When disconnecting the transducer’s plug, make sure that the connection cable is not twisted.
- Do not touch the pins inside the hand piece plug of the transducer. Static discharge from the pins can cause an electric shock.

Electrosurgical treatment

WARNING

- Never operate the electrosurgical unit's spray coagulation mode when high-frequency treatment is performed. As resistance against spray coagulation is not warranted, an insulation defect may occur and leaking current may burn the patient and/or operator. If an excess voltage such as spray coagulation is attempted, an insulation defect would occur.
- The high-frequency voltage rating of this instrument is 1500 Vp (3000 Vp-p) for both cutting and coagulating. If a higher voltage than 1500 Vp is used, an insulation defect may occur and burn the patient and/or operator.
- Only the probe tip should come in contact with tissue. If other parts of the instrument (e.g. insertion section) come in contact with the tissue, they may cause burns due to leakage current.

CAUTION

- Since the temperature of the probe tip increases with continued use of the instrument, make sure that it does not come in contact with non-target tissue. Otherwise, a burn may occur.
- If a laser instrument is also used during the procedure, do not allow the laser to contact the insertion section of the instrument. Laser exposure may damage the instrument's insulation, which may result in current leakage.
- Do not attempt to grasp or fix the A-cord or the hand piece cord using a forceps or a similar tool. If the A-cord's insulation is damaged, it may affect the connection and/or cause current leakage.
- Do not connect the A-cord while either the A-cord or the A-cord setting pin is wet. Otherwise, patient and/or operator burns or an electric shock may occur.
- To prevent patient burns, do not apply high-frequency current if the patient's skin surfaces are touching each other (e.g., the bare arm and side of chest).
- To prevent patient burns, make sure that the patient's clothes are dry.
- To prevent patient burns, make sure that the patient is not in contact with any metal objects (e.g., metal parts of the operating table, etc.).

CAUTION

- To prevent unexpected or accidental output, the electrosurgical unit should be turned OFF until immediately before use.
- Immediately after performing high-frequency output either turn the electrosurgical unit OFF or put the unit into the stand-by mode.
- Do not activate high-frequency output while the probe tip is not in contact with the tissue. Doing so could cause instrument damage or electrical shock by rectification.
- High-frequency output must only be activated when the hand piece plug is connected to the SonoSurg generator. Otherwise, leakage current from the hand piece plug could cause burns.
- Do not touch the pins of the hand piece plug when activating high-frequency output. Leakage current from the pins could cause burns.
- High-frequency output should be performed at the minimum level and for the minimum time possible, as determined by basic experiments conducted before the instrument is used. Do not increase the output too much or too quickly, as this may cause operator and/or patients burns.
- Do not apply high-frequency output while the probe tip is in contact with other metallic parts (e.g. metal trocar tube, hand instrument, clip, etc.). Otherwise, the patient may be burned by current flowing through the metallic parts into non-target tissue.
- Never attempt high-frequency treatment if the plug and socket are not connected. Otherwise, the high-frequency current leakage from the plug's internal contacts may cause operator and/or patient burns.

NOTE

- Simultaneous ultrasonic and high-frequency output cannot be performed. If an attempt is made to activate high frequency output while ultrasonic output is active, the SonoSurg generator will detect it and suspend the ultrasonic output.
- For more details on the electrosurgical unit, refer to its instruction manual.

6.1 Turning the power ON

WARNING

Confirm that the system includes the correct optimal equipment combination for the procedure, and that it has been properly inspected and connected as described in Chapter 3, “Preparation and Inspection of the SonoSurg Irrigation Unit” and Chapter 4, “Preparation, Inspection and Connection of the Handpiece”. Only after confirmation of these conditions, the power switches of the SonoSurg generator (SonoSurg-G2) and the SonoSurg irrigation unit (SonoSurg-IU) should be turned ON.

6.2 Setting the suction pressure

WARNING

- During the procedure, set the suction pressure within the range given below. Settings outside this range may not permit sufficient cooling of the probe, which could cause burns and/or probe damage.
- Always begin with a relatively low suction pressure and increase it gradually as required during use. If a high suction pressure is used from the beginning, tissue may be easily damaged by aspiration or subjected to unexpected dissection, fragmentation, emulsification or aspiration during ultrasonic treatment.

CAUTION

Be sure to use the laparoscopic suction mode during insufflation in laparoscopic surgery. When the normal suction mode is selected, the pressure drop may cause obstruction of view.

NOTE

The effects of ultrasonic treatment on the tissue do not only depend on the ultrasonic output setting but also on the suction pressure setting and the way in which the probe comes in contact with the tissue.

1. While pressing the suction mode switch, select the suction mode appropriate for the procedure to be performed.
   Normal suction mode (indicated by illumination of the normal suction mode lamp.):
   Suction is activated permanently (it only stops during high-speed irrigation.).
   Laparoscopic suction mode (indicated by illumination of the laparoscopic suction mode lamp.).
   Suction is activated only during ultrasonic output and when the suction pedal on the foot switch (MAJ-1102) is pressed.
2. Activate the suction device and set the suction pressure within the following range:
   −8 to −85 kPa

6.3 Setting the output level

WARNING

Always start the ultrasonic output at a relatively low setting and increase it gradually as required during use. If a higher setting is used from the beginning, unexpected problems such as bleeding and perforation may result.

NOTE

When the SonoSurg irrigation unit is turned ON, “Irr” flashes on the irrigation level setting indicator of the unit. In this condition, the ultrasonic output cannot be set and/or activated. Press the flush switch so that “Irr” is displayed continuously.

1. While pressing the flush switch of the irrigation unit, confirm that cooling water is fed to the sheath tip.
2. Set the output level by pressing the ultrasonic output setting switches (see Figure 6.1).

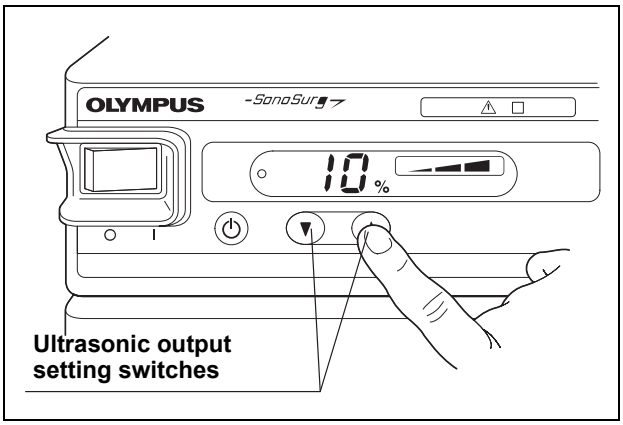


Figure 6.1

6.4 Setting the irrigation level

NOTE

The cooling water quantity is set automatically according to the hand piece being used and the ultrasonic setting level. The quantity cannot be set lower than the automatic setting but can manually be set to a higher value.

The irrigation quantity is set automatically according to the ultrasonic output setting (see Table 6.1). When it is necessary to change the quantity, press the irrigation level setting switches on the SonoSurg irrigation unit (see Figure 6.2).

Ultrasonic (%)	10	15	20	25	30	35	40	45	50	55	60	65	70	75	80	85	90	95	100
Irrigation (%)	10	10	10	10	10	10	10	10	10	10	10	10	10	10	15	25	30	35	40

Table 6.1

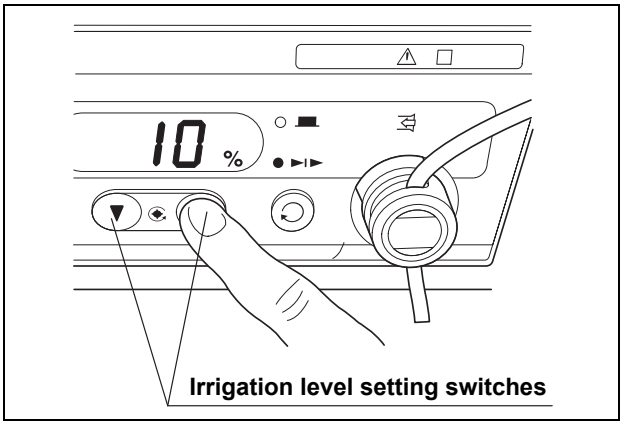


Figure 6.2

6.5 Procedure

WARNING

- Never activate ultrasonic output while the probe is pressed forcefully against tissue, as doing so may result in hazardous events, including bleeding or perforation. In addition, heating of the probe tip and tissue may cause burns and/or equipment damage.
- Do not keep the probe tip in one position for a prolonged period during ultrasonic output. Doing so could cause bleeding or tissue damage.
- Do not activate ultrasonic output in the proximity of organs for which ultrasonic output is contraindicated. Otherwise, ultrasonic output transmitted to organ may damage it.

CAUTION

- During ultrasonic output, do not press the sheath against tissue with excessive force, as doing so may result in burns.
- If the irrigation/suction tube for SonoSurg (MAJ-1099) is damaged or the suction channel becomes narrower or clogged during the procedure, the probe and sheath may not be cooled sufficiently, which could cause burns.

NOTE

- Do not press the probe against tissue with an excessive force during the procedure.
- During ultrasonic treatment, mist or cooling water is produced at the probe tip due to ultrasonic oscillations. Therefore, do not bring an observation device such as a telescope close to the probe tip.
- When the SonoSurg irrigation unit (SonoSurg-IU) and the SonoSurg generator (SonoSurg-G2) are interlocked (when a “HP1” or “HP2” hand piece is detected), the maximum output pedal of the foot switch (MAJ-1102) cannot be used. A warning tone is generated if the maximum output pedal is pressed.
- During ultrasonic treatment, the SonoSurg irrigation unit generates an output tone. The SonoSurg generator does not generate an output tone simultaneously.

1. Advance the probe tip toward the tissue to be treated, and press the ultrasonic variable output pedal to apply ultrasonic output (see Figure 6.3).

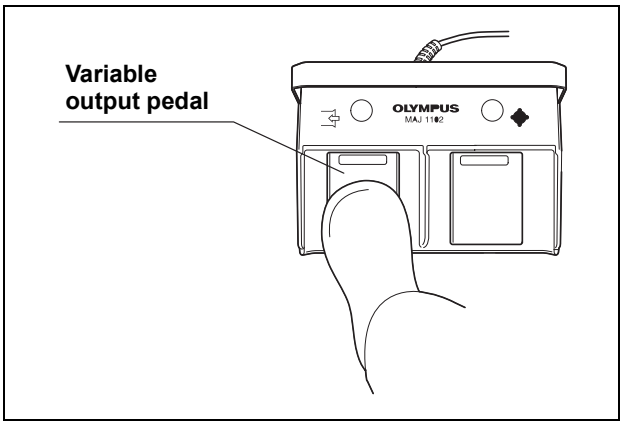


Figure 6.3

2. Touch the probe tip lightly to the tissue and perform ultrasonic treatment.
3. Adjust the ultrasonic output setting, suction pressure and/or cooling water quantity as required.
4. To clean the tissue, advance the probe tip toward the tissue and press the high-irrigation pedal of the foot switch (MAJ-1102) (see Figure 6.4).

