THE ARM - ENHANCING PATIENT TRAINING SIMULATORS THROUGH MODULAR PRODUCT ARCHITECTURE

Mechanical Engineering Master's Thesis

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Abstract

The modular function deployment process (MFD) is one methodology used to develop a modular product architecture which distills complex monolithic systems down into manageable modules that utilize common interfaces to build up products. These modules can then be individually managed, decreasing a company's time to market and cost while increasing the sustainability and customer satisfaction for the modular product.

The main objective of this thesis is providing Laerdal Medical AS with a feasibility study into how a modular product architecture could be used to elevate their products. To do this, a modular product architecture was designed, implemented, and tested for the arm of a theorized future full body medical patient training solution for Laerdal Medical.

The proposed modular product architecture was realized in the design and prototyping of six configurable product baselines that cover the market segments and customer values provided by product managers at Laerdal Medical AS. Internal user testing performed at Laerdal Medical AS showed an unwavering satisfaction of the users, indicating the proposed modular architecture would perform well in the target markets. Quantitative analysis done on a module from the proposed modular product architecture showed a 68.77% reduction in CO_2 emissions and a 74.15% reduction in cost over the lifetime of the product when compared to a full body medical training simulator currently sold by Laerdal Medical AS.

These results indicate that the proposed modular product architecture, if implemented in future Laerdal Medical AS products could significantly help in achieving the sustainability and lifesaving commitments made by the company.

Dedication

To my late brother Marc Shapiro, a firefighter, EMT, and user of Laerdal Medical training simulators. His unwavering commitment to helping save strangers lives inspires me daily. It is my hope that my work with Laerdal Medical AS can serve as a legacy to his commitment to saving lives.

Preface

This thesis report was written to fulfill the June 2024 graduation requirements for a Master of Science in Structural and Mechanical Engineering, Mechanical Engineering Specialization from the University of Stavanger. For this thesis, an opportunity was taken to deep dive into modular product architecture, a topic not taught in the master's coursework at UiS. Product development is something I am familiar with having have worked an a mechanical product developer for the past year, but modularity and product architecture in general were topics I was only recently exposed to. With the support of Laerdal Medical AS, I was able to research and develop my own modular product architecture with the theorized product being an arm of a medical patient training simulator. It should be noted that while this project did make great progress in developing and implementing a modular product architecture on a theoretical project. The progress made only reached a proof-of-concept level as this project was done alone over a course of four months. The benefits to modularity identified by the results of this project align with those seen in other product industries signaling that the proposed modular product architecture was merit to its design. It is theorized that, given the time and resources, this proposed modular product architecture could be matured into a completed product for use by Laerdal Medical AS.

Acknowledgement

I would first like to acknowledge the support given to me by Laerdal Medical AS, who hired me as a product development intern and now a mechanical product developer, which has enabled me to extend my stay in Norway past my master's degree. Without their support of my thesis idea, I would not have been able to follow this topic to the extent that I have for this thesis. I am very grateful for the opportunity Laerdal Medical AS has given me and hope they are able to gain knowledge from the results presented in this thesis report.

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Thank you Hirpa for seeing the value in my proposed thesis topic and for the invaluable help you provided me when planning my thesis and helping control my scope to a manageable project.

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And lastly, but not least, my parents, Terre Shapiro and Glen Crabtree for putting up with me moving over 7000 km away from my home in Bellingham, WA, USA to Stavanger, Norway to pursue a master's degree in mechanical engineering. Without their support my move to Norway would not have been possible.

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1. Introduction

1.1. Background and Research Aims

Laerdal Medical is a global medical technology company headquartered in Stavanger, Norway. With a goal of saving "…one million more lives. Every year. By 2030."[1]; providing dependable products is essential to this mission. One focus of the substantial Laerdal product portfolio is patient simulation. Currently, Laerdal has four distinct adult patient simulator product families: Resusci Anne, SimMan, Mamma Anne, Nursing Anne, used to meet the market segments of their customers: Emergency Medical Services, Military, Clinical, and Healthcare Education. Each product family has multiple product variants that are used to encompass the entirety of needs within a given market segment. Searching through the product offerings on Laerdal Medical's website [2], there are currently 17 different adult patient manikins and simulators available for immediate purchase. Supporting this large number of products with manufacturing, storage, shipping, and maintenance is extremely resource intensive. In addition, given the integral product architecture used to design these products, there are very few carryover parts that exist between each product. Even within the same product families, most parts are exclusive to a single product variant. With market competition strengthening each year, Laerdal can no longer rely on being a 'whale in the pond' of the patient training simulator market to keep their market stance. Adopting a modular product architecture for Laerdal Medical's future training solutions presents a promising opportunity to improve the product portfolio's efficiency. This thesis explores how a modular product architecture can be developed for a complex, interconnected product to improve a company's product offerings. This research aims to demonstrate how modular design principles can streamline product development, increase flexibility in product configurations, and lead to more economical and sustainable customer centered product offerings.

1.1.1. Intended Beneficiaries

This project is based on the view that a product developed using a modular product architecture will have a positive impact on the product's end user. However, the end user is not the intended beneficiary of this research. With successful implementation, a modular product architecture has the ability to enhance efficiency, reduce complexity, and improve sustainability for the development and maintenance of training solutions. The following groups have been identified as the intended beneficiaries of a modular product approach:

- Product Development
  - Engineers and Designers
    - By shifting focus from developing entire systems to developing modules, designers are able to streamline the design process, especially for product variants. Instead of redesigning the entire system, variants of modules with standardized interfaces can be implemented to drive product variants. [3], [4]
  - Product Managers
    - By decreasing the resources required for product variants, product managers are better able to meet a wider set of customer needs without having to compromise resource allocation. [3], [4]
- Supply Chain and Procurement
  - Sourcing Managers
    - By increasing the number of common parts between product variants and product families, sourcing departments are able to decrease the number of

external suppliers they rely on. This helps create a more stable supply chain. [4]
    - Inventory Managers
        - Another benefit of increasing the number of common parts is a reduction in the quantity of unique parts that must be maintained in inventory. This simplifies the work for inventory managers which can lead to a decrease in lead-time for completing customer orders. [4], [5]
- Strategies and Operation Management
    - Business Executives
        - From a top level business standpoint, modularity can allow a business to quickly adapt to changes in market needs or technology advancements. The ability to update modules without redesigning the entire product reduces development costs and time to market, both big benefits to a company's bottom line. [3], [4]
- Sales and Marketing
    - Sales Representatives
        - Modular design allows for increased customization for the customer, this can be used as a marketing tactic to highlight the individuality that the product can provide to the customer. [4]
- Manufacturing and Assembly
    - Production Line Workers
        - A reduction in unique parts increases efficiency for part manufacturing and product assembly. This increased efficiency can result in improvements to first pass yield and reduced assembly and manufacturing costs. [4], [5]
- After-Sales Support and Service
    - Field Service Engineers
        - A modular product decreases the complexity and time required for product repair as modules can be interchanged and repaired without affecting other parts of the product. This reduces product downtime for the customer. [6]

1.1.2. Market Segments

The term market segment has different meanings depending on who you ask. For the purpose of this report, a market segment will be defined as a sector of customers who operate in the same industry. Using information provided by product managers and other stakeholders within Laerdal Medical, the following list was created for the purpose of this thesis. This list aligns with the market segments identified by MoSAic, the internal team working on modularizing the product architecture for future medical training manikins and simulators [7].

