Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical
Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 247 **dated** 26/11/2023 **Regarding NCMDR Field Safety Notice of EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE from (mfr: Olympus Corporation of the Americas).**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DGPA&DC**
- **Director of Pharmacovigilance & Drug Information Dept, DGPA&DC**
- **Director of Drug Control Department, DGPA&DC**
- **Director of Pharmaceutical Licensing Department, DGPA&DC**
- **Director of Central Quality Control Lab., DGPA&DC**
- **Supdt. of Central Drug Information**

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

ISO 9001:2015 CERTIFIED

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

Sultanate of Oman
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Circular No. 247 / 2023

12 -05-1445 H
26 -11-2023

FSN of EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE from Olympus Corporation of the Americas.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19768
Product	EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE.
Description	Endoscopy and endoscopic treatment.
Manufacturer	Olympus Corporation of the Americas.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	Material ID: N4505850 and N4505840 Model: GIF-1TH190 All Serial Numbers
Reason	EOG sterilization failures have been discovered in which the GIF-1TH190 failed to achieve sterilization following the GIF-1TH190's Reprocessing Manual.
Action	1. Please carefully read the content of the attachment as well as "Addendum". The Addendum provides the new, revised channel drying steps. Please ensure all reprocessing personnel are completely knowledgeable and thoroughly aware of the contents. 2. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
Director General

PADC
Directorate General of Pharmaceutical Affairs & Drug Control
ISO

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

OLYMPUS

Date: October 30,2023
Olympus Reference: QIL FY24-EMEA-20- FY24-OMSC-20-GIF-1TH190

URGENT FIELD SAFETY NOTICE

RE: EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-1TH190
Attention: Endoscopy Department, Risk Management Department

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

Dear Health Care Provider,

Olympus has become aware of a matter that requires your attention. This Urgent Field Safety Notice pertains to the EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-1TH190 (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 mandatory instructions for cleaning and disinfection with an optional final Ethylene Oxide Gas (EOG) sterilization.
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 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 "Dry the endoscope" in Chapter 5.7 of the GIF-1TH190 Reprocessing Manual are provided in the attached Addendum.

Risk to Health, if EOG is performed

In the current drying procedure for the channels prior to EOG sterilization, the endoscope may not be adequately sterilized.
The risk to patient health is patient infection, in case the channels drying procedure from the Olympus IFU is used prior to EOG sterilization.

Action steps to be taken by the end user:

Olympus requests you to take the following actions:

1. Carefully read the content of this Urgent Field Safety Notice (FSN) as well as the attached "Addendum." The Addendum provides the new, revised channel drying steps.
2. Ensure all reprocessing personnel are completely knowledgeable and thoroughly aware of the contents.

OLYMPUS

3. Inspect your inventory for the referenced device. Please check all areas of the hospital to determine if any of these devices remain in inventory.
4. Indicate on the Reply Form that you have received and understood this Field Safety Notice by filling out and returning the completed enclosed Reply Form back to your local Olympus representative latest by 13.11.2023.
5. If you have distributed these devices outside your facility, please notify your customers of this matter immediately by forwarding them this Field Safety Notice. Please appropriately document your notification process and let us know the end-customer feedback accordingly.

Olympus requests that you report any complaints to ra@olympus-mea.com

Olympus regrets any inconvenience caused and fully appreciates your cooperation in this matter. Please do not hesitate to contact me directly at ra@olympus-mea.com for any additional information or support concerning this matter.

Sincerely,

Fadila Ezzahid
Regional Quality Assurance & Regulatory Affairs Specialist Middle East & Africa
Olympus MEA FZ-LLC, P.O. Box: 33607 Dubai
Registration No. 93456 (Dubai Development Authority)
Dubai Science Park - Laboratory Complex - Dubai - United Arab Emirates

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REPLY FORM – QIL FY24-EMEA-20- FY24-OMSC-20-GIF-1TH190

OLYMPUS URGENT FIELD SAFETY NOTICE **EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-1TH190**
[Name & Address of Hospital/Medical Facility]
[Dept/Attn]
[Date]

I herewith acknowledge the receipt of your Field Safety Notice.
Further I confirm that I have transferred the content of the attached FSN to all affected departments on which this action has an impact. I understand the necessity of following the instructions carefully.

