COMPARING NURSE PERFORMANCE BETWEEN AN INFUSION PUMP MEDICAL DEVICE ON DIFFERING MEDIUMS

By

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ABSTRACT

Medical devices are pervasive in all healthcare environments and the means in which healthcare professionals interact with medical device user interfaces is of interest to the researcher. In this research study, an intravenous infusion pump model used most frequently in the researcher's local environment was observed against a sample of the local nursing population. This research study aimed to determine the suitability of established user interface evaluations and analytical modelling laws to predict nurse performance when interacting with the selected medical device user interface. This research study also aimed to observe and compare any changes in performance times and reported cognitive loads for the same user interface of a selected medical device on two different mediums; the actual medical device and a simulated user interface mock-up on a handheld tablet device. This research study concluded that the differences in performance task times and reported cognitive load between both mediums was minor and not statistically significant. When evaluating the estimated performance task times generated through usability evaluations and analytical modelling laws, this research study concluded that although the estimated times were similar to the performance time averages of the whole sample, these estimates are not reliable to predict individual expected task times. Additionally, this research study highlighted how additional factors such as performing safety checks, and the user's individual duration to complete these safety checks influences the time required to complete a task.

Keywords: Human-Computer Interaction; User Interface Design; Medical Devices; Nursing; Infusion Pump; Cognitive Load

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CHAPTER ONE - INTRODUCTION

Medical devices encompass a vast range of instruments utilized to perform activities related to treatment, mitigation, diagnosis or prevention of a condition (Health Canada, 2004). Medical devices are inescapable in any health care environment and are vital to providing safe, quality, and state-of-the-art care towards patients. A level of expectation among the public and a requirement from national regulatory bodies exists regarding the level of effectiveness and safety of any medical device (Swayze & Rich, 2011). Medical devices were defined by Health Canada as “a health or medical instrument that is used in the treatment, mitigation, diagnosis or prevention of a disease or abnormal physical condition” (Health Canada, 2004, para.1). This can range from devices as rudimentary as a tongue depressor to more complex devices such as respiratory ventilators.

Alternatively, the U.S. Food and Drug Association (FDA) defined a medical device as "[…] an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article […]” that would be intended for use in the domains of diagnosis, treatment, or prevention of a disease. The FDA also stated that a medical device must be recognized in the official National Formulary or the United States Pharmacopoeia. The primary purpose of a medical device should also not alter the function or structure of a human or animal through chemical means (FDA, 2018, para. 3). Similarly, the World Health Organization (WHO) defined medical devices as “[…] any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings […]”. In addition, the medical device should aim to fulfill the purpose of monitoring, prevention, diagnosis, treatment or alleviation of disease (WHO, 2019, para. 1). The WHO also recognized that medical devices

should not achieve their primary purpose through "[…] pharmacological, immunological, or metabolic means [..]" (WHO, 2019, para. 3). Martin et al. (2008) further clarifies how medical devices include a diverse group of instruments that can range from simplistic tools such as band-aids, to more complex devices such as heart-bypass machines.

Considering this research study focused on medical devices that must consist of a programmable user interface, the previously stated definitions from Health Canada, FDA, WHO and Martin et al. were used to inform and develop the following simplified, yet focused definition of a medical device. The definition of a medical device for this research study was defined as a device that possesses a sophisticated, programmable user interface and is utilized in a healthcare environment for the purpose of treatment, mitigation, diagnosis or prevention of a disease or condition.

Medical device user interfaces were selected as a focus for the research study as medical device use often occurs in serious contexts that can result in detrimental outcomes such as injury and death (Carayon et al., 2014). In addition, a large pool of medical device user interface designs also exists which are coupled with their own unique mental models to operate the devices (Giuliano, 2015). Considering nurses were selected as the population of interest for this research study, they have an increased likelihood of interacting with a wide range of medical devices and their numerous user interface designs (Makary & Daniel, 2016; Viviani & Calil, 2015). It is known that the nurse population are viewed as vulnerable workers based on their high levels of workloads that contribute to stress and burnout that can negatively impact their quality of work life (Carayon & Gurses, 2008) (refer to Section 2.2.2). Considering the close relationship some medical devices may have with patients, medical devices can be seen as an extension of the patient that may cause an increased cognitive burden on medical device users

(Bonney, 2014). Patients that are intimately connected to a medical device have an increased risk to patient injury when medical errors relating to medical devices occur (Bonney, 2014). Effects that medical errors have on the healthcare professionals include the loss of productivity, the inability to use the device optimally, and additional costs are all outcomes of medical errors (Bonney, 2014). In addition, numerous psychological effects such as evoking feelings of guilt, anger, depression and inadequacy often occur (Grober & Bohannon, 2005). As a result, the relationship nurses have with sophisticated medical device user interfaces and the unique contexts of their work can impact their quality of work life when delivering care with medical devices. The interplay between medical device user interface use and the nurse population as device users was an interest of the researcher and therefore was explored in this research study.

The motivation for this thesis consisted of two main components:

1) To determine the suitability of established user interface laws and analytical models to predict nurse performance when interacting with a selected medical device user interface.
2) To observe any changes in user performance and perceived cognitive load when users were interacting with a selected medical device and a simulated mock-up of the same medical device's user interface on a handheld tablet.

The purpose of carrying out this research study was to explore the capability of substituting an actual medical device for a tablet that displayed a simulated version of the same user interface to evaluate participant interface interaction characteristics. This research was the first study of a larger subset of studies that will aim to explore the differences in user interface designs of medical devices that possess the same functionality. In subsequent research studies, numerous medical device user interfaces of the same functionality will be interacted against and users will be evaluated based on how they interpret and interact with standard tasks, error messages,

prompts, troubleshooting, etc. To elicit these situations organically using an actual medical device would be time-consuming to both the researcher and the participants. In addition, this method would also increase the number of accessories required to elicit specific scenarios within the medical device, thus increasing research study costs. Furthermore, intentionally creating medical device errors or other scenarios may pose a risk to participants as eliciting certain errors on an actual medical device may be hazardous. As a result, the ability of utilizing a simulated tablet user interface where device errors, prompts, and other device settings can be quickly manipulated, imitated and will pose no risk to the participant would be advantageous for future research studies.

The use of a simulated user interface would also allow future studies to benefit from increased accuracy and ease of data collection. The presence of researchers in the study environment will decrease the chance of impacting participant performance and will eliminate any inaccuracies in data collection from researchers that would be required to manually record participant performance times and errors. Due to the simulated nature of the tablet user interface, a simple text document can be created and exported to track the performance of each participant. Should this research study exhibit no statistically significant differences of participant performance and perceived cognitive load between both user interface mediums, this would justify the use of the simulated tablet user interface to be used in place of the actual medical device selected in future research studies as a viable option to legitimately evaluate participant performances on.

The remainder of this thesis was structured as follows. Chapter 2 depicted the three fundamental characteristics associated with medical device interaction that can influence how a medical device is used correctly and efficiently. These characteristics included physical design,

device user attributes, and user interface design. Chapter 3 described the experimental design used to observe medical device users' performance when interacting with an actual medical device user interface and a simulated mock-up user interface on a handheld tablet for the same medical device. Chapter 4 presented the results generated from the heuristics evaluations, cognitive walkthroughs and analytical modelling (Goals, Operators, Methods, and Selection rules (GOMS) model, Keystroke Level Model (KLM), Fitts' law, Hick-Hyman law). In addition, the task times and perceived cognitive load results were presented from users that participated in the experiment between the differing medical device user interface mediums. Chapter 5 described and interpreted the results found in Chapter 4 and also presented a conclusion of the work performed in this thesis as well as future directions of this work.

CHAPTER TWO – LITERATURE REVIEW

2.1 Introduction

The literature review associated with this research study explored the current means of medical device user interface examinations and comparisons that have been previously researched. In addition, this research literature review explored what forms of user interface comparison testing has already been performed that involved user interface manipulation. In order to retrieve relevant research literature, the following keywords were utilized to generate relevant search results: human-computer interaction; human-machine interaction; medical device; user interface design; human factors; design; interface changes; interface manipulation; nursing; infusion pump; usability; interface evaluation. These keywords were used in combination with one another as search queries to find relevant research studies using the following research databases: Google Scholar; Association for Computing Machinery (ACM) Digital Library; Institute of Electrical and Electronics Engineers (IEEE) Xplore; Human Factors; Journal of Computer Science and Engineering; Cumulative Index to Nursing and Allied Health Literature (CINAHL); ProQuest Nursing & Allied Health Source.

From these means, three main themes were discussed in this chapter: characteristics of medical device interaction and evaluation, evaluation of usability and user experience, and examining system and physical user interface manipulation and its effects on users. These research articles were selected to highlight the literature regarding this research's specific focus of medical device user interface manipulation and its resulting user performance outcomes. Through examining the research articles included in this study strengths, weaknesses and gaps related to the focus of this research study were identified and explored in relation to the research

study's main focus. As a result, a need for this research study was highlighted in order to fill a gap in the literature.

2.2 Characteristics of Medical Device Interaction and Evaluation

2.2.1 Medical Device User Interface Design Characteristics

According to the Food and Drug Association (FDA), elements such as the physical design of the device, the graphic user interface, and the logic of the overall user-system interaction represent parts of a device's user interface. A device's user interface includes every point of interaction between the device and the user (FDA, 2011). How a medical device is designed physically or designed in terms of a device's software and user interface can influence how a user interacts with the device. For example, a device that operates in a counterintuitive way from what the user expects will increase the risk of an error occurring (Salditt & Bothell, 2004). The outcomes of interacting with user interfaces can result in producing the intended result or producing an error through a slip, lapse, or mistake. Slips and lapses occur when the incorrect execution of a procedure is due to a failure of execution or memory, respectively (Norman, 2013). Mistakes occur when a user engages in an incorrect procedure for a task (Norman, 2013). In an ideal use case, a device user should be knowledgeable about what the expected outcome of a device should be after they interact with it. Effective human factors design relies on a device adapting to the user, rather than the user adapting to the devices (Johnson et al, 2005).

Medical devices can be seen in numerous environments such as: health facilities, patient homes, public facilities as well as specialized environments (e.g. emergency transportation, mass casualty events). Numerous factors in an environment can greatly affect how efficient a device performs or how a user interacts with the device. A medical device's environment can enhance

or impair how a device is utilized, depending on what the environmental characteristics influence. For example, an extremely quiet environment increases the ease of detecting alarms whereas operating a medical device in a restricting space may result in visual cues being overlooked. Other examples of environmental characteristics that can influence how a medical device is used include: dim lighting, loud noise level, increased environment clutter, numerous interruptions from other alarms or staff (FDA, 2011). Considering the examples listed, it is imperative that manufacturers are aware of the characteristics of the environments that their devices can be used in to optimize the design of their products to better accommodate the environment's characteristics that might alter the outcome of its use (Ali et al., 2015).

Medical devices that are centered on how the user works are seen as more intuitive to the user and decrease the risk of creating an error (Viviani & Calil, 2015). Device user interfaces that are well designed will decrease the prevalence of actions that could result in harm (FDA, 2011). There exist five "usability principles" that determine the functionality of a user interface: learnability, efficiency, visibility, errors, and satisfaction. Failing to optimize a user interface in the five domains of usability may result in a counterintuitive design, increased prevalence of mistakes, increased device training and/or decreased pleasure when interacting with the device (Swayze & Rich, 2011).

Furthermore, user interface designs can largely be categorized into one of two types: Direct Manipulation and Conversational Interfaces (Norman & Draper, 1986). Direct manipulation user interfaces often represent tasks through manipulating icons and objects as a means to increase learnability, decrease human errors, and allow for an easy path of reversal for actions (Schniederman et al., 2016). Alternatively, conversational user interfaces rely on the user

engaging in a conversation with the system using language as the medium of exchange (Norman & Draper, 1986).

The research studies that were selected to be reviewed for this section of the literature review mainly focused on evaluating a single aspect of a medical device's user interface. The researcher selected five research studies describe in the literature review to highlight the differences and inadequacies in evaluating single aspects of medical device user interfaces. The five research studies included research contributed by from Ginsburg (2005), Gagnon et al. (2004), Graham et al. (2004), Furniss et al. (2014) and Torney et al. (2018). These literature studies seldom evaluated all domains of usability and how the interplay of device and user characteristics can shape how these devices are utilized. In the highlighted literature, their conclusions either aim to influence design specifications of future medical devices or instead highlight the design flaws in the current medical device(s) evaluated to ultimately declare one medical device as being superior to another.

For example, Ginsburg (2005) recruited health care professionals to compare three infusion pump devices from differing manufacturers in order to inform the researcher's local hospital about which infusion pump should be purchased. In this study, user preferences from healthcare staff were collected based on which devices were easier to use for specific tasks. Ultimately, the device with the greatest feedback pertaining to ease of use was selected as the researcher's recommendation to the hospital for purchase. Although ease of use is an important factor in device usability, the researchers may have failed to collect pertinent data surrounding other performance measures that may have influenced their final recommendation. It is important to note that the easiest to use device does not always translate to mean it was the most optimal to use if was at the expense of affecting other performance factors.

Gagnon et al.'s (2004) and Graham et al.'s (2004) both explored usability testing of medical devices through usability and expert heuristic evaluators only. Gagnon et al.'s (2004) research specifically explored the effectiveness and advantages of three infusion pumps and the evaluations were conducted through heuristic evaluation (refer to section 2.1.4 for details) using expert heuristic evaluators and did not include the target population (i.e. nurses) in their evaluation. Graham et al. (2004) explored the design and interface deficiencies of an infusion pump frequently utilized in an Intensive Care Unit (ICU). The user interface and physical design of a three-channel infusion pump was evaluated against a set of fourteen heuristic evaluations that were developed by the authors in their previous research. The infusion pump was analyzed for heuristic violations from the fourteen heuristic evaluation domains. Graham et al. then concluded which heuristic domains were inadequate on the three-channel infusion pump. Device heuristics related to *Consistency* and *Language* were stated to be frequently violated when the evaluators were carrying out tasks or observing the user interface design for that specific device. It is important to note that these usability tests often occur under inorganic contexts that a medical device would rarely be used under (e.g. evaluators having unlimited time to evaluate each state of the system; evaluators and are not under similar stressors that target users would experience).

Furniss et al. examined how the medical device design and use of a glucometer medical device was influenced through layers of Distributed Cognition to better understand the design of the device and its resulting impact on components of its context. The researchers relied on observational studies to explore how differing domains (e.g. physical, artifact, social, evolutionary, and information flow models) contributed to the cognition of using the medical device in the wild. The resulting information gathered by the researchers added to their

understanding of how the cognition related to the glucometer was distributed among the previously listed domains.

Alternatively, Torney et al. compared the visual hierarchy of user interface designs of ten automated external defibrillators (AED) through eye-tracking equipment. Participants were asked to observe the designs of the AEDs and the eye tracking data that was collected categorized what components of each AED were the most to least prominent (visual hierarchy). The results from Torney et al. displayed that when only considering the visual characteristics of a medical device's user interface, all of the AED devices displayed a unique visual hierarchy that was theorized to have impacted how the participants would have used the AED.

2.2.2 Medical Device User Characteristics

Medical device users can be generally categorized into two main groups: highly skilled personnel and unskilled personnel. Highly skilled personnel include healthcare practitioners or any user that has been extensively trained on using the medical device. Unskilled personnel can include infrequent medical device users such as: children, adolescents, parents/guardians, and older adults. The FDA listed personal characteristics that affected the ability of any user to operate a medical device, which included but were not limited to physical dexterity, sensory abilities, cognitive abilities, literacy and language skills, and knowledge of and experience with the particular device (FDA, 2011).

When focusing on highly skilled personnel, additional characteristics related to their occupation could greatly affect how they operated a medical device. For example, acute care nurses are routinely exposed to factors such as: long working hours, physical and emotional labour demands, fatigue and neglect of personal needs during their shift. These factors have been consistently reported by nursing staff to contribute to create high levels of job stress (Carayon &

Gurses, 2008). Increased stress translated to increases in the nurse's risk of making medical errors, especially when operating sophisticated medical devices are involved (Carayon & Gurses, 2008; Dall'Ora et al., 2015). Therefore, manufacturers need to take into account that the target population of their device users, such as nursing staff, are known to work under high levels of stress and are often subjected to burnout, among other factors. This knowledge should influence how manufacturers consider how their devices should be designed as well.

Considering the close relationship some medical devices may have with patients, medical devices can be seen as an extension of the patient that may cause an increased cognitive burden on medical device users (Bonney, 2013). Patients that are intimately connected to a medical device have an increased risk to patient injury when medical errors relating to medical devices occur (Bonney, 2013). When evaluating the effect that medical errors had on healthcare professionals, numerous psychological effects such as evoking feelings of guilt, anger, depression and inadequacy often occur (Groeber & Bohnen, 2005). In addition, the loss of productivity, the inability to use the device optimally, and additional costs were all outcomes of medical errors (Bonney, 2013).

The FDA encourages medical device users to submit user interface design problems related to suspected device-related deaths, serious injuries and malfunctions. The information provided from reporting adverse events related to medical devices coupled with human factors knowledge would be available to inform manufacturers when developing safer and user-friendly devices. A decreased application of human factors knowledge towards device design is known to perpetuate errors made by both the user and the device (Carayon et al., 2008; Dhillon, 2011).

A popular issue regarding medical device design is that these devices can be created by developers that have no ties to the healthcare industry and often have no experience in the real-

world applications of their devices being utilized in care settings (Martin et al., 2012). As a result, the devices created may be viewed as having a mismatch between the device's functionality and the device's environment, user, and/or device user interface.

2.3 Evaluating Usability and User Experience

2.3.1 Heuristic Evaluation

Nielson's heuristic evaluation aimed to thoroughly analyze the usability of a system based on ten usability principles, referred to as "heuristics" and is one of the most commonly used inspection techniques (Zhang et al., 2003). Neilson's principles aimed to evaluate high-level design principles (e.g. reducing the reliance on user memory, use of easily understandable terms, consistent design and interactions, etc) (Nielson, 1992; Sharp et al. 2019). The following usability principles, described by Nielson and reinforced by Sharp et al. were:

1) Visibility of System Status: When a user is interacting with the system, were they aware of which side is waiting for an interaction to occur (the user or the system was waiting for a response)? For example, this is often evident through the use of loading wheels or timers when the system is busy processing information and the user is awaiting a response from the system and knows that an action on their part is not necessary at this step (Nielson, 1992; Sharp et al. 2019).
2) Match Between the System and the Real World: Did the system reflect and react in the same manner as items and concepts in the real world? For example, does the system's use of slider bars mimic how slider bars occur in the real world? Any variations from the system to the real world would result in increases in user cognitive load during the interaction (Nielson, 1992; Sharp et al. 2019).

3) User Control and Freedom: To what degree can the user manipulate the system during tasks? For example, will the user have access to “Advanced Settings” when performing a task or will the user only be presented with limited system options? Allowing a vast range and depth of user control and freedom has the ability to overwhelm the user if they were novice users, or conversely, experienced users would feel more in control. The inverse option exists where limiting system options to basic options or not presenting the user with any options at all may ease the interaction difficulty for novice users but may conversely displease experienced users who would prefer to have a greater influence on the system (Nielson, 1992; Sharp et al. 2019).
4) Consistency and Standards: Does the system as a whole consist of uniform and predictable characteristics within itself and compared to other similar systems? Inconsistencies can create confusion for the user and may potentially increase task completion times or influence task errors. For example, website links that do not follow the traditional appearances (e.g. blue hued and underlined) may not be recognized as links (Nielson, 1992; Sharp et al. 2019).
5) Help Users Recognize, Diagnose, and Recover from Errors: Was the system equipped with meaningful error prompts that adequately informed the user that an error occurred, why the error occurred, and how to alleviate the error? Systems that lack adequate error prompts can increase user frustration and may perpetuate the error’s occurrence (Nielson, 1992; Sharp et al. 2019).
6) Error Prevention: Systems that were well-designed and thoroughly tested should have error prevention strategies in place to allow the user to have a seamless interaction experience. Error prevention in systems should carefully prevent any problems from

arising in the first place by eliminating erroneous conditions and/or flagging errors to users before they can proceed to the next step in a process (Nielson, 1992; Sharp et al. 2019).

