

URGENT FIELD SAFETY NOTICE

RE: Bronchofiberscope, Bronchovideoscope
Serial numbers: all serial numbers

Attention: Endoscopy Examination Room Manager, Operating Room Manager, Risk Management Department

Dear Health Care Practitioner:

Olympus has become aware of a matter that requires your attention. This Safety Notice pertains to the below referenced Olympus bronchoscopes models and our records indicate that your facility has purchased one or more of these models. These bronchoscopes are intended for use in endoscopic diagnosis and treatment within the airways, the tracheobronchial tree.

The specific models relevant to this alert include the following:

Affected BF series bronchoscopes

BF-XT40**	BF-XT160*	BF-H190	BF-6C260*
BF-P60	BF-Q170	BF-Q190	BF-H290
BF-MP60	BF-1TQ170	BF-XT190	BF-Q290
BF-1T60	BF-P180*	<u>BF-1TH190</u>	BF-1TQ290
BF-PE2	BF-Q180**	BF-260*	BF-H1100
BF-TE2	BF-Q180-AC*	BF-F260	BF-1TH1100
BF-P150*	BF-1T180*	BF-P260F*	BF-H1200
BF-1T150	BF-1TQ180*	BF-1T260*	BF-1TH1200

* Sales discontinued

** Sales and Service discontinued

Note: Product availability is dependent upon country

Olympus has received complaints of endobronchial combustion during therapeutic laser procedures with the Olympus bronchoscope model BF-1TH190. Three (3) adverse event complaints with endobronchial combustion during laser procedures have occurred, and one (1) complaint resulted in patient death. There are a total of 32 models of the BF series endoscopes (including BF-1TH190) that can be used in combination with laser therapy equipment. The 32 bronchoscope models indicated above are listed as laser compatible in the respective model's Operation Manuals.

In an effort to maximize patient safety and mitigate any potential risk to patient health, Olympus is notifying users of these complaints and the **requirement to only use Nd:YAG laser or 810 nm diode lasers with Olympus laser compatible bronchoscopes**. Olympus has not evaluated any other lasers for compatibility with the indicated bronchoscope models. Additionally, users should pay careful attention to Warnings in the Operation Manual on laser cauterization with Olympus bronchoscopes. Olympus Operation Manuals warn not to perform laser cauterization while supplying oxygen. This may

result in combustion during cauterization. In addition, to avoid patient injury (burns, bleeding, & perforation) or damage to the device, never emit laser radiation before confirming that an appropriate distance between the target and the endoscope's distal end with the tip of the laser probe is in the correct position in the endoscopic image.

Action steps to be taken by the end user:

Our records indicate that your facility has purchased one or more of the affected bronchoscopes.

Olympus **requests you to take the following actions:**

1. Inspect your inventory for the referenced devices and identify any device with the model names specified above. Please check all areas of the hospital to determine if any of these devices remain in inventory.
2. Carefully read the content of this Medical Device Correction Action as well as the attached "Addendum". The addendum provides compatible laser type.
3. Ensure all personnel are completely knowledgeable and thoroughly **aware that Olympus laser compatible bronchoscopes are compatible only with Nd: YAG laser or 810 nm diode lasers.**
4. Send the completed Reply Form back to your local Olympus representative at [XXXXXXXX] latest by [XX.XX.XXXX].
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 complaints, including any injuries associated with laser procedures with Olympus bronchoscopes, 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].

Olympus regrets any inconvenience caused and fully appreciates your cooperation in this matter. Please do not hesitate to contact me directly at [phone] or at [email] for any additional information or support concerning this matter.

