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Risk Review Analysis Summary
Omnifuse and Omnifuse PCA Syringe Pumps
July 2011

Summary
As of July 2011, Smiths Medical has received a total of 2 confirmed reports of incorrect information with the last infusion data on the totaliser display. Investigations into this issue have identified the root cause as a software anomaly that makes the software unable to update the displayed totals when a System Fault occurs or when the battery is allowed to run to zero power during ongoing infusion activity – and, then the pump is restarted. None of the reported complaints has resulted in permanent serious injury or death.

Statement of Issue
Smiths Medical has become aware that under certain circumstances, Omnifuse or Omnifuse PCA Pumps ("Omnifuse Pump") may experience a loss of the last infusion data from the totaliser displayed totals on the pump screen. This can only occur when:

- A system fault occurs during ongoing infusion activity and the pump is restarted; or
- The battery is allowed to run to zero power during ongoing infusion activity and the pump is restarted.

For example, if during the second round of 100-mL infusions, where the first 100-mL was already delivered and 25-mL of the second 100-mL infusion was delivered, a System Fault Code is triggered, then the totaliser will display only 100-mL as delivered after the Pump is reset to clear the System Fault. It will not display the 125-mL that was actually delivered.

In both of these situations, the totaliser display does not update to show the ongoing infusion, although the ongoing infusion details are still available in the downloadable memory.

Investigation Summary
Smiths Medical's investigation found that this issue can occur with Omnifuse pumps with the occurrence of any System Fault Code that occurs during infusion or when the batteries are allowed to run down to zero power during infusion – and, then the pump is restarted.

Based on a review of the complaint data, this issue has occurred extremely rarely. It is hypothesized that this issue does not occur in practical use for several reasons, including:

1) The current Instruction Manual instructs the user to withdraw the pump from use when a System Fault occurs and to return the pump to a suitably qualified engineer, so the clinician does not restart the pump; therefore they do not see the failure of the totaliser to display the last infusion data.

2) In the case of the pump being allowed to completely run to zero battery power, the current Instruction Manual warns the user: "Correct management of battery charging is essential to make sure that the pump can operate on batteries for the time specified. Failure to do so may lead to impaired functioning of the pump, resulting in patient injury or death".

3) Standard clinical practice (discussed in detail in the Clinical section of this report).

Root cause has been identified as a software anomaly that makes the software unable to update displayed totals when a System Fault occurs or when the battery is allowed to run to zero power during ongoing infusion activity. The pump does, however, correctly save all totaliser data to the down-loadable memory

within the pump. The down-loadable history is only accessible through the pump's PC software program, which is typically maintained by the facility's biomedical department.

Customer Complaint Summary
A review of the complaint database for the period January 2008 to 4th July 2011, found 2 confirmed complaints for this issue. This represents a complaint rate of 0.019% when compared across the global installed base.

There have been no reports of serious permanent injury or death related to this issue.

Potential Harm:
Omnifuse Pumps are used for a variety of medication delivery protocols across neonatal, pediatric and adult populations. The Omnifuse PCA pumps are used for pain management across pediatric and adult populations.

It is highly unlikely for a clinician to make a miscalculation based on the incorrect data on the pump display; however, if the clinician does not follow good clinical practices and does not rely on other clinical data in addition to the pump display totals, this could lead to subsequent incorrect intervention to remediate conditions or circumstances that do not exist. The potential clinical harm is drug and patient dependant, and typically no patient harm would occur. The worst case scenario, although very unlikely, is additional medical intervention or patient death.

Mitigations
In normal clinical practice, manual records are kept of the prescribed doses and the ongoing infusion syringe will still contain the partially infused quantity remaining at the time the infusion stopped. On comparison of stored memory data with the manual records, full traceability of all infused doses is maintained and independently verifiable.

Also, correct infusion data is still retained within the pump history with full data, correct values and dates.

The current Instruction Manual instructs the user to withdraw the pump from use when a System Fault occurs and to return the pump to a suitably qualified engineer, so the clinician does not restart the pump; therefore they do not see the failure of the totaliser to display the last infusion data.

When the pump battery is running low on power, it will first alarm with a low battery condition (providing audible and visual alarms) and then it will eventually alarm with a continuous audible alarm to alert the user that the battery is exhausted and the pump must be connected to a mains supply immediately or the pump will automatically shut off. It would be highly irregular and unlikely for clinicians in clinical practice to ignore such an alarm event.

Conclusion
The probability of occurrence for both of these issues is extremely rare and the probability of occurrence for these issues leading to patient harm is lower yet. Based on an analysis of the investigation results, reported complaints, and the mitigations described above, Smiths Medical has concluded that the immediate potential for risk of harm to patients is low.

The immediate potential for risk of harm to patients for the issue of a loss of the last infusion data from the totaliser displayed totals on the pump screen when the battery is allowed to run to zero power during

ongoing infusion activity and the pump is restarted is viewed as extremely low as this type of actions (i.e., ignoring the pump alarms regarding battery power) is contrary to normal clinical practice.

Plan of Action

As part of Smiths Medical's plan to provide customers with additional information on System Fault Code issues, Smiths Medical will provide a Customer Information Bulletin that describes what happens when a system fault occurs during ongoing infusion activity and the pump is restarted. This information will be provided to all Omnifuse Pump customers with a Field Safety Notice. Also, the Instruction Manuals for the Omnifuse Pumps will be updated with a new Warning: "Failure to reset the cumulative total as advised in the 'clearing system fault codes' process may result in inaccurate infusion data being displayed by the totaliser function. The use of inaccurate infusion data in clinical decisions may result in inappropriate or unnecessary clinical intervention which could lead to patient injury or death."

In regards to totaliser display issue occurring when the battery is allowed to run to zero power during ongoing infusion activity and the pump is restarted, because this type of event is highly irregular and unlikely to occur in clinical practice, and because only 1 complaint of this nature has been reported within the last 3 years, it has been decided that the current Instruction Manual provides sufficient information to the customer to avoid this issue. Within the Manual, there are various instructions that describe the low battery and battery exhausted alarms, and there is also a Warning that addresses battery management: "Correct management of battery charging is essential to make sure that the pump can operate on batteries for the time specified. Failure to do so may lead to impaired functioning of the pump, resulting in patient injury or death".

No further corrective or preventative actions are planned at this time. We will continue to monitor this issue for any new complaints or trends.

Regards,

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