

Urgent Field Safety Notice

GETINGE
GETINGE GROUP

Dear Sir/Madam

Date 2014-08-07

Getinge is initiating a field safety correction with regards to Washer-Disinfector of GETINGE Getinge 46-Series (CM302) with PACS 300/350 control.

Summary

Getinge Disinfection AB (GDSE) has received two customer complaints from Germany regarding sediment residuals in the manifold of the washer and disinfector of Getinge 46-Series (CM302) with PACS 300/350 control.

We have however now after performing detailed root cause analysis identified the problem as insufficient water flow throughout the manifold due to formation of air-pockets where sedimentation may occur. Use of detergents that are not recommended might also have negative impact.

Description of Risk

The potential risk that exists is that during drying phase the air circulating may transport particles from the sedimentation and deposit it on goods. And if the particle contains bacterial flora there might be risk for cross contamination.

The probability for patient risk is however low for the following reasons.

1. The path from area with sedimentation to the chamber is a labyrinth where particles would be trapped before reaching the chamber.
2. Test carried out on installed machines in use show no sign of sedimentation on instruments.

So probability of occurrence of harm (cross infection) is low.

Actions to be taken:

The actions that will be carried out will fully address the problem of sedimentation ie stop any future sedimentation. You will be contacted by a Getinge representative to schedule a visit.

The following will be done by Getinge.

- Cleaning of the manifolds.
- Adding ventilation-hole at the top of the manifold and linking it to the chamber i.e. preventing the formation of any air-pockets and secure a continuous water flow. See details in appendix 1
- Getinge will examine and exchange the check valve twice per year to ensure that there will be no sedimentation.
- In addition during the first 6 months after the corrective measures, monthly visual checks will be carried out by a Getinge service technician or a trained "user-facility" service technician who has received training/instructions from Getinge.
- Getinge will amend the instruction for use regarding the use of detergents, including a list of recommended detergents.

After the corrective measures, Getinge will randomly request some user for samples. Getinge will send the samples to a test lab for testing to ensure that there are no sediments on goods.

Enclosed is a Customer Response Form that must be completed and faxed to XXXXXX. Our receipt of the response form provides us with the required feedback that you received and understand this notification.

Getinge regrets any inconvenience that this field correction may cause. Your satisfaction with Getinge products and service is of the utmost importance to us. If you should have any questions, please contact your local Service Representative by calling XXXXXXXXXX.

Regards/SSU designated person

Urgent Field Safety Notice

Appendix 1: Photos of ventilation hole eliminating any trapped air in the manifold..



Figure 1: vent hole added on top of manifold to prevent trapping of air.

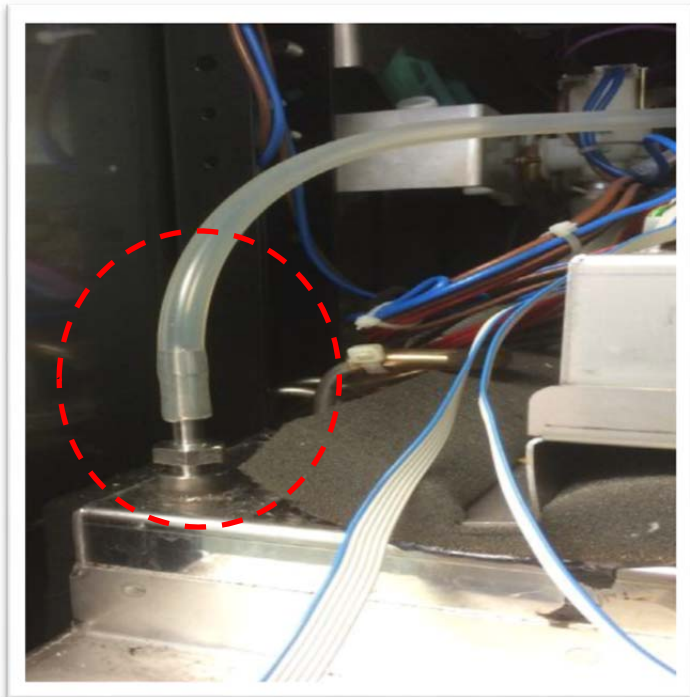


Figure 2: The vent hole is linked back to the chamber through a pipe