**Date: XX.XX.XXXX**
**Olympus Reference: QIL FY24-EMEA-38-OMSC-06 UHI-4 CR Board**

# URGENT FIELD SAFETY NOTICE

**Product: HIGH FLOW INSUFFLATION UNIT**
**Attention: Surgical Department, Risk Management Department**

| Material ID | Model | Description | UDI | Serial Numbers |
|---|---|---|---|---|
| N3829650 | UHI-4 | Insufflator, UHI-4, 220-240V | 04953170435881 | All |
| N3829660 | UHI-4 | Insufflator UHI-4, 220-240V | 04953170324154 | All |
| N3829670 | UHI-4 | Insufflator, UHI-4, 220-240V | 04953170324161 | All |

Dear Healthcare Professional:
Olympus previously informed you about an action regarding reported over insufflation of the abdominal cavity in procedures which used the HIGH FLOW INSUFFLATION UNIT UHI-4 in November 2023.

Olympus informed users to stop use of the UHI-4 and to quarantine all devices unless your facility did not have or was unable to obtain an alternative device in which case you may have chosen to use the UHI-4 with extreme caution in compliance with the Field Safety Notice ref. QIL FY24-EMEA-19-FY24-OMSC-19 UHI-4 Overpressure.

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 issue was determined to be associated with a Control board, or CR board, pressure sensor circuit failure.

In an effort to maximize patient safety and mitigate any potential risk to patient health, Olympus will replace the CR board of UHI-4 devices which were manufactured more than 5 years ago. Olympus will be contacting customers to schedule this replacement requirement.

**Root cause investigation and quarantine of UHI-4:**

Olympus has completed the root cause investigation of the UHI-4 over insufflation issue. The root cause analysis has revealed pressure sensor failure combined with inadequate software detection of pressure sensor malfunction causes the over insufflation issue. Further, the design safety features to help relieve over pressure specified in the November 2023 letter, specifically, excessive pressure alarm, relief mode and automatic suction function, will not function as intended under certain scenarios as these safety functions are triggered by an over pressure condition which is not detected when a pressure sensor malfunction occurs.

Olympus has received 41 complaints of a serious injury, (conversion to open surgery, arrythmias and respiratory problem/hypertension during surgery), and 2 reports of death related to the UHI-4 associated with both over pressurization and CR board failure. The total UHI-4s installed globally is approximately 24,000.

As a result, Olympus will provide a software update to mitigate the risk of over insufflation in the future. Olympus will be communicating with you at the end of summer 2024 regarding this software update for the UHI-4 device.

You should **continue to quarantine the product unless** your facility does not have or is unable to obtain an alternative device and chooses to use the UHI-4 with extreme caution, after weighing the potential benefits of the procedure versus the potential risk to health of over insufflation described below until:

**For units 5 years and older:**

Your unit receives both the software update and a CR Board replacement.

**For units under 5 years:**

Your unit receives the software update.

**Relief Mode**

As explained above, the Relief Mode may not function as intended under certain scenarios. Nevertheless, in the event you use your UHI-4 unit before the remediation actions above are made to your device, we recommend that the **Relief Mode setting should be in the "ON" position** as this feature may help mitigate over pressure situations which are not a result of an intermittent sensor failure. When the cavity pressure exceeds the set pressure value by 5 mmHg or more, and the Relief Mode is "ON", the channels inside the UHI-4 are opened and can help release the internal gas until the cavity pressure drops to the set pressure value.

When relief mode is set to ON, cavity gas and/or body fluids (e.g., blood) can flow backward into and potentially contaminate the equipment. To prevent this, Olympus **strongly recommends the use of a disposable filter** in the $CO_2$ supply line between the UHI-4 and the patient. Olympus recommends filter type PALL OR01H (0.2 µm, hydrophobic) or equivalent filters.

**Risk to Health**

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, and stops the $CO_2$ supply. If this occurs before the procedure during set up, it may delay 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).

In connection with over insufflation, 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 gas embolism, arrythmias (bradycardia, asystole, or cardiac arrest), pneumothorax, kidney or urinary problems, hypoxia, subcutaneous emphysema, delay to treatment, and more complex procedures. These complications could potentially lead to death.

**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. You should **continue to quarantine the product** until:

   **For units 5 years and older:**

   Your unit receives both the software update and a CR Board replacement.

   **For units under 5 years of age:**

   Your unit receives the software update.

2. Indicate in the reply form if your facility continues using any of the UHI-4 devices.
3. Olympus will contact you based on device age and parts availability to schedule a repair of the CR Board. Olympus will be prioritizing customers who have continued to use the UHI-4.
4. Olympus will contact you in late summer of 2024 regarding the software update to address the over insufflation.
5. Olympus requests that you acknowledge receipt of this letter even if you no longer have this unit. Complete the reply form enclosed and email or fax it to [e-email address]. [local facility to adjust per local procedures].
6. If you have further distributed this product forward this letter to those facilities.

As always, Olympus requests that you report complaints, including any injuries during the procedure with UHI-4, to [local facility complaint reporting contact]. [If applicable:] Adverse events experienced with the use of this product may also be reported [local competent authority] by [method]

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 or have any concerns, please do not hesitate to contact me at [phone number] or [e-mail address].

Sincerely,

**REPLY FORM – QIL FY24-EMEA-38-OMSC-06 UHI-4 CR Board**

**OLYMPUS URGENT FIELD SAFETY NOTICE**
**HIGH FLOW INSUFFLATION UNIT**

**[Name & Address of Hospital/Medical Facility]**

**[Dept/Attn]**

**Are any of the UHI-4 devices at your facility continued to be used?**

____ **No**, all UHI-4 devices are in quarantine.

____ **Yes**, following serial numbers are continued to be used:

| **Material ID** | **Serial Number** |
|---|---|
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[**Date]**

I herewith acknowledge the receipt of your Field Safety Notice.
Further I confirm that I have transferred the content of the attached FSN to all affected departments on which this action has an impact. I understand the necessity of following the instructions carefully.

Name (Signature) _____

Name (Print) _____

Position _____

Please send your completed paper form response to XXXXX mailto:latest by XXXX.