

Urgent Field Safety Notice (FSN)

Product Name: Digital Diagnostic Mobile X-ray System GM85

Single Registration Number (SRN): [KR-MF-000020682]

Unique Device Identifier (UDI-DI): [8806090DGRGM001XK]

Title: Reinforcement of Moving Arm Frame Strength

Dear Valued Customer,

The purpose of this field safety notification is to notify you that we have identified a potential issue that affects the Samsung Digital Diagnostic Mobile X-ray System GM85 arm frame strength for systems produced during a certain time.

Affected devices:

This issue affects GM85 systems produced between October 2016 to April 2018

Description of the problem:

During a sampling inspection of GM85 systems, Samsung Electronics has become aware that during the manufacturing phase of the GM85 arm frame between the period of October 2016 to April 2018, the quality of the welding was not carried out correctly. There is a potential safety risk that the arm could fall causing potential bodily harm to a user or patient. Even though the potential risk of the arm falling has been determined as low, to eliminate the hazard, Samsung Electronics will add a high tensile bolt for the affected systems preventing any potential risk of injury.

Action to be taken by the user:

You may continue to use the system. Please acknowledge receipt of this Field Safety Notification.

Action being taken by Samsung:

Samsung Electronics will carry out the field safety corrective action for all affected systems produced between October 2016 to April 2018. The corrective action is to fasten the arm with a high tensile bolt to eliminate the risk of the moving arm falling and preventing any potential risk of injury. Service

engineers will correct all affected systems free of charge and contact you to arrange for the correction.

Transmission of this 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. Please transfer this notice to other organizations 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. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

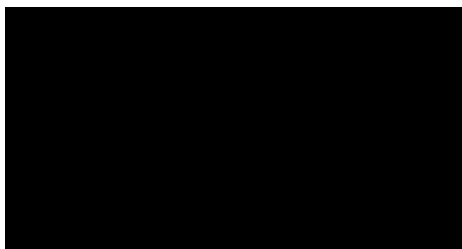
Other Information:

If you need any further information or support concerning this issue, please contact your local Samsung representative in addition to the EU Authorised Representative (eu.vigilance@samsung.com).

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 Notice has been notified by the manufacturer or its representative to the appropriate regulatory authorities.

Yours faithfully,



Subong Bae

Head of Regulatory Affairs

Regulatory Affairs, Health & Medical Equipment

Customer Reply Form and Action Notification Report

*CRF : Customer Reply Form, ANR : Action Notification Report, FSN : Field Safety Notice,

FSN-GM85-231117-1, dated Nov. 17th, 2023 regarding the Reinforcement of Moving Arm Frame Strength.

Please read the FSN and indicate the appropriate answers to the questions below.

----- Customer fill in -----

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

Site Information	System Model			
	System S/N	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		
	Country			Company(Hospital)
	Tel			Email
	Address			

Responsible person who completed this form	Print Name	Date[YYYY-MM-DD]	Signature

----- Engineer fill in -----

Service Engineer Details	FSE Name		Company	
	Email		Tel	
	Address			

Action (Engineer)	Service Ticket No :	Please check '√' applicable box below
	Signature	<input type="checkbox"/> Completed it on the site
		<input type="checkbox"/> Completed by the factory before delivery
		<input type="checkbox"/> Refused this Action by customer (Need customer Signature)

Please ensure all fields have been completed.

Please return this form by e-mail or App 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.