Designing For Sterile Human-Machine Interfaces

Submitted for partial fulfillment of the requirements for the degree of
Master of Science in User Experience & Interaction Design

Austin Davis
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ABSTRACT

The purpose of this research is to explore how incorporating hand gesture technology with a medical device can reduce the spread of dangerous microorganisms from hospital staff to patients who have a central line catheter. Lessing this form of contamination will allow healthcare professionals to comply with the aseptic technique's sterile-to-sterile contact rule and result in a decline in the number of patients who get a central line-associated bloodstream infection. In the healthcare market, hand gesture technology is mainly used in operating rooms but at a research level. Researchers are using different types of technology, such as Microsoft Kinect and other forms of software,combined with various types of hardware. Combining the success of hand gesture technology in operating rooms with research on how healthcare professionals interact with the medical devices in a patient's room is the key measure of success.

Through this research, an understanding of the users and their goals will come to light. Aside from meeting this objective, it is also important to consider how the use of sterile human-machine interfaces will work in a doctor-patient environment to aid in reducing central line-associated bloodstream infections and provide an overall better quality of life for the patient.

BACKGROUND

According to the Centers for Disease Control and Prevention (CDC) and other health organizations around the world, a center line-associated bloodstream infection (CLABSI) is one of four healthcare-associated infections (HAI). A CLABSI occurs when a patient has a central line that leads to the patient getting a bloodstream infection (BSI). A central line or a central venous catheter (CVC) is a tube that gets inserted into a large vein, either in the patient's neck, chest or groin ("Healthcare-associated Infections," 2010). In some cases, a peripherally inserted central catheter (PICC) gets inserted into the patient's arm instead. These tubes are used by doctors to give the patient medication, fluids or collect blood for testing purposes ("Healthcare-associated Infections," 2010). The typical intravenous catheter (I.V.) that a regular patient is familiar with is the type that is inserted into the patient's arm, either hand or at the crook of the elbow. However, these I.V.s differ from a CVC because they get inserted into veins near the surface for short periods of times, while a CVC is in place for several weeks or months in a major vein that is close to the patient's heart ("Healthcare-associated Infections," 2010). The term central line-associated bloodstream infections can have many definitions. The CDC uses it to describe a primary bloodstream infection that a patient develops when they have a CVC inserted 48-hours before showing symptoms of an infection and is not associated with an infection from another site ("Preventing Central Line-Associated Bloodstream Infections," 2012).

The reasons why a patient develops a CLABSI can range from poor hand hygiene to less than adequate insertion conditions, i.e., life or death situations in the emergency room. Nevertheless, research shows that there are two major ways microorganisms can contaminate a CVC. The first way is called extraluminal: this form of contamination comes from the organisms on the patient's skin that travel along the surface of the catheter at the insertion site and settle at the catheter's tips ("Preventing Central Line-Associated Bloodstream Infections,"

2012). The second mode of infection is called intraluminal: this happens to patients who have a CVC longer than ten days where contamination occurs at any point along the I.V.'s pathway while being manipulated by a healthcare professional ("Preventing Central Line-Associated Bloodstream Infections," 2012).

Out of the four HAIs, CLABSI is preventable, which can lead to a decline in hospital cost and the number of patients and families affected. Approximately 80,000 CLABSIs occur in ICUs across the United States every year ("Preventing Central Line-Associated Bloodstream Infections," 2012). However, for that number to decline, healthcare professionals must follow evidence-based guidelines put out by the CDC for inserting and maintaining central lines. A study done by the CDC showed that in 2009 there were 18,000 CLABSIs in ICUs versus 43,000 CLABSIs in 2001; this is a 58% reduction that represents an estimated $414 million saved in healthcare costs and 6,000 lives saved ("Preventing Central Line-Associated Bloodstream Infections," 2012).

Hospitals and healthcare professionals have made great strides in preventing CLABSIs. These span from educating staff members on the proper procedures for CVC insertion and maintenance to the use of different techniques in preventing microorganisms from contaminating medical supplies and patients. Education and training are one of the most important factors in reducing CLABSIs. However, this reduction is not limited to the United States; studies have shown that in developing countries CLABSI rates drop once healthcare professionals have the proper training and education ("Preventing Central Line-Associated Bloodstream Infections," 2012).

Aside from educating and training healthcare professionals, hand hygiene is another key component in reducing CLABSIs, as well as the spread of other infections. In 2011 the CDC released hand hygiene guidelines to decrease the risk of CLABSI caused by microorganisms spreading from healthcare professional's hands to patients ("Preventing Central Line-Associated Bloodstream Infections," 2012). These guidelines are to be performed before and after touching the site of catheter insertion, before and after inserting the catheter, before

and after accessing, replacing, repairing or dressing the catheter ("Preventing Central Line-Associated Bloodstream Infections," 2012).

Even though the CDC has stressed the importance of hand hygiene and healthcare professionals widely agree its importance in reducing the spread of the infections, there is evidence to suggest that there is limited acceptance in practice. These studies have shown that there is an average of less than 40% of healthcare professionals complying with the hand hygiene guidelines ("Preventing Central Line-Associated Bloodstream Infections," 2012). To successfully reduce the number of patients affected by CLABSIs, healthcare professionals need to adhere to these guidelines at all times.

There are two techniques used to prevent microorganisms from contaminating a healthcare setting. The first one is the aseptic technique, also called the sterile technique; the second is the clean technique ("Preventing Central Line-Associated Bloodstream Infections," 2012). Both methods strive to minimize the presence of microorganisms in hopes of reducing their spread. However, these two techniques differ: the aseptic technique is used to keep objects and areas free of contamination to lessen the chance of infection for the patient, while the clean technique only reduces the overall number of microorganisms present in a healthcare setting ("Preventing Central Line-Associated Bloodstream Infections," 2012). The aseptic technique is more stringent than the clean technique on what is allowed and what is not. The aseptic technique uses:

- Barriers like sterile gloves, sterile gowns, sterile drapes and masks to stop the transfer of microorganisms from healthcare personnel to patients during a procedure ("Preventing Central Line-Associated Bloodstream Infections," 2012).

- Sterile equipment, devices and skin antiseptic for the patient at the time of the procedure ("Preventing Central Line-Associated Bloodstream Infections," 2012).

- Controlling the patient's environment which includes keeping doors closed and keeping unnecessary people out of the room during the procedure ("Preventing Central Line-Associated Bloodstream Infections," 2012).

- Only sterile-to-sterile contact is allowed; sterile-to-non sterile contact must be avoided ("Preventing Central Line-Associated Bloodstream Infections," 2012).

While the clean technique is a rigorous method, it is far less strict than the aseptic technique. The clean technique requires:

- Proper hand hygiene ("Preventing Central Line-Associated Bloodstream Infections," 2012).

- Clean gloves used to prevent direct contamination of supplies and decrease the opportunity of microorganisms getting transmitted to the patient by healthcare professionals ("Preventing Central Line-Associated Bloodstream Infections," 2012).

- The patient's environment gets routinely cleaned and there are no sterile-to-sterile rules ("Preventing Central Line-Associated Bloodstream Infections," 2012).

The aseptic and clean technique play a significant role in reducing the spread of microorganisms. However, many studies suggest that hospital surfaces and frequently used medical equipment get contaminated by a number of pathogenic organisms. These surfaces and medical devices can transfer these organisms to the gloves healthcare professionals wear, subsequently transferring the organisms to the patients or other inanimate surfaces (Arias, 2010). Even though some of these organisms may not be harmful, there is evidence to suggest multidrug-resistant bacteria can be present on inanimate surfaces.

In a study conducted in 2011 at Hospital da Restaurão in Recife, Pernambuco, Brazil, showed evidence of multidrug-resistant bacteria on inanimate surfaces within the hospital's adult ICU (Maria Sales, Oliveira, Célia, Ramos Gonçalves & Carvalho de Melo, 2014). The multidrug-resistant bacteria that the study tested for was Acinetobacter baumanii. The results showed that this bacteria was present in 83% of the respirators tested, 37.5% of the I.V. pumps tested, 25% of the stethoscopes and 12.5% of bed rails (Maria Sales et al., 2014). These results strongly suggest that healthcare professionals' hands can be a mode of contamination for harmful microorganisms.

Although the study mentioned above only tested for Acinetobacter baumanii, there is a growing amount of data that suggests other multidrug-resistant bacteria such as Methicillin-resistant Staphylococcus aureus (MRSA) and Vancomycin-resistant enterococci (VRE) can also be present on inanimate surfaces. MRSA, for example, can survive on a dry surface for seven days to seven months (Kramer, Kampf & Schwebke, 2006). It is worth noting that these inanimate surfaces and medical devices do get cleaned but there is no universal guideline as to how frequently. An I.V. pump may only get cleaned after the patient gets discharged from the hospital. Meaning, once the patient is admitted to the hospital and requires an I.V. pump, that pump stays with the patient even if the patient gets moved to a different floor. If a patient gets transferred to an ICU, it is fair to say that the patient may be in the hospital for an extended period. In which, these multidrug-resistant bacteria have a greater opportunity to contaminate the surface of the I.V. pump or the I.V. pump's pole. As seen with MRSA that can survive for several months, so can VRE (five days to 4 months), and Clostridium difficile more commonly known as C. diff (five months); all three are known factors for HAIs (Kramer et al., 2006).

The role medical devices can have in spreading harmful microorganisms that can cause CLABSIs and other HAIs is gaining notice. However, the overall evidence has been weak due to the central focus on hand washing, despite studies that prove pathogens can be transmitted from surfaces to healthcare personnel to patients, and that routine cleaning does not always remove these pathogens (Arias, 2010). By incorporating hand gesture technology into a preexisting medical device to create a sterile human-machine interface, sterile-to-sterile contact will always be implemented making it easier for healthcare professionals to adhere to the aseptic technique and aid in the reduction of CLABSIs.

TERMINOLOGY

BSI	Bloodstream Infection
CDC	Centers for Disease Control and Prevention
CLABSI	Central Line-Associated Bloodstream Infection
CVC	Central Venous Catheter
HAI	Healthcare-Associated Infection
ICU	Intensive Care Unit
I.V.	Intravenous Catheter
I.V. Pump	Infusion Pump
MVP	Minimum Viable Product
PICC	Peripherally Inserted Central Catheter
SSI	Surgical Site Infection

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DESCRIPTION

The purpose of this project is to explore how healthcare professionals will interact with a medical device that has a hand gesture interface. The goal is to understand how this type of interface will affect the user's ability to perform their duties correctly and how it can aid in the decline of the number of patients affected by a CLABSI. Since most patients who have a central line are in an ICU, the device should be one that is common to that hospital environment. The device should also be one that is frequently touched. However, it should not be a medical device that only a specialist can interact with—such as a ventilator or dialysis machine. Taking these guidelines into consideration, this project focuses on infusion pumps as the device best suited to incorporate a hand gesture interface.

SECTION 01:

BUSINESS REQUIREMENTS

MISSION

Central line-associated bloodstream infections are a type of healthcare-associated infection and are one of the CDC's most important healthcare issues. CLABSIs are preventable, and through the use of evidence-based guidelines based on the CDC recommendations, hospitals across the U.S. have seen a decline in CLABSIs (Barnes, Olmsted, Monsees, Harris, Khoury, Hadaway, & Downham, 2015). Every patient's room in a hospital will have medical devices that range from heart monitors to life support devices such as ventilators. Healthcare staff can spread dangerous microorganisms unintentionally to the patient when they have to interact with these medical devices. These machines are usually cleaned to decrease the chances of this happening, but they are still a mode of contamination. It is in this situation where there is a breakdown in the aseptic technique's sterile-to-sterile contact rule. Reducing the spread of microorganisms from these medical devices that are necessary for a patient's health is vital for the continued reduction of CLABSIs and HAIs overall.

By researching and understanding the role hand gesture technology can have in creating a sterile human-machine interface and its benefits in preventing the spread of dangerous microorganisms will enable healthcare professionals always to maintain the sterile-to-sterile contact rule. Thus resulting in fewer deaths associated with CLABSIs along with an overall decrease in HAIs and a reduced financial strain on the U.S. healthcare system.

SHORT-TERM GOALS

The short-term goals descend from the long-term goals. These are goals that are achievable within a time frame of a week, month, or up to a year. Ideally, short-term goals usually span a six-month timeline. These goals are specific and easily obtainable, as well as easy to measure and evaluate the progress of the long-term goals accurately. The short-term goals are flexible, which provide room for improvement; if a goal is proven to be unobtainable or needs reworking then the goal will be adjusted to ensure that the desired result is obtainable and aligns with the long-term goals.

Short-Term Goals:

- Build a website to aid in awareness and sales of the product
- Establish benchmark for user approval
- Release the MVP to regional hospitals
- Develop a sustainable sales model
- Create contract for service packages

LONG-TERM GOALS

Long-term goals are vital for the longevity of any product to be sustainable within its market. A long-term goal(s) establishes the expectation for the product's future and creates a clear path to reach the desired goals. These goals are more general and require a longer time for completion usually extending out to three or five years. These goals correlate with the mission and each has their measurements for success.

Long-Term Goals:

- Increase sales to a national level
- Double the user approval rating
- R&D for new product features and product development
- Release the second version of the product
- Partner with an IV pump manufacturer
- Empirical evidence showing a decline in CLABSIs
- Partner with Intertek to provide consumer testing and FDA 510(k) consulting
- Solve the problem of how to control multiple Sigma Spectrum I.V. pumps and multiple Alaris™ PC channels
- Obtain FDA approval

OBJECTIVES

The short-term and long-term goals, while precise as they are, are still flexible and can change or be adapted to fit a certain need. However, the objectives differ from the short-term goals and long-term goals because they are specific and measurable. The objectives help underline all planning and strategic activities for continuing forward.

Objectives:

- Have 10+ daily visitors to the website
- Achieve a user approval rating of 75%
- Have a funded study conducted by a 3rd party
- Reach a 2% sales increase
- Expand sales to a national level
- Release the second version

SUCCESS METRICS

Success metrics are quantifiable measurements or numbers that get completed within a given time frame. Some metrics will evaluate the success of the product, while others will determine the usability success. The usability metrics support the product's parameters. The success metrics outlined below encompass both product and usability metrics.

Success Metrics

- In three months have a website built
- Within two years have a 75% user approval rating
- Within six months release the MVP
- By eighteen months increase sales by 2%
- In two years reach a national sales level
- 3rd party study showing a 3–5% decline in patients affected by CLABSIs
- In five years release the second version
- In seven years have FDA approval

SWOT ANALYSIS

The SWOT analysis is a process that will aid in identifying the products strengths, weaknesses, opportunities, and threats. It is an analytical framework to assess what the product can and cannot do. These abilities and limitations are internal and external factors. By completing this SWOT analysis, it will determine what will assist the product in accomplishing its objectives and the obstacles it will need to overcome to achieve the overall mission.

SWOT

STRENGTHS

- A reduction in the spread of microorganisms from inanimate objects to healthcare professionals then to patients
- Advancements in healthcare innovation
- Combining pre-existing medical equipment with pre-existing technology to create a new but already familiar product

OPPORTUNITIES

- Growing advancements in hand gesture technology that will make the product better in the near future
- Early adopters, i.e., large tech and healthcare companies might buy in
- Zero direct competitors with only a few indirect competitors

WEAKNESSES

- High price to produce the product
- Possible learning curve
- A chance to make an improper setting input
- Lack of marketing to get knowledge of product to appropriate decision makers

THREATS

- Possibly the product does not reduce CLABSIs enough for hospitals to buy it
- Indirect competitors move into the market
- Competitors have a new and more innovative solution to reduce CLABSIs
- Competitors have more financial resources and a better channel of distribution

GROWTH STRATEGY

A growth strategy is a road map that a business will use to grow and succeed in its given market. The plan aligns with the long-term goals to ensure that they get accomplished. The proposed growth strategy is for internal growth, which focuses on four factors: market penetration, market development, product expansion, and diversification.

- **Market penetration:** increase sales within the current market by using effective marketing approaches.
- **Market development:** increase the sales from a regional level to a national level.
- **Product expansion:** release of newer versions. Already existing customers and new customers from adjacent markets will have the opportunity to buy the new versions with improved/new features. Inadvertently this will increase sales and profits.
- **Diversification**: expand into other medical device markets where a sterile human-machine interface could be incorporated.

BUSINESS CANVAS MODEL

The business canvas model is a graphical representation that describes how an organization creates and delivers value to its customers. The model is made up of nine components: Customer Segments, Value Propositions, Channels, Customer Relationships, Revenue Streams, Key Resources, Key Activities, Key Partners and Cost Structure. The following page contains the projected business canvas model.

Business Model Canvas

Designed for: UXD Thesis Project *Designed by:* Austin Davis *Date:* 9/13/17 *Version:* 02

Key Partners

- Hardware manufacturers
- Plastic molding manufacturers
- Office landlord
- I.V. pump manufacturer(s)

Key Activities

- Advancements in hand gesture technology
- R&D for technology improvements

Key Resources

- 3D printers
- Electronic and engineering components for prototyping
- Servers for customer database
- Employees
  - Industrial designers
  - Software Developers
  - Biomedical engineers
  - User experience designers
  - Human resources personnel
  - Accounting and finance personnel
  - Marketing and advertising personnel
  - Sales and purchasing personnel
  - Customer service personnel
  - Legal personnel
  - IT personnel
  - Quality assurance personnel

Value Propositions

- Reduce CLABSIs and HAIs
- Decreased money spent by hospitals on CLABSI patients
- An interface more suited with the technology seen today
- Increased longevity of the I.V. pump due to fewer people who touch it

Customer Relationships

Personal assistance

- Call center
- Email
- Technicians

Channels

- Sales team
- Direct marketing
- Website
- Industry publications
- Press releases
- Medical technology conferences
- 3rd party dealers and brokers
- Brochures
- Partnership(s) with I.V. pump manufacturers

Customer Segments

Niche Market

- Hospitals
- Outpatient clinics
- Urgent care centers

Cost Structure

Fixed Cost

- Developing the software
- Maintaining & increasing server storage
- Staff
- Office supplies
- Prototyping supplies
- R&D costs
- Buying manufactured product
- Rent
- Web hosting

Revenue Streams

- Tiered pricing based on volume
- Service packages
- Wholesale agreements
- Dealer/broker agreement

SECTION 02:

UX RESEARCH & DESIGN

RESEARCH STRATEGY

The research strategy is a combination of three main areas of focus: Looking, Understanding and Making. Throughout this section all three of these design skills and their various topics are utilized. Researching CLABSIs and its current state of prevention was the first step in understanding the problem. This research was accomplished by reading several medical journals, articles and research papers on CLABSIs and I.V. pumps. From there the three design skills mentioned above could start being implemented.

The first phase, Looking, deals with ethnographic research, where Fly-on-wall-observation was performed in a medical ICU at Thomas Jefferson Hospital (see Appendix A for supporting materials). A medical ICU is an intensive care unit that specializes in the care of critically ill patients. These patients could have respiratory failure, pulmonary disease, septic shock, liver failure, multisystem failure and mechanical ventilation. This observation was done over two four hour days to gain insight into a healthcare professionals everyday environment. The next aspect of the ethnographic research was conducting interviews. The data from these interviews was used in the Understanding phase to develop the personas.

The second phase is Understanding, where the use of empathy maps, personas and experience maps come into play. These tools allowed for a better understanding of the user's mental model. Also, a Rose, Thorn, Bud analysis was completed for the Gesteir device. This examination helped with identifying strengths, problems and potential opportunities for the design of the device.

The final phase is Making, during this stage of the research thumbnail sketching of the hand gestures and the design of the device was completed. The thumbnail sketches assisted in the creation for the storyboards. These storyboards show how the users will be interacting and experiencing the device.

COMPETITIVE ANALYSIS

This competitive analysis was conducted to see how hand gesture technology is being used in healthcare today. The primary purpose was to find any direct competitors that are utilizing this technology to interact with the medical machines in a patient's hospital room without having to touch the device physically. The secondary purpose was to explore for any indirect competitors that use hand gesture technology in any other aspects of healthcare. This competitive analysis took place during March 2017 and updated during September 2017 with the addition of Nichii Gakkan's OPECT.

At the time of this review, there are no direct competitors. That is to say, that hand gesture technology has not made its way into the patient's room. However, hand gesture technology is in use in the operating rooms. These would be the indirect competitors. GestSure is an indirect competitor but can develop into a direct competitor. GestSure has created a touchless gestural interface that allows surgeons to control medical images without having to scrub out or wait for a non-sterile nurse to become available. GestSure accomplishes this through the use of the Microsoft's Kinect and a small box that connects to the operating room's computer. Once connected, GestSure waits for the surgeon to make a particular hand signal and then tracks the surgeon's arm. GestSure utilizes the Kinect's hardware to recognize depth, making it easier to track and identify objects. GestSure is simple to use because it requires no software installation and works with all medical imaging viewers. As of now it is only being used in operating rooms and is relatively unknown to the healthcare system.

Gestix is an indirect competitor and cannot become a direct competitor. It is a hand gesture recognition system that allows doctors to manipulate digital images during medical procedures. Researchers at Ben Gurion University in Israel developed Gestix in 2008. It uses a camera to digitalize the images of the surgeon's hands. This camera is placed over a monitor and interfaced to an Intel Pentium 4-based PC using a frame grabber. Gestix allows for a

sterile interaction with the image data. It also responds in real time and without needing a microphone or foot pedals. As a result, Gestix reduces the surgery time and cost. Gestix requires a calibration process before the surgeon can use the system. This technology is at a research stage for the use in operating rooms.

The Microsoft Kinect is an indirect competitor with the ability to become a direct competitor. Companies like Nichii Gakkan and GestSure uses this product, as well as other forms of research associated with healthcare. While companies like GestSure use this product to reduce surgical site infections, it is fair to say that this product could aid in the reduction of CLABSIs and HAIs as a whole. One way of doing this is by using it in a telehealth system, which allows doctors to treat patients via telecommunication. As a result, the patient would not have to visit the hospital where chances of them getting an infection increase. The Kinect is inexpensive, costing about one hundred U.S. dollars. The particular advantages and disadvantages for Microsoft's Kinect as a whole are unknown because researchers are still finding ways to use it. In the case of GestSure, it has great potential, but there can be other applications for it.

Nichii Gakkan's OPECT is an indirect competitor. It is a system much like GestSure in that it uses the Microsoft Kinect to allow the surgical team to operate image files in a non-contact manner. Along with using hand gestures, OPECT also permits the use of eye gestures. The OPECT system comes with a mobile workstation and is currently only used in Japan.

The final indirect competitor is Google's Project, Soli. It has the most chances of becoming a direct competitor. Soli is a microchip that can be embedded into devices to create a sterile hand gesture interface. It uses radar to detect the user's hand movements. The sensor can detect the user's hand motion with fast and reliable accuracy. Soli mimics interactions that are familiar to the user, which makes it easy to learn how to communicate with Soli. These interactions feel physical and responsive because the user's feedback is the sensation of their fingers touching each other. Soli is still in research/ building phase, and its use in healthcare may get overlooked for the use in wearables, phone, computers, smart cars and other IoT devices. An advantage to Soli is that its hardware is agnostic.

PERSONA DEVELOPMENT

The personas represent the users with the use of qualitative and quantitative data gathered at various stages of the research strategy. Four different personas will serve for the users: Nurses, IT professionals, patients, and family members. To aid in the development of the personas, each one will have an empathy map. These empathy maps will allow for a greater insight into each user's mental model.

Thinking & Feeling

- What are the doctors going to choose for the next course of treatment
- Overwhelmed
- That alarm is not that important

Seeing

- Family members not washing their hands
- Patient's medical charts
- Patient's family members trying to cope

Hearing

- I.V. pump's alarm going off
- Patient's calling for a nurse
- Doctors talking about how to treat a patient

Saying

- Why can't they just get a better machine
- I always wash my hands

Pain

- Having to reprogram a medical device
- A patient getting worse

Gain

- Patient recovering faster
- Less administration paper work

Devoted Nurse

"I'm always mindful of what I touch because we touch everything, and I wash my hands all of the time."

Sara Lynch

Age: 25–30

Occupation: ICU Staff Nurse

Education: BS in Nursing

Status: Married

Location: Philadelphia, PA

Compassionate

Supportive

Hardworking

Background

Sara begins her shift at 7PM after she has spoken to nurses on the previous shift about the patients in her care. She then makes her rounds to assess her patient's vital signs and learn if they are presenting with any new symptoms. During these rounds, Sara has to interact with the medical machines in the patient's room. Even though she has washed her hands and is wearing gloves, Sara still worries about spreading germs to her patients. Sara knows this can easily happen due to a lack of control over the patient's environment. Her primary concern is when she has to manually adjust a setting on one the medical machines in the room. Even though Sara will wipe these machines down at the end of her shift, she is not sure if the nurse on the last shift has done the same. After her rounds, Sara returns to her station where she spends most of her work day monitoring her patient's vitals and logging her records.

Goals:

- Provide the best care to her patients
- Monitor the patient's vitals from her station
- Keep accurate records
- Decrease any chances of spreading germs to the patient

Frustrations:

- I.V. pump is not connected to patient records database
- I.V. pump saying there is an occlusion when there isn't
- Being away from her station

Thinking & Feeling

- A little overwhelmed with his workload
- Frustrated at times
- Happy when an issue is fixed

Seeing

- His inbox filling up with IT requests
- Staff trying to fix an IT problem themselves
- More medical devices being bought

Hearing

- His work phone ringing
- Other IT techs talking about an issue
- People typing on their keyboard

Saying

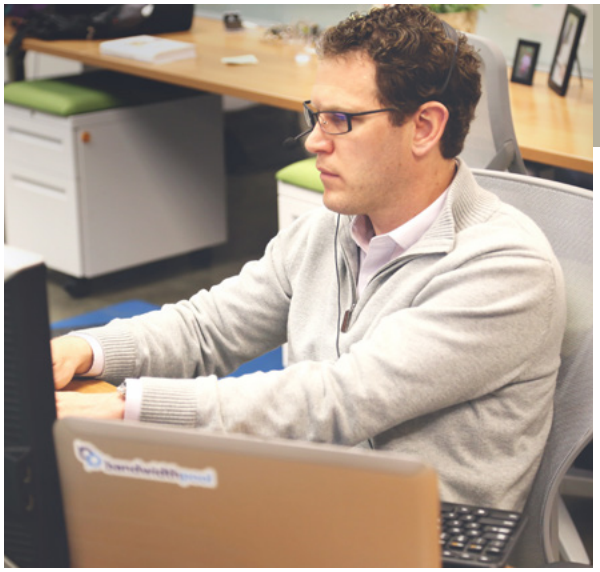
- It should only take me a few minutes to fix that
- Our network is running slow due to old infrastructure, but we will get it working

Pain

- A delay in solving an IT problem
- A lack of communication from the IT manager

Gain

- Fulfillment in helping healthcare staff
- Better understand on how each department works



Motivated Technician

Allen Taylor

Age: 30–35

Occupation: IT Technician

Education: BS in Information Science

Status: Married

Location: Philadelphia, PA

Analytical

Detail-Oriented

Responsible

> "Some of these devices are still using technology from the 90's, and I don't understand why."

Background

Allen Taylor has been working in Information Technology ever since he graduated college. His day usually begins at 7 AM when he goes through his inbox looking for any urgent IT request. After that, he starts his day-to-day task, which involves maintaining and updating the hospital's network. As the day progresses, Allen receives more IT requests which he tries to solve as quickly as he can. Along with any IT issues and his day-to-day task, Allen will also configure any and all new medical equipment that the hospital has bought.

Goals:

- Providing hospital staff with quick technical solutions
- Insure that all equipment is configured correctly
- Understand each department's technical needs

Frustrations:

- Staff trying to fix the equipment themselves
- Outdated medical device software
- Lack of communication between department heads and IT staff

Thinking & Feeling

- Frustrated
- Sad
- Will loved one get better

Seeing

- Family members and healthcare professionals coming in and out of the hospital room
- Healthcare professionals doing all they can for loved one
- Nurses standing in front of I.V. pump making hand gestures

Hearing

- We still don't know what type of infection it is
- We are running more tests
- Family members asking questions

Saying

- Are there any new updates
- How long do these tests take
- Why did this happen

Pain

- Seeing loved one suffer
- Not understanding what the doctors are talking about

Gain

- Loved one recovering
- Returning to a "normal" life

Loving Family Member

Holly Phillips

Age: 55–60

Occupation: Receptionist

Education: B.L.A.

Status: Divorced

Location: Philadelphia, PA

Understanding

Curious

Angry at times

> "I never wanted to see my daughter look like a 90-year-old woman."

Background

Holly's daughter contracted a bloodstream infection from her central line while she was recovering from a liver transplant. Everyday Holly is at her daughter's side while the doctors and nurses do their best to heal her daughter. The doctors are not exactly sure how Holly's daughter got the infection but believe it had to do with the environment in her daughter's room. A nurse had to explain to Holly that what most likely happened was a nurse or doctor touched one of the medical machines in the room and failed to adhere to proper clean technique requirements. Meaning they did not have adequate hand hygiene or clean gloves. Holly understands that she and her daughter are in an unfortunate situation and that these things happen. However, Holly doesn't know why there is not more of an effort on the hospital's part to control a patient's environment.

