

URGENT - FIELD SAFETY NOTICE

Getinge ED-FLOW, Automated Endoscope Reprocessor (AER)

Date:	01-Jul-2022
Product Issue:	Temperature not reached ED-FLOW, CAPA 627769
Affected Product:	ED-FLOW AER, 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 complementary instruction to the User manual how to review critical parameters on the daily process ticket. Getinge also propose to make a software update to implement a new range of alarms.</i>
Affected Serial Nos.:	All ED-FLOW AER-models manufactured since start 2010 until 2022-05-05.
Field Correction Notice:	<i>GD11599 Instruction Process ticket for User</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 a temperature sensor in the ED-FLOW AER chamber may not work as intended and may provide incorrect temperature readings for washing and disinfection temperature during process. The result on the process ticket has shown OK despite the temperature not having reached the parameters required for validated biocidal activity.

The ED-Flow chamber is equipped with two temperature sensors, the Controlling value (CTRL) and the Independent Value (I.V.). These sensors values are shown on the process ticket.

The difference between the Controlling value (CTRL) and the Independent value (I.V) must not differ more than 2°C.

The machine does not give an alarm if the temperature differ between CTRL and I.V. The machine only alarms when the Controlling value (CTRL) temperature is too low or too high. It does not alarm if only the Independent value (I.V.) temperature is too low or too high.

The printed ticket displays "OK" even when there is a greater difference in washing or disinfection temperature than allowed.

If a larger difference than 2°C occur, the temperature sensors (CTRL and I.V.) need to be recalibrated and the endoscopes reprocessed.

Action:

As an immediate action, Getinge have issued a complementary instruction *GD11599 Instruction Process Ticket for User ED-FLOW AER* that together with the *ED-FLOW User manual* will show how to review the values on the process ticket. This instruction is attached to this FSCN and shall be distributed to all operators of the Getinge ED-FLOW AER.

NOTE!

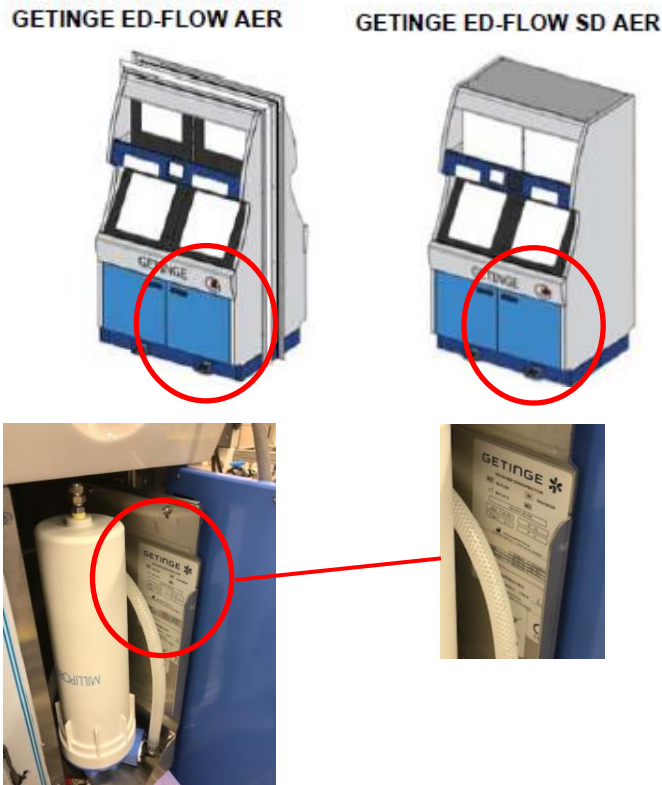
GD11599 Instruction Process Ticket for User ED-FLOW AER shall be used upon awareness of this FSCN.

Getinge will update *The Getinge ED-FLOW AER User manual 60024642xx* with clarification on how to review the information of the values provided on the process tickets.

Getinge will release a new device software that provides an alarm when controlling temperature (CTRL) and Independent value temperature (I.V.) differ too much.

