

Urgent Field Safety Notice (FSN)

Product Name: Digital Diagnostic Mobile X-ray System GM60A

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

Title: Potential interference with the anti-fall system

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 GM60A (SEDECAL Mobile 3.1) produced between 2016 to 2020.

Description of the problem:

Samsung Electronics (Own Brand Labeler) have been notified by Sedecal (Original Equipment Manufacturer) of a potential safety issue related to the steel cable installed inside the Samsung GM60A (SEDECAL Mobile 3.1) system's column. The column supports the weight of the telescopic arm with the tube head. There have been no known occurrences in the field. However, there is a potential risk of an interference, between the cable's terminal and the anti-fall safety system (which blocks the arm, if the cable cut off does not work properly). The interference occurs between the cable and a metal plate of the arm's carriage due to the shape of the cable's crimped terminals.

Affected devices:

This issue only affects the installed base of Samsung Digital Diagnostic Mobile X-ray System GM60A (SEDECAL Mobile 3.1) systems manufactured between 2016 to 2020

Action to be taken by the user:

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

Action being taken by Samsung:

Samsung Electronics will carry out the field safety corrective action for all affected GM60A (SEDECAL Mobile 3.1) systems produced between 2016 to 2020. Samsung will inspect the cable of your device and will replace it in case of any potential interference.

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 preventive 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.

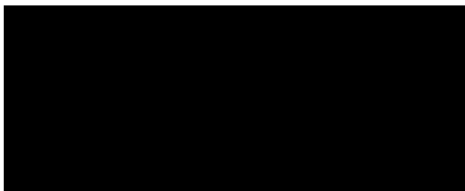
Other Information:

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,



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-GM60A-240404-1, dated Apr. 4th, 2024 regarding Potential interference with the anti-fall system.

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="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"/> <input type="checkbox"/>		
	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.