CONTENTS

Introduction
5 Potential Risks and Signal Words
6 Symbols
7 Quality Management

Use of Endoscopic Equipment
8 General Policy
9 Inspection
13 Wiring Video Equipment
15 Video Equipment: Troubleshooting

Energetic Applications
19 Electro-Medical Equipment
21 Light
24 HF Surgery
33 Laser Surgery

Reprocessing
36 General Policy
37 Compatible Procedures and Agents
40 Health and Safety at Work
41 Decontaminating Electrical Units
42 Preparation for Reprocessing at the Point of Use
44 Manual Cleaning
50 Ultrasonic Cleaning
51 Automatic Cleaning/Disinfection
53 Maintenance
55 Disinfection
60 Steam Sterilization
64 Gas Sterilization
66 Other Sterilization Procedures
67 Storage and Handling
Service

72  The Olympus Organization
73  Repairs
INTRODUCTION

Olympus Instruction Manuals have been prepared to provide the user with all the necessary knowledge about the safe use of Olympus endoscopes and their related accessory equipment.

For further questions about how-to-use the product, about the product’s safety, or about this or other Olympus manuals, please feel free to contact your local Olympus representative or visit our website (www.olympus-owi.com).

■ Instruction Manuals

Olympus provides two different types of instruction manuals:
- A system-related instruction manual called “Olympus Endoscopy System Guide” (this brochure)
- The Product-Specific Instruction Manuals

■ Olympus Endoscopy System Guide

The system-related instruction manual “Olympus Endoscopy System Guide” combines information on those topics that apply to virtually all instruments. Therefore, the Olympus Endoscopy System Guide must be considered as part of all instruction manuals.

The System Guide applies for:
- All products manufactured by Olympus Winter & Ibe in Germany. These products are labelled “OLYMPUS Germany”.
- Products distributed by Olympus Winter & Ibe, Germany, which are accompanied by a Product-Specific Instruction Manual referencing to the Olympus Endoscopy System Guide.

■ Product-Specific Instruction Manuals

Olympus products are supplied with their own Specific Instruction Manual giving all details necessary for the use of the product.

In some respects, the Product-Specific Instruction Manuals only make reference to the System Guide. In these cases all the related information given in
the System Guide is applicable to the product. If the information given in the System Guide is not applicable to a certain product, specific information is given in the Product-Specific Instruction Manual.

■ Latest Version of the Olympus Endoscopy System Guide
Due to a continuous development in technology, the content of the Olympus Endoscopy System Guide is regularly updated. To make sure to use the most recent version of the Olympus Endoscopy System Guide, please check with our web-site (www.olympus-owi.com). The version number of a particular issue of the Olympus Endoscopy System Guide can be identified on the rear page of its cover. It is the number following the 7-digit order number (for example: 7.035.000 9.0_05/05).

■ Carefully Read all Instruction Manuals
Before use, carefully read the Product-Specific Instruction Manual, the Olympus Endoscopy System Guide, and all instruction manuals pertaining to additional equipment used in the procedure. Follow all instructions given in these manuals. Failure to understand these instructions may result in:
- Death or severe injury to the patient
- Severe injury to the user
- Damage to the equipment

■ Use of Instruction Manuals
Instruction manuals contain valuable specifications, care, and problem solving information which will help using the endoscope safely and effectively. Keep instruction manuals in a safe, accessible location.

■ The Olympus Endoscopy System Guide in Other Languages
The Olympus Endoscopy System Guide is also available in the following languages:
- Bulgarian ............................................................................W7.035.020
- Chinese (simplified Chinese).................................................7.035.016
- Chinese (Taiwan, ROC) ....................................................W7.035.026
- Czech ......................................................................................7.035.011
Potential Hazards and Signal Words

Safety is the most important issue when using medical devices. This means safety for the patient as well as for the medical personnel. Therefore Olympus manuals include safety information which help the user to identify potential hazards and to avoid them.

Olympus instruction manuals highlight potential hazards by using three signal words: Danger, Warning, and Caution. In addition, the signal word Note has been introduced for helpful information.
■ DANGER!
Indicates an imminently hazardous situation which, if not avoided, may result in death or serious injury.

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

■ CAUTION!
Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.
This signal word may also be used to highlight unsafe practices or potential equipment damage.

■ NOTE
Indicates additional helpful information.

Symbols
Potential hazards, mandatory actions, prohibitions, and user actions are illustrated using the same symbol shapes throughout all instruction manuals.

■ Hazard Alerting
An equilateral triangle is used to convey hazard alert messages, regardless of their hazard level. Hazard level is conveyed by use of the appropriate signal word (for signal words, see above).

■ Mandatory Actions
A solid color circle is used to convey mandatory action.
Prohibition
A circular band with a diagonal slash at 45° from upper left to lower right is used to indicate prohibition.

User Actions
A bullet at the beginning of a sentence indicates a required user action.

Quality Management
Olympus Winter & Ibe has installed a quality management system. The basis of this quality management system are:
- Standard DIN EN ISO 9001
- Standard DIN EN 46001
- “Good Manufacturing Practices” of the US Food and Drug Administration (FDA)

Certification
Since September 1995 Olympus Winter & Ibe is allowed to label their products with the CE mark according to directive 93/42 EEC. Therefore, the quality management system is regularly audited and certified by an independent notified body (TÜV Rheinland).
Since May 2001 Olympus Winter & Ibe have installed a certified environmental management system according to DIN EN ISO 14001.
USE OF ENDOSCOPI

General Policy

■ User Qualification
The user of endoscopic equipment must be a physician or medical personnel under the supervision of a physician. The user must have received sufficient training in clinical procedures. Olympus instruction manuals do not explain or discuss clinical procedures.

■ WARNING!
Infection Control Risk with Reusable Equipment
Properly reprocess all reusable equipment before first and each subsequent use following the instructions in this Endoscopy System Guide or in the Product-Specific Instruction Manual. Improper and/or incomplete reprocessing can cause infection of the patient and/or medical personnel.

■ WARNING!
Infection Control Risk with Sterile Single Use Equipment
The equipment is delivered in a sterilized condition. Use only if the package is undamaged. Only open the package immediately before use.

■ WARNING!
Infection Control Risk with Non-Sterile Single Use Equipment
Properly reprocess the equipment before use following the instructions in this Endoscopy System Guide or in the Product-Specific Instruction Manual. Improper and/or incomplete reprocessing can cause infection of the patient and/or medical personnel.
Instrument Compatibility
The combinations of equipment and accessories that can be used with a certain product are listed in its Product-Specific Instruction Manual. The section is headed “Compatible Components”. New products released after the introduction of a product may also be compatible for use. For details, contact Olympus.

WARNING!
Risk of Injury or Equipment Damage.
Using incompatible equipment can result in patient injury and/or equipment damage.
If combinations of equipment other than those listed in the “Compatible Components” section are used, the full responsibility is accepted by the user.

Inspection
Before each use, perform an inspection as described in the following. Always refer to the product’s Product-Specific Instruction Manual.

General Inspection
• The product must be free of damage (e.g. dents, cracks, bents).
• The product must be free of dirt.
• The product must be free of remaining cleaning agents or disinfectants.
• Make sure that no parts are missing or loosened (e.g. sealing rings, sealing caps).
• Make sure that connecting elements between instruments function properly.
• Inspect working channels for free passage.
• Make sure that all modules of an instrument system are assembled correctly and properly fixed (e.g. electrodes, knives).
■ Inspecting Telescopes
• Inspect for soilings on the objective window, the ocular window and the light guide connector.
• The telescope’s image must not be cloudy, out of focus or dark.
• Make sure that efficient light transmission from the light guide connector to the distal end is obtained. If in doubt, compare with a new telescope.

■ Inspecting Light Guide Cables
• Make sure that efficient light transmission is obtained. If in doubt, compare with a new light guide cable.
• Inspect for cuts or other damages to the cable’s outer sleeve.
• Visually inspect the connector to be plugged into the light source. Make sure that the cover glass is not broken.
Inspecting HF Cables

- Make sure that the cable is not broken.
- Make sure that the insulation is not defective.
- Make sure that connectors are not defective and free of corrosion.

Inspecting Electrodes

- Inspect for secure fixation of HF resection electrodes.
- Inspect for free movement in the assembled instrument.
- Make sure that contact surfaces are free of damages, corrosion, and/or wear.
- Make sure that the insulation is not damaged.
Inspecting Hand Instruments

- Make sure that the jaws and the handle move freely and are properly fixed to the instrument.
- Make sure that the shaft’s insulation is not damaged.
- Test scissors for cutting ability.
Wiring Video Equipment

- **Cable Types**

There are several ways to connect video equipment. Common cable types are:
- BNC type
- Y/C type
- RGB type
- Cinch type
- Digital type

A BNC cable is a two pole coaxial cable. Color signal, luminance signal, and synchronizing signal are transmitted in one cable.

