



AneticAid

The Theatre Equipment Specialists

Peter J Bedford
Senior Coroner for Berkshire
Yeomanry House
131 Castle Hill
Reading
Berkshire
RG1 7TA

Our Ref: [REDACTED]
Date: 2nd February 2015

Dear Mr Bedford,

Re: JAMES WILSON FYFE decd REGULATION 28 REPORT

With reference to the regulation 28: report to prevent future deaths (1) received on 5th January 2015, please find below our comments as requested in relation to the areas for concern in section (1) of paragraph five.

Design

The QA3 trolley was designed to the relevant standards (including but not limited to BS 5402, BS EN 60601-1 and the relevant particular standards of the BS EN 60601-2 range), leading up to its launch in 1998.

- The side rail (cotside) is counterbalanced so that positive force is required by the end user to fully lower it and this also assists the end user whilst raising it, before it locks into place. This is a specific design feature to ensure that the side rail does not descend in an uncontrolled manner; as we had determined this to be an unacceptable risk.
- Tolerance variations in components, materials, finishes and workmanship – along with wear and tear - may result in variations in performance, but do not affect the locking mechanism.
- The 11,680 QA3's produced to date have an exceptional safety record after 17 years in use, with a conservative estimate of 65,000,000 side rail operations having taken place.

Naturally following the incident at Royal Berkshire Hospital, we have been rigorously examining our design criteria and our user safety records. Based on extensive post market surveillance, we find the design has a 100% safety record in its primary role of retaining the side rail in a raised position when locked – irrespective of levels of maintenance, or variations in performance.

This post market surveillance also indicates positive feedback in regards to the QA3's usability: its primary functions being simple and intuitive. We believe that incorporating additional safety features would have unintended consequences: adversely effecting usability, create additional unacceptable risks, and will not make the mechanism immune from user error.

It should also be noted that the QA3 side rail is not unique in its locking mechanism and the risks associated with side rails are well known (refer to the attached issued in 2004) – therefore the issue is proved to be not solely linked to this device.

Maintenance

Our maintenance schedules are a basic guideline for clients who wish to know what our engineers are inspecting during scheduled service visits by Anetic Aid. They act as a reminder to both parties of the steps to be followed during on-site visits. The full criteria for work carried out during a scheduled maintenance visit – including the side rail mechanism - is part of our on-going training regime for our engineers.

While Anetic Aid annually services 3,700 QA3 trolleys, to date, no feedback has been received – either from end users, or from our engineers - to suggest the performance of the QA3 side rail should be subject to review for retrospective field action.

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Anetic Aid Ltd. is part of the Portsmouth Surgical Holdings Group

Registered offices: Anetic Aid Ltd., Queensway, Guiseley, Leeds, West Yorkshire, LS20 9JE. UK

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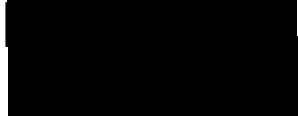
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The incident involved in Mr Fyfe's death remains the only reported incident of this nature and Royal Berkshire Hospital is the only known site where an issue with the side rail performance has been raised as a concern.

We would therefore suggest that the design of the QA3 side rails, their performance and our methods of maintaining them, do not require retrospective change to prevent future deaths, but that our actions should be focused specifically on supporting Royal Berkshire Hospital.

As has been recognised, we have commenced with a programme of QA3 end user training with Royal Berkshire Hospital staff, and this has been on-going since the incident. We will actively continue to support this. Through our communication with the Hospital, we understand a program of safety notices and reminders to staff; highlighting the careful use of side rail, has been undertaken. We would suggest this to be an effective way of addressing what we perceive to be a localised issue.

Yours sincerely



Technical Controller

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