

Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control
MUSCAT



سِلاطِنَة عُمان
وَزَارَة الصِّحَّة
وَالرِّقَابَة الدَّوْلِيَّة
مَسَقَط

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. 203... dated 25/11/21. Regarding NCMDR Field Safety Corrective Action of Surgical Microscope Leica M220 F12 from (mfr: Leica Microsystems (Schweiz) AG).

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



Circular No. 203/2021

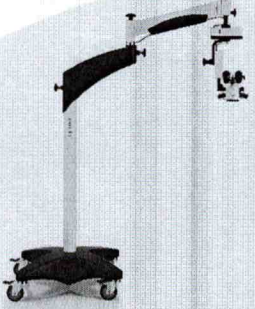
نتقدم بثقة
Moving Forward
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رؤية عمان
2040
Oman Vision

20-04-1443 H

25-11-2021

Field Safety Corrective Action of Surgical Microscope Leica M220 F12 from Leica Microsystems (Schweiz) AG.

Source	NCMDR- National Centre for Medical Devices Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=15912
Product	Surgical Microscope Leica M220 F12.
Description	General-purpose surgical microscope.
Manufacturer	Leica Microsystems (Schweiz) AG.
Local agent	Aston Medical Supplies LLC.
The affected products	All Leica M220 F12 Surgical Microscopes that were manufactured since introduction in January 2009 until March 9th, 2017.
Reason	M220 optics carrier may unintentionally drop into the surgical field, risking contact with the patient.
Action	1. Please refer to "Urgent and important mandatory action to be taken by the user" in the attached FSN. 2. Leica Microsystems will provide you a retention fixture as an additional means of securing the M220 Optics Carrier free of charge 3. 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: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General



Irrespective of the additional safety feature to be implemented on your M220, Leica Microsystems advises to immediately take action as described below.

Urgent and important mandatory action to be taken by the user:

Prior each use of your M220 F12, please perform the following mandatory inspection:

- If the gap between the black adapter and the white housing at the end of the swing arm becomes bigger than 3mm (see Figure 4) or a free rotation of the optics carrier is possible for more than 360° (see Figure 5): → **Immediately stop using the device!**

In this case the M220 F12 can no longer be used.

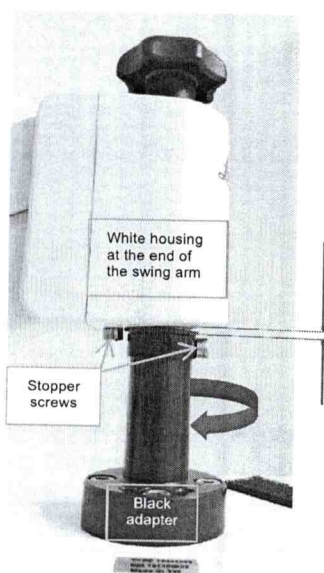
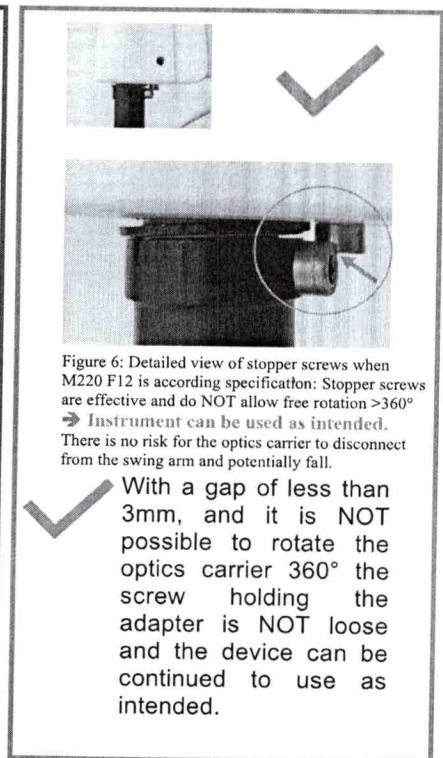
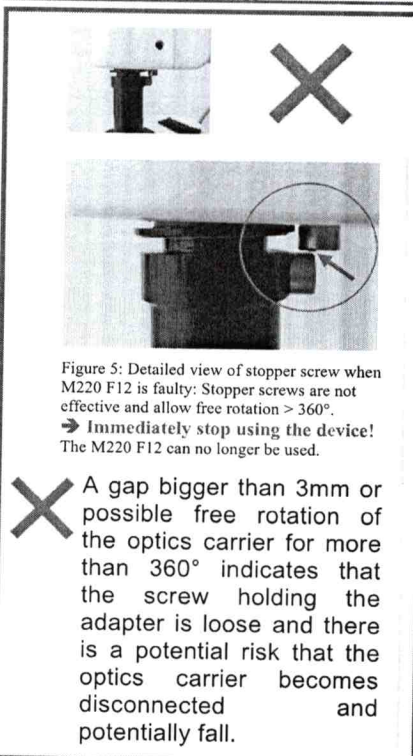


Figure 4: Detailed view of gap between black adapter and white housing of swing arm.



- If you notice any anomalies with your M220 F12 Microscope System before the additional retention fixture is attached to your instrument, please contact your Leica representative for relevant repair of your instrument.
- If the mandatory inspection performed prior using your M220 F12 does not result in an observed potential defect, you can continue to use the system pending fixation of the retention fixture.