Goals:

- Loved one with a bloodstream infection recovers from it
- Find as much information on the type of infection
- Make sure loved one feels loved and supported
- Get the best care for loved one

Frustrations:

- When doctors or nurses don't explain things in layman's term
- Worry of loved one getting another infection or passing away
- Complex medical and/or scientific research that she doesn't understand

Thinking & Feeling

- When am I going to get better
- Why doesn't anyone know how I got a BSI
- Depressed

Seeing

- People coming in and out of the room
- Nurses having to run more tests on her
- Nurses standing in front of I.V. pump making hand gestures

Hearing

- Healthcare professionals talking about her
- Alarms from the medical machines
- Family members talking

Saying

- How did I get an infection
- When can I go home

Pain

- Physical discomfort from the central line
- Lack of sleep

Gain

- Love and support from family and friends
- Getting back to her normal life

Hopeful Patient

Kristina Powell

Age: 30–35

Occupation: Dental hygienist

Education: A.S.

Status: Married

Location: Philadelphia, PA

Determined

Strong willed

Affectionate

> "The worst part is when no one, not even the doctors or nurses, can tell you when you are getting out, and you just feel trapped."

Background

Kristina Powell never wanted to be known as "the sick woman," but when diagnosed with an autoimmune disease, that is how people started to view her. Her battle with the illness has been long and tiresome, but she has never felt sorry for herself. While in the hospital recovering from her surgery, Kristina got a CLABSI. What was suppose to be a two-day hospital stay resulted in a five-week hospital stay. As a consequence of the BSI, she struggled to recover from her surgery and was bedridden for most of the time while she was in the hospital. Kristina is now out of the hospital and back at work but has some psychological trauma from getting the CLABSI that she now has to deal with on top of her autoimmune disease.

Goals:

- Recover from the infection
- Get healthy enough to go back to work
- Get out of the hospital

Frustrations:

- Not knowing how long her hospital stay will be
- Understanding all of the medical terms
- Feeling like she cannot take care of herself

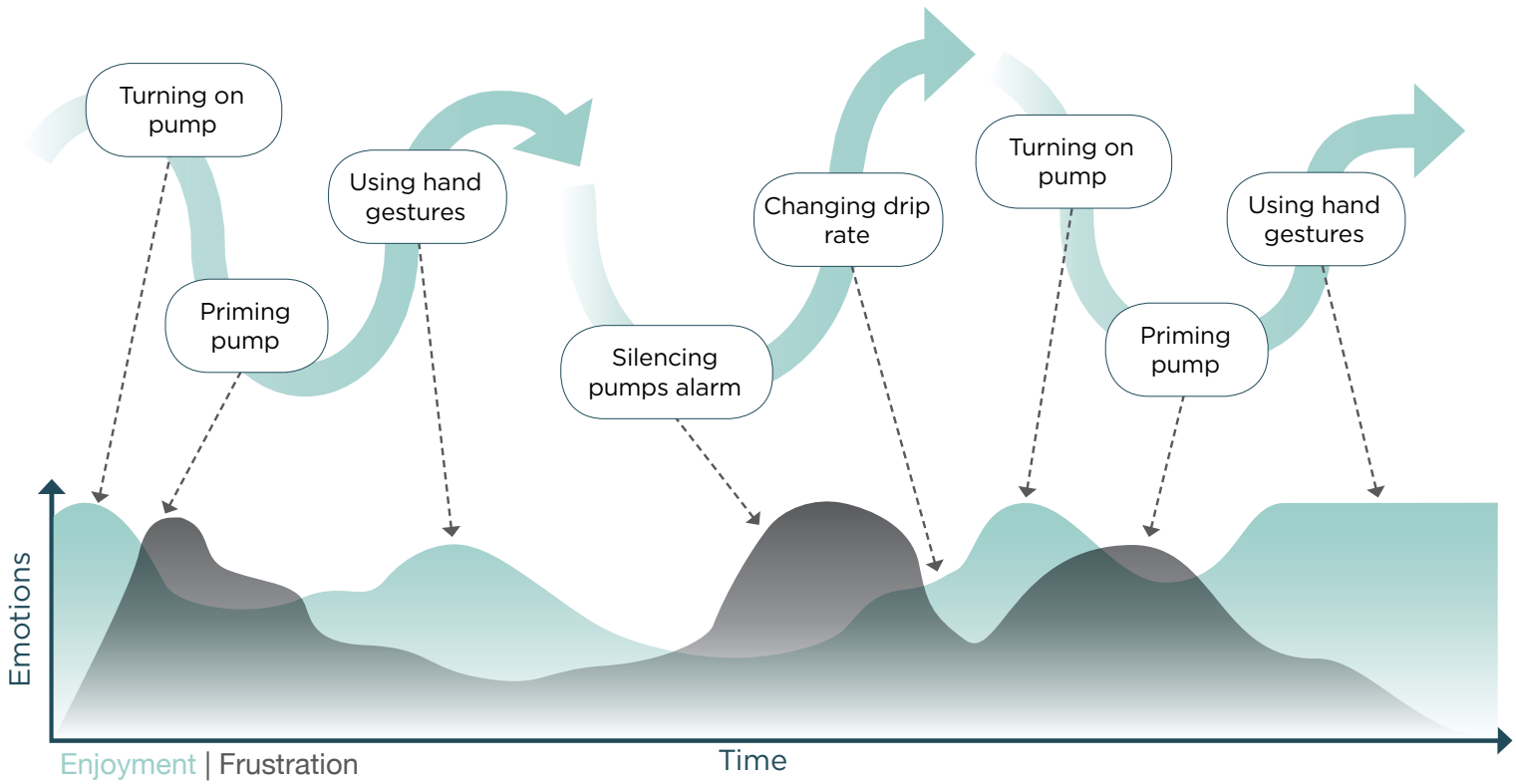
EXPERIENCE MAPS

Each user will have their unique goals and experiences when interacting with the Gesteir device. It is vital that the goals of the users are at the forefront of designing the hand gesture interactions. By not doing so will result in an experience that fails the users and can lead to an increase in CLABSIs; thus, an increase in deaths per year and more financial stress on the U.S. healthcare system. In the pages that follow are the experience maps for the users.

Lens	Programing The I.V. Pump	Adjusting The Settings	Reprogramming The I.V. Pump
Goals	• Setting up correct patient medical information • Inputting correct doses and drip rate	• Turning off any alarms • Making sure the right drip rate is inputted	• Clearing previous patient history • Setting up correct patient medical information • Inputting correct doses and drip rate
Doing	• Turning on the I.V. pump • Priming the pump • Using correct hand gestures to input the information	• Using hand gestures to change the rate of drip • Using hand gestures to silence the alarm	• Turning on the I.V. pump • Priming the pump • Using correct hand gestures to input the information

Touchpoints

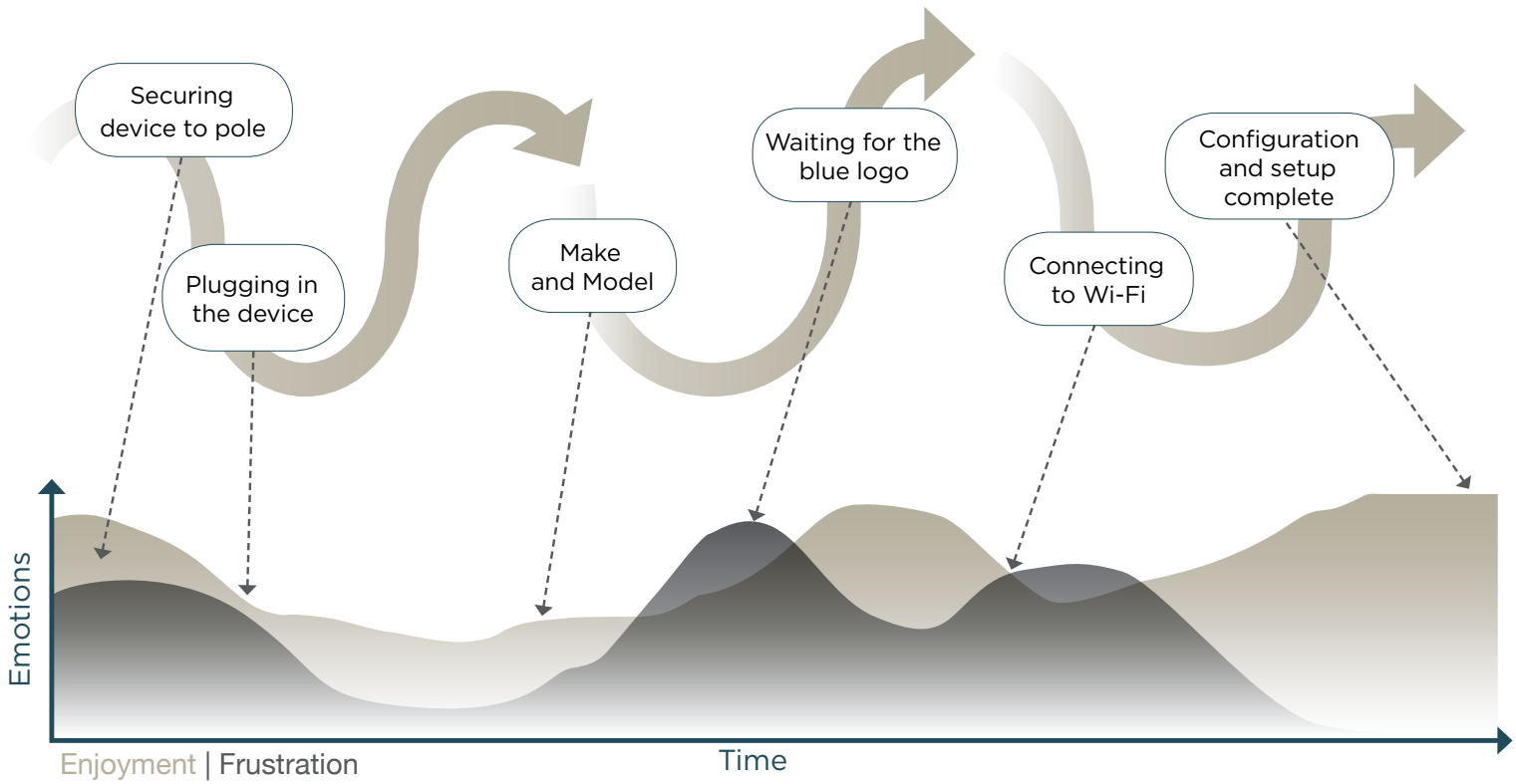
Experience Time line



Lens	Installing The Device	Configuring The Device	Setting Up The Wi-Fi
Goals	• Make sure the Gesteir device is positioned correctly above the I.V. pump	• Make sure the Gesteir device is configured to the right I.V. pump make and model	• Setup the Wi-Fi so the Gesteir device can download any software packages it may need
Doing	• Tightening the Gesteir device to the I.V. pump pole • Plugging in the device's power cord and cord/arm to the I.V. pump	• Follow the Gesteir app's instructions for choosing the right make and model • Waiting for Gesteir logo to turn blue	• Follow the steps to connect to the hospital's Wi-Fi network • Closing the app after the Gesteir device has downloaded any packages and disconnected from the hospital's Wi-Fi

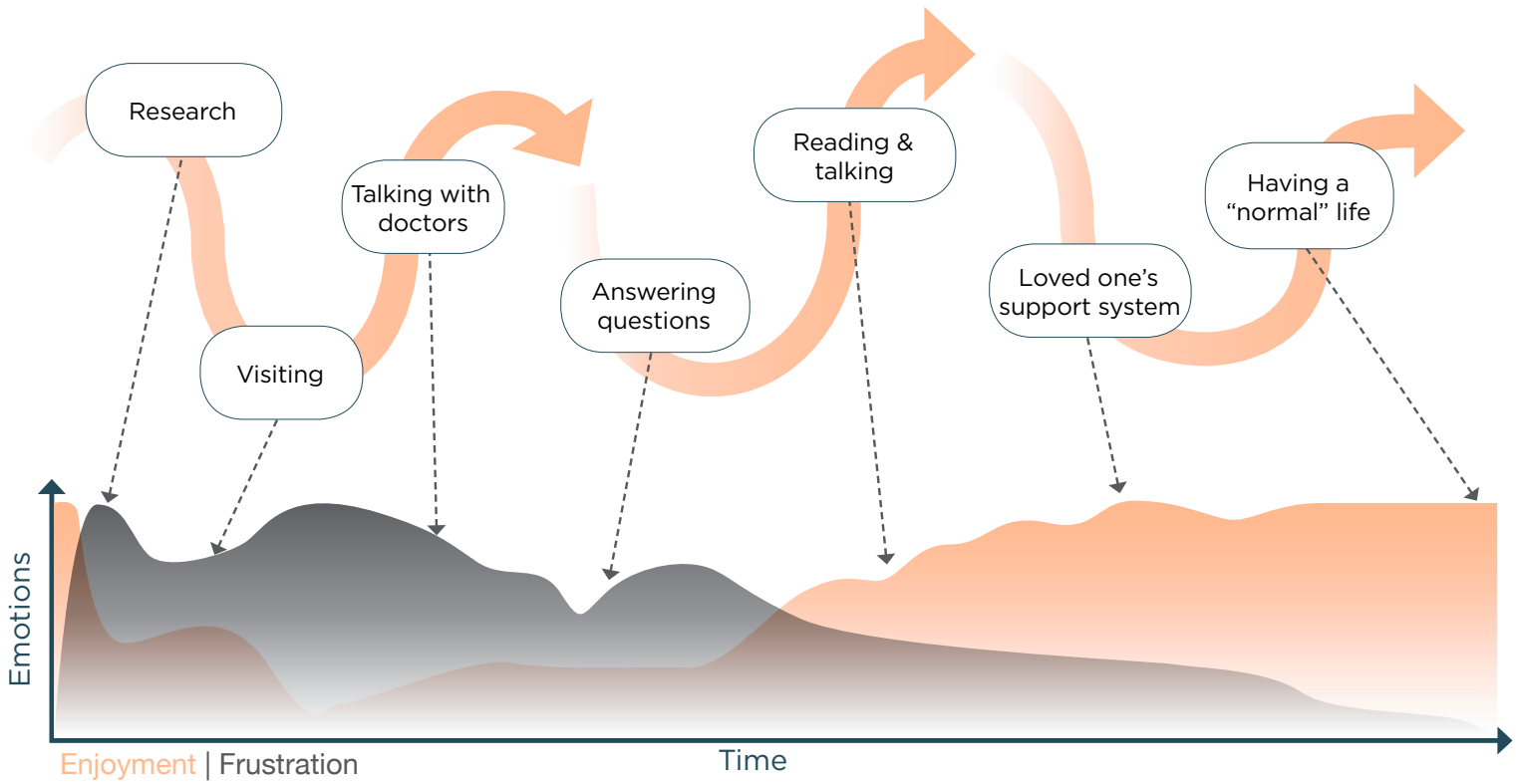
Touchpoints

Experience Time line



Lens	Loved One Getting A CLABSI	Loved One Recovering From CLABSI	Loved One Discharged From Hospital
Goals	• Find information on the type of infection • Be there for support	• Answer questions friends and family members will have • Continued support	• Return to an everyday life • Help loved one fully recover
Doing	• Research CLABSIs • Visiting loved one • Talking to the doctors	• Responding to phone calls, text, and emails • Reading and talking to loved one	• Make sure loved one follows all discharge orders and takes any medications • Help loved one return to a “normal” life

Touchpoints

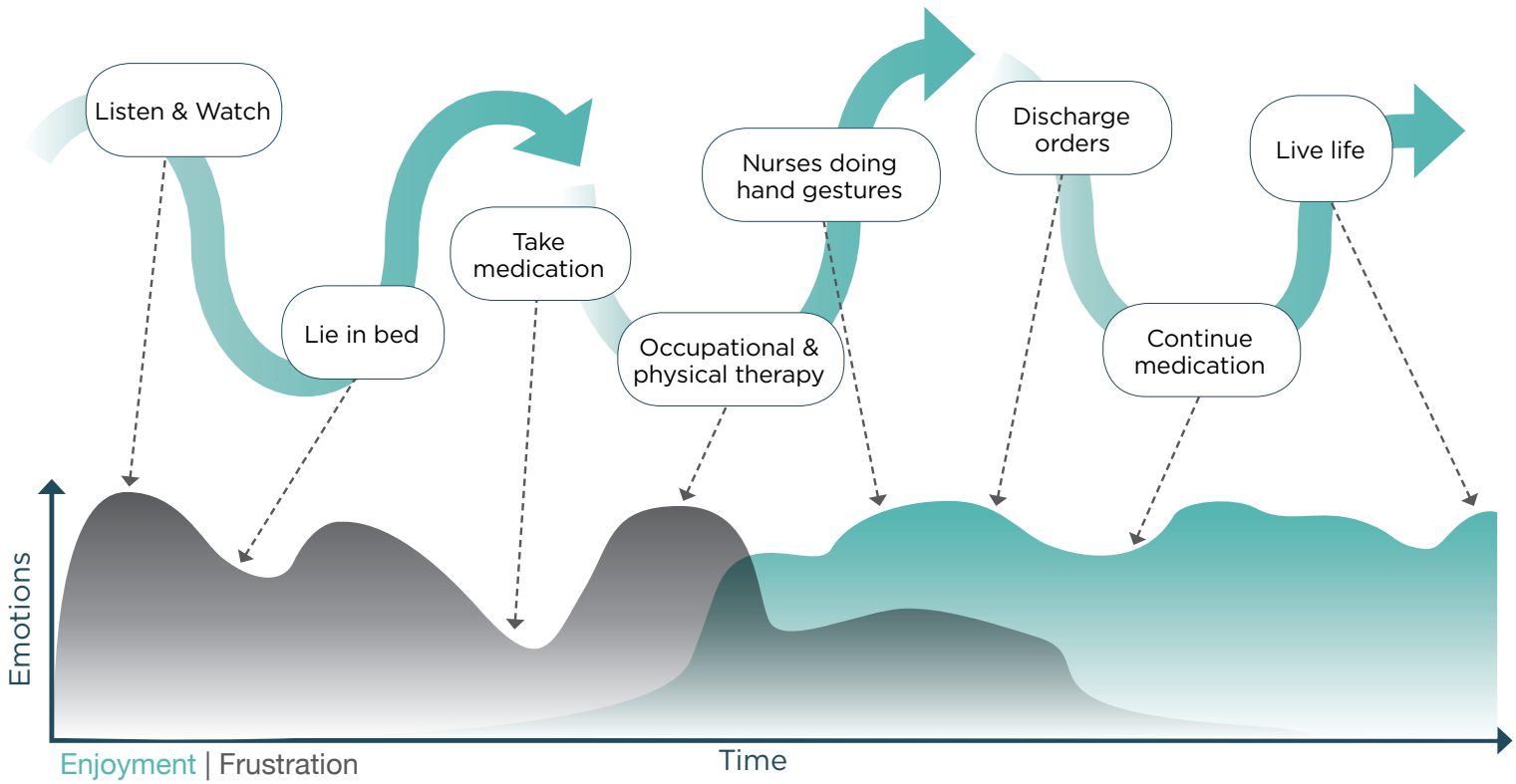


Experience Time line

Lens	Getting A CLABSI	Recovering From CLABSI	Being Discharged From Hospital
Goals	• Survive	• Continue to get better • Get moved to a less critical floor	• Get healthy enough to go back to work • Return to a “normal” life
Doing	• Listen and watch what the physicians and nurses say • Lying in the hospital bed	• Take prescribed medication • Work with occupational therapist and/or physical therapist • Watch the nurses do their job	• Follow discharge orders • Take prescribed medication • Enjoy life again

Touchpoints

Experience Time line



STORYBOARDS

The hand gestures used to control the I.V. pump are the critical component to creating an experience that will not hinder healthcare professionals from completing their tasks, thus creating an enjoyable experience. Much like the design of the I.V. pumps, the hand gestures need to encompass a function over form design mentality. While this has led to many design issues with the I.V. pump, the hand gestures are meant to be easily performed to reduce any problems healthcare professionals might have when programming an I.V. pump.

To reduce any issues, the concept of natural mapping plays an essential role in which hand gestures control which buttons. By using principles from Gestalt psychology and grouping buttons that are either close to each other or that have a similar function will aid in creating a natural map for the healthcare professional (Norman, 2013). The gestures for buttons that are in proximity to each other have slight variations to reinforce the concept of natural mapping. For example, the buttons on the left side of the screen for an Alaris™ PC pump are controlled with the user's left hand, while the buttons on the right are the same gestures as the left, but done with the user's right hand. To input numbers, the user will use the "everyday" hand gestures for one through five. For numbers six through nine the user's forearm is horizontal with their finger(s) extended to designate the number added to five, as described in the Department of the Navy's Aircraft Signals NATOPS Manual, NAVAIR 00-80T-113 on page 1-3. The link this manual is located in Appendix B. Illustrations on how to perform these numbers are depicted in the following pages.

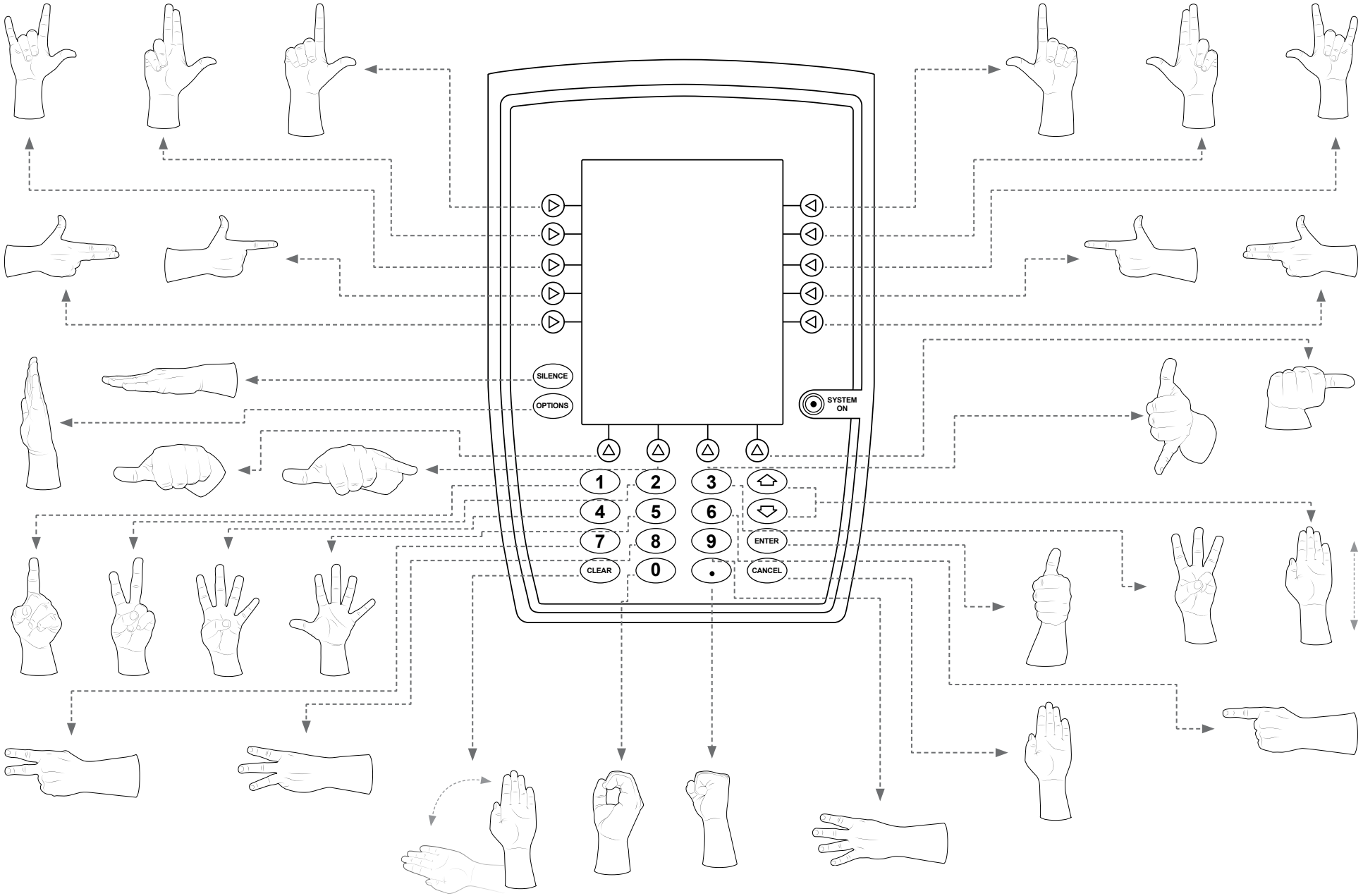
With the Alaris™ PC pump having thirty-one different gestures to learn, one can argue that none of the users will be able to recall that many hand gestures. While there will be a longer period of learning for the Alaris™ PC pump, it is still possible for a user to recall all of the gestures. By looking at other professions where hand gestures get used, we can see that there is proof that a person can learn a large

number of hand gestures. Military aviation is an example of this, where the military personnel in charge of launching an aircraft has to learn sixty-four different hand gestures according to the Aircraft Signals NATOPS Manual. These hand signals also differ between the various types of aircraft and helicopters, if they are performed on land or a carrier's flight deck and some can even change for night flights. In general, the personnel conducting these hand gestures are only a few years out of high school and typically do not have an education that extends past a high school diploma.

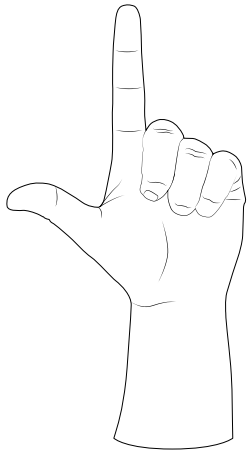
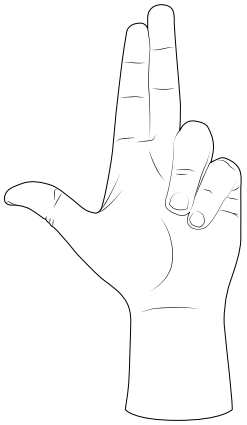
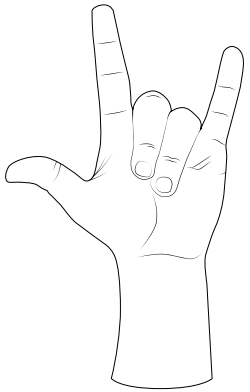
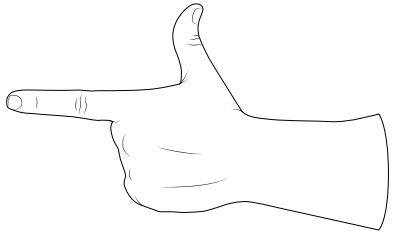
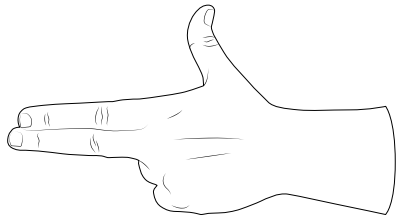
While the design of the hand gestures is meant to be natural, there is still a chance that the user can make a wrong gesture, resulting in an input error. It is most likely that gesture recognition software will never be 100% accurate, which is why there needs to be a way to tell the user if an input error has occurred (Prekopcsák, Halácsy, & Gáspár-Papanek, 2008). When a user inputs a mistake, two signals will take place. One, the I.V. pump will make an audible sound; this is already the standard "error message" for I.V. pumps today. The second way of informing a user of a wrong gesture will be the Gesteir logo on the device will turn red through the use of an RGB LED.

For the Gesteir device to accurately recognize a user's hand gesture; the maximum distance between the device and the user needs to be four feet. This distance will allow for the hand gestures to get recognized by the cameras required for the hand recognition software and enable the users to see what they are programming into the I.V. pump. The tilt of the Gesteir device should be no more than a 45-degree angle up or down. A 0 to 45-degree angle ensures that the depth camera will sense the user's whole body to recognize the hand gestures correctly.

