

Reference: 2023-011M

16 October 2023

## **URGENT - FIELD SAFETY NOTICE**

To all users of Olympus Evis X1 Video System Centre **CV-1500 (All serial numbers)**

**Re: Recommendation to utilize the Lock touch panel function and follow the instruction manual including the WARNING.**

Attention: **Endoscopy Department**

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.

**Actions 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 Field Safety Notice and identify where EVIS X1 VIDEO SYSTEM CENTER OLYMPUS CV-1500 is in your facility.
2. 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.
3. Olympus requests that you acknowledge receipt of this letter return the 'Response Form' to us.
4. If you have further distributed this product, identify your customers, forward them this notification, 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 and adverse events experienced with the use of this product to Olympus.

Olympus regrets any inconvenience caused and fully appreciates your cooperation in this matter. Please do not hesitate to contact us for any additional information or support concerning this matter.

**Contact for enquiries.**

Regulatory Affairs and Quality Assurance Department

Email : [mes-ra.oml@olympus.com](mailto:mes-ra.oml@olympus.com)

Tel : (603) 7650 8990

Fax : (603) 7650 8999

The **Medical Device Authority** has been informed of this notice.

Yours sincerely,

*Hideki Nagai*

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Hideki Nagai

Managing Director

Olympus (Malaysia) Sdn. Bhd.

## Response Form

Please send the complete and signed Response Form to Regulatory Affairs and Quality Assurance Department at:

To : Olympus (Malaysia) Sdn. Bhd, Regulatory Affairs & Quality Assurance  
Fax/Email : (603) 7650 8999 / [mes-ra.oml@olympus.com](mailto:mes-ra.oml@olympus.com)  
From : \_\_\_\_\_ [Facility Name] Contact no.: \_\_\_\_\_  
Date : \_\_\_\_\_  
Ref : 2023-011M

### **URGENT - FIELD SAFETY NOTICE**

**Re: Recommendation to utilize the Lock touch panel function and follow the instruction manual including the WARNING.**

I acknowledge receipt of the Field Safety Notice (“FSN”) referenced above. I understand that I need to undertake the action(s) listed in the FSN.

Check the applicable boxes below:

- I DO NOT have affected devices remaining. All have been condemned or discarded.
- I DO have the affected devices, which I will adhere to the FSN.

Name: \_\_\_\_\_

Designation: \_\_\_\_\_

.....  
Signature & Company Stamp

.....  
Date

## 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.



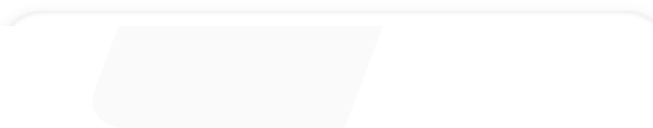
Figure 5.190

- 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.








# 2023-011M FSN - Customer Letter

Final Audit Report

2023-10-16

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