

**URGENT - FIELD SAFETY CORRECTIVE NOTICE****GETINGE CM320**

Date: 21-Dec-2020

Product Issue: Water leakage CM320, CAPA 326680

Affected Product: 189 units of Getinge Washer Disinfector CM320

UDI DI  
07340153700178 GETINGE CM320WD CM320-2 CHAMBER WD  
07340153700185 GETINGE CM320WU CM320-2 CHAMBER WU  
07340153700192 GETINGE CM320WUWD CM320-4 CHAMBER WUWD  
07340153700208 GETINGE CM320WWD CM320-3 CHAMBER WWD  
07340153700215 GETINGE CM320WWWD CM320-4 CHAMBER WWWD  
07340153710153 GETINGE CM320WDK966 CM320-2 CHAMBER WD

SRN N/A

Resolution: *Getinge propose to repair the devices to make sure all devices present in the market are working effectively and safely.*

Affected Serial Nos.: 31244 – 31306, W50024942 – W50048716, WAA052208 – WAA096623

Field Correction Notice: N/A

Pages: 5

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Ref.no: GD10007 Rev C

Dear Customer:

Our records indicate that you have bought one or more Getinge CM320 with a serial number listed above.

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

Getinge has discovered a water inlet plastic hose connection that may deform or break due to material fatigue or hose clamp overtightening. A broken hose connection can cause a water leakage and water spray.

The potential water leakage from the hose connector is within the service area of the device, behind the cover sheet.

This potential for malfunction may be caused by incorrect choice of material when the machine was designed. Other contributors are that the hoses not always are supported and attached to the equipment and that the hose clamps are tightened too hard, which causes deformation and potentially cracks.

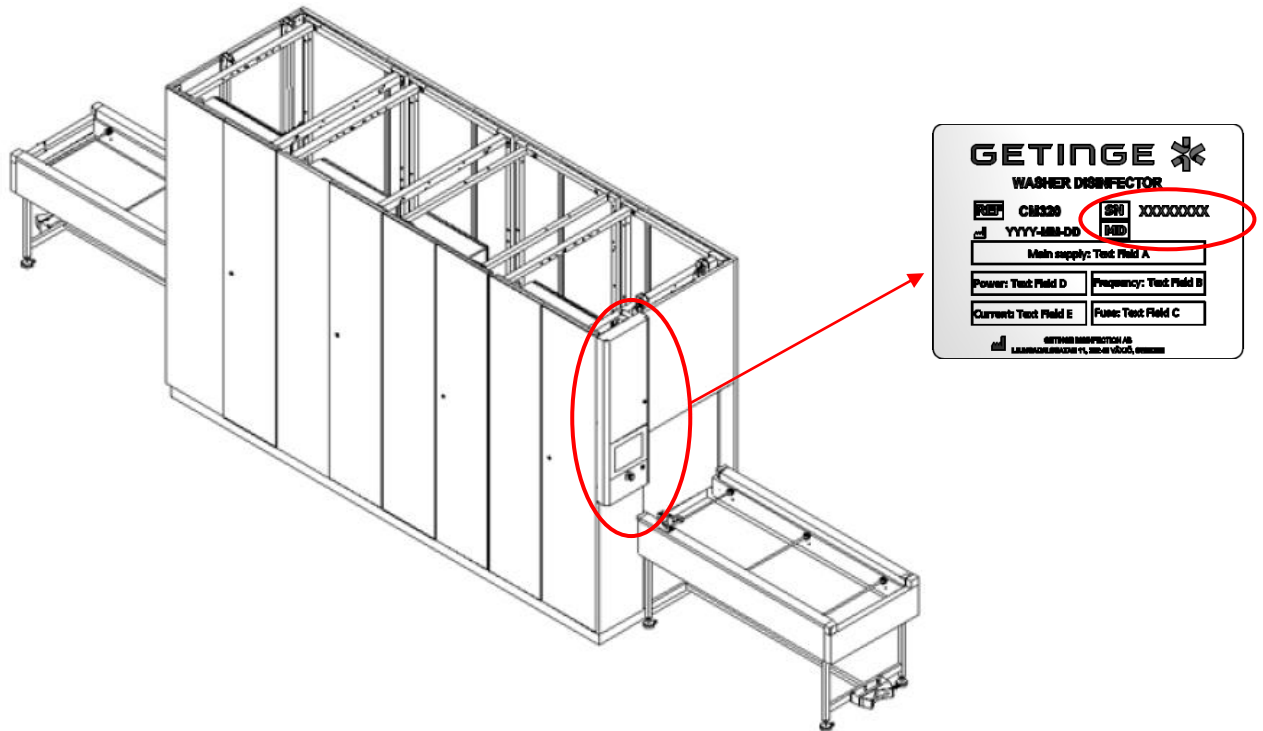
The device model is still being manufactured and as we see this issue as a potential long-term hazard and want to prevent any related event from occurring with our customers, Getinge has developed new hose connectors in stainless steel to replace the connectors in plastic.

The device is still safe to use but be extra cautious for any water leaks and follow the instruction for daily maintenance.

A correction kit is currently available and the correction will be completed at no cost to affected customers.

### 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. The marking label is located on the inside of the Panel door see below.



2. Please make sure that all caregivers and users of the CM320 referenced on the previous page are made aware of this Field Notice and all listed devices at your facility are available to be checked 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 to correct your device, free of charge.

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**Transmission of this Field Notice:**

This Getinge CM320 Field 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.

## Customer Response Form

### Appendix 1

**Reference: Urgent Field Safety Corrective Notice, Getinge CM320.**

Our records indicate that the Getinge CM320 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.	SHIPPING DATE
X	1	XXXX	<Date>
Y	2	YYYY	<Date>

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

Please check the appropriate boxes below:

We have read the Getinge CM320 Field Safety Corrective Notice and we understand the communication

and the required actions.

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

#### Field Safety Notice Receipt and Customer Response Form Completion and Certification

<b>Current Facility Name</b>			
<b>Contact Name / Title</b>			
<b>Address (no PO boxes)</b>			
<b>City, State, Zip</b>			
<b>Phone Number</b>		<b>Fax:</b>	
<b>E-Mail Address:</b>			

We have sold/moved our Getinge CM320 to another facility.

**If checked : please provide new facility information below.**

<b>New Facility Name</b>			
<b>Contact Name / Title</b>			
<b>Address*</b>			
<b>City, State, Zip</b>			
<b>Phone Number</b>		<b>Fax:</b>	
<b>E-Mail Address:</b>			

**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>