



نتقدم 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 103 dated 24/5/23 Regarding NCMDR Field Safety Corrective Action of 4K CAMERA HEAD from (mfr: Olympus).

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



PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical
Affairs & Drug Control



ص.ب: ٣٩٣ مسقط - الرمز البريدي: 100 - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩

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

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Circular No. 103/2023

نتقدم بـ
Wing Forward
with Confidence

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2040
Oman Vision

04 -11-1444 H

24 -05-2023

Field Safety Corrective Action of 4K CAMERA HEAD from Olympus.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19535
Product	4K CAMERA HEAD.
Description	Optics / Precision engineering – endoscopes.
Manufacturer	Olympus.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	Material ID: N5401750 Model Name: CH-S400-XZ-EB All serial numbers after 7030001 and before 7231311
Reason	4K CAMERA HEAD OLYMPUS CH-S400-XZ-EB is not autoclave-compatible but the table in the reprocessing manual incorrectly shows it is autoclave-compatible.
Action	1. Inspect your inventory for the referenced devices and identify any device with the CH-S400-XZ-EB model name. 2. Carefully read the content of this Field Safety Notice as well as the attached "Addendum". 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 FIELD SAFETY NOTICE

Reprocessing Manual Update for 4K CAMERA HEAD OLYMPUS CH-S400-XZ-EB

Material ID	Model Name	Product Name	Serial Number
N5401750	CH-S400-XZ-EB	4K CAMERA HEAD	all serial numbers after 7030001 and before 7231311

Dear Customer,

Olympus is writing to inform you of a revised, corrected repossessing manual for 4K CAMERA HEAD OLYMPUS CH-S400-XZ-EB. The camera head has been designed to be used with Olympus endoscopes, camera control unit, and other ancillary equipment for endoscopic diagnosis, treatment, and observation.

Background

4K CAMERA HEAD OLYMPUS CH-S400-XZ-EB is not autoclave-compatible but the table in the reprocessing manual incorrectly shows it is autoclave-compatible.

Corrected reprocessing instruction for the CH-S400-XZ-EB

Olympus is providing in this letter an Addendum that corrects the List of compatible methods in the reprocessing manuals. Please review the enclosed Addendum for detail.

Risk to Health

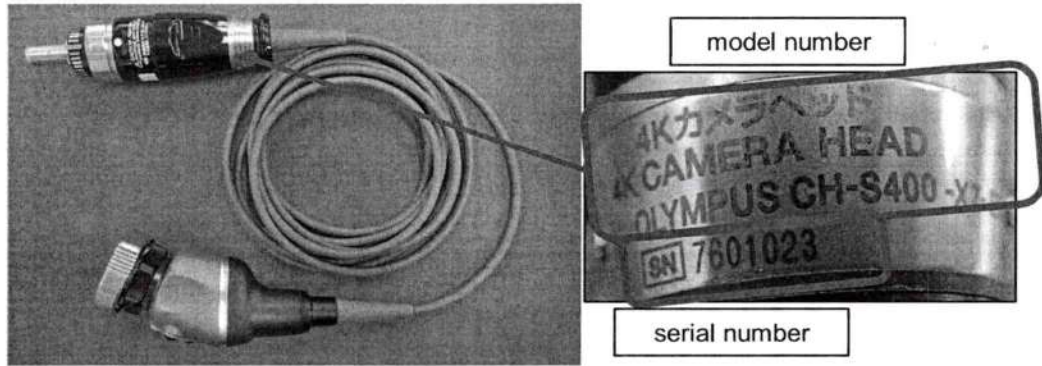
Autoclaving can severely damage the device potentially resulting in image loss prior to or during a procedure. This may result in a delay, prolongation, or cancellation of a procedure. Image loss while performing critical portions of a procedure could result in tissue/organ injury, hemorrhage, and an additional intervention/surgery.

Action steps to be taken by the end user:

Our records indicate that your facility has purchased one or more of the affected CH-S400-XZ-EB. Olympus requires you to take the following actions:

1. Inspect your inventory for the referenced devices and identify any device with the CH-S400-XZ-EB model name. Please check all areas of the hospital to determine if any of these devices remain in inventory. The model number and serial number can be found on the device as illustrated in the following picture.

OLYMPUS®



2. Carefully read the content of this Field Safety Notice as well as the attached "Addendum". List of compatible methods was corrected. (Correct: Not compatible, Incorrect: Compatible).
3. Ensure all personnel is completely knowledgeable on this labeling change.
4. If your facility requires the latest version of the CH-S400-XZ-EB reprocessing manual, please indicate this in the reply form.
Alternatively, the new version of the CH-S400-XZ-EB reprocessing manual can be found on the Olympus webpage www.olympus-europa.com under Medical Systems → Products & Solutions → 🔍 → Instruction Manual → **Search for "CH-S400-XZ-EB" model name.**
5. Send the completed Reply Form back to your local Olympus representative at ra@olympusmea.com latest by 08.05.2023
6. If you have distributed these devices outside your facility, please notify your customers of this matter immediately by forwarding them this Field Safety Notice. Please appropriately document your notification process and let us know the end-customer feedback accordingly.

