



August 16, 2024

**URGENT: MEDICAL DEVICE CORRECTIVE ACTION  
UPDATED INFORMATION  
OLYMPUS UHI-4 INSUFFLATOR  
All Serial Numbers Purchased before August 2024  
UDI: 04953170324147**

Attention: Surgical Department, Risk Management

Dear Healthcare Professional:

Olympus Medical Systems Corporation (“Olympus”) previously informed you of a corrective action on the UHI-4 Insufflator (enclosed). The UHI-4 is intended to facilitate laparoscopic and endoscopic observation, diagnosis, and treatment. It is used to insufflate the abdominal cavity and colon and provides automatic suction and smoke evacuation.

Further to the attached letter, October 25, 2023, Olympus is now writing to inform customers about a software update to correct for the causes of over pressurization associated with the UHI-4. The new software version corrects a pressure sensor failure detection algorithm. It will detect any pressure sensor failure, intermittent or continuous, during UHI-4 insufflation and will turn off the front panel display and stop gas insufflation as intended.

The over pressure issue discussed above, and which will be addressed by the software update, is not the same as the CR board part failure communicated February 16, 2024, which requires a CR board replacement. The software update is intended to turn off the system as a normal safety mechanism when a sensor failure is detected. The CR board replacement action is to replace sensors on UHI-4 units that are prone to failure.

The UHI-4 should remain quarantined at your site until the following corrections are completed:

- Units manufactured before October 2019 requires both a CR Board replacement and a software update
- Units manufactured after October 2019 requires a software update only

Once the required correction(s) has been performed, you no longer need to quarantine the UHI-4.

The software update can be performed on-site at your healthcare facility by Olympus service personnel, or at an Olympus repair center by Olympus service personnel. Units which already had the CR Board replaced by an Olympus repair center are also eligible for an on-site software



update. If you require assistance with obtaining your unit's repair history, please contact the Olympus Technical Assistance Center (TAC) at 1-800-848-9024 (option 1).

Starting September 2024, UHI-4 units returned to Olympus repair centers for the CR Board replacement will also receive the software update. Olympus will continue to contact customers to schedule a repair based on parts availability.

Contact your local Olympus service centers at [regions to add their local contact information] to confirm if a CR board replacement is required for your UHI-4 unit.

**Action Steps:**

Our records indicate that your facility has purchased one or more UHI-4 units.

1. 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: "0451"
  - c. Complete the form as instructed
2. Starting September 2024, an Olympus representative will reach out to you to arrange a mutually convenient time to have your UHI-4 software and/or CR Board updated on-site or returned to our Olympus repair center where applicable. Alternatively, you may contact the Olympus Technical Assistance Center (TAC) at 1-800-848-9024 (option 1) to schedule service.
3. If you have distributed these devices outside your facility, please notify your customers of this corrective action immediately. Your notification to your customers may be enhanced by including a copy of this field safety notice.

Olympus fully appreciates your prompt cooperation in addressing this situation. Please do not hesitate to contact me directly, by phone at (647) 999-3203 or by email at [Cynthia.Ow@Olympus.com](mailto:Cynthia.Ow@Olympus.com), for any additional information concerning this matter.

Sincerely,

*Cynthia Ow*

Cynthia Ow  
Field Corrective Action Regional Lead, Americas