

Niki T34 Incident Investigation Report Summary

1.0 Background

The Niki T34 is an ambulatory syringe driver used primarily in oncology and palliative care departments. There are currently 52 in service in Queensland Health with the first entering service in May 2008. These have been purchased as replacements for the ageing Graseby MS16 and MS26 syringe pumps which are no longer commercially available.

2.0 Incident Description

There were two independent reports that during set up of infusions there was a noticeable discrepancy between the calculated volume of fluid in the syringe and the visible volume indicated by the syringe markings. Erroneous occlusion alarms were also reported. Further concern was raised over the ability to generate infusion duration times other than 24 hours.

3.0 BTS Investigation

Preliminary testing was undertaken by Biomedical Technology Services (BTS) which confirmed the reported incorrect volume detection. Consultation with the Australian supplier, REM Systems, traced this fault to erroneous syringe dimension data stored in the pump which is used in the volume calculation algorithm. Further testing revealed a small potential to induce infusion duration times outside of the set period (nominally 24 hours). All pumps were removed from service and sent to BTS for re-programming. It was also identified that the majority of pumps had occlusion pressure alarm thresholds outside of the specified range.

4.0 Resolution

After re-programming with the correct data sets and re-calibration of the occlusion pressure alarm, performance verification testing confirmed all Niki T34s were operating satisfactorily in accordance with the manufacturer's specification. The volume detection issue was also reported to the Therapeutic Goods Administration (TGA) who subsequently initiated an Australia-wide product correction.

The risk of incorrect or confusing infusion duration times being generated is mitigated by the several user prompts that are displayed prior to the infusion commencing. BTS has recommended that the power should be cycled (turn pump off then on) between each infusion to avoid potential setup errors.

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