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

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

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 179 **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**

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control
ISO 9001:2015 CERTIFIED

ص.ب: ٣٩٣ مسقط – الرمز البريدي: ١٠٠ – هاتف: ٢٢٣٥٧١١١ – فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code : 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

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Circular No. 179 / 2022

07-03-1444 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.
Reason	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 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	1. 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. 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

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