- Emergency Medical Services – Basic
    - Emergency Medical Responder (EMR): Proficient with administering basic lifesaving medical attention, such as CPR. Responsible for stabilization of patients while waiting for additional medical personnel to arrive. [7], [8], [9]
    - Emergency Medical Technician (EMT): Similar to EMR, technicians have the minimum qualification needed to transport a patient in an ambulance along with CPR-D certification. [7], [8], [9]
- Emergency Medical Services – Intermediate
    - Advanced Emergency Medical Technician (AEMT): AEMTs have EMT certification with additional certification to administer medications, fluids and operate medical equipment

in an ambulance. They are proficient with IV and IO medication administration, CPR-D, and patient stabilization. [7], [9]

- Emergency Medical Services – Advanced
    - Paramedic: Proficient with advanced pre-hospital care. Paramedic's training includes a focus on advanced areas of medicine like anatomy, pharmacology, and cardiology. Advanced knowledge and experience with operation of medical equipment and administration of fluids and medication through IV and IO. [7], [9]
- Healthcare Education – Basic
    - Certified nursing assistant (CNA): CNAs are the main line of communication between patients and the nurses. CNAs typically take care of the patients' hygiene, feeding, and mobility needs. [7], [10]
- Healthcare Education – Intermediate
    - Licensed Practical Nurse (LPN): LPNs certified to perform basic medical procedures such as taking blood pressure, inserting catheters, changing bandages, and starting IVs. [7], [10]
    - Registered Nurses (RN): RNs are certified to preform all functions of an LPN in addition to operation of medical equipment and administration of medicine. [7], [10]
- Healthcare Education – Advanced
    - Registered Nurses (RN): Advanced RNs specialize in areas such as pediatric, emergency, or military which could require advanced healthcare skills. [7], [10]
    - Resident doctor: Residents are licensed physicians who are in the process of receiving specialized training in a particular medical field. They directly care for patients under the supervision of senior physicians. Their duties are comprehensive and include diagnosing and treating illnesses, performing medical procedures, and managing patient care. [7], [11]
- Clinical – Emergency Room Personnel
    - Focus on patient triage, acute care, and stabilization to a point where the patient is stable enough to be transferred to a different team or for release. [7], [12]
- Clinical – Intensive Care Unit Personnel
    - Focused care; continuous monitoring with importance on detail, accuracy, and frequency of information available using medical examination equipment. Additional proficiencies include: Invasive procedures, weening patients off a ventilator, neurological assessment, pathological assessment/tests, responding to sudden or slow changes, and monitoring of medication levels (weening on/off). More technical decision-making based on monitoring trends. [7], [12]
- Military – Combat Medics
    - In-field triage, first aid to EMT level, multiple casualties, stretch resources due to lots of patients. Training outside, moving the patient. Focus on trauma, specifically with bleeding and breathing. Inclusion of nuclear, biological, chemical (NBC) training. Special environment use - helicopter, vehicles, etc. [7], [13]
- Military – Military Hospital Personnel
    - Confirming diagnosis of combat medics. Military hospital personnel preform acute care & stabilization of the patient to a point where they are stable enough to maneuver and move patient on to the relevant team required for next point of care - importance on transition between teams (hand-over training). Special environment use - helicopter, vehicles, etc. [7], [13]

1.1.3. Customer Values

To encompass the large, international group of customers using Laerdal manikins and simulators customer values have been meticulously drafted by product managers and the MoSAic team at Laerdal Medical through analysis of years of customer interviews and market trends. These core values act as the foundation for the development of future products. By enabling the development team to rate initial designs against the customer values, they are better able to align their designs with customer values from the beginning of the development process. Customer values form the foundation upon which this thesis is built. Incorporating these values into a modular product architecture gives voice to customer needs and enhances the utility and desirability when choosing Laerdal Medical products. Listed below is a list of identified customer values and description of each. These values were identified by the MoSAic team and were adapted to fit the scope of this thesis [14].

- Easy to learn how to use the product
    - Clear, concise, and easily accessible instructions for use. This can include quick-start guides, labeled diagrams, or instructional videos that demonstrate basic operations. [14]
    - Functions and controls should be simplified to remove unnecessary steps or complications that could confuse new users. [14]
- Easy to set up (preparation)
    - Setting up the product for the first time (out of the box) and for each session after this. [14]
- Accessible consumables
    - Ensure the required consumables do not prohibit the use of any feature due to cost or usability. [14]
- Ease of maintenance
    - The product should be easy to maintain. Thus different levels of complexity for the day-to-day user, sim-tech, service-tech should be considered when designing functions. [14]
- Easy management of fluids
    - Easy filling, emptying and maintenance of IV sites, IO sites, and blood glucose. [14]
- Easy of running/operating/controlling training
    - Minimize the time commitments for simulation operators/facilitators. [14]
    - Cleary written manuals, instructions, and in-person training. [14]
- Easy to choose the product that I need
    - Clear product documentation ensures customers purchase the correct product for their needs. [14]
- Easy to clean
    - After use, it should be easy to clean surfaces, remove liquids from the system, remove marks, patches etc. to prevent damage to products. [14]
- Easy to understand product disposal
    - Understand what can be recycled and what must go to a landfill. [14]
- Training of basic patient related skills
    - Clear instructions regarding how to check the vital signs of the patient and assess the level of consciousness, positioning of the patient. [14]
- Effective trauma training
    - IO Access; capability of simulating different trauma scenarios, e.g. gunshot wound, amputated limb, severe burns etc. [14]
- Realism in human-like product

    - The product should resemble real human anatomy to enable deeper immersion. To examine the patient properly, full exposure of the body may be necessary. Touch and feel should be realistic. [14]
- Easy to customize
    - Easy to customize scenarios, symptom states, skill training features. [14]
- Training of advanced patient related skills
    - IV access, IO access, wound care, drug administration. [14]
- Use with real equipment
    - The product should allow the use of users own Pulse Oximeter/Glucometer/ Stethoscope. [14]
- Use in special environments
    - Ability to use manikin in special environments (i.e. in a helicopter, airplanes, ambulance, outdoors, extreme humidity areas, extreme temperature areas, etc.) without the need for delicate handling by the user. [14]
- High level of functional fidelity
    - Realism in functions. Product instructions should clarify that procedures which are performed in one specific way on the product and in several ways on a real patient may lead to negative learning. More crucially, a way of performing/simulating a procedure on a product can pose a danger if done the same way on a real patient (e.g. simulated injections with air) [14]
- Long lasting product
    - Durable and robust design for long life of the product for its intended use. [14]

1.1.4. Patient Training Manikins and Simulators

Laerdal's medical patient training solutions Laerdal Medical can be broadly categorized as either a manikin or simulator. The contrast between them is based on the complexity of functions and level of interaction they offer, specifically when it comes to training tasks versus scenarios.

- Manikins
    - Tasks: Manikins (Figure 1) are designed for training on specific tasks or medical procedures. This could include, but is not limited to CPR or airway management training.
    - Interaction: Manikins are typically not sensorized and therefore do not provide feedback on the task. However, some higher end manikins are sensorized and provide feedback on how the task was performed.
    - Use Case: Manikins are used for mastery of a basic skill with the focus on repetition of a task.

Figure 1 – Resusci Anne QCPR Manikin. From: Laerdal.com [15]

- Simulators
    - Scenarios: Simulators (Figure 2 – SimMan Critical Care SimulatorFigure 2) are designed to perform dynamic scenarios that mimic real-life medical situations. They have the capacity to change and adapt over time based on user interactions.

- Interaction: Simulators are highly sensorized and can provide immediate feedback. They can also be programmed for various medical scenarios. This provides the user with a more immersive learning experience.
- Use Case: Simulators are used for advanced medical training where critical thinking, quick decision making and experience with medical procedures is required and developed.

Figure 2 – SimMan Critical Care Simulator. From: Laerdal.com [16]

Laerdal manikins are less expensive than simulators, typically under $25,000 USD and sell in higher volumes with some models selling up to 30,000/year. In contrast, simulators are more expensive, up to $150,000 USD and sell in lower volumes, around 1,000/year [17].

1.2. Scope

The primary objective of this thesis is to explore the benefits and drawbacks of using a modular product architecture to develop future manikins and simulators within Laerdal Medical's product portfolio. By focusing on the arm – a part of a full body product that is dense of functions that are not reliant on the rest of the body – this thesis aims to provide the internal product architecture team at Laerdal with a functional feasibility study. The intention is that insight gained on terms of both benefits and drawbacks, will inform the team as they work towards development of a modular product architecture addressing complete patient training solutions. This analysis aligns with Laerdal Medical's strategic vision where enhancing customer satisfaction, streamlining product development, decreasing manufacturing cost, and increasing sustainability are crucial for success.

The scope of this thesis includes the following specific aims:

- Develop a Modular Product Architecture
  - Establish a modular product architecture for the arms as part of full body patient training solutions. The product architecture will incorporate both manikin and simulators into the product baselines. This product architecture will be designed to highlight how modules can be used to reduce the need for standalone product variants by increasing the number of product configurations offered using common, interchangeable parts.
- Provide a Proof of Concept Product Design Model
  - Design the modular arm using existing parts from current adult Laerdal manikins and simulators, alongside modified components and novel parts as needed. The design process will utilize a selection criteria based on compatibility, performance, and integration to ensure the design meets the requirements defined in the modular product architecture.
- Develop a Physical and Digital Prototype to Test Product Configurations
  - Build a physical prototype that will be used to demonstrate the configuration from product baselines. This prototype will serve as a proof-of-concept for the idea that end-users can upgrade or replace modules to enhance performance or simplify repair the modular arm configuration. Simultaneously, digital prototypes will be

constructed using CAD software to ensure that all product baselines can be assembled using the same arm frame. These prototypes will be judged against the arm of a SimMan 3G PLUS to provide quantifiable evidence to support the theory that a modular product architecture can reduce the number of standalone variants through increased use of common parts.

- Focus on Adult Patient Training Solutions
    - This project will focus on creating a modular product architecture for adult patient training solutions. While the same product architecture principles can likely be adapted for pediatric and baby training solutions, the specialized functionalities associated with these age groups presents a broader scope than can be accommodated within the project's timeframe.

1.3. Research Questions

The research questions have been composed to guide the exploration on the feasibility and implications of adopting a modular product architecture for Laerdal Medical's patient training solutions, with the specific focus for this thesis being on the arm of a full-size adult manikin/simulator. These questions are designed to ensure that the relevant benefits – and potential pitfalls – of the modular product architecture can be directly compared with Laerdal Medical's strategic values of increased customer satisfaction, shorter development time, lower manufacturing cost, and increased sustainability.

- Feasibility of Modular Product Architecture
    - Do the benefits of modular product architecture outweigh the integration complexity of a feature dense product like the arm of an adult Laerdal manikin/simulator?
    - Can a modular product architecture meet the diverse requirements of Laerdal's market segments while maintaining the benefits of flexible configuration, reduced development time, reduced manufacturing cost, and increased sustainability?
- Sustainability Assessment
    - Do products developed using a modular product architecture have a lower level of CO2 emission over their lifecycle than those developed using an integral product architecture?
- Cost Analysis
    - Are products developed using a modular product architecture more cost efficient with respect to production, assembly, and maintenance when compared to those developed with an integral product architecture?
- Design and Prototyping
    - How can physical and digital prototyping be used to iterate the modular product architecture in the early stages of product design?
- Customer Satisfaction and Market Response
    - What level of configuration of a product baseline enhances the satisfaction of a single customer?
    - How does use of a modular product architecture affect Laerdal's ability to respond to market changes?
- Scalability
    - To what extent does a modular product architecture allow scalability across different product lines and sizes, including pediatric and baby?

Through the investigation of these research questions, the thesis aims to provide a detailed understanding of the potential impact a modular product architecture will have on the product

lifecycle of Laerdal Medical's patient training solutions. An overall purpose of this thesis is to provide Laerdal Medical with a feasibility study that can be used in part to make informed strategic decisions based on the implementation of a modular product architecture.

