

URGENT - FIELD SAFETY CORRECTIVE NOTICE

Getinge 9100-series Washer Disinfector

Date: 08-MAR-2022

Product Issue: Missing Installation verification 91xxE/ EW-models, CAPA 555530

Affected Product: 9120E, 9125E, 9127E, 9128E, 9122EW, 9128EW

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07340153710023
07340153710030
07340153710047
07340153710054
07340153710061
07340153710078

SRN N/A

Resolution: *Getinge propose to make a verification of installed units to ensure that all devices present in the market are working effectively and safely.*

Affected Serial Nos.: All 91xxE/ EW-models manufactured since start 2017 until 2021-12-21.

Field Correction Notice: N/A

Pages: 5

Ref.no: GD11271 Rev B

Dear Customer:

Our records indicate that you have bought one or more Getinge 9100-series Washer Disinfector (models: 9120E, 9125E, 9127E, 9128E, 9122EW, 9128EW).

This letter is to inform you of a corrective action that will be performed to verify and document installation activities for previously installed Getinge 9100-series Washer Disinfectors. The documented verification of installation shall assure that the unit is performing as intended and prevent a possible hazard to patient and/or user and equipment.

It is important to note that there have been no adverse events attributable to this issue.

As manufacturer of Medical Device we have regulatory requirements which mean we shall verify and document installation activities to show that installed units meet regulatory compliance and perform safely and effectively.

All units are delivered with an installation manual that describes how the installation shall be done and what needs to be checked and tested before handed over to customer.

Getinge has discovered that verification of installation is not always documented or the documentation is incomplete and does not confirm that all installation activities have been performed as required by the installation manual.

We have no reason to believe that any installation has been performed incorrectly.

The purpose of this Field Action is to ensure to have the proper documentation for all installed units in the field to verify that each installed unit is meeting all requirements regarding efficiency, safety and regulatory compliance.

To ensure this Getinge will perform a corrective action in form of an Installation Qualification verification.

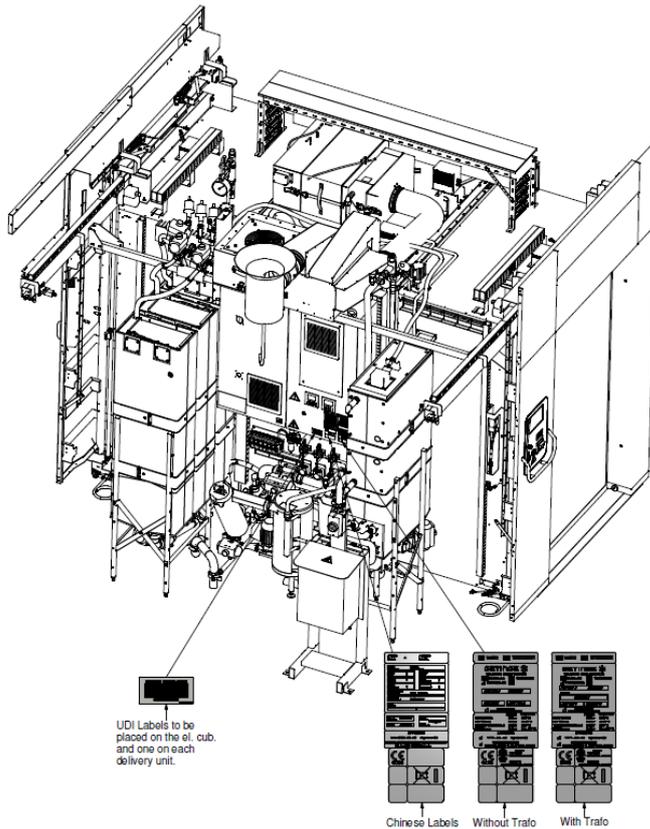
A technician qualified by Getinge will perform and verify a number of checkpoints and document these according to Field Action instruction.

You can continue to use the machine until the correction action is performed and you do not need to take any precaution actions meanwhile.

This corrective action will be performed at no cost to affected customers.

Next Steps

1. Check the serial number of the Getinge 9100-series, model 91xxE/ EW unit. The serial number shall correspond with the serial number on the customer response form (Appendix 1). The serial number can be found on the product label, located on the electrical cabinet.



Picture 1. Location of serial number product label

2. Please make sure that all caregivers and users of the Getinge 9100-series, model 91xxE/ EW are made aware of this Field Notice and all listed devices at your facility are available for the Field safety corrective action 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 the field safety corrective action for your device, free of charge.

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Transmission of this Field Notice:

This Getinge 9100-series, model 91xxE/ EW Washer Disinfector 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 9100-series, model 91xxE/EW.

Our records indicate that the Getinge 9100-series, model 91xxE/ EW 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 9100-series, model 91xxE/ EW 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

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

We have read the Getinge 9100-series model 91xxE/ EW Field Safety Corrective Notice and we understand the communication and the required actions. Corrective activity is not needed as the affected device(s) in our facility were removed from usage/decommissioned.

We have sold/moved our Getinge 9100-series, model 91xxE/ EW 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>

CONTACT

<contact ddress>@getinge.com
Tel: <SSU contact phone number>

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<local SSU address line 3>
<local SSU address line 4>

Fax: <SSU contact fax number>