

Getinge Deutschland GmbH
 Kehler Str. 31
 76437 Rastatt
 Germany

Urgent FIELD SAFETY NOTICE, Getinge 86-series, Correction

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|-------------------------------------------------------|--------------------------------------|------------|
| Device deficiency | Date | Ref. no. |
| Collapsing pump hose | 07.05.2019 | CAPA199553 |
| Affected Product: | Affected Serial No. | |
| Getinge 86-series with appl. models S-8666, S-8668 | Devices delivered after 28. Nov 2018 | |
| Resolution | | |
| Notification letter of a corrective action. | | |

Dear Customer:

Our records indicate that you have bought one or more Getinge 86-series(S-8666, S-8668) washer disinfector with serial number listed above.

This letter is to inform you of a corrective action that will be performed to prevent a possible hazardous situation.

It has come to our attention that on some units of the model Washer Disinfector S-8666 and S-8668 the pump hose can collapse during the washing process. This error is a result from a faulty rubber compound in the process from supplier.

If the issue occurs there will be low water pressure to the spray arms which will lead to slow movement of the spray arm and less water flow. This can result in uncleaned goods after finished process.

Correction:

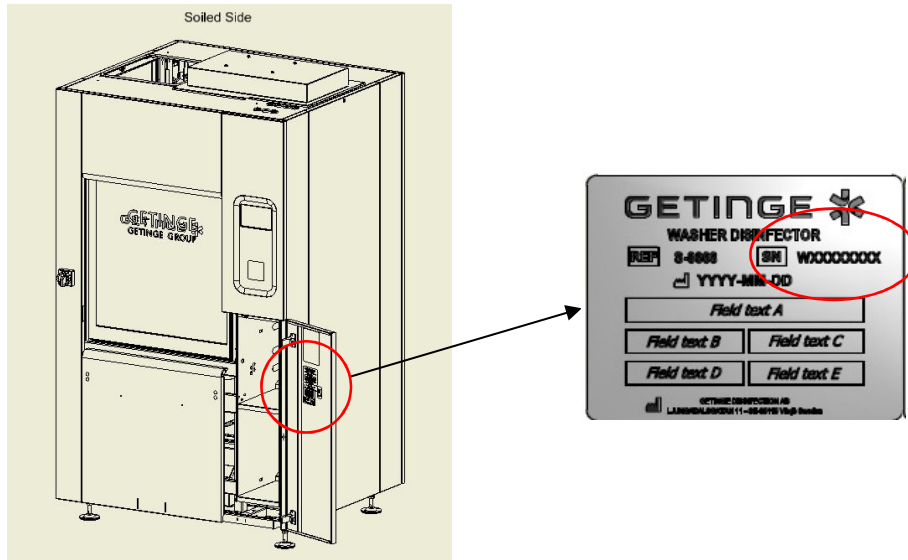
As we see a potential hazardous situation and want to prevent any related event from occurring with the Washer Disinfector, the pump hose will be exchanged with a pump inlet made of stainless steel. The update is prepared in a kit and our service units will make sure the correction is done accordingly.

This Safety Notification contains important information for the continued safe and proper use of your equipment

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Next steps

1. Check the serial number of the Washer Disinfector to see if your device is affected by this field action. The serial number is located on the marking label on the machine, see location below.



2. Please make sure that all caregivers and users of the 86-series Washer Disinfector (referenced on the previous page) are made aware of this Field Safety Notice and all affected devices at your facility are available during the Getinge service technician visit.
3. 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 for update of your device, free of charge.
4. Take below precautions until the Field action has been performed!

Precaution!

It is recommended not to operate the machine unattended.

Always inspect the processed goods after a wash cycle.

If below points is noticed call for a service technician who can examine the washer:

- If the washer starts to sound different than usual during a wash cycle, abort the process.
- Uncleaned goods after process.

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Transmission of this Field Notification:

This Getinge 86-series 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 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 take any responsibility for safety related issues or legal liabilities caused by the failure to respond to this Field Safety Notice.

Further information and support

We deeply regret any inconvenience this may cause. We appreciate your understanding as we take actions to ensure a safe and reliable product. If you have any questions regarding your installed machine or need assistance in completing your Customer response form, please contact your Getinge representative.