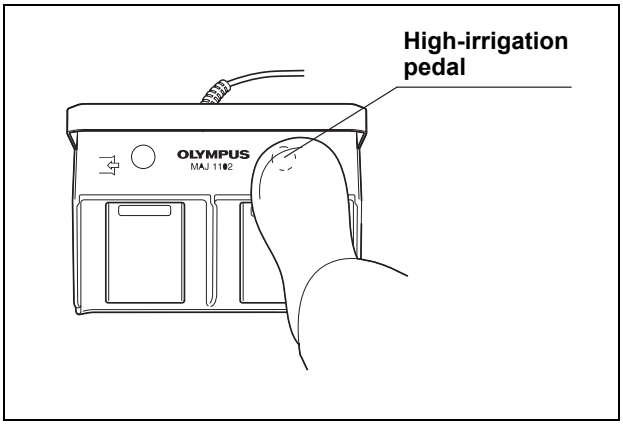


Figure 6.4

5. Irrigation water can also be supplied by pressing the flush switch on the irrigation unit (see Figure 6.5).

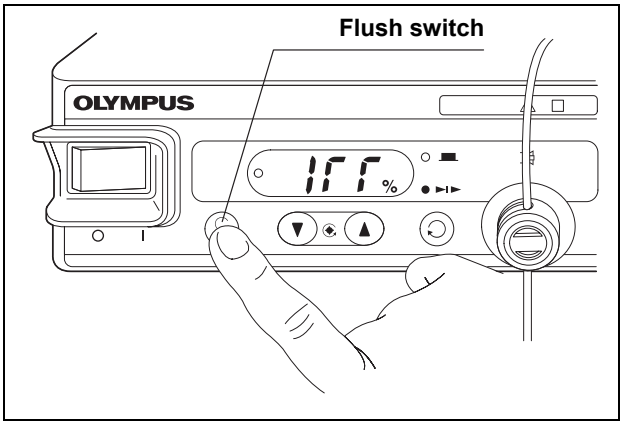


Figure 6.5

6. To perform suction in the laparoscopic suction mode, immerse the probe tip in the liquid to be removed. Press the suction pedal on the foot switch (MAJ-1102) to activate suction (see Figure 6.6).

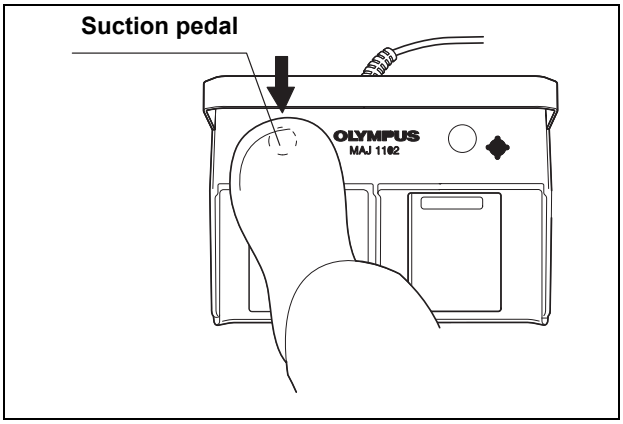


Figure 6.6

7. If the probe and/or the transducer is clogged, remove the sheath, the probe and the irrigation/suction tube from the transducer as described in Section 7.3, “Compatible reprocessing methods and chemical agents”.
Then remove any blockages from the suction channel by inserting the cleaning rod (MAJ-1178) into both ends of the channel.

❍ Replacement of the transducer

1. Firmly hold the plug of the transducer, and simultaneously press the two buttons on the socket of the connection cable (MAJ-1121). Slowly remove the plug from the socket.
2. Place the disconnected transducer on a flat surface that is far away not to disturb the sterile field.
3. Firmly hold the replaced hand piece, and align the red triangles on the plug and socket.
4. Insert the plug into the socket, until it clicks.

6.6 Electrosurgical treatment

CAUTION

Do not perform irrigation while performing electrosurgical treatment. Otherwise, high-frequency cauterization may not be performed normally.

NOTE

When the electrosurgical unit generates high-frequency output, “HF” appears on the ultrasonic output setting indicator of the SonoSurg generator (see Figure 6.7). While the electrosurgical unit is generating the output, ultrasonic output from the SonoSurg generator is inactivated for safety purposes. When performing ultrasonic output, stop the high-frequency output from the electrosurgical unit.

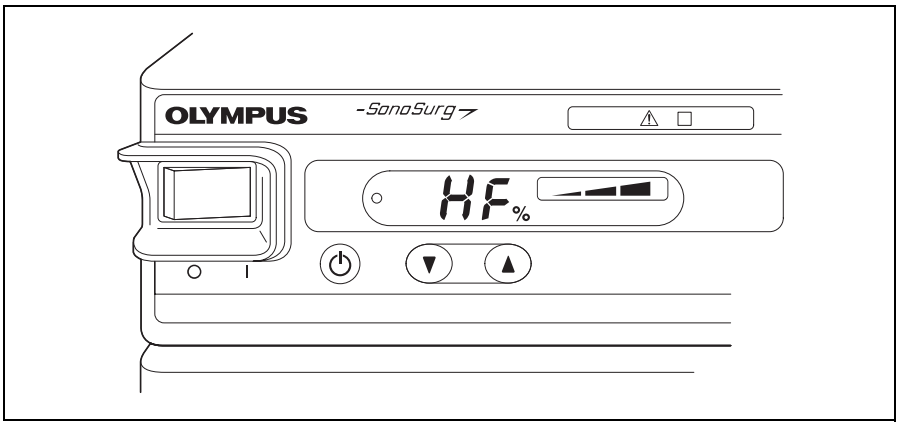


Figure 6.7

Perform output with the foot switch

1. Just before the beginning of the procedure, push the A-cord (A0355, A0358) onto the A-cord mounting pin of the transducer (SonoSurg-T2L-GE/SonoSurg-T2L-GE-C) until it stops.
2. Before turning the electrosurgical unit ON, make sure that the target area is clearly visible in the field of view.
3. Turn the electrosurgical unit ON. Select the cutting mode (pure or blend) using the cut mode select switch, and press the normal coagulation mode switch.
4. Set appropriate cutting and coagulation output levels.
5. While viewing the target area, step on the appropriate pedal of the foot switch to perform cutting and/or coagulation.

Perform output with the hand switch

1. Just before the beginning of the procedure, push the connection receptacle of the hand switch onto the A-cord mounting pin of the transducer (SonoSurg-T2L-GE/SonoSurg-T2L-GE-C) until it stops.
2. Before turning the electrosurgical unit ON, make sure that the target area is clearly visible in the field of view.
3. Turn the electrosurgical unit ON. Prepare and set an appropriate setting as described in the instruction manual of the electrosurgical unit.
4. While viewing the target area, press the HF switch on the GE hand switch to perform coagulation.

6.7 After use

CAUTION

- When extracting this instrument from the trocar tube, take care not to leave mucous membranes or other patient material in the space between the trocar tube and the instrument.
- Do not pull out the trocar tube and the instrument simultaneously. Otherwise, the probe may damage the surrounding tissue, or the instrument itself may be damaged.
- When the SonoSurg generator (SonoSurg-G2) and the SonoSurg irrigation unit (SonoSurg-IU) will not be used for a long period of time after the procedure is completed, disconnect the power cords from the hospital grade wall-mains outlet.

1. Turn OFF the power of the SonoSurg generator and the SonoSurg irrigation unit.
2. Turn OFF each accessory being used with this instrument as described in their instruction manuals.
3. Clean and sterilize this instrument as described in Chapter 7, “Reprocessing and Storage”.
4. When the equipment will not be used for a long period of time after the procedure is completed, disconnect all power cords from the wall-mains outlet.

6.8 Warning indications

Foot switch short-circuit error

If error code “E0.5” is displayed when the irrigation unit is turned ON (see Figure 6.8), it could indicate a foot switch abnormality such as:
The safety circuit was activated when a pedal was pressed, or there is an internal short-circuit. Take appropriate measures as described in Chapter 8, “Troubleshooting”.

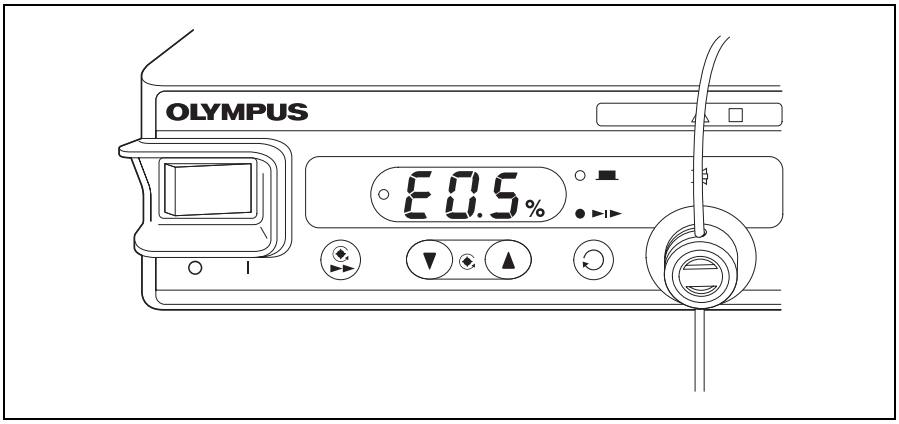


Figure 6.8

Irrigation pump error

If error codes “E0.A” or “E0.C” are displayed during the procedure or when the irrigation unit is turned ON (see Figure 6.9), it is possible that the irrigation pump is overloaded. Take appropriate measures as described in Chapter 8, “Troubleshooting”.

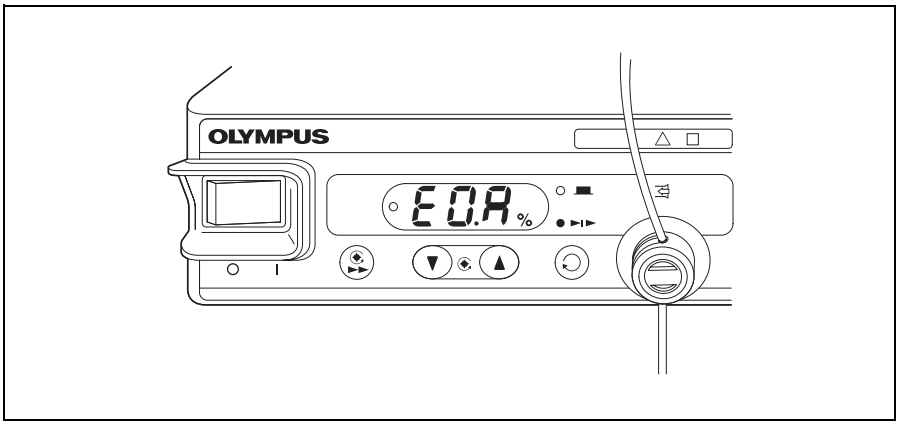


Figure 6.9

Communication error

If the communication warning lamp lights (see Figure 6.10), there may be an improper connection between the communication cable (MAJ-1103) and the generator (SonoSurg-G2) or irrigation unit (SonoSurg-IU). Take appropriate measures as described in Chapter 8, “Troubleshooting”.