1.4. Limitations

All projects are – to an extent – controlled by constraints, this thesis is no different. In acknowledging these constraints, it helps provide context to the thesis scope and research questions chosen. It has been determined that this thesis has the following limitations:

- Time Constraints
  - The timeframe for this thesis allows for a focus on the module interfaces and spatial configurations of the modular arm components. As a result, the research does not extend to the development of a fully functional prototype as that would require a longer timeframe.
- Scope of the Prototypes
  - The limited scope of the thesis means that the product architecture, design, and prototype focuses on the adult manikin/simulator. These findings will act as a basis for future expansion into different age demographics such as pediatric and neonatal.
- Resource Availability
  - This study is dependent on the availability of certain resources. Limitations may constrain the depth of prototype testing which could limit final results.
- Technical Complexity
  - The development of a medical training solution requires a multidisciplinary team of industrial designers, mechanical engineers, electrical engineers, and software engineers. For this project, the design is largely limited to mechanical engineering as the competency for industrial design, electrical and software engineering limits the ability to design a fully functional manikin/simulator arm.
- Market Dynamics
  - While the study hopes to estimate market response through physical prototype testing and customer feedback on the modular product baselines and available customization. The implementation of this will likely be limited to in-house testing with product managers.
- Sustainability Assessment
  - The sustainability assessment will be limited to analysis of materials within the product. A comprehensive life cycle analysis exceeds the scope of this project.
- Cost Analysis
  - The cost analysis will be limited to the reuse of existing parts and estimation of the cost of novel parts. A comprehensive cost analysis, especially of cost associated with shipping and storage exceeds the scope of this project.
- User Interaction
  - The thesis will not include a detailed study of the user interaction with the modular arm prototype. This will limit the data and feedback associated with usability and functionality of the design. A detailed study of user interaction exceeds the scope of this project.

These limitations should not be seen as a reduction in research quality, but rather a way to define boundaries to what the project will and will not explore. Understanding these limitations helps focus the research to ensure that proper depth is given to subjects inside the boundaries. These limitations also highlight areas of future research that could be used to build on the results of this study.

1.5. Previous and Concurrent Work

Prior to starting this Masters' Thesis, Laerdal Medical had already started exploring how a transition to a modular product architecture would enhance their future product portfolio. Working with Modular Management (Swedish Modularity Consultancy Firm), Laerdal has decided to utilize the Modular Function Deployment (MFD) process to create the modular product architecture.

The collaboration between Laerdal Medical and Modular Management has been crucial for laying the foundation for the transition to a modular product architecture. The following are a list of efforts that are being done within Laerdal separate from the research conducted in this thesis.

- Modular Management Workshops
    - In collaboration with Modular Management, Laerdal product managers have been part of specialized workshops where the existing product portfolio has been analyzed for areas of improvement. These workshops have also been targeted at determining the customer values and aimed market segments to lay the groundwork for the MFD process.
- MoSAic team's work
    - From these workshops with Modular Management, a dedicated team tasked with creating a modular product architecture following the MFD process has been formed. This team is currently working through the MFD process for a full sized adult manikin, concurrent, but independent of this thesis project.

2. Theoretical Framework

2.1. Medical Terminology

2.1.1. Arm Anatomy

Skeletal System

The human arm skeleton consists of three main bones:

- Humerus: This bone is located between the shoulder and elbow joints [18]. This bone is important in a clinical setting because it is used for landmark palpation prior to giving muscular injections into the deltoid muscle or intraosseous infusion into the humeral head (top of the humerus bone)
- Radius and Ulna: These two bones are located between the elbow and wrist joints and make up the forearm [18]. The radius bone in located on the thumb side while the ulna is located on the little finger side. With their joint connection at the elbow and wrist, they are able to rotate with one rotational degree of freedom to create forearm pronation and supination [19].

These main bones are connected by joints that allow for movement between them. These joints are constrained to certain degrees of freedom that correlate to the movement of the human arm.

- Shoulder Joint: This joint can be described as a “ball-and-saucer” [20] joint and has three rotational degrees of freedom [19] which enables the full range of motion of the upper arm.
- Elbow Joint: This joint can be modeled as a hinge joint [20] and only has one rotational degree of freedom [19]. This joint connected the humerus bone of the upper arm to the radius and ulna bones of the forearm. In part, the lower area of the elbow joint where it is connected to the radius and ulna allows for the rotation of the forearm [20].
- Wrist Joint: This joint is a condyloid joint [20] which allows the wrist to have two rotational degrees of freedom [19]. This joint connects the bones of the hand to the radius and ulna.

A labeled diagram of these bones and joints can be seen in Figure 3. Specifically the humeral head, radius and ulnar, humerus are relevant to this thesis.

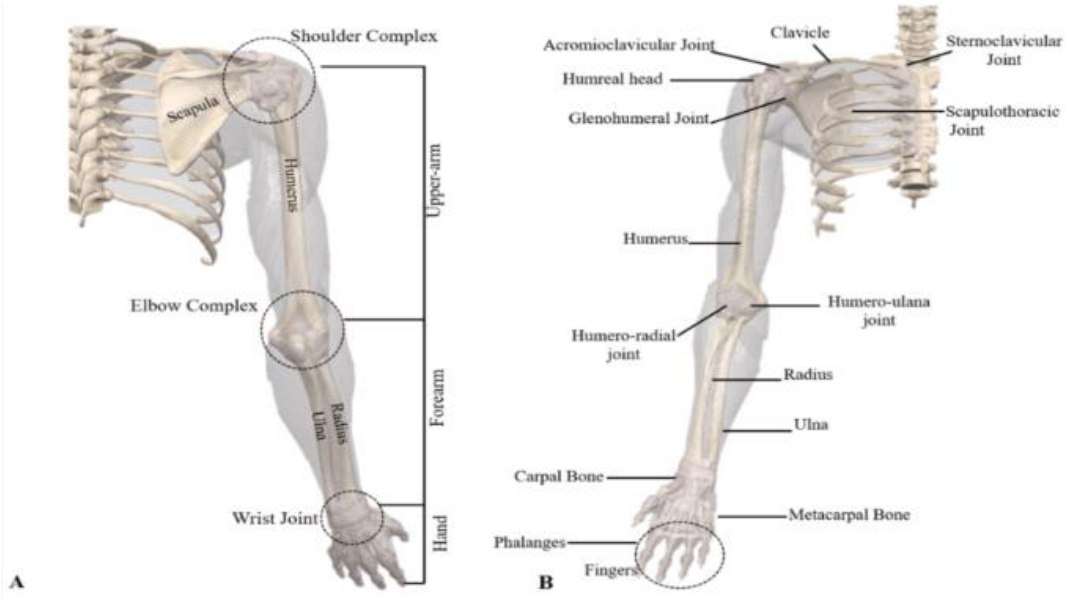


Figure 3 – Diagram of bones and joints in arm. From: A Review on Design of Upper Limb Exoskeletons, Figure 1 [21]

