

**FIELD – CORRECTIVE/ SAFETY - NOTICE****GETINGE AGS, FSUC, RC supplemented products for  
Medical Devices; Getinge 88-Series, 86-Series  
Field Action CCS (CAPA 191045)**

<b>Date:</b>	Day Month, 2018
<b>Product Issue:</b>	Cart with disinfected goods unloads although no trolley docked. Disinfected goods will end up on the floor and there is a risk for staff working nearby.
<b>Affected Product:</b>	Getinge AGS - Air Glide System, incl. shuttle, loading and unloading station Getinge RC - Free standing return conveyer Getinge FSUC - Free Standing Unloading Conveyer Getinge FSLC – Free Standing loading conveyor*
<b>Resolution:</b>	Getinge propose to repair the devices to make sure all devices present in the market are working effectively and safely.
<b>Affected Serial No.:</b>	See attached list of devices. Generally all devices in this model from serial number WAA052075. Every unit delivered since production start August 2014**.
<b>Pages:</b>	3 (Including Customer respons form)

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**Dear Customer:**

Our records indicate that you bought one or more of our Automation product for our Washer Disinfector, AGS, RC, FSUC, FSLC with a serial number listed as above.

This letter is to inform you of a corrective action that will be performed to prevent problem with the product concerning unloading of goods. A possible hazardsous situation can occur if the end stop is jammed in down position and the RESET and/or power ON/OFF (only on FSUC) button is pressed. The Cart with disinfected goods could then pass the end stop and fall of the conveyer to the floor, which could cause injury to person nearby and damage to goods and wash cart.

We have received some complaints with indication that the issue could have led to harm. From our investigation which includes our evaluation of worst-case scenarios it was concluded that the Intended use of the Washer Disinfector is not affected and therefore no risk for patients applies, however there is a risk off harm to operator. The probability of harm is considered low as

operators normally are not located at the end of the unloading conveyor when the hazardous situation may occur.

This potential hazardous situation is caused by a combination of two malfunctions, a damaged end stop and a software RESET and/or power ON/OFF function. As we see a potential long term hazardous situation and want to prevent any related event from reoccurring with our customers we have developed a more robust solution for the end stop.

### **Next Steps**

1. Please make sure that all caregivers and users of the AGS, RC, FSUC, FSLC (referenced on the previous page) are made aware of this Field Notice and all affected devices at your facility are available during the Getinge service technician visit.
2. Complete and sign the enclosed Customer Response Form and return this form to the local Getinge office.  
**Note:** A Getinge Sales or Service person will contact the person you listed on the Customer Response Form to schedule service for update of your device, free of charge.

### **Transmission of this Field Notice:**

This Getinge AGS, FSUC, RC, FSLC\* Field Notice needs to be distributed to those individuals who need to be aware within your organization - or to any organization where the potentially affected devices have been transferred.

Please maintain awareness of this notice and resulting action for the use period of the device to ensure effectiveness of the corrective action.

In cases where you as customer choose not to proceed with completion of the corrective action requirements described above, Getinge cannot take any responsibility for safety related issues or legal liabilities caused by the failure to respond to this Field Corrective/Safety Notice.

### **Additional Comment**

We deeply regret this inconvenience for you, but we greatly appreciate your understanding as we take actions to ensure correct product performance. If you have any further questions or require assistance completing the Customer Response Form, please contact Getinge.

\* FSLC only for preventive action to be inline with the other devices in the system.

\*\* All units delivered after May 2017 update due to performance.

# Customer Response Form

## CAPA 191045 (Field action number not generated yet)

**Reference: GD7391- Field Corrective/Safety Notice, Getinge AGS, RC, FSUC, FSLC**

Our records indicate that the AGS, RC, FSUC shown below was delivered to your location. Please verify if you have any of the listed devices that are potentially affected and complete the information below.

GETINGE ORDER NO.	ITEM (FSUC, AGS etc)	SERIAL NO.

Record the total number of affected device currently located at your facility here please → \_\_\_\_.

Please check the appropriate boxes below:

- We have read the Field Notice (GD7391) and we understand the communication and the required actions. We will take action as soon as possible according to instructions.
- We have read the Field Notice (GD7391) and we understand the communication and the required actions. We can not take action but are aware of the addressed problem.

If checked: please provide information where the affected devices are physically located.

### Field Notice Receipt and Customer Response Form Completion and Certification

<b>Current Facility Name</b>			
<b>Contact Name / Title</b>			
<b>Address</b> (no PO boxes, please)			
<b>City, State, Zip</b>			
<b>Phone Number</b>		<b>Fax:</b>	
<b>E-Mail Address:</b>			

We have sold/moved our device to another facility

- Getinge AGS    Getinge RC    Getinge FSUC    Getinge FSLC

If checked : please provide new facility information below.

<b>New Facility Name</b>			
<b>Contact Name / Title</b>			
<b>Address</b>			
<b>City, State, Zip</b>			
<b>Phone Number</b>		<b>Fax:</b>	
<b>E-Mail Address:</b>			

**PLEASE RETURN YOUR COMPLETED FORM TO:**

**MAIL**

<local SSU address line 1>  
 <local SSU address line 2>  
 <local SSU address line 3>  
 <local SSU address line 4>

**CONTACT**

<contact address>@getinge.com  
 Tel: <SSU contact phone number>  
 Fax: <SSU contact fax number>