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 221 **dated** 29/11/2022 **Regarding NCMDR Field Safety Corrective Action of Syngo.via with VB20, VB30, VB40, VB60 and VB70 software 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**

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

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. 221 / 2022

5 -05-1444 H
29-11-2022

Field Safety Corrective Action of Syngo.via with VB20, VB30, VB40, VB60 and VB70 software from SIEMENS.

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=17352
Product	Syngo.via with VB20, VB30, VB40, VB60 and VB70 software.
Description	Radiology DICOM image processing application software.
Manufacturer	SIEMENS.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	VB20, VB30, VB40, VB60 and VB70 software.
Reason	In case: 1. Enhanced MRI images with rectangular FoV (Field of View) are created at the MR scanner and sent to syngo.via, and 2. at the syngo.via system, the user rotates the images to display the images in arbitrary orientation and saves them, and 3. afterwards, the user exports the images to another DICOM node using MR Export Rules (interoperability mode) then distance measurements on the newly created series might be wrong when being performed at systems that receive these new series.
Action	1. Customers are advised to follow the workaround steps outlined in the customer letter (supplied to impacted facilities). 2. Siemens will solve the issue with a software update which is now available. 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
Directorate General of Pharmaceutical Affairs & Drug Control

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