7) Recognition vs. Recall: Did the system offload the user's cognitive load through using recognizable prompts or did the system rely on the user's memory to recall the correct action to execute. For example, providing the user with a list of available pizza toppings to select from rather than asking the user in an open-ended manner what toppings they would like to add to their order (Nielson, 1992; Sharp et al. 2019).
8) Flexibility and Efficiency of Use: As a user's level of experience with a system increases, they may seek shortcuts or techniques to increase efficiency when executing a task. Did the system possess flexibility in the sense that it recognized that user efficiency was not present during the first interaction? (Nielson, 1992; Sharp et al. 2019)
9) Aesthetic and Minimal Design: A system's visual design impacts how a user feels about wanting to use the system as well as how they interact with the system. For example, system user interfaces that appear cluttered and disorganized may interfere with how the user navigates through the interface and may ultimately affect user performance and perceived satisfaction of the system (Nielson, 1992; Sharp et al. 2019).
10) Help and Documentation: Systems that require additional instructions may allude to being more difficult to use during initial interactions. Any "Help" or documentation information should be easily accessible to locate and search within, focused on the user's task and should be succinct (Nielson, 1992; Sharp et al. 2019).

The main intention of evaluating a system through Neilson's (1992) heuristic evaluation was to analyze the ten heuristics against a system's overarching task(s) that were aimed to be

completed. For instance, if Neilson's heuristics was applied to a television system, the evaluation should consider the how a user would carry out tasks unique to this system, such as selecting a television program to play and manipulating the volume of the television. In addition, the different types and needs of users who would interact with a television system should also be considered.

2.3.2 Cognitive Walkthrough

Cognitive walkthroughs are an effective means for predicting users' difficulties when interacting with a system without the need to perform user testing (Jacko, 2012). Cognitive walkthroughs focus on examining a system's level of learnability. Unsatisfactory usability features are uncovered by "walking through" a task and simulating the target users' problem solving process. During each task, cognitive walkthroughs repeatedly examine if a "user's goals and memory for actions can be assumed to lead to the next correct action" (Mack & Nielsen, 1994, p. 413).

To effectively carry out a cognitive walkthrough, typical users are depicted and sample tasks that pertain to the characteristics of the system's design that are to be evaluated are defined. Subsequently, the context of a typical scenario is coupled with walking through a task while repeatedly considering the following three questions whenever a response is required from the user:

1) Will the user know what to do? (Will the correct action be logically evident to the user to achieve the task?)
2) Will the user see how to do it? (Will the user notice that the correct action is apparent when it is needed?)

3) Will the user understand from feedback if they did what they wanted to do? (Will the user interpret the response from the action to inform them that they have made a correct or incorrect choice of action?)

2.3.3 Goals, Operators, Methods, and Selection rules (GOMS) Model

The GOMS model is an acronym that represents the *goals*, *operators*, *methods*, and *selection rules* involved to model the knowledge and cognitive processes that users deploy when interacting with a system (Card et al., 1983).

1) Goals: depicts a specific outcome the user wants to accomplish (e.g. find a website that displays local theatre performances).
2) Operators: refers to cognitive processes and any physical actions required to reach the desired outcome (e.g. think of keywords to then enter into a search engine).
3) Methods: pertain to learned procedures/ the steps needed to be carried out to accomplish a goal (e.g. typing keywords into Google and clicking the “Search” button).
4) Selection Rules: when more than one path exists to accomplish a task, selection rules are utilized to determine which path should be traversed in a certain instance (e.g. clicking the “Search” button or hitting the enter key to submit a keyword search on Google).

2.3.4 Keystroke Level Model (KLM)

The Keystroke Level Model (KLM) aims to generate quantitative predictions for the time required to properly execute a task (Kieras, 2001). Card et al. (1983) utilized the outcomes of many empirical studies of user performance to then produce a standard set of approximate times

for popular operators used to achieve a task. As a result, average times to complete common physical actions (e.g. pressing a button) were derived (see Table 1).

Table 1

Empirically Derived Keystroke-Level Model Performance Times

Operator Name	Description	Time (sec)
K	Pressing a single key or button	0.35 (average)
	Skilled Typist (55 wpm)	0.22
	Average Typist (40 wpm)	0.28
	User unfamiliar with keyboard	1.20
	Pressing Shift or Control key	0.08
P	Pointing with a mouse or other device to a target on display	1.10
P_1	Clicking the mouse or similar device	0.20
H	Homing hands on the keyboard or other device	0.40
H_1	Traversing from Button A to Button B	Variable t
D	Draw a line using a mouse	Variable t
M	Mentally prepare to do something	1.35
M_1	Make a decision from equally plausible options	Variable t
R_t	System response time – counted only if it causes the user to wait when carrying out his/her task	t

To calculate the predicted time to complete a specific task, the sequence of actions must be defined and categorized based on the type of operation required to execute the action. The empirically determined times associated with each operator is then summed to produce the approximate time that each task should take in seconds:

$$T_{execute} = T_K + T_P + T_H + T_D + T_M + T_R$$

2.3.5 Fitts' Law

Fitts' Law (1954) aims to predict the estimated time required to reach a target using a pointing device, based on the size of the target object and the distance to the object. The finalized Fitts' law including an updated stabilized Index of Difficulty (ID) formula is:

$$MT = a + b\log_2(A/W + 1)$$

Where:

MT = the movement time for a pointer to travel to a target

a = y-intercept of the Fitts' law regression line

b = slope of the Fitts' law regression line

A = the distance (amplitude) between the pointer and the target to move

W = the width (tolerance) of the target

2.2.9 Hick-Hyman Law

The Hick-Hyman law determines the estimated time taken to make a decision as a result of the number of possible choices available (Seow, 2005). Hick-Hyman states that increasing the number of choices available to a user will resultantly increase the decision time required logarithmically. Hick-Hyman law is expressed as:

$$RT = a + b\log_2(n)$$

Where

RT = response and reaction time

a = the time that is not compromised when making a decision

b = the empirically derived value of processing time (~0.155 seconds for humans)

n = the number of equally probable choices

2.4 System and Physical User Interface Manipulation

2.4.1 Changes to System User Interface and Effects on Users

A research study explored how changes to a system's structural design for a user interface from one iteration to a subsequent iteration can lead to errors and possible ensuing accidents (Besnard & Cacitti, 2005). Although the user interfaces explored were not related to the healthcare domain, the case study they evaluated was still relevant to this research study. The authors critiqued an incident that involved the use of a two-status button (e.g. On/Off) by which the On/Off modes were in an opposite orientation compared to the traditional orientation found on every other machine being used in the environment. The operator of the machine was experienced with the use of the machine and was considered an expert as the operator routinely performed their job on eleven of these devices simultaneously.

Although this user interface change was perceived as minor to the manufacturers of the machine, the operator ended up turning the switch incorrectly to the opposite status mode at a key point during their task and as a result was deceased. Besnard and Cacitti state that based on the tool's illogical incompatibility between itself and the operator, and itself and the other machines that possessed the same functionality, that this incident did not occur because the operator made an error (switching to the opposite mode than was desired). In fact, the authors concluded that the error occurred because the conditions in which this error occurred were unusual. Besnard and Cacitti extended their critique of the situation with the fact that when a device changes, the skills must adapt accordingly in order to reflect what has been updated in order to, at minimum, maintain the level of accuracy for the interaction. The authors also addressed how updating skills after a user interface change relies on repetitive feedback from the

system so that users can progressively reduce the discrepancies between the system's expected behaviour and how it actually behaves.

The concept of *surface similarity* was presented by Besnard and Cacitti whereby similar interfaces that share similar specific features with other interfaces are viewed as interacting in similar, if not identical, means. These key user interface components or layouts can trigger the user to relate the interface to a previously similar interface and apply its corresponding mental model onto the current interface. This was viewed as a common strategy for users when met with an interface that was unknown. The authors highlight how surface similarity was also a component of *cognitive resource saving strategy*.

Considering both user interfaces appeared at first glance to be identical, Besnard and Cacitti explained how the similarity between interfaces likely caused an expert mapping of the button controls to persist across conditions as the expert likely relied on their long-standing use of cognitive resource saving strategy during the routine task. The authors believe that the user's reliance on cognitive resource saving strategy added to their *rigidity* of expert knowledge. Rigidity was explained by the authors as: when users become experts of utilizing a device, they may cross the threshold of their expertise without recognizing that they have done so. When considering this concept within the example previously stated concerning an expert operator, they had overlooked an exception (the opposite modes on a two-status button) and progressed with routine actions under undetected non-standard settings.

An alternative research experiment explored how changes to the system user interface were manipulated whereby either the layout of a user interface was altered or the labels in an interface were removed once eleven routine computer-based tasks were carried out to observe any implications to user performance (Chung, 2006). Out of these two changes, the researcher

found that changes to user interface layout had a greater effect on changing user performance metrics (time to complete tasks and error frequency). In addition, a second experiment was conducted that involved manipulation of the user interface's colour. The researcher compared an interface with coloured control buttons for key actions (e.g. On/Off, Start, etc) against the same interface with all control buttons possessing a shade of black or white. The association of colour to quickly distinguish a button and/or action was evident in this experiment as the interface with key buttons with a distinct colour were recognized faster as being the desired keystroke needed to complete a task. Through this research, Chung displayed how the visual design of an interface can be engineered to influence a user's performance.

A significant research study addressed the effects of *negative transfer* in relation to completing a task on an unfamiliar interface (Kershaw, 2006). Negative transfer was defined by Kershaw as the belief that prior knowledge structures will lead to poor learning outcomes in tasks with changed demands. The author's experiment involved participants engaging in a complex typing task on a standard typing keyboard while switching two pairs of target letters, up to a maximum of four letters switched, as the experiment progressed. Specifically, the "r" and "o", and the "f" and "y" key pairs were switched pairs. The participants practiced typing for one hour a day for four days with the first day typing on the traditional QWERTY layout and subsequent days the key pair changes were enforced. For this experiment, negative transfer effects were considered present if the participants performance decreased with the key pair changes. Decreased performance was evident to the researchers if the participants took more time to type a word compared to their baseline times and/or typed the wrong letter on the keyboard. The researchers saw that when the change was first made, increased response time to type the key letters was evident and over time this reaction time did decrease however it was still

elevated compared to baseline response times for an untouched QWERTY layout, thus displaying the effects of negative transfer and how it persisted over time.

2.4.2 Changes to Physical User Interface and Effects on Users

In a research study input device types of a touchscreen and mouse were compared to observe if there was any effect on a participant's memory retrieval (Senecal et al., 2013). The authors argued that touchscreens (a direct input device) involved a multisensory experience within a user and activated increased cerebral activity compared to an indirect input device (pointing via mouse). Due to the increased cerebral activation and multisensory experience perceived by the authors, they concluded that this led to richer information encoding and as a result, increased information retrieval from memory. This finding in their research was especially true for participants who disclosed that they possessed a higher need for touch during these tasks. This research demonstrated how differences in user interface input mediums can change a user's perceived and/or actual experience when interacting with an interface.

Similarly, researchers explored touch-based controls compared against physical controls in the context of gaming inputs (Zaman et al., 2010). The authors compared two differing inputs using two different mediums, an iPhone mobile device and a Nintendo DS handheld gaming system. Participants completed the same game on each medium for a total of four times where the duration to complete each game and the number of player deaths were recorded. In this study, the researchers concluded that physical buttons allowed for significantly better performance than virtual buttons, as there were 150% more deaths experienced on the iPhone relying on virtual buttons and a 45% faster game completion time on the Nintendo DS medium with physical buttons.

Alternatively, researchers also compared gamepad and touchscreen inputs for action-selection tasks (Oshita et al., 2013). A gamepad controller device with eight standard buttons was utilized to achieve a total of twenty-four actions through simultaneous or in sequence selection of two-button combinations. A touchscreen interface was developed in two configurations whereby the first configuration involved the top half of the screen to display the status of the game character and the bottom half of the screen to display a grid of six action buttons (three columns and two rows) that the participant would tap to engage in an action. The second touchscreen configuration consisted of the same interface layout but instead displayed twenty-four buttons (in six columns and four rows). A twelve-inch touchscreen was utilized for both configurations and resulted in button sizes created approximately three cm by three cm each (for the six-button configuration) or two cm by two cm each (for the twenty-four-button configuration). During the experiment, the participants was instructed to carry out the action written on a screen by pressing the appropriate button or combination of buttons. Selection times were recorded and the number of errors until the correct action was achieved was also recorded. This research demonstrated that touchscreen interfaces either exceeded or matched the results of the gamepad interface (twenty-four-button and six-button, respectively).

2.5 Summary of Review of Literature

In summary, current research literature did address numerous forms of medical device user interface evaluation; however, it was often focused on a specific aspect of an interface or fails to observe multiple factors and performance measures that can be affected in relation to one another. An unfortunate weakness of medical device user interface evaluation research was its usability testing measures that often lack proper input from the target population intended for the use of the medical device. Although valid usability concerns do emerge when expert usability

professionals evaluate a medical device user interface, this approach often fails to capture real-world concerns that would only be uncovered through actual users interacting with these devices in the proper environments and under realistic conditions. Alternatively, in the instances where the target population is involved in usability testing, the data that is collected is often reduced and simplified to make certain claims. An additional flaw in the literature presented involves the comparison of interface mediums that possess too many differing variables which therefore makes it more difficult to pinpoint where changes in performance and other metrics were originating from (Oshita et al., 2013; Senecal et al., 2013; Zaman et al. 2010).

After conducting this literature review, no studies were found involving medical devices that explored whether interacting with the same user interface on two or more differing interface mediums would affect how users performed or perceived their performance. The need to explore the effect of different user interface mediums on user performance is due to the fact that this research is a part of a larger set of research studies that will ultimately aim to uncover effects on medical device nurse users when interacting with numerous medical device user interfaces of the same functionality. An aspect of these future research studies will include how nurses interact during situations that would be too time-consuming, costly and precarious to organically manipulate on actual medical device user interfaces. As a result, testing future participants on a simulated mock-up of a medical device interface on an alternative medium would allow the researcher to create these unique testing situations with ease.

In order to determine whether utilizing an alternative interface medium is valid in future research studies, this specific research study aimed to uncover whether introducing a minor change, the interface medium in which the user interacts with, is enough to elicit a statistically significant difference in perceived cognitive load and/or duration to complete tasks. As seen in

the research studies previously highlighted, different user interface changes elicit different performance changes. However, comparing the same user interface across two differing interface mediums (an actual infusion pump and a tablet touchscreen device) for a medical device is not found in the literature. This research focus has yet to be explored in the literature in relation to medical devices as a whole, especially when considering infusion pumps and the specific Hospira Plum A+ Volumetric Pump that is focused on for this research study.

CHAPTER THREE – METHODS

3.1 Purpose

The purpose of this research study was to compare the same user interface for an intravenous infusion pump device (Hospira Plum A+ Volumetric Infusion Pump) on two differing interface mediums, the actual intravenous infusion pump device and a touchscreen tablet device (refer to Figure 1 and 3, respectively). The two main domains of comparison for this research study focused on: participant performance outcomes, and usability testing and analytical modelling evaluation outcomes (defined in section 2.3). In relation to participant performance outcomes, participant metrics involving duration to complete tasks and perceived cognitive load were measured to detect any statistically significant differences that existed between mediums. By comparing the results of both of the domains of interest, the researcher's confidence in substituting one of the interface mediums for the other during future research testing will either be confirmed or denied.

3.2 Research Hypotheses

For this research study, it was hypothesized that there would be no statistically significant differences in performance times to complete tasks or perceived cognitive load when comparing the interaction results between the two intravenous infusion pump mediums, the actual pump and the touchscreen tablet device. The null hypotheses for this research study are as follows:

1) There is no statistically significant difference in task performance times between the actual intravenous infusion pump and the simulated tablet medium.
2) There is no statistically significant difference in perceived cognitive load between the actual intravenous infusion pump and the simulated tablet medium.

Conversely, the alternative hypotheses for this research study are as follows:

1) There exists a statistically significant difference in task performance times between the actual intravenous infusion pump and the simulated tablet medium.
2) There exists a statistically significant difference in perceived cognitive load between the actual intravenous infusion pump and the simulated tablet medium.

Considering the tablet user interface was created to mimic the actual intravenous infusion pump user interface's design, both in its physical and interactive nature, it was expected that both null hypotheses would be accepted and both alternative hypotheses would then be rejected.

3.3 Methodology

This research study aimed to follow a repeated-measures experimental design to observe any changes in task duration times and perceived cognitive load between two interface mediums for the same group of participants. This experimental design was chosen to capitalize on the nature of the participants acting as their own controls to eliminate factors that would normally cause variability between subjects. In addition, due to the limited pool of available participants for this research study (as described in section 3.5.1), engaging in a repeated measures experimental design allowed for the reuse of participants. Considering the nature of the experiment tasks, which will be discussed later on in this chapter, the researcher was willing to select an experimental design that would likely demonstrate learned testing effects (further described in section 5.2.2).

3.3.1 Selecting an Intravenous Infusion Pump Medical Device

Infusion pumps that deliver intravenous fluids were selected as the medical device of interest for this study considering they are a staple in most areas of patient care that a nurse would encounter (Lamsdale et al., 2005). Examples of these patient care areas include medical/surgical units, Intensive Care Units (ICU), Mobile Intensive Care environments, Home

Health Nursing, etc. In addition, that majority of nurses targeted to participate in this study would be familiar with the purpose and function of an infusion pump device to a basic degree as it is taught as a required fundamental nursing skill in all nursing programs in Ontario, Canada (Canadian Nurses of Ontario (CNO), 2014).

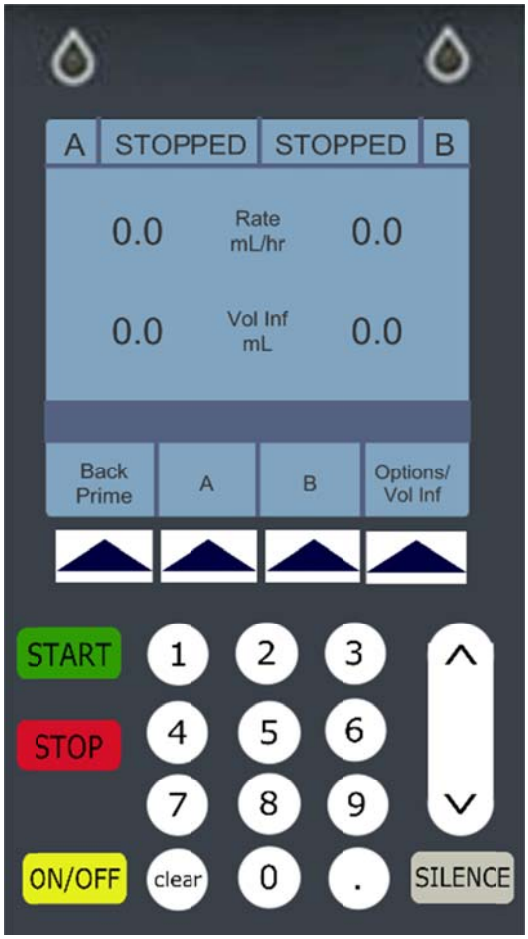
Figure 1 – Hospira Plum A+ Volumetric Infusion Pump

The specific intravenous infusion pump selected for this study was the Hospira Plum A+ Volumetric Infusion Pump (also referred to as an Abbott Plum A+ Infusion Pump in select markets) (refer to Figure 1). Hopsira Plum A+ Volumetric Infusion Pumps are currently the main infusion pump models utilized by Health Sciences North (HSN) and Laurentian University's School of Nursing, which are local organizations to this research study. The Hospira Plum A+ Volumetric Infusion Pump is described by its manufacturer as "designed to meet the fluid delivery requirements of today's evolving healthcare environments" (Hospira Inc., 2004). The selected infusion pump is a cassette based multi-function infusion system that is capable of infusing up to two lines in (primary and secondary lines) and one line out via three delivery modes (standard, piggyback, or concurrent). For this study, one Hospira Plum A+ Volumetric Infusion pump was borrowed from Laurentian University's School of Nursing to conduct all usability testing, analytical modelling and experiment tests on.

3.3.2 Designing the Simulated Intravenous Infusion Pump User Interface

The main design goals for creating a simulated mock-up for the Hospira Plum A+ Volumetric Infusion Pump was to mimic the user interface design and interaction conventions used on the actual pump device. This was achieved in order to test if task performance times or perceived cognitive load would differ based on the medium the nurse participants interacted with. The resulting simulated intravenous infusion pump user interface is shown in Figure 2.

Figure 2 – Simulated Mock-Up User Interface for Tablet Medium



The main physical design characteristics the simulated user interface had to adhere to was to maintain a touch input method as the Hospira Plum A+ Volumetric Infusion Pump relied on the nurse user to input settings via a touch keypad. In addition, the final simulated user interface dimensions for the entire screen panel and the distance between keys should resemble as closely to the dimensions exhibited by the Hospira Plum A+ Volumetric Infusion Pump. The main user interface characteristics the simulated user interface had to adhere to was to maintain the correct

menu paths, menu options and interface conventions that are evident on the Hospira Plum A+ Volumetric Infusion Pump.