Sincerely,

Name

Title, Department/Region

Addendum Compatible laser type

x: compatible

Model name	Product name	Laser type	
		Nd: YAG	810 nm diode
BF-XT40	OES BRONCHOFIBERSCOPE OLYMPUS BF TYPE XT40	x	-
BF-P60	OES BRONCHOFIBERSCOPE OLYMPUS BF TYPE P60	x	x
BF-MP60	OES BRONCHOFIBERSCOPE OLYMPUS BF TYPE MP60	x	x
BF-1T60	OES BRONCHOFIBERSCOPE OLYMPUS BF TYPE 1T60	x	x
BF-PE2	BRONCHOFIBERSCOPE OLYMPUS BF TYPE PE2	x	-
BF-TE2	BRONCHOFIBERSCOPE OLYMPUS BF TYPE TE2	x	-
BF-P150	BRONCHOVIDEOSCOPE OLYMPUS BF TYPE P150	x	x
BF-1T150	BRONCHOVIDEOSCOPE OLYMPUS BF TYPE 1T150	x	x
BF-XT160	EVIS EXERA BRONCHOVIDEOSCOPE OLYMPUS BF TYPE XT160	x	x
BF-Q170	BRONCHOVIDEOSCOPE OLYMPUS BF-Q170	x	x
BF-1TQ170	BRONCHOVIDEOSCOPE OLYMPUS BF-1TQ170	x	x
BF-P180	EVIS EXERA II BRONCHOVIDEOSCOPE OLYMPUS BF TYPE P180	x	x
BF-Q180	EVIS EXERA II BRONCHOVIDEOSCOPE OLYMPUS BF TYPE Q180	x	x
BF-Q180-AC	EVIS EXERA II BRONCHOVIDEOSCOPE OLYMPUS BF TYPE Q180-AC	x	x
BF-1T180	EVIS EXERA II BRONCHOVIDEOSCOPE OLYMPUS BF TYPE 1T180	x	x
BF-1TQ180	EVIS EXERA II BRONCHOVIDEOSCOPE OLYMPUS BF TYPE 1TQ180	x	x
BF-H190	EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-H190	x	x
BF-Q190	EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-Q190	x	x
BF-XT190	EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-XT190	x	-
BF-1TH190	EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-1TH190	x	x
BF-260	EVIS LUCERA BRONCHOVIDEOSCOPE OLYMPUS BF TYPE 260	x	x
BF-F260	EVIS LUCERA BRONCHOVIDEOSCOPE OLYMPUS BF TYPE F260	x	x
BF-P260F	EVIS LUCERA BRONCHOFIBERVIDEOSCOPE OLYMPUS BF TYPE P260F	x	x
BF-1T260	EVIS LUCERA BRONCHOVIDEOSCOPE OLYMPUS BF TYPE 1T260	x	x
BF-6C260	EVIS LUCERA BRONCHOVIDEOSCOPE OLYMPUS BF TYPE 6C260	x	x
BF-H290	EVIS LUCERA ELITE BRONCHOVIDEOSCOPE OLYMPUS BF-H290	x	x
BF-Q290	EVIS LUCERA ELITE BRONCHOVIDEOSCOPE OLYMPUS BF-Q290	x	x
BF-1TQ290	EVIS LUCERA ELITE BRONCHOVIDEOSCOPE OLYMPUS BF-1TQ290	x	x
BF-H1100	BRONCHOVIDEOSCOPE OLYMPUS BF-H1100	x	-
BF-1TH1100	BRONCHOVIDEOSCOPE OLYMPUS BF-1TH1100	x	-
BF-H1200	BRONCHOVIDEOSCOPE OLYMPUS BF-H1200	x	-
BF-1TH1200	BRONCHOVIDEOSCOPE OLYMPUS BF-1TH1200	x	-



REPLY FORM – QIL FY24-EMEA-06-FY24-OMSC-04

URGENT FIELD SAFETY NOTICE Bronchofiberscope, Bronchovideoscope	
[Name & Address of Hospital/Medical Facility]	
[Dept/Attn]	
[Inventory information (Material and Serial Number(s) of Bronchofiberscopes, Bronchovideoscopes)]	
Model	Serial Number
[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**