

### **Urgent Field Safety Notice (FSN)**

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Product Name: Digital Diagnostic Mobile X-ray System GM85

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

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

Title: Perform a check and replacement for the Arm Latch Spring

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Dear Valued Customer,

The purpose of this letter is to notify you that we have identified a potential issue that may affect the Samsung Digital Diagnostic Mobile X-ray System GM85.

#### **Affected devices:**

All GM85 systems

#### **Description of the problem:**

Samsung Electronics has recently become aware of a potential issue related to the operation of the arm latch within the column that supports the arm. This arm latch mechanism serves as a backup in the unlikely event that the column wire breaks and there could be a possibility of potential bodily harm due to the arm falling in very rare instances. There have been no injuries reported.

#### **Action to be taken by the user:**

You may continue to use the system.

#### **Action being taken by Samsung:**

Samsung Electronics will undertake the voluntary corrective action to exchange the Arm Latch Spring with an improved one.

Service engineers will correct 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 all those who need to be aware within your organization or to any organisation 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.

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.

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,



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-GM85-230228-1, dated Feb. 28th, 2023 regarding *a check and replacement for the Arm Latch Spring.*

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

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

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

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

<b>Service Engineer Details</b>	FSE Name		Company	
	Email		Tel	
	Address			

<b>Action (Engineer)</b>	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 [your local representative](#) 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.