



URGENT: FIELD SAFETY NOTICE - ***UPDATED**

Batteries Supplied by CSB and Used with Plum Infusion Systems

Product Name	Pump List Number	Replacement Battery List Number
Plum 360™ Infusion System	30010	SUB0000864
Plum A+™ & Plum A+3™ Infusion Systems	11005, 11971, 12391, 12618, 20678, 20679, 20792, 60529, 12348, 11973	SUB0000864 SUB0000594

27th May 2024

Dear Valued Plum Infusion System Customers:

This is an update to the previous communication dated 3rd April 2023: ICU Medical worked with the battery supplier, CSB, to implement corrective actions in their manufacturing process for the original communicated field safety notice. Unfortunately, some batteries display behavior similar to that identified in the original notice. Therefore, ICU Medical is expanding the scope of this issue to include all batteries manufactured by CSB.

ICU Medical is working with our battery supplier to resolve this issue fully. We will communicate further updates when new information becomes available.

Content different from previous communication dated April 2023 is shown in red font.

Issue:

Due to a manufacturing defect from the battery supplier, Plum 360 and Plum A+ battery life may be substantially diminished. If an affected battery has diminished capacity, as defined by the triggering of the replace battery alarm, and has not been replaced, Low and Depleted Battery alarms may not trigger at the appropriate times, reducing the time the user has to plug the pump into AC power before an ongoing infusion stops and the pump shuts off.

If a Plum 360 or Plum A+ infusion system is running on battery power, a Low Battery and Depleted Battery alarm will activate when thirty minutes and three minutes, respectively, of estimated battery runtime remain (note, estimated battery runtime could exceed 30 minutes). In addition, when the pump detects a significant reduction in battery capacity, the pump will issue an alarm with a message to replace the battery. On a Plum 360 pump, the screen will display *“Keep Plugged into AC! Service Battery/ Replace Pump”* and Plum A+ pump will display *“Warning: Replace Battery.”*

Battery capacity and runtime diminish with age and use. However, batteries affected by this manufacturing defect may experience faster than anticipated reduction in capacity and overall runtime. In the most extreme examples, the pump indicates the batteries should be replaced after only a few months of use. If the battery is not replaced when the pump displays a message to replace the battery, these reductions in battery capacity and overall runtime significantly limit the effectiveness of the battery alarms, and the time the user has to plug the pump into AC power before an ongoing infusion stops and the pump shuts off.



Potential Risk:

Batteries should be replaced the first time the pump issues a replace battery alarm. Continued use of pumps on battery after the first instance of the replace battery alarm will reduce the time from a low battery alarm to a depleted battery/infusion stopping.

If the pump is running on battery power and the pump has triggered the replace battery alarm, the user may not have sufficient time to plug the pump into AC power after the Low Battery alarm is activated, which may result in an interruption or delay of therapy. An interruption or delay of therapy can lead to serious patient injury or death, depending on the clinical situation and the type of medication being administered. **To date, ICU Medical has received one report of an adverse event potentially related to this issue.**

Affected Product:

All Plum A+ and Plum 360 batteries manufactured by the supplier, CSB, are included within the scope of this notice. CSB batteries are identified with the following logo:



Actions to be taken by the Customer:

There is no need to return or discontinue using your Plum 360 or Plum A+ pumps.

Actions for Clinical Users:

Whenever possible, keep the pump plugged into AC power. Before disconnecting the pump from AC power (e.g., to transport a patient), please ensure that the battery is fully charged. Closely monitor the Battery Status Indicator while the pump is disconnected from AC power to help ensure there is sufficient battery capacity to power the pump. Additionally, have a backup pump available when infusing critical medications.

If a Plum pump displays the replace battery alarm mentioned above, continue the infusion with a different pump and remove the pump from clinical use until the battery is replaced.

Actions for Biomedical Engineering:

Replace batteries when the pump triggers a replace battery alarm. Do not use a replacement battery with corroded battery terminals.

1. Ensure all users or potential users of these pumps are immediately made aware of this notification and proposed mitigations.
2. Complete and return the attached Response Form to EMEA-FSN@icumed.com **within ten days of receipt** to acknowledge your understanding of this notification.
3. **DISTRIBUTORS:** If you have distributed potentially affected products to your customers, please immediately forward this notice to them and ask them to return completed response forms and affected product **to you**. When you have received all completed response forms and affected product from your customers, please complete a **SINGLE COMPLETED form** with the required details and return to EMEA-FSN@icumed.com



Follow-up Actions by ICU Medical:

ICU Medical is working with our battery supplier to resolve this issue fully. We will communicate further updates when new information becomes available.

For further inquiries, please contact ICU Medical using the information provided below.

ICU Medical Contact	Contact Information	Areas of Support
Technical Assistance	emeapumptechnicalsupport@icumed.com	Additional information or assistance
Global Complaint Management	ProductComplaintsPP@icumed.com	To report adverse events or product complaints

Your country regulatory agency has been notified of this action.

ICU Medical is committed to patient safety and is focused on providing exceptional product reliability and the highest level of customer satisfaction. Thank you for your prompt support on this important matter. We appreciate your cooperation.

Sincerely,



Enclosures:

- *Customer Response Form (see below)*



URGENT: FIELD SAFETY NOTICE RESPONSE FORM

Batteries supplied by CSB and used with Plum Infusion Systems

27th May 2024

Check your inventory and complete the information below, even if you do not have the affected product. Complete this form and return it to EMEA-FSN@icumed.com. If you have questions about this form please contact ICU Medical using the contact provided.

Name of Hospital / Facility	
Hospital / Facility Address	
Telephone Number	
Name and Title of Person Completing this Form	
Signature of Person Completing this Form	
Date	
If affected product was purchased through a distributor, please list distributor name/location here for traceability purposes	

YES, I have affected product, I have notified users in my facility and I have followed the instructions provided to me (complete and return this form to the e-mail address provided above)

Indicate the number of devices in inventory requiring corrected batteries (when available):	
Indicate the Individual's Name, Phone, and Address where corrected batteries should be sent (when available):	

I have **NO** affected product (complete and return this form to the e-mail address provided above)

Adverse events and complaints associated with the use of these products should be reported and emailed to ProductComplaintsPP@icumed.com.