22 March 2023

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

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

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.

<table>
<thead>
<tr>
<th>ICU Medical Contact</th>
<th>Contact Information</th>
<th>Areas of Support</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global Complaint Management</td>
<td>1-844-654-7780 (M-F, 8:00am – 5:00pm CT) or <a href="mailto:ProductComplaintsPP@icumed.com">ProductComplaintsPP@icumed.com</a></td>
<td>To report adverse events or product complaints</td>
</tr>
<tr>
<td>Technical Assistance</td>
<td>1-800-241-4002, option 3 (M-F, 8:00 am – 6:00 pm CT)</td>
<td>Additional information or assistance</td>
</tr>
</tbody>
</table>

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 Glerych
Vice President, Global Regulatory Affairs

Dr. Jesus Cabrera
Chief Medical Officer

Enclosures:

- **Customer Response Form**
- **FAQs**