

State of California—Health and Human Services Agency

California Department of Public Health



Food and Drug Branch - Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Baxter recalls Inline Ventilator Adaptor for Risk of Reduced Ventilation or Pneumothorax

Recall Date	Product Description	Recalling Firm	Recall Reason
4/26/2022	In-Line ventilator adaptor	Baxter Healthcare Corporation Deerfield, Illinois	There is a potential of reduced oxygenation or pneumothorax /barotrauma to occur when the Volara system is used with in-line ventilator in home care environment.
4/26/2022	In-Line ventilator adaptor	Baxter Healthcare Corporation Deerfield, Illinois	Potential of reduced oxygenation or pneumothorax.

Recall Class	Product Identification	Distribution	Affected Dates
I	M08473 OPTIMUS OLE AC PAT.CIRCUIT KIT UDI-DI: 00887761981492.	259 Units Nationwide including California	February 2020 to April 2022
I	M07937 MODULE, OPTIMUS HANDSET 2; UDI-DI: 00887761984622.	9 Units Nationwide including California	October 2019 to April 2022

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

