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 which holds the THU

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 moving arm holding strength for systems produced during a certain time.

Affected devices:

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

Description of the problem:

We have received a report regarding the loosening or breakage of bolts that connect the Tube Head Unit (THU) to the arm. An investigation determined that this may be caused by metal fatigue resulting from accumulated stress over a long period of use. If all connecting bolts were to fail, it could potentially cause the THU to detach from the arm, posing a risk of serious injury to a patient or user.

To date, we have received no reports of complete THU detachment or any related serious injuries. To eliminate any risks, Samsung is implementing a field corrective action for affected systems produced between the dates October 2016 to July 2018 to reinforce the arm assembly.

This Field Safety Notice is intended to inform you about:

- The nature of the problem and the circumstances under which it may occur.
- The actions that should be taken by you to prevent potential risks.
- The corrective actions planned by Samsung.

This document contains important information for the continued safe and proper use of your equipment.
PLEASE READ AND FOLLOW THE INSTRUCTIONS BELOW.

Please share this information with all relevant personnel within your organization. We sincerely regret any inconvenience this may cause.

If you have any questions, please contact your local Samsung representative.

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Yours faithfully,

Dongwook Shin

Head of Regulatory Affairs

Regulatory Affairs, Health & Medical Equipment

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DETAILS OF THE FIELD SAFETY NOTICE

AFFECTED PRODUCTS

Model: GM85 (Digital Mobile X-ray System)

Scope: Systems manufactured between October 2016 and July 2018.

A Samsung Service Engineer will contact you to confirm if your specific device is affected by this action.

PROBLEM DETAILS

The four (4) M5 bolts that secure the Tube Head Unit to the end of the arm may loosen or fracture due to metal fatigue. This can lead to instability or wobbling of the arm. In a worst-case scenario where all bolts fail, the Tube Head Unit could detach.

Action to be taken by customer/user:

You may continue to use the system. If any issues with the bolts are detected, then please contact the service engineer immediately for inspection. We request you to please acknowledge receipt of this Field Safety Notification as soon as it is received and send the signed acknowledgement to ukrp.med@samsung.com

Action being taken by Samsung:

Samsung Electronics will carry out the field safety corrective action for all affected systems produced between October 2016 to July 2018. The corrective action is to reinforce the arm with a high tensile bolt to eliminate the risk of the THU falling and preventing any potential risk of injury. Samsung 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 and include the UK responsible person in the communication ukrp.med@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.

Customer Reply Form (CRF)

FSN Reference: FSN-GM85-250827-1 **Date: Aug. 27th, 2025**

Product: GM85 (Digital Mobile X-ray System) Batch: Systems manufactured between October 2016 and July 2018. **Action: Reinforcement of Moving Arm which holds the Tube Head Unit.**

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

----- Customer to complete -----

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	☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐		
	Country		Company(Hospital)	
	Tel		Email	
	Address			

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

Action Notification Report (ANR)

----- Engineer to complete-----

Service Engineer Details	FSE Name		Company	
	Email		Tel	
	Address			

Action (Engineer)	Service Ticket No :	Please check '√' applicable box below
	Signature	☐ Completed it on the site
		☐ Completed by the factory before delivery
		☐ Refused this Action by customer (Need customer Signature)

Please ensure all fields have been completed. Please return to ukrp.med@samsung.com within 10 days from receipt. 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.