600 N. Field Drive
Lake Forest, IL 60045
www.icumed.com

13 July 2023

URGENT: MEDICAL DEVICE CORRECTION
Plum 360 Infusion System – Audible Alarm
List Number 30010

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 the Plum 360 Infusion System. The following information details the issue and the required steps for you to perform.

Issue:
Due to a manufacturing defect of a supplier provided component, the audible signal for an alarm may not sound under certain conditions.

Alarms on Plum 360 consist of three elements: a visual alarm indication, an audible signal, and a message that appears on the display. Plum 360 pumps conduct a self-test of the primary alarm audible signal during the power-on sequence.

If the pump detects a failure of the audible signal during power-on, the pump display will remain off and the line B drip indicator will flash, indicating the pump has failed power-on. If the audible alarm signal fails after passing the power-on test and during the use of the pump, a situation may occur where the pump has stopped infusing and an alarm is triggered without an audible signal. The pump will remain in this state until a clinician addresses the alarm. The visual alarm indication and the message will still appear on the display.

Potential Risk:
If the audible signal fails and the user is not able to see the visual indicator and display, the user may not be aware that an alarm condition has stopped infusion, which may further delay the interrupted therapy. A delay or interruption of therapy can lead to injuries requiring medical intervention. To date, no patient harm or adverse events have been reported related to this issue.

Affected Product:
This issue affects all Plum 360 pumps manufactured between July 2020 and December 2021. The manufacturing date is shown on the Product Identification label on the side of the pump, as shown in Figure 1 below.

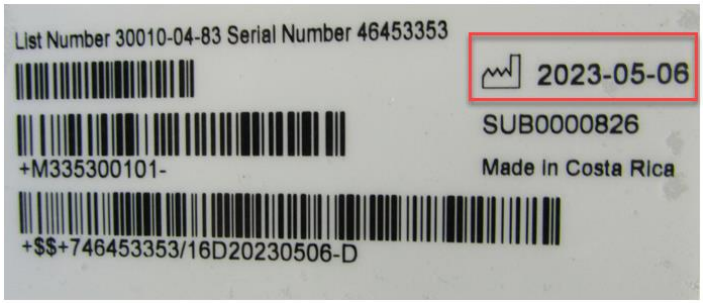

Figure 1. Sample label showing Manufacturing Date in the red box – date format is shown in YYYY-MM-DD

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Actions to be Taken by the Customer:

Actions for Clinical Users:

If your Plum 360 pump does not power on or indicates an Audio Alarm failure, please remove the pump from use and send the pump to Biomedical Engineering.

Actions for Biomedical Engineering:

If you have Plum 360 pumps with Audio Alarm failures, please contact ICU Medical.

1. Locate all affected pumps in your possession and ensure all users or potential users of these devices are immediately made aware of this notification and required actions.
2. Complete and return the attached Response Form to icumedical8320@sedgwick.com **within ten days of receipt** to acknowledge your understanding of this notification.
3. **DISTRIBUTORS:** If you have distributed affected products to your customers, please immediately forward this notice to them. Request that they complete the response form and return it to icumedical8320@sedgwick.com.

Follow-up Actions by ICU Medical:

ICU Medical will address the issue described in this letter through an upcoming software release. The software patch will ensure that there is always an audible signal for an alarm, even if the primary audible alarm is defective. When the corrected software is available, ICU Medical will contact you to schedule the software update of your Plum 360 infusion pumps.

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

Jesus Cabrera, MD, PHD
Chief Medical Officer

Enclosures:

- *Customer Response Form*
- *FAQs*

13 July 2023

Plum 360 Infusion System – Audible Alarm
List Number 30010

Urgent: Medical Device Correction
Frequently Asked Questions

General Information:

Alarms on Plum 360 consist of three elements: a visual alarm indication, an audible signal, and a message that appears on the display. Plum 360 pumps test the primary alarm audible signal during the power-on sequence. If the pump detects a failure of the audible signal during power-on, the pump display will remain off and the line B drip indicator will flash, indicating the pump has failed power-on.

