

Addendum to Operation Manuals for OLYMPUS ULTRASOUND ENDOSCOPES

Affected Models: GF-UE190、GF-UE290

Affected Serial Numbers: All Serial Numbers

Inspection of air/water feeding function for detection of full clogs of the air/water channel

Purpose: The purpose of this new Instructions for Use (IFU) update for the referenced endoscopic ultrasound endoscopes is to assist users in detecting a full clog of the air/water channel following a patient procedure and prior to endoscope reprocessing. If channel blockage is identified, as per the new Instructions below, you should no longer use the endoscope and contact Olympus to make arrangements to repair the endoscope.

Instructions

The section below provides instructions and additional inspection points that need to be followed in connection with the sections described in chapter 3, chapter 4 and chapter 5 in the operation manual. Changes are summarized below and are denoted by underlined text in the subsequent sections of this Addendum.

- *During the inspection steps for the air /water feeding function and water feeding function into the balloon before use in chapter 3: Specific times for each step and a warning were added to help clarify these steps. The handling and cautions relating to the air/water valve used were also added in chapter 3 and chapter 5.*
- *A warning relating to the air/ water valve during the air/water feeding was added in chapter 4. Upon withdrawal, a new inspection step for the air/water channel was also added in chapter 4.*

The additional steps or warnings are highlighted denoted by underlined text in the instructions

Other parts of the instructions in chapter 3, chapter 4 and chapter 5 are not changed. Please refer to the operation manual of each specific endoscope, including the instructions for when any irregularity is suspected.

1. "Inspection of the endoscopic system" in Chapter 3

WARNING

If the air/water valve seals have excessive scratching and/or tears, body cavity pressure may make could cause patient fluids to flow into the air channel or water channel from the air/water nozzle (see Figure 1) , which could lead to channel clogging. Using an endoscope with a clogged channel could pose an infection control risk. If the air/water valve seals have excessive scratching and/or tears, replace it with a new one.

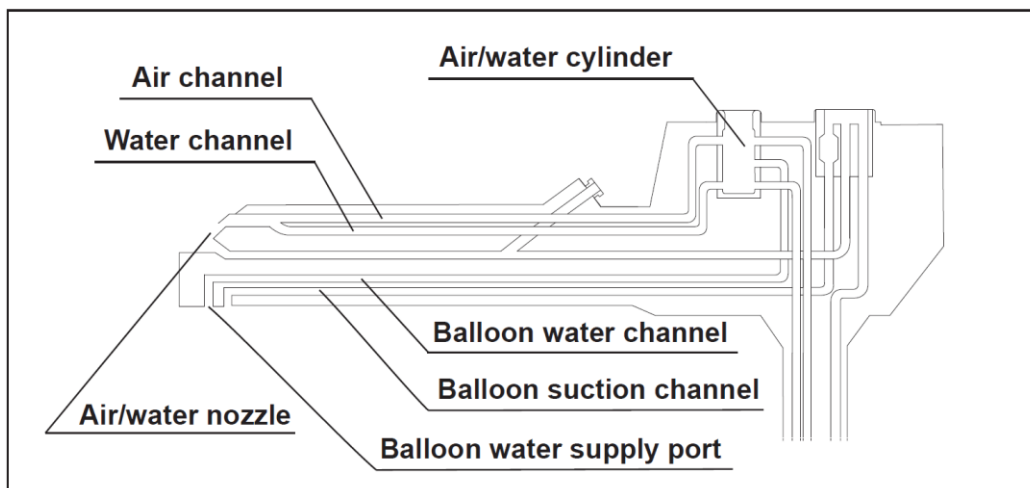


Figure 1

■ Inspection of the air-feeding function

○ Confirmation of emitting no air bubbles

1. Set the airflow regulator on the light source to “High”, as described in the light source’s instruction manual.
2. Immerse the distal end of the endoscope in sterile water to a depth of approximately 10cm.
3. Confirm that no air bubbles are emitted when the air/water valve is not operated.

WARNING

If a stream of air bubbles is emitted from the air/water nozzle even though the air/water valve is not being operated and the distal end of endoscope is 10cm or more below the surface of the sterile water, remove and reattach the air/water valve correctly, or replace it with a new one. If the endoscope is used while air is continuously fed, over-insufflation and patient injury may result.

NOTE

When the distal end of the endoscope is immersed less than 10cm below the surface of the sterile water, a small amount of air bubbles may be emitted from the air/water nozzle even when the air/water valve is not operated. This does not indicate a malfunction.

○ Confirmation of emitting air bubbles

1. Cover the hole in the air/water valve with your finger and confirm that air bubbles are continuously emitted from the air/water nozzle for 10 seconds.
2. Uncover the hole in the air/water valve and confirm that no air bubbles are emitted from the air/water nozzle.

■ Inspection of the objective lens cleaning function

○ Inspection of the water feeding function

1. Keep the air/water valve's hole covered with your finger
2. Depress the valve to the first stage. Observe the endoscopic image and confirm that water flows from the air/water nozzle on the entire objective lens for 10 seconds.
3. Release the valve. Observe the endoscopic image and confirm that the emission of water stops and that the valve returns smoothly to its original position.

○ Inspection of removing the remaining water from the objective lens

1. While observing the endoscopic image, feed air after feeding water by covering the hole in the air/water valve with your finger. Confirm that the emitted air dries the objective lens and clears the endoscopic image.
2. Release the air/water valve.

