

URGENT - FIELD SAFETY CORRECTIVE NOTICE**Getinge ED-FLOW**

Date:	26-JAN-2022
Product Issue:	ED-Flow Flooding, CAPA 424109
Affected Product:	Getinge ED-Flow AER and Getinge ED-Flow SD AER
UDI DI	No UDI – product not sold in USA and is not an MDR product.
SRN	N/A
Resolution:	<i>Getinge propose to repair the devices to make sure all devices present in the market are working effectively and safely.</i>
Affected Serial Nos.:	All ED-Flows manufactured since start 2010 until 2021-10-20.
Field Correction Notice:	N/A
Pages:	5

Ref.no: GD11046 Rev A

Dear Customer:

Our records indicate that you have bought one or more Getinge ED-Flow AER/ Getinge ED-Flow SD AER.

This letter is to inform you of a corrective action that will be performed to prevent a possible hazard to persons and equipment.

Getinge has discovered that the incoming water valve can be stuck in open position, causing the machine to flood the floor.

We have seen two failures that can affect the valve to stay in open position:

1. The incoming water valve can be stuck in open position due to wearing.
2. The relay that feed the water valve with power can be overloaded and melted and that will also affect the valve.

The potential water leakage from the unit is within the device, behind the cover sheet and the operator will notice this as water on the floor.

The device models are still being manufactured and as we see this issue as a potential long-term hazard and want to prevent any related event from occurring at our customers, Getinge has developed a correction KIT containing a new water valve with flow-restrictor and new relay to replace the old design of valve.

The device is still safe to use but be extra cautious for any water leaks and follow the instruction for daily maintenance.

A correction kit is currently available and the correction will be completed at no cost to affected customers.

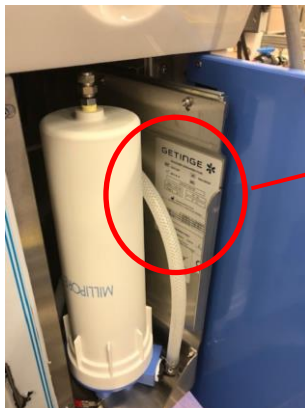
Next Steps

1. Check the serial number of the ED-Flow. The serial number shall correspond with the serial number on the customer response form (Appendix 1).
The serial number can be found on the marking label, located on the inside of the right Panel door, see below.

GETINGE ED-FLOW AER



GETINGE ED-FLOW SD AER



2. Please make sure that all caregivers and users of the ED-Flow are made aware of this Field Notice and all listed devices at your facility are available to be corrected during the Getinge service technician visit.
3. 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 to correct your device, free of charge.

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Transmission of this Field Notice:

This Getinge ED-Flow 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 accept any responsibility for safety related issues or legal liabilities caused by the failure to respond to this Field Safety Corrective Notice.

Additional Comment

We deeply regret this inconvenience, 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.

Customer Response Form

Appendix 1

Reference: Urgent Field Safety Corrective Notice, Getinge ED-Flow.

Our records indicate that the Getinge ED-Flow device 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 NO.	SERIAL NO.	SHIPPING DATE
X	1	XXXX	<Date>
Y	2	YYYY	<Date>

Record the total number of affected device currently located at your facility here please → ____

Please check the appropriate boxes below:

We have read the Getinge ED-Flow Field Safety Corrective Notice and we understand the communication and the required actions.*

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

Field Safety Notice Receipt and Customer Response Form Completion and Certification

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

We have read the Getinge ED-Flow Field Safety Corrective Notice and we understand the communication and the required actions. Replacement activity is not needed as the affected device(s) in our facility were removed from usage/decommissioned.

We have sold/moved our Getinge ED-Flow to another facility.**

** If checked: please provide new facility information below.

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

PLEASE RETURN YOUR COMPLETED FORM TO:

MAIL

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

CONTACT

<contact ddress>@getinge.com
Tel: <SSU contact phone number>

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

Fax: *<SSU contact fax number>*