



نقدم بثقة
Moving Forward
with Confidence



To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES

Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)

Director General of Engineering Affairs, MOH

Director General of Royal Hospital

Director General of Khoula Hospital

Director General of Medical Supplies (MOH)

Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)

Hospital Director (Al Nahda Hospital)

Hospital Director (Al Massara Hospital)

The Head of Medical Services in SQU Hospital

The Head of Medical Services in Royal Oman Police

The Head of Medical Services in Ministry of Defence

The Head of Medical Services in The Diwan

The Head of Medical Services in The Sultan's Special Force

The Head of Medical Services in Internal Security Services

The Head of Medical Services in Petroleum Development of Oman

The Head of Medical Services in LNG Oman

ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 105 dated 19/5/2025 Regarding SFDA Field Safety Corrective Action of GETINGE AQUADIS 56 from (mfr: Getinge).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DSC
- Director of Pharmacovigilance & Drug Information Dept, DSC
- Director of Drug Control Department, DSC
- Director of Pharmaceutical Licensing Department, DSC
- Director of Central Quality Control Lab., DSC
- Supdt. of Central Drug Information



DSC
مركز سلامة الدواء
Drug Safety Center



ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩

P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489

✉ @DSCPHO Email: dscpho@moh.gov.om



Circular No. 105 / 2025

21 -11-1446 H
19 -05-2025

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Field Safety Corrective Action of GETINGE AQUADIS 56 from Getinge.

Source	SFDA- Saudi Food & Drug Authority. https://ade.sfda.gov.sa/Fsca/PublishDetails/356
Product	GETINGE AQUADIS 56.
Manufacturer	Getinge.
Local agent	Waleed Pharmacy & Stores LLC.
The affected products	Washer Disinfector Getinge Aquadis 56 of model number 56M and 56A. All units manufactured between the release of the machine model 2022 until 30th August 2024. Refer to the consignee list.
Reason	There is a possibility that the device can have an unprogrammed Frequency Inverter.
Action	1. Please make sure that all caregivers and users of the Getinge Washer Disinfector Aquadis 56 are made aware of the attachment, A Getinge Sales or Service person will plan this service within next planned maintenance. 2. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: vigilance-md@moh.gov.om

Ph. Ibrahim Nasser Al Rashdi
Director General



URGENT – FIELD CORRECTIVE NOTICE

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

Date:	April 7 th , 2025
Product Issue:	GETINGE AQUADIS 56 – Frequency Inverter not programmed Field Action 1202136_CAPA 1127926 Field Action Plan GD13822
Affected Product:	Washer Disinfector Getinge Aquadis 56 of model number 56M and 56A
UDI DI	73401537000484
SRN	SE-MF-000001012
Resolution:	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.
Affected Serial Nos.:	All units manufactured between the release of the machine model 2022 until 30 th August 2024. Refer to the consignee list
Field Correction Notice:	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
Pages:	4

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.

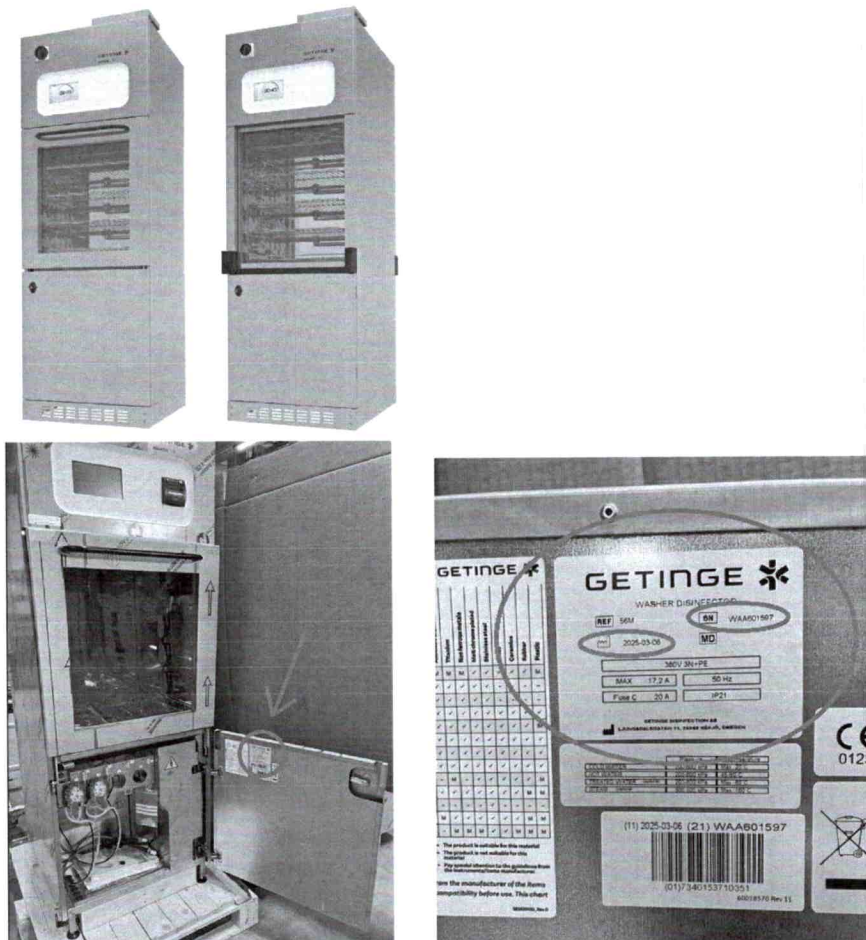
Risks to health:

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

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

☐ 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. s

**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

mubashir.javed@getinge.com; anusuyaa.mohandass@getinge.com;
dina.alabbas@getinge.com