

To our customers

cc: Chairman Medical Board and relevant Head of Departments

Corrective Actions for X-ray fluoroscopic system

DREX-UI80, DREX-ZX80, DREX-KL80

We appreciate that you have used the Toshiba X-ray fluoroscopic system. The purpose of this letter is to bring to your attention the following problem. It has been found the following information.

One-shot images were displayed on the live monitor, but they were not displayed on the system monitor and were not saved in the hard disk.

Given the above situation, we have decided to take measures to address this matter, as described below. We regret that this action is necessary, and very much appreciate your understanding and cooperation.

We apologize for any inconvenience that this may cause you.

Sincerely

Description

1. Applicable model

System :DREX-UI80, DREX-ZX80, DREX-KL80 ; I.I.(image intensifier) combined system
Model: HDR-08A ; Version ; V1.01.21-V1.31.09 , V1.50.00-V1.50.02

2. Problem

One-shot images were displayed on the live monitor, but they were not displayed on the system monitor and were not saved in the hard disk due to software problem for the image processing device.

3. Corrective Measures

Modified software to correct this issue will be installed on your system. When the new parts become available, your Toshiba service representative will contact you for an appointment to schedule the installation.

4. Request to customers

Should this problem occur before the modified software is installed on your system, please also check an image on the system monitor just to make sure during an inspection.

When a photography image is not normally displayed on the system monitor,

Please switch on the power supply for the system again after waiting 10 seconds or more.

In this case, if any abnormalities are found in your operation, stop using it, and contact your Toshiba service representative.

Additionally, it is strongly requested that you share the contents of this letter with all users and reviewing radiologist as well as clinical engineering or biomedical group at your facility. If you have any questions regarding this matter, please contact your Toshiba Representative.

Your affected system(s) details:

System Model:
System software version:
Serial Number:

I hereby acknowledge that I have received, read and understand the above details and will disseminate this information to user(s) of the affected systems.

Delivered and Explained by:

Acknowledged By:

Engineer name/signature/date

Customer name/signature/date