

Date: November XX, 2023

Olympus Reference: QIL FY24-EMEA-19-FY24-OMSC-19 UHI-4 Overpressure

URGENT FIELD SAFETY NOTICE

Product: HIGH FLOW INSUFFLATION UNIT

Attention: Endoscopy, 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:

This customer notification pertains to the Olympus HIGH FLOW INSUFFLATION UNIT **UHI-4** to request you to take action detailed hereafter.

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.

HIGH FLOW INSUFFLATION UNIT - UHI-4



Olympus has become aware of patients experiencing complications from over insufflation, including arrhythmias reported as “short cardiac arrests”, gas embolism, and one death, during surgical procedures where UHI-4s were used.

These complications may have been due to over insufflation of the abdominal cavity resulting from use of the UHI-4 during the procedures. This includes events where the device was reported to not alarm or otherwise notify the user and events where the device did not relieve the over insufflation to the set pressure. As a result, you should take the following actions:

- Discontinue use of the UHI-4 until the root cause investigation is completed and you receive additional instructions from Olympus.
- Devices should be quarantined and marked appropriately by your site to prevent usage.
- If your facility does not have alternatives or is unable to obtain alternatives, you may choose to use the UHI-4 while exercising extreme caution, after weighing the potential

benefits of the procedure versus the potential risk to health of over insufflation described below.

Risk to Patient 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 gas-embolism, arrhythmias (bradycardia, asystole, or cardiac arrest), pneumothorax, kidney or urinary problems, hypoxia, subcutaneous emphysema, delay to treatment, 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:

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 is “OFF”.
 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.

- 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, arrhythmias, 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 patient of normal stature.

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.
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- Be aware of the following updated warning:

“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. These complications could potentially lead to 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.

Status of Olympus Investigation:

Olympus has investigated the complications that have occurred during use of the UHI-4 device in the field and cannot confirm at this moment of time any UHI-4 device malfunction which could cause or contribute to over pressure or over insufflation.

Olympus is continuing a broader investigation for a root cause of over insufflation of the abdominal cavity in procedures which used the UHI-4. This includes concomitant devices, patient conditions and the specifics of the reported events, including an event where the user

stated that the device did not alarm or otherwise notify the user and did not relieve the over insufflation to the set pressure. Olympus will update you upon the conclusion of these investigations, including any further corrective actions necessary.

Action steps to be taken by the end user:

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

1. Inspect your inventory and identify any UHI-4 High flow insufflation unit(s). Quarantine and mark your units appropriately by your site to prevent usage. If your facility does not have alternatives or is unable to obtain alternatives, you may choose to use the UHI-4 while using extreme caution and after reviewing the information above.
2. Carefully read the content of this Field Safety Notice (FSN).
3. Ensure all personnel are completely knowledgeable and thoroughly trained on the content of this FSN.
4. Indicate on the Reply Form that you have received and understood this Field Safety Notice by filling out and returning the completed enclosed Reply Form back to your local Olympus representative latest by **XX.XX.XXXX**.
5. If you have further distributed this product, identify your customers, and forward them this Letter. Please appropriately document your notification process and let us know the end-customer feedback accordingly.

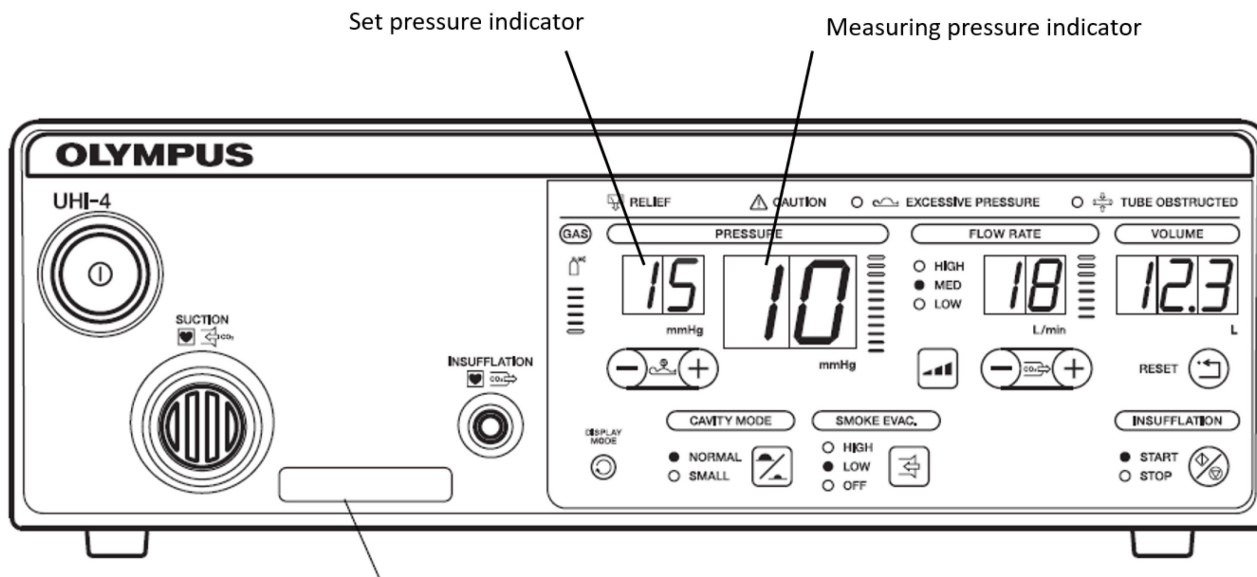
Olympus requests that you report complaints, including any injuries associated with over insufflation during the procedure with UHI-4, to Olympus. Please report complaints to **[local facility complaint reporting contact]**. **[If applicable:]** Adverse events experienced with the use of this product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

