OCCLUSION LIMIT PRESSURE SETTINGS: *RETHINKING THE DEFAULTS*

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INTRODUCTION

Volumetric infusion pumps are one of the most ubiquitous medical devices used in hospitals. Pumps provide therapy across a full spectrum of patient populations (pediatrics, adult, geriatric, etc) for the delivery of fluids, blood, medication or nutritional fluids intravenously. Despite being a 'simple technology' the risks of using a volumetric infusion pump should not be downplayed or ignored.

Unnoticed and/or unreported intravenous (IV) infusion complications as well as delays or cessations in therapy can have real impacts on patient safety. The primary safety risks that can occur during IV therapy are infiltration and extravasation. Infiltration is defined by the Intravenous Nurse Society as the `inadvertent administration of a non-vesicant solution into surrounding tissue`; and Extravasation as the `inadvertent administration of a vesicant solution into surrounding tissue` [2]. Vesicants are solutions capable of causing tissue injury or destruction if they escape into surrounding tissue [3].

In addition, problems with the infusion site such as a misplaced needle, patient movement, or aspiration caused by the pump's peristaltic effect can collapse or damage the vein. This problem can also increase the risk of leakage from the vein [5], and leakage can lead to extravasations resulting in tissue necrosis, skin loss, scarring around nerves or compartment syndrome [6].

Gault et al. showed that 5 % of adult patients receiving cytotoxic injections experience infiltration injuries. The same study suggests that the incidence of infiltration in children is even higher at 11 % to 58 % of patients [7]. Extravasations are frequent in NICU, occurring in 28% of patients, and may in part be due to the nature of the smaller bore catheters and the fragility of pediatric veins [8].

In part, this can be avoided by appropriately setting the occlusion limit on the infusion device, so that when an occlusion occurs the time to alarm is reduced and clinical intervention is hastened, thereby lowering the risk to patients.

BACKGROUND

The working pressure delivered by the pump overcomes the circuit resistance to deliver fluid to the IV site. The Alaris Signature pumps detect in-the-line occlusion using a pressure sensor distal to the pumping mechanism. The pressure sensor can be set by the user to a threshold value called the *occlusion limit*. The time between the occurrence of an occlusion and the alarm condition depends primarily on the occlusion limit setting and the flow rate [1].

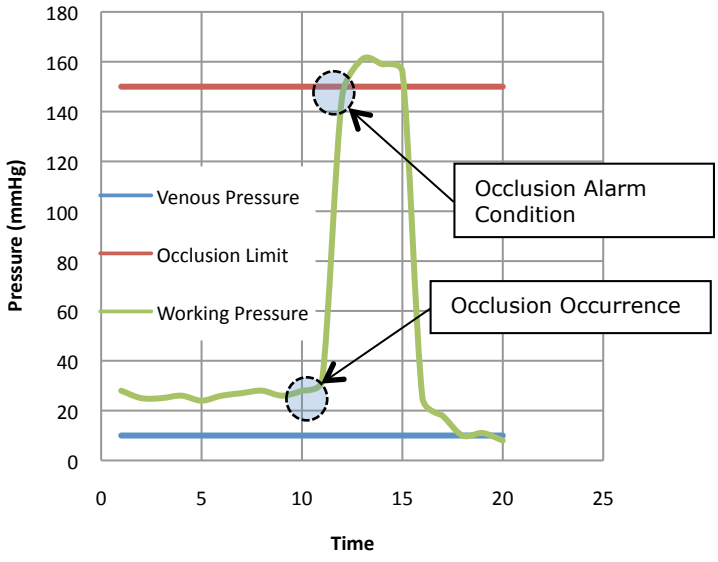

Figure 1: Pump Occlusion Alarm Pictorial

Downstream occlusions in the IV line can be triggered by technical faults such as a closed roller clamp, a kinked line, or a ruptured catheter, or by physiological faults such as a thrombus or phlebitis. An occlusion can cause either a delay or cessation of therapy for the patient that can lead to patient injury, particularly for the patient requiring short half-life medications such as vasoactive drugs, insulin or sedatives [1].

