October 18, 2024

URGENT: MEDICAL DEVICE CORRECTION

Olympus EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE

Product Name:

Catalog number	Serial Number Range	UDI-DI
GIF-1TH190	Before 2446103 and After 2500453	04953170343360 04953170437014

Attention: Endoscopy Department and Risk Management

Dear Healthcare Provider:

Olympus is writing to inform you that we are issuing validated, new reprocessing instructions for the Olympus GIF-1TH190 Gastrointestinal Videoscope ("GIF-1TH190") consisting of revised channel drying times before ethylene oxide sterilization or prior to storage, following disinfection. The GIF-1TH190 is intended for use in the upper digestive tract, including the esophagus, stomach and duodenum.

Reason for Action:

Olympus previously revised cleaning instructions for the GIF-1TH190 in October 2023 to issue new updated channel drying steps. Olympus conducted user evaluation, through human factors validation, and determined further clarification is required to improve the instructions for easier understanding of each drying step. As a result, Olympus is issuing a revised IFU addendum that informs customers that the channel drying time has been extended by 12 minutes to purge water from the channels. This is accomplished by drying each channel for 3 minutes, in the sequence described in the addendum. Ensure all reprocessing personnel are completely knowledgeable and thoroughly trained on the new water purge requirements. Olympus has received 16 reportable complaints related to this issue.

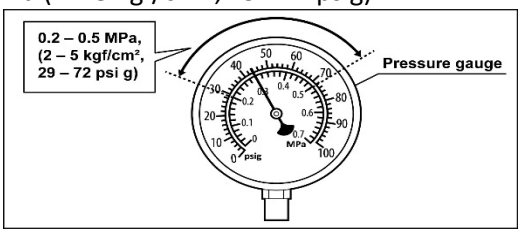
- The revised instructions are described BELOW AND in the ATTACHED addendum.

■***Dry the endoscope***

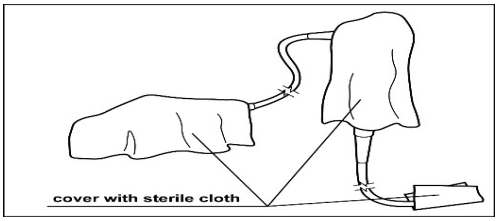
CAUTION

When aerating the endoscope channels, the air pressure must not exceed 0.5 MPa (5 kgf/cm2, 72 psig).
Higher pressures may cause damage to the endoscope.

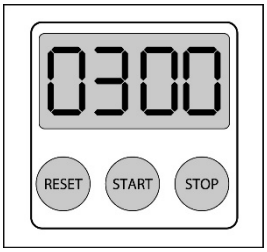
1. Confirm that the compressed filtered air is 0.2 – 0.5 MPa (2 – 5 kgf/cm2, 29 –72 psig).



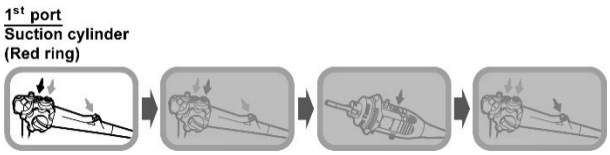
2. To prevent splashing from the channel openings, cover the distal end, the control section, and the endoscope connector of the endoscope in sterile lint-free cloths.

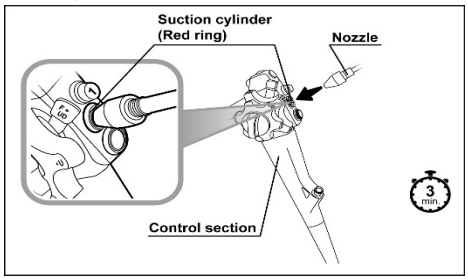


3. Prepare a timer and set the alarm to beep in 3minutes.



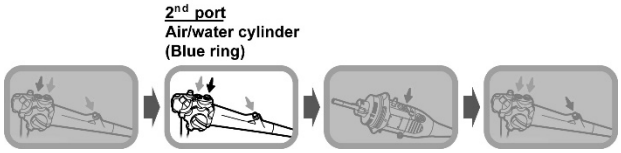
4. (1st port) Hold the control section, and aerate the suction cylinder, as follows:

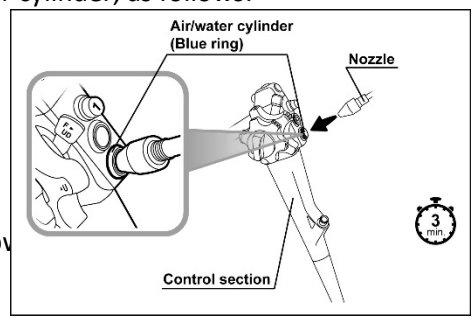




a) Start the timer. (3 minutes)
b) Push the nozzle straight into the suction cylinder and blow.
c) Keep blowing until the timer alarm beeps.

