



To whom it may concern

14 December 2023

Olympus Reference: QIL FY24-EMEA-19-FY24-OMSC-19 UHI-4 Overpressure

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 or at info@olympus.ie

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

Sincerely,

Niamh Billings

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