



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 241.. dated 19/11/23. Regarding NCMDR Field Safety Notice of EVIS X1 VIDEO SYSTEM CENTER OLYMPUS CV-1500 from (mfr: Olympus Corporation of the Americas).

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. 241 / 2023

05-051445 H

19 -11-2023

نقدم بثقة
Moving Forward
with Confidence

رؤية عمان
2040
Oman

Field Safety Notice of EVIS X1 VIDEO SYSTEM CENTER OLYMPUS CV-1500 from Olympus Corporation of the Americas .

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19756
Product	EVIS X1 VIDEO SYSTEM CENTER OLYMPUS CV-150.
Description	Light source/processing unit, endoscope.
Manufacturer	Olympus Corporation of the Americas .
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	Material ID : N6011250 Description: CV-1500 PAL W/O POWERCORD (EU). Serial Numbers: All
Reason	There is a potential for the water delivery tube come in contact with the touch panel which may lead to the Air flow button unintentionally turned on.Unintentional contact with the touch panel may result in the activation of unintended functions which could cause patient symptoms or injuries that include abdominal distention, procedure delays, pneumothorax, air embolism, or tissue injury.
Action	1. Customers are to utilize the Lock touch panel function for all procedures. The detailed operation of this function is explained in section 5.12 of the instruction manual and reproduced in the appendix of the attachment. 2. Customers are to closely follow the warning section in the updated instruction manual (supplied to customers in the attachment), which informs users to keep objects away from the touch panel. 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



Date: October 20, 2023

Olympus Reference: QIL FY24-EMEA-21-FY24-OMSC-26 for CV-1500

URGENT FIELD SAFETY NOTICE

RE: EVIS X1 VIDEO SYSTEM CENTER OLYMPUS CV-1500

Attention: ENDOSCOPY DEPARTMENT

Material ID	Description	Serial Numbers
N6011250	CV-1500 PAL W/O POWERCORD (EU)	All

Dear Health Care Practitioner:

Olympus has become aware of a matter that requires your attention. This Safety Notice pertains to the EVIS X1 VIDEO SYSTEM CENTER OLYMPUS CV-1500 referenced above.

The EVIS X1 VIDEO SYSTEM CENTER OLYMPUS CV-1500 has been designed to process electronic signals transmitted from Olympus video endoscopes, output images to monitors, provide illumination to the endoscope, supply air through the endoscope while inside the body and control/monitor ancillary equipment.

Olympus has received one complaint that the water delivery tube came in contact with the touch panel and the Air flow button was unintentionally turned on. This resulted in an adverse event and the patient had a pneumothorax due to the air insufflation during the Peroral Endoscopic Myotomy, POEM procedure.

In an effort to maximize patient safety and mitigate any potential risk to patient health, Olympus is recommending the utilization of the Lock touch panel function for all procedures utilizing the CV-1500 and reminding users to closely follow the instruction manual including the WARNING to keep objects away from the touch panel. Specifically:

■ **Lock touch panel function**

Olympus recommends utilizing the Lock touch panel function for all procedures. The detailed operation of this function is explained in section 5.12 of the instruction manual and reproduced in the appendix of this letter.

■ **WARNING related to this complaint (Excerpt from instruction manual)**

The Precaution Section of the instruction manual includes the following WARNING: "Tubes, cables, and other objects should be placed away from the touch panel of this instrument so that they do not touch the touch panel. If tubes, cables, or other objects come into contact with the touch panel of this instrument, the touch panel may react and activate unintended functions."


Potential risk to health

Unintentional contact with the touch panel may result in the activation of unintended functions which could cause patient symptoms or injuries that include abdominal distention, procedure delays, pneumothorax, air embolism, or tissue injury.

OLYMPUS

Action steps to be taken by the end user:

Our records indicate that your facility has purchased one or more CV-1500 video system centers. Olympus requests you to take the following actions:

1. Carefully read the content of this Urgent Field Safety Notice (FSN).
2. Identify where EVIS X1 VIDEO SYSTEM CENTER OLYMPUS CV-1500 is in your facility.
3. Ensure all personnel are completely knowledgeable and thoroughly aware of the recommendation to utilize the Lock touch panel function during procedures and the warning to keep objects away from the touch screen in order to prevent unintentional actuation of the touch panel.
4. Please indicate on the enclosed reply form that you have received this notification and taken the required actions by filling out and returning the completed enclosed Reply Form back to your local Olympus representative latest by 08.11.2023.
5. If your facility requires the latest version of the EVIS X1 VIDEO SYSTEM CENTER OLYMPUS CV-1500 Instruction for Use, please indicate this in the reply form. Alternatively, the new version of the EVIS X1 VIDEO SYSTEM CENTER OLYMPUS CV-1500 Instruction for Use can be found on the Olympus webpage www.olympus-europa.com under Medical Systems → Products & Solutions →  → Instruction Manual and search for "CV-1500" model name.
6. If you have further distributed this product, identify your customers, forward them this Field Safety Notice, and appropriately document your notification process.

Olympus requests that you report complaints, including patient physical condition suspected to be affected by unintentional actuation of the touch panel, to Olympus. Please report complaints to ra@olympus-mea.com

Olympus regrets any inconvenience caused and fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact me to ra@olympus-mea.com

Sincerely,

Fadila Ezzahid
Regional Quality Assurance & Regulatory Affairs Specialist Middle East & Africa
Olympus MEA FZ-LLC, P.O. Box: 33607 Dubai
Registration No. 93456 (Dubai Development Authority)
Dubai Science Park - Laboratory Complex - Dubai - United Arab Emirates

Appendix

■ **Disabling the touch panel operation**

In this operation, disable touch panel operation.

- 1 Tap the "Lock touch panel" button on Home > Function List > Prepare/End Exam > End exam tab.

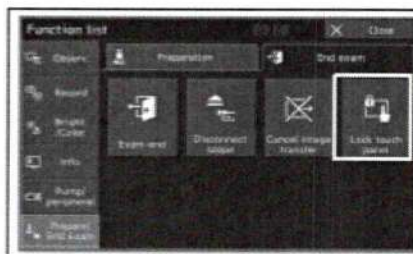


Figure 5.189

- 2 The message "Touch panel is locked" is displayed, and then touch panel is locked.



Figure 5.190

- 3 Touch the locked touch panel.
- 4 Press and hold the "Unlock" button for 5 sec or longer to unlock touch panel.

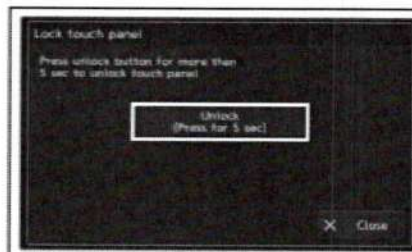


Figure 5.191

- 5 Touch panel is unlocked.

OLYMPUS

REPLY FORM – QIL FY24-EMEA-21-FY24-OMSC-26 for CV-1500

OLYMPUS URGENT FIELD SAFETY NOTICE EVIS X1 VIDEO SYSTEM CENTER OLYMPUS CV-1500
[Name & Address of Hospital/Medical Facility]
[Dept/Attn]
[Quantity of EVIS X1 VIDEO SYSTEM CENTER OLYMPUS CV-1500 Instructions for Use hard copies or electronic pdf documents required]
[Date]

I herewith acknowledge 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 of following the instructions carefully.

Name (Signature) _____

Name (Print) _____

Position _____

Please send your completed paper form response to ra@olympus-mea.com: latest by 08.11.2023..