
Urgent Field Safety Notice

Commercial name of the affected product: ARIETTA 60 & 70 series

FSCA-identifier: FE0618/14

Type of action: Device modification

Date: 25th June 2014

Attention: Hospital / Medical Practice

General Management / Vigilance Manager

To whom it may concern,

Hitachi Aloka Medical Ltd. has issued an “Urgent Field Safety Notice” for usage of the diagnostic ultra-sound system ARIETTA 60 series and ARIETTA 70 series.

Details on affected devices:

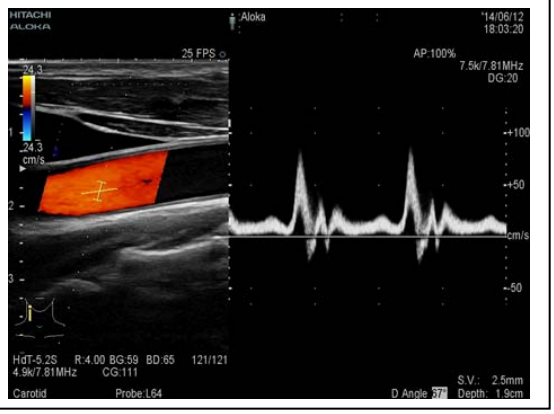
Diagnostic ultrasound system, model ARIETTA 60 & ARIETTA 70 series, software version 1.2.

Description of the problem:

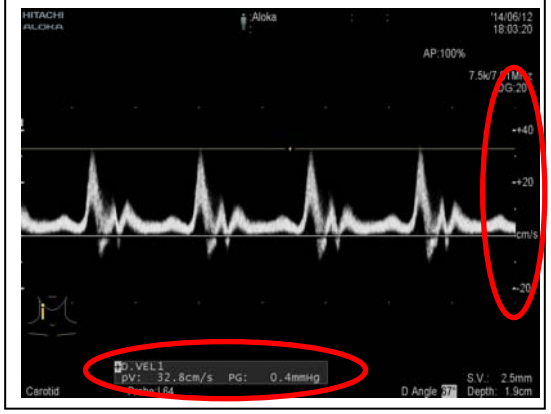
- Phenomenon : Doppler scale of Full Doppler display mode, PW or CW, becomes an incorrect value.
- Condition : The phenomenon occurs when measured only on full Doppler display mode, PW or CW.
- Procedure :
  1. When Angle Correction value is set other than 0°on Doppler mode.
  2. When a mode is changed to Full Doppler display mode only.
- Frequent : 100% occurs by above procedure.

However, freeze or angle correction adjustment on wrong Doppler scale display makes correct value displayed. There is no problem on 2 displays like B and Doppler mode as a following left side image.

Doppler Mode（Angle Correction）



PW wave after change to Doppler mode



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Health Hazard :

There is no report of health damage caused by this malfunction so far as of this moment. Also, there may be very low possibility to immediately lead to health hazards. Flow velocity values obtained in Pulsed Wave or Continuous Wave Doppler is a part of indexes of other test results to judge severity of valve stenosis, valvular regurgitation, pulmonary hypertension, etc. Flow velocity value is not treated as a single decision index.

However, in cases in doubt, flow velocity value might effect when it is difficult to make the final decision. In the assumption of the worst case, health damage might occur theoretically in the case that treatment of patients is selected not optimal or delayed.

Advice on action to be taken by the user:

Freeze or angle correction adjustment on wrong Doppler scale display makes correct value displayed. Do not use the wrong display images stored into RGB or Video Clip.

Action of manufacturer/distributor:

Hitachi Aloka will provide corrective software for all applicable units. A Technical Bulletin will be issued by the manufacturer for this case by the 7th of July 2014.

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Contact reference person:

Please find your local contact person on the cover letter of our local sales organization to this “Urgent Field Safety Notice”.

We confirm that this item has been reported to the responsible National Competent Authority.

Sincerely

Hitachi Aloka Medical, Ltd.

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