California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Vyaire Medical AirLife Infant Heated Wire Circuit

Recall Date	Product Description	Recalling Firm	Recall Reason
05/09/2025	Brand Name: AirLife Product Name: AirLife Infant Heated Wire Circuit Model/Catalog Number: AH165, AH265 Software Version: N/A Product Description: AirLife Infant Heated Wire Circuit dual-limb, dual-heat, high-flow circuit (>4 L/min) Component: No. a conduit for respiratory gas between the patient and a ventilator.	Vyaire Medical	Adapters may disconnect during setup or while in use, potentially interrupting ventilation. Any disconnection can result in severe consequences for neonates, including hypoxia, hypercapnia, and organ failure.

Recall Class	Product Identification	Distribution	Affected Dates
I	Lot/Serial Number(s): 0004240347 - 0004301668 AirLife Label UDI-DI: 10889483595862 AirLife Case UDI-DI: 30889483595866	4,948 units nationwide	April and prior

	Vyaire Label UDI-DI: 10190752145139 Vyaire Case UDI-DI: 50190752145137 Lot/Serial Number(s): 0004247924 – 0004289514 AirLife Label UDI-DI: 10889483595909 AirLife Case UDI-DI: 30889483595903 Vyaire Label UDI-DI: 10190752145160 Vyaire Case UDI-DI: 50190752145168		

For additional information, please visit: FDA Website (AH165) and FDA Website (AH265).