



ننقدم بثقة
Moving Forward
with Confidence

رؤية عُمان
2040
Oman Vision

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 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



Circular No. 97/2023

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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	1. 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. 2. All affected Customers will be contacted by a STERIS Service Technician to arrange an onsite inspection of their unit(s) and perform the correction. 3. 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



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.

Description of the product – 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.

Description of the problem – 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.

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

User Action – 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,

A handwritten signature in black ink that reads "Michelle LaVan".

Michelle LaVan
Lead, Quality & Regulatory Compliance Specialist
STERIS

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

3600416016	3604417032	3608519001	3616109004	3624018002	3629014002	3633013003
3600622024	3604520026	3608615002	3616111012	3624210004	3629108006	3633206001
3600714004	3604612002	3609014014	3616113019	3624521001	3629112001A	3633317002
3600908001	3604710009	3609207002	3616318001	3624616022	3629119023	3633319035
3600908011	3605009011	3609422016	3616320002	3624812020	3629217002	3633321010
3601011012	3605013002	3609512007	3616914006	3624919019	3629420002	3633511005
3601014015	3605015001	3609809008A	3616918017	3625010007	3629711013	3633514038
3601017002	3605219005	3609814014	3617007001	3625114031	3629719006	3633515002
3601210008	3605312002	3609819030	3617009001	3625213015	3629921003	3633515004
3601215025	3605317002	3610007005	3617219002	3625220019	3630214002	3633520032
3601414005	3605411007	3610108008	3617310007	3625321002A	3630218043	3633609012
3601822001	3605510007	3610113001	3617414019	3625412018	3630320001	3633613033
3602108001	3605514027	3610312006	3617516021	3625518003	3630419006	3633707001
3602108005	3605715001	3610614003	3617520001	3625611009	3630511006	3633718036
3602110011	3605809011	36111115001	3618021027	3626009006	3630617003	3633813008
3602114001	3605814002	3611208008	3618407005	3626119006	3630618025	3634010002
3602213002	3606012003	3611222002	3618419005	3626120002	3630716003	3634019028
3602323012	3606110010	3611507014	3618506004	3626217001	3630921002	3634111014A
3602411012	3606111003	3611512001	3618517001	3626410001	3631006005A	3634116003
3602511011	3606117003	3611618001	3618709008	3626611005	3631019002	3634421001
3602512001	3606216001	3611709005	3618915003	3626621028	3631212002	3634608008A
3602517002	3606319035	3611717001	3618919003	3626719002	3631216030	3634707001
3602609007	3606414002	3611915001	3619020001	3626807001	3631217002	3634914028
3602714001	3606415003	3612318005	3619108006	3626912007	3631415002	3635313002
3602822001	3606416009	3613309009	3619312002A	3627210004	3631420028	3635820001
3602915001	3606712001	3613514002	3619509001	3627220001	3631513032	21361632135
3603014002	3606712003	3613713002	3619514016	3627314008	3631514002	980000005982
3603111001	3606717002	3614214002	3619615001	3627319043	3631709004	980000006284
3603117002	3606718005	3614318001	3621815016	3627517039	3631712023	980000006290
3603316002	3606722001	3614408006	3622413006	3627611013	3631719003	980000006291
3603420039	3606816007	3614715002	3622515004	3627612004	3631817002	980000006292
3603514019	3606914022	3614814010	3622620001	3627708005	3631916033	980000006293
3603615002	3607019041	3614909001	3622711006	3627718004	3632006004A	980000006294
3603817002	3607115001	3615022012	3622810002	3627721008	3632120029	980000006295
3603910011	3607217034	3615117002	3622812008	3627809004	3632213019	980000006332
3603912002	3607314001	3615216002	3622916001	3627817004	3632216004	980000006453
3603918005	3607411010	3615306011	3623014002	3628011011	3632221028	980000006458
3604114026	3607509011	3615311007	3623113010	3628019040	3632314002	980000006459
3604120029	3607616001	3615413018	3623308004A	3628110011	3632319002	980000006474
3604209012	3607620030	3615514008	3623412001	3628320001	3632610003	980000006475
3604219042	3607813001	3615618001	3623412001A	3628412002	3632812002	980000006498
3604222002	3607915001	3615717002	3623419003	3628419027	3632820027	980000006500
3604308012	3608022914	3615816011	3623510006	3628518014	3632914002	980000006502
3604313001	3608112002	3615819027	3623516024	3628621001	3632915001	980000006503
3604315005	3608116012	3616016002	3623521012	3628709002	3632916002	980000006546
3604414001	3608414012	3616017019	3623820001	3629011014	3632919037	980000006853