Sultanate of Oman Ministry of Health Directorate General of Pharmaceutical Affairs and Drug Control Muscat



سلطنة عُمان وزارة الصحة المديرية العامة للصيدلة والرقابة الدوائية مسقط

To:

Moving Forward

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 97 dated 24/5/23 Regarding NCMDR Field Safety Notice of Reliance® Vision Multi-Chamber Washer/Disinfector from (mfr: STERIS Corporation).

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





ص.ب: ۳۹۳ مسقط - الرمز البريدي: ۱۰۰ - هاتف: ۲۲۳۰۷۱۱۱ - فاکس: P.O. Box: **393** Muscat - Postal Code: **100** - Tel: **22357111** - Fax: **22358489**

Sultanate of Oman Ministry of Health Directorate General of Pharmaceutical Affairs and Drug Control Muscat



المديرية العامية لل والسرقابة الدوائ

Circular No. 97/2023 to pain in Forward

04 -11-1444 Н

24 -05-2023

Field Safety Notice of Reliance® Vision Multi-Chamber Washer/Disinfector from STERIS Corporation.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19520						
Product	Reliance® Vision Multi-Chamber Washer/Disinfector.						
Description	Single-chamber washer/disinfector.						
Manufacturer	STERIS Corporation.						
Local agent	Perfect Business.						
The affected products	Reliance Vision Multi-Chamber Washer/Disinfectors (UDI Number 00724995193164) Distributed between June 7, 2006 – February 21, 2023 Refer to "Attachment A" in the attached FSN.						
Reason	STERIS has identified that in the remote occurrence in which the electrical contactor component present in the drying chambers of the Reliance Vision Multi-Chamber Washer/Disinfector malfunctions, the heating elements in the drying chamber could overheat, eventually resulting in smoke and/or fire.						
Action	 Users can continue to use their Reliance Multi-Chamber Washer/Disinfectors prior to completion of the correction. Should your unit alarm "Drying Temperature Too High," abort the cycle, turn off the power to the unit, and contact STERIS. All affected Customers will be contacted by a STERIS Service Technician to arrange an onsite inspection of their unit(s) and perform the correction. 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 Rubaic

Director General





ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩ P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489



URGENT MEDICAL DEVICE FIELD CORRECTION

Reliance® Vision Multi-Chamber Washer/Disinfector

March 28, 2023

ATTN: MATERIALS MANAGEMENT OR STERILE PROCESSING DEPARTMENT

Dear Valued STERIS Customer:

STERIS is voluntarily implementing a field correction for Reliance Vision Multi-Chamber Washer/Disinfectors (UDI Number 00724995193164) distributed between June 7, 2006 – February 21, 2023. Our records indicate that your facility purchased one or more of the Washer/Disinfectors included in this field correction. Please reference Attachment A to this letter for the full list of affected serial numbers.

<u>Description of the product</u> – The Reliance Vision Multi-Chamber Washer/Disinfector is intended for use in the cleaning and intermediate level disinfection of soiled reusable utensils, trays, glassware, bedpans and urinals, rubber and plastic goods, simple hard-surfaced rigid surgical instruments, such as forceps and clamps, and other similar and related articles found in healthcare facilities.

<u>Description of the problem</u> – STERIS has identified that in the remote occurrence in which the electrical contactor component present in the drying chambers of the Reliance Vision Multi-Chamber Washer/Disinfector malfunctions, the heating elements in the drying chamber could overheat, eventually resulting in smoke and/or fire.

STERIS has developed an automatic shut off of the power to prevent the heating elements from overheating if this malfunction were to occur. The unit would remain "ON" in an alarm state, informing the user that service is required. There have been thirteen (13) complaints associated with this issue.

<u>STERIS Action</u> – All affected Customers will be contacted by a STERIS Service Technician to arrange an onsite inspection of their unit(s) to perform the correction.

<u>User Action</u> – Users can continue to use their Reliance Vision Multi-Chamber Washer/Disinfector prior to completion of the correction. Should your unit alarm "Drying Temperature Too High," abort the cycle, turn off the power to the unit, and contact STERIS. The competent (regulatory) authority of your country has been informed of this notice. Customer response is not required.

Users are reminded to report any adverse events via FDA's MedWatch Database should an event occur. We apologize for any inconvenience this matter may cause, and as always, STERIS is dedicated to supporting our products and valued Customers. If you have questions regarding this matter, please contact Sarah Brown, Senior Product Manager at 440-392-7571, STERIS Customer Service at 1-800-548-4873, or your local STERIS Representative.

Sincerely,

Michelle LaVan

Lead, Quality & Regulatory Compliance Specialist

nichellezavan

STERIS

Attachment A – List of affected serial numbers Reliance Vision Multi-Chamber Washer/Disinfector

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