

**Urgent – Field Safety Notice**  
**Diagnostic X-ray system GC80, GC85, GC70**

***Infrared Ray (IR) sensor applied to the bottom of the table and  
Software upgrade***

Dear Customer,

As part of Samsung Electronics' continuous focus on performance and safety, we have identified a potential issue that may affect the Samsung Digital X-ray system GC80, GC85, GC70.

This Field Safety Notice is intended to provide you with information regarding:

- what the issue is and under what circumstances it may occur
- the actions that should be taken by the customer / user to prevent any risks for patients or users
- the actions planned by Samsung Electronics to correct the problem.

**This document contains important information for the safe and proper use of  
Samsung Electronics HME Products**

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication. Please retain a copy of this Field Safety Notice with the Instructions for Use.

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.

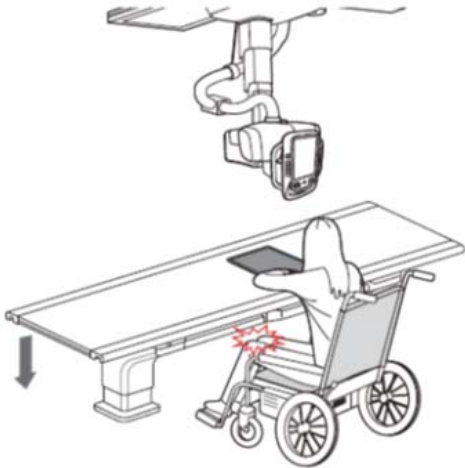
Yours faithfully,



Aeyoung Ha  
Regulators Affairs Director  
Regulatory Affairs, Health & Medical Equipment

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<p><b>Affected products</b></p>	<p>Samsung Digital X-ray system GC80, GC85, GC70</p>
<p><b>Description of the problem</b></p>	<p>1. The patient's lower body could be pressed by the table when it's moving automatically down.</p>  <p>2. Under the only certain condition, not rebooting the detector for more than the several months, the process that helps the connection between the system and the detector can cause the detector to be overloaded. There is not the problem if the detector periodically is rebooted. However, if the detector is getting overloaded, it may cause the image to be uncaptured before rebooted.</p>
<p><b>Potential hazards</b></p>	<p>1. If the table moves down and the patient's lower body is under the table, it may cause injury.</p> <p>2. If the image is uncaptured, it has to be retaken.</p>
<p><b>Actions to be taken by users</b></p>	<p>1. Before and after the capturing, check that their lower body is not directly under the table and then operate the automatic movement features (Parking, Table Mode, P1, P2, P3 and Auto Run buttons of the THU or remote controller).</p> <p>2. Please turn off the detector when you don't need to use it to avoid the detector overloaded or the image uncaptured. After software upgrade, you don't need to do that and the problem will not happen again.</p>
<p><b>Corrective actions taken by Samsung</b></p>	<p>To prevent such issues, Samsung has prepared IR sensors which would be attached to the bottom of the table and also prepared an upgraded software package.</p>

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	<p>1. After the IR sensor applied to the bottom of the table, if a patient body is under the table board when using the automatic movement features, the IR sensor does not allow the table to move downward.</p> <p>2. This software includes the removal of unnecessary processes that cause the problem. Therefore, after the software upgrade, the problem will not happen again.</p> <p>A service Engineer will contact you as soon as possible to apply all of this package.</p>
<b>Support contacts</b>	If you need any further information, or have any concerns, please contact your local Samsung representative.

**INSTRUCTIONS FOR END USERS:**

- 1) Please read the Field Safety Notice.
- 2) Follow the instructions provided in this Field Safety Notice.
- 3) Complete the acknowledgement form and return to Samsung via email ([eu.vigilance@samsung.com](mailto:eu.vigilance@samsung.com)) as soon as possible. Your organization’s reply is the evidence we need to monitor the progress of the corrective actions and which we report to Competent Authorities.
- 4) Please forward this notice to those who need to be aware within your organization or to any organization to whom the potentially affected devices have been transferred.

**INSTRUCTIONS FOR DISTRIBUTORS:**

- 1) Please read the Field Safety Notice.
- 2) Complete the acknowledgement form and return to Samsung via email ([eu.vigilance@samsung.com](mailto:eu.vigilance@samsung.com)) as soon as possible. Your organization’s reply is the evidence we need to monitor the progress of the corrective actions and which we report to Competent Authorities.
- 3) Please forward this entire package of Field Safety Notice documentation on to your customers, and ask them to return the completed acknowledgement form. Please forward the reconciliation rate for your customers to Samsung regularly. Samsung requires this evidence to monitor the progress of the corrective actions.

**FSN Acknowledgement**  
**Diagnostic X-ray system GC80, GC85, GC70**

*IR sensor applied to the bottom of the table and  
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This response form is to confirm receipt of the enclosed Samsung Electronics Field Safety Notice (FSN- GC\_180530-1). Please read the Field Safety Notice and indicate the appropriate answers to the questions below.

I have read and understood the Field Safety Notice instructions provided in this  Yes  No letter.

	Serial Number	Location
Affected serial number(s)		
Company/facility name		
Address		
Responsible person	Name:  Date:  Signature:	

**Please ensure all fields have been completed.**

**Please return this form by e-mail to [eu.vigilance@samsung.com](mailto:eu.vigilance@samsung.com) within 10 business days.**