

State of California—Health and Human Services Agency

California Department of Public Health



Food and Drug Branch - Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Getinge Recalls Maquet Critical Care Ab/Getinge Servo-u Ventilator System

Recall Date	Product Description	Recalling Firm	Recall Reason
8/31/2022	Maquet Critical Care AB/Getinge Servo-u Ventilator System Part Number 6694800 Servo- n Ventilator System, Part Number 6688600 Servo-u MR ventilator: Part Number 6888800 Servo-air: Part Number 6882000	Getinge Usa Sales Inc Wayne, New Jersey	Ventilators may generate a combination of alarms which may result in loss of communication, technical alarms being triggered, and loss of ventilation. If the device stops ventilating due to this issue, it may lead to hypoventilation and consequently desaturation, with patient outcomes including hypoxemia and hypoxic injury, which might result in circulatory failure.

Recall Class	Product Identification	Distribution	Affected Dates
I	UDI-DI: Servo-air: 73257100031183 Servo-u, Servo-n, Servo-u MR: 7325710001117R Serial Numbers: 46385 – 44687	11,089 Units US Nationwide	July 2022 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE

