

Toshiba Ultrasound scanner SSA-660A (Xario) with S/N [xxxxxx]

Customer notification

date

Dear [customer],

We are writing to you to bring to your attention a potential problem.

It has been found that the TI (Thermal Index) is not displayed in a certain operating mode. This problem will be corrected in a field modification as described below. We ask for your understanding and cooperation regarding this issue and apologize for any inconvenience this may cause you.

1. Applicable systems

SSA-660A, Xario, manufactured from October 2004 till November 2005.

2. Description of the problem

Xario (SSA-660A) systems are designed to display indices (TI etc.) for the acoustic power during examination on the touch command screen. The TI represents the ratio of the current acoustic power to the acoustic power required to locally increase the temperature of the patient by 1°. The TI is thus a measure of the local increase in patient temperature. The TIS (Soft Tissue Thermal Index) represents the ratio in regard to the soft tissue, the TIC (Cranical Bone Thermal Index) represent the ratio in regard to the cranial bone and the TIB (Bone Thermal Index) represent the ratio in regard to the fetal or neonatal cephalic. However the TI (TIS, TIC and TIB) are not displayed even if the value is 0.4 or more in 2D mode (B mode) due to a software error. There is no problem with TI (TIS, TIC and TIB) display in modes other than 2D mode (B mode).

3. Countermeasure

The software will be corrected in a field modification so that the TI (TIS, TIC and TIB) is displayed in 2D mode (B mode).

4. Request

Until the field modification is performed, please use the system referring to the maximum TI values for 2D mode (B mode) as given in manual 2B730-686 "Acoustic Power and Surface Temperature Data". In the case where you are using the TI value as part of your regular routine, please complete the reply slip below and return in the prepaid envelope.

Should you have any questions, or require further explanation of this situation, please contact the [Toshiba Medical Systems Service Department on nnnnnnn]

Thank you for your understanding and attention to this matter.

Yours sincerely,

[Local Toshiba representative]

Reply slip

Priority request

We confirm that the use of the TI index forms part of the daily routine at [*hospital/clinic name + department*]. We would therefore claim priority in the installation of the corrective software.

Applicable to Toshiba US Scanner SSA-660A with S/N [*xxxxxx*]

Name:

Signature:

Date:

Please return in reply paid envelope to:

Toshiba Medical Systems [*xxx*]
Service Department

Toshiba Ultrasound scanner SSA-700A/770A (Aplio) with S/N [xxxxxx]

Customer notification

date

Dear [customer],

We are writing to you to bring to your attention a potential problem.

It has been found that the TI (Thermal Index) is not displayed in a certain operating mode. This problem will be corrected in a field modification as described below. We ask for your understanding and cooperation regarding this issue and apologize for any inconvenience this may cause you.

1. Applicable systems

SSA-700A, SSA-770A Aplio series manufactured from October 2004 till October 2005

2. Description of the problem

Aplio systems are designed to display indices (TI etc.) for the acoustic power during examination on the touch command screen. The TI represents the ratio of the current acoustic power to the acoustic power required to locally increase the temperature of the patient by 1°. The TI is thus a measure of the local increase in patient temperature. The TIS (Soft Tissue Thermal Index) represents the ratio in regard to the soft tissue, the TIC (Cranical Bone Thermal Index) represent the ratio in regard to the cranial bone and the TIB (Bone Thermal Index) represent the ratio in regard to the fetal or neonatal cephalic. However the TI (TIS, TIC and TIB) are not displayed even if the value is 0.4 or more in 2D mode (B mode) due to a software error. There is no problem with TI (TIS, TIC and TIB) display in modes other than 2D mode (B mode).

3. Countermeasure

The software will be corrected in a field modification so that the TI (TIS, TIC and TIB) is displayed in 2D mode (B mode).

4. Request

Until the field modification is performed, please use the system referring to the maximum TI values for 2D mode (B mode) given in manual 2B730-707, "Acoustic Power and Surface Temperature Data". In the case where you are using the TI value as part of your regular routine, please complete the reply slip below and return in the prepaid envelope.

Should you have any questions, or require further explanation of this situation, please contact the [Toshiba Medical Systems Service Department on [nnnnnnnnnn]].

Thank you for your understanding and attention to this matter.

Yours sincerely,

[Local Toshiba representative]

Reply slip

Priority

We confirm that the use of the TI index forms part of the daily routine at [*hospital/clinic name+department*]. We would therefore claim priority in the installation of the corrective software.

Applicable to Toshiba US Scanner SSA-[*xxxxA*] with S/N [*xxxxxx*]

Name:

Signature:

Date:

Please return in reply paid envelope to:

Toshiba Medical Systems [*xxx*]
Service Department