

**URGENT: MEDICAL DEVICE REMOVAL**  
**OLYMPUS High Flow Insufflation Unit**

Product Name	Model Number	Serial Numbers	UDI-DI
High Flow Insufflation Unit	UHI	All	N/A
High Flow Insufflation Unit	UHI-2	All	N/A
High Flow Insufflation Unit	UHI-3	All	04953170140280 04953170140297

Date: 16-JAN-2026

Attention: Surgical Department, Risk Management

Dear Healthcare Professional:

Olympus is writing to inform you of a Medical Device Removal action pertaining to the High Flow Insufflation Unit models UHI, UHI-2, and UHI-3. These instruments are designed to insufflate the abdominal cavity and provide automatic suction and smoke evacuation to facilitate laparoscopic observation and treatment. These products have been discontinued for sale and repair.

**Immediately cease usage of any UHI, UHI-2 and/or UHI-3 in your inventory.**

**Reason for Action:**

Olympus has determined that the software algorithm on High Flow Insufflation Unit, models UHI, UHI-2 and UHI-3, requires correction to address a potential issue which could lead to overpressure events. These events may occur due to an over insufflation of the abdominal cavity resulting from use of the UHI, UHI-2 or UHI-3 during patient procedures. This includes events where the device may not alarm or otherwise notify the user and/or may not relieve the over insufflation to the set pressure. Because no corrective solution is available, Olympus has decided to remove these devices from the market.

**Risk to Health:**

Olympus conducted a health hazard assessment, including an examination of adverse events and complaints. The assessment indicates that over insufflation may lead to various patient harms during a procedure, which may include air embolism, arrhythmias (bradycardia, asystole, or cardiac arrest), pneumothorax, kidney or urinary problems, hypoxia, subcutaneous emphysema, delay to treatment, more complex procedures, and potentially death.

**Actions Required:**

You should cease usage of the affected product immediately. Use available alternatives including an existing UHI-4 if available or switching to an insufflation device from another manufacturer. If no alternative is available on site, contact Olympus to arrange a loaner or purchase a replacement.

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

1. Examine your inventory and quarantine any identified devices immediately.
2. **Immediately cease usage of any UHI, UHI-2, and/or UHI-3 in your inventory.**
3. Call Olympus Customer Service at 1-800-848-9024, option 2 to obtain a Return Material Authorization to return your device.
4. 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 "0489"
  - c. Complete the form as instructed.Please indicate in your response if you no longer have the device(s).
5. If you have further distributed this UHI product, please identify your customers and forward this notice to them immediately.

Olympus requests you to 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 (647) 999-3203 or by email at [Cynthia.Ow@Olympus.com](mailto:Cynthia.Ow@Olympus.com).

Sincerely,

*Cynthia Ow*

Cynthia Ow  
Sr. Manager  
Field Corrective Action, Americas