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



سلطنة عُـمان وزارة الـصحـة الـمـديـريـة الـعـامـة للـصـيـدلـة والـرقـابـة الـدوائـيـة مـسـقـط

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 178 dated 28/9/2022 Regarding NCMDR Field Safety Corrective Action of Artis system from (mfr: SIEMENS).

### Copy to:

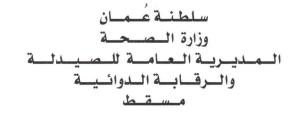
- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information





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Circular No. 178 / 2022

**2** -03-1444 H

28 - 19-2022

## Field Safety Corrective Action of Artis system from SIEMENS.

Source	NCMDR- National Center for Medical Devices Reporting- SFDA <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=17266">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&amp;rid=17266</a>
Product	Artis system.
Description	Interventional fluoroscopic x-ray system.
Manufacturer	SIEMENS.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	System IDs: Artis Q / Q.zen / pheno / icono Model numbers: 10848280, 10848281, 10848282, 10848283, 10848353, 10848354, 10848355, 10848460, 10849000, 11327600, 11327700, 11328100
Reason	Siemens Healthcare is informing users of a potential issue with the Artis system dedicated error detection mechanism.  In rare cases of failure of the error detection mechanism, it is not possible to release X-rays until the system resets. If this issue occurs, the system message "No X-ray, tube too hot!" is shown without an additional audible sound and the operator is unable to release X-rays. A system shutdown is required to enable the release of X-ray.
Action	<ol> <li>Siemens are advising customers that a hardware modification will be performed to correct the issue and they will be contacted in order to schedule an appointment.         In the interim, customers are also advised that a shutdown and restart of the system should recover the normal operation of the system.     </li> <li>Contact the local agent for remedial action.</li> </ol>
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** 





