

URGENT – FIELD SAFETY NOTICE

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

Date:	May 2026
Product Issue:	A Getinge 88-5 Washer Disinfector caught fire due to overheating of a heater element.
Affected Product:	Getinge 88-5 Washer Disinfector (all units with electrical heating) Only the units identified by the serial numbers listed below are affected in your market.
UDI-DI	07340153700109 07340153700116
SRN	SE-MF-000001012
Resolution:	Getinge proposes that a Getinge technician shall verify that the alarm limit for the water circulation pressure is 20 kPa and perform a calibration of the pressure sensor, according to the updated calibration method in the manual.
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 Disinfector, where smoke was emitted due to overheating of a 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,

This letter provides an update on Getinge's voluntary Field Safety Corrective Action for electrically heated 88-5 Washer Disinfectors, originally communicated in August 2025.

This Revision E of Customer Letter GD14271 supersedes all previous versions.

Issue Description

The initial investigation determined that the device was found to overheat during operation if the calibration of the circulation pressure was not performed or had been performed incorrectly and the alarm for low circulation pressure was not triggered.

The information sent out in previous customer letter was a precautionary action that was taken by checking the Circulation Pressure value in Stand By mode, to verify it was 0,0 kPa or otherwise re-calibrate.

Further investigation determined that the device could overheat during operation if the following conditions occurred:

- the water circulation pressure is too low *in combination with*:
- the circulation pressure calibration not being performed or performed incorrectly *and/or*
- The low circulation pressure alarm is not triggered due to the alarm limit being changed by a technician.

This can result in the melting of insulation, cables, and hoses, and in some cases, may lead to smoke emission or fire.

Risks to Health

Between January 2015 and February 2026, Getinge has received six complaints associated with this issue. No serious injuries or patient harm were reported; although, Getinge's investigation has concluded it is possible that injuries such as skin burns or smoke inhalation may occur.

Recommended Mitigations

Getinge service technicians will be proactively reaching out to you to ensure your device is working appropriately. In this check the Getinge service technician will perform:

- A verification that the alarm limit for low pressure in the circulation system does not deviate from the factory settings of 20 kPa and correct it if any deviation is found.
- A calibration of the pressure sensor according to the updated procedure in the Service Manual. The method for calibration is revised and improved and will include the entire measurement chain, including the actual pressure sensor.

The updates to the service manual can be found in **Appendix 2**.

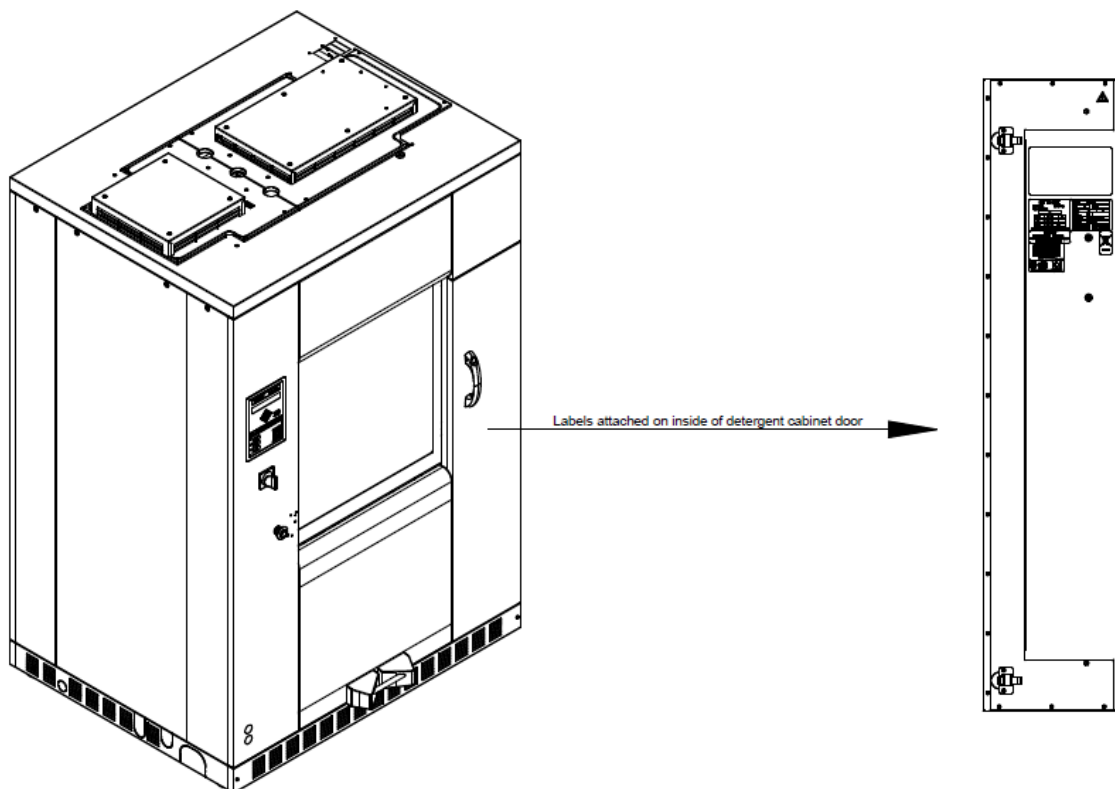
The devices involved for your market are limited to those listed below in **Appendix 1** of this notice.

