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Urgent Field Safety Notice
Commercial name of the affected product: ARIETTA 60 & 70 series
FSCA-identifier: FE1215/16(EU)
Type of action: Device modification

Date: 16th December 2015

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 ultrasound system ARIETTA 60 & 70 series.

Details of affected devices:

ARIETTA 70 series (diagnostic ultrasound system).
All serial numbers that have been shipped with the software version Ver.3.0.0.

ARIETTA 60 series (diagnostic ultrasound system)
All serial numbers that have been shipped with the software version Ver.3.0.0.

Description of the problem:

- Phenomenon : Surface temperature of convex probe C251 will exceed the international safety standard under a certain condition as below.
- Condition : The phenomenon occurs when connecting probe model C251 on ver.3.0.0 of ARIETTA 60 & 70, with THI ON, THI Mode HdT, Frequency(B) High, and under several conditions, such as but not limited to: Acoustic Power 100%, Depth 12 cm, Focus position F7 (the deepest focus position), Scan Area Minimum
- Frequent : Phenomenon occurs 100% occurs in above condition.

Health Hazard:
There is no report of health damage caused by this error so far as of this moment.
We believe it is very low possibility of the system being used under above condition.
However, if the physician and the patient are not aware of this phenomenon a health hazard may be caused. Therefore we have decided to announce urgent notice and take corrective action.

Hitachi Aloka Medical, Ltd.
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Advice on action to be taken by the user:
Do not use C251 with ARIETTA 60 & 70 Ver.3.0.0 and above mentioned conditions.

Action of manufacturer/distributor:
We will provide a Technical Bulletin and corrective software for all applicable units by the end of December 2015.

Transmission of this Field Safety Notice:
This notice needs to be passed on to 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 yours,

HITACHI ALOKA MEDICAL, LTD.

[redacted]

Quality Assurance Department

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