

Urgent FIELD SAFETY NOTICE, Getinge 86-series, Correction

Device deficiency	Date	Ref. no.
Collapsing pump hose	25 April 2019	CAPA199553
Affected Product:	Affected Serial No.	
Getinge 86-series with appl. models S-8666, S-8668	None affected	
Resolution		
Notification letter of a corrective action.		

Dear Customer:

cc to the Chairman Medical Board and relevant Head-of-Department

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:

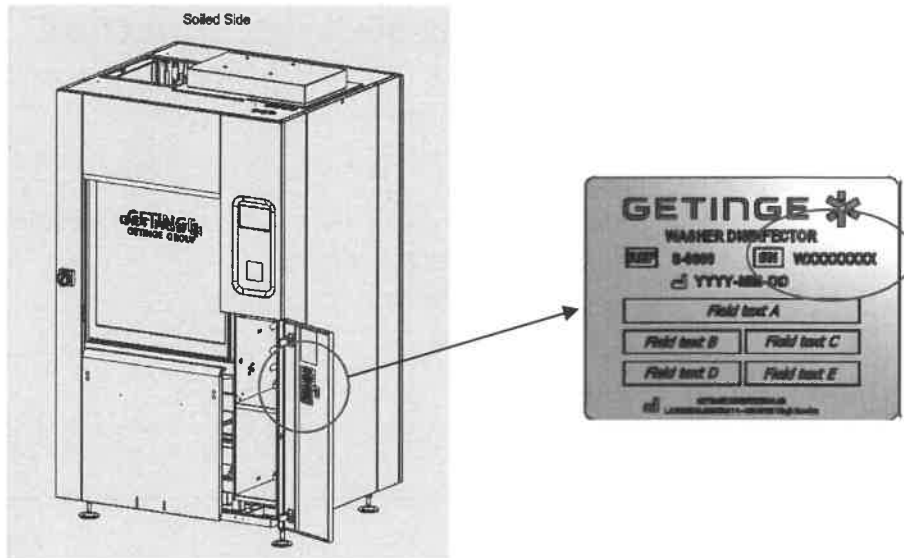
As we see a potential hazardous situation and want to prevent any related event from occurring with the Washer Disinfector, the pump hose will be exchanged with a pump inlet made of stainless steel. The update is prepared in a kit and our service units will make sure the correction is done accordingly.

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

Urgent FIELD SAFETY NOTICE, Getinge 86-series

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.

Urgent FIELD SAFETY NOTICE, Getinge 86-series

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.

Yours sincerely



/George Tan

Director, Quality & Regulatory Compliance
South Asia Pacific

Getinge South East Asia Pte Ltd

Customer Response Form

CAPA199533

Reference: GD8495 – Urgent Field Safety Notice, Getinge 86-series

Our records indicate that a Getinge 86-series as 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.	Model / Item	SERIAL NO.
To be filled in by SSU		

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

Please check the appropriate boxes below:

- ☐ We have read the Field Safety Notice (GD8495) and we understand the communication and the required actions. **We will take action** as soon as possible according to instructions.
- ☐ We have read the Field Safety Notice (GD8495) and we understand the communication and the required actions. **We cannot take action** but are aware of the addressed problem.

If checked: please provide information where the affected devices are physically located.

Field 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 86-series 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>