

URGENT FIELD SAFETY NOTICE

Product: Olympus Flexible Endoscopes (Refer to Attachment)
Attention: Endoscopy, Otorhinolaryngology, Respiratory, Pulmonary and Urology Departments, Risk Management Department

Dear Healthcare Professional:

Olympus has become aware of a matter that requires your attention. This letter pertains to all flexible endoscopes repaired by Olympus or a licensed repair facility. Olympus flexible endoscopes are used in gastroenterology, otorhinolaryngology, respiratory, and urology endoscopic procedures. Our records indicate that Olympus has serviced your flexible endoscope at one of our Olympus repair facilities.

Following repair activities, Olympus uses a water flush of endoscope channels as part of our final endoscope channel inspection, and we subsequently dry the endoscope channels with compressed filtered air. Olympus discovered that our channel air drying process was not validated, and that a small percentage of scopes returned to customers after repair had a wet channel. Olympus is in the process of implementing a validated drying process at our repair centers.

Water remaining in the channel of the endoscopes has the potential for contamination that could lead to the risk of infection. Olympus has not received any reports of adverse events associated with this issue. Olympus reminds facilities of the importance of adhering to the Instructions for Use, which requires that high-level disinfection of the endoscope be performed prior to using the endoscope in a clinical procedure.

As a precautionary measure, Olympus requires that you inspect endoscopes received from our repair facilities for the presence of water prior to reprocessing. If you observe any moisture or water in your returned endoscope, please contact your local Olympus representative to coordinate a return. Until we have implemented the validated process, you will receive a reminder with each returned repaired device.

Olympus requests you to take the following actions:

1. Carefully read the content of this Field Safety Notice (FSN).
2. Ensure all personnel are completely knowledgeable and thoroughly trained on the content of this FSN.
3. Going forward, inspect each Olympus flexible endoscope returned to you from an Olympus repair facility prior to reprocessing. If you observe any moisture or water, you are requested to send the scope back to the repair center. Please contact your Olympus representative **[Regions to revise to reflect their resources]** to coordinate the return of your scope.
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.

5. Olympus requests that you report complaints, including infections, and endoscopes returned wet from our repair centers to Olympus. Please report complaints to **[local facility complaint reporting contact]**. [If applicable:] Adverse events experienced with the use of this product may also be reported [local competent authority] by [method].

Your National Competent Authority is aware of the actions described in this letter.

Olympus regrets any inconvenience this action may have caused and fully appreciates your prompt cooperation.

Sincerely,

[SIGNATORY]

[Contact Name]

Attachment: Affected model number list

BF-1T180	BF-1TQ290	BF-H1200	BF-P190	BF-Q180-AC	BF-XP190
BF-1T20D	BF-20D	BF-H190	BF-P260F	BF-Q190	BF-XP260F
BF-1T260	BF-260	BF-H290	BF-P290	BF-Q290	BF-XP290
BF-1T60	BF-3C160	BF-MP160F	BF-P30	BF-TE2	BF-XP60
BF-1TH1100	BF-3C30	BF-MP190F	BF-P40	BF-UC180F	BF-XT160
BF-1TH1200	BF-3C40	BF-MP290F	BF-P60	BF-UC190F	BF-XT190
BF-1TH190	BF-6C260	BF-MP60	BF-PE	BF-UC260FW	
BF-1TQ170	BF-F260	BF-P150	BF-PE2	BF-UC290F	
BF-1TQ180	BF-H1100	BF-P180	BF-Q170	BF-XP160F	

CF-2T160I	CF-H170I	CF-H190I	CF-HQ1100DL	CF-Q160DI	CF-Q180AL
CF-2T160L	CF-H170L	CF-H190L	CF-HQ190I	CF-Q160DL	CF-Q260AL
CF-E3I	CF-H180AI	CF-H260AL	CF-HQ190L	CF-Q160S	CF-Q260DL
CF-E3L	CF-H180AL	CF-H260AZL	CF-HQ290I	CF-Q160ZI	CF-UM20
CF-EZ1500DI	CF-H180DI	CF-H260DL	CF-HQ290L	CF-Q160ZL	CF-XZ1200I
CF-EZ1500DL	CF-H180DL	CF-H290ECI	CF-HQ290ZI	CF-Q165I	CF-XZ1200L
CF-FH260AZI	CF-H185I	CF-H290L	CF-HQ290ZL	CF-Q165L	
CF-FH260AZL	CF-H185L	CF-HQ1100DI	CF-LV1L	CF-Q180AI	

CHF-B290	CHF-BP30	CHF-CB30L	CHF-P60	CHF-V
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CYF-4	CYF-5	CYF-V2	CYF-VH	CYF-VHR	CYF-VHA
CYF-4A	CYF-5A	CYF-VA2			

ENF-T3	ENF-VT	ENF-VT2	ENF-VT3
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GF-UC140P-AL5	GF-UCT180	GF-UCT260	GF-UE160-AL5	GF-UE190	GF-UE290
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GIF-1100	GIF-2TQ260M	GIF-H185	GIF-H290Z	GIF-Q180	GIF-XP260N
GIF-1T100	GIF-E3	GIF-H190	GIF-HQ190	GIF-Q260	GIF-XP290N
GIF-1T140	GIF-EZ1500	GIF-H190N	GIF-HQ290	GIF-V70	GIF-XQ260
GIF-1TH190	GIF-FQ260Z	GIF-H260	GIF-LV1	GIF-XP170N	GIF-XTQ160
GIF-1TQ160	GIF-H170	GIF-H290	GIF-N180	GIF-XP180N	GIF-XZ1200
GIF-2T160	GIF-H180	GIF-H290EC	GIF-Q160Z	GIF-XP190N	
GIF-2TH180	GIF-H180J	GIF-H290T	GIF-Q165	GIF-XP260	

HYF-XP

JF-140R	JF-260V
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LF-DP	LF-GP	LF-TP	LF-V
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MAF-DM2	MAF-GM2	MAF-TM2
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PCF-H180AI	PCF-H190I	PCF-H290DL	PCF-H290TL	PCF-HQ190L	PCF-Q180AL
PCF-H180AL	PCF-H190L	PCF-H290I	PCF-H290ZI	PCF-PH190I	PCF-Q260AL
PCF-H190DI	PCF-H190TI	PCF-H290L	PCF-H290ZL	PCF-PH190L	
PCF-H190DL	PCF-H190TL	PCF-H290TI	PCF-HQ190I	PCF-Q180AI	

SIF-H190	SIF-H290S	SIF-Q180	SIF-Q260
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TGF-UC180J

TJF-140R	TJF-145	TJF-160VR	TJF-260V	TJF-Q180V	TJF-Q190V
TJF-Q290V					

URF-P6	URF-P7	URF-V	URF-V2R	URF-V3	URF-V3R
URF-P6R	URF-P7R	URF-V2			



REPLY FORM – QIL FY24-EMEA-17-FY23-OMTA-43

URGENT FIELD SAFETY NOTICE Olympus Flexible Endoscopes
[Name & Address of Hospital/Medical Facility]
[Dept/Attn]
[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 **XXXXXXXX**