

Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/093

Issued: 31st October 2007

For:

IMMEDIATE ACTION	✓
ACTION	
UPDATE	
INFORMATION	



HEALTH ESTATES

creating healing environments

	Section
Medical Device/Equipment: General ultrasound scanner: Nemio and Nemio XG systems manufactured by Toshiba Medical Systems Ltd.	▶ ①
Problem: <ul style="list-style-type: none"> A software error has been identified which can lead to an increased transducer tip temperature and an increased thermal index, along with incorrectly displayed MI (mechanical index) and TI (thermal index) values. Some of the acoustic power values in the manual are incorrect. 	▶ ②
Action by: Radiologists and radiographers.	▶ ③
Action: <ul style="list-style-type: none"> Identify implicated devices (see device section overleaf). Ensure you have been contacted by the manufacturer to arrange for a software upgrade and replacement user manuals. Follow guidance given by Toshiba to ensure the safe use of the device in the interim before the software upgrade is performed (see appendix). 	▶ ④
Distributed by NIAIC to: Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers For onward distribution see Section 5	▶ ⑤
Contacts Details of manufacturer contacts and NIAIC contacts for technical aspects.	▶ ⑥
Feedback Requirements to NIAIC In accordance with PEL(06)17 acknowledgment of assurance should be given:-	▶ ⑦

This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

1. DEVICE/EQUIPMENT:

The implicated ultrasound units are detailed below.

- Nemio system, model number SSA-550A, software versions 3.1.000B to 4.5.000A. Toshiba use letters as a prefix to a unique serial number to identify variations within a particular model, for example Cxxxxxxx. To identify implicated units, users must ignore the prefix letter and extract the seven digit serial number that follows. Any number lower than 7523056 is affected by this software error.
- Nemio XG system, model number SSA-580A, software versions 1.5.0 to 2.0.0. The unique seven digit serial number is prefixed by a letter and a model code, for example E3Cxxxxxxx. Again, to identify implicated units, users must extract the remaining seven digits of this code. Any serial number lower than 0733711 is affected.

2. PROBLEM:

During laboratory testing, Toshiba identified that a software error could lead to an increase in temperature in the transducer tip, increased thermal index (TI) and incorrectly displayed mechanical index (MI) / thermal index (TI) values. Toshiba advises that the risks associated with these problems include low temperature burn or foetal growth disorders. The likelihood of these risks are low as these occur in circumstances where the transducer is held in the same position for 30 minutes or longer. Although the circumstances under which these problems occur are limited, Toshiba has advised users of precautionary measures which should be adopted to ensure the safety of patients (see appendix). Software upgrades and replacement manuals will be provided.

The thermal index (TI) gives a relative indication of the potential for temperature increase at a specific point along an ultrasound beam. It is designed to make the operator aware of the possible temperature rise at a particular point in tissue.

The mechanical index (MI) is associated with cavitations and bio effects of ultrasound on the tissue. Cavitations are high negative acoustic pressures that can cause temporary microscopic vacuum pockets. When these collapse, they produce very high local temperatures that can cause damage to tissue in the immediate region. Limits of both MI and TI are set by the manufacturer of the device to maintain patient safety.

3. ACTION BY:

Radiologists and radiographers.

4. ACTION:

- Identify implicated devices (see device section above).
- Ensure you have been contacted by the manufacturer to arrange for a software upgrade and replacement user manuals.
- Follow guidance given by Toshiba to ensure the safe use of the device in the interim before the software upgrade is performed (see appendix).

5. ONWARD DISTRIBUTION TO:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution to:

- Medical directors
- Radiographers
- Radiologists
- Risk managers
- Sonographers
- Independent Health and Social Care Providers – Private Hospitals & Clinics through RQIA

6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Mr Paul Jarvis
Ultrasound Product Support Manager
Toshiba Medical Systems Ltd
Boundary Court
Gatwick Road
Crawley RH10 9AX

Tel: 01293 653 722
0808 131 2110 (free phone service hotline)

Fax: 01293 653 770

E-mail: pjarvis@tmse.nl

Enquiries to NIAIC should quote reference number MDEA(NI)2007/93 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US

Tel: 028 9052 3868

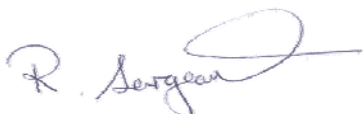
Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

In accordance with PEL(06)17 the following acknowledgment of assurance should be given:-

Deadline (Email received)	: 2nd Nov 2007
Deadline (action underway)	: 7th Nov 2007
Deadline (action complete)	: 21st Nov 2007



Robert Sergeant
NIAIC Operational Manager

HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2006/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at www.dhsspsni.gov.uk/niaic

Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety

APPENDIX to MDEA(NI)2007/093

TOSHIBA
Leading Innovation >>>

TOSHIBA MEDICAL SYSTEMS LIMITED

Boundary Court, Gatwick Road, Crawley, West Sussex RH10 9AX
Tel: 01293 653700 Fax: 01293 653770
E-mail: infotmsu@tmse.nl www.toshiba-medical.co.uk

Hospital
Hospital Department
f.a.o. Ms First Name Surname
Superintendent
Hospital Road
Hospital City,

01 October 2007

Customer Notification EU-2512

Potential problem in ultrasound system SSA-5xxxx s/n sample serial number

Dear Ms Surname,

During laboratory testing we identified a possible deviation from applicable standards with the above mentioned Nemio (XG) system. We emphasise that this has not led to any reported incidents with this product.