Vascular System

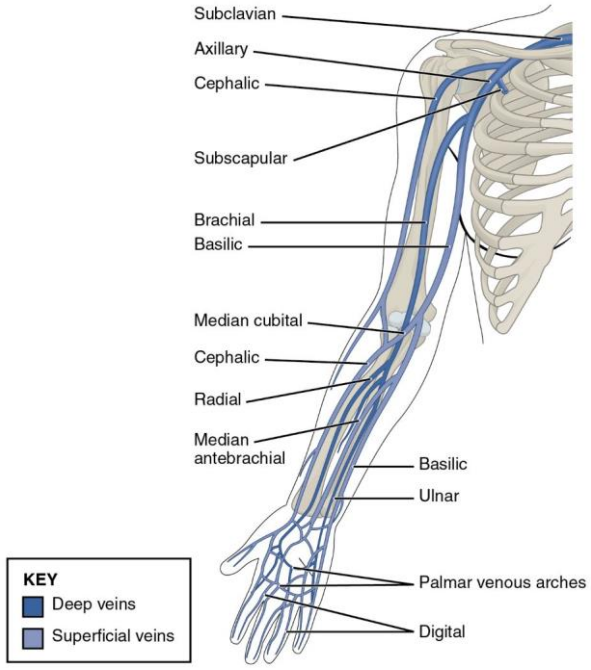


Figure 4 – Labeled Diagram of Arm Vascular System. From: Anatomy and Physiology, Chapter 20.5, Figure 20.38 [23]

The vascular system is a network of veins and arteries that supply blood around the human body [20], [22], [23]. This system contains a large number of veins and arteries. To reduce complexity of this section, only the veins and arteries relevant to this thesis will be discussed. Clinically the brachial and radial arteries are used to measure the pulse in the arm [22]. The radial pulse site is located near the wrist and the brachial pulse site is located near the elbow. Three common areas for intravenous insertion in the arm are the dorsal veins (on top of the hand), cephalic vein (along forearm), and medina cubital (inside of elbow) [24]. A simplified diagram of the arm vascular system can be seen in Figure 4.

Muscular System

The muscular system of the arm is responsible for movement and stability. Without it, the joints could rotate but there would be nothing holding them together or allowing them to hold a specific position [20]. Similar to the vascular system, the muscular system of the arm is a network of many different muscles and tendons. To simplify this, only the muscles specific to intramuscular injection sites will be discussed. On the arm, there is one injection site located in the deltoid muscle [25], [26], the location of this site is shown in Figure 5. The deltoid muscle is located at the top of the shoulder and covers the humeral head and part of the scapula.

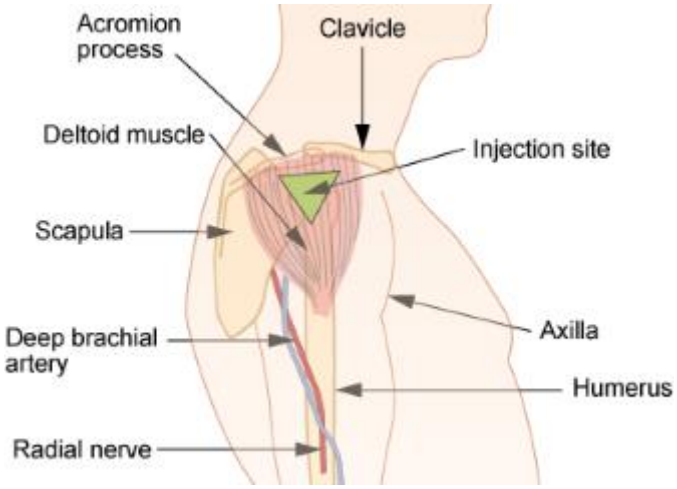


Figure 5 –Diagram of Intramuscular Injection Site in the Arm. From: Clinical Procedures for Safer Patient Care, Chapter 7.4 [26]

2.1.2. Arm Medical Procedures and Symptoms

Intraosseous Infusion (IO)

Intraosseous is a medical procedure only used in emergency and critical care situations. It involves inserting a needle through the bone so fluid can be injected into the bone marrow. This procedure is often preformed when drugs or fluids need to be administer quickly as intraosseous infusion is faster and has a higher first attempt success than venous catheterization [27]. For adults there is one interosseous infusion site in the arm, located at the humeral head behind the deltoid muscle (see Figure 3, Figure 5). This site is advantageous for patients that are experiencing cardiac arrest or shock

as the site is closer to the heart meaning the fluid will circulate the body faster [27], [28]. To perform the procedure, a two part needle is used to pierce the skin, muscle, and bone, either manually or with a power drill. Once the needle is in place, the inner needle is removed and a fluid line can be attached to the needle. A syringe is used to draw blood out of the bone marrow to ensure the needle has puncture the bone (but not gone all the way through the bone). Once correct insertion is confirmed, fluid is injected into the bone marrow, typically in quantities smaller than 60mL for adults [27] for single injections, however larger volumes can be used for continuous infusion.

Intramuscular Injection (IM)

Intramuscular injections are used to administer drugs and vaccines when other methods – such as oral, intravenous, and subcutaneous – should not be used [29]. Certain drugs can be destroyed by the digestive system or cause irritation to the veins or subcutaneous tissue, for this reason intramuscular injections may be required [29].

As seen in Figure 6, the deltoid muscle is the designated location for an intramuscular injection. This muscle has a smaller mass than other intramuscular injection sites and is recommended to be used for injections that are smaller than 1mL [29], [30]. Depending on the age of the patient, different needle lengths are used to ensure the needle fully penetrates both the skin and subcutaneous tissue and into the muscle below. All intramuscular injections are given at a 90° angle to the skin [25] which is shown in Figure 6.

