

Dear Sir/Madam,

Please find enclosed the field safety notice for the FSCA **GETINGE AQUADIS 56 – Frequency Inverter not programmed Field Action 1202136\_CAPA 1127926**.

Sincerely,

*Ye Da Tee* Electronically signed by: Ye Da Tee  
Reason: I have reviewed this document  
Date: Apr 15, 2025 16:23 GMT+8

Tee Ye Da  
QRC Specialist  
Getinge South East Asia Pte Ltd

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URGENT – FIELD CORRECTIVE NOTICE

**GETINGE AQUADIS 56 – Frequency Inverter not programmed  
Field Action 1202136\_CAPA 1127926**

<b>Date:</b>	April 15, 2025
<b>Product Issue:</b>	GETINGE AQUADIS 56 – Frequency Inverter not programmed Field Action 1202136_CAPA 1127926 Field Action Plan GD13822
<b>Affected Product:</b>	Washer Disinfector Getinge Aquadis 56 of model number 56M and 56A
<b>UDI DI</b>	73401537000484
<b>SRN</b>	SE-MF-000001012
<b>Resolution:</b>	Getinge propose to rework the units which does not have a programmed Frequency Inverter, by replacing the memory module inside the frequency Inverter, to make sure all devices present in the market perform as intended and are working effectively.
<b>Affected Serial Nos.:</b>	All units manufactured between the release of the machine model 2022 until 30 <sup>th</sup> August 2024. Serial numbers of affected units can be found in Appendix 1.
<b>Field Correction Notice:</b>	This correction is triggered to prevent a possible failure of the device. The failure is related to that a component can wear and tear earlier than expected. The unit is safe to use, and you do not have to undertake any preventive actions
<b>Pages:</b>	5 including Appendix 1

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Dear Customer:

Our records indicate that you bought one or more Washer Disinfector Aquadis 56 with a serial number listed as below.

This letter is to inform you of a corrective action that will be performed to prevent a possible failure of a device.

It has come to our attention that there is a possibility that the device can have an unprogrammed Frequency Inverter.

The Frequency Inverter is facilitated in the electrical cabinet which is a part of the washer disinfector.

The Frequency inverter controls the rotational speed of the circulation pump. When the Frequency inverter is not programmed, this causes the circulation pump to start earlier than expected, creating possibility for a short dry run, before lubrication of axial seal is maintained by the waterflow in the pump housing. As a consequence, if the frequency inverter is not programmed, this can potentially cause additional wear and tear on the axial seal in the pump housing.

**The device is still safe to use and you do not have to undertake any preventive actions.** The machine is working as intended with the exception that in the long run, this can cause wear and tear earlier than expected and the water consumption might be higher than intended.

**Risks to health:**

The potential risk to health is defined as a possible procedural delay in case of an unplanned downtime caused by the failure.

This potential for malfunction is caused by a supplier nonconformity and measures have been taken to prevent this issue for appearing again. During the next normal planned maintenance, the technician will check if your device(s) is affected and in that case, perform all necessary actions to ensure that the device/machine is working according to specification. This will be performed during the normal planned maintenance to avoid any inconvenience for you as a customer.

**Customer Actions**

1. Check the serial number of the Washer Disinfector Aquadis 56. The serial number (WAAxxxxxx) shall correspond with the serial number on the customer response form (Appendix 1). The serial number can be found on the marking label, located on the inside of the lower door, see below.



2. Please make sure that all caregivers and users of the Getinge Washer Disinfector Aquadis 56 are made aware of this Field Corrective Notice.
3. Complete and sign the enclosed Customer Response Form and return this form to the local Getinge office.
4. A Getinge Sales or Service person will plan this service within next planned maintenance. **Note:** If no service agreement with Getinge, a Sales or Service person will contact the person you listed on the Customer Response Form to investigate if your device is affected by this failure and if so, replace the memory module in the Frequency Inverter, free of charge.
5. Make sure that all listed devices at your facility are available for the Field corrective action during the Getinge service technician visit.

**Transmission of this Field Notice:**

This Getinge Washer Disinfector Aquadis 56 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 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

Field Action 1202136 / CAPA 1127926

**Reference: Urgent Field Corrective Notice, Getinge Washer Disinfector Aquadis 56.**

Our records indicate that the Washer Disinfector Aquadis 56 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 devices currently located at your facility here please → \_\_\_\_.

Please check the appropriate boxes below:

\*We have read the Getinge Washer Disinfector Aquadis 56 Field Corrective Notice and we understand the communication and the required actions.

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

### Field Corrective 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 read the Getinge Washer Disinfector Aquadis 56 Field 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 Washer Disinfector Aquadis 56 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**

Getinge South East Asia Pte Ltd  
20 Bendemeer Road, #06-01/02  
BS Bendemeer Centre  
Singapore 339914

**CONTACT**

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