A Y/C cable is a four pole cable. The luminance signal is transmitted separately from the other signals. Therefore the transmission quality is higher. Y/C cables are used for S-VHS and Hi-8 systems.

A RGB cable is an eight pole cable. Color signals for red, green, blue, and the synchronizing signal are transmitted separately. RGB wiring features the highest transmission quality.

A cinch cable is a two pole cable. It is used for transmitting audio signals.

Digital cables transmit video and audio signal as digital data. There are several different types of plug connectors and transmission protocols.
The choice of cables depends on the interfaces featured by the individual ancillary video equipment.

### Principles of Wiring
There are a few principles for wiring video equipment.

1. Always connect the OUT connector of the source unit to the IN connector of the receiving unit.

2. If a unit features a 75 Ω terminating impedance, check the IN and OUT connectors of the unit.
   - If the IN connector is occupied and the OUT connector free, switch on the terminating impedance.
   - If IN and OUT connectors are occupied, switch off the terminating impedance.

3. Make sure that all cables are connected to a unit at both ends. If a cable cannot be connected at both ends, disconnect the cable.

4. Always use the connection with highest transmission quality possible.
   - Transmission quality decreases in the following order:
     - RGB, Y/C, BNC

5. If a cable connection is used for documentation of signals (VCR, video printer), use the connection with highest transmission quality possible.
   - For example:
- Connect a printer via Y/C cable.
- Connect the monitor via BNC cable.

6. If possible, avoid looping the signal through several units. Use multiple source connectors of one unit, if available, to connect other equipment directly.

7. When using endoscopes with fiber bundle optics (e.g. fiberscopes, ureteroscopes) prefer Y/C or RGB wiring to prevent moiré pattern.

**Video Equipment: Troubleshooting**

Always perform a functional check of the imaging equipment before each use.

- **No Image Appears on the Monitor Screen.**
  - Make sure that camera control unit and monitor are connected to mains supply.
    Connect to mains supply if necessary.
  - Does the power switch (ON) of the camera control unit and the monitor illuminate?
    If not, check fuses.
    If necessary, replace fuses.
  - Check wiring of camera control unit and monitor:
    Is the camera control unit’s VIDEO OUT connector connected to the monitor’s VIDEO IN connector?
  - If the monitor features a selector for more than one video signal source:
    Check the selector switch (e.g. LINE A, LINE B).
    Select the appropriate video signal source.
  - Set all monitor settings (brightness, color, contrast) to default values.
  - Make sure that the camera head’s connecting cable is securely connected to the camera control unit.
  - Replace the video cable between camera control unit and monitor by another cable to rule out cable defects.
• If the camera control unit features a color bar test chart, switch it on to test the monitor.
If the color bars do not appear on the monitor screen, contact an authorized Service Center for repair.

■ “Running” Image on the Monitor Screen.
• Turn the V-HOLD knob on the monitor’s rear panel until the image comes to a halt.

■ Blue Cast or Green Cast Image.
• Humidity has been intruded into the camera head’s connecting plug.
Dry the camera head cautiously at 60°C for 30 minutes.

■ Image Disappears Temporarily.
• Make sure that all cables and connectors are securely connected.
• Visually inspect all cables for externally visible damages.

■ Image on the Monitor Screen Appears Dark.
• Check the optical surfaces of the light guide cable and the telescope’s light guide cable connectors for soilings.
If necessary, clean the optical surfaces with a cotton swab soaked in 70% alcohol (ethanol, isopropanol).
• Replace the light guide cable by a new one to rule out light guide defects.
• Check the intensity setting of the light source.
If necessary, readjust intensity setting.
• Check the light source’s lamp.
Has the emergency lamp been switched on?
If necessary, switch on or replace the main lamp.
• If the light source features filters, make sure that any filters have been switched off.
• Contact an authorized Service Center.

**Color Reproduction not Satisfying.**
• Set all monitor settings (brightness, color, contrast) to default values.
• If any of the units in the imaging chain features a $75\Omega$ terminating impedance, check the IN and OUT connectors of the unit.
  If the IN connector is occupied and the OUT connector free, switch on the terminating impedance. If IN and OUT connectors are occupied, switch off the terminating impedance.
• If the monitor features a selector for color temperature, select 6500 Kelvin.
• Try to adjust color reproduction using the camera control unit’s red and blue balancing function.
• If this does not help, perform a white balancing with the camera.
  Turn the camera control unit’s red and blue balancing function to default setting.
  Direct the endoscope’s distal end to a white surface in a distance of round about 30 mm and with the light source turned on.
  Use only matt white paper. Do not use shiny paper. Do not use paper with color cast.
  Make sure that the endoscope’s illumination does not interfere with any lighting in the operating room during white balancing.
  Perform the camera control unit’s white balancing function.

**Image on the Monitor Screen Out of Focus.**
• Adjust focus by turning the video adapter’s focussing ring.
• Check the connection of the telescope, video adapter, and camera head for proper attachment and secure fixation.
• Check the optical surfaces of the telescope, video adapter, and camera head for soilings and humidity.
  If necessary, clean the optical surfaces with a cotton swab soaked in 70% alcohol (ethanol, isopropanol).
  If necessary dry optical surfaces using a soft cotton cloth.
• Check the imaging of the telescope itself. Disconnect the telescope from the video adapter and view through the eyepiece. If the telescope itself is out of focus, contact an authorized Service Center.

• Check the imaging of the camera head itself. Disconnect the telescope from the video adapter. Leave the video adapter attached to the camera head. Check the image appearing on the monitor screen now. If this image is out of focus, contact an authorized Service Center.

■ Image on the Monitor Screen Out of Center.
• Disconnect telescope, video adapter and camera head.
• Make sure that the telescope’s eyepiece cup, the video adapter and the camera head’s connecting thread are free of mechanical damages.
• Make sure that the eyepiece cup is securely fixed to the telescope.
• Make sure that the video adapter’s fixation mechanisms are not damaged and work properly.
• Connect telescope, video adapter, and camera head. Make sure that all components are securely fixed.
• If the image is still out of center, contact an authorized Service Center.
ENERGETIC APPLICATIONS

Electro-Medical Equipment

This section describes general precautions which should be taken in the use of electro-medical equipment.
For specific safety precautions of particular equipment, refer to the Product-Specific Instruction Manual.

■ Installation
• Do not install the equipment in a location where liquids may splash.

• Do not install the equipment under environmental conditions such as:
  - high atmospheric pressure
  - high or low temperatures
  - high or low humidity
  - ventilation
  - direct sunlight
  - dust
  - salty or sulfureous air
For detailed data on environmental conditions, refer to the Product-Specific Instruction Manual.

• Install the equipment on a flat surface. Do not incline the equipment. Make sure that the equipment is not subjected to vibration and impacts.
• Never install and operate the equipment where there is a risk of flammable gases.

• Connect the equipment only to a grounded hospital grade AC mains supply that complies with IEC requirements.
• Connect the equipment to a supply circuit that meets the input requirements indicated on the rating plate on the equipment’s rear panel.

• Make sure that batteries are not discharged and inserted in correct polarity.

• Connect the equipment to a potential equalization line, if:
  - national regulations require.
  - local hospital regulations require.
  - CF certified equipment is used during interventions at the heart.

■ Before Use
• Inspect:
  - electrical contacts of switches and connectors
  - polarity
  - dial settings
  - indicators
  Make sure that the equipment functions properly.
• Make sure that all cables are connected correctly and securely.
• Inspect for possible interferences with other equipment.
• Test the batteries (if applicable).
During Use
- Prolonged use or a higher dosage more than necessary for diagnosis and treatment may reduce patient safety.
- Continuously observe the equipment as well as the patient for abnormal reactions.
- If any abnormal reactions of the equipment or the patient are observed, stop the equipment without impairing the patient safety.

After Use
- Set control switches, dials, etc. back to the initial position.
- Switch off the unit.
- When disconnecting cables, do not pull at the cable. Grasp the plug and pull to disconnect.

Light

Energy Emission of Light Sources
Light sources emit large amounts of light energy and thermal energy. As a result:
- The light guide connector and the telescope’s distal end become extremely hot.
- The light energy is concentrated in a relatively small area.

Risks Related to Light Sources
- Thermal injury to the patient’s tissue (e.g. from prolonged exposure to the intense illumination in cavities with small lumens, or if the telescope’s distal end is placed into close proximity with the tissue).
- Burns to the patient’s or user’s skin.
- Burns or thermal damage to surgical equipment (e.g. surgical drapes, plastic materials, etc.).