Alaris™ PC I.V. Pump Hand Gestures

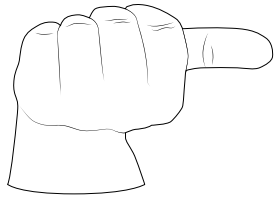


Left and Right Side Buttons

Bottom Buttons

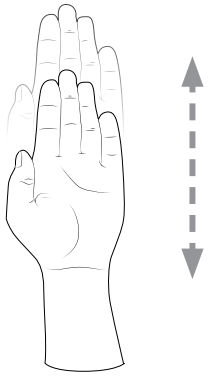


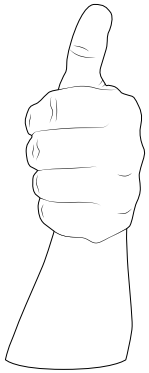
Silence Button

Options Button

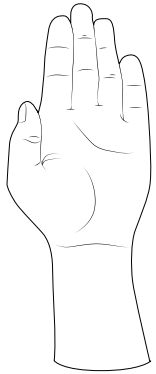
Up and Down Buttons



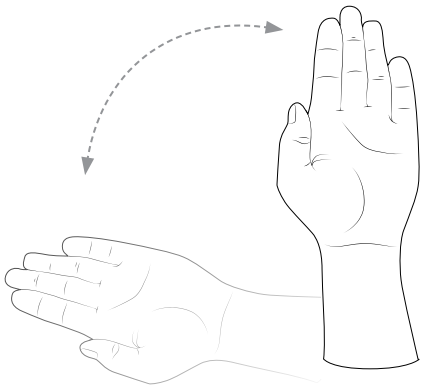
Enter Button



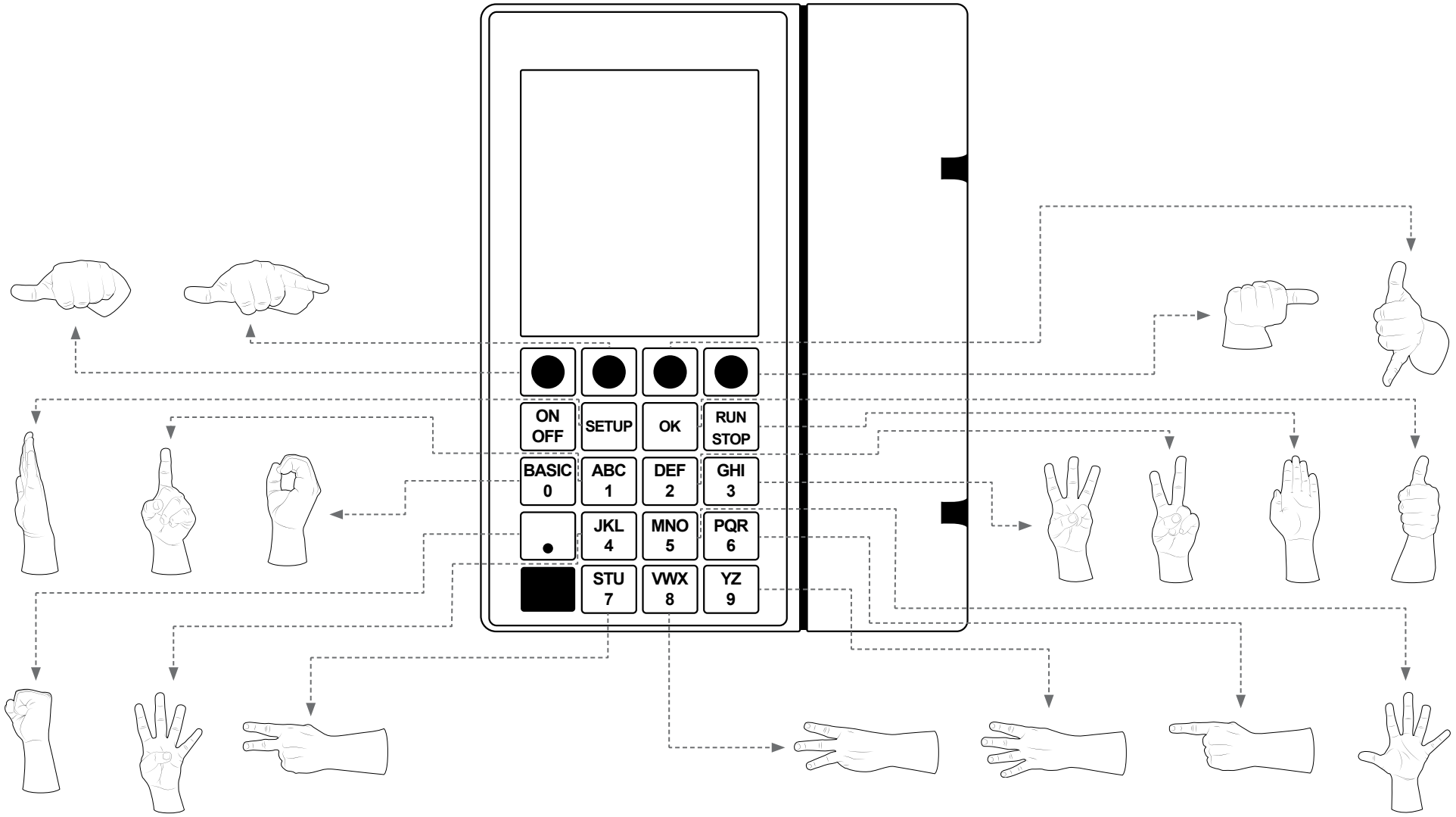
Cancel Button



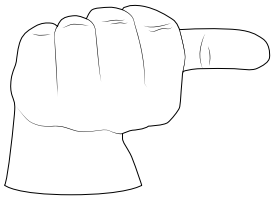
Clear Button



Sigma Spectrum I.V. Pump Hand Gestures

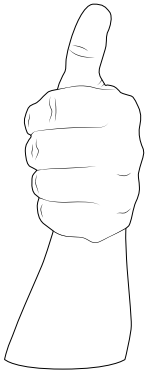


Bottom Buttons

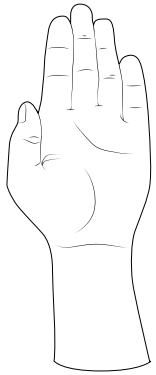


Setup Button

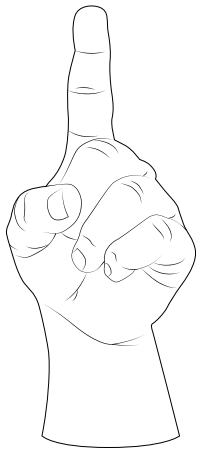
Okay Button



Run Stop Button

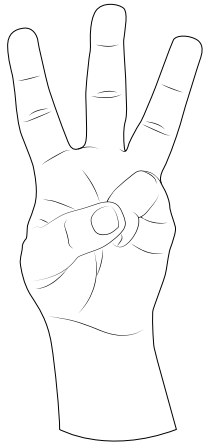


General Hand Gestures

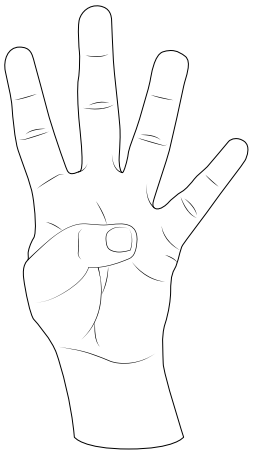


One

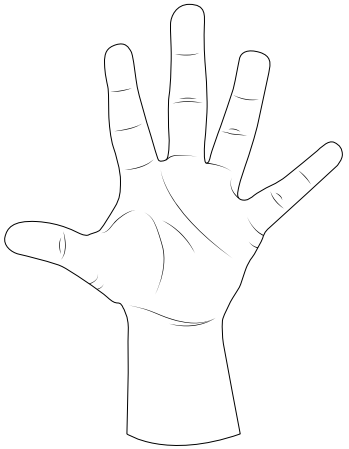
Two



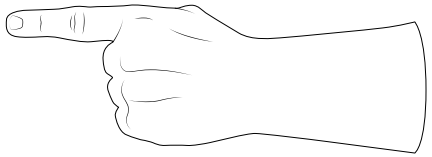
Three



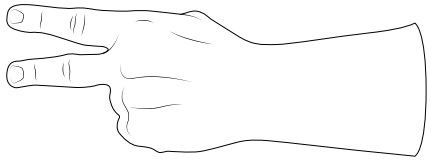
Four



Five

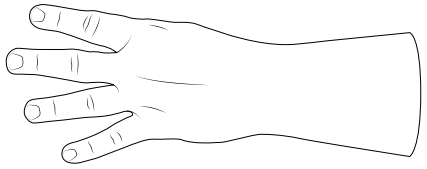


Six



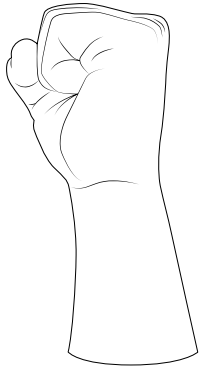
Seven

Eight

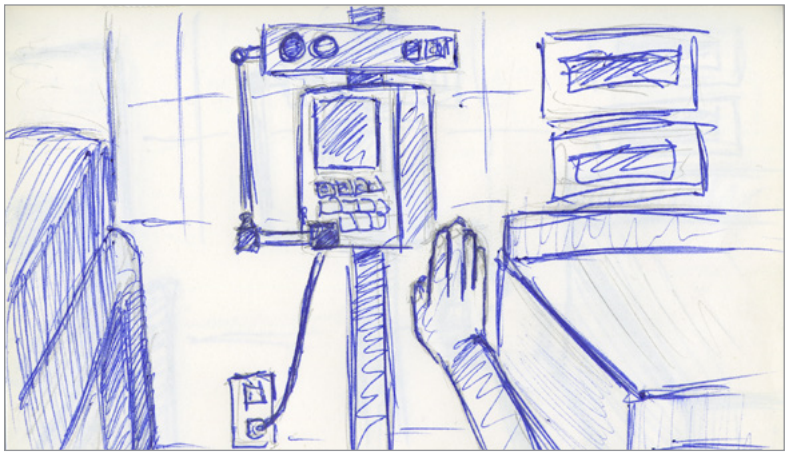


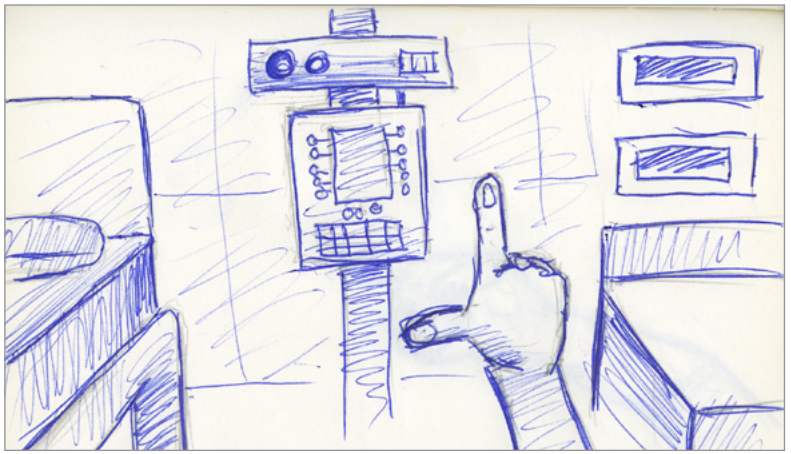
Nine

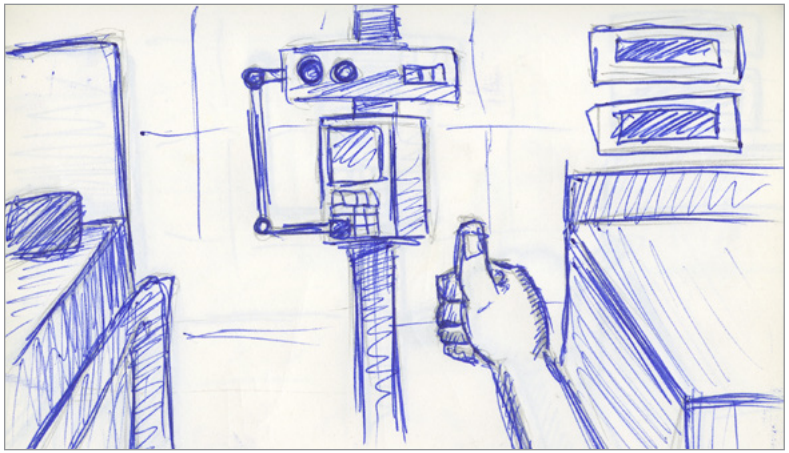
Zero

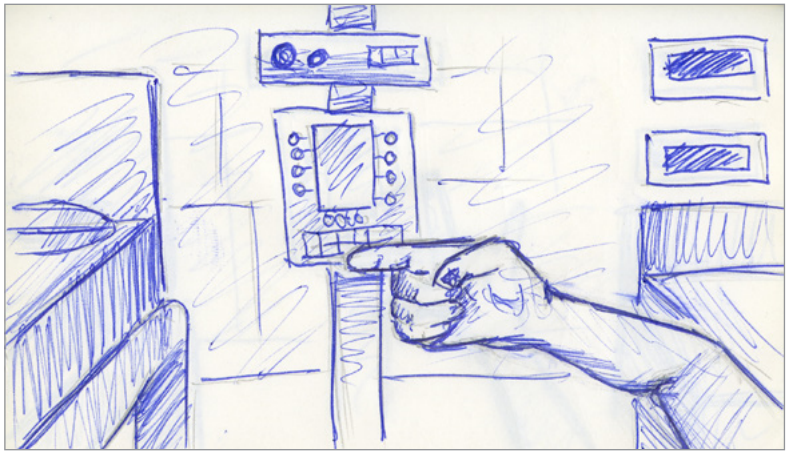


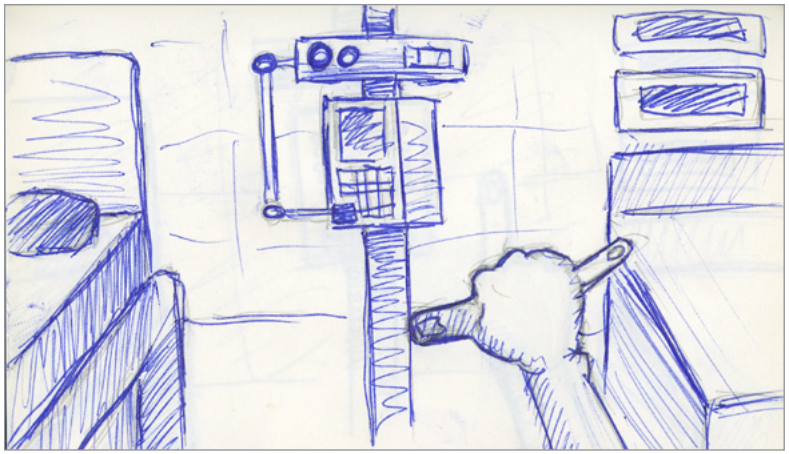
Decimal Point

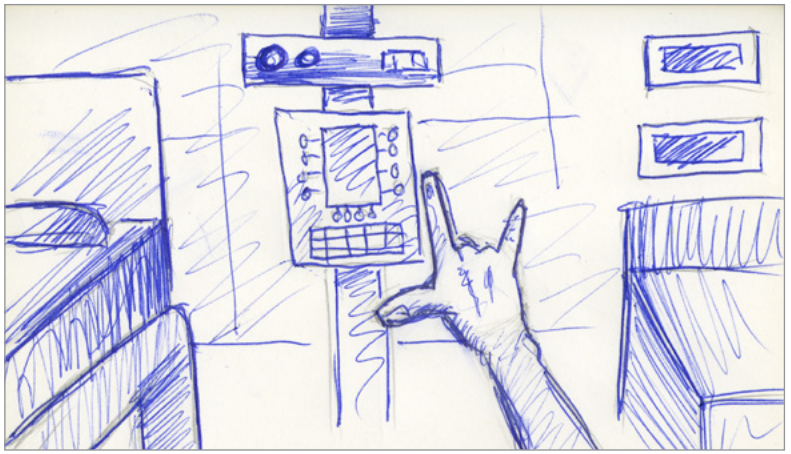






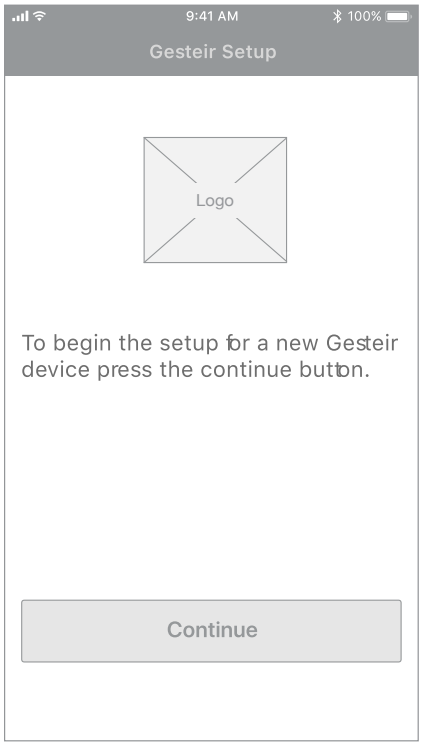


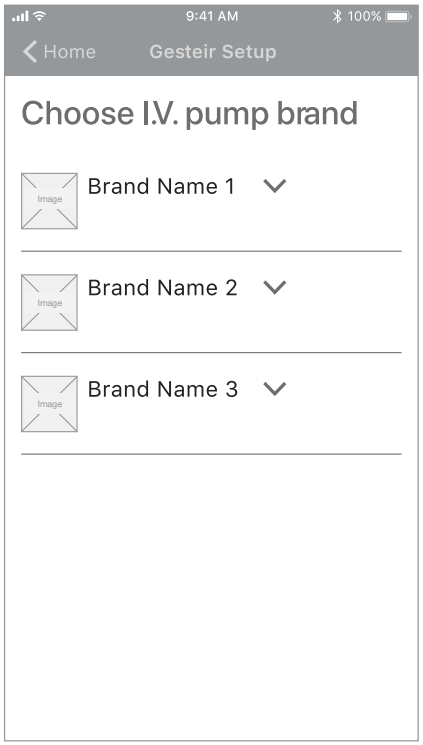


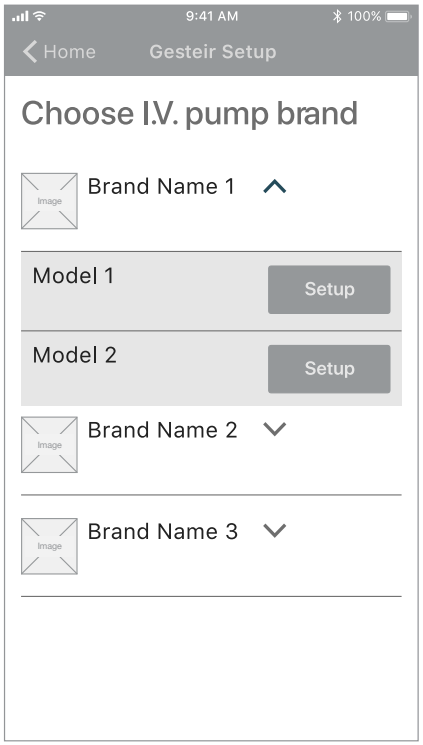


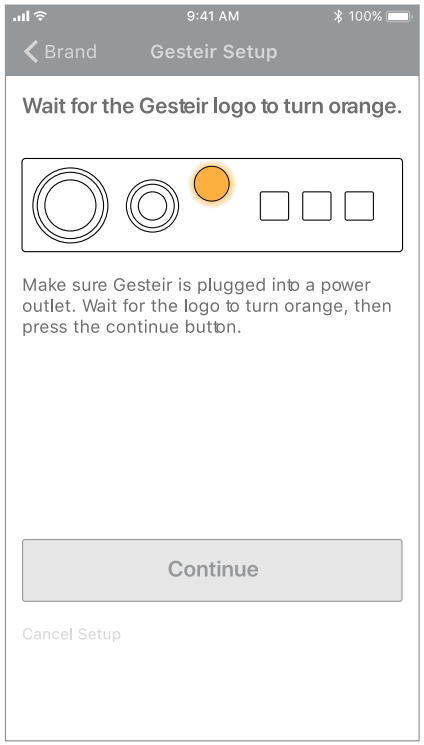
WIREFRAMES

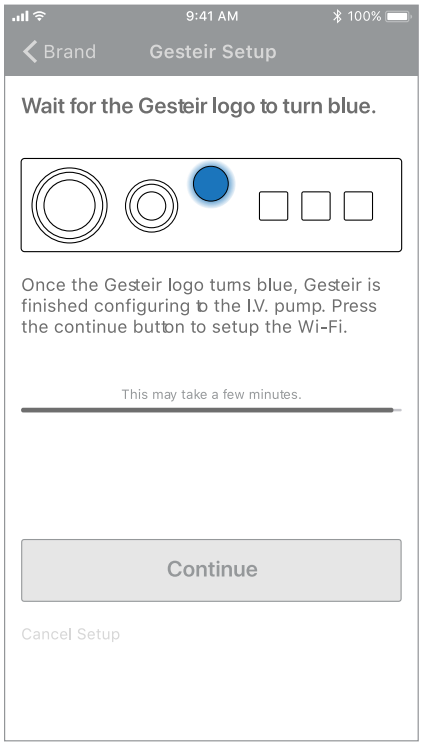
Gesteir Configuration App

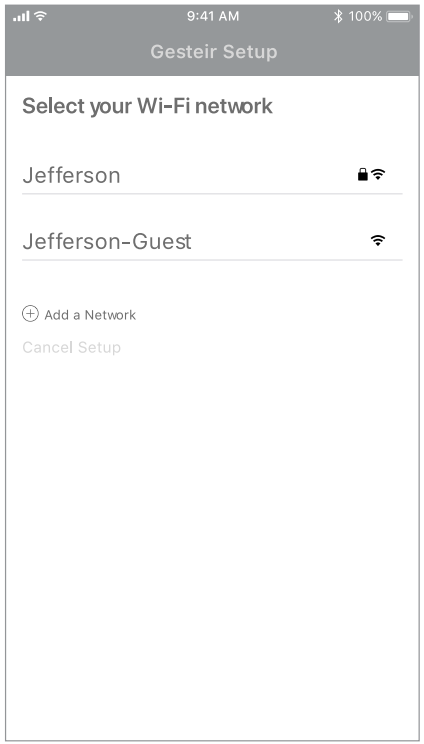


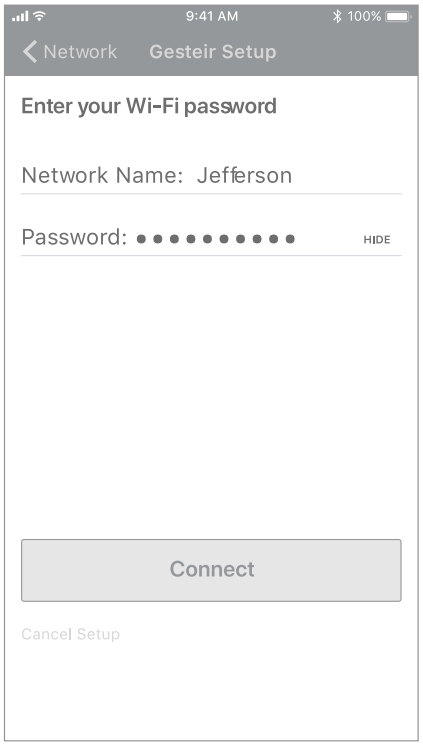


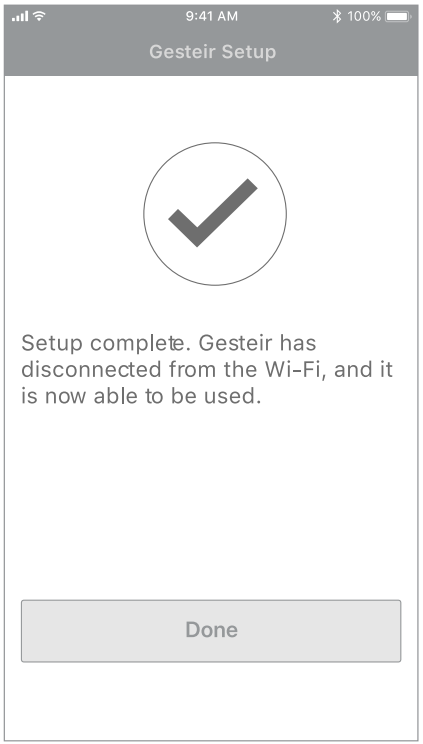





9:41 AM
100%
Brand
Gesteir Setup
Wait for the Gesteir logo to turn blue.
Once the Gesteir logo turns blue, Gesteir is finished configuring to the I.V. pump. Press the continue button to setup the Wi-Fi.
This may take a few minutes.
Continue
Cancel Setup

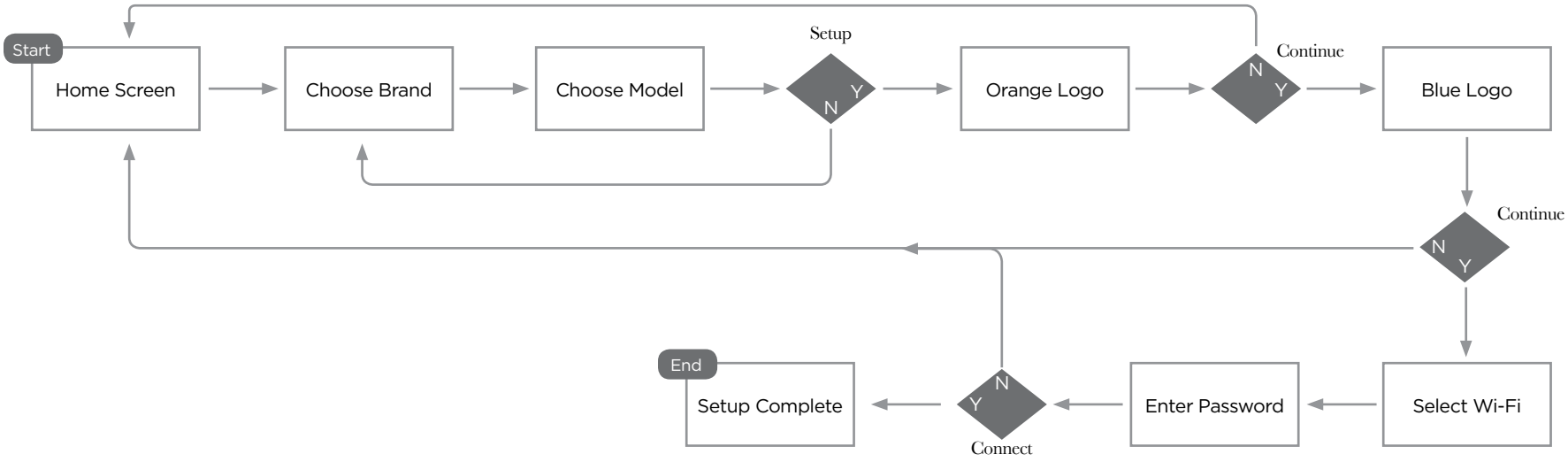

9:41 AM
100%
Gesteir Setup
Select your Wi-Fi network
Jefferson
Jefferson-Guest
Add a Network
Cancel Setup


9:41 AM
100%
Network
Gesteir Setup
Enter your Wi-Fi password
Network Name: Jefferson
Password:
HIDE
Connect
Cancel Setup

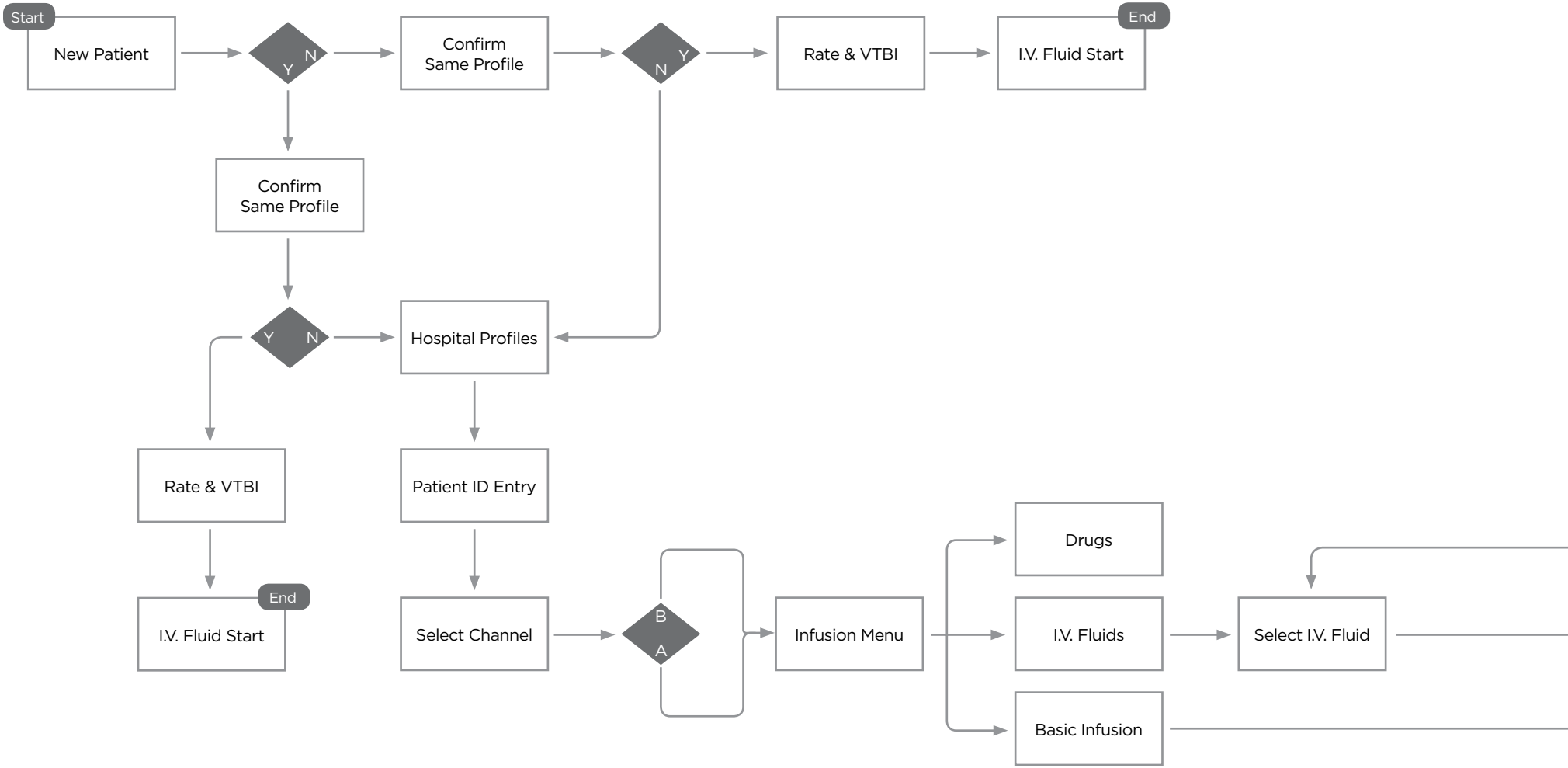

9:41 AM
100%
Gesteir Setup
Setup complete. Gesteir has disconnected from the Wi-Fi, and it is now able to be used.
Done

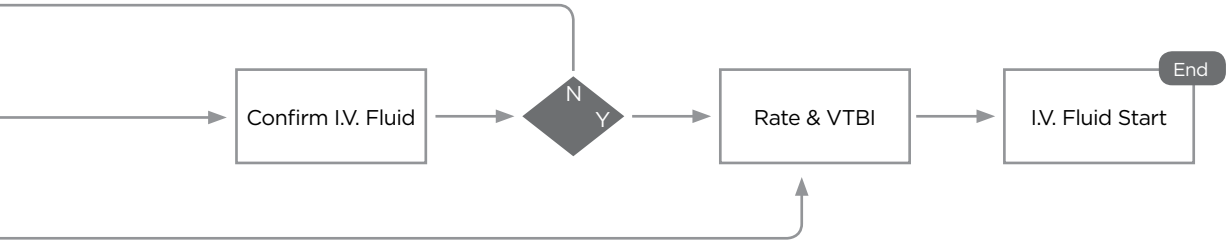
USER FLOW

Gesteir Configuration App



I.V. Pump User Flow




Confirm I.V. Fluid
N
Y
Rate & VTBI
I.V. Fluid Start
End

SECTION 03:

VISUAL DESIGN

The branding and identity were designed by a graphic designer I hired named Dana Banks. Dana has more than eight years of design experience and specializes in identity branding, making her the perfect designer for the job. Her tasks were to design the moodboard, logo, style guide and application icon. Within a three week deadline, there were a total of five iterations: two for the moodboard and three for the logo design. From these iterations, Dana was able to design a logo that has a look and feel that I wanted for Gesteir.

