Date: XX-04-2025

Olympus Reference: QIL FY25-EMEA-29 UHI-4 Calibration Check

URGENT FIELD SAFETY NOTICE

RE: UHI-4 HIGH FLOW INSUFFLATION UNIT
Attention: Endoscopy, Surgical, Gynecology and Urology Department; Risk Management Department

Material ID	Product Name	Model Number	Serial/Lot Number(s)
N3829670	HIGH FLOW INSUFFLATION UNIT	UHI-4	7944868, 7535509, 7536129, 7433804, 7536183, 7535742, 7535743, 7433208, 7944621, 7944640, 7637750, 7649709, 7434883, 7536215, 7649719, 7740234, 7536233, 7741632, 7434618, 7638541, 7638573, 7637804 & 7649279

Date: XX-04-2025

Dear Healthcare Professional /Provider:

On February 17, 2025, Olympus informed you that as a part of our quality process we had identified that the UHI-4 device we recently serviced for you may not have been calibrated properly during the process due to an out of specification piece of test equipment. At that time, we requested that you quarantine and not utilize your affected product(s) until Olympus conducts additional calibration testing. **Olympus has completed the testing of all affected devices and determined that all devices passed calibration tests and therefore, no longer require quarantine. This letter notifies you of the issue, associated risks, and any additional action to be taken.**

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.

Reason for Action:
An Olympus repair facility in Italy became aware that the flowmeter, used for final inspections of UHI-4 (CO2 insufflators), was showing an incorrect flow rate value. The issue was identified during an annual check of the flowmeter by an external provider. The potential effect on the UHI-4 device if the flowmeter used to test the UHI-4 flow rate was out of specification could be that the actual flow rate may be higher than the flow rate displayed on screen of the UHI-4. However, as noted above Olympus has now completed the testing of all affected devices and determined that all devices passed calibration tests and therefore, no longer require quarantine.

Risk to Health:
Olympus conducted a health hazard assessment, which indicates that delivery of a higher flow rate than set may lead to various potential patient harms during a procedure. These harms may include air embolism, arrythmias (bradycardia, asystole, or cardiac arrest), pneumothorax, kidney or urinary problems, hypoxia, subcutaneous emphysema, and potentially death. There were no adverse events reported in relation to this issue.

Actions Required:
Our records indicate that your facility has received one or more of the affected units. Olympus requests you to take the following actions:

1. Olympus requests that you acknowledge receipt of this letter. Indicate on the Reply Form that you have received and understood this notification by filling out and returning the completed enclosed Reply Form back to your local Olympus representative XXX latest by XXX.

2. If your facility has one or more of the impacted serial numbers listed in the table above, your facility will have already been contacted by Olympus and your unit has already been checked, and passed the calibration test, therefore, your device can be removed from quarantine and can continue to be used for clinical procedures.

3. Please forward this notice to other departments within your facility to ensure that they are aware of this letter.

[If applicable:] [competent authority] is aware of the actions described in this letter.
Olympus requests that you report any complaints, including [general issue in letter], 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 FY25-EMEA-29 UHI-4 Calibration Check

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

I acknowledge receipt of this notification. I confirm that I have further communicated 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 date *XXX*.