

07 May 2024

**UPDATED URGENT MEDICAL DEVICE CORRECTION**  
**Batteries Supplied by CSB and Used with Plum Infusion Systems**

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

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

This is an update to the previous communication dated 22 March 2023: ICU Medical worked with the battery supplier, CSB, to implement corrective actions in their manufacturing process for the original communicated medical device correction. 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 March 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 [icumedical5967@sedgwick.com](mailto: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](mailto:icumedical5967@sedgwick.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
Global Complaint Management	1-844-654-7780 (M-F, 8:00am – 5:00pm CT) or <a href="mailto:ProductComplaintsPP@icumed.com">ProductComplaintsPP@icumed.com</a>	To report adverse events or product complaints
Technical Support	1-800-241-4002 (M-F, 8:00 am – 6:00 pm CT)	Additional information or technical assistance
Field Corrections	<a href="https://icumed.custhelp.com/app/market-action">https://icumed.custhelp.com/app/market-action</a>	Questions about this Field Correction Notice

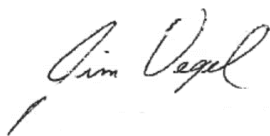
The U.S. Food and Drug Administration (FDA) has been notified of this action.

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](http://www.fda.gov/medwatch)
- **Regular Mail or Fax:** Download the form at [www.fda.gov/medwatch](http://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,



Jim Vogel  
Vice President, Quality



Dr. Jesus Cabrera  
Chief Medical Officer

Enclosures:

- *Customer Response Form*
- *FAQs*

## Batteries Supplied by CSB and Used with Plum Infusion Systems

### UPDATE Urgent: Medical Device Correction Frequently Asked Questions

Product Name	Pump List Number	Replacement Battery List Number
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ICU Medical identified a potential issue with batteries used in Plum infusion systems. The attached updated 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?**

All Plum A+/A+3 and Plum 360 batteries manufactured by CSB.

**4. Q Has ICU Medical corrected this issue?**

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

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

- No. Only Plum batteries manufactured by CSB 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.



- 7. 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.
- 8. 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.
- 9. 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.
- 10. Q Is it ok to reset the battery in Biomed Mode without replacing the battery?**  
No, a pump that has alarmed and indicated the battery needs to be replaced requires a battery replacement to correctly resolve this alarm.
- 11. Q I have a device that is alarming “Replace Battery”. Who do I contact to get a replacement?**  
Contact [productcomplaintsPP@icumed.com](mailto:productcomplaintsPP@icumed.com) to log a complaint and initiate a replacement.
- 12. Q Where can I find more information?**

ICU Medical Contact	Contact Information	Areas of Support
Global Complaint Management	1-844-654-7780 (M-F, 8:00am – 5:00pm CT) or <a href="mailto:ProductComplaintsPP@icumed.com">ProductComplaintsPP@icumed.com</a>	To report adverse events or product complaints
Technical Support	1-800-241-4002 (M-F, 8:00 am – 6:00 pm CT)	Additional information or technical assistance
Field Corrections	<a href="https://icumed.custhelp.com/app/market-action">https://icumed.custhelp.com/app/market-action</a>	Questions about this Field Correction Notice