Name (Signature) _____

Name (Print) _____

Position _____

Please send your completed paper form response to ra@olympus-mea.com latest by 13.11.2023.

OLYMPUS INSTRUCTIONS Addendum

EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE

OLYMPUS GIF-1TH190

Instructions

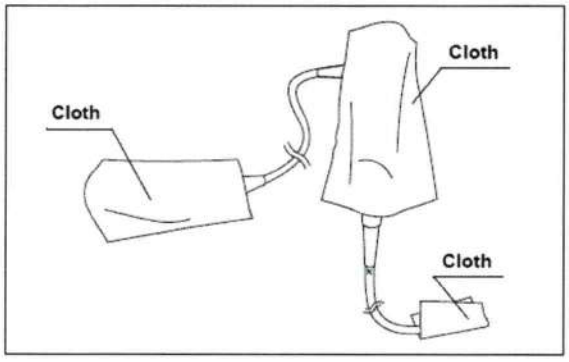
The sections below provide updated information on the drying procedure during rinsing step in Chapter "5.7 Rinsing the endoscope and accessories following disinfection". Specifically, the steps below replace or add the "■ Dry the endoscope" section of Chapter 5.7 (following the "■*Alcohol flush*" section).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

■ *Dry the endoscope*

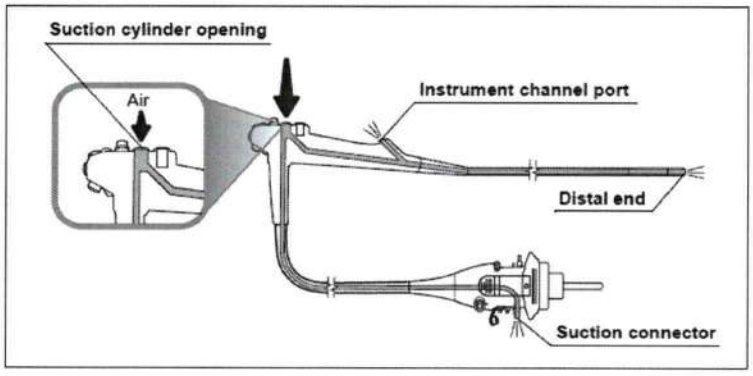
CAUTION

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.

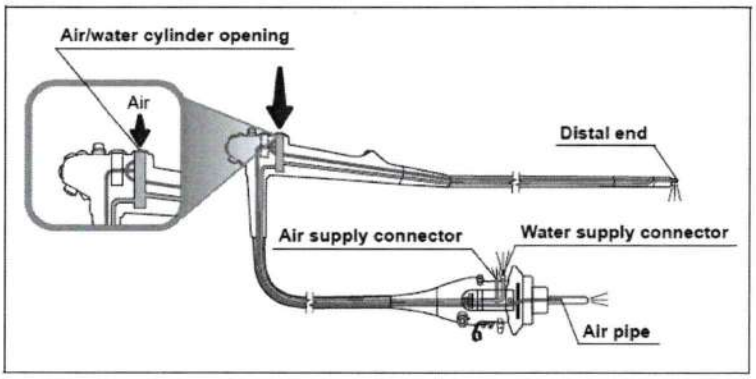


2. Supply compressed filtered air at a pressure of 0.2 – 0.5 MPa into the suction cylinder opening until no alcohol or water exits from the distal end, the instrument channel port, or the suction connector. Supply compressed air for 3 minutes minimum for alcohol and 90 seconds minimum for water.

