

Date: **October XX, 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.

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 **XX.XX.XXXX**.
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 **[local facility complaint reporting contact]**. **[If applicable:]** Adverse events experienced with the use of this product may also be reported **[local competent authority]** by **[method]**.

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 at **[phone number]** or **[e-mail address]**.

Sincerely,

[SIGNATORY]
[Contact Name]

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.

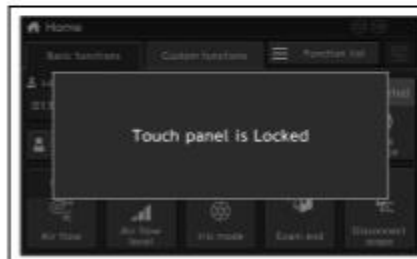


Figure 5.190

- 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.



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 XXXXX <mailto:>latest by XXXX.