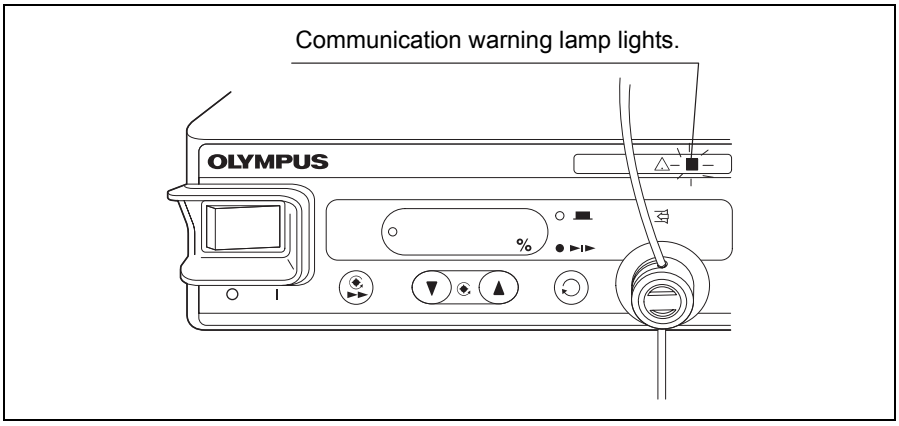


Figure 6.10

Chapter 7 Reprocessing and Storage

7.1 Reprocessing: General policy

- The medical literature reports incidents of patient cross contamination resulting from improper cleaning or sterilization. It is strongly recommended that reprocessing personnel have a thorough understanding of and follow all national and local hospital guidelines and policies.
  A specific individual or individuals in the endoscopy unit should be responsible for reprocessing this equipment. 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
  - the mechanical aspects of this equipment
  - pertinent germicide labeling

7.2 Precautions

WARNING

- Failure to properly clean and sterilize this instrument after each examination can compromise patient safety. To minimize the risk of transmitting diseases from one patient to another, after each examination the equipment must undergo thorough manual and ultrasonic cleaning followed by sterilization.
- Patient debris and reprocessing chemicals are hazardous. Wear personal protective equipment to guard against dangerous chemicals and infectious material. During cleaning and sterilization, wear appropriate personal protective equipment, such as eye wear, face mask, moisture-resistant clothing, and chemical-resistant gloves that fit properly and are long enough so that your skin is not exposed. Always remove contaminated protective clothing before leaving the reprocessing area.
- Thoroughly rinse off the detergent solution.
- If this instrument is not cleaned meticulously, effective sterilization cannot be obtained. Clean the instrument thoroughly before sterilization to remove any microorganisms or organic material that could reduce sterilization efficiency.
- For effective cleaning and sterilization, disassemble this instrument into its components (the transducer (SonoSurg-T2L-GE/SonoSurg-T2L-GE-C), the connection cable (MAJ-1121), the sheath and the probe) before cleaning. If the instrument is not disassembled, it cannot be cleaned or sterilized effectively.
- To ensure a maximum cleaning effect, be sure to perform both manual and ultrasonic cleaning prior to sterilization.
- With the cleaning and sterilization methods stated in this instruction manual, prions, which are considered to be the pathogenic substance of the Creutzfeldt-Jakob disease (CJD) cannot be destroyed or inactivated. When using this instrument on a patient with CJD or variant Creutzfeldt-Jakob disease (vCJD), be sure to use this product for such patient only and/or immediately dispose of this product after use in an appropriate manner. For methods to handle CJD, please follow the respective guidelines in your country.

WARNING

- This instrument is not durable, or does not have sufficient durability against the respective methods stated in the guidelines of each country for destroying or inactivating prions. For information on the durability against each method, please contact Olympus. If cleaning and sterilization methods not stated in this instruction manual are performed, Olympus cannot guarantee the effectiveness, safety and durability of this instrument. Make sure to confirm that there is no abnormality before use, and use under responsibility of a physician. Do not use if any abnormality is found.
- Confirm that there is no damage to or dirt in/on the shaft or the head of the cleaning brush (MH-140, MSG-BW). If an abnormality is suspected after inspection, use a new brush instead. Use of an abnormal or damaged brush will make it difficult to effectively reprocess the instrument.

CAUTION

- Clean and sterilize this instrument immediately after each use. If reprocessing is delayed, residual organic debris will solidify and it will be difficult to effectively reprocess the instrument.
- If the cleaning and sterilization procedures are not performed as described in Chapter 7, equipment damage may occur.

7.3 Compatible reprocessing methods and chemical agents

Compatibility summary

The following components of this instrument are compatible with several methods of reprocessing:

SonoSurg transducer (SonoSurg-T2L-GE/SonoSurg-T2L-GE-C)

SonoSurg connection cable (MAJ-1121)

SonoSurg GE hand switch (MAJ-1100)

Probe (MH-112/MH-113/MH-125)

Sheath (T3310/T3320/T3330)

SonoSurg GE sheath attachment (T3300)

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

Cleaning	Sterilization
Ultrasonic cleaning	Autoclave

Table 7.1

Detergent solution

Use a medical-grade, low-foaming, neutral pH detergent with no abraside or enzymatic detergent and follow the manufacturer's dilution and temperature recommendations. Contact Olympus for the names of specific brands that have been tested for compatibility with this instrument. Do not reuse detergent solutions.

WARNING

Excessive detergent foaming can prevent fluid from adequately contacting internal lumens (e.g., the inside of the insertion section).

Steam sterilization (autoclaving)

Autoclave the instruments within the parameters given in Table 7.2 below. When autoclaving, follow the hospital's protocol and the sterilization equipment manufacturer's instructions. Prior to autoclaving, meticulous manual cleaning followed by at least 5 minutes of ultrasonic cleaning at 38 – 47 kHz is required.

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

- Employ the full autoclaving cycle indicated in Table 7.2, including the vacuum-drying cycle after autoclaving. Without the vacuum-drying cycle, the instrument may malfunction or become damaged.
- Do not autoclave at a temperature above 134°C. The instruments may malfunction if it is exposed to a temperature above 134°C.
- Exceeding the recommended parameters may cause equipment damage.

Autoclaving cycle	Temperature	Exposure time
Pre-vacuum	–	–
Autoclave	132 – 134°C (270 – 274°F)	5 minutes
Vacuum-drying	Lower than 134°C	–

Table 7.2

Attaching and detaching the water-proof cap

❍ Attaching

CAUTION

- Before cleaning the transducer (SonoSurg-T2L-GE/SonoSurg-T2L-GE-C) or the connection cable (MAJ-1121), be sure to attach the waterproof cap to the hand piece plug. If the waterproof cap is not attached, water will enter the hand piece plug, which could result in equipment damage.
- Before attaching the waterproof cap to the hand piece plug, confirm that there are no scratches, foreign objects or liquids on the cap's internal surfaces.

1. Remove the hand piece plug from the SonoSurg generator (SonoSurg-G2) as described in Section 3.5, “Connection to the SonoSurg generator (SonoSurg-G2)”.
2. Attach the waterproof cap to the hand piece plug as shown in Figure 7.1. Make sure that the hand piece plug is inserted securely.

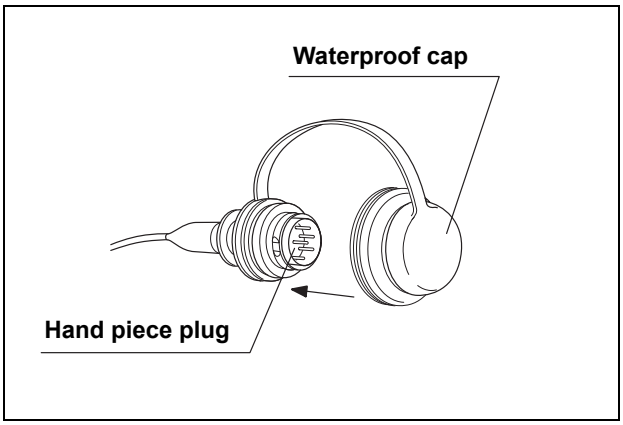


Figure 7.1

❍ Detaching

CAUTION

Do not pull on the hand piece cord in order to unplug it from the generator or to detach the waterproof cap. Doing so may damage the cord or the wires inside of it.

Hold the hand piece plug and remove the waterproof cap.

Disassembly

❍ Detaching the irrigation/suction tube

WARNING

- The irrigation/suction tube for SonoSurg (MAJ-1099) is a disposable product that must not be reused. Doing so may result in infection, tissue inflammation and/or equipment damage.
- After using the tube, dispose of it in accordance with hospital and local guidelines. Otherwise, infection may result.

CAUTION

- When disconnecting the irrigation tube from the irrigation fitting or the suction tube from the suction fitting, be always sure to pull the tube straight. Pulling the tube out in an oblique direction or with excessive force may damage the fitting.
- When disconnecting the irrigation and suction tubes from the transducer, do not allow cooling water or suctioned fluid to be discharged. These fluids can pose an infection control risk.
- When detaching the hand piece cord from the cord clip, take care not to bend the hand piece cord or detach it with force, as doing so may damage the cord.