Olympus regrets any inconvenience caused and fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact me at **[XXXXXX@olympus.com]**.

Sincerely,

APPENDIX A: Important Instructions for Use Reminders

1. As indicated in section 4.6 of the instructions for use, after turning the power "ON", confirm that all indicator lamps light for 2 seconds and three tones sound. If the indicator lamps fail to light for 2 seconds or three tones fail to sound, the equipment may be faulty. Immediately turn the POWER switch OFF, disconnect the power cord and contact Olympus.
2. As indicated in section 5.2 of the instructions for use, when this instrument is switched ON, it recalls the pressure and flow rate settings used the last time (both of "SMALL" and "NORMAL" cavity mode settings). Ensure that the settings are correct before starting insufflation.
3. As indicated in the summary of equipment function of the instructions for use, the relief mode can be set to ON or OFF as required (refer to Section 5.13, "Relief mode"). Please refer to the Instruction Manual regarding tubing configuration to ensure the relief mode is appropriately configured to ON or OFF as required. Refer to the summary of equipment function of the instructions for use for additional information. When the relief mode is set to ON (active) and the cavity pressure is 5 mmHg or more above the set pressure, the gas is released through the internal channel until the cavity pressure readout reaches the set pressure.
4. The instrument displays the set pressure (**set pressure indicator**) and actual pressure in the cavity (measuring pressure indicator) as indicated below. As noted on in section 5.10 of the instructions for use, when the cavity pressure exceeds the set pressure by 5 mmHg, the excessive pressure warning lamp will light and an alarm will sound.



5. As indicated in the addendum with this letter, excessive flow rates and/or pressures may result in an excessive absorption of CO₂ and/or gas embolism. The cavity can be adequately distended using a maximum pressure of 20 mmHg. It is seldom necessary to use a cavity pressure greater than 20 mmHg. Little

intravasation should occur at these levels. Pressures over 20 mmHg are rarely necessary and will increase the amount and the rapidity of intravasation of gas. Adequate respiration helps avoid problems related to CO₂.

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 gas embolism, arrhythmias (bradycardia, asystole, or cardiac arrest), prolonged or more complex procedures, delay to treatment, pneumothorax, hypoxia, subcutaneous emphysema, kidney or urinary problems. These complications could potentially lead to death.



Please complete and submit this form by e-mail to **XXXXX** latest by **XX.XX.XXXX**

REPLY FORM – QIL FY24-EMEA-19-FY24-OMSC-19 UHI-4 Overpressure

- ☐ I herewith acknowledge the receipt of your Field Safety Notice.
- ☐ 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.
- ☐ We have further distributed these products and this letter has been forwarded to those facilities.
- ☐ I no longer have this product at my facility.

[Name & Address of Hospital/Medical Facility]

[Dept/Attn]

[Date]

Name (Print) _____

Position _____

Signature _____

OLYMPUS INSTRUCTIONS

Addendum

HIGH FLOW INSUFFLATION UNIT

Model; UHI-4

1. Instructions

The sections below provide updated information on warning of complications related to over insufflation. Changes are summarized below and are denoted by underlined text in the subsequent sections of this Addendum. Other parts of the instruction manual have not changed.

Warning in “Important Information — Please Read Before Use”

WARNING

Excessive flow rates and/or pressures may result in an excessive absorption of CO₂ and/or gas embolism. The cavity can be adequately distended using a maximum pressure of 20 mmHg. It is seldom necessary to use a cavity pressure greater than 20 mmHg. Little intravasation should occur at these levels. Pressures over 20 mmHg are rarely necessary and will increase the amount and the rapidity of intravasation of gas. Adequate respiration helps avoid problems related to CO₂.

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 gas embolism, arrhythmias (bradycardia, asystole, or cardiac arrest), prolonged or more complex procedures, delay to treatment, pneumothorax, hypoxia, subcutaneous emphysema, kidney or urinary problems. These complications could potentially lead to death.