

URGENT FIELD SAFETY NOTICE

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Control No. : QAD-Z3273

Type of Action : FSCA

March 31, 2021

Information about

Shear Wave Elastography software problem on SOP-ARIETTA850-73/73-SE

Dear customer,

In the Shear Wave Elastography (SWE) function of HITACHI's diagnostic ultrasound system ALOKA ARIETTA 850, it has been found that the acoustic output exceeds the limit of safety regulation depending on the focus position of the examined region. See the Q&A sheet for further explanation.

Since the possibility of health hazard/damage due to acoustic output cannot be ruled out, the system will be upgraded to Ver. 4.1.1 this time, as its countermeasure.

Details of Affected Devices :

Product Name : ALOKA ARIETTA 850, ALOKA ARIETTA 850SE

Software Version : Ver. 4.0.0, Ver. 4.0.1, Ver. 4.0.2

Description of problem :

1. Acoustic output exceeds the limit of safety regulation under certain conditions on SWE.
2. SWE software function is only available with C252 convex probe.
3. SWE software function can be used with the above 3 software versions only.

Advice on action to be taken by the users:

1. Please accept to upgrade the system to Ver. 4.1.1. as soon as possible.
2. There is no influence with using Shear Wave Measurement (SWM).
3. Do not use the Shear Wave Elastography (SWE) function until the system is upgraded.

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 device has been transferred.

Yours sincerely,

Hitachi, Ltd.

Rev.1.8

Q&A sheet of customer explanations regarding the recall of Shear Wave Elastography (SWE) in the update

	#	Question	Answers
Issue details	1	Why do customers need to stop using SWE?	In SWE it was found that the acoustic output exceeds the regulation value of MI, TI, and Ispta specified in the safety standard under some conditions.
	2	Which indexes are exceeded?	Mechanical Index, Thermal Index, Ispta (Spatial Peak Temporal Intensity). There is no problem with the probe surface temperature.
	3	Was SWM influenced by this issue?	We have confirmed that the malfunction does not influence Shear Wave Measurement (SWM).
	4	What means "some conditions"?	Placing the ROI deeper can exceed safety standards.
	5	Will the probe be damaged if used under these excess conditions?	There is no risk of probe breakage. We have confirmed the durability equivalent to the service life with an acoustic output that exceeds the safety standard.
Patient side effect	6	What are the possible effects on patients? What happens if I exceed the standard?	The effects on the human body due to the excessive acoustic output are generally thought to be tissue damage due to heating or cavitation of human tissue, but it is not clear to what extent these damages will occur.
	7	Are there any reports of health hazards?	No reports of health hazards have been received.
	8	Can the patient's measurements already taken be used?	No problem. We have confirmed that there is almost no decrease in measurement accuracy even in this issue.

End