Safety Precautions
- Avoid prolonged exposure to intense illumination.
• Use the minimum level of illumination necessary to satisfactorily illuminate the target area.
• Do not place the telescope’s distal end or the light guide connector on the patient’s skin, on flammable materials, or on heat-sensitive materials.

• Do not touch the telescope’s distal end or the light guide connector.
• Turn the light source off when detaching the telescope from the light guide cable.
• Allow the telescope and the light guide cable to cool down after use.

■ **Adapters on the Telescope’s Light Guide Connector**

Light guide adapters allow the telescope to be connected to light guide cables of various manufacturers.

1. Olympus OES light guide cable and Storz light guide cables
2. Wolf light guide cables
3. Olympus OES Pro and ACMI light guide cables

■ **Adapters on the Light Guide Cable’s Connector Plug**

Light guide adapters allow the light guide cable to be connected to light sources of various manufacturers. The nested adapter A3200 allows connection to an Olympus light source. To use other adapters, remove adapter A3200 and attach the required adapter.
**NOTE:**

**Light Guide Cable Adapters**

Olympus recommends the use of an Olympus light guide cable and an Olympus light source. Only this combination will guarantee optimum illumination of the endoscopic image and excellent color reproduction.

**Interferences of Light Sources With Imaging Equipment**

Video systems feature different brightness control functions like an electronic shutter and an auto focus function. These mechanisms control the brightness of the video image on the monitor screen but do NOT control the light source’s output. In the case of improper settings at camera and light source, the light source might be set to full power output, although this is not visible on the monitor screen. Such improper settings lead to enhanced heat emission at the telescope. For a proper connection of light source and video system, refer to the Product-Specific Instruction Manuals.

**Testing the Light Source’s Brightness Control Function**

- Move the endoscope’s distal end towards an object.
  The light emission from the telescope’s distal end must decrease.
• Move the endoscope’s distal end away from an object. The light emission from the telescope’s distal end must increase.

HF Surgery

An electrical current applied to biological tissue generates three effects:
- a thermical effect causing heat
- a Faraday effect stimulating nerves and muscles
- an electrolytical effect causing movement of ions

Effects of HF Current

In HF surgery the Faraday effect is avoided by using high-frequency alternating current with a frequency of more than 300 kHz that generates heat. This heat can be used for three types of application:
- thermical coagulation of tissue
- cutting of tissue
- vaporisation

For thermical coagulation the electrical current heats the tissue only slowly. The water inside the tissue evaporates slowly and cellular proteins are denatured, thus resulting in coagulation of the tissue.

For cutting of tissue the electrical current heats the tissue very fast. The temperature inside the cells of the tissue increases fast, the intracellular water evaporates, thus resulting in destroyed cell membranes.

For vaporisation the electrical power is set to high values. The intracellular water evaporates immediately, thus resulting in shrunked tissue and a large coagulation zone.

### Unipolar HF Surgery

In unipolar HF surgery the electrosurgical current passes from the point-shaped “active” electrode (A) to the larger sized “patient plate” (P). On the small surface of the active electrode a high current density accumulates which creates enough heat to coagulate, cut and/or vaporize tissue.

Active electrodes as described in this System Guide are:
- all HF-electrodes
- HF-resection electrodes (in resectoscopes)
- unipolar hand instruments (e.g. unipolar forceps and scissors)

Other terms used for patient plate are:
- neutral electrode
- indifferent electrode
- p-plate
**Bipolar HF Surgery**

In bipolar HF surgery the electrosurgical current passes between the two electrodes of the instruments (e.g. the jaws of a bipolar forceps). On the small surface between both electrodes a high current density accumulates which creates enough heat to coagulate and/or cut tissue. Bipolar HF surgery does not require any long distance current flow through the patient’s body.

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**Connecting the Patient Plate (only for unipolar HF surgery)**

- Place the patient plate close to the operational field, if possible on the upper arm or on the thigh.
- Make sure that the skin is free from hair and grease.
- Apply conductive gel evenly on the patient plate.
  Refer to the patient plate’s instruction manual. Most single use patient plates do not require conductive gel.
- Make sure that contact has been established over the electrode’s entire surface.
- Place the long edge of the patient plate towards the active electrode.

Correct application of a neutral electrode with even current distribution on the two electrode surfaces.

Wrong application of a neutral electrode. Uneven current distribution on the two electrode parts. An alarm is issued and the activation of the surgical instrument is prevented.
■ **Current Flow in the Body**  
* (only for unipolar HF surgery)  
The current paths inside the patient’s body should be short and must proceed diagonally. Current paths must never run in transverse direction through the body or across the thorax.

Illustration:  
Connecting the patient plate (black) and permitted range of application of the active electrodes (grey).  
Make sure that the current path is as short as possible!

■ **Patient Position**  
- The patient must be insulated against all electrically conductive parts. Make sure that the patient does not come into contact with other metal parts (e.g. operating table) in any case.  
- Ground the operating table.  
- Place the patient on a dry, electrically insulating layer.  
- Prevent any contact between different skin areas (arms, legs). Place dry gauze between the body and arms and legs to prevent contact of skin areas.
**HF-Cables**
Always use Olympus HF-cables.
Do not use HF-cables with brittle or defective insulation. Replace defective HF-cables. In order to plug or unplug an HF-cable always pull at the plug. Never pull at the cable.
Do not place HF-cables directly on the patient’s skin.
Do not lay HF-cables in loops.
Use only plastic clips to fix HF-cables to surgical drapes. Do not use metal clips.

**Active Instruments**
Do not use worn-out or defective active electrodes, forceps, or scissors.
Dispose of worn-out or defective active electrodes, forceps, or scissors.
Do not repair active electrodes, forceps, or scissors.
Do not bend electrodes in shape.

**HF-Unit Instruction Manual**
Refer to the HF-unit’s instruction manual.

**Power Output and Electric Strength**
The maximum power output and the electric strength for the instruments is limited as indicated in the table below. Always use the lowest possible output setting necessary.

<table>
<thead>
<tr>
<th></th>
<th>Maximum Power Output</th>
<th>Electric Strength (recovered peak voltage)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Unipolar applications</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Standard</td>
<td>400 W</td>
<td>2000 V&lt;sub&gt;p&lt;/sub&gt;</td>
</tr>
<tr>
<td>Pediatric urology</td>
<td>100 W (cutting)</td>
<td>1000 V&lt;sub&gt;p&lt;/sub&gt;</td>
</tr>
<tr>
<td></td>
<td>50 W (coagulation)</td>
<td>1000 V&lt;sub&gt;p&lt;/sub&gt;</td>
</tr>
<tr>
<td><strong>Bipolar applications</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Standard</td>
<td>150 W</td>
<td>1200 V&lt;sub&gt;p&lt;/sub&gt;</td>
</tr>
<tr>
<td>BiQ+ series</td>
<td>100 W</td>
<td>800 V&lt;sub&gt;p&lt;/sub&gt;</td>
</tr>
</tbody>
</table>

Always refer to the Product-Specific Instruction Manual for possible differences to these values.
WARNING!

Spray Coagulation

Some HF-units feature a so-called “spray coagulation”.
The application of “spray coagulation” destroys the electrodes. There is a risk of spark-over to the patient.
Do not apply the “spray coagulation” function of the HF-unit during endoscopic interventions.
Spray coagulation should only be used if the compatibility of the instruments to be used is certified in their Product-Specific Instruction Manuals.

Safety Precautions for Unipolar Interventions

- Switch off the HF-unit when not using it.
- To coagulate tissue, first position the electrode on the target area and then activate the HF current.
- Do not activate the HF current if the electrode is not in touch with tissue.
- Make sure that the electrode is at least 10 mm away from all other endoscopic equipment.
- Tissue areas that are in contact with the active electrode must not touch other tissue areas. Coagulate cord-like tissue parts on their narrowest point. Otherwise, side coagulation or perforation may result.

Safety Precautions for Bipolar Interventions

- Switch off the HF-unit when not using it.
- First position the bipolar instrument on the target area and then activate the HF current.
- Do not activate HF current without tissue between both electrodes of the bipolar instrument, the bipolar instrument might be destroyed.
- Some HF-units feature a so-called AUTO START mode. In the case of accidental tissue contact the AUTO START mode involves the risk of unintentional coagulation. Therefore some equipment does not operate in the AUTO START mode. Do not select the AUTO START mode.

■ **Inflammable Gases**
When performing electrosurgery, use only non-flammable gases (e.g., CO₂) for insufflation.

