Dräger Oxylog Ventilators – Infection Control & Use

Dear Healthcare Professional,

As you may be aware, the Health Products Regulatory Authority (HPRA) is the competent authority for medical devices in Ireland and as such has a role in ensuring the safety and performance of devices placed on the Irish market.

The HPRA are highlighting important information recently published on the Dräger website in a letter titled Filtration Efficiency of Ambient Air Filters for Savina, Savina 300, Carina, Gas supply unit GS500 for V-series and Oxylog. This letter states that;

"*Devices of the Oxylog family provide a dust filter for ambient air only. To protect the device against possible infections in contaminated environment the FiO2 setting must be set to 100%.*"

In the context of this information the HPRA would like to highlight the following recommendations;

- Review the publications on the Dräger website.
- Be aware of the potential of infection transmission both to other patients on the ventilator and in the vicinity of this ventilator and also to healthcare professionals.
- Consider implementing the risk mitigation measures as outlined by Dräger, ensure that the **FiO2 setting must be set to 100%.**
- For a maximum safety of equipment, users and patients it is recommended by Dräger to use additional Breathing System Filters (BSF) at the y-piece.
- Undertake a risk assessment (as appropriate) in relation to Oxylog ventilators that have already been in use with patients who are SARS CoV 2 positive.

The HPRA is liaising further with Dräger to and will communicate further as deemed appropriate.

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Yours sincerely,

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