

Urgent Field Safety Notice

Reference: FSN-WS80A_190604-1, FSN-HS70A_190604-1

Affected device: Ultrasonic Diagnostic Apparatus WS80A and HS70A

Product Correction: Sequence Update

Dear Valued Customer,

The purpose of this letter is to notify you that we have identified a potential issue that may affect the Ultrasonic Diagnostic Apparatus WS80A and HS70A.

Affected devices:

Model	Version
WS80A	1.00.16
	3.00.17
	3.00.18, 3.00.19
	3.01.00, 3.01.01, 3.01.02
	3.01.03, 3.01.04, 3.01.05, 3.01.06, 3.01.07
	3.01.08, 3.01.09
	4.00.08
	4.00.09, 4.00.10, 4.00.11
	4.01.00, 4.01.01, 4.01.02
	4.01.03, 4.01.04, 4.01.05, 4.01.06, 4.01.07
	4.01.08, 4.01.09
HS70A	2.01.00, 2.01.01, 2.01.02, 2.01.03, 2.01.04, 2.01.05, 2.01.06
	1.00.06, 1.00.07, 1.00.08, 1.00.09, 1.00.10, 1.00.11, 1.00.12

Description of the problem:

Samsung Medison has recently become aware that a specific mode of operation of certain versions of WS80A/HS70A systems may pose a risk to patient safety. The manufacturer discovered that probes may overheat when decreasing the Doppler SV (Sample Volume) size value set by the user in the Doppler Only mode on WS80A / HS70A systems. There has been no actual injury reported to Samsung Medison.

Action to be taken by the user:

If the user wants to decrease the Doppler SV (Sample Volume) size value set by himself/herself in the Doppler Only mode on WS80A and HS70A systems, the user should press 'set' button to update the PW Doppler mode.

Action being taken by Samsung Medison:

Service engineers will upgrade software for all affected devices free of charge and contact you to arrange for the correction.

Transmission of this Field Safety Notice:

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

Please transfer this notice to other organisations on which this action has an impact.

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

Other Information:

If you need any further information or support concerning this issue, please contact your local Samsung representative.

We apologize for any inconvenience this may have caused and appreciate your understanding as we take action to ensure customer safety and satisfaction.

The signatory confirms that this Field Safety Notice has been notified by the manufacturer or its representative to the appropriate regulatory authorities.

Yours faithfully,

A handwritten signature in black ink, appearing to be "Donghwan Kim".

Donghwan Kim
Regulatory Affairs Director

Customer Reply Form

This reply form is to confirm receipt of the enclosed Samsung Medison Field Safety Notice (FSN-WS80A_190604-1, FSN-HS70A_190604-1) regarding a Product Correction: Sequence Update.

Please read the Field Safety Notice and indicate the appropriate answers to the questions below.

I confirm receipt of the Field Safety Notice and that I read and understood its content. Yes No N/A

I performed actions requested by the FSN. Yes No N/A

I have returned / destroyed / transfered affected devices. Return Destroy Transfer
 N/A

Affected serial / lot number(s)		Quantity	
Company/facility name			
Address			
Responsible person	Name: Date: Signature:		

Please ensure all fields have been completed.

Please return this form by e-mail to eu.vigilance@samsung.com within 10 business days.

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN. Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.