

URGENT – FIELD SAFETY CORRECTIVE NOTICE

**GETINGE 88-5 Washer disinfectors
Field Action 1303821 – CAPA 1287961**

Date:	August 15, 2025
Product Issue:	A Getinge 88-5 washer-disinfectors caught fire due to overheating of the heater element, caused by absent or incorrect calibration of the circulation pressure sensor.
Affected Product:	Getinge 88-5 Washer disinfectors (all units with electrical heating) Only those units identified in the below list of affected serial numbers for your market were identified to be affected.
UDI DI	07340153700109 07340153700116
SRN	SE-MF-000001012
Resolution:	Getinge proposes to verify that the pressure in the circulation system reads 0.0 kPa during stand-by mode to make sure all devices present in the market are working effectively and safely. If the pressure does not indicate 0.0 kPa, the device must be calibrated by a qualified technician. An instruction will be provided to support the verification process.
Affected Serial Nos.:	See the below list of affected serial numbers for your market.
Field Correction Notice:	This Field Action is planned with the reason that there was a fire incident registered on a Getinge 88-5 washer disinfectors, where smoke was emitted due to overheating of the heater element. The heater element was overheated and caused the insulation on cover plates to melt and create smoke. Other items like cables, hoses etc. did also melt and cause smoke.
Pages:	See in the footer

Dear Customer:

Our records indicate that you bought or rented one or more Getinge 88-5 Washer Disinfectors with a serial number listed in Appendix 1 below.

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

The issue we found can cause the device to overheat during operation if the circulation pressure calibration was not performed or been performed incorrect and the low-pressure alarm is not triggered. This can result in the melting of insulation, cables, and hoses, and in some cases, may lead to smoke emission or fire.

From our investigation, which includes an evaluation of worst-case scenarios, it was concluded that there is a medium risk that this issue may cause injury, such as skin burns or smoke inhalation. While the likelihood is low, the potential consequences justify immediate corrective action.

This potential for malfunction is caused by a combination of incorrect or not performed calibration of the circulation pressure sensor and changes to the pressure alarm lower limit, which may prevent the device from triggering a low-pressure alarm during operation. This condition can lead to overheating of the heater elements and, in rare cases, result in smoke or fire.

We have developed a verification procedure to ensure that the circulation pressure in standby mode is correctly calibrated to 0.0 kPa. If the value deviates, recalibration by a qualified technician is required. We see this issue as a potential long-term hazard and are taking proactive steps to prevent any recurrence of such events with our customers.

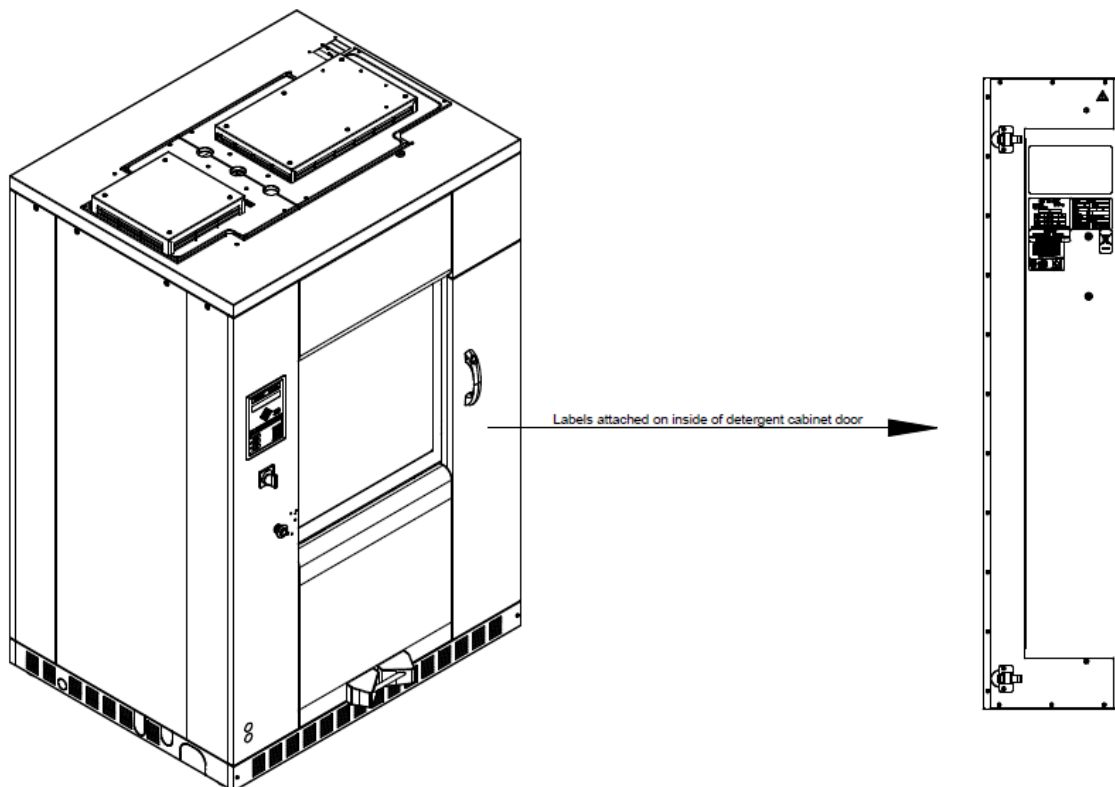
This action is to verify the calibration status of the circulation pressure system and, where necessary, recalibrate the affected devices, see next steps below.

The devices involved for your market are limited to those listed in Appendix 1 of this notice.

Next Steps

1. Check the serial number of your Getinge 88-5 Washer disinfectant. The serial number shall correspond with the serial number on the customer response form (Appendix 1).

The serial number is located on the marking label attached to the machine. This label is placed on the inside of the detergent cabinet door, see picture below:



2. Please make sure that all caregivers and users of the 88-5 referenced on the previous page are made aware of this Field Safety Corrective Notice.
3. The verification of the circulation pressure shall be performed by the operator or Getinge technician according to the provided instruction, see GD14265. Please document the circulation pressure value in the table below.
4. If the value deviates from 0.0 kPa out of allowed tolerances (± 1 kPa), stop using the device immediately and contact a Getinge representative to arrange recalibration of the pressure sensor free of charge.
5. Complete and sign the enclosed Customer Response Form and return this form to the local Getinge office.

Transmission of this Field Notice:

This Getinge 88-5 Field Safety Corrective 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.

Sincerely,

Emelie Szabo

Electronically signed by: Emelie Szabo
Reason: I approve this document.
Date: Aug 19, 2025 19:58:46 GMT+2

Emelie Szabo

Acting Quality Manager

fsca-disinfectionse32.sw@getinge.com

Getinge Disinfection AB

Ljungadalsgatan 11, 35246 Växjö

Sweden

Appendix 1

Customer Response Form

GETINGE 88-5 Washer disinfecter

Field Action 1303821 – CAPA 1287961

Reference: Urgent Field Safety Corrective Notice, Getinge 88-5 Washer disinfecter

Our records indicate that the Getinge 88-5 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.

SERIAL NO.	PRESSURE CIRC-value (should be 0.0 kPa; acceptable range: ± 1 kPa)	Recalibration needed (Yes / No)
1	XXX.X	XXX
2	YYY.Y	YYY

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

Please check the appropriate boxes below:

☐ We have read the Getinge 88-5 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 Corrective 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 88-5 Field Safety 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 88-5 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>
<local SSU address line 3>
<local SSU address line 4>

CONTACT

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