

Urgent Field Safety Notice

Samsung Reference: FSN-GM85_190326-1

Affected device: Samsung Mobile Digital Batteries X-ray Units GM85

Product Correction: Perform a check and adjustment for the Safety Latch

Date: 10 April 2019

Dear Valued Customer,

cc: Chairman Medical Board and relevant Head of Departments

The purpose of this letter is to notify you that we have identified a potential issue that may affects the Samsung Mobile Digital Batteries X-ray Units 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 safety latch within the column that supports the arm. There could be a possibility of potential bodily harm due to a fall of the arm in an unlikely event that the column wire breaks. 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 considering the possibility of potential bodily harm due to the fall of the arm.

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.

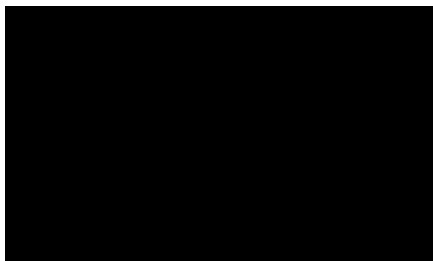
Other Information:

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,



Aeyoung Ha

Regulatory Affairs Director

Regulatory Affairs, Health & Medical Equipment

Customer Reply Form

This reply form is to confirm receipt of the enclosed Samsung Electronics Field Safety Notice ([FSN-GM85-190326-1]) regarding a check and adjustment for the Safety Latch.

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 hmevigilance@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.