Effect of Dose Error Reduction Software on the Ability of Nurses to Safely and Efficiently Administer Intravenous Medications

by

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A thesis submitted in conformity with the requirements for the degree of Masters of Health Science in Clinical Biomedical Engineering
Institute of Biomaterials and Biomedical Engineering
University of Toronto

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Abstract

The purpose of this research was to compare the design of Dose Error Reduction Software (DERS) between smart pumps to determine which features affect the ability of nurses to safely and efficiently program intravenous medications. A high-fidelity usability experiment was conducted. Twenty-four Registered Nurses completed a series of infusion tasks, in a simulated clinical environment, using three smart pumps (Cardinal Alaris System, BBraun Infusomat, and Hospira Symbiq). Results found significant differences in nursing performance across the smart pumps. Nurses were more likely to override clinically inappropriate soft limit alerts when using BBraun Infusomat, than when using Hospira Symbiq or Cardinal Alaris System. Furthermore, when asked to program an infusion over a specific duration, nurses were found to make significantly more parameter entry errors when using Hospira Symbiq than when using Cardinal Alaris System. Results from this study will help set DERS design principles, and assist hospitals during their procurement processes.
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A List of Abbreviations

**AHRQ**: Agency for Healthcare Research and Quality

**BCMA**: Bar Code Medication Administration

**CCA**: Critical Care Area

**CPOE**: Computer Physician Order Entry

**CVICU**: Cardiovascular Intensive Care Unit

**DERS**: Dose Error Reduction Software

**ECRI**: Emergency Care Research Institute

**EMR**: Electronic Medical Record

**ISMP**: Institute of Safe Medication Practices

**ICU**: Intensive Care Unit

**IV**: Intravenous

**GIM**: General Internal Medicine

**JCAHO**: Joint Commission on Accreditation of Healthcare Organizations

**MAR**: Medication Administration Record

**MoHLTC**: Ministry of Health and Long-Term Care

**PACU**: Post-Anaesthesia Care Unit

**PIS**: Pharmacy Information System

**TGH**: Toronto General Hospital

**UHN**: University Health Network

**VTBI**: Volume To Be Infused

**VBT**: Vendor Based Training
A List of Definitions

Rate: Volume of drug that is administered over time (mL/hr)

Dose: Quantity of drug (mg)

Dose-Rate: Quantity of drug that is administered over time (mg/hr)

Continuous Infusion: A therapy given at a continuous rate or dose-rate

Intermittent Infusion: A therapy given over a certain period of time

Intravenous Therapy: The process of administering a liquid directly into the vein

High-Alert Medications: Medications that if used inappropriately can cause significant harm to the patient

Tall Man Lettering: Upper case lettering used in medication names to help users differentiate between look-a-like and sound-a-like medications

Soft key button: performs the function that is displayed on the screen

Hard key button: performs one function and is not dependent on what is displayed on the screen
1. INTRODUCTION

The administration of medications intravenously is an important part of the management of patients in hospitals. Due to the frequency of high-risk-of-harm medications given intravenously and the rapid onset of infusion medications, medication errors that occur in this method of therapy have great potential for patient harm (Hicks & Becker, 2006; Institute of Medicine, 2000). In an attempt to reduce medication errors at the administration stage, manufacturers have introduced smart pumps with medication safety software referred to as Dose Error Reduction Software (DERS). This software allows hospitals to customize a library of drugs, concentrations, dosing units, and dosing limits to meet the needs of specific user groups or clinical care areas. When a nurse programs in the DERS, the software checks to make sure the dosage values are in dosage range before the infusion is started. If the dosage value is outside of the dosage limits, the software will warn the nurse of the discrepancy.

Many healthcare facilities and researchers feel that smart pump technology has not lived up to expectations (Cassano, 2006; Rothschild et al. 2005; Nucklos et al. 2008). Most hospitals have chosen to implement smart pumps as a stand-alone system instead of integrating smart pumps with other clinical information systems. This decision severely limits the ability of smart pumps to intercept medication errors because only dose errors can be detected, omitting wrong patient, drug name, duration, and route errors. Furthermore, smart pumps may also add to the overall demands of the drug administration because of the increase in complexity of the software. This may cause nurses to make new types of errors (such as selecting the wrong drug or concentration), and develop unsafe workarounds (such as bypassing safety features) that did not occur when using traditional infusion pumps.

Given that medication administration is a high-risk activity, there is a need to understand how the design of the DERS affects the ability of nurses to safely and efficiently administer IV medications. Previous work in this area has focused on individual case studies (such as analyzing the pump selected by their hospital). Although this can provide valuable information, there is a lack of comparative evidence regarding the impact of pump design between commercially available smart pumps on IV medication administration. Therefore, research is needed to quantify and compare the impact of DERS design on nursing performance.

The purpose of this research is to compare the design of DERS between commercially available smart pumps to determine which features enhance or compromise the ability of nurses to safely and efficiently administer IV medications. Specifically, the aim of this research is to answer the following hypotheses:
1. It is hypothesized that the ability of nurses to safely (defined as the ability to detect and recover from written and/or programming errors), and efficiently (defined as the ability to quickly and successfully navigate through the software) program an IV medication will differ across smart pump models because of differences in key design elements in the Dose Error Reduction Software.

2. It is hypothesized that a high-fidelity simulated experimental environment with tight controls over training, common infusion tasks, and interactions between the experimental team and nurse, will enable differences in Dose Error Reduction Software design and performance to be delineated.

It should be noted that the experimental design hypothesis (hypothesis #2) was included because this is one of the first studies to use this experimental approach to examine the effect of Dose Error Reduction Software on nursing performance.

A high fidelity usability test was conducted to examine how the design of the DERS between three commercially available smart pump models affected nursing performance. It is expected that results from this study will help set design principles so manufacturers can minimize hazards associated with their use and assist hospitals during procurement of this technology.

1.2 Chapter Roadmap

Chapter 2 is a survey of the literature in the areas of intravenous medication errors, infusion pump technology, and human factors initiatives used to improve IV infusion safety. This chapter examines the impact of smart pump technology on nursing workflow, specifically how the design of the DERS affects nursing workflow in terms of safety and efficiency. Human factors methods that have been used to improve IV infusion safety are also discussed. Chapter 3 describes the experiment design, experiment protocol, data collection methods, and data analysis methods. Chapter 4 presents the results of the experiment. Chapter 5 is a discussion of the experiment findings. Specifically, this chapter discusses design elements in DERS that were found to affect nursing performance, nursing perception after using the smart pump models, limitations of the study, and relevance to the field. Chapter 6 is a summary of the key findings that should be considered by hospitals in their procurement process and manufacturers when designing the next generation of their smart pump models.
2. BACKGROUND

2.1 MEDICATION ERRORS AND IV INFUSION TECHNOLOGY

2.1.1 Medication Errors in the Medication Delivery System

The occurrence of medical errors in our health care system has raised many alarms. In 2000, a landmark report published by Institute of Medicine (IOM), entitled “To Error Is Human: Building A Safer Health System” catapulted the occurrence of medical errors to the forefront, grabbing the attention of health care professionals, the public, and political leaders. In the release of this report, the state of patient safety in the medication delivery system was realized, but more importantly acknowledged. IOM found that as many as 98,000 hospitalized patients die annually from medical errors that could have been prevented. Alarmingly, this estimate only represented patients who died in hospitals and only for deaths where a medication error was documented. Based on this seemingly low estimate, deaths from preventable medical errors is the eighth leading cause of death in the USA, exceeding deaths caused from motor vehicle accidents, breast cancer, and AIDS (Institute of Medicine, 2000).

Medication errors are one of the most common types of medical errors. The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) defines a medication error as:

A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use (NCCMERP, 1998).

In 2007, IOM estimated that over 1.5 million patients per year were injured by a medication error, and patients were at risk for at least one medication error a day while being cared for in a hospital (Institute of Medicine, 2007). Bates, Boyle, Vander Vliet, Schneider, and Leape (1995) found that the rate of injuries resulting from drug-related medical errors was 6.5 per 100 non-obstetrical admissions. Furthermore, of the serious and life threatening injuries, 42% could have been prevented (Bates et al., 1995).

As shown in Table 1, medication errors occur at all stages in the medication delivery system. The medication delivery system can be broken down into four phases: (1) prescribing, (2) transcribing, (3)
dispensing, and (4) administering. The occurrence of medication errors varies between the phases, with the prescribing and administering phases having the highest rate of medication errors. The impact of medication errors on patients also depends on the stage of the medication process in which the error occurs. If an error occurs in the initial phases of the medication delivery system, there is a greater chance that the error will be intercepted by other health care professionals in later phases before reaching the patient. However, if an error occurs at the final stage of the medication delivery process, there may be no chance of recovering from the error. As shown in Table 1, more than half the total errors resulting in harm occur at the final stage in the medication delivery system.

Table 1: Medication errors in the medication delivery system (Leape, Bates, Cullen, Cooper, Demonaco, Gallivan, et al., 1995)

<table>
<thead>
<tr>
<th></th>
<th>Prescribing</th>
<th>Transcribing</th>
<th>Dispensing</th>
<th>Administering</th>
</tr>
</thead>
<tbody>
<tr>
<td>% of Errors Occurring</td>
<td>39%</td>
<td>12%</td>
<td>11%</td>
<td>38%</td>
</tr>
<tr>
<td>% of Errors Resulting in Harm</td>
<td>28%</td>
<td>11%</td>
<td>10%</td>
<td>51%</td>
</tr>
<tr>
<td>% of Errors Intercepted</td>
<td>48%</td>
<td>33%</td>
<td>34%</td>
<td>2%</td>
</tr>
</tbody>
</table>

2.1.3 IV Medication Errors

The administration of medications intravenously (IV) is an important part in the management of patients. Due to the frequency of high-risk-of-harm medications given intravenously, and the rapid onset of infusion medications, medication errors that occur in this therapy method have great potential to cause patient harm (Hicks & Becker, 2006). As Thurman, Sullivan, Williams, and Gaffney (2004) phrased it, “Whereas it is unlikely that a clinician would give 100 tablets to a single patient as a dose, the same clinician could inadvertently give 100-fold overdose of an IV medication by not recognizing the miscalculated dose” (Thurman et al., 2004).

The occurrence of IV medication errors is well documented in the literature. A study completed by Kaushal, Bates, & Landrigan (2001) found that 54% of potential adverse drug events (ADEs) were associated with IV medications. Similarly, Bates, Vanderveen, Seger, Yamaga, & Rothschild (2005) found that 61% of serious potential ADEs involved IV medications. Furthermore, a study completed in two United Kingdom hospitals found that in 49% of infusions, one or more errors were made in the preparation and/or administration phases (Taxis & Barber, 2003). Husch, Sullivan, Rooney, Barnard, Fotis, Clarke, & Noskin (2005) also reported similar findings, citing that 66.9% of infusions had one or more errors associated with their administration.
2.1.4 Evolution of IV Infusion Safety and the Introduction of Smart Infusion Pumps

In the 1960s, advancements in vascular access technology, and the introduction of IV infusion sets with volumetric chambers allowed infusion therapy to become a more common practice in hospitals (Lindley & Deloatch, 1993). As the use of infusion therapies rose, problems began to surface regarding the safety and accuracy of infusion therapies. Infusion therapies at this time were delivered by gravity, and regulated by manually adjusted clamps on the IV tubing. Using this technique, the following issues arose when attempting to maintain an accurate flow rate:

(a) The clamps required constant monitoring because any change in the location of the clamp or pressure exerted on the tubing would change the flow rate and,

(b) There was no mechanism to monitor changes in backpressure when the patient changed their position or activity level (Lindley & Deloatch, 1993).

As the complexity of medications increased, it became even more important to maintain an accurate flow rate due to the potency of the medications used.

IV infusion pump technology continued to evolve because of the increase in demand for more sophisticated systems, and advancements in new technologies and polymer materials (Lindley & Deloatch, 1993). Infusion Control Devices (ICDs) were introduced. There were two classifications of ICDs, controllers and positive pressure pumps. Controllers regulated the flow rate by using a photoelectric sensor that compared the actual flow rate (counting drops in the drip chamber) to the pre-programmed rate. If a difference was found, the device adjusted an automatic roller clamp to eliminate the difference. The controller functioned within gravity limits, and was dependent on the height difference between the infusion bag and the IV access site. The main limitations of this technology included, (a) no adjusts to flow rate when droplet size changed, (b) narrow range of accurate flow rates, and (c) inability to produce a pressure greater than atmospheric pressure (Lindley & Deloatch, 1993). Positive-pressure pumps regulated flow rate by generating a mechanical pressure to push the fluid through the IV tubing. This technology removed the limitations of Controllers because the infusion pump could produce a pressure greater than atmospheric pressure. As a resulted, the flow rate range and accuracy was extended, more viscous solutions could be infused, and arterial infusions could be administered to patients (Lindley & Deloatch, 1993).

Infusion pump technology at this stage now offered greater accuracy of flow rates, and safety features such as occlusion and air-in-line detection, empty container alarms, and free flow protection (ECRI Institute, 2002). However, the devices also required nurses to enter Volume To Be Infused (VTBI) and rate, which created an opportunity for new types of programming errors to occur. For instance, a
nurse could accidentally administer an overdose of a medication to a patient by entering the wrong rate value. The technology was unable to intercept these types of errors before they reached the patient. Thus, there was a need to incorporate electronic safeguards in infusion pump technology that could help prevent IV medication errors (ECRI Institute, 2002).

In an attempt to reduce IV medication errors, manufacturers have introduced smart pumps with medication safety software referred to as Dose Error Reduction Software (DERS). Smart pumps allow hospitals to configure the software to specific characteristics of either a patient type (such as adult or pediatric) or treatment type (such as oncology or emergency). Based on the type selected, hospitals can customize a library of drugs, concentrations, dosing units, and dosing limits to meet the needs of the specific user group or clinical care area (Cohen, 2007a). When the dosage parameters are entered by a nurse, the software checks to make sure the dosage values are within pre-determined dosage ranges set by the institution. If the dosage value is outside of the acceptable dosage limits, a limit alert will be displayed to the nurse. Depending on the established dosage range, the nurse will receive either a soft or hard limit alert. A soft limit alert will allow the nurse to override the warning and administer the fluid as is, whereas a hard limit will not allow the nurse to administer the fluid under its present dosage values. If the nurse programs outside of DERS the dosage values will not be checked by the software to make sure the values are in an acceptable dosage range. This method is called generic programming.

In the fight against IV medication errors, many healthcare facilities and researchers feel smart pump technology has not lived up to expectations because IV medication error rates have not decreased to a level where the benefit of the technology significantly outweighs its cost (Cassano, 2006; Rothschild et al. 2005; Nucklos et al. 2008). Most health care facilities have chosen to implement the technology as a stand-alone system instead of integrating smart pumps with other clinical information systems such as Computer Physician Order Entry (CPOE), Pharmacy Information System (PIS), Bar Code Medication Administration (BCMA) and Electronic Medical Record (EMR) (Husch et al. 2005; ISMP, 2002; Keohane et al. 2005; Rothschild & Keochane, 2008). This decision severely limits the ability of smart pumps to intercept medication errors because only dose errors can be intercepted, omitting patient, drug name, time, and route errors. This limitation was observed by Nuckols et al. (2008), who analyzed medical records from 4604 patients with 20,559 bed-days in ICU, and found that only 4% of medication errors could have been intercepted by smart pump technology.

Smart pumps may add to the overall demands on drug administration process because of the increase in complexity of their software. This may cause nurses to make new types of errors (such as selecting the wrong drug or concentration) and develop unsafe workarounds (such as bypassing safety
features and programming a generic infusion) that did not exist while using traditional infusion pumps. Given that medication administration is a high-risk activity, there is a need to understand how the design of the DERS affects the ability of nurses to safely and efficiently administer IV medications.

2.2 CHALLENGES OF SMART INFUSION PUMP TECHNOLOGY

The effect of DERS design on the occurrence of new types of errors, and workarounds has yet to be adequately addressed in the literature. The following is a brief review of current challenges faced by health care organizations that have cited the DERS design as a possible contributing factor to a problem.

2.2.1 Poor Drug Library Compliance

Drug library compliance continues to be an issue affecting hospitals that have implemented smart pumps. To take advantage of the safety features smart pumps provide, nurses must enter and program in the drug library. If nurses choose not to use drug library, the safety features will not be activated, and dosage values will not be checked to make sure the values are within the pre-determined dosage range. Thus, there is a risk that the nurse will administer a medication outside of the appropriate dosage range that could have been caught by the software if the nurse had used the drug library. A randomized time-series trial, that compared medication error rate between smart pumps (with DERS) and traditional infusion pumps (without DERS), found that 25% of programming occurred outside the DERS (Rothschild et al., 2005). Three separate studies found similar results reporting that 44.4% (Eckel, Anderson, Zimmerman, Szandzik, & McAllister, 2006), 46% (Cassano, 2006) and approximately 50% of medications were programmed outside of DERS (Birk, 2008).

Programming errors cannot be intercepted by the technology if nurses program outside of DERS. This can increase the opportunity of administration errors reaching the patient. The Emergency Care Research Institute (ECRI) and the Institute of Safe Medication Practices (ISMP) (2007) described one such incident where a nurse programmed an infusion of heparin as a generic drug at a rate of 650 mL/hr instead of a dose-rate 650 units/hr. If the medication had been programmed in the DERS, this error would have never reached the patient (ECRI Institute & ISMP, 2007). Rothschild et al. (2005) found that 25% of medication errors made by nurses were programmed outside the DERS. The researchers hypothesized that poor drug library compliance was likely the reason why the introduction of smart pump technology has modestly impacted the occurrence of medication errors.
Causes of poor drug library compliance fall into four main categories:

a. *Difficulties navigating through the menu pathways:* Nurses can find the transition from traditional infusion pumps to smart pumps difficult because of the extra programming steps and non-intuitive menu structures. This can cause frustration from getting lost in the menu structures or not being able to program the pump quickly (Keohane et al., 2005). In turn, this can lead to more nurses bypassing the drug library (Eckel et al., 2006; ECRI Institute & ISMP, 2007; Rothschild et al., 2005).

b. *Drug library composition:* Many health care organizations fail to routinely assess whether the drug library meets the needs of the users once the technology has been implemented. This includes re-assessing on a regular basis whether new drugs need to be added or if soft and/or hard limits of a particular drug need to be altered. If the drug library fails to meet the needs of the nurse, the nurse may be more inclined to bypass the drug library and program outside of the DERS (McAlearney et al., 2007). Rothschild et al. (2005) described one such example where a nurse programmed an infusion of nesiritide outside of the drug library because the medication was not present in the drug library. The nurse entered the dose incorrectly, which resulted in a 1000-fold dosing error. This error could have been prevented if nesiritide was present in the drug library.

c. *Low perception of risk:* Canadian health care institutions are a part of a culture that unintentionally supports at-risk behaviours such as technology workarounds (Cohen, 2007b; ECRI Institute & ISMP, 2007). If nurses are unsatisfied with smart pump technology or fail to recognize the benefits of using the safety features, they may take a less safe programming route to “just get the job done” (Cohen, 2007; Keohane et al., 2005).

d. *Easy access to the generic programming mode:* The ease with which a nurse can access the generic programming feature during programming may affect whether a nurse chooses to follow standard protocol, which states nurses must program in DERS whenever possible (known as drug library compliance). Manufacturers of smart pump technology have employed a variety of methods to give nurses access to this feature in their software. Some manufacturers have designed their software so that the user is defaulted into generic programming at start-up, whereas others default the nurse into the drug library and require the user to take extra steps to access generic programming. The latter case is thought to be more desirable because the extra steps required to access generic programming compared to programming in the drug library may discourage nurses from using generic programming when not appropriate (ECRI Institute & ISMP, 2007; Leape, 2005). Although this factor is commonly overlooked in literature that report on drug library compliance rates, a recent article published by Birk (2008) attributed their initial compliance rate
of less than 15% to the design of their smart pump model that required users to opt into DERS at start-up.

2.2.2 User Errors

Smart pumps require nurses to enter more parameters that traditional Rate-VTBI infusion pumps (such as drug name, concentration, patient weight, and rate, VTBI, dose-rate, and/or duration). These additional programming steps and new terminology may increase the occurrence of user errors. User errors (such as parameter selection and data entry errors) can only be intercepted by smart pump technology if the combination of parameters causes a limit to be breached. Even then, it is the responsibility of the nurse to make the correct decision once a limit is breached. Failure to notice or understand that an error has occurred can result in the error reaching the patient. Common user errors that have been addressed in the literature include:

a. **Multiple of ten errors:** This type of error occurs when an infusion is programmed with a dose-rate, rate, or duration value that is a multiple of 10 higher or lower than the intended value. ECRI Institute and ISMP (2007) cited one example where a nurse bypassed the drug library, and programmed the patient’s total parental nutrition to run at 625 mL/hr instead of 62.5 mL/hr, which resulted in a 10-fold overdose. Other institutions have found similar multiple of ten errors at their facilities (Eskew, Jacobi, Buss, Warhurst, & Debord, 2002; Fanikos et al., 2007; Hahn & Whitbeck, 2007; Husch et al. 2005; Keohane et al., 2005; Peterson et al., 2008; Pratt, 2004; Rothschild et al., 2005).

b. **Transposition of rate and dose-rate errors:** This type of error occurs when the rate is entered in the dose-rate field, or vice-versa. An analysis of collected CQI data at one institution revealed an incident where a nurse accidentally programmed nitroglycerin at a rate of 80 ml/hr instead of a dose-rate of 80 mcg/min. In this case the software alerted the user that the dosage values were out of range and the pump was reprogrammed to the correct dose (Keohane et al., 2005). Other authors have cited similar errors (ECRI Institute & ISMP, 2007; Malashock, Shull, & Gould, 2004).

c. **Unit errors:** Unit errors are mix-ups between units of weight, dose-rate, rate or duration. ECRI Institute and ISMP (2007) cited one example where propofol was ordered at 80 mcg/kg/hr, but was programmed at 80 mcg/kg/min. Rothschild et al. (2005) also described a similar event where the patient’s weight of 140 lbs was entered as 140 kg. This resulted in a 2.2 – fold dosing error. Other researchers have cited similar examples (Cohen, 2007b; Peterson et al., 2008).
c. **Calculation errors:** These types of errors occur when the nurse makes a mistake in calculating a parameter, and programs the infusion with the wrong parameter value. For instance, if an IV medication is to infuse over 30 minutes the user multiplies the volume of the bag by two instead of dividing by two to calculate the corresponding rate.

d. **Keystroke errors:** These types of errors occur when the nurse accidentally pushes a wrong button on the infusion pump while programming. Malashock et al. (2004) cited one example where a nurse accidentally pressed zero instead of the decimal point, and programmed an order of cistracurium at 105 mcg/kg/min instead of 1.5 mcg/kg/min. After hitting a limit, the nurse noticed the error, and subsequently changed the dose to the correct value. In another case, a nurse programmed dopamine at 510 mcg/kg/min instead of 10 mcg/kg/min. Other researchers have cited similar examples (Hahn & Whitbeck, 2007; Husch et al., 2005).

e. **Parameter selection errors:** These types of errors include selecting the wrong item in the programming menu such as drug name or concentration. Health care facilities cannot determine the extent of this issue unless the pump logs can be traced back to the patient receiving the infusion.

f. **Key bounce Errors:** Key bounce errors occur when the user presses a number key and receives a repeat of the same number (ISMP, 2006). ECRI Institute and ISMP (2007) cited one incident where a nurse delivered propofol at a rate of 225mL/hr instead of 25mL/hr. The nurse realized the mistake and corrected the error.

g. **Failure to correctly adjust dosage parameters after an infusion has started:** These types of errors occur when the nurse is required to change the parameters in the pump after the infusion has started. Hicks and Becker (2006) cited one example where the concentration of an insulin replacement bag was different than the bag previously used. The nurse forgot to adjust the pump to reflect the new concentration and as a result, the dose was significantly less than intended (Hicks & Becker, 2006). This type of error was also observed in another study, where a nurse adjusted the rate of the infusion to administer a bolus, but failed to correctly reset the rate once the bolus was given (Peterson et al., 2008).

### 2.2.3 Override of Limit Alerts Judged Clinically Inappropriate

Hard and soft limit alerts act as a warning system for nurses when a dosage parameter is outside of its typical range. Essentially, limit alerts are presented to the nurse to trigger critical thinking because limits are not patient specific. Thus, if the nurse hits a soft limit but feels the dosage parameters are appropriate for the patient’s condition, the nurse could start the infusion by overriding the limit. Similarly,
if the nurse hits a hard limit, the nurse could ultimately start the infusion by programming the order in the generic programming mode. The scenario in which the nurse bypasses a warning message for a dosage parameter that is clinically inappropriate is the most worrisome because it has the potential to cause harm to the patient.

The response of nurses to limit alert messages in smart pumps has yet to be fully explored. Many researchers have analyzed data from dose alert and operational logs using Continuous Quality Improvement (CQI) software in the hope that the number of limits hit, and the response of the nurse to the limit could correspond to the number of prevented medication administration errors (Cassano, 2006; Eckel et al., 2006; Fanikos et al., 2007; Husch et al., 2005; Keohane et al., 2005; Malashock et al., 2004; Pratt, 2004; Rothschild et al., 2005; Wetterneck et al., 2006). As a standalone system, smart pumps record the time and date of administration, drug name and concentration, dosage parameters, the limit that was exceeded, and the response of the nurse to limit. Unless the alert is connected to the history of the patient (or the nurse manually enters the patient’s name into the pump), it is difficult to determine whether the response to the alert was appropriate. Thus, it is unreasonable to assume that if a nurse reprogrammed the pump after hitting a limit, the pump was programmed correctly. Similarly, one cannot assume that every override resulted in an infusion that was clinically inappropriate without knowing the condition of the patient receiving the therapy. To determine if a response to a limit alert message was clinically appropriate, smart pumps must be integrated with other IT systems. Incorporating these technologies into the IV medication administration process means that smart pump data could be linked to patient data.

Many researchers have published lists of medications that are commonly programmed outside of established limits (Cassano, 2006; Eckel et al., 2006; Fanikos et al., 2007; Jacobs, 2005; Keohane et al., 2005; Wetterneck et al., 2006). These data are more likely to indicate poor drug library configuration settings, or a lack of standard administration policies than user errors caused by the design of the DERS. For example, if phenylephrine resulted in over 2000 alerts within a span of 1 month it is more of an indication of poor configuration settings, and not nurses incorrectly programming phenylephrine approximately 66 times a day (Fanikos et al., 2007). When certain medications, such as phenylephrine, are frequently programmed outside of the dosage limits, health care facilities should take immediate action to rectify the problem. Excessive alerting can result in alert fatigue; a condition where users become fatigue from receiving too many alerts and as a result, start to ignore or override alerts without considering their importance (van der Sijs, Aarts, Vulto, & Berg, 2006). Excessive alerting can also reduce the credibility of the system. If a nurse repeatedly receives false positive alerts (inappropriate alerts), their trust in the safety features can decline. In turn, this could result in a decrease in nurse responsiveness to positive alerts that require attention (van der Sijs et al., 2006).
The design of the limit alert messages varies greatly between smart pump models with respect to the type of information presented and the layout of the items on the screen. Currently, no literature has specifically examined how the design of limit alert message affects the ability of nurses to make the correct decision when presented with a limit alert message. However, this issue has been discussed when examining the response of nurses to limit alert messages from CQI data. A study completed by Fanikos et al. (2007) found that 27.2% of limits that were breached while programming an anticoagulant infusion were reprogrammed with the same values. Although the authors did not address the reason behind this result, one can speculate that the design of the DERS was a contributing factor. This facility used the Cardinal Alaris System (Fanikos et al., 2007). The limit alert message in this smart pump model displays the limit value breached, but not the value that caused the alert to be activated. Thus, there is no method to verify that the parameter value which breached the limit was the value the nurse intended to enter. If the nurse chooses not to override the limit, the software re-directs the nurse back to the parameter entry screen. However, the values previously entered on this screen are erased and thus the nurse is still unable to verify the values that were first entered. The only way for the nurse to check if the intended values had activated the alert is to re-enter the same values and see if the same limit appears (assuming that the nurse entered the parameters correctly the first time). This is an excellent example of the importance of considering the design of the DERS when analyzing CQI data or other events relating to infusion therapies.

2.2.4 Problems Completing Complex Multi-Step Tasks

The added programming steps and new menu structures in DERS may increase the complexity of already difficult medication administration tasks such as secondary infusions, and boluses, and generic programming in crisis situations. The following reviews high-risk IV medication administration tasks and the effect of DERS design on their processes.

2.2.4.1 Secondary Infusions

A secondary infusion, or piggyback infusion, is a common infusion technique that was introduced to increase administration safety when delivering drugs intermittently. To deliver a secondary infusion, a therapeutic bag is connected to the upper Y port of a primary infusion line. The therapeutic bag is then hung higher than the primary bag. The difference in hydrostatic pressure stops the flow of the primary infusion, and allows only the secondary infusion to flow once the secondary clamp is opened. When the secondary infusion is completed, the hydrostatic pressure decreases and the primary infusion resumes.

The set-up and programming of a secondary infusion is a complex task that is prone to errors. A study completed by Nunnally and Bitan (2006), found that 53% of nurses could not successfully complete
a secondary infusion task in a stimulated clinical environment (Nunnally & Bitan, 2006). The low success rate was attributed to difficulties navigating through the menu levels, and the occurrence of user errors when entering parameters into the pump. This study also found that 38% of nurses forgot to open the secondary clamps and/or adjust the height of the bag, which resulted in the primary bag infusing instead of the secondary bag. ISMP Canada (2005) reported a similar case where a nurse forgot to open the roller clamp of a secondary bag containing potassium chloride and as a result, the pump drew from the primary solution of insulin (ISMP, 2005). Modifying the design of the DERS may increase success rate by improving the intuitiveness of the menu levels. However, physical set-up errors are unlikely to be intercepted by most smart pump models on the market.

2.2.4.2 Boluses

Administering a bolus is a high-risk medication administration task because a concentrated dose of a medication is given in a short period of time to the patient. Using traditional infusion pumps, nurses would typically increase the rate of the infusion to administer a bolus and then decrease the rate back to the original value. With the introduction of smart pumps, users must now navigate to a separate menu to administer a bolus. This change in practice has caused new programming errors to develop. For instance, two separate studies found that the majority of limit alerts were the result of nurses giving a bolus in an inappropriate menu in the DERS (Peterson et al., 2008; Pratt, 2004).

2.2.4.3 Generic Infusions

Although nurses are encouraged to program infusions in the safety of the DERS, it is also important for nurses to be able to easily access the generic programming mode, which allows them to program an infusion without safety limits. This can be very important in clinical emergencies or in situations where it is clinically appropriate to administer a dose above the maximum limit. However, as previously discussed in Section 2.2.1, many researchers feel that easy access to the generic programming mode was likely the reason for the low drug library compliance rates at their hospitals (Birk, 2008; ECRI Institute & ISMP, 2007; Leape, 2005). Thus, it would seem that an appropriate balance between these two needs has yet to be reached.

2.2.5 Multi-Channels

Multi-channel infusion pumps allow for the administration of multiple infusions on a single pump. Although multi-channel infusion pumps are space saving, multi-channel pumps can create new opportunities for errors when users attempts to program two or more infusions on the same screen. The most prominent type of error reported in literature is administration line mix-up. However, more attention has recently been given to complexity of programming multiple infusions on one screen, and poor user
interface design. In 2005, an Agency for Healthcare Research and Quality (AHRQ) Case & Commentary described the occurrence the infusion administration errors from a channel mix-up errors (Gosbee, 2005). The author described at length the need for industry and health care organizations to apply human factors engineering methods to reduce error-prone areas like IV medication administration. Burdeu, Crawford, van der Vreede & McCann (2006) also reported that as a part of a quality improvement initiative their hospital replaced all 4-channel pumps with 2-channel pumps because there were a significant number of channel mix-ups. The nursing staff reported that they had difficulties reading the electronic screen and navigating through the programming pathways. There have also been advisories published by ECRI Institute and ISMP regarding line mix-up between dual-chambered infusion pumps such as a mix-up during an IV tubing change on a dual-channel pump where heparin (13mL/hr) and normal saline (125mL/hr) lines were reversed (ECRI Institute & ISMP, 2007; ISMP, 2004).

2.3 IMPROVING IV INFUSION SAFETY USING HUMAN FACTORS METHODS

Human Factors is a scientific discipline that studies the how people interact with technology. Human Factors deals with how the psychological, social, physical, biological and safety characteristics of users interact in a work environment or with a device (Step-by-step usability guide, 2009). The main goal of Human Factors is to design work environments and devices that increase user performance while reducing the occurrence of errors (Step-by-step usability guide, 2009). In health care, Human Factors has been used to evaluate the usability of pre-market medical devices, evaluate how the technology fits into its intended environment, and uncover design issues that affect the ability of users to safely and efficiently use a medical device. The following is a brief overview of some of the different Human Factors methods that have been used by manufacturers and health care facilities to design and evaluate smart pump technology.

2.3.1 Inquiry Methods

Failure Mode and Effects Analysis (FMEA): FMEA is a method used to identify potential failure modes associated with a technology, and prioritize potential failures and errors according to severity, probability of occurrence, and detection (Step-by-step usability guide, 2009). FMEAs have been conducted by hospitals before and after implementation of smart pumps to uncover possible risks and take proactive steps to minimize implementation risks such as programming errors and adverse events (Carayon et al., 2007; Wetterneck et al., 2006).
Focus Groups: Focus Groups are an informal technique used to obtain information relating to the personal feelings of users toward a technology and/or physical environment. Although this is a relatively easy method to gain insight on user perceptions, information should be used with caution because often what users say they want or do, are not actually what they want or do (Step-by-step usability guide, 2009). Furthermore, responses from people can be influenced by other people in the focus group. Both events can affect the truth of the information received. Focus groups have been used to assess user perception before and after the implementation of smart pump technology (McAlearney et al., 2007). Information retrieved from this method included challenges users faced when using smart pumps (such as physical set-up difficulties or inconsistencies in drug library content), perceived impact on workflow, and perceptions relating to the added safety benefits of using smart pump technology.

Questionnaires: Questionnaires are a useful tool to gain information about a technology or environment from the point of view of the user (Step-by-step usability guide, 2009). Questionnaires have been used by researchers to understand how smart pumps affect nursing attitudes and workflow (Rosenkoetter, Bowcutt, Khasanshina, Chernecky, & Wall, 2008).

2.3.2 Inspection Methods

Heuristic Evaluations: A heuristic evaluation refers to the systematic inspection of a user interface design for usability. Using a checklist of usability principles (or heuristics) as a guide, each screen of the interface and aspect of the hardware can be evaluated according to how well it satisfies each principle. The overall goal of heuristic evaluation is to find usability problems so that they can be addressed as part of an iterative design process (Step-by-step usability guide, 2009). Examples of usability heuristics as outlined by Zhang, Johnson, Patel, Paige & Kubose, (2003) are: consistency and standards, visibility of system state, match between system and world, minimalism, minimizing memory load, informative feedback, flexibility and efficiency, good error messages, prevention of errors, clear closure, reversible actions, use of users’ language, users are in control, and help and documentation.

A heuristic evaluation is a cost-effective method to uncover usability issues; however, it also has its drawbacks. When performing a heuristic evaluation it is unlikely that all usability issues will be discovered (Nielsen & Mack, 1994). Furthermore, a heuristic evaluation of a technology is normally completed outside of its use environment. This could leave out unforeseen usability issues that could impact user performance and safety while using the device (Zhang et al., 2003). Thus, even though a large portion of the usability issues can be uncovered using this type of evaluation, the severity of the usability issues can only be hypothesized by the evaluators (Ginsburg, 2005).
Heuristic evaluations have generally been used by hospitals in comparative evaluations of commercially available smart pumps during the procurement process. Zhang et al. (2003) usability heuristics have been used to perform expert reviews, and develop questionnaires to obtain user feedback after interacting with the smart pump (Ginsburg, 2005; Graham et al., 2004; Husch & Fennessy, 2008).