The simulated user interface was created using Unity version 2018.2.11f1, a cross-platform game development platform (Unity, 2019). Unity scripts were created using C# and Java programming languages to create all interactive and physical design characteristics associated with the Hospira Plum A+ Volumetric Infusion Pump. The simulated user interface was exported as an Android application when completed and was subsequently ran on a Lenovo TAB 2 tablet with Android version 4.4.2 (refer to Figure 3). A Lenovo TAB 2 tablet was selected due to its accessibility to be used by the study's researcher and the tablet's 7-inch screen display closely resembled the Hospira Plum A+ Volumetric Infusion Pump's screen panel size.

When interacting with the simulated user interface, the nurse user is able to administer an infusion program in the same manner using the same steps and conventions required on the original Hospira Plum A+ Volumetric Infusion Pump. Nurse users can program primary and/or secondary pump lines; start, stop and delay infusions; program which pump lines are infusing which drug by selecting the drug from a drug list; clearing previous patient settings and pump line history; and turn the device on and off among other tasks found on the Hospira Plum A+ Volumetric Infusion Pump.

Figure 3 – Lenovo Tab2 Tablet

3.3.3 Selecting a Cognitive Load Scale Measurement Tool

Paas and Van Merriënboer's cognitive load scale (CLS) tool was selected to collect the perceived cognitive load of the participants. The CLS consists of a nine-point likert scale whereby a value of 1 on the likert scale was synonymous with a "low cognitive load" elicited by the participant to complete the set of tasks. Conversely, a value of 9 on the likert scale was synonymous with a "high cognitive load" elicited by the participant to complete the set of tasks.

The CLS is regarded as one of the most popular scales used when obtaining self-reported cognitive load measures (Klepsch, 2017; Sweller, 2018). Hadie (2016) concluded that the CLS

factors in which the scale measures were statistically sound and was an effective at measuring self-measured cognitive loads of its users. Hadie explored the reliability and validity of the cognitive load scale (CLS) using medical students involved in a problem-based learning scenario. The authors utilized Analysis of Moment Structure (AMOS) software to conduct a confirmatory factor analysis to evaluate the psychometric properties of the CLS. To measure the reliability of the CLS, Cronbach's alpha coefficient measured reliability using the Statistical Package for Social Sciences (SPSS) software and values that exceeded 0.7 were considered to reflect high internal consistency (with values ranging between 0.6 to 0.7 to reflect satisfactory internal consistency).

When evaluating the construct validity of the CLS, convergent validity and discriminant validity were assessed. The size of factor loading, average variance extracted, and composite reliability were assessed to determine convergent validity. Convergent validity was achieved if average variance extracted values were greater than 0.5 and composite reliability values were greater than 0.6. Alternatively, discriminant validity was assessed by comparing shared variable and average variance extracted values. If the average variance extracted values were greater than the shared variable values, this signified an acceptable level of discriminant validity.

After performing a problem-based learning scenario with ninety-three medical student participants, when examining the reliability and validity of the CLS tool, the authors concluded that the "CLS had an appropriate latent construct to measure cognitive loads as the goodness-of-fit indices were attained— indicating an acceptable level of construct validity. The reliability analysis showed that there was a high internal consistency of CLS components, as the Cronbach's alpha values were greater than 0.7." **(**Hadie, 2016, p. 199).

Considering Paas and Van Merrinboer's Cognitive Load Scale remains the most popular tool to collect the cognitive loads of users (Sweller, 2018), and its proven reliability and validity from authors such as Hadie, the CLS has also been used to validate alternative measures of cognitive load (Aldekhyl et al., 2018). As a result, Paas and Van Merrienboer's CLS was selected based on these validations as well as its quick completion times from users since the tool is regarded as easy to use (Sweller, 2018).

In addition, from the results of the CLS, a cognitive effort score, known as an E-Score can also be generated to represent the level of mental effort and resulting performance related to a task. The E-Score value is calculated based on coupling the self-reported cognitive load with a task performance outcome. To view the full post-test questionnaire form containing the CLS, refer to Appendix D.

3.4 Ethics Approval and Considerations

Approval from the Laurentian University Research Ethics Board (REB) was obtained in July of 2018 (refer to Appendix E). During the research study all participants were identified via a numerical identification badge in order to maintain anonymity, confidentiality and privacy concerning the participant's personal information as well as how they performed during the experiment. All digital experiment results were encrypted using 256-bit AES and Windows BitLocker technology. All research experiment data was stored in a portable USB key which was located in a locked cabinet in a locked room at Laurentian University in the Human-Computer Interaction Laboratory (Room FA-3-344) which was only accessible to the researcher and their research supervisor. In addition, any significant characteristics that may have aided in identifying

a participant was removed from the publication of results. These measures were performed to decrease the likelihood of any possibility of loss of status, privacy or reputation of the participant.

3.5 Research Design

To differentiate the two mediums being evaluated in this research experiment, the Hospira Plum A+ Volumetric Pump was referred to as the "Actual Pump" whereas the simulated infusion pump displayed on the Lenovo tablet was referred to as the "Tablet".

Participants were expected to complete a set of five basic tasks on each of the two mediums associated with this research study. When referring to the user manual for the Hospira Plum A+ Volumetric Infusion Pump, device tasks are separated into "Basic" and "Advanced" tasks based on the level of experience and additional knowledge required to execute certain tasks. For this research study, only basic tasks were selected as they best represented fundamental knowledge and skills that all nurses are required to learn during their nursing education in Ontario, Canada.

Due to the linear nature of the tasks, whereby one task was required to be executed before advancing to the subsequent task, the five basic tasks were not counterbalanced between participants and mediums. For example, a secondary line cannot be programed and started if a primary line has yet to be programmed. Additionally, a program line's settings cannot be altered if the program has not been previously inputted. Once the participant had executed each task and believes they are finished, the participant was instructed to notify the researcher to stop the time being recorded for each task.

The five main basic tasks expected to be completed on each medium included:

<u>Task #1: Clear Pump Volume Infused History</u>

- Clear the "Total Volumes Infused" value remaining in the device.

- Return to the Main Menu.
- Notify Researcher Once Task was Completed.

Task #2: Program and Administer a Primary Line Infusion

Doctor's Infusion Pump Order: 1L of 0.9% NaCl @ 30ml/hr

- Program Primary Line Infusion
- Start Infusion
- Notify Researcher Once Task was Completed

Task #3: Alter and Administer the Primary Line Infusion.

Doctor's Infusion Pump Order: 1L of 0.9% NaCl @ 100ml/hr

- Stop Current Infusion
- Alter Primary Line Infusion
- Start Infusion
- Notify Researcher Once Task was Completed

Task #4: Program and Administer a Piggyback Secondary Infusion

Doctor's Infusion Pump Order (Secondary Line): 200mg of Ceftriaxone in 100ml 0.9% NaCl mini-bag to be infused over 30 minutes.

- Stop Current Infusion
- Add Secondary Line Piggyback Infusion
- Start Infusion
- Notify Researcher Once Task was Completed

Task #5: Clear Primary Pump Settings Only

- Stop Current Infusion
- Clear Primary Line Program Settings

- Return to Main Menu
- Notify Researcher Once Task was Completed

The research study followed the following steps for each experiment:

1) Participant welcomed and consent was obtained

Participants were informed that their involvement with the research study was voluntary and that they would not be financially compensated for their time. In addition, participants were reassured that their background data, study results and any other identifying information would be kept anonymous. Furthermore, participants were informed that they could withdraw from the research study at any time and would not be met with any penalty. To view the full consent form utilized, refer to Appendix B.

2) Experiment tasks and differing IV pump mediums explained to participants.

Participants were notified that they would be completing the same set of tasks on two different infusion pump mediums (the actual infusion pump and a simulated infusion pump on a tablet device). Participants were encouraged to complete all tasks on both mediums to the best of their ability. In addition, participants were informed that there were no time constraints to complete any of the tasks and they were also informed to notify the researcher when they completed each task.

3) Participants completed a pre-test questionnaire.

Demographic data related to sex, age, highest level of nursing qualification, and years of professional nursing experience were collected from the participant through a paper pre-test questionnaire. Related to intravenous infusion pump use, the questionnaire collected the participant's perceived level of confidence interacting with infusion pumps in general as well as an open-ended question prompting the participant to state any infusion pump models they most

frequently interact with (if they are able to recall this information). This pre-test questionnaire was developed by the researcher to capture the demographic data they perceived was the most important for this research study. To view the full pre-test questionnaire form utilized, refer to Appendix C.

4) Participants completed tasks on Medium 1

Recruited participants were assigned to alternating starting mediums based on the order they participated in the study. As a result, odd numbered participant identification numbers interacted with the actual Hospira Plum A+ Volumetric Infusion Pump first whereas even numbered participant identification numbers interacted with the simulated tablet user interface first.

5) Participants completed post-test questionnaire #1

Participants were instructed to fill out a paper-based post-test questionnaire that described cognitive load as “the level of mental effort being used in your working memory to accomplish a task”. With examples of low and high cognitive load described, the participant is then prompted to select their perceived level of cognitive load associated with completing the previously completed set of tasks on a 9-point likert scale. This 9-point likert scale mimics the cognitive load scale developed by Paas and Van Merriënboer (1993) (refer to section 3.3.3).

6) Participants completed tasks on Medium #2

Participants then repeat the same set of five tasks on the infusion pump medium they have not interacted with yet. As a result, odd numbered participant identification numbers interacted with the simulated tablet user interface last whereas even numbered participant identification numbers interacted with the actual Hospira Plum A+ Volumetric Infusion Pump last.

7) Participants completed post-test questionnaire #2

Participants then repeat the post-questionnaire that is fully depicted in step 5.

3.5.1 Sample

Participants were recruited for this research study through word of mouth and a recruitment poster (refer to Appendix A). In order to qualify as a participant for this study, individuals were required to be active in the nursing field, and have prior knowledge and experience interacting with intravenous infusion pumps from any manufacturer. The target participant population was aimed to recruit nursing students (second year students and above) and nursing professionals (Registered Nurses, Nurse Practitioners, and Registered Practical Nurses) with an active nursing license in Canada. In addition, nurse participants were recruited if they self-identified as being proficient in the English language. No restrictions related to sex, age, or years of experience were enforced. The final sample size for this research study consisted of sixteen participants that were selected through convenience sampling. Due to the time restraints of the research study, as many participants that were able to be recruited who then also matched the recruitment criteria were resultantly involved in the experiment.

3.5.2 Research Experiment Settings

Due to the lack of participant availability, testing environments were conducted at one of two sites in an attempt to decrease the burden of attending a testing session. In order to maintain participant confidentiality and anonymity, the locations of both testing locations are unable to be disclosed. At both testing locations, the participant completed the experiment in a room that contained a desk, chair, adequate lighting and only contained the participant and the researcher as an observer in the room. In both testing environments, the height at which the device mediums were interacted with were consistent (approximately 120 cm from the floor) and the distance the participant was away from the device mediums was also consistent (approximately 45 cm distance).

3.5.3 Data Collection

For this research study, data collection occurred over the experiment's two-week testing period. Data collection involved measuring the time in seconds to complete each of the five tasks associated with both mediums. A handheld stopwatch application was used to record the elapsed time required by the participant to complete a task. The stopwatch time was terminated only when the participant signaled that they had completed the task (e.g. verbal confirmation or through a signal like raising one's hand). The researcher would then document the task performance times on the back of the participant's post-test questionnaire form. In addition, when observing the participants, if the researcher noted that an error was evident and carried through to the end of the task, this was documented as well. However, if during a task an error occurred but was successfully corrected, this incident was not documented as possessing an error but was recorded as a "near miss" event.

The second data collection method observed was the participant's perceived cognitive load associated with completing the set of tasks on each medium. A nine-point likert scale was utilized to collect perceived cognitive load from the participants and was developed by Paas and Van Merriënboer (1993) (refer to section 3.3.3). A value of one on the likert scale was synonymous with a low cognitive load elicited by the participant to complete the set of tasks. Conversely, a value of nine on the likert scale was synonymous with a high cognitive load elicited by the participant to complete the set of tasks. The participant was given examples related to low and high cognitive load where a low cognitive load was on par with "filling out your first and last name on a form". Alternatively, a high cognitive load was on par with counting upwards in multiples of 37 while memorizing a random sequence of words. These examples of cognitive load were depicted in an attempt to orient each participant to what the

extremes of the likert scale could represent. To view the full post-test questionnaire form utilized, refer to Appendix D.

3.5.4 Data Analysis

Considering the repeated measures design of this research experiment, in order to determine the mean differences between interface mediums for task times and perceived cognitive load, pairwise T-Tests were performed. The Data Analysis tool within Microsoft Excel 2016 was utilized as it possessed the computational power required to perform statistical tests on all of the data.

In regard to analyzing the cognitive load scores from Paas and Van Merriënboer's (1993) CLS, an E-Score can also be calculated. This score is subsequently plotted on a cross of axes to visually compare scores that may fall into different levels of efficiency based on their differences of cognitive load and task performance. The calculated E-Score then represents the level of mental effort and performance related to interacting with a specific medium. For this research study, reported cognitive load and total task interaction time raw scores were translated into z-scores before finally generating the E-score.

3.6 Summary

Through this research study, the researcher was able to address the research hypotheses stated in section 3.2. As a result, the selected methodology, research design and data collection methods and analyses performed during this research experiment proved to be suitable. The researcher was capable of conducting a research experiment that showcased a unique snapshot of the outcomes of interacting with the same user interface on two differing mediums.

CHAPTER FOUR – RESULTS

4.1 Sample Demographics

Data collection was conducted over a two-week testing period and the resulting sample size consisted of sixteen participants, ranging from eighteen to forty-five years of age, with the majority of participants being female and aged eighteen to twenty-five years of age. An overwhelming majority of participants were currently employed as Registered Nurses (RNs) with the remaining participants being students currently enrolled in a four-year Bachelor of Science in Nursing program at an Ontario university. The research sample contained individuals with varying years of nursing experience with the majority of participants possessing between one to ten years of formal nursing experience. Participants in the sample reported an average confidence rating of 3.8 out of a five-point likert scale when asked about their level of confidence for interacting with intravenous infusion pumps (refer to Appendix C to view the Pre-Test Questionnaire Form).

An overwhelming number of participants had previous experience interacting with the Hospira Plum A+ Volumetric Infusion pump and of that subset of the sample, the majority of those participants confirmed that they identified the Hospira Plum A+ Volumetric Infusion Pump as the infusion pump that they most frequently used. Alternative infusion pumps that were recognized as being the most frequently used model included the Baxter Colleague CX Infusion Pump and the Baxter Sigma Spectrum Infusion Pump. A small number of participants did not declare having a most frequently used infusion pump. However, of the participants that declared the Hospira Plum A+ Volumetric Infusion Pump as the infusion pump that they most frequently used, the average confidence level of using an infusion pump in general was rated as 4.33 out of a five-point likert scale.

4.2 Task Duration Results

4.2.1 Task 1 Results

When participants were asked to clear the previous “Total Volume Infused” value within the “Options/Vol Inf” panel of the infusion pump, performance times were: Actual Pump (M = 13.77 seconds; SD = 6.42 seconds) and Tablet (M = 13.38 seconds; SD = 5.29 seconds). A pairwise t-test was performed on the task 1 results with a null hypothesis stating there is no statistically significant difference in task 1 performance times between the two infusion pump mediums. The pairwise t-test and yielded a t-Statistic value of 0.356 and a t-Critical two-tail value of 2.131. Additionally, the calculated two-tail p-value was 0.727 (with alpha conditions of 0.05).

4.2.2 Task 2 Results

When participants were asked to program and start a primary line infusion through the “A” panel of the infusion pump, performance times were: Actual Pump (M = 15.53 seconds; SD = 5.95 seconds) and Tablet (M = 15.05 seconds; SD = 6.07 seconds). A pairwise t-test was performed on the task 2 results with a null hypothesis stating there is no statistically significant difference in task 2 performance times between the two infusion pump mediums. The pairwise t-test and yielded a t-Statistic value of 0.645 and a t-Critical two-tail value of 2.131. Additionally, the calculated two-tail p-value was 0.529 (with alpha conditions of 0.05).

4.2.3 Task 3 Results

When participants were asked to alter and start the previously programmed primary line infusion through the “A” panel of the infusion pump, performance times were: Actual Pump (M = 11.26 seconds; SD = 5.11 seconds) and Tablet (M = 11.17 seconds; SD = 4.24 seconds). A pairwise t-test was performed on the task 3 results with a null hypothesis stating there is no

statistically significant difference in task 3 performance times between the two infusion pump mediums. The pairwise t-test and yielded a t-Statistic value of 0.108 and a t-Critical two-tail value of 2.131. Additionally, the calculated two-tail p-value was 0.915 (with alpha conditions of 0.05).

4.2.4 Task 4 Results

When participants were asked to program and start a secondary line infusion through the "B" panel of the infusion pump, performance times were: Actual Pump (M = 40.66 seconds; SD = 21.03 seconds) and Tablet (M = 40.46 seconds; SD = 20.36 seconds). A pairwise t-test was performed on the task 4 results with a null hypothesis stating there is no statistically significant difference in task 4 performance times between the two infusion pump mediums. The pairwise t-test and yielded a t-Statistic value of 0.081 and a t-Critical two-tail value of 2.131. Additionally, the calculated two-tail p-value was 0.937 (with alpha conditions of 0.05).

4.2.5 Task 5 Results

When participants were asked to clear all primary line settings through the "A" panel of the infusion pump, performance times were: Actual Pump (M = 11.17 seconds; SD = 7.77 seconds) and Tablet (M = 9.96 seconds; SD = 5.99 seconds). A pairwise t-test was performed on the task 5 results with a null hypothesis stating there is no statistically significant difference in task 5 performance times between the two infusion pump mediums. The pairwise t-test and yielded a t-Statistic value of 0.519 and a t-Critical two-tail value of 2.131. Additionally, the calculated two-tail p-value was 0.9611 (with alpha conditions of 0.05).

4.3 Task Near Miss Results

During a task if an error had occurred but was successfully corrected this incident was not documented as possessing an error but was recorded as a "near miss" event. Errors were

considered to be any action performed by the user that deviated from achieving the end goal of the task. The researcher expected errors to cascade to the end of the task, however this was not the case for any of the participants. A low amount of near miss events was witnessed and documented and no trend between the number of near misses and the task associated with the near misses was discernable. Near miss events that were evident during the research study included: selecting the incorrect menu path to complete a task, miscalculating medication calculation values, and incorrectly inputting values (e.g. 1000 instead of 100).

