OLYMPUS

URGENT: MEDICAL DEVICE FIELD CORRECTIVE ACTION

OLYMPUS High Flow Insufflation Unit

Product Name	Model/Catalog Number	Serial Number(s)	UDI
High Flow Insufflation Unit	UHI-4	All	04953170324147 04953170467219

Date: 16-Jun-2026

Attention: *Surgical Department, Risk Management*

Dear Healthcare Professional:

Olympus is writing to inform you of a Medical Device Field Corrective Action pertaining to the High Flow Insufflation Unit model UHI-4. This instrument has been designed for insufflation of the abdominal cavity and provides automatic suction and smoke evacuation to facilitate laparoscopic observation, diagnosis, and treatment. This instrument is also designed for controlled CO2 insufflation to create a cavity along the saphenous vein and/or radial artery to facilitate observation during an endoscopic vessel harvesting procedure.

You may continue to use your UHI-4. As noted in the Instructions for Use (IFU), prepare a spare UHI-4 unit as a backup to ensure operation can be completed without complication in the case of a malfunction.

Note: If a spare UHI-4 is not available, any commercially available insufflator that meets the clinical requirements of the procedure may be used as a backup device.

Reason for Action:

Olympus identified an increase in UHI-4 front-panel 'blackout' complaints, where the front-panel display turns off unexpectedly, and air delivery (insufflation) ceases. An investigation found these blackouts (fault code E03) were primarily caused by the pressure sensors drifting positively from zero over time; when the pressure difference between the two sensors exceeds 7 mmHg, the UHI-4 generates the E03 fault, the front panel shuts off, and insufflation stops. In total, 324 front-panel blackout complaints were reported since October 2019, including two that were reported to regulators as serious injuries. No deaths were reported.

Olympus is working to implement a long-term solution for front panel blackout. In the interim, the UHI-4 pressure sensors must receive an offset adjustment to reset the sensor to zero because of sensor drift. This adjustment can be completed onsite and does not require returning your unit to Olympus. An Olympus field service representative will contact you to schedule a mutually convenient time to perform the offset adjustment.

If your UHI-4 displays a front panel blackout (fault code E03) during use, you must either reboot the unit or switch to a backup insufflator. To reboot the UHI-4, turn the unit OFF and ON again. If during reboot, the caution continuously sounds, the reboot did not work, and you must switch to the backup insufflator and contact Olympus.

Risk to Health:
When the front panel display turns off unexpectedly, insufflation ceases. If this occurs during preparation, it may result in a delay in initiating the procedure. If insufflation stops during a procedure, intra-abdominal pressure will gradually decrease, leading to progressively poorer visualization. As a result, instrument manipulation may become difficult to perform safely and with adequate control. Potential harms include prolonged surgery due to troubleshooting or device replacement, the need to convert to a more complex procedure than originally planned, and tissue injury or bleeding requiring additional medical or surgical intervention.

Actions Required:
You may continue to use your UHI-4 until the offset adjustment is performed. However, as noted in the Instructions for Use (IFU), prepare a spare UHI-4 unit as a backup to ensure uninterrupted operation can be completed without complication in the case of a malfunction.

Our records indicate that your facility has purchased one or more of the affected devices. Olympus requires you to take the following actions:

1. Carefully read the contents of this letter.
2. Ensure all personnel are completely knowledgeable on the content of this notification. You may continue to use your UHI-4 until the offset adjustment is performed and according to the instruction for use, which cautions users to prepare a spare UHI-4 unit as back-up to ensure operation can be completed without complication in the case of a malfunction.
3. An Olympus field service representative will contact you to schedule a mutually convenient time to perform the offset adjustment.
4. Olympus requests that you acknowledge receipt of this letter through our recall web portal.
   - Go to https://olympusamerica.com/recall
   - Enter the recall number: 0502
   - Complete the form as instructed.
   - Please indicate in your response if you no longer have the device(s).
5. Please forward this notice to other users who may have the affected products if you have further distributed it.

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.mitch@olympus.com.

Sincerely,

Ashley Mitch

Ashley Mitch
Senior Manager, Medical Device Recalls