

**[2007][A1595] Not a Black Box: Infusion Devices Are Not Used like Aviation Data Recorders in Accident Analysis**

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**Introduction:** The aviation "Black Box" supports accident investigations in ways that are well represented in subsequent reports (1). Modern infusion devices frequently have event logs that record programming and use information that could be useful to subsequent investigations. The ways the logs are used might speak to their ability to support investigations. We sought to measure the usefulness of device logs for accident investigations by looking at actual accident reports for instances of device use.

**Methods:** We searched the Food and Drug Administration's MAUDE database for device incident investigations for all reports related to one modern infusion device between March 22, 2005 and March 24, 2006. All reviewed reports were for the same generation device. Reports were individually screened for mention of the use of log or device history data, and those reports were reviewed separately. Of particular interest to analysis were data that 1) provide useful clues as to how the incident might have occurred, and 2) data use that is clearly attributable.

**Results:** We found 330 reports submitted between the dates mentioned. Of these, 37 (11.2%) made use of log file data. Several attributive statements were noted. The statement "delivered as programmed" appeared in 18 reports (5.5%). Attributions of operator error, phrased as "result of operator error" or "probable...error" occurred in 12 reports (3.6%). Reports frequently highlighted discrepancies between log data and user reports. Seven reports note a difference between the log clock and actual time at the site of the event. For two incidents, the manufacturer merely asserted that the log data did not correlate with the account of the event, without providing further data. In four cases, the memory buffer of the log had been overwritten because of subsequent use and no data were available for study. Two reports cited discrepancies regarding alarms between the user narrative or manufacturer simulation and the log files. Date discrepancies occurred in two cases.

**Conclusions:** As measured by use in an existing incident reporting database, the device's log file data do not support accident investigations in the same productive way other recorders, such as the aviation "Black Box" do. Examples of log file use suggest problems related to the memory buffer and availability of useful data, as well as investigative use that supports simple attributions rather than detailed analyses of activities. Future investigations into the types of data that would be useful to investigation and productive methods to use the data to improve safety might facilitate more insightful accident analysis.

**References:**

1. <http://freshgasflow.flight401.htm>
2. [www.nts.gov/aviation/cvr\\_fdr.htm](http://www.nts.gov/aviation/cvr_fdr.htm).  
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**Session Info:** Poster Session: PATIENT SAFETY: Drug and Device Safety, Medical Errors and Prevention (9:00 AM-11:00 AM)

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