Literature recommending *occlusion limit* settings is scarce. The manufacturer's default *occlusion limit* setting is 600 mmHg for the Alaris Signature pump. Pump manufacturers do not recommend occlusion limits specific to their device claiming it is a clinical practice issue. This leaves biomedical engineering (BME) and clinical staff having to define acceptable occlusion limit(s) that address the needs of patient safety for venous access.

St. Paul's Hospital BME traditionally used three legacy default settings based on area: General 225mmHg, Parenteral Nutrition 600mmHg, and Renal 300mmHg, without documentation and evidence to support the decision.

The purpose of this study was to re-evaluate the historic occlusion limit settings and assess the technology to better understand the relationship between the *working pressure* and the *occlusion limit* settings for three common catheters: Peripheral Intravenous (PIV), PIV Neonatal Intensive Care Unit (PIV_{NICU}) and Peripherally Inserted Central Catheter (PICC). Flow rates were varied to determine the *time to alarm* to provide greater awareness and understanding of the appropriate occlusion limit setting.

Keywords: working pressure, occlusion limit, time to alarm, infiltration, extravasation

MATERIALS AND METHODS

This study was performed using the Alaris Signature (*Carefusion Corporation, San Diego, CA, USA*) volumetric infusion pump.

A Fluke IDA4+ flow tester (*Fluke Corporation, Everett, WA, USA*) was used to perform these trials.

All pressure data was obtained with a manometer and data acquisition software (Manometer 407910 and software 407001, Extech Instruments Corporation, Waltham, MA, USA). All equipment was calibrated to manufacturer or factory specifications prior to the trials.

Table 1: Alaris Signature Infusion Pump

Characteristic	Value
Model Number	7230
Software Revision	v2.79
Fluid Delivery Rate	1.0-999.9 mL/h
Occlusion Limit Setting	25-600 mmHg

Trials were performed at standard temperature and pressure (STP) conditions. Set combinations were replaced for each trial to eliminate compliance bias with repetitive trials. Saline was used as the working fluid.

All infusion sets, extensions and connectors were Carefusion, PIV catheters were Jelco and PICC catheters were Groshong.

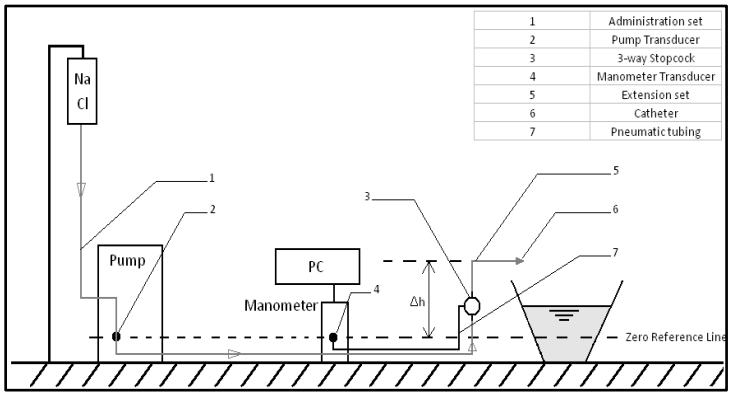

Figure 2: Schematic of the test apparatus

The infusion rate and *occlusion limit* was set and controlled by the pump for each trial. The manometer measured the *working pressure* during steady state operation and the pressure at the catheter during an occlusion alarm. The time to alarm was determined by trends provided by the acquisition software.

Pump flow was considered to be in steady state condition when the measured flow rate matched the programmed flow rate ±5% range for 60 seconds. Flow rates ≥25 mL/h achieved steady state after 4 minutes whereas flow rates of 10 mL/h required 6 minutes.

Venous backpressure was simulated by changing the Δh of the catheter tip from the zero reference line (see Table 2).

Table 2: Venous Backpressure Simulation

	PVP Adult	PVP Neonate	CVP Adult
Reference	11mmHg [9]	14 mmHg [10]	9 mmHg [9]
Δh	15 cm	19 cm	12 cm
Note: Backpressure verified before and after trial.			

