Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical
Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

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 15 **dated** 11/2/2024 **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, DGPA&DC**
- **Director of Pharmacovigilance & Drug Information Dept, DGPA&DC**
- **Director of Drug Control Department, DGPA&DC**
- **Director of Pharmaceutical Licensing Department, DGPA&DC**
- **Director of Central Quality Control Lab., DGPA&DC**
- **Supdt. of Central Drug Information**

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

Sultanate of Oman
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Circular No. 15 / 2024

01 -08-1445 H

11 -02-2024

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.
Description	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	1. Discontinue use of the UHI-4 until the root cause investigation is completed and you receive additional instructions from Olympus. 2. Devices should be quarantined and marked appropriately by your site to prevent usage. 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. 4. Please read "Considerations for Provisional Usage" in the attachment. **Update action:** Please refer to "Consideration for Provisional Use" in the attachment. 5. Contact the local agent for remedial action.
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

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
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dgpa_dc Email: dg-padc@moh.gov.om

OLYMPUS

To whom it may concern

14 December 2023

Supplementary Letter: Field Corrective Action on UHI-4 HIGH FLOW INSUFFLATION UNIT

Dear Healthcare Professional,

We are writing to further update you on the UHI-4 field corrective action and to provide additional information on the Olympus root cause investigation status as well as considerations for provisional use.

Status of Olympus Root Cause Investigation

As shared in the Field Safety Notice, Olympus initiated a broader investigation into this matter. We aim to provide you with a status update of our investigation by the end of February 2024. We trust that this information will support your facility's considerations regarding using alternative devices or continuing the provisional use of UHI-4 as described in the Field Safety Notice.

Consideration for Provisional Use

Olympus highlights the following information in addition to the Field Safety Notice to facilitate your decision making on any provisional use of the UHI-4 while you seek alternatives or in the absence of alternatives:

- Relief mode: When turning the "Relief mode" ON and when the cavity pressure exceeds the set value by 5 mmHg or more, the relief mode is activated to open the channels inside the instrument and release the internal gas until the cavity pressure drops to the set value. **Olympus therefore recommends to always have the Relief Mode turned ON**. However, when doing so please pay attention to the following:
  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;
  If a filter is not used and fluid (e.g., blood) flows back into the insufflation tube, make sure that it does not enter the UHI-4. Should any fluids enter the UHI-4, immediately terminate its use and contact Olympus.
- If the insufflator emits a warning (warning light or alarm) for intra cavity over pressurization, quickly open the stopcock or valve of the trocar.

For further information please contact your local Olympus representative.

We regret any inconveniences caused by the situation and appreciate your continued patience and understanding. At Olympus, patient safety is our highest priority.