

URGENT FIELD SAFETY NOTICE

System: Aplio 500
FSCA-identifier : PS EU 8201
Type of action: Notice about the safety issue and corrective action

Date: 06/06/2017

Attention:

DETAILS ON AFFECTED DEVICES:

Unit 1: Model: Aplio500 Serial Number:

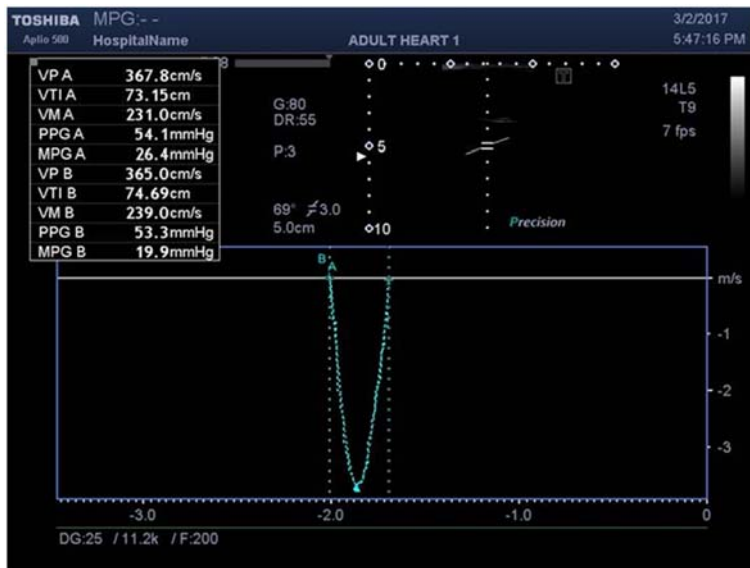
DESCRIPTION OF THE PROBLEM:

The purpose of this letter is to bring to your attention a problem that, in the above-mentioned Ultrasound Diagnostic systems when tracing Doppler velocity waveforms using Continuous Trace, an incorrect value may be displayed.

A description of the problem is set forth below along with the corrective measure. We strongly request that you share the contents of this letter with all users of the above-mentioned Ultrasound System in your facility.

Problem:

It has been reported that when velocity trace measurement is performed using Continuous Trace, the displayed MPG (mean pressure gradient) value may be substantially lower than that obtained by spline tracing in the diagnostic ultrasound system models and the ultrasound workstation models listed above. As a result, impaired function of the cardiac valves may be overlooked or normal cardiac valves may be incorrectly assessed.



- Applicable velocity trace measurement items
- AV V Trace
 - LVOT V Trace
 - AR V Trace
 - MV V Trace
 - PV V Trace
 - PR V Trace
 - TR V Trace
 - TV V Trace
 - PISA V Trace
 - Vel Trace for basic measurement
 - User registered Vel Trace measurement

**FIGURE 1 COMPARISON OF MPG VALUES
(A: SPLINE TRACE, B: CONTINUOUS TRACE)**

Occurrence conditions for the problem

The problem occurs when velocity trace measurement is performed on image data acquired in PW mode or CW mode, and Continuous Trace is used for tracing Doppler waveforms.

Corrective Measures:

The improved software will be installed to prevent the occurrence of this problem.

When the new software becomes available your Toshiba service representative will contact you for an appointment to install it on your system.

ADVICE ON ACTION TO BE TAKEN BY THE USER:

Until modification is performed, do not use Continuous Trace as the tracing method for velocity trace measurement when calculating the MPG (mean pressure gradient) value. Instead, use Range, Spline Trace, or Line Trace as the tracing method. Refer to the operation manual <Measurement volume> provided with the system for the procedures for changing the preset for the tracing method selected automatically at the start of measurement or for changing the tracing method during measurement.

Product model numbers and corresponding operational manual numbers:

TUS-X100/TUS-X200/TUS-X200S	2B771-076/2B771-069/2B771-083
TUS-A300/TUS-A400/TUS-A500	2B771-006 (common to all systems)
TUS-AI700/TUS-AI800/TUS-AI900	2B771-143 (common to all systems)
TUW-U001/TUW-U001S	2B771-054/2B771-054

TRANSMISSION OF THIS FIELD SAFETY NOTICE:

This notice needs to be passed on all users and reviewing radiologist as well as clinical engineering or Biomedical group at your facility, or to any organisation where the potentially affected devices have been transferred.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

This notice has been notified to the appropriate National Competent Authority via a Field Safety Corrective Action notification.

Please complete and return the attached form via faxing it to **+353 1 2963671** or via email to cronan@toshmed.ie.

We thank you for your urgent attention to this matter. If you have any questions regarding this letter please feel free to contact your Toshiba Representative at [cronan@toshmed.ie].

Yours sincerely.



Ciaran Ronan
Sales Director



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**Attachment
User Reply Form**

Subject: Urgent Medical Device Correction of a US scanner (Data saving issue)

Device:
SEG:
Serial Number:

Facility:

Contact Information:

Name: _____

Title: _____

Telephone Number: _____ Fax Number: _____

Were the instruction contained in the “**Request to Customers:**” section of the attached letter understood?

- Yes No

If “No”, please explain:

Was the information shared with your staff? Yes No

If “No”, please explain:

Signature: _____

Date: _____