All trials performed were below the current St. Paul's setting of 225mmHg and with flow rates below 600mL/h (see Table 3). Trials with flow rates 10-100 mL/h and >100 mmHg for were not performed because the time to alarm was considered clinically unacceptable. Trials <100mmHg were not performed because the working pressures for the concerned flow rates were considered to be too close to the occlusion pressure which would trigger false positive alarm situations.

Table 3: Trial "window" based on operating parameters.

	Flow rate (mL/h)							
Occlusion limit (mmHg)	**10**	**25**	**50**	**100**	**200**	**300**	**500**	**600**
25	T3	T3	T3	T3				
50	T2	T2	T2	T2	T2	T2		
100	T1	T1	T1	T1	T1	T1	T1	T1
150					T2	T2	T2	T2
200					T3	T3	T3	T3

RESULTS

The results of the trials are summarized in Figure 3.

Figure 3 shows that flow rate has the greatest effect on occlusion characteristics. 3 distinct flow rate groups emerged from the trials. a) Very low flow rates (10, 25 mL/h), b) Low

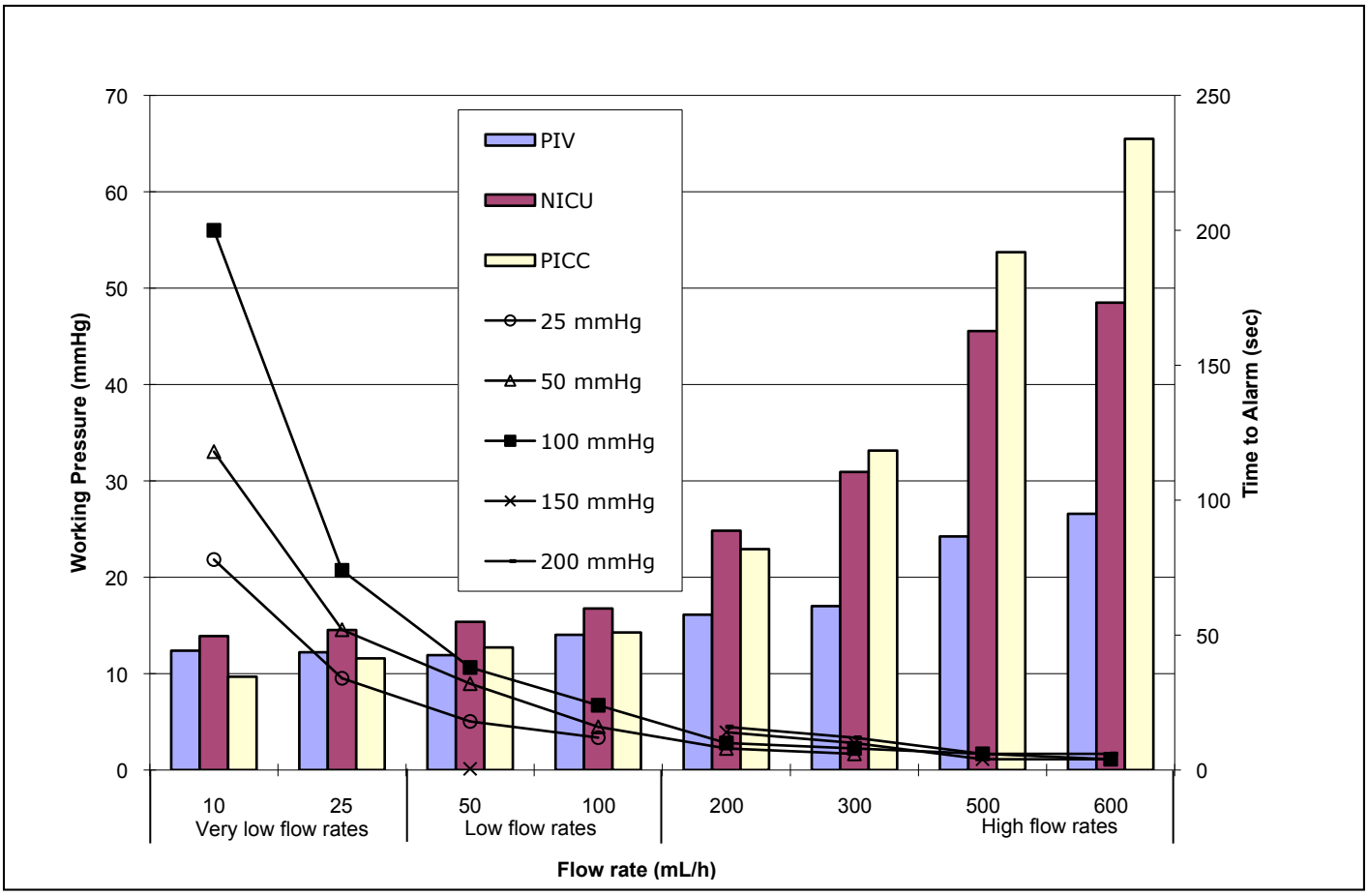

Figure 3: Working Pressure and Time to Alarm with respect to Flow Rate

For high flow rates the working pressure increased as the flow rate increased for trials >100mL/h. Specifically, smaller bore catheters (PICC & PIV_{NICU}) have higher intrinsic resistances and tend to have a more pronounced increase in working pressure with an increase in flow rate.

The working pressure and the time to alarm have an inverse relationship. It was found that all flow rates above 50mL/h yielded an acceptable time to alarm of less than 60 seconds. However, very low flow rates have exceptionally higher time to alarms even with low occlusion settings. This area of the flow rate spectrum requires the most vigilance and consideration in pediatric populations.

Previously unknown working pressure values were determined for catheters at flow rates of 10mL/hr & 600mL/hr respectively: PIV (12.4 & 26.6mmHg), PIV_{NICU} (13.9 & 48.5mmHg), and PICC (9.7 & 65.5mmHg).

DISCUSSION

There are many 'degrees of freedom' that influence the time between the occurrence of an occlusion and its detection at the pump and therefore make it difficult to determine a single static default occlusion limit. These variables include: the patient's venous pressure, in-line filters, the flow rate, the viscosity of the fluid and the resistance of the tubing and IV catheter used.