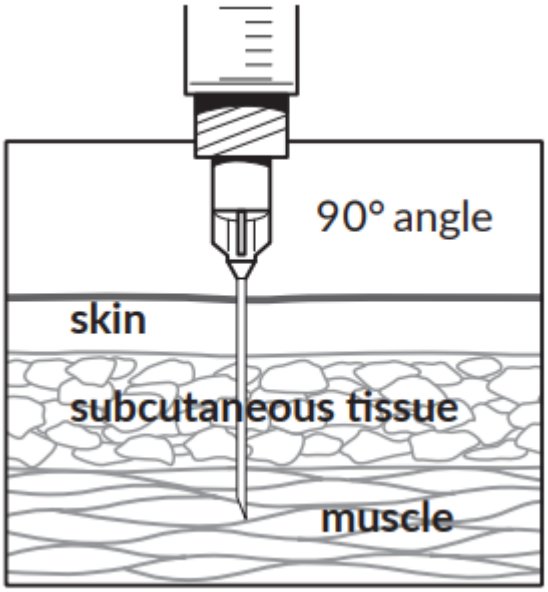


Figure 6 – Diagram of Intramuscular Injection. From: Administering Vaccines: Dose, Route, Site, and Needle Size [30]. Image courtesy of Immunize.org

Intravenous (IV) Injection, Fluids, or Blood Draw

In the arm, there are three common places to IV insertion. These are – as described earlier – the dorsal veins on the top of the hand, the cephalic vein in the side of the arm, and the median cubital on the inside of the elbow [24]. The locations of these veins are shown in Figure 4 above. Clinically, these sites are often used for different things.

Typically, blood is drawn from the median cubital or cephalic veins [31]. Prior to taking the blood sample, a tourniquet should be applied near the IV site and the area should be cleaned properly. After palpating for the vein, the needle should be inserted at an angle of 10 to 30 degrees to the skin. If inserted correctly, there should be blood flashback. If no flashback occurs, the needle should be slowly removed and repositioned. Once the needle is inserted correctly, a vacuum tube should be

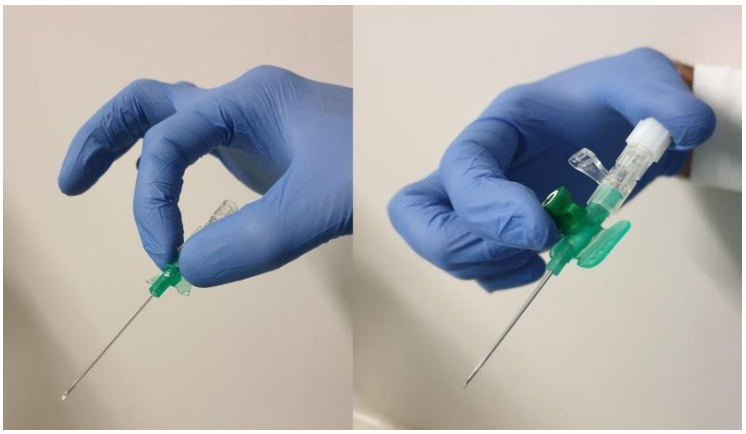


Figure 7– Image of IV catheter prior to insertion. From: Peripheral Line Placement [33]

attached to the end of the needle and tourniquet released. This will allow the blood to flow into the tube. Once collection is completed, the insertion point should be cleaned again and a cotton gauze and tape should be placed over the site [31].

Often in a hospital setting, continued access to a vein is necessary. This procedure which is known as intravenous cannulation inserts an in needle catheter into the vein long term for continued access to the IV site [32]. This is typically done when fluids or drugs are administers by IV or when continued venous blood sampling is required for patients that are saying in the hospital [32], [33]. A IV catheter prior to insertion into a vein can be seen in Figure 7.

Blood Pressure

Blood pressure is an important measurement preformed as part of a vitals assessment done on almost all patients. It can be defined as the force the blood presses on the walls of the arteries as blood flows through your body and consists of two readings, systolic and diastolic, together these values are used to determine if you blood pressure is in high, low, or in the normal range [34]. Blood pressure is measured with units of millimeters of mercury (mmHg) and can be tested in many ways, but three common ways are as described. One way is to manually test the blood pressure using a stethoscope and a manual blood pressure cuff [35], [36]. When measuring blood pressure manually, the stethoscope is used to listen for *Kortokoff sounds* which are used to differentiate between the systolic and diastolic readings of blood pressure. Alternatively, an automatic blood pressure cuff that does not require a stethoscope [35] can be used to non-invasively measure the blood pressure of a patient. For certain patients that require constant blood pressure monitoring, an IV line can be placed in the arm to take constant blood pressure measurements [37].

Cyanosis

Cyanosis is medically used to describe the change of a person's skin color to a blue or purple, usually in the lips and nails, due to low oxygen content in your blood [38]. Cyanosis does not always require emergency medical treatment but it can signify that there is an issue with the patients vascular system, heart, or lungs. Cyanosis can be split into three categories: circumoral, peripheral, and central [38]. Circumoral cyanosis is limited to lips and mouth, this is typically due to cold temperatures and is not often associated with a medical emergency. Peripheral cyanosis is when the hands and/or feet have changed to a blue/purple color, this is also associated with cold temperatures but is more extreme and measures should be taken to warm the affected areas. Central cyanosis does signify a medical emergency and is when other parts of the body aside from the hands and feet are blue/purple. Central cyanosis is associated with serious conditions to the heart and or lungs.

Seizure

Seizures are caused by bursts of electrical activity to the brain that causes the body to lose control of motor function, behavior, feeling, and can result in loss of consciousness. Typically, seizures last between 30 seconds to two minutes. A seizure lasting longer than five minutes is considered a medical emergency [39]. Seizures can be caused by a wide variety of medical conditions such as

stroke, head injury, or infection. In a medical scenario, knowing how to safely manage a patient that is having a seizure is important as seizures alone are not often used to diagnose a condition.

SpO2

The oxygen saturation (SpO2) is used to gauge the amount of oxygen in your blood. It is measured as a percentage with 100% being the maximum amount of oxygen your blood can carry. A pulse oximeter is commonly used to measure a patient's SpO2 level and is usually done non-invasively on the fingertip [40]. Drawing a patients blood can also be used to measure the oxygen content but this method takes longer but is more accurate than using a pulse oximeter which is only accurate to 2-4% [40]. When measuring your SpO2 at home, It is recommended that if your level is below 92% that you see a doctor, and if it is below 88% that you go to an emergency room as this can be related to serious heart or lung problems [40]. Checking your SpO2 level is done as part of a vitals check in a pre-hospital and hospital setting as it can quickly determine if the patient needs supplemental oxygen. Once again, only using SpO2 is not a means for diagnosis but rather a way to understand how the bodies vascular system is working.

Capillary Refill

The capillary refill test is a fast test that is commonly performed on the fingers or toes, either on the nail bed or backside of the appendage [41]. This test is used to measure the blood flow to tissue which helps indicate how well (or poorly) the body is circulating blood. This quick test can be used to monitor dehydration, shock, or hypothermia. To perform this test, the nailbed (or backside) is pressed between the examiners fingers for 10 seconds until the skin underneath goes white. If the patients circulatory system is responding normally, the skin should return to its original color in less than 3 seconds [42]. Clinically, this procedure is commonly done by first responders are part of an initial vitals assessment of the patient.

