



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 42 dated 24/3/2024 Regarding NCMDR Field Safety Notice of FUJIFILM MOBILE DIGITAL X-RAY SYSTEM FDR nano from (mfr: FUJIFILM Medical Systems).

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. 42 / 2024

13 -09-1445 H
24 -03-2024

نتقدم بثقة
Moving Forward
with Confidence



Field Safety Notice of FUJIFILM MOBILE DIGITAL X-RAY SYSTEM FDR nano from FUJIFILM Medical Systems.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=20960
Product	FUJIFILM MOBILE DIGITAL X-RAY SYSTEM FDR nano.
Description	Radiological technology - mobile radiological diagnostic facilities.
Manufacturer	FUJIFILM Medical Systems.
Local agent	Advanced International Business Group (AIBG).
The affected products	FUJIFILM MOBILE DIGITAL X-RAY SYSTEM FDR nano.
Reason	Examinations carried out in pediatric, neonatal and maternity departments with default exposure values that are intended for adult chest imaging and could lead to a risk of overexposure.
Action	1. Please refer to the additional Information in the attachment to mitigate the chance of this issue occurring. Please keep a copy of the attachment with the operation manual. 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



February , 2024

Advisory Notice

RE: FUJIFILM MOBILE DIGITAL X-RAY SYSTEM FDR nano

Dear Sir or Madam:

We would like to inform you that FUJIFILM has recently been alerted to examinations carried out in pediatric, neonatal and maternity departments with default exposure values that are intended for adult chest imaging and, consequently, could lead to a risk of a higher exposure than intended. There have been no reported patient injuries associated with this issue.

More specifically, when the key switch is turned on, the exposure conditions are set to the default values intended for adult chest imaging. In addition, if exposure conditions are set from the console while the key switch is off, the set exposure conditions will not be reflected. Therefore, in an effort to mitigate the chance of this issue occurring, we are providing the information in this letter which is in addition to the information contained in our operation manual.

FUJIFILM appreciates your understanding and cooperation. Please keep a copy of this letter with our operation manual. If you have any questions regarding this letter or if you would like to schedule additional training/in-service, please contact <<name>>, via <<e-mail address>>.

Sincerely,

<<sign>>

<<name>>

<<Division>>

<<company name>>

FUJIFILM MOBILE DIGITAL X-RAY SYSTEM FDR nano / Additional Information

Warning

- Whenever the key switch is turned on, the exposure conditions are set to the default values (85 kV, 1.6 mAs, approx. 0.13mGy@ SID 1m) which are intended for adult chest imaging. Before making an exposure, make sure that intended exposure conditions are set.
- Failure to follow the above warning may result in overexposure in comparison with the selected study, especially for children.
- If exposure conditions are set from the console while the key switch is off, the set exposure conditions will not be reflected.

Turning on the key switch



When the key switch is turned on, the exposure condition panel lights up.



Steps to Re-set Exposure Conditions

1. Closing the Study screen

Exiting the Study screen and Starting over a study.

Press [Complete] to exit the Study screen.

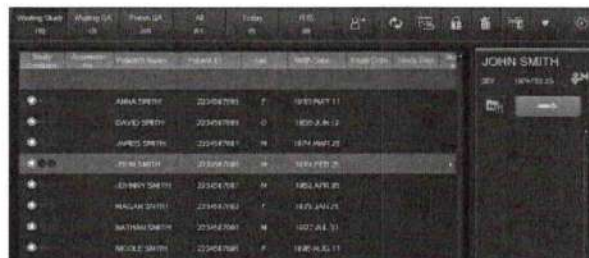


Study screen

2. Re-setting a study

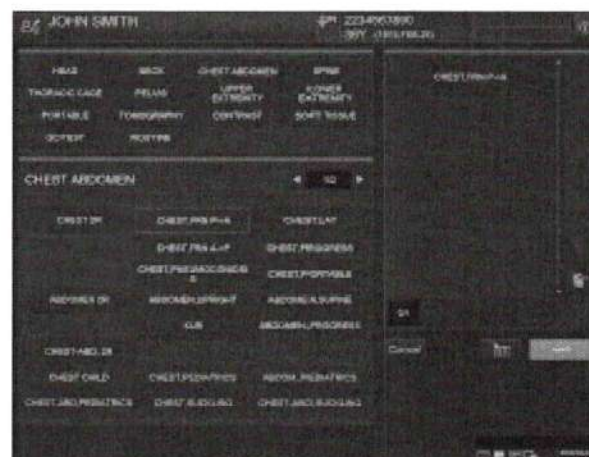
2.1 When connected to RIS

Start over from selecting a Study
(See Section 4.1.2 of “DR-ID 300CL Reference Guide”.)



2.2 Other than RIS connection

Start over from selecting Exposure Menu
(See Section 4.1.1 of “DR-ID 300CL Reference Guide”.)



3. Exposure

Before making an exposure, make sure that intended exposure conditions are set.

Note: For other operational procedures, please refer to “FDR nano Operation Manual”.

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