HSE National Patient Safety Alert (NPSA)
Date of issue 25 March 2024 *Unique ID* HSENPSA 001/2024

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UPDATED: Risk of patient harm from medical device: Olympus Insufflation Unit-UHI-4

WHO needs to take action?

Following a second Field Safety Notice (FSN) from Olympus Ireland (Ref: QIL FY24-EMEA-38-OMSC-06 UHI-4 CR Board – Issued 21 Mar 2024), in relation to the Olympus Insufflation Units-UHI-4 the HSE is recommending the removal of the device from use.

This alert is for action by all HSE and HSE Funded Services that are using Olympus High Flow Insufflation Unit UHI – 4 (see Appendix A). UHI – 4 is used 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.

HIGH FLOW INSUFFLATION UNIT - UHI-4

WHAT is the safety issue?

This updated alert pertains to a **second** FSN in relation to the UHI-4 medical device. The FSN highlights an increased trend in complaints about the device control panel and sets out the findings from a root cause investigation regarding the previously reported over-insufflation risk. In light of this recent FSN a HSE Serious Incident Management Team (SIMT) meeting was held with stakeholders and a decision has been made by the HSE to **remove all affected devices from use at the earliest opportunity.** The HSE Medical Devices Office has been in direct contact with each site individually and provided advice and information on ordering replacement devices. The HSE Medical Devices Office will be in contact with sites seeking updates in relation to progress in replacement of devices and any supports that may be required as part of the change process.

HOW to take action?

1. Circulate this HSE NPSA to relevant staff including but not limited to Clinical Directors, Surgeons, Anaesthetists, operators of the device, staff working in theatres/endoscopy units, managers of those areas and medical device engineers.
2. Replace all affected UHI-4 devices at the earliest opportunity.
3. While waiting for a replacement unit to be provided alternative devices should be used where available.
4. During the transition period, in the absence of an alternative device, where cancelling surgeries or procedures may lead to greater risk or harm, the HSE recommends that extreme caution is exercised in the continued use of the UHI-4 device, noting the new information in the FSN (Nov 23). Heightened vigilance is required through careful physiological monitoring for signs of complications.
5. If using a UHI-4 device the lead surgeons should conduct a call out – **'insufflation commencing – please be extra vigilant…'** to the attending anaesthetist during insufflation of the peritoneal cavity to allow hyper-vigilance to observe for bradycardias etc.
6. The risks associated with insufflation, with reference to the FSN should be included in the consent process.
7. Report any incidents or near misses related to medical devices onto the National Incident Management System (NIMS), to the device manufacturer and the HPRA

WHEN does action need to be completed?

Please circulate this HSE NPSA to relevant staff by latest 27th March 2024.

Whilst the replacement of the device is dependent on some external factors, the HSE Medical Devices Office will be in contact with sites seeking updates in relation to progress in replacement of devices.

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Why is this action required?

The medical device company 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".

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).

This follows completion of the root cause investigation of the over insufflation issue (FSN: Ref: QIL FY24-EMEA-19-FY24-OMSC-19 UHI-4 Overpressure – Issued 22 Nov 23) which has revealed pressure sensor failure combined with inadequate software detection of pressure sensor malfunction. As a result Olympus proposes further quarantine of UHI-4 devices pending a software update by end of summer 2024.

A HSE SIMT was convened to review the new FSN and consider the updated advice on the Nov 2023 FSN. The SIMT determined that in light of the issues identified with the UHI – 4 in both FSN that all remaining 43 devices in use in HSE and HSE funded services must be removed from use at the earliest opportunity and replaced by an alternative device.

The decision to continue with the use of the UHI-4 while waiting for a replacement device is supported by the HSE where there is a risk of harm by cancelling surgeries and procedures that involve use of a UHI-4 device.

References

- Olympus Ireland Field Safety Notice Ref: QIL FY24-EMEA-38-OMSC-06 UHI-4 CR Board (see attached)
- HSE Consent policy

What evidence supports this HSE NPSA?

The Olympus FSN indicates that issues with the front LED control panel could potentially result in delayed or prolonged procedures with the potential for additional medical intervention(s).

In connection with the issue of over insufflation, highlighted in the Nov 23 FSN Olympus's health hazard 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/urinary problems, hypoxia, subcutaneous emphysema, delay to treatment, and more complex procedures. These complications could potentially lead to death.

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.

What stakeholders were involved in issuing this HSE NPSA?

This alert was developed collaboratively by the following:

- HSE/RCSI Clinical Programme in Surgery
- HSE National Quality and Patient Safety Directorate
- College of Anaesthesiologists of Ireland
- HSE Acute Operations
- HSE Capital and Estates, National Medical Devices Office
- Input from Health Products Regulatory Authority
- HSE National Patient Safety Alerts Committee

Where can I get further information?

For queries on this alert or other HSE National Patient Safety Alerts please visit www.hse.ie/pst or email patientsafetytogether@hse.ie

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Appendix A

The following HSE and HSE funded hospitals implemented the previous recommendations and mitigations following FSN 1 [Ref: QIL FY24-EMEA-19-FY24-OMSC-19 UHI-4 Overpressure] issued 22 Nov 2023. When FSN 2 [Ref: QIL FY24-EMEA-38-OMSC-06 UHI-4 CR Board] issued on 21 Mar 2024 the following sites had UHI-4 devices in clinical use that now require replacement, noting some sites have already undertaken mitigating actions since FSN 2 was issued last week:

- Mater Misericordiae University Hospital
- Mercy University Hospital
- Midland Regional Hospital Mullingar
- Midland Regional Hospital Portlaoise
- Midland Regional Hospital Tullamore
- Naas General Hospital
- Rotunda Hospital
- St Columcille's Hospital
- St James's Hospital
- St Luke's General Hospital Kilkenny
- St Vincent's University Hospital

The following HSE and HSE funded hospitals currently have UHI-4 devices in quarantine, as they have replacement devices available. The quarantined UHI-4 devices now need to be replaced and must not re-enter circulation

- Beaumont Hospital
- Connolly Hospital, Blanchardstown
- Letterkenny University Hospital
- Mayo University Hospital
- Our Lady's Hospital, Navan
- Our Lady of Lourdes Hospital, Drogheda
- Roscommon University Hospital
- Sligo University Hospital
- St Michaels Hospital, Dún Laoghaire
- Tallaght University Hospital
- Tipperary University Hospital
- University Hospital Waterford
- Wexford General Hospital