

Reference: 2024-007M

16 October 2024

URGENT - FIELD SAFETY NOTICE

To user of **Olympus Evis Exera III Gastrointestinal Videoscope**

Product Name:

Catalog number	Serial Number Range
GIF-1TH190	Before 2446103 and After 2500453

Re: Olympus to Provide New Reprocessing Instructions for GIF-1TH190.

Attention: **Endoscopy Department, Risk Management Department**

Dear Health Care 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 27th September 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.

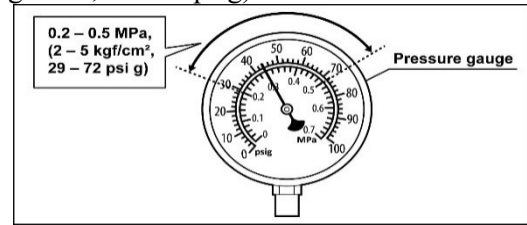
- The revised instructions are described BELOW AND in the ATTACHED addendum.

■ **Dry the endoscope**

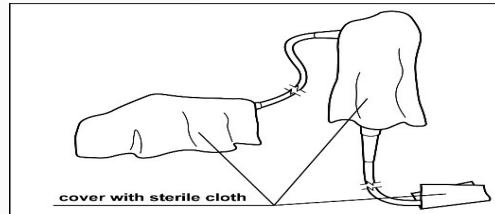
CAUTION

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.

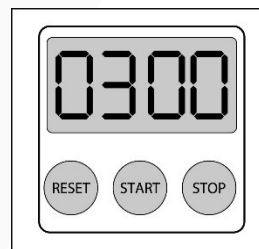
1. Confirm that the compressed filtered air is 0.2 – 0.5 MPa (2 – 5 kgf/cm², 29 – 72 psig).



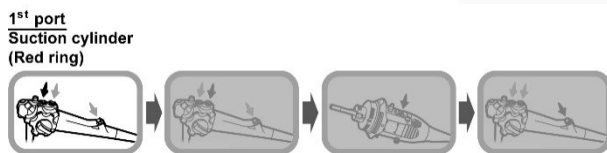
2. To prevent splashing from the channel openings, cover the distal end, the control section, and the endoscope connector of the endoscope in sterile lint-free cloths.



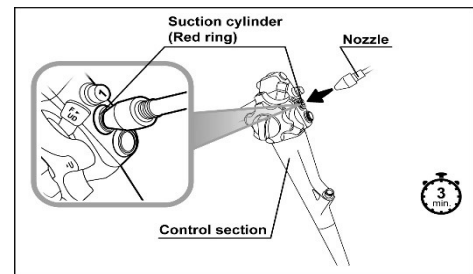
3. Prepare a timer and set the alarm to beep in 3 minutes.



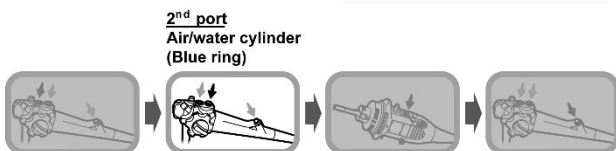
4. (1st port) Hold the control section, and aerate the suction cylinder, as follows:



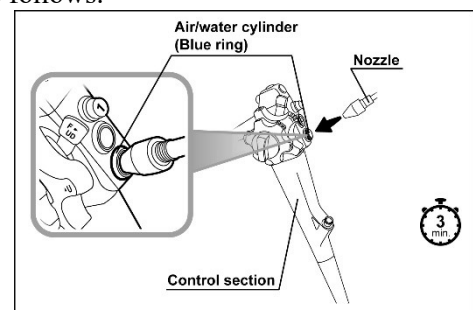
- a) Start the timer. (3 minutes)
- b) Push the nozzle straight into the suction cylinder and blow.
- c) Keep blowing until the timer alarm beeps.



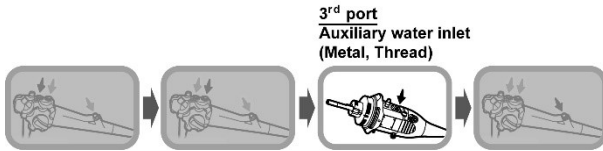
5. (2nd port) Hold the control section, and aerate the air/water cylinder, as follows:



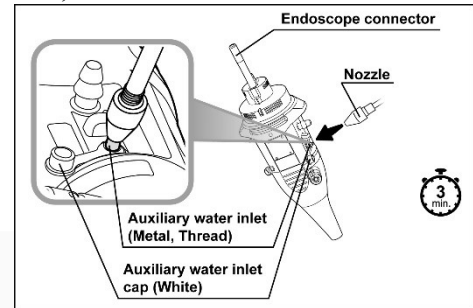
- a) Start the timer. (3 minutes)
- b) Push the nozzle straight into the air/water cylinder and blow.
- c) Keep blowing until the timer alarm beeps.