2.3.3 Testing Methods

Usability Testing: Usability testing is a Human Factors method used to assess the user’s interaction with the device (Step-by-step usability guide, 2009). The main advantage of usability testing is that users interact with the device in a simulated environment that mimics the actual environment the device would be used in. The results from this technique are more representative of what would appear in the actual environment. Hospitals and manufacturers can use this technique to uncover specific design issues that impact the ability of the user to safely and effectively use a technology. Furthermore, it can be used to better understand how the technology fits into the environment and existing workflows.

Usability testing has been used by researchers and hospitals to evaluate smart pump models (Ginsburg, 2005; Husch & Fennessy, 2008; Nunnally et al., 2004). Evaluators developed tasks for the users to perform on the smart pumps, and analyzed the data to determine differences in user performance and safety across the smart pump models. Information extracted from the tests was used to help make decisions during the procurement process and understand how the design of DERS impacted nursing performance.

Validity of the usability test depends on the extent to which the real environment is replicated during the testing. In studies completed by Ginsburg, G et al. (2004) and Husch and Fennessy (2008), the clinical environment was not stimulated during testing, and thus results obtained could be very different from results obtained when evaluating the technology in its clinical environment. Furthermore, the testing was not video or audio recorded for subsequent viewing. There is a risk that the evaluator could have missed or misinterpreted an event, and without a recording the evaluator is unable to confirm their observations.
3. METHODLOGY

A high-fidelity simulated experiment was developed to answer the hypotheses of this research: (1) the ability of nurses to safely and efficiently program IV medications will differ across the smart pump models because of differences in DERS design, and (2) a high-fidelity simulated experiment design will enable differences in DERS design and nursing performance to be delineated.

3.1 MATERIALS

3.1.1 Smart Pump Selection

This project was sponsored by Ontario Ministry of Health and Long-Term Care (MoHLTC), and limited to the investigation of DERS design for smart pump models available in Canada. There were five smart pump models that were available in Canada: Hospira Symbiq, Hospira Plum A+, Baxter Colleague CX, BBraun Infusomat and Cardinal Alaris System. Of the five smart pump models available, three were selected for this study. The following is a brief overview of the selection criteria used to formulate the decision. The complete decision matrix can be found in Appendix A.

- **DERS Design Evaluation**: Specific design elements of DERS were examined by the investigator for each smart pump model. The design elements were selected based on (a) findings uncovered in the literature review pertaining to DERS design, and (b) general programming subtasks that nurses must complete to program an infusion.

- **Heuristic Evaluation**: A heuristic evaluation of each smart pump model was completed by two Human Factors specialists from Healthcare Human Factors Group at the Centre for Global eHealth Innovation. Results from this analysis (number of usability issues and the severity of usability issues) were used in the decision matrix because it was an extensive analysis that incorporated all physical and software components, not just specific components of the DERS that the investigator had evaluated.

- **Ontario Market Share**: The more widespread the use of the smart pump model across Ontario, the more favorable the rating.

- **Point in Product Lifecycle**: Results from this study would be more valuable to hospitals and manufacturers if the smart pump model examined was in the early stages of its lifecycle. For instance, hospitals planning on implementing smart pumps in the upcoming years could still incorporate the results from this study in this procurement decision.
The three smart pump models selected for this study were Cardinal Alaris System, Hospira Symbiq, and BBraun Infusomat. Hospira Symbiq was selected for this study because it received the highest usability rating in the DERS design and heuristic evaluation compared to the other smart pump models. Furthermore, Hospira Symbiq was a new product on the market, and was a recipient of the 2007 Medical Design Excellence Award (MDEA) (MDEA, 2007) and the 2006 user-centered product design award from the Human Factors and Ergonomics Society (HFES) (HFES, 2006). Cardinal Alaris System was chosen because it had been purchased or leased for a previous study that examined smart pump technology migration. Cardinal Alaris System was selected for this study because it received the second highest usability rating in the DERS design and heuristic evaluation. Furthermore, this product had the second largest Ontario market share and was mid-way through its product lifecycle. Although Hospira Symbiq and Cardinal Alaris System had similar ratings, the difference in the design of their DERS was the reason why both models were selected. BBraun Infusomat was chosen because it had the lowest evaluation score across the smart pump models, and had unique design elements compared to Hospira Symbiq and Cardinal Alaris System. Although Baxter Colleague and Hospira Plum A+ had similar scores to BBraun Infusomat, these models were not selected because many design elements were similar to Cardinal Alaris System and/or Hospira Symbiq. As the purpose of this research was to compare different design elements in DERS, it was important to examine models that had unique design elements. Please refer to Appendix A for the smart pump model selection decision matrix.

3.1.2 Drug Library Set-up

3.1.2.1 Drug Library Content

The drug library was populated with therapeutic and non-therapeutic fluids from the University Health Network (UHN) IV Formulary. Dose limit values for each therapeutic fluid were taken from the UHN standard protocol for intravenous medication delivery. A total of six CCA types were used (Cardiac, Clinics, Intensive Care Unit (ICU), Medical Surgical, Peri-operative, and Oncology) and each CCA contained the same drug list. The drug list contained a total of 28 non-therapeutic fluids, and 59 therapeutic fluids with 149 drug name and concentration combinations. Medications used in the generic infusion task were omitted from the drug library.

All smart pump models contained the same drug library content. All medications had the same soft minimum, soft maximum, and hard maximum dose limits across the smart pump models. A UHN pharmacist verified the validity of the dose limit values for the therapeutic fluids used in the experiment. Hard minimum limits were not used in this study because all manufacturers indicated this was not a
common practice in hospitals. Tall-Man lettering was used for high-alert medications as recommended by ISMP. High-alert medications were also highlighted so that they were visually unique from other medications. This feature was also used across the smart pump models as recommended by ISMP.

It should be noted that the drug library content was not necessarily a complete version of what UHN would use. The development of a complete drug library, tailored to the needs of UHN, would require an extensive amount of time and involvement from many stakeholders such as pharmacists, nurses and physicians. However, this was considered a minor drawback because the investigator felt the size of the drug library was large enough to adequately observe the nurses interacting with the drug library.

3.1.2.2 Drug Library Software Configuration

The drug library set-up software for each smart pump model was analyzed to determine what design elements were constant across the smart pump models, and what design elements were unique to a particular smart pump model. Design features that were configurable across all smart pump models were set the same. For design elements that were unique to a particular model, the investigator consulted the manufacturer to determine what features to activate and the recommended settings (if required). If the unique design element added more programming steps to the programming sequence, the design element was not activated. Only design features that were not a part of the common programming steps (load IV set, turn on pump, enter DERS, enter CCA, select drug name, select concentration, enter parameters, and start infusion) were removed. Although removing design elements may change nursing performance, given the complexity of the DERS, it was important to minimize compounding factors to enable the investigator to better understand how key design elements impacted nursing performance. For more information regarding the specific set-up of each smart pump model, please refer to Appendix A.

3.1.3 Pump Configuration Settings

Standardization of pump configuration settings across the smart pump models was attempted to prevent unfair advantages. Pump configuration software for each smart pump model was analyzed to determine which settings could be configured the same across all smart pump models, and which settings were unique to a particular smart pump model. Design elements and settings that were configurable across all smart pump models were set the same. These included settings such as alarm options (for proximal and distal occlusion pressure and air-in-line sensitivity etc.). Pump configuration settings unique to a particular model were configured to the setting recommended by the manufacturer. For more information about the smart pump configuration settings, please refer to Appendix A.
3.1.4 Medication Orders, labels and patient ID wristbands

A UHN pharmacist developed the medication orders used in the experimental protocol. All medications used in this study could be prescribed by a doctor for patients in an ICU or non-ICU at Toronto General Hospital (TGH), and were consistent with UHN medication administration policies. A TGH nurse and another pharmacist validated all medication orders to ensure accuracy. The medication orders were programmed in the Medication Order Entry and Medication Administration Record system (MOE/MAR). Medication orders commonly prescribed on paper, such as insulin and heparin, were written on the standard paper forms used at UHN to mimic the actual workflow. All medication labels were displayed in the same format used at UHN. Orders that are normally mixed on the ward were set-up before the experiment and given the appropriate labels. No real medications were used in the study. The IV bags were filled with 0.9% Normal Saline (NS). Each mannequin was given a patient Identification (ID) wristband. The wristbands were designed to match the current information layout of patient ID wristbands at UHN.

3.2 Participants

Research ethics approval was granted by the Research Ethics Board at the University Health Network (Research Ethics Board Number: 09-0135-AE) and the Office of Research Ethics at the University of Toronto (Protocol Reference Number: 23366).

Nurses were recruited from six clinical areas at Toronto General Hospital. All clinical care areas (CCAs) had similar medication delivery and therapy methods, and were familiar with most of the medications and patient conditions presented in the experiment. A pharmacist at Toronto General Hospital verified that the CCAs were acceptable before the Investigator contacted potential CCAs. Involvement in this study by the CCAs was voluntary. The following CCAs were selected to take part in this study: Cardiovascular Intensive Care Unit (CVICU), Cardiac Intensive Care Unit (CICU), Post-Anesthesitic Care Unit (PACU), General Internal Medicine (GIM), Transplant, and General Surgery (GenSurg).

To recruit participants, the investigator attended nursing staff meetings of the CCAs that expressed interest and explained the study to potential participants. The investigator also reviewed information such as the risks and benefits of participating, their right to withdraw, and the use of collected information.
Sign-up sheets were then left in the CCAs for interested people to leave their contact information. The sheets were then collected, and the investigator contacted interested nurses.

A sample size and power calculator tool was used to determine appropriate sample size. It was determined that a sample size of 24 was required to ensure that the probability was 80 percent that the study would detect a difference between the conditions at a $p < .05$ significance level for an effect size of 0.66.

Twenty-three females and one male completed the study. Twelve nurses were taken from ICU areas (equally divided between CVICU, CICU and PACU) and twelve nurses were taken from non-ICU areas (equally divided between GIM, Transplant and GenSurg). Twenty-one nurses were employed as full-time Registered Nurses, two were employed as part-time Registered Nurses, and one was employed as a Care Leader. At the time of the study, 46% of the nurses had been employed as a Registered Nurse between 0-4 years, and 52% had been employed as a Registered Nurse over 5 years. Most nurses had worked at UHN between 1-4 years (46%), followed by 5-9 years (21%) and 10-19 years (21%). All except one participant had been employed at UHN for over one year.

Thirty-three percent of nurses indicated that they were somewhat comfortable using new technologies, 42% indicated they were comfortable and 25% indicated they were very comfortable. All nurses used the Graseby 3000 infusion pump to deliver IV medications in their CCA. The frequency of infusion pump use was: less than once a day (13%), 1 to 2 times a day (8%), 3 to 5 times a day (33%), and over 5 times a day (46%). No nurses had used a smart infusion pump before the study. Please refer to Tables 15 – 19 in Appendix D for additional information regarding participant demographics.

### 3.3 Experiment Design

A repeated measures design was adopted to assess the differences in DERS design between the three smart pump models. The following reviews the independent and dependent variables of this experiment.
3.3.1 Independent Variables

3.3.1.1 DERS Design

Participants performed infusion tasks on three different smart pump models (BBraun Infusomat, Hospira Symbiq, and Cardinal Alaris System) to explore which features enhanced or reduced the ability of nurses to safely and efficiently administer IV medications.

3.3.1.2 Infusion Task

Each nurse completed seven infusions on each smart pump model. Unless otherwise stated, all medication orders contained medications that were familiar to the majority of Registered Nurses in the selected CCAs. The following describes each task and the rationale behind the selection of the task.

Task 1: Continuous infusion, wrong patient error, first channel of all pumps: The medication orders given in this task asked nurses to program a continuous infusion. However, the patient in the bed was not the patient the medication order was intended for. A patient error was selected because verifying the right patient before administration is a part of the 5-rights (right patient, right dose, right time, right route and right drug). Furthermore, wrong patient is an error that cannot be intercepted by smart pump technology without integration with other IT systems because the software cannot prevent nurses from administering a medication if the patient name in the smart pump does not match the patient name on the medication order. This error was also included in this study because the same experiment design was used for a separate smart pump migration study. As this study examined the use of bar coding when administering IV medications, it was valuable to examine the impact of this technology on the occurrence of patient mix-up errors. This task was also selected to obtain efficiency data because it was expected that nurses would complete the entire programming sequence without interruption (it was suspected that nurses would be more likely to catch the planted error when checking the 5-rights before the pump was programmed). This error was incorporated into the task by having the patient’s name and MRN number on the medication order and medication label differ from the patient’s name and MRN number on the patient ID wristband.

Task 2: Intermittent infusion, wrong drug error, first channel of single-channel pump, second channel of dual-channel pumps: The medication orders given in this task asked the nurses to program an intermittent infusion. However, the participant was given the wrong drug to administer to the patient. A drug error was selected because verifying the right drug before administration is part of the 5-rights, and wrong drug is an error that cannot be intercepted by smart pump technology without integration with other IT systems because the software cannot prevent nurses from administering a medication if the drug name in the smart pump does not match the drug name on the medication order. This error was also
included in this study because of the smart pump migration study (as discussed above in Task 1). This task was also selected to obtain efficiency data (as discussed in Task 1). The medications chosen for this task were sound-alike-look-alike medications such as hydromorphone and morphine.

**Task 3: Intermittent Infusion of a medication not available in drug library, no planted error, first channel of all pumps**. The medication orders given in this task asked the nurses to program an intermittent infusion for a medication not available in the drug library. In this situation, the nurse would have to exit from the drug library and program the infusion in the generic programming mode. This task was selected because it is an atypical task that could be required in an emergency situation. Furthermore, this task required nurses to program outside the safety of the DERS. Thus, it is important that nurses are able to safely navigate through this programming sequence without making errors. No errors were incorporated into this task because this task was expected to be challenging as is.

**Task 4: Continuous infusion of non-therapeutic fluid (referred to as maintenance fluid), no planted error, first channel of all pumps**. The medication orders given in this task asked the nurse to program a maintenance line of 0.9% sodium chloride (NaCl) normal saline. This task was selected as a precursor to the secondary infusion task that is completed immediately after the maintenance line is set-up.

**Task 5: Secondary Infusion, no planted error, first channel of all pumps**. The medication orders given in this task asked the nurse to program a secondary infusion once. This task started immediately after Task 6 was completed. The task of programming a secondary infusion was selected because it was a common task performed by nurses at TGH, and is often considered a high-risk activity prone to set-up and programming errors (as discussed in Section 2.2.41). No errors were incorporated into this task because this task was challenging as is.

**Task 6: Intermittent Infusion, wrong dose that exceeds maximum soft dose limit value, first channel of single-channel pump, second channel of dual-channel pumps**. The medication orders given in this task asked the nurses to program an intermittent infusion that contained a clinically inappropriate dose value larger than the maximum soft dose limit value. The task of programming an intermittent infusion was selected because it is a common infusion task performed by nurses. A dose error that breached a soft limit value was selected because verifying the right dose before administration is a part of the 5-rights, and smart pump technology has the ability alert the nurse of a potentially inappropriate dose if the dose value is above pre-set limits. The dose error was incorporated into task by changing the decimal place of the dose value on the medication order.
Task 7: Continuous Infusion, wrong dose that exceeds maximum hard dose limit value, first channel of single-channel pump, first channel of dual-channel pumps. The medication orders given in this task asked the nurses to program a continuous infusion that contained a dose value higher than the maximum hard dose limit value. The task of programming a continuous infusion was selected because it is a common infusion task performed by nurses. A dose error that breached the hard limit value was selected because verifying the right dose before administration is a part of the 5-rights, and smart pump technology has the ability to alert the user of a potentially inappropriate dose if the dose value is above pre-set limits. The dose error was incorporated into task by changing the decimal place of the dose or rate on the medication order.

Both soft and hard limits were incorporated into the study because nurses can make different decisions on how to proceed once a limit is hit (nurses can override or reprogram after a soft limit, but nurses can only reprogram after a hard limit is hit).

3.3.2 Dependent Variables

Both objective and subjective data were collected. Objective data were collected from audio and video recordings and included time to complete task, deviations and success rate. Subjective data were collected from the following questionnaires:

- **Background questionnaire:** collected demographic information such as age, profession, length of time working as a Registered Nurse, length of time employed at UHN, and current use of infusion pumps.

- **Post-condition questionnaire:** was completed at the end of each experiment condition for each smart pump. This questionnaire covered judgements about the ease of use, efficiency, effectiveness of catching medication errors and overall impression of the smart pump and adequacy of training. The questionnaire also incorporated open-ended questions and a comment section where participants could provide additional comments about the design and features of the smart pump.

- **Final comparison questionnaire:** was administered after all conditions were completed. This questionnaire compared judgements between the pumps about the ease of use, effectiveness of catching medication errors and overall preference. The questionnaire also included an additional comment section for the participant.
3.3.3 Training Design

Prior to testing, the nurse underwent Vendor Based Training (VBT) on the system being evaluated. The purpose of training was to expose the nurse to general concepts, and provide a standard baseline comprehension of the pump hardware functionality and software programming. The training scripts were developed from current VBT scripts used by the manufacturer. The scripts resembled the manufacturer’s current training scripts with regard to terminology used to describe the features, and the steps used by the manufacturer to train a nurse on an infusion task. Each training script covered the same concepts and tasks at the same level of generality. The following is a list of the concepts and tasks covered:

- **Concepts:** Introduction to the safety features of DERS including the use of drug libraries, soft and hard limit alerts, and the concept of a generic infusion

- **Tasks:** Loading an IV set, programming a primary infusion, programming a maintenance fluid, programming a secondary infusion, clearing shift totals, stopping an infusion and programming a new infusion on the same channel, and programming an infusion in the generic programming model

To ensure the same information was provided to every nurse during training, nurses were asked to hold their questions until end of the training session. Questions that did not introduce new information, such as the nurse asking the trainer to clarify a concept previously discussed, were answered immediately after the training session was completed. Questions that introduced new information to the training session (such as “how would I administer a bolus?”) were answered at the end of the experiment.

Training received in this experiment differed from traditional VBT training in the following ways,

- **Amount of information provided:** the nurses only received training on seven tasks, whereas in traditional VBT training nurses would be trained on many other tasks such as priming IV sets, troubleshooting alarms, bolus delivery and/or advanced therapy options. Although nurses were given less information about each pump, the nurses were only required to perform 4 out of the 7 tasks, and any unintentional events that occurred were immediately rectified by the nurse actor

- **Length of training:** The duration of training on each smart pump was 15 minutes. In traditional VBT training, nurses would have a longer training period depending on the manufacturer and hospital, and whether the nurse is classified as a casual or super user. Due to the experiment time limit of 3 hours, this was not feasible.
• **Interaction between trainer and trainee:** Nurses received one-on-one training, whereas in traditional VBT, nurses are often trained in large groups.

• **Time difference between training and go-live date** – Due to the large number of nurses that must be trained before the smart pumps are implemented in hospitals, nurses are often trained weeks in advance of the go-live date. In this experiment nurses performed the infusion tasks immediately after training. It was anticipated that recruiting nurses to come into the lab twice (one session for training and one session for testing) would be challenging. Furthermore, ensuring a constant time period between the training session and testing for every nurse would be very difficult.

The level of knowledge retained after training was not measured in this experiment and thus it was not possible to determine if each nurse completed each protocol at the same level of knowledge. Although this may affect performance, most hospitals do not verify the performance level of their nurses before they are required to use the infusion pump on their ward. Furthermore, it can be expected that nurses will have a range of abilities when using infusion pumps because of the different therapy methods used in the CCAs, technology comfort levels, and the current frequency of infusion pump use.

### 3.3.4 Experiment Set-up Design

This experiment was conducted in the simulation labs at the Centre for Global eHealth Innovation, based at UHN. The simulation lab was set-up to simulate a Medical/Surgical Unit. There were three hospital beds in the unit, each containing a patient mannequin. To the right of each bed was a small table with hand sanitizer, alcohol wipes, gloves, and needle box. A mobile table with a laptop was used to represent a computer-on-wheels. The nurse could access the medication orders on MOE/MAR from this laptop. The mobile table was moved to the bottom of the patient’s bed while the Nurse Actor debriefed the nurse on the medical history of the patient. After debriefing, the nurse had the option to move the table to a different location if desired.

Each patient mannequin was dressed in a patient gown and covered with a blanket. Each patient mannequin had a peripheral IV line attached to each arm. The patient in Bed 2 also had a central line (a requirement for a medication in protocol B). The peripheral IV lines were secured to the patient using surgical tape and drained into empty IV bags located underneath the bed.

One dual channel smart pump model or two single channel smart pump models were placed on an IV pole beside each bed. A secondary infusion hook was placed on each IV pole. The orientation of the pump was set-up to obtain maximum coverage of the pump interface from the eight ceiling mounted pan-tilt-zoom video cameras. The wheels on the IV poles were removed and the legs of the IV poles where
taped to the floor to prevent the nurse from moving the pump. Each pump was attached to the pole at the same height and the pump screen faced a specific angle to favour maximum coverage. On the floor in front of the pump, an area was outlined in tape that the nurse was encouraged to stand when programming to reduce the event of the nurse blocking the camera.

A separate area of the lab was set-up as the training area. The training area contained an IV pole, smart pump, two primed lines, and a white board that listed medication orders used during training. This area also contained a desk and a desktop computer where the nurse could review the consent form and complete questionnaires. Concealed behind curtains, in the back right corner was the prep area. This area contained all materials required for the experiment, such as the smart pumps, administration sets, placebo IV medications, patient ID bands and other props. A nursing station was placed in the front of the simulation lab and consisted of a desk and phone.

Although the stimulated clinical environment was not entirely realistic, major components of the medication administration workflow were present. Furthermore, the experiment set-up could also make this study more comparable to results seen in other hospitals because the clinical environment had a higher level of generality. Please refer to Figure 32 in Appendix A for a diagram of the experimental set-up.

3.4 EXPERIMENT PROTOCOL

3.4.1 Roles of Experiment Team

The nurse interacted with three test instructors during the experiment: the investigator, nurse actor, and trainer. The role of the investigator was to meet and greet the nurse, introduce the nurse to the study and lab, review the consent form with nurse, collect time data during the experiment, and act as the patient transport employee in Task 1 if wrong patient was detected. The role of the nurse actor was to bring up patient orders, set-up IV medications, guide the nurse through the scenarios, provide assistance to the nurse if needed, and document final parameter values once an infusion task is completed. The role of the trainer was to train the nurse on the smart pumps, operate the cameras during the experiment, and act as the doctor if the nurse wanted to clarify a medication order. During the experiment there was minimal contact between the investigator and the nurse. If the nurse actor required assistance the investigator communicated to the nurse actor through a wireless radio.
3.4.2 Protocol

The following is a brief overview of the experiment protocol. For the complete experiment protocol please refer to Appendix B.

Upon arrival, the nurse was greeted by the investigator and oriented to the lab. The investigator reviewed the purpose of the study and the nurse’s role. The nurse was encouraged to maintain normal nursing practices (such as ensuring the 5-right and following infection control practices). Elements of the experiment protocol that were different from their normal workflow were reviewed. The nurses were assured that their skills as a nurse were not being evaluated, and that any negative impressions or problems they encountered with the system were not a reflection of their skills, but rather an indication that the system required improvement. After an introduction to the study and stimulated environment, the consent form was reviewed and signed by the nurse. The nurse then completed a background questionnaire to obtain demographic information.

The experiment protocol was divided into three conditions (A, B, and C). Each condition contained the same infusion tasks and planted errors. The experiment conditions were always completed in the same order (A, B, and C). The order of the smart pump models was counterbalanced and the order of the infusion tasks in the protocols was partially counterbalanced to prevent any learning effects.

At the beginning of a condition, the nurse was trained on the smart pump model being evaluated. After training was completed, soft and hard limit hospital policies were reviewed with the nurse by the nurse actor. The medical history of Patient 1 was reviewed with the nurse by the nurse actor, and the nurse was asked to complete the patient’s medication orders. The same steps were repeated for Patient 2 and 3.

Assistance from the nurse actor was provided in a condition if a nurse became stuck or confused while on a programming step. If the nurse asked for assistance, the nurse actor would first ask “What do you think you should do?” If the nurse was unable to work out the problem on their own, the nurse actor would give a hint such as “the drug must not be in the drug library”. If the nurse was still unable to move to the next programming sequence the nurse actor would instruct the nurse exactly how to solve the problem. By instructing the nurse exactly how to solve the problem, it was easy to distinguish between assistance that required a hint versus assistance that required instructions. To prevent additional information from being given to the nurse, the nurse actor would only provide enough information to take the nurse to the next menu level. The nurse actor did not provide any information beyond what was required to solve the problem. Once the nurse reached the next menu level, the nurse actor stopped assisting the nurse and the task continued. Errors unrelated to programming of the pump (such as a broken
IV cassette) were handled immediately by the nurse actor because the type of error was beyond the scope of the study.

After a condition was completed, the nurse was asked to complete a brief questionnaire pertaining to their perceptions of usability and overall performance of the smart pump model. The nurse was then given the option to have a break before continuing the experiment. Once the break had concluded, the nurse completed the same steps for the remaining two smart pump models. At the end of the experiment, the investigator answered any additional questions the nurse had about the smart pump models or smart pump technology in general. The nurse was paid $175 for their time. If the study ran over three hours, nurses were also given a gift certificate of $10.

3.5 Data Collection

All scenarios were audio and video taped. An audio recorder was used to capture conversations between the participant and the experiment team, and the verbalization of the participant’s thoughts (if this event occurred). A video recorder was used to collect data about how the participant interacted with the smart pump models.

Excel spreadsheets for each protocol and each smart pump were developed that contained all programming steps. A programmed time-macro was used to timestamp each programming step as the participant moved through the programming sequence. Deviations from the optimal programming path were also recorded during the experiment (the nurse actor also recorded the parameter values in the pump after an infusion task was completed). The investigator reviewed all video recordings after the experiment was completed to ensure all deviations and timestamps were accounted for and accurate. Questionnaires were programmed on SurveyMonkey, an online survey program, and were downloaded from after the experiment was completed for analysis (SurveyMonkey.com).

3.6 Data Analysis

3.6.1 Error Detection

Error detection was classified as a pass or fail. The following addresses the criteria used for each planted error to determine whether a nurse passed or failed this component.
3.6.1.1 Wrong Patient

The nurse passed this component if the nurse detected wrong patient error before the infusion was started. The nurse failed if they did not notice wrong patient error before the infusion was started.

3.6.1.2 Wrong Drug

The nurse passed this component if the nurse detected wrong drug error before the infusion was started. The nurse failed if they did not notice wrong drug error before the infusion was started.

3.6.1.3 Wrong Dose

All medication orders that contained a dose error were clinically inappropriate if not corrected before being administered to the patient. For a dose error, nurses passed if they (a) detected the dose error before hitting the limit and called the physician, or (b) called a physician immediately after hitting the limit. Instances where a nurse violated the hospital’s soft and hard limit policies by modifying the dose prior to or after a soft limit is hit without confirmation from the physician were considered a pass if the dose value was in the soft dose limit range.

The definition of task failure depended on whether the dose error exceeded a soft limit or a hard limit. For the infusion task that contained a dose error that exceeded a soft limit, nurses failed if they (a) overrode the soft limit alert and proceeded with the existing dose value, (b) programmed a generic infusion after the alert was hit, (c) reprogrammed the dose value outside of the soft dose limit range, or (d) required instructions from the nurse actor to understand that a limit was breached. For the infusion task that contained a dose error that exceeded a hard limit, nurses failed if they (a) programmed a generic infusion after the alert was hit, (b) reprogrammed the dose value outside of the soft dose limit range, or (c) required instructions from the nurse actor to understand that a limit was breached. Nurses that entered the parameters into the pump incorrectly such that a limit was not breached were considered incomplete and excluded from the analysis.

3.6.1.4 Error Detection Statistical Analysis

Error detection rates were analyzed using Cochran Q chi-square tests. This statistical method is appropriate because it is used to assess the significance of the differences between 3 or more dichotomous variables. Pair-wise comparisons were analyzed using the McNemar chi-square test. This statistical method was appropriate because it is used to assess the significance of the differences between two dichotomous variables.
3.6.2 Efficiency

Efficiency (task completion time and subtask completion time) was measured for the continuous, intermittent, maintenance, secondary, and drug not in drug library infusions. Overall task completion time was defined as the time it took a user to complete the entire infusion task from start (turn on pump or open the latch to load the set) to finish (infusion is started with line attached to the patient). The programming sequence for each infusion task was also divided into programming subtasks to examine differences in efficiency between smart pump models in specific programming areas. A separate analysis was completed for each infusion task because not every infusion task required the same programming steps.

Time resulting from events unrelated to programming the pump was removed from the data. This included time accumulated from:

- The physical set-up of the infusion (hanging the bag on the IV pole and attaching the line to the patient)
- Resolution of errors not made by the nurse (for example, a broken cassette): Time removed was taken from the moment the error occurred to the moment the error was fixed by the nurse actor.
- Detection of planted error mid programming: The time interval was taken from the moment the nurse detected the error to the moment the error was resolved by the nurse actor. The nurse was instructed to stop programming until the error was resolved.

Data from a nurse was removed from the analysis if the nurse actor provided assistance that required instructions. The primary reason for this decision was that the time interval between the time the problem occurred and the time assistance was received could not be standardized. For instance, if a nurse forgot how to access the generic programming mode, it was difficult to determine the point that the nurse stopped searching for the drug and began looking for the generic programming mode. Data from a nurse was also removed from the analysis if the nurse programmed an infusion in the generic programming mode that was available in the drug library. Data from this event cannot be used because the steps to program an infusion in the generic programming mode is different from the steps to program an infusion in the drug library.

The following reviews the breakdown of each infusion task into programming subtasks and any information unique to the analysis of the infusion task.
3.6.2.1 Continuous Infusion

This task was always performed on the first channel of the dual-channel infusion pumps. The programming sequence was divided into four programming sections, (1) Loading the set, (2) Enter into DERS and select CCA, (3) Select drug name and concentration and (4) Enter parameters and start infusion. Please refer to Table 2 for a breakdown of the programming sequence.

Table 2: Breakdown of programming sequence for the continuous infusion task into programming subtasks for each smart pump model

<table>
<thead>
<tr>
<th>Programming Subtask</th>
<th>Cardinal Alaris System</th>
<th>BBraun Infusomat</th>
<th>Hospira Symbiq</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Load Set</td>
<td>Start: Open latch Stop: Close latch</td>
<td>Start: Press open door button Stop: Press no to prime</td>
<td>Start: Press LOAD/EJECT to open door or time that door begins to open automatically Stop: Close door</td>
</tr>
<tr>
<td>2. Enter into DERS and select CCA</td>
<td>Start: Press ON button or open latch Stop: Select DERS</td>
<td>Start: Press ON button Stop: Select CCA</td>
<td>Start: Press ON button Stop: Select CCA</td>
</tr>
<tr>
<td>3. Select drug name and concentration</td>
<td>Start: Select DERS Stop: Press next to confirm</td>
<td>Start: Select CCA Stop: Select drug name and concentration</td>
<td>Start: Select CCA Stop: Select drug concentration</td>
</tr>
<tr>
<td>4. Enter parameters and start infusion</td>
<td>Start: Press next to confirm Stop: Infusion is started with line attached to patient</td>
<td>Start: Select drug name and concentration Stop: Infusion is started with line attached to patient</td>
<td>Start: Select drug concentration Stop: Infusion is started with line attached to patient</td>
</tr>
</tbody>
</table>

3.6.2.2 Intermittent Infusion

This task was performed on the second channel of the dual-channel infusion pumps. The programming sequence was divided into three programming subtasks, (1) Load the set, (2) Enter DERS, select CCA, select drug name and concentration, and (3) Enter parameters and start infusion. Enter DERS and CCA, and select drug name and concentration were combined into one programming subtask because this infusion task was programmed on the second channel of Cardinal Alaris System and Hospira Symbiq. When programming the second channel, the programming steps change depending on the smart pump model (for instance, Cardinal Alaris System still requires the nurse to select the CCA, whereas Hospira Symbiq does not require the nurse to select the CCA). Furthermore, BBraun Infusomat is a single channel pump, and thus the nurse will always navigate through the same programming sequence. Given the variety of steps in the initial portion of the programming sequence between the smart pump models, the investigator decided to combine the two steps. The difference in the programming sequence between the first and second channel also prevented the continuous and intermittent infusion from being combined into one analysis. Please refer to Table 4 for a breakdown of the programming sequence.
Table 3: Breakdown of programming sequence for the intermittent infusion task into programming subtasks for each smart pump model

<table>
<thead>
<tr>
<th>Programming Subtask</th>
<th>Cardinal Alaris System</th>
<th>BBraun Infusomat</th>
<th>Hospira Symbiq</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Load Set</td>
<td>Start: Open latch</td>
<td>Start: Press open door button Stop: Press no to prime</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Stop: Close latch</td>
<td>Stop: Press LOAD/EJECT to open door or time that door begins to open automatically Stop: Close door</td>
<td></td>
</tr>
<tr>
<td>2. Enter into DERS, select CCA, select drug name and concentration</td>
<td>Start: Channel B or open latch Stop: Press next to confirm drug name and concentration</td>
<td>Start: Press ON button Stop: Select drug name and concentration</td>
<td>Start: Press Tab B or press LOAD/EJECT Stop: Select drug concentration</td>
</tr>
<tr>
<td>3. Enter parameters and start infusion</td>
<td>Start: Press next to confirm Stop: Infusion is started with line attached to patient</td>
<td>Start: Select drug name and concentration Stop: Infusion is started with line attached to patient</td>
<td>Start: Select drug concentration Stop: Infusion is started with line attached to patient</td>
</tr>
</tbody>
</table>

3.6.2.3 Maintenance Fluid

This task was performed on the first channel of the dual-channel infusion pumps. As shown in Table 4, the programming sequence was divided into four programming sections, (1) Loading the set, (2) Enter into DERS and select CCA, (3) Select 0.9% NaCl, and (4) Enter parameters and start infusion.

Table 4: Breakdown of programming sequence for the maintenance infusion task into programming subtasks for each smart pump model

<table>
<thead>
<tr>
<th>Programming Subtask</th>
<th>Cardinal Alaris System</th>
<th>BBraun Infusomat</th>
<th>Hospira Symbiq</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Load Set</td>
<td>Start: Open latch</td>
<td>Start: Press open door button Stop: Press no to prime</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Stop: Close latch</td>
<td>Stop: Press LOAD/EJECT to open door or time that door begins to open automatically Stop: Close door</td>
<td></td>
</tr>
<tr>
<td>2. Enter into DERS and select CCA</td>
<td>Start: Press ON button or open latch Stop: Select DERS</td>
<td>Start: Press ON button Stop: Select CCA</td>
<td>Start: Press ON button Stop: Select CCA</td>
</tr>
<tr>
<td>3. Select 0.9% NaCl</td>
<td>Start: Select DERS Stop: Press next to confirm</td>
<td>Start: Select CCA Stop: Select 0.9% NaCl</td>
<td>Start: Select CCA Stop: Select 0.9% NaCl</td>
</tr>
<tr>
<td>4. Enter parameters and start infusion</td>
<td>Start: Press next to confirm Stop: Infusion is started with line attached to patient</td>
<td>Start: Select drug name and concentration Stop: Infusion is started with line attached to patient</td>
<td>Start: Select drug concentration Stop: Infusion is started with line attached to patient</td>
</tr>
</tbody>
</table>
3.6.2.4 Secondary Infusion

Overall task completion time was measured (please refer to Table 5 for more details). The method in which the nurse started the task varied and thus, the event that was performed first was used as the start time of the task. To take into account time nurses spent thinking about how to program a secondary infusion, time started after the secondary line was set up (with the condition that the nurse was at the smart pump with the intention of programming). If the secondary line was not set-up before programming, time started when the nurse was in front of the pump with the intent of programming. Although the start time was subjective, the investigator felt it was important to include this time because it could be an indication of the accessibility of the secondary function. If the secondary line was set-up mid-programming, the time was removed from overall task completion time.

