

To Whom It May Concern,

This is Field Safety Notice (FSN) acknowledgement that you received and understood the contents in pages 2 and 3.

Description of the problem

It has been reported that when velocity trace measurement is performed using Continuous Trace, the displayed MPG (mean pressure gradient) value may be as low as half 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.

Your affected System Details

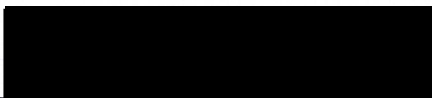
System Model: TUS-A400

System Software Version: V6.50*R308

**Please acknowledge and sign below that:**

- You have understood the contents in pages 2 and 3.
- You will disseminate this information to user/s of the affected system in your establishment.
- You understand that modification software to patch system software version is required to permanently solve the stated problem.
- Until modification software is available and performed, do 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.

Delivered and explain by Engineer:

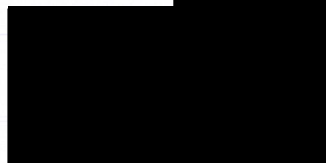


Name/Signature/Date

Acknowledge by:



Owner Name/Signature/Date/
Company Stamp



Modification of diagnostic ultrasound systems

Thank you for using our diagnostic ultrasound systems and ultrasound workstations.

It has been reported that when tracing Doppler velocity waveforms using Continuous Trace, an incorrect value may be displayed in the diagnostic ultrasound systems and ultrasound workstations listed below. These systems will be modified to address this issue. Until the modification is performed, please take the measures indicated in section 4 "Request to customers" below. We apologize for any inconvenience that this may cause.

Details

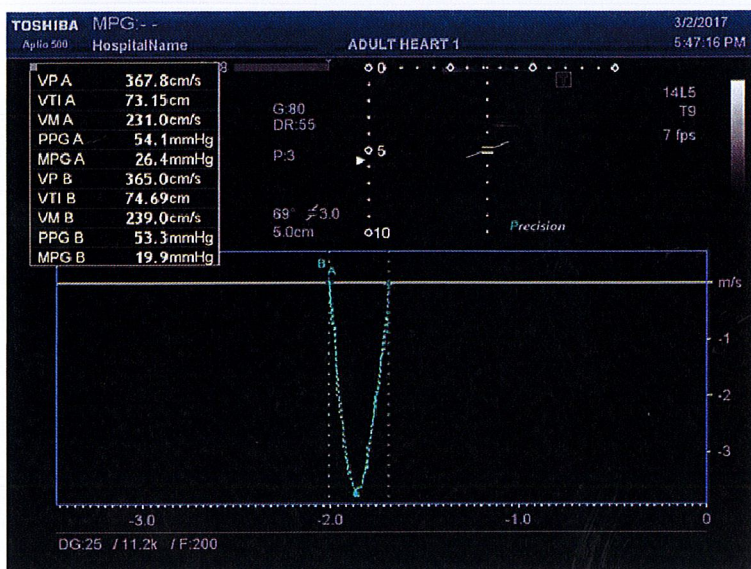
1. Applicable systems and shipment (or software upgrade) dates

Diagnostic ultrasound system	XARIO100	TUS-X100	November 2016 to March 2017
Diagnostic ultrasound system	XARIO200	TUS-X200/TUS-X200S	November 2016 to March 2017
Diagnostic ultrasound system	APLIO300	TUS-A300	April 2016 to March 2017
Diagnostic ultrasound system	APLIO400	TUS-A400	April 2016 to March 2017
Diagnostic ultrasound system	APLIO500	TUS-A500	April 2016 to March 2017
Diagnostic ultrasound system	APLIOi700	TUS-AI700	May 2016 to March 2017
Diagnostic ultrasound system	APLIOi800	TUS-AI800	May 2016 to March 2017
Diagnostic ultrasound system	APLIOi900	TUS-AI900	May 2016 to March 2017
Ultrasound workstation UltraExtend FX	TUW-U001		August 2016 to March 2017
Ultrasound workstation UltraExtend FX	TUW-U001S		August 2016 to March 2017

* Note that systems are applicable if their software versions have been upgraded using a software upgrade kit.

2. Description of the problem

It has been reported that when velocity trace measurement is performed using Continuous Trace, the displayed MPG (mean pressure gradient) value may be as low as half 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.

3. Description of modification

Modified software will be provided to correct the problem described above.

4. Request to customers

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.

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

If you have any questions regarding this matter, please contact your service representative.

End of document