Dana's work can be viewed at danabanks.com

MOODBOARD

LOGO

EXPLORATION

GESTEIR

GESTEIR

GESTEIR

FINAL

This is the configuration application icon.

STYLE GUIDE

The Gesteir style guide is designed with the designer in mind. And we hope that you keep these words in the front of yours—modern, innovative, clean, approachable, hands-free, healthy and convenient. The user is our primary focus and that starts from the first time they come in visual contact with a brand element.

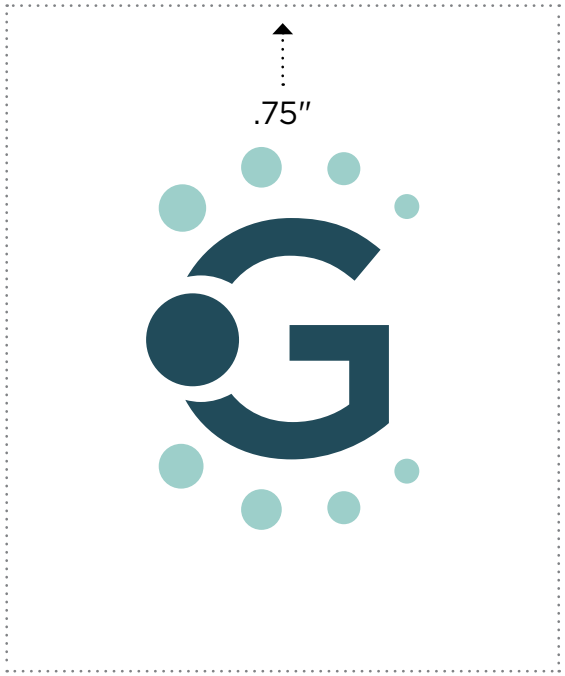
Our logo design begins with a san serif “G,” from an ariel view, taking the form of a person using their arms and hands to gesture. The surrounding circles represent the movement involved. Again, the importance of the user is displayed—we’ve put them in our mark!

We hope this reference will guide you to a fluid understanding of the Gesteir brand. Our mission is of great importance and has the power to positively effect just about every human, regardless of age, income, sex, race, or any other classification. Help us reduce the risk of CLABSIs.

OUR LOGO

PLEASE DO!

***SPACING:** The dotted line below represents the required padding. Leave .75″ between the logos and other design elements, at any scale.



Stand alone “G” is primarily used for packaging and equiptment. It is the best option when a small scale logo is required.

This is our full word mark. Please use this logo when a design will come in contact with a potentially unexposed audience or advertisement.

Both the word mark and the stand alone “G” may be used in one color. The only acceptable colors are displayed under the section titled “OUR COLORS.”

PLEASE DON'T.

~~SKEW~~

~~ALTER~~

~~CHANGE~~

***FOR PRINT & DIGITAL BRANDING**—We encourage you to keep the two original colors in most situations. However, changing the logo to one color, any color in this style guide under the "OUR COLORS" section, is acceptable.

~~OUTLINE~~

~~OPACITY~~

~~KERNING~~

TYPE

GOTHAM BOOK

ABCDEFGHIJKLMNOPQRSTUVWXYZ
abcdefghijklmnopqrstuvwxyz

GOTHAM BOOK ITALIC

ABCDEFGHIJKLMNOPQRSTUVWXYZ
abcdefghijklmnopqrstuvwxyz

GOTHAM MEDIUM

ABCDEFGHIJKLMNOPQRSTUVWXYZ
abcdefghijklmnopqrstuvwxyz

GOTHAM MEDIUM ITALIC

ABCDEFGHIJKLMNOPQRSTUVWXYZ
abcdefghijklmnopqrstuvwxyz

GOTHAM BOLD

ABCDEFGHIJKLMNOPQRSTUVWXYZ
abcdefghijklmnopqrstuvwxyz

GOTHAM BOLD ITALIC

ABCDEFGHIJKLMNOPQRSTUVWXYZ
abcdefghijklmnopqrstuvwxyz

GOTHAM BLACK

ABCDEFGHIJKLMNOPQRSTUVWXYZ
abcdefghijklmnopqrstuvwxyz

HEADERS

While we don't like kerning in our logo, we love it in our headers! 60-140

OUR 35 pt/black

TYPE 28 pt/book

BODY

We'll take some 9/12 pt any day of the week! Gotham Book only for body copy.

OUR COLORS

PRIMARY

LOGO

PMS 7464

HEX—a0d0cb
RGB—160, 208, 203
CMYK—37, 4, 22, 0

PMS 7477

HEX—244c5a
RGB—36, 76, 90
CMYK—87, 60, 48, 32

PMS 1555

HEX—ffba8f
RGB—255, 186, 143
CMYK—0, 33, 43, 0

PMS 7535

HEX—b7b09d
RGB—183, 176, 157
CMYK—30, 26, 38, 0

SECONDARY

PMS 155

HEX—f2d1a0
RGB—242, 209, 160
CMYK—4, 17, 40, 0

PMS 3155

HEX—006072
RGB—0, 96, 114
CMYK—100, 45, 45, 19

PMS 7472

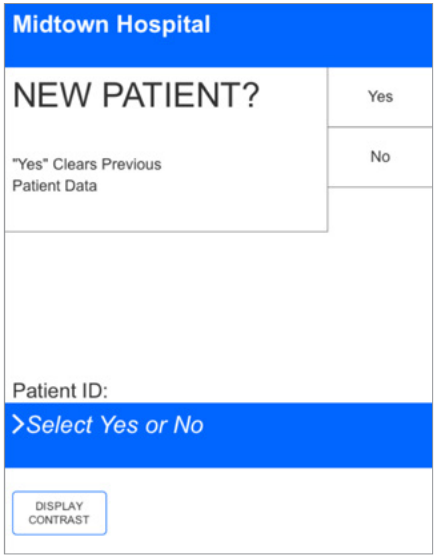
HEX—5ab7b2
RGB—90, 183, 78
CMYK—63, 7, 33, 0

PMS Neutral Black

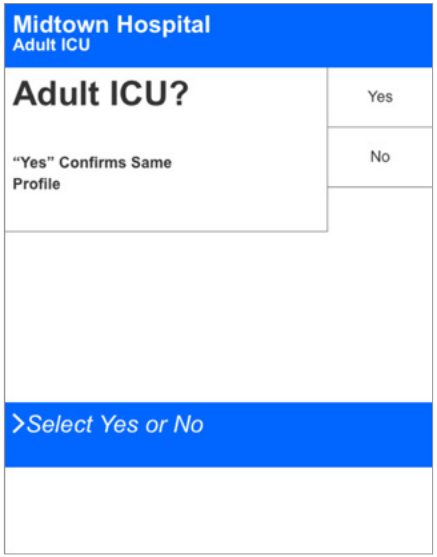
HEX—232221
RGB—35, 34, 33
CMYK—71, 66, 65, 73

MOCKUP OF UI DESIGNS

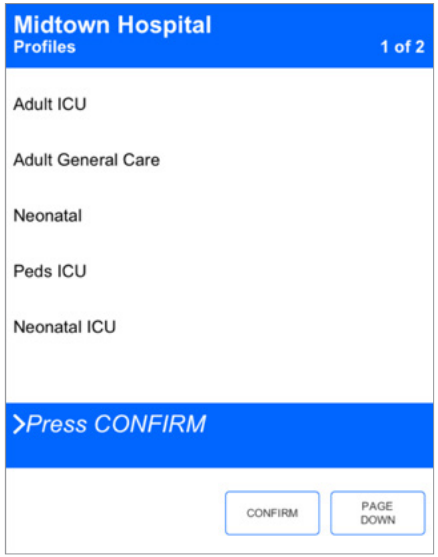
The UI mockups are visual representations of an Alaris ™ PC I.V. pump. The design and layout of the mockups are how the actual screens appear. The flow follows the path a user takes when programming the pump for a new patient who does not have a saved profile.



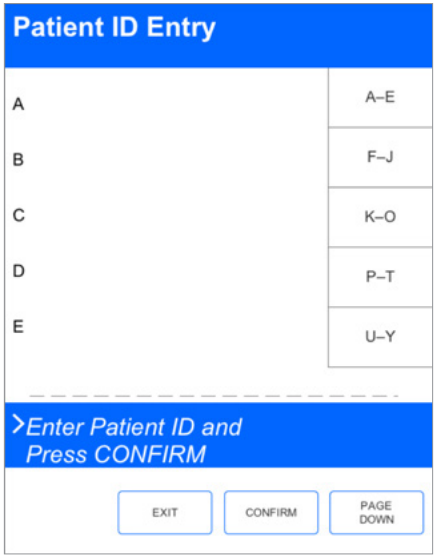
New Patient Screen



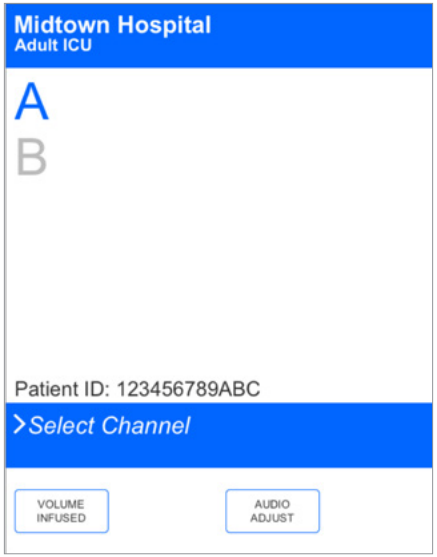
Confirm Same Profile Screen



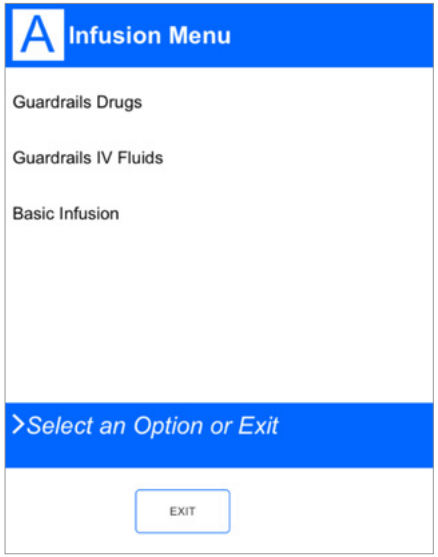
Hospital Profiles Screen



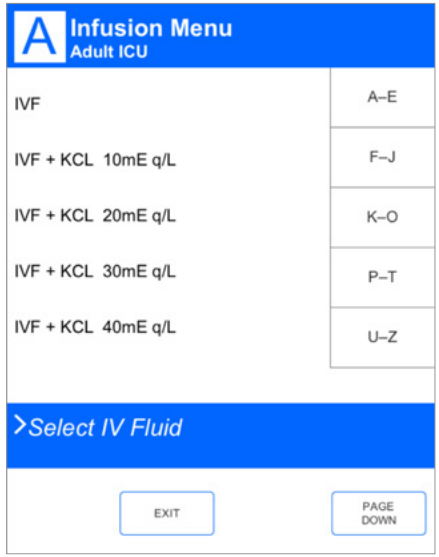
Patient ID Entry Screen



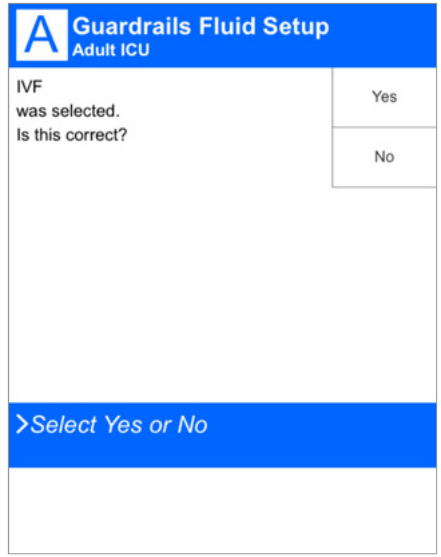
Select Channel Screen



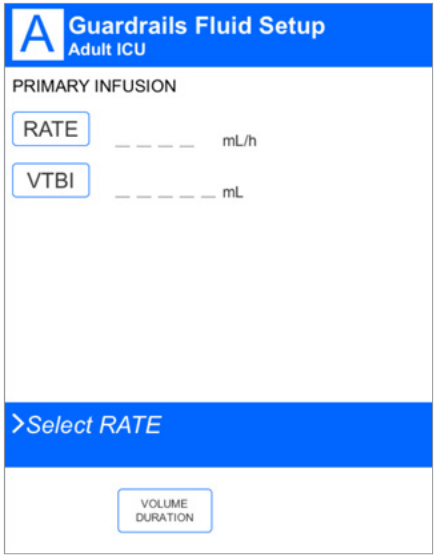
Infusion Menu Screen



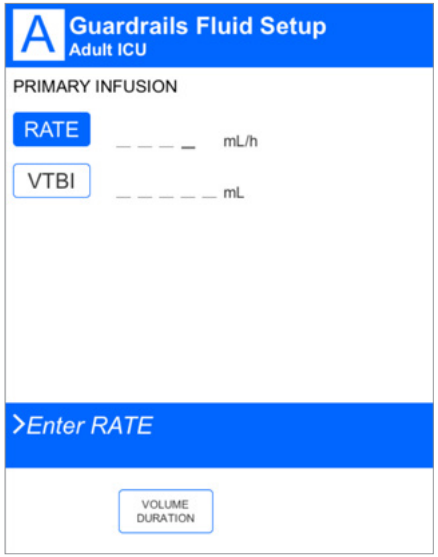
Infusion Menu:
Select I.V. Fluid Screen



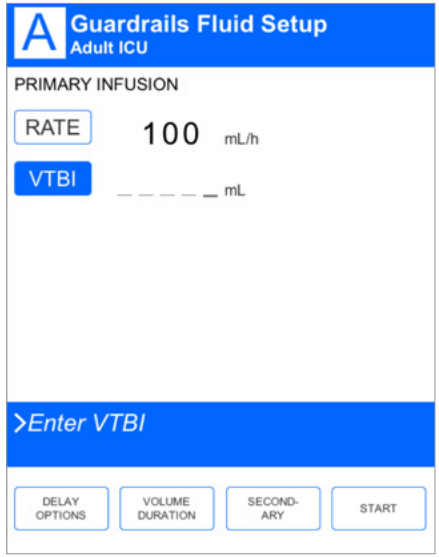
Confirm I.V. Fluid Screen



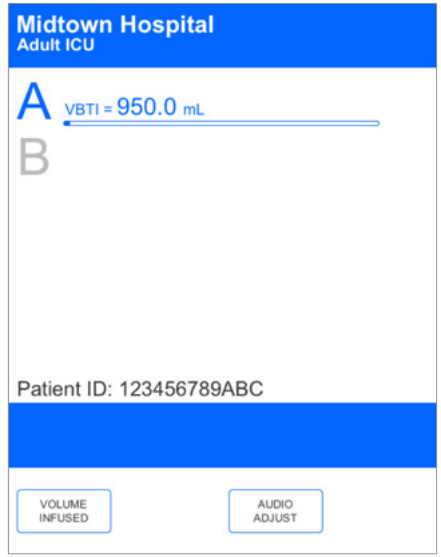
Primary Infusion:
Select Rate Screen



Primary Infusion:
Enter Rate Screen

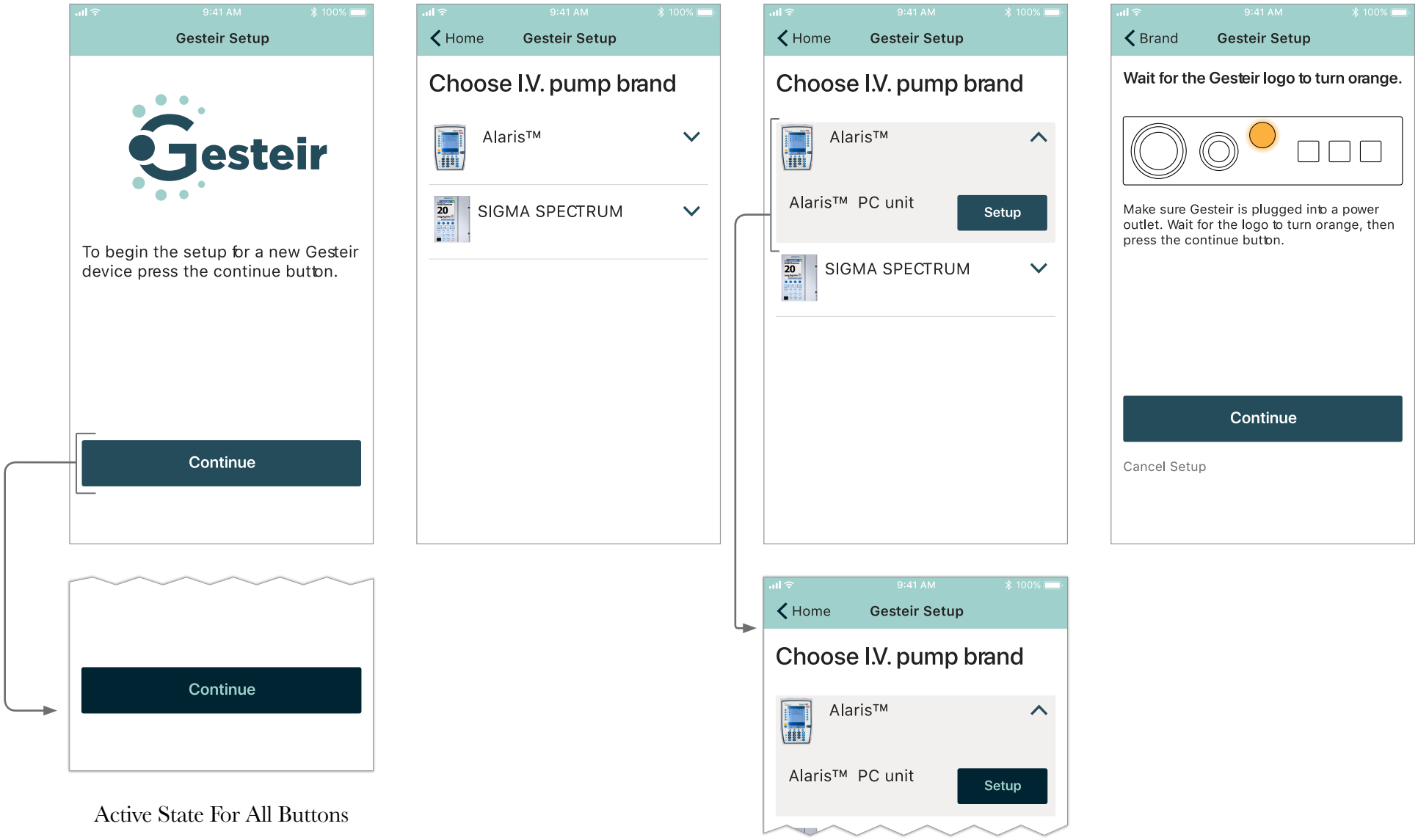


Primary Infusion:
Enter VTBI Screen

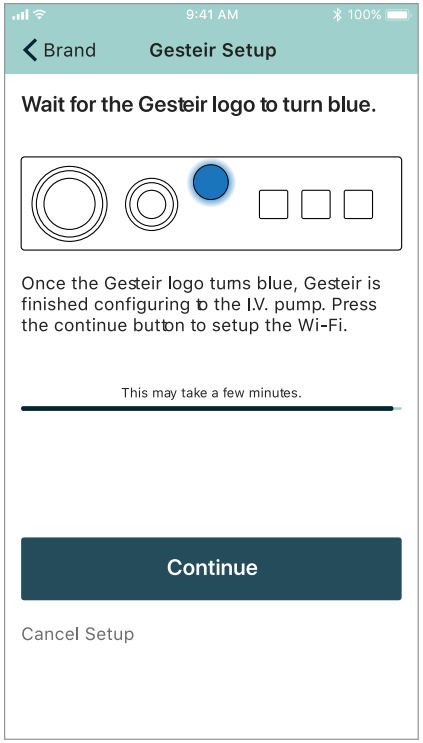


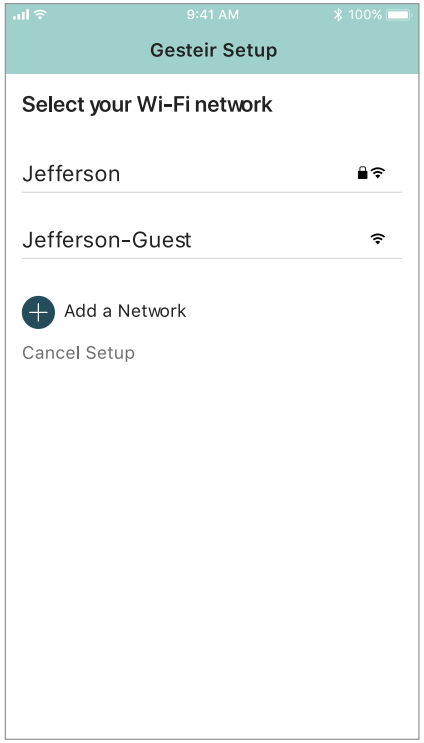
Start Infusion Screen

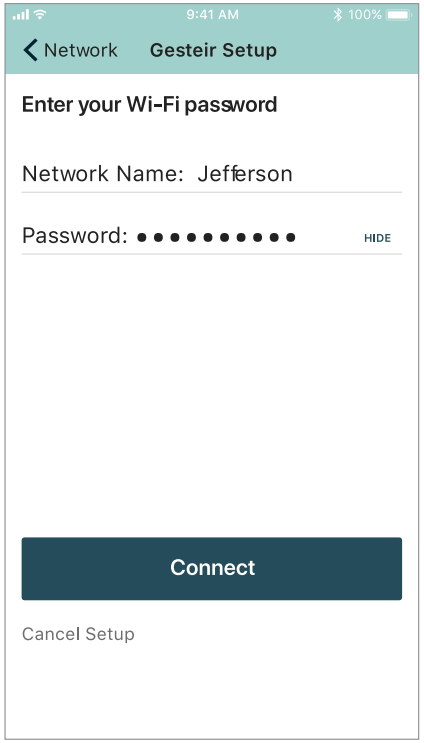
Gesteir Configuration App

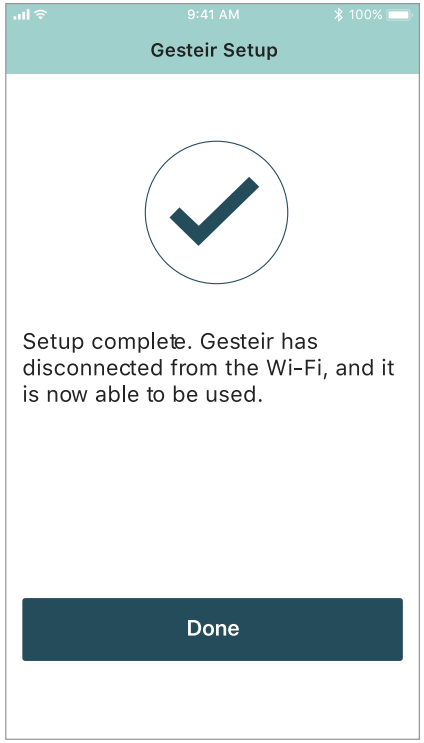


Active State For All Buttons

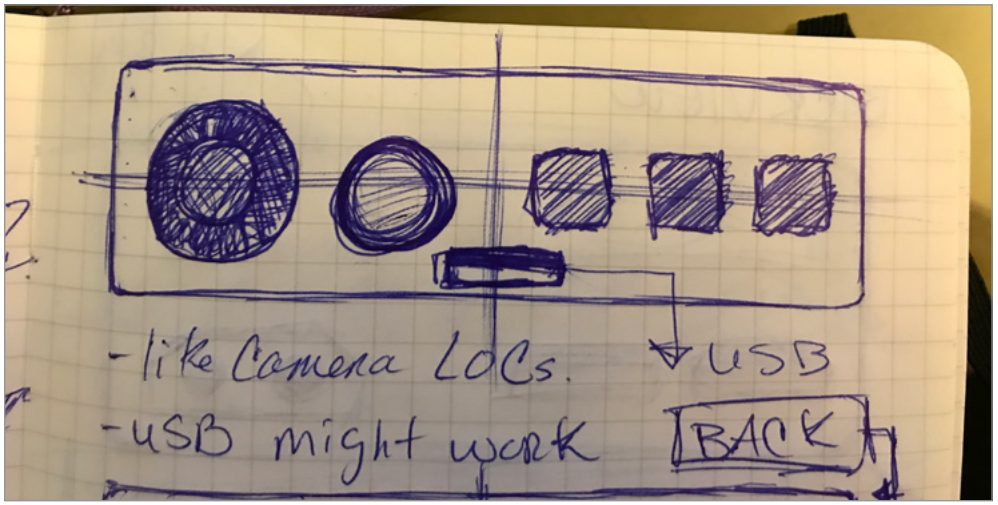

9:41 AM
100%
Brand
Gesteir Setup
Wait for the Gesteir logo to turn blue.
Once the Gesteir logo turns blue, Gesteir is finished configuring to the I.V. pump. Press the continue button to setup the Wi-Fi.
This may take a few minutes.
Continue
Cancel Setup

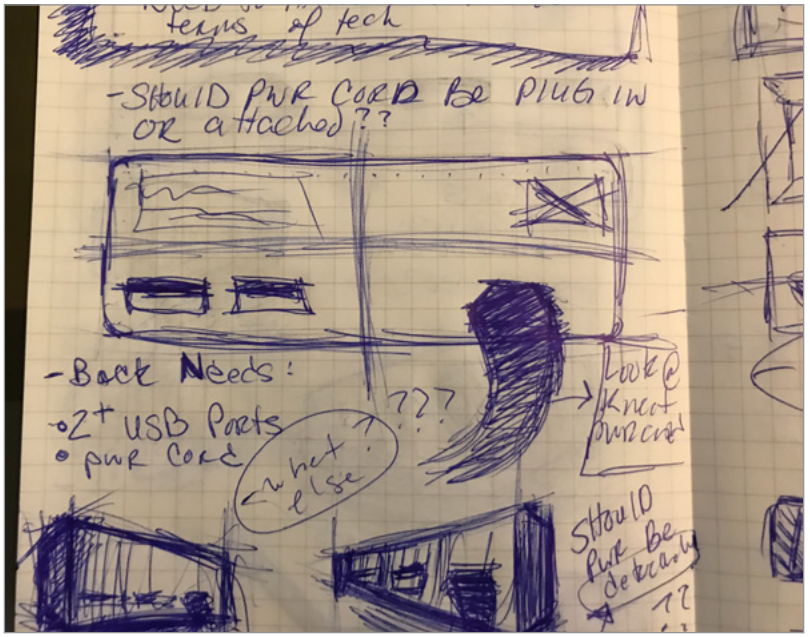

9:41 AM
100%
Gesteir Setup
Select your Wi-Fi network
Jefferson
Jefferson-Guest
Add a Network
Cancel Setup

