Reference: 2024-002M

29 March 2024

URGENT - FIELD SAFETY NOTICE

To all users of Olympus High Flow Insufflation Unit **UHI-4 (All serial numbers)**

Re: Informing To Stop Using the Device Until Corrections Are Completed

Attention: Endoscopy Department, Surgical, Gynecology and Urology Department; Risk Management Department

Dear Healthcare Professional,

This updated customer notification pertains to the Olympus HIGH FLOW INSUFFLATION UNIT UHI-4 and is a follow up to a communication issued on 7 December 2023.

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.

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 until October 2019. Olympus will be contacting customers to schedule this replacement requirement.

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, 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 in late August 2024 regarding this software update for the UHI-4 device. Olympus is now informing you that until these corrections are made **you should consider to stop use of this 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:

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Tel: (603) 7650 8990 Fax: (603) 7650 8999

For units manufactured October 2019 and earlier:
Your unit receives both the software update and a CR Board replacement.

For units manufactured November 2019 and later:
Your unit receives the software update.

If you decide to continue using the UHI-4, Olympus recommends a compatible insufflator be readily accessible as a backup during procedures. Please see the section below "Considerations for Provisional Usage" which provides information to assist you in making a decision regarding provisional usage.

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.

Considerations for Provisional Usage:

Olympus is providing the following information to assist you in making a decision regarding provisional usage while you seek alternatives to the UHI-4:

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BEFORE THE PROCEDURE

- Function checks for the UHI-4 should be conducted prior to using the UHI-4. These can be found in Appendix A of this letter as well as in the device instructions for use.

- Review and re-familiarize the operating room team with the design safety features to relieve over pressure:
    1. Excessive Pressure Alarm: When the cavity pressure exceeds the set pressure by 5 mmHg, the excessive pressure caution lamp will light and an alarm will sound.
    2. Relief Mode: When the cavity pressure exceeds the set value by 5 mmHg or more, the relief mode is activated to open the channels inside the instrument and release the internal gas until the cavity pressure drops to the set value. The relief mode can be set to ON or OFF as required. The default setting for Americas including the U.S. is "ON".
    3. Automatic suction function: When the cavity pressure has exceeded the set value by 5 mmHg for more than 10 seconds, the automatic suction function is activated to perform suction until the cavity pressure drops to the set value. (See section "5.14 Pinch Valve Release" of the Instructions for Use)

  The operating room team should not rely on only these features to identify or address an overpressure event. Further, as noted above these design safety features to help relieve over pressure 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.

- Consideration should be given to populations which may be at greater risk: Laparoscopic surgeries require careful application of gas pressure within the peritoneal cavity to secure the required visibility and working space. Over-pressurization may occur during insufflation, which can lead to serious patient harms. Certain subpopulations of patients may be at higher risk for over-pressurization, including:
    - Obesity – Obese patients may be more susceptible to over-pressurization, as insufflation can lead to a more rapid rise in pressure due to the excess volume of adipose tissue within the peritoneal cavity.
    - Pulmonary Disease - Patients with chronic lung disease (Chronic Obstructive Pulmonary Disease - COPD) may be at increased risk because an elevated diaphragm due to insufflation can decrease the functional residual capacity of the lungs, potentially exacerbating breathing difficulties.
    - Cardiac Disease - Elevated intra-peritoneal pressure can decrease venous return to the heart and lower cardiac output which would be exacerbated with preexisting cardiac disease (congestive heart failure, arrythmias, ischemia due to coronary artery disease).
    - Pregnancy – Partum patients may be more susceptible to over-pressurization because the peritoneal cavity contains an expanded uterus and insufflation can lead to a more rapid rise of pressurization potentially compromising blood flow to the uterus, endangering both mother and fetus. Conversely, post-partum patients with a more compliant abdominal wall that can distend more easily and may require less pressures than anticipated for adequate visualization.
    - Abdominoplasty – Patients that have undergone cosmetic surgery to improve the shape and appearance of the abdomen may have a less compliant abdominal wall and this may result in higher insufflation pressures being required.
    - Aged or Frail - Patients with decreased physiological reserves or multiple co-morbidities, are at increased risk of being able to tolerate adverse events.
    - Pediatric - Due to the smaller abdominal cavity of these patients, the volume of insufflating gas required may be much lower than those patients of normal stature.

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DURING THE PROCEDURE

- Consideration should be given to clinical factors that may mitigate the risk of potential over-insufflation:
  - Patient positioning tailored to the surgery, slower insufflation flow rates, lower final set pressures sufficient to achieve adequate visualization, while exerting caution not to over- pressurize the peritoneal cavity.

- Be aware of the following updated warning, which was also shared in our letter dated 7 December 2023.

  "It is recommended to use the lowest intraabdominal pressure allowing adequate visualization of the operative field for each procedure to help reduce risk of complications related to over insufflation. Complications related to over insufflation include: air embolism, arrhythmias (bradycardia, asystole, or cardiac arrest), prolonged or more complex procedures, delay to treatment, pneumothorax, hypoxia, subcutaneous emphysema, kidney or urinary problems, and potentially death."

- If you notice the unit is over insufflating the operative field, i.e., the pressure in the cavity exceeds the set pressure without resolution, then discontinue use of that unit, replace the equipment with an alternative, and notify Olympus.

Actions steps to be taken by the end user:
Our records indicate that your facility has purchased one or more of the Olympus UHI-4.
Therefore, Olympus **requires you to take the following actions:**

1. You **should consider to stop use of this product** until both repairs to the device are completed **unless** your facility does not have or is unable to obtain an alternative device and choose to use the UHI-4 with extreme caution.
2. Olympus will contact you in late August 2024 regarding the software update to address the over insufflation.
3. Additionally, Olympus will contact you based on device age and parts availability to schedule a repair of the CR Board.
4. Olympus requests that you acknowledge receipt of this letter return the 'Response Form' to us even if you no longer have this unit.
5. 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 Olympus. Adverse events experienced with the use of this product may also be reported to Olympus.

We appreciate your cooperation in addressing this matter. Our goal is always to ensure patient safety while minimizing disruption to patient care. Our goal with this action is to allow facilities to receive the required inspection of the UHI-4.

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Please do not hesitate to contact us for any additional information or support concerning this matter.

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,

29/03/2024
Hideki Nagai
……
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
Fax/Email : (603) 7650 8999 / mes-ra.oml@olympus.com
From : _____ [Facility Name] Contact no.:_____
Date : _____
Ref : 2024-002M

URGENT - FIELD SAFETY NOTICE

Re: Informing To Stop Using the Device Until Corrections Are Completed

I acknowledge receipt of the Field Safety Notice ("FSN") referenced above. I understand that I need to undertake the action(s) listed in the FSN.

Check the applicable boxes below:

☐ I DO NOT have affected devices remaining. All have been condemned or discarded.

☐ I DO have the affected devices, which I will adhere to the FSN.

MODEL NO.	SERIAL NUMBERS
HIGH FLOW INSUFFLATION UNIT **UHI-4**	

Name: _____

Designation: _____

…… ……

Signature & Company Stamp Date

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2024-002M FSN (1)

Final Audit Report 2024-03-29

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