



To:

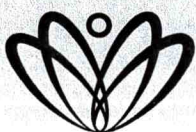
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES  
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salah)  
Director General of Engineering Affairs, MOH  
Director General of Royal Hospital  
Director General of Khoula Hospital  
Director General of Medical Supplies (MOH)  
Director 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 .2.1.3 dated .21/12/12 Regarding NCMDR Field Safety Corrective Action of TJF-Q180V duodenoscopes 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



ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩

P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489

✉ a\_dc Email: dg-padc@moh.gov.om



Circular No. 213 / 2021

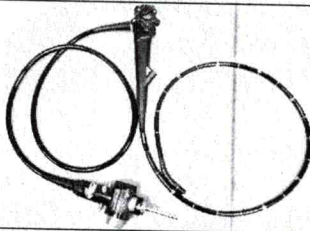
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21 -12-2021

التميز بثقة  
Moving Forward  
with Confidence



Field Safety Corrective Action of TJF-Q180V duodenoscopes from Olympus.

Source	NCMDR - National Center Medical Device Reporting- SFDA. <a href="http://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=15943">http://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=15943</a>
Product	TJF-Q180V duodenoscopes.
Description	Dudoenoscope, flexible, video.
Manufacturer	Olympus.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	Product code: TJF-Q180V All serial numbers.
Reason	A probability of damage to or deterioration of the TJF-Q180V's distal end adhesive may pose a risk of endoscope contamination due to ineffective reprocessing or fluid invasion.
Action	1. The customers have been advised that an illustrated checklist has been created to supplement the Operation and Reprocessing Manuals. The checklist contains reference photos showing TJF-Q180V deteriorations and damages to aid users in identifying when an endoscope requires repair prior to clinical use. 2. Contact the local agent for remedial action.
Product image	
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: <a href="mailto:Med-device@moh.gov.om">Med-device@moh.gov.om</a>

Dr. Mohammed Hamdan Al Rubaie  
Director General



PADDC  
المديرية العامة للصحة والرقابة الدوائية  
Directorate General of Pharmaceutical  
Affairs & Drug Control



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