

Regulatory Affairs & Vigilance Department  
Toshiba Medical Systems Corporation

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To our customers

### **Notice regarding modification to diagnostic ultrasound systems TUS-X200/X200S and TUS-X100**

Thank you for using our diagnostic ultrasound systems.

It has been found that for the above systems, the surface of the acoustic lens of a transducer may become hot. This is due to the occurrence of a software error when a transducer is disconnected and reconnected, a transducer is changed, or another transducer is selected.

In order to correct this problem, the following modification work by the service engineer will be required. We apologize for any inconvenience this may cause.

#### Information for users of ultrasound systems

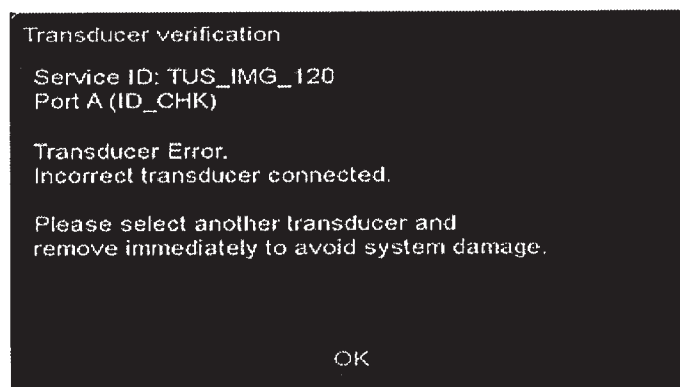
##### 1. Affected devices

Commercial name	System version	Time of shipment
XARIO 200 TUS-X200	V1.3 SP0000* to V3.0 SP0105*	May 2013 to August 2015
XARIO 200 TUS-X200S	V1.3 SP0000* to V3.0 SP0105*	June 2013 to August 2015
XARIO 100 TUS-X100	V1.0 SP0001* to V3.0 SP0105*	October 2013 to August 2015
XARIO 100 TUS-X100S	V1.0 SP0001* to V3.0 SP0105*	October 2013 to August 2015

##### 2. Description of the problem

For the systems specified in section 1, an error message may be displayed due to the occurrence of a software error when a transducer is disconnected and reconnected, a transducer is changed, or another transducer is selected.

It has been found that when the following error message is displayed and the system continues to be used, the surface of the acoustic lens of the transducer may become hot, which can result in moderate burns if the transducer is used on one area of the patient's body for a long time.






<Figure> Display of error message

### 3. Modification required

For the problem described above, software containing corrective measures will be installed as modification support.

### 4. Request to customers until modification is performed

If the error message shown in section 3 is displayed before the modification has been performed, immediately stop using the system and perform the procedure described in steps 1) to 4) below to check the problem.

- 1) Shut down the system by pressing the power button .
- 2) After the system power is completely turned OFF, disconnect and reconnect the transducers.
- 3) Start up the system by pressing the power button .
- 4) After startup of the system is completed, press the transducer selection button  and select all transducers that are currently connected to the connector ports.

The system can be used with no problem if the error message shown in figure 2 is not displayed. If the error message is displayed again even after performing the procedure described in steps 1) to 4), it is likely that the system or the transducers are faulty. In this case, contact your service representative.

For any questions or for further information related to the contents of this document, contact your service representative.

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