■ **Irrigation Fluids**
When performing unipolar electrosurgery, use only non-conductive fluids.

■ **Suction/Irrigation**
When using active electrodes with suction channel, do not simultaneously activate the HF-current and the suction/irrigation function.

■ **Conductive Lubricant**
When inserting instruments into the urethra during electrosurgical procedures, use conductive lubricants only.

■ **WARNING!**
**Risk of Injury**
Do not use conductive lubricants for lubrication of working elements. There is a risk of spark-over to the patient.

■ **Malfunction**
If the unit is set to a level which previously worked sufficiently but now does not satisfactorily coagulate the tissue, do not increase the output setting. Instead, make sure that:
- the patient plate is seated correctly.
- all HF-cables and -plugs are securely attached and free of corrosion.
- the HF resection electrode is securely attached.
- the insulation of the HF-cables, the HF-electrode, and the instrument are not damaged.
- the electrode’s distal end is clean and free of corrosion.
- the instrument has been assembled properly and all parts are securely attached.
- a non-conductive irrigation fluid is used.
- a conductive lubricant is used with instruments inserted into the urethra.

### Potential Risks

The application of HF current involves the risk of burns. According to their cause burns can be divided into:
- endogenous burns
- exogenous burns

### Endogenous Burns

Endogenous burns are burns which are caused by a high current density in the patient’s tissue.
Possible reasons are:
- the available conductive surface of the patient plate is too small in relation to the power output used (select a suitably sized patient plate!)
- the actual conductive surface of the patient plate is too small (make sure that the patient plate is in contact to the patient’s skin over the electrode’s entire surface),
- the patient is inadvertently positioned in contact with electrically conductive parts (make sure that the patient has been insulated against all electrically conductive parts),
- direct contact between skin areas and HF-cables may lead to electrical capacitance which in turn may cause burn.

### Exogenous Burns

Exogenous burns are burns which are caused by the heat of ignited fluids or gases. They may also be caused by explosions.
Possible reasons are:
- ignition of skin cleaning agents and disinfectants,
- ignition of narcotic gases,
- ignition of insufflated gases (use only non-flammable gases for insufflation!),
- ignition of endogenous gases (bowel),
- explosion of oxyhydrogen gas inside the urinary bladder, kidney, or the uterine cavity (evacuate accumulated gas!).

**Interferences**
The application of HF current interferes with other medical equipment. Interferences with ECG, cardiac pacemakers, laser application, and video imaging are widely known. For possible other interferences refer to the HF unit’s instruction manual.

**ECG**
If an electrocardiograph is used, the indifferent ECG cable has to be coupled to the patient plate of the HF-unit. Place the active electrode at a minimum distance of 150 mm from the ECG electrodes. Do not use ECG needle electrodes for monitoring. All ECG electrodes must be equipped with protective impedances or HF choke coils.

**Cardiac Pacemakers**
Pacemakers may be damaged by electrosurgical current. Consult a cardiologist for the intervention. Never use electrosurgical current on outpatients with pacemakers.

**Video Imaging**
Video images may be interfered by HF current. To prevent noisy images, HF equipment and video imaging equipment should be connected to different mains supply circuits.
Laser Surgery

The term laser stands for “Light Amplification by Stimulated Emmission of Radiation”. A laser is a device for producing monochromatic coherent luminous beams.

As soon as the luminous beam hits alive tissue, its energy is converted into thermal energy creating a cutting or coagulation effect.

■ Instruction Manual
Refer to the laser unit’s instruction manual.

■ Switch Off Laser
If the laser is not being used or if surgical instruments are changed, switch off the laser.

■ Power Output
Always select the lowest possible laser output for the procedure.

■ Potential Risks
The application of Laser involves certain risks like:
- Eye damage
- Skin damage
- Chemical risks
- Mechanical risks
- Electrical risks

■ Eye Damage
Eye damage includes:
- in the range of wave lengths between 200-400nm (UV): photophobia and diseases of the front eye parts (inflammation, watering),
- in the range of wave lengths between 400-1400nm (visible light and near infrared): damages of the retina and the eye’s vitreous body,
- in the range of wave lengths between 1.4-1000μm (infrared): damages of the cornea and the front eye parts.
Skin Damage
The most frequent skin damage includes burns. Burns up to the fourth degree are possible. Additionally, lasers in the range of wavelengths between 250-320 nm are carcinogenic.

Chemical Risks
Inflammable or explosive substances may be ignited by the laser beam.

Mechanical Risks
Parts can be hurled away from the spot of the incident laser beam.

Electrical Risks
Electrical risks are caused by the high voltage applied to the laser.

Safety Precautions
- Protective glasses:
  When using a laser always wear protective glasses that fit to the laser’s wavelength.
- Patient’s eyes:
  To protect the patient’s eyes against the laser beam, cover them or use protective glasses that fit to the laser’s wavelength.
- Non-reflecting equipment
  Do not use reflecting equipment within the laser range. Endoscopic instruments must be black or matted.
WARNING!

Interferences with Insufflators
Uncontrolled inflow of gaseous insufflation media may cause lethal emboli.ms. Beside the insufflator other systems might become a source of gas supply. Other systems with active delivery may include: lasers with probe tips cooled using CO₂ or other gases, and Argon-Enhanced Coagulation Systems (AEC).
When using such systems in laparoscopy, make sure that insufflators with an active suction control system are used.
If the insufflator emits a warning for intra-abdominal over-pressurization, quickly open the stopcock or valve of the instrument inserted into the patient for insufflation.

WARNING!

Inflammable and/or Explosive Gases
Lasersurgical procedures may only be carried out if non-flammable gases (CO₂) are used for insufflation.
Do not carry out lasersurgical procedures in the presence of explosive gases.
Not only anaesthetic agents but also the formation of gas inside the intestinal tract represents an explosion hazard.
**REPROCESSING**

**General Policy**

- **The Reprocessing Cycle**
  Olympus endoscopic instrumentation is designed to be reprocessed by methods described in this chapter (if not labelled as single-use product). To minimize the risk of cross-contaminating patients, reprocess the endoscopic instrumentation before each use.

- **Disinfection vs. Sterilization**
  The U.S. Centers for Disease Control and Prevention (CDC) characterizes those reusable medical devices and instruments that enter sterile tissues, including the vascular system, as critical. After meticulous cleaning, these should be sterilized prior to each patient use.

  The U.S. Centers for Disease Control and Prevention (CDC) characterizes those reusable medical devices and instruments that come into direct or indirect contact with mucous membranes, but do not ordinarily penetrate body surfaces, as semi-critical. After meticulous cleaning, these should, at a minimum, receive high-level disinfection prior to each patient use.

  Contact your local hygiene representative to determine the situation in which disinfection rather than sterilization would be appropriate in your facility.

- **Manual Cleaning vs. Automatic Cleaning**
  In general, instruments can be cleaned manually or automatically with sufficient results. Manual cleaning methods involve infection control risks for the cleaning personnel. Automatic methods reduce these risks and provide the advantage of standardized and validated procedures. Therefore, Olympus recommends to prefer automatic cleaning procedures.

  Contact your local hygiene representative to determine the situation in manual cleaning rather than automatic cleaning would be appropriate in your facility.
■ **Standards**
Refer to American National Standard ANSI/AAMI ST35 “Good Hospital Practice: Handling and Biological Decontamination of Reusable Medical Devices”.
Contact your local hygiene representative for local standards and regulations.

■ **After Use**
After use immediately treat the instruments as described in the section “Preparation for Reprocessing at the Point of Use”.

■ **Brand-New Instruments**
Always treat brand-new instruments as if they were already used. Brand-new instruments must be cleaned before disinfection or sterilization.

**Compatible Procedures and Agents**
The materials and construction of the Olympus endoscopic instrumentation may not be compatible with certain reprocessing methods. Olympus differentiates between two degrees of compatibility:
- microbiological compatibility
- material compatibility

■ **Microbiological Compatibility**
Microbiological compatibility means that an instrument has been successfully reprocessed using the standardized method described in this manual.
Material Compatibility
Material compatibility means that negative effects on the material of the instruments have not been noticed so far. Material compatibility does not necessarily mean that a certain degree of microbiocidal effectiveness can be guaranteed.

Choosing a Reprocessing Method
The actual reprocessing method chosen by your institution should be determined by national and local guidelines as well as your hospital’s infection control committee.

Monitoring
Regularly monitor all disinfection and sterilization processes. Although there are no biological indicators available to verify the disinfection processes, there are strips which will permit monitoring the concentration of the disinfectant agent. Monitor the concentration daily to ensure that the solution has not been diluted below its effective concentration. To monitor sterilization processes, use an appropriate biological indicator.