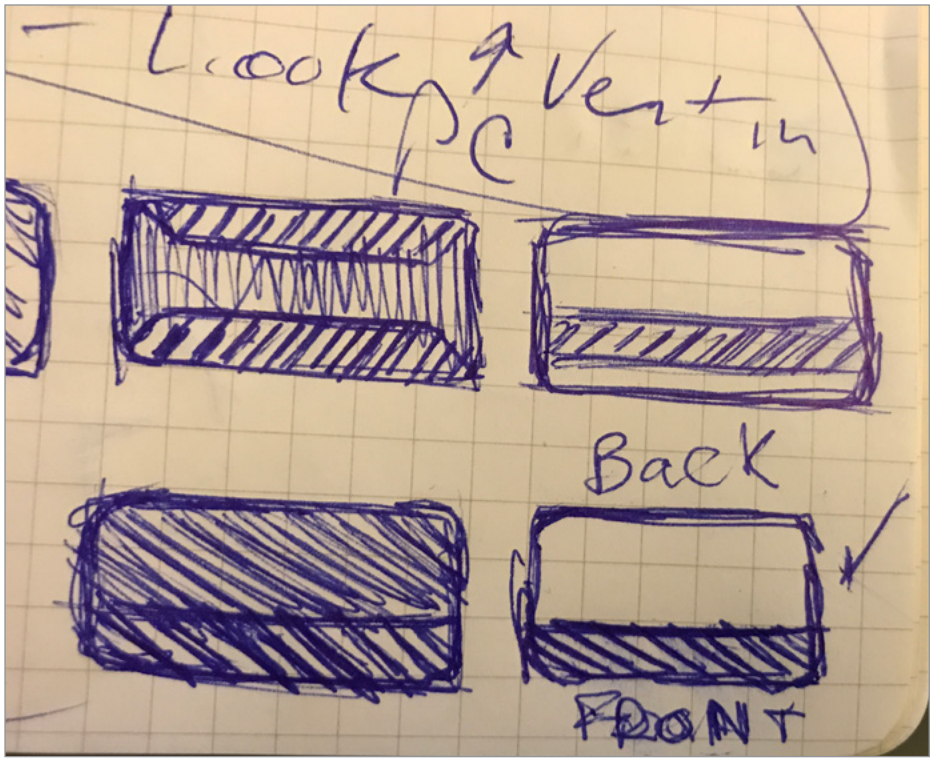

9:41 AM
100%
Network
Gesteir Setup
Enter your Wi-Fi password
Network Name: Jefferson
Password:
HIDE
Connect
Cancel Setup

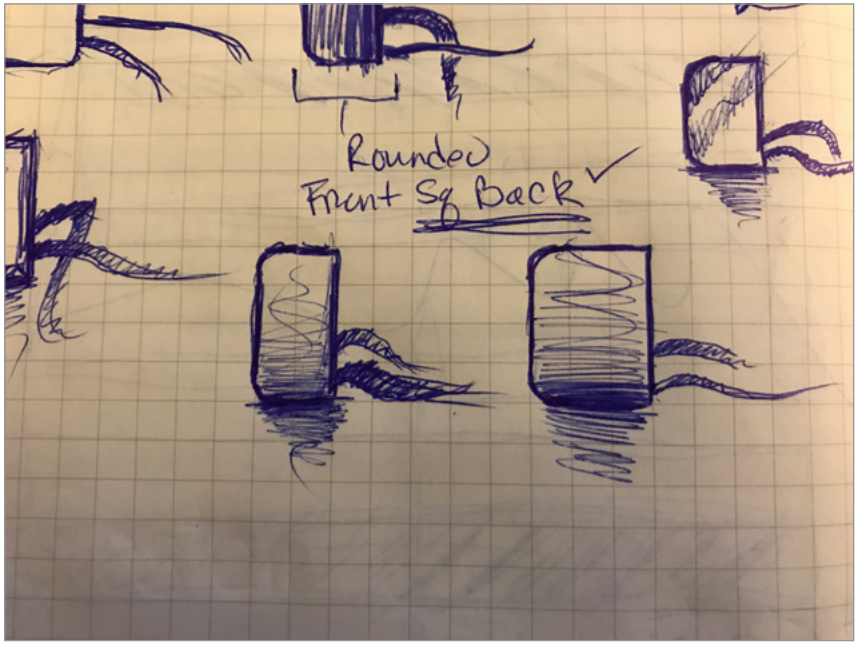

9:41 AM
100%
Gesteir Setup
Setup complete. Gesteir has disconnected from the Wi-Fi, and it is now able to be used.
Done

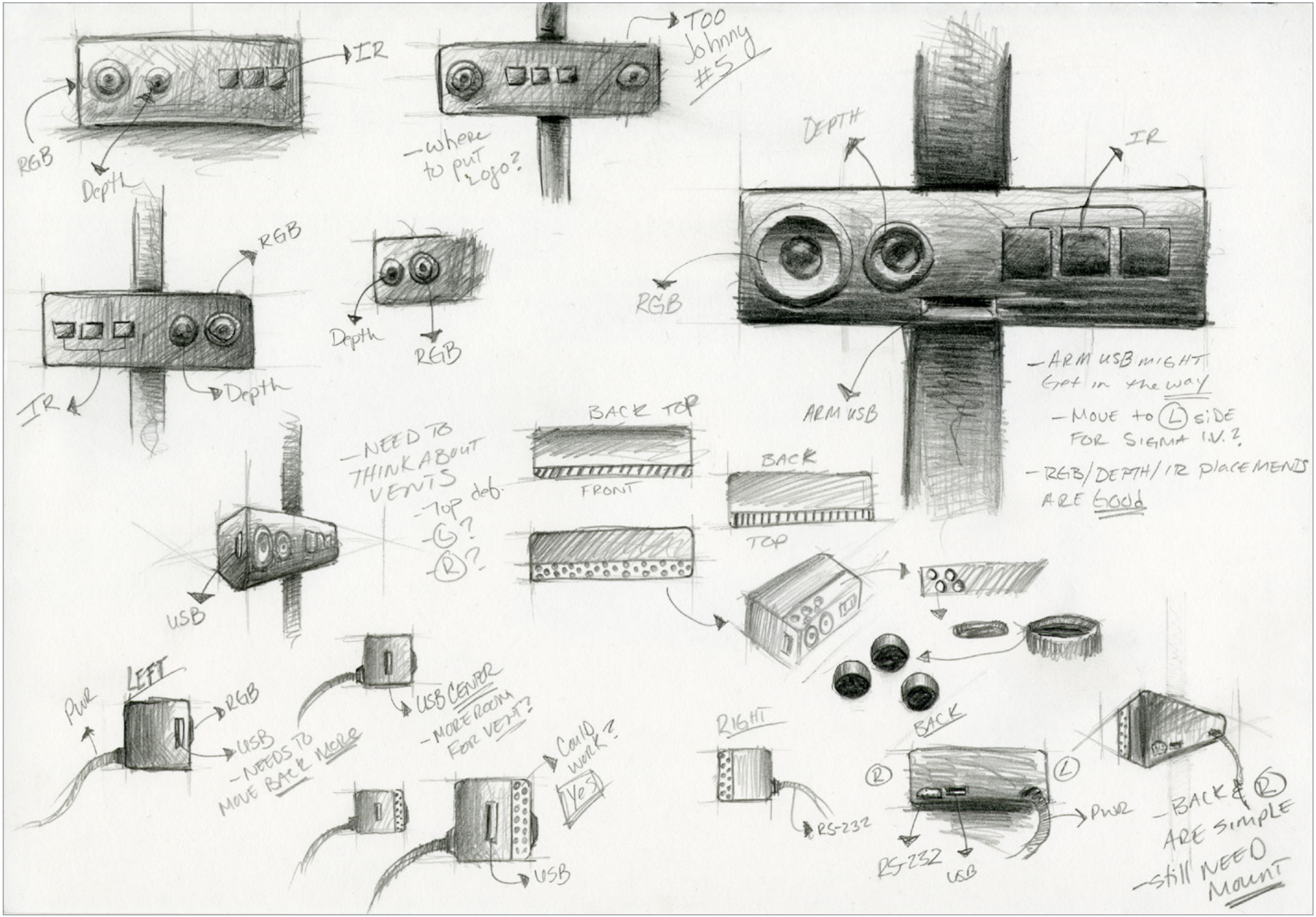
PROTOTYPE RENDERINGS

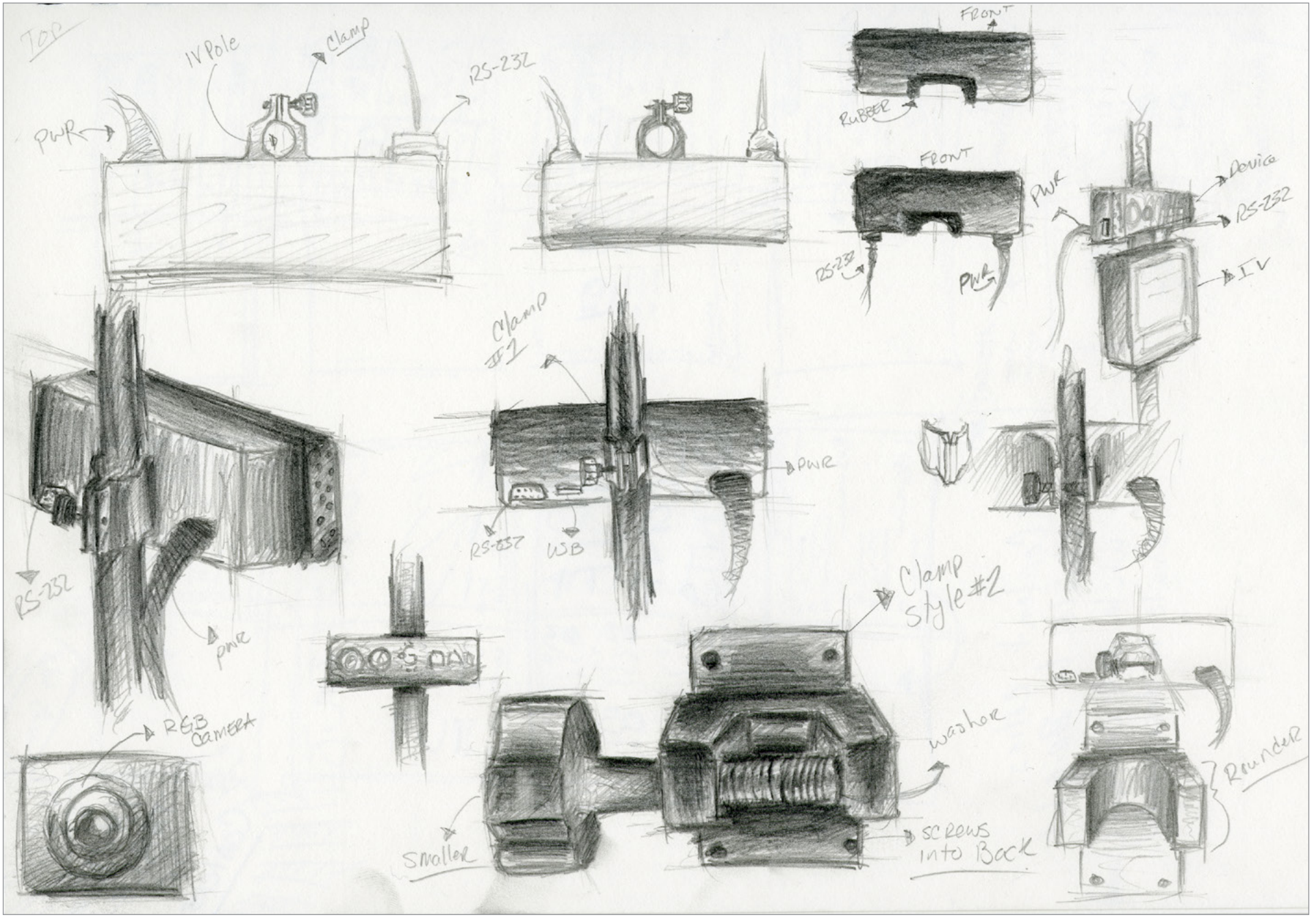


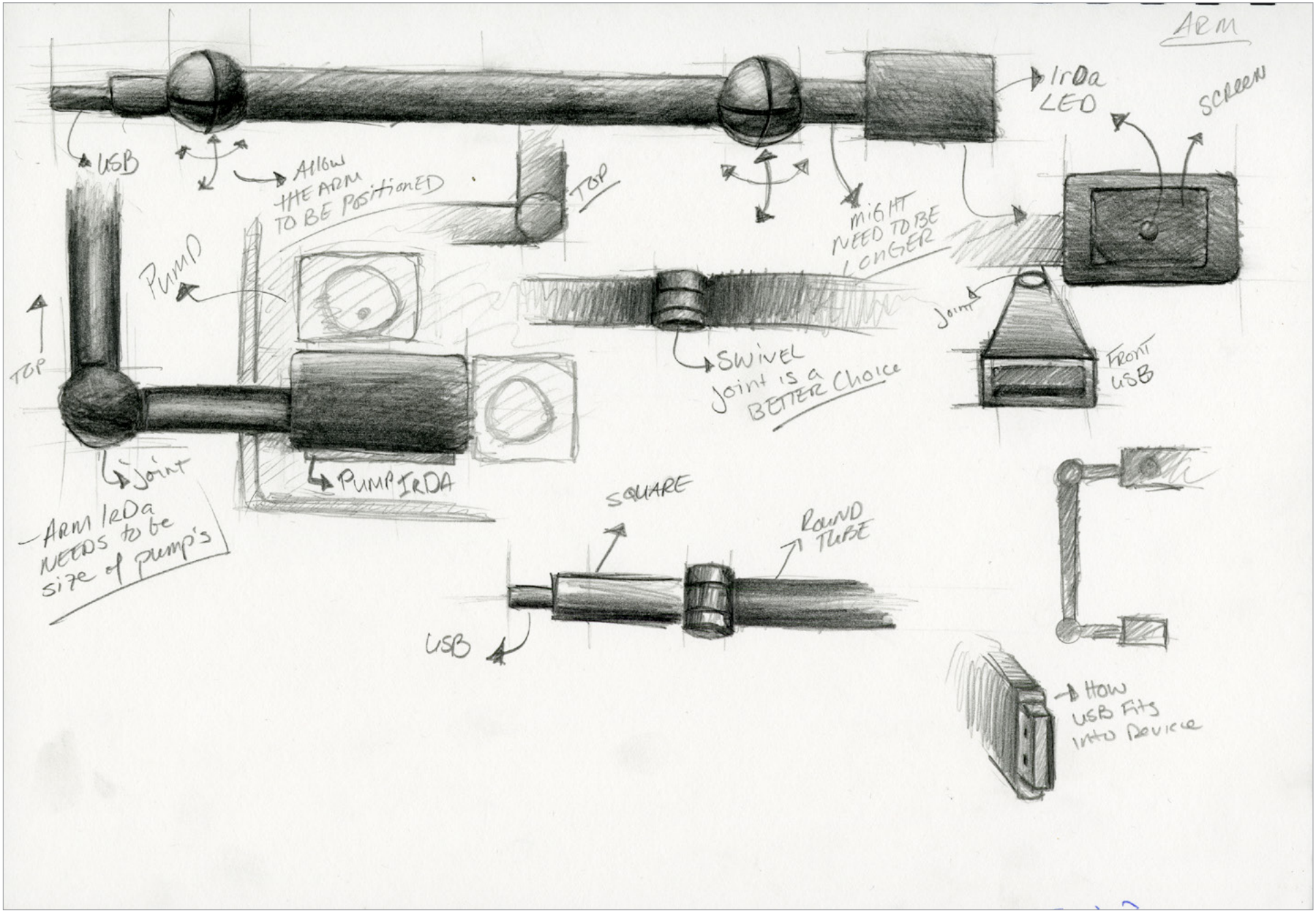







RGB
IR
Depth
Too Johnny #5
-where to put Logo?
RGB
IR
Depth
Depth
RGB
DEPTH
IR
RGB
ARM USB
-ARM USB MIGHT Get in the way
-Move to (L) side FOR SIGMA I.V.?
-RGB/DEPTH/IR placements ARE Good
-NEED TO THINK ABOUT VENTS
-Top deb.
-(L)?
-(R)?
BACK TOP
FRONT
BACK
TOP
USB
PWR
LEFT
RGB
USB
-NEEDS TO MOVE BACK More
USB CENTER
-MORE ROOM FOR VENT?
Could work?
Yes
USB
RIGHT
RS-232
BACK
(R)
(L)
PWR
RS-232
USB
-BACK & (R) ARE SIMPLE
-still NEED Mount


Top
IV Pole
Clamp
RS-232
PWR
FRONT
RUBBER
FRONT
PWR
RS-232
PWR
Clamp #1
PWR
RS-232
USB
RS-232
PWR
Clamp Style #2
RGB Camera
Smaller
washer
screws into Back
Rounder


ARM
IrDa LED
SCREEN
USB
ALLOW THE ARM TO BE POSITIONED
TOP
MIGHT NEED TO BE LONGER
PUMP
TOP
JOINT
SWIVEL Joint is a BETTER Choice
FRONT USB
PUMP IRDA
ARM IrDa NEEDS to be size of pump's
SQUARE
ROUND TUBE
USB
HOW USB FITS INTO DEVICE

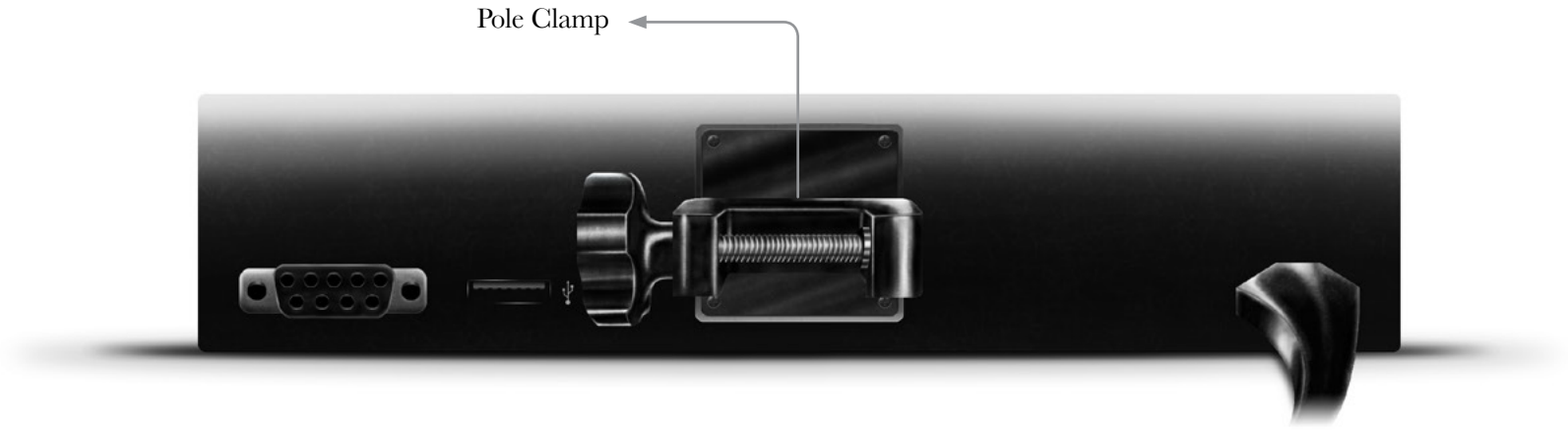
Front View

Error Signal

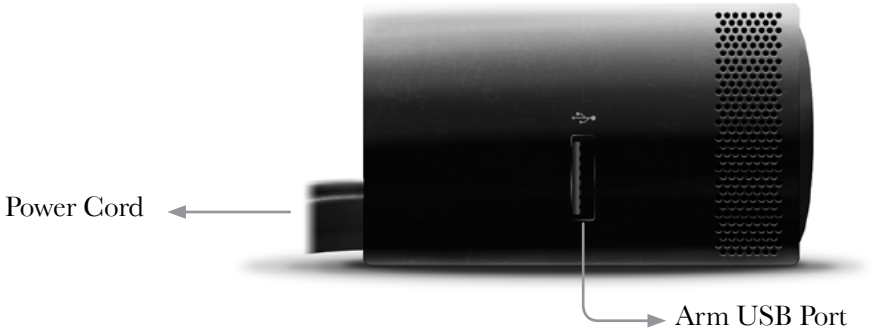
Orange Light for Configuration App

Blue Light for Configuration App

Back View



Back View With Pole Clamp



Left View

Right View

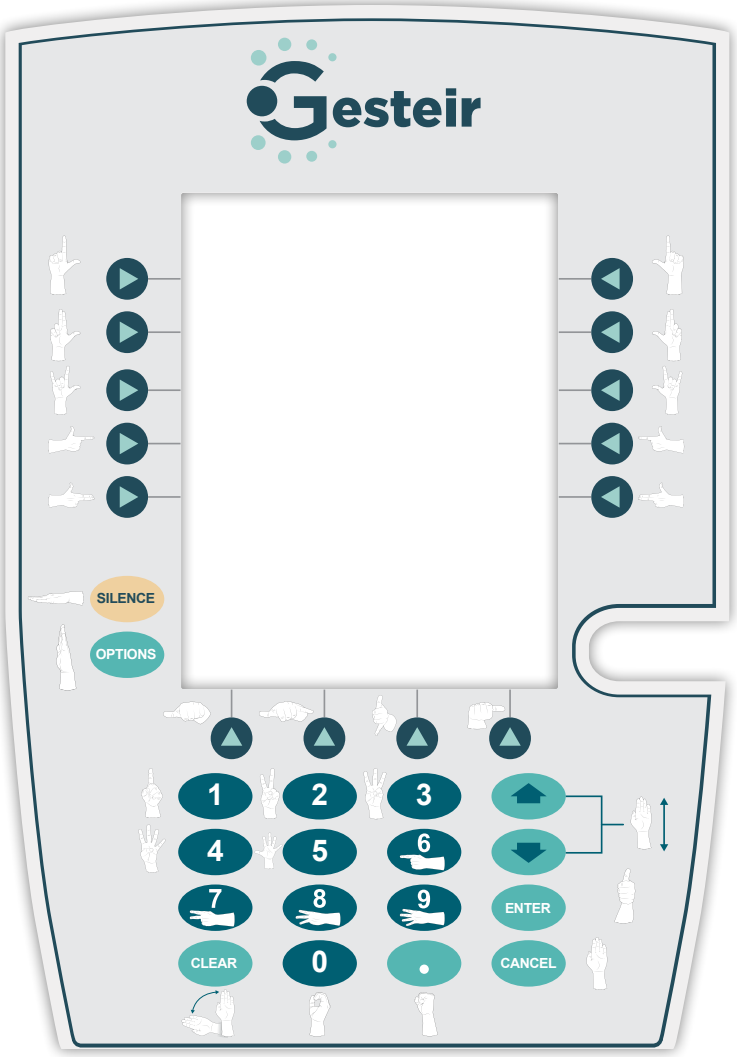
Gesteir Arm Accessory

Top View

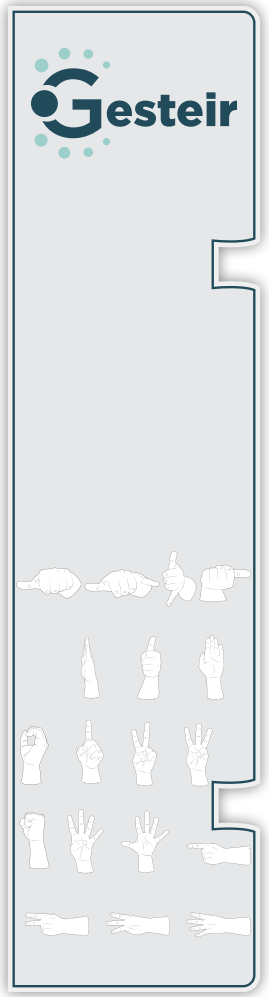
Front View

Back View

Gesteir Decal Accessory



Alaris™ PC I.V. Pump



Sigma Spectrum I.V. Pump

Gesteir In Use Without Decals

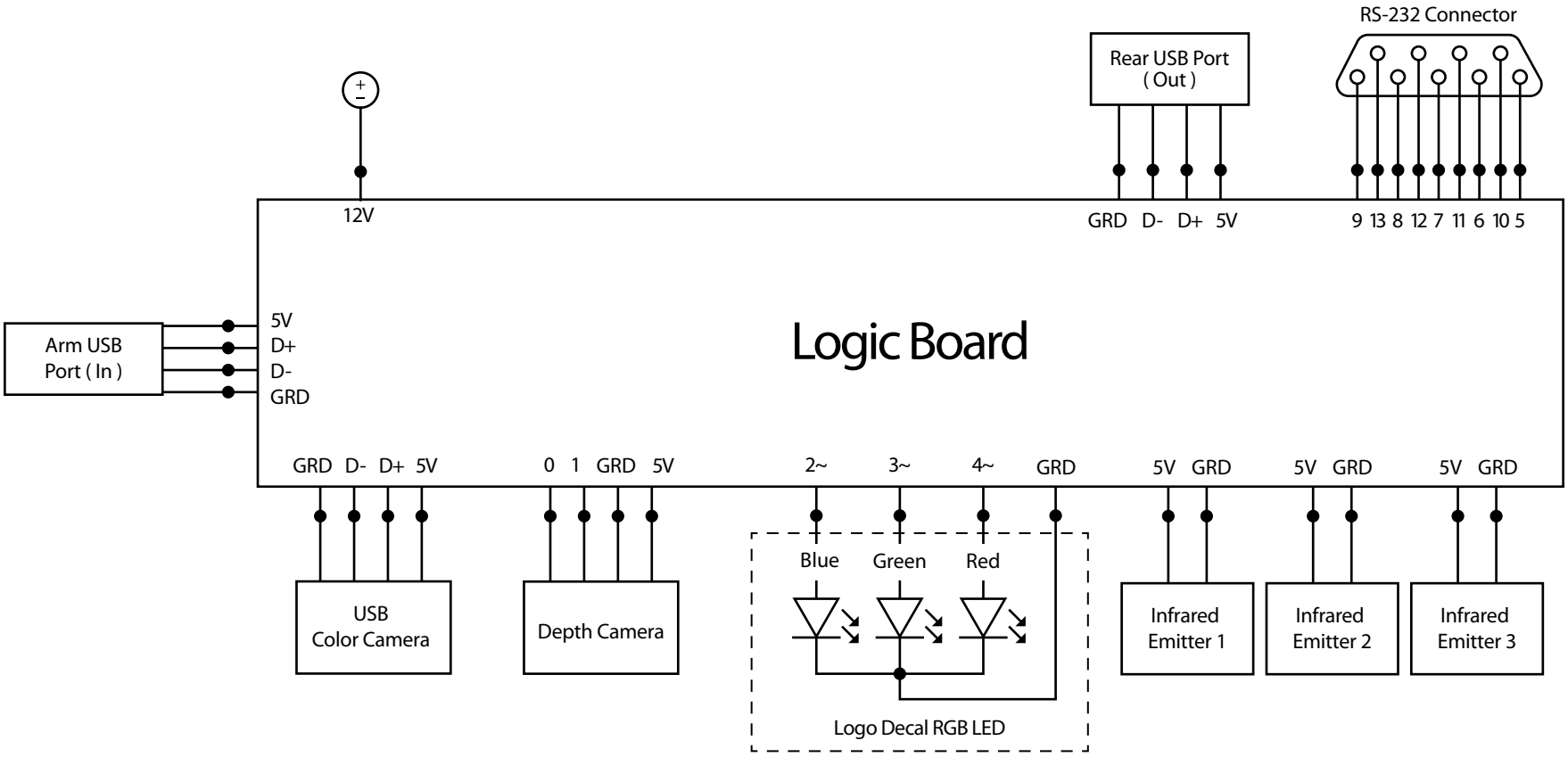

ALARM
INFUSE
STANDBY
Alaris Pump
RATE (mL/h)
CHANNEL SELECT
Close clamp before opening door
PAUSE
CHANNEL OFF
RESTART
CareFusion
CareFusion
Alaris PC
Guardrails
Medical/Surgical
A VTBI = ALL (7.96 mL)
B VTBI = 99.5 mL
C VTBI = ALL (16.5 mL)
SILENCE
OPTIONS
VOLUME INFUSED
AUDIO ADJUST
SYSTEM ON
1 2 3
4 5 6
7 8 9
CLEAR 0 .
ENTER
CANCEL

Gesteir In Use With Decals

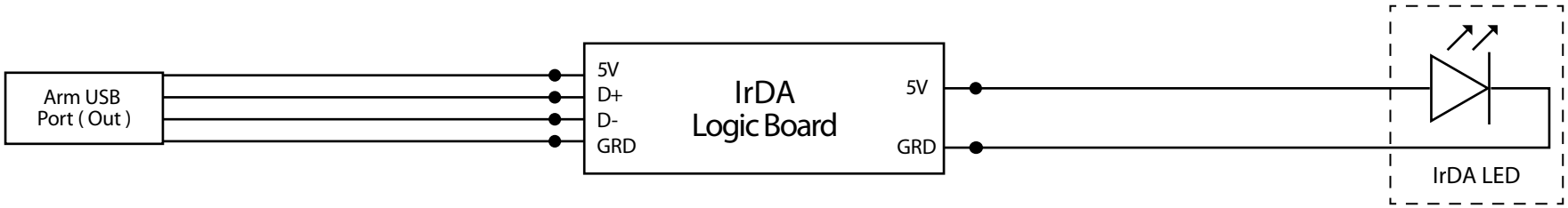

ALARM
INFUSE
STANDBY
Alaris Pump
RATE (mL/h)
CHANNEL SELECT
Close clamp before opening door
PAUSE
CHANNEL OFF
RESTART
CareFusion
Gesteir
Medical/Surgical
A VTBI = ALL (7.96 mL)
B VTBI = 99.5 mL
C VTBI = ALL (16.5 mL)
SILENCE
OPTIONS
VOLUME PAUSED
AUDIO ADJUST
SYSTEM ON
1
2
3
4
5
6
7
8
9
ENTER
CLEAR
0
CANCEL

WIRE DIAGRAMS

Gesteir Device



Gesteir Device Arm Accessory



SECTION 04:

TESTING & ITERATION

USER TESTING PLAN & SCRIPT

The user testing was conducted to determine the efficiency of the hand gestures. The test was divided into three parts. One, the introduction and explanation of the test. Two, user training, where the users studied the hand gestures and their associated buttons for five minutes. The final stage was the actual test, where the users were asked to perform the hand gestures for ten different buttons while being assessed on their ability to perform the gestures correctly, followed by a few questions.