4.4 Reported Cognitive Load Results

4.4.1 Raw Cognitive Load Scores

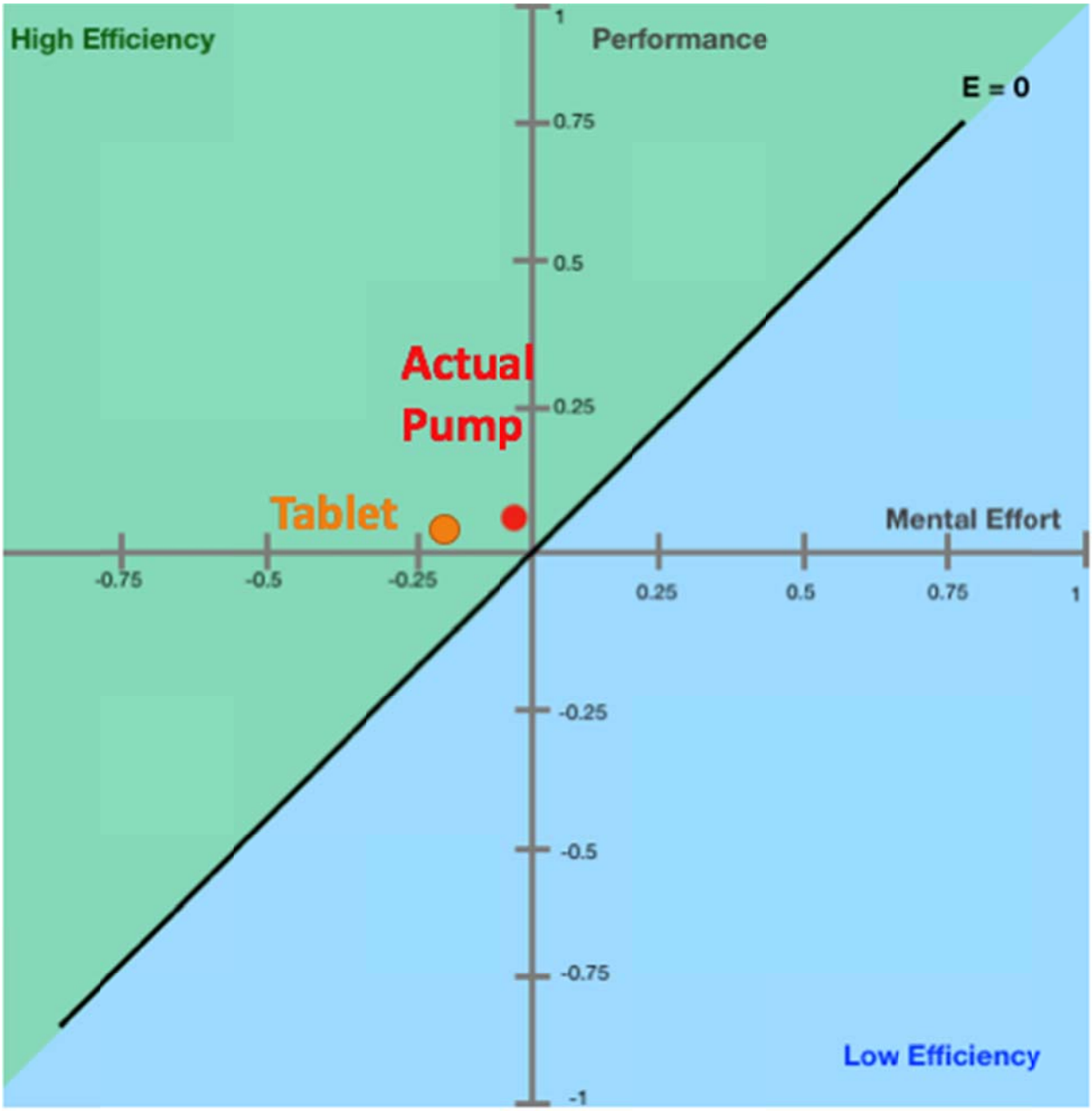
When participants were asked to rate their level of cognitive load when completing the tasks on each medium, reported cognitive load times were: Actual Pump ($M = 3.125$; $SD = 1.5$) and Tablet ($M = 3.125$; $SD = 1.408$). A pairwise t-test was performed on the cognitive load score results with a null hypothesis stating there is no statistically significant difference in reported cognitive load levels exist between the two infusion pump mediums. The pairwise t-test and yielded a t-Statistic value of 0 and a t-Critical two-tail value of 2.131. Additionally, the calculated two-tail p-value was 1 (with alpha conditions of 0.05).

Considering the t-Statistic value was less than the generated t-Critical value ($0 < 2.131$), we fail to reject the null hypothesis as there was no statistically significant difference in reported cognitive load levels between the Actual Pump and the Tablet mediums. Alternatively, the two-tail p-value were also evaluated, where its value of one is greater than the alpha level, and therefore also confirmed that the null hypothesis cannot be rejected.

4.4.2 Calculated E-Score

Paas and Merrienboer's (1993) calculational approach to combining measures of cognitive load and task performance was utilized to generate an "E score" (refer to section 3.5.4 for details). An E-Score of 0.02 for the Actual Pump and an E-Score of 0.12 for the Tablet medium were calculated and both possessed a positive value, which classified the interactions on both mediums as being "High Efficiency". A figure of the average E-Score for each medium is shown in Figure 4. It should be noted that an E-Score value of zero (depicted in Figure 6 as the diagonal line labelled E=0) represents an efficiency of zero whereby all E-Scores on imaginary lines that are parallel to the E=0 line are considered to represent the same level of mental efficiency. Considering the Actual Pump and the Tablet medium has a minimal difference in E-Scores of 0.1, this can be interpreted as the mental efficiency required when interacting with each infusion pump medium is very similar. In addition, the closely plotted E-Scores display how participants used their cognitive resources in roughly the same magnitude for both mediums.

Figure 4 – Plotting Actual Pump and Tablet E-Scores

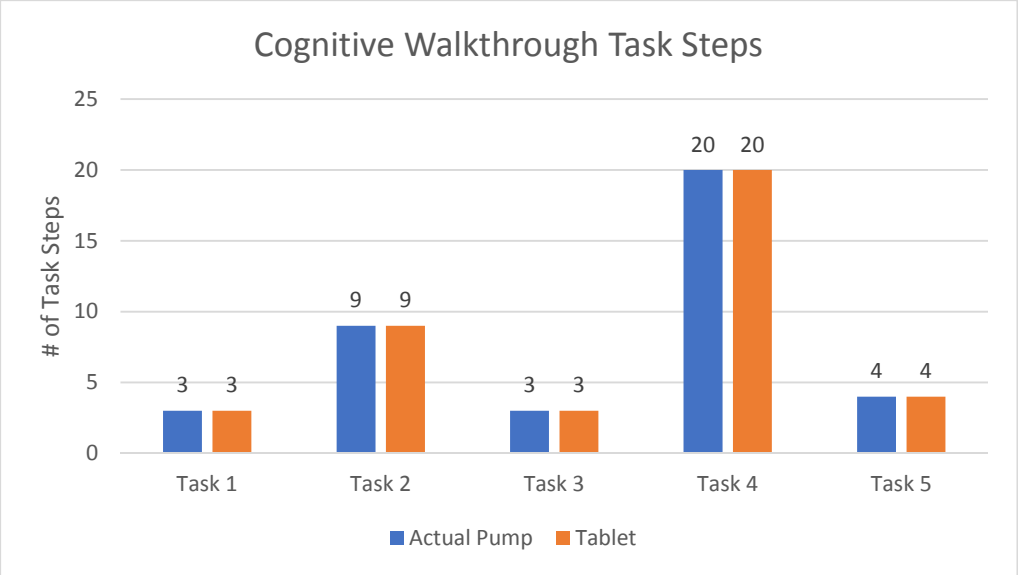


4.5 Heuristic Evaluation and Cognitive Walkthrough Evaluation

When evaluating the actual IV pump against the simulated tablet, both mediums possessed almost identical heuristic evaluation results and cognitive walkthrough results. The main difference between mediums was the absence of raised buttons with feedback that on the tablet that are evident on the actual IV pump. Alternatively, when comparing the cognitive

walkthrough steps for both mediums the simulated tablet medium required the identical steps to achieve a task as the actual IV pump as information and menu paths were laid out in an identical manner. Full heuristic evaluation and cognitive walkthrough evaluations for the Hospira Plum A+ Volumetric Infusion Pump and the simulated tablet medium can be found in Appendix F and G**.** Figure 5 displays the identical task steps required from each medium to perform each of the five tasks in this research study.

Figure 5 – Cognitive Walkthrough Task Steps



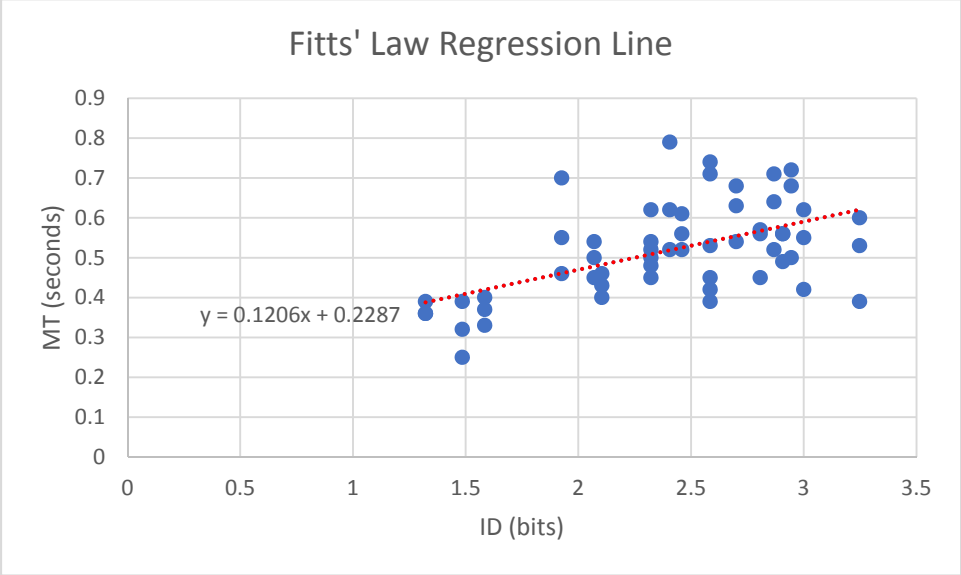
4.6 Establishing Analytical Modelling Values

In order to generate expected task completion times for the tasks outlined in this research study, GOMS, Keystroke-Level Model, Hick-Hyman and Fitts' laws were utilized. The expected task completion times depicted in this research study will only focus on the specific tasks the participants were expected to complete.

4.6.1 Establishing Fitts' Law Values

In order to predict the estimated time to move a pointer object (finger) from Button A to Button B, a wide range of physically plausible distances and the times (in seconds) to move between them were recorded on a scatter plot. For example, metrics for buttons that were found on opposite ends of the user interface as well as metrics for buttons that were directly next to each other were recorded. As a result, a regression line was calculated based on the target button widths and distances from other buttons present on the infusion pump's user interface (refer to Figure 6).

Figure 6 – Fitts' Law Regression Line



The slope and y-intercept values of the regression line then influenced the *b* and *a* values, respectively, in Fitts' equation. The resulting Fitts' equation for the Hospira Plum A+ Volumetric Infusion Pump to predict average time (in seconds) to traverse from Button A to Button B is:

$$MT = 0.2287 + 0.1206 \log_2(A/W + 1)$$

4.6.2 Establishing Hick-Hyman Law Values

To calculate the average reaction time for users to decide on an option based on the number of choices available, Hicks-Hyman Law was manipulated to possess the empirically derived value of processing time in humans (approximately 0.155 seconds) with no time compromised when making a decision. The resulting Hick-Hyman equation for average reaction time to make a decision is:

$$RT = 0.155\log2(N)$$

where n represents the number of equally probable alternatives to choose from. It should be noted that Hick-Hyman law should only be applied to reaction time options that are simple and not syntactically dense.

4.7 Predicted Task Performance Times

Predicted task times were estimated on the assumption that the user would not make any mistakes and would follow the same path described in the GOMS. The estimated performance times did not include any variation in input times based on the level of experience of the user as only one value was associated with pressing a single button (0.35 seconds) from the Keystroke-Level Model. An average system response time, R, between pump panel changes was calculated to be 0.8 seconds.

4.7.1 Estimated Task 1 Performance Time

In this task, the participant is asked to clear the existing “Total Volume Infused” value that has remained in the infusion pump’s logs from a previous infusion administration. Table 2 depicts the steps of the task with their associated estimated times to complete the GOMS operator listed. To successfully complete this task, users would have needed to traverse to the Options and subsequent Volume Infusion panel using a combination of soft keys and selection

arrow keys. After arriving to the Volume Infused panel, the participant must press the Clear button from the keypad, confirm the cleared value, and then traverse back to the Main Menu panel. The GOMS operators required to complete the task were selected and their associated empirically derived time (in seconds) to complete an action were summed. As a result, the eleven steps required to complete Task 1 resulted in an estimated performance time of 10.58 seconds. This estimated task time is compared against the performance times generated from participants interacting with the actual IV pump and the simulated Tablet medium in Table 7.

Table 2

Task 1 GOMS-KLM/Hick-Hyman/Fitts Predicted Performance Time

Step	Action	GOMS Operator	Time (seconds)
1	Recall the key press to traverse to the Main Options Panel	M	1.35
2	Accomplish goal of moving hand to keypad	H	0.40
3	Determine correct menu path (4 paths available)	M1	0.31
	Accomplish goal of pressing “Options/Vol Inf” soft key	K	0.35
4	System Response Time	R	0.80
5	Recall the menu path to traverse to the Volumes Infused Panel	M	1.35
6	Determine correct menu path (4 paths available)	M1	0.31
	Move to new button(s)	H1	0.41
	Accomplish goal of pressing the “Choose” soft Key	K	0.35
7	System Response Time	R	0.80
8	Recall the key press to clear value	M	1.35
9	Accomplish goal of pressing Clear key	K	0.35
10	Recall the key press to confirm cleared volumes infused	M	1.35
11	Determine correct menu path (2 paths available)	M1	0.16
	Move to new button(s)	H1	0.59
	Accomplish goal of pressing “Enter” soft key	K	0.35
	Estimated Task Time:		**10.58**

4.7.2 Estimated Task 2 Performance Time

In this task, the participant is asked to program and start a primary line infusion. Table 3 depicts the steps of the task with their associated estimated times to complete the GOMS

operator listed. To successfully complete this task, users would have needed to traverse to the "A" line settings panel and using a combination of soft keys and selection arrow keys, enter in the infusion values depicted in section 3.5. After inputting the infusion settings, the participant must start the infusion by pressing the dedicated Start button on the keypad. The GOMS operators required to complete the task were selected and their associated empirically derived time (in seconds) to complete an action were summed. As a result, the ten steps required to complete Task 2 resulted in an estimated performance time of 10.8 seconds. The reader is reminded that the estimated performance time for Task 2 is specific to the primary line settings (e.g. rate of administration, volume to be infused, duration of infusion) outlined in Section 3.5. This estimated task time is compared against the performance times generated from participants interacting with the actual IV pump and the simulated Tablet medium in Table 7.

Table 3

Task 2 GOMS-KLM/Hick-Hyman/Fitts Predicted Performance Time

Step	Action	GOMS Operator	Time (seconds)
1	Recall the key press to traverse to the Primary Program Panel	M	1.35
2	Accomplish goal of moving hand to keypad	H	0.40
3	Determine correct menu path (4 paths available)	M1	0.31
	Accomplish goal of pressing "A" soft key	K	0.35
4	System Response Time	R	0.80
5	Recall Rate input	M	1.35
6	Move to new button(s)	H1	0.62
	Accomplish goal of entering rate value of 30	Kx2	0.70
7	Move to new button(s)	H1	0.42
	Accomplish goal of pressing Select Down key	K	0.35
8	Recall VTBI input	M	1.35
9	Move to new button(s)	H1	0.51
	Accomplish goal of entering VTBI value of 1000	Kx4	1.40
10	Move to new button(s)	H1	0.54
	Accomplish goal of pressing "Start" key	K	0.35
	Estimated Task Time:		**10.8**

4.7.3 Estimated Task 3 Performance Time

In this task, the participant is asked to alter and start the previously programmed primary line infusion. Table 4 depicts the steps of the task with their associated estimated times to complete the GOMS operator listed. To successfully complete this task, users would have needed to traverse to the "A" line settings panel and using a combination of soft keys and selection arrow keys, alter the infusion values depicted in section 3.5. After inputting the altered infusion settings, the participant must start the infusion by pressing the dedicated Start button on the keypad. The GOMS operators required to complete the task were selected and their associated empirically derived time (in seconds) to complete an action were summed. As a result, the eight steps required to complete Task 3 resulted in an estimated performance time of 9.41 seconds. The reader is reminded that the estimated performance time for Task 3 is specific to the altered primary line settings (rate of administration) outlined in Section 3.5. This estimated task time is compared against the performance times generated from participants interacting with the actual IV pump and the simulated Tablet medium in Table 7.

Table 4

Task 3 GOMS-KLM/Hick-Hyman/Fitts Predicted Performance Time

Step	Action	GOMS Operator	Time (seconds)
1	Recall the key press to stop infusion	M	1.35
2	Accomplish goal of moving hand to keypad	H	0.40
	Accomplish goal of pressing "Stop" key	K	0.35
3	Recall the key press to traverse to the Primary Program Panel	M	1.35
4	Determine correct menu path (4 paths available)	M1	0.31
	Move to new button(s)	H1	0.59
	Accomplish goal of pressing "A" soft key	K	0.35
5	System Response Time	R	0.80
6	Recall new Rate input	M	1.35
7	Move to new button(s)	H1	0.62
	Accomplish goal of entering rate value of 100	Kx3	1.05
8	Move to new button(s)	H1	0.54

Accomplish goal of pressing “Start” key	K	0.35
Estimated Task Time:		**9.41**

4.7.4 Estimated Task 4 Performance Time

In this task, the participant is asked to program and start a secondary line infusion via Piggyback mode. Table 5 depicts the steps of the task with their associated estimated times to complete the GOMS operator listed. To successfully complete this task, users would have needed to traverse to the “B” line settings panel and using a combination of soft keys and selection arrow keys, enter in the infusion values depicted in section 3.5. After inputting the infusion settings, the participant must start the infusion by pressing the dedicated Start button on the keypad. The GOMS operators required to complete the task were selected and their associated empirically derived time (in seconds) to complete an action were summed. As a result, the twenty-one steps required to complete Task 4 resulted in an estimated performance time of 32.32 seconds. The reader is reminded that the estimated performance time for Task 4 is specific to the secondary piggyback line settings (e.g. rate of administration, volume to be infused, duration of infusion) outlined in Section 3.5. This estimated task time is compared against the performance times generated from participants interacting with the actual IV pump and the simulated Tablet medium in Table 7.

Table 5

Task 4 GOMS-KLM/Hick-Hyman/Fitts Predicted Performance Time

Step	Action	GOMS Operator	Time (seconds)
1	Recall the key press to stop infusion	M	1.35
2	Accomplish goal of moving hand to keypad	H	0.40
	Accomplish goal of pressing “Stop” key	K	0.35
3	Recall key press to traverse to the Secondary Program Panel	M	1.35
4	Determine correct menu path (4 paths available)	M1	0.31

	Move to new button(s)	H1	0.61
	Accomplish goal of pressing “B” soft key	K	0.35
5	System Response Time	R	0.80
6	Recall Rate input	M	1.35
7	Move to new button(s)	H1	0.59
	Accomplish goal of entering rate value of 200	Kx3	1.05
8	Move to new button(s)	H1	0.42
	Accomplish goal of pressing Select Down key	K	0.35
9	Recall VTBI input	M	1.35
10	Move to new button(s)	H1	0.51
	Accomplish goal of entering VTBI value of 100	Kx3	1.05
11	Recall key press to traverse to Program Options Panel	M	1.35
12	Determine correct menu path (3 paths available)	M1	0.25
	Move to new button(s)	H1	0.61
	Accomplish goal of pressing “Program Option” soft key	K	0.35
13	System Response Time	R	0.80
14	Recall key press to traverse to Drug List Panel	M	1.35
15	Determine correct menu path (3 paths available)	M	0.25
	Accomplish goal of pressing “Drug List” soft key	K	0.35
16	System Response Time	R	0.80
17	Recall key press to change Drug List Page	Mx3	4.05
	Determine correct menu path (3 paths available)	Mx3	0.75
	Move to new button(s)	K	0.41
	Accomplish goal of pressing “Page Down” key	Kx3	1.05
	Move to new button(s)	K	0.51
	Accomplish goal of pressing “Select Down” key	Kx5	1.75
	Move to new button(s)	K	0.51
	Accomplish goal of pressing “Enter” key	K	0.35
18	System Response Time	R	0.80
19	Recall key press to traverse to Secondary Line Program Panel	Mx2	2.70
20	Determine correct menu path (3 paths available)	M	0.25
21	Move to new button(s)	H1	0.54
	Accomplish goal of pressing “Start” key	K	0.35
	Estimated Task Time:		**32.32**

4.7.5 Estimated Task 5 Performance Time

In this task, the participant is asked to clear the primary line’s program settings that were programmed in an earlier task. Table 6 depicts the steps of the task with their associated estimated times to complete the GOMS operator listed. To successfully complete this task, users would have needed to traverse to the “A” primary line panel using a combination of soft keys

and selection arrow keys. After arriving to the Primary Line panel, the participant must press the Clear Program soft key, confirm the cleared program, and then traverse back to the Main Menu panel. The GOMS operators required to complete the task were selected and their associated empirically derived time (in seconds) to complete an action were summed. As a result, the thirteen steps required to complete Task 5 resulted in an estimated performance time of 12.7 seconds. This estimated task time is compared against the performance times generated from participants interacting with the actual IV pump and the simulated Tablet medium in Table 7.