Table 5: Task completion time start and end points for secondary infusion task for each smart pump model

<table>
<thead>
<tr>
<th>Time to complete task</th>
<th>Cardinal Alaris System</th>
<th>BBraun Infusomat</th>
<th>Hospira Symbiq</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start: Finish set-up of secondary line or select channel or first key press on pump screen Stop: Start infusion with secondary line set-up</td>
<td>Start: Finish set-up of secondary line or press stop to halt primary infusion or first key press on pump screen Stop: Start infusion with secondary line set-up</td>
<td>Start: Finish set-up of secondary line or first key press on pump screen Stop: Start infusion with secondary line set-up</td>
<td></td>
</tr>
</tbody>
</table>

The programming sequence was divided into four programming sections, (1) Enter secondary function, (2) Select drug name and concentration, and (3) Enter parameters and start infusion. Please refer to Table 6 for more details regarding the breakdown of the programming sequence.

Table 6: Breakdown of programming sequence for the secondary infusion task into programming subtasks for each smart pump model

<table>
<thead>
<tr>
<th>Programming Subtask</th>
<th>Cardinal Alaris System</th>
<th>BBraun Infusomat</th>
<th>Hospira Symbiq</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Enter Secondary Function</td>
<td>Start: Finish set-up of secondary line or select channel or first key press on pump screen Stop: Press “Secondary”</td>
<td>Start: Finish set-up of secondary line or press stop to halt primary infusion or first key press on pump screen Stop: Select CCA</td>
<td>Start: Finish set-up of secondary line or first key press on pump screen Stop: Press “Secondary”</td>
</tr>
<tr>
<td>2. Select drug name and concentration</td>
<td>Start: Press “Secondary” Stop: Press Next to confirm drug name and concentration</td>
<td>Start: Select CCA Stop: Select drug name and concentration</td>
<td>Start: Press “Secondary” Stop: Select drug concentration</td>
</tr>
<tr>
<td>3. Enter parameters and start infusion</td>
<td>Start: Press Next to confirm drug name and concentration</td>
<td>Start: Select drug name and concentration</td>
<td>Start: Select drug concentration</td>
</tr>
</tbody>
</table>
3.6.2.5 Drug not in Drug Library Infusion

The programming sequence was divided into four programming subtasks, (1) Load the set, (2) Enter into DERS and select CCA, (3) Look for drug name and concentration, enter generic programming mode, and (4) Enter parameters and start infusion. Please refer to Table 7 for more details regarding the breakdown of the programming sequence.

Table 7: Breakdown of programming sequence for the drug not in drug library infusion task into programming subtasks for each smart pump model

<table>
<thead>
<tr>
<th>Programming Subtask</th>
<th>Cardinal Alaris System</th>
<th>BBraun Infusomat</th>
<th>Hospira Symbiq</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Load Set</td>
<td>Start: Open latch</td>
<td>Start: Press open door button</td>
<td>Start: Press LOAD/EJECT to open door or time that door begins to open automatically</td>
</tr>
<tr>
<td></td>
<td>Stop: Close latch</td>
<td>Stop: Press no to prime</td>
<td>Stop: Close door</td>
</tr>
<tr>
<td>2. Enter into DERS and select CCA</td>
<td>Start: Press ON button or open latch Stop: Select DERS</td>
<td>Start: Press ON button Stop: Select CCA</td>
<td>Start: Press ON button Stop: Select CCA</td>
</tr>
<tr>
<td>3. Look for drug name and concentration. Enter Generic programming mode</td>
<td>Start: Select DERS Stop: Select Basic Infusion</td>
<td>Start: Select CCA Stop: Press “No” to use drug library</td>
<td>Start: Select CCA Stop: Select Other Drug</td>
</tr>
<tr>
<td>4. Enter parameters and start infusion</td>
<td>Start: Select Basic Infusion Stop: Infusion is started with line attached to patient</td>
<td>Start: Press “No” to use drug library Stop: Infusion is started with line attached to patient</td>
<td>Start: Select Other Drug Stop: Infusion is started with line attached to patient</td>
</tr>
</tbody>
</table>

3.6.2.6 Efficiency Statistical Analysis Method

Each infusion task was analyzed separately. Task completion time was analyzed with an ANOVA. Subtask completion time was analyzed using a repeated measures ANOVA.

3.6.3 Success Rate

Infusion task success rate was defined as the proportion of nurses that successfully completed the infusion task. Success rate was examined for the continuous, intermittent, maintenance, secondary, and drug not in drug library infusion tasks. Nurses either passed or failed an infusion task. Nurses passed the infusion task if the infusion was started with the correct parameters selected and entered into the pump as displayed on the medication order. Nurses passed if they needed assistance that only required a hint from
the nurse actor to solve the problem. Nurses failed the infusion task if one or more of the following occurred, (a) infusion was not started, (b) infusion was started with different parameters selected and/or entered into the pump than displayed on the medication order, and (c) needed assistance that required instructions from the nurse actor to solve the problem. Errors unrelated to the programming of the infusion pump, such as a broken IV set or inappropriate physical set-up of lines, were not included in the analysis because the type of errors were not in the scope of the experiment.

Each infusion task was divided into the same programming subtasks as described Section 3.6.2. The same pass and fail criteria used for infusion task success rate was used for programming subtask success rate.

Infusion task success rates were analyzed using a Cochran Q chi-square test. Pair-wise comparisons were analyzed using the McNemar chi-square test. Programming subtask success rates were analyzed using three individual Cochran Q chi-square tests (one for each subtask). Pair-wise comparisons were analyzed using the McNemar chi-square test. A Cochran Q chi-square test was an appropriate statistical method because it is commonly used to assess the significance of the differences between 3 or more dichotomous variables. McNemar chi-square test was an appropriate statistical method because it is commonly used to assess the significance of the differences between two dichotomous variables.

3.6.4 Deviations

Deviations were examined in this study to assess and compare the intuitiveness of the programming sequence across the smart pump models. The optimal programming sequence was mapped out for each programming task. Each infusion task was divided into the same programming subtasks as described in Section 3.6.2. If the nurse moved away from the optimal programming sequence in the programming subtask it was counted as a deviation, regardless of whether or not the nurse successfully recovered from the deviation. Events such as checking the medication order, or asking the nurse actor for clarification or hint were not considered deviations because the nurse still advanced in the programming sequence. Deviations unrelated to the programming of the infusion pump were not included. These events included,

- The detection of patient or drug name error mid programming
- Deviations caused by the test instructors (e.g. in one scenario the nurse actor forgot to give a paper order to the nurse)
- Broken IV set
• Deviations from occlusion alarms that resulted from a closed roller clamp: At the time of the experiment, Hospira Symbiq had a software bug where an IV set alarm would appear if the roller clamp was closed when the set was loaded. To avoid this event, roller clamps were left opened for Hospira Symbiq. However, the roller clamp on Cardinal Alaris System and BBraun Infusomat IV sets were closed because the lines would leak. Thus, to prevent an unfair advantage if the user forgot to open the roller clamp before starting the infusion, all deviations resulting from occlusion alarms were removed.

A deviation was placed in the subtask that it occurred in. For instance, if a nurse could not find a drug that was available in the drug list and proceeded to program a generic infusion, the deviation would fall under “Select drug name and Concentration” not “Enter DERS and CCA”.

A Cochran Q was used to assess the interaction between the percentage of nurses that deviated in each intermittent infusion subtask and pump type. Specifically, individual Cochran Q tests were done for each programming subtask in each infusion task. Each analysis was followed by a series of pair-wise comparisons using the McNemar chi-square test. These statistical methods were appropriate because the data analyzed was dichotomous.

3.6.5 Parameter Entry

To understand how the design of the parameter entry screen influenced the choice in parameters nurses used to start the infusion, the parameters the nurses chose to enter into the pump were examined.

Two analyses were completed for each infusion task:

(a) First parameter the nurse entered: This analysis was completed to examine the initial response of the nurse to the parameter entry screen and determine if the parameter entry screen can motivate a nurse to enter a particular parameter. The first parameter the nurse entered or attempted to enter was recorded (dose-rate, rate or duration). Entering VTBI was excluded because all nurses entered VTBI as one of their parameters.

(b) The final parameter used to start the infusion: This analysis was completed to determine if the design of the parameter entry screen affected the parameter the nurse used to start the infusion (dose-rate, rate or duration). Entering VTBI was excluded because all nurses entered VTBI as one of their parameters.

A Cochran Q was used to determine if there was a difference between the parameter type nurses entered and pump type. Specifically, three individual Cochran Q tests were used for each pump type.
Each analysis was followed by a series of pair-wise comparisons using a McNemar chi-square test. These statistical methods were appropriate because the data analyzed was dichotomous.

### 3.6.6 User Errors

The occurrence of user errors was analyzed to determine if the type and frequency of errors differed between smart pump models. The following types of errors were examined,

- **Calculation Errors**: occurred when the incorrect dose-rate, rate or duration entry resulted of a calculation error.
- **Unit Errors**: occurred when the incorrect dose, rate or duration entry resulted from a unit mix-up. For instance, the nurse put the dose in the dose-rate field.
- **Parameter Selection Errors**: occurred when the nurse selected the wrong item in the menu (such as selecting the wrong drug name or concentration).
- **Transcription Errors**: occurred when the incorrect dose-rate, rate or duration entry resulted from an error when copying the value from the medication order (such as entering the wrong duration even though the value is presented on the medication order and/or IV bag label).

A nurse recovered from an error if the error was detected and successfully remedied without receiving instructions from the Nurse Actor before the infusion was started. A nurse did not successfully recover from an error if the error was not detected and/or successfully remedied without instructions from the Nurse Actor. Errors that originated from a preceding error were excluded if the error was a direct result of the preceding error. For instance, if the nurse entered the dose in the dose-rate field and as a result the volume automatically changed to an incorrect value, it was classified as a unit error not a transcription error. User errors were analyzed using an ANOVA.

### 3.6.7 Survey Results

Data obtained from survey questions that were similar to a 5-point Likert Scale (Strongly Disagree – Disagree – Neutral – Agree – Strongly Agree) where treated as ordinal because it cannot be assumed that the choices on the Likert Scale are evenly spaced apart. Based on this assumption, the Friedman test was used to assess the significance of the differences between the three smart pump models, and the Wilcoxon test was used for pair-wise comparisons. Survey questions that asked the nurse to rank the order of the smart pump models were treated as ordinal-order data. The Friedman test was used to assess whether the rank orders differ across the different smart pump models. Pair-wise comparisons were completed using Wilcoxon tests.
4. RESULTS

The results section is presented in the following format:

a) Sections 4.1 – 4.5: Results from performance measure analyses are presented for each infusion task (continuous, intermittent, drug not in drug library, maintenance, and secondary infusion tasks).

b) Section 4.6: Results regarding the detection of dose errors that breach either a soft or hard limit are presented

c) Section 4.7: Results regarding the occurrence of user errors are presented

d) Section 4.8 – 4.9: Results from the detection of wrong patient and wrong drug are presented.

e) Section 4.10: Results from the Inter Rater Reliability analysis are presented.

4.1 CONTINUOUS INFUSION TASK

4.1.1 Efficiency

Task Completion Time: There was significant difference in the continuous infusion task completion time across the three pump types, $F(2,34) = 3.16$, $p < .05$. As shown in Figure 1, nurses took significantly more time to complete the continuous infusion task when using BBraun Infusomat ($M =167.72$, $SD = 9.30$) than when using Cardinal Alaris System ($M =127.72$, $SD = 8.95$). There were no other significant differences across the pump types.
Subtask Completion Time: Continuous infusion subtask completion time was measured using a 4 (programming subtask: 1. Load Set, 2. Turn on pump. Enter DERS and CCA, 3. Select drug name and concentration, 4. Enter parameters and start infusion) x 3 (pump type: 1. Cardinal Alaris System, 2. BBraun Infusomat, 3. Hospira Symbiq) repeated measures ANOVA design. Each analysis was followed by a series of pair-wise comparisons. All tests were conducted using Bonferroni adjusted alpha levels (0.05/12). As shown in Figure 2, there was significant interaction between subtask and pump type, $F(6,102) = 14.73, p < .001$. Results indicated that nurses took a significantly greater amount of time to load an IV set when using BBraun Infusomat ($M = 65.34, SD = 5.43$), than when using Cardinal Alaris System ($M = 19.67, SD = 2.61$) or Hospira Symbiq ($M = 10.17, SD = 1.20$). Additionally, nurses took significantly more time to load an IV set when using Cardinal Alaris System than when using Hospira Symbiq. During the subtask “Turn on pump, enter DERS and CCA”, nurses took significantly more time when using Hospira Symbiq ($M = 49.28, SD = 5.4$), than when using BBraun Infusomat ($M = 29.06, SD = 2.07$). There were no other significant interactions between subtask and pump type.

Figure 1: Mean task completion time and standard deviation for Cardinal Alaris System, BBraun Infusomat, and Hospira Symbiq when programming a continuous infusion (n = 18)
4.1.2 Success Rate

Task success rate: There was no significant difference in continuous infusion task success rate across the three pump types, Cochran Q = 6; df = 2; p > 0.05. Please refer to Figure 48 in Appendix D for further information regarding the results of this analysis.

Subtask success rate: A Cochran Q was used to determine if there was a difference between programming subtask success rate and pump type. Specifically, four individual Cochran Q tests were done for each programming subtask. Each analysis was followed by a series of pair-wise comparisons. All tests were conducted using Bonferroni adjusted alpha levels (0.05/3). There was no significant difference across the tests (p > .05). Please refer to Figure 49 in Appendix D for more information regarding the results of this analysis.

4.1.3 Deviations

A Cochran Q was used to determine if there was a difference between the percentage of nurses that deviated in each intermittent infusion subtask and pump type. Specifically, four individual Cochran Q tests were done for each programming subtask. Each analysis was followed by a series of pair-wise
comparisons. All tests were conducted using Bonferroni adjusted alpha levels (.05/3). There was a significant difference in the percentage of nurses that deviated in the subtask “Load the IV set” across the pumps, Cochran Q = 6.5; df = 2; \( p < .05 \). However, pair-wise comparisons were not significant using the correction factor. Without an adjustment to the p-value, the percentage of nurses that deviated when using BBraun Infusomat (42%) was significantly higher than when using Cardinal Alaris System (13%). There was a significant difference in the percentage of nurses that deviated in the subtask “Enter DERS and CCA” across the pumps, Cochran Q = 6.5; df = 2; \( p < .05 \). However, pair-wise comparisons were not significant using the correction factor. Without an adjustment to the p-value, the percentage of nurses that deviated when using Hospira Symbiq (42%) was significantly higher than when using BBraun Infusomat (8%). There was a significant difference in the percentage of nurses that deviated in the subtask “Select drug name and concentration” across the pumps, Cochran Q = 6.5; df = 2; \( p = .05 \). However, pair-wise comparisons were not significant using the correction factor. Please refer to Figure 50 in Appendix D for more information regarding the results of this analysis.

4.2 INTERMITTENT INFUSION TASK

4.2.1 Efficiency

Task Completion Time: There was significant difference in the intermittent infusion task completion time across the three pump types, \( F(2,28) = 5.35, p < .05 \). As shown in Figure 3, nurses took significantly more time when using BBraun Infusomat (\( M = 206.53, SD = 36.25 \)) than when using Hospira Symbiq (\( M = 95.00, SD = 11.08 \)). There were no other significant differences across the pump types.
Subtask Completion Time: Intermittent infusion subtask completion time was measured using a 3 (programming subtask: 1. Load Set, 2. Select DERS, CCA, Drug name and concentration, 3. Enter parameters and start infusion) x 3 (pump type: 1. Cardinal Alaris System, 2. BBraun Infusomat, 3. Hospira Symbiq) repeated measures ANOVA design. This analysis was followed by a series of pair-wise comparisons. All tests were conducted using Bonferroni adjusted alpha levels (.05/9). There was significant interaction between programming subtask and pump type, \( F(4,56) = 5.21, \ p < .002 \). As shown in Figure 4, nurses took significantly longer to load the IV set when using BBraun Infusomat (\( M = 59.20, \ SD = 2.82 \)), than when using Cardinal Alaris System (\( M = 22.00, \ SD = 3.02 \)) or Hospira Symbiq (\( M = 9.67, \ SD = 1.02 \)). Additionally, nurses took a significantly greater amount of time to load the IV set when using Cardinal Alaris System than when using Hospira Symbiq. Nurses also took significantly more time to navigate through the programming subtask “Enter DERS and CCA” when using BBraun Infusomat (\( M = 60.00, \ SD = 4.08 \)), than when using Cardinal Alaris System (\( M = 36.60, \ SD = 4.05 \)). There were no other significant differences between programming subtasks and pump type.
4.2.2 Success Rate

Task Success Rate: There was significant difference in intermittent infusion task success rate across the three pump types, Cochran Q = 6; df = 2; \( p = .05 \). However, pair-wise comparisons were non-significant using the Bonferroni adjusted alpha level (.05/3). Without an adjustment to the \( p \)-value, nurses were found to have a significantly higher success rate when using Cardinal Alaris System (92%) than when using BBraun Infusomat (63%). Please refer to Figure 51 in Appendix D for additional information regarding the results of this analysis.

Subtask Success Rate: A Cochran Q was used to determine if there was a significant difference between programming subtask success rate and pump type. Specifically, three individual Cochran Q test were done for each programming subtask. Each analysis was followed by a series of pair-wise comparisons. All tests were conducted using Bonferroni adjusted alpha levels (.05/3). As shown in Figure 5, nurses had a significantly higher success rate when using Cardinal Alaris System (96%) than when using Hospira Symbiq (67%). There were no other significant differences between programming subtask success rate and pump type.
4.2.3 Parameter Entry

A Cochran Q was used to determine if there was a significant difference between the parameter type that nurses chose to enter to start the infusion and pump type. Specifically, three individual Cochran Q tests were used for each pump type. Each analysis was followed by a series of pair-wise comparisons. All tests were conducted using Bonferroni adjusted alpha levels (.05/3). There was significant difference in the parameter type nurses chose to enter when using Cardinal Alaris System, Cochran Q = 30; df = 2; \( p < .001 \). Specifically, when programming Cardinal Alaris System nurses were more likely to enter duration (92 %) than dose-rate (0 %) or rate (8 %) to start the infusion. There was also significant difference in the parameter type that nurses chose to enter when using BBraun Infusomat, Cochran Q = 37; df = 2; \( p < .001 \). Specifically, nurses were more likely to enter either duration (83 %) than dose-rate (4 %) or rate (12 %) to start the infusion. There was significant difference in the parameter type that nurses chose to enter when using Hospira Symbiq, Cochran Q = 21; df = 2; \( p < .001 \). Specifically, nurses were more likely to enter duration (75 %) than dose-rate (8 %) or rate (12 %) to start the infusion. Please refer to Figure 52 in Appendix D for more information regarding results from this analysis, and Figure 53 in Appendix D for results from the first parameter entered analysis.
4.2.4 Deviations

A Cochran Q was used to determine if there was a significant difference between the percentage of nurses that deviated in each intermittent infusion subtask and pump type. Specifically, three individual Cochran Q tests were done for each programming subtask. Each analysis was followed by a series of pairwise comparisons. All tests were conducted using Bonferroni adjusted alpha levels (.05/3). There was a significant difference in the percentage of nurses that deviated when loading the IV set across the pumps, Cochran Q = 7; df = 2; \( p < .05 \). Specifically, the nurses tended to deviate more when using BBraun Infusomat (33%) than when using Hospira Symbiq (4%). There were no other significant differences in this programming subtask across the pumps. There was a significant difference in the percentage of nurses that deviated when entering parameters across the pumps, Cochran Q = 13; df = 2; \( p < .002 \). Specifically, when entering parameters the percentage of nurses that deviated when using Hospira Symbiq (92%) was significantly higher than when using Cardinal Alaris System (21%). There were no other significant differences in this programming subtask across the pumps. Furthermore, there were no other significant differences in the percentage of nurses that deviated in the remaining subtasks. Please refer to Figure 6 for more information regarding the results of this analysis.

**Figure 6:** Percentage of nurses that deviated in the intermittent infusion subtasks when using Cardinal Alaris System, BBraun Infusomat, and Hospira Symbiq (N=24)
4.3 Drug Not in Drug Library Infusion Task

4.3.1 Efficiency

Task Completion Time: There was no significant difference in drug not in drug library infusion task completion time across the three pump types, $F(2,18) = 1.18, p > .05$. Please refer to Figure 54 in the Appendix D for additional information regarding the results of this analysis.

Subtask Completion Time: Drug not in drug library subtask completion time was measured using a 4 (programming subtask: 1. Load Set, 2. Enter DERS and CCA, 3. Look for drug name. Enter generic, 4. Enter parameters and start infusion) x 3 (pump type: Cardinal Alaris System, BBraun Infusomat, Hospira Symbiq) repeated measures ANOVA design. Each analysis was followed by a series of pair-wise comparisons. All tests were conducted using Bonferroni adjusted alpha levels (.05/12). As shown in Figure 7, there was significant interaction between programming subtask and pump type, $F(6,48) = 13.84, p < .001$. Nurses took a significantly greater amount of time to load an IV set when BBraun Infusomat ($M = 63.67, SD = 6.75$), than when using Cardinal Alaris System ($M = 18.22, SD = 2.23$) or Hospira Symbiq ($M = 8.78, SD = 1.02$). Although there was no significant difference between Hospira Symbiq and Cardinal Alaris System when loading the IV set, the difference approached significance ($p = .006$). Nurses took a significantly greater amount of time to enter the parameters into the pump when using Hospira Symbiq ($M = 117.11, SD = 16.13$) than when using Cardinal Alaris System ($M = 65.89, SD = 15.96$). There were no other significant differences entering parameters across the pumps. Furthermore, there were no other significant differences between programming subtask completion time across the pumps.
4.3.2 Success Rate

Task Success Rate: There was no significant difference in drug not in drug library infusion task success rate across the three pump types, Cochran Q = 2; df = 2; \( p > .05 \). Please refer to Figure 55 in Appendix D for additional information regarding the results of this analysis.

Subtask Success Rate: A Cochran Q was used to determine if there was a significant difference between programming subtask success rate and pump type. Specifically, four individual Cochran Q tests were done for each programming subtask. Each analysis was followed by a series of pair-wise comparisons. All tests were conducted using Bonferroni adjusted alpha levels (.05/3). There was significant interaction between the subtask “Looking for drug name, enter generic” and pump type, Cochran Q = 15; df = 2; \( p < .001 \). As shown in Figure 8, there was a significantly higher success rate when using Hospira Symbiq (100%) than when using BBraun Infusomat (58%). There were no other significant differences in this subtask across the pumps. Furthermore, there were no other significant differences between subtasks across the pumps.
4.3.3 Parameter Entry

A Cochran Q was used to determine if there was a significant difference between the parameter type that nurses chose to enter to start the infusion and pump type. Specifically, four individual Cochran Q tests were done for each pump type. Each analysis was followed by a series of pair-wise comparisons. All tests were conducted using Bonferroni adjusted alpha levels (.05/3). There was significant difference in the parameter type nurses chose to enter when using Cardinal Alaris System, Cochran Q = 28; df =2; \(p < .001\). Specifically, when programming Cardinal Alaris System nurses were more likely to enter rate (83\%) than duration (17\%) to start the infusion. A significant difference was also found in the parameter type that nurses chose to enter when using BBraun Infusomat, Cochran Q = 16; df = 2; \(p < .001\). Specifically, nurses were more likely to enter either duration (66\%) than dose-rate (0\%), and rate (33\%) than dose-rate to start the infusion. There were no other significant differences between parameter type across the three pumps. Please refer to Figures 56 and 57 in Appendix D for additional information regarding the results of this analysis and the first parameter entry analysis.

4.3.4 Deviations

A Cochran Q was used to determine if there was a significant difference between the percentage of nurses that deviated in each drug not in drug library infusion programming subtask and pump type.
Specifically, four individual Cochran Q tests were done for each programming subtask. Each analysis was followed by a series of pair-wise comparisons. All tests were conducted using Bonferroni adjusted alpha levels (.05/3). There was a significant difference in the percentage of nurses that deviated in the “Enter DERS and CCA” subtask across the pumps, Cochran Q = 7; df = 2; \( p < .05 \). Specifically, the percentage of nurses that deviated was significantly higher when using Hospira Symbiq (33\%) than when using BBraun Infusomat (4\%). There were no other significant differences in this subtask across the pumps.

There was also a significant difference in the percentage of nurses that deviated when entering parameters across the pumps, Cochran Q = 15; df = 2; \( p < .05 \). Specifically, the percentage of nurses that deviated was significantly higher when using Hospira Symbiq (92\%) than when using BBraun Infusomat (33\%). There were no other significant differences in this subtask across the pumps. Furthermore, there were no other significant differences in subtasks across the pumps. Please refer to Figure 9 for further information regarding the results of this analysis.

Figure 9: Percentage of nurses that deviated in each programming subtask for the drug not in drug library infusion task when using Cardinal Alaris System, BBraun Infusomat and Hospira Symbiq (N=24)
4.4 MAINTENANCE INFUSION TASK

4.4.1 Efficiency

Task Completion Time: There was no significant difference in maintenance infusion task completion time across the three pump types, $F(2,30) = 16.68, p > .05$. Please refer to Figure 58 in Appendix D for additional information regarding the results of this analysis.

Subtask Completion Time: Maintenance infusion subtask completion time was measured using a 4 (programming subtask: 1. Load Set, 2. Turn on pump select DERS and CCA, 3. Select drug name and concentration, 4. Enter parameters start infusion) x 3 (pump type: 1. Cardinal Alaris System, 2. BBraun Infusomat, 3. Hospira Symbiq) repeated measures ANOVA design. Each analysis was followed by a series of pair-wise comparisons. All tests were conducted using Bonferroni adjusted alpha levels (.05/12). There was significant interaction between programming subtask and pump type $F(6,84) = 17.15, p < .001$. Results indicated that the average time to load an IV set was significantly greater when using BBraun Infusomat ($M = 76.53, SD = 7.46$), than when using Cardinal Alaris System ($M = 25.87, SD = 3.70$) or Hospira Symbiq ($M = 8.27, SD = 0.90$). Additionally, nurses took significantly more time to load an IV set when using Cardinal Alaris System than when using Hospira Symbiq. When entering parameters into the pump, nurses took a significantly greater amount of time when using Hospira Symbiq ($M = 30.07, SD = 3.17$) than when using Cardinal Alaris System ($M = 18.33, SD = 2.06$). Furthermore, the difference in completion time between Cardinal Alaris System and BBraun Infusomat ($M = 27.60, SD = 2.4$) when entering parameters approached significance. There were no other significant differences in this subtask across the pumps. Furthermore, there were no other significant differences in the subtasks across the pumps. Please refer to Figure 10 for more information regarding the results of this analysis.
4.4.2 Success Rate

**Task Success Rate:** There was significant difference in maintenance infusion task success rate across the three pump types, Cochran Q = 7; df = 2; \( p < .05 \). However, pair-wise comparisons were non-significant using the Bonferroni adjusted alpha level (.05/3). Without an adjustment to the \( p \)-value, nurses were found to have a significantly higher success rate when using Hospira Symbiq (100%) than when using Cardinal Alaris System (75%). Please refer to Appendix D, Figure 59 for more information regarding the results of this analysis.

**Subtask Success Rate:** A Cochran Q was used to determine if there was a significant difference between programming subtask success rate and pump type. Specifically, four individual Cochran Q tests were done for each programming subtask. Each analysis was followed by a series of pair-wise comparisons. All tests were conducted using Bonferroni adjusted alpha levels (.05/3). There was a significant difference in subtask “Enter DERS and CCA” success rate across the pumps, Cochran Q = 4; df = 2; \( p < .05 \). Pair-wise comparisons were non-significant with the correction factor. However, without an adjustment to the \( p \)-value, nurses were found to have a significantly higher success rate when using
Hospira Symbiq (100%) than when using Cardinal Alaris System (75%). Please refer to Figure 60 in Appendix D for more information regarding the results of this analysis.

4.4.3 Deviations

A Cochran Q was used to determine if there was a significant difference between the percentage of nurses that deviated in each intermittent infusion subtask and pump type. Specifically, four individual Cochran Q tests were done for each programming subtask. Each analysis was followed by a series of pair-wise comparisons. All tests were conducted using Bonferroni adjusted alpha levels (.05/3). There was significant difference between the percentage of nurses that deviated when loading the IV set and pump type, Cochran Q = 7; df = 2; \( p < .05 \), however pair-wise comparisons were not significant using the correction factor. Without an adjustment to the p-value, nurses were found to deviate more when using BBraun Infusomat (42%) than when using Hospira Symbiq (13%) or Cardinal Alaris System (13%). There was also a significant difference between the percentage of nurses that deviated when entering parameters and pump type, Cochran Q = 7; df = 2; \( p < .05 \), however pair-wise comparisons were not significant using the correction factor. Without an adjustment to the p-value, nurses were found to deviate more when using Hospira Symbiq (38%) than when using Cardinal Alaris System (8%). Please refer to Figure 61 in Appendix D for further information regarding the results of this analysis.

4.5 SECONDARY INFUSION TASK

4.5.1 Efficiency

Task Completion Time: There was significant difference in secondary infusion task completion time across the three pump types, \( F(2,20) = 7.72, \ p < .05 \). As shown in Figure 11, nurses took a significantly longer time to program BBraun Infusomat (\( M = 133.55, SD = 14.34 \)) than to program Cardinal Alaris System (\( M = 78.45, SD = 9.88 \)). There were no other significant differences in task completion time across the pumps.
Subtask Completion Time: Secondary infusion subtask completion time was measured using a 3 (programming subtask: 1. Enter secondary feature, 2. Select drug name and concentration, 3. Enter parameters and start infusion) x 3 (pump type: 1. Cardinal Alaris System, 2. BBraun Infusomat, 3. Hospira Symbiq) repeated measures ANOVA design. Each analysis was followed by a series of pair-wise comparisons. All tests were conducted using Bonferroni adjusted alpha levels (.05/9). There was significant interaction between enter secondary feature subtask completion time and pump type $F(4,40) = 3.416, p < .005$, however pair-wise comparisons were non-significant using the correction factor. Without an adjustment to the p-value, nurses were found to take significantly more time to enter the secondary feature when using BBraun Infusomat ($M = 50.82, SD = 5.17$) than when using Hospira Symbiq ($M = 12.09, SD = 3.42$). Without an adjustment to the p-value, nurses were found to take significantly more time to enter the parameters when using Hospira Symbiq ($M = 59.18, SD = 9.13$) than when using Cardinal Alaris System ($M = 25.36, SD = 5.48$). There were no other significant differences across the smart pump models. Please refer to Figure 62 in Appendix D for more information regarding the results of this analysis.

4.5.2 Success Rate

Task Success Rate: There was significant difference in intermittent infusion task success rate across the three pump types, Cochran $Q = 6; df = 2; p = .05$. However, pair-wise comparisons were non-significant using the correction factor. Without an adjustment to the p-value, nurses had a significantly
higher success rate when using Cardinal Alaris System (82%) than when using BBraun Infusomat (50%). Please refer to Figure 63 in Appendix D for more information regarding the results of this analysis.

Subtask Success Rate: A Cochran Q was used to determine if there was a significant difference between programming subtask success rate and pump type. Specifically, three individual Cochran Q tests were done for each programming subtask. Each analysis was followed by a series of pair-wise comparisons. All tests were conducted using Bonferroni adjusted alpha levels (.05/3). There was a significant difference in subtask success rate when entering the secondary feature across the pumps, Cochran Q = 15; df = 2; p < .001. Results indicated that nurses had a significantly higher success rate entering the secondary feature when using Hospira Symbiq (100%) than when using BBraun Infusomat (58%). There were no other significant differences when entering the secondary feature across the pumps. The difference in success rate when entering parameters across the pumps approached significance, Q = 5; df = 2; p < .06. Pair-wise comparisons indicated that nurses had a significantly higher success rate entering parameters when using Cardinal Alaris System (96%) than when using Hospira Symbiq (63%). There were no other significant differences when entering parameters across the pumps. Furthermore, there were no significant differences between programming subtask success rate across the pumps. Please refer to Figure 12 for further information regarding the results of this analysis.

Figure 12: Percentage of nurses that successfully completed the secondary infusion subtasks when using Cardinal Alaris System, BBraun Infusomat, and Hospira Symbiq (N=24)
4.5.3 Parameter Entry

A Cochran Q was used to determine if there was a significant difference between the parameter type that nurses chose to enter to start the infusion and pump type. Specifically, three individual Cochran Q tests were used for each pump type. Each analysis was followed by a series of pair-wise comparisons. All tests were conducted using Bonferroni adjusted alpha levels (.05/3). There was significant difference in the parameter type nurses chose to enter when using Cardinal Alaris System, Cochran Q = 42; df = 48; \( p < .001 \). Specifically, when programming Cardinal Alaris System nurses were more likely to enter duration (100%) than rate (0%) to start the infusion. There was also significant difference in the parameter type nurses chose to enter when using BBraun Infusomat, Cochran Q = 16; df = 2; \( p < .001 \). Specifically, when programming BBraun Infusomat nurses were more likely to enter duration (71%) than dose-rate (4%) to start the infusion. There was significant difference in the parameter type nurses chose to enter when using Hospira Symbiq, Cochran Q = 22; df = 2; \( p < .001 \). Specifically, nurses were more likely to enter duration (79%) than dose rate (13%) or rate (8%) to start the infusion. There were no other significant differences in the parameter type nurses chose to enter for each pump type. Please refer to Figure 63 in Appendix D for more information regarding this analysis, and Figure 64 in Appendix D for information regarding the first parameter entered analysis.

4.5.4 Deviations

A Cochran Q was used to determine if there was a significant difference between the percentage of nurses that deviated in each secondary infusion subtask and pump type. Specifically, three individual Cochran Qs were done for each programming subtask. Each analysis was followed by a series of pair-wise comparisons. All tests were conducted using Bonferroni adjusted alpha levels (.05/3). There was a significant difference in the percentage of nurses that deviated when entering the secondary feature across the pumps, Cochran Q = 7; df = 2; \( p < 0.05 \). However, pair-wise comparisons were non-significant using the correction factor. Without an adjustment to the p-value, nurses were found to deviate more when using BBraun Infusomat (51%) than when using Hospira Symbiq (21%). There was also a significant difference in the percentage of nurses that deviated when entering parameters across the pumps, Cochran Q = 7; df = 2; \( p < .05 \). As shown in Figure 13, nurses deviated more when using Hospira Symbiq (71%) than when using Cardinal Alaris System (29%).
There was significant difference in the effectiveness of the soft limit alert across the three pumps, Cochran $Q = 15; df = 2; p < .001$. As shown in Figure 14, nurses had a significantly lower success rate when using BBraun Infusomat (50%), than when using Cardinal Alaris System (96%) or Hospira Symbiq (83%). There were no other significant differences across the pumps.

**Figure 13:** Percentage of nurses that deviated during the secondary infusion subtasks for Cardinal Alaris System, BBraun Infusomat and Hospira Symbiq (N=24)

### 4.6 Limit Alert Messages

There was significant difference in the effectiveness of the soft limit alert across the three pumps, Cochran $Q = 15; df = 2; p < .001$. As shown in Figure 14, nurses had a significantly lower success rate when using BBraun Infusomat (50%), than when using Cardinal Alaris System (96%) or Hospira Symbiq (83%). There were no other significant differences across the pumps.
There was no significant difference in the effectiveness of the hard limit alert across the three pumps. Please refer to Figure 66 in Appendix D for more information regarding the result of this analysis.