Introduction:

So, what we are going to do is test how easily you can learn a set of hand gestures. You will be given five minutes to review the hand gestures and what buttons they are associated with. After that, I will ask you to perform a series of ten gestures. For example, I will say button 1, and you will make the hand gesture for button one, then I'll say number 5, and you will make the gesture for the number 5. After the test, I'll ask you a few questions about the hand gestures.

With your permission, I'm going to be recording this to help me figure out any ways to improve the hand gestures. Are you okay with that?

Do you have any questions before we begin?

So, now I'm going to walk you through each button and their hand gestures then you will have the five minutes to review on your own.

Begin Walk Through:

Okay, do you have any questions about the buttons or the gestures?

User Training:

Using the two sheets in front of you take five minutes to look over the hand gestures and what buttons they correspond with.

Begin Five-Minute Timer:

Begin Testing:
So, now we are going to start the test. As you may recall, I'm going to say a button or a number and you will perform the gesture. You ready?

Button 1, Button 3, Button 4, Run Stop, Okay, Number Six, Number Nine, Zero, Number 3, Decimal Point

Okay, that is all of the gestures.

Follow Up Questions:
Do you feel that the gestures are easy to perform or difficult to perform?

Were there any that you thought were difficult to remember?

USER TESTING SESSIONS & FINDINGS

As stated in the previous section, the user testing was to test the efficiency of the hand gestures. A total of five users were tested and were people who were completely unaware of what these gestures were. The users were tested on the Sigma Spectrum I.V. pump and had two handouts. One was a picture of the I.V. pump and the second was the hand gestures and their corresponding buttons and numbers. These printouts, as well as the user testing evaluation sheet, can be found in Appendix C.

User One:

- Time to complete: 40 seconds
- Number Correct: 7
- Number Incorrect: 3
- Key Findings: The user knows sign language which made learning the hand gestures more manageable. However, because the user knows sign language, three of the tasks were the right gestures but done as if the user was signing to a person and not standing in front of a machine, making them incorrect gestures. As a result of this, the tests that follow have an added question of, "Do you know sign language?" as well as clearer instructions on the importance of wrist position when performing the hand gestures. The user has arthritis which made the decimal point gesture a little complicated, but the user was able to do it correctly.

User Two:

- Time to complete: 45 seconds
- Number Correct: 7
- Number Incorrect: 3
- Key Findings: The user performed button one, three, and four incorrect because the user misinterpreted buttons as numbers.

However, the user realized this mistake and made the right gestures for the corresponding buttons. This error is not a result of the inefficiency of the hand gestures but an oversight on my part in conducting the test. The tests that proceed had clear instructions as to what gestures correspond to what buttons and that there is a difference between "button one" and "number one" etc. The user felt that the hand gestures were easy to perform and remember other than differentiating between "button" and "number."

User Three:

- Time to complete: 45 seconds
- Number Correct: 9
- Number Incorrect: 1
- Key Findings: By the time of this user testing, all of the mistakes of the test on my part had been worked out, and the user understood correct wrist position and the difference between "button" and "number." Therefore, the user only got one hand gesture wrong: the user performed Setup instead of Run Stop. The user had no issues performing the gestures and felt that given more time to learn the hand gestures the user would have done it correctly.

User Four:

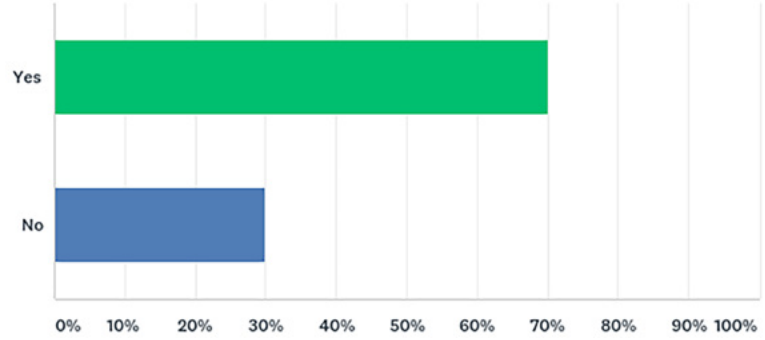
- Time to complete: 42 seconds
- Number Correct: 9
- Number Incorrect: 1
- Key Findings: The user felt that the hand gestures were natural to do and were very straightforward. The user also thought that they were not difficult to remember, but when asked to do out of order it took the user a few seconds to recall the proper gesture. The user held up the correct number of fingers for "number 3" but did it in the way that was correct for the user's culture. Even though the right amount of fingers were held up, the gesture was incorrect. Performing numbers this way is a cultural difference that will have to be addressed in the standardizing of the users learning the hand gestures.

User Five:

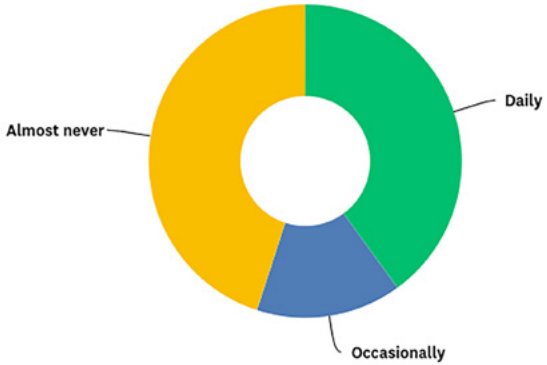
- Time to complete: 54 seconds
- Number Correct: 10
- Number Incorrect: 0
- Key Findings: The user thought that “button 2” was a little odd to perform due to having to stick out the user’s pinky. This user was the only user who felt this way. In the future, when more testing gets completed, there can be an analysis of the data to see if this hand gesture is an issue. However, as of right now, this gesture appears to have no impact on the majority of the users tested. The user is left-handed which made learning the gestures a little harder because the illustrations show a right hand. The user was still able to make the hand gestures correctly but look longer to map a right hand to a left hand. The user also felt given more time the user would be able to recall buttons one, three, and four a lot quicker since these were new hand gestures to the user.

SURVEY

Q1 Are you a nurse or a healthcare professional?



Q2 How often do you interact with an I.V. pump?



Q3 What unit of the hospital are you currently working in? For example, ICU, emergency room, etc.

Answered: 8 Skipped: 12

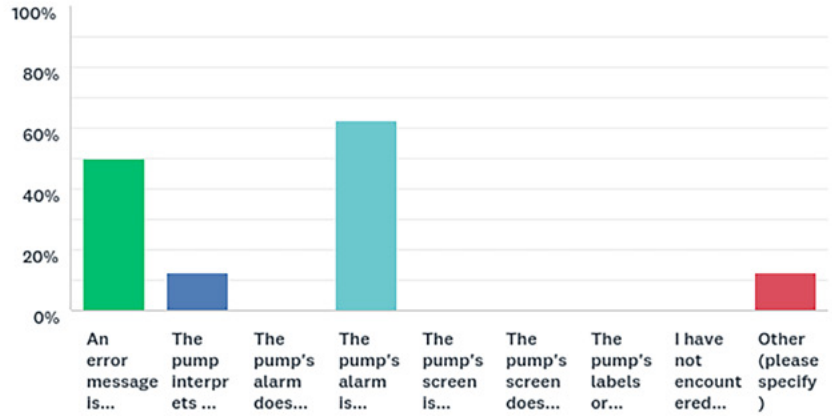
#	RESPONSES	DATE
1	Medical Oncology	11/6/2017 2:09 PM
2	NICU	10/13/2017 10:35 PM
3	Emergency Room	10/8/2017 11:40 AM
4	ICU	10/6/2017 10:07 PM
5	ICU	10/5/2017 2:44 PM
6	Education on medical	9/30/2017 8:07 AM
7	Oncology	9/29/2017 10:25 PM
8	Surgical step down	9/29/2017 2:28 PM

Q4 What is the most common brand and model of I.V. pumps you have used?

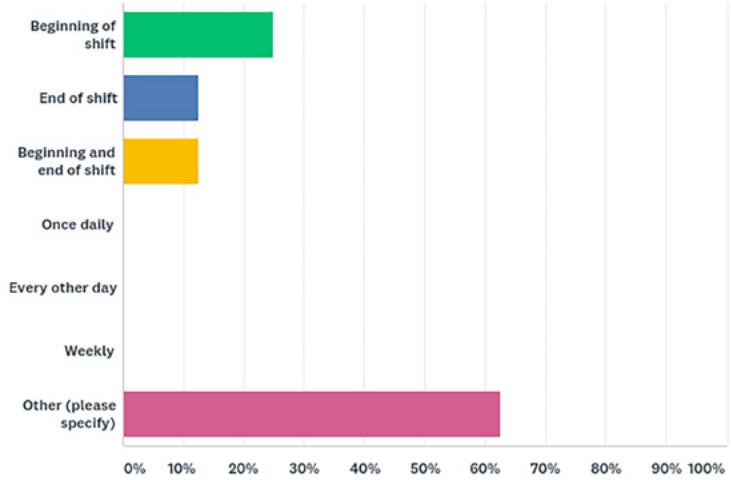
Answered: 8 Skipped: 12

#	RESPONSES	DATE
1	Alaris	11/6/2017 2:09 PM
2	Alaris	10/13/2017 10:35 PM
3	Baxter (?)	10/8/2017 11:40 AM
4	Baxter	10/6/2017 10:07 PM
5	Alaris	10/5/2017 2:44 PM
6	Aleris	9/30/2017 8:07 AM
7	Alaris	9/29/2017 10:25 PM
8	Alaris	9/29/2017 2:28 PM

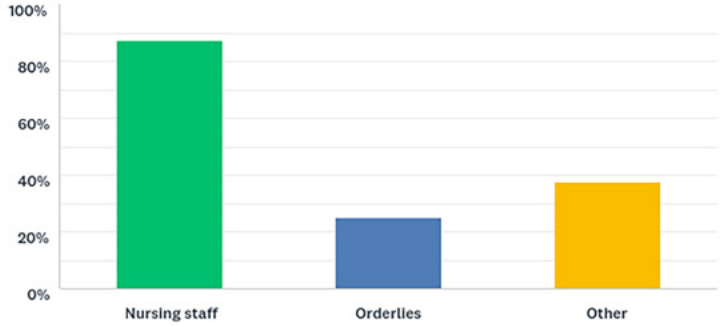
Q5 In the past six months, what was the primary issue or issues you encountered when using an I.V. pump? Check all that apply.



Q6 At your place of work, how often are the I.V. pumps cleaned? Check all that apply.



Q7 At your place of work, who typically cleans the I.V. pumps? Check all that apply.

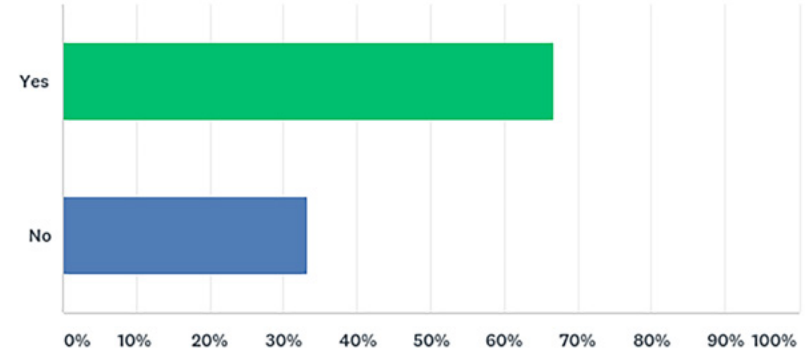


Q8 What is one thing you would change on the I.V. pump you use?

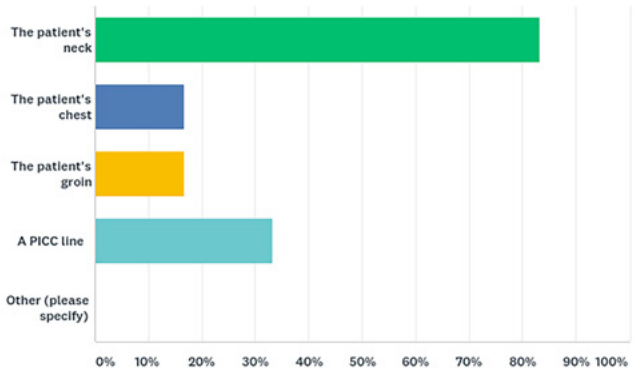
Answered: 6 Skipped: 14

#	RESPONSES	DATE
1	How quickly you can get to store information and data	11/6/2017 2:09 PM
2	The air in line alarm	10/13/2017 10:35 PM
3	Tubing that does not kink so easily	10/8/2017 11:40 AM
4	Repeatsd alarming despite resolution of problem. This is problematic with certain continuous medications i.e. Vasopressors	10/6/2017 10:07 PM
5	Not sure	9/29/2017 10:25 PM
6	Make the screen clearer/bigger	9/29/2017 2:28 PM

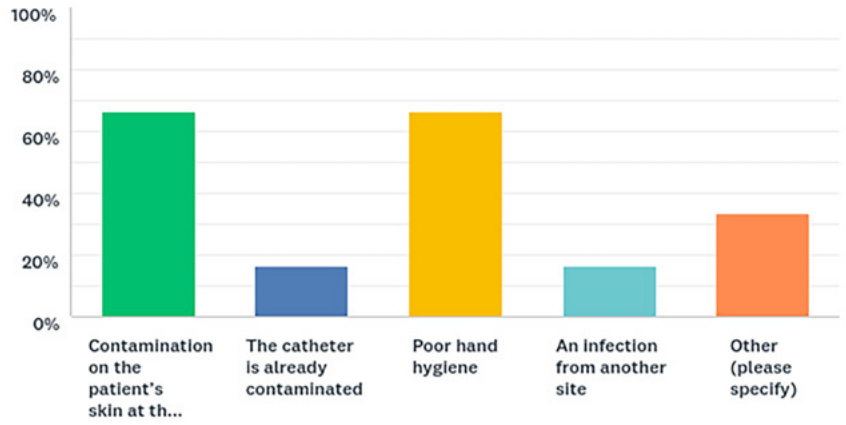
Q9 Have you assisted in inserting a central line?



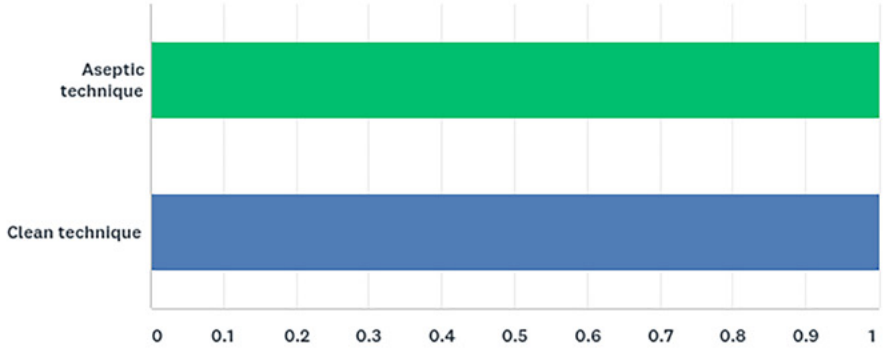
Q10 In the past six months, where on the patient was the central line most commonly inserted? Check all that apply.



Q11 Blood infections can be a result of all these causes, in your experience which cause do you think is a primary reason? Check all that apply.



Q12 How familiar are you with these techniques used to keep an area free of contamination?



Q13 In your opinion what do you think is the best way to reduce the spread of infections in hospitals?

Answered: 6 Skipped: 14

#	RESPONSES	DATE
1	Handwashing and smaller nurse to patient ratios	11/6/2017 2:10 PM
2	Visitor restrictions	10/13/2017 10:37 PM
3	Increased nurse pt ratios to allow more time for nurses to carefully follow through with proper technique	10/8/2017 11:45 AM
4	Eliminate blood draws from lines; maintaining sterile technique during insertion	10/6/2017 10:09 PM
5	Hand hygiene, knowing how to properly clean central lines and IV sites, following the gold standard and hospital protocol	10/5/2017 2:48 PM
6	Hand hygiene, proper aseptic and clean technique, have someone direct observing in case you break sterility	9/29/2017 2:29 PM

FEEDBACK

From the user testing, it shows that the hand gestures are easy to learn. By taking the scores from each user: user one, 70%, user two, 70%, user three, 90%, user four 90%, and user five, 100% and calculating the average, we get an average score of 84%. It is fair to say that this score could have been higher if there had been no oversights in the testing parameters, such as proper wrist position and a clear difference between the buttons labeled one through four and numbers one through four.

The survey aided in determining which I.V. pump the most users use. Out of all of the people who answered the question, Alaris™ PC is the most used. This data supported the decision to use it as the main case study in the UI mockups. The other questions were used to gain a better understanding of the work environment a healthcare professional might deal with because at the time of the surveys the MICU observations had not been completed.

As far as any changes to the hand gestures themselves, further testing is needed. Future testing should expand beyond the Sigma Spectrum I.V. pump to the Alaris™ PC I.V. pump, which has more hand gestures, as well as testing for any inefficacies in the hand gestures.

SECTION 05:

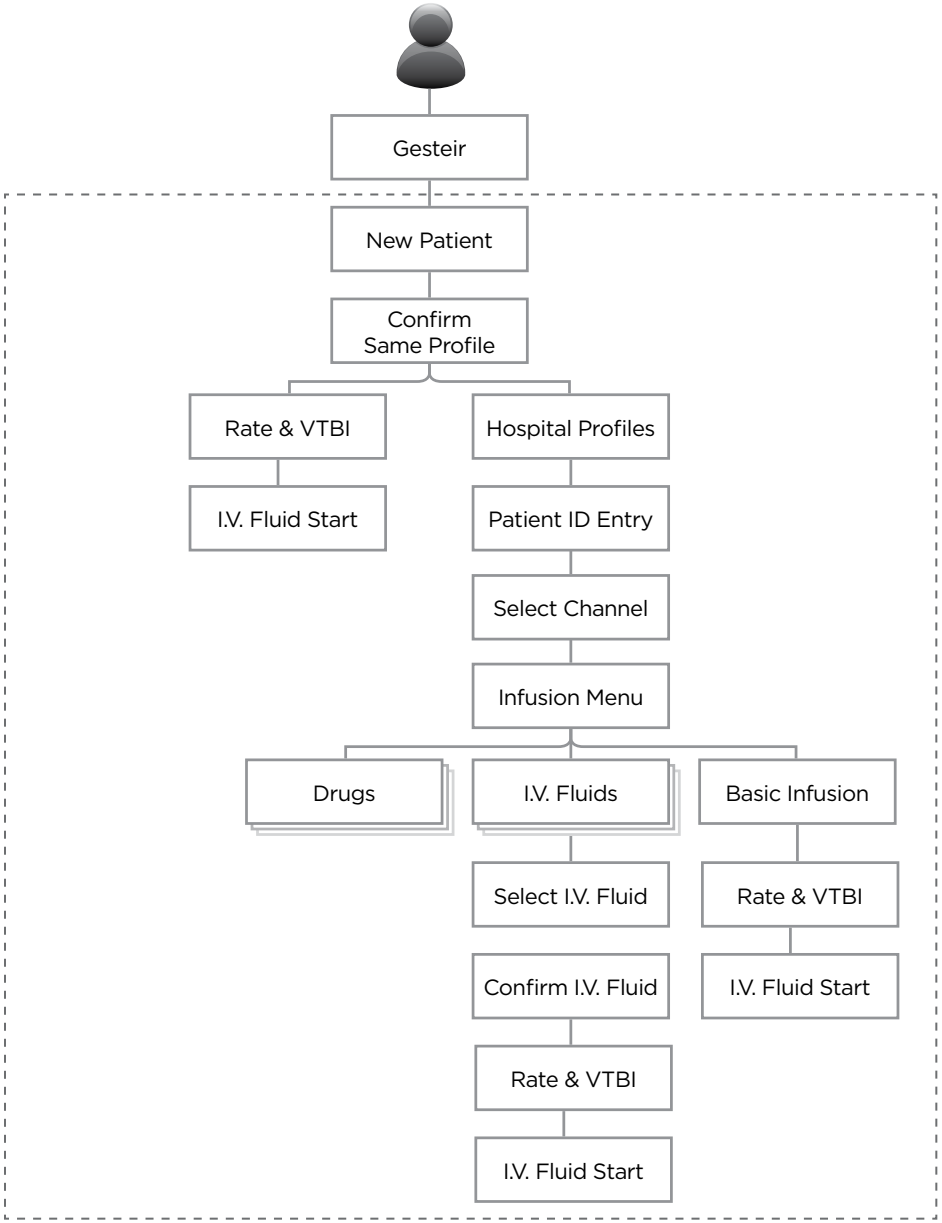
PRODUCTION

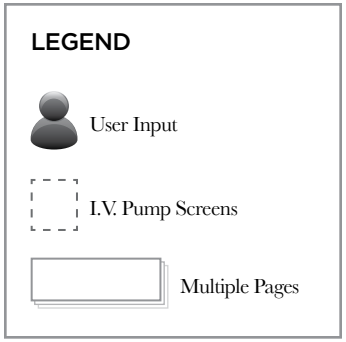
FUNCTIONAL REQUIREMENTS

Feature	Description
Gesteir	Dimensions: 7" W x 1.5" H x 2.5" D (without pole clamp), 4.5" D (with pole clamp).
Color Camera	A video camera that helps with gesture detection by detecting red, green, and blue (RGB) color components.
Depth Camera	An infrared sensor that allows the device to "see" the room in 3-D despite lighting conditions.
Infrared Emitters	Allows the device to track gestures in low lighting conditions.
Side USB Port	This port serves as an attachment point and power supply for the arm accessory.
Arm Accessory	The arm accessory allows Gesteir to communicate with I.V. pumps that have an infrared interface that uses Infrared Data Association (IrDA) protocol. IrDA provides a wireless line-of-sight connectivity between Gesteir and the I.V. pump. Dimensions: 16.5" W x 0.25" H x 0.5" D
RS-232 Connector	This connector is for I.V. pumps that have an RS-232 communication data port with an RJ45 connector that allows Gesteir to communicate with the I.V. pump.
Rear USB Port	This USB port is for any other needs and future R&D purposes in the following versions of the device.
Power Cord	Supplies power to Gesteir and has its own AC to DC converter.
Configuration App	Allows users to configure Gesteir to the I.V. pump.

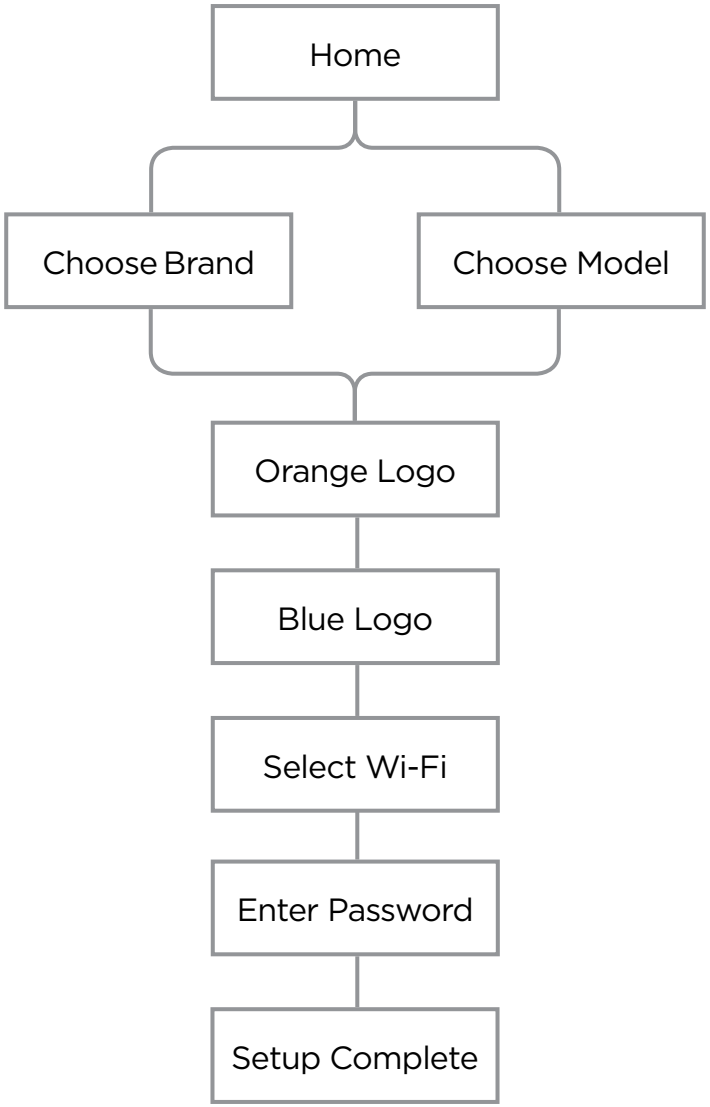
INFORMATION ARCHITECTURE

I.V. Pump





Gesteir Configuration App

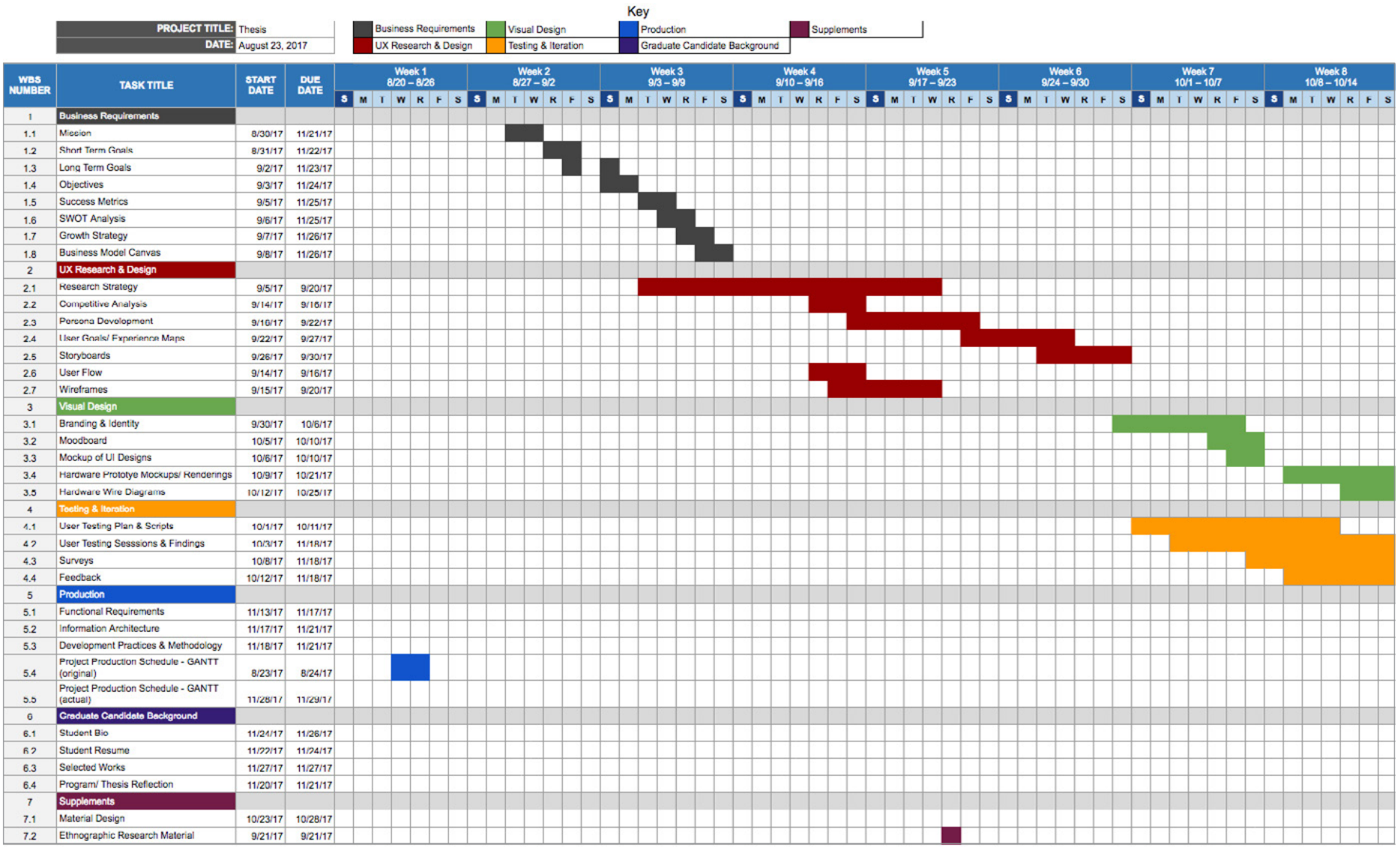


DEVELOPMENT PRACTICES & METHODOLOGY

The development practices and methodology for Gesteir align with agile development, allowing for an ease of continuing software and hardware development for future versions. In addition to the agile development practices, Gesteir's programming languages are C and C++. Gesteir sends its inputs to the I.V. pump in accordance with the IHE PCD technical framework volume 2, via a PCD-03 transaction which is a Communicate Infusion Order (see Appendix B for link).