Table 6

Task 3 GOMS-KLM/Hick-Hyman/Fitts Predicted Performance Time

Step	Action	GOMS Operator	Time (seconds)
1	Recall the key press to stop infusion	M	1.35
2	Accomplish goal of moving hand to keypad	H	0.40
3	Accomplish goal of pressing “Stop” key	K	0.35
4	Recall the key press to traverse to the Primary Program Panel	M	1.35
5	Determine correct menu path (4 paths available)	M1	0.31
	Move to new button(s)	H1	0.59
	Accomplish goal of pressing “A” soft key	K	0.35
6	System Response Time	R	0.80
7	Recall the key to clear program settings	M	1.35
8	Determine the correct menu path (4 paths available)	M1	0.31
	Move to new button(s)	H1	0.62
	Accomplish goal of pressing “Clear Program” soft key	K	0.35
9	System Response Time	R	0.80
10	Recall the key to confirm cleared program settings	M	1.35
11	Determine the correct menu path (2 paths available)	M1	0.16
	Move to new button(s)	H1	0.41
	Accomplish goal of pressing “Yes” soft key	K	0.35
12	Recall key press to return to Main Program Panel	M	0.35
13	Determine the correct menu path (3 paths available)	M1	0.25
	Move to new button(s)	H1	0.55
	Accomplish goal of pressing “Cancel/Back” soft key	K	0.35
	Estimated Task Time:		**12.7**

4.8 Comparing Estimated and Tested Task Performance Times

Table 7 summarized the estimated task performance times with the actual tested times for each task on both mediums. It was noted that the actual tested duration times were more similar to their alternative interface medium than they were to the estimated task performance times that were derived through analytical modelling. An exception existed with Task 5 whereby the average actual task time was closer to the estimated task time than to its interface medium counterpart. A deviation from estimated task performance times for Task 4 can be explained when considering the nature of the task which asked participants to mentally calculate the desired rate of administration. Due to variations in mental calculation processing times between participants, this had the ability to influence overall mean times associated with completing this specific task. As a result, an empirically derived mental calculation processing time would not be suitable to estimate the completion time for a task. Furthermore, differences between the estimated and tested performance times can be explained when considering differences in participant experience levels and comfort levels when interacting with infusion pump devices which are further discussed in Section 5.2.1 and 5.2.3.

Table 7

Comparing Estimated and Tested Task Performance Times

Task	Estimated Time (sec)	Average Actual Pump Time (sec)	Average Tablet Time (sec)
1	10.58	13.77 (SD = 6.42)	13.38 (SD = 5.29)
2	10.8	15.53 (SD = 5.95)	15.05 (SD = 6.07)
3	9.41	11.26 (SD = 5.11)	11.17 (SD = 4.25)
4	32.32	40.66 (SD = 21.03)	40.46 (SD = 20.36)
5	12.7	11.17 (SD = 7.77)	9.96 (SD = 5.99)

4.9 Conclusion

In summary, the purpose of this research study was to explore what differences, if any, in performance and reported cognitive load exist between two differing interface mediums for the same intravenous infusion pump medical device user interface. The results depicted in this chapter displayed that despite the obvious physical differences, user interaction on the interfaces for both mediums did not uncover any statistically significant difference in task duration times and perceived cognitive load. This is finding is strengthened by the resulting E-Score calculated which shows a difference between interface medium performance of 0.1 as well as placing both mediums in the “High Efficiency” category. In addition, empirically derived analytical modelling laws were tested to observe if they could accurately predict the estimated time a user would require to correctly perform a task. Although the estimated task times that were generated were briefer compared to the average duration times associated with each task, they varied from actual average performance times by approximately one to eight seconds. Through these results, the researcher was confident to accept all paired T-Test null hypotheses and conclude that no statistically significant difference exists between interface mediums in regard to duration task time and perceived cognitive load.

CHAPTER FIVE – DISCUSSION

5.1 Introduction

In this chapter, the results presented in the previous chapter were further interpreted and explained in order to increase the reader's understanding of the results. The limitations of the research study were also described in addition to their potential effects on the research study. And lastly, the results were discussed against the research studies depicted in chapter two in order to review this research's findings in the context of the literature.

5.2 Interpreting the Results

5.2.1 Familiarity and Increased Experience with User Interface

As described earlier regarding the sample population, a large portion of participants recognized and declared the Hospira Plum A+ Volumetric Infusion Pump as their most frequently used infusion pump model. This was an expected finding considering the academic institutions and healthcare organizations local to the research study currently utilize this specific pump. The researcher was aware that this increased familiarity and use experience of the device user interface may have had an influence on decreasing the average task duration times that were calculated (refer to Table 7). From this understanding, the researcher is under the impression that the analytical modelling estimated duration times may better suit and predict performance times for users who were more experienced and familiar with the user interface that was tested.

When compared against the research presented by Besnard and Cacitti (2005), although a change in interface medium was evident, according to Besnard and Cacitti, they addressed how negative performance outcomes occurred when conditions were unusual after changing a notable aspect of an interface. Considering the increased familiarity of tablet and touchscreen interfaces in today's use and that the leap between a physical button keypad and a touchscreen is minor,

this could explain why minimal differences were observed in the participant's task performance times. In addition, considering the tablet medium preserved the identical physical and structural layout of the original user interface, this likely decreased the need for the user to adapt their actions to carry out tasks on the tablet medium. Besnard and Cacitti spoke about the user interface system requiring repetitive feedback after implementing a design change in order to "update" the user's skill set. Unsurprisingly, considering both mediums possess the same user interface system, the reassurance of both mediums interacting in identical means therefore increased the users' confidence and ability to use the device according to Besnard and Cacitti's remarks. This likely plays a role in why almost all participants scored both interface mediums as requiring the same level of cognitive load from the user.

In addition, the researcher also acknowledged how the presence of *negative transfer*, described by Kershaw (2006) may have worked to the researcher's advantage for encouraging participants to interact with the interface mediums in the same manner. By participant's assuming that both interface mediums that look the same and therefore likely act in the same manner is a favourable perception in this research study.

5.2.2 Learned Testing Effects Influencing Task Duration

When observing the raw duration times for the first medium versus the second medium that was interacted with, a general trend that was evident was the decreased time to perform a task on the second medium. The researcher believed this phenomenon can be explained through the presence of learned testing effects. Testing effects were observed when participants almost consistently decreased their performance times when interacting with their second interface medium since they were already familiar with what was expected of the task from their short-term memory. For example, when calculating the proper rate to administer the secondary line

medication, the participant was required to calculate a rate of 200mL per hour to administer a 100mL medication in thirty minutes. When the participant was required to perform the same calculation on the second tested medium, the participant was often able to recall the previously inputted rate from the previous experiment medium and therefore was able to complete the task quicker. An additional example of the learned testing effects seen in this research study occurred when participants were required to traverse through a Drug List that displayed eight medications per page. On the second tested medium, participants were able to recall that the desired medication could be found on the fourth Drug List page and therefore did not have to check the first three Drug List pages to find the correct drug. As a result, this learned effect often decreased the time to complete the task on the second tested medium.

5.2.3 Varying Levels of Nurse Experience

Speaking to the rigidity of expert knowledge discussed by Besnard and Cacitti (2005), the researcher wonders if the lack of participants identifying who would be considered expert users could have affected overall performance results. Based on the sample's reported level of expertise, as some participants stated they had less than ten years of nursing experience but self-reported that they felt they possessed moderate-high to high confidence when interacting with infusion pumps. In this subset of the population, an overwhelming majority of these participants were able to state what their most frequently used intravenous infusion pump model was, as they possessed the most work experience in a setting that routinely used intravenous infusion pumps. Alternatively, participants who possessed increased years of nursing experience (sixteen to twenty years) reported a lower confidence level in regard to interacting with infusion pumps (Low-Moderate to Moderate Confidence). In this subset of the sample, the majority of these participants were unable to state what their most frequently used intravenous infusion pump

model was as the majority of their work experience as well as their most recent work experience was in a setting that did not rely on them having to interact with these types of medical devices. Considering the lack of expert users in the sample, this may have contributed to the malleability of the sample's knowledge to interacting with a user interface on a new medium, as expressed by Besnard and Cacitti. Considering these participants could be viewed by some as not being experts they therefore may have not built a cognitive resource saving strategy to automatically default to. The researcher postulates that due to the almost identical nature of both interface mediums, that the presence of expert users would likely not create a result in which a statistically significant difference arises between the use of both interface mediums.

5.2.4 Uncaptured Nursing Practices Affecting Performance

An important observation that was noted by the researcher that occurred before a task was declared completed by a participant was the varying times associated with "double-checking" inputs on the device mediums. It is common practice for nursing professionals to conduct a number of safety checks prior to administering any medications (Cloete, 2015; Jones & Treiber, 2010). These safety checks include verifying the correct dosage, route of administration, time, patient, and medication name, among other safety checks (Elliott & Liu, 2010; Macdonald, 2010). During the research experiment, instances occurred where participants stated that in a real-world setting, they would have confirmed the medication administration information against written medical orders, the patient's identification tag, and against the actual medication before starting an infusion pump. As a result, the researcher recognizes how the performance times for some of the participants may actually be increased to allow for these medication safety checks in real-world contexts.

Conversely, the researcher recognized that reactive effects, such as the “Hawthorne Effect” (McCarney, 2007) may have impacted participant behaviour considering the presence of the researcher observing the participants may have had an effect on performance outcomes. Due to the nature of the research study, the researcher was closely observing the participant to collect accurate performance task times. The researcher understands how this close observation may have altered how some participants typically interact with infusion pump devices. For example, participants may have felt pressured to double- or triple-check what they inputted into the device mediums to appear more diligent when in reality this may not be a part of their normal medication administration routine. Alternatively, it was plausible that some participants, knowing they were being timed, may have attempted to complete the task as quick as possible to appear efficient.

As a result, although the estimated task times are similar yet briefer to the average means of performance times for both mediums, these analytical modelling laws are not appropriate to be applied to estimating nurse performance in this context. The additional processes that are expected of nurses to perform and the duration of completing these processes varies largely from one individual to another. For example, the time span and number of times a nurse conducts the medication administration safety checks are different between each nurse and is also dependent on the context of the medication administration.

5.2.5 Cognitive Load Scores and Calculated E-Scores

Similar and closely resembling cognitive load and E-Scores were also an expected finding as the researcher believed that identical user interfaces with similar interface inputs would not be considered distinct enough for the participants to believe they were “working harder” to achieve tasks on one interface medium compared to another. However, it was

expected that the E-Scores would not be identical as expected testing effects would have an effect on the performance times and instead were estimated to be similar.

The researcher believes this study and its results benefitted from Besnard and Cacitti's (2005) defined phenomena, *surface similarity*, as users who viewed something that looked familiar would then believe it acted similar based on the mental model they have attached to the layout of the "surface". The researcher theorizes that the straightforward nature of the buttons may have added to the ease in which users were able to navigate and program the user interface, regardless of what medium they were interacting with. For instance, the buttons are straightforward (e.g. a keypad is a commonplace and intuitive, the directional arrow keys match their function, the soft keys are below the menu path that they traverse to).

Similarly, when contrasting this research study to Chang's (2006) research, considering the layout of the tablet interface medium was maintained and closely mimicked, it is understandable how no significant performance differences were evident in the results. This also extends to the perceived cognitive load scale reported by participants. In addition, the colour of buttons and the overall interface colours were matched to the best of the researcher's ability when creating the tablet interface medium. Unsurprisingly, due to the likeness between the two user interfaces this most likely aided in the fact that there was no statistically significant difference in performance and perceived cognitive load between the two interface mediums.

5.2.6 Differences in Medium Inputs

When considered in the context of Senecal et al.'s (2013), Zaman et al.'s (2010) and Oshita et al.'s (2012) research, the researcher believes that despite minor differences in input characteristics between both interface mediums, a similar style of input still remained. The difference between the two mediums is that the actual pump possesses button feedback (the

spongey nature of the buttons give a “bounce-back” to the user to register that they have likely pressed the button) compared to touchscreens where no distinguishable barrier was present to declare where a button begins or ends. The researcher believed that despite the differences, the similar input style at the core of the interaction still being present helped to explain why no statistically significant difference in performance was found between interface mediums. These direct means of input both relied on the participant to use their own fingers or thumb to directly manipulate the interface. It is important to note that the actual pump’s tangible buttons had advantages, whereby the raised buttons allowed for the user to rely on tactile feedback instead of visually confirming what button they want to press in some instances. However, the researcher believes that the lack of this advantage on the tablet medium did not elicit a large enough performance change to show a statistically significant difference between both interface mediums.

5.3 Limitations of the Study

When collecting participant data, the context and environment the nurse participants were required to complete the tasks under did not attempt to mimic the real-world characteristics that nurses often are exposed to. For example, participants were under no time-constraints, additional stressors, or were not expected to multi-task or experience any interruptions when interacting with either of the device mediums. These are only a few of the factors that can be present and affecting a nurse during their typical use of an intravenous infusion pump medical device (Mattox, 2012; Potter et al., 2005; Sasangohar et al., 2012). Instead, participants were seated in front of the device medium in a closed room to decrease any form of distraction.

Due to the physical limitations of the simulated Tablet medium, this may have impacted the performance of some participants who were accustomed to relying on tactile features when

interacting with the Actual Pump. Some participants expressed how the raised buttons of the Actual Pump allowed them to easily navigate from one button to another based on feeling adjacent buttons. This physical feature allowed some participants to input information without the need to check where a specific button was located. For example, when a participant pressed the first soft key and then desired to press the third soft key, they would rely on gliding their thumb over two raised bumps to then press the third soft key without having to visually verify if they were on the correct button. The absence of this physical characteristic on the Tablet medium may have impacted the performance times of some participants that rely on tactile cues.

An additional research study limitation was the composition and size of the research sample that was recruited due to the constraints of the research study. In future research studies, it would be ideal to test on a wider range of participants with a broader range of clinical experiences to avoid *undercoverage*, whereby the target population is inadequately represented in the research sample (Sharp et al., 2019). Considering the research study had a limited number of available participants to recruit, a convenience sampling method was utilized instead of a randomized sampling method which was described as a method to decrease the selection bias effects of undercoverage (Kendler & Strochlic, 2015; Sharp et al., 2019). Sharp et al. described how undercoverage in a sample can lead to unintentionally excluding certain groups of the target population that may influence research experiment results. By testing from a sample that was more representative of the target population of the medical device being tested on, this perhaps could have uncovered unique results that were not captured in this study. The sporadic demographics of the current sample may have inherently created a selection bias in the results that were not reflective of the actual interactions that occur on the medical device selected for this research study.

In addition, a larger sample size than sixteen participants would be encouraged for future research studies in order to increase the richness of the research's results and to potentially produce more accurate mean values and identify outliers (Kendler & Strochlic, 2015). The researcher recognized that a possibility exists in the research study whereby participants could have been considered outliers if a larger sample was employed. When calculating the power associated with the two-sided paired T-Tests utilized in this study, a calculated power level of 0.4649 was achieved when considering the sixteen participants in the sample, an estimated 0.5. effect size (standard assumption stated by Meyers et al. (2016) as it assumes a moderate difference), and a significance level of 0.05. A calculated random sample of thirty-four participants was required in order to achieve a 0.8 power level with a 0.05 significance level and 0.5 effect size. As a result, in future research studies, the researcher should engage in randomized participant recruitment for a larger sample that meets the 0.8 power levels required to confidently accept or reject the null hypothesis of the study. In addition, the researcher would be mindful to ensure the sample was representative of the target population to produce results that can be generalizable to the population.

5.4. Research Conclusions

This research study sought to determine the suitability of established user interface laws and models to predict nurse performance when interacting with a selected medical device user interface. This research study also aimed to observe and compare the any changes in performance times and reported cognitive loads for the same user interface of a selected medical device on two different mediums, the actual medical device and a simulated user interface mock-up on a handheld tablet device. From the results and discussion detailed in chapter four and five, this research study concluded that the differences in performance task times and reported

cognitive load between both mediums was minor and not statistically significant. As a result, the researcher's expectations to accept the null hypotheses which state there is no statistically significant difference in performance times and perceived cognitive load between both mediums is confirmed. The researcher has increased confidence in the future use of the simulated Tablet user interface in place of the Hospira Plum A+ Volumetric Infusion Pump as a viable option to collect accurate user performance metrics.

In addition, when evaluating the estimated performance task times generated through analytical modelling laws, this research study concluded that although the estimated times were similar to the performance time averages of the whole sample these estimates are not reliable to predict individual expected task times. This research study highlighted how additional factors such as performing safety checks, and the user's individual duration to complete these safety checks influences the time required to complete a task.

5.5 Future Directions

When considering the results of this experiment and the direction of future research studies that will result from this research, the researcher believes that the data uncovered has the potential to influence stakeholders that are involved in the development, distribution and use of medical device user interfaces. Domains of medical device use that have the potential to be influenced include how medical devices are selected for use; how blame for erroneous events involving medical devices is allocated; how medical devices are designed for the nurse population when regarding the numerous factors they work under. The researcher forecasts that through uncovering how user interface designs can influence nurse performance outcomes, this can then inform policies related to medication or intervention administration using medical devices. The researcher possesses the opinion that the results from the larger research study can

have the ability to alter how medical devices are approved for use by health governing bodies such as Health Canada, and also which medical devices are selected for use (e.g. hospital procurement). Through addressing how medical device user interfaces may be inadequate and/or unsuitable for target nurse populations, this may influence how medical devices are tested and approved for use. The researcher also believes that this research has the gravity to shift paradigms related to blame culture and therefore shift the initial scrutinization onto medical devices when analyzing for a root cause of error instead of automatically placing the blame onto the nurse user.

In terms of future directions of this research study, the researcher aims to interchange the simulated Tablet user interface in the place of the Actual Pump device to achieve unique use scenarios. The future use of this simulated Tablet interface could be utilized to generate and display specific message prompts, device errors and manipulate pump device settings to be shown without painstakingly attempting to orchestrate these errors and prompts organically on the Actual Pump.

In addition, safety risks will be significantly reduced when interacting with a simulated infusion pump user interface as infusion fluids will not be necessary to run the device which then translates to eradicating any risk of a participant coming into contact with any unwanted intravenous infusion fluid. Furthermore, costs related to purchasing infusion fluids, pump tubing lines and cassettes will be non-existent which is ideal for future experiments that require user interface testing and interaction evaluation for this infusion pump. For example, in order for the Actual Pump to operate under normal conditions, infusion pump tubing, infusion solutions and tubing cassettes are required for the device to recognize that it can operate. With the use of the Tablet medium there is no longer a need to purchase these additional pieces of equipment.

As a result, the opportunity to test responses to unique use cases would be more efficient to test on the Tablet medium in future experiment studies. For example, if future research studies aimed to explore nurse performances when they are met with error messages, the Tablet medium could be programmed to display any desirable error whereas the Actual Pump would need to be manipulated to achieve the error message organically. For example, in this research study the first task to be completed required the participants to clear a previous “Total Volume Infused” value. Prior to starting the experiment for each participant, the Actual Pump needed to be programmed to start an infusion in order to display a non-zero value in the “Volume Infused” panel in order for the participant to be able to clear the value later on. Conversely, for the Tablet medium, the program simply was restarted to display a pre-programmed value in the “Volume Infused” panel. This increased level of control can allow for increased and more efficient test cases in the future.

An additional feature that can be implemented on future uses of the Tablet medium would be to generate a task performance summary that would record every button the participant pressed, the time to complete a task and verification that a task was completed correctly. The ability to rely on this automated data collection method would increase the quality of data to be analyzed as participants would no longer require the researcher directly behind them to observe if they completed a task correctly and to measure the time to complete a task. This future feature may promote participants to engage with the device in an authentic manner as the participants would not feel as if they are being constantly watched.

Future research directions that involve the use of the simulated Tablet user interface include the ability to explore how minor, moderate, and major alterations to the user interface have an effect on nurse performance for users who are already familiar with the original user

interface. This research has the opportunity to highlight the margin of change in which device designers can manipulate newer versions of their devices without negatively affecting performance.

REFERENCES

Aldekhyl, S., Cavalcanti, R. B., & Naismith, L. M. (2018). Cognitive load predicts point-of-care ultrasound simulator performance. *Perspectives on medical education*, *7*(1), 23-32.

Ali H, Li H, Lisboa P. (2015) Usability Analysis and Redesign of Infusion Pump User Interface. Proc. Int. Symp. *Hum. Factors Ergon. Health Care*. 4(1):129–133.

Besnard, D., & Cacitti, L. (2005). Interface changes causing accidents. An empirical study of negative transfer. *International Journal of Human-Computer Studies*, *62*(1), 105-125.

Bonney, W. (2014). Medical errors: Moral and ethical considerations. *Journal of Hospital Administration*, *3*(2), 80-88.

Carayon, P., & Gurses, A. P. (2008). Nursing workload and patient safety—a human factors engineering perspective. In *Patient safety and quality: An evidence-based handbook for nurses*. Agency for Healthcare Research and Quality (US).

Carayon, P., Xie, A., & Kianfar, S. (2014). Human factors and ergonomics as a patient safety practice. *BMJ Qual Saf*, *23*(3), 196-205.