Compatibility Chart
This chart lists those cleaning, disinfection, and sterilization procedures and agents that have been thoroughly tested on components of rigid endoscopes and their accessories.
### CAUTION!
#### Risk of Damage

Not every instrument is compatible with all procedures mentioned in this System Guide. Before disinfecting or sterilizing the instrumentation read the Product-Specific Instruction Manual.

<table>
<thead>
<tr>
<th>Manual Cleaning</th>
<th>High-Level Disinfection/ Ethyleneoxide</th>
<th>Autoclaving, 134°C, 5 min.</th>
<th>Ultrasonic Cleaning</th>
<th>Sterrad 100S</th>
<th>Steris</th>
<th>Low Temperature Steam and Formaldehyde Sterilization</th>
<th>Automatic Cleaning/Disinfection</th>
</tr>
</thead>
<tbody>
<tr>
<td>O</td>
<td>O</td>
<td>−</td>
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<td>compatible</td>
</tr>
</tbody>
</table>

- compatible
- incompatible
- only with protection cap
- without handle
- only OES 4000 and OES PRO series, except albarran inserts
- only OES 4000 and OES PRO series
- only with mounted video-adapter and protection-cap
- refer to the product-specific instruction manual

---

**Autoclavable Telescopes**

**Telescopes**

**Sheaths and Obturators**

**Bridges**

**Working Inserts**

**Working Elements**

**Trocars**

**Knives**

**Electrodes**

**Hand Instruments**

**Rectoscopes/Proctoscopes**

**Rectoscopes with Illumination Ring**

**Probes with Plug**

**EKLProbes**

**Camera Heads, not autoclavable**

**Camera Heads, autoclavable**

**Camera Adapter, not autoclavable**

**Camera Adapter, autoclavable**

**Light Guide Cable**

**Mechanical Light Guide Adapter**

**Optical Light Guide Adapter**

**HF Cable**

**Sealing Caps/Sealing Rings**

**Other Products**

---

**Microbiologically validated and tested for material compatibility**

**Tested for material compatibility**
Health and Safety at Work

■ WARNING!
  Protection Against Infection or Skin Irritation
Patient debris and reprocessing chemicals are hazardous. Wear personal equipment to guard against dangerous chemicals and potentially infectious material. During cleaning and disinfection or 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 equipment before leaving the cleaning area.

■ WARNING!
  Toxic Chemical Fumes
The disinfection/sterilization room must be adequately ventilated. Adequate ventilation protects against toxic chemical fumes.

■ WARNING!
  Inflammable Liquids
Store alcohol (ethanol, isopropanol) in an air-tight container. Alcohol stored in an open container may cause fires and will lose its efficacy due to evaporation.
Decontaminating Electrical Units

This section describes how to decontaminate the surfaces of electrical units. Units are not sterilizable. Units should be cleaned and disinfected.

■ Cleaning Units
  • Turn off the power switch.
  • Disconnect the power cable.
  • Let the unit cool down to room temperature.
  • Remove all dust and soilings with a soft cloth.
  • Remove hard-to-clean soilings with a damp cloth.

■ Disinfecting the Unit’s Surface
  • To disinfect the unit, wipe it with a cloth that has been dampened with an aqueous solution of 1-4 % glutaraldehyde or 70% alcohol (ethanol, isopropanol) solution.
  When using 70% alcohol, make sure that the unit has been completely cooled down to room temperature to avoid any risk of ignition or explosion.
  Refer to national and local guidelines regarding the approval of using alcohol as a disinfectant.
  Never immerse units in liquid!
Preparation for Reprocessing at the Point of Use

Prepare reusable instruments for later reprocessing immediately after use directly in the operating room as described in this section.

■ Single-Use Products
  • Separate single-use products from reusable products.
  • Destroy and dispose of single-use products.
  • Dispose of refuse according to legal requirements.
  • If necessary, sterilize refuse before disposal.

■ Reusable Products
  • Remove debris from insertion portions of instruments by wiping with a soft cloth.
  • Disassemble instruments.
    • Clean active parts of HF-electrodes and jaws of unipolar and bipolar forceps using 3% hydrogen peroxide.
    • Remove sealing caps.
    • Open all stopcocks.
• Separate telescopes from other instruments.

• If desired, instruments can be immersed in disinfectant solution immediately after use.

■ Transport of Reusable Products
• Transport reusable products from the point of use to the reprocessing area.
The transport can be performed as well in dry condition as immersed in liquids.
• Contain reusable products during transport to avoid possible environmental or personnel contamination.
• If instruments are contained in dry condition, make sure that debris does not dry. Close the container’s lid. Start the following cleaning procedure within 3 h after use. If this timeframe has to be exceeded the user has to take special action to get an appropriate cleaning result.
• If instruments are contained immersed in liquids, start the following cleaning procedure within 1 h after use. Do not use physiological saline solution for immersion.

■ CAUTION!
Risk of Instrument Damage
Reprocess the instruments immediately after use. Do not exceed the time limits for transport indicated above. Do not leave used instruments overnight before reprocessing.
If instruments are left in dry condition for a longer period, debris may dry to the instrument, leading to hardly removable incrustations.
If instruments are left immersed in liquids for a longer period, the instrument’s sealings may macerate.

**Manual Cleaning**

This section describes how to clean endoscopes and their accessories manually.

- **Manual Cleaning Procedure**
  - Immediately after use, disassemble the instruments.
  - Open all stopcocks.
  - Thoroughly rinse all instrument components with water (< 20° C).
• Use a low-tenside medical endoscope cleaning agent with neutral pH to clean persistent soilings in a hand-hot solution.

• Do not immerse instrumentation for more than 60 min.

• To clean internal parts, use cleaning pistol (O0190, see bottom for details), Olympus cleaning brushes, and cleaning wire (see bottom for details).

• Perform this procedure until all visual debris has been completely removed.

• After cleaning the instrument, rinse it with de-ionized water (Aq. dest.).

• Let all parts drain.
• Use a soft cloth or sponge to wipe off remaining water.

■ Cleaning Pistol

• Select an appropriate attachment:
  ① For syringes and cannulas with “Record”-connector.
  ② For pipettes.
  ③ For catheters, stopcocks, valves, and endoscopes.
  ④ For syringes and cannulas with Luer-Lock-connector.
  ⑤ For drainage tubes.
  ⑥ For glass jars.
  ⑦ Spray nozzle.
  ⑧ Water jet blast for suction.

• Immerse the instrument to be cleaned in water.
• Firmly press the attachment onto the nozzle port of the cleaning pistol.
• Open the water tap. If fibrescopes are cleaned, do not exceed a maximum pressure of 0.5 bar.
• Firmly press the cleaning pistol with the attachment against the instrument to be cleaned (while submersed in water).
• Activate the handle several times until all soilings are removed. Adjust the pressure of the water jet by means of the knurled nut (see arrow).
• Close the water tap after use.
**Cleaning Brushes and Cleaning Wire**

- Select an appropriate cleaning brush/wire:

<table>
<thead>
<tr>
<th>Cat.No.</th>
<th>Dimensions</th>
<th>Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>A0440</td>
<td>0.6 x 500 mm</td>
<td>channels in uretero-renoscopes, channels for guidance of catheters</td>
</tr>
<tr>
<td>A0441</td>
<td>2.5 x 360 mm</td>
<td>sheaths (5-7.5 Fr.), working inserts, bridges, channels for guidance of resection electrodes</td>
</tr>
<tr>
<td>A0442</td>
<td>2.5 x 500 mm</td>
<td>channels in uretero-renoscopes</td>
</tr>
<tr>
<td>A0443</td>
<td>6 x 360 mm</td>
<td>4-5 mm trocar tubes, sheaths (15-17 Fr.), arthroscope trocar tubes, telescope channels of urologic and gynaecologic instruments</td>
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<tr>
<td>A0444</td>
<td>4 x 500 mm</td>
<td>shafts of HiQ hand instruments with a length of 450 mm</td>
</tr>
<tr>
<td>A0445</td>
<td>9 x 360 mm</td>
<td>sheaths (19-5-27 Fr.)</td>
</tr>
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<td>A0446</td>
<td>4 x 360 mm</td>
<td>shafts of HiQ hand instruments (8-12 Fr.), shafts of 250 and 330 mm</td>
</tr>
<tr>
<td>A0447</td>
<td>12 x 360 mm</td>
<td>sheaths (28.5-30 Fr.), 8-11 mm trocar tubes</td>
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<td>A0448</td>
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<td>stopcocks</td>
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<td>A0449</td>
<td>16 x 360 mm</td>
<td>13-15 mm trocar tubes, rectoscopes, anoscopes, proctoscopes</td>
</tr>
<tr>
<td>A0450</td>
<td>20 x 360 mm</td>
<td>20 mm trocar tubes, rectoscopes, anoscopes, proctoscopes, amnioscope sheaths</td>
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<tr>
<td>A0451</td>
<td>-</td>
<td>for all surfaces</td>
</tr>
<tr>
<td>A0452</td>
<td>1.0 x 700 mm</td>
<td>channels in uretero-renoscopes</td>
</tr>
</tbody>
</table>