1. Detach the hand piece cord from the cord holder of the tube (see Figure 7.2).

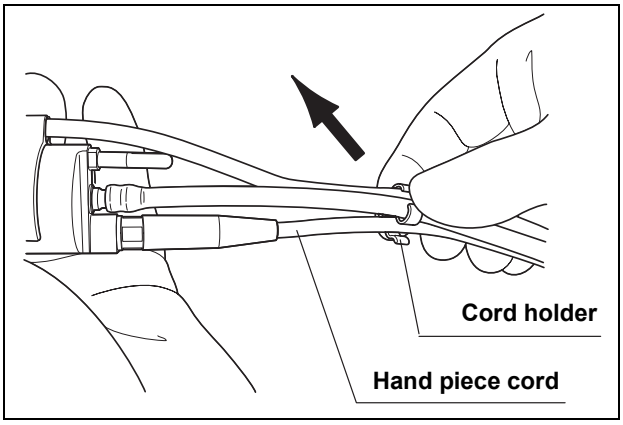


Figure 7.2

2. Disconnect the irrigation tube from the irrigation fitting of the sheath (see Figure 7.3).

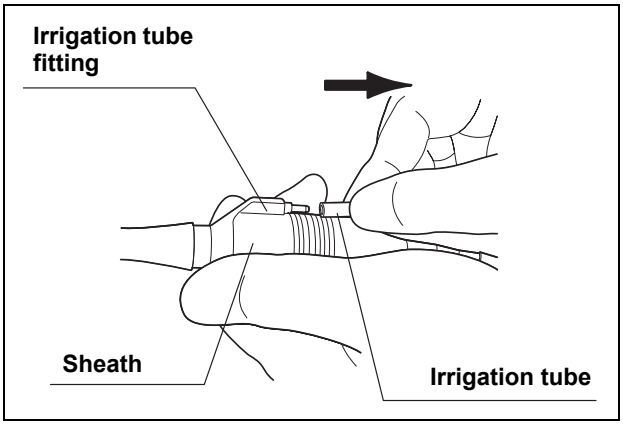


Figure 7.3

3. Detach the tube holder from the transducer (see Figure 7.4).

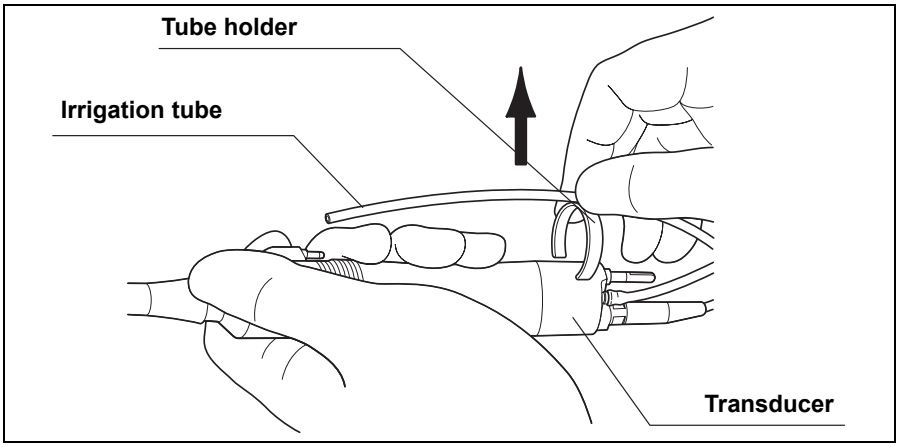


Figure 7.4

4. Disconnect the suction tube from the suction fitting of the sheath (see Figure 7.5).

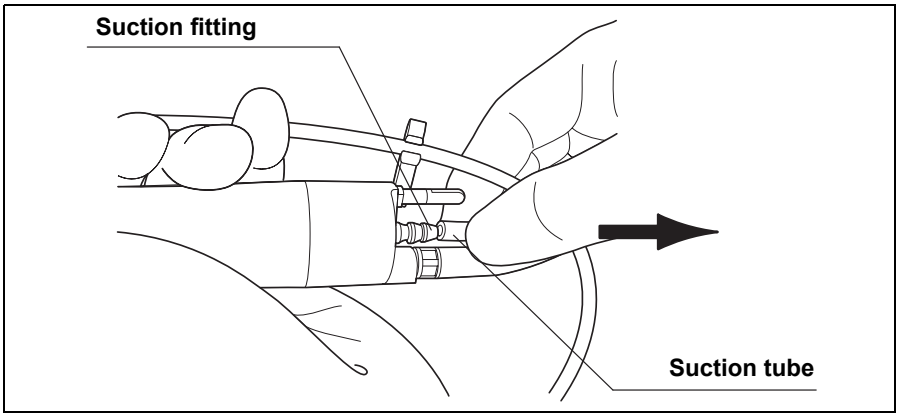


Figure 7.5

5. Detach the suction tube from the pinch valve (see Figure 7.6).

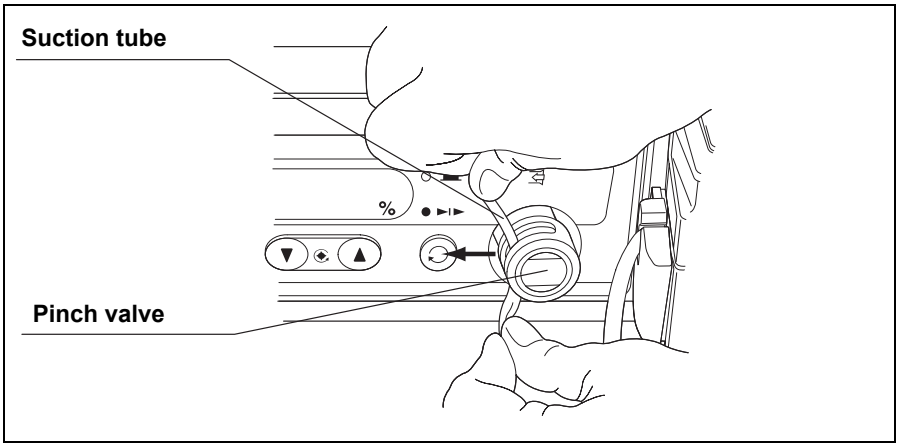


Figure 7.6

6. Detach the suction bottle cap of the irrigation/suction tube from the "PATIENT" fitting of the suction bottle (see Figure 7.7).

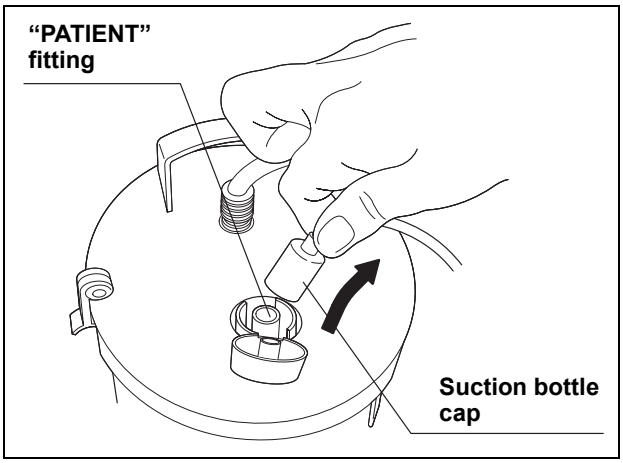


Figure 7.7

7. Remove the needle of the irrigation/suction tube from the saline solution bag (see Figure 7.8).

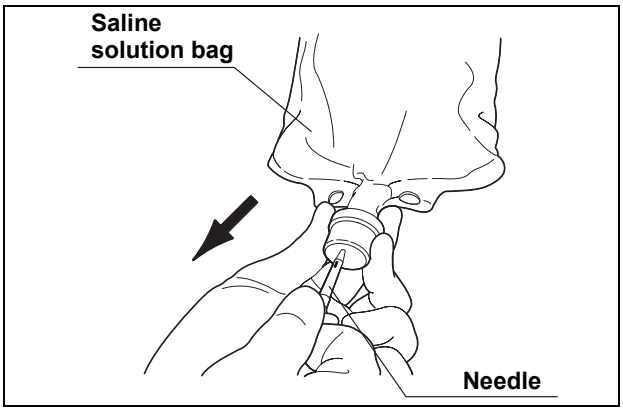


Figure 7.8

8. Rotate the pump head cover upward to open it (see Figure 7.9).

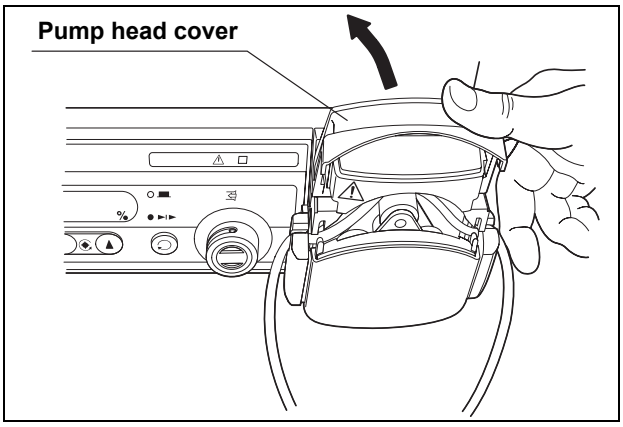


Figure 7.9

9. Detach the irrigation tube of the irrigation/suction tube from the roller (see Figure 7.10).

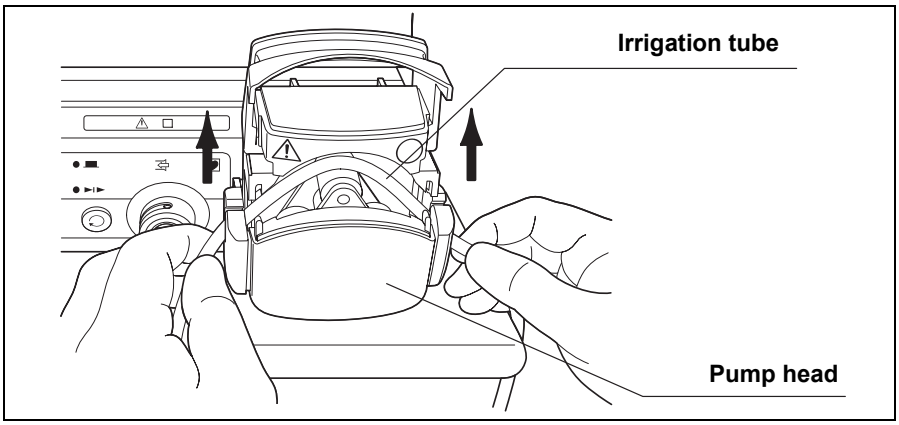


Figure 7.10

10. Close the pump head cover (see Figure 7.11).

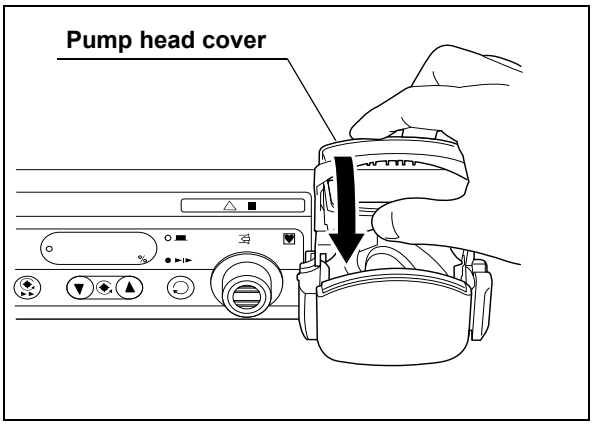


Figure 7.11

11. Dispose of the irrigation/suction tube in an appropriate manner.

❍ Disassembly of the transducer, the probe and sheath

CAUTION

- When detaching the sheath from the transducer (SonoSurg-T2L-GE/SonoSurg-T2L-GE-C), be careful not to come in contact with residual liquids inside the sheath. These liquids may pose an infection control risk.
- When detaching the sheath from the transducer, be careful not to apply excessive force to the irrigation fitting. Otherwise, the fitting may be damaged.

