

State of California—Health and Human Services Agency

California Department of Public Health



Food and Drug Branch - Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

ICU Medical Recalls Replacement Batteries For Plum 360, Plum A+, And Plum A+3 Infusion Systems Due To Diminished Battery Life That May Impact Infusion Delivery

Recall Date	Product Description	Recalling Firm	Recall Reason
5/22/2023	Replacement Batteries For Plum 360, Plum A+, And Plum A+3 Infusion Systems Plum 360: SUB0000864 Plum A+ and Plum A+3: SUB0000594	ICU MEDICAL San Clemente, California	Manufacturing defect has substantially diminished how long the batteries can be used to run the system. If the pump is running on battery power and there is no AC power backup available, the system may shut down an ongoing infusion and power down. This issue may cause serious injury or death to patients.

Recall Class	Product Identification	Distribution	Affected Dates
I	Product 1 Product 1 Identification Details UDI etc	1904 Units Nationwide	March, 2023 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE <u>FDA WEBSITE</u> or call ICU Medical at: 1-800-241-4002, option 3 (M-F, 6:00 am – 4:00 pm)

