

March 12, 1999

William J. Lucas, M.D., C.C.F.P.
Office of the Regional Coroner
15 Grosvenor Street
Toronto, Ontario M4Y 1A9
CANADA

Re: Graseby Model 3300 PCA Pump
ECRI Case No. 517-625

Dear Dr. Lucas:

This letter reports our findings in regard to the Graseby Model 3300 patient-controlled analgesic (PCA) pump that you arranged to have shipped from the Hospital for Sick Children in Toronto to ECRI for inspection and testing. We understand that this pump may have been associated with an overinfusion on October 22, 1998. Photographs sent with the pump show the pump mounted on an IV pole above an IVAC general-purpose infusion pump. The incident infusion sets were not retained, and we received no information about the infusion before the incident or about the pump's settings/display at the time of the incident. We were informed by the hospital's patient care equipment service coordinator that the pump was impounded and was not tested at the hospital after the incident.

The pump was received at ECRI on November 3, 1998. There was no evidence of damage from shipping, and we connected the device to line power. Three new infusion sets (Benlan Inc. Med-Rx, Code No. 10-1097, Lot No. 6682) and three Monoject 60 cc syringes (Lot No. 362595) were included with the pump. The pump's serial number is 001873, and the hospital control number is T2739. A tag on the right side of the unit indicates that it was last inspected on October 2, 1998. A permanent label on the pump's control pad states "Use Monoject Syringes Only" and a paper tape label on the syringe cover states "MORPHINE." We have examined and tested the unit, guided by the manufacturer's specifications, our experience in evaluating PCA pumps (see *Health Devices* 1988 May;17[5]:137-67), and our procedure for inspecting infusion devices (see *Health Devices Inspection and Preventive Maintenance System, Procedure/Checklist* 416-0595).

We turned the pump on, and after it successfully executed its self-test, we stepped through the following displays of pump settings and operational history:

- Drug Concentration 1.00 mg/mL
- Loading Dose 0.0 µg (0.0 mL)
- PCA (Bolus) Dose 1.50 mg (1.5 mL)
- Dose Duration STAT
- Lockout Period 6 MINUTES

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- Total Dose Limit 20 mg IN 2 HOURS
- Continuous Infusion 0.0 µg/hr (0.0 mL/hr)
- Totals Since Reset 10.5 mg (10.5 mL)
34 DEMANDS, 7 GOOD
- End of Sequence, Check Syringe, Close Cover and Press Start to Run

We then attached a printer to the pump using an interface cable provided by the hospital. We obtained a five-page record (enclosed) of the pump's operation between 0:05:35 on October 22, 1998—the date of the incident—and 16:30:22 on November 18, 1998, the date that we downloaded this record. In addition to the information obtained from the display, the record provides time/date information for several events. Shortly after midnight on October 22nd, the start key was pressed (0:15:40). The first demand was two minutes later (0:17:47), and the last of six additional "good" demands was at 1:07:49. The record indicates that no further delivery occurred after this time. In summary, seven 1.5 mg boluses of a 1 mg/mL drug should have been delivered over 50 minutes. This represents a total of 10.5 mL and, if the concentration of the drug was truly 1.0 mg/mL, a total of 10.5 mg of drug.

Using a Dynatech Model 404 infusion analyzer, we ran several flow accuracy tests on line and battery power at a continuous flow setting of 10 mL/hr. The results were 1% less than the programmed setting. We also gravimetrically assessed the accuracy of the pump's PCA doses (1.5 mL boluses) by weighing the boluses on a Mettler AE163 electronic balance. The doses were 1% to 2% less than expected. However, these results are well within ECRI's accuracy criterion for PCA pump delivery ($\pm 5\%$). Pump operation was also acceptable on battery power and was unaffected by moderate shaking and jarring against a wooden countertop.

During the course of testing, we verified operation of all sensors and alarms. Audible alarms automatically reset within two minutes after the silence button was pressed.