1. **What is the issue?**
   Due to a manufacturing defect of a supplier provided component, there is a potential that the audible signal for an alarm may not sound under certain conditions.

   If the audible signal fails after passing the power-on test and during the use of the pump, a situation may occur where the pump has stopped infusion and an alarm is triggered without an audible signal. The pump will remain in this state until a clinician addresses the alarm. The visual alarm indication and the display message will still be displayed.

2. **What is the potential risk?**
   If the audible signal fails and the user is not able to see the visual indicator and display, the user may not be aware that an alarm condition has stopped infusion, which may further delay the interrupted therapy. A delay or interruption of therapy can lead to injuries requiring medical intervention. To date, no patient harm or adverse events have been reported related to this issue.

3. **What products are affected by this field notice?**
   Plum 360 pumps manufactured between July 2020 and December 2021 are potentially affected.

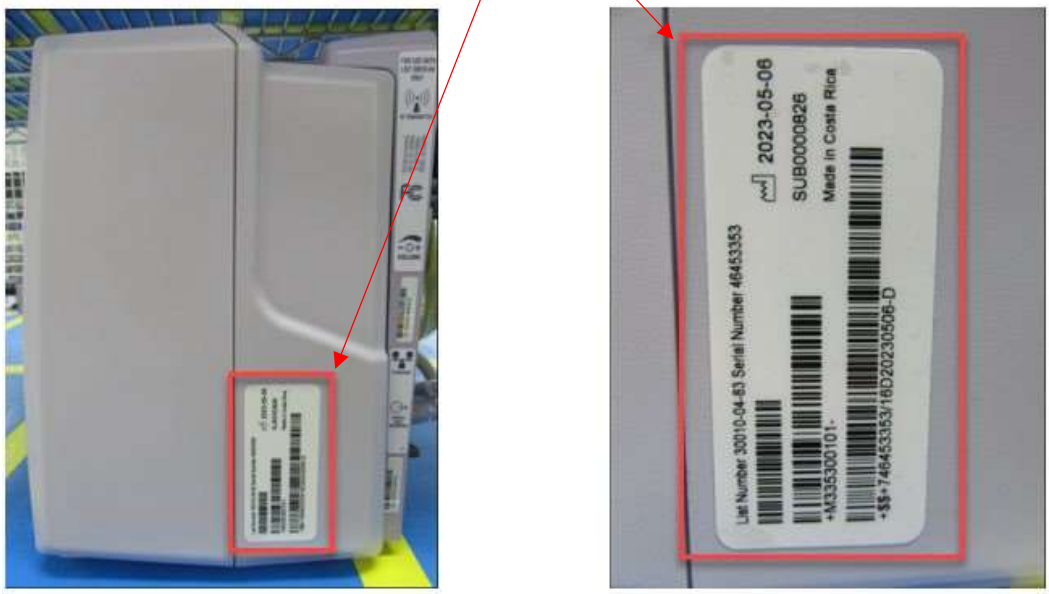
4. **Has there been any patient harm due to this issue?**
   To date, no patient harm or adverse events have been reported related to this issue.