Olympus regrets any inconveniences caused by this Field Safety Notice and fully appreciates your prompt cooperation in addressing this situation. In case of any questions or concerns, please do not hesitate to contact Olympus directly at ra@olympusmea.com

Sincerely,

Iman Ibrahim

Regional Head of Quality Assurance and Regulatory Affairs Middle East & Africa
Healthcare, Industrial and Life Science Divisions
Olympus MEA FZ-LLC, P.O. Box: 33607 Dubai
Registration No. 93456 (Dubai Development Authority)
Dubai Science Park - Laboratory Complex - Dubai - United Arab Emirates

Addendum to the Reprocessing Manual of the CH-S400-XZ-EB Revised "List of compatible methods" in the Section 3.2

Before revised (RA6335 ver.03 -P.12)

3.2 List of compatible methods

Reprocessing methods listed in Table 3.1 have been validated with this camera head and accessory.
For details on the chemicals and devices that can be used, refer to Section 3.3 and subsequent sections.

Ch.3

		Camera head (CH-S400-XZ-EB)	Cleaning brush (MAJ-1534)
Ultrasonic cleaning			
Manual cleaning	Alkaline enzymatic detergent		
	Neutral enzymatic detergent		
Manual disinfection	Peracetic acid		
	Glutaraldehyde		
Drying	Alcohol		
Automatic cleaning and disinfection	AER	ETD Double (Peracetic acid)	
		ETD 4 (Peracetic acid)	
		ETD 4 (Glutaraldehyde)	
Disinfection	WD (Alkaline detergent, thermal disinfection)		
Sterilization	Hydrogen peroxide	V-PRO® maX (Non lumen cycle)	
		STERRAD® NX® with ALLClear™ Technology (Standard cycle)	
		STERRAD® NX® (Standard cycle)	
		STERRAD® 100NX® with ALLClear™ Technology (Duo cycle)	
		STERRAD® 100NX® (Duo cycle)	
		STERRAD® 100S (Short cycle)	
Steam (autoclaving)			
Ethylen oxide gas			
Low Temperature steam and formaldehyde (LTSF)			

compatible not compatible




Table 3.1 List of compatible methods

After revised (RA6335 ver.04 -P.12)

3.2 List of compatible methods

Reprocessing methods listed in Table 3.1 have been validated with this camera head and accessory. For details on the chemicals and devices that can be used, refer to Section 3.3 and subsequent sections.

Ch.3

		Camera head (CH-S400-XZ-EB with Silver focus ring) 	Camera head (CH-S400-XZ-EB with Black focus ring) 	Cleaning brush (MAJ-1534) 
Ultrasonic cleaning				
Manual cleaning	Alkaline enzymatic detergent			
	Neutral enzymatic detergent			
Manual disinfection	Peracetic acid			
	Glutaraldehyde			
Drying	Alcohol			
Automatic cleaning and disinfection	AER	ETD Double (Peracetic acid)		
		ETD 4 (Peracetic acid)		
		ETD 4 (Glutaraldehyde)		
	WD (Alkaline detergent, thermal disinfection)			
Sterilization	Hydrogen peroxide	V-PRO® max (Non lumen cycle)		
		STERRAD® NX® with ALLClear™ Technology (Standard cycle)		
		STERRAD® NX® (Standard cycle)		
		STERRAD® 100NX® with ALLClear™ Technology (Duo cycle)		
		STERRAD® 100NX® (Duo cycle)		
		STERRAD® 100S (Short cycle)		
	Steam (autoclaving)			
Ethylene oxide gas				
Low Temperature steam and formaldehyde (LTSF)				

 compatible  not compatible

Table 3.1 List of compatible methods

(EOF)



REPLY FORM – QIL FY24-EMEA-02-FY23-OMTA-39

URGENT FIELD SAFETY NOTICE Model name: CH-S400-XZ-EB	
[Name & Address of Hospital/Medical Facility]	
[Dept/Attn]	
[Inventory information (Serial Number(s) of CH-S400-XZ-EB)]	
Model	Serial Number
[Quantity of CH-S400-XZ-EB Reprocessing Manual hard copies or electronic pdf documents required]	
[Date]	

Dear Sirs or Madams,

I herewith confirm the receipt of your Field Safety Notice.
Further I confirm that I have transferred the content of the attached FSN to all affected departments on which this action has an impact. I understand the necessity to follow the steps.

Name (Signature) _____

Name (Print) _____

Position _____

Please scan / email your completed paper form response to ra@olympusmea.com.