



To:

رؤية عُمان | نتقدم بثقة
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

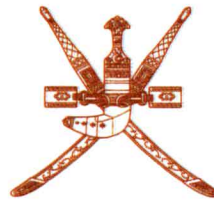
After Compliments,

Please find attached our Circular No 58 dated 28/3/2023 Regarding NCMDR FSCA of EarlyVue VS30 Vital Signs Monitor and EarlyVue VS30 Vitals monitor from (mfr: Philips Healthcare).

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. 58 / 2023

نتقدم بـ
Moving Forward
with Confidence



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28-03-2023

FSCA of EarlyVue VS30 Vital Signs Monitor and EarlyVue VS30 Vitals monitor from Philips Healthcare.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=18481
Product	EarlyVue VS30 Vital Signs Monitor and EarlyVue VS30 Vitals monitor.
Description	Vitals monitor.
Manufacturer	Philips Healthcare.
Local agent	Mustafa Sultan Science and Industry Co.LLC.
The affected products	EarlyVue VS30 Vital Signs Monitor, Product number: 863359. EarlyVue VS30 Vitals monitor, Product Number: 863380. Software Version: A.00.02 and A.00.01
Reason	Philips has become aware of a potential safety issue with EarlyVue VS30 Vital Signs Monitor with Microstream™ sidestream etCO2 method to measure carbon dioxide (CO2) option where the user is not notified about the required first year calibration technical alarm.
Action	1. Identify the last calibration date of the device and review your hospital maintenance plan. 2. Determine if your device has E01 End Tidal CO2 and has not been calibrated within one year of the production calibration. If needed adjust the maintenance plan and incorporate the calibration of your affected device. 3. Philips representative will reach out to you to arrange a software upgrade to your monitor(s). 4. 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