### 4.7 User Errors

Percentage of user errors were measured using a 4 (error type: 1. unit, 2. parameter selection, 3. calculation, 4. transcription) x 3 (pump type: 1. Cardinal Alaris System, 2. BBraun Infusomat, 3. Hospira Symbiq) repeated measures ANOVA design. This analysis was followed by a series of pair-wise comparisons. Tests were conducted using Bonferroni adjusted alpha levels (.05/12). As shown in Figure 15, there was significant interaction between error type and pump type $F(6,138) = 5.47, p < .001$. Specifically, nurses made significantly more unit errors when using the Hospira Symbiq (22%) than when using the Cardinal Alaris System (0%). There were no other significant differences in the percentage of unit errors made across the pumps. Furthermore, there were no significant differences between the percentage of parameter selection and calculation errors across the pumps.
The percentage of user errors that resulted in task failure were measured using a 4 (error type: 1. unit, 2. parameter selection, 3. calculation, 4. transcription) x 3 (pump type: 1. Cardinal Alaris System, 2. BBraun Infusomat, 3. Hospira Symbiq) repeated measures ANOVA design. This analysis was followed by a series of pair-wise comparisons. Tests were conducted using Bonferroni adjusted alpha levels (0.05/12). As shown in Figure 16, there was significant interaction between error type and pump type $F(6,138) = 4.17, p < .001$. Specifically, nurses made significantly more unit errors that resulted in task failure when using Hospira Symbiq (12%) than when using the Cardinal Alaris System (0%). There were no other significant differences in the percentage of unit errors that resulted in task failure across the pumps. Furthermore, there were no significant differences between the percentage of parameter selection and calculation errors across the pumps.
There was no significant difference in wrong drug detection rate across the three pumps, Cochran $Q = 0; df = 2; p > .05$. Please refer to Figure 67 in Appendix D for more information regarding the result of this analysis.

4.9 Wrong Patient Detection

There was no significant difference in wrong patient detection rate across the three pumps, Cochran $Q = 0.12; df = 2; p > .05$. Please refer to Figure 68 in Appendix D for more information regarding the result of this analysis.
4.10 INTER RATER RELIABILITY

To determine the degree of agreement among raters for qualitative coding scheme used to measure error detection, success rate, percentage of nurses that deviated, parameter entry, and user errors, a second reviewer reviewed the video and audio taped sessions of two participants. The second reviewer was provided with instructions for each coding scheme (please refer to Section 3.6 for more information). The results from the second reviewer were then compared against the results from the first reviewer (as shown in Table 8). Quantitative data was not used in this analysis because the first reviewer obtained timestamps from video footage and thus, there would be little disagreement between reviewers. Please refer to Table 22 in Appendix D For further information regarding the events where the two raters disagreed, and how each event was resolved.

Table 8: Degree of agreement among two raters for qualitative coding schemes used to measure error detection, success rate, percentage of nurses that deviated, parameter entry and user errors.

<table>
<thead>
<tr>
<th></th>
<th>Number of possible agreements</th>
<th>Number of agreements between raters</th>
<th>Percent Agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Error Detection</td>
<td>24</td>
<td>24</td>
<td>100%</td>
</tr>
<tr>
<td>Infusion Task Success Rate</td>
<td>30</td>
<td>30</td>
<td>100%</td>
</tr>
<tr>
<td>Infusion Subtask Success Rate</td>
<td>108</td>
<td>107</td>
<td>99%</td>
</tr>
<tr>
<td>Deviations in Infusion Subtask</td>
<td>108</td>
<td>98</td>
<td>91%</td>
</tr>
<tr>
<td>Occurrence of user errors</td>
<td>84</td>
<td>81</td>
<td>96%</td>
</tr>
<tr>
<td>Occurrence of user errors</td>
<td>84</td>
<td>83</td>
<td>99%</td>
</tr>
<tr>
<td>Parameter Order Entry</td>
<td>60</td>
<td>57</td>
<td>95%</td>
</tr>
</tbody>
</table>
5.0 DISCUSSION

The Discussion is broken down into several components. Section 5.1 discusses overall task performance across the smart pump models. To gain a deeper understanding of how the design elements in DERS affect the ability of nurses to safely and efficiently program an infusion, the general programming sequence is divided into subtasks, and examined in Section 5.2. Sections 5.3 – 5.4 discuss the design elements in programming subtasks that are outside of the general programming sequence such as entering the secondary infusion feature or generic programming mode. Sections 5.5 – 5.7 discuss how the design of DERS affect the ability of nurses to detect planted errors (specifically, dose, patient and drug error), and influence the type and occurrence of errors nurses make. Section 5.8 examines nursing perception of the smart pump models, and compares nursing perception to nursing performance. Section 5.9 addresses the limitations of study. In Section 5.10 the validation of the hypotheses are discussed. Finally, Sections 5.11 and 5.12 discuss future work and how results from this study can be used in the health care.

5.1 INFUSION TASKS: OVERALL PERFORMANCE

5.1.1 Task completion time

There were significant differences in task completion time between smart pump models. Nurses took a significantly longer time to program a continuous infusion when using BBraun Infusomat than when using Cardinal Alaris System (see Figure 1). This was likely due to an accumulated effect of specific programming subtasks that required a greater amount of time to navigate through when using BBraun Infusomat than when using Cardinal Alaris (such as loading the IV set and entering the parameters (see Figure 4.2). Although Hospira Symbiq had a similar average task completion time to BBraun Infusomat, it was not found to be significantly different from Cardinal Alaris System. It is hypothesized that with a large sample size a difference would have been found between Hospira Symbiq and Cardinal Alaris System. Nurses also took a significantly longer time to program a secondary infusion when using BBraun Infusomat than when using Cardinal Alaris System (see Figure 11). This was likely due to the large amount of time nurses spent looking the secondary infusion feature, and entering the
parameters subtasks when using BBraun Infusomat compared to Cardinal Alaris System (see Figure 63). Nurses also took significantly more time to complete the intermittent infusion task when using BBraun Infusion than when using Hospira Symbiq (see Figure 3). It is expected that this difference occurred because (a) BBraun Infusomat is a single-channel pump and thus programming steps that are bypassed when using a dual-channel pump do not exist, and (b) nurses had difficulties loading the IV set when using BBraun Infusomat.

5.1.2 Task success rate

There were no significant differences in task success rate across the smart pump models for all infusion tasks when the bonferroni correction factor was used. However, without an adjustment to the p-value, significant differences were found. When programming the secondary infusion, nurses had a significantly higher success rate when using Cardinal Alaris System than when using BBraun Infusomat (see Figure 63). This was likely due to the higher failure rate when entering the secondary feature and parameters using BBraun Infusomat compared to Cardinal Alaris System. When programming the maintenance fluid, nurses had a significantly higher success rate when using Hospira Symbiq than when using Cardinal Alaris System (see Figure 59). This was due to the lack of distinction between Cardinal Alaris System’s multiple drug libraries (as discussed in Section 5.2.2.2).

It should be noted that the majority of task failures across the smart pump models were due to usability issues and would have not resulted in patient harm.

5.2 Subtask Usability

In this section, the general programming sequence is broken down into programming subtasks. Each programming subtask is examined to better understand how the design of the DERS affects the ability of nurses to safely and efficiently administer IV medications. All infusion tasks that contained a programming subtask that are a part of the general programming sequence are discussed. The sections are arranged in the same order that nurses would tend to see when programming a smart pump (1. Load IV set, 2. Enter DERS and CCA, 3. Select drug name and concentration, 4. Enter parameters and start infusion). Each section is divided into at least two parts, (a) a description of the programming steps nurses must take for each smart pump model to complete the programming subtask (please refer to Appendix C for workflow diagrams of each smart pump), and (b) a discussion of the usability issues that affected nursing performance.
5.2.1 Loading the IV set

Loading the IV Set Design Overview

- **Cardinal Alaris System**: To gain access to the loading compartment, the latch on the channel door is lifted up and the channel door is opened. To load the IV set, the upper fitment on the IV set is lowered into the pump module’s recess, and the lower safety clamp fitment is pressed into the recess below mechanism. The tubing of the IV set is then pushed toward the back of the air-in-line detector. The door is then closed and the latch is locked into place.

- **BBraun Infusomat**: The pump must be turned on before loading the IV set. To unlock the pump door, the nurse presses a hard key button (located on the far right hand corner of the pump). Once the door is unlocked, the door is pulled open by the nurse. To load the IV set the following steps are taken: (1) route the tubing through the upstream sensor, (2) insert the two-hole clamp and the white clip, and (3) insert the free-flow clamp into the open slot until the opening lever locks in and the flashing warning lamp turns off. The ends of the IV set are inserted into the slots on the left- and right-hand side of the pump. The door is pushed closed until it locks in place. Please refer to Figures 43-47 in Appendix C for pictures of BBraun Infusomat’s loading compartment.

- **Hospira Symbiq**: The pump must be turned on to load the IV set. To open the cassette carriage, a hard button called “LOAD/EJECT” is pressed. The IV set is held above and below the cassette (with the flow stop facing the nurse and the purple collar at the top), and inserted into the cassette carriage. To close the cassette carriage, the user presses the LOAD/EJECT button, or waits for the cassette carriage to automatically close (cassette carriage automatically closes 6 seconds after being opened).

5.2.1.2 Loading the Set Design Usability

The design of the IV set and loading compartment was found to affect nursing performance. Nurses took a significantly greater amount of time to load an IV set when using BBraun Infusomat than when using Cardinal Alaris System or Hospira Symbiq (see Figures 2, 4, 7, and 10). Furthermore, in 2 out of the 4 tasks nurses look significantly more time to load the IV set when using Cardinal Alaris System than when using Hospira Symbiq (see Figures 2 and 10). The percentage of nurses that deviated when loading the IV set was significantly greater when using BBraun Infusomat than when using Hospira Symbiq (see Figure 6). Furthermore, without an adjustment to the p-value the same result was also found in the continuous and maintenance infusion tasks (see Figures 50 and 61). The following discusses the
main features of each smart pump model that either hindered or enhanced the ability of the nurse to load the IV set efficiently.

The design of Hospira Symbiq’s IV set and holding compartment is considered to be the most optimal design compared to the other smart pump models. The use of automatic doors, and the design of a one component IV set made it easy for nurses to quickly load an IV set into the pump.

It is suspected that nurses required more time to load an IV set when using Cardinal Alaris System than when using Hospira Symbiq because the IV set had more components (nurses had difficulties finding the correct orientation for each component to insert into the loading compartment), and the door had to be manually opened and closed (nurses often had difficulties closing the latch door properly). It is suspected that nurses took the longest amount of time to load an IV set into BBraun Infusomat because the IV set had the greatest number of components and the pump door was difficult to close. When inserting the IV set, nurses often had difficulties determining the correct orientation to insert each component into the loading compartment. With respect to closing the pump door, challenges often arose when the door partially locked from either nurses not applying enough pressure to the door, or nurses forgetting to insert the tubing into the notches located at either end of the pump. In this event, the software did not notify nurses of the problem until the nurses attempted to start the infusion. Furthermore, many nurses required assistance because they did not realize that the OPEN button had to be pressed to reopen the door and fix the error.

Depending on the design of the IV set and loading compartment, the process of loading the IV set can take up a large portion of task completion time. Table 9 displays the percentage of task completion time that was spent loading the IV set when completing the infusion tasks for each smart pump model. Although, this is only meant as an approximation, it illustrates the need for manufacturers and health care facilities to consider how the design of this component impacts the ability of users to efficiently program infusions.

Table 9: Percentage of time spent loading the set (mean load set time/mean task completion time*100)

<table>
<thead>
<tr>
<th>Smart pump model</th>
<th>Continuous Infusion</th>
<th>Intermittent Infusion</th>
<th>Maintenance Fluid</th>
<th>Drug not in Drug Library Infusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardinal Alaris System</td>
<td>15%</td>
<td>20%</td>
<td>28%</td>
<td>10%</td>
</tr>
<tr>
<td>BBraun Infusomat</td>
<td>39%</td>
<td>29%</td>
<td>54%</td>
<td>32%</td>
</tr>
<tr>
<td>Hospira Symbiq</td>
<td>6%</td>
<td>10%</td>
<td>9%</td>
<td>4%</td>
</tr>
</tbody>
</table>

The design of the IV set and loading compartment was found to affect nursing performance. The IV set should have a low number of components for the nurse to insert in the loading compartment, and
the pump door should require minimal effort to open and close. If the IV set is loaded improperly or the pump door is not closed properly, the software should notify the nurse immediately to better assist in the error recovery process.

5.2.2 Enter DERS and CCA

5.2.2.1 Enter DERS and CCA Design Overview

- **Cardinal Alaris System:** After the pump is turned on, the nurse selects either “New Patient” or “Old Patient”. If “New Patient” is selected, the nurse confirms the CCA. The channel the nurse wishes to program is then selected by pressing a hard button called “Channel Select’ located on the pump module. To enter into a drug library the nurse selects either Guardrails Drugs (infusion therapy list that contains therapeutic fluids), or Guardrails Fluids (infusion therapy list that contains non-therapeutic fluids and limits around the rate of delivery).

- **B Braun Infusomat:** After the pump is turned on, the nurse selects either “Use last therapy” or “New therapy”. If new therapy is selected, the nurse selects the drug library. Once in the drug library, the nurse chooses the CCA from a list.

- **Hospira Symbiq:** After turning on the pump, the nurse selects either “New Patient” or “Old Patient”. If “New Patient” is selected, the nurse then selects the CCA. The nurse is automatically placed in the DERS at start-up.

5.2.2.2 Enter DERS and CCA Design Usability

Although there were no significant differences between smart pump models in this programming subtask (using the adjusted p-value), trends were observed across the infusion tasks. In this programming subtask, BBraun Infusomat was found to have better nursing performance (lowest subtask completion time, and lowest percentage of nurses that deviated) compared to Cardinal Alaris System and Hospira Symbiq (please refer to Figures 2 and 7). Furthermore, Cardinal Alaris System tended to have better nursing performance than Hospira Symbiq. It is speculated that if a larger sample size was used, significant differences between the smart pump models would have been found. The following discusses design elements of each smart pump model that could have potentially contributed to these results.

It is speculated that nurses have better performance levels when using BBraun Infusomat than the other smart pump models because it had the lowest number of programming steps and menu branches in this subtask. Thus, there were fewer opportunities for nurses to deviate from the optimal programming path.
When using Cardinal Alaris System, there were two events that could have contributed to nursing performance: (a) selecting the channel from the module instead of the pump brain, and (b) selecting the wrong drug library. In this study, nurses often attempted to select the channel on the pump brain instead of on the pump module. It is expected that the design of the pump screen encouraged nurses to select the channel on the pump brain because (a) the names of channels were listed on the main screen next to commonly used selection buttons, and (b) there were no visual cues reminding nurses to select the channel from the pump module. Although this design decreased nursing performance, it is considered favourable because the action could make nurses more aware of the channel they are programming. In turn, this may decrease the likelihood of nurses making channel mix-up errors. Nurses often had difficulties differentiating between Cardinal Alaris System’s three drug libraries. For instance, 21% of nurses programmed a maintenance fluid in Basic Infusion instead of in Guardrails IV Fluids (see Figure 60). Without an adjustment to the p-value, this specific error would be the reason why nurses were found to have a significantly higher success rate in this programming subtask when programming a maintenance fluid on Hospira Symbiq than on Cardinal Alaris System. This indicates that drug libraries were not easily distinguished by nurses.

Hospira Symbiq tended to have the lowest performance compared to the other smart pump models. This was likely due to the active fields not registering when touched (the most common type of deviation in this programming subtask for this smart pump model). The accuracy of the touch screen could have been attributed to the quality of the Liquid Crystal Display touch screen and/or the design of the active fields. With respect to the design of the active fields, it is speculated that there are two design elements that could have contributed to this problem:

1. **The height of the active field:** The height of the active field is small and does not give leniency for co-ordination and perceptual errors made by nurses (see Figure 17). It is recommended that the height of the active fields be increased.

2. **Drop down menu in the active field:** An active field that contains a drop down menu has an arrow button located at the left boundary of the active field (as shown in Figure 17). Although the drop down menu could be initiated by pressing anywhere in the active field, nurses often chose to press directly on top of the arrow. In this event, there is a higher probability that the point of contact will be outside the boundary and will not activate the intended field. It is recommended that the boundary be extended or an alternative design be used to indicate that a drop down menu is available.
5.2.2.3 Drug Library Compliance

A more favourable drug library compliance rate was observed in this study (between 1-4% of infusions were programmed outside of the drug library) compared to compliance rates documented by other health care facilities in literature (Birk, 2008; Cassano, 2006; Eckel et al., 2006; Rothschild et al., 2005). The probable cause of this difference could be attributed to,

(a) *The content of the drug library:* the drug library contained all the medications nurses needed to complete the infusion tasks that were to be programmed in the drug library. Thus, there was no need for nurses to use the generic programming mode.

(b) *The simulated clinical environment and protocol:* Each time the generic programming mode was entered (excluding the drug not in drug library infusion task), the nurse actor approached the nurse and indicated that the infusion could be programmed in the drug library. To retrieve data on subsequent subtasks, it was important to have the nurse use the correct programming sequence. However, this event could have also decreased the likelihood of nurses using the generic programming mode in subsequent infusion tasks. Furthermore, being under observation, having no time constraints, and having no outside interferences could have also decreased the likelihood of nurses using the generic programming mode.

This study was unable to determine whether the location of the generic programming mode affects drug library compliance rates. Although using the generic programming mode was uncommon, the majority of incidents occurred after the nurse failed to locate the drug in the drug library.

5.2.3 Select Drug Name and Concentration

5.2.3.1 Select Drug Name and Concentration Design Overview

- **Cardinal Alaris System:** Drug name and concentration are selected separately on different menu levels. For instance, the drug name “Fentanyl” is selected on the first menu level, and the concentration “1 mcg/mL” on the next menu level. Hierarchical alphabetical short-cuts or up/down soft keys are used to navigate through the drug list. Figure 18 illustrates an example of how a nurse could find Morphine. The nurse would first select the alphabetical short-cut “M-N-O-P”, select “M” and then select Morphine.
• **BBraun Infusomat:** The drug name and concentration are selected simultaneously from the drug list (for example, “Fentanyl 1 mcg/mL”). Embedded alphabetically grouped short-cuts and up/down hard keys are used to navigate through the drug list (please refer to Figure 19). The navigation method advances the nurse in the drug list, but does not change the number of therapies available to select.

![Figure 18: Illustration of Cardinal Alaris System's hierarchical drug list navigation method](image)

• **Hospira Symbiq:** The drug name and concentration are selected separately on different menu levels. A vertical scroll bar is used to navigate through the drug list. Depending on where the nurse touches the vertical scroll bar, the drug list will move down or up by either 1, 2, 3 or 4 drug names. The navigation method advances the nurse in the drug list, but does not change the number of therapies available to select.

![Figure 19: Example of drug list navigation method for BBraun Infusomat](image)

5.2.3.2 Select Drug Name and Concentration Design Usability

Although there were no visible differences in performance measures across the smart pump models, deviation trends would suggest that the navigation method used to select the drug name and concentration can influence nursing performance (see Figures 6, 13, 13, and 62). The following discusses design elements of each smart pump model that are speculated to affect the ability of the nurse to navigate through this programming subtask.

When using Cardinal Alaris System, nurses rarely deviated when searching for the drug name or concentration. Specifically, only 4% of nurses deviated in the continuous and intermittent infusion tasks (Figures 6 and 50), and 0% of nurses deviated in the remaining infusion tasks (Figures 13 and 62). Based on this result, it is speculated that the hierarchical navigation method used by Cardinal Alaris System is a
favourable design element. When using Cardinal Alaris System, the majority of deviations were made on the drug name and concentration confirmation screen. This particular confirmation screen had a single purpose (to confirm settings) for non weight-based medications, and a dual-purpose purpose (to enter weight and confirm settings) for weight-based medications. Nurses often became confused about the purpose of the screen, and what was required to proceed to the next menu level. As a result, nurses often tried to select parameter fields that were not active (such as weight and dosing units) on the single purpose confirmation screen. This event suggests that it is favourable for the purpose of a confirmation screen to be consistent across all infusion types.

When navigating through BBraun Infusomat’s drug list, there were common types of deviations that were made by nurses in all infusion tasks (see Figures 6, 13, 50, and 62). The frequency of certain types of deviations would suggest a lack of understanding in the navigation method. The majority of deviations resulted from one of two events, (a) scrolling past the drug name and concentration, or (b) ceasing to use the alphabetical short-cuts and scrolling through the drug list one drug at a time. It is expected that embedded alphabetical short-cuts coupled with a small screen display made it challenging for nurses to determine where they were in the drug list and re-locate to the alphabetical short-cut navigation tool when needed. Furthermore, the use of arrow buttons to navigate through the list could have also been challenging.

When using Hospira Symbiq, nurses often scrolled past the drug name or concentration (42%, 38%, 4% of nurses scrolled past the drug name and/or concentration in the continuous, secondary and intermittent infusion tasks, respectively (see Figures 6, 13, 50, and 63). This was likely attributed to the vertical scroll bar navigation tool. Depending on where the nurse touched on the vertical scroll bar, the drug list would move down or up by either 1, 2, 3 or 4 drug names. Although the jumps are separated into chevrons on the scroll bar, the size of each chevron is small and does not give a lot of leniency for co-ordination and perceptual errors. For instance, a nurse could want to press the chevron that jumps 2 drug names, however s/he could accidentally press the chevron that jumps 4 drug names. This event illustrates the importance of designing a navigation tool where the expected outcome of an action matches the actual action that occurs.

The display of the drug name and concentration was not found to affect safety because there was no difference in parameter selection errors between smart pump models (see Figures 15-16). Although no differences were detected, the design where the drug name and concentration are displayed on separate menu levels is speculated to be the safest design because there are fewer items to select from. In turn, this could decrease the likelihood of nurses selecting the wrong item.
5.2.4 Enter Parameters

5.2.4.1 Parameter Entry Screen Design Overview

- **Cardinal Alaris System:** The parameter fields are selected using soft keys, and the numerical values are entered into the parameter fields using a numerical keypad. As shown in Figure 20, the parameter fields that are activated on the parameter entry screen depend on the type of infusion being programmed. If it is a primary infusion (referred to as intermittent infusion in this study), the nurse is presented with duration and VTBI (VTBI is pre-programmed), and rate is inactivated. If it is a continuous infusion, the nurse is presented with rate, VTBI, and dose, and duration is inactivated. To activate an inactive field the nurse presses a toggle soft key button located at the bottom of screen. The dose field on the parameter entry screen is actually a dose-rate parameter field for all smart pump models. To avoid confusion between dose (mg) and dose-rate (mg/hr), this parameter field will be referred to as dose-rate in this study.

![Figure 20: Parameter entry screens for Cardinal Alaris System. Left figure displays the parameter entry screen for primary infusions, and the right figure display the parameter entry screen for continuous infusions.](image)

- **B Braun Infusomat:** The parameter fields are selected and the numerical values are entered into the parameter fields using the up/down and right/left arrows located on the pump door. During this programming subtask, the nurse must navigate through a series of menu levels to enter parameters. On the first menu level the nurse enters the patient’s weight (if applicable), on the second menu level the nurse enters VTBI, and on the final menu level the nurse enters either rate, dose (referred to as dose-rate in this study), or time (referred to as duration in this study). Please refer to Figure 21 for further information regarding the design of the parameter entry screen.

![Figure 21: Design of the parameter entry screen.](image)
Figure 21: Parameter entry screens for BBraun Infusomat. Left figure displays the parameters visible on the main screen upon entry to this menu level. Right figure displays the second set of parameters that can be accessed by scrolling down the parameter list.

- **Hospira Symbiq**: The parameter fields are selected by touching the field on the screen, and the numerical values are entered using a touch screen numerical keypad that appears once a parameter field is activated. As shown in Figure 22, the order of the parameters displayed on menu level is weight (if applicable), dose (referred to as dose-rate in this study), rate, VTBI, and time (referred to as duration in this study). The nurse has the option to enter any parameters to start the infusion.

![Parameter entry screen for Hospira Symbiq](image)

Figure 22: Parameter entry screen for Hospira Symbiq

5.2.4.2 **Influence of parameter entry screen design**

Entering parameters was a subtask prone to error in both the intermittent and secondary infusion tasks. Specifically, nurses had a significantly lower success rate when using Hospira Symbiq than when using Cardinal Alaris System in the intermittent and secondary infusion tasks (see Figures 5 and 12). Results also suggest that the events that led to subtask failure were unique to the smart pump model the nurse was programming. When using Cardinal Alaris System, the 2 programming errors that led to subtask failure were duration transcription errors. When using BBraun Infusomat, there were a variety of events that led to subtask failure (3 duration unit errors, 3 rate calculation errors, and 2 dose unit errors). Conversely, when using Hospira Symbiq, 13 out of 16 errors that led to subtask failure centred around dose-rate (the nurses entered the dose in the dose-rate field). It is speculated that difference in success rate between the smart pump models, and the characteristics of the events that led to subtask failure, where influenced by the design of the DERS in this programming subtask.

The design of the parameter entry screen may influence the parameter a nurse chooses to enter. All medication orders in the intermittent and secondary infusion tasks contained duration (rate and dose-rate were not listed). Thus, duration would be the most appropriate choice to enter because all other
parameters would have to be calculated. When using Cardinal Alaris System, nurses were more likely to enter duration than rate to start the infusion for both intermittent and secondary infusions (see Figures 53 and 65). It is likely that the majority of nurses chose to enter duration because the duration field was the only field activated upon entry into the menu level. Although rate could have been used, it may not be the preferred choice to nurses because it cannot be activated without additional programming steps. The design of the parameter entry screen is thought to be favourable for programming intermittent infusions because nurses had a consistently high success rate (there were no calculation or unit errors seen across both infusion tasks). It is speculated that a major factor that contributed to its success was the fact that the design of the parameter entry screen closely resembled the design of the medication orders given to the nurses.

When using BBraun Infusomat, nurses were more likely to enter duration than rate or dose-rate to start the infusion for both intermittent and secondary infusion tasks (see Figures 53 and 65). Although most nurses entered duration, a considerable portion of nurses chose to perform a calculation to enter rate. It is speculated that nurses were motivated to enter rate because rate was the first parameter on the parameter entry screen. The use of a general parameter entry screen for all infusion types can provide flexibility for nurses to enter a parameter of their choosing. However, by providing this flexibility nurses may be more inclined to use parameters not listed on the medication order or IV bag label. In turn, this may increase the likelihood of nurses making user errors.

When using Hospira Symbiq, nurses were significantly more likely to enter duration than rate or dose-rate to start the infusion for both intermittent and secondary infusion tasks (see Figures 53 and 65). However, 25% and 33% of nurses that used duration to start the infusion had first attempted to enter dose-rate for intermittent and secondary infusion tasks, respectively (see Figures 52 and 64). In this event, nurses had entered the dose (mg) in the dose-rate field (mg/hr), and either hit a limit and/or required assistance to recover from the error before entering duration. Nurses could have been motivated to use the dose-rate field because (a) dose-rate is the first parameter listed on the screen, and/or (b) they thought it was actually a dose field, and chose to enter the parameter because the dose value was listed on the IV bag label. The low success rate when entering parameters suggests that the design of the parameter entry screen for Hospira Symbiq is not favourable for programming intermittent infusions. Like BBraun Infusomat, the flexibility of Hospira Symbiq’s general parameter entry screen likely hindered the ability of nurses to safely program an intermittent infusion.

The effect of parameter entry screen design on user errors (transcription, unit, and calculation errors) was observed in this study. Although the investigator suggests that there is a relationship between
the design of parameter entry screens and user errors, results are not conclusive. It is expected that there are other factors that influence the parameters nurses chose to enter into the pump such as the parameters available on the medication order and IV bag label, and parameter preferences acquired from previous experiences. Further research should be conducted to determine how these different factors affect nurses and the occurrence of user errors.

5.2.4.3 Parameter Entry Mathematical Relationships

All smart pump models have mathematical relationships between the parameters (rate, dose-rate, duration, and in some cases VTBI). Mathematical relationships are favourable because once two parameters are known, the software automatically calculates the remaining parameters and inserts the values into the respective fields. Furthermore, mathematical relationships can provide a second check for nurses, to make sure the correct parameter values were entered. For instance, a nurse could enter the wrong dose-rate, but upon noticing that the duration value was wrong, could correct the error. As shown in Figure 23, each smart pump model has a different mathematical relationship. Cardinal Alaris System uses two different relationships depending on the type of infusion. When programming a continuous infusion, dose-rate auto-populates rate, and vice versa (VTBI must be manually entered and is not a part of the relationship). When programming an intermittent infusion, duration auto-populates rate, and vice versa (VTBI is already populated). When programming BBraun Infusomat, the nurse is required to enter VTBI first. Once VTBI is known, a relationship between rate, dose-rate and duration is initiated where entering one parameter auto-populates the remaining parameters. Hospira Symbiq uses two different relationships, dose-rate auto-populates rate and vice versa, and VTBI auto-populates duration and vice versa.
Figure 23: Auto-population relationships between parameters (rate, dose-rate, duration, and VTBI) for Cardinal Alaris System, BBraun Infusomat, and Hospira Symbiq

The mathematical relationship used by Hospira Symbiq is speculated to affect the ability of nurses to recover from user errors based on the events that occurred in this study. When programming an intermittent or secondary infusion, many nurses entered the dose (mg) in the dose-rate field (mg/hr). Subsequently, nurses often experienced difficulties recovering from the dose unit error, and often became trapped in a programming loop. The following is an incident that occurred during a session of this study. The sequence of events described was experienced by many nurses that participated in this study:

<table>
<thead>
<tr>
<th>Last Name, First Name</th>
<th>05/11/10</th>
<th>MR#</th>
<th>01228496</th>
<th>ORDER</th>
<th>11</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication</td>
<td></td>
<td>DUE</td>
<td>Immediately</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amphotericin liposomal 42mg</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dextrose Inf 5% 250 mL</td>
<td>Concentration: 1.7 mg/mL</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infuse IV over 3 hrs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exp: 11/08 IV use Q24h</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The nurse entered 425 mg into the dose-rate field (425 mg/hr) instead of 142 mg/hr, and a volume of 250 mL. Upon noticing the duration had auto populated to 1 hr, the nurse changed duration to 3 hrs. After changing the duration, the dose-rate field remained the same but the volume changed to 750 mL. The nurse then changed the volume back to 250 mL, which changed the duration back to 1 hr. The nurse then entered a rate value of 50 mL/hr, which activated a soft limit alert. The nurse asked for assistance from the nurse actor. The nurse actor informed the nurse of the dose-rate error.

Figure 24: Medication Order for IV therapy used in study

In the mathematical relationship used by Hospira Symbiq dose-rate and rate are not connected to duration. If there is an error in the dose-rate or rate value, the only way to recover from the error is to change the dose-rate or rate value. In the intermittent and secondary infusion tasks nurses often realized there was a problem when the auto-populated duration value did not match the value on the IV bag label. However, after entering the correct duration (which would have corrected the problem if using BBraun Infusomat) many nurses were still unable recover from the dose unit error. In September 2008, an ISMP
Medication Safety Alert warned of a similar event where nurses would change the duration but only VTBI would be changed (ISMP, 2008). To prevent this error, the authors recommended that (a) nurses recheck the parameters on the confirmation screen before starting the infusion and (b) hospitals design drug libraries to contain common standard times for infusion medications. Based on the results of this study, this is may not be the most appropriate recommendation because it fails to address the root of the problem. It is hypothesized that the best way to prevent this error is to change the mathematical relationships such that a relationship between rate, dose-rate and duration always exists for general parameter entry screens.

5.3 SECONDARY INFUSIONS

5.3.1 Secondary Infusion Design Overview

The following is a brief overview of the programming steps a nurse must take to program a secondary infusion once the primary infusion is running. For further information, please refer to the workflow diagrams in Appendix C.

- **Cardinal Alaris System:** The nurse first selects the channel to be programmed. The secondary infusion feature is then accessed from the main screen by pressing a soft key button called “Secondary”. The nurse then selects the drug name and concentration, and enters the parameters. Since a secondary infusion is administered intermittently, the nurse is presented with the intermittent parameter entry screen (as described in Section 5.2.4.1).

- **B Braun Infusomat:** The primary infusion must be stopped before accessing the secondary infusion feature. The secondary infusion feature is accessed through the “Special Features” menu located on the main screen. Once in “Special Features”, the “Piggyback Mode” is selected. The nurse then selects to use the drug library and selects the CCA. The parameters are then entered in the same fashion as described in Section 5.2.4.1.

- **Hospira Symbiq:** The secondary infusion feature is accessed from the main screen under the heading “Secondary”. Once in this programming mode, the nurse navigates through the same programming sequence as outlined in Sections 5.2.3.1 and 5.2.4.1.
5.3.2 Accessing the Secondary Feature

There were key design features that affected the ability of nurses to access in the secondary infusion feature. In this programming subtask, nurses had a significantly higher success rate finding the secondary infusion feature when using Hospira Symbiq (100%) than when using BBraun Infusomat (58%) (see Figure 12). Without an adjustment to the p-value, results found that the subtask completion time and percentage of nurses who deviated was higher when using BBraun Infusomat than when using Hospira Symbiq (see Figures 62 and 63). Furthermore, nurses tended to perform better when using Hospira Symbiq (subtask completion time, percentage of nurses that deviated, and subtask success rate), followed by Cardinal Alaris System, and BBraun Infusomat (see Figures 12, 13, and 63). It is possible that if a larger sample size was used, additional significant differences in performance measures would have been observed. The following discusses design elements of each smart pump model that could have enhanced or hindered the ability of nurses to access the secondary infusion feature.

It is speculated that nurses had better performance level when using Hospira Symbiq because the secondary infusion feature could be accessed directly from main screen under an intuitive heading name. Although there were no significant differences in performance between Cardinal Alaris System and Hospira Symbiq, the method used by Cardinal Alaris System is considered less intuitive because of the trend in the types of deviations observed, and the higher subtask completion time. When using Cardinal Alaris System, nurses often forgot how to access the secondary infusion feature, and strayed away from the optimal programming path in an attempt to locate this feature in other menus. It is expected that if a visual cue was provided to nurses to help find this feature, nurses would be less likely to have difficulties. The method used by BBraun Infusomat to gain access to the secondary infusion feature was highly detrimental to the ability of nurses to program a secondary infusion. It is speculated that the following design elements reduced nursing performance in this subtask:

1. **Location of the secondary infusion feature**: The secondary infusion feature was embedded within a secondary menu level called “Special Features”. The nurse had to rely on memory to find this feature.

2. **Requiring the nurse to stop the primary infusion before accessing the secondary infusion feature**: If a nurse attempted to access the “Special Features” while the primary infusion was still running, the feature would not be available. An error message would then appear stating “Feature not available”. This error message does not provide adequate feedback to the nurse to understand the origin of the error and how to recover from the error. It is expected that if the error message read “Special Features not available, please stop primary infusion”, nurses would have been more successful in this subtask.
3. Action of the correction button: Many nurses pressed the correction button (hard key located on the pump door) in an attempt to find the secondary infusion feature. However, the correction button took the nurse to the first menu level of the programming sequence where the nurse must decide whether to use the last therapy programmed or program a new therapy. Due to the sequence of events that led up to this decision, it was unclear to many nurses whether this decision was for the primary or secondary infusion. When faced with this decision, most nurses chose to program a new therapy. As a result, all primary infusion programming was lost, and nurses were taken back to the primary infusion parameter entry screen. Many nurses then began to program the secondary infusion as a primary infusion. All except one nurse realized they were programming the secondary infusion as a primary infusion before the infusion was started.

Results indicate that it is favourable if the secondary infusion feature can be accessed directly from the main screen because it will be easier for the nurse to locate. If the secondary infusion feature is embedded in another menu, or requires the nurse to complete steps (such as stopping the primary infusion) before accessing the feature, the DERS should provide guidance information to reduce memory load and increase effectiveness. There should also be a visual distinction between the primary and secondary infusion programming to avoid mix-ups.

5.4 Drug Not in Drug Library

5.4.1 Generic Programming Design Overview

The following is a brief overview of the programming steps a nurse must take to program a generic infusion upon realizing a medication is not in the drug list. For more information, please refer to the workflow diagrams in the Appendix C.

- **Cardinal Alaris System:** To access the generic programming mode from the drug list, the nurse exits the drug list and selects “Basic Infusion”. Once in the generic programming mode, the parameters are entered on the parameter entry screen. The nurse is presented with rate and VTBI, and duration is inactivated.

