

Name
Address
Country

Urgent FIELD SAFETY NOTICE, Getinge WD15 Claro, Correction

Device deficiency

Potential water leakage

Affected Product:

Getinge WD15 Claro,
Model GE15

Resolution

Date

August, 2018 (to be changed)

Affected Serial No. (See location on next page)

WAA078527 to WAA079522

WAA082404 to WAA085431 and WAA085543

Ref. no.

CCS219711

Getinge propose to repair the devices to make sure all devices present in the market are working effective and safe.

Dear Customer:

Ower records indicate that you have bought a Getinge WD15 Claro with serial number as listed above. This is a second letter with follow up information of a correction.

The problem is a possible water leakage on limited Washer Disinfectors of model GE15. If the issue occurs, there will be alarm both aucustic and visual on the machines' display. This leakage may take place in the last part of the cleaning and disinfection cycle, during operation.

If the issue is left unattended there can be a leakage of cold water out from the water supply to the machine. If no reaction to the alarm there can be a significant amount of water to the floor with the consequences of a slippery floor which could lead to a person might fall and get hurt and there is also a risk for property damage from the water.

Correction:

As we see a potential hazardous situation and want to prevent any related event from occurring with the Washer Disinfecor we have now a solution in place. This is a change of the design and will require an update to the device. The update is prepared in a kit and our service units will make sure the correction is done accordingly.

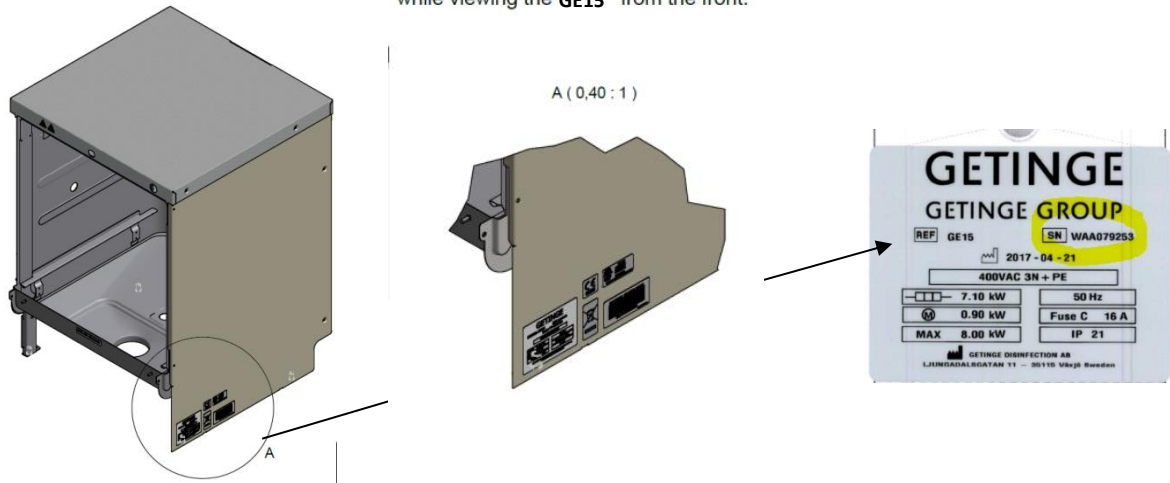
This Safety Notification contains important information for the continued safe and proper use of your equipment

Urgent FIELD SAFETY NOTICE, Getinge WD15 Claro

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.

The label has a right sideplacement while viewing the **GE15** from the front.



2. Please make sure that all caregivers and users of the **GE15 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 - especially if any water is not possible to be diverted to the building drain. Please react on the device alarms at once.

If an alarm, do the following;

- Switch off the main switch
- Close shut off valves in the water supply lines
- Contact service technician

Urgent FIELD SAFETY NOTICE, Getinge WD15 Claro

Transmission of this Field Notification:

This Getinge WD15 Claro 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 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 regret any inconvenience this may cause or have caused you. 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

First name Last name

Title

Company SSU

Customer Response Form

CCS 219711 (Field action 221514)

Reference: GD7734 – Urgent Field Safety Notice, Getinge WD15 Claro

Our records indicate that a Getinge WD15 Claro 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 (GD7734) 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 (GD7734) and we understand the communication and the required actions. **We can not 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 WD15 Claro 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>