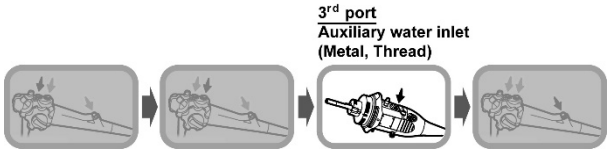
5. (2nd port) Hold the control section, and aerate the air/water cylinder, as follows:

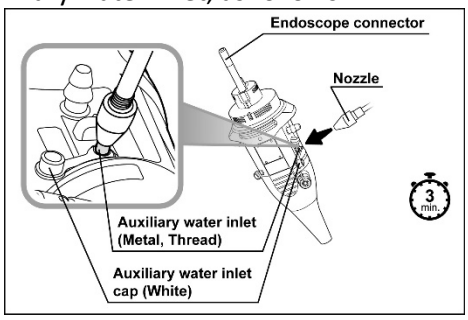




a) Start the timer. (3 minutes)
b) Push the nozzle straight into the air/water cylinder and blow
c) Keep blowing until the timer alarm beeps.

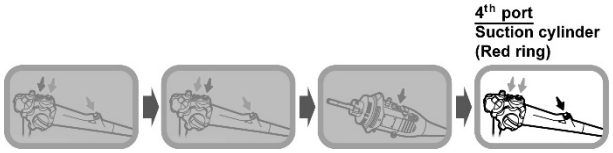
6. (3rd port) Hold the endoscope connector, and aerate the auxiliary water inlet, as follows:

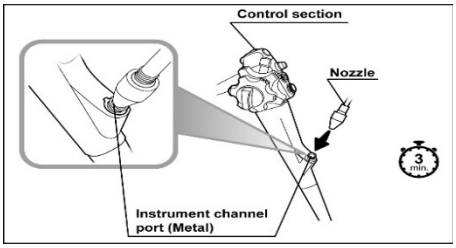




a) Start the timer. (3 minutes)
b) Push the nozzle tip straight into the auxiliary water inlet to minimize air leaks and blow air.
c) Keep blowing until the timer alarm beeps.

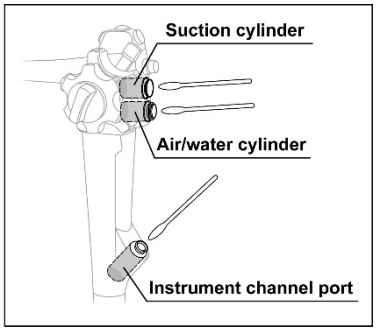
7. (4th port) Hold the control section , and aerate the instrument channel port, as follows:





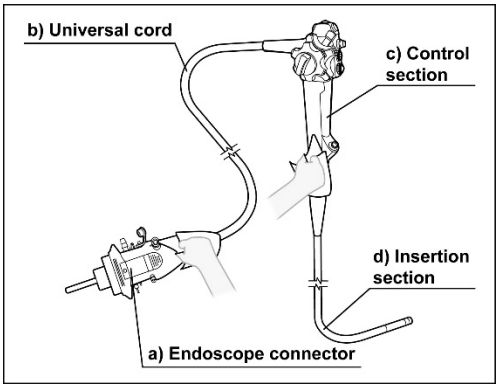
a) Start the timer. (3 minutes)
b) Push the nozzle straight into the instrument channel port and blow.
c) Keep blowing until the timer alarm beeps.

8. Thoroughly dry the inside of the suction cylinder, the air/water cylinder, and the instrument channel port of the endoscope, using sterile cotton swabs.



9. Wipe all of the following external surfaces of the endoscope with a sterile lint-free cloth until they are thoroughly dry.

a) Endoscope connector
b) Universal cord
c) Control section
d) Insertion section



Risk to Health:

Failure to purge moisture from endoscope channels was identified as a factor contributing to ineffective ethylene oxide sterilization, which could potentially cause patient infections, and in rare cases, sepsis and/or death. These infections may require medical interventions, the administration of antibiotics, and/or hospitalization. Ethylene oxide sterilization is an alternative to high level disinfection as described in the GIF-1TH190 Reprocessing Manual.

Actions Required:

Our records indicate that your facility has purchased one or more of the affected products. The range of affected serial numbers is included at the top of this letter.

Olympus requires you to take the following actions:

1. Carefully read the content of this notification.
2. Implement use of the enclosed Addendum stating that the channel drying time has been extended by 12 minutes to purge water from the channels. This is accomplished by drying each channel for 3 minutes, in the sequence described in the addendum. Ensure all reprocessing personnel are completely knowledgeable and thoroughly trained on the new water purge requirements.
3. Olympus requests that you acknowledge receipt of this letter. Acknowledge receipt of this letter through the Olympus web portal:
    a. Go to https://olympusamerica.com/recall
    b. Enter the recall number "0461"
    c. Complete the form as instructed and include your account ID number: [XXXXXXXX]
4. If you have further distributed this product, identify your customers, and forward them this notification.

Olympus requests that you report any complaints, including infections or persistent microbial colonization associated with any Olympus endoscope to the Technical Assistance Center (TAC) at 1- 800-848-9024 (option 1), and the FDA. Adverse events experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact me by phone at (647) 999-3203 from Monday through Friday, 9 am to 5 pm EDT, or by e-mail at Cynthia.Ow@olympus.com.

Sincerely,

Cynthia Ow

Cynthia Ow
Field Corrective Actions Lead, Americas