

Reference: 2023-010M

27 September 2023

URGENT - FIELD SAFETY NOTICE

To all users of Olympus EVIS EXERA III Gastrointestinal Videoscope **GIF-1TH190 (All serial numbers)**

Re: Revised Instructions of Updated Drying Procedure for the GIF-1TH190.

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

Dear Health Care Practitioner,

Olympus has become aware of a matter that requires your attention. This Safety Notice pertains to the Olympus EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-1TH190.

Our records indicate that your facility has purchased one or more of the GIF-1TH190.

This endoscope is intended for use in endoscopic diagnosis and treatment within the upper digestive tract (including the esophagus, stomach, and duodenum).

The GIF-1TH190 Reprocessing Manual has instructions for either High Level Disinfection (HLD) reprocessing or Ethylene Oxide Gas (EOG) sterilization after endoscope cleaning.

As a result of testing, Olympus discovered EOG sterilization failures in which the GIF-1TH190 failed to achieve sterilization following the GIF-1TH190's Reprocessing Manual. As a result of the subsequent investigation, Olympus determined that changes are required to the endoscope's channel drying steps following cleaning and prior to EOG sterilization in order to ensure effective endoscope sterilization. Accordingly, Olympus has updated the instructions for the endoscope channel's drying process and validated that the new, updated channel drying steps will result in GIF-1TH190 endoscope EOG sterilization. The revised instructions for the "Dry the endoscope" in Chapter 5.7 of the GIF-1TH190 Reprocessing Manual are provided in the attached Addendum.

Risk to Health

In the current drying procedure for the channel prior to EOG sterilization, the endoscope may not be adequately sterilized.

The risk to patient health is patient infection if the endoscope is not sterilized.

Actions to be taken by the end user.

Olympus request you to take the following actions:

1. Inspect your inventory for the referenced device. Please check all areas of the hospital to determine if any of these devices remain in inventory.
2. Carefully read the content of this Field Safety Notice as well as the attached "Addendum". The Addendum provides the new, revised channel drying steps.
3. Ensure all reprocessing personnel are completely knowledgeable and thoroughly aware of the contents.
4. Olympus requests that you acknowledge receipt of this letter return the 'Response Form' to us.
5. If you have further distributed this product, identify your customers, forward them this notification, and appropriately document your notification process.

Olympus requests that you report any complaints including adverse events experienced with the use of this product to Olympus.

Olympus regrets any inconvenience caused and fully appreciates your cooperation in this matter. Please do not hesitate to contact us for any additional information or support concerning this matter.

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.

EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE

OLYMPUS GIF-1TH190

Instructions

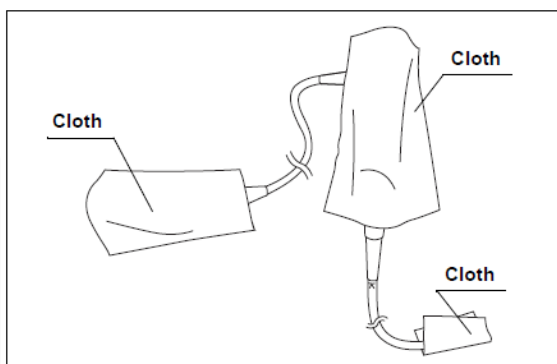
The sections below provide updated information on the drying procedure during rinsing step in Chapter “5.7 Rinsing the endoscope and accessories following disinfection”. Specifically, the steps below replace or add the “■ Dry the endoscope” section of Chapter 5.7 (following the “■ Alcohol flush” section). Other parts of the instruction manual have not changed.

■ Dry the endoscope

CAUTION

When aerating the endoscope channels, the air pressure must not exceed 0.5 MPa (5 kgf/cm², 71 psig). Higher pressures may cause damage to the endoscope.

1. Cover the distal end, the control section, and the endoscope connector of the endoscope with sterile lint-free cloths to prevent splashing alcohol or water from the channel openings.



2. Supply compressed filtered air at a pressure of 0.2 – 0.5 MPa into the suction cylinder opening until no alcohol or water exits from the distal end, the instrument channel port, or the suction connector. Supply compressed air for 3 minutes minimum for alcohol and 90 seconds minimum for water.

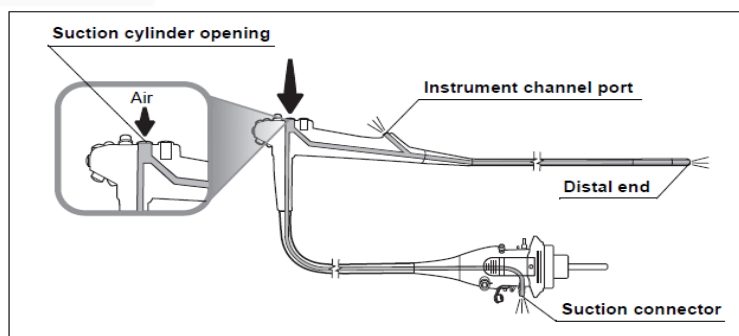


Figure 5.90

3. Supply compressed filtered air at a pressure of 0.2 – 0.5 MPa into the air/water cylinder opening until no alcohol or water exits from the distal end, the air supply connector, the water supply connector, and the air pipe of the endoscope. Supply compressed air for 3 minutes minimum for alcohol and 90 seconds minimum for water.