Static occlusion limit defaults should be selected as close as possible to the working pressure for two reasons: 1) To reduce the time associated with the delay of therapy, and 2) to detect occlusions early, thereby reducing infiltration and extravasation risk without introducing false positive alarms. One paper suggested that Adult alarm settings should be 150 mmHg above the working pressure, suggesting that a default setting of 300 mmHg is adequate, whereas neonatal defaults should be significantly lower at 100 mm Hg [11]. Other studies have recommended an occlusion limit depending on flow rate of 200 mmHg/L/h [4].

The occlusion limit default on the Alaris pumps can be overridden at the bedside by clinicians. This built-in tool allows the user to display the working pressure and the occlusion limit on the same bar graph and make "on the fly" adjustments. Clinicians should be trained to use this to ensure a "tailored fit" occlusion limit for the patient (See Figure 4).

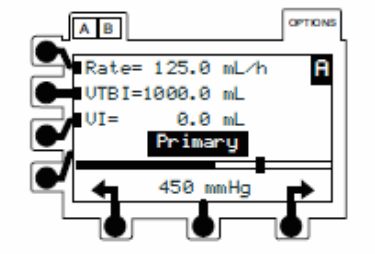

Figure 4: Alaris Signature built-in working pressure tool

Current infusion pumps do not automatically adjust to accommodate these 'degrees of freedom' and the challenge for pump manufacturers is to design a system that both considers and trends the dynamics of the circuit. Smart pumps have the ability to store medications; perhaps they should also store fluid viscosity, IV access and the flow rate for each fluid in memory. One or more occlusion limit(s) could be set for each drug as a function of these parameters.

CONCLUSIONS

Occlusion limits with high alarm thresholds may contribute to unnoticed and therefore unreported patient harm. BME and clinical staff need to rethink the defaults to determine suitable occlusion limits appropriate for their facility. A reduced time to alarm can be achieved by lowering the manufacturer's default occlusion limit of 600mmHg. Knowledge of the *working pressure* can make selection of a revised *occlusion limit* easier. This study has shown that the *occlusion limit* of 225 mmHg currently used at St Paul's Hospital is safe but could still be further reduced.

ACKNOWLEDGEMENTS

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