

FDA Recall - Draeger VentStar Resus Neo

Purpose of this communication:

We are writing to inform you that the FDA has issued an Early Alert regarding the Draeger VentStar Resus Neo, a disposable breathing circuit used to convey breathing gas from a source to an infant weighing up to 22 pounds. The affected device is model MP00310, UDI 04048675422358. Draeger reported cases in which users identified obvious cracks in the hose before use. If a cracked hose is used, it may detach or leak, resulting in restricted ventilation or delayed therapy and potentially causing desaturation, hypoxia, or patient death. On September 1, 2026, Draeger notified affected customers to carefully inspect hoses for damage before use and discard products with cracks or detached hoses. As of August 27, 2026, Draeger reported no serious injuries or deaths associated with this issue.

What do I need to do?

- Please review the following recall notice: <https://www.fda.gov/medical-devices/medical-device-recalls-and-early-alerts/early-alert-breathing-circuit-issue-draeger>
- Notify impacted patients and facilitate the repair, replacement and/or resolution of the recall, according to guidelines issued by the manufacturer in the FDA notification
- Confirm if you have any CareCentrix patients affected by this recall and notify the CareCentrix Quality Department by faxing information to: 919-792-6718 Attn: Quality Department.

Thank you in advance for your cooperation and continued partnership.