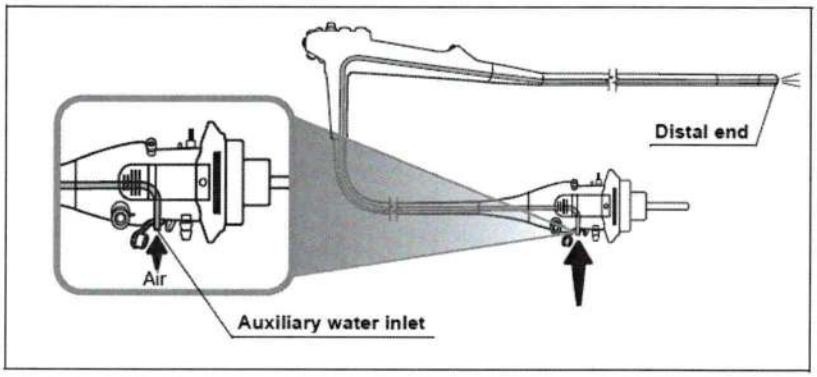


3. Supply compressed filtered air at a pressure of 0.2 – 0.5 MPa into the air/water

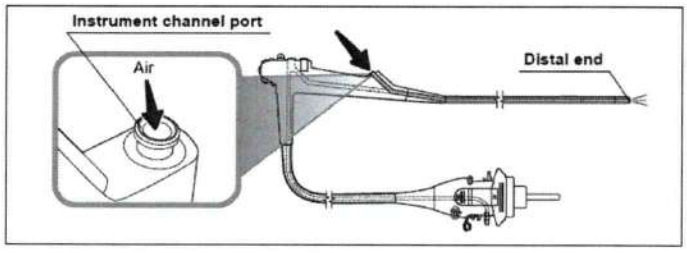
cylinder opening until no alcohol or water exits from the distal end, the air supply connector, the water supply connector, and the air pipe of the endoscope. Supply compressed air for 3 minutes minimum for alcohol and 90 seconds minimum for water.



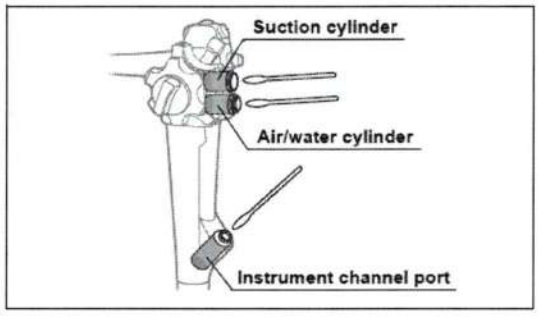
4. Supply compressed filtered air at a pressure of 0.2 – 0.5 MPa into the auxiliary water inlet until no alcohol or water exits from the distal end of the endoscope. Supply compressed air for 3 minutes minimum for alcohol and 90 seconds minimum for water.



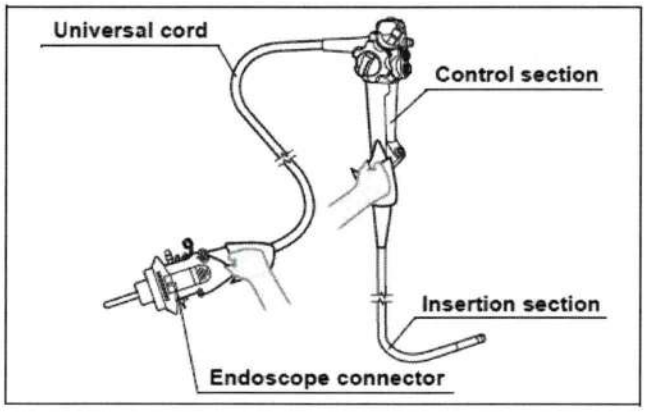
5. Supply compressed filtered air at a pressure of 0.2 – 0.5 MPa into the instrument channel port until no alcohol or water exits from the distal end of the endoscope. Supply compressed air for 3 minutes minimum for alcohol and 90 seconds minimum for water.



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.



End.

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