

URGENT FIELD SAFETY NOTICE

RE: EVIS LUCERA ELITE BRONCHOFIBERVIDEOSCOPE BF-MP290F(BF-MP290F), EVIS LUCERA ELITE BRONCHOVIDEOSCOPE BF-1TQ290(BF-1TQ290)

Issue: Operation Manual Update

Attention: Endoscopy Department, Risk Management

Material ID	Model Number	Description	Serial Numbers
N5768550	BF-MP290	BF-MP290F BRONCHOSCOPE	2100556,2100560, 2100561, 2100562, 2200583, 2300742, 2300764, 2300771
N3829150	BF-1TQ290	BF-1TQ290 BRONCHOVIDEOSCOPE	2122732, 2222836,2222887, 2222888, 2222889, 2222890, 2222891, 2222892, 2222893, 2222894, 2222895, 2222985, 2222987, 2222992, 2223030, 2223031, 2223148

Dear Healthcare Practitioner:

Olympus has become aware of a matter that requires your attention. This Safety Notice pertains to the above-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 and the tracheobronchial tree.

Olympus discovered that the aforementioned models of EVIS LUCERA ELITE Bronchoscopes were shipped with Operation Manuals with missing product specification information. Please refer to Attachment 1 of this letter for the Missing Specifications table.

Corrective Action

Olympus is providing the updated Operation manual (RC7304_0200).

Risk To Health

Olympus has not received any complaints related to this issue. Potential patient harms that could occur in the event that the product specification information is not immediately available to the user include delay in treatment, prolonged episode of care, or unspecified tissue injury.

Action steps to be taken by the end user:

Our records indicate that your facility has purchased one or more of the affected BF-MP290F and BF-1TQ290. **Olympus requests you to take the following actions:**

1. Carefully read the content of this Field Safety Notice.
2. Inspect your inventory for the referenced devices and identify any device with the BF-MP290F and BF-1TQ290 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.



3. Please confirm that the specification tables for BF-MP290F and BF-1TQ290 are listed in the attached "Operation Manual 2.2 Specifications".
4. Ensure all personnel are completely knowledgeable on this labeling change.
5. Additional copies of the new operation Manuals can be obtained by your local Olympus organization.
6. Alternatively, the new version of BF-MP290F and BF-1TQ290 Operation Manual can be found on the Olympus webpage www.olympus-europa.com under Medical Systems → Products & Solutions → 🔍 → Instruction Manual and search for relevant model name "BF-MP290F" or "BF-1TQ290".
7. 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 23.01.2024.
8. 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.

The competent authority is aware of the actions described in this letter.

Olympus requests that you report any complaints to concerns@olympus.co.uk.

Olympus regrets any inconvenience caused and fully appreciates your cooperation in this matter. Please do not hesitate to contact me at 01 4260100 or at info@olympus.ie for any additional information or support concerning this matter.

Sincerely,

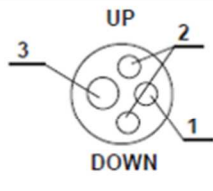
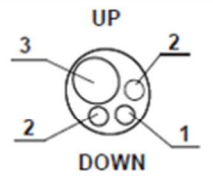


Niamh Billings

NIAMH BILLINGS

Olympus Ireland

Attachment 1

Table1. Missing Specifications table

Model		BF-1TQ290	BF-MP290F
Optical system	Field of view	120°	90°
	Direction of view	0° (Forward viewing)	0° (Forward viewing)
	Depth of field	2 – 100 mm	2 – 50 mm
Insertion section	Distal end outer diameter	ø 5.9 mm	ø 3.0 mm
	Distal end enlarged 1 Objective lens 2 Light guide lens 3 Instrument channel outlet		
	Insertion tube outer diameter	ø 6.0 mm	ø 3.7 mm
	Insertion section working length	600 mm	600 mm
	Rotation range	Right: 120° Left: 120°	Right: 120° Left: 120°
	Instrument channel	Channel inner diameter	ø 3.0 mm
	Minimum visible distance ^{*1}	3 mm	2 mm
	Direction from which EndoTherapy accessories enter and exit the endoscopic image		
Bending section	Angulation range	UP: 180° DOWN: 130°	UP: 210° DOWN: 130°
Total length		880 mm	880 mm
Pre-freeze function ^{*2}		Available	Available
Electronic zoom function ^{*2}		Not available	Not available
Records of endoscope's information ^{*2}		Available	Available
NBI observation ^{*2}		Available	Not available
Structure enhancement type B ^{*2}		Not available	Not available
Image size large 1 ^{*2, *3}		Available	Available
Image size large 2 ^{*2, *3}		Not available	Not available
High-frequency treatment		Compatible	Not compatible
Laser treatment		Compatible	Not compatible



REPLY FORM – QIL FY24-EMEA-31-FY24-OMSC-17-BF-290

OLYMPUS URGENT FIELD SAFETY NOTICE BF-290 BRONCHOSCOPE
[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 info@olympus.ie latest by 23.01.2024.