- **BBraun Infusomat:** To access the generic programming mode from the drug list, the nurse presses the correction button and then selects “No” to “Use Drug Library?” The nurse then enters VTBI, and proceeds to the next menu level where they have to choice to enter either rate or time (referred to as duration in this study).
• **Hospira Symbiq:** The generic programming mode is embedded in the drug list under the heading “Other Drug”. Once in the generic programming mode, the nurse enters the concentration and selects dosing units. The nurse then has the option to enter two of the following parameters: dose (referred to as dose-rate in this study), rate, VTBI or time (referred to as duration in this study).

### 5.4.2 Accessing the Generic Programming Mode

There were key design features that affected the ability of nurses to effectively access the generic programming mode. In this programming subtask, nurses had a significantly higher success rate when using Hospira Symbiq (100%) than when using BBraun Infusomat (58%) (see Figure 7). When using Hospira Symbiq, all nurses were able to access the generic programming mode successfully. This is an interesting result as Hospira Symbiq is the only smart pump model that embeds the generic programming mode in the drug list. This result may indicate that it is more intuitive for nurses to think of the generic programming mode as a drug name and concentration combination instead of a programming sequence outside of the DERS.

When using BBraun Infusomat, subtask failure was attributed to one of two events, (a) the nurse selecting the wrong drug and requiring assistance to go back into the drug list, or (b) the nurse being unable to find the generic programming mode without assistance. Seventy-five percent of subtask failures were the result nurses accidentally selecting the wrong drug. It is suspected that this event occurred because nurses thought the hard button (< ) would transfer them back to the beginning of the programming sequence where the generic programming mode is located. However, the actual purpose of this button is to select the drug name and concentration that is highlighted. Although this misunderstanding was problematic, the subsequent event that was triggered proved highly detrimental to the ability of the nurse to recover from this error. Once a drug is selected, the nurse must enter and accept a VTBI value before a correction feature is available to return to the drug list. This design violates two heuristic design principles, (a) nurse control and freedom because there is no exit to leave the unwanted state, and (b) match between system and real world because upon realizing the parameter selection error, it is expected that a nurse would never continue programming the wrong drug (Zhang et al., 2003). Twenty-five percent of nurses required assistance to find the generic programming mode. Low success rate was likely attributed to the lack of visual cues given to the nurse to exit the drug list and enter the generic programming mode.
Unlike BBraun Infusomat, the DERS in Cardinal Alaris System provided the nurse with visual cues to exit out of the drug list. This is likely the reason for the high success rate when accessing the generic programming mode using this model.

Results suggest that embedding the generic programming mode in the drug list or having the generic programming mode as a separate menu with visual cues are both favourable designs.

5.4.3 Entering Parameters

Entering parameters in the generic programming mode was a subtask prone to error across all smart pump models (see Figure 8). Although there was no significant difference in success rate across the different designs, many events that led to subtask failure were unique to the smart pump model the nurse was programming. When using Cardinal Alaris System, 6 out of 7 events that led to task failure centred around rate (4 nurses made calculation errors and 2 nurses required assistance to calculate rate). Conversely, when using Hospira Symbiq, 10 out of 11 task failures centred around dose-rate (4 nurses required assistance to select the correct dosing units, 5 nurses entered the dose in the dose-rate field, and 1 nurse selected the wrong dosing units). When using BBraun Infusomat, there were a variety of events that led to subtask failure (2 rate calculation errors, 2 duration unit errors, and 1 transcription error). Thus, although success rate did not differ across the smart pump models, it is speculated that the characteristics of the events that led to subtask failure were influenced by the design of the generic parameter entry screen.

The design of the parameter entry screen may influence the parameters nurses chose to enter. All medication orders in the intermittent and secondary infusion tasks contained duration (rate and dose-rate were not listed). Thus, duration would be the most appropriate choice to enter because all other parameters would have to be calculated. When using Cardinal Alaris System, nurses were more likely to enter rate (83%) than duration (17%) to start the infusion. This was expected because the generic parameter entry screen for Cardinal Alaris System only had rate and VTBI activated (with the option to enter duration if the Duration/Volume toggle button was pressed). When using BBraun Infusomat, there was no significant difference in the type of parameter used to start the infusion. Specifically, 67% of nurses entered duration, and 33% of nurses entered rate. When using Hospira Symbiq, there was no significant difference in the type of parameter used to start the infusion. Specifically, 42% of nurses entered duration, 37% of nurses entered rate, and 21% of nurses entered dose-rate. However, 36% of nurses that entered duration had first attempted to use dose-rate to start the infusion. In this event, the nurses were unable to recover from a dose unit error, and chose to enter duration instead (for more information on the results of this analysis, please refer to Figures 56 and 57 in Appendix D). Given that
the same nurses performed this infusion task on all three smart pump models, and all medication orders contained the same information, the design of the parameter entry screen was likely the factor that influenced the type of parameters nurses chose to enter to start the infusion.

Although there were no significant differences in performance levels, nurses tended to have the best performance when using BBraun Infusomat than when using Cardinal Alaris System or Hospira Symbiq (higher success rate and lower percentage of nurses that deviated). It is suspected that providing flexibility on the parameter entry screen to enter any parameter type, and using a simple programming sequence were likely the reasons behind BBraun Infusomat’s success. The lower success rate and type of user errors observed would suggest that the design of Cardinal Alaris System’s generic programming screen is too restrictive, and does not provide the nurse with the necessary tools to safely program an intermittent infusion in this programming mode. When using Hospira Symbiq, nurses tended to have the lowest performance (lowest success rate and greatest percentage of nurses that deviated). This was likely due to the complex programming sequence nurses had to navigate through, and the parameter mathematical relationship employed (see Section 5.2.4.3). In a task that requires simplicity to help nurses safely program an infusion outside of the safety of the DERS, Hospira Symbiq seems to have taken the opposite approach.

The design of the generic parameter entry screen should require minimum information from the nurse while allowing the necessary freedom to enter the parameters of their choosing. Limiting the parameters available on the parameter entry screen, or requiring the nurse to enter more information than what is necessary, can reduce the ability of the nurse to safely and efficiently administer IV medications in the generic programming mode.

5.5 LIMIT ALERT MESSAGES

The design of the soft limit alert message was found to influence the effectiveness of the soft limit alert. (Effectiveness is defined as the ability of the nurse to make the correct decision (reprogram or override) when presented with a limit alert.) As shown in Figure 14, nurses tended to override clinically inappropriate soft limit alert messages more often when using the BBraun Infusomat (Figure 27) than when using Cardinal Alaris System (Figure 25) or Hospira Symbiq (Figure 26). As both the Cardinal Alaris System and Hospira Symbiq soft limit messages performed equally as well, it is speculated that the design elements present in Hospira Symbiq and Cardinal Alaris System, but absent in BBraun Infusomat are likely key design elements that enhance the effectiveness of the soft limit alert message. These design elements include,
1. **A statement on the limit alert message that clearly states a limit has been exceeded**

2. **A recommendation on how to proceed once the limit is hit** – Both smart pump models provide written guidance to help the nurse understand the options they can choose once a limit is hit and the outcome of each option. For instance, Hospira Symbiq provides a message at the bottom of the screen saying “Press Override to bypass Limit, Press Edit to re-enter value”, whereas BBraun Infusomat provides no explanation of the outcome of their options.

3. **Use of colour to relay severity of the limit alert message** – Both smart pump models display the limit alert message in a different colour than what is used on normal programming screens. This could not only make it more eye-catching, but also increase the perceived severity of the alert message by the nurse.

   - **Figure 25:** Example of soft limit alert message for Cardinal Alaris System
   - **Figure 26:** Example of soft limit alert message for Hospira Symbiq
   - **Figure 27:** Example of soft limit alert message for BBraun Infusomat

The design of the hard limit alert message was not found to influence the effectiveness of the hard limit alert (see Figure 67). The only common attribute across all hard limit alert message designs is the forced function that prevents nurses from starting the infusion until the dose value is within limits. Thus, it is speculated that if the hard limit alert is a forced function, the design of the message will not impact the effectiveness of the hard limit alert. Figures 28 – 30 are examples of the different hard limit alert messages used by the smart pump models evaluated.
5.6 **Wrong Patient and Drug Errors**

As expected, the design of the DERS did not influence the ability of nurses to detect wrong patient or wrong drug errors. The correct patient and drug can only be verified if smart pump technology is integrated with other IT systems such as CPOE, PIS, and BCMA. As only two-thirds of nurses noticed wrong patient and wrong drug before administering the medication to the patient (Figures 67 and 68), it illustrates the importance for health care facilities to seriously consider the integration of this technology with other IT systems.

5.7 **User Errors**

5.7.1 **Calculation Errors**

For each infusion task, nurses were provided with enough information such that no calculations would have to be performed to enter parameters into the pump. However, many nurses chose to calculate a desired parameter instead of transcribing the parameter presented on the medication order and IV bag label. As a result, nurses made calculation errors in 6 – 9.5% of infusion tasks across the smart pump...
models (see Figure 15). Furthermore, less than half of the calculation errors were caught by either the nurse or the smart pump (see Figure 16). With that said, it should be noted that most calculation errors in this study resulted in the patient receiving an under dose that was in the allowable dosage range, and therefore did not trigger a limit alert. This could explain why most calculation errors were not caught before reaching the patient.

Although there were no significant differences in the occurrence of calculation errors between smart pump models, key trends suggest that the design of DERS could influence the type of calculation error made. Calculation errors that were made when using Cardinal Alaris System occurred when programming in the generic programming mode (see 5.4.3). Unlike Cardinal Alaris System, calculation errors were not specific to one infusion task or parameter type when using BBraun Infusomat or Hospira Symbiq. This was likely due to the use of a general parameter entry screen.

Although there were no significant differences across the smart pump models, where the calculation error occurred in the DERS and the type of calculation error that occurred, suggests the design of the DERS may impact calculation errors. Thus, there is an opportunity for manufacturers to advance patient safety by improving the design of the parameter entry screens to better meet the needs of the users.

5.7.2 Parameter Selection Errors

As shown in Figures 15 and 16, the design of the DERS was not found to significantly affect the occurrence of parameter selection errors. However, like calculation errors there were key areas in the programming sequence where parameter selection errors occurred when using each smart pump model. When using Cardinal Alaris System, there were two events where nurses selected the wrong drug or concentration. Both nurses found the error when reviewing the programmed settings on the drug setup confirmation screen. The most prominent type of parameter selection error that occurred when using BBraun Infusomat was selecting the wrong drug name and concentration. Five out of eight of these errors occurred in the drug not in drug library infusion task. Furthermore, only 20% of nurses recovered from the error because the software did not provide an “emergency exit” to leave the parameter entry screen until VTBI was entered (as described in Section 5.4.2). When using Hospira Symbiq, 4 out of 6 infusions programmed had the wrong concentration selected. All errors were corrected by the nurse.

This is one of the first studies that has documented the occurrence of parameter selection errors when using smart pumps. The extent of parameter selection errors when using smart pumps in an actual clinical setting is unknown because the errors (such as wrong drug, concentration, and CCA) can only be known if the dose alert and operational logs are attached to the patient’s information.
5.7.3 Unit Errors

As shown in Figures 15 and 16, the design of the DERS was found to affect the occurrence of unit errors. When using Cardinal Alaris System, no nurses made unit errors in any infusion tasks. However, unit errors occurred in 9% of infusions programmed on BBraun Infusomat, and in 20% of infusions programmed on Hospira Symbiq. When using Hospira Symbiq, the most common type of unit error was entering the dose into the dose-rate field. As discussed in Section 5.2.4.3, error recovery from dose unit errors was hindered by the mathematical relationship between the parameters. A unique programming error that was made when using BBraun Infusomat was duration unit errors. Many nurses entered the duration value in the wrong unit column (for instance, instead of entering 60 minutes the nurse entered 60 hours). This error could be attributed to the small screen size and/or poor visibility of the explanation of the duration unit columns (as shown in Figure 31). A less common unit error that occurred when using BBraun Infusomat was entering the dose in the dose-rate field. All unit errors made by nurses that reached the patient resulted in an under dose and were within the dosing limits.

![BBraun Infusomat Duration Entry Screen](image)

**Figure 31:** BBraun Infusomat Duration Entry Screen

5.7.4 Transcription Errors

The design of the DERS was not found to affect the occurrence of transcription errors. In this experiment, 4-5% of infusions contained transcription errors across the smart pump models (see Figures 13 and 14). Common transcription errors included entering the wrong volume or duration. It should be noted that in some cases, duration transcription errors could have been deliberate. For instance, the nurses could have realized the duration was too short given the medical condition of the patient, and subsequently increased the duration without consulting the physician. However, in this situation it is still counted as a transcription error because the nurse entered a value other than what was given on the order without indicating that a physician would be contacted. Results show that motivating users to transcribe values into the pump instead of calculating values cannot prevent all user errors from occurring when entering parameters into infusion pumps.
5.8 Nursing Perceptions

Survey results indicated that nurses thought the design of the pump screen of Cardinal Alaris System and Hospira Symbiq was easier to read, and used more intuitive terminology than the design of BBraun Infusomat’s pump screen. Nurses also thought the drug list navigation method employed by Cardinal Alaris System was easier to use than BBraun Infusomat. This perception is supported by the performance measurements.

Interestingly, there was no perceived difference in the usability of the parameter entry screen across the smart pump models even though this menu level was challenging for many nurses. It is speculated that nurses did not perceive a difference in usability because nurses were not informed of their programming errors during their session. This is also likely the reason why nurses did not perceive a difference in the ability to correct programming errors across the smart pump models.

Although nurses did not perceive a difference in set-up and programming time between smart pump models, nurses did feel that the number of steps to program an infusion using BBraun Infusomat was less acceptable than the number of steps to program an infusion using Hospira Symbiq. This is an interesting result because Hospira Symbiq typically requires more programming steps than BBraun Infusomat. This result could be attributed to the redundancy of steps (such as selected CCA when programming a secondary infusion), difficulties using the arrow keys to navigate through the menu levels, or loading the IV set when using BBraun Infusomat.

Nurses felt that Cardinal Alaris System and Hospira Symbiq would be more likely to meet their needs for a general infusion pump compared to BBraun Infusomat. Similarly, nurses indicated that they would prefer to use Cardinal Alaris System and Hospira Symbiq in their CCA compared to BBraun Infusomat. Although there were key elements in DERS that nurses had difficulties navigating through when using BBraun Infusomat (such as accessing the secondary infusion feature or generic programming mode), performance measures in common programming subtasks were not always different from Hospira Symbiq and Cardinal Alaris System. It is possible that the physical structure of the pump also influenced nursing perception. For instance, BBraun Infusomat had a much smaller screen size and did not use multiple colours in their screen display.
At the end of each post-condition questionnaire, nurses had the opportunity to comment on the features of each smart pump model that they liked and disliked. Table 10 provides a brief overview of common features that were mentioned by nurses for each smart pump model.

Table 10: Comments provided by nurses relating to the features of the DERS and hardware components for Cardinal Alaris System, BBraun Infusomat and Hospira Symbiq.

<table>
<thead>
<tr>
<th>Smart pump model</th>
<th>Features nurses liked</th>
<th>Features nurses disliked</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardinal Alaris System</td>
<td>• Drug list hierarchal navigation method</td>
<td>• Amount of time required to load the set</td>
</tr>
<tr>
<td></td>
<td>• Screen size and colour</td>
<td>• Number of initial steps a user had to go through before programming the infusion</td>
</tr>
<tr>
<td>BBraun Infusomat</td>
<td>• Small size of the pump</td>
<td>• Small screen size</td>
</tr>
<tr>
<td></td>
<td>• Battery life displayed in hours and minutes</td>
<td>• Time required to load the IV set</td>
</tr>
<tr>
<td></td>
<td>• Arrow navigation buttons</td>
<td>• Arrow navigation buttons</td>
</tr>
<tr>
<td></td>
<td>• Redundant questions</td>
<td>• Redundant questions</td>
</tr>
<tr>
<td></td>
<td>• Poor limit alert message visibility</td>
<td>• Poor limit alert message visibility</td>
</tr>
<tr>
<td>Hospira Symbiq</td>
<td>• Large screen display</td>
<td>• Active fields not registering when touched</td>
</tr>
<tr>
<td></td>
<td>• Touch screen</td>
<td>• Vertical scroll bar drug list navigation method</td>
</tr>
<tr>
<td></td>
<td>• Easy to read information on pump screen</td>
<td>• Too many options or steps</td>
</tr>
<tr>
<td></td>
<td>• Time to load the set</td>
<td></td>
</tr>
</tbody>
</table>
2. *Limited infusion tasks evaluated:* Study time limitations restricted this evaluation to only 7 infusion tasks. Therefore, only a portion of the features were evaluated. Although this is a limitation of the study, all infusion tasks evaluated were carefully chosen, and represented either infusion tasks that were commonly completed by nurses, or atypical infusion tasks that were important to the usability of the product. Thus, the investigator feels strongly that the general usability of each smart pump model was properly evaluated.

3. *Compounding factors:* Given the complexity of the DERS and physical structure of the smart pump models, it was often difficult to determine exactly which feature enhanced or hindered nursing performance. For instance, a performance measure could have been influenced by not only the design of the DERS, but the design of the numerical keypad on the face of the pump. The investigator could only speculate which design feature had the greatest influence on nursing performance.

4. *Finding the most optimal design:* There are multiple design elements in DERS that must integrate for nurses to be able to safely and effectively program a smart pump. Thus, the approach that worked best among these three smart pump models may not necessarily be the ultimate design solution for every smart pump model. However, information gathered from this study is expected to provide manufacturers with a strong base to move forward in the development of a safe and intuitive product.

5. *Training:* As discussed in Section 3.3.3, training in this study differed from traditional VBT training. This difference could have affected the ability of nurses to quickly navigate through the programming sequence without making programming mistakes. However, as the purpose of this study was to examine the intuitiveness of the technology, this is not considered a significant limitation.

### 5.10 Validation of the Hypotheses

This study examined two hypotheses:

1. The ability of nurses to safely (ability to detect and recover from written and/or programming errors), and efficiently (ability to quickly and successfully navigate through the software) program an IV medication will differ across smart pump models because of differences in key design elements in the Dose Error Reduction Software.
2. A high-fidelity stimulated experimental environment with tight controls over training, common infusion tasks, and interactions between the experimental team and nurse, will enable differences in Dose Error Reduction Software design and performance to be delineated.

Overall performance analyses (such as task completion time and success rate) partially validated the first hypothesis. Significant differences in task completion time between smart pump models were only found when programming the continuous (see Figure 1) and intermittent infusions (see Figure 3), and there were no significant differences in task success rate across the infusion tasks. As overall performance analyses measured the accumulated effect of multiple design elements, the findings do not reveal how individual design elements impacted nursing performance. This would suggest that analyses that assess overall performance may not be an effective method to evaluate this hypothesis because the accumulated effect of multiple design elements is examined, not individual design elements. Thus, the analysis of subtasks in an infusion task is required to properly evaluate this hypothesis.

The analyses of subtasks (subtask completion time and success rate) revealed that there were significant differences in nursing performance across the smart pump models in certain subtasks, but not in others. Specifically, there were significant differences in (a) subtask completion time when loading the iv set (see Figures 2, 4, 7, and 10) and entering the parameters (see Figures 7 and 10), and (b) in subtask success rate when entering parameters (see Figures 5 and 12), entering the generic programming mode (see Figure 8), and entering the secondary feature (Figure 12). There were no other significant differences in subtask performance across the smart pump models. These findings validate the first hypothesis and show that different designs used in a subtask can result in similar performance levels.

Uncertainties in the validation of this hypothesis using subtask analyses do exist. Performance measures of subtasks that occurred in multiple infusion tasks tended to have similar performance trends. However, analyses did not always produce the same significance differences across the smart pump models. This finding could be due to the stringent correction factor used, unknown effects on nursing performance relating to the type infusion task, or incomplete counter balancing of the infusion tasks.

The analyses of the percentage of nurses that deviated in the programming subtasks revealed that there were significant differences in nursing performance across the smart pump models in certain subtasks, but not in others. Specifically, there were significant differences in the percentage of nurses that deviated when entering parameters in the intermittent and secondary infusion tasks (Figures 9 and 10). The results of this analysis were found to be less robust than subtask completion time and subtask success rate analyses because the severities of the deviations were not measured. Examining where nurses deviated in the programming sequence proved extremely useful to understand the results from subtask
completion time and success rate analyses. Although the findings could validate the first hypothesis, the investigator is hesitant to support this conclusion without further investigation.

The analysis of soft limit alert message effectiveness revealed significant differences in nursing performance across the smart pump models. Nurses tended to override clinically inappropriate soft limit alert messages more often when using the BBraun Infusomat than when using Cardinal Alaris System or Hospira Symbiq (see Figure 14). Unlike soft limit alerts, the design of the hard limit alert message was not found to influence the effectiveness of the hard limit alert (see Figure 15). Based on these findings, the analysis of limit alert message effectiveness validated the first hypothesis.

The use of a high-fidelity stimulated experimental environment should be considered an appropriate method to examine the differences in DERS design and performance of nurses across smart pump models. Tight controls over training, common infusion tasks, interaction between the experiment team (investigator, nurse actor and trainer) and nurse were maintained throughout the study. Furthermore, the investigator took every measure possible to ensure this environment matched the actual environment. As discussed in Sections 3.3.3 and 5.9, there were limitations in the experiment design that could have impacted the findings of this study such as differences in workflow compared to actual nursing workflow, and differences in the experiment training protocol compared to VBT training protocols. However, given that all nurses completed the same infusion tasks on all smart pump models, and the tight controls set during the experiment, differences found in this study were likely be attributed to the design of the DERS.

5.11 Future Work

The following are recommendations for future work to further examine the hypotheses of this study, and expand this area of research.

1. Examine design elements in DERS and smart pump models not evaluated in this study: To further expand our understanding of the effect of DERS design on nursing performance, it would be valuable to evaluate other smart pump models and/or design elements (such as administering a bolus, recovering from physical alarms, accessing programming logs, or changing the parameters once an infusion is running) not examined in this study.

2. Examine the use of smart pumps in a real clinical environment: While every effort was made to replicate a real clinical environment, the findings of this study may not be completely reflective of what would happen in a real clinical environment. Observational studies in comparable clinical...
environments should be completed using the same smart pump models to determine if the differences observed experimentally manifest themselves in a clinical setting. This could be accomplished by implementing smart pumps in similar nursing units (one per unit), and then comparing nursing performance across the smart pumps.

3. **Investigate how the design of the medication IV order and IV bag label affect the ability of nurses to correctly enter the parameters on the parameter entry screen:** Results suggested that nurses may make fewer errors if the design of the parameter entry screen matches the design of the IV medication order and IV bag label. Further investigation is required to determine if this hypothesis is valid.

4. **The use of multi-channels:** Research has shown that nurses often have difficulties differentiating between channels and navigating through the programming sequence when programming a smart pump with multiple channels (Burdeu, G. et al. 2006; Gosbee, 2006). It would be interesting to see if an increase in the number of channels on a smart pump can increase the likelihood of nurses making programming errors.

### 5.12 Relevance to the Field

This study was one of the first high-fidelity usability tests of smart pump technology used to determine how the design of DERS affects nursing performance. The results from this study are highly relevant to numerous stakeholders involved in smart pump technology.

1. **Importance of integrating smart pump technology with other Information Technology (IT) systems in the clinical setting:** Results from this study support the concern many researchers and health care facilities have expressed regarding the need for this technology to be integrated with other IT systems (such as CPOE, PIS, and BCMA) to impact medication administration error rate (Husch et al., 2005; ISMP, 2002; Rothschild & Keochane, 2008; Rothschild et al., 2005). As seen in this study, errors relating to incorrect programming of a smart pump can still reach the patient (seen Figures 15 and 16). Specifically, this work indicates that smart pumps are not safe on their own and should be integrated with other IT systems to improve patient safety. If integrated with other IT systems, the 5-rights (right patient, right drug, right dose, right route, and right time), could be verified before administration. In this event, the nurse would first scan the patient’s ID band, the bar code on the medication IV bag and his/her ID badge. The information would then
be wirelessly transmitted to the smart pump and the parameters would be automatically programmed. If the 5-rights matched, the infusion pump would allow the nurse to start the infusion (Rothschild & Keochane, 2008).

2. **Support to hospitals during procurement:** Given that many hospitals in Ontario will be implementing smart pumps as a stand-alone system, it becomes increasingly important during the procurement process to consider how the design of the DERS affects nursing performance. Results from this study can be used by hospitals during the procurement process to evaluate the usability of smart pump models. Furthermore, general design principles extracted from this study can be used by hospitals to assess the usability of other smart pump models not evaluated in this study.

3. **Assist smart pump manufacturers to develop more user friendly products:** Information from this study can be used by manufacturers to help design out hazardous programming sequences. Manufacturers of smart pump models that participated in this study now have a wealth of information pertaining to the usability of their product. Furthermore, general design principles can be used by any manufacturer to increase the usability of their own products.

4. **Incident Reporting:** Results from this study provided important information on how and why certain events occurred when using smart pumps. For instance, nurses hitting a limit, pressing reprogram and then hitting a second limit using the same parameter values (as described in Section 2.2.3).

5. **Improve Training Material:** Results from this study can be used by manufacturers and hospitals to build customized training materials that focus on parts of the DERS that are prone to programming errors. This in turn, could help prevent programming errors from occurring.
6.0 CONCLUSION

The ability of nurses to safely and efficiently program IV medications can differ across smart pump models because of differences in DERS design. Certain design elements caused significant differences in nursing performance across the smart pump models (such as entering parameters, accessing the secondary infusion feature etc.), whereas other design elements resulted in no significant differences (such as entering drug name and concentration). The experimental design used in this study is considered an appropriate method to evaluate DER design. However, observational studies in comparable clinical environments should be completed to determine if the same findings would appear.

Each smart pump model was found to have its own strengths and weaknesses. Where one smart pump model would excel in the design of an element, it would falter in the design of another. This concludes that there is no optimal solution available out of the three smart pump models examined. With that said, this study was able to extract important information regarding the impact of certain design elements on nursing performance. These key findings can be used by hospitals in their procurement process, and by manufacturers when designing the next generation of their smart pump models.

The following is a summary of the key findings:

**Loading the IV Set**

- The IV set should contain the lowest number of components as possible that need to be inserted into the loading compartment.
- The pump door should be easy to open and close. Specifically it should be easy to unlock the pump door, open the door, and then lock the pump door once the IV set is inserted.
- The software should notify the nurse if the pump door is not closed properly.

**Enter DERS and CCA**

- If more than one drug library is available, the drug libraries should be easy to distinguish.

**Select Drug Name and Concentration**

- The drug name and concentration should be selected on separate menu levels because there are fewer items to select, which in turn could decrease the chance of selecting the wrong item.
• A hierarchical navigation method used to navigate through the drug list was found to be the most intuitive navigation method.

**Enter Parameters**

• The design of the parameter entry screen should match the design of the medication order and IV bag label. Specifically, the parameters listed on the medication order and IV bag label should match the parameters listed on the parameter entry screen. In turn, this may motivate nurses to transcribe values to the pump instead of calculating values, which could lead to a decrease in user errors.

• It is favourable to have different types of parameter entry screens for different types of infusions if it means the parameter entry screens match the medication orders and IV bag orders.

• In the mathematical relationship between parameters, rate, dose-rate and duration should always be related. The VTBI parameter field should not auto-populate when another parameter is changed.

**Secondary Infusions**

• Nurses should be able to access the secondary infusion feature directly from the main screen after a primary infusion has been programmed. If the secondary infusion feature is embedded in another menu or requires the nurse to complete steps (such as stopping the primary infusion) before accessing the feature, the DERS should provide written guidance to reduce memory load and increase effectiveness.

• There should be a clear visual distinction between programming a primary infusion and programming a secondary infusion to avoid mix-ups.

**Generic Programming Mode**

• Embedding the generic programming mode in the drug list or having the generic programming mode in a separate menu (with visual cues to find the mode from the drug list) are both favourable designs.

• The design of the generic parameter entry screen should require minimum information from the nurse while allowing the necessary freedom to enter a parameter of their choosing. It is suggested that the parameter entry screen should contain all parameter types (rate, dose-rate, duration and VTBI) to be the most effective.
• The generic programming mode should have the lowest number of programming steps possible, and require only information from the nurse that is pertinent to starting the infusion.
• The nurse should be able to tell when they are programming in the generic programming mode and when they are programming in the drug library.

Limit Alert Messages

• The design of the soft limit alert message can influence the effectiveness of the alert. To help ensure the maximum effectiveness of a soft limit alert, the message should (a) clearly state a limit has been exceeded, (b) provide a recommendation on how to proceed once the limit is hit, and (c) display the message in a different colour than what is used on other programming screens.
• A hard limit alert will be effective if the software prevents the nurse from starting the infusion until the nurse changes the parameter to a value below the hard limit.
• Although hard limits are not design dependent, it is favourable if the hard limit message contains the same design elements as soft limit alert messages (as described above).

General Design Recommendations

• Software should provide nurses with an “emergency exit” at every menu level
• DERS should have minimal programming steps and be simple to navigate.
• DERS should provide visual cues for nurses to help find features outside of the general programming sequence.
• DERS should only require information from the nurse that is pertinent to ensuring the therapy is within hospital guidelines before the infusion is started. Unnecessary steps or information should be removed.
7.0 REFERENCES


8.0 APPENDIX A: METHODS
Table 11: Smart pump model decision matrix

<table>
<thead>
<tr>
<th>Features</th>
<th>Weight</th>
<th>Cardinal Alaris System</th>
<th>Hospira Symbiq</th>
<th>Hospira Plum A+</th>
<th>Baxter Colleague</th>
<th>BBraun Infusomat</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DESIGN [55]</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Accessing DERS</td>
<td></td>
<td>Presents user with three options: Guardian Drugs, Guardian IV, and Basic. User must select Guardian Drugs to enter DERS</td>
<td>Defaults the user into DERS at start up</td>
<td>Defaults user into the generic programming mode.</td>
<td>Defaults user into the generic programming mode. User must select primary or piggyback and then select DERS from next menu level</td>
<td>Prompts user to select [yes/no] to drug library</td>
</tr>
<tr>
<td></td>
<td>3.5</td>
<td>5</td>
<td>1.5</td>
<td>1.5</td>
<td>3.5</td>
<td></td>
</tr>
<tr>
<td>Selecting drug name and concentration</td>
<td>Drug name and concentration are selected on separate menu levels. User navigates through drug list using alphabetical short-cuts, page up/down, and/or scroll up/down.</td>
<td>Drug name and concentration are selected on separate menu levels. User navigates through drug list by touching a vertical scroll bar.</td>
<td>Drug name and concentration are selected on the same menu level. User navigates through drug list by page up/down, and/or scroll up/down.</td>
<td>Drug name and concentration are selected on the same menu level. User navigates through drug list using page up/down, and/or scroll up/down</td>
<td>Drug name and concentration are selected on the same menu level. User navigates through drug list using embedded alphabetical short-cuts, and/or scrolling up/down</td>
<td></td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>4</td>
<td>1</td>
<td>2.5</td>
<td>2.5</td>
<td></td>
</tr>
<tr>
<td>Programming parameters</td>
<td>Data fields are selected using soft keys and values are entered using a hard numerical keypad. On the keypad the zero and decimal point are located beside each other</td>
<td>Data fields are selected by touching the field the user wishes to enter. Values are entered using a hard numerical keypad. On the numerical keypad, the zero and decimal point are located beside each other</td>
<td>Data fields are selected using soft keys. Values are entered using a hard numerical keypad. On the keypad, the zero and decimal point are located beside each other</td>
<td>Data fields are selected using soft keys and values are entered using a hard numerical keypad. On the keypad, the zero and decimal point are located beside each other</td>
<td>Data fields are selected using soft keys and values are entered using a hard numerical keypad. On the keypad, the zero and decimal point are located beside each other</td>
<td></td>
</tr>
<tr>
<td>- <strong>Method</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


### Order of Data Entry Fields

- General Order: Weight (on separate menu level), Rate, Dose, VTBI (users are able to toggle between VTBI and Duration).
- For intermittent infusions: user enters Rate (user is able to toggle between rate and duration).

<table>
<thead>
<tr>
<th></th>
<th>2</th>
<th>5</th>
<th>3.5</th>
<th>3.5</th>
<th>1</th>
</tr>
</thead>
</table>

### Confirmation of Programming

- Visually unique confirmation screen. Three confirmation screens: drug name and concentration, dosing units, and all settings before starting the infusion.
- Visually unique confirmation screen. User must confirm settings before starting the infusion.
- After entering all values into the data entry fields user presses start and is then asked to confirm settings.
- No visually unique confirmation screen. User confirms settings and then presses start.
- No confirmation screens.

<table>
<thead>
<tr>
<th></th>
<th>4.5</th>
<th>4.5</th>
<th>3</th>
<th>2</th>
<th>1</th>
</tr>
</thead>
</table>

### Error Recovery
### - Limits

<table>
<thead>
<tr>
<th>Description</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contains soft and hard limits. Limit message displays the parameter in question, the severity of the alert using colour and prompts the user to the next steps. If the user chooses to reprogram the values are erased from the parameter entry fields.</td>
<td>Limit message displays parameter in question, the severity of the alert using colour and prompts the user to next steps. If the user chooses to reprogram the values are erased from the parameter entry fields.</td>
</tr>
<tr>
<td>Soft and hard limits. Limit message is displayed on the same screen. The prompt bar at the bottom of the screen displays a message to the user that the dose is out of range. Out-of-limit warnings are not displayed while programming parameters.</td>
<td>Does not contain hard limits. Limit messages are displayed when user confirms settings. Limit message contains the value the user entered that resulted in the limit and the dosage range it should be in. User can choose to accept dose or cancel dose. Original values are still on screen if dose was cancelled. Screen is crowded with information.</td>
</tr>
<tr>
<td>Contains soft and hard limits. Limit messages are displayed on the same screen. The prompt bar at the bottom of the screen displays a message to the user that the dose is out of range. Out-of-limit warnings are not displayed while programming parameters.</td>
<td>Contains soft and hard limits. Limit messages are poorly displayed. Hard limit message disappears after 3 seconds. User cannot enter values into field that are greater than the hard limit value. If the user chooses to reprogram, the values are defaulted to the upper soft limit value.</td>
</tr>
</tbody>
</table>

### - Physical alarms

<table>
<thead>
<tr>
<th>Description</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alarms messages are displayed on the channel but not on the main screen. After a physical alarm, the user must restart the infusion. The user is not provided with a recommendation of how to fix the problem.</td>
<td>Physical alarms are in different colours and located in the same screen location. The alarm message tells the user what the problem is and provides a recommendation of how to fix the problem. The infusion automatically resumes after the problem is fixed.</td>
</tr>
<tr>
<td>Alarms contain unnecessary information (such as N186) and there is no recommendation on how to fix the problem. The user must restart the infusion after the problem is fixed.</td>
<td>Alarm message tells the user what the problem is but doesn't provide a recommendation of how to fix it. Alarm message is displayed in a different colour.</td>
</tr>
<tr>
<td>Poor wording of alarm messages that describe the problem and no recommendation of how to fix the problem.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Soft Limit</th>
<th>Hard Limit</th>
<th>Soft Limit</th>
<th>Hard Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>4</td>
<td>1.5</td>
<td>1</td>
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<td>2</td>
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<td>3.5</td>
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<td>4</td>
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<td>5</td>
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</tr>
<tr>
<td>6</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### - Edit programming mistakes

<table>
<thead>
<tr>
<th></th>
<th>An error correction function is available on almost all programming screens. However, the language to access this function is inconsistent (for instance, cancel, drug library and exit all move the user to the previous programming menu)</th>
<th>An error correction function is available on almost all programming screens. Common language is used to access this function (cancel and clear). Software provides user with prompts of how to go back in the programming sequence</th>
<th>Depending on the menu level, the &quot;Cancel/Back&quot; error correction button takes the user back to the beginning of the programming sequence or back to the previous menu level. If the error correction button takes the user back to the beginning of the programming sequence all programming is lost.</th>
<th>Easy to correct data entry errors. There is a function to change the medication on the parameter programming screen. Can view limit ranges on parameter programming screen</th>
<th>An error correction function is not available on all programming screens and the function often takes the user back the beginning of the programming sequence instead of the previous menu level (user loses all programming)</th>
</tr>
</thead>
</table>

### Piggyback

<table>
<thead>
<tr>
<th></th>
<th>Piggyback option is presented to the user on the main screen. Can have a separate drug library of only piggyback infusions</th>
<th>Piggyback option is presented to the user on the main screen. Can have a separate drug library of only piggyback infusions. Prompts user to hang the 2nd bag higher than primary and to open line</th>
<th>Can limit drug library to only drugs compatible with primary. User selects Piggyback which is the default for Channel B. Infusions are programmed in the safety of the DERS.</th>
<th>Piggyback option is presented to the user on the main screen using the word &quot;Piggyback&quot;. All piggyback infusions are programmed outside of the safety of the DERS. User enters Rate-Volume or can change mode to enter Volume-time</th>
<th>User must stop primary infusion to access piggyback option. User must enter &quot;Special Functions&quot; menu to enter piggyback. User must select CCA and enter drug library again.</th>
</tr>
</thead>
</table>

### Bolus

<table>
<thead>
<tr>
<th></th>
<th>Can access the bolus feature by pressing channel select and then selecting &quot;Bolus&quot;. Can choose which drugs have the bolus feature enabled. Software has soft and hard limits for boluses and users must confirm settings before giving the bolus</th>
<th>The bolus feature is accessed directly from the main screen by pressing &quot;Bolus&quot;. Can choose which drugs have the bolus feature enabled. User must confirm settings before giving the bolus and all boluses require an override</th>
<th>Can select the bolus feature from the drug library by selecting &quot;drug name Bolus&quot; or selecting &quot;loading dose&quot;. User must confirm settings before starting infusion.</th>
<th>No bolus feature.</th>
<th>The bolus feature is a hard button located on the front of the pump. User press OK for manual bolus (no units listed), press &lt; to set bolus limit. No confirmation screens available.</th>
</tr>
</thead>
</table>
### Generic Infusion

The generic programming mode is accessed through the Basic Infusion menu. The user programs rate and VTBI.

