LANCER
GETINGE GROUP

URGENT – FIELD SAFETY NOTICE

GETINGE ED-FLOW AER, ED-FLOW SD AER
SOFTWARE UPDATE – Field Action 2016-01

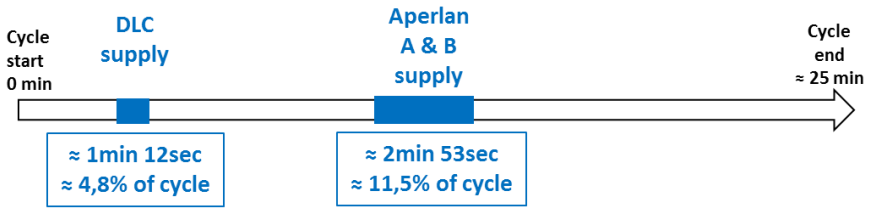
Date:	**September XX, 2016**
Product Issue:	**Because of a software issue, if the compressed air supply of the machine is lost right before or during product supply (DLC detergent, Aperlan Poka-Yoke Agent A/B disinfectant), the machine does not launch or complete the product supply when reprocessing a scope. As a result, no alarm is triggered.**
Affected Product:	**All Getinge ED-FLOW AER and ED-FLOW SD AER of model number 01280004 – 01280010 – 01280012 – 01280014 - 01280015**
Resolution:	**Getinge proposes to update the machines to make sure all devices present on the market are working effectively and safely, by updating the software to version 3.1.0**
Affected Serial Nos.:	**3H070234; 3H070233; 5H100465; 5H100466; 5H100467; 5H100468; 2H100169; 3H100244; 3H020205**
Field Correction Notice:	**Update the software to version 3.1.0**
Pages:	**4**

Dear Customer:

Our records indicate that you bought one or more GETINGE ED-FLOW AER or ED-FLOW SD AER with a model number listed as above.

This letter is to inform you of a corrective action that will be performed to prevent a possible failure of the device with a potential hazard to persons.

The issue we found can cause a lack of product supply (DLC detergent or Aperlan Poka-Yoke Agent A and Agent B disinfectant) if the compressed air supply of the machine is lost right before or during product supply, and after cycle start, and not re-established before cycle end (periods in blue on timeline).



Duration of reprocessing cycle and product intake in an ED-FLOW or ED-FLOW SD AER

If the quantity of DLC detergent or Aperlan Poka-Yoke Agent A and Agent B disinfectant introduced into the Automated Endoscope Reprocessor chamber is not in line with the validation performed according to ISO 15883-4, this can cause a cross-contamination of the next patient if the scope is not properly washed/disinfected.

This issue was raised during final testing of an ED-FLOW during the manufacturing process at the factory and we have not received any complaint related to this issue. **From our investigation, it was concluded that the probability of failure occurring is limited to a compressed air supply loss right before or during the product supply phases of the machine (about 4 minutes and 5 seconds).**

This potential for malfunction is caused by a design error in the software source code: the product supply function is wrongly conditioned by air presence. We have developed a new version of the software and removed this wrong condition in the source code. **In version 3.1.0, the product supply function is no longer conditioned by air presence.** The devices involved for your market are all Getinge ED-FLOW AER or ED-FLOW SD AER.

Next Steps

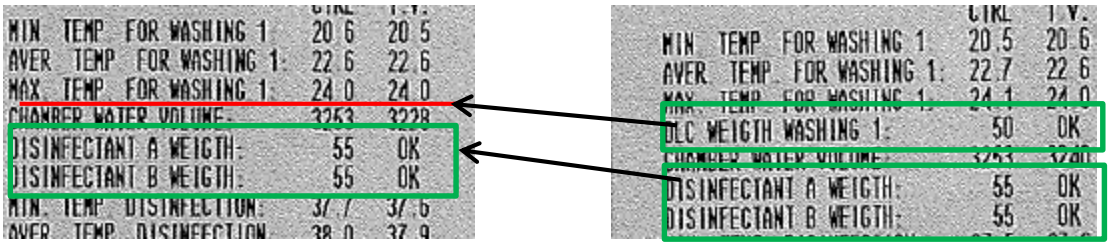
1. Please make sure that all caregivers and users of the Getinge ED-FLOW AER or ED-FLOW SD AER referenced on the previous page are made aware of this Field Notice and all listed devices at your facility are available to be updated during the Getinge service technician visit.

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 to **update your device to version 3.1.0 of the software**, free of charge.

3. **In the meantime, this issue can be detected by careful examination of the ticket printed at the end of each reprocessing cycle. <u>Please make sure to systematically check and record that there are 3 lines printed on the ticket</u> (example below) :**

   - **DLC weight washing 1 OK**
   - **Disinfectant A weight OK**
   - **Disinfectant B weight OK**

   If any of these 3 lines is not printed, the reprocessing cycle was not performed properly. <u>You need to reprocess the endoscope to ensure proper washing and disinfection</u>.



<u>Wrong ticket :</u>
DLC line is missing

<u>Correct ticket :</u>
all 3 product weight lines are printed

Transmission of this Field Notice

This Getinge ED-FLOW AER or ED-FLOW SD AER 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 Notice.

Additional Comment

The MHRA has been informed of this Field Safety Corrective Action.

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.

Best regards,

LANCER
GETINGE GROUP

Keith Jenner
Director of QHSE
Surgical Workflows, UK & Ireland

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Customer Response Form

Field Action 2016-01 / CAPA 167835

Reference: Urgent Field Safety Notice, Getinge GETINGE ED-FLOW AER, ED-FLOW SD AER

Our records indicate that the GETINGE ED-FLOW AER or ED-FLOW SD AER 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.

Model Number	Designation
01280004	GETINGE ED FLOW LDE
01280010	LDE ED FLOW V2 50Hz - 400V TRI+N+T
01280012	LDE ED FLOW V2 60HZ - 400V TRI+N+T
01280014	LDE ED FLOW SD 50Hz - 400V TRI+N+T
01280015	LDE ED FLOW SD 60Hz - 400V TRI+N+T

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 or ED-FLOW SD 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, please)				
City, State, Zip				
Phone Number		**Fax:**		
E-Mail Address:				

☐ We have sold/moved our GETINGE ED-FLOW AER or ED-FLOW SD 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**

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