According to our records you are using the above system. (see note)

It was found that a software problem could, under specific circumstances, cause:

- an increased transducer tip temperature and increased thermal index (TI),
- incorrectly displayed MI/TI values.

In addition it was found that some of the acoustic power values are incorrectly listed in the manual. A more detailed description of the problems and the circumstances under which these can occur, are given on the next page.

We would advise you that the MHRA have been informed of this matter and that a copy of this notification was sent to them in advance. We will contact you shortly with a proposal to correct your system. Should you require further information please do not hesitate to get in touch with

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

Thank you for your understanding and attention to this matter.

Yours sincerely,
For Toshiba Medical Systems Ltd



D. Hoogmoed
QA Manager/ Quality Expert

Note

In case the product involved is no longer in your possession, we kindly ask you to pass on this information to the current user and to let us know the new location.

Boundary Court, Gatwick Road, Crawley, West Sussex RH10 9AX Tel: 01293 653700 Fax: 01293 653770
Registered in England No. 563579 Registered Office: As Above VAT Registered No. GB 218 1388 66

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FIELD SAFETY NOTICE

Device Modification

Applicable products:

TOSHIBA Diagnostic Ultrasound systems

Nemio SSA-550A with software version from 3.1.000B to 4.5.000B

Nemio XG SSA-580A with software version from 1.5.0 to 2.0.0

Important information about a possible Acoustic Power Problem

Could you please ensure that all users of the above mentioned systems are informed of this Field Safety Notice

1. Description of the Problem

An error was found in the software of these systems, which, in exceptional cases, may result in the following:

(1) When a transition is made from the Dynamic Flow mode to the Full-screen pulsed Doppler (PWD) mode, the maximum temperature of the transducer surface may reach 51°C if the transducer is applied to the same position for 30 minutes (exceeding the limit of 43°C as described in IEC 60601-2-37).

(2) When the system is under the multi-step focusing state in the 2D mode with reduced scan angle, the indicated MI/TI values on the monitor may exceed the maximum value described in the manual. The maximum temperature of the transducer surface may reach 49°C if the transducer is applied to the same position for 30 minutes (exceeding the limit of 43°C as described in IEC 60601-2-37).

For both issues:

Low temperature burn or fetal growth disorders could result under the conditions explained above:

full screen PWD or reduced Field of View with Multi step Focus 2D mode. It is considered that these specific conditions are not commonly used in daily examination. As such, likelihood of these occurrences is considered to be negligible by the manufacturer.

(3) The TI value on the monitor may be incorrectly displayed, however actual TI value will not exceed 4. (Please note that the FDA track 3 specifies a limit of 6)

This occurs if:

- 2D mode is used in combination with PWD or,
- 2D CDI mode,
- 2D CDI mode is used in combination with other modes.

In addition it was found that some of the acoustic power values contained in the manual (Acoustic Power and Surface Temperature Data For Diagnostic Ultrasound System) are incorrect.

This is the case with combined 2D + M mode where the maximum value of TI in the manual is smaller than the actual and displayed value.

Note

In case the product involved is no longer in your possession, we kindly ask you to pass on this information to the current user and to let us know the new location.

2. Countermeasures

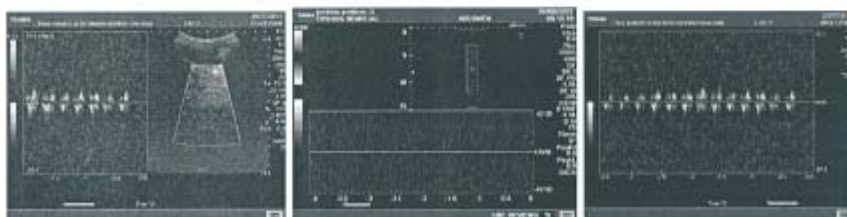
A software update will be installed in your system and the relevant manual will be replaced. We will contact you shortly with details about the implementation plan.

3. Precautionary measures

Although the chances of any of the abovementioned problems occurring are minimal (the indicated effects have only been simulated in the laboratory), users are advised to take note of the following precautions until the software is updated.

To avoid the risk of temperature rise of the transducer:

- Avoid scanning in Dynamic flow mode together with full screen PWC mode



Allowed

Allowed

Avoid

- Avoid the use of Multi step focus 2D mode with reduced scan angle
- Be alert of a possible temperature increase of the transducer

Should you require further information please do not hesitate to get in touch with

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

Note

In case the product involved is no longer in your possession, we kindly ask you to pass on this information to the current user and to let us know the new location.

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