The generic programming mode is embedded in the drug list under "Other Drug". The user must enter drug concentration and dose units. User can then program dose, rate, VTBI and/or time.

The user is defaulted into the generic programming mode. User must enter rate, VTBI, duration. User can select "No Drug Selected" at the top of the drug list, which also takes them into generic programming mode.

The user is defaulted into the generic programming mode at start-up. There is a method to exit DERS at the top of the drug list when selecting the medication. Can access generic programming by selecting "change mode" or "Change med" on programming parameter screen.

The generic programming mode is accessed at the beginning of the programming sequence by pressing "No" to "Use Drug Library?" Once in the generic programming mode, the user programs rate and VTBI.

<table>
<thead>
<tr>
<th></th>
<th>4.5</th>
<th>4.5</th>
<th>2.5</th>
<th>1</th>
<th>2.5</th>
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</thead>
<tbody>
<tr>
<td>Generic Infusion</td>
<td></td>
<td></td>
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<td></td>
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</table>

### HEURISTIC EVALUATION [30]

<table>
<thead>
<tr>
<th>Heuristic Evaluation completed by Healthcare Human Factors Group</th>
<th>Average number of severe usability and overall usability issues</th>
<th>Least number of usability issues overall and average number of severe usability issues</th>
<th>Most severe usability issues, had the second greatest amount of usability issues overall</th>
<th>Average number of severe usability issues and overall usability issues</th>
<th>Second most number of severe usability issues and most usability issues overall</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>3.5</td>
<td>5</td>
<td>1</td>
<td>3.5</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>0.3</td>
<td>1.05</td>
<td>1.5</td>
<td>0.3</td>
<td>1.05</td>
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</table>

### ONTARIO MARKETSHARE [5]

<table>
<thead>
<tr>
<th>Ontario Marketshare</th>
<th>5 sites (3,060 pumps)</th>
<th>0 sites</th>
<th>4 sites (2,304 pumps)</th>
<th>9 sites (3,679 pumps)</th>
<th>1 site (50 pumps)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>4</td>
<td>1.5</td>
<td>3</td>
<td>5</td>
<td>1.5</td>
</tr>
<tr>
<td>Total</td>
<td>0.05</td>
<td>0.2</td>
<td>0.075</td>
<td>0.15</td>
<td>0.25</td>
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</tbody>
</table>

### PRODUCT LIFECYCLE [10]

<p>| | | | | | |</p>
<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Lifecycle</td>
<td>mid-cycle</td>
<td>new product</td>
<td>mid-cycle</td>
<td>end of life</td>
<td>mid-cycle</td>
</tr>
<tr>
<td>-------------------</td>
<td>-----------</td>
<td>-------------</td>
<td>-----------</td>
<td>-------------</td>
<td>-----------</td>
</tr>
<tr>
<td>Total</td>
<td>0.1</td>
<td>0.3</td>
<td>0.5</td>
<td>0.3</td>
<td>0.1</td>
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<tr>
<td>TOTAL</td>
<td>22.725</td>
<td>27.925</td>
<td>13.125</td>
<td>12.675</td>
<td>11.7</td>
</tr>
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</table>
Table 12: Hospira Symbiq pump configuration settings

<table>
<thead>
<tr>
<th>CCA SETTINGS</th>
<th>Other Infuser Parameters (Cont.)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient Limits</strong></td>
<td><strong>HOSPIRA SYMBIQ PUMP CONFIGURATION SETTINGS</strong></td>
</tr>
<tr>
<td>BSA m² Minimum</td>
<td>Time to Increase Alarm Volume (min)</td>
</tr>
<tr>
<td>BSA m² Maximum</td>
<td>Time to Dim Backlight</td>
</tr>
<tr>
<td>Patient Height (cm) Minimum</td>
<td>Nearing End of Infusion Alarm</td>
</tr>
<tr>
<td>Patient Height (cm) Maximum</td>
<td>Brightness Default Setting</td>
</tr>
<tr>
<td>Patient Weight Select unit of measure</td>
<td>Inactivity Callback Alarm</td>
</tr>
<tr>
<td>Patient Weight Minimum</td>
<td>Infusion Complete Callback Default Settings</td>
</tr>
<tr>
<td>Patient Weight Maximum</td>
<td>Bolus</td>
</tr>
<tr>
<td><strong>Alarm Settings</strong></td>
<td><strong>Multistep</strong></td>
</tr>
<tr>
<td>Proximal Occlusion Pressure Default Setting</td>
<td>Solution Container</td>
</tr>
<tr>
<td>Distal Occlusion Pressure</td>
<td>Key Press Volume</td>
</tr>
<tr>
<td>Units</td>
<td>mmHg</td>
</tr>
<tr>
<td>Default Setting</td>
<td>Default Far View Setting</td>
</tr>
<tr>
<td>Maximum Setting</td>
<td>Display on Infuser</td>
</tr>
<tr>
<td>Occlusion Pressure Auto Reset</td>
<td>3</td>
</tr>
<tr>
<td>Air Sensitivity</td>
<td>Drug Name</td>
</tr>
<tr>
<td>Settings allowable in Clinical Mode</td>
<td>all</td>
</tr>
<tr>
<td>Default Setting</td>
<td>500</td>
</tr>
<tr>
<td>Alarm Volume</td>
<td>3</td>
</tr>
<tr>
<td><strong>Other Infuser Parameters</strong></td>
<td><strong>Standby</strong></td>
</tr>
<tr>
<td>Maximum Volumetric Rate</td>
<td>1000mL/hr</td>
</tr>
<tr>
<td>Maximum VTBI (mL)</td>
<td>9999</td>
</tr>
<tr>
<td><strong>MASTER INFUSER SETUP</strong></td>
<td><strong>Allow Programming Without a Cassette</strong></td>
</tr>
<tr>
<td>Nurse Callback Feature Default</td>
<td><strong>Cleaning lock timeout</strong></td>
</tr>
<tr>
<td>Device-Level Program Lock/Unlock</td>
<td>Date/Time</td>
</tr>
<tr>
<td>Operation Test</td>
<td>Clock format</td>
</tr>
<tr>
<td>Notify when test is due</td>
<td>Date Display Format</td>
</tr>
</tbody>
</table>
### Table 13: Cardinal Alaris System pump configuration settings

<table>
<thead>
<tr>
<th>CARDINAL PUMP CONFIGURATION SETTINGS</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MODULE SETTINGS</strong></td>
<td></td>
</tr>
<tr>
<td>Accumulated air-in-line</td>
<td>Checked</td>
</tr>
<tr>
<td>Air In Line (Microfilter)</td>
<td>250</td>
</tr>
<tr>
<td>Auto-Restart Attempts</td>
<td>3</td>
</tr>
<tr>
<td>KVO Rate Adjusted (mL/hr)</td>
<td>10</td>
</tr>
<tr>
<td>Max Occulusion Pressure (mmHg)</td>
<td>525</td>
</tr>
<tr>
<td>Default Pressure (mmHg)</td>
<td>300</td>
</tr>
<tr>
<td>Maximum Rate (mL/hr)</td>
<td>99</td>
</tr>
<tr>
<td>Maximum VTBI (mL)</td>
<td>9999</td>
</tr>
<tr>
<td>Pressure Mode Lock Status</td>
<td>Unlocked</td>
</tr>
<tr>
<td>Pressure Mode Selection</td>
<td>Selectable</td>
</tr>
<tr>
<td>SEC-PRI Audio Alert</td>
<td>Checked</td>
</tr>
<tr>
<td><strong>Shared Infusions Settings (Pump &amp; Syringe)</strong></td>
<td></td>
</tr>
<tr>
<td>Delayed Start Option</td>
<td>Checked</td>
</tr>
<tr>
<td>Delay Start Callback</td>
<td>None</td>
</tr>
<tr>
<td>Multidose</td>
<td>Checked</td>
</tr>
<tr>
<td>Multidose Callback</td>
<td>None</td>
</tr>
<tr>
<td>Pressure Dynamic Display</td>
<td>Not Checked</td>
</tr>
<tr>
<td><strong>PC UNIT SETTINGS</strong></td>
<td></td>
</tr>
<tr>
<td>Alarm Audio Profile</td>
<td>Profile 1</td>
</tr>
<tr>
<td>Audio Volume</td>
<td>1</td>
</tr>
<tr>
<td>Batter Meter Display</td>
<td>Checked</td>
</tr>
<tr>
<td>Colour Display</td>
<td>Checked</td>
</tr>
<tr>
<td>Key Click Audio</td>
<td>Checked</td>
</tr>
<tr>
<td>Limit Checking</td>
<td>Always</td>
</tr>
<tr>
<td>Max Patient BSA (m2)</td>
<td>3</td>
</tr>
<tr>
<td>Max Patient Weight (Kg)</td>
<td>500</td>
</tr>
<tr>
<td>Patient ID Entry</td>
<td>Unchecked</td>
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<tr>
<td>Pending IV Orders</td>
<td>Unchecked</td>
</tr>
<tr>
<td>Preventive Maintenance Reminder</td>
<td>Unchecked</td>
</tr>
<tr>
<td>Tamper Resistance</td>
<td>Checked</td>
</tr>
<tr>
<td>Authorized User Mode</td>
<td>Enabled with Override</td>
</tr>
</tbody>
</table>
Table 14: BBraun Infusomat pump configuration settings

<table>
<thead>
<tr>
<th>BBRAUN INFUSOMAT PUMP CONFIGURATION SETTINGS</th>
<th>OPTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>RATES</strong></td>
<td></td>
</tr>
<tr>
<td>Basal min</td>
<td>0.1 mL/hr</td>
</tr>
<tr>
<td>Basal max</td>
<td>1200 mL/hr</td>
</tr>
<tr>
<td>Bolus min</td>
<td>50 mL/hr</td>
</tr>
<tr>
<td>Bolus max</td>
<td>1200 mL/hr</td>
</tr>
<tr>
<td>Bolus Volume min</td>
<td>0.01 mL</td>
</tr>
<tr>
<td>Bolus Volume max</td>
<td>99.99 mL</td>
</tr>
<tr>
<td>Venting</td>
<td>10mL</td>
</tr>
<tr>
<td><strong>KVO</strong></td>
<td></td>
</tr>
<tr>
<td>Rate: Rate &lt; 1mL/hr</td>
<td>0.1mL/hr</td>
</tr>
<tr>
<td>Rate: 1mL/h &lt;= R &lt; 10mL/hr</td>
<td>0.1mL/hr</td>
</tr>
<tr>
<td>Rate: Rate &gt;= 10mL/hr</td>
<td>0.1mL/hr</td>
</tr>
<tr>
<td>Time limit</td>
<td>240 min</td>
</tr>
<tr>
<td>Alarm</td>
<td>10 min</td>
</tr>
<tr>
<td><strong>OTHER</strong></td>
<td></td>
</tr>
<tr>
<td>General</td>
<td></td>
</tr>
<tr>
<td>Dosage calculation</td>
<td>unchecked</td>
</tr>
<tr>
<td>Drug database</td>
<td>checked</td>
</tr>
<tr>
<td>Bolus Mode</td>
<td>checked</td>
</tr>
<tr>
<td>Start-up</td>
<td></td>
</tr>
<tr>
<td>New Patient</td>
<td>not available</td>
</tr>
<tr>
<td>Last Therapy</td>
<td>checked</td>
</tr>
<tr>
<td>Use dosage mode</td>
<td>unchecked</td>
</tr>
<tr>
<td>Drug database</td>
<td>checked</td>
</tr>
<tr>
<td><strong>Dose calculation</strong></td>
<td></td>
</tr>
<tr>
<td>patient weight unit select able</td>
<td>unselected</td>
</tr>
<tr>
<td><strong>Special functions</strong></td>
<td></td>
</tr>
<tr>
<td>Dosage calculation</td>
<td>unchecked</td>
</tr>
<tr>
<td>Drug database</td>
<td>checked</td>
</tr>
<tr>
<td>Piggyback</td>
<td>checked</td>
</tr>
<tr>
<td><strong>STATUS</strong></td>
<td></td>
</tr>
<tr>
<td>Total volume</td>
<td>checked</td>
</tr>
<tr>
<td>Total time</td>
<td>checked</td>
</tr>
<tr>
<td>Intermediate volume</td>
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<tr>
<td>intermediate time</td>
<td>checked</td>
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<td>Disposable Article</td>
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<td>Storage battery</td>
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<td>Version</td>
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<td>Total dosage</td>
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<tr>
<td>Intermediate dosage</td>
<td>checked</td>
</tr>
<tr>
<td>Drug information</td>
<td>checked</td>
</tr>
</tbody>
</table>

**TIME**

| Passive Display | 1 |
| time format | hh:mm:#am#pm |
| date format | mm/dd/yyyy |
| List of Drugs: Drugs only | checked |
| List of Drugs: Drugs & categories | unchecked |

**Figure 32:** Set-up of Simulation Lab

**LEGEND**

- Curtains
- Garbage Can
- Table
- White Board
- One-way mirror
- Bed Tray
- IV pole with Smart Pumps
Figure 33: UHN Medication Order prepared by pharmacy

Figure 34: UHN medication label prepared by the nurse in the clinical area
9.0 APPENDIX B: EXPERIMENTAL PROTOCOL
1.0 EQUIPMENT SET-UP

1.1 Items to give participant before coming to the center
- Information on how to locate the centre and a number to call if they get lost
- Required time of arrival
- Reminder that the experiment will last approximately 3 hrs
- Reminder that they will not be paid on the spot but rather though their paycheck
- Explanation of study and participant requirements
- Please come to the session in normal work attire

1.2 MOE/MAR Pre-experiment Set-up

*Discharge all previous orders and bring up new orders all patients:
1. Maria, Gonzalez
   a. Potassium Phosphate
   b. Heparin (paper order)
2. Steven Campbell
   a. NS
   b. Dimenhydrinate
   c. Insulin (paper order)
3. Mr. John Smith
   a. Danaparoid
   b. Morphine
4. Ms. Agnes Taylor
   a. Colistimethate Sodium
   b. Procainamide HCl drip
5. Mr. Xian Chan
   a. N-Acetylcysteine (paper order)
   b. Amphotericin Liposmol
6. Mr. Peter Wilson
   a. Normal Saline
   b. Cyclosporine
   c. Vancomycin
7. Ms. Gloria Clark
   a. Normal Saline
   b. Phenytoin
   c. Ceftriaxone
8. Mr. Mark Lee
   a. Foscarent
   b. Ciprofloxacin **Change duration from 60min to 15 min on MOE/MAR
9. Mr. Kevin Piu
   a. Pantoprazole
   b. Octreotide

1.3 General Ward Pre-experiment Set-up
- See Equipment setup list
- Adjust MOE/MAR cart height for participant
- Paper, pen, pencil, calculator on MOE/MAR cart
Bring out bins for the first scenario and put on sink counter
- Dim lights to the second highest level
- Tape (put on MOE/MAR cart)
- Change IV collection bags
- Laptop and extension cord (plug in laptop)
- Make sure tubing is primed and IV bags are full
- Garbage can, alcohol wipes and hand sanitizer at each bed
- Put pillow on shelf
- Have paper doctors orders in case MOE/MAR goes down

**Nurse Participant**
- Wireless microphone
- Lab coat

**Nurse Actor**
- Wireless microphone
- Walkie Talkie
- Scrubs and ID badge
- Print off copy of log sheet

**Physician and/or orderly actor**
- Lab coat (place in control room)
- Have orders for hard/soft limits in control room

**Training Station Set-up**
- Pump: 2 channels
- Bags: two (size not matter)
- Lines: two, primed
- IV bag for collecting the fluids
- Questionnaire on Survey Monkey
- Put questionnaires on desktop computer
- Have paper questionnaires in case internet goes down
- White board
- Consent forms (in both paper and electronic form)
- Have signed cheque reqs ready on debriefing table
- Sign on to computer
- Lab coat for trainer
- Drinks/snacks

**Control Room Set-up**
- Easel pad (write participant name, ID and pump rotation for each experiment)
- Laptop for data collection
- Synch time on laptops with camera recording time
- Put do not disturb signs on lab and control room doors
- Walkie Talkie
1.4 Protocol A: Pre-experiment set-up

1.41 Maria Gonzalez (bed 1)

**Patient Name:** Mrs. Maria Gonzalez

**Patient Set-up:**
- Access points: 2 separate peripheral IV lines
- Put wrong wristband on patient (Mrs. Maria Gonzales)
- Put correct wristband and wig under patient’s pillow

**Documentation:**
- Heparin paper order on MOE/MAR Cart

**MOE/MAR:**
- Bring up order for Potassium Phosphate

**Equipment Set-up:**
- 1 dual channel pump or 2 single channel pumps
- Adjust pole and pump height for participant
- Every Monday, replace tubes with new ones
- Bin of IV medications (place on sink table)
  - Heparin
    - 25000 units/250mL
    - Ensure bag full and line primed
  - Potassium Phosphate: Wrong dose: soft limit
    - 15 mmol/415mL
    - Ensure bag full and line primed
1.42 Steven Campbell (bed 2)

Patient Name: Mr. Steven Campbell

Patient set-up:
- Access points: 2 separate peripheral IV lines and 1 central line
- Wristband for Mr. Steven Campbell

Documentation:
- Insulin Paper Order on MOE/MAR chart

MOE/MAR:
- Bring up order for NS
- Bring up order for Dimenhydrinate

Equipment Set-up:
- 1 dual channel pump or 2 single channel pumps
- Adjust pole and pump height for participant
- Piggyback hook
- Every Monday, replace tubes with new ones
- Bin of IV medications (place on sink table)
  - NS
    - 1000mL Normal Saline bag
    - Ensure bag full and line primed
  - Dimenhydrinate: piggyback
    - 25mg/50mL
    - Ensure bag full and line primed
  - Insulin: Dose error – hard limit
    - 25 units/250mL
    - Ensure bag full and line primed
1.43 John Smith (bed 3)

**Patient Name:** Mr. John Smith

**Patient set-up:**
- Access points: 2 separate peripheral IV lines
- Wristband for Mr. John Smith

**MOE/MAR:**
- Bring up order for Danaparoid
- Bring up order for Morphine

**Equipment Set-up:**
- 1 dual channel pump or 2 single channel pumps
- Adjust pole and pump height for participant
- Every Monday, replace tubes with new ones
- Bin with IV medications (place on sink table)
  - Danaparoid: Not in drug library
    - 2250 units/50mL
    - Ensure bag full and line primed
  - Hydromorphone: wrong drug name
    - 2mg/50mL
    - Ensure bag full and line primed
- In Med Room
  - Morphine (correct drug name)
    - 2mg/50mL
    - Ensure bag full and line primed
1.5 Protocol B: Pre-experiment set-up

1.51 Ms. Agnes Taylor (bed 1)

Patient Name: Ms. Agnes Taylor

Patient Set-up:
- Access points: 2 separate peripheral IV lines
- Put wristband for Mr. Agnes Taylor

Documentation:
- No documentation

MOE/MAR:
- Bring up order for Colistimethate Sodium
- Bring up order for Procainamide HCl drip

Equipment Set-up:
- 1 dual channel pump or 2 single channel pumps
- Adjust pole and pump height for participant
- Every Monday, replace tubes with new ones
- Bin of IV medications (place on sink table)
  - Colistimethate sodium (Drug not in DL)
    - 150mg/100mL
    - Ensure bag full and line primed
  - Procainamide HCl drip (wrong dose –hard limit)
    - 1g/250mL
    - Ensure bag full and line primed
1.52 Mr. Xian Chan (bed 2)

**Patient Name:** Mr. Xian Chan

**Patient set-up:**
- Access points: 2 separate peripheral IV lines
- Put wrong wristband on patient (Mr. Xiao Chan)
- Put correct wristband and beard under pillow

**Documentation:**
- N-Acetylcysteine paper order

**MOE/MAR:**
- Bring up order for Amphotericin Liposomal

**Equipment Set-up:**
- 1 dual channel pump or 2 single channel pumps
- Adjust pole and pump height for participant
- Every Monday, replace tubes with new ones
- Bin of IV medications (place on sink table)
  - N-Acetylcysteine (correct patient name: Mr. Xian Chan)
    - 9g/1000mL
    - Ensure bag full and line primed
  - Amphotericin B (wrong drug name)
    - 425mg/250mL
    - Ensure bag full and line primed
- In Med Room
  - Amphotericin Liposomal (correct drug name)
    - 425mg/250mL
    - Ensure bag full and line primed
1.53 Mr. Peter Wilson (bed 3)

**Patient Name:** Mr. Peter Wilson

**Patient set-up:**
- Access points: 2 separate peripheral IV lines
- Wristband for Mr. Peter Wilson
- Patient Accessories (gown, no wig or breasts)

**Documentation:**
- No documentation

**MOE/MAR:**
- Bring up order for Normal Saline
- Bring up order for Cyclosporine
- Bring up order for Vancomycin

**Equipment Set-up:**
- 1 dual channel pump or 2 single channel pumps
- Adjust pole and pump height for participant
- Hook for piggyback
- Every Monday, replace tubes with new ones
- Bin of IV medications (place on sink table)
  - NS (Maintenance fluid)
    - 1000mL Normal Saline IV
    - Ensure bag is full and line is primed
  - Cyclosporine (Piggyback)
    - 125mg/100mL
    - Ensure bag is full and line is primed
  - Vancomycin
    - 1g/250mL
    - Ensure bag is full and line is primed
1.6 Protocol C: Pre-experiment set-up

1.61 Ms. Gloria Clark (bed 1)

- **Patient Name:** Ms. Gloria Clark

- **Patient Set-up:**
  - Access points: 2 separate peripheral IV lines
  - Put wristband for Ms. Gloria Clark

- **Documentation:**
  - No documentation

- **MOE/MAR:**
  - Bring up order for Normal Saline
  - Bring up order for Phenytoin
  - Bring up order for Ceftriaxone

- **Equipment Set-up:**
  - 1 dual channel pump or 2 single channel pumps
  - Adjust pole and pump height for participant
  - Piggyback hook
  - Every Monday, replace tubes with new ones
  - Bin of IV medications (place on sink table)
    - Normal Saline (Maintenance Fluid)
      - 1000mL
      - Ensure bag is full and line is primed
    - Phenytoin (Piggyback)
      - 300mg/100mL
      - Ensure bag is full and line is primed
    - Ceftriaxone Sodium (correct drug name)
      - 1g/50mL
      - Ensure bag is full and line is primed
  - **In Med Room**
    - Ceftriaxone Sodium (correct drug name)
      - 1g/50mL
      - Ensure bag is full and line is primed
1.62 Mr. Mark Lee (bed 2)

**Patient Name:** Mr. Mark Lee

**Patient set-up:**
- Access points: central line
- Wristband for Mr. Mark Lee
- Patient Accessories (gown, no wig)

**Documentation:**
- No Documentation

**MOE/MAR:**
- Bring up order for Foscarent
- Bring up order for Ciproflaxacin

**Equipment Set-up:**
- 1 dual channel pump or 2 single channel pumps
- Adjust pole and pump height for participant
- Every Monday, replace tubes with new ones
- Bin of IV medications (place on sink table)
  - Foscarent (Drug not in Drug Library)
    - 3300mg/137.5mL (glass bottle)
    - Ensure bag full and line primed
  - Ciproflaxacin (wrong dose – soft limit)
    - 400mg/200mL
    - Ensure bag full and line primed
1.63 Mr. Kevin Piu (bed 3)

<table>
<thead>
<tr>
<th>CHANNEL 1</th>
<th>CHANNEL 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Hit Hard Limit</td>
</tr>
<tr>
<td>Error Type:</td>
<td></td>
</tr>
<tr>
<td>Wrong</td>
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<td>Patient</td>
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<td>Error Type:</td>
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<tr>
<td>Wrong</td>
<td></td>
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<tr>
<td>Patient</td>
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</tbody>
</table>

**Patient Name:** Mr. Kevin Piu

**Patient set-up:**
- Access points: 2 separate peripheral IV lines
- Put wrong wristband on patient (Mr. Kevin Siu)
- Put correct wristband and beard under pillow

**Documentation:**
- No Documentation

**MOE/MAR:**
- Bring up order for Pantoprazole
- Bring up order for Octreotide (Cl)

**Equipment Set-up:**
- 1 dual channel pump or 2 single channel pumps
- Adjust pole and pump height for participant
- Every Monday, replace tubes with new ones
- Bin of IV medications (place on sink table)
  - Pantoprazole (correct patient name)
    - 40mg/100mL
    - Ensure bag full and line primed
  - Octreotide (Cl) (Wrong Dose - Hard Limit)
    - 500 mcg/250mL
    - Ensure bag full and line primed
2.0 PRE-EXPERIMENT SCRIPT

2.1 Meet and greet participant

Location: Main office area and innovation lab hallway

Equipment needed: small poster in a visible area to (a) ensure the participant that they are in the correct location for the study and (b) extension to contact study coordinator when they reach the center.

Estimate time:

[Person 1] “Hi ______________________, welcome to the centre! My name is Sarah Rothwell and I’m the study coordinator for the infusion pump study. How are you? [Small talk … i.e. did you have any problems finding the center etc?] We are really happy that you’re able to participate in this study, it’s going to be great getting your insight on this new technology. Have you ever been to center before? No? All right, let me give you a quick summary of what goes on here.”

Lead participant into innovation lab hallway toward lab [While walking to lab give quick summary of the center]

[Person 1] “So, [Name of Participant] this center was created to improve healthcare for people through safe, usable and effective technologies and processes. Here at Healthcare Human Factors Group, we conduct usability testing on medical devices. We often require the help of nurses because nurses are frequently the main users of these devices. By understanding user needs and limitations we can hopefully improve clinical workflow and patient safety.”

2.2 Introduction to the study and the lab

Location: Scenario section of lab

Equipment needed: none

Estimate time:

☐ Lead participant into lab

[Person 1] “Okay, so here is the lab that you will be working in this morning/afternoon. The study you will be helping us with today is sponsored by the Ministry of Health. We will be looking at how the differences in software between smart infusion pumps affect the ability of nurses to efficiently and safely administer iv medications to patients. You will be introduced and trained on three different types of infusion pumps. You will be then asked to complete a series of infusion tasks on each pump and after we’ll get you to complete short questionnaires about your thoughts on each type.

We would like you to pretend that you are a float nurse and that this is your first time on this unit. Nurse Alvita, another nurse on this unit, will help you orient yourself to the unit. Specifically, she will discuss the patient histories with you and will remain in the room at all times in case you have any questions.

The scenarios are meant to be as realistic as possible, and you should try to practice your nursing as you regularly would (for instance, ensuring the five-rights). But there are a few areas where things will not be entirely realistic:

☐ This is your computer on wheels and this is the computer you will be using to pull-up the orders on MAR (explain that they will be in the MAR view). We recognize that you would normally get
the drugs in the drug preparation room, but for purposes of this experiment, Nurse Alvita will place the drugs on the computer on wheels for you. As you can see, we have placed a calculator and pen and paper for you to use. Also, if there are any drugs that you are unfamiliar with, we have placed a Drug Formulary binder here so that you can look it up. Or, you can look it up online as well. Then, Nurse Alvita will wheel the cart over to the bedside.

- There will be mannequins playing the role of patients. They all have PIVs in each arm and a central line. Please always put each iv in a different access point…. and don’t attach the iv tubing too tightly as we will need to disconnect it after the study!

- There will be actors playing the role of the charge nurse. (He/she will guide the scenarios but he/she doesn’t have any more training on the infusion pumps than you.)

- There will be no real drugs used

- In the interest of time, IV bags will be pre-primed in the interest of time and already attached to the bag. However, please just check air hasn’t been introduced into set so we can minimise air inline alarms as this isn’t a priority for this study. Also, the downstream roller clamp is rolled closed so to minimise downstream occlusion alarms, please remember to open this up before starting the infusion. Could you also please attach the line to the patient, but don’t pierce the skin.

- You are not responsible for any documentation

- Some intermittent infusions that are normally a piggyback may be put on a primary line

- In the interest of time, we will not be actually running infusions over the true length of time that they would run. However, you will program the infusion as if it will run over the appropriate length of time

- Also, please always stand within the taped box on the floor and try not to move the pump

- You don’t have to check off the items in Nursing inbox in MOE/MAR

While you are administering iv fluids to the patients I will be observing you from behind a one-way mirror (show participant window). This will prevent me from distracting you when you are completing the tasks. I want to keep this session as close to your normal working environment as possible. Also, this session will be videotaped and audio taped just in case I miss anything after the session is completed. The videotapes and audiotapes are strictly confidential. No names or identifying information will be used in any reports, publication or presentations that may come from this study. If you allow use to share your video clips your face will be blurred.

I want to stress that the purpose of this study is not to assess your skills and will in no way affect your position at TGH. If you encounter any problems while using the pumps, it is not a reflection on your skills but rather an indication to me that this technology requires improvements.

During the scenarios, you may find that when you ask questions to me, I throw another question back at you. This is not to be patronising but rather to see what you would actually do.

Great, so that’s about it. Any questions?”
2.3 Explanation of consent form and signing of consent form

Lead participant into 2nd lab space (2nd lab space would be an area that is not in the testing space)

  Location: Training space  
  Equipment needed: Desktop computer, table for computer, chair for participant, consent form  
  Estimate time: 15 min

[Person 1] “All right, the next thing I would like to you do is fill out a consent form. This is to make sure that you understand what is going on in the study and your rights as a participant. If you have any questions or need clarification just let me know.

  □ Participant reads consent form and signs it
2.4 Background questionnaire

*Location:* Training space  
*Equipment needed:* Desktop computer, table for computer, chair for participant, paper questionnaires, questionnaire on survey monkey  
*Estimated time:* 10min

[Person 1] “Okay, now that all the paper work is taken care of, I would like you to complete a short background questionnaire.”

- Participant completes background questionnaire
3.0 TRAINING SCRIPTS

Location: 2nd lab space
Equipment needed: infusion pump, iv bags and sets, white board
Estimated time: 15 min

3.1 Cardinal Alaris Training

1. Introduction to pump layout
   a. This pump is called the Alaris,
   b. Pharmacy, nursing, biomed etc. they all got together and figured out what drugs,
      concentrations and infusion settings the hospital uses.
   c. Then they put that information into the pump.
   d. One of the advantages of this pump is that they could then put upper and lower limits on
      things like the infusion rate or the duration of infusion.
   e. On this pump, these limits are called ‘guardrails’, just like the ones on either side of the
      road, they are meant to keep you from going too far on either side.
   f. There are two types of limits or guardrails: a soft limit, or a hard limit.
   g. If you hit a soft limit you can continue your infusion or stop and go back.
   h. A hard limit will stop you and force you to go back and reprogram the pump.
   i. These safety features don’t only protect your patients from errors, but they protect you
      from errors as well, and that’s a good thing.
   j. So if we look at the pump, you’ll see that it has this central part, which is the ‘brain’, and
      these two units on the side, which are the actual pumps – so it’s a two channel pump.
   k. If we look at the brain, you’ll see these arrows around the screen which are called soft
      keys, because what they do changes depending on what they are connected to on the
      screen just like an ATM.
   l. These lower buttons with words and numbers are called hard keys, because they always
      do the same thing. A seven always means seven.
   m. Among the hard keys, you won’t really use the ‘enter’ key (as you’ll see when we
      program later), the cancel key will usually back you out of whatever you’re doing, and
      the clear key will clear the number you are working on; if you hit a 2 instead of a 1, you
      can hit clear to start over.
   n. The silence key is yellow, because silence is golden.
   o. The options key we won’t use much today, just know this is where it is.

2. Loading a set
   a. Alright, so before I let you try it, let me first show you how to load the pump.
   b. Open the latch
   c. Drop from the top, blue to blue and then floss the blue knuckles at the bottom.
   d. The reason we do it like this is because this middle section shouldn’t be stretched or
      twisted because it can cause inaccurate fluid delivery. So its better when you just let it
      drop from the top and hang naturally.
   e. Also, when you’re pushing the blue piece in, don’t push the white piece in because that’s
      your free flow protection
      i. – it should stick out.
   f. Finally, it’s important that you floss the knuckles at the end because these blue pieces
      detect air-in line, so if it’s not loaded properly, you will get nuisance alarms.
   g. Alright, you give it a shot on the other channel!

3. Programming a continuous infusion
   a. Okay good, So before we turn the pump on, let me just tell you what will happen.
b. The first thing the pump will do is ask you if you have a new patient. Pretend we do, so you can say yes to that.

c. Next it will ask you for the correct profile.
   i. Different units in the hospital have different needs – maybe they use different drugs or have different limits, so you have to pick the right one.
   ii. Today we are in the med surg unit.

d. Okay, so let’s turn on the pump. Go ahead and press system on. It will take a moment.
   Yes to new patient, and med surg is the profile we want, so you can say yes to that as well.

e. main screen
f. you’re at the right profile
g. two channels
h. This blue bar at the bottom is your GPS. It will always tell you what to do so make sure you read it to and the pump will guide you along.
i. Let’s say we need to program an order for magnesium sulphate.
j. First we would connect the tubing to the patient’s access point.
k. The order is on the whiteboard if you miss what I said.
l. Right now, it is telling you to select a channel.
m. The way you tell the brain which channel you want to use is to press the channel select button on the pump itself.

n. Then, pick guardrails drugs,
o. Either page down to magnesium sulphate, or use the letters on the side to jump ahead to the m’s.
p. So now, just read the screen and then follow the GPS’ directions.
q. Anything with a box around it means that you can select it.
r. Roller clamp off!
s. Press start.

4. **Hitting a hard limit**
   a. What happened? We hit a hard limit.
   b. How do you know it’s a hard limit? You can’t do anything but go back.
   c. So let’s go back and change our rate to 10mL/h

5. **Programming a maintenance fluid**
   a. So now let’s do a maintenance fluid of normal saline
   b. So what do we do when we want to program an infusion? Channel select on the pump we want.
   c. This time pick iv fluids, and select 0.9% NS.
   d. Yup, just follow what the GPS tells you to do.
   e. The values are…
   f. Roller clamp off!
   g. Press start!