Blood Glucose

The blood glucose test is used determine the amount of glucose (sugar) present in your blood. This can be done as part of a routine blood panel test after taking blood from a vein. It can also be tested for individually using a glucose meter after pricking a fingertip. Testing the blood glucose level is commonly used to screen for Type 2 diabetes [43]. The finger prick blood glucose test is usually performed by nurses and is done on a case-by-case basis depending on the patient's medical history.

Pulse Palpation

Measuring the pulse is a quick way to determine how the vascular system is performing as it allows the examiner to find a patients heartrate, and feel any abnormalities to pulse strength and rhythm [44]. In the arm, there are two main sites for pulse palpation; below the thumb on the inside of the wrist along the radial artery and above the inside of the elbow along the brachial artery. Palpation of the pulse is done with the fingertips, the examiner then rates pulse strength on a subjective scale of 0 to 4 with 0 – no pulse detected, 1 – hard to detect, 2 – softer than normal, 3 – normal, 4 – stronger than normal [45]. After the intensity is graded, the examiner then feels for abnormalities in the rhythm of the pulse, it is expected that small variations will occur with the breathing cycle. Lastly, the rate of the pulse is measured over 15 seconds. That number is then multiplied by four to find the pulse in beats per minute.

Bleeding Control

- Wound Packing

Packing a wound is commonly done to stop the bleeding in a large wound. To perform this procedure, gauze is packed tightly into the wound until even with the skin. Pressure is then applied to the wound with both hands until the bleeding has stopped [46]. If the wound continues to bleed

out after being packed with applied pressure, then another method needs to be used to stop the bleeding.

- Tourniquet

Applying a tourniquet above a large would is another method used to stop bleeding. This procedure is not performed unless wound packing has been unsuccessful in stopping the bleeding as it can damage the extremity due to sustained loss of blood flow [47], [48]. However, in a life threating situation, that is an acceptable risk. On the arm, the tourniquet should be placed above the elbow to ensure the artery is adequately collapsed to stop blood flow. When placing the tourniquet, it should be placed between the wound and the heart at least 2-3 inches (5-8 cm) above the wound and not on a joint [47]. Once the tourniquet band is in place, the rod on the band should be twisted to increase pressure until the bleeding stops. Once the bleeding has stopped, the rod is secured and the time is noted. Noting the time can help avoid damaging the tissue below the wound due to loss of blood flow.

Skin Changes

- Changes to Skin Color

Visible changes in a patients skin color can be indications of medical issue that need to be further addressed. Specifically, there are four skin color changes that are associated with specific medical conditions. Yellowing of the skin and eyes is consistent with liver issues, paleness or bluing of lips or fingers (cyanosis) can be associated with lung or heart issued due to lack of oxygen, and redness can indicate irritation or an allergic reaction [49].

- Changes to Skin Appearance

More localized changes to the skins appearance and color are often also caused by underlying medical conditions. Rashes on the skin are characterized by red, inflamed skin that can be bumpy. These rashes can happen for multiple reasons stemming from bacteria, viruses, or allergies [50]. Skin burns also change the appearance of the skin, and depending on the severity of them can cause extreme pain, discoloration, and blistering. Most commonly burns are caused by a heat source, but chemical exposure can also lead to burns on the skin [51]. Brusing is another cause of skin appearance change and is typically caused by blunt impact. Swelling can occur in early stages of the bruise and it will often look red and or purple at the sight of impact [52].

2.2. Product Architecture

2.2.1. Integral Product Architecture

This design philosophy emphasizes the development of a product as a single system where every component is designed to function cohesively within the unified structure. Although subassemblies and subsystems are present within integral products, the primary objective is to ensure these elements function in harmony with the central system, rather than as independent entities, as seen in modular product architectures.

Integral product architecture is typically adopted for products that depend on cross-functions of numerous essential components to achieve the desired overall functionality. Such products generally exhibit stable life cycle characteristics, where maintenance, updates, and customization post-manufacture are infrequent or non-essential.

Benefits of Integral Product Architecture

1. **Single Unit:** Products developed with an integral product architecture are constructed as a single entity. The interdependence of all components is crucial for the product to operate as designed. This unified approach can enhance system reliability and durability, as it minimizes the number of discrete parts that could potentially fail [53], [54].

2. **Streamlined Development:** The development process for an integral product can be more straightforward, as it avoids the complexity of designing and managing the interfaces between multiple subsystems. This can translate to more efficient product development cycles as the number of parts to be designed and assembled is reduced [53], [54].

3. **Performance:** A integral product has components that work closely with each other, they can often perform tasks faster than if they were separate subsystems. The close integration of components can lead to optimized performance, as there is less room for errors and lag in communication between separate modules [53], [54].

Drawbacks of Integral Product Architecture

1. **Interdependency:** Changes or modifications in one part of the product can affect the entire system due to the interconnectivity of components in an integral product. This interdependency means that making modifications or updates can be complex and time-consuming, as it potentially requires redesign or adjustment of other parts of the product to accommodate the changes [53], [54].

2. **Maintenance and Upgrades:** Maintenance and updates can be more challenging and time-consuming in an integral system because changes can impact the entire product, rather than just a single component or subsystem. This can lead to longer downtimes and higher costs for maintenance and updates [53], [54].

3. **Lack of Customization**: An integral product design offers less flexibility for customization to specific users as the product is designed to function as one single unit and adding or removing functions can require redesign of interconnected functions within the system [53], [54].

2.2.2. Modular Product Architecture

Modular product architecture refers to an approach to product development in which a product is organized into separate modules. These modules have the ability to function independently but can also work in conjunction to perform a holistic function. This system of design and production offers a myriad of benefits, but like any method, also has drawbacks. Prior to considering the switch to modular product architecture, it is paramount that an analysis of benefits and drawbacks is considered to determine the best product architecture methodology is employed.

In the case of Laerdal Medical's training simulators, it seems that moving towards a more modular architecture could yield significant benefits. This switch would not only streamline development and manufacturing processes but also enhance flexibility, scalability, and efficiency. This change would make it easier to perform updates or adjustments and could potentially result in cost savings in the long run.

Benefits of Modular Product Architecture

1. **Separate Components**: A modular product is comprised of a series of separate, interchangeable modules. Each module is designed to perform a specific function independent of the other modules. An allure of this approach is the ability to mix and match different modules to create configurations that are catered towards different needs. In essence, modular products allow for versatility in product offerings without requiring the redesign of the entire product each time [55], [53], [56].

