URGENT: MEDICAL DEVICE CORRECTION

4K UHD LCD Monitor

Product Name	Model Number	UDI-DI	Serial Numbers
4K UHD LCD Monitor	OEV321UH	04953170418723	See listing of affected serial numbers on page 2 of this notice

Date: July 6, 2026

Attention: Endoscopy, Surgical Integration, Operating Room / Surgery and Risk Management Departments

Dear Healthcare Professional:

This letter is to inform you that Olympus is initiating a field corrective action regarding the 4K UHD LCD monitor, model number OEV321UH. These monitors may be used with the following products:

- VISERA™ S video system center (OTV-S500)
- VISERA ELITE III™ multi-specialty surgical visualization & imaging system (OTV-S700)
- EVIS X1™ endoscopy system (CV-1500)
- EU-ME3 endoscopic ultrasound system

Reason for Action:

This action is being taken because it has been determined that the HDMI and DisplayPort (DP) connectors can become faulty resulting in image loss or image abnormalities if using one of those connectors. The affected HDMI connectors on these monitors are commonly used with the VISERA™ S video system center (OTV-S500).

> **Note:** While the monitor is identified as being compatible with the other three systems indicated above, its use with these systems does not typically involve the affected HDMI or DP connectors.

Figure 1. Image of the 4K UHD LCD monitor, model number OEV321UH (left), and the VISERA S system (right) with which it may be used via the HDMI connector.

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Risk to Health:

Image loss or abnormalities during use of the 4K UHD LCD monitor may result in procedure delays, prolonged procedure time, or procedural interruption due to the need for troubleshooting or equipment replacement. If unresolved, procedures may require conversion to an alternative system or the procedure may need to be rescheduled for a later date.

Additionally, complete image loss or significant abnormalities during active use may impair visualization, increasing the risk of challenging device manipulation and loss of procedural control, which may lead to unintended tissue injury (e.g., mucosal trauma, bleeding or perforation) or compromised procedural performance, potentially requiring additional medical or surgical intervention.

The detectability of image issues during device setup and use, along with the availability of alternative monitors or backup visualization systems, reduces the likelihood of prolonged disruption and the potential for sustained patient harm.

Actions Required:

Our records indicate that your facility has received one or more of the affected products. Olympus therefore requests that you take the following actions:

1. Examine your equipment looking for the monitor model number and serial numbers listed in the table on page 2 of this notice.
2. Olympus requests that you acknowledge receipt of this letter through our recall web portal.
    a. Go to https://olympusamerica.com/recall
    b. Enter the recall number: 0503
    c. Complete the form
    d. Please indicate in your response if you no longer have the device(s).
3. If you have further distributed it, forward this notice to other users who may have affected products.
4. If there is a need to use the monitor prior to its repair for this issue, it is recommended that a spare unit be available in case issues are encountered with the primary unit during use, consistent with the recommendation made on page 8 of the IFU.

Olympus requests that you report any complaints to our Technical Assistance Center (TAC) at 1- 800-848-9024, option 1, and the FDA. Adverse events experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact me by phone at (484) 553-1029 or by e-mail at ashley.troiani@olympus.com.

Sincerely,

Ashley Troiani

Ashley Troiani

Senior Manager, Medical Device Recalls

Affected Serial Numbers

Affected LCD monitors have the model number “OEV321UH” and one of the serial numbers indicated below:

7503259	7503263	7503439	7503477	7503506
7503260	7503264	7503444	7503479	7503509
7503261	7503335	7503474	7503492	7503526
7503262	7503403	7503476	7503504	