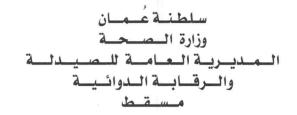
Sultanate of Oman Ministry of Health Directorate General of Pharmaceutical Affairs and Drug Control Muscat







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 79 dated 02/10/2022 Regarding NCMDR Field Safety Corrective Action of ZEISS CLARUS from (mfr: Carl Zeiss Meditec Inc).

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





Sultanate of Oman Ministry of Health Directorate General of Pharmaceutical Affairs and Drug Control Muscat



سلطنة عُـمان وزارة الـصحـة الـمديـريـة العامـة للـصيـدلـة والـرقـابـة الـدوائـيـة مسـقـط

Circular No. |79 / 2022

○**6**-03-1444 H

02 -10-2022



Field Safety Corrective Action of ZEISS CLARUS from Carl Zeiss Meditec Inc.

	Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=17274
	Product	ZEISS CLARUS.
	Description	Imaging system for true color and high resolution ultra-wide field imaging.
	Manufacturer	Carl Zeiss Meditec Inc.
	Local agent	Muscat Pharmacy & Stores LLC.
	The affected products	Any CLARUS 500 or 700, regardless of original manufactured configuration, that is operating with software version 1.1.1 is susceptible to this issue when the site has more than one CLARUS device, or a CLARUS and VISUCAM or FF450 with VISUPAC system.
	and and any the same of the sa	When the Auto Import function is turned on, CLARUS monitors a directory or folder for any new data. If data is found in the directory or folder, CLARUS application proceeds with importing that data into the CLARUS database. When import of data completes, the application's patient list is
	Reason	refreshed. If, at the same time of Auto Import completion, a user has selected a patient to be imaged and proceeds to acquire images for that patient, the selected patient may get deselected without the user coming to know about the deselection. This change of patient could lead to an acquired image to be placed under the wrong patient ID.
	Action	 Upgrade to CLARUS software version 1.1.3 is required to prevent any possibility of future occurrence of the mentioned issue. If you cannot perform the update immediately, you may continue to use your CLARUS instrument for normal clinical use. However, please remember the Auto Import function must be disabled until an updated CLARUS software version is installed. 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