Actions to be taken by the customer

Our records indicate that you have received one or more Getinge 88-5 Washer Disinfectors with a serial number listed in Appendix 1 below. As a result, Getinge requests that you take the following actions:

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

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 ensure this message is forwarded to any individuals that need notification within your organization or any organization where the affected devices have been transferred.
3. Complete and sign the enclosed Customer Response Form and return this form to the local Getinge office. Contact information can be found at the bottom of Appendix 1, below.
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, i.e verify the alarm limit for water circulation pressure and perform a calibration of the pressure sensor.
5. Make sure that all listed devices at your facility are available for the field safety corrective action during the Getinge service technician visit.

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

Transmission of this Field Safety Notice:

This Getinge 88-5 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 field safety corrective action.

In cases where you as customer choose not to proceed with completion of the field safety 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.

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,

Nina Stewén
Local Quality Manager
Getinge Disinfection AB
Ljungadalsgatan 11
35246 Växjö
Sweden

Enclosures:
Appendix 1 – Customer Response Form
Appendix 2 – Updates to the Service Manual

Appendix 1

Customer Response Form
GETINGE 88-5 Washer Disinfector
UPDATED Field Action 1303821 – CAPA 1287961

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

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.

GETINGE ORDER NO.	ITEM NO.	SERIAL NO.	MANUFACTURING DATE
X	1	XXXX	<Date>
Y	2	YYYY	<Date>

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>

APPENDIX 2

GETINGE 88-5 Washer Disinfector UPDATED Field Action 1303821 – CAPA 1287961

In addition to actions specified in the Customer Letter we hereby also inform you about the updates made in the Service Manual and the Preventive Maintenance Checklist (PM Checklist).

The Manual and the PM Checklist are included as attachments to the customer letter. Both documents are provided in English; the manual is also available in Swedish, German, and French:

6001235002_SERV_88_EN_RevL

6002523102_PM Checklist_88_EN_Rev B

A summary of the updates made, related to this issue, in the Service Manual rev L are:

- **In section 5.3 - TROUBLE SHOOTING – page 70**
 - Clarification of alarm A21 – Low pressure from circulation pump
 - New added Section 5.3.1 – A21 Low circulation pressure alarm / A21 Low circulation pressure alarm general – page 73 – 74
- **In section 6.3 – Loading a program to flash memory – page 96**
 - Two warnings added:
 - When loading a new, updated, or from another 88-series prm file to an existing or new CPU/relay boards flash memory, calibrations of the pressure sensor, temperature sensor, conductivity sensor, and dosing system must be performed.
 - An incorrectly calibrated pressure sensor can contribute to overheating, which can lead to a fire.
- **Section 6.3.3 Loading a new application into PACS and 6.3.3.1 With CS1000 – page 99 – 101**
 - Updated and clarified
- **Section 6.4.3 Pressure sensor for circulation pump – page 107 – 109**
 - Two warnings are added
 - When loading a new, updated, or from another 88-series prm file to an existing or new CPU/relay boards flash memory, calibrations of the pressure sensor, temperature sensor, conductivity sensor, and dosing system must be performed.
 - An incorrectly calibrated pressure sensor can contribute to overheating, which can lead to a fire.
 - And the method for calibration of the pressure sensor is changed. The actual pressure sensor is now included in the calibration.

- **Section 7.4.3 P-parameters – page 178**

- A warning added that the alarm limit for low pressure (CIRC PRESS L) shall not be changed. If this is changed, it can contribute to overheating, which can lead to a fire.
- In the table, the interval for CIRC PRESS L is removed.

- **PM Checklist 6002523102_PM Checklist_88_EN_Rev B**

- The PM Checklist is also updated with checkpoints related to the alarm limit and the calibration under point 6.4.3.