Prolonged time to alarm in infusion devices operated at low flow rates

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Objective: To evaluate the time to occlusion alarm for peristaltic infusion devices used in Toronto adult critical care units.

Design: Cross-sectional study.

Setting: Biomedical engineering departments of four Toronto teaching hospitals.

Subjects: Twenty peristaltic infusion devices (five Sigma 8000-plus, five Graseby 3000, five Baxter Colleague, and five Alaris 7230B).

Interventions: None.

Measurements: Time to occlusion alarm at flow rates of 2, 10, and 100 mL/hr at a full range of available pressure thresholds for occlusion detection, and with commonly used tubing sets.

Main Results: At default (mid-range) pressure thresholds, mean (sd) time to occlusion alarm was 0.3 (0.1) min at a flow rate of 100 mL/hr, 2.3 (0.5) min at a flow rate of 10 mL/hr, and 11.7 (3.1) min at a flow rate of 2 mL/hr.

Conclusions: Time to occlusion alarm in peristaltic infusion devices is long at low flow rates. Patients receiving important medications with short half-lives at low flow rates could experience clinically important interruptions in treatment. Time to occlusion alarm at high flow rates is short, which could lead to excessive alarms and "alarm mistrust" by clinical staff. (Crit Care Med 2008; 36:2763–2765)

KEY WORDS: infusion pumps; equipment alarm systems; safety; critical care

Intravenous infusion pumps are designed to alarm when flow is interrupted. The time-to-alarm is the time from flow interruption to alarm activation. The time-to-alarm is primarily dependent upon the infusion device's pressure threshold for triggering an alarm, the tubing's elasticity and length, and the flow rate (1, 2). The time-to-alarm will lengthen if the pressure threshold is raised, if the tubing's elasticity or length is increased, or if the flow rate is decreased.

The time-to-alarm should ideally be short when patients are receiving important medications with short half-lives,

such as vasoactive medications. However, many of these medications are administered at low flow rates, where the time-to-alarm may be longer.

Alarms resulting from short-lasting interruptions in infusions of noncritical medications could be regarded as false alarms, and when repeated, they can result in certain operator responses, such as switching the alarms off (3). If the false alarm rate is high, then clinicians will tend to reduce their response to alarms accordingly (4, 5).

We found reports only about measurements of time-to-alarm in syringe pumps

(1, 6–9), while all adult critical care units at University of Toronto centers use peristaltic infusion devices. Therefore, we set out to evaluate the time-to-alarm for the peristaltic infusion devices used in our critical care units in a laboratory setting at various flow rates and pressure thresholds.

MATERIALS AND METHODS

We measured the time-to-alarm in four peristaltic infusion device models used by nine adult critical care units in five University of Toronto teaching hospitals (Table 1). Biomedical engineering technicians selected convenience samples of five individual devices of each model in use at each study site. All devices were in proper working order based on routine quality assurance assessments.

Technicians set up a fresh tubing set (with the standard tubing in use at each center; Table 1), primed it with a normal saline solution and ran the first device at 2 mL/hr into a dead end occlusion pressure sensor. We recorded time to occlusion alarm at each occlusion pressure setting, starting with the lowest and releasing the pressure after each run. We repeated the protocol for flow rates of 10 mL/hr and 100 mL/hr in this order. Technicians then loaded fresh tubing sets and repeated the same protocol for the other four devices of each model.

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Table 1. Characteristics of infusion devices tested for time-to-alarm

Device Model	Tubing Set	Pressure Thresholds (PSI)		
		Low/Minimum	Default ^a /Moderate	High/Maximum
Sigma 8000-plus (Sigma, Medina, NY)	Lifeshield primary IV set # 11961-68	2	10	15
Graseby 3000 (Smiths Medical, Watford, Herts, United Kingdom)	Administration set # 8C4220	2	5	10
Baxter colleague (Baxter, Deerfield, IL)	Baxter infusion set # JC6386	2	5	9
Alaris 7230B (Alaris Medical Systems, San Diego, CA)	Alaris infusion set # 4091066	—	8	12

PSI, pound per square inch; IV, intravenous.

^aThe default setting is the usual pressure threshold in the institution, and the default value set by the manufacturer.