Along with C and C++ as Gesteir's programming languages, the configuration app utilizes iOS and Android native languages.

ORIGINAL GANTT CHART



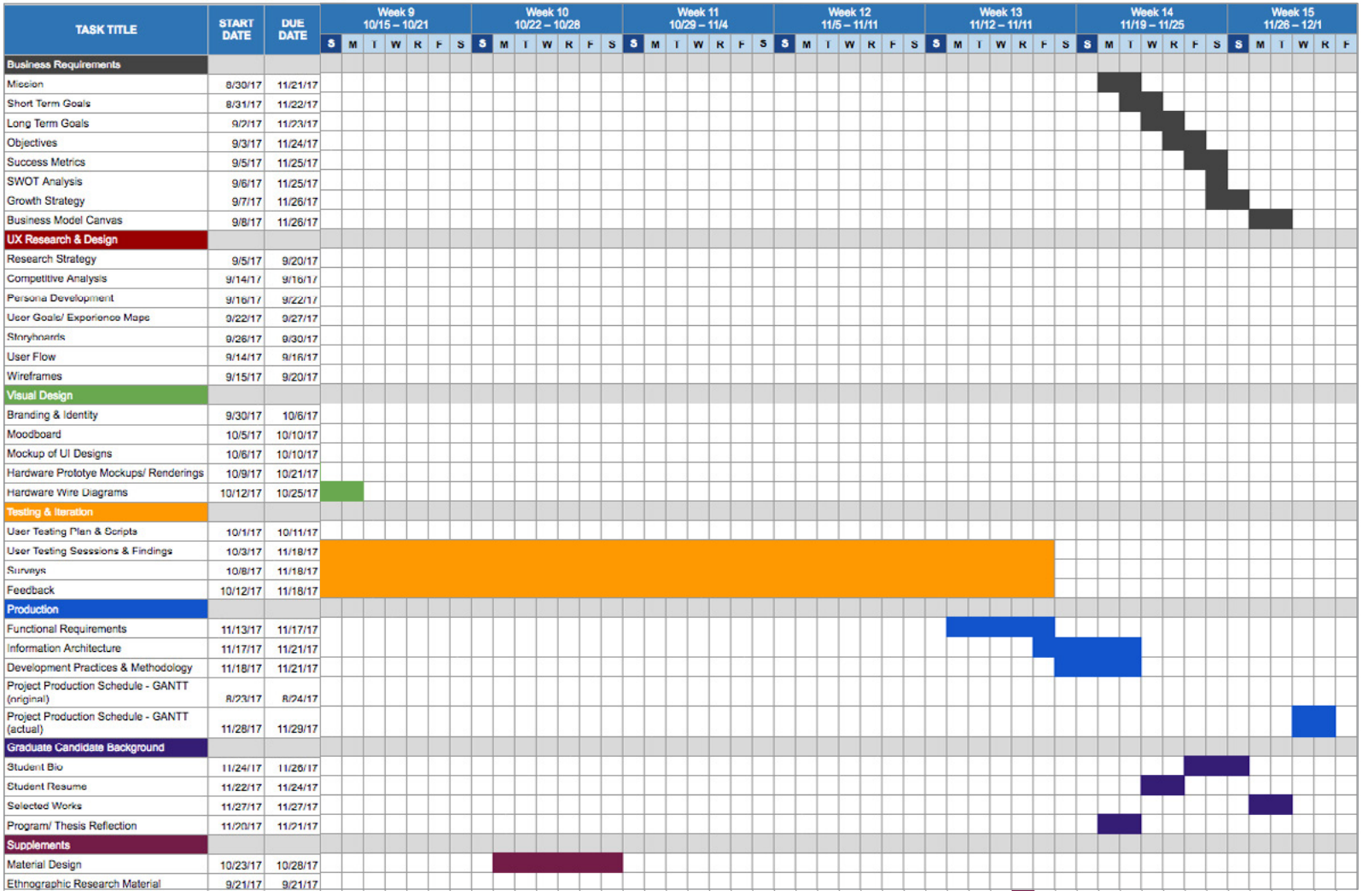
PROJECT TITLE:	Thesis
DATE:	August 23, 2017

Key

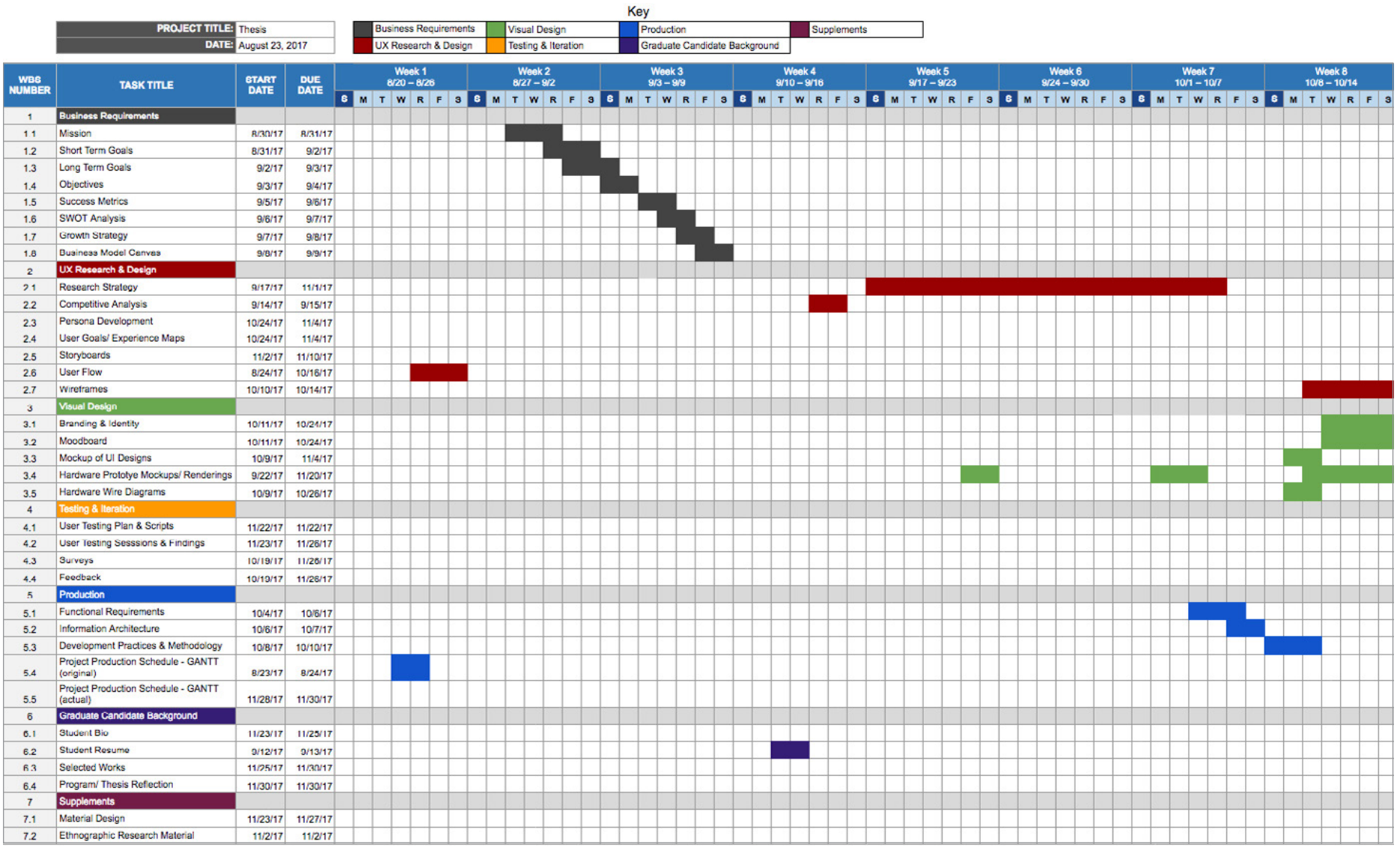
Business Requirements | Visual Design | Production | Supplements

UX Research & Design | Testing & Iteration | Graduate Candidate Background

TASK TITLE	START DATE	DUE DATE
Business Requirements		
Mission	8/30/17	11/21/17
Short Term Goals	8/31/17	11/22/17
Long Term Goals	9/2/17	11/23/17
Objectives	9/3/17	11/24/17
Success Metrics	9/5/17	11/25/17
SWOT Analysis	9/6/17	11/25/17
Growth Strategy	9/7/17	11/26/17
Business Model Canvas	9/8/17	11/26/17
UX Research & Design		
Research Strategy	9/5/17	9/20/17
Competitive Analysis	9/14/17	9/16/17
Persona Development	9/16/17	9/22/17
User Goals/ Experience Maps	9/22/17	9/27/17
Storyboards	9/26/17	9/30/17
User Flow	9/14/17	9/16/17
Wireframes	9/15/17	9/20/17
Visual Design		
Branding & Identity	9/30/17	10/6/17
Moodboard	10/5/17	10/10/17
Mockup of UI Designs	10/6/17	10/10/17
Hardware Prototye Mockups/ Renderings	10/9/17	10/21/17
Hardware Wire Diagrams	10/12/17	10/25/17
Testing & Iteration		
User Testing Plan & Scripts	10/1/17	10/11/17
User Testing Sesssions & Findings	10/3/17	11/18/17
Surveys	10/8/17	11/18/17
Feedback	10/12/17	11/18/17
Production		
Functional Requirements	11/13/17	11/17/17
Information Architecture	11/17/17	11/21/17
Development Practices & Methodology	11/18/17	11/21/17
Project Production Schedule - GANTT (original)	8/23/17	8/24/17
Project Production Schedule - GANTT (actual)	11/28/17	11/29/17
Graduate Candidate Background		
Student Bio	11/24/17	11/26/17
Student Resume	11/22/17	11/24/17
Selected Works	11/27/17	11/27/17
Program/ Thesis Reflection	11/20/17	11/21/17
Supplements		
Material Design	10/23/17	10/28/17
Ethnographic Research Material	9/21/17	9/21/17



ACTUAL GANTT CHART



PROJECT TITLE:	Thesis
DATE:	August 23, 2017

Key

Business Requirements	Visual Design	Production	Supplements
UX Research & Design	Testing & Iteration	Graduate Candidate Background	

WBS NUMBER	TASK TITLE	START DATE	DUE DATE
1	**Business Requirements**		
1.1	Mission	8/30/17	8/31/17
1.2	Short Term Goals	8/31/17	9/2/17
1.3	Long Term Goals	9/2/17	9/3/17
1.4	Objectives	9/3/17	9/4/17
1.5	Success Metrics	9/5/17	9/6/17
1.6	SWOT Analysis	9/6/17	9/7/17
1.7	Growth Strategy	9/7/17	9/8/17
1.8	Business Model Canvas	9/8/17	9/9/17
2	**UX Research & Design**		
2.1	Research Strategy	9/17/17	11/1/17
2.2	Competitive Analysis	9/14/17	9/15/17
2.3	Persona Development	10/24/17	11/4/17
2.4	User Goals/ Experience Maps	10/24/17	11/4/17
2.5	Storyboards	11/2/17	11/10/17
2.6	User Flow	8/24/17	10/16/17
2.7	Wireframes	10/10/17	10/14/17
3	**Visual Design**		
3.1	Branding & Identity	10/11/17	10/24/17
3.2	Moodboard	10/11/17	10/24/17
3.3	Mockup of UI Designs	10/9/17	11/4/17
3.4	Hardware Prototye Mockups/ Renderings	9/22/17	11/20/17
3.5	Hardware Wire Diagrams	10/9/17	10/26/17
4	**Testing & Iteration**		
4.1	User Testing Plan & Scripts	11/22/17	11/22/17
4.2	User Testing Sesssions & Findings	11/23/17	11/26/17
4.3	Surveys	10/19/17	11/26/17
4.4	Feedback	10/19/17	11/26/17
5	**Production**		
5.1	Functional Requirements	10/4/17	10/6/17
5.2	Information Architecture	10/6/17	10/7/17
5.3	Development Practices & Methodology	10/8/17	10/10/17
5.4	Project Production Schedule - GANTT (original)	8/23/17	8/24/17
5.5	Project Production Schedule - GANTT (actual)	11/28/17	11/30/17
6	**Graduate Candidate Background**		
6.1	Student Bio	11/23/17	11/25/17
6.2	Student Resume	9/12/17	9/13/17
6.3	Selected Works	11/25/17	11/30/17
6.4	Program/ Thesis Reflection	11/30/17	11/30/17
7	**Supplements**		
7.1	Material Design	11/23/17	11/27/17
7.2	Ethnographic Research Material	11/2/17	11/2/17

Week 1 8/20 – 8/26	Week 2 8/27 – 9/2	Week 3 9/3 – 9/9	Week 4 9/10 – 9/16	Week 5 9/17 – 9/23	Week 6 9/24 – 9/30	Week 7 10/1 – 10/7	Week 8 10/8 – 10/14
S M T W R F S	S M T W R F S	S M T W R F S	S M T W R F S	S M T W R F S	S M T W R F S	S M T W R F S	S M T W R F S

PROJECT TITLE:	Thesis
DATE:	August 23, 2017

Key

Business Requirements	Visual Design	Production	Supplements
UX Research & Design	Testing & Iteration	Graduate Candidate Background	

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Long Term Goals	9/2/17	9/3/17
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SWOT Analysis	9/6/17	9/7/17
Growth Strategy	9/7/17	9/8/17
Business Model Canvas	9/8/17	9/9/17
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Competitive Analysis	9/14/17	9/15/17
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User Goals/ Experience Maps	10/24/17	11/4/17
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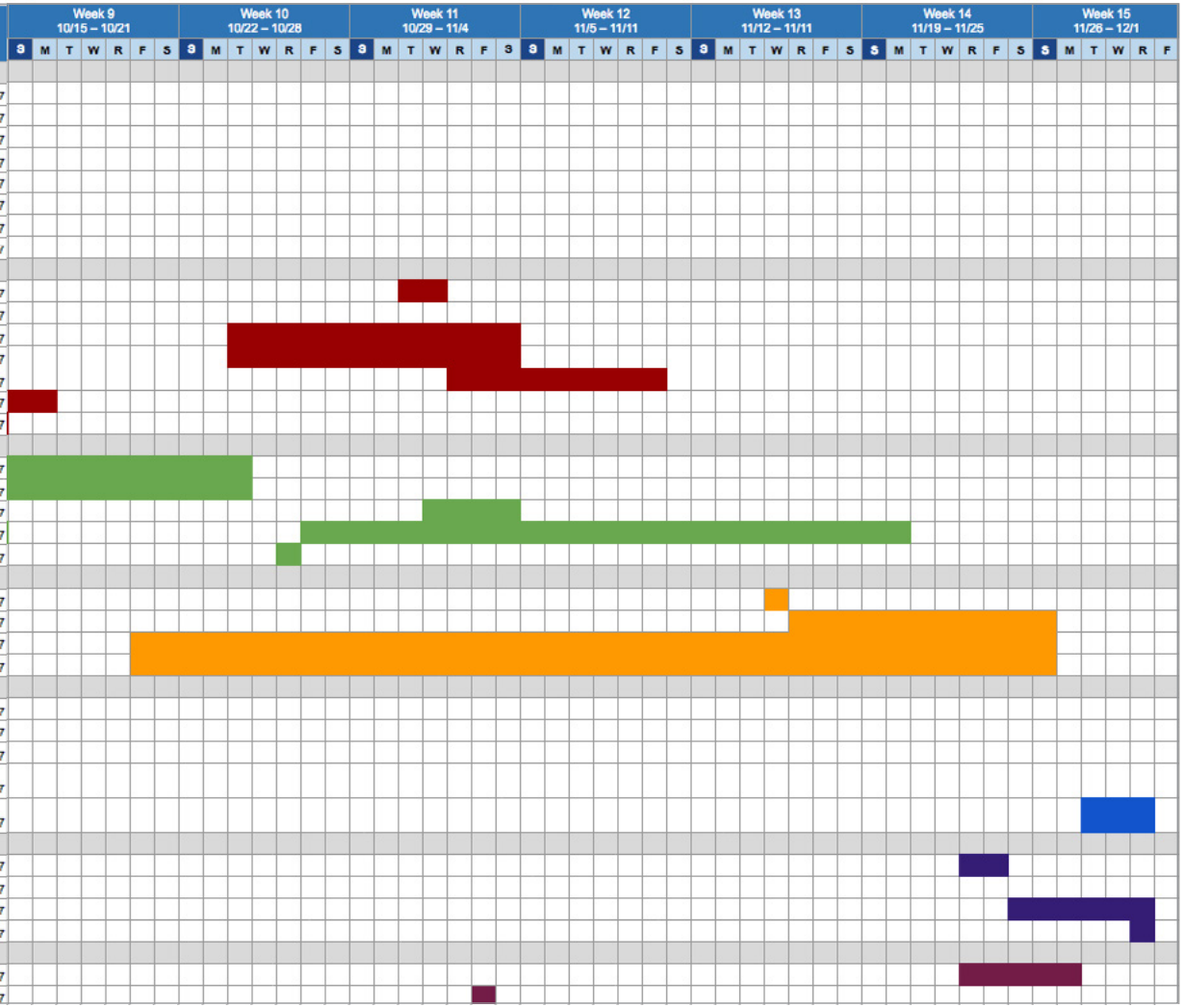
Program/ Thesis Reflection	11/30/17	11/30/17
Supplements		
Material Design	11/23/17	11/27/17
Ethnographic Research Material	11/2/17	11/2/17



SECTION 07:

SUPPLEMENTS

MATERIAL DESIGN

According to the FDA's ISO 10993-1, Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process; Gesteir and its accessories fall under the category "non-contact." The link to this document is in Appendix B. This classification means that Gesteir does not have direct or indirect contact with the body; therefore, no biocompatibility information is required other than proof that Gesteir and its accessories have no contact with the human body (Food & Drug Administration, 2016). However, Gesteir and all of its accessories will be made out of antimicrobial plastic. Under the FDA guidelines, this is not required, but the added protection against the growth of microorganisms on the device and spread of microorganisms from the device align with Gesteir's mission.

REFERENCES

Arias, K. M. (2010). Contamination and Cross Contamination on Hospital Surfaces and Medical Equipment[PDF]. Burlington, VT: Saxe Healthcare Communications.

Barnes, S., Olmsted, R. N., Monsees, E., Harris, J., Khoury, R., Hadaway, L., & Downham, G. (2015, December). Guide to Preventing Central Line-Associated Bloodstream Infections [PDF]. Washington, DC: Association for Professionals in Infection Control and Epidemiology.

Healthcare-associated Infections. (2010, April 01). Retrieved September 14, 2017, from https://www.cdc.gov/hai/bsi/clabsi-resources.html

IHE Patient Care Device (PCD) Technical Framework Volume 2 10 IHE PCD TF-2 Transactions[PDF]. (2017, November 9). Integrating the Healthcare Enterprise.

Innovating for people: handbook of human-centered design methods. (2012). Pittsburgh, PA: LUMA Institute, LLC.

Kramer, A., Kampf, G., & Schwebke, I. (2006, August 16). How long do nosocomial pathogens persist on inanimate surfaces? A systematic review. Retrieved November 27, 2017, from https://bmcinfectdis.biomedcentral.com/articles/10.1186/1471-2334-6-130

Maria Sales, V., Oliveira, E., Célia, R., Ramos Gonçalves, F., Carvalho de Melo, C. (2014). Microbiological analysis of inanimate surfaces in an Intensive Care Unit and patient safety. Revista de Enfermagem Referência. IV Série. 45-53. 10.12707/RIII1293.

Norman, D. (2013). The design of everyday things. New York: Basic Books.

Osterwalder, A., & Pigneur, Y. (2013). Business model generation a handbook for visionaries, game changers, and challengers. New York: Wiley&Sons.

Prekopcsák, Z., Halácsy, P., & Gáspár-Papanek, C. (2008, September 5). Design and Development of an Everyday Hand Gesture Interface [PDF]. Amsterdam: MobileHCI.

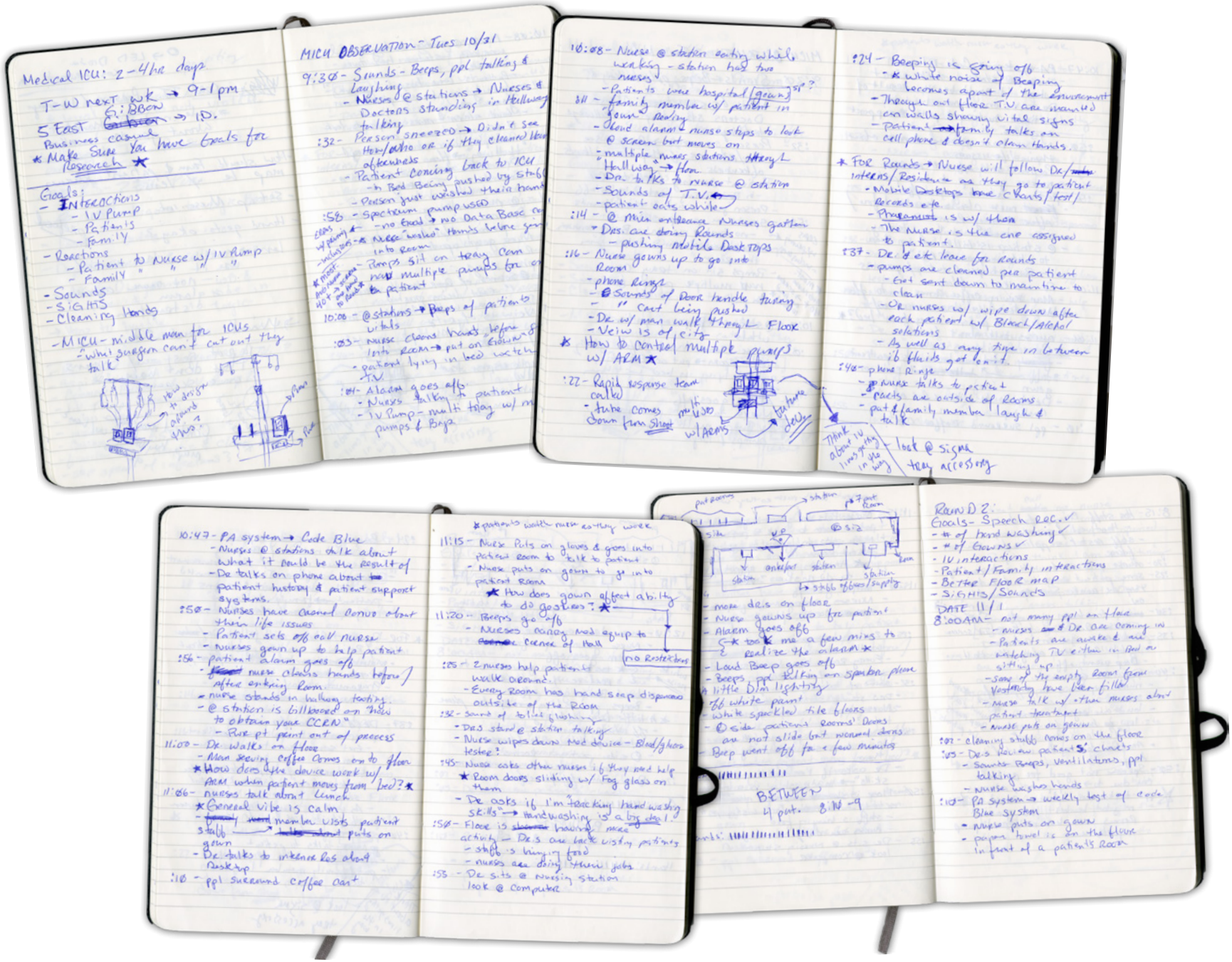
The Joint Commission. Preventing Central Line-Associated Bloodstream Infections: A Global Challenge, a Global Perspective. Oak Brook, IL: Joint Commission Resources, May 2012. http://www.PreventingCLABSIs.pdf

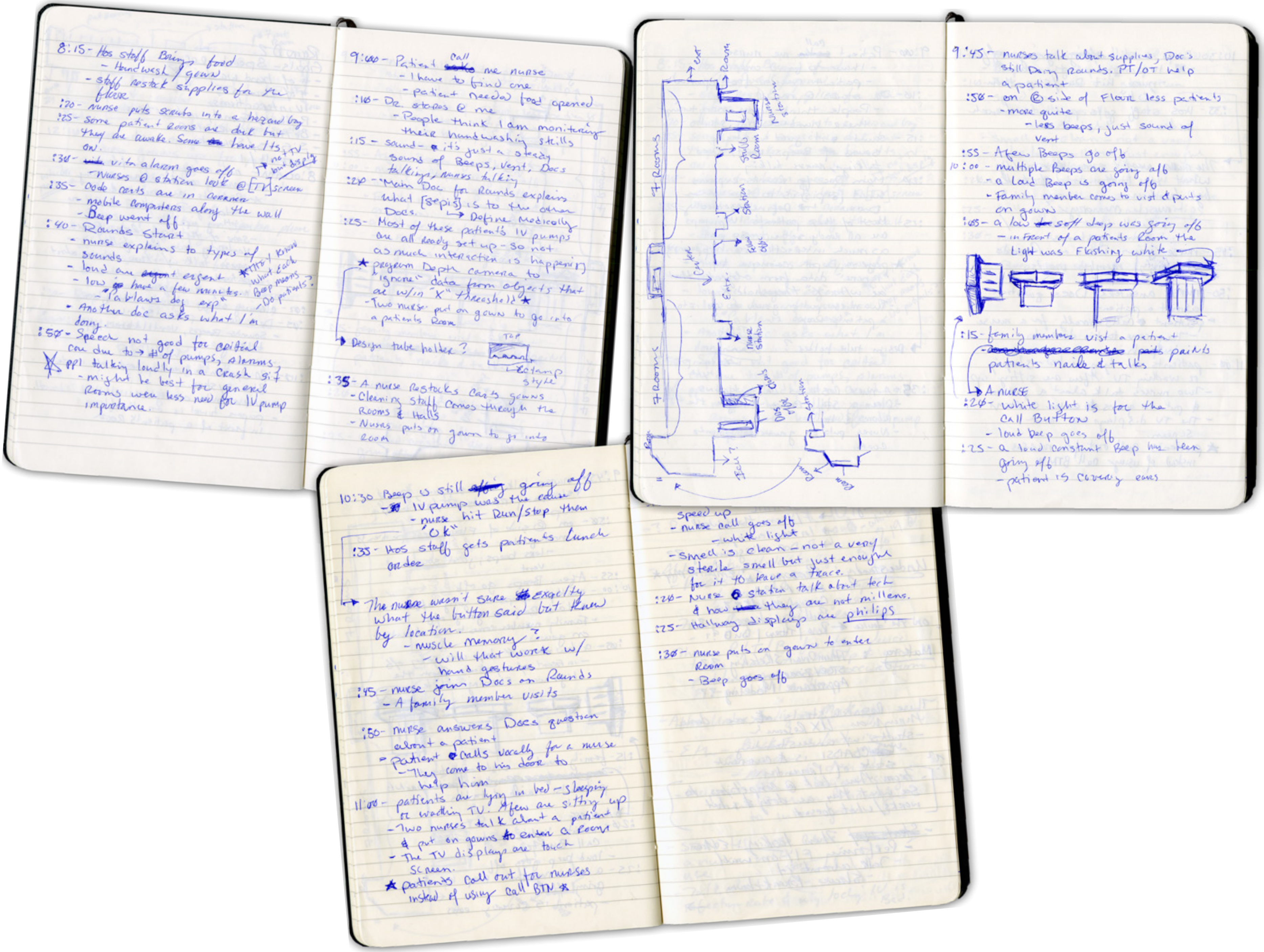
United States, Department of the Navy, Office of the Chief of Naval Operations. (2001). Aircraft Signals NATOPS Manual, NAVAIR 00-80T-113. Retrieved November 14, 2017, from http://www.navybmr.com/study%20material/NAVAIR_113.pdf

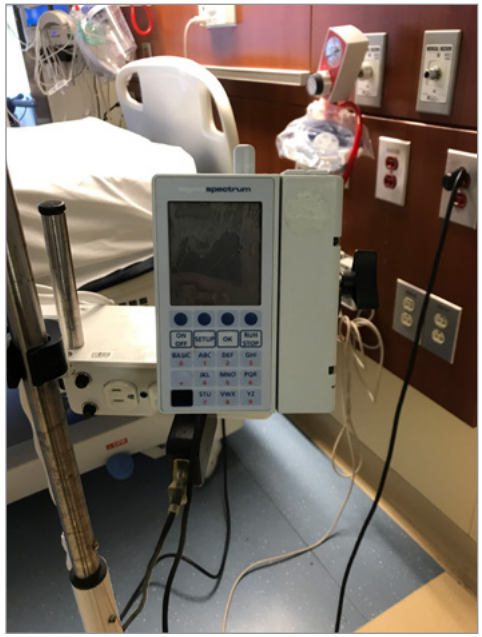
United States, Food & Drug Administration, Center for Devices and Radiological Health. (2016, June 16). Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" Guidance for Industry and Food and Drug Administration Staff. Retrieved November 23, 2017, from https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm348890.pdf

