



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. 246, dated 26/11/23. Regarding NCMDR Field Safety Notice of BRONCHOFIBERSCOPE, BRONCHOVIDEOSCOPE 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



12 -05-1445 H
26 -11-2023

لنقدم بثقة
Moving Forward
with Confidence



Field Safety Notice of BRONCHOFIBERSCOPE, BRONCHOVIDEOSCOPE from Olympus Corporation of the Americas

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19759
Product	BRONCHOFIBERSCOPE, BRONCHOVIDEOSCOPE
Description	Endoscopy.
Manufacturer	Olympus Corporation of the Americas .
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	Affected BF Series Bronchoscopes: BF-1T150, BF-1TQ170, BF-H1200, BF-P60, BF-1T180*, BF-1TQ180*, BF-H190, BF-Q170, BF-1T260*, BF-1TQ290, BF-H290, BF-Q180-AC*, BF-1T60, BF-260*, BF-P150*, BF-Q190, BF-1TH1100, BF-6C260*, BF-P180*, BF-Q290, BF-1TH1200, BF-F260, BF-P190, BF-XT160*, BF-1TH190, BF-H1100, BF-P290, BF-XT190 All serial numbers.
Reason	There is a risk of endobronchial combustion if high-frequency cauterization is performed while supplying oxygen [and/or] the electrode section of the electrosurgical accessory is too close to the distal end of the endoscope.
Action	1. Carefully read the content of attachment which is reminding of Warnings, found in the affected bronchoscopes' Operation Manual(s), related to the use of high-frequency therapy equipment. 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