Card, S. K., Newell, A., and Moran, T. P. (1983). The Psychology of Human-Computer Interaction . *Lawrence Erlbaum Associates, Inc.*, Mahwah, NJ, USA.

Chung, P. H. (2006). *Changing the interface with minimal disruption: The roles of layout and labels* (Doctoral dissertation).

Cloete, L. (2015). Reducing medication errors in nursing practice. *Cancer Nursing Practice*, *14*(1).

College of Nurses of Ontario (CNO) (2014). Competencies for Entry-Level Registered Nurse Practice. https://www.cno.org/globalassets/docs/reg/41037_entrytopracitic_final.pdf

Dall'ora, C., Griffiths, P., & Ball, J. (2015). 12 hour shifts: nurse burnout, job satisfaction & intention to leave. *Evidence Brief*, (3), 1-2.

Dhillon, B. S. (2011). *Patient Safety: An Engineering Approach*. CRC Press.

Elliott, M., & Liu, Y. (2010). The nine rights of medication administration: an overview. *British Journal of Nursing*, *19*(5), 300-305.

Fitts, P. M. (1954). The information capacity of the human motor system in controlling the amplitude of movement. *Journal of Experimental Psychology*, *47*, 381-391.

Food and Drug Association (FDA). (2011). Applying Human Factors and Usability Engineering to Medical Devices. Available at: http://www.fda.gov/downloads/MedicalDevices /DeviceRegulationandGuidance/GuidanceDocuments/UCM259760.pdf

Food and Drug Association (FDA). (2018). Medical Device Overview. Available at: https://www.fda.gov/industry/regulated-products/medical-device-overview

Furniss, D., Masci, P., Curzon, P., Mayer, A., & Blandford, A. (2015). Exploring medical device design and use through layers of distributed cognition: how a glucometer is coupled with its context. *Journal of biomedical informatics*, *53*, 330-341.

Gagnon, R., Laberge, J., Lamsdale, A., Histon, J., Hudson, C., Davies, J., & Caird, J. (2004). A user-centered evaluation of three intravenous infusion pumps. In *Proceedings of the Human Factors and Ergonomics Society Annual Meeting* (Vol. 48, No. 15, pp. 1773-1777). Sage CA: Los Angeles, CA: SAGE Publications.

Garmer, K., Liljegren, E., Osvalder, A. L., & Dahlman, S. (2002). Application of usability testing to the development of medical equipment. Usability testing of a frequently used infusion pump and a new user interface for an infusion pump developed with a

human factors approach. *International Journal of Industrial Ergonomics*, *29*(3), 145-159.

Ginsburg, G. (2005). Human factors engineering: A tool for medical device evaluation in hospital procurement decision-making. *Journal of biomedical Informatics*, *38*(3), 213-219.

Giuliano KK. (2015). IV Smart Pumps: The Impact of a Simplified User Interface on Clinical Use. Biomed. Instrum. Technol. Assoc. Adv. Med. Instrum. Suppl:13–21.

Graham, M. J., Kubose, T. K., Jordan, D., Zhang, J., Johnson, T. R., & Patel, V. L. (2004). Heuristic evaluation of infusion pumps: implications for patient safety in Intensive Care Units. *International journal of medical informatics*, *73*(11-12), 771-779.

Grober, E. D., & Bohnen, J. M. (2005). Defining medical error. *Canadian Journal of Surgery*, *48*(1), 39.

Hadie, S. N., & Yusoff, M. S. (2016). Assessing the validity of the cognitive load scale in a problem-based learning setting. *Journal of Taibah University Medical Sciences*, *11*(3), 194-202.

Health Canada. (2014). Medical Device Regulations. Available at: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices.html

Hospira Inc. (2004). Plum A+ System Operating Manual. *Hospira Incorporated*.

Jacko, J. A. (Ed.). (2012). *Human computer interaction handbook: Fundamentals, evolving technologies, and emerging applications*. CRC press.

Johnson, C. M., Johnson, T. R., & Zhang, J. (2005). A user-centered framework for redesigning health care interfaces. *Journal of biomedical informatics*, *38*(1), 75-87.

Jones, J. H., & Treiber, L. (2010). When the 5 rights go wrong: medication errors from the nursing perspective. *Journal of nursing care quality*, *25*(3), 240-247.

Kendler, J., & Strochlic, A. Y. (2015). *Usability testing of medical devices*. CRC press.

Kershaw, T. C. (2006). Negative Transfer in the Learning of Typing Tasks. In *Proceedings of the Annual Meeting of the Cognitive Science Society* (Vol. 28, No. 28).

Kieras, D. (2001). Using the keystroke-level model to estimate execution times. *University of Michigan*, *555*.

Klepsch, M., Schmitz, F., & Seufert, T. (2017). Development and validation of two instruments measuring intrinsic, extraneous, and germane cognitive load. *Frontiers in psychology*, *8*, 1997.

Lamsdale, A., Chisholm, S., Gagnon, R., Davies, J., & Caird, J. (2005). A usability evaluation of an infusion pump by nurses using a patient simulator. In *Proceedings of the human factors and ergonomics society annual meeting* (Vol. 49, No. 11, pp. 1024-1028). Sage CA: Los Angeles, CA: SAGE Publications.

Macdonald, M. (2010). Patient safety: Examining the adequacy of the 5 rights of medication administration. *Clinical nurse specialist*, *24*(4), 196-201.

Mack, R. L., & Nielsen, J. (1994). Executive summary, Usability inspection methods.

Makary, M. A., & Daniel, M. (2016). Medical error—the third leading cause of death in the US. *Bmj*, *353*, i2139.

Martin, J. L., Norris, B. J., Murphy, E., & Crowe, J. A. (2008). Medical device development: The challenge for ergonomics. *Applied ergonomics*, *39*(3), 271-283.

Martin, J. L., Clark, D. J., Morgan, S. P., Crowe, J. A., & Murphy, E. (2012). A user-centered approach to requirements elicitation in medical device development: A case study from an industry perspective. *Applied ergonomics*, *43*(1), 184-190.

Mattox, E. (2012). Medical devices and patient safety. *Critical care nurse*, *32*(4), 60-68.

McCarney, R., Warner, J., Iliffe, S., Van Haselen, R., Griffin, M., & Fisher, P. (2007). The Hawthorne Effect: a randomised, controlled trial. *BMC medical research methodology*, *7*(1), 30.

Meyers, L. S., Gamst, G., & Guarino, A. J. (2016). Applied multivariate research: Design and interpretation. Sage publications.

Nayak, B. K. (2010). Understanding the relevance of sample size calculation. *Indian journal of ophthalmology*, *58*(6), 469.

Nielsen, J. (1992). Finding usability problems through heuristic evaluation. In *Proceedings of the SIGCHI conference on Human factors in computing systems* (pp. 373-380). ACM.

Norman DA. (2013). The Design of Everyday Things: Revised and Expanded Edition. *Basic Books*.

Norman, D. A., & Draper, S. W. (1986). User centered system design: New perspectives on human-computer interaction. *CRC Press*.

Oshita, M., & Ishikawa, H. (2012). Gamepad vs. touchscreen: a comparison of action selection interfaces in computer games. In *Proceedings of the Workshop at SIGGRAPH Asia* (pp. 27-31). ACM.

Paas G. W. C. and J. G. Van Merriënboer (1993), The Efficiency of Instructional Conditions: An Approach to Combine Mental Effort and Performance Measures.. *Human Factors.* Vol 35, Issue 4, pp. 737 – 743

Potter, P., Wolf, L., Boxerman, S., Grayson, D., Sledge, J., Dunagan, C., & Evanoff, B. (2005). Understanding the cognitive work of nursing in the acute care environment. *JONA: the journal of nursing administration*, *35*(7), 327-335.

Rosner, B (2011). *Fundamentals of Biostatistics*. 7th ed. Boston, MA: Brooks/Cole.

Salditt, P., & Bothell, W. A. (2004). Trends in medical device design and manufacturing. *SMTA News and Journal of Surface Mount Technology*, *17*, 19-24.

Sasangohar, F., Donmez, B., Trbovich, P., & Easty, A. C. (2012). Not all interruptions are created equal: positive interruptions in healthcare. In *Proceedings of the Human Factors and Ergonomics Society Annual Meeting* (Vol. 56, No. 1, pp. 824-828). Sage CA: Los Angeles, CA: SAGE Publications.

Sénécal, S., Léger, P. M., Fredette, M., Courtemanche, F., Cameron, A. F., Mirhoseini, S., ... & Riedl, R. (2013). Touch Screen as Input Device: Does it Influence Memory Retrieval?

Seow, S. C. (2005). Information theoretic models of HCI: a comparison of the Hick-Hyman law and Fitts' law. *Human-Computer Interaction*, *20*(3), 315-352.

Sharp. H., Preece. J., & Rogers. Y. (2019). Interaction Design: Beyond Human-Computer Interaction. (5th edition). Hoboken, New Jersey: *Wiley*.

Shneiderman, B., Plaisant, C., Cohen, M., Jacobs, S., Elmqvist, N., & Diakopoulos, N. (2016). *Designing the user interface: strategies for effective human-computer interaction*. Pearson.

Swayze, S., & Rich, S. (2011). Promoting safe use of medical devices. *OJIN: The Online Journal of Issues in Nursing*, *17*(1), 9.

Sweller, J. (2018). Measuring cognitive load. *Perspectives on medical education*, *7*(1), 1-2.

Torney, H., Harvey, A., Finlay, D., Magee, J., Funston, R., & Bond, R. R. (2018, May). Eye-tracking analysis to compute the visual hierarchy of user interfaces on automated external defibrillators. In *British HCI Conference 2018*.

Unity. (2019). Unity for All: Products. Available at: https://unity3d.com/unity?_ga=2.131554767.1332499143.1563506270-1732763741.1563506270

Viviani, C. A. B., & Calil, S. J. (2015). Smart pump user interface evaluation. In *World Congress on Medical Physics and Biomedical Engineering, June 7-12, 2015, Toronto, Canada* (pp. 1512-1514). Springer, Cham.

World Health Organization (WHO). (2019). Medical Device – Full Definition. Available at: https://www.who.int/medical_devices/full_deffinition/en/

Zaman, L., Natapov, D., & Teather, R. J. (2010). Touchscreens vs. traditional controllers in handheld gaming. In *Proceedings of the international academic conference on the future of game design and technology* (pp. 183-190). ACM.

Zhang, J., Johnson, T. R., Patel, V. L., Paige, D. L., & Kubose, T. (2003). Using usability heuristics to evaluate patient safety of medical devices. *Journal of biomedical informatics*, *36*(1-2), 23-30.

APPENDIX A – RECRUITMENT POSTER

Hello,

My name is Amy Doan and I am a graduate student completing a Masters in Computational Sciences at Laurentian University. For my graduate thesis I am looking to recruit possible nursing students and nursing professionals as participants. The area of research for my study is Human-Computer Interaction and I am specifically exploring the performance of the nursing population when interacting with medical device user interfaces. The medical device I am focusing on are Intravenous Infusion Pump medical devices. Participating in this study requires a single appointment, whereby you will complete a pre-questionnaire, complete five standard intravenous infusion pump programming tasks on two devices, and complete a post-test questionnaire after each device is used. The length of participating will be approximately half an hour. Raw participant results from this study will not be shared with your employer or academic institution and participants will remain anonymous by concealing their personal information using a numerical participant identification number.

If you are interested in the study, please contact me at **adoan@laurentian.ca** to schedule a time to participate. Participation is completely voluntary, and you may withdraw from the study at any time during the process for any reason. If you have more question about the study or its protocols but don't necessarily want to participate, please feel free to contact me and I will gladly answer any questions or concerns you may have.

Thank you

Amy Doan
M.Sc. Computational Sciences
adoan@laurentian.ca

Supervisor: Dr. Ratvinder Grewal (705.675.1151 ext 2351)

APPENDIX B – PARTICIPANT CONSENT FORM

Consent Information Regarding the Study:
"Comparing Nurse Performance Between An Infusion Pump Medical Device on Differing Mediums"

Investigator: Amy Doan
Contact: adoan@laurentian.ca
Supervisor: Dr. Ratvinder Grewal (705.675.1151 ext 2351)

This study strives to explore if a digital mockup of a select intravenous infusion pump (Hospira Plum A+ Infusion Pump) produces similar performance results to the physical medical device currently in use today. The focus of the study is on understanding nurse participant cognitive load and task performance times that result from the physical and digital mock-up mediums. This research is important to understanding how differing user interface mediums for medical devices of the same functionality and design impact their use.

What will be asked of you during the study includes:

- ï Filling out one pre- and two post-test questionnaires, asking for some basic demographic information, as well as your level of experience and confidence using intravenous infusion pump medical devices.

- ï Executing five tasks related to intravenous infusion pump administration on each device medium.

As a participant, you have the right to drop out of the study at any time. Any concerns participants have can be voiced before, during, or after the study at any time. You have the right to drop out of the study at anytime without giving reason for dropping out.
If any participants state their desire to drop out of the study, they must contact the investigator (Amy Doan) via the provided email and inform the investigator that they no longer want to participate. Similarly, if participants state their desire to drop out during the actual scheduled experiment testing time, they must inform the investigator they wish to do so at any point during the study and will receive no penalty. Participating in this study and/or dropping out will not have any effect on the participants future prospects with their employer as all information is kept confidential and any participant names or other participant identified.

In the course of the study, certain personal information will be collected, including: age, gender level of professional nursing experience and perceived confidence interacting with intravenous infusion pumps. All information will be maintained using anonymous ID's for each participant, and the data will be stored in the Computer Human Interaction Laboratory (FA-344) in a locked cabinet. The data will be kept in this secured area until the completion of the study, after which it

will be maintained in this secure location. No information will be shared with any third parties, and information will only be used for the writing and completion of the study only.

Concerns for participants may be:

- Reading comprehension from the provided written material
- Dexterity to interact with device user interfaces

Participants may contact the Research Ethics Board at any time if they have any concerns or questions regarding this study. Participants may contact an official not attached to the research team regarding possible issues or complaints about the research itself:

Research Ethics Officer
Laurentian University Research Office
Telephone: 705-675-1151 ext. 3213, 2436 or toll free at 1-800-461-4030
Email ethics@laurentian.ca.

If all of the following above is acceptable to you as a participant, please leave you signature, date and email address below.

Signature:_____

Email: _____

Date: _____

I would like a copy of the results sent to my email once the study is complete (Circle One):

Yes No

APPENDIX C – PRE-TEST QUESTIONNAIRE

Pre-Test Questionnaire

1. Gender (Circle One): Male Female Prefer Not To Say

2. Age (Circle One):

<18 18-25 26-35 36-45 >45

3. Level of Nursing Qualification (Circle One):

Student Registered Practical Nurse Registered Nurse Nurse Practitioner

4. Years of Professional Nursing Experience (Circle One):

<1 1-5 6-10 11-15 16-20 >20

5. Level of Confidence Interacting with Intravenous Infusion Pumps (Circle One):

1 2 3 4 5
Low Confidence Moderate Confidence High Confidence

6. Most Frequently Used Intravenous Infusion Pump Model (If able to recall):

_____

APPENDIX D – POST-TEST QUESTIONNAIRE

Cognitive Load

Cognitive load refers to the level of mental effort being used in your working memory to accomplish a task.

e.x. Low Cognitive Load: Filling out your first and last name on a form.

e.x. High Cognitive Load: Counting upwards in multiples of 37 while memorizing a random sequence of words.

Experiment #1 (Select Device): Actual IV Pump Tablet

Please rate the level of cognitive load you experienced when completing the previous tasks.

O—-———-O———-O———-O—-———O———-—O———-O—-———O———-—-O

Low Cognitive Load High Cognitive Load

Experiment #2 (Select Device): Actual IV Pump Tablet

Please rate the level of cognitive load you experienced when completing the previous tasks.

O—-———-O———-O———-O—-———O———-—O———-O—-———O———-—-O

Low Cognitive Load High Cognitive Load

APPENDIX E – ETHICS APPROVAL FORM

APPROVAL FOR CONDUCTING RESEARCH INVOLVING HUMAN SUBJECTS

Research Ethics Board – Laurentian University

This letter confirms that the research project identified below has successfully passed the ethics review by the Laurentian University Research Ethics Board (REB). Your ethics approval date, other milestone dates, and any special conditions for your project are indicated below.

TYPE OF APPROVAL / New X / Modifications to project / Time extension	
Name of Principal Investigator and school/department	Amy Doan, supervisor Ratvinder Grewal, Math and Computer Sciences
Title of Project	The Outcomes of Nurses and User Interface Interactions in Acute Care Settings
REB file number	6012352
Date of original approval of project	July 05, 2018
Date of approval of project modifications or extension *(if applicable)*	
Final/Interim report due on: *(You may request an extension)*	July 05, 2019

Conditions placed on project	

During the course of your research, no deviations from, or changes to, the protocol, recruitment or consent forms may be initiated without prior written approval from the REB. If you wish to modify your research project, please refer to the Research Ethics website to complete the appropriate REB form.

All projects must submit a report to REB at least once per year. If involvement with human participants continues for longer than one year (e.g. you have not completed the objectives of the study and have not yet terminated contact with the participants, except for feedback of final results to participants), you must request an extension using the appropriate LU REB form. In all cases, please ensure that your research complies with Tri-Council Policy Statement (TCPS). Also please quote your REB file number on all future correspondence with the REB office.

Congratulations and best wishes in conducting your research.

Rosanna Langer, PHD, Chair, *Laurentian University Research Ethics Board*

APPENDIX F – HEURISTIC EVALUATION RESULTS

Heuristics Evaluation of Hospira Plum A+ Intravenous Infusion Pump

1. Visibility of system status

Always keep users informed about what is going on.

Provide appropriate feedback within reasonable time.

Evaluation

Line A/B Status Headers indicate what state the pump is in (Pumping, Delayed, Stopped)

Status Bar states of the system is waiting for actions from user (i.e. “Enter value using keypad”, “Select, then Enter”, etc)

When programming line, no indication of how many steps is stated because this relies on what the user is trying to program (could need just rate/vtbi or also drug list/dose calculation/delayed start/etc)

Main page informs user how much of the infusion is completed (Vol Inf) but does not inform the user with the remaining time

If user navigates to program summary page they will be able to see how long the infusion has left

States drug to be seen by user

2. Match between system and the real world

Speak the users' language, with words, phrases and concepts familiar to the user, rather than system-oriented terms.

Follow real-world conventions, making information appear in a natural and logical order.

Evaluation

Speaks the user’s language: abbreviations such as “VTBI” are familiar to nurse users back prime, KVO, (volume to be infused); ml/hr (millilitres per hour), etc

Line programming follows natural order of inputting information: rate, vtbi, duration (comparable to some doctors orders)

Start is green, Stop is red

3. User control and freedom

Users often choose system functions by mistake.

Provide a clearly marked "out" to leave an unwanted state without having to go through an extended dialogue.

Support undo and redo.

Evaluation

Clearly marked “Cancel/Back” soft key path option if users navigate down an incorrect path

Going back does not restart the whole programming action, just goes back one step

Altering line configuration does not clear all pump line data (changing rate alters duration instead of clearing all data)

Does not support redo option, users are expected to navigate and select previously inputted and altered data from the beginning

4. Consistency and standards

Users should not have to wonder whether different words, situations, or actions mean the same thing.

Follow platform conventions.

Evaluation

Therapy and Drug List allow the user to select the drug to be infused (two different path options)

Consistency with highlighted bar indicating what can be interacted with at that moment

Consistent colours used throughout the system (light/darker hues of blue)

Status bar is consistently placed to show system status or what they are waiting for from the user

Consistent placement of soft key menu paths

Line A and B are consistent programming wise

Title header for panel is consistently displayed at the top of the screen

Drug List and Dose Calculation list orders are consistent for Line A and B (other program options are the same for Line A and B

INCONSISTENT: with the Change Mode option for Line B where Clear Program is not evident right away until mode is not selected

System consistency with only allowing up/down scrolling and no left/right scrolling selection (some lists appear in 2 columns and users must traverse the first column to access the second column)

Keypad follows traditional keypads (numerical order 1 to 0)

5. Error prevention

Even better than good error messages is a careful design which prevents a problem from occurring in the first place.

Evaluation

When programming line, 3 attributes can be collected from the user (rate, vtbi, duration) only 2 attributes need to be entered as the remaining attribute with automatically populate based on te values used in the other two attributes (this generates a point of reference/visual check for the user to confirm their line programming)

Drug List smart levels notify user if drug infusion is outside of safe limits

Beeps/flashes when idle or have not completed program information to prevent user from forgetting about infusion

Message appears during concurrent where it will finish and not have KVO or auditory notification. Is this ok Yes/No? to prevent error

6. Recognition rather than recall

Make objects, actions, and options visible.