CAUTION

- Always pull the sheath straight out when disconnecting it from the transducer. Pulling the sheath in an oblique direction may damage the equipment.
- When detaching the probe from the transducer, always use the torque wrench (MAJ-1117). Otherwise, the probe and/or the transducer could be damaged.
- When detaching the probe from the transducer, do not hold the probe or bring it in contact with other objects. Otherwise, the probe and/or the transducer may be damaged.

1. Press both release buttons on the socket and remove the transducer gently from the socket of the connection cable.
2. While holding both the sheath and transducer, pull the sheath out from the transducer (see Figure 7.12).

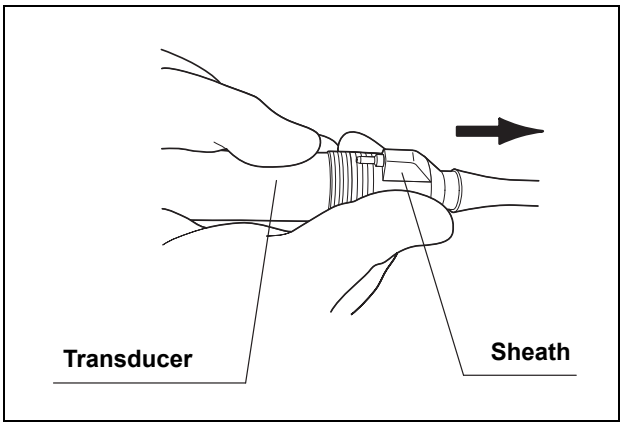


Figure 7.12

3. While holding the sheath and the sheath attachment, remove the attachment by turning it counterclockwise (see Figure 7.13).

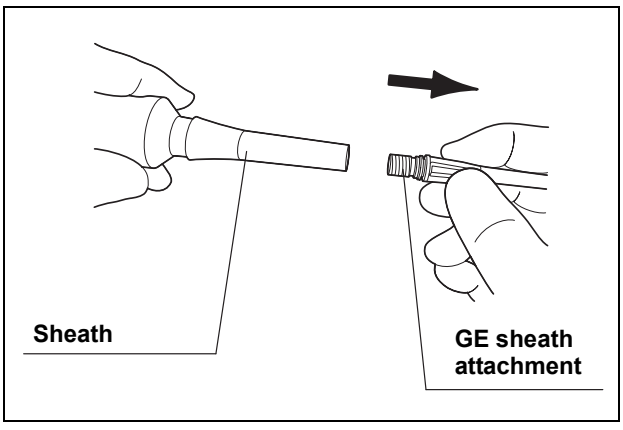


Figure 7.13

4. Loosen the screw section by attaching the torque wrench (marked “This side up”) to the notch of the probe and turning it counterclockwise. Then detach the probe from the transducer (SonoSurg-T2L-GE/SonoSurg-T2L-GE-C) manually (see Figure 7.14).

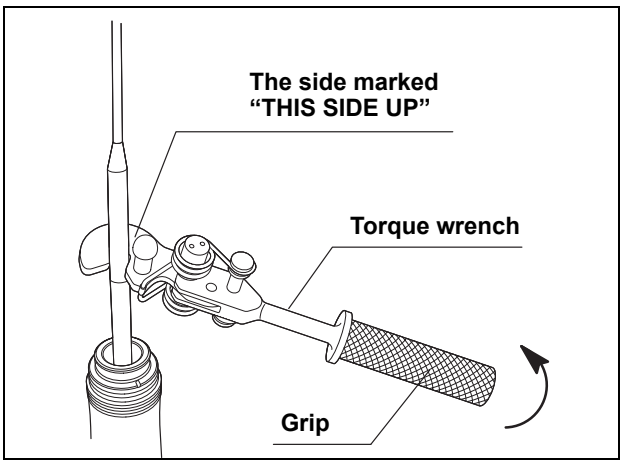


Figure 7.14

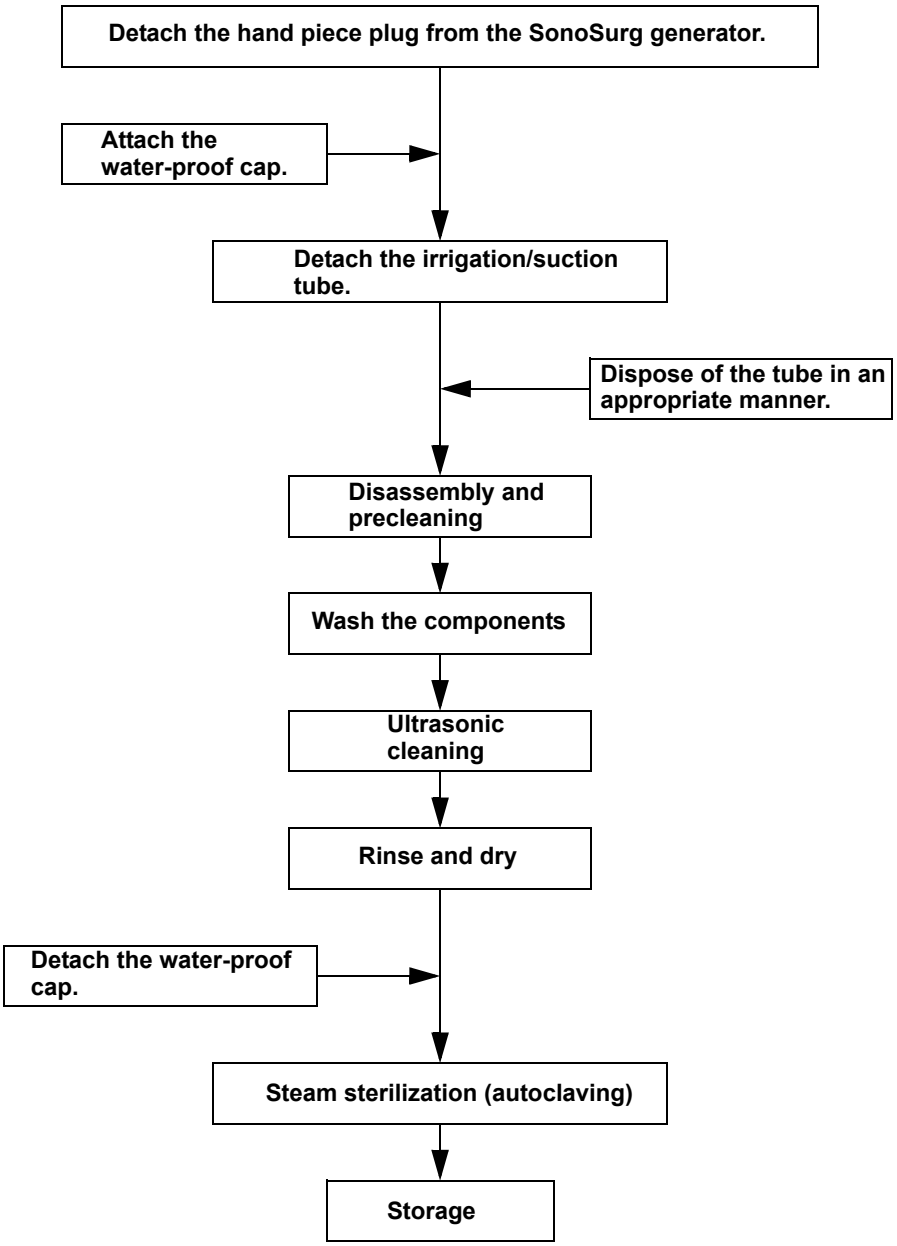
7.4 Cleaning and sterilization procedures

Equipment needed

Prepare the following equipment and the wear appropriate personal protective equipment.

- Personal protective equipment
- Detergent solution
- Clean water
- Sink (Place a mat in the sink), or cleaning basin (approximately 40 cm by 40 cm (16” by 16”), and 15 cm (6”) height)
- Clean, lint-free cloths
- Chemical-resistant gloves
- Soft-bristled brush
- Syringe (more than 20 mL)
- Cleaning brush (MH-140)
- Cleaning brush (NSG-BW)
- Cleaning rod (MAJ-1178)
- Brush (MH-507)

Cleaning and sterilizing procedure



Disassembly and precleaning

Completely disassemble this instrument into its components (the transducer, the connection cable, the probe and the sheath) immediately after use, rinse them in water, then immerse them in detergent solution. Use a sufficiently large basin so that all components may be fully immersed.

Wash the components

WARNING

- Be sure to wash the components thoroughly while they are immersed in the detergent solution. Otherwise, full cleaning efficiency may not be obtained.
- If the probe is contaminated by carbonized tissue, use a piece of moistened, soft gauze to remove the tissue. Never attempt to scrape it with a sharp object such as a scalpel. Doing so can scratch or break the tube.

CAUTION

- Since this instrument is composed of precision parts, take care not to bend or twist it excessively while cleaning it, and do not drop or place objects on top of it.
- When cleaning, avoid damaging the seals.
- When cleaning, take care that the water-proof cap does not come off the hand piece plug. Equipment damage can result if water penetrates the hand piece plug.
- Always use a cleaning brush such as the MH-507 to clean the insides of the plug and the socket.
- Do not attempt to clean the contacts inside the plug or the socket with a sharp tool such as the tip of a pair of tweezers. Otherwise, the contacts may become deformed or damaged, and ultrasonic output may be impaired.
- When cleaning the inside of the plug or the socket, do not try to push or rub the contacts with the metallic tip of the brush. Otherwise, the contacts may become deformed or damaged, and ultrasonic output may be impaired.

1. Fill a basin with water and low-foaming detergent solution at the temperature and concentration recommended by the manufacturer. Use a basin which is large enough so that the components of the instrument may be completely immersed.
2. Immerse all components in the detergent solution. Then remove any debris adhering to components using soft gauze and a soft-bristled brush while both are immersed in the detergent solution.
3. While immersed in detergent solution, insert the cleaning brush (NSG-BW) into the tip section of the probe (MH-112/MH-113/MH-125). Pull the brush out of the channel and remove debris from the brush. Perform this procedure eight (8) times. When cleaning the MH-125 probe, after brushing the tip, insert the brush MH-140 into the proximal opening of the suction channel. Pull the brush out of the channel and remove debris from the brush. Perform this procedure eight (8) times.
   If necessary, insert and withdraw the cleaning rod (MAJ-1178) to remove additional residues from inside the channel.
4. While immersed in detergent solution, insert the cleaning brush (MH-140) into the suction channel of the sheath (T3310/T3320/T3330). Withdraw the brush from the channel and remove debris from the brush. Perform this procedure eight (8) times.
5. While immersed in detergent solution, insert the cleaning brush (MH-140) into the suction channel of the transducer (SonoSurg-T2L-GE/SonoSurg-T2L-GE-C). Pull the brush out of the channel and remove debris from the brush. Perform this procedure eight (8) times.
6. Connect a 20 ml syringe filled with detergent solution to the sheath's irrigation fitting and flush the solution into the fitting. Perform this procedure at least six (6) times to flush at least 120 ml of detergent solution.
7. Gently clean the gaps inside the plug of the transducer (SonoSurg-T2L-GE-C) using a cleaning brush such as the MH-507. Do not press against or rub the contacts with the metallic tip of the brush. Clean inside the socket of the connection cable (MAJ-1121) in the same manner.

