

URGENT FIELD SAFETY NOTICE

RE: IFU update of UHI-4

Attention: Endoscopy, Gynecology, General Surgery, Thoracic, Urology and other Surgical Departments; 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** and is to inform you of an amendment to the instructions for use.

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 suffering complications from over insufflation including arrhythmias reported as “short cardiac arrests,” gas embolism, and death during surgical procedures where UHI-4s were used.

These events may have been due to an over insufflation of the abdominal cavity resulting from use of the UHI-4 during the procedures. This includes events 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. As a result, you should take the following actions:

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.

In addition, the instructions for use has been updated with the following 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, and potentially death. “

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 air embolism, arrhythmias (bradycardia, asystole, or cardiac arrest), pneumothorax, kidney or urinary problems, hypoxia, subcutaneous emphysema, delay to treatment, more complex procedures, and potentially death.

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. Carefully read the content of this Field Safety Notice (FSN).
2. Ensure all personnel are completely knowledgeable and thoroughly trained on the content of this FSN.
3. 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**.
4. If you have distributed these devices outside your facility, please notify your customers of this matter immediately by forwarding them this Field Safety Notice. 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 **XXXXXXXXXX**

Sincerely,



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

OLYMPUS URGENT FIELD SAFETY NOTICE IFU update of UHI-4
[Name & Address of Hospital/Medical Facility]
[Dept/Attn]
[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.