User should not have to remember information from one part of the dialogue to another.

Instructions for use of the system should be visible or easily retrievable whenever appropriate.

Evaluation

Broad path titles are given to the user (Therapy, Program Options) that do not clearly state what path options are available to the user; may result in user relying on recall over recognition during some menu paths (wanting to delay start and needing to remember to go to program options/ wanting to change dose calculation and remembering it is only available through Drug List from Therapy and not Drug List from program options)

Battery symbol recognition

Drug List/ Dose Calculation Options not requiring user to remember and choose instead

Line configure panels display current infusion rate/vtbi so that the user does is aware of current settings and is convenient when the user wants to alter program

Instructions for basic use of system are located on side of device

7. Flexibility and efficiency of use

Accelerators -- unseen by the novice user -- may often speed up the interaction for the expert user so that the system can cater to both inexperienced and experienced users.

Allow users to tailor frequent actions.

Evaluation

Expert vs Novice Users: no quick settings are evident/ preset programs/ cant select frequently used drugs, etc

Advanced Therapies are not presented during main programming screens (experienced users would find these paths; novice users finding these paths are less likely but still likely)

Frequent option such as KVO is available (but does not state what the specific KVO rate is)

8. Aesthetic and minimalist design

Dialogues should not contain information which is irrelevant or rarely needed.

Every extra unit of information in a dialogue competes with the relevant units of information and diminishes their relative visibility.

Evaluation

Minimal information is reduced to bare necessity information on main/home panel (Line rates and vol infused) to reduce information overload

Clean aesthetic (squares) clearly defined Lines (A, B that match the location of the lines)

Clearly defined paths for soft keys (whatever is on top of soft key is option)

9. Help users recognize, diagnose, and recover from errors

Expressed in plain language (no codes)

Precisely indicate the problem

Constructively suggest a solution.

Evaluation

State all error explanations in user manual

Codes are given in addition to main language

Not all errors state how to troubleshoot; not constructive

Error may not be effectively deciphered by novice users (?)

10. Help and documentation

Even though it is better if the system can be used without documentation, it may be necessary to provide help and documentation.

Help information should be easy to search, focused on the user's task, list concrete steps to be carried out, and not be too large.

Evaluation

Full system user manuals are available

Side panel instructions are available

Help is segmented based on the task to be achieved

APPENDIX G – COGNITIVE WALKTHROUGH RESULTS

Cognitive Walkthrough Tasks

Basic Operation Tasks

Task 1: Power ON/Start-Up Pump

Typical Users: Novice and Experienced Healthcare Professionals (Registered and Practical Nurses)

Step 1: Press On/Off to turn on the Plum A+ Intravenous Infusion Pump

Will users know what to do?

Yes, the user will recognize the pump's "Off" state when viewing the pump's unlit display and will instinctively understand that the system should be in an "On" state in order to interact with it. However, novice users may interpret the pump's unlit display to be in a "Sleep" mode and instead may press any key to arouse the system.

Will users see how to perform this step?

Yes, a boldly yellow coloured and prominently placed On/Off key is visible to the user and is labelled in explicit, laymen's terms to avoid inaccurate action interpretations.

Will users understand from feedback whether the action was correct?

Yes, pressing the On/Off key will result in a distinct auditory notification tone, the flashing of both the Line A and Line B Flow Indicators and then the pump's display will turn on and inform the user with a "System Self-Test In Progress" message followed by an "Insert PLUM Set Close Lever" message if a PLUM set cassette is not inserted prior to pump start-up.

Step 2: Insert PLUM Set and Close Lever

Will users know what to do?

No, not all users will know what to do at this step as only those who are knowledgeable about priming intravenous infusion lines and have prior experience with priming the PLUM set for the PLUM A+ Intravenous Infusion Pump will know how to prepare the PLUM set. First-time users and potentially novice users will not know or recall how to correctly prepare the PLUM set from reading the “Insert PLUM Set Close Lever” message.

Will users see how to perform this step?

No, there are no visible instructions available to the user at this step to guide them with performing this step correctly. A label does exist adjacent to the display that indicates where the lever is located and informs the user that it should be closed. However, no instruction is available from the system to guide the user to correctly insert the PLUM set cassette into its corresponding reservoir.

Will users understand from feedback whether the action was correct?

Yes, when the PLUM set cassette is correctly inserted into the cassette reservoir and the lever is properly closed, the display shows a “Mechanism Initialization In Progress” message and then proceeds to show a “Clear Settings?” message if the device has previously saved program settings.

Step 3: Clear Previous Device Settings

Will users know what to do?

Yes, although the user is not instructed about what to do from the Message Region, it intuitive to the user that they would need to select “Yes” to clear the all program settings or “No” to maintain all previous program settings.

Will users see how to perform this step?

Yes, two options are available to the user: “Yes” and “No”. The two options are clearly associated with two distinct soft keys that appear on opposite sides of the display to reduce the possibility of accidentally pressing the wrong option.

Will users understand from feedback whether the action was correct?

Yes, after the user’s selection, the Main Delivery Screen is shown and would display zeroed data for rate, volume infused and drugs selected for both line A and B if the user chose to clear settings. Alternatively, the Main Delivery Screen would show populated data in either of the rate, volume infused and/or drugs selected for line A and/or B if the user chose to not clear settings.

Task 2: Start a Simple Infusion Delivery Through Primary Line

Typical Users: Novice and Experienced Healthcare Professionals (Registered and Practical Nurses)

Step 1: Traverse to Primary Program Screen

Will users know what to do?

No, the Main Delivery Screen does not indicate to the user how they can start a primary infusion. In addition, the Message Region is left blank. Not all users will know what to do at this step as only those who have prior experience with the PLUM A+ Intravenous Infusion Pump will recognize the soft key selector associated with the “A” soft key label as the correct key press to traverse to the Primary Line Program Overview Screen. The “A” soft key label may not be intuitive for first-time or novice users of the pump. The “A” soft key label menu option is not straightforward for some users to understand that this soft key traverses to the Primary Line Program Overview Screen. In addition, novice or first-time users may attempt to configure the primary line program from the Main Delivery Screen.

Will users see how to perform this step?

Yes, the “A” soft key label is clearly associated with a distinct soft key selector as the soft key label is found directly above its corresponding soft key selector.

Will users understand from feedback whether the action was correct?

Yes, the user would be shown the Primary Program Screen which consists of two confirming headers: “A” and “Program” as well as an overview of the primary line’s rate, volume to be infused (VTBI) and duration.

Step 2: Program Primary Delivery Rate

Will users know what to do?

Yes, the user is instructed through the Message Region to “Enter Value using keypad”. The input region for Rate is distinctly highlighted by a dark-hued bar and an inverted text colour. Compared to other input regions that are not coupled with dark-hued bars and inverted text colours, it is intuitive for the user to identify the Rate input as being in an interactable state.

Will users see how to perform this step?

Yes, a fixed keypad is located below the four soft key selectors and contains numeric keys ranging from 0-9, a decimal key and a “Clear” key. The numeric keys appear in a standard layout: in order and starting from lowest to highest number, that users would be familiar with (the numeric keypad layout is comparable to a phone, calculator).

Will users understand from feedback whether the action was correct?

Yes, the user will gain visual feedback from the system by the numbers appearing in the Rate in the same order that the user inputted the numbers field (or zeros will appear if the “Clear” key was pressed). In addition, each key press is met with an auditory tone to confirm the user’s key press.

Step 3: Select Primary Delivery VTBI Input Field

Will users know what to do?

No, the user is not instructed through the Message Region on how to proceed to the VTBI input field. Not all users will know what to do at this step as only those who have prior experience with the PLUM A+ Intravenous Infusion Pump will recognize the Select Down soft key as the

correct key press to traverse to the VTBI input. The Select Down soft key may not be intuitive for first-time or novice users of the pump.

Will users see how to perform this step?

Yes, the Select Up and Down soft keys are located to the right of the numeric keypad. The Select Up and Down soft keys appear in a standard, familiar layout, with the Select Up soft key appearing above the Select Down soft key.

Will users understand from feedback whether the action was correct?

Yes, the user will gain visual feedback from the system when the dark-hued bar and inverted text colour from the Rate input moves to the VTBI input. In addition, each key press is met with an auditory tone to confirm the user's key press.

Step 4: Program Primary Delivery VTBI

Will users know what to do?

Yes, the user is instructed through the Message Region to "Enter Value using keypad". The input region for VTBI is distinctly highlighted by a dark-hued bar and an inverted text colour. Compared to other input regions that are not coupled with dark-hued bars and inverted text colours, it is intuitive for the user to identify the VTBI input as being in an interactable state.

Will users see how to perform this step?

Yes, a fixed keypad is located below the four soft key selectors and contains numeric keys ranging from 0-9, a decimal key and a “Clear” key. The numeric keys appear in a standard layout: in order and starting from lowest to highest number, that users would be familiar with (the numeric keypad layout is comparable to a phone, calculator).

Will users understand from feedback whether the action was correct?

Yes, the user will gain visual feedback from the system by the numbers appearing in the VTBI in the same order that the user inputted the numbers field (or zeros will appear if the “Clear” key was pressed). In addition, each key press is met with an auditory tone to confirm the user’s key press.

Step 5: Select Primary Delivery Duration Hours Input

Will users know what to do?

No, the user is not instructed through the Message Region on how to proceed to the Duration Hours input field. Not all users will know what to do at this step as only those who have prior experience with the PLUM A+ Intravenous Infusion Pump will recognize the Select Down soft key as the correct key press to traverse to the Duration Hours input field. The Select Down soft key may not be intuitive for first-time or novice users of the pump.

Will users see how to perform this step?

Yes, the Select Up and Down soft keys are located to the right of the numeric keypad. The Select Up and Down soft keys appear in a standard, familiar layout, with the Select Up soft key appearing above the Select Down soft key.

Will users understand from feedback whether the action was correct?

Yes, the user will gain visual feedback from the system when the dark-hued bar and inverted text colour from the VTBI input moves to the Duration Hours input field. In addition, each key press is met with an auditory tone to confirm the user's key press.

Step 6: Program Primary Delivery Duration Hours

Will users know what to do?

Yes, the user is instructed through the Message Region to "Enter Value using keypad". The input region for Duration Hours is distinctly highlighted by a dark-hued bar and an inverted text colour. Compared to other input regions that are not coupled with dark-hued bars and inverted text colours, it is intuitive for the user to identify the Duration Hours input as being in an interactable state.

Will users see how to perform this step?

Yes, a fixed keypad is located below the four soft key selectors and contains numeric keys ranging from 0-9, a decimal key and a "Clear" key. The numeric keys appear in a standard layout: in order and starting from lowest to highest number, that users would be familiar with (the numeric keypad layout is comparable to a phone, calculator).

Will users understand from feedback whether the action was correct?

Yes, the user will gain visual feedback from the system by the numbers appearing in the Duration Hours in the same order that the user inputted the numbers field (or zeros will appear if the “Clear” key was pressed). In addition, each key press is met with an auditory tone to confirm the user’s key press.

Step 7: Select Primary Delivery Duration Minutes Input

Will users know what to do?

No, the user is not instructed through the Message Region on how to proceed to the Duration Minutes input field. Not all users will know what to do at this step as only those who have prior experience with the PLUM A+ Intravenous Infusion Pump will recognize the Select Down soft key as the correct key press to traverse to the Duration Minutes input field. The Select Down soft key may not be intuitive for first-time or novice users of the pump.

Will users see how to perform this step?

Yes, the Select Up and Down soft keys are located to the right of the numeric keypad. The Select Up and Down soft keys appear in a standard, familiar layout, with the Select Up soft key appearing above the Select Down soft key.

Will users understand from feedback whether the action was correct?

Yes, the user will gain visual feedback from the system when the dark-hued bar and inverted text colour from the Duration Hours input moves to the Duration Minutes input field. In addition, each key press is met with an auditory tone to confirm the user's key press.

Step 8: Program Primary Delivery Duration Minutes

Will users know what to do?

Yes, the user is instructed through the Message Region to "Enter Value using keypad". The input region for Duration Minutes is distinctly highlighted by a dark-hued bar and an inverted text colour. Compared to other input regions that are not coupled with dark-hued bars and inverted text colours, it is intuitive for the user to identify the Duration Minutes input as being in an interactable state.

Will users see how to perform this step?

Yes, a fixed keypad is located below the four soft key selectors and contains numeric keys ranging from 0-9, a decimal key and a "Clear" key. The numeric keys appear in a standard layout: in order and starting from lowest to highest number, that users would be familiar with (the numeric keypad layout is comparable to a phone, calculator).

Will users understand from feedback whether the action was correct?

Yes, the user will gain visual feedback from the system by the numbers appearing in the Duration Minutes in the same order that the user inputted the numbers field (or zeros will appear

if the “Clear” key was pressed). In addition, each key press is met with an auditory tone to confirm the user’s key press.

Step 9: Start Primary Infusion

Will users know what to do?

No, once all Primary Line Program data is entered, the user is not prompted to start the infusion via the Message Region. Not all users will know what to do at this step as only those who have prior experience with the PLUM A+ Intravenous Infusion Pump will recognize that pressing the “Start” key is permissible at this step.

Will users see how to perform this step?

Yes, a boldly green coloured and prominently placed “Start” key is visible to the user and is labelled in explicit, laymen’s terms to avoid inaccurate action interpretations. This key is located to the left of the numeric keypad.

Will users understand from feedback whether the action was correct?

Yes, the pump’s Line A Flow Indicator will begin flashing to mimic the production of droplets, an auditory confirm tone is produced, and the Status Region delegated to the Primary Line Status will change from “Stopped” to “Pumping”. In addition, the primary program data entered will populate the Main Delivery Screen.

Task 3: Primary Line Rate Titration

Typical Users: Novice and Experienced Healthcare Professionals (Registered and Practical Nurses)

Step 1: Traverse to Primary Program Screen

Will users know what to do?

No, the Main Delivery Screen does not indicate to the user how they can titrate a primary infusion. In addition, the Message Region is left blank. Not all users will know what to do at this step as only those who have prior experience with the PLUM A+ Intravenous Infusion Pump will recognize the soft key selector associated with the “A” soft key label as the correct key press to traverse to the Primary Line Program Overview Screen. The “A” soft key label may not be intuitive for first-time or novice users of the pump. The “A” soft key label menu option is not straightforward for some users to understand that this soft key traverses to the Primary Line Program Overview Screen.

Will users see how to perform this step?

Yes, the “A” soft key label is clearly associated with a distinct soft key selector as the soft key label is found directly above its corresponding soft key selector.

Will users understand from feedback whether the action was correct?

Yes, the user would be shown the Primary Program Screen which consists of two confirming headers: “A” and “Program” as well as an overview of the primary line’s rate, volume to be infused (VTBI) and duration.

Step 2: Alter Primary Delivery Rate

Will users know what to do?

Yes, the user is instructed through the Message Region to “Enter Value using keypad”. The input region for Rate is distinctly highlighted by a dark-hued bar and an inverted text colour. Compared to other input regions that are not coupled with dark-hued bars and inverted text colours, it is intuitive for the user to identify the Rate input as being in an interactable state.

Will users see how to perform this step?

Yes, a fixed keypad is located below the four soft key selectors and contains numeric keys ranging from 0-9, a decimal key and a “Clear” key. The numeric keys appear in a standard layout: in order and starting from lowest to highest number, that users would be familiar with (the numeric keypad layout is comparable to a phone, calculator).

Will users understand from feedback whether the action was correct?

Yes, the user will gain visual feedback from the system by the numbers appearing in the Rate in the same order that the user inputted the numbers field (or zeros will appear if the “Clear” key was pressed). In addition, each key press is met with an auditory tone to confirm the user’s key press.

Step 3: Start Primary Infusion

Will users know what to do?

No, once all Primary Line Program data is populated, the user is not prompted to start the infusion via the Message Region. Not all users will know what to do at this step as only those who have prior experience with the PLUM A+ Intravenous Infusion Pump will recognize that pressing the “Start” key is permissible at this step.

Will users see how to perform this step?

Yes, a boldly green coloured and prominently placed “Start” key is visible to the user and is labelled in explicit, laymen’s terms to avoid inaccurate action interpretations. This key is located to the left of the numeric keypad.

Will users understand from feedback whether the action was correct?

Yes, the pump’s Line A Flow Indicator will begin flashing to mimic the production of droplets, an auditory confirm tone is produced, and the Status Region delegated to the Primary Line Status will change from “Stopped” to “Pumping”. In addition, the primary program data entered will populate the Main Delivery Screen.

Task 4: Piggyback Delivery

Typical Users: Novice and Experienced Healthcare Professionals (Registered and Practical Nurses)

Step 1: Traverse to Primary Program Screen

Will users know what to do?

No, the Main Delivery Screen does not indicate to the user how they can start a primary infusion. In addition, the Message Region is left blank. Not all users will know what to do at this step as only those who have prior experience with the PLUM A+ Intravenous Infusion Pump will recognize the soft key selector associated with the “A” soft key label as the correct key press to traverse to the Primary Line Program Overview Screen. The “A” soft key label may not be intuitive for first-time or novice users of the pump. The “A” soft key label menu option is not straightforward for some users to understand that this soft key traverses to the Primary Line Program Overview Screen.

Will users see how to perform this step?

Yes, the “A” soft key label is clearly associated with a distinct soft key selector as the soft key label is found directly above its corresponding soft key selector.

Will users understand from feedback whether the action was correct?

Yes, the user would be shown the Primary Program Screen which consists of two confirming headers: “A” and “Program” as well as an overview of the primary line’s rate, volume to be infused (VTBI) and duration.

Step 2: Program Primary Delivery Rate

Will users know what to do?

Yes, the user is instructed through the Message Region to “Enter Value using keypad”. The input region for Rate is distinctly highlighted by a dark-hued bar and an inverted text colour.

Compared to other input regions that are not coupled with dark-hued bars and inverted text colours, it is intuitive for the user to identify the Rate input as being in an interactable state.

Will users see how to perform this step?

Yes, a fixed keypad is located below the four soft key selectors and contains numeric keys ranging from 0-9, a decimal key and a “Clear” key. The numeric keys appear in a standard layout: in order and starting from lowest to highest number, that users would be familiar with (the numeric keypad layout is comparable to a phone, calculator).

Will users understand from feedback whether the action was correct?

Yes, the user will gain visual feedback from the system by the numbers appearing in the Rate in the same order that the user inputted the numbers field (or zeros will appear if the “Clear” key was pressed). In addition, each key press is met with an auditory tone to confirm the user’s key press.

Step 3: Select Primary Delivery VTBI Input Field

Will users know what to do?

No, the user is not instructed through the Message Region on how to proceed to the VTBI input field. Not all users will know what to do at this step as only those who have prior experience with the PLUM A+ Intravenous Infusion Pump will recognize the Select Down soft key as the correct key press to traverse to the VTBI input. The Select Down soft key may not be intuitive for first-time or novice users of the pump.

Will users see how to perform this step?

Yes, the Select Up and Down soft keys are located to the right of the numeric keypad. The Select Up and Down soft keys appear in a standard, familiar layout, with the Select Up soft key appearing above the Select Down soft key.

Will users understand from feedback whether the action was correct?

Yes, the user will gain visual feedback from the system when the dark-hued bar and inverted text colour from the Rate input moves to the VTBI input. In addition, each key press is met with an auditory tone to confirm the user's key press.

Step 4: Program Primary Delivery VTBI

Will users know what to do?

Yes, the user is instructed through the Message Region to "Enter Value using keypad". The input region for VTBI is distinctly highlighted by a dark-hued bar and an inverted text colour. Compared to other input regions that are not coupled with dark-hued bars and inverted text colours, it is intuitive for the user to identify the VTBI input as being in an interactable state.

Will users see how to perform this step?

Yes, a fixed keypad is located below the four soft key selectors and contains numeric keys ranging from 0-9, a decimal key and a "Clear" key. The numeric keys appear in a standard layout:

in order and starting from lowest to highest number, that users would be familiar with (the numeric keypad layout is comparable to a phone, calculator).

Will users understand from feedback whether the action was correct?

Yes, the user will gain visual feedback from the system by the numbers appearing in the VTBI in the same order that the user inputted the numbers field (or zeros will appear if the “Clear” key was pressed). In addition, each key press is met with an auditory tone to confirm the user’s key press.

Step 5: Select Primary Delivery Duration Hours Input

Will users know what to do?