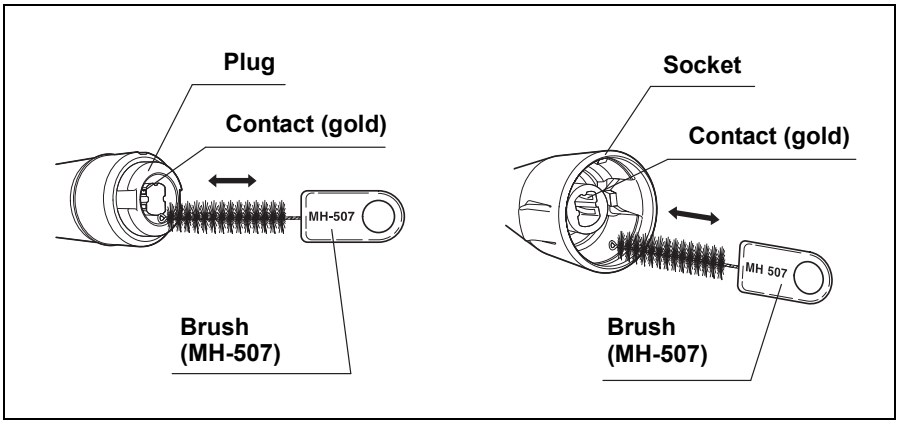


Figure 7.15

Ultrasonic cleaning

Use a medical-grade ultrasonic cleaner with a frequency range of 38 – 47 kHz, and with a sufficient size and depth to allow complete immersion of all components of the instrument. Contact Olympus for information on compatible ultrasonic cleaners.

1. Immerse all the components in the ultrasonic cleaner.
2. Clean the components for at least 5 minutes. For details on the operation of the ultrasonic cleaner, refer to its instruction manual.
3. Remove the components from the ultrasonic cleaner.

Rinse and dry

CAUTION

After ultrasonic cleaning, rinse and dry the components thoroughly. Water can leave spots on and/or cause corrosion of the equipment. Residual moisture also inhibits sterilization.

1. Rinse the components under clean running tap water.
2. Confirm that no debris is left on the surfaces of the components.
3. Wipe and dry the components with a piece of clean, dry gauze or lint-free cloth.

Steam sterilization (autoclaving)

WARNING

The results of sterilization depend on various factors such as how the sterilized instrument was packed or the positioning, method of placing and loading of the instrument in the sterilization device. Please verify the sterilization effects by using biological or chemical indicators. Also follow the guidelines for sterilization issued by medical administrative authorities, public organizations or the infection management sections at each medical facility, as well as the instruction manual of the sterilization device.

CAUTION

- After sterilizing, do not touch a plug contact, socket contact or hand piece plug pin. Static electricity accumulated during autoclaving may cause an electric shock.
- After sterilizing, allow the instrument to cool down gradually to room temperature. Sudden changes in temperature may damage the components.

1. Before sterilization, the parts and equipment must be thoroughly cleaned and dried. Residual moisture inhibits sterilization.
2. Seal the individual components in packages appropriate for steam sterilization according to your hospital's protocol.
3. Steam sterilize the instrument according to the parameters given in "Steam sterilization (autoclaving)" on page 116, and the sterilizer manufacturer's instructions.
4. Following steam sterilization, allow all components to gradually cool down to room temperature. Sudden changes in temperature may damage the components.

7.5 Care

The instructions given below apply to the following products:

SonoSurg irrigation unit (SonoSurg-IU)

Foot switch for SonoSurg irrigation unit (MAJ-1102)

SonoSurg communication cable (MAJ-1103)

The endurance of the following products has been confirmed assuming that they are maintained as described in this section.

CAUTION

- When using alcohol, always use 70% ethyl or isopropyl alcohol as directed on the container labels. Alcohol should be stored in a hermetically-sealed container. Alcohol in an open container is a fire hazard, and will lose its efficacy due to evaporation.
- Never allow fluids to come in contact with any connectors or contact points. Fluids may impair proper contact and can cause equipment damage.
- Do not autoclave or gas sterilize the SonoSurg irrigation unit, the foot switch and the SonoSurg communication cable. These methods will cause severe equipment damage.

After each use, perform the following cleaning procedure immediately. If cleaning is delayed, debris encrustation may become a source of infection. Encrustation may also result in device malfunction.
For maintenance and storage of other optional items than those described below, refer to the respective instruction manuals.

1. Turn the power OFF and disconnect the power cord of the irrigation unit from the wall-mains outlet.
2. To remove dust, dirt and other non-patient debris, wipe the product surface with a soft and lint-free cloth moistened with 70% ethyl or isopropyl alcohol. Clean away dust accumulated around air vents using a vacuum cleaner or similar appliance.
3. If the products are soiled with blood or other potentially infectious materials, first wipe off all gross debris using neutral detergent, and then wipe its surface using lint-free cloth moistened with a surface disinfectant.
4. Make sure that each of these products is completely dry before use and storage.

7.6 Storage

CAUTION

- Do not store this instrument in the shipping box. Doing so may present an infection-control risk.
- During storage, make sure that the hand piece cord is not subjected to excessive bending, straining or twisting. This could damage the cord and/or the wires inside the cord.
- Do not store the instrument in a place that is exposed to X-rays, radioactivity, strong electromagnetic waves (e.g., in the vicinity of a microwave therapeutic device, short-wave therapeutic device, MRI, wireless set, etc.). Otherwise, the instrument may be damaged and/or an infection-control risk may be created.
- Do not subject this instrument to strong impacts during storage. Otherwise, the instrument could be damaged.

Store this instrument in a clean, dry, well-ventilated environment.

7.7 Disposal

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

Chapter 8 Troubleshooting

If the instrument is visibly damaged, does not function as expected or is found to have other irregularities during the inspection described in Chapter 3, “Preparation and Inspection of the SonoSurg Irrigation Unit” and Chapter 4, “Preparation, Inspection and Connection of the Handpiece”, do not use the instrument, contact Olympus.
Problems that appear to be malfunctions may be correctable by referring to Section 8.1, “Troubleshooting guide”. Should you fail to correct the problem even after taking the described remedial action, stop using the instrument and send it to Olympus for repair.

Olympus will repair the transducer (SonoSurg-T2L-GE/SonoSurg-T2L-GE-C) and SonoSurg irrigation unit (SonoSurg-IU). Olympus does not repair the following components:

- Foot switch for the SonoSurg irrigation unit (MAJ-1102)
- SonoSurg communication cable (MAJ-1103)
- SonoSurg irrigation/suction tube (MAJ-1099)
- SonoSurg GE hand switch (MAJ-1100)
- Probe (straight) (MH-112)
- Probe (15° angled) (MH-113)
- Probe (tapered, long) (MH-125)
- SonoSurg GE straight sheath (T3310)
- SonoSurg GE sheath (15° angled) (T3320)
- SonoSurg GE tapered sheath (T3330)
- SonoSurg GE sheath attachment (T3300)
- Cleaning brush (MH-140)
- Cleaning brush (NSG-BW)
- Brush (MH-507)
- 6 mm torque wrench (MAJ-1117)

If these parts become damaged, contact Olympus to purchase a replacement.

WARNING

- If the setting indicator of the SonoSurg Generator or SonoSurg Irrigation Unit changes and power can not be supplied, turn the SonoSurg Generator or SonoSurg Irrigation Unit off and then turn it on again. Confirm that the indicator returns to the normal state. If the setting indicator does not return to the normal state as described in Chapter 3, “Preparation and Inspection of the SonoSurg Irrigation Unit”, stop using the device at once, as it may cause patient injury.
- Never use the instrument on a patient if an irregularity is observed.

8.1 Troubleshooting guide

Irregularity description	Possible cause	Solution
The SonoSurg generator is not supplied with power	The power cord is not securely plugged into a hospital grade 3-pin receptacle (wall mains outlet).	Securely connect the power cord to the receptacle.
	The power cord is not securely plugged into the generator.	Securely connect the power cord to the generator.
	The SonoSurg generator is not turned ON.	Turn the SonoSurg generator ON.
	The fuses have blown.	Contact Olympus.
The SonoSurg irrigation unit is not supplied with power	The power cord is not securely plugged into a hospital grade 3-pin receptacle (wall mains outlet).	Securely connect the power cord into the receptacle.
	The power cord is not securely plugged into the unit.	Securely connect the power cord into the unit.
	The SonoSurg irrigation unit is not turned ON.	Turn the SonoSurg irrigation unit ON.
	The fuses have blown.	Contact Olympus.

Irregularity description	Possible cause	Solution
After turning SonoSurg generator ON, the ultrasonic output level cannot be set	The transducer is not connected securely.	Reconnect the generator, transducer and connection cable securely.
	The SonoSurg generator is in stand-by mode (The stand-by indication lamp is lit).	Press the stand-by switch.
	The communication cable is not connected securely.	Securely connect the cable to the system connector B of both the generator and the irrigation unit.
	Preparation of the irrigation has not been made yet.	Prepare the irrigation as described in Section 5.3, “Inspection of cooling water” then, press the flush switch of the irrigation unit, and confirm that water flows from the sheath tip.
	A foreign substance may have hardened on the contacts inside of the transducer’s plug or the connection cable’s socket.	Clean the contacts inside of the transducer’s plug using a sterile cleaning brush such as the MH-507. Clean the contacts inside the socket in the same manner. Then connect and disconnect the socket and the plug about 10 times.

Irregularity description	Possible cause	Solution
Ultrasonic output cannot be activated (The ultrasonic output warning lamp is lit.).	The probe is damaged (e.g. cracks and/or breaks).	Replace the damaged probe with a spare one.
	The probe is not properly connected to the transducer (The connection is loose.).	Reconnect the probe by tightening with the wrench.
	Excessive force is applied to the probe tip.	Reduce force applied to the probe.
	The transducer is not working properly.	Replace the damaged transducer with a spare one.
	Ultrasonic output has been activated while high-frequency equipment (e.g. electrosurgical unit) is active.	Stop the output of the high-frequency equipment.
	A foreign substance may have hardened on contacts inside of the transducer's plug or the connection cable's socket.	Clean the contacts inside of the transducer's plug using a sterile cleaning brush such as the MH-507. Clean the contacts inside of the socket in the same manner. Then connect and disconnect the socket and the plug about 10 times.
	The plug of the foot switch is not properly connected to the irrigation unit.	Reconnect the plug properly.
	The transducer is damaged.	Replace the damaged transducer with a new one.
	The communication cable is not connected securely.	Securely connect the cable to the system connector B of both the generator and the irrigation unit.

