
URGENT - FIELD SAFETY NOTICE

**GETINGE TRANS STEAM STERILIZER
Field Action 249797**

Date: 15-JUN-2020

Product Issue: EN285 Compliance-Back Door Problem

Affected Product: 1, Getinge Trans Steam Sterilizer- All models are affected.

Resolution: Getinge propose to update the all software (hardware if necessary) of affected devices to make sure all devices present in the market are compliance with regulations.

Affected Serial Nos.: Please see attached consignee list with serial numbers.

Field Correction Notice: The software of the affected devices in the field will be updated in accordance with EN285: 2016, 4.3.2.2 *'It shall not be possible to open the unloading door in routine use until "cycle complete" is indicated' clause.*

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Dear Customer:

Corrective and preventive action has been initiated to make sure your product is up to the related standards. Getinge technical personnel will come to visit to carry out the action.

Our records indicate that you bought one or more Trans Steam Sterilizer with serial number listed as above.

This letter is to inform you of a corrective action that will be performed to prevent possibility of non-sterile material problem. The action will be taken for the devices listed herein to make sure they have the updated software according to standard.

Getinge became aware of an event with Trans pass through sterilizers with description suggesting a possibility to open the unloading door without "cycle complete" is indicated. There was no adverse event reported however, we decided to report this case in abundance of caution as the open the back door during not completed cycle could lead to use unsterilized/contaminated load.

This non-compliance situation is caused by software error. The software has been updated since 2019 Jan and all devices manufactured since that date are compliant with the standard. However, software updates must be made on devices manufactured until that date. We see the issue as a potential hazard and want to prevent any related event from occurring with our customers. This action is to update the device software. The devices involved for your market are limited to those listed on this page.

Next Steps

1. Please make sure that all caregivers and users of the Trans Steam Sterilizer referenced on the previous page are made aware of this Field Notice and all listed devices at your facility are available to for the service intervention during the Getinge service technician visit.
2. 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 update the software, free of charge.

Transmission of this Field Notice:

This Trans Steam Sterilizer 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 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

<Getinge field action number>

Reference: Urgent Field Safety Notice, Getinge <Device Name>.

Our records indicate that the <Device Name> 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.	MANUFACTURING 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 <Device Name> Field Safety 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 sold/moved our <Device Name> 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>