



Circular No. 25 / 2023

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07-07-1444 H

29-01-2023

Field Safety Corrective Action of Dako CoverStainer CS10030 from Agilent Technologies, Inc.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=10&rid=18414
Product	Dako CoverStainer CS10030.
Description	Instrument/analyser IVDs.
Manufacturer	Agilent Technologies, Inc.
Local agent	Mustafa Sultan Science & Industry Co LLC.
The affected products	Multiple serial numbers.
Reason	Some AFGS modules incorrectly detect a too low air flow in the above Dako CoverStainer instrument which causes air flow alarms and instrument shutdowns.
Action	1. A) Upon installation, customers should verify the function of the ventilator on CoverStainer start up, by visual and audible inspection. B) For customers already running the external ventilator accessory, they should continue verifying the function of the ventilator on CoverStainer start up. 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: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
Director General





To:

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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 25 dated 29/2023 Regarding NCMDR Field Safety Corrective Action of Dako CoverStainer CS10030 from (mfr: Agilent Technologies, Inc).

Copy to:

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



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TGA Recall

Reference Number: mdprc 006 01 23 000

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Date submitted: 1/15/2023

Manufacturer:	Agilent Technologies, Inc.
Device Type:	Dako CoverStainer CS10030
Description:	Instrument/analyser IVDs
Medical Device Identifier:	Multiple serial numbers
Reason of Field Safety Corrective Action:	Some AFGS modules incorrectly detect a too low air flow in the above Dako CoverStainer instrument which causes air flow alarms and instrument shutdowns.
Remedy Action:	The customers will be contacted shortly to schedule the installation of the external ventilator accessory on their instrument. A) Upon installation, customers should verify the function of the ventilator on CoverStainer start up, by visual and audible inspection. B) For customers already running the external ventilator accessory, they should continue verifying the function of the ventilator on CoverStainer start up.
Athorized Representative/Importer/Distributor:	Dar Al-Zahrawi Medical Co. LLC
Report Source:	https://apps.tga.gov.au/Prod/sara/arn-detail.aspx?k=RC-2022-RN-01581-1
Source Ref. Number:	RC-2022-RN-01581-1
SFDA Comments:	SFDA urges all hospitals that have devices subjected to this FSCA to contact the company.
Attachments:	No Attachments

[View History](#)

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Recall detail

Type of Productⁱ	Medical Device
TGA Recall Referenceⁱⁱ	RC-2022-RN-01581-1
Product Name/Descriptionⁱⁱⁱ	Dako CoverStainer CS10030. An in vitro diagnostic medical device (IVD) Multiple serial numbers ARTG 181957 (Agilent Technologies Australia Pty Ltd - Instrument/analyser IVDs)
Recall Action Level^{iv}	Wholesale
Recall Action Classification^v	Class II
Recall Action Commencement Date^{vi}	5/01/2023
Responsible Entity^{vii}	Agilent Technologies Australia Pty Ltd
Reason / Issue^{viii}	Agilent Technologies Australia has identified that some AFGS modules incorrectly detect a too low air flow in the Dako CoverStainer instrument which causes air flow alarms and instrument shutdowns. In these instances investigation determined that the air flow on the instruments is adequate. During service of Dako CoverStainer, technicians installed an air flow simulator mimicking sufficient air flow signals to the system to keep the instrument operable which disabled the AFGS. Further investigation is ongoing and until a permanent fix to this issue is implemented, temporary risk mitigation is required to ensure safety.
Recall Action^{ix}	Product Defect Correction
Recall Action Instructions^x	Agilent Technologies Australia will contact customers shortly to schedule the installation of the external ventilator accessory on their instrument. A) upon installation, customers should verify the function of the ventilator on CoverStainer start up, by visual and audible inspection B) for customers already running the external ventilator accessory, they should continue verifying the function of the ventilator on CoverStainer start up.
Contact Information^{xi}	tbc

Footnotes

ⁱ Type of Product: Medicine, Medical Device, or Biological

ⁱⁱ TGA Recall Reference: Unique number given by the TGA

ⁱⁱⁱ Product Name/Description: Brand name (including active ingredient for medicines) and may include generic reference for the kind of medical devices. Includes all necessary information such as affected: catalogue / model and / or batch / serial numbers.

^{iv} Recall Action Level: The level to which the recall action is to be undertaken. This is based on the significance of the