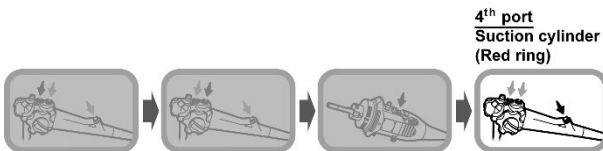
6. (3rd port) Hold the endoscope connector, and aerate the auxiliary water inlet, as follows:



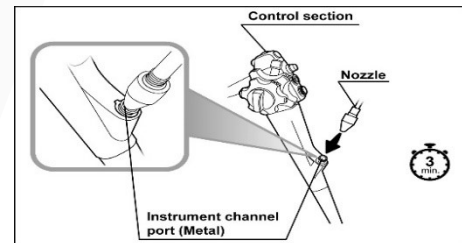
- Start the timer. (3 minutes)
- Push the nozzle tip straight into the auxiliary water inlet to minimize air leaks and blow air.
- Keep blowing until the timer alarm beeps.



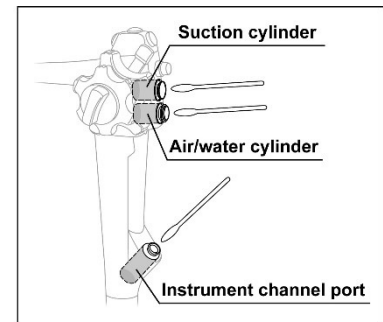
7. (4th port) Hold the control section, and aerate the instrument channel port, as follows:



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

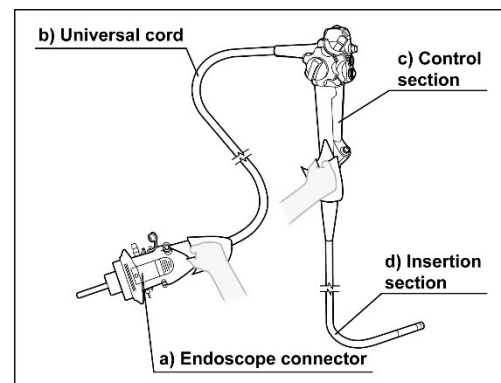


8. Thoroughly dry the inside of the suction cylinder, the air/water cylinder, and the instrument channel port of the endoscope, using sterile cotton swabs.



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

- Endoscope connector
- Universal cord
- Control section
- 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 one or more of the affected products. The range of affected serial numbers is included at the top of this letter. Therefore, 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. If you have further distributed this product, identify your customer's, and forward them this notification.
4. Olympus request that you acknowledge receipt of this letter and return the 'Response Form' to us.

Olympus requests that you report any complaints, including infections or persistent microbial colonization associated with any Olympus endoscope and adverse events experienced with the use of this product to Olympus.

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact us.

Contact for enquiries.

Regulatory Affairs and Quality Assurance Department

Email : mes-ra.oml@olympus.com

Tel : (603) 7650 8990

Fax : (603) 7650 8999

The **Medical Device Authority** has been informed of this notice.

Yours sincerely,

Hideki Nagai

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Hideki Nagai
Managing Director
Olympus (Malaysia) Sdn. Bhd.

Response Form

Please send the complete and signed Response Form to Regulatory Affairs and Quality Assurance Department at:

To : Olympus (Malaysia) Sdn. Bhd, Regulatory Affairs & Quality Assurance
Fax/Email : (603) 7650 8999 / mes-ra.oml@olympus.com
From : _____ [Facility Name] Contact no.: _____
Date : _____
Ref : 2024-007M

URGENT - FIELD SAFETY NOTICE

Re: Olympus to Provide New Reprocessing Instructions for GIF-1TH190.

I acknowledge receipt of the Field Safety Notice (“FSN”) referenced above. I confirm that I have further communicated to any affected departments.

Check the applicable boxes below:

- I DO NOT have affected product remaining. Product has been condemned or discarded.
- I DO have the affected product, which I will adhere to the New Reprocessing Instructions.

Additional Customer Requests:

(Indicate if you have any additional requests to support this action)

Name: _____

Designation: _____

.....
Signature & Company Stamp

.....
Date