Results are reported as mean and SD. The time-to-alarm had a right-skewed distribution; we therefore applied a logarithmic transformation. We fitted an analysis of variance model to look for association between the time-to-alarm and pump brands, pressure thresholds, and flow rates. The model contained the main effects—brand, pressure threshold, and flow rate—and all the two-way and three-way interactions, and adjusted for potential correlation between repeated measures of time-to-alarm on the same pump. Because the three-way interaction was significant, a separate model was fitted for each brand. The interaction between flow rate and pressure threshold was significant for all models except the Alaris, for which a model with main effects only was fitted. To compare differences in time-to-alarm among different brands for the same flow rates and pressure thresholds; between different flow rates for the same brands and pressure thresholds; and between different pressure thresholds for the same brands and flow rates, we performed a posthoc, pair-wise, multiple comparison using Bonferroni-Holm adjustment. We used a two-tailed α of <0.05 as the threshold for statistical significance. Statistical analyses were performed using SAS (version 9.1.2; SAS Institute Inc., Cary, NC).

RESULTS

Characteristics of studied infusion devices are presented in Table 1. Tubing sets are those used by participating institutions. Three of the tested infusion devices had a selection of three pressure thresholds for occlusion detection; one model (Alaris 7230B) had two.

We obtained a total of 165 measurements of time to occlusion alarm at various pressure thresholds and flow rates in the four device models (Tables 2–4). Across all devices at default (mid-range) pressure thresholds, the mean (SD) time

Table 2. Time to occlusion alarm in peristaltic infusion devices (flow rate = 2 mL/hr)

Device Model (n = 5)	Time to Occlusion Alarm, Minutes; Mean (SD)			
	Sigma 8000-Plus	Graseby 3000	Baxter Colleague	Alaris 7230B
Pressure threshold				
Low/minimum (PSI)	2 2.6 (0.6)	2 6.7 (2.3)	2 4.8 (0.5)	—
Default/moderate (PSI)	10 13.1 (1.6)	5 12.8 (4.4)	5 10.6 (3.6)	8 10.3 (1.4)
High/maximum (PSI)	15 17.7 (1.8)	10 34.5 (1.8)	9 22.9 (2.9)	12 16.3 (1.6)

PSI, pound per square inch.

Table 3. Time to occlusion alarm in peristaltic infusion devices (flow rate = 10 mL/hr)

Device Model (n = 5)	Time to Occlusion Alarm, Minutes; Mean (SD)			
	Sigma 8000-Plus	Graseby 3000	Baxter Colleague	Alaris 7230B
Pressure threshold				
Low/minimum (PSI)	2 0.5 (0.1)	2 0.7 (0.5)	2 0.7 (0.2)	—
Default/moderate (PSI)	10 2.2 (0.3)	5 2.9 (0.5)	5 2.0 (0.5)	8 2.2 (0.2)
High/maximum (PSI)	15 3.1 (0.2)	10 5.7 (0.8)	9 3.4 (0.9)	12 3.15 (0.5)

PSI, pound per square inch.

to occlusion alarm was 0.3 (0.1) min at a flow rate of 100 mL/hr, 2.3 (0.5) min at a flow rate of 10 mL/hr, and 11.7 (3.1) min at a flow rate of 2 mL/hr.

At $\alpha = 0.05$, there were statistically significant differences in time-to-alarm among different brands at the same flow rate and pressure threshold settings. The greatest difference between two brands was observed at a flow rate of 2 mL/hr and at the maximal pressure threshold settings. The time-to-alarm at these settings was 16.3 (1.6) min for the Alaris and 34.5 (1.8) min for the

Graseby, a difference of about 18 min (Table 2).

Differences in time-to-alarm among the three studied flow rates for the same brands and at the same pressure thresholds were all statistically significant at $\alpha = 0.05$. For example, the Sigma's time-to-alarm at the default pressure threshold was 13.1 (1.6) min at a flow rate of 2 mL/hr; 2.2 (0.3) min at 10 mL/hr; and 0.2 (0.0) min at 100 mL/hr (Tables 2–4).