- Introduce the cleaning brush/wire into the instrument’s distal opening and advance the brush/wire until it reaches the proximal opening.
- Move the brush/wire back and forth until the brush/wire is free of visible debris.
- Remove the cleaning brush/wire.
- Check the channel’s lumen for free passage. If this is not the case, repeat the procedure.
- Clean and decontaminate the brush/wire after use.
Cleaning Optical Surfaces

Optical surfaces are:
- a telescope’s objective lens window
- a telescope’s eyepiece lens window
- a telescope’s light guide connector
- a camera head’s lens window
- the video adapter’s lens windows
- the light admission surface on the light guide plug that is attached to the light source
- the light emission surface on the light guide plug that is attached to the instrument

• Remove all adapters from the telescope’s light guide connector.
• Remove all adapters from light guide cables.
• Remove the telescope’s eyepiece cup (if applicable).
• Clean the optical surfaces with a cotton swab that has been moistened with 70% alcohol (ethanol, isopropanol) solution.

Never wipe with a metal cotton applicator.
Do not use other instruments for cleaning optical surfaces.

WARNING!
Infection Control Risk with Cleaning Agents

There is an infection control risk when using insufficient cleaning agents. Use only those cleaning agents which feature validated processes in accordance to national and local guidelines.

WARNING!
Risk of Reduced Cleaning Effectiveness in Instruments with Small Lumen

If instruments with small lumen are cleaned there is a risk that the inner lumen is not soaked with water and/or cleaning agent. Always rinse instruments with small inner lumen by connecting them to a water hose, a rinsing syringe or the cleaning pistol.
CAUTION!
Risk of Damage due to Incompatible Cleaning Agents
Incompatible cleaning agents may considerably damage Olympus endoscopes and accessories. Use only solutions that are certified by their manufacturers safe for endoscopic instrument cleaning. For further information on cleaning agents, please contact Olympus.

CAUTION!
Risk of Damage due to Remnants of Cleaning Agents
Cleaning solutions may contain various aggressive compounds (e.g. chlorine) which damage the instrument by corrosion. To remove all remnants rinse the instrument thoroughly with de-ionized water (Aq.dest.). Do not use tap water for rinsing because it might be chlorinated.

CAUTION!
Risk of Damaging Telescopes
Always clean each telescope separately. Do not clean with other telescopes or other instruments. Make sure that telescopes do not touch each other.
**WARNING!**  
**Infection Control Risk with Cleaning Pistol**  
Water splashing from the cleaning pistol may contain infectious agents. Always use a face screen. Adjust the water pressure to a minimum level to satisfactorily clean the instruments. Always perform the procedure with the instrument to be cleaned and the cleaning pistol submersed in water to prevent splashing.

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**Ultrasonic Cleaning**

**Ultrasonic Cleaning Procedure**

- Use only ultrasonic cleaners which are intended to use for cleaning of endoscopic instruments by the cleaner’s manufacturer or a 1-4% glutaraldehyde disinfectant suitable to be used for ultrasound cleaning of endoscopes. Refer to the ultrasonic cleaner instruction manual.
- Use grasping forceps for instruments 00185 with padded jaws.
- Immerse instrument in an ultrasonic cleaner for 5 min and a max of 15 min at a frequency of 38-47 kHz.
- Switch off the bath’s heating system.
- Only clean components at room temperature.
- Let all parts drain.
- Use a soft cloth or sponge to wipe off remaining water.

**WARNING!**  
**Infection Control Risk with Ultrasonic Cleaning**  
Vapors from ultrasonic cleaning units may contain infectious agents as aerosols. Always use a face screen and air exhaust during ultrasonic cleaning.
Automatic Cleaning/Disinfection

Automatic cleaning procedures are reproducible and feature a validated cleaning process.

- **Appropriate Washer/Disinfectors**
  Use only washer/disinfectors which are intended to use for cleaning and disinfection of endoscopic instruments by the washer/disinfector’s manufacturer. Use only washer/disinfectors according to prEN ISO 15883-1-4. Refer to the washer/disinfector instruction manual.

- **Selection of Programs**
  Select a program optimized for endoscope cleaning. The program should start with a precleaning cycle running at a temperature of ≤20° C. The washing cycle with cleaning agent should run at temperatures of 40-45° C for at least 5 min. The final rinse should run a 93° C for at least 10 min. Do not use programs starting with high temperatures (e.g. 93° C). This leads to a denaturation of proteins and debris, thus inhibiting effective cleaning. Make sure that the program does not include any sudden changes in temperature.
1. Pre-Rinse
2. Cleaning
3. Rinsing
4. Disinfection
5. Final Rinse
6. Drying

**Automatic Cleaning/Disinfection Procedure**
- Make sure that all instruments have been securely fixed to the unit’s trays. Make sure that instruments do not touch each other.
- For telescopes, use instrument tray A5940 or other adequate trays to fix the telescope.
- Instruments with lumen must be attached to special trays with rinsing devices. Make sure that all lumens are sufficiently rinsed. Check lumens for free passage before starting the procedure.
- Open the jaws of hand instruments.
- Do not overload washers/disinfectors.
- Remove the instruments from the washer/disinfector immediately when the automatic procedure has stopped to prevent corrosion.

**Cleaning/Disinfection Agents in Automatic Cleaning**
Use only agents that are certified by their manufacturers safe for endoscopic instrument cleaning/disinfection.

Use enzyme-based agents with neutral pH, since they do not affect the endoscope’s material. Avoid non-pH-neutral agents containing alkaline or acidic compounds such as citric acid or phosphoric acid. Even minor residues of non-pH-neutral agents may lead to corrosion of the endoscope’s material (especially older chromium-plated instruments are affected). However, if rinsing with neutralizers after cleaning/disinfection is necessary, make sure to remove all traces of neutralizers by a final rinsing cycle using de-ionized water. Anyway, to remove all remnants rinsing cycles must be run using de-ionized water (Aq.dest.) according to EN 285 (refer to section “Steam Sterilization”).

Do not use tap water for rinsing because it might be chlorinated. For further information on agents for automatic cleaning/disinfection processes, please contact Olympus.
**WARNING!**

**Infection Control Risk with Cleaning Agents**
There is an infection control risk when using insufficient cleaning agents. Use only those cleaning agents which feature validated processes in accordance to national and local guidelines.

**CAUTION!**

**Reduced Cleaning Effectiveness in Automatic Cleaning due to Coagulation of Proteins**
Preferably return the instruments from the point of use to the cleaning area in dry condition to avoid protein fixation caused by cleaning agents. Make sure that the water inflow into the cleaning units starts with cold temperatures (< 20° C) to avoid thermal coagulation of proteins.

**CAUTION!**

**Risk of Damage due to Exceeded Concentration of Cleaning/Disinfection Agents**
Defects of the washer’s/disinfector’s feeding pump can lead to an exceeded concentration of cleaning/disinfection agents, which will damage the instruments. Regularly maintain the washer/disinfector as recommended by its manufacturer.

**Maintenance**

Instruments should be regularly treated with lubricants to maintain their function and to protect them from corrosion and aging.

**Lubricants**
Olympus distributes two lubricants:
- stopcock grease (O0170)
- moving metal part oil (A0273)
■ **CAUTION!**

**Decrease of Image Quality**

Apply all lubricants sparingly. Make sure that the telescopes’ objective or eyepiece lens windows are not smudged with lubricant. Lubricants on objective or eyepiece lens windows considerably decrease viewability and imaging quality.

■ **Moving Metal Parts**

Lubricate moving metal parts in joints or attachment devices.
- Apply a drop of oil to all parts to be lubricated.
- Use a cotton pad to remove excess oil.

■ **Stopcocks**

Olympus instruments are equipped with two different stopcocks:

1. Dismantable stopcocks (featuring a knurled nut)
2. Maintenance-free stopcocks (not featuring a knurled nut)
■ **Dismantable Stopcocks**
Each time after using an instrument with dismantable stopcock, do the following:
- Detach the knurled nut on the cock plug.
- Remove the cock plug.
- Thoroughly clean all components.
- Lightly grease the cock plug with stopcock grease (cat.no. O0170).
- Reinsert the cock plug.
- Fasten the knurled nut.

