Infusion Pump Remediation in Lower Mainland B.C. Health Authorities

A.Bateman[1], E.Gable[2] and J.Warwicker[3]

[1] Lower Mainland Biomedical Engineering, Providence Healthcare, Vancouver, Canada
[2] Clinical Equipment & Supplies, Vancouver Coastal Health, Vancouver, Canada
[3] Inter Campus Operations, BC Children's Hospital and BC Women's Hospital, Vancouver, Canada

I. Introduction

Infusion pumps deliver fluids and medications at controlled flow or dose rates into a patient's body. All health authorities in the Lower Mainland (LM), British Columbia are standardized to use Becton Dickinson (BD) Alaris pumps.

In 2020, BD initiated four voluntary recalls to address several software and hardware issues with the Alaris infusion system [1]-[4], all of which have the potential to result in severe patient harm or death. In June 2022, the required software and hardware fixes to mitigate these risks were released by the vendor. All device components of the Alaris infusion system require remediation, including the Point of Care Unit (PCU) and pumping modules. Every device must be temporarily removed from clinical service to be upgraded by BD.

Within the LM, over 18,000 devices require remediation across 62 facilities, including 27 acute hospitals. Remediated devices are backwards incompatible (e.g., an errors occurs if remediated PCU is connected to non-remediated module). Given the scope and incompatibility constraint, a coordinated and planned approach is required to remediate all pumps.

II. Regional planning

Remediation will take over a year to complete across the LM. To minimize pump shortages and disruption on clinical workflow, each site will be remediated in a blitz format, and sites will be remediated in an intentional, prioritized order dependent on several criteria (e.g., medical device incident prevalence, planned maintenance (PM) status, pump compatibility constraints, and competing site priorities).

Remediation is addressing several alerts and includes PM work; thus, a plan for documenting work in the computerized maintenance management system (CMMS) is required.

III. Site specific planning

To minimize disruption on clinical workflow and ensure success of this project, a local multidisciplinary team is required to develop and execute a site specific project plan. Representatives from biomedical engineering, professional practice, site operations, housekeeping, and BD are required. Key planning items include:

1. Book remediation space.
2. Order remediation parts and spare parts for required repairs.
3. Identify and secure dedicated resources for cleaning and transporting pumps.
4. Book sufficient biomedical engineering resources to manage pump PM and repairs.
5. Develop a communication plan to inform operational leaders and clinical staff of project and required clinical user actions.
6. Develop logistics plan for removing pumps from service (e.g., target clinical areas on specific days).

IV. Lessons leaned

At present, 40% of LM's fleet is remediated. There have been many lessons learned throughout this process including:

1. Clinical buy-in–ensure staff are aware of the project and pump incompatibility. To reach all staff, multiple forms of communication are required (e.g., posters, attendance at bed meetings, memos).
2. Work Space–book remediation space well in advance due to space limitations.
3. Project team responsibilities–define clear roles and expectations for team stakeholders.
4. Identify key unit contacts–to help project team find pumps and swap patients to remediated pumps to free up non-remediated pumps to be upgraded.
5. Project team check-ins–schedule frequent touch-bases to quickly resolve issues that arise on-site.
6. Keep the site appraised–as progress and issues arise send routine updates to operational leaders and ask for help to mitigate issues.
7. Logistics–dedicate team lead to coordinate pump flow between clinical areas and remediation space.
8. Parts–historical CMMS data can provide valuable data for informing repair parts needed for each site. Consider parts for RFID if this technology is used.
9. Pump identification–label remediated pumps (e.g., sticker) as indicator for clinical staff. Ensure high-quality adhesive to withstand cleaning cycles.

V. References

1. ECRI. (2021) BD—Model 8100 Alaris Pump Modules: Fluid Ingress May Cause Keypad to Exhibit Unresponsive or Stuck Keys. A36529
2. ECRI. (2020) BD—Model 8015 Alaris System PC Units: Fluid Ingress May Cause Keypad to Exhibit Unresponsive or Stuck Keys. A35489
3. ECRI. (2020) BD—Model 8110 Alaris Syringe Modules, Model 8120 Alaris PCA Modules, and Syringe/PCA Sizer Sensor Replacement Kits: Excessive Force May Damage Internal Mechanism of Syringe Barrel Clamp. A35494
4. ECRI. (2020) BD—Model 8000 and 8015 Alaris System PC Units: Software May Exhibit Various Problems. A34232