Reference: 2026-005M

12th June 2026

URGENT - FIELD SAFETY NOTICE

To all users of **Olympus High Flow Insufflation Unit**

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

Re: Olympus to Provide Offset Adjustment for UHI-4 Pressure Sensors

Attention: Surgical Department, Risk Management

Dear Healthcare Professional:

Olympus is writing to inform you of a Medical Device Advisory Notice 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 and return the 'Response Form' to us.
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 and adverse events experienced with the use of this product to Olympus.

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact us.

Contact for enquiries.
Regulatory Affairs and Quality Assurance Department
Email : 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
Hideki Nagai (Jun 12, 2026 16:58:14 GMT+8)

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
From : _____ [Facility Name] Contact no.:_____
Date : _____
Ref : 2026-005M

URGENT - FIELD SAFETY NOTICE

Re: Olympus to Provide Offset Adjustment for UHI-4 Pressure Sensors

I acknowledge receipt of the Field Safety Notice ("FSN") referenced above. I confirm that I have further communicated to any affected departments.

Check the applicable boxes below:

☐ I DO NOT have affected product remaining. Product has been condemned or discarded.

☐ I DO have the affected product, which I will adhere to this FSN letter.

Serial Number(s) : _____

Additional Customer Requests:

(Indicate if you have any additional requests to support this action)

Name: _____

Designation: _____

……..…… ...……..……
Signature & Company Stamp Date

2026-005M FSN Customer Letter

Final Audit Report 2026-06-12

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