



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

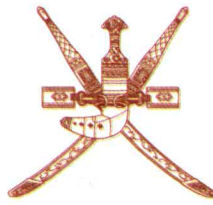
After Compliments,

Please find attached our Circular No 130 dated 21/6/2023 Regarding NCMDR Field Safety Corrective Action of Vivid S60 / Vivid S70 / Vivid S60N / Vivid S70N Ultrasound Systems from (mfr: GE 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. 130/2023

نقدم بتقديركم
Moving Forward
with Confidence



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21 -06-2023

FSCA of Vivid S60 / Vivid S70 / Vivid S60N / Vivid S70N Ultrasound Systems from GE Healthcare.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19591
Product	Vivid S60 / Vivid S70 / Vivid S60N / Vivid S70N Ultrasound Systems.
Description	Ultrasound systems.
Manufacturer	GE Healthcare.
Local agent	Emitac Healthcare.
The affected products	Vivid S60 v203, v204 Vivid S70 v203, v204 Vivid S60N v203, v204, v205, v206 Vivid S70N v203, v204, v205, v206
Reason	The above ultrasound systems cannot boot up in a timely fashion. If this occurs, it can delay availability of the device in time-critical emergency situations.
Action	1. You can continue to use your device. Please follow clinical practice guidelines, which include having a backup imaging plan when performing time-critical examinations or image-guided interventions. 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