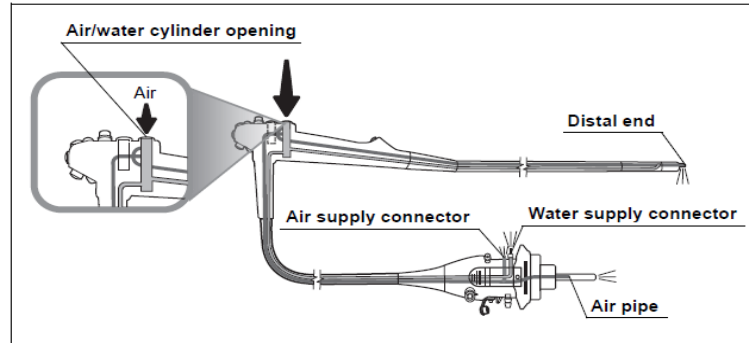


Figure 5.91

4. Supply compressed filtered air at a pressure of 0.2 – 0.5 MPa into the auxiliary water inlet until no alcohol or water exits from the distal end of the endoscope. Supply compressed air for 3 minutes minimum for alcohol and 90 seconds minimum for water.

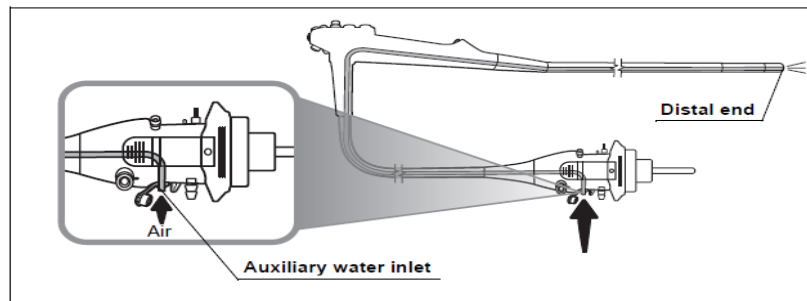
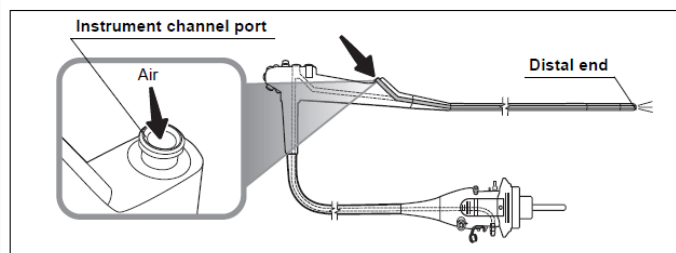
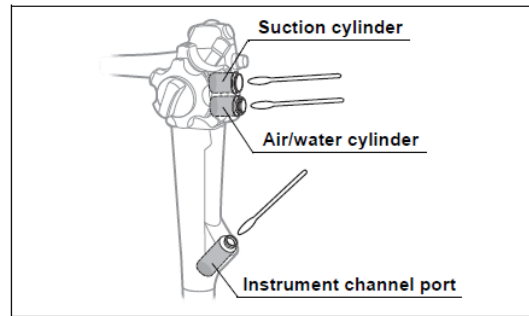


Figure 5.92

5. Supply compressed filtered air at a pressure of 0.2 – 0.5 MPa into the instrument channel port until no alcohol or water exits from the distal end of the endoscope. Supply compressed air for 3 minutes minimum for alcohol and 90 seconds minimum for water.



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



7. Thoroughly dry the external surfaces of the endoscope by wiping with sterile lint-free cloths.

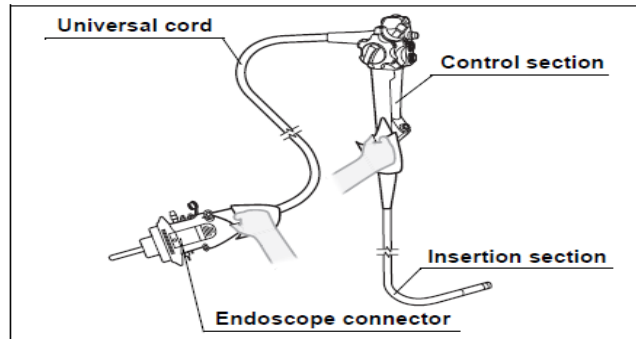


Figure 5.95

End.

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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 and Quality Assurance
Fax/Email : (603) 7650 8999 / mes-ra.oml@olympus.com
From : _____ [Facility Name] Contact no.: _____
Date : _____
Ref : 2023-010M

URGENT - FIELD SAFETY NOTICE

Re: Revised Instructions of Updated Drying Procedure for the GIF-1TH190.

I acknowledge receipt of the Field Safety Notice (“FSN”) referenced above. I understand that I need to undertake the action(s) listed in the FSN.

Check the applicable boxes below:

- I DO NOT have affected devices remaining. All have been condemned or discarded.
- I DO have the affected devices, which I will adhere to the FSN.

MODEL NO.	SERIAL NUMBERS
EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-1TH190	

Name: _____

Designation: _____

.....
Signature & Company Stamp

.....
Date






2023-010M FSN - Customer Letter

Final Audit Report

2023-09-27

Created:	2023-09-27
By:	Seo Ching Yeoh (seoching.yeoh@olympus.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAAdDu8tehbRw6YaJol6ELo3EG6Hxqx4Ayw

"2023-010M FSN - Customer Letter" History

-  Document created by Seo Ching Yeoh (seoching.yeoh@olympus.com)
2023-09-27 - 6:30:50 AM GMT
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