Olympus Reference: QIL FY25-EMEA-20-FY25-024 GIF-1TH190 IFU
Date: 18.10.2024

URGENT FIELD SAFETY NOTICE

RE: Olympus EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE

Material ID	Model Number	Serial Numbers
N4505840	GIF-1TH190	All
N4505850	GIF-1TH190	All

Attention: Endoscopy Department, Risk Management Department

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 issued 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.

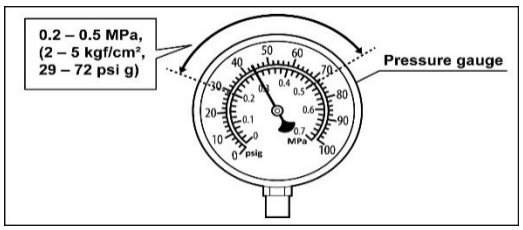
- The revised instructions are described BELOW AND in the ATTACHED addendum.

■*Dry the endoscope*

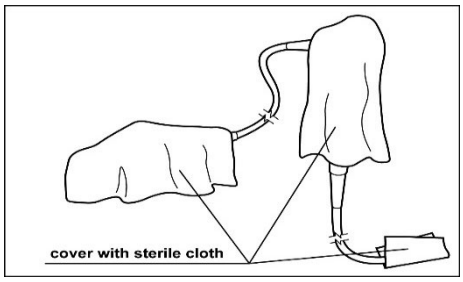
CAUTION

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.

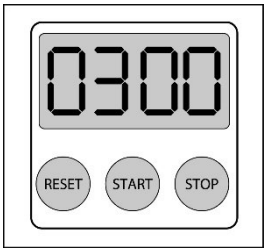
1. Confirm that the compressed filtered air is 0.2 – 0.5 MPa (2 – 5 kgf/cm2, 29 –72 psig).



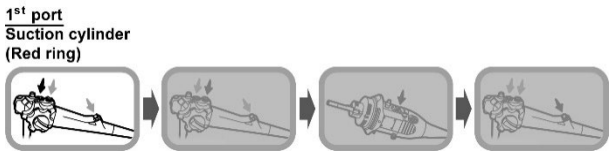
2.To prevent splashing from the channel openings, cover the distal end, the control section, and the endoscope connector of the endoscope in sterile lint-free cloths.

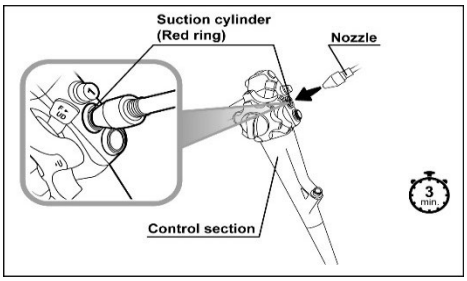


3. Prepare a timer and set the alarm to beep in 3minutes.



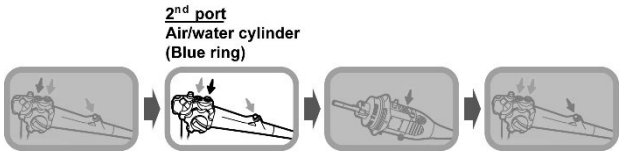
4. (1st port) Hold the control section, and aerate the suction cylinder, as follows:

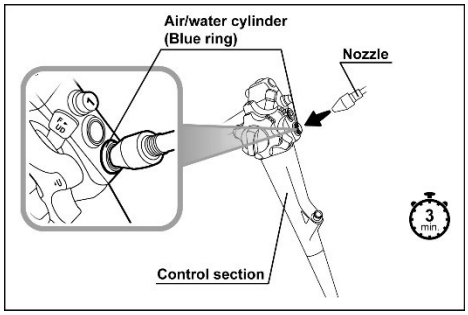




a) Start the timer. (3 minutes)
b) Push the nozzle straight into the suction cylinder and blow.
c) Keep blowing until the timer alarm beeps.

