



بمقدم بثقة
Moving Forward
with Confidence



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. 117/22 dated 26.1.22 Regarding NCMDR Field Safety Corrective Action of Ysio systems with VC10 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



Circular No. 117 / 2022

26-11-1443 H

26-06-2022

بخدمت بيققة
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Field Safety Corrective Action of Ysio systems with VC10 software from Siemens.

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=16176
Product	Ysio systems with VC10 software.
Description	X-ray system, diagnostic, general-purpose, stationary, digital.
Manufacturer	Siemens.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	Product code: 10281013
Reason	In another software version of the Ysio fully automated system (VB10) it was identified that the system may incorrectly process the position values of the ceiling tube stand. An update will performed to definitively exclude this hazard for VC10 systems.
Action	1. The field corrective action will update the software of Ysio fully automated VC10 systems. 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