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 230 **dated** 18/12/2022 **Regarding FSCA of ENDOEYE FLEX 3D DEFLECTABLE VIDEOSCOPE from (mfr: Olympus).**

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

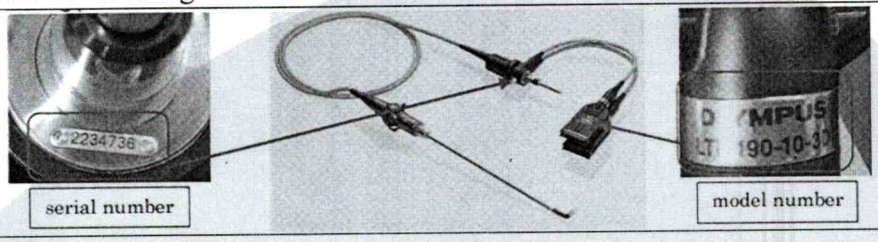
Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
مسقط

Circular No. 230 / 2022

24 -05-1444 H
18 -12-2022

Field Safety Corrective Action of ENDOEYE FLEX 3D DEFLECTABLE VIDEOSCOPE from Olympus

Source	Olympus through their local agent.
Product	ENDOEYE FLEX 3D DEFLECTABLE VIDEOSCOPE.
Manufacturer	Olympus.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	**Product name** / **Model name** / **Serial number** / **Material Number** ENDOEYE FLEX 3D DEFLECTABLE VIDEOSCOPE / LTF-190-10-3D / All / N4501730 ENDOEYE FLEX 3D DEFLECTABLE VIDEOSCOPE / LTF-190-10-3D / All / N4501750
Reason	Olympus is writing to inform you of a revised, corrected reprocessing manual for the LTF-190-10-3D DEFLECTABLE VIDEOSCOPE ("LTF-190-10-3D"). The LTF-190-10-3D is used with other supporting equipment for endoscopy and endoscopic surgery within the thoracic and abdominal cavities including female reproductive organs. Olympus identified the wrong glutaraldehyde (GA) concentration in the reprocessing manual. The reprocessing manual incorrectly stated 2-35% GA concentration. The corrected GA concentration is 2- 3.5% GA concentration. Olympus is providing in this letter an Addendum which corrects the disinfectant concentration of GA in the reprocessing manuals. Please review the enclosed Addendum for detail.
Action	1. Refer to the action in the attached FSN. 2. Contact the local agent for remedial action.
Product image	 serial number / model number
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
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

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

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Date: 29.11.2022
Olympus reference: QIL FY23-EMEA-09

URGENT FIELD SAFETY NOTICE

RE: Reprocessing manual update for ENDOEYE FLEX 3D DEFLECTABLE VIDEOSCOPE OLYMPUS LTF-190-10-3D

Attention: Endoscopy Department, Risk Management

Product name	Model name	Serial number	Material Number
ENDOEYE FLEX 3D DEFLECTABLE VIDEOSCOPE	LTF-190-10-3D	All	N4501730
ENDOEYE FLEX 3D DEFLECTABLE VIDEOSCOPE	LTF-190-10-3D	All	N4501750

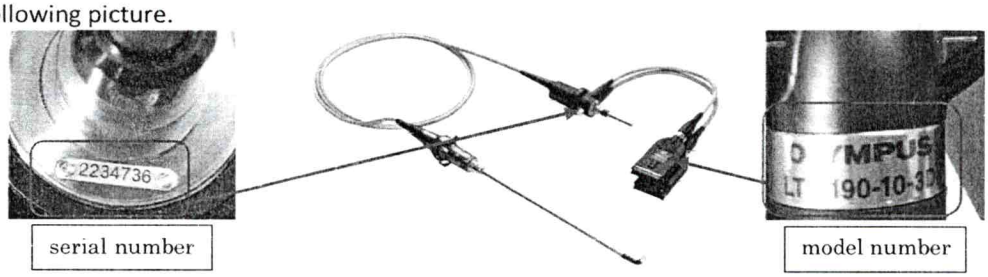
Dear Healthcare Practitioner,

Olympus is writing to inform you of a revised, corrected reprocessing manual for the LTF-190-10-3D DEFLECTABLE VIDEOSCOPE ("LTF-190-10-3D"). The LTF-190-10-3D is used with other supporting equipment for endoscopy and endoscopic surgery within the thoracic and abdominal cavities including female reproductive organs.
Olympus identified the wrong glutaraldehyde (GA) concentration in the reprocessing manual. The reprocessing manual incorrectly stated 2-35% GA concentration. The corrected GA concentration is 2-3.5% GA concentration. Olympus is providing in this letter an Addendum which corrects the disinfectant concentration of GA in the reprocessing manuals. Please review the enclosed Addendum for detail.