2. **Customizability**: With modular products, modifications can be made to individual modules without impacting the entire product. This approach allows forthright personalization to meet unique user requirements cost-effectively, as there is no need for comprehensive product redesigns with each variant [55], [53].

3. **Efficiency**: Modular products allow for more stream-lined product assembly as modules can be mass-produced and then assembled in different combinations to create a variety of product versions. This can result in significant cost savings, streamlined inventory management, and faster production times [55], [53].

4. **Maintenance and Upgrades**: Maintenance and upgrades can be easier and more cost-effective with modular products. It's often possible to replace or upgrade individual modules instead of the whole product. This not only reduces maintenance and upgrade costs but also decreases maintenance complexity as modules that are shared between products are standardized [55], [53], [56].

Drawbacks of Modular Product Architecture

1. **Complexity in Design**: Modular systems require mindful consideration to interfaces and interactions between modules. This can quickly increase the complexity of the design process and require higher levels of planning prior to starting on development [55], [53].

2. **Increased Initial Development Costs**: Initial development is longer than integral product architecture due to the increased complexity and planning required to properly map and design interface and interactions between modules [55], [53].

3. **Reverse Engineering**: A competitor looking at a modular product has a much easier time understanding the functions, interconnections, and interfaces of the product compared to a integral product. This makes reverse engineering of a product easier to achieve by competitors [55], [53].

4. **Potential for Compatibility Issues**: Ensuring the modules remain compatible with each other after upgrades is a consideration that must be made prior to development of the modules as this has potential to cause significant issues in future module iterations [55], [53].

2.2.3. Modular Function Deployment (MFD) Process

The Modular Function Deployment (MFD) process is a product development methodology that is founded on the principles of modular product architecture. The MFD process was created in the 1990s from a collaboration between researchers at the KTH Royal Institute of Technology and the IVF Swedish Institute Of Production Engineering Research [57]. Since its inception, the MFD process has been refined and advanced by Modular Management, a Swedish consultancy firm that specializes in product architecture and configuration management.

The MFD process integrates the "voice of the customer," the "voice of business," the "voice of engineering" and the "voice of modularity" to create a functional modular product architecture. This process is methodically broken down into five critical steps [58]:

1. **Clarify Customer Requirements**: This initial step involves understanding the customer needs and values to ensure the final product architecture aligns with market demands.
2. **Identify Functions and Solutions**: The second step is to detail the functions the product must fulfill and identify potential solutions that could be modularized.
3. **Propose Modules and Interfaces**: Modules are proposed based on the solutions identified, and their interfaces are designed to ensure compatibility and flexibility.
4. **Define Variants and Configurations**: The various product baselines and configurations are outlined to cater to different market segments and customer requirements.
5. **Confirm Architecture Feasibility**: The final step is to validate the proposed modular architecture's feasibility, ensuring it meets business goals and engineering feasibility.

Each of these steps consists of detailed tasks that organize information and support decision-making, ensuring a thorough and structured approach to modular product development. By following the MFD process, the modular product architecture can encompass changing customer needs and evolving technology offerings, resulting in products that are versatile, scalable, and cost-effective.

Clarify Customer Requirements

The first step of the MFD process involves gaining a better understanding of the needs and values of customers [59]. To better understand the required functionalities of the product, these customer profiles are used to build the foundation for which the product will be built on. To complete this portion of the MFD process, the customers are sectioned into market segments based on their respective values. These bins are then combined into a customer value ranking list. This is used to determine variance needed in the product to ensure all market segments and customer values are met. In essence, this first step in the MFD process determines if and the extent to which variance needs to be built into the product architecture [58]. In the next step of the process, these variances are further defined to gain a clearer picture of performance steps and variations required of the product.

Identify Functions and Solutions

The goal of the second step is to is to determine what functions are required in the product to satisfy the market needs defined in the first step. The functions must be measurable and controlled through product design. However, at this stage of the development process, the properties are used to connect market needs to technical capabilities rather than linking them to specific technical solutions. Using the customer values and product properties, a Quality Function Deployment (QFD) matrix is created. This matrix establishes links between the market values and product properties. Goal values for these properties are then characterized to give values to the variants using the connections uncovered in the QFD matrix. With the QFD matrix created, a functional analysis is conducted to determine the best technical solution for each function [58]. A key aspect of modular product architecture, is standardization so ensuring there is only one technical solution for each function in essential. The final step for the second stage of the MFD process is to create the Design Property Matrix (DPM) which is used to expose connections between the technical solutions and the product properties [58], [59]. Unlike the QFD matrix, the DPM matrix is used to track how product variants and customer values impact the complexity of the technical solutions. This matrix can be used to better understand the need for product performance steps and if there are any customer values that could be refined or eliminated to simplify the product.

Propose Modules and Interfaces

This stage of the MFD process the focus shifts to defining what drives the induvial module by considering three strategic segments. While each segment must be considered when defining the module drivers, there must also be no conflicting strategies between them.

1. **Operational Excellence**: This is defined as the ability to achieve economic scale through high output volumes. To achieve this, modules are design with two primary objectives [58], [60].
    - Commonality: Modules are designed to share common units across the different product variants to help reduce complexity of the product.
    - Carry Over: Some parts are designed with the intention of not being changed through the product life cycle to help separate what can be enhanced in the future with what will stay consistent.
2. **Customer Intimacy**: This strategy underlines the requirement of a versatile product that meets many different customer's needs. This is done by utilizing two module drivers [58], [60].
    - Technical Specification: Modules are created to meet the technical requirements of specific customer needs with different performance levels as necessary to encompasses the entire market.
    - Design Language: Distinct visual continuity is created between product lines to build familiarity between the customers and the companies products to help create brand recognition.
3. **Product Leadership**: The goal for this strategy is to be the market leader for each industry the company performs in. To do this, two main module drivers are implemented [58], [60].
    - Technology Advancement: Determining which modules will grow with advancing technology and changing customer needs allows the product to remain innovative.
    - Planned Evolution: Planning for future technology improvements is crucial for companies to adapt to changes in industry and ensure the product remains an industry leader.

With module drivers defined based on the segments above, the modules themselves can be created. However, prior to implementing the modules, the interfaces between them must be identified and validated. Module interfaces is a critical part of creating a modular system as it largely determines how flexible the final product will be. When outlining module interfaces it is first important to determine if an interface is necessary by deciding if Module A relies on Module B or vice versa. If an interface is necessary, then the physical attachment, required transfer, how it is controlled, and the space it occupies are all important considerations to make [58].

Define Variants and Configurations

With the product architecture defined based on the company strategy and customer values from the previous steps. Step four of the MFD process focuses on creating product variants based on the different market segments by determining which modules and modules variants are required to meet the needs of each market