Differences in time-to-alarm among available pressure thresholds for the same brands and at the same flow rates

Table 4. Time to occlusion alarm in peristaltic infusion devices (flow rate = 100 mL/hr)

Device Model (n = 5)	Time to Occlusion Alarm, Minutes; Mean (SD)			
	Sigma 8000-Plus	Graseby 3000	Baxter Colleague	Alaris 7230B
Pressure threshold				
Low/minimum (PSI)	2 0.04 (0.05)	2 0.16 (0.01)	4 0.17 (0.01)	—
Default/moderate (PSI)	10 0.2 (0.0)	5 0.45 (0.05)	8 0.34 (0.05)	8 0.19 (0.01)
High/maximum (PSI)	15 0.26 (0.05)	10 0.74 (0.06)	12 0.43 (0.07)	12 0.28 (0.03)

PSI, pound per square inch.

were all statistically significant at $\alpha = 0.05$, with the exception of Baxter Colleague at 100 mL/hr between default and high pressure threshold. For example, the Graseby's time-to-alarm at 10 mL/hr was 5.7 (0.8) min at the high pressure threshold, 2.9 (0.5) min at the moderate pressure threshold, and 0.7 (0.5) min at the low pressure threshold (Table 3).

DISCUSSION

We found that 1) the time-to-alarm is lengthy (>10 min) at low flow rates (2 mL/hr); 2) the time-to-alarm is short (<30 sec) at high flow rates (100 mL/hr); and 3) there are differences in time-to-alarm among infusion device models.

Our results have immediate clinical implications in the critical care unit. The first concerning finding is that the time-to-alarm is long when the flow rate is low. This represents a potential safety concern for critically ill patients who are receiving important medications with short half-lives at low flow rates, such as vasoactive drugs, sedatives, and insulin. For example, an infusion of 10 μ g/min of norepinephrine mixed as 16 mg in 250 mL (a standard concentration in our intensive care unit) requires a flow rate of about 10 mL/hr. On default pressure threshold settings, the time-to-alarm for studied pumps would be 2.0–2.9 min (Table 3). Such a long interruption could cause blood drug levels to fall and result in consequences to the patient.

The second concern is that at high flow rates, alarms will sound quickly. If these alarms signify clinically unimportant events, such as a transient occlusion of a maintenance saline infusion, then busy clinicians may gradually develop "alarm mistrust." Alarm mistrust leads to delayed responses to future alarms, some of which may be "true alarms" (5, 10).

Finally, we found that the time-to-alarm at similar infusion settings differed among different pump models. The largest difference (18.2 min) was measured at a flow rate of 2 mL/hr and at maximal pressure thresholds. Clinicians may not expect such variability in infusion device performance.

Our study is the first report of the time-to-alarm in peristaltic infusion devices.

Health Canada recently issued an alert to healthcare professionals regarding delayed occlusion detection in syringe infusion pumps (11). Observations in syringe pumps have demonstrated time-to-alarm between 10 and 30 min at flow rates of 3–5 mL/hr, and shorter delays in higher flow rates (1, 6, 7, 9).

Our study has some important limitations. First, tubing compliance can change with repeated use, which is termed hysteresis (2). We minimized the impact of hysteresis by using fresh tubing sets for each tested pump; and by using the lowest pressure thresholds first. Future studies should evaluate the effect of hysteresis on time to alarm by varying the order of infusion characteristics. In clinical practice, the time-to-alarm would become longer as intravenous tubing becomes more compliant. Another limitation is that we studied a limited number of flow rates; the time-to-alarm at other flow rates needs to be defined. Future studies should evaluate actual infusion practices, such as flow rates, medication types, and tubing lengths, in the critical care unit setting. Such studies will help to characterize the potential clinical impact of prolonged time-to-alarm. Subsequent studies could focus on the development and evaluation of safe methods for adapting the time-to-alarm to suit the clinical needs of the patient and the characteristics of particular infusions.

CONCLUSION

Peristaltic infusion devices have a prolonged time-to-alarm at low flow rates. Clinicians should be aware of this limitation in infusion devices' design, particularly when administering important medications with short half-lives at low flow rates. Infusion devices may also alarm very quickly at high flow rates, leading to frequent alarms in low severity settings, and contributing to alarm mistrust. Variability in time-to-alarm may exist among different infusion devices and be influenced by tubing characteristics and infusion settings. Studies of actual infusion practices are needed to better inform clinically appropriate alarm thresholds.

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