
URGENT - FIELD SAFETY CORRECTIVE NOTICE

**GETINGE ED-FLOW, Automated Endoscope Reprocessor (AER)
Field Action CAPA 657027**

Date:	25-Oct-2022
Product Issue:	ED-FLOW Dosing issue, CAPA 657027
Affected Product:	Getinge ED-FLOW AER and 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 rework the devices and remove mechanical interferences causing inconvenience and to make sure that all devices present in the market are working effectively and safely.</i>
Affected Serial Nos.:	All ED-FLOW AER-models manufactured since start 2010 until 2022-08-24.
Field Correction Notice:	<i>GD11651 Instruction for Field Action ED-Flow</i>
Pages:	6

Dear Customer:

Our records indicate that you have bought one or more Getinge ED-FLOW Automated Endoscope Reprocessor (AER) with a serial number listed as below.

This letter is to inform you of a corrective action that will be performed to prevent an issue with the device that could lead to a hazardous situation if not supervised carefully.

The issue:

Getinge has discovered that washer disinfector ED-FLOW AER range potentially exhibit behavior whereby dosing of disinfectant may be incorrect.

This behavior is due to mechanical interference with internal device components, leading in all cases to an alarm and aborted process risking delayed treatment.

Two mechanical interferences identified:

1. The placement of the colored indicator caps on weighing scale

The indicator caps on the weighing scale mark the place for the disinfectant container, red for Aperlan A and blue for Aperlan B. The distance between the indicator caps and the inside of cabinet door of the device is very small. During disinfection process, vibrations from the cabinet doors can interfere with the indicator caps on the weighing scale causing it to show potentially incorrect value of dosed detergent.

2. Routing of the dosing pump hose

The hose between the disinfectant container and the dosing pump is routed in such way that during dosing, interference is created, possibly causing the scale to show incorrect value of dosed detergent during a disinfection process.

The device is still safe to use. In case of alarm, the process will be aborted and the cycle status will be printed NOK (Not Ok) on the ticket.

Action:

Getinge has released a Field action upgrade hardware kit to correct the issue of incorrect dosing value.

We see the issue as a long-term hazard and want to prevent any related event from reoccurring with our customer. This action is to reposition the indicator caps and change the routing of the dosing hose.

This Field action will be performed at no cost for affected customer.

Next steps:

1. Check the serial number of the ED-FLOW AER. 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.



2. Please make sure that all caregivers and users of the Geringe ED-FLOW AER and Geringe ED-FLOW SD AER are made aware of this Field Safety Notice.
3. Complete and sign the enclosed Customer Response Form and return this form to the local Geringe office.
4. A Geringe Sales or Service person will contact the person you listed on the Customer Response Form to schedule the field safety corrective action (Upgrade hardware kit) for your device, free of charge.
5. Make sure that all listed devices at your facility are available for the Field safety corrective action during the Geringe service technician visit.

You can continue to use the device until the correction is performed. In case of any alarm call for a Geringe service technician for support.

This corrective action will be performed at no cost to affected customers.

Transmission of this Field Notice:

This Getinge ED-Flow AER Field Safety 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

CAPA 657027

Reference: Urgent Field Safety Notice, Getinge ED-FLOW AER washer disinfectors, models ED-FLOW AER and ED-FLOW SD AER.

Our records indicate that the Getinge ED-FLOW AER washer disinfectors, model ED-Flow AER and ED-Flow SD AER 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.	MANUFACTURING 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 AER, Field Safety 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 AER Field Safety Corrective Notice and we understand the communication and the required actions. Corrective 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 AER 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

CONTACT

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

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