

To our customers

**Corrective Actions for X-ray interventional system**

**INFX-8000, INFX-9000/ XIDF-AWS801**

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

Peak skin dose (PSD) value displayed on Dose Tracking System (DTS; option of XIDF-AWS801) was larger than the expected value during the case.

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 :INFX-8000V,INFX-8000C,INFX-8000F,INFX-9000V,INFX-9000C

Model: XIDF-AWS801 Version ; V6.20\*R001,V6.30\*R000,and V6.35\*R000 for XIDF-AWS801

### **2. Problem**

This matter occurs when turn on the power for XIDF-AWS801 after turn on the power for INFX system. The software of DTS checks whether position information for INFX system is stored before DTS starts dose calculation. But the check does not include the information for a compensation filter and X-ray beam quality filter in the collimator due to the software coding mistake.

As a result, the calculated value is bigger than the expected value because these filters information is not considered. Therefore, the PSD value becomes larger than the expected value in the operation.

### **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 turn on the power for XIDF-AWS801 before turn on the power for INFX system.

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 together with Chairman Medical Board and relevant Head of Departments.

If you have any questions regarding this matter, please contact your Toshiba Representative.

