



To:

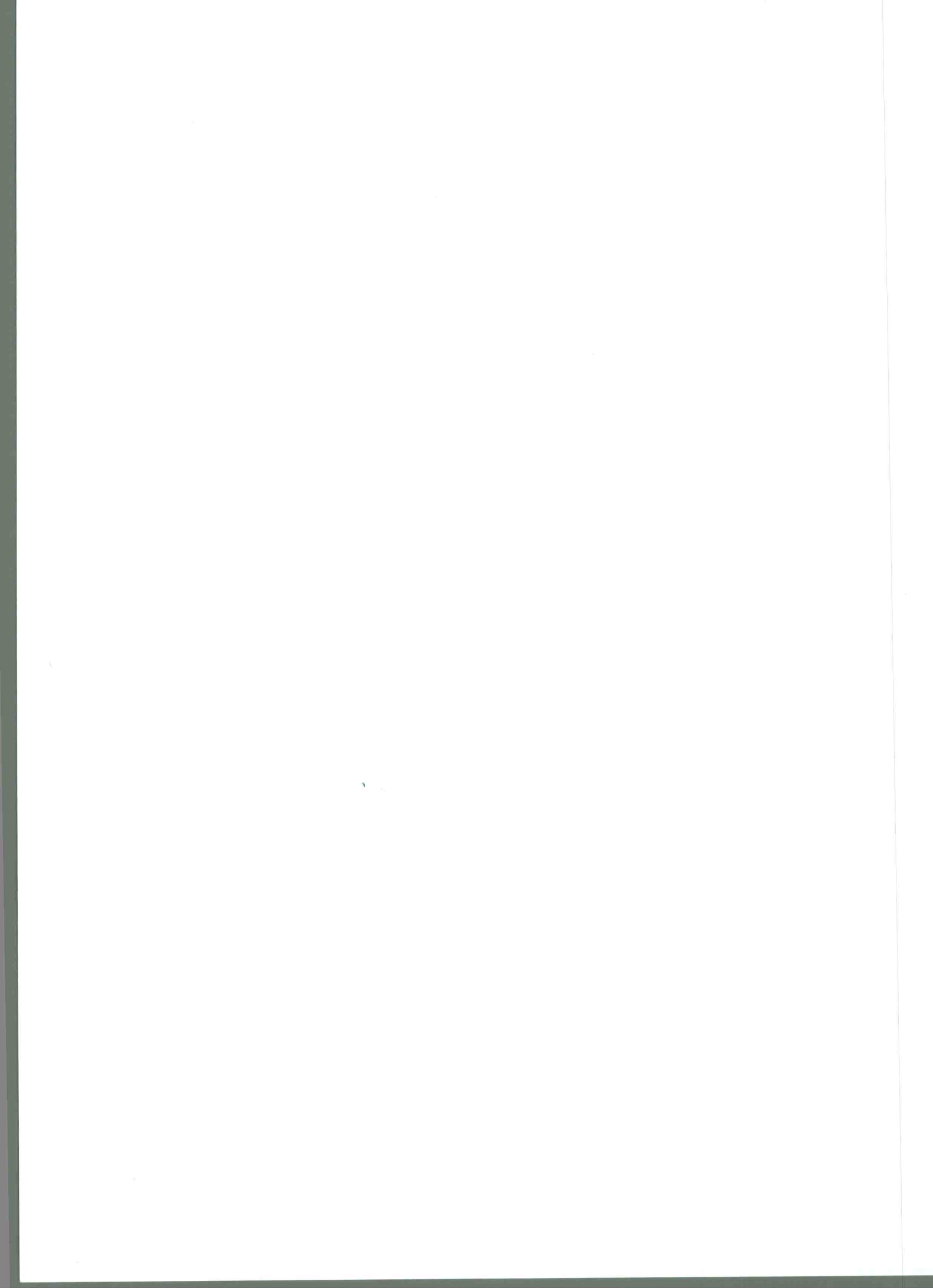
**THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES**  
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)  
Director General of Engineering Affairs, MOH  
Director General of Royal Hospital  
Director General of Khoula Hospital  
Director General of Medical Supplies (MOH)  
Director 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 88 dated 30/4/2023 Regarding NCMDR Field Safety Corrective Action of Digital Diagnostic Mobile X-ray System GM85 from (mfr: Samsung Electronics).

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. 88 / 2023

نتقدم بثقة  
Moving Forward  
with Confidence



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30 -04-2023

Field Safety Corrective Action of Digital Diagnostic Mobile X-ray System GM85 from Samsung Electronics.

Source	NCMDR - National Center Medical Device Reporting- SFDA. <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&amp;rid=19507">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&amp;rid=19507</a>
Product	Digital Diagnostic Mobile X-ray System GM85.
Description	Mobile radiological diagnostic facilities
Manufacturer	Samsung Electronics.
Local agent	Emitac Healthcare Solutions SPC.
The affected products	All GM85 systems.
Reason	A potential issue related to the operation of the arm latch within the column that supports the arm. This arm latch mechanism serves as a backup in the unlikely event that the column wire breaks and there could be a possibility of potential bodily harm due to the arm falling in very rare instances.
Action	1. Samsung Electronics will undertake the voluntary corrective action to exchange the Arm Latch Spring with an improved one. 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: <a href="mailto:Med-device@moh.gov.om">Med-device@moh.gov.om</a>

Dr. Mohammed Hamdan Al Rubaie  
Director General



