



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 13 dated 30/11/24 Regarding NCMDR Field Safety Notice of MAMMOMAT Revelation system from (mfr: SIEMENS).

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





نتقدم بثقة
Moving Forward
with Confidence



Circular No. 13 / 2024

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30 -01-2024

Field Safety Notice of MAMMOMAT Revelation system from SIEMENS.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19901
Product	MAMMOMAT Revelation system.
Description	Digital full field mammography diagnosis.
Manufacturer	SIEMENS.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	Versions VC10B, VC10C or VC10D using Tomo Biopsy Unit.
Reason	If an examination is interrupted due to any system error while - the InSpect Projection View (PV) is active and - a vacuum biopsy system is used the tube arm can only be moved to a $\pm 6^\circ$ position by using the rotation buttons instead of the $\pm 15^\circ$ position that is possible with other Projection Views.
Action	1. If the operator encounters the situation described in the attachment, the InSpect PV functionality should be deactivated by using a right mouse click, selecting "PV" option and choosing "deactivate" function. Following this action, the normal biopsy mode remains active, and the tube head can be moved to the $\pm 15^\circ$ position, providing enough space to easily remove the vacuum needle out of the needle holder. 2. Siemens Healthineers will provide a field software update VC10E for MAMMOMAT Revelation with VC10B, VC10C and VC10D versions that will resolve the issue described. 3. 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



PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical
Affairs & Drug Control



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