APPENDIX A

ETHNOGRAPHIC NOTES




8:15 - Hos staff Brings food
- Handwash / gown
- staff restock supplies for the floor
:20 - nurse puts scrubs into a hazard bag
:25 - Some patient rooms are dark but they are awake. Some have TVs on.
:30 - vita alarm goes off
- Nurses @ station look @ [TV] screen
:35 - code carts are in corner
- mobile computers along the wall
- Beep went off
:40 - Rounds Start
- nurse explains to types of sounds
- loud are urgent
- low have a few minutes.
- Another doc asks what I'm doing
:50 - Speech not good for critical care due to # of pumps, alarms.
ppl talking loudly in a crash sit
- might be best for general rooms were less need for IV pump importance
9:00 - Patient call me nurse
- I have to find one
- patient needed food opened
:10 - Dr. stops @ me
- People think I am monitoring their handwashing skills
:15 - sound - it's just a steady sound of Beeps, Vent, Docs talking, nurses talking
:20 - Main Doc for Rounds explains what [Sepsis] is to the other Docs.
→ Define medically
:25 - Most of these patients IV pumps are all ready set up - so not as much interaction is happening
★ program Depth camera to "ignore" data from objects that are w/in "X" threshold ★
- Two nurse put on gown to go into a patients Room
Design tube holder?
TOP
Rectangle style
:35 - A nurse Restocks Carts gowns
- Cleaning staff comes through the Rooms & Halls
- Nurse puts on gown to go into room
Exit
Room
Nurse Station
7 Rooms
Center
Nurse Station
Exit
7 Rooms
9:45 - nurses talk about supplies, Doc's still Doing Rounds. PT/OT help a patient
:50 - on @ side of Floor less patients
- more quite
- less beeps, just sound of vent
:55 - After Beeps go off
10:00 - multiple Beeps are going off
- a loud Beep is going off
- Family member comes to visit & puts on gown
:05 - a low soft beep was going off
- in front of a patients Room the Light was Flashing white
:15 - family members visit a patient
patients nails & talks
A nurse
:20 - white light is for the call Button
- loud beep goes off
:25 - a loud constant Beep has been going off
- patient is covering ears
10:30 Beep is still going off
- IV pump was the cause
- nurse hit Run/Stop then "Ok"
:35 - Hos staff gets patients lunch order
The nurse wasn't sure exactly what the button said but knew by location.
- muscle memory?
- will that work w/ hand gestures
:45 - nurse join Docs on Rounds
- A family member visits
:50 - nurse answers Docs question about a patient
- Patient calls vocally for a nurse
- They come to his door to help him
11:00 - patients are lying in bed - sleeping or watching TV. A few are sitting up
- Two nurses talk about a patient & put on gowns to enter a room
- The TV displays are touch screen.
★ patients call out for nurses instead of using call BTN ★
speed up
- nurse call goes off
- white light
- Smell is clean - not a very sterile smell but just enough for it to leave a trace.
:20 - Nurse @ station talk about tech & how they are not millens.
:25 - Hallway displays are philips
:30 - nurse puts on gown to enter Room
- Beep goes off


spectrum


stryker

MICU Observation Round 1

Date: 10/31/17 Observer: Austin Davis Location: Jefferson Hospital

Goals:

- Interaction with I.V. pumps
- Interactions with patients and family members
- Patient's reactions to the nurses
- Family member's reactions to the nurses
- Sounds
- Sights
- Amount of hand cleaning
- Amount of gowns put on
- Floor plan drawing
- Speech recognition ability

Time	Notes
9:30 AM	• Sounds: beeps, people talking & laughing • Nurses are sitting at their stations • Nurses, Doctors are standing in hallway talking
:32	• A person sneezed - didn't see who it was or if they cleaned their hands afterwards • A patient is coming back to ICU • In a bed and being pushed by staff • Staff member washed their hands
:58	• Spectrum Sigma pump is used • Not liked due to small screen, no connection to patient record database, errors with and priming the pump and occlusion • Most average nurses are 40 years old and these little screens are hard to read • Pumps sit on tray • Allow for multiple pumps for a single patient
10:00 AM	• Sounds coming from the nurse stations: Beeps of patient's vital signs
:03	• A nurse cleans their hands before going into a room and puts on PPE gown • A Patient is lying on bed watching TV
:04	• An alarm goes off • A nurse is talking to a patient • I.V. pump: multi tray with multi pumps and bags

Time	Notes
10:08 AM	• A nurse at a station eats while working • A nurse on the other side of the station stares at the computer screen • Patients have to wear hospital gowns
:11	• A family member reads to a patient • Family member is wearing a PPE gown • A loud alarm goes off, a nurse stops to look at TV screen displaying vital signs but moves on • Multiple nurse stations throughout floor • A Doctor talks to a nurse at a station • Sounds of TVs • A patient eats while watching TV
:14	• At the main nurse station/entrance, nurses gather • Doctors are doing rounds • Pushing mobile desktops
:16	• A nurse puts on PPE gown to go into a patient's room • A Phone rings • Sounds of door handle turning • Sounds of a cart being pushed • A doctor walks through the floor with a man • Patient's have a view of the city • **How to control multiple pumps with the arm accessory**
:22	• Rapid response team called • A tube comes down from shoot
:24	• A beeping is going off • **Beeping become white noise and apart of the environment** • Throughout the floor TVs are mounted on the walls displaying vital signs • A family member is talking on their cell phone and walks into a patient's room without cleaning their hands • **For rounds a nurse assigned to the patient will talk with the doctors (interns and residents) as they go from patient to patient. The mobile carts are for charts, test results, and order tests. An ICU pharmacist is also on rounds.**
:37	• All of the doctors leave • Pumps are cleaned in between patients • The pumps will be sent to maintenance for a deep cleaning or a nurse will wipe down the pump with a bleach/alcohol solution • A nurse might wipe down the pump any time if a fluid gets on it

Time	Notes
10:40	• A phone rings • A nurse talks to a patient • Carts are outside of rooms • A patient and family member are talking and laughing
:47	• Over the PA system a code blue is called • Nurses at the station talk about what could have been the result of the code • A Doctor talks on the phone about a patient's history and support system
:50	• Nurses have a casual conversation about their "life" issues • A patient sets off the nurse call • A nurse puts on PPE gown to help a patient
:56	• A patient's alarm goes off • A nurse cleans their hands before entering room and after leaving room • At a nurse station is a billboard on "how to obtain your CCRN" • PowerPoint print out of process
11:00 AM	• A doctor walks onto the floor • A man serving coffee comes onto the floor • **** How does the device work with the arm when a patient moves from the bed? ****
:06	• Nurses talk about what to have for lunch • **** The general vibe of the staff is calm **** • A hospital staff member visits a patient and has to put on a PPE gown • A doctor talks to an intern or resident about how to use a mobile computer
: 10	• ICU staff surround coffee cart and engage in casual conversation
:15	• **** Patients watch nurses as they do their jobs **** • A nurse puts on gloves and goes into a patient's room to talk to the patient • A nurse puts on a PPE gown and goes into a patient's room • **** How does the gown affect the nurse's ability to do hand gestures? **** • **It does not restrict the nurse's ability**
:20	• Beeps are going off • A nurse carries a medical device to a corner of the floor
:25	• 2 nurses help a patient walk around • Every room has hand soap dispensers outside of the room

Time	Notes
11:32	• **Sound of a toilet flushing** • Doctors stand at a nurse station talking to each other • A nurse wipes down a medical device, maybe a blood glucose meter
:45	• A nurse asked the other nurses if they need any help • **** The "left" side of the floor's patient's rooms have sliding doors with fog glass **** • A doctor asked me if I'm **"tracking hand washing skills"** • Hand washing is a big deal and floors get audited

:50	• Floor is having more activity
	  • Doctors are back to check in on the patients
	  • Hospital staff is bringing food to the patients
	  • Nurses are doing their duties

:55	• A doctor sits at a nursing station looking at the computer screen

12:10 PM	• There are more doctors on the floor
	• A nurse puts on a PPE gown to enter a patient's room
	• An alarm goes off
	  • **** White noise - it took me a few minutes to realize that there was an alarm going off ****
	• A loud beep goes off
	• Beeps, people talking on speaker phone
	• **** Lighting is a little dim, off white paint, white speckled tile floor**
	  • Right side of floor's patient's rooms have normal doors, while the left side has sliding doors **

:20	• A beep went off for a few minutes
:30	• End of observation

MICU Observation Round 2

Date: 11/01/17 Observer: Austin Davis Location: Jefferson Hospital

Goals:

- Interaction with I.V. pumps
- Interactions with patients and family members
- Patient's reactions to the nurses
- Family member's reactions to the nurses
- Sounds
- Sights
- Amount of hand cleaning
- Amount of gowns put on
- Floor plan drawing
- Speech recognition ability

Time	Notes
8:00 AM	• Not very many people on the floor • Nurses and doctors are coming onto the floor • Patients are awake and are watching TV or sleeping, some are sitting up • Some of the empty rooms from yesterday are now occupied • Nurses talk with each other about patient treatment • A nurse puts on PPE gown to go into a room
:02	• A cleaning staff comes onto the ICU floor
:05	• Doctors review patients' charts • **** Sounds - Beeps, ventilators, and people talking **** • A nurse washing hands before entering a room
:10	• PA system, "weekly test of code blue system" • A nurse puts on a PPE gown to go into a room • A paper towel is on the floor in front of a patient's room
:15	• Hospital staff brings breakfast to patients • Washes hands and put on a PPE gown • A staff member restocks floor supplies
:20	• A nurse puts scrubs into a hazard bag because a patient splashed "fluids" all over the nurse

Time	Notes
8:25 AM	• Some patient's rooms have the lights turned off but they are awake • Some patients have the lights on
:30	• A vital alarm goes off • Nurses at their stations look at the displays mounted on the walls
:35	• Sights: crash carts are in the corner, mobile computers are along the walls • A beep went off

:40	• Rounds start
	• A nurse explained to me the types of beeps
	  • Nurses know what each beep means
	  • How about the patients?
	• Loud beeps are urgent
	• Low beeps mean that the nurse has a few minutes to respond
	  • **As described to me "Pavlov's Dogs"**
	• A doctor asked me what I am taking notes of

:50	• **"Conversation breakdown with Medical ICU Nurse Manager** • In a critical care environment speech recognition is not productive because of the number of pumps a patient might have and how to voice operate each individual pump. As well as, in certain situations, like a crash where everyone is talking very loudly and having to make adjustments to the medical devices very quickly. On top of a situation like this there are constant alarms going off and doctors and nurses talking to each other and to patients. • However, voice recognition might be better suited for general rooms where there is less need for dependence on I.V. pumps
9:00 AM	• A patient thinks that I am a nurse and asked me for help • I had to find a nurse and the patient needed help opening their food
:10	• A doctor stares at me • People think I am monitoring their hand washing skills
:15	• **** Sound - a steady sound of beeps and ventilators, doctors and nurses talking ****
:20	• The "main" doctor for rounds explains what sepsis is to the other doctors • "Sepsis: A life threatening blood infection"
:25	• Most of the patient's I.V. pumps are already set up because they have been here for a while, so the amount of interactions is limited
:35	• A nurse restocks the PPE gowns in the carts outside of each patient's rooms • The cleaning staff cleans the rooms and the hall • A nurse puts on a gown to go into a patient's room

Time	Notes
9:45	• A nurse talks about supplies • Doctors are still doing rounds • A physical therapist and an occupational therapist help a patient

:50	• The "Right" side of the floor has less patients
	  • More quiet
	  • Less beeps, just the sound of a ventilator

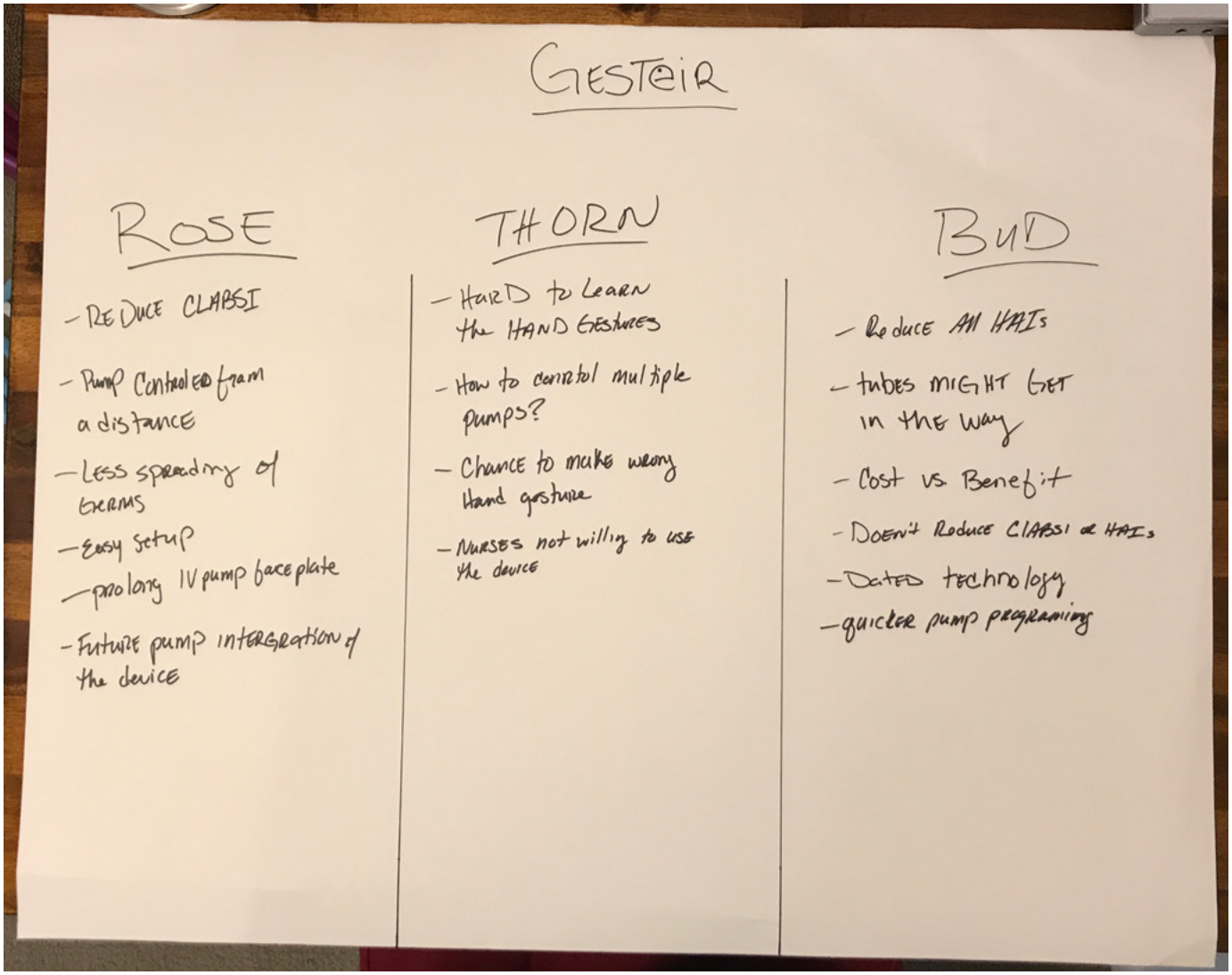
:55	• A few beeps are going off
10:00 AM	• Multiple beeps are going off • A loud beep is now going off • A family member visits a patient and puts on a PPE gown
:05	• **** A low soft beep was going off **** • In front of the patient's room the overhead light was flashing
:15	• A family member visits a patient • A nurse paints a patient's fingernails and talks to the patient
:20	• The white light is for the nurse call button • A loud beep goes off
:25	• A loud constant beep has been going off • The patient is covering their ears

:30	• Beeping is still going off
	  • I.V. pump was the cause
	  • The nurse hits "Run/Stop" then "Okay"
	  • The nurse wasn't sure exactly as to what the buttons said
	  • **Muscle memory?**
	  • **** How will this work with remembering hand gestures? ****

:35	• A hospital staff member gets patient's lunch orders
:45	• A nurse joins the doctors on rounds because they are talking about the nurse's patient • A family member visits a patient
:50	• A nurse answers a doctor's question about a patient • A patient calls out vocally for a nurse • The nurse comes to the patient's door to help him

Time	Notes
11 : 00 AM	• Patients are lying in bed, either sleeping or watching TV. A few patients are sitting up • Two nurses talk about a patient and put on a PPE gowns to enter a patient's room • The TV displays are touch screen - making them not TVs but just display screens • **** Patients call out for nurses rather than use call button ****
: 05	• Nurses at station have a casual conversation • A beep is going off
: 10	• A beep started out slow but speed up • A nurse call goes off • White light also goes off
: 20	• Nurses at station talk about technology and how they are not millennials
: 25	• Hallway displays are Phillips
: 30	• A nurse puts on a PPE gown to enter a patient's room • A beep is going off • End of observation

Rose, Thorn, Bud



APPENDIX B

LINKS

Aircraft Signals NATOPS Manual,
NAVAIR 00-80T-113.

- http://www.navybmr.com/study%20material/NAVAIR_113.pdf

IHE Patient Care Device (PCD) Technical Framework Volume 2 10 IHE PCD TF-2

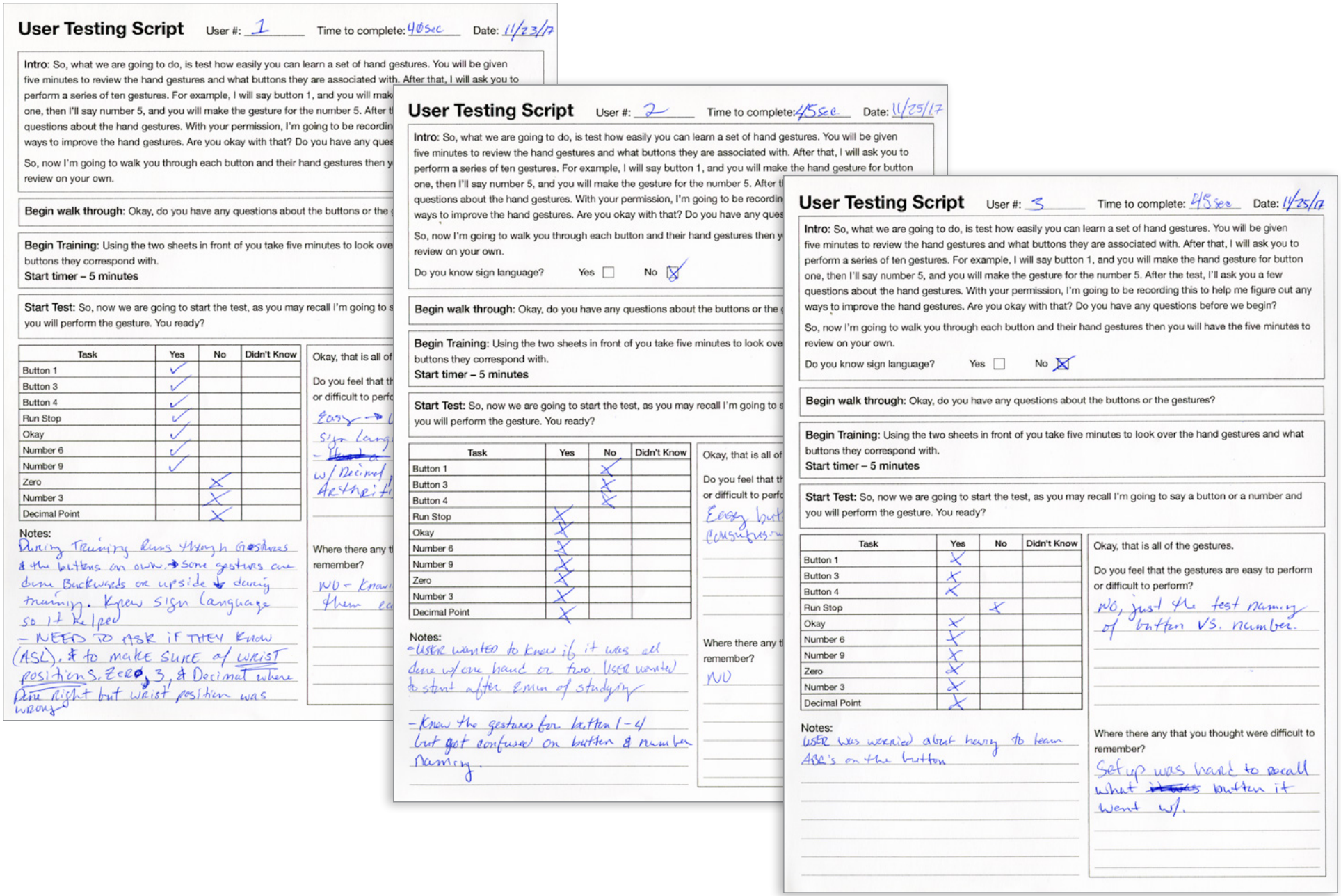
- https://www.ihe.net/uploadedFiles/Documents/PCD/IHE_PCD_TF_Vol2.pdf

FDA, CDRH, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" Guidance for Industry and Food and Drug

- https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm348890.pdf

APPENDIX C

USER TESTING EVALUATION SHEETS



User Testing Script User #: 1 Time to complete: 40sec Date: 11/23/17

Intro: So, what we are going to do, is test how easily you can learn a set of hand gestures. You will be given five minutes to review the hand gestures and what buttons they are associated with. After that, I will ask you to perform a series of ten gestures. For example, I will say button 1, and you will mak one, then I'll say number 5, and you will make the gesture for the number 5. After t questions about the hand gestures. With your permission, I'm going to be recordin ways to improve the hand gestures. Are you okay with that? Do you have any ques

So, now I'm going to walk you through each button and their hand gestures then y review on your own.

Begin walk through: Okay, do you have any questions about the buttons or the

Begin Training: Using the two sheets in front of you take five minutes to look ove buttons they correspond with.
Start timer – 5 minutes

Start Test: So, now we are going to start the test, as you may recall I'm going to s you will perform the gesture. You ready?

Task	Yes	No	Didn't Know
Button 1	✓		
Button 3	✓		
Button 4	✓		
Run Stop	✓		
Okay	✓		
Number 6	✓		
Number 9	✓		
Zero		X	
Number 3		X	
Decimal Point		X	

Notes:
During Training Runs through Gestures & the buttons on own. → some gestures can done Backwards or upside ↓ during training. Knew sign language so it helped
- NEED TO ASK IF THEY KNOW (ASL), & to make sure of WRIST positions, Zero, 3, & Decimal where done right but wrist position was wrong

Okay, that is all of

Do you feel that th or difficult to perfo

Easy → C
Sign Langu
- Thumb a
w/ Decimal
Arthritis

Where there any t remember?

NO - Know them ea

User Testing Script User #: 2 Time to complete: 45sec Date: 11/25/17

Intro: So, what we are going to do, is test how easily you can learn a set of hand gestures. You will be given five minutes to review the hand gestures and what buttons they are associated with. After that, I will ask you to perform a series of ten gestures. For example, I will say button 1, and you will make the hand gesture for button one, then I'll say number 5, and you will make the gesture for the number 5. After t questions about the hand gestures. With your permission, I'm going to be recordin ways to improve the hand gestures. Are you okay with that? Do you have any ques

So, now I'm going to walk you through each button and their hand gestures then y review on your own.

Do you know sign language? Yes ☐ No ☒

Begin walk through: Okay, do you have any questions about the buttons or the

Begin Training: Using the two sheets in front of you take five minutes to look ove buttons they correspond with.
Start timer – 5 minutes

Start Test: So, now we are going to start the test, as you may recall I'm going to s you will perform the gesture. You ready?

Task	Yes	No	Didn't Know
Button 1		X	
Button 3		X	
Button 4		X	
Run Stop	X		
Okay	X		
Number 6	X		
Number 9	X		
Zero	X		
Number 3	X		
Decimal Point	X		

Notes:
- USER wanted to know if it was all done w/ one hand or two. USER wanted to start after 5min of studying
- Know the gestures for button 1-4 but got confused on button & number Naming.

Okay, that is all of

Do you feel that th or difficult to perfo

Easy but
Consfusing

Where there any t remember?

NO

User Testing Script User #: 3 Time to complete: 45sec Date: 11/25/17

Intro: So, what we are going to do, is test how easily you can learn a set of hand gestures. You will be given five minutes to review the hand gestures and what buttons they are associated with. After that, I will ask you to perform a series of ten gestures. For example, I will say button 1, and you will make the hand gesture for button one, then I'll say number 5, and you will make the gesture for the number 5. After the test, I'll ask you a few questions about the hand gestures. With your permission, I'm going to be recording this to help me figure out any ways to improve the hand gestures. Are you okay with that? Do you have any questions before we begin?

So, now I'm going to walk you through each button and their hand gestures then you will have the five minutes to review on your own.

Do you know sign language? Yes ☐ No ☒

Begin walk through: Okay, do you have any questions about the buttons or the gestures?

Begin Training: Using the two sheets in front of you take five minutes to look over the hand gestures and what buttons they correspond with.
Start timer – 5 minutes

Start Test: So, now we are going to start the test, as you may recall I'm going to say a button or a number and you will perform the gesture. You ready?

Task	Yes	No	Didn't Know
Button 1	X		
Button 3	X		
Button 4	X		
Run Stop		X	
Okay	X		
Number 6	X		
Number 9	X		
Zero	X		
Number 3	X		
Decimal Point	X		

Notes:
USER was worried about having to learn ASL's on the button

Okay, that is all of the gestures.

Do you feel that the gestures are easy to perform or difficult to perform?

NO, just the test naming of button VS. number.

Where there any that you thought were difficult to remember?

Set up was hard to recall what ~~button~~ button it went w/.

User Testing Script

User #: 4 Time to complete: 42sec Date: 11/25/17

Intro: So, what we are going to do, is test how easily you can learn a set of hand gestures. You will be given five minutes to review the hand gestures and what buttons they are associated with. After that, I will ask you to perform a series of ten gestures. For example, I will say button 1, and you will mak… one, then I'll say number 5, and you will make the gesture for the number 5. After t… questions about the hand gestures. With your permission, I'm going to be recordin… ways to improve the hand gestures. Are you okay with that? Do you have any ques…

So, now I'm going to walk you through each button and their hand gestures then y… review on your own.

Do you know sign language? Yes ☐ No ☒

Begin walk through: Okay, do you have any questions about the buttons or the …

Begin Training: Using the two sheets in front of you take five minutes to look ove… buttons they correspond with.
Start timer – 5 minutes

Start Test: So, now we are going to start the test, as you may recall I'm going to s… you will perform the gesture. You ready?

Task	Yes	No	Didn't Know
Button 1	✓		
Button 3	✓		
Button 4	✓		
Run Stop	✓		
Okay	✓		
Number 6	✓		
Number 9	✓		
Zero	✓		
Number 3		✓	
Decimal Point	✓		

Okay, that is all of …

Do you feel that th… or difficult to perfo…

Easy → … very str…

Where there any t… remember?

NO, but … them m… a few sec…

Notes:
- USER felt he was ready after a min of studying.
- three was ~~done~~ Right number of fingers but done in a cultural way.

User Testing Script

User #: 5 Time to complete: 54 secs Date: 11/25/17

Intro: So, what we are going to do, is test how easily you can learn a set of hand gestures. You will be given five minutes to review the hand gestures and what buttons they are associated with. After that, I will ask you to perform a series of ten gestures. For example, I will say button 1, and you will make the hand gesture for button one, then I'll say number 5, and you will make the gesture for the number 5. After the test, I'll ask you a few questions about the hand gestures. With your permission, I'm going to be recording this to help me figure out any ways to improve the hand gestures. Are you okay with that? Do you have any questions before we begin?

So, now I'm going to walk you through each button and their hand gestures then you will have the five minutes to review on your own.

Do you know sign language? Yes ☐ No ☒

Begin walk through: Okay, do you have any questions about the buttons or the gestures?

Begin Training: Using the two sheets in front of you take five minutes to look over the hand gestures and what buttons they correspond with.
Start timer – 5 minutes

Start Test: So, now we are going to start the test, as you may recall I'm going to say a button or a number and you will perform the gesture. You ready?

Task	Yes	No	Didn't Know
Button 1	✓		
Button 3	✓		
Button 4	✓		
Run Stop	✓		
Okay	✓		
Number 6	✓		
Number 9	✓		
Zero	✓		
Number 3	✓		
Decimal Point	✓		

Okay, that is all of the gestures.

Do you feel that the gestures are easy to perform or difficult to perform?

Easy, USER found button #2 was a little ~~odd~~ odd to perform due to stretching out pinky.

Where there any that you thought were difficult to remember?

No, just mapping @ hand to @ friend. & Since the bottom buttons were new to USER having to recall them took a few seconds.

Notes:
USER was Left handed & had to reverse the gestures in his mind because the illustrations were @ mirrored.