Date: *{DD-MM-YYYY}*
Olympus Reference: QIL FY26-EMEA-23-FY26-056 UHI, -2, -3

URGENT FIELD SAFETY NOTICE

RE: OLYMPUS High Flow Insufflation Unit
Attention: Surgical Department, Risk Management

Catalogue Number	Product Name	Model Number	Serial Numbers
A5661	High Flow Insufflation Unit	UHI	All
A90100A	High Flow Insufflation Unit	UHI-2	All
A90120A (N1000161) A90120AR N1000142	High Flow Insufflation Unit	UHI-3	All

Dear Healthcare Professional:

Olympus is writing to inform you of a Medical Device Removal action pertaining to the High Flow Insufflation Unit models UHI, UHI-2, and UHI-3. The UHI, UHI-2, and UHI-3 instruments are designed to insufflate the abdominal cavity and provide automatic suction and smoke evacuation to facilitate laparoscopic observation and treatment. These products have been discontinued for sale and are out of service.

Immediately cease usage of any UHI, UHI-2, and/or UHI-3 in your inventory.

Reason for Action:
Olympus has determined that the software algorithm on High Flow Insufflation Unit, models UHI, UHI-2, and UHI-3, requires correction to address a potential issue which could lead to overpressure events. These events may occur due to an over insufflation of the abdominal cavity resulting from use of the UHI, UHI-2, or UHI-3 during patient procedures. This includes events where the device may not alarm or otherwise notify the user and/or may not relieve the over insufflation to the set pressure. Because no corrective solution is available, Olympus has decided to remove these devices from the market.

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

Actions Required:
You should cease usage of the affected product immediately. Use available alternatives including an existing UHI-4 if available or contact Olympus to discuss other options.

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

1. Examine your inventory and quarantine any identified devices immediately.
2. **Immediately cease usage of any UHI, UHI-2, and/or UHI-3 in your inventory.**
3. Olympus will contact you to arrange the return of your affected device.
4. Olympus requests that you acknowledge receipt of this letter. Indicate on the Reply Form that you have received and understand this notification by filling out and returning the completed enclosed Reply Form to your local Olympus representative by *XX.XX.XXXX*.
   Please indicate in your response if you no longer have the device(s).
5. Please forward this notice to other users who may have the affected products if you have further distributed it.

[If applicable:] [competent authority] is aware of the actions described in this letter.
Olympus requests that you report any 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 fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact *[me directly at XXXX@olympus.com/ Olympus directly at (XXX) XXX-XXXX from Monday through Friday or by e-mail at XXX].*

Sincerely,
Name
Olympus title

REPLY FORM: QIL FY26-EMEA-23-FY26-056 UHI, -2, -3

Facility Name	
Facility Address	
Contact Name	
Additional Customer Requests (Indicate if you have any additional requests to support this action)	

Please confirm the status of the products recorded in your ownership by selecting the appropriate option:

☐Yes (Products still exist)

Serial Numbers

☐No (Products have been disposed)

Serial Numbers

I acknowledge receipt of this notification. I confirm that I have communicated further to any affected departments.

Completed By:		
		Click or tap to enter a date.
Name	*Signature*	*Date (YYYY-MM-DD)*

Please send the completed form to *XXX* by *XX.XX.XXXX*