

URGENT FIELD SAFETY NOTICE

Service Information on modification work concerning duplicate allocation of DICOM Study Instance UID

No. : FCO-XR-14-0010Z
Control No. : QAX 14-041
Type of Action : Recall
Apr.2015

Dear customer ,

This document contains important information for the continued safe and proper use of your medical device.

Details of Affected Devices :

Product Name : DR-1000XB, DR-1000X, DR-2000X, DR-2000F
Software Version : Previous version of V2ND

Description of problem :

1. A Phenomenon of duplication of a Study Instance UID in a DICOM image has occurred on the Hitachi manufactured X-ray Radiography/Fluoroscopy System, POPULUS Ti.
2. This has not caused physical harm.
3. This might cause such as image reception failure, mixing of images, or an image overwrite phenomenon when multiple images of X-ray radiography and fluoroscopy system of the same type are managed in system being used with DICOM connection (PACS, Workstation, etc.).
4. DR-X System Software
Previous version of V2ND

Advise on action to be taken by the users:

We have prepared software for measures against this phenomenon, and will perform version upgrade work of the system software. We apologize for any inconvenience this may cause, but your generous understanding and cooperation in this matter will be appreciated.

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected device has been transferred.

Geographic Distribution : Japan, China, Korea, Thailand, Mongolia, Taiwan,
Philippines, Bangladesh, Saudi Arabia,
VietNam, Singapore, Nepal, Jordan, Republic of Mauritius

Contact reference person:

Please find your local contact person on the cover letter of our local sales organization to this "Urgent Field Safety Notice".

We confirm that this item has been reported to the responsible National Competent Authority.

Yours sincerely
HITACHI MEDICAL CORPORATION.