

FDA Recall – React Health (Ventec) VOCSN V+Pro Ventilators

Purpose of this communication:

- We are writing to inform you that React Health has initiated a voluntary recall to the consumer level for certain VOCSN V+Pro ventilators due to a manufacturing process deviation that may result in an undetected oxygen leak condition. The affected products are VOCSN V+Pro package, REF PRT-01198-000, and VOCSN V+Pro unit, REF PRT-01185-000, involving specific serial numbers identified by the manufacturer. The issue may lead to delivery of lower-than-intended oxygen concentrations prior to and during ventilation and may also increase fire risk in an oxygen-enriched environment. The FDA has classified this as a Class I recall, the most serious type, because continued use may cause serious injury or death.

Potential health consequences include hypoxemia from reduced oxygen delivery, respiratory compromise, and increased risk of serious injury or death in ventilator-dependent patients. In addition, an oxygen leak may create an oxygen-enriched environment that increases the risk of fire.

What do I need to do?

- Please review the [FDA recall notice](#) regarding the React Health VOCSN V+Pro ventilator recall.
- Check inventory and patient equipment, if applicable, for affected VOCSN V+Pro ventilators; immediately discontinue use, remove from clinical service, and quarantine any impacted device; use a non-affected ventilator when possible; and notify impacted patients, caregivers, providers, or facilities, share the recall notice as needed, and complete the manufacturer response process, including updating ownership information if applicable.
- Notify impacted patients/providers as appropriate and facilitate resolution of the recall according to the manufacturer's guidance. If you identify any impacted patients, notify the Quality Department per your standard internal process.

Thank you in advance for your cooperation and continued partnership.