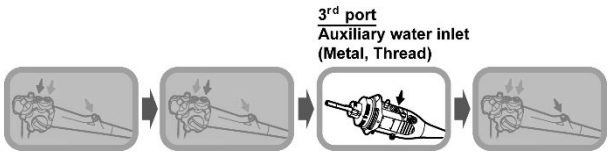
5. (2nd port) Hold the control section, and aerate the air/water cylinder, as follows:

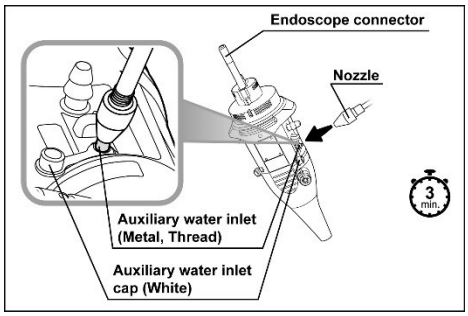




a) Start the timer. (3 minutes)
b) Push the nozzle straight into the air/water cylinder and blow.
c) Keep blowing until the timer alarm beeps.

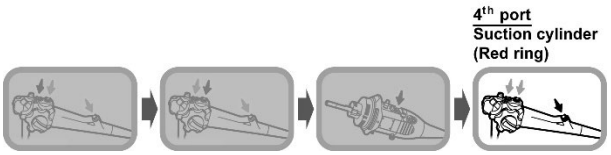
6. (3rd port) Hold the endoscope connector, and aerate the auxiliary water inlet, as follows:

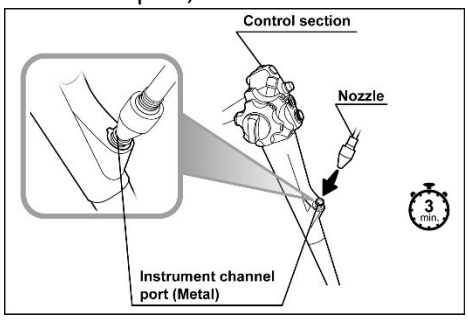




a) Start the timer. (3 minutes)
b) Push the nozzle tip straight into the auxiliary water inlet to minimize air leaks and blow air.
c) Keep blowing until the timer alarm beeps.

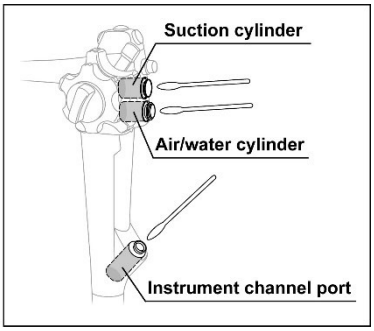
7. (4th port) Hold the control section , and aerate the instrument channel port, as follows:



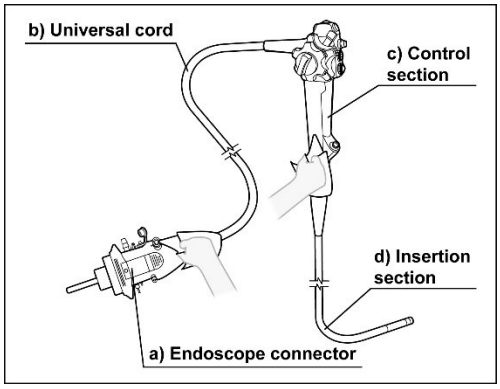


a) Start the timer. (3 minutes)
b) Push the nozzle straight into the instrument channel port and blow.
c) Keep blowing until the timer alarm beeps.

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.

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. Indicate on the Reply Form that you have received and understood this notification by filling out and returning the completed enclosed Reply Form back to your local Olympus representative XXX latest by XXX.
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 *[local facility complaint reporting contact].* Adverse events experienced with the use of this product may also be reported *[local competent authority]* by *[method].*

If you require additional information about the GIF-1TH190 reprocessing, you can obtain additional information as follows:

- You can contact our *[local technical support department]* at *[phone number/method]* and the *[department name]* can assist you in answering questions.

Olympus fully appreciates your prompt cooperation. If you require additional information, please do not hesitate to contact *[me directly at XXXX@olympus.com/ Olympus directly at (XXX) XXX-XXXX from Monday through Friday or by e-mail at XXX].*

Sincerely,
Name
Olympus title

REPLY FORM

QIL FY25-EMEA-20-FY25-024 GIF-1TH190 IFU

Facility Name	
Facility Address	
Contact Name	
Additional Customer Requests (Indicate if you have any additional requests to support this action)	

I acknowledge receipt of this notification. I confirm that I have further communicated to any affected departments.

Completed By:		
Name	*Signature*	*Date (YYYY-MM-DD)*

Please send the completed form to *XXX* by date *XXX*.