

URGENT - FIELD SAFETY CORRECTIVE NOTICE

**GETINGE ED-FLOW, Automated Endoscope Reprocessor (AER)
Field Action CAPA 657266**

Date:	25-Oct-2022
Product Issue:	ED-FLOW RFID Faulty, CAPA 657266
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 make a software update to implement a new range of alarms to make sure that all devices present in the market are working effectively and safely. Getinge also propose to make recipe number visible on the process ticket.</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 disinfectors ED-FLOW AER range potentially exhibit behavior due to a system error whereby, during disinfection process, program parameter values or data block values for the endoscope tag have been overwritten with value "0" instead of the correct values.

Tags with value "0" have no monitoring (for pressure and flow) of channels and no alarm will be generated.

If an endoscope tag has been corrupt, "0" will be displayed on the HMI when loading the endoscope in the ED-FLOW. If this happens, the tag needs to be reprogrammed.

The device is still safe to use but pay extra attention to view the information on the HMI when loading an endoscope for a new process.

Action:

Getinge has released a Field action upgrade kit (hardware and software) to correct the issue of corrupt endoscope tags.

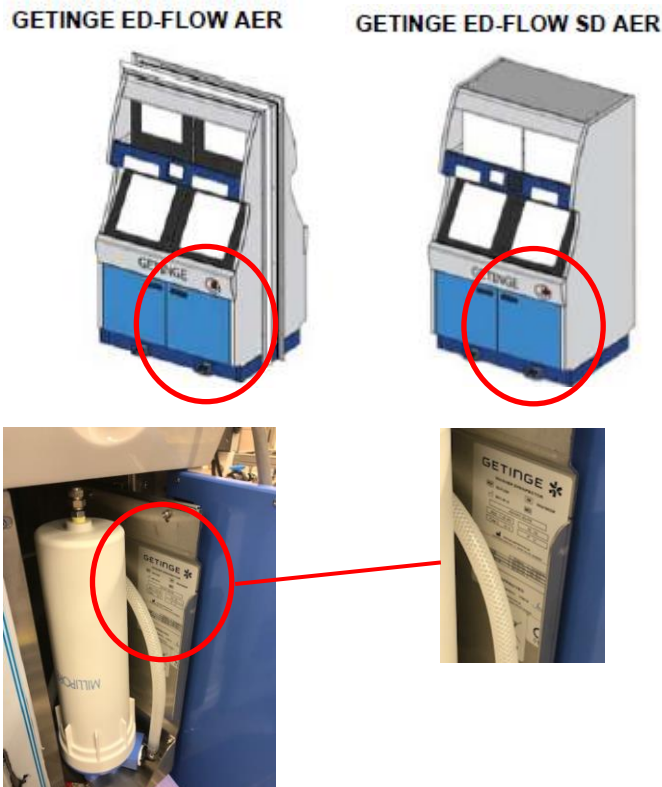
We see the issue as a long-term hazard and want to prevent any related event from reoccurring with our customer.

This action is to implement new software to the device that detects any corrupt endoscope tag. The recipe number will also be visible on the process ticket. The 24V earth power cabling will be rerouted to stabilize the voltage.

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 Getinge ED-FLOW AER and Getinge 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 Getinge office.
4. A Getinge 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 Getinge service technician visit.

You can continue to use the device until the correction is performed but pay extra attention to the recipe number displayed on the HMI when loading an endoscope for process.

If any endoscope should display recipe "0", the tag shall be reprogrammed and before the endoscope can be processed.

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 657266

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>