■ **Maintenance-Free Stopcocks**
Do not disassemble maintenance-free stopcocks.
Do not grease maintenance-free stopcocks.
Reprocess and store maintenance-free stopcocks in opened condition.

■ **Silicone Sealings**
- Apply oil A0273 to sealing rings and sealing caps.
**Disinfection**

- **Prior Cleaning**
  Endoscopic instrumentation must be meticulously cleaned prior to disinfection. Thorough cleaning removes both micro-organisms and organic material. Failure to remove organic material decreases effectiveness of the disinfection procedure.

- **High-Level Disinfection**
  In the U.S., agents used to achieve high-level disinfection are defined as liquid chemical germicides registered with the Environmental Protection Agency as “sterilants/disinfectants” which are used according to time, temperature and dilution recommended by the disinfectant manufacturer for achieving high-level disinfection. These conditions usually coincide with those recommended by the disinfectant manufacturer for 100% kill of Mycobacterium tuberculosis.

- **Germicidal Effectiveness**
  For information on the germicidal effectiveness of any solution, refer to the solution’s instructions or contact the solution’s manufacturer.
  The chemical agent used for disinfection should be capable of killing/deactivating:
  - Mycobacteria
  - Bacterial spores
  - Viruses (hepatitis, HIV)

- **Disinfection Procedure**
  - Fill a disinfection tank (e.g. O0264) with disinfection solution.
• Take out the disinfection tank’s sieve tray.

• Disassemble the instrument.

• Open the stopcocks.

• Place the instrument’s components on the sieve tray.

• Lower the sieve tray into the tank.
• Make sure that all components have been completely immersed. Make sure that air bubbles do not stick to the instrument. Do not exceed an immersion time of 1 h.

• Use grasping forceps with rubber-padded jaws (O0185) to handle instruments once they are immersed to avoid damaging the instruments. Grasp telescopes, sheaths, and trocar tubes at their main body.

### Rinsing

- Make sure that the area in which the instrument is rinsed is sterile.
- Thoroughly rinse all of the instrument’s components with sterile de-ionized water (Aq.dest.) to remove all disinfectant remnants from the components.
- Always rinse instruments with small inner lumen by using a syringe.
- If non-sterile water is used for rinsing, wipe the instrument components and flush the channels with 70% alcohol (ethanol, isopropanol).

Do not reuse rinsing water.

### Drying

- Dry the instruments with sterile cloths and sponges.
- Use instruments immediately after disinfection.

Do not store disinfected instruments.
**WARNING!**

**Risk of Reduced Disinfection Effectiveness in Instruments With Small Lumen**

If instruments with small lumen are disinfected there is a risk that the inner lumen is not soaked with disinfectant solution. When disinfecting instruments with small inner lumen, disinfectant solution must be injected into the small lumen using a syringe.

**CAUTION!**

**Risk of Damage due to Incompatible Disinfectants**

Incompatible disinfectant solutions may considerably damage Olympus endoscopes and accessories. Use only solutions that are certified by their manufacturers safe for endoscopic instrument cleaning and disinfection. For further information on disinfectant agents, please contact Olympus.

**Material Tolerance**

Olympus instruments have been tested regarding their tolerance of aqueous solutions 1-4% (w/v) glutaraldehyde (immersion). The maximum immersion time is 1 h.

This statement only refers to material tolerance and does not indicate any germicidal effectiveness level.

**CAUTION!**

**Risk of Damage due to Exceeded Concentration and Immersion Time**

For information about the concentration and immersion time refer to the instructions given by the disinfectant solution’s manufacturer. Do not exceed the manufacturer’s maximum recommended levels.
CAUTION!
Risk of Instrument Damage
Do not immerse instruments for more than 60 min in any liquids. If instruments are left immersed in liquids for a longer period, the instrument’s sealings may macerate.

CAUTION!
Risk of Damage due to Remnants of Disinfectants
Disinfectant solutions may contain various aggressive compounds (e.g. chlorine) which damage the instrument by corrosion. To remove all remnants rinse the instrument thoroughly with de-ionized water (Aq.dest.). Do not use tap water for rinsing because it might be chlorinated.

Steam Sterilization
If possible, Olympus recommends using prevacuum steam sterilization. Steam sterilization with prevacuum has been validated for its germicidal effectiveness with most of the Olympus endoscopes. Refer to the Product-Specific Instruction Manual for compatibility with steam sterilization.

Prior Cleaning
Endoscopic instrumentation must be meticulously cleaned prior to sterilization. Thorough cleaning removes both micro-organisms and organic material. Failure to remove organic material decreases effectiveness of the sterilization procedure.
Steam Sterilization Procedure

- Disassemble the instrumentation. Refer to the Product-Specific Instruction Manual for instruments which can be assembled before steam sterilization.

- Open all stopcocks.

- Seal the instruments in appropriate instrument trays and in sterilizing foil (for Olympus instrument trays, see “Storage and Handling” section).

- Refer to the autoclave’s instruction manual.

- Use only prevacuum autoclave cycles to ensure that all lumens are filled with steam.

- After steam sterilization cool down to room temperature without additional cooling. Sudden changes in temperature may damage the instruments. Never rinse the instruments with cold water for cooling.
Steam Sterilization Conditions

Olympus recommends to autoclave the instruments for 5 min at 134° C with prevacuum.

Autoclavable Olympus products are designed for steam sterilization according to the following standards:
- British standard BS3970
- European standard EN 285

Do not exceed a temperature of 138° C.
Prevacuum steam sterilization cycle
1. Evacuation (-0.935 bar)
2. Steaming and evacuation (-0.330 bar) 2x
3. Heating
4. Sterilization (134° C, 2.3 bar)
5. Evacuation (-0.935 bar)
6. Drying
7. Aeration

Proposed water and steam quality acc. to EN 285 : 1996

<table>
<thead>
<tr>
<th></th>
<th>Condensate</th>
<th>Feed-water</th>
</tr>
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<tr>
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<td>≤ 1 mg/l</td>
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<td>Pb</td>
<td>≤ 0.05 mg/kg</td>
<td>≤ 0.05 mg/l</td>
</tr>
<tr>
<td>Traces of heavy metals (except Fe, Cd, Pb)</td>
<td>≤ 0.1 mg/kg</td>
<td>≤ 0.1 mg/l</td>
</tr>
<tr>
<td>Cl</td>
<td>≤ 0.1 mg/kg</td>
<td>≤ 2 mg/l</td>
</tr>
<tr>
<td>P₂O₅</td>
<td>≤ 0.1 mg/kg</td>
<td>≤ 0.5 mg/l</td>
</tr>
<tr>
<td>Conductivity (at 20 °C)</td>
<td>≤ 3 μS/cm</td>
<td>≤ 15 μS/cm</td>
</tr>
<tr>
<td>pH</td>
<td>5 - 7</td>
<td>5 - 7</td>
</tr>
<tr>
<td>Colour</td>
<td>colourless</td>
<td>colourless</td>
</tr>
<tr>
<td></td>
<td>clear</td>
<td>clear</td>
</tr>
<tr>
<td></td>
<td>without residues</td>
<td>without residues</td>
</tr>
<tr>
<td>Water hardness (total alkaline earth ions)</td>
<td>≤ 0.02 mmol/l</td>
<td>≤ 0.02 mmol/l</td>
</tr>
</tbody>
</table>
Gas Sterilization

**Gas Sterilization Procedure**

- Disassemble the instrumentation.
- Open all stopcocks.
- Seal the instruments in appropriate instrument trays and in sterilizing foil (for Olympus instrument trays, see “Storage and Handling” section).
- Refer to the sterilizer’s instruction manual.
- Aerate the instruments sufficiently.

**Conditions for Low Temperature Steam and Formaldehyde Gas Sterilization (LTDF)**

Refer to EN 1480 or DIN 58 948-16.

Do not exceed the parameters outlined in the chart below.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gas concentration</td>
<td>2-6%</td>
</tr>
<tr>
<td>Temperature</td>
<td>60 °C (135 °F)</td>
</tr>
<tr>
<td>Pressure</td>
<td>max. 0.17 MPa (24 psi)</td>
</tr>
<tr>
<td>Humidity</td>
<td>&gt;70%</td>
</tr>
<tr>
<td>Exposure time</td>
<td>&gt;1 h</td>
</tr>
</tbody>
</table>

**Conditions Ethylene Oxide Gas Sterilization**

Refer to ANSI/AAMI ST41-1992 or DIN 58 948 for recommendations and standards.

