

Customer Name  
f.a.o. Mr First Last  
Superintendent Radiographer  
Dept  
Address  
City Post Code

26 Sept 2016

Toshiba Ref: **EU-7856**

**Field Safety Notice for Toshiba Ultrasound Scanner TUS-X100/200 s/n serial number**

**Xario Series Ultrasound Scanner**

Dear Mr Last,

The purpose of this letter is to bring to your attention a problem that may occur with your Toshiba CT system indicated above.

**Affected versions**

Xario 100, Xario 200 – Software versions 3.xx

**Description of the Problem:**

The purpose of this letter is to bring to your attention a problem with the above mentioned Toshiba Ultrasound Scanner. 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, only 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






A description of the problem is set forth below along with the corrective measure. It is strongly requested that you share the contents of this letter with all users of the above-mentioned Toshiba Ultrasound medical device in your facility.

**ACTION: We recommend to take the following actions**

We would like you to adopt the following temporary measures to avoid the above problem until corrective actions have been taken.

If the error message shown above 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 avoid 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 start-up of the system is completed, press the transducer selection button  and select all transducers that are currently connected to the connector ports.

Please note that the system can be used without 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.

**Actions Being Taken by Toshiba**

Corrective software will be installed to prevent the occurrence of this problem. When the measures become available, your Toshiba service representative will contact you for an appointment to install it on your system.

**Device Vigilance**

This FSN has been notified to the MHRA.

**Transmission of the Field Safety Notice**

Please pass on these instructions to all relevant staff and potential users of this system.

**Confirmation of receipt**

Please return the reply slip on the last page to Toshiba, either by fax, email or reply paid envelope.

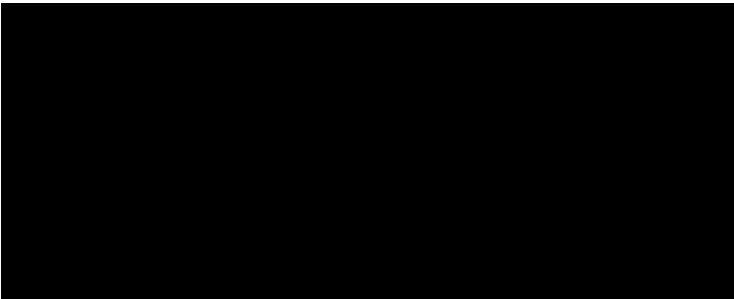
**Further information**

Should you have further questions, please do not hesitate to contact our service department. Details you will find below.

Toshiba Medical Systems Ltd  
Boundary Court, Gatwick Road  
Crawley, West-Sussex  
RH10 9AX  
Service Hotline - Free Phone: 0808 13121110 or 01293 653710

Thank you for your understanding and attention to this matter.

Yours sincerely,  
For Toshiba Medical Systems Ltd



Cc: [Redacted]

**REPLY SLIP for FSN EU-7856**

PLEASE FILL OUT AND RETURN

Toshiba Medical Systems Ltd

f.o.a. RA/QA Dept [REDACTED]

The undersigned confirms that this Notice regarding Toshiba CT Scanners has been received and understood. The undersigned further agrees to notify users of this error.

**PLEASE CONFIRM:**

I have read and understand the instructions provided in the FSN EU-7856 letter. Yes No

FACILITY NAME: Customer Name

Location/ Address: Dept, City Post Code

Product: **TUS-X100/200** s/n **serial number**

Printed Name:

Title:

Contact Information

Phone:

Email:

Signature:

Date:

Submit form to [TMSUKFieldSafetyNotice@tmse.nl](mailto:TMSUKFieldSafetyNotice@tmse.nl), fax to 01293653770 or post in the reply paid envelope.