Accidental change in the exposure settings of a mobile radiology device

The combination of a particularity in the design of the mobile radiology device and lack of knowledge of the steps for stopping and restarting it leads to additional exposure in children. Following on from the Bordeaux University Hospital, several centres have informed ASN that they have come across the same problems. Other notifications could follow. Let's take a closer look at this serial event in the light of the Bordeaux hospital's experience.

THE EVENT IN BRIEF

A dosimetric study by the medical physics team of the Bordeaux University Hospital in connection with a recent Irish publication of Local Dose Reference Levels on infants, revealed the delivery of a large number of higher-than-expected doses during radiography examinations carried out using FUJIFILM's FDR Nano mobile radiography device in paediatric, neonatology and maternity departments.

The retrospective analysis of the doses delivered by these devices and recorded by the DACS[1], showed that the problem concerned 248 children between 2022 and 2023. These doses, representing a few tens of microsieverts, have no clinical consequences and require no specific monitoring.

They result from the use of adult pulmonary radiography constants (85 kV and 1.575 mAs) whereas the users thought they were using paediatric radiography constants. Depending on the order in which the mobile imaging device is switched off, switched back on, and the protocol and patient's name are entered, the exposure parameters can change. This is because setting the main switch to the powered off position (key turned to OFF) does not switch off the console; the console remains on unless switched off separately. In this situation the users can select the name of the patient and choose the corresponding radiological protocol on the console, which is still powered on, but they cannot use the light beam centring device and deliver the X-rays. In this case the users must actuate the main switch (key turned to ON) to power on the tube and the beam centring device. Doing this immediately changes the previously selected exposure parameters, replacing them with the adult thorax radiography parameters, set in the factory. The device does not send a warning message or enter a fault condition to prevent the taking of a radiograph following the change in exposure constants.

[1] *DACS: Dosimetry Archiving and Communication System*

ANALYSIS OF THE CAUSES AND INFLUENCING FACTORS

Technical factors

- Replacement of the exposure parameters selected by the radiographer by "factory-set" parameters
- Deficiency in the Human-Machine Interface (HMI) because no warning message is displayed when the exposure parameters are reinitialised

Human factors

- The radiographers' habit of setting the device to safe condition when moving or stowing it using a main switch which the manufacturer has not provided for this purpose on this machine, unlike other devices.
- The radiographers do not re-check the exposure parameters (protocol entered on the console just before powering on the X-ray tube again)

Organisational factors

- The User's Guide does not indicate the consequences of powering off the X-ray tube alone
- Lack of clarity in the manufacturer's instructions, leading to confusion in the order of the steps to switch on the device
- Inadequate training provided by the manufacturer regarding the conditions of use
- Ambiguity between the instructions for switching off the device given in the User's Guide and in the Quick Start Guide drawn up by the manufacturer at the request of the Bordeaux University Hospital, without querying the associated potential risks

With the participation of HAS, IRSN and ANSM

BARRIERS PUT IN PLACE BY THE UNIVERSITY HOSPITAL AND COMPLEMENTARY MEASURES

- Period from July to September 2023
- Radiographers reminded of the procedures for switching off and restarting the device, and informed of the effects of switching the tube back on if these procedure are not applied correctly.
- Communication on dosimetry in neonatology at the *Journées Française de Radiologie –JFR* radiology seminar: raising awareness about the variability of the protocols between devices of the same type and the effects of switching the X-ray tube back on.
- At the request of the Bordeaux University Hospital, the manufacturer drafted a Quick Start Guide, which was posted in the hospital for the Health Executive and the team of radiographers.
- Connection of the mobile devices to the DACS to collect the dosimetric data in order to be able, if necessary, to reconstitute the doses delivered.
- Analysis of the dosimetric data of patients in paediatrics, neonatology and the accident and emergency department in order to optimise the doses, in the context of a proactive approach by the medical physics department.
- Setting up of an automatic warning on the DACS if the local dose reference levels (LDRL) are exceeded
- Multidisciplinary consultation on the conservative measures to put in place to prevent recurrence.
- Request for a functional modification of the mobile device submitted to the manufacturer (expected in September 2024).

Since December 2023.

- Radiographers reminded of good practices by the medical physics team and a paediatric radiologist.
- Team review of lessons learned from the event, the progress made and reminder of the points requiring vigilance when using the mobile radiography device.

TEMPORARY COURSES OF ACTION

The solutions proposed below are temporary measures pending the software modification scheduled for September 2024 (keeping the same exposure parameters after switching off the tube power supply) and updating of the User's Manual by the manufacturer.

1. ORGANISATIONAL MEASURES

- Training in the use of the mobile radiography device by FUJIFILM.
- Organise, jointly with FUJIFILM, periodic refresher training sessions to highlight practices that diverge from the recommendations.

2. TECHNICAL SOLUTIONS

- Only use the main switch for daily reinitialisation:
  - cover it with a removable guard
  - post this restriction on the device
- Post an instruction beside the main switch to remind users not to forget to switch off the imaging station after each imaging session.

ADDITIONAL COURSES OF ACTION PROPOSED BY THE LEARNING-FROM-EXPERIENCE WORKING GROUP

This event, which had no serious consequences, concerns a cohort of several hundred children, but could also concern adults. It multifactorial origin highlights shortcomings in the design of the device, a work environment that is poorly grasped by the manufacturer, and misuse of the device.
Analysis of the doses received by the patients examined on mobile imaging devices is still rare, even though it is required by the regulations. And in this case it revealed the event.

- Report any malfunction linked to a device to the ANSM.
- Train the users (radiographers and physicians) in the use of medical devices emitting ionising radiation (qualification under ASN resolution 2019-DC-0660 and joint recommendations from ASN and the learned societies).
- Indicate the usage restrictions on the device.
- Analyse the feedback from professional practices in order to improve them.
- Connect the mobile units to the DACS so that the actual doses can be recorded to facilitate their analysis.
- Carry over the doses displayed by the mobile imaging devices to the RIS[2]/PACS and the reports in the patient's file.
- Regularly analyse the doses delivered to the patients using either the RIS or the DACS.
- Improve the HMI at the design stage and harmonise the displayed dose units (mGy.cm^2, dGy.cm^2) which can also be a source of errors.

[2] *RIS: Radiological Information System*

With the participation of HAS, IRSN and ANSM