



نتقدم بثقة
Moving Forward
with Confidence



To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 59 dated 29/4/2024 Regarding Field Safety Notice of High Flow Insufflation Unit from (mfr: Olympus Medical Systems Corp).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DSC
- Director of Pharmacovigilance & Drug Information Dept, DSC
- Director of Drug Control Department, DSC
- Director of Pharmaceutical Licensing Department, DSC
- Director of Central Quality Control Lab., DSC
- Supdt. of Central Drug Information



DSC
مركز سلامة الدواء
Drug Safety Center





Circular No. 59 / 2024

20-10-1445 H

29-04-2024

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Field Safety Notice of High Flow Insufflation Unit from Olympus Medical Systems Corp.

Source	Olympus Medical Systems Corp through their local agent Muscat Pharmacy & Stores LLC.
Product	High Flow Insufflation Unit. (Laproscopic Insufflators).
Manufacturer	Olympus Medical Systems Corp
Local agent	Muscat Pharmacy & Stores L.L.C.
The affected products	Model: UHI-4 Description: Insufflator, UHI-4, 220-240V Material ID (UDI): N3829650 (04953170435881); N3829660 (04953170324154); N3829670 (04953170324161) All serial numbers
Reason	Complications may experiencing due to over insufflation of the abdominal cavity resulting from use of the UHI-4 during the procedures.
Action	<p>1. Discontinue use of the UHI-4 until the root cause investigation is completed and you receive additional instructions from Olympus.</p> <p>2. Devices should be quarantined and marked appropriately by your site to prevent usage.</p> <p>3. 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 in the attachment.</p> <p>4. Please read "Considerations for Provisional Usage" in the attachment.</p> <p>Update action: Please refer to "Consideration for Provisional Use" in the attachment.</p> <p>Update action: You should continue to quarantine the product until: For units 5 years and older: Your unit receives both the software update and a CR Board replacement. For units under 5 years of age: Your unit receives the software update.</p> <p>5. Contact the local agent for remedial action.</p>
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General



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
N3829660	UHI-4	Insufflator UHI-4, 220-240V	04953170324154	All
N3829670	UHI-4	Insufflator, UHI-4, 220-240V	04953170324161	All

Dear Healthcare Professional:

Olympus previously informed you about an action regarding reported over insufflation of the abdominal cavity in procedures which used the HIGH FLOW INSUFFLATION UNIT UHI-4 in November 2023.

Olympus informed users to stop use of the UHI-4 and to quarantine all devices unless your facility did not have or was unable to obtain an alternative device in which case you may have chosen to use the UHI-4 with extreme caution in compliance with the Field Safety Notice ref. QIL FY24-EMEA-19-FY24-OMSC-19 UHI-4 Overpressure.

Olympus is now informing you of a new action regarding the UHI-4 front LED control panel.

Reason for Letter:

Olympus has become aware of an increased trend from both repairs and customer complaints of the "UHI-4 stopping CO₂ gas supply with the front panel LED turning off". Based on the analysis of customer complaints, this issue was determined to be associated with a Control board, or CR board, pressure sensor circuit failure.

In an effort to maximize patient safety and mitigate any potential risk to patient health, Olympus will replace the CR board of UHI-4 devices which were manufactured more than 5 years ago. Olympus will be contacting customers to schedule this replacement requirement.

Root cause investigation and quarantine of UHI-4:

Olympus has completed the root cause investigation of the UHI-4 over insufflation issue. The root cause analysis has revealed pressure sensor failure combined with inadequate software detection of pressure sensor malfunction causes the over insufflation issue. Further, the design safety features to help relieve over pressure specified in the November 2023 letter, specifically, excessive pressure alarm, relief mode and automatic suction function, will not function as intended under certain scenarios as these safety functions are triggered by an over pressure condition which is not detected when a pressure sensor malfunction occurs.

Olympus has received 41 complaints of a serious injury, (conversion to open surgery, arrhythmias and respiratory problem/hypertension during surgery), and 2 reports of death related to the UHI-4 associated with both over pressurization and CR board failure. The total UHI-4s installed globally is approximately 24,000.

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As a result, Olympus will provide a software update to mitigate the risk of over insufflation in the future. Olympus will be communicating with you at the end of summer 2024 regarding this software update for the UHI-4 device.

You should **continue to quarantine the product unless** your facility does not have or is unable to obtain an alternative device and chooses to use the UHI-4 with extreme caution, after weighing the potential benefits of the procedure versus the potential risk to health of over insufflation described below until:

For units 5 years and older:

Your unit receives both the software update and a CR Board replacement.

For units under 5 years:

Your unit receives the software update.

Relief Mode

As explained above, the Relief Mode may not function as intended under certain scenarios. Nevertheless, in the event you use your UHI-4 unit before the remediation actions above are made to your device, we recommend that the **Relief Mode setting should be in the "ON" position** as this feature may help mitigate over pressure situations which are not a result of an intermittent sensor failure. When the cavity pressure exceeds the set pressure value by 5 mmHg or more, and the Relief Mode is "ON", the channels inside the UHI-4 are opened and can help release the internal gas until the cavity pressure drops to the set pressure value.

When relief mode is set to ON, cavity gas and/or body fluids (e.g., blood) can flow backward into and potentially contaminate the equipment. To prevent this, Olympus **strongly recommends the use of a disposable filter** in the CO₂ supply line between the UHI-4 and the patient. Olympus recommends filter type PALL OR01H (0.2 µm, hydrophobic) or equivalent filters.

Risk to Health

If the UHI-4 detects a pressure sensor failure, the UHI-4 will raise an error. This error causes activation of the alarm, the front-panel LEDs turn off, and stops the CO₂ supply. If this occurs before the procedure during set up, it may delay initiating treatment. In the event the UHI-4 CO₂ supply stops during a procedure, the device becomes unusable. This could potentially result in a prolonged procedure and/or require additional medical intervention(s).

In connection with over insufflation, 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, and more complex procedures. These complications could potentially lead to death.

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Action steps to be taken by the end user:

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

1. You should **continue to quarantine the product** until:

For units 5 years and older:

Your unit receives both the software update and a CR Board replacement.

For units under 5 years of age:

Your unit receives the software update.

2. Indicate in the reply form if your facility continues using any of the UHI-4 devices.
3. Olympus will contact you based on device age and parts availability to schedule a repair of the CR Board. Olympus will be prioritizing customers who have continued to use the UHI-4.
4. Olympus will contact you in late summer of 2024 regarding the software update to address the over insufflation.
5. Olympus requests that you acknowledge receipt of this letter even if you no longer have this unit. Complete the reply form enclosed and email ra@olympus-mea.com
6. If you have further distributed this product forward this letter to those facilities.

As always, Olympus requests that you report complaints, including any injuries during the procedure with UHI-4, to ra@olympus-mea.com

We appreciate your cooperation in addressing this matter. Our goal is always to ensure patient safety while minimizing disruption to patient care. If you require additional information or have any concerns, please do not hesitate to contact me at ra@olympus-mea.com

Sincerely,

Fadila Ezzahid
Regional Quality Assurance & Regulatory Affairs Specialist Middle East & Africa
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