In summary, our investigation reveals nothing remarkable about the operation of this Graseby 3300 infusion pump. I will call you next week to see if you have any questions about this report before we return the pump to the hospital's patient care equipment service coordinator. We will ship the pump by Federal Express.

Sincerely,



H. Tim Ritter
Senior Project Engineer

HTR/cb
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Enclosure

March 12, 1999

William J. Lucas, M.D., C.C.F.P.
Office of the Regional Coroner
15 Grosvenor Street
Toronto, Ontario M4Y 1A9
CANADA

Re: IVAC Model 560 Infusion Pump
ECRI Case No. 517-626

Dear Dr. Lucas:

This letter reports our findings in regard to the IVAC Model 560 infusion pump that you arranged to have shipped from the Hospital for Sick Children in Toronto to ECRI for inspection and testing. We understand that this pump may have been associated with an overinfusion in October 1998. Photographs sent with the pump show the pump mounted on an IV pole below a Graseby Model 3300 patient-controlled analgesic (PCA) pump. The incident infusion sets were not retained, and we received no information about the infusion before the incident or about the pump's settings/display at the time of the incident. We were informed by the hospital's patient care equipment service coordinator that the pump was impounded and was not tested at the hospital after the incident.

The pump was received at ECRI on November 3, 1998. There was no evidence of damage from shipping and we connected the device to line power. Three new infusion sets (IVAC Model 52063) were included with the pump. The pump's serial number is 56M-36595-212644-8614 and the hospital control number is L1011. A tag on the back of the unit indicates that it was last inspected on July 24, 1998. We have examined and tested the unit, guided by the manufacturer's specifications, our experience in evaluating general-purpose infusion pumps (see *Health Devices* 1997 Feb;26[2]:36-75 and 1998 Apr-May;27[4-5]:151-70), and our procedure for inspecting infusion devices (see *Health Devices Inspection and Preventive Maintenance System, Procedure/Checklist* 416-0595).

We installed a new infusion set primed from a bag of normal saline hanging 30 inches above the pump. When the pump was turned on, it went through a self-test and indicated software rev. 0.19. It displayed a rate setting of 20 mL/hr and a volume infused of 132.9 mL. Using a Dynatech Model 404 infusion analyzer, we ran several flow accuracy tests on line and battery power at 20 (which we assume was the programmed rate at the time of the incident) and 100 mL/hr. The results were 3% to 5% less than the programmed flow setting. ECRI's flow accuracy criterion for general-purpose infusion pumps is $\pm 5\%$, and in our experience, the flow accuracy of this pump model is typically within 5% of flow settings under 200 mL/hr. Pump operation was unaffected by moderate shaking and jarring against a wooden countertop.

We then programmed the pump for 20 mL/hr with the infusion set directed into a 2 L canister graduated in mL. With the volume limit programmed for 400 mL, we operated the pump in this fashion for 20 hours. At the end of the test, approximately 400 mL had been pumped into the canister (the product of 20 mL/hr \times 20 hr is 400 mL), the pump audibly alarmed, and the Volume Infused display indicated that 400 mL had been infused.

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We observed the pump revert to a keep-the-vein-open (KVO) setting when the programmed volume limit was completely delivered. We verified the mechanical integrity of the flow stop; the stop pinches closed when the pump door is opened, and no fluid flowed from the tubing set as long as it remained installed in the pumping mechanism.

During the course of testing, we verified operation of all sensors and alarms. The pump detected and alarmed for upstream and downstream occlusions within a reasonable time. Audible alarms automatically reset approximately two minutes after the silence button was pressed.

In summary, our investigation reveals nothing remarkable about the operation of this IVAC 560 infusion pump. I will call you next week to see if you have any questions about this report before we return the pump to the hospital's patient care equipment service coordinator. We will ship the pump by Federal Express.

Sincerely,



H. Tim Ritter
Senior Project Engineer

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