



Date: 19.08.2024

Olympus Reference: QIL FY25-EMEA-11-FY24-OMSC-19 UHI-4 Software Update

URGENT FIELD SAFETY NOTICE

Product: HIGH FLOW INSUFFLATION UNIT

Attention: Surgical Department, Risk Management Department

Material ID	Model	Description	UDI	Serial Numbers
N3829650	UHI-4	Insufflator, UHI-4, 220-240V	04953170435881	All purchased before August 2024
N3829660	UHI-4	Insufflator UHI-4, 220-240V	04953170324154	
N3829670	UHI-4	Insufflator, UHI-4, 220-240V	04953170324161	

Dear Healthcare Professional:

Olympus Medical Systems Corporation (“Olympus”) previously informed you of a corrective action on the UHI-4 Insufflator (enclosed). 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.

Further to the attached letter, dated 21 March 2024, Olympus is now writing to inform customers about a software update to correct for the causes of over pressurization associated with the UHI-4. The new software version corrects a pressure sensor failure detection algorithm. It will detect any pressure sensor failure, intermittent or continuous, during UHI-4 insufflation and will turn off the front panel display and stop gas insufflation as intended.

The over pressure issue discussed above, and which will be addressed by the software update, is not the same as the CR board part failure communicated in March 2024, which requires a CR board replacement. The software update is intended to turn off the system as a normal safety mechanism when a sensor failure is detected. The CR board replacement action is an action to replace sensors on UHI-4 units that are prone to failure.

The UHI-4 should be considered to remain quarantined at your site until the following corrections are completed:

- Units manufactured before October 2019 requires both a CR Board replacement and a software update
- Units manufactured after October 2019 requires a software update only



Once the required correction(s) has been performed, you no longer need to quarantine the UHI-4.

The software update can be performed on-site at your healthcare facility by Olympus service personnel, or at an Olympus repair center by Olympus service personnel. Units which already had the CR Board replaced by an Olympus repair center are also eligible for an on-site software update. If you require assistance with obtaining your unit's repair history, please contact your local Olympus repair center at 01702 616333 option 1, option 2, option 2 - Field Service or OKM-Field-Service-Coordiators-CG@olympus.com

Starting [September 2024/or as revised by region], UHI-4 units returned to Olympus repair centers for the CR Board replacement will also receive the software update. Olympus will continue to contact customers to schedule a repair based on parts availability.

Contact your local Olympus Customer Service at [regions to add their local contact information] to confirm if a CR board replacement is required for your UHI-4 unit.

Action Steps:

Our records indicate that your facility has purchased one or more UHI-4 units.

1. 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 on ra@olympus.co.uk, latest by 13 September 2024.
2. Starting September 2024 an Olympus representative will reach out to you to arrange a mutually convenient time to have your UHI-4 software and/or CR Board updated on-site or returned to our Olympus repair center where applicable. Alternatively, you may contact your local Olympus Repair Center at 01702 616333 option 1, option 2, option Field Service or OKM-Field-Service-Coordiators-CG@olympus.com to schedule service.
3. If you have distributed these devices outside your facility, please notify your customers of this corrective action immediately. Your notification to your customers may be enhanced by including a copy of this field safety notice.

Olympus fully appreciates your prompt cooperation in addressing this situation. Please do not hesitate to contact me directly at 01702 616333 for any additional information concerning this matter.

Sincerely,

A handwritten signature in black ink that reads "Charlotte Bell".



Charlotte Bell
FSCA & QA Projects Lead/Region UI

REPLY FORM: QIL FY25-EMEA-11-FY24-OMSC-19 UHI-4 Software Update

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.
<i>Name</i>	<i>Signature</i>	<i>Date (YYYY-MM-DD)</i>

Please send the completed form to ra@olympus.co.uk by 13 September 2024