Do not exceed the parameters outlined in the chart below.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gas concentration</td>
<td>600-700 mg/l</td>
</tr>
<tr>
<td>Temperature</td>
<td>55 °C (130 °F)</td>
</tr>
<tr>
<td>Pressure</td>
<td>0.1-0.17 MPa (16-24 psi)</td>
</tr>
<tr>
<td>Humidity</td>
<td>55%</td>
</tr>
<tr>
<td>Exposure time</td>
<td>&gt;2 h</td>
</tr>
</tbody>
</table>

**Aeration cycle**

- at room temperature ...7 days
- in an aeration chamber..12 h at 50-60 °C
- .........................................................(122-135 °F)
WARNING!
Gas Sterilization is Toxic
Ethylene oxide and formaldehyde are toxic and may present health hazards. Follow domestic health care regulations for compatibility of the procedures. After sterilizing the instruments, aerate them to remove toxic residues.
Other Sterilization Procedures

**STERRAD® Low Temperature Plasma Sterilization Procedure**
- For sterilization, disassemble the instrumentation.

- Open all stopcocks.

- Instruments with long narrow lumen must be sterilized using boosters. For details, refer to the sterilizer’s instruction manual.

- Seal the instruments in sterilizing foil or containers (any containment must be certified by its manufacturer for Sterrad use).

- Refer to the sterilizer’s instruction manual.

**CAUTION!**

**Risk of Discoloring in Sterrad Procedures**
Plasma sterilization may cause discoloring in some materials (e.g. aluminium). However, this does not impair the instrument’s function.
Steris Peracetic Acid Sterilization Procedure

- For sterilization, disassemble the instrumentation.
- Open all stopcocks.
- Refer to the sterilizer’s instruction manual.

Storage and Handling

Ambient Conditions for Storage

- Store the equipment in a clean and dry condition at room temperature (10-40°C, 30-85% humidity).
- Do not expose the equipment to direct sunlight.
- Do not expose the equipment to constant X-ray radiation.
- Do not store the equipment in a location where liquids may splash.
- Do not store the equipment under environmental conditions such as:
  - high atmospheric pressure
  - high or low temperatures
  - high or low humidity
  - ventilation
  - direct sunlight
  - dust
  - salty or sulfureous air
• Do not store the equipment where there is a risk of flammable gases.

■ **Preparation for Storage**
  • Disassemble the instruments.

• Open all stopcocks.

• Store electrical units on a flat surface. Do not incline the units. Make sure that units are not subjected to vibration and impacts.
• During short-term storage keep instruments in sterile condition and ready for next use.
• During long-term storage keep any equipment clean and ready for re-processing.

■ **Instrument Trays**
As the product’s transport packaging is not designed for storage, do not store the product in the transport packaging. Use instrument tray systems for storage (for Olympus instrument tray systems, see bottom).

■ **Storage Life of Sterilized Instruments**
The storage life of sterilized instruments depends on the type of packaging and the storage conditions (refer to DIN 58953, Teil 9, or local regulations). Double sterile package according to DIN 58946, Teil 9 prolongs the storage life.
Packaging stored on shelves in a cabinet
- Single sterile packaging: 24 hours 6 weeks
- Double sterile packaging: 6 weeks 6 months

**CAUTION!**

*Handle with Care*

Handle and store endoscopic equipment carefully. Do not expose it to mechanical shocks such as impact or fall. Instrument damage may occur.

**Olympus Instrument Tray Systems**

Olympus feature two lines of instrument tray systems, meeting the exact demands of individual customers:
- Moulded plastic instrument trays
- Stainless steel instrument trays

For details of these product lines and their availability in different markets, please contact your local Olympus representative. Olympus instrument tray systems are compatible to steam and gas sterilization.
Moulded Plastic Instrument Trays

The Olympus instrument tray system made of moulded plastic features differently designed instrument trays:
- Instrument trays for telescopes (part of delivery of some telescopes)
- Universal instrument tray A5970
- Universal insert trays for A5970
- Customized insert trays for A5970

Procedure:
- Open the instrument tray’s lid.
- Choose a compatible tray insert (only for instrument trays with tray inserts).
- Place compatible silicone mats into the tray and the tray insert (only for A5970, A5971, A5973).
- Place the tray insert into the instrument tray.
- Place the instruments into the instrument tray. Refer to the instrument tray’s instruction manual for a loading chart.
- Close the instrument tray’s lid.
- Before sterilization, seal the instrument tray in either an appropriate sterilizing foil or sterilization container.

Stainless Steel Instrument Trays

The Olympus instrument tray system made of stainless steel features two different tray designs:
- Instrument trays with filter
- Tray inserts customized for various instruments
- Instrument trays without filter and integrated tray insert

Instrument trays with filter can be directly used for steam sterilization. No other sealing is required.
For gas sterilization procedures use instrument trays without filter or remove the filter from the instrument tray.

A wrapping cloth is available which serves as a double sterile packaging according to DIN 58 946, Teil 9 (see above, only for steam sterilization).

Procedure:
- Open the instrument tray’s lid.
- Place the instruments into the tray insert. Refer to the tray insert’s instruction manual for a loading chart.
- Place the tray insert into the instrument tray.
- Close the instrument tray’s lid.
- For steam sterilization: Make sure that the instrument tray is equipped with a filter or seal the instrument tray in an appropriate sterilizing foil.
- If filters are used: Replace filters after 60 autoclave cycles.
- For gas sterilization procedures: Make sure that any filters are removed from the instrument tray. Seal the instrument tray in an appropriate sterilizing foil.

CAUTION!
Risk of Damage
When loading instrument trays, always press telescopes into the notches of the silicone bars as shown in the illustration.
SERVICE

The Olympus Organization

Manufacturer of this Equipment
If there is no other statement in the product specific instruction manual, items labelled with OLYMPUS GERMANY are manufactured by:
Olympus Winter & Ibe GmbH
Kuehnstraße 61
22045 Hamburg, Germany
Phone: .....................................................+49 40 66 96 60
Fax: .....................................................+49 40 66 96 62 06

Distributor in Asia, Australia, and Oceania
Olympus Singapore Pte. Ltd.
491B River Valley Road #12-01/04
Valley Point Office Tower
Singapore 248373
Phone: .....................................................+65 6834 -00 10
Fax: .....................................................+65 6834 -24 38

Distributor in Ireland
KeyMed (Ireland) Ltd.
KeyMed House, Lord Edward Court
Bridge Street Dublin 8
Phone: .....................................................01 677 48 55
Fax: .....................................................01 667 41 26

Distributor in the United Kingdom
KeyMed Ltd.
KeyMed House, Stock Road
Southend-on-Sea, Essex SS2 5QH, England
Phone: .....................................................01702-616 333
Fax: .....................................................01702-465 677
Distributors in Other Countries
For addresses of distributors in other countries, please contact Olympus Winter & Ibe, or see the address list on our web-site: www.olympus-owi.com

Repairs

Authorized Service Centers
Repairs may only be carried out by qualified servicing personnel which has been authorized by Olympus Winter & Ibe. Otherwise Olympus Winter & Ibe can not be held responsible for the safety, reliability, and performance of the product.

WARNING!
Effects on Patient and User Safety
There is a risk of damage to the product if the user or an unauthorized servicing agency attempts repair of a defect. A damaged product may cause injury of the patient or the user.

Loss of Warranty
Any guarantee or warranty claims towards Olympus Winter & Ibe are forfeited if the user or an unauthorized servicing agency attempts repair of a defect.
Unauthorized repair (left) compared to authorized repairs (right).

**Description of Defects**

To enable the Service Center to effect repairs speedily send the product together with a detailed description of the defect. The following particulars should be included:

- Catalog number
- Serial number or lot number (if possible)
- Precise description of the fault
- Delivery date
- Invoice copy (for possible claims on guarantee or warranty)
- Internal order number of the customer (for correct accounting of the repair order)

■ Hygiene
As a protective measure for the safety of the servicing staff submit the product to a complete cleaning and disinfection/sterilization procedure before sending it for repair.
In case this is not possible, for example because further disinfection or sterilization would damage the product completely, clean the product as thoroughly as possible and mark it accordingly.
Service Centers are entitled to refuse to repair soiled or contaminated products for reasons of safety.

■ Shipment
For transportation of the defective product use the original cardboard packing. If this is not possible, wrap each component individually in sufficient paper or sheets of foamed material and place them in a cardboard box.
Service Centers do not accept warranty claims for damage that was caused by insufficient packaging.
Telescopes should be shipped in an appropriate Olympus instrument tray.
Telescopes originally delivered with a protection tube should only been shipped with this protection tube.