6. **Programming a secondary infusion**
   a. Good, now let’s do a piggyback infusion of aminophylline.
   b. Since we want to program, what do we do? Channel select!
   c. Since the primary is already running, it takes us here.
   d. Look at the bottom see secondary?
   e. Pick secondary, find aminophylline,
   f. Enter the order…
   g. Roller clamp off!
   h. Go ahead and start it.

7. **Hitting a soft limit**
   a. So here we’ve hit a soft limit.
So as you can see, you can either proceed past the limit, or go back.

c. **What you do depends on your hospital’s policy.**

d. Let’s press no, and change the duration to 30 minutes.

e. Press start.

8. **Clearing volume totals**

a. Pretend it’s end of shift and you have to clear the volume totals.

b. Press volume infused at the bottom here.

c. Here you can see total volumes.

d. You can press pri/sec to see more detail.

e. To clear it, just press clear all

f. They’re gone!

g. Then main screen to return.

9. **Stop previous medication and program order for new medication on same channel**

a. Now I want to show you one more infusion, but we only have 2 channels, so we have to use channel 1 again.

b. Let’s say this infusion was done < I press pause>,

c. And the new bag and cassette are already in there

d. You have to tell the pump we’re not infusing magnesium sulphate anymore.

e. So you press and hold channel off until it beeps.

f. So go ahead

g. Now let’s say you only had one channel running to begin with, if you used channel off, the brain would just shut everything down, because nothing is needed. So what you have to do is press a hard key while it says powering down, and that way you’ll be at the main screen and you can then pick a new drug. [demonstrate]. Now you give it a shot.

10. **Programming a generic infusion**

a. Okay, now for a basic infusion.

b. A basic infusion has no guardrails - safety limits.

c. You might use this for research drugs that aren’t in the library, or in an emergency when you don’t have time to go through all those menus.

d. So, start the same way you always do when you want to program an infusion – channel select

e. We’ve used the top two already. They start with ‘guardrails’ because they have those safety limits.

f. So pick basic infusion. You just get rate and volume.

g. Do 50mL/h and 250mL and press start.

h. As you can see there is no drug showing up on the marquee, where it would normally appear, because for basic infusions, the pump doesn’t know what its delivering.

i. You should not be using this unless you can’t find the drug in the guardrails library or like I said, an emergency.

11. **Checking battery life**

a. Okay, now the last thing, let’s say you were unplugging this pump so it could go with the patient.

b. If you want to see how long it will last on battery, press options, page down, and press battery run-time.

c. This is how long the battery will last under the current demands.

d. Okay, we’re all done! I’ll let you move on to the next phase of our study.

### 3.2 Hospira Symbiq Training

1. **Introduction to smart pumps**

a. This is the SYMBIQ infusion system.
b. Pharmacy, nursing, biomed etc. they all got together and figured out what drugs, concentrations and infusion settings the hospital uses.
c. Then they put that information into the pump.
d. One of the advantages of this pump is that they could then put upper and lower limits on things like the infusion rate or the duration of infusion.
e. There are two types of limits: a soft limit, or a hard limit.
f. If you hit a soft limit you can continue your infusion or stop and go back.
g. A hard limit will stop you and force you to go back and reprogram the pump.
h. These safety features don’t only protect your patients from errors, but they protect you from errors as well, and that’s a good thing.

2. Introduction to pump layout
   e. If we look at the pump, you’ll see it has a large touch screen in the middle and two channels, one on either side.
   f. Lets go over some features on the pump:
      i. This is the LOAD/EJECT button for opening and closing the cassette carriage
      ii. This is the ON/OFF button to turn power on and off
      iii. This is the Silence button which silences alarms for 2 minutes
      iv. This is the Emergency stop button that stops all channels and generates high urgency alarm

3. Loading the set (Channel 1)
   a. All right, so first, let me first show you how to load the cassette into the pump.
   b. The pump has to be on when loading or unloading a set.
   c. First power on the infuser by pressing the on/off button. You do have to keep your finger on this button for a few seconds. The pump then goes through a self-test and synchronizes itself.
   d. At this point you can load the set. So press the LOAD/EJECT button to open the cassette carriage
   e. To insert the cassette, you want to hold the tubing above and below the cassette (position the cassette with the flow stop facing the infuser and the purple collar at the top) and then just slide the cassette to the cassette carriage
   f. The door will automatically close after 6 sec or you can press LOAD/EJECT
   g. All right, now you give it a shot on the other channel!

4. Start up
   a. So now we’re going to get into the programming of the device
   b. This is the first screen you are going to see. This is the patient information screen. The first thing we have to do on this screen is select the clinical care area (CCA) we will be working in
      i. Different units in the hospital have different needs – maybe they use different drugs or have different limits, so you have to pick the right one.
      ii. Today we will be in the MedSurg unit so press the CCA button and select MedSurg
   c. The pump can also accept patient ID and clinician ID, but for today, you do not have to enter any of that.
   d. When you are done, you can press the DONE key which will bring you to the main screen
   e. You’ll notice here that the screen is spill into two. That is because we working with a dual channel pump. So we have channel A on the left hand side and channel B on the right hand side
   f. So we’re going to press Channel A to get to the main screen for working within channel A
   g. I would like to point out a few areas on the main screen
h. Along the top is your channel level therapy buttons. We have a bolus button, a basic button (always going to be your primary infusion), advanced key (for advance therapies such as multi-step) and piggyback button (for when we want to do a secondary infusion).

i. The middle part of the screen is your working programming screen.

j. The dark bar at the bottom is the Help Text Status area. Any messages for you will come up in this bar.

k. The bottom row is your device status bar. We’re not going to go into this too much at this point.

5. Programming a continuous infusion (Channel 1)
   a. All right we’re now going to go ahead and program a basic infusion of magnesium sulphate.
   b. The first thing we have to do is select the infusion. In order to scroll through the medications in this library you can use this colour arrow on the right hand side. If you press the arrow toward the centre it will scroll one medication at a time. If you press the arrow to the outer edge of the arrow it will scroll 2 or 3 meds at a time.
   c. So find magnesium sulphate.
   d. Now pick concentration (4g/250mL).
   e. Now you have to input your rate and VTBI before you can start the infusion. Select Rate/Dose and use the numerical keypad to enter the value and then press enter.

6. Hit Hard Limit (Channel 1)
   a. When they enter Rate/Dose: What happened? We hit a hard limit.
   b. You know it’s a hard limit because you’re in the red. The green area is acceptable.
   c. You can’t do anything but press OKAY and reprogram.
   d. So let’s go back (press Okay) and change our rate to 10mL/h.
   e. Now enter VTBI.
   f. Now press next A.
   g. And here is your safety confirmation screen. This is your last chance to check to make sure your programming is correct.

2. Maintenance Fluid (Channel 2)
   a. So now let’s do a maintenance fluid of NS on Channel B.
   b. Select Tab B and find 0.9% NS in the drug list.
   c. Now enter the rate and VTBI.
   d. Confirm and press start.

3. Piggyback (Channel 2)
   a. Good, now let’s do a piggyback infusion of aminophylline.
   b. From the main screen, press Piggyback.
   c. Press Select Infusion field and use the scroll bar to select the desired medication.
   d. Select Rate field and enter desired rate.

4. Hit Soft Limit (Channel 2)
   a. So here we’ve hit a soft limit. As you can see, you can either proceed past the limit (override) or go back (edit). What you do depends on your hospital’s policy. Let’s press Edit, and change the duration to 30 minutes.

5. Clearing Shift Totals
   a. Pretend its end of shift and you have to clear the shift totals.
   b. From the main screen, press Logs at the bottom of the screen.
   c. From the logs menu screen, press Shift Total to display the Logs Shift Totals screen.
   d. So this is Channel A and B shift totals for volume infused.
   e. Now press Clear shift totals, confirm it and that’s it! They are back to zero.
6. **Stop previous medication and program order for new medication on same channel**
   a. I want to show you one more infusion, but since we only have two channels I’ll have to reuse one.
   b. So let’s say the infusion is done <I press Stop Infusion> and we want to infuse a different drug on the same channel.
   c. So first press Basic and then press Clear
   d. Now press continue to clear previous programming
   e. See it takes you right back to the start of the programming sequence and now you can select the new infusion

7. **Generic infusion**
   a. So now we are going to program an infusion that is not in the drug library. These drugs will not have safety limits so we only want to use this function if drugs are not in the drug library.
   b. So start the same way you always do when you want to program an infusion.
   c. Select Channel
   d. To program a medication that is not available in the drug list you select Other Drug in the Select Infusion Field.
   e. The pump needs to know what the concentration is, so you have to select this one.
   f. Let’s say we have an experimental drug that 50mg in 250mL. Now you want to press the Select drop-down field to display and select a medication unit. Select Drug amount in Container and Total Volume in Container field and enter desired values.
   g. Press Select to enter dose units. **Now you can go ahead and enter your order.**
   h. When finished, press Next, confirm settings and press Start Basic Infusion.

8. **Checking Battery Life**
   h. Okay, now the last thing. Let’s say you were unplugging this pump so it could go with the patient.
   a. If you want to see how long it will last on battery, you can look at the battery power indicator on the lower right corner of the touch screen. If the battery is completely green it is at full capacity. As the green starts to recede, it indicates less power in the battery. For instance, if the green occupies half of the battery icon it means the battery is at half capacity.

### 3.3 BBraun Infusomat Space Training

1. **Introduction to smart pumps**
   a. This is the BBraun Infusomat, and we have two of them here.
   b. Pharmacy, nursing, biomed etc. they all got together and figured out what drugs, concentrations and infusion settings the hospital uses.
   c. Then they put that information into the pump.
   d. One of the advantages of this pump is that they could then put upper and lower limits on things like the infusion rate or the duration of infusion.
   e. There are two types of limits: a soft limit, or a hard limit.
   f. If you hit a soft limit you can continue your infusion or stop and go back.
   g. A hard limit will stop you and force you to go back and reprogram the pump.
   h. These safety features don’t only protect your patients from errors, but they protect you from errors as well, and that’s a good thing

2. **Introduction to pump interface**
   a. As you can see, this is a compact pump that can be used in a modular fashion, as we see here. Each pump can be secured to a docking station so you can power the pumps by a single cable.
b. So if you look at the pump you’ll see that there is no numerical input, and it has been eliminated in favor of up/down arrow soft keys. You’ll see how they work when we start programming
   i. This is the start button that starts and stops infusions
   ii. This is the bolus button that allows you to deliver a bolus to the patient
   iii. This is the correction button which you can press to reset whatever number you’re working on to zero or it will let you go back to the previous screen/menu level
   iv. This is the button that opens the pump door for loading the set.
   v. The OK button is used mostly to open certain functions and confirm values/settings/alarms.

3. Loading a set
   a. Let me show you how to load the pump. The pump must always be turned on when loading or unloading a set, so to turn it on…
   b. Press the green power switch on the front, right hand corner of the pump.
   c. Press the up arrow on the far right corner to open the pump door and select yes on the display by pressing ‘up’. Pull the door with your hand to open it completely
   d. Align center section of set so that the silicon tubing segment has the gray 2-hole clip aligned to the right. Press the clip over the 2 pins and press the tubing into the notch on the right side
   e. Holding on to the gray clip, align the white clip to the left and over the ridge on the left side of the pumping section.
   f. Now press the green free flow clamp into the green chamber. It must be pressed all the way down in order for the clip to align in the chamber securely
   g. To insert the free flow clip, press the clip into the green lever. You will know when the clip is properly inserted when the green lever moves outward.
   h. Then push the door, the motor will pick up the closing door and the door will then close automatically
   i. Press the left arrow to accept the to Original Space Line to begin programming
   j. You can also say no to priming for today. So let me take it out and let you give it a try.
   k. [take out set and turn pump OFF]

4. Start up
   a. Okay good! So before we start programming the iv order, there is a series of questions that you will have to answer in the Start Up Menu using the up and down arrow buttons
   b. The first thing the pump will do is ask you whether you would like to prime the line. You can assume that the line is already primed. So press NO.
   c. Next it will ask you if you want to use the last therapy that was programmed on the pump. We’re going to program a new order, we will select no.
   d. The next question will ask you if you want to use the drug library. Press “Yes”
   e. Now its asking you for the correct profile.
      i. Different units in the hospital have different needs – maybe they use different drugs or have different limits, so you have to pick the right one.
      ii. Today we are in the med surg unit, so go ahead and pick that one.

5. Programming a continuous infusion
   a. Let’s say we need to program an order for magnesium sulphate
   b. The order is on the whiteboard if you miss what I said
   c. You can pick the drug name and concentration from the drug list. To move through the drug list you can use the UP or DOWN arrow buttons or use LEFT and RIGHT to jump to different letter grouping in the alphabet. Press the left arrow to select the drug name and concentration
d. Right now, it is asking you to enter VTBI. To input VTBI highlight VTBI with the UP or DOWN arrow button and select with the Left Arrow Button
   i. Press up/down to change setting of numbers from 0-9
   ii. Press left/right to switch between which digits when numbers are entered

e. Enter VTBI with the arrow buttons and confirm with OK

f. So now you can start entering the other parameters. If you press the down arrow button you can select rate, Dose, time etc and access these parameter by pressing the left arrow button. Let’s finish programming the order…

6. Hit Hard limit
   a. When they enter RATE: What happened? We hit a hard limit.
   b. How do we know it’s a hard limit? If the set rate/dose rate exceeds the values stored in the drug library, you will be unable to enter the rate/dose at a value higher than the limit.
   c. You can’t do anything but go back.
   d. So let’s go back and change our rate to 10mL/h
   e. Now press Start

7. Maintenance Fluid (2nd pump)
   a. So now let’s do a maintenance line of normal saline
   b. So turn on the pump and insert the set
   c. Press No to prime the line. Press Yes to new patient. Press No last therapy. Press Yes to using the drug library. And the MedSurg profile is what we want, so you can select that as well.
   d. Find 0.9% NS in the drug list
   e. Now just follow the steps to program the order…
   f. The values are…
   g. Roller clamp off!
   h. Press start

8. Secondary Infusion
   a. Good, now let’s program a piggyback infusion of aminophylline
   b. First we need to stop the maintenance fluid on the pump
   c. Use up/down arrow keys to scroll to “Special Functions”. If you don’t stop the maintenance fluid you won’t see the piggyback option in Special Functions
   d. Now select Piggyback mode
   e. Press “Yes” Automatic change and press “Yes” to use drug library
   f. Select CCA (MedSurg)
   g. Select drug and concentration
   h. Input Weight, VTBI, and Time (the length of the infusion)
   i. Press OK to confirm

9. Hit Soft limit
   a. So here we’ve hit a soft limit. As you can see, you can either proceed past the limit or go back.
   b. What you do depends on your hospital’s policy
   c. Let’s press no, and change the duration to 30 minutes
   d. Press Start

10. Clearing shift totals
    a. Good! Now pretend it’s the end of the shift and you have to clear the volume totals
    b. In the Main Menu, use the bottom arrow button to scroll down to the Status function and select it
    c. Here you can see total volumes Volume
    d. You can access Volume by pressing the left arrow. Now press left arrow to access Volume and press Yes to reset all
11. Stop previous medication and program order for new medication on same channel (reset parameters)
   a. Let’s pretend this drug is finished and I would press stop and pretend that I have a new drug set up. I have to tell the pump I’m not running MgSO4 anymore
   b. So what I want to do is press the correction button to cancel out of the current settings. As you can see, it brings me to this menu level and I can start over and program the new order.

12. Generic infusion
   a. Okay, now for a generic infusion. A generic infusion has no safety limits.
   b. You might use this for research drugs that are not in the drug library, or in an emergency situation when you don’t have time to go through all those menus.
   c. So in this case, you are going to select no to the use of the drug library since you don’t want to use the safety limits.
   d. Now enter VTBI and rate
   e. Program 50mL/hr and 250mL and press start
   f. As you can see there is no drug name showing up on the display, where it would normally appear, because for basic infusions, the pump doesn’t know what its delivering
   g. You should not be using this unless you can’t find the drug in the drug list or like I said, in an emergency.

13. Checking Battery Life
   a. Okay, now the last thing. Let’s say you were unplugging this pump so it could go with the patient.
   b. If you want to see how long it will last on battery, you can look at the battery status indicator that is displayed on the pump screen. That display is only a trend indicator (low-medium-high). To view specific battery capacity, access the status menu and select “Batt. Cap”
   c. Okay, we’re all done! I’ll let you move on to the next phase of our study.
4.0 PROTOCOL A: EXPERIMENT SCRIPT

NOTE: Nurse Actor is in charge of all questions from the participant. If the participant gets stuck, the nurse actor will tell the participant how to get the next programming step.

4.1 Introduction to ward

If first protocol of experiment:

*Data Collection: Synch time on laptops with camera recording time*

[Nurse Actor] “Hi ______________, nice to meet you! You must be my float nurse! My name is Alvita and I’m another nurse on this ward. It is so good to see you because we are way behind in delivering our meds to our patients. These three patients have just come up to ward and we need to finish their orders. You haven’t worked on this unit before, right? So there is a couple of things I would like to cover before I introduce you to the patients that you will be taking care of. First, here is our MOE/MAR cart (I’ll make sure the cart is at the bedside). You are responsible for administering the IV medications, but I will take care of any documentation. There is a formulary of IV medications in the binder on the MOE/MAR cart. You can also access it online.

[Nurse Actor] “The hospital has just gone live with these new pumps. I think you have received training on these pumps, but I don’t know if you are aware that the hospital has released new policies regarding the soft and hard limits. If you hit a soft limit you must first recheck your programming. If your programming is the same as the physician’s order and you feel the dosing parameters are appropriate for the patient you may start with the infusion. However, if you think that the dosage value is inappropriate, please call the patient’s physician. If you hit a hard limit you must check with the patient’s physician.

If second or third protocol of experiment:

[Nurse Actor] Hi, Welcome back to the ward! As you can see, the hospital has just implemented these new infusion pumps. The hospital has released new policies regarding the soft and hard limits. If you hit a soft limit you must first recheck your programming. If your programming is the same as the physician’s order and you feel the dosing parameters are appropriate for the patient you may start with the infusion. However, if you think that the dosage value is inappropriate, please call the patient’s physician. If you hit a hard limit you must check with the patient’s physician.

[Nurse Actor] We have three new patients that have just arrived on our ward. So I’m glad you’re here because I definitely need some help! Do you have any questions before we begin?

4.2 Experiment: Mrs. Gonzalez (Patient 1)

- Nurse Actor: Puts Heparin and Potassium Phosphate IV bag on MOE/MAR cart
- Nurse Actor: put Heparin paper order on MOE/MAR cart
- Nurse Actor: move training pumps to Bed 3

4.21 Mrs Gonzalez: pump/channel 1, Heparin, Wrong Patient
VTBI: 250mL

[Programming] “All right let’s get started. Our first patient came into the Emergency Department complaining of chest pain and shortness of breath a couple of days ago. After a lung scan, she was diagnosed with pulmonary embolus, and as now been sent to us! She has been put on blood thinners and at the moment has low phosphate levels. Her vitals are good, CBC: 120 (normal), white count: 6 (normal), Platelets: 250 (normal). She is 123 kg. She is also a little dehydrated, so we will be giving her more fluids than normal.

[Programming] “I’m just started setting up her infusions. I was hoping that you could take over, because I just got a page and have to run. Here is the IV order for Heparin (Nurse Actor hands over order to participant). This will be the first time Heparin will be administered to this patient and the physician has indicated that he does not want her to receive an initial bolus. So if you could start it as a continuous infusion that would be great. The order for Potassium Phosphate should be on MOE/MAR. If you can start with Heparin that would be great. Thanks a lot! I’ll be back soon.”

Order:
- Drug name: Heparin
- Concentration: 25000 units/ 250 mL
- Order: Standard protocol for 123 kg. 100 units/mL

Programming:
- Dose: 2,200 units/h
- Rate: 22mL/h
- VTBI: 250mL

NOTE: Nurse should notice bag is for the wrong patient

If participant detects the wrong patient before programming or during programming:

[Nurse Actor] “Oh, you’re right good catch. There must have been a mix-up. I’ll call the orderly.”

- Nurse Actor goes to door to get orderly
- Person 2 comes into ward wearing lab coat
- [Person 2] “Hi, what seems to be the problem?”
- [Nurse Actor] “There seems to be a patient mix-up. We don’t have the correct patient in this bed. Could you please figure out what happened?”
- [Person 2] “Sure, I’ll get right on it.”
- [Nurse Actor] (to participant) In the mean time why don’t I introduce you to the next patient while they find the correct patient for this room.”

- Person 2: switches wristbands to correct patient name
- Person 2: put on new wig
- Nurse Actor takes participant to bed 2 while Person 2 changes the patients

[Nurse Actor] Our next patient is a newly diagnosed non-insulin diabetic patient. He is currently being investigated for possible stressed induced hyperglycemia. His weight is 58kg and Accucheck is 15. Right now, he is experiencing a little bit of nausea, so we’re going to give him some dimenhydrinate (gravol). Also I think he has an order for insulin that will be taking care of. If you could start with the maintenance line first that would be great. I need to hunt down Dr. Moe because
he told me earlier to hold off on the orders for Insulin and dimenhydrinate (gravol) and I haven’t heard back from him.”

[Nurse Actor] “Oh it looks like Mrs. Gonzalez is back! Why don’t you finish her orders before we move to the next patient? If you can finish up the Heparin order first that would be great.

☐ Participant moves back to Mrs. Gonzalez’s bed and finishes her orders before moving on to the next patient

4.22 Mrs Gonzalez: Pump/channel 2, Potassium Phosphate, Soft Limit

*Note: Potassium Phosphate is normally run through a central line, however if it is diluted such as in this case, it can be run peripherally.

Order: Drug name: Potassium Phosphate
      Concentration: 15 mmol/500 mL
      Order: 15 mmol IV-int in 500mL D5W once over 1 hrs

Programming: VTBI: 415mL
            Duration: 1h
            Rate: 15mmol/h

**NOTE: Participant should hit a soft limit**

*If participant notices the planted error before starting programming or before the limit is hit:*

[Nurse Actor] “Hmmm… yeah – that can’t be right. Let me call the physician. “

☐ Nurse Actor: calls physician
☐ Person 2 (physician enters ward)

**Person 2 (physician):** Hi, I’m Mrs. Gonzalez’s physician. What seems to be the problem? Yes I think you’re right, the duration of the infusion needs to be longer. It should be 10 hrs instead of 1h. I’ve written a paper order for you with the correct dosage values. I will change it on MOE/MAR as soon as I get back to my office. Thanks.”

*If the participant does not notice the planted error and hits a soft limit:*

☐ Participant notifies Nurse Actor

[Nurse Actor] Hmm… (Nurse Actor looking at alert message) what do you think we should do?

**NOTE:** Ask why the participant wants to contact the physician if not already known. For instance ask “So you don’t feel that this order is appropriate for the patient”.

4.3 Experiment: Steven Campbell (Patient 2)

☐ Nurse Actor: Put NS, dimenhydrinate and Insulin IV bags on MOE/MAR cart
4.31 Steven Campbell: Pump/channel 1, Normal Saline

[Nurse Actor] “Are you finished with her orders?” “Great – I just started the order for our next patient and need some help so if you are free to finish off his orders. But first, let me give you a quick update on his condition. Our next patient is a newly diagnosed non-insulin diabetic patient. He is being investigated for possible stressed induced hyperglycemia. Right now he is experiencing nausea, so we’re going to give him some dimenhydrinate (gravol). Also I think he has an order for insulin that we will be taking care of. If you could start with the maintenance line first, I need to hunt down Dr. Moe because he told me earlier to hold off on the orders for Insulin and dimenhydrinate (gravol) and I haven’t heard back from him.”

- Nurse Actor: Records parameter values and turns off pumps used in previous bed
- Nurse Actor: disconnect lines, collect caps and put on lines

**Order:**
- Drug name: Normal Saline
- Concentration: N/A
- Order: 1000mL Normal Saline IV at 100mL/h

**Programming:**
- Rate: 100mL/h
- VTBI: 1000mL

4.32 Steven Campbell: Pump/channel 1, Dimenhydrinate (Piggyback)

[Nurse Actor] “I just talked to Dr. Moe, he said to go ahead with the other two orders. I’m not sure if you already saw the dimenhydrinate (di-men-hy-dri-nate), order in MOE/MAR but if not, all the info is there. Please start with the piggyback of dimenhydrinate on the saline line and then do the insulin. Here is the order for insulin”

- Nurse Actor: Hands over paper order of insulin

**Order:**
- Drug name: Dimenhydrinate
- Concentration: 25mg/50mL
- Order: 25mg IV q4h prn Infuse over 15min

**Programming:**
- VTBI: 50mL
- Duration: 15min
- Rate: 200mL/h

4.33 Steven Campbell: Pump/channel 2, Insulin, Hard Limit

**Order:**
- Drug name: Insulin
- Concentration: 25 units/250mL
- Order: 25 units/250mL D5W, run at 25 units per hr, then as per sliding scale according to qid Accuchecks = 15

**Programming:**
- Rate: 250mL/h
- VTBI: 250mL
- Dose: 25 units/h

*NOTE: Nurse should hit a hard limit*
If participant notices the planted error before starting programming or before the limit is hit:

[Nurse Actor] “Hmmm… yeah – that can’t be right. Let me call his physician.”

☐ Nurse Actor: calls physician
☐ Person 2 (physician enters ward)

**Person 2 (physician):** Hi, I’m Mr. Campbell’s physician. What seems to be the problem? Hmmm… yeah – you are right….that can’t be right. I think the decimals are hidden and the order should read 2.5 units instead of 25 units. Here is the paper order for you to change the order to 2.5 units. As soon as I get back to my office, I will change it on MOE/MAR. Thanks.”

If the participant does not notice the planted error and hits a hard limit:

**Participant notifies Nurse Actor**

[Nurse Actor] “Hmm… (Nurse Actor looking at alert message) what do you think we should do?”

**NOTE:** Ask why the participant wants to contact the physician if not already known. For instance ask “So you don’t feel that this order is appropriate for the patient”.

4.4 Experiment: John Smith (Patient 3)

☐ Nurse Actor: Put Danapariod and Hydromorphone IV bags on MOE/MAR cart

4.41 John Smith: Pump/channel 1, Danapariod, Drug not in Library

[Nurse Actor] “Hi! I’m back! When you are done there, could you please help me finish up over here?”

[Nurse Actor] “This is our final patient. He is currently recovering from cardiovascular surgery. Initially, he was given heparin to prevent thrombosis. However, after a couple of days he developed Heparin Induced Thrombocytopenia (throm-boh-sahy-tuh-pee-nee-uh) (H.I.T.). So I think we’re going to put him on danaparoid (da-na-pa-riod) this morning/afternoon. He is also complaining of severe pain, which we will also treating for.”

[Nurse Actor] “Let’s just finish up his orders. I believe there are orders for Danaparoid and Morphine in MOE/MAR. Could you please start with Danaparoid?”

☐ Nurse Actor: Records programmed parameters and turns off pumps used in previous bed
☐ Nurse Actor: disconnect lines, collect caps and put on lines

**Order:**

- Drug name: Danaparoid
- Concentration: 2250units/50mL
- Order: 2250 units iv-int (date, time) Infuse over 15 min

**Programming:**

- VTBI: 50mL
- Duration: 15min
Rate: 200 mL/h

**NOTE:** Nurse should not find Danaparoid in the library and as such, the nurse will have to program a generic infusion:

Response to participants question about drug not being in DL (if req):
[Nurse Actor] “What do you think you should do?”

If participant still needs help:
[Nurse Actor] “Hmm… it must not be in the drug library.”

If participant STILL needs help: Nurse Actor will tell them the steps to enter generic programming and participant will continue the task on their own once in this function.

4.42 John Smith: Pump/channel 2, Morphine, Wrong Drug

**Order:**
Drug name: Morphine  
Concentration: 2mg/50mL  
Order: 2mg inj IV-int (date time). Administer over 10 min

**Programming:**
VTBI: 50mL  
Duration: 10min  
Rate: 300 mL/h

**NOTE:** Participant should notice the wrong drug on the iv bag label

If the participant realizes the planted error before or during programming:

- Nurse Actor: compares drug name on bag to drug name on MOE/MAR

  [Nurse Actor] “Yes, I think you are right, I must have mixed up the drug names when I was preparing them in the med room. Let me go get the correct drug. (Nurse Actor goes to med room and gets correct drug). Here it is!”

- Nurse Actor: hands bag to participant

  [Nurse Actor] “Great! Thank you for all of your help, all the orders for these patients have been completed.”

- Nurse Actor: records programmed parameters and turns off pumps for once scenario is completed.  
- Nurse Actor: disconnect lines, collect caps and put on lines
**Refer to Changeover procedures in section 7.0**
5.0 PROTOCOL B: EXPERIMENT SCRIPT

NOTE: Nurse Actor is in charge of all questions from the participant. If the participant gets stuck, the nurse actor will tell the participant how to get the next programming step.

5.1 Introduction to ward

If first protocol of experiment:

**Data Collection:** Synch time on laptops with camera recording time

[Nurse Actor] “Hi ______________, nice to meet you! You must be my float nurse! My name is Alvita and I’m another nurse on this ward. It is so good to see you because we are way behind in delivery our meds to our patients. These three patients have just come up to ward and we need to finish their orders. You haven’t worked on this unit before, right? So there is a couple of things I would like to cover before I introduce you to the patients that you will be taking care of. First, here is our MOE/MAR cart (I’ll make sure the cart is at the beside). You are responsible for administering the iv medications, but I will take care of any documentation. There is a formulary of iv medications in the binder on the MOE/MAR cart. You can also access it online.

[Nurse Actor] “The hospital has just gone live with these new pumps. I think you have received training on these pumps, but I don’t know if you are aware that the hospital has released new policies regarding the soft and hard limits. If you hit a soft limit you must first recheck your programming. If your programming is the same as the physician’s order and you feel the dosing parameters are appropriate for the patient you may start with the infusion. However, if you think that the dosage value is inappropriate, please call the patient’s physician. If you hit a hard limit you must check with the patient’s physician.

If second or third protocol of experiment:

[Nurse Actor] Hi, Welcome back to the ward! As you can see, the hospital has just implemented these new infusion pumps. The hospital has released new policies regarding the soft and hard limits. If you hit a soft limit you must first recheck your programming. If your programming is the same as the physician’s order and you feel the dosing parameters are appropriate for the patient you may start with the infusion. However, if you think that the dosage value is inappropriate, please call the patient’s physician. If you hit a hard limit you must check with the patient’s physician.

[Nurse Actor] We have three new patients that have just arrived on our ward. So I’m glad you’re here because I definitely need some help! Do you have any questions before we begin?

5.2 Experiment: Ms. Anges Taylor

- Nurse Actor: Put Colistimethate sodium and Procainamide HCl drip IV bags on MOE/MAR cart

5.21 Ms. Anges Taylor: Pump/channel 1, Colistimethate Sodium, Drug not in Drug Library

[Nurse Actor] I just started setting up our first patient’s infusions. I was wondering if you would be able to take over for me. I really need to finish some paper work before my shift ends.”
“Let me give you a quick update on her history. She is experiencing ventricular arrhythmias, which we will be starting her on a Procainamide (pro-cain-amid) HCl drip before she is transferred to the CICU for ECG monitoring. She was also found to have a multi-drug resistant pseudomonas (sue-de-mon-as) in her sputum (spU – tum), which we will be treating with Colistimethate sodium.

The order is in MOE/MAR. If you can start with Colistimethate sodium that would be great. Thanks a lot!

*Note: if a patient has pseudomonas they would be in contact isolation in their room. The nurse would have to gown and mask.

Yes, Nurse Actor goes to nurse station and begins filling out paper work (maybe patient’s charts)

**Order:**
- Drug name: Colistimethate sodium
- Concentration: 150mg/100mL
- Order: 150 mg IV q12h at 1000/2200. Infuse over 30min

**Programming:**
- Duration: 30 min
- VTBI: 100mL

**NOTE:** Nurse should not find Colistimethate sodium in the library and as such, the nurse will have to program a generic infusion:

**Response to participants question about drug not being in DL (if req):**

>Nurse Actor** “What do you think you should do?”

**If participant still needs help:**

>Nurse Actor** “Hmm… it must not be in the drug library.”

**If participant STILL needs help:** Nurse Actor will tell them the steps to enter generic programming and participant will continue the task on their own once in this function.

5.22 Ms. Anges Taylor: Pump/channel 2, Procainamide HCl drip, Hard Limit

**Order:**
- Drug name: Procainamide HCl drip
- Concentration: 1g/250mL
- Order: 1g/250mL ing-IV-cont 3mg/min

**Programming:**
- Dose: 3mg/min
- Rate: 45mL/h
- VTBI: 250 mL

**NOTE:** Participant should hit a hard limit:

**If participant notices the planted error before starting programming or before the limit is hit:**

>Nurse Actor** “Hmmm… yeah – that can’t be right. Let me get her physician. “
Nurse Actor: calls physician
Person 2 (physician enters ward)

Person 2 (physician): Hi, I’m Ms. Taylor’s physician. What seems to be the problem? Yes I think there is a problem. The decimals are hidden and the order should be read 0.3 mg/min instead of 3mg/min. Here is the paper order for the new order. I’ll change the order on MOE/MAR as soon as I get back to the office. But in the mean time can you please administer this order at the correct dosage?

If the participant does not notice the planted error and hits a hard limit:

Participant notifies Nurse Actor

[Nurse Actor] “Hm… (Nurse Actor looking at alert message) what do you think we should do?”

NOTE: Ask why the participant wants to contact the physician if not already known. For instance ask “So you don’t feel that this order is appropriate for the patient”.

5.3 Experiment: Mr. Xian Chan

- Nurse Actor: Put N-Acetylcysteine and Ampho B, regular IV bags on MOE/MAR cart
- Put N-Acetylcysteine paper order on MOE/MAR cart

5.31 Mr. Xian Chan: Pump/channel 1, N-Acetylcysteine, Wrong Patient

[Nurse Actor] “I haven’t finished my paperwork yet, so I was wondering if you could complete our next patient’s orders for me?”

[Nurse Actor] “Let me give you a quick update on his condition. He is a 90 kg NPO transplant patient with renal impairment. He has developed an invasive fungal infection, which I think we will be treating for with Ambisome. We will also be treating him for an accidental Tylenol overdose with Acetylcysteine.

[Nurse Actor] The orders are in MOE/MAR, if you can start with N-Acetylcysteine that would be great.”

- Nurse Actor: Records programmed parameters and turns off pumps used on previous bed
- Nurse Actor: Disconnect lines, collect caps and put on lines

Order:
- Drug name: N-Acetylcysteine
- Concentration: 9g/1000mL
- Order: 9g/1000mL at 6.25mg/kg/h (note: 100 mg/kg in 1L for 16h)

Programming:
- Rate: 62.5 ml/h
- Dose: 6.25 mg/kg/h
- VTBI: 1000mL
- Weigh: 90 kg

NOTE: Participant should notice Wrong Patient Error
If participant detects the wrong patient name on the bag prior to programming or during programming:

- Nurse Actor goes to door to get orderly
- Person 2 comes into ward wearing lab coat

[Person 2] “Hi, what seems to be the problem?”

[Nurse Actor] “There seems to be a patient mix-up. We don’t have the correct patient in this bed. Could you please figure out what happened?”

[Person 2] “Sure, I’ll get right on it.”

[Nurse Actor] (to participant) In the mean time why don’t I introduce you to the next patient while they find the correct patient for this room.”

- Person 2: switches wristbands to correct patient name
- Person 2: put on new wig
- Nurse Actor takes participant to bed 2 while Person 2 changes the patients

[Nurse Actor] “All right, let me give you a quick update on our next patient. He is a NPO transplant patient. He is unable to take oral cyclosporine to help prevent transplant rejection, so he is now receiving this medication intravenously. He was also found to have coagulase (co-ag-u-lace) negative Staphylococcus (staph-e-low-coc-us) bacteremia (bak-tuh-ree-mee-uh) from an infected IV line. This will be treated with Vancomycin.”

