

Getinge Disinfection AB
Ljungadalsgatan 11, 352 46 Växjö
Sweden

FIELD SAFETY NOTICE, Getinge 88-series

Device deficiency	Date	Ref. no.
Potential Leakage	17 th of January 2020	GD8980
Affected Product:	Affected Serial No.	
Model: 88-5	Devices manufactured before November 2012	
	<ul style="list-style-type: none"> • Serial number before W50038660 • All machines with SEVxxxxxxx 	
Resolution		
Field Safety Notice		

Dear Customer:

This letter is to inform you of a potential leakage that can occur on devices produced before November 2012. Our records indicate that you have bought one or more of 88-5 washer disinfectors within the range described affected. On some units of the model Washer Disinfectors 88-5, leakage can occur from ruptured spot welds in the chamber. If leakage occurs it will be noticed by hospital staff.

This message is to point out and remind you to call for service technician.

User manual (6001234702) Safety – Important!
Leakage in the system, e.g. due to a worn door seal, must be repaired without delay.

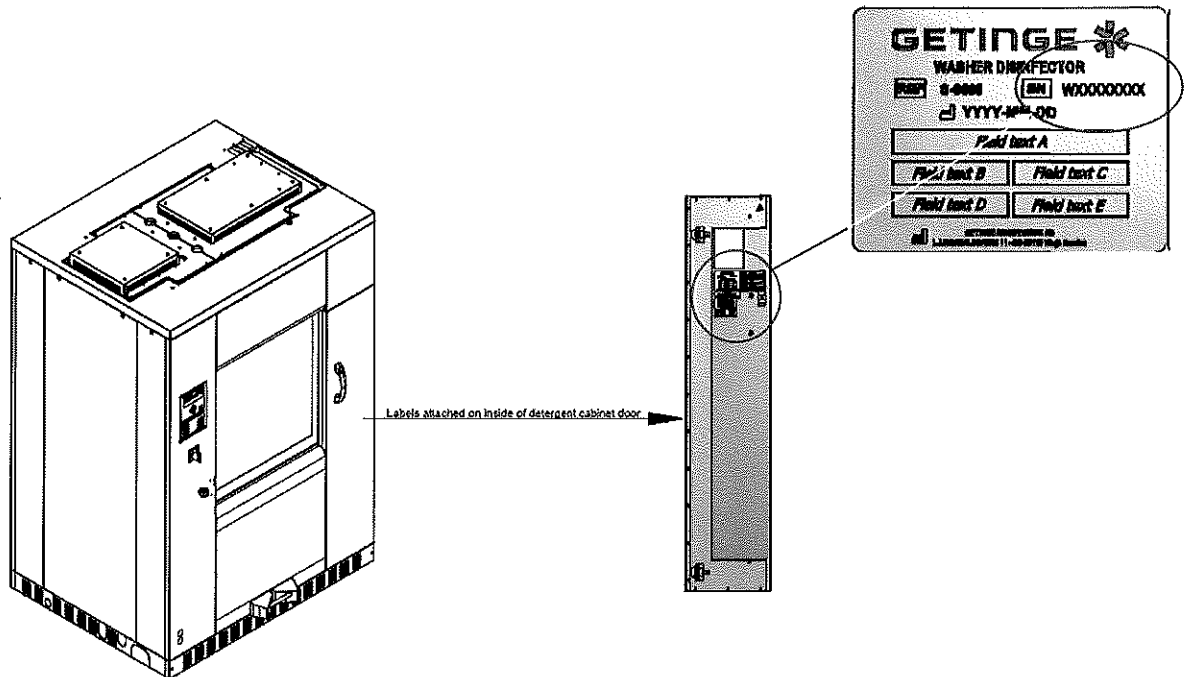
A leaking device could generate a potential hazardous situation for the user; risk for slipping or infection from contaminated water. To prevent any possible event to occur with users working in the environment of the Washer Disinfectors please follow the steps on next page.

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. The serial number is located on the marking label on the machine, see location below.



2. Check if the machine is leaking underneath the machine or near the machines foot print.
3. If the machine is leaking, call for Service Technician and plan for service!
You can continue to use the machine but we recommend a sign for precaution.
4. Complete and sign the enclosed Customer Response Form and return this form to the local Getinge office.

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Transmission of this Field Notification:

This Getinge 88-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 inform Getinge, we 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



Maria Elovsson
Quality Manager
Getinge Disinfection

Customer Response Form

Reference: GD8980– Field Safety Notice, Getinge 88-series

Our records indicate that a Getinge 88-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 and we understand the communication and will take action according to FSN.

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 scrapped our Getinge 88-serie

We have sold/moved our Getinge 88-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>