Action steps to be taken by the end user:

Our records indicate that your facility has purchased one or more of the affected LTF-190-10-3D. Therefore, Olympus requires you to take following actions:

1. Inspect your inventory for the referenced devices and identify any device with the LTF-190-10-3D model name. Please check all areas of the hospital to determine if any of these devices remain in inventory. The model number can be found on the device as illustrated in the following picture.



2. Carefully read this Field Safety Notice as well as the attached "Addendum". Disinfectant concentration of glutaraldehyde (GA) was corrected.
(Correct GA concentration: 2 – 3.5 %, Incorrect GA concentration: 2 – 35 %)

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3. Ensure all personnel are completely knowledgeable on this labeling change.
4. If your facility requires the latest version of the LTF-190-10-3D reprocessing manual, please indicate this in the reply form.
   Alternatively, the new version of the LTF-190-10-3D Reprocessing manual can be found on the Olympus webpage www.olympus-europa.com under Medical Systems → Products & Solutions → 🔍 → Instruction Manual and search for "LTF-190-10-3D" model name.
5. Send the completed Reply Form back to ra@olympusmea.com latest by 11.12.2022 regardless of whether you have any affected inventory at your facility.
6. If you have further distributed the listed products, identify your customers, forward them this Field Safety Notice, appropriately document your notification process, and let us know the end-customer feedbacks accordingly.

Olympus regrets any inconveniences caused by this Field Safety Notice and fully appreciates your prompt cooperation in addressing this situation. In case of any questions or concerns, please do not hesitate to contact Olympus directly at ra@olympusmea.com

Sincerely,

Iman Ibrahim
Regional Head of Quality Assurance and Regulatory Affairs Middle East & Africa
Healthcare, Industrial and Life Science Divisions
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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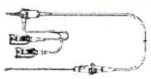
Addendum to the Reprocessing Manual of the LTF-190-10-3D

Revised "List of compatible methods validated in terms of microbiological efficacy and material durability" in the Section 3.1

Before **revised (RC0881 ver.9 -P.13)**

	For sterilization	Ethylene oxide gas sterilization (gas mixture 20% ethylene oxide gas/80% CO_2)				
		Ethylene oxide gas sterilization (100% ethylene oxide gas)				
	For disinfection	2 – 35% glutaraldehyde				
	For cleaning	Detergent solution				
		Ultrasonic cleaning				
Endoscope 						
Sterilization cap (MAJ-1538) 						

compatible not compatible

Table 3.1

After **revised (RC0881 ver.10 -P.13)**

	For sterilization	Ethylene oxide gas sterilization (gas mixture 20% ethylene oxide gas/80% CO_2)				
		Ethylene oxide gas sterilization (100% ethylene oxide gas)				
	For disinfection	2 – 3.5% glutaraldehyde				
	For cleaning	Detergent solution				
		Ultrasonic cleaning				
Endoscope 						
Sterilization cap (MAJ-1538) 						

compatible not compatible

Table 3.1

(EOF)

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REPLY FORM – QIL FY23-EMEA-09

URGENT FIELD SAFETY NOTICE Model name: LTF-190-10-3D
[Name & Address of Hospital/Medical Facility]
[Dept/Attn]
[Inventory information (Serial Number(s) of LTF-190-10-3D)]
[Quantity of LTF-190-10-3D Reprocessing Manual hard copies or electronic pdf documents required]
[Date]

Dear Sirs or Madams,

I herewith confirm 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 to follow the steps.

Name (Signature) _____

Name (Print) _____

Position _____

Please scan / email your completed paper form response to ra@olympusmea.com latest by 11.12.2022.