[Nurse Actor] “Oh it looks like Mr. Chan is back! I think we should finish his order before we move to the next patient. Why don’t you start where you left off with N-Acetylcysteine?”

- Participant moves back to Mr. Chan’s bed and finishes her orders before moving on to the next patient

5.32 Mr. Xian Chan: Pump/channel 2, Amphotericin Liposomal, Wrong Drug Name

Order: Drug name: Amphotericin Liposomal
Concentration: 425mg/250mL
Order: 425 mg ing-IV-int q12h at 1000/2200. Infuse over 3 hr

Programming: Duration: 3 hr
VTBI: 250 mL
Rate: 83.3 mL/hr

NOTE: The participant should notice Wrong Drug Name (Ampho B, regular)

If the participant realizes the planted error before or during programming:

- Nurse Actor: compares drug name on bag to drug name on MOE/MAR (correct drug name is Amphotericin Liposomal, incorrect drug name is Ampho B. regular)
[Nurse Actor] “Yes, I think you are right, let me go get the correct drug from the med room.

Nurse Actor: goes to med room and gets correct drug. Nurse actor hands bag to participant.

[Nurse Actor] “Here it is!”

5.4 Experiment: Mr. Peter Wilson

Nurse Actor: Put NS, Cyclosporine and Vancomycin IV bags on MOE/MAR cart

5.41 Mr. Peter Wilson: Pump/channel 1, Normal Saline, Maintenance fluid

Nurse Actor] “Have you finished Mr. Chan’s orders?”

[Nurse Actor] “Great, if you could help me with the last patient that would be great.”

[Nurse Actor] “To give you a quick update, he is a NPO transplant patient. He is unable to take oral cyclosporine to help prevent transplant rejection, so he is now receiving this medication intravenously. He was also found to have coagulase (co-ag-u-lace) negative Staphylococcus (staph-e-low-coc-us) bacteremia (bak-tuh-ree-mee-uh) from an infected IV line. This will be treated with Vancomycin.”

[Nurse Actor] I believe there are orders for Cyclosporine and Vancomycin in MOE/MAR. Let’s hold off on Vancomycin for the moment, Dr. Moe said he was thinking of changing the order.

[Nurse Actor] “Can you please set-up and start the maintenance fluid and set up Cyclosporine as a secondary infusion while I track down Dr. Moe? Thanks!

- Nurse Actor: Goes out of room to “track down doctor”. Comes back into testing area in 30 sec
- Nurse Actor: Records programmed parameters and turns off pumps used on previous bed
- Nurse Actor: Disconnect lines, collect caps and put on lines

Order: 
Drug name: Normal Saline
Concentration: N/A
Order: 1000mL Normal Saline 100mL/hr inj

Programming: 
Rate: 100ml/hr
VTBI: 1000mL

5.42 Mr. Peter Wilson: Pump/channel 1, Cyclosporine, Piggyback

Order: 
Drug name: Cyclosporine
Concentration: 150mg/100mL
Order: 125 mg IV int at 0900/2100 q12h Infuse over 6 hrs

Programming: 
VTBI: 100mL
Duration: 6 hrs
Rate: 16.7 mL/hr
5.43 Mr. Peter Wilson: Pump/channel 2, Vancomycin, Soft limit

[Nurse Actor] “I just talked to Dr. Moe, he said we should proceed with the original order in MOE/MAR. Can you please finish up Mr. Wilson’s order?”

Order: 
- Drug name: Vancomycin
- Concentration: 1g/250mL
- Order: 1g int-IV q12h at 1000/2200. Infuse over 30 min

Programming: 
- Duration: 30min
- VTBI: 250mL

NOTE: Participant should hit a soft limit

If participant notices the planted error before starting programming or before the limit is hit:

[Nurse Actor] “Hmmm… yeah – that can’t be right. Let me call the physician. “
- Nurse Actor: calls physician
- Person 2 (physician enters ward)

Person 2 (physician): Hi, I’m Mr. Wilson’s physician. What seems to be the problem? Yes I think you’re right, the duration should be longer. The duration should be 60 minutes instead of 30 minutes. Here is the paper order with the changes. As soon as I’m back in the office, change the order on MOE/MAR. Thanks.”

If the participant does not notice the planted error and hits a soft limit:

Participant notifies Nurse Actor

[Nurse Actor] “Hmm… (Nurse Actor looking at alert message) What do you think we should do?”

NOTE: Ask why the participant wants to contact the physician if not already known. For instance ask “So you don’t feel that this order is appropriate for the patient”.

[Nurse Actor] “Great! Thank you for all of your help, all the orders for these patients have been completed.”
- Nurse Actor: Records programmed parameters and turns off pumps used on bed
- Nurse Actor: Disconnect lines, collect caps and put on lines

**Refer to Changeover procedures in section 7.0**
6.0 PROTOCOL C: EXPERIMENT SCRIPT

NOTE: Nurse Actor is in charge of all questions from the participant. If the participant gets stuck, the nurse actor will tell the participant how to get the next programming step.

6.1 Introduction to Ward

If first protocol of experiment:

*Data Collection: Synch time on laptops with camera recording time*

[Nurse Actor] “Hi ________________, nice to meet you! You must be my float nurse! My name is Alvita and I’m another nurse on this ward. It is so good to see you because we are way behind in delivery our meds to our patients. These three patients have just come up to ward and we need to finish their orders. You haven’t worked on this unit before, right? So there is a couple of things I would like to cover before I introduce you to the patients that you will be taking care of. First, here is our MOE/MAR cart (I’ll make sure the cart is at the beside). You are responsible for administering the iv medications, but I will take care of any documentation. There is a formulary of iv medications in the binder on the MOE/MAR cart. You can also access it online.

[Nurse Actor] “The hospital has just gone live with these new pumps. I think you have received training on these pumps, but I don’t know if you are aware that the hospital has released new policies regarding the soft and hard limits. If you hit a soft limit you must first recheck your programming. If your programming is the same as the physician’s order and you feel the dosing parameters are appropriate for the patient you may start with the infusion. However, if you think that the dosage value is inappropriate, please call the patient’s physician. If you hit a hard limit you must check with the patient’s physician.

If second or third protocol of experiment:

[Nurse Actor] Hi, Welcome back to the ward! As you can see, the hospital has just implemented these new infusion pumps. The hospital has released new policies regarding the soft and hard limits. If you hit a soft limit you must first recheck your programming. If your programming is the same as the physician’s order and you feel the dosing parameters are appropriate for the patient you may start with the infusion. However, if you think that the dosage value is inappropriate, please call the patient’s physician. If you hit a hard limit you must check with the patient’s physician.

[Nurse Actor] We have three new patients that have just arrived on our ward. So I’m glad you’re here because I definitely need some help! Do you have any questions before we begin?

6.2 Experiment: Ms. Gloria Clark (Patient 7)

- Nurse Actor: Put NS, Phenytoin and Cefuroxime on MOE/MAR cart
- Nurse Actor: Move training pump to Bed 3

6.2.1 Ms. Gloria Clark: Pump/channel 1, Saline, Maintenance Fluid
[Nurse Actor] “All right let’s get started! I just started setting up our first patient’s infusions. I was hoping that you could take over for me.”

[Nurse Actor] “Let me give you a quick update on her condition. She was in a minor motor vehicle accident and has an open leg wound. So we will be starting her on ceftriaxone (sef-tri-ak-son) to prevent any infections. She also has a history of seizures, so we will also be giving her phenytoin to help control her seizures during her stay with us.

[Nurse Actor] “If you can start with maintenance fluid first so we can get Phenytoin (fen-i-toh-IN) started as a secondary right away that would be great. Thanks a lot! I’ll be back soon.”

Order:

Drug name: Normal Saline  
Concentration: N/A  
Order: 1000mL Normal Saline 100mL/hr inj

Programming:

Rate: 100ml/hr  
VTBI: 1000mL

6.22 Ms. Gloria Clark: Pump/channel 1, Phenytoin, Piggyback

Order:

Drug name: Phenytoin  
Concentration: 300mg/100mL  
Order: 300 mg IV-int (date time) Infuse over 45 min

Programming:

Rate: 133.33 mL  
VTBI: 100 mL  
Duration: 45 min

6.23 Ms. Gloria Clark: Pump/channel 2, Ceftriaxone, Wrong Drug Name

Order:

Drug name: Ceftriaxone Sodium  
Concentration: 1g/50mL  
Order: 1g IV-int q24h. Infuse over 10 min

Programming:

Rate: 300mL/h  
VTBI: 50 mL  
Duration: 10 min

Participant:

Go to MOE/MAR and read order  
Attach to patient, insert tubing  
Program and deliver drug on pump/channel 2

Note: Participant should notice wrong drug name error

If participant notices the planted error before or during programming:

[Nurse Actor] “Let me see. (Nurse Actor compares drug label with order on MOE/MAR). Yup, you’re right I think pharmacy made a mistake. It should be Ceftriaxone not Cefuroxime. Let me go get the correct drug from the med room.”
Nurse Actor: goes and get correct bag (CEFTRIAXONE) with tubing attached and primed, and hands it to the participant.

[Nurse Actor] “Yes, I think you are right, let me go get the correct drug from the med room.

[Nurse Actor] “Here it is!”

6.3 Experiment: Mr. Mark Lee (Patient 8)

- Nurse Actor: when the participant is done using the MOE/MAR cart for previous patient, move cart to bed 2 (ask participant if he/she is done with it first though)
- Nurse Actor: pulls up patient’s MOE/MAR orders
- Nurse Actor: Put Foscarnet and Ciprofloxacin IV bags on MOE/MAR cart

6.31 Mr. Mark Lee: Pump/channel 1, Foscarnet, Drug Not in Drug Library

[Nurse Actor] “Are you finished with her orders?”

[Participant] “Yes, I’m finished with her order…”

[Nurse Actor] “Great – I need some help so if you are free, I would greatly appreciate if you could help me finish off our next patients orders.”

[Nurse Actor] “Let me give you a quick update on our next patient’s condition. He is an HIV-positive patient who has been recently admitted with CMV retinitis. He requires foscarnet (fos-car-net) therapy due to a ganciclovir (gan-cyclo-vir) resistance. He has also been recently diagnosed with PCP, which requires Ciprofloxacin (Cip-ro-flox-a-cin).

[Nurse Actor] “If you can start with Foscarnet that would be great!”

- Nurse Actor: Records programmed parameters and turns off pumps used on previous bed
- Nurse Actor: Disconnect lines, collect caps and put on lines

Order: Drug name: Foscarnet
Concentration: 3300mg/137.5mL (glass bottle undiluted)
Order: 3300 mg IV int daily at 1000. For central line only. Infuse over 2 hrs

Programming:
- Rate: 68.75 mL/h
- VTBI: 137.5 mL
- Duration: 2hr

NOTE: Nurse should not find Foscarnet in the library and as such, the nurse will have to program a generic infusion

Response to participants question about drug not being in DL (if req):
[Nurse Actor] “What do you think you should do?”

If participant still needs help:
[Nurse Actor] “Hmm… it must not be in the drug library.”
**If participant STILL needs help:** Nurse Actor will tell them the steps to enter generic programming and participant will continue the task on their own once in this function.

### 6.32 Mr. Mark Lee: Pump/channel 2, Ciprofloxacin, Soft Limit

**Order:**
- Drug name: Ciprofloxacin (Cip-ro-flox-a-cin)
- Concentration: 400mg/200mL
- Order: 400 mg IV int q12h at default 1000/2200. Infuse over 15 min

**Programming:**
- Rate: 800mL/h
- VTBI: 200 mL
- Duration: 15 min

**NOTE: Participant should hit a soft limit:**

**If participant notices the planted error before starting programming or before the limit is hit:**

- [Nurse Actor] “Hmmm… yeah – that can’t be right. Let me call the physician. “
- Nurse Actor: calls physician
- Person 2 (physician enters ward)

----------

**[Person 2 (physician)]** Hi, I’m Mr. Lee’s physician. What seems to be the problem? Yes I think you’re right, the duration should be longer. The order should read 1.5 hours instead of 15 minutes. Here is the paper order with the duration changed. I’ll change the order on MOE/MAR as soon as I get back to my office. Thanks.”

----------

**If the participant does not notice the planted error and hits a soft limit:**

- Participant notifies Nurse Actor

- [Nurse Actor] Hmm… (Nurse Actor looking at alert message) what do you think you should do?

**NOTE:** Ask why the participant wants to contact the physician if not already known. For instance ask “So you don’t feel that this order is appropriate for the patient”.

### 6.4 Experiment: Mr. Kevin Piu (Patient 9)

- Nurse Actor: Put Pantoprazole and Octreotide IV bags on MOE/MAR cart

### 6.41 Mr. Kevin Piu: Pump/channel 1, Pantoprazole, Wrong Patient

- [Nurse Actor] “Great – ready for your break? Me too…..I haven’t taken one all shift. Let’s just finish up the orders for our last patient.”

- [Nurse Actor] “This is our last patient. He is experiencing an upper G.I. bleed, which requires an IV octreotide infusion. I think he also has an order for pantoprazole to help prevent bleeding.”

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“I believe there are orders for Pantoprazole and Octreotide in MOE/MAR. If you can start with Pantoprazole that would be great.”

Nurse Actor

- Records programmed parameters and turns off pumps used on previous bed
- Disconnect lines, collect caps and put on lines

Order:
- Drug name: Pantoprazole sodium
  - Concentration: 40mg/100mL
  - Order: inj IV-cont 8 mg/hr

Programming:
- Rate: 20mL/h
- Dose: 8 mg/hr
- VTBI: 100mL

NOTE: Participant should notice Wrong Patient Error

If participant detects the wrong patient name on the bag prior to programming or during programming:

[Person 3] “Hi, what seems to be the problem?”

[Nurse Actor] “There seems to be a patient mix-up. We don’t have the correct patient in this bed. Could you please figure out what happened?”

[Person 3] “Sure, I’ll get right on it.”

[Nurse Actor] While they are finding the correct patient, Ms. Clark in bed 1 has been asking for a pillow. Could you please go give it to her? The pillow is on the shelf in the corner. Thanks.”

[Nurse Actor] “Oh it looks like Mr. Piu is back! Why don’t you finish his orders and then we’ll be done. If you could finish programming pantoprazole that would be great.

- Person 2: switches wristbands to correct patient name
- Person 2: put on new wig

6.42 Mr. Kevin Piu: Pump/channel 2, Octreotide, Hard Limit

Order:
- Drug name: Octreotide
  - Concentration: 500mcg/250mL
  - Order: iv-cont 500 mcg/hr. Mix 500mcg in 250mL D5W. Mix a new bag every 10 hours

Programming:
- Rate: 250 mL/hr
Dose: 500mcg/hr  
VTBI: 250 mL

**NOTE: Participant should hit a hard limit**

**If participant notices the planted error before starting programming or before the limit is hit:**

[Nurse Actor] “Hmmm… yeah – that can’t be right. Let me call her physician. “

- Nurse Actor: calls physician
- Person 2 (physician enters ward)

**Person 2 (physician):** Hi, I’m Mr. Piu’s physician. What seems to be the problem? Hmm… I think you’re right, the dose should be 50 mcg/hr (25mL/hr). Here is a paper order with the new changes. I’ll change the order on MOE/MAR as soon as I get back to my office. But in the mean time can you please administer this order at the correct dosage? Thanks."

**If the participant does not notice the planted error and hits a hard limit:**

Participant notifies Nurse Actor

[Nurse Actor] “Hmm… (Nurse Actor looking at alert message) let me call pharmacy. When I get the correct order, I’ll finish up his order for you.”

**Nurse Actor**

- Records programmed parameters and turns off pumps used on bed
- Disconnect lines, collect caps and put on lines

**NOTE:** Ask why the participant wants to contact the physician if not already known. For instance ask “So you don’t feel that this order is appropriate for the patient”.

[Nurse Actor] “Great, all of the patient’s orders have been finished. You are now done this scenario.”

**Refer to Changeover procedures in section 7.0**
7.0 POST-PROTOCOL

7.1 Break and Questionnaire

Location: Training space
Equipment needed: Laptop, desk, chairs, Drinks/snacks, Questionnaire on survey monkey is set-up on desktop computer
Estimated Time: 10min

Person 1: All right, that was great! While we’re setting up for the next scenario we would like you to complete a short questionnaire about your experiences with the pump that you just used. There are also drinks and snacks if you would like anything. Also, if you need to use the washroom at any time one of us can show you where they are located.

Participant completes questionnaire.

7.2 Training

Location: Training space
Equipment needed: infusion pump, iv bag, desk, 2 chairs, video
Estimated time: 15 min

Person 1: All right, Mark is going to now train you on the final pump for the next scenario.

☐ Participant is handed over to Mark. Participant completes training (Refer to section 2.5 for training)

7.3 Protocol Equipment Change-Over

While the questionnaire and training is being completed, the lab is being set up for the next scenario:

Nurse Actor (brings in new equipment)
☐ Pull up first patient’s MOE/MAR orders
☐ Put wristbands for new patients
☐ Bring out drugs and paper orders for new patients
☐ Patient characteristics (wigs, beards etc.)
☐ Plug in laptop

Person 1 (takes down old equipment)
☐ Put new pumps on poles
☐ Remove IV bags and paper orders
☐ Remove wristbands
☐ Collect IV bag caps
☐ Check IV collection bags
☐ Remove old pumps
8.0 POST – EXPERIMENT

Location: Training space

Equipment needed: 1 pump of each model with name of each pump beside it, desk, chair, computer, questionnaire on survey monkey

Estimated time: 10 minutes

[Person 1] “We would like you to complete two short questionnaires. The first questionnaire is about you experiences with the pump that you just used. The second questionnaire, which I will pull up after you have completed the first questionnaire, will give you an opportunity to tell us how you feel about each pump now that you have had the chance to try out each model.”

- Participant completes questionnaire #1
- Person 1: opens 2nd survey for participant
- Participant completes questionnaire #2

[Person 1] “Thank you again for participating in this study... Because there is a possibility that your co-workers will participate in this study, please don’t discuss this experiment with others.”

- Participant is escorted outside of lab area.
10.0 APPENDIX C: WORKFLOW DIAGRAMS
Figure 35: B Braun Infusomat UML Activity Diagram (part 1)
Figure 36: BBraun Infusomat UML Activity Diagram (part 2)
Figure 37: Cardinal Alaris System UML Activity Diagram (part 1)
Figure 38: Cardinal Alaris System UML Activity Diagram (part 2)
Figure 39: Cardinal Alaris System UML Activity Diagram (part 3)
Figure 40: Hospira Symbiq UML Activity Diagram (part 1)
Figure 41: Hospira Symbiq UML Activity Diagram (part 2)
Figure 42: Hospira Symbiq UML Activity Diagram (part 3)
**Figure 43:** BBraun Infusomat IV set loading compartment without IV set inserted

**Figure 44:** BBraun Infusomat IV set loading compartment with IV set inserted

**Figure 45:** BBraun Infusomat’s green flow stop

**Figure 46:** BBraun Infusomat’s white clip

**Figure 47:** BBraun Infusomat’s two hole clamp
11.0 APPENDIX D: RESULTS

Appendix D is an additional results section for analyses that did not show any significant differences between the smart pump models, or secondary analyses such as examining the parameters nurses entered on the parameter entry screen. Appendix D is organized in the same format as the Results Section (Section 4.0).

11.1 CONTINUOUS INFUSION

![Bar chart showing the percentage of nurses that successfully completed the continuous infusion task when using different pump models.](chart.png)

**Figure 48:** Percentage of nurses that successfully completed the continuous infusion task when using Cardinal Alaris System, BBraun Infusomat, and Cardinal Alaris System (N = 24)
Figure 49: Percentage of nurses that successfully completed the continuous infusion subtasks for Cardinal Alaris System, BBraun Infusomat and Hospira Symbiq (N=24)

Figure 50: Percentage of nurses that deviated in the continuous infusion subtasks for Cardinal Alaris System, BBraun Infusomat and Hospira Symbiq (N=24)
11.2 **INTERMITTENT INFUSION**

![Bar chart showing percentage of nurses that successfully completed the intermittent infusion task when using different pumps.](image)

**Figure 51:** Percentage of nurses that successfully completed the intermittent infusion task when using Cardinal Alaris System, BBraun Infusomat, and Cardinal Alaris System (N = 24)

A Cochran Q was used to determine if there was a difference between the parameter type nurses entered first and pump type. Specifically, three individual Cochran Q tests were used for each pump type. Each analysis was followed by a series of pair-wise comparisons. All tests were conducted using Bonferroni adjusted alpha levels (0.05/3). There was significant difference in the parameter type nurses entered first when using Cardinal Alaris System, Cochran Q = 37; df = 2; *p* < 0.001. Specifically, when programming Cardinal Alaris System nurses were more likely to enter duration (87.5 %) than dose-rate (0 %) or rate (12.5 %). There was also significant difference in the parameter type that nurses entered first when using BBraun Infusomat, Cochran Q = 30; df = 2; *p* < 0.001. Specifically, nurses were more likely to enter either duration (79 %) than dose-rate (4 %) or rate (17 %). There were no other significant differences in the parameter type nurses chose to enter first across the pumps.
Figure 52: Percentage of nurses entered each parameter type first when programming an intermittent infusion using Cardinal Alaris System, BBraun Infusomat and Hospira Symbiq. VTBI was excluded from graph because nurses always used VTBI as one of the two parameters required to start the infusion. (N=24)

Figure 53: Percentage of nurses that choose each parameter type to start the infusion programming the intermittent infusion using Cardinal Alaris System, BBraun Infusomat and Hospira Symbiq. VTBI was excluded because nurses always used VTBI as one of the two parameters required to start the infusion. (N=24)
11.3 Drug Not in Drug Library

**Figure 54:** Mean task completion time and standard deviation for Cardinal Alaris System, BBraun Infusomat, and Hospira Symbiq when completing the drug not in drug library infusion task (n = 10)

**Figure 55:** Percentage of nurses that successfully completed the drug not in drug library infusion task when using Cardinal Alaris System, BBraun Infusomat and Hospira Symbiq (N=24)

A Cochran Q was used to determine if there was a difference between the parameter type that nurses entered first and pump type. Specifically, three individual Cochran Q tests were used for each
pump type. Each analysis was followed by a series of pair-wise comparisons. All tests were conducted using Bonferroni adjusted alpha levels (.05/3). There was significant difference in the parameter type nurses entered first when using Cardinal Alaris System, Cochran Q = 28; df = 2; \( p < .001 \). Specifically, when programming Cardinal Alaris System nurses were more likely to enter rate (83\%) than duration (17\%) to start the infusion. There was also significant difference in the parameter type that nurses chose to enter when using BBraun Infusomat, Cochran Q = 16; df = 2; \( p < 0.001 \). Specifically, nurses were more likely to enter either duration (66\%) than dose-rate (0\%), and rate (33\%) than dose-rate to start the infusion. There were no other significant differences in the parameter type nurses chose to enter first across the pumps.

Figure 56: Percentage of nurses that chose to enter each parameter type first when programming a generic infusion (drug not in drug library infusion task) using Cardinal Alaris System, BBraun Infusomat and Hospira Symbiq. VTBI was excluded from graph because nurses always used VTBI as one of the two parameters required to start the infusion. (N=24)
**Figure 57:** Percentage of nurses that choose each parameter type to start the infusion programming a generic infusion (drug not in drug library infusion task) using Cardinal Alaris System, BBraun Infusomat and Hospira Symbiq. VTBI was excluded from graph because nurses always used VTBI as one of the two parameters required to start the infusion. (N=24)

11.4 **MAINTENANCE FLUID**

**Figure 58:** Mean task completion time and standard deviation for maintenance infusion task when using Cardinal Alaris, BBraun Infusomat, and Hospira Symbiq (n = 16)
**Figure 59:** Percentage of nurses that successfully completed the maintenance infusion task when using Cardinal Alaris System, BBraun Infusomat and Hospira Symbiq (N=24)

**Figure 60:** Percentage of nurses that successfully completed the maintenance infusion programming subtasks for Cardinal Alaris System, BBraun Infusomat and Hospira Symbiq. (N=24)
Figure 61: Percentage of nurses that deviated during the maintenance infusion subtasks for Cardinal Alaris System, BBraun Infusomat and Hospira Symbiq (n = 16)

11.5 SECONDARY INFUSION

Figure 62: Mean subtask completion time and standard deviation for secondary infusion task when using Cardinal Alaris, BBraun Infusomat, and Hospira Symbiq (n = 11)
A Cochran Q was used to determine if there was a difference between the parameter type nurses entered first and pump type. Specifically, three individual Cochran Qs were used for each pump type. Each analysis was followed by a series of pair-wise comparisons. All tests were conducted using Bonferroni adjusted alpha levels (.05/3). There was significant difference in the parameter type nurses entered when using Cardinal Alaris System, Cochran Q = 42; df = 2; p < .001. Specifically, when programming Cardinal Alaris System nurses were more likely to enter duration (96 %) than rate (4 %). There was also significant difference in the parameter type nurses entered first when using BBraun Infusomat, Cochran Q = 17; df = 2; p < .001. Specifically, when programming BBraun Infusomat nurses were more likely to enter duration (71%) than dose-rate (4%). There was significant difference in the parameter type nurses entered first when using Hospira Symbiq, Cochran Q = 14; df = 2; p < .001. Specifically, nurses were more likely enter duration (63%) than rate (4%). There were no other significant differences in the parameter type nurses chose to enter first across the pumps.
**Figure 64:** Percentage of nurses that chose to enter each parameter type first when programming a secondary infusion using Cardinal Alaris System, BBraun Infusomat and Hospira Symbiq. VTBI was excluded from graph because nurses always used VTBI as one of the two parameters required to start the infusion. (N=24)

**Figure 65:** Percentage of nurses that choose each parameter type to start the infusion programming a secondary infusion using Cardinal Alaris System, BBraun Infusomat and Hospira Symbiq. VTBI was excluded because nurses always used VTBI as one of the two parameters required to start the infusion. (N=24)
11.6 Hard Limit Alerts

Figure 66: Percentage of nurses that detected and successfully remediated the dose error that would result in a hard limit alert when using Cardinal Alaris System, BBraun Infusomat and Hospira Symbiq. (n = 22)

11.7 Wrong Drug

Figure 67: Percentage of nurses that detected wrong drug when using Cardinal Alaris System, BBraun Infusomat and Hospira Symbiq (N=24)
11.8 Wrong Patient

Figure 68: Percentage of nurses that detected wrong patient when using Cardinal Alaris System, BBraun Infusomat and Hospira Symbiq (N=24)

11.9 Survey Results

Table 15: Age distribution of nurses that participated in study

<table>
<thead>
<tr>
<th>Age Range</th>
<th>% of nurses</th>
</tr>
</thead>
<tbody>
<tr>
<td>18 – 35 years old</td>
<td>62.5%</td>
</tr>
<tr>
<td>36 – 45 years old</td>
<td>29.2%</td>
</tr>
<tr>
<td>46 – 60 years old</td>
<td>8.3%</td>
</tr>
<tr>
<td>61 years old and over</td>
<td>0%</td>
</tr>
</tbody>
</table>

Table 16: Role of nurses at UHN that participated in the study

<table>
<thead>
<tr>
<th>Role at UHN</th>
<th>% of nurses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registered Nurse, full-time</td>
<td>87.5%</td>
</tr>
<tr>
<td>Registered Nurse, part-time</td>
<td>8.3%</td>
</tr>
<tr>
<td>Registered Nurse, casual</td>
<td>0%</td>
</tr>
<tr>
<td>Other</td>
<td>4.2%</td>
</tr>
</tbody>
</table>
Table 17: Number of years working in the nursing profession for nurses that participated in this study

<table>
<thead>
<tr>
<th>Number of years in the nursing profession</th>
<th>% of nurses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 1 year</td>
<td>4.2%</td>
</tr>
<tr>
<td>1 – 4 years</td>
<td>41.7%</td>
</tr>
<tr>
<td>5 – 15 years</td>
<td>29.2%</td>
</tr>
<tr>
<td>15 years and over</td>
<td>25%</td>
</tr>
</tbody>
</table>

Table 18: Number of years working in the nursing profession at UHN for nurses that participated in this study

<table>
<thead>
<tr>
<th>Number of years in the nursing profession at UHN</th>
<th>% of nurses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 1 year</td>
<td>4.2%</td>
</tr>
<tr>
<td>1 – 4 years</td>
<td>45.8%</td>
</tr>
<tr>
<td>5 – 9 years</td>
<td>20.8%</td>
</tr>
<tr>
<td>10 -19 years</td>
<td>20.8%</td>
</tr>
<tr>
<td>20 years and over</td>
<td>8.3%</td>
</tr>
</tbody>
</table>

Table 19: Number of times in a day nurses that participated in this study typically program an infusion pump

<table>
<thead>
<tr>
<th>Number of times in a day an infusion pump is programmed</th>
<th>% of nurses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than once a day</td>
<td>12.5%</td>
</tr>
<tr>
<td>1 – 2 times a day</td>
<td>8.3%</td>
</tr>
<tr>
<td>3 – 5 times a day</td>
<td>33.3%</td>
</tr>
<tr>
<td>More than 5 times a day</td>
<td>45.8%</td>
</tr>
</tbody>
</table>
Table 20: Post-Condition Survey Analysis for Cardinal Alaris System, BBraun Infusomat and Hospira Symbiq. Survey questions use Likert Scale (1 Strongly Disagree, 2 Disagree, 3 Neither Disagree or Agree, 4 Agree, 5 Strongly Agree).

<table>
<thead>
<tr>
<th>Rating</th>
<th>Avg</th>
<th>test-performed</th>
<th>test statistic</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Overall, the pump was easy to use</td>
<td>Cardinal Alaris System</td>
<td>3.96</td>
<td>Friedman</td>
<td>18.0</td>
</tr>
<tr>
<td></td>
<td>BBraun Infusomat</td>
<td>2.96</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hospria Symbiq</td>
<td>3.96</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. The terminology on the pump was familiar and easy to understand</td>
<td>Cardinal Alaris System</td>
<td>4.13</td>
<td>Friedman</td>
<td>15.0</td>
</tr>
<tr>
<td></td>
<td>BBraun Infusomat</td>
<td>3.61</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hospria Symbiq</td>
<td>4.12</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. It was easy to navigate the menus and find what I wanted</td>
<td>Cardinal Alaris System</td>
<td>3.79</td>
<td>Friedman</td>
<td>16.0</td>
</tr>
<tr>
<td></td>
<td>BBraun Infusomat</td>
<td>3.13</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hospria Symbiq</td>
<td>4.04</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. The pump screen was easy to read</td>
<td>Cardinal Alaris System</td>
<td>4.04</td>
<td>Friedman</td>
<td>25.0</td>
</tr>
<tr>
<td></td>
<td>BBraun Infusomat</td>
<td>3.26</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hospria Symbiq</td>
<td>4.36</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. It was easy to enter the pump programming parameters (e.g. dose, volume, time and/or rate)</td>
<td>Cardinal Alaris System</td>
<td>3.92</td>
<td>Friedman</td>
<td>5.0</td>
</tr>
<tr>
<td></td>
<td>BBraun Infusomat</td>
<td>3.3</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hospria Symbiq</td>
<td>3.8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. It was easy to correct mistakes while programming</td>
<td>Cardinal Alaris System</td>
<td>3.58</td>
<td>Friedman</td>
<td>6.0</td>
</tr>
<tr>
<td></td>
<td>BBraun Infusomat</td>
<td>3.22</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hospria Symbiq</td>
<td>3.88</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. It was easy to find and select a drug from the drug library</td>
<td>Cardinal Alaris System</td>
<td>4</td>
<td>Friedman</td>
<td>12.0</td>
</tr>
<tr>
<td></td>
<td>BBraun Infusomat</td>
<td>3.22</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hospria Symbiq</td>
<td>3.96</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. The number of steps required to program the pump was acceptable</td>
<td>Cardinal Alaris System</td>
<td>3.79</td>
<td>Friedman</td>
<td>11.0</td>
</tr>
<tr>
<td></td>
<td>BBraun Infusomat</td>
<td>2.86</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hospria Symbiq</td>
<td>3.76</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. This pump meets all my needs for a general infusion pump</td>
<td>Cardinal Alaris System</td>
<td>3.63</td>
<td>Friedman</td>
<td>12.0</td>
</tr>
<tr>
<td></td>
<td>BBraun Infusomat</td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hospria Symbiq</td>
<td>3.84</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. I want to use this pump in my unit</td>
<td>Cardinal Alaris System</td>
<td>3.54</td>
<td>Friedman</td>
<td>11.0</td>
</tr>
<tr>
<td></td>
<td>BBraun Infusomat</td>
<td>2.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hospria Symbiq</td>
<td>3.64</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 21: Post-Experiment Final Comparison Survey Results for Cardinal Alaris System, BBraun Infusomat and Hospira Symbiq (N = 24)

<table>
<thead>
<tr>
<th>Rating</th>
<th>Avg</th>
<th>test-performed</th>
<th>test statistic</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Which pump was the easiest to use? (1 to 3, with 1 = most easy)</td>
<td>Cardinal Alaris System</td>
<td>2.67</td>
<td>Friedman</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>BBraun Infusomat</td>
<td>1.83</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hospria Symbiq</td>
<td>1.50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Which pump would you prefer to use in your unit? (1 to 3, 1 = most preferred)</td>
<td>Cardinal Alaris System</td>
<td>2.58</td>
<td>Friedman</td>
<td>14</td>
</tr>
<tr>
<td></td>
<td>BBraun Infusomat</td>
<td>1.92</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hospria Symbiq</td>
<td>1.50</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### 11.10 Inter Rater Reliability

Table 22: Inter rater reliability results – reasons for disagreements between the two raters, and the action taken to resolve the issue

<table>
<thead>
<tr>
<th>Reason for disagreement and action taken</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Error Detection</strong></td>
<td>No disagreements to reconcile.</td>
</tr>
<tr>
<td><strong>Infusion Task Success Rate</strong></td>
<td>No disagreements to reconcile.</td>
</tr>
<tr>
<td><strong>Infusion Subtask Success Rate</strong></td>
<td>Reviewers disagreed in one case. The nurse had the wrong drug in her hand (not a planted error) and attempted to find the drug in the piggyback menu. After being unable to find it, the nurse required assistance from the Nurse Actor to understand she had the wrong drug in her hand. The conversation between the nurse and the Nurse Actor was difficult to hear on the videotape. Thus, this is likely the reason why the event was not caught by the second reviewer. However, notes from the Nurse Actor taken during the experiment confirmed with the investigator that this event occurred.</td>
</tr>
</tbody>
</table>
| **Deviations in Infusion Subtasks**      | The second reviewer had initially only counted the major deviations and not every key stroke where the nurse deviated from the optimal programming path. The investigator discussed the coding scheme with the second reviewer, and the definition of a deviation in the methods section was defined better so that the reader understood its meaning. The following deviations had initially resulted in disagreements:  
  *Cardinal Alaris System:* (1) “selecting A on pump not channel”  
  *BBraun Infusomat:* (1) inserting the flow stop backwards, (2) Going past the drug in the drug library for the Drug not in Drug Library, and (3) Nurse Actor providing assistance to the nurse  
  *Hospira Symbiq:* (1) active fields not registering and (2) nurse scrolling past the drug name in the drug list |
| **Occurrence of user errors**            | Two rate calculation errors and one transcription error was observed by the investigator but not by the second reviewer. Disagreements were corrected by looking at the nurse actor logs, which documented the parameters entered into the pump once the nurse had started the infusion. |
| **Occurrence of user errors that resulted in task failure** | The investigator observed a rate calculation error that was not observed by the second reviewer. Disagreements were corrected by looking at the nurse actor logs. |
| **Parameter Order Entry**                | The second review counted the actual parameter entered as the parameter the user first chose to enter. The coding of first parameter entry was changed such that it would be clear to the reader that the first parameter entered was the first parameter the nurse attempted to activate or activated. |