

22 March 2023

URGENT: MEDICAL DEVICE CORRECTION
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	SUB0000594

Dear Valued Plum Infusion System Customers:
 Director of Biomedical Engineering
 Director of Nursing
 Director of Risk Management

ICU Medical is issuing this letter to notify you of an issue with certain batteries used in Plum infusion systems. The following information details the issue and the required steps for you to perform.

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 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 should activate when thirty minutes and three minutes, respectively, of estimated battery runtime remain. In addition, when the pump detects a significant reduction in battery capacity, the pump will display 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:

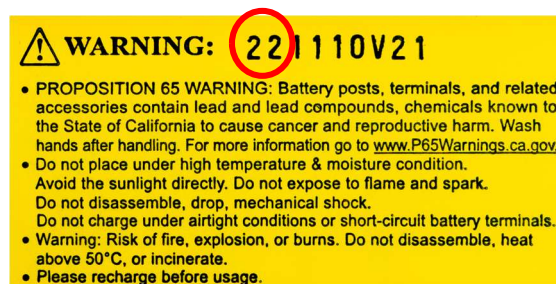
If the pump is running on battery power, the user may not have sufficient time to plug the pump into AC power after the Low Battery alarm is activated, which may result in an interruption or delay of therapy. An interruption or delay of therapy can lead to serious patient injury or death, depending on 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:

Plum A+ and Plum 360 batteries from the supplier, CSB, manufactured before January 1, 2023 are included in this notice. We cannot confirm which CSB batteries manufactured before 2023 are impacted, so all should be considered affected. CSB batteries are identified with the following logo:



As demonstrated below, the first two characters on the label indicate the year the battery was manufactured. **If the first two characters are 22 or lower, consider the battery to be affected.**



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:

You may replace affected batteries with a new CSB battery until corrected batteries are available. Please do not use a replacement battery with corroded battery terminals.

1. Identify all affected batteries in your possession and 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 icumedical5967@sedgwick.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. Request that they complete the response form and return it to icumedical5967@sedgwick.com.

Follow-up Actions by ICU Medical:

ICU Medical will replace all batteries affected by this issue. We will contact you when replacement batteries are available to schedule the battery replacement.

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

ICU Medical Contact	Contact Information	Areas of Support
Global Complaint Management	1-844-654-7780 (M-F, 8:00am – 5:00pm CT) or ProductComplaintsPP@icumed.com	To report adverse events or product complaints
Technical Assistance	1-800-241-4002, option 3 (M-F, 8:00 am – 6:00 pm CT)	Additional information or assistance

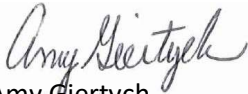
The U.S. Food and Drug Administration (FDA) has been notified of this action.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

- Complete and submit the report **Online:** www.fda.gov/medwatch
- **Regular Mail or Fax:** Download the form at www.fda.gov/medwatch or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178

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,



Amy Giertych
Vice President, Global Regulatory Affairs



Dr. Jesus Cabrera
Chief Medical Officer

Enclosures:

- *Customer Response Form*
- *FAQs*

Batteries Supplied by CSB and Used with Plum Infusion Systems

Urgent: Medical Device Correction Frequently Asked Questions

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	SUB0000594

ICU Medical identified a potential issue with batteries used in Plum infusion systems. The attached Urgent Medical Device Correction letter describes the issue and the actions for users to take.

1. Q What is the issue?

ICU Medical identified a potential issue with certain batteries used in Plum Infusion Systems. Due to a manufacturing defect from the battery supplier, affected batteries may experience a loss of capacity earlier in the battery lifecycle than expected and overall battery runtime may decrease earlier in the battery lifecycle than expected.

2. Q What is the potential risk?

If the pump is running on battery power, 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 may potentially lead to serious patient injury or death, depending on the clinical situation and the type of medication being administered.

3. Q What products are affected by this notice?

- CSB replacement batteries for the Plum 360 manufactured before January 1, 2023
- New Plum 360 pumps built with CSB batteries manufactured before January 1, 2023
- CSB Plum A+ replacement batteries manufactured before January 1, 2023

4. Q Has ICU Medical corrected this issue?

Yes. ICU Medical worked with CSB to identify and correct the manufacturing defect that led to this issue.

5. Q Are all Plum batteries affected by this field notice?

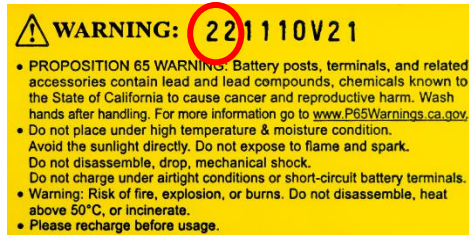
- No. Only CSB batteries manufactured before January 1, 2023 are affected.
- The affected CSB batteries have been supplied with new Plum 360 pumps and installed as replacements for Plum 360 and Plum A+ pumps.
- Panasonic batteries are not affected by this issue.

6. Q How do I know if I have affected batteries?

All affected batteries have the CSB logo.



The first two characters on the label indicate the year the battery was manufactured. If the first two characters are 22 or lower, consider the battery to be affected.



7. Q What do I do with the affected batteries in my stock?

ICU Medical will replace all affected batteries you have in your possession free of charge. ICU Medical is working to secure as many batteries as possible from our manufacturer as quickly as possible to replace all affected batteries with all customers.

8. Q What should I do until I get my allotment of new batteries?

Your Plum A+ and Plum 360 pumps can continue to be used. Please identify all affected batteries in your possession and ensure all users or potential users of these pumps are immediately made aware of this notification and proposed mitigations.

9. Q Can non-ICU Medical batteries be used with Plum A+ or Plum 360 pumps?

No. ICU Medical cannot validate the quality of any alternative battery and will not reimburse any purchases for non-ICU Medical batteries.

10. Q Do I need to stop using my Plum 360 and/or Plum A+ pumps?

No. 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.

11. Q Will ICU Medical come on-site and replace all batteries?

No. ICU Medical will not come on-site to remove/replace all batteries. ICU Medical will ship replacement batteries to you as quickly as our supply allows.

12. Q Can I return my pumps to ICU Medical to replace my device batteries?

No. There is no need to return your Plum A+ or Plum 360. ICU Medical will send replacement batteries to you as quickly as our supply allows.

13. Q Has there been any patient harm due to this issue?

To date, ICU Medical has received one report of an adverse event potentially related to this issue.

14. Q Where can I find more information?

ICU Medical Contact	Contact Information	Areas of Support
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