■ Inspection of the water feeding function into the balloon

1. Keep the air/water valve's hole covered with your finger.
2. Completely depress the valve.
Confirm that water is emitted through the balloon water feeding port for 10 seconds.
3. Release the air/water valve. Confirm that the emission of water stops and that the valve returns smoothly to its original position.

2. "Air/water feeding and suction" in Chapter 4

WARNING

If air/water feeding does not stop, turn the airflow regulator on the light source OFF and withdraw the distal end of the endoscope from the patient. After withdrawal, replace the air/water valve with a new one.

If the air/water valve is detached while the distal end of the endoscope is inserted into a patient, there is a higher potential of back flow of patient fluids from the air/water nozzle.

Patient fluids flowing into the air/water cylinder from the air/water channel may pose an infection control risk.

3. "Withdrawal of the endoscope" in chapter 4

■ Inspection of the air /water and balloon water feeding function after endoscopy

After withdrawal of the endoscope from the patient, perform the following channel inspection steps to detect residual blood and foreign material clogging the air/water and balloon channels.

Use MAJ-1444 Air/Water valve to conduct the following inspection steps.

1. When using the balloon method, remove the balloon as described in Section 4.6, "Removal of the balloon" and discard it.
2. Switch the airflow regulator to maximum output ("HIGH" or "3").
3. Prepare clean water in a 500 cm³ (500 ml) container.
4. Immerse the distal end of the insertion tube in the water.
5. Cover the hole in the air/water valve with your finger and confirm that air bubbles are continuously emitted from the air/water nozzle for 10 seconds.

WARNING

If air bubbles are not emitted continuously, the air/water channel may be clogged by patient fluids. If your scope does not continuously emit air bubbles during this step, please immediately cease use of the scope and contact Olympus to schedule service and repair of the scope.

6. Keep the air/water valve's hole covered with your finger and depress the valve to the first stage. Observe the endoscopic image and confirm that water flows from the air/water nozzle on the entire objective lens for 10 seconds.

WARNING

- If water does not exit, the air/water channel may be clogged by patient fluids. If water does not exit from your scope during this step, please immediately cease use of the scope and contact Olympus to schedule service and repair of the scope.
- Spray may occur because water comes out from the air/water nozzle.

7. Keep the air/water valve's hole covered with your finger and completely depress the valve. Observe the water is emitted through the balloon water supply port for 10 seconds.

WARNING

- If water does not emit, the balloon water channel may be clogged by patient fluids. If water is not emitted from your scope during this step, please immediately cease use of the scope and contact Olympus to schedule service and repair of the scope.
- Spray may occur because water comes out from the balloon water supply port.
- Using an endoscope with a clogged channel could pose an infection control risk.

8. Reprocess the endoscope and accessories after withdrawal of the endoscope and inspection of air/water and balloon channel function as described in the "REPROCESSING MANUAL" with your endoscope model listed on the cover.

4. "Troubleshooting guide" in Chapter 5

■ Air/water feeding and water feeding function into the balloon

Irregularity description	Possible cause	Solution
No air feeding.	The air pump of the light source is not operating.	Press the "LOW", "MED", or "HIGH" button on the light source as described in the light source's instruction manual.
	The air/water valve is damaged.	<u>After withdrawing the distal end of the endoscope from the patient, replace it with a new one.</u>
No water feeding.	The air pump of the light source is not operating.	Press the "LOW", "MED", or "HIGH" button on the light source as described in the light source's instruction manual.
	There is no sterile water in the water container.	Add sterile water to fill the container to the specified water level.
	The air/water valve is damaged.	<u>After withdrawing the distal end of the endoscope from the patient, replace it with a new one.</u>
No water is fed to the objective lens surface.	The air/water valve is not depressed properly.	Confirm whether the air/water valve is depressed to the first position or the air/water valve is depressed completely by hand and adjust it.
	There is not enough sterile water in the water container.	Add sterile water to the water container until it reaches the specified water level.
	The air/water valve is broken.	<u>After withdrawing the distal end of the endoscope from the patient, replace it with a new one.</u>

Irregularity description	Possible cause	Solution
The balloon cannot be inflated.	The air/water valve is not depressed properly.	Depress the air/water valve completely.
	There is not enough sterile water in the water container.	Add sterile water to the water container until it reaches the specified water level.
	The band of the balloon is detached.	Firmly attach the band of the balloon to the balloon attachment groove of the endoscope's distal end.
	There is a hole in the balloon.	Replace it with a new one.
	The air/water valve is broken.	<u>After withdrawing the distal end of the endoscope from the patient, replace it with a new one.</u>
The air/water valve is sticky.	The air/water valve is dirty.	Remove the air/water valve. Reprocess the air/water valve and then attach it again.
	The air/water valve is damaged.	<u>After withdrawing the distal end of the endoscope from the patient, replace it with a new one.</u>
The air/water valve cannot be attached.	An improper air/water valve is used.	Use a proper air/water valve.
	The air/water valve is damaged.	<u>After withdrawing the distal end of the endoscope from the patient, replace it with a new one.</u>
The air/water valve cannot be attached.	An incompatible air/water valve is used.	Use a compatible air/water valve.
	The air/water valve is damaged.	<u>After withdrawing the distal end of the endoscope from the patient, replace it with a new one.</u>
The air is continuously fed.	The air/water valve is damaged.	<u>After withdrawing the distal end of the endoscope from the patient, turn the airflow regulator on the light source OFF and replace the valve with a new one.</u>

Irregularity description	Possible cause	Solution
Water is continuously fed.	The air/water valve is damaged.	<u>After withdrawing the distal end of the endoscope from the patient, turn the airflow regulator on the light source OFF and replace the valve with a new one.</u>

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