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 and as an immediate action provide them with *GD11599 Instruction Process ticket for User ED-FLOW AER*.
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 (update of software) 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, provided that *Geringe ED-FLOW AER User manual* and the complementary instruction *GD11599 Instruction Process Ticket for User* is followed.

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

Reference: Urgent Field Safety Corrective 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.	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 AER, 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 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

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

CONTACT

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

Ref.no: GD11594 Rev A

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

Fax: *<SSU contact fax number>*

ID: GD11599 Rev A

Instruction Process ticket for User Getinge ED-FLOW AER

This instruction is a complement to the procedure described in the Getinge ED-FLOW AER range User manual 60024642xx, chapter 8 Traceability and is applicable to all operators of the Getinge ED-FLOW AER.

Follow the user manual and pay extra attention to the review of the critical parameters displayed on the process ticket.

Procedure

The process ticket shall be reviewed in direct connection with the completed cycle.

Review that the critical program parameters on the process ticket are corresponding to the values in the program sheets 11.1 (Flexible Endoscope Disinfection programs) and 11.2 (Self-disinfection programs) in chapter 11 *Appendixes* of the Getinge ED-FLOW AER User manual.

Critical parameters

- A. In the Washing phase the temperature needs to be above 20°C according to the program sheet.*
- B. In the Disinfection phase of any program the temperature must stay between the described value in the program sheet with a tolerance of -0/+5°C for disinfection efficacy.*

The temperatures in the disinfection phase and the washing phase are displayed in the CTRL (Controlling Value) and I.V. (Independent Value) values on the process ticket.

The difference between the Controlling value (CTRL) and the Independent value (I.V.) must not differ more than 2°C.

If a larger difference than 2°C occur, the temperature sensors needs to be recalibrated and the endoscope reprocessed. Call service for recalibrating the temperature sensors in the ED-FLOW chamber before use of the device.

ID: GD11599 Rev A

Below shows examples of a typical process ticket from ED Flow, with information of what the user must look for in the review of the ticket.

CTRL

This column shows the value of the Controlling temperature sensor (CTRL)

I.V.

This column shows the value of the Independent Value temperature sensor (I.V.)

Critical parameter A

	CTRL	I.V.
MIN. TEMP. FOR WASHING 1:	20.8	21.0
AVER. TEMP. FOR WASHING 1:	22.0	22.1
MAX. TEMP. FOR WASHING 1:	23.1	23.3
DLC WEIGHT WASHING 1:	51	OK
MIN. TEMP. FOR WASHING 2:	21.5	21.6
AVER. TEMP. FOR WASHING 2:	22.7	22.9
MAX. TEMP. FOR WASHING 2:	23.8	24.0
DLC WEIGHT WASHING 2:	51	OK
CHAMBER WATER VOLUME:	3251	3276
DISINFECTANT A WEIGHT:	55	OK
DISINFECTANT B WEIGHT:	55	OK
MIN. TEMP. DISINFECTION:	37.3	37.4
AVER. TEMP. DISINFECTION:	37.6	37.7
MAX. TEMP. DISINFECTION:	38.0	38.2
CONTACT TIME AT REGULATED TEMP.:	300	
FINAL RINSING CONDUCTIVITY:	264.0	
PUMP PRESSURE:	1003	991

Critical parameter B

The difference between CTRL and I.V. must not be more than 2°C.

Ticket shows a standard cycle for endoscope reprocessing

Critical parameter A	MIN. TEMP. FOR WASHING 1:	CTRL	I.V.
		37.7	37.6
	AVER. TEMP. FOR WASHING 1:	41.0	40.9
	MAX. TEMP. FOR WASHING 1:	42.3	42.2
	DLC WEIGHT WASHING 1:	54	OK
Critical parameter B	CHAMBER WATER VOLUME:	3900	3838
	MIN. TEMP. DISINFECTION:	85.4	85.3
	AVER. TEMP. DISINFECTION:	85.7	85.6
	MAX. TEMP. DISINFECTION:	86.3	86.2
	CONTACT TIME AT REGULATED TEMP.:	190	
	FINAL RINSING CONDUCTIVITY:	1.0	

Ticket shows a Self-disinfection A0-600 cycle