Date: February 16, 2024

URGENT: MEDICAL DEVICE FIELD CORRECTIVE ACTION
Product: HIGH FLOW INSUFFLATION UNIT UHI-4
Catalog number: UHI-4
Serial: All serial numbers
UDI-DI: 04953170324147

ATTENTION: Surgical Department, Risk Management Department

Dear Healthcare Professional:

Olympus previously informed you about an action on October 25, 2023, regarding reported over insufflation of the abdominal cavity in procedures which used the UHI-4. Olympus has requested users to quarantine the UHI-4 to prevent usage unless your facility did not have or was unable to obtain an alternative device and chose to use the UHI-4 with extreme caution.

Olympus is now informing you of a new action regarding the UHI-4 front LED control panel.

Reason for Letter:
Olympus has become aware of an increased trend from both repairs and customer complaints of the "UHI-4 stopping CO_2 gas supply with the front panel LED turning off". Based on the analysis of customer complaints, this phenomenon was determined to be associated with a CR board pressure sensor circuit failure. Olympus has received 523 complaints in the last 3 years associated with this phenomenon including one conversion to open surgery case.

In an effort to maximize patient safety and mitigate any potential risk to patient health, Olympus will replace the CR board for UHI-4 older than 4.5 years. Olympus will be contacting customers to schedule the repair of your UHI-4 based on device age and parts availability.

Quarantine of UHI-4 Should Continue:
This repair of the CR board will not correct or address the overpressure issue which was the reason for the quarantine noted in our October 25, 2023, communication regarding the overpressure situation.

In connection with the overpressure issue, Olympus has identified software mitigations that will aid in the prevention of over pressurization situations. Olympus will be communicating with you at the end of summer 2024 regarding this software update for the UHI-4 device.

If you decided to continue using the UHI-4, Olympus recommends a compatible insufflator be readily accessible as a backup during procedures.

Risk to Health

UHI-4 is designed with a pressure sensor. If the UHI-4 detects a pressure sensor failure, the UHI-4 will raise an error. This error causes activation of the alarm, the front-panel LEDs turn off,

stopping the CO_2 supply. If this occurs prior to the procedure during set up, it may lead to a delay in initiating treatment. In the event the UHI-4 CO_2 supply stops during a procedure, the device becomes unusable. This could potentially result in a prolonged procedure and/or require additional medical intervention(s).

Action steps to be taken by the end user:

Our records indicate that your facility has purchased one or more UHI-4 devices. Therefore, Olympus requires you to take the following actions:

1. Olympus will contact you based on device age and parts availability to schedule a repair to replace the CR board. Olympus will also be prioritizing this action for customers who have to continue using the UHI-4 during the quarantine action. To ensure continuity of care, Olympus will make every effort to provide a loaner while the unit is sent to the Olympus Service Center.

2. Please acknowledge receipt of this letter and, if applicable, indicate which serial numbers are still in use by your facility. Access the Olympus recall portal as follows:
   a) Go to https://olympusamerica.com/recall
   b) Enter the recall number "0442"
   c) Complete the form as instructed and include your account ID number.
   d) Under the comments section, note the serial numbers which are still being used by your facility or if you have quarantined all your units.

3. If you have further distributed this product, forward this letter to those facilities.

Please contact your local Sales Representative for support regarding alternatives to the UHI-4 should you no longer wish to keep your UHI-4.

As always, Olympus requests that you report complaints, including any injuries during procedures with UHI-4, to the Olympus 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.

We appreciate your cooperation in addressing this matter. Our goal is always to ensure patient safety while minimizing disruption to patient care. If you require additional information, please do not hesitate to contact me directly by phone at (647) 999-3203 or by e-mail at Cynthia.Ow@olympus.com.

Sincerely,

Cynthia Ow

Cynthia Ow
FCA Regional Lead, Americas