Irregularity description	Possible cause	Solution
Ultrasonic output cannot be activated (“HP” is displayed on the ultrasonic output setting indicator.).	The hand piece plug is not properly connected to the generator.	Reconnect the plug properly.
	Ultrasonic output has been activated while high-frequency equipment (e.g. electrosurgical unit) is active.	Stop the output of the high-frequency equipment.
	A foreign substance or liquid is on the contacts inside the plug or the socket.	Clean the contacts inside of the transducer’s plug or socket using a sterile cleaning brush such as MH-507. Then connect and disconnect the socket and the plug about 10 times.
	The plug and the socket are not connected securely.	Reconnect the plug properly.
	Internal wires of the connection cable may be damaged.	Replace the damaged cable with a spare one.
Ultrasonic output cannot be activated (“HF” is displayed on the ultrasonic output setting indicator.).	Ultrasonic output has been activated while high-frequency equipment (e.g. electrosurgical unit) is activate.	Stop the output of the high-frequency equipment.
Ultrasonic output cannot be activated (“E0.2” is displayed on the ultrasonic output setting indicator.).	The safety mechanism is activated because of overheating due to excessive continuous activation.	Keep the SonoSurg generator ON, and wait several minutes for it to cool down.
Ultrasonic output cannot be activated (“E0.4” is displayed on the ultrasonic output setting indicator.).	The SonoSurg generator is connected to a receptacle which does not meet the required specifications.	Connect the SonoSurg generator to a hospital grade 3-pin wall-mains outlet that meets the power requirements indicated on the generator’s electrical rating plate.

Irregularity description	Possible cause	Solution
Ultrasonic output cannot be activated (“E0.5” is displayed on the ultrasonic output setting indicator.).	The SonoSurg generator has been turned ON while a pedal of the foot switch is pressed.	Release the pedal and turn the SonoSurg generator ON again.
	The foot switch is not working properly.	Replace it with a spare one.
Ultrasonic output cannot be activated (“E0.7” is displayed on the ultrasonic output setting indicator.).	The SonoSurg generator is not working properly.	Contact Olympus.
An alarm sounds when the power of the irrigation unit ON (“E0.5” is displayed on the irrigation level setting indicator.).	The SonoSurg generator has been turned ON while a pedal of the foot switch is pressed.	Release the pedal and turn the SonoSurg irrigation unit ON again.
	The foot switch is not working properly.	Replace it with a spare one.
An alarm sounds when the power of the irrigation unit is turned ON (“E0.A” or “E0.C” is displayed on the irrigation level setting indicator.).	The irrigation pump may be overloaded.	Check for proper attachment of the tubing. Reattach correctly if necessary.
Ultrasonic output cannot be activated (The communication warning lamp on the irrigation unit is lit.).	The communication cable has not been connected securely.	Securely connect the cable to system connector B of both the generator and the irrigation unit.
Ultrasonic output cannot be activated (“Irr” is displayed on the irrigation level setting indicator.).	Preparation of the irrigation is not made yet.	Press the flush switch of the irrigation unit, and confirm that water is discharged from the sheath tip.
Ultrasonic output cannot be activated (“OPE” is displayed on the irrigation level setting indicator.).	The pump head cover is not closed securely.	Close the cover securely.

Irregularity description	Possible cause	Solution
Suction is not possible.	Aspirated material is clogging the probe or the transducer.	Remove the material from the probe or the transducer as described in Section 6.5, “Procedure”.
	Aspirated material is clogging the suction tube.	Disconnect the suction tube and attempt to remove the clog. If the clog cannot be removed, replace it with a new one.
	The suction tube is bent, crushed or broken.	Eliminate the bending or crushing. If suction is still impossible, replace the tube with a spare one. If the tube is broken, simply replace it with a new one.

8.2 When the ultrasonic output warning lamp is lit

WARNING

If the ultrasonic output stops during the procedure, causing the ultrasonic output warning lamp of the SonoSurg generator to light up and a warning tone to sound, immediately remove the insertion section of the instrument from the patient. Then inspect the probe as follows. Otherwise the probe may be damaged, which should cause the probe tip to fall off.

Inspection and solution

Remove the sheath and probe from the transducer as described in “Disassembly of the transducer, the probe and sheath” on page 108. Perform the following steps to determine whether or not the equipment should still be used:

Inspection and solution

1. Confirm that the probe is free from cracks. If cracks are observed, stop using the probe immediately and replace it with a new one.
2. If the probe is free from cracks, extract the probe from the sheath as described in “Disassembly of the transducer, the probe and sheath” on page 108.
3. If body fluids or tissue have become attached to the probe tip, remove them using a clean, lint-free cloth or gauze, or by immersing the probe tip in saline solution.
4. If the suction channel is clogged, insert and withdraw the cleaning rod (MAJ-1178) and the cleaning brush (NSG-BW, MH-140) into/from the channel.
5. Reassemble the probe and the transducer as described in Section 4.2, “Inspection and connection of the transducer, probe and sheath”.
6. Reassemble the sheath and the transducer with the probe as described in Section 4.2, “Inspection and connection of the transducer, probe and sheath”.

7. Confirm that cooling water flow has been prepared and inspected as described in Section 5.3, “Inspection of cooling water”. Then, step on the ultrasonic variable output pedal of the foot switch (MAJ-1102) as described in Section 5.4, “Inspection of ultrasonic output”, and confirm that the ultrasonic output warning lamp is not illuminated.

If the ultrasonic output warning lamp is still lit, replace the probe with a new one. If the ultrasonic output warning lamp is still lit after the probe has been replaced, the generator and/or the transducer may not be working properly. In this case, immediately stop using the system, and contact Olympus.

8.3 Returning the equipment for repair

CAUTION

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

When returning the equipment for repair, include a description of its 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.

Before returning the instrument, sterilize it.