No, the user is not instructed through the Message Region on how to proceed to the Duration Hours input field. Not all users will know what to do at this step as only those who have prior experience with the PLUM A+ Intravenous Infusion Pump will recognize the Select Down soft key as the correct key press to traverse to the Duration Hours input field. The Select Down soft key may not be intuitive for first-time or novice users of the pump.

Will users see how to perform this step?

Yes, the Select Up and Down soft keys are located to the right of the numeric keypad. The Select Up and Down soft keys appear in a standard, familiar layout, with the Select Up soft key appearing above the Select Down soft key.

Will users understand from feedback whether the action was correct?

Yes, the user will gain visual feedback from the system when the dark-hued bar and inverted text colour from the VTBI input moves to the Duration Hours input field. In addition, each key press is met with an auditory tone to confirm the user's key press.

Step 6: Program Primary Delivery Duration Hours

Will users know what to do?

Yes, the user is instructed through the Message Region to "Enter Value using keypad". The input region for Duration Hours is distinctly highlighted by a dark-hued bar and an inverted text colour. Compared to other input regions that are not coupled with dark-hued bars and inverted text colours, it is intuitive for the user to identify the Duration Hours input as being in an interactable state.

Will users see how to perform this step?

Yes, a fixed keypad is located below the four soft key selectors and contains numeric keys ranging from 0-9, a decimal key and a "Clear" key. The numeric keys appear in a standard layout: in order and starting from lowest to highest number, that users would be familiar with (the numeric keypad layout is comparable to a phone, calculator).

Will users understand from feedback whether the action was correct?

Yes, the user will gain visual feedback from the system by the numbers appearing in the Duration Hours in the same order that the user inputted the numbers field (or zeros will appear if

the “Clear” key was pressed). In addition, each key press is met with an auditory tone to confirm the user’s key press.

Step 7: Select Primary Delivery Duration Minutes Input

Will users know what to do?

No, the user is not instructed through the Message Region on how to proceed to the Duration Minutes input field. Not all users will know what to do at this step as only those who have prior experience with the PLUM A+ Intravenous Infusion Pump will recognize the Select Down soft key as the correct key press to traverse to the Duration Minutes input field. The Select Down soft key may not be intuitive for first-time or novice users of the pump.

Will users see how to perform this step?

Yes, the Select Up and Down soft keys are located to the right of the numeric keypad. The Select Up and Down soft keys appear in a standard, familiar layout, with the Select Up soft key appearing above the Select Down soft key.

Will users understand from feedback whether the action was correct?

Yes, the user will gain visual feedback from the system when the dark-hued bar and inverted text colour from the Duration Hours input moves to the Duration Minutes input field. In addition, each key press is met with an auditory tone to confirm the user’s key press.

Step 8: Program Primary Delivery Duration Minutes

Will users know what to do?

Yes, the user is instructed through the Message Region to “Enter Value using keypad”. The input region for Duration Minutes is distinctly highlighted by a dark-hued bar and an inverted text colour. Compared to other input regions that are not coupled with dark-hued bars and inverted text colours, it is intuitive for the user to identify the Duration Minutes input as being in an interactable state.

Will users see how to perform this step?

Yes, a fixed keypad is located below the four soft key selectors and contains numeric keys ranging from 0-9, a decimal key and a “Clear” key. The numeric keys appear in a standard layout: in order and starting from lowest to highest number, that users would be familiar with (the numeric keypad layout is comparable to a phone, calculator).

Will users understand from feedback whether the action was correct?

Yes, the user will gain visual feedback from the system by the numbers appearing in the Duration Minutes in the same order that the user inputted the numbers field (or zeros will appear if the “Clear” key was pressed). In addition, each key press is met with an auditory tone to confirm the user’s key press.

Step 9: Start Primary Infusion

Will users know what to do?

No, once all Primary Line Program data is entered, the user is not prompted to start the infusion via the Message Region. Not all users will know what to do at this step as only those who have prior experience with the PLUM A+ Intravenous Infusion Pump will recognize that pressing the "Start" key is permissible at this step.

Will users see how to perform this step?

Yes, a boldly green coloured and prominently placed "Start" key is visible to the user and is labelled in explicit, laymen's terms to avoid inaccurate action interpretations. This key is located to the left of the numeric keypad.

Will users understand from feedback whether the action was correct?

Yes, the pump's Line A Flow Indicator will begin flashing to mimic the production of droplets, an auditory confirm tone is produced, and the Status Region delegated to the Primary Line Status will change from "Stopped" to "Pumping". In addition, the primary program data entered will populate the Main Delivery Screen.

Step 10: Traverse to Secondary Line Program Overview Screen

Will users know what to do?

No, the Main Delivery Screen does not indicate to the user how they can start a secondary piggyback infusion. In addition, the Message Region is left blank. Not all users will know what to do at this step as only those who have prior experience with the PLUM A+ Intravenous Infusion Pump will recognize the soft key selector associated with the "B" soft key label as the

correct key press to traverse to the Primary Line Program Overview Screen. The “B” soft key label may not be intuitive for first-time or novice users of the pump. The “B” soft key label menu option is not straightforward for some users to understand that this soft key traverses to the Primary Line Program Overview Screen.

Will users see how to perform this step?

Yes, the “B” soft key label is clearly associated with a distinct soft key selector as the soft key label is found directly above its corresponding soft key selector.

Will users understand from feedback whether the action was correct?

Yes, the user would be shown the Secondary Program Screen which consists of two confirming headers: “B” and “Program” as well as an overview of the secondary line’s mode, rate, volume to be infused (VTBI) and duration.

Step 11: Program Secondary Delivery Mode To Piggyback

Will users know what to do?

Yes, the user is instructed through the Message Region to “Change using Change Mode”. The input region for Mode is distinctly highlighted by a dark-hued bar and an inverted text colour. Compared to other input regions that are not coupled with dark-hued bars and inverted text colours, it is intuitive for the user to identify the Mode input as being in an interactable state.

Will users see how to perform this step?

Yes, the “Change Mode” soft key label is clearly associated with a distinct soft key selector as the soft key label is found directly above its corresponding soft key selector.

Will users understand from feedback whether the action was correct?

Yes, the user will gain visual feedback from the system by the Mode changing from “Piggyback” to “Concurrent” each time the soft key is pressed. In addition, each key press is met with an auditory tone to confirm the user’s key press.

Step 12: Select Secondary Delivery Rate Input Field

Will users know what to do?

No, the user is not instructed through the Message Region on how to proceed to the Rate input field. Not all users will know what to do at this step as only those who have prior experience with the PLUM A+ Intravenous Infusion Pump will recognize the Select Down soft key as the correct key press to traverse to the Rate input. The Select Down soft key may not be intuitive for first-time or novice users of the pump.

Will users see how to perform this step?

Yes, the Select Up and Down soft keys are located to the right of the numeric keypad. The Select Up and Down soft keys appear in a standard, familiar layout, with the Select Up soft key appearing above the Select Down soft key.

Will users understand from feedback whether the action was correct?

Yes, the user will gain visual feedback from the system when the dark-hued bar and inverted text colour from the Mode input moves to the Rate input. In addition, each key press is met with an auditory tone to confirm the user's key press.

Step 13: Program Secondary Delivery Rate

Will users know what to do?

Yes, the user is instructed through the Message Region to "Enter Value using keypad". The input region for Rate is distinctly highlighted by a dark-hued bar and an inverted text colour. Compared to other input regions that are not coupled with dark-hued bars and inverted text colours, it is intuitive for the user to identify the Rate input as being in an interactable state.

Will users see how to perform this step?

Yes, a fixed keypad is located below the four soft key selectors and contains numeric keys ranging from 0-9, a decimal key and a "Clear" key. The numeric keys appear in a standard layout: in order and starting from lowest to highest number, that users would be familiar with (the numeric keypad layout is comparable to a phone, calculator).

Will users understand from feedback whether the action was correct?

Yes, the user will gain visual feedback from the system by the numbers appearing in the Rate in the same order that the user inputted the numbers field (or zeros will appear if the "Clear" key was pressed). In addition, each key press is met with an auditory tone to confirm the user's key press.

Step 14: Select Secondary Delivery VTBI Input Field

Will users know what to do?

No, the user is not instructed through the Message Region on how to proceed to the VTBI input field. Not all users will know what to do at this step as only those who have prior experience with the PLUM A+ Intravenous Infusion Pump will recognize the Select Down soft key as the correct key press to traverse to the VTBI input. The Select Down soft key may not be intuitive for first-time or novice users of the pump.

Will users see how to perform this step?

Yes, the Select Up and Down soft keys are located to the right of the numeric keypad. The Select Up and Down soft keys appear in a standard, familiar layout, with the Select Up soft key appearing above the Select Down soft key.

Will users understand from feedback whether the action was correct?

Yes, the user will gain visual feedback from the system when the dark-hued bar and inverted text colour from the Rate input moves to the VTBI input. In addition, each key press is met with an auditory tone to confirm the user's key press.

Step 15: Program Secondary Delivery VTBI

Will users know what to do?

Yes, the user is instructed through the Message Region to “Enter Value using keypad”. The input region for VTBI is distinctly highlighted by a dark-hued bar and an inverted text colour. Compared to other input regions that are not coupled with dark-hued bars and inverted text colours, it is intuitive for the user to identify the VTBI input as being in an interactable state.

Will users see how to perform this step?

Yes, a fixed keypad is located below the four soft key selectors and contains numeric keys ranging from 0-9, a decimal key and a “Clear” key. The numeric keys appear in a standard layout: in order and starting from lowest to highest number, that users would be familiar with (the numeric keypad layout is comparable to a phone, calculator).

Will users understand from feedback whether the action was correct?

Yes, the user will gain visual feedback from the system by the numbers appearing in the VTBI in the same order that the user inputted the numbers field (or zeros will appear if the “Clear” key was pressed). In addition, each key press is met with an auditory tone to confirm the user’s key press.

Step 16: Select Secondary Delivery Duration Hours Input

Will users know what to do?

No, the user is not instructed through the Message Region on how to proceed to the Duration Hours input field. Not all users will know what to do at this step as only those who have prior experience with the PLUM A+ Intravenous Infusion Pump will recognize the Select Down soft

key as the correct key press to traverse to the Duration Hours input field. The Select Down soft key may not be intuitive for first-time or novice users of the pump.

Will users see how to perform this step?

Yes, the Select Up and Down soft keys are located to the right of the numeric keypad. The Select Up and Down soft keys appear in a standard, familiar layout, with the Select Up soft key appearing above the Select Down soft key.

Will users understand from feedback whether the action was correct?

Yes, the user will gain visual feedback from the system when the dark-hued bar and inverted text colour from the VTBI input moves to the Duration Hours input field. In addition, each key press is met with an auditory tone to confirm the user's key press.

Step 17: Program Secondary Delivery Duration Hours

Will users know what to do?

Yes, the user is instructed through the Message Region to "Enter Value using keypad". The input region for Duration Hours is distinctly highlighted by a dark-hued bar and an inverted text colour. Compared to other input regions that are not coupled with dark-hued bars and inverted text colours, it is intuitive for the user to identify the Duration Hours input as being in an interactable state.

Will users see how to perform this step?

Yes, a fixed keypad is located below the four soft key selectors and contains numeric keys ranging from 0-9, a decimal key and a “Clear” key. The numeric keys appear in a standard layout: in order and starting from lowest to highest number, that users would be familiar with (the numeric keypad layout is comparable to a phone, calculator).

Will users understand from feedback whether the action was correct?

Yes, the user will gain visual feedback from the system by the numbers appearing in the Duration Hours in the same order that the user inputted the numbers field (or zeros will appear if the “Clear” key was pressed). In addition, each key press is met with an auditory tone to confirm the user’s key press.

Step 18: Select Secondary Delivery Duration Minutes Input

Will users know what to do?

No, the user is not instructed through the Message Region on how to proceed to the Duration Minutes input field. Not all users will know what to do at this step as only those who have prior experience with the PLUM A+ Intravenous Infusion Pump will recognize the Select Down soft key as the correct key press to traverse to the Duration Minutes input field. The Select Down soft key may not be intuitive for first-time or novice users of the pump.

Will users see how to perform this step?

Yes, the Select Up and Down soft keys are located to the right of the numeric keypad. The Select Up and Down soft keys appear in a standard, familiar layout, with the Select Up soft key appearing above the Select Down soft key.

Will users understand from feedback whether the action was correct?

Yes, the user will gain visual feedback from the system when the dark-hued bar and inverted text colour from the Duration Hours input moves to the Duration Minutes input field. In addition, each key press is met with an auditory tone to confirm the user's key press.

Step 19: Program Secondary Delivery Duration Minutes

Will users know what to do?

Yes, the user is instructed through the Message Region to "Enter Value using keypad". The input region for Duration Minutes is distinctly highlighted by a dark-hued bar and an inverted text colour. Compared to other input regions that are not coupled with dark-hued bars and inverted text colours, it is intuitive for the user to identify the Duration Minutes input as being in an interactable state.

Will users see how to perform this step?

Yes, a fixed keypad is located below the four soft key selectors and contains numeric keys ranging from 0-9, a decimal key and a "Clear" key. The numeric keys appear in a standard layout: in order and starting from lowest to highest number, that users would be familiar with (the numeric keypad layout is comparable to a phone, calculator).

Will users understand from feedback whether the action was correct?

Yes, the user will gain visual feedback from the system by the numbers appearing in the Duration Minutes in the same order that the user inputted the numbers field (or zeros will appear if the “Clear” key was pressed). In addition, each key press is met with an auditory tone to confirm the user’s key press.

Step 20: Start Secondary Piggyback Infusion

Will users know what to do?

No, once all Secondary Line Program data is entered, the user is not prompted to start the infusion via the Message Region. Not all users will know what to do at this step as only those who have prior experience with the PLUM A+ Intravenous Infusion Pump will recognize that pressing the “Start” key is permissible at this step.

Will users see how to perform this step?

Yes, a boldly green coloured and prominently placed “Start” key is visible to the user and is labelled in explicit, laymen’s terms to avoid inaccurate action interpretations. This key is located to the left of the numeric keypad.

Will users understand from feedback whether the action was correct?

Yes, the pump’s Line A Flow Indicator will stay lit and Line B’s Flow Indicator will begin flashing to mimic the production of droplets, an auditory confirm tone is produced, and the

Status Region delegated to the Primary Line Status will change from “Pumping” to “Delayed” and the Secondary Line Status will change from “Stopped” to “Pumping”. In addition, the primary and secondary program data entered will populate the Main Delivery Screen.

Task 5: Stop Primary Line Infusion

Typical Users: Novice and Experienced Healthcare Professionals (Registered and Practical Nurses)

Step 1: Stop Primary Infusion

Will users know what to do?

No, once the primary line is infusing, the user is not prompted to stop the infusion via the Message Region. Not all users will know what to do at this step as only those who have prior experience with the PLUM A+ Intravenous Infusion Pump will recognize that pressing the “Stop” key is permissible at this step.

Will users see how to perform this step?

Yes, a boldly red coloured and prominently placed “Stop” key is visible to the user and is labelled in explicit, laymen’s terms to avoid inaccurate action interpretations. This key is located to the left of the numeric keypad.

Will users understand from feedback whether the action was correct?

Yes, the pump's Line A Flow Indicator will stop flashing to mimic the termination of droplet production, an auditory confirm tone is produced, and the Status Region delegated to the Primary Line Status will change from "Pumping" to "Stopped".

Task 7: Stop Simultaneous Primary and Secondary Line Infusions

Typical Users:

Step 1: Stop All Infusions

Will users know what to do?

No, once the primary and secondary lines are infusing, the user is not prompted to stop the infusion via the Message Region. Not all users will know what to do at this step as only those who have prior experience with the PLUM A+ Intravenous Infusion Pump will recognize that pressing the "Stop" key is permissible at this step.

Will users see how to perform this step?

Yes, a boldly red coloured and prominently placed "Stop" key is visible to the user and is labelled in explicit, laymen's terms to avoid inaccurate action interpretations. This key is located to the left of the numeric keypad.

Will users understand from feedback whether the action was correct?

Yes, the Message Region will display the message "Choose line(s) to stop:" and all four soft key labels will change to "Stop All", "Stop A", "Stop B", and "Cancel", respectively.

Step 2: Select “Stop All” Infusions

Will users know what to do?

Yes, the user is instructed through the Message Region to “Choose line(s) to stop:”.

Will users see how to perform this step?

Yes, the “Stop All” soft key label is clearly associated with a distinct soft key selector as the soft key label is found directly above its corresponding soft key selector.

Will users understand from feedback whether the action was correct?

Yes, both the pump’s Line A and Line B Flow Indicator will stop flashing to mimic the termination of droplet production, an auditory confirm tone is produced, and the Status Regions delegated to the Primary and Secondary Line Status will both change from “Pumping” to “Stopped”.

Task 8: Backpriming

Typical Users:

Step 1: Press and Hold “Back Prime” Soft Key Selector

Will users know what to do?

No, the Main Delivery Screen does not prompt or inform the user about how they can backprime the proximal end of the PLUM line set. In addition, the Message Region is left blank. Not all users will know what to do at this step as only those who have prior experience with the PLUM A+ Intravenous Infusion Pump will recognize the soft key selector associated with the “Back Prime” soft key label as the correct key press to initiate backpriming of the proximal end of the PLUM line set.

Will users see how to perform this step?

Yes, the “Back Prime” soft key label is clearly associated with a distinct soft key selector as the soft key label is found directly above its corresponding soft key selector.

Will users understand from feedback whether the action was correct?

Yes, when the “Back Prime” soft key selector is pressed and held down the Message Region displays the message “Release Backprime to Stop”. In addition, the user can visually verify that the proximal end of the PLUM line set is backpriming.

Task 9: Clearing Primary Program Settings

Typical Users:

Step 1: Stop Primary Infusion

Will users know what to do?

No, once the primary line is infusing, the user is not prompted to stop the infusion via the Message Region. Not all users will know what to do at this step as only those who have prior experience with the PLUM A+ Intravenous Infusion Pump will recognize that pressing the “Stop” key is permissible at this step.

Will users see how to perform this step?

Yes, a boldly red coloured and prominently placed “Stop” key is visible to the user and is labelled in explicit, laymen’s terms to avoid inaccurate action interpretations. This key is located to the left of the numeric keypad.

Will users understand from feedback whether the action was correct?

Yes, the pump’s Line A Flow Indicator will stop flashing to mimic the termination of droplet production, an auditory confirm tone is produced, and the Status Region delegated to the Primary Line Status will change from “Pumping” to “Stopped”.

Step 2: Traverse to Primary Program Screen

Will users know what to do?

No, the Main Delivery Screen does not indicate to the user how they can clear the program settings for a primary infusion. In addition, the Message Region is left blank. Not all users will know what to do at this step as only those who have prior experience with the PLUM A+ Intravenous Infusion Pump will recognize the soft key selector associated with the “A” soft key label as the correct key press to traverse to the Primary Line Program Overview Screen. The “A”

soft key label may not be intuitive for first-time or novice users of the pump. The “A” soft key label menu option is not straightforward for some users to understand that this soft key traverses to the Primary Line Program Overview Screen.

Will users see how to perform this step?

Yes, the “A” soft key label is clearly associated with a distinct soft key selector as the soft key label is found directly above its corresponding soft key selector.

Will users understand from feedback whether the action was correct?

Yes, the user would be shown the Primary Program Screen which consists of two confirming headers: “A” and “Program” as well as an overview of the primary line’s rate, volume to be infused (VTBI) and duration. When previously inputted data is saved to a program a “Clear Program” soft key label will appear and be associated with the second soft key selector.

Step 3: Select “Clear Program” Soft Key Selector

Will users know what to do?

Yes, the user will recognize the “Clear Program” soft key label and the explicit labelling of the soft key label is intuitive for the user to understand that this is the correct menu path to follow.

Will users see how to perform this step?

Yes, the “Clear Program” soft key label is clearly associated with a distinct soft key selector as the soft key label is found directly above its corresponding soft key selector.

Will users understand from feedback whether the action was correct?

Yes, the display will change to a screen that consists of the headers “A” and “Clear Program” with the message “Clear Line A Settings?” displayed.

Step 4: Confirm Clearing of Primary Program Settings

Will users know what to do?

Yes, although the user is not instructed about what to do from the Message Region, it intuitive to the user that they would need to select “Yes” to clear the primary line’s program settings.

Will users see how to perform this step?

Yes, two options are available to the user: “Yes” and “No”. The two options are clearly associated with two distinct soft keys that appear on opposite sides of the display to reduce the possibility of accidentally pressing the wrong option.

Will users understand from feedback whether the action was correct?

Yes, after the user’s selection, the Main Delivery Screen is shown and would display zeroed data for rate, volume infused and drugs selected for the primary program.