carecentrix

Provider Newsflash
June 2026

FDA Recall – Baxter Volara System

Purpose of this communication:

We are writing to inform you that Baxter has issued an Urgent Medical Device Correction for Volara System single-patient use circuits due to a potentially high-risk device issue involving air and medication leakage from the nebulizer cup during therapy. The FDA has issued an Early Alert to notify the public while it continues reviewing information and will update its web page as significant new information becomes available.

Affected Volara System patient circuits include VOLARA P.CIRCUIT KIT, HC (M08085; UDI-DI 00887761985018), VOLARA P.CIRCUIT 5KIT (M08270; UDI-DI 10887761985015), VOLARA P.CIRCUIT KIT AC (M08473; UDI-DI 00887761981492), and VOLARA P.CIRCUIT 5KIT AC (M08474; UDI-DI 10887761981499). Baxter stated that leakage may occur if the nebulizer cup is damaged or not properly locked after medication is added. This may result in ineffective nebulization, reduced medication delivery, patient desaturation, hypoxia, hypoventilation, worsening shortness of breath, mucus retention or plugging, infection risk, and other serious or critical adverse health consequences. Pediatric patients receiving therapy at home may be at particular risk. As of May 21, Baxter reported one serious injury and no deaths associated with this issue.

What do I need to do?

- Please review the FDA Early Alert for the Baxter Volara System positive pressure breathing device issue and Baxter's Urgent Medical Device Correction notice.
- Before each use, carefully inspect the nebulizer cup for damage and confirm the cup is full and securely locked during assembly. If leakage is observed during therapy, discontinue use of that nebulizer and replace the patient circuit. Home care patients should contact their healthcare provider or care team if leakage persists or if they are unsure whether to continue therapy.
- Confirm whether any CareCentrix patients are affected by this device issue. If affected product or impacted patients are identified, 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.