

Urgent - Field Safety Notice

Mobile Digital X-Ray GM60A

Potential unintended over exposure

Dear Customer,

As part of Samsung's continuous focus on performance and safety of our devices we have identified a potential issue that may affect the Mobile Digital X – Ray GM60A system.

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

- what the issue is, and what circumstances It may occur
- actions that should be taken by the customer/ end user to prevent any risks for patients or users
- the actions planned by Samsung Electronics for further investigation.

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.

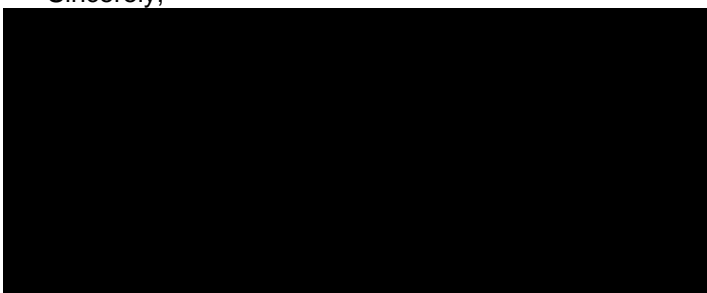
It is important to understand the implications of this communication.

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 signature confirms that this Field Safety Notice has been notified by the manufacturer to the appropriate Regulatory Agency.

Sincerely,



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Affected Products	Device Name(s)	[Serial Number/Lot Number/Reference Number]
	GM60A	All –GM60A-32S & GM60A-40S
<p>Description of Problem</p>	<p>Samsung had been notified of over exposed X- Ray images with the GM60A system. The investigation results had showed that mAs value had increased without any interaction of the user even when the correct protocol had been followed by the operator. From the analysis of log files, it has been observed that the mAs values had increased during the examination and had showed that patients received different dose values than what was stored in the pre-defined protocols.</p> <p>Samsung had discovered as a result of this investigation that the touch screen is sensitive to unintended touch which may occur if any liquid or foreign bodies are on the screen. It had also been identified that in these particular incidents, the tube cable had touched the mSec up button when the tube head unit of GM60A was at the parked position. Protocols had been set before the device had been moved and positioned by the patient. Whilst the device had been moved, the cable had touched the panel and had increased the exposure condition to the maximum value.</p>	
<p>Root Cause(s)</p>	<p>The operator had failed to recognize the increase in exposure and ensure that it has been correctly set before exposing the patient. It is the user responsibility to check the exposure parameters before exposing patients.</p>	
<p>Potential Hazards</p>	<p>Unintended over exposure</p>	
<p>How to Identify Affected Products</p>	<p>All GM60A which are sold in the market are affected</p>	
<p>Remedial actions to be Taken by Users</p>	<ul style="list-style-type: none"> • To ensure the GM60A system is moved into position before parameters are set and that there are no obstructions to the touchscreen which may cause an increase in values during the examination. • To always ensure that the correct exposure levels have been set before exposure to the patient. <p>If you have any issues then please contact your local representative.</p>	
<p>Corrective Actions Planned by Samsung</p>	<p>Samsung are currently developing a software function that notifies the user via a warning pop-up message if the exposure parameters are set 20 times higher than the standard and in addition the operator will have to confirm via the pop-up message first if the parameters are correct to proceed with the exposure. The improved SW will be released in the first half of 2017</p> <p>As a preventive measure newly manufactured products will have additional Velcro</p>	

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	straps to fixate cables which will be stated in the service manual and work manual.
Support Contacts	If you need any further information or have any concerns with this issue then please contact your local representative.

INSTRUCTIONS FOR DISTRIBUTORS:

- 1) Please read the Field Safety Notice documentation in detail.
- 2) Please review and complete the acknowledgement form provided in this FSN and return to [s.sur@samsung.com/](mailto:s.sur@samsung.com) eu.vigilance@samsung.com
- 3) Please pass this entire package of FSN documentation onto your customers and ask them to return the completed acknowledgement form. Please forward copies of acknowledgements from end users onto the email addresses stated above. Samsung require this evidence to monitor the progress of the corrective actions.
- 4) If required and instructed by this FSN documentation, please undertake all relevant service actions as soon as is practicably possible.

INSTRUCTIONS FOR END USERS:

- 1) Please read the Field Safety Notice documentation in detail.
- 2) Follow the instructions provided in this FSN in relation to any actions which are required of you.
- 3) Complete the provided acknowledgement form and return to your supplier or to Samsung via email [s.sur@samsung.com/](mailto:s.sur@samsung.com) eu.vigilance@samsung.com as soon as possible. Your organizations' reply is the evidence we need to monitor the progress of the corrective actions.
- 4) If required and instructed by this FSN documentation, please undertake all relevant service actions as soon as is practicably possible.



Medical Device

FSN-GM60A- 160728006

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<p>FSN Recipient</p>	<p>Please indicate your status as a recipient</p> <p><input type="checkbox"/> Distributor <input type="checkbox"/> End-User</p>						
<p>Affected Serial Number(s) (S/N)</p>	<p>Please insert serial numbers of all devices affected in your country by this FSN for which you are responsible:</p> <p>DISTRIBUTORS – please record the serial numbers for all devices which you have purchased and/or re-sold</p> <p>END-USERS – please record the serial numbers for all devices which are currently in your possession or have ever been in your possession</p> <table border="1" data-bbox="451 907 1428 945"> <thead> <tr> <th data-bbox="451 907 778 945">Model</th> <th data-bbox="778 907 1098 945">Serial Number</th> <th data-bbox="1098 907 1428 945">Location</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table> <p>Any notes/ comments:</p>	Model	Serial Number	Location			
Model	Serial Number	Location					
<p>For Distributors only:</p>	<ul style="list-style-type: none"> • Please confirm the dates of when all the end users were informed of the FSN? <p>(Please attach a confirmation of receipt of the FSN from each end user)</p> <ul style="list-style-type: none"> • Please confirm the method of delivery: <p><input type="checkbox"/> Post <input type="checkbox"/> Email <input type="checkbox"/> In person <input type="checkbox"/> Other - If other is selected (<i>please describe</i>)</p> <ul style="list-style-type: none"> • Was the FSN translated into your local language? (<input type="checkbox"/> Yes <input type="checkbox"/> No) If yes, please also send us the translated FSN. 						



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<p>Statement of receipt & recipient's confirmation</p>	<p>I the undersigned sign to confirm that I have received notification of this Field Safety Notice GM60 -160728006 initiated by Samsung Electronics and have made efforts to inform all relevant persons in my organization and all end users.</p> <p>Full name :</p> <p>Name of the Company/ Organization:</p> <p>Address:</p> <p>Signature :</p> <p>Date:</p>
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Please ensure all fields have been filled in.

Once completed then please print it, sign it and send a scanned copy to [s.sur@samsung.com/](mailto:s.sur@samsung.com) eu.vigilance@samsung.com stating the reference: FSN-GM60A-160728006 acknowledgement in the subject field