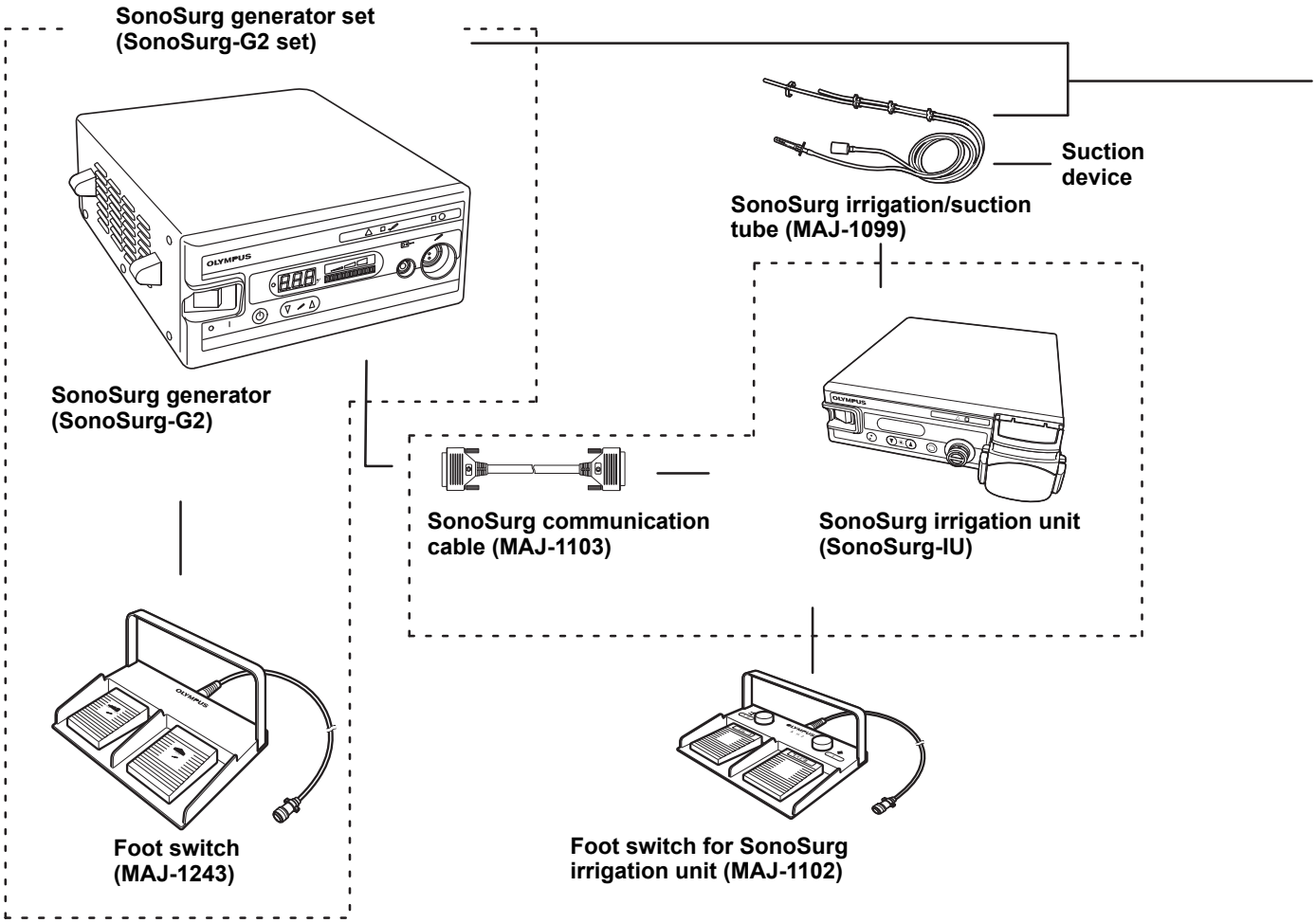
Appendix

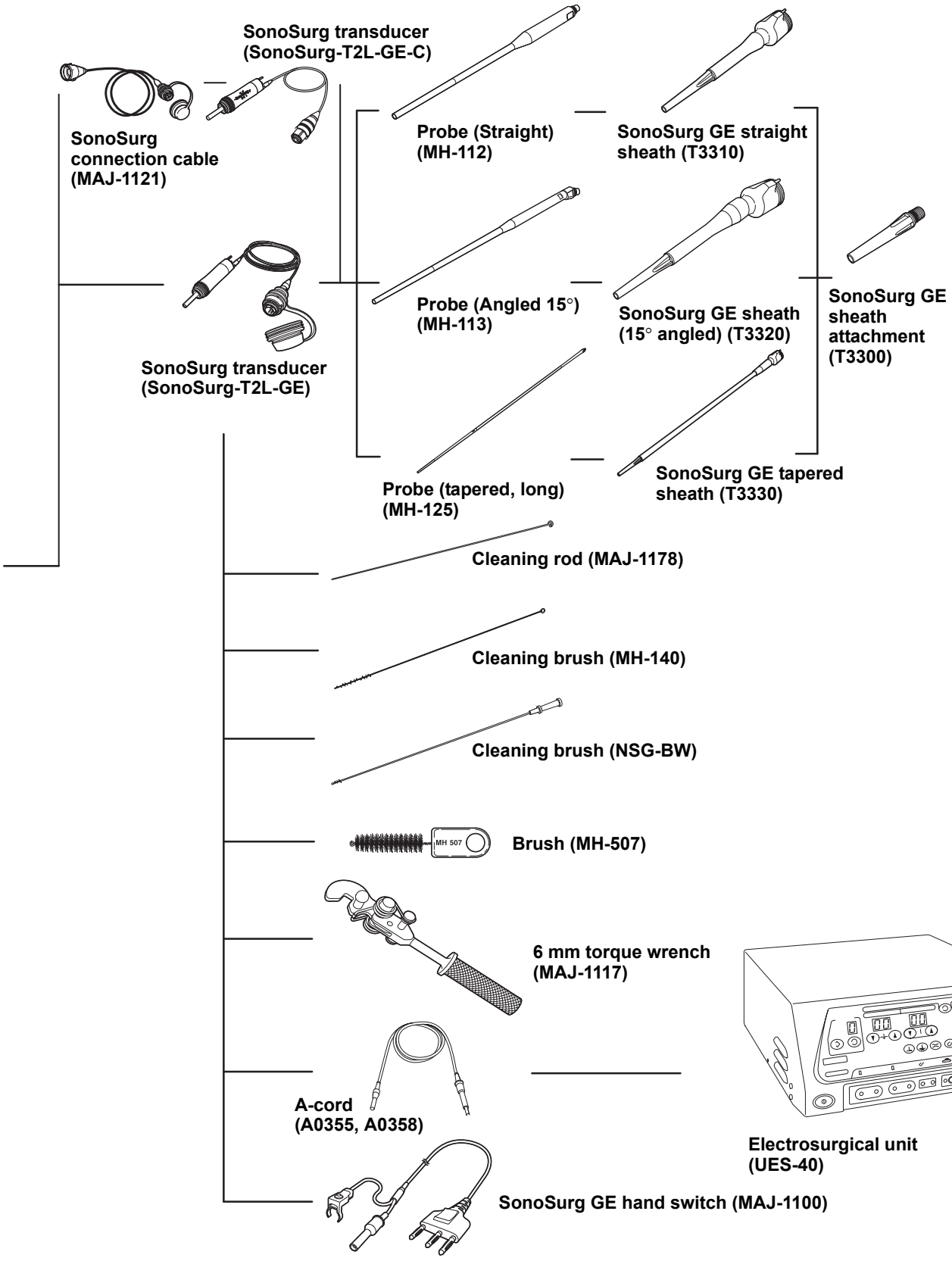
System chart

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, full responsibility is assumed by the medical treatment facility.




SonoSurg transducer
(SonoSurg-T2L-GE-C)
SonoSurg
connection cable
(MAJ-1121)
Probe (Straight)
(MH-112)
SonoSurg GE straight
sheath (T3310)
Probe (Angled 15°)
(MH-113)
SonoSurg GE sheath
(15° angled) (T3320)
SonoSurg GE
sheath
attachment
(T3300)
SonoSurg transducer
(SonoSurg-T2L-GE)
Probe (tapered, long)
(MH-125)
SonoSurg GE tapered
sheath (T3330)
Cleaning rod (MAJ-1178)
Cleaning brush (MH-140)
Cleaning brush (NSG-BW)
MH 507
Brush (MH-507)
6 mm torque wrench
(MAJ-1117)
A-cord
(A0355, A0358)
Electrosurgical unit
(UES-40)
SonoSurg GE hand switch (MAJ-1100)

Environment

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

Specifications

❍ SonoSurg transducer (SonoSurg-T2L-GE/SonoSurg-T2L-GE-C)

Ultrasonic output	**Frequency**	23.5 kHz
Size	**Diameter of the transducer**	Outer diameter 27.4 mm
	Length	135 mm
	Length of the hand piece cord	3400 mm (SonoSurg-T2L-GE) 850 mm (SonoSurg-T2L-GE-C)
Sterilization method	Steam sterilization (autoclaving). See Chapter 7, “Reprocessing and Storage” for more information.	
Output cycle (recommended)	30 sec.ON/15 sec.OFF	
Weight	120 g (Not including the hand piece cord and the hand piece plug.)	

❍ SonoSurg irrigation unit (SonoSurg-IU)

Power supply	**Voltage**	120/220 – 240 V AC
	Power fluctuation	Within ±10%
	Frequency	50/60 Hz
	Frequency fluctuation	Within ±1 Hz
	Input current	1 A (at 120 V AC) 0.5 A (at 220 – 240 V AC)
Size	**Dimensions**	295 (W) × 83.5 (H) × 414 (D) mm
	Weights	5.3 kg
Classification (electromedical equipment)	**Type of protection against electric shock**	Class I
	Degree of protection against electric shock of applied part	TYPE CF at the irrigation/suction tube (low frequency leakage current below 10 μA)
	Degree or protection against explosion	Never use the SonoSurg irrigation unit in a flammable atmosphere
Irrigation	**ON/OFF operation**	Foot switch for SonoSurg irrigation unit (MAJ-1102)
	Irrigation level setting	The irrigation level can be set by pressing the irrigation level setting switches on the front panel of the unit (10 – 100%, 19 level max).
Safety features	**Abnormal irrigation**	When overload of the roller pump is detected, the warning light is illuminated and the alarm sounds.
	Abnormality in foot switch	When a short-circuit of the foot switch is detected, the warning lamp lights and the alarm sounds.
	Pump head cover open	When the pump head cover is not closed securely, the safety mechanism is activated to prevent operation.

❍ Foot switch for SonoSurg irrigation unit (MAJ-1102)

Classification (electromedical equipment)	**Degree of water resistance**	IEC 60529 IPX8 watertight type (except the plug section)
	Degree of protection against explosion	IEC 60601-1 AP type
Size	**Dimensions**	256 (W) × 137 (H) × 182 (D) mm
	Weight	2.2 kg
	Length of the cord	4000 mm

❍ Irrigation/suction tube for SonoSurg (MAJ-1099)

Length	5000 mm
Sterilization method	ETO sterile package, disposable

❍ SonoSurg GE hand switch (MAJ-1100)

Length	4000 mm
Sterilization method	Steam sterilization (autoclaving). See Chapter 7, “Reprocessing and Storage” for more information.
Weight	140 g

❍ SonoSurg GE straight sheath (T3310)

Length	145 mm
Outer diameter	26.4 mm
Sterilization method	Steam sterilization (autoclaving). See Chapter 7, “Reprocessing and Storage” for more information.
Weight	18 g

❍ SonoSurg GE sheath (15° Angled) (T3320)

Length	153 mm
Outer diameter	26.4 mm
Sterilization method	Steam sterilization (autoclaving). See Chapter 7, “Reprocessing and Storage” for more information.
Weight	20 g

❍ SonoSurg GE tapered sheath (T3330)

Length	458 mm
Outer diameter	26.4 mm
Outer diameter (Insertion section)	10 mm
Sterilization method	Steam sterilization (autoclaving). See Chapter 7, “Reprocessing and Storage” for more information.
Weight	56 g

❍ Probe (Straight) (MH-112)

Ultrasonic output	**Frequency**	23.5 kHz
	Maximum amplitude	350 µm
Length		117 mm
Outer diameter		7 mm
Sterilization method		Steam sterilization (autoclaving). See Chapter 7, “Reprocessing and Storage” for more information.
Weight		8 g

❍ Probe (15° Angled) (MH-113)

Ultrasonic output	**Frequency**	23.5 kHz
	Maximum amplitude	200 µm
Length		129 mm
Outer diameter		7 mm
Sterilization method		Steam sterilization (autoclaving). See Chapter 7, “Reprocessing and Storage” for more information.
Weight		5 g

Probe (Tapered, long) (MH-125)

Ultrasonic output	**Frequency**	23.5 kHz
	Maximum amplitude	290 µm
Length		430 mm
Outer diameter		7 mm
Sterilization method		Steam sterilization (autoclaving). See Chapter 7, “Reprocessing and Storage” for more information.
Weight		22 g

Medical Devices Directive	CE 0197	This device complies with the requirements of Directive 93/42/EEC concerning medical devices. Classification: Class II b This device complies with the EMC requirements of EN 60601-1-2 when used in combination with devices bearing CE marking either on the products or in their instructions for use. Emission: Class B of EN 55011
EMC	Applied standards; IEC 60601-1-2: 2001	This instrument complies with the standard listed in the left column CISPR 11 of emission: Group 1, Class B This instrument complies medical electrical equipment edition 2 (IEC 60601-1-2: 2001). However when connecting with a instrument complies with medical electrical equipment edition 1 (IEC 60601-1-2:1993), the whole system complies edition 1.
WEEE Directive		In accordance with European Directive 2002/96/EC on Waste Electrical and Electronic 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.
Year of manufacture	**9<u>4</u>12345**	The year of manufacture is the second digit of the serial number.

Degree of protection against electric shock of applied part	Classification: TYPE CF applied part electromedical equipment. The degree of protection against electric shock of this instrument depends upon the electromedical equipment employed. Refer to the particular unit and its instruction manual.

EMC compliance information

Electromagnetic emission compliance information and recommended electromagnetic circumstances

Standard	Compliance	Guidance
RF emissions CISPR 11	Group 1	This instrument uses RF 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.
RF 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.
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 own radio variability and has no affect such as flicker of a lighting apparatus.

❍ Electromagnetic immunity compliance information and recommended electromagnetic circumstances

Immunity test	IEC 60601 test level	Compliance level	Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	Contact: ±2, ±4, ±6 kV Air: ±2, ±4, ±8 kV	Same as the left-mentioned	Floor should be wood, concrete or ceramic tile that hardly produces static. If floors are covered with synthetic material that produces 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	Same as the left-mentioned	Mains power quality should be that of a typical commercial (original condition of feeding to the facilities) or hospital environment.
Surge IEC 61000-4-5	Differential mode: ±0.5, ±1 kV Common mode: ±0.5, ±1, ±2 kV	Same as the left-mentioned	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dip, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec	Same as the left-mentioned	Main power quality should be that of a typical commercial or hospital environment. If the user of this instrument required operation during power mains interruptions, it is recommended that this instrument should be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Same as the left-mentioned	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE

U_T is the a.c. mains voltage prior to application of the test level.

❍ Cautions and recommended electromagnetic environment regarding portable and mobile RF communications equipment such as a cellphone

Do not use portable and mobile RF communications equipment such as a cellphone closer to any part of this instrument, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Immunity test	IEC 60601 test level	Compliance level	Guidance
Conducted RF IEC 61000-4-6	3 Vrms (150 kHz to 80 MHz)	Same as the left-mentioned	Recommended separation distance: $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m (80 MHz to 2.5 GHz)	Same as the left-mentioned	Recommended separation distance: $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz

NOTE

- Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
- This instrument complies the requirements of IEC 60601-1-2. However, under the electromagnetic environment that exceeds its noise level, electromagnetic interference may occur on this instrument.
- Electromagnetic interference may occur on this instrument near high-frequency electrosurgical equipments and/or other equipments marked with the following symbol:

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

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

NOTE

These guidances may not apply in situations.
Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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