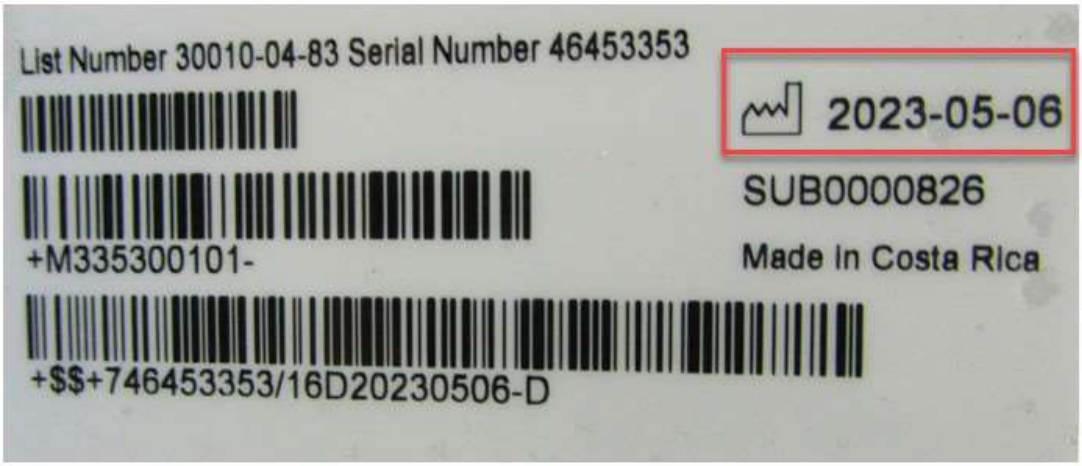
5. **What action is ICU Medical taking to address this issue?**
   ICU Medical is developing a software patch to address the issue. ICU Medical will notify customers when the software is available and schedule the software update for affected Plum 360 pumps. The software patch will ensure that there is always an audible signal for an alarm, even if the primary audible alarm is defective.

6. **Does this notice affect all Plum 360 pumps?**
   No, only the Plum 360 pumps manufactured between July 2020 and December 2021 potentially have this defect.

7. **How do I know if I have a Plum 360 pump potentially affected by this issue?**
   The manufacturing date is shown on the Product Identification label on the side of the pump. If the manufacturing date on the label falls between July 2020 and December 2021, the pump may be potentially affected by this issue.

The Product Identification Label can be found on the side of the pump.





8. **What should I do if my Plum 360 displays an Audio Alarm Failure message?**
   If your Plum 360 pump does not power on or indicates an Audio Alarm failure, please remove the pump from use and send the pump to Biomedical Engineering.

9. **Can I continue to use the pump with only the backup audio alarm?**
   No. Do not use the pump if your Plum 360 pump does not power on or indicates an Audio Alarm failure. Stop using the pump immediately and remove the pump from use.

10. **What action should I take if my pump is potentially affected?**
    Pumps that fall within the manufacturing dates noted above can continue to be used but will need to receive the upcoming software patch.

    Plum 360 pumps test the alarm audible signal during the power-on sequence. If the pump detects a failure of the audible signal during power-on, the pump display will remain off and the line B drip indicator will flash, indicating the pump has failed power-on. Pumps that display this message should be removed from service and have the Piezo Alarm replaced.

11. **Can the audible alarm fail after the initial power-on test?**
    Yes. The audible alarm can fail after the power-on test and during the use of the pump. If the audible signal fails after passing the power-on test and during the use of the pump, a situation may occur where the pump has stopped infusion and an alarm is triggered without an audible signal. The pump will remain in this state until a clinician addresses the alarm. The visual alarm indication and the message will still appear on the display.

12. **Can my affected pump be fixed by my hospital's Biomedical Engineering team?**
    Yes. If you have Plum 360 pumps with Audio Alarm failures, please contact ICU Medical.

13. **Does the Piezo Alarm need to be replaced?**
    No. ICU Medical is developing a software patch to address the issue.

14. **Will ICU Medical come on-site and replace defective pumps?**
    No. ICU Medical will not come on-site to replace defective pumps but will schedule a software update to address the issue.

15. **Can I return my pumps to ICU Medical to replace my defective pump?**
    If you received the Audio Alarm Failure message, contact ICU Medical Technical Service Support Center at 1-800-241-4002 to return your Plum 360 pump to be repaired.

16. **Is information about this issue available online?**
    Customer Communications and Clinical Bulletins on the ICU Medical website: https://www.icumed.com/support/customer-communications-and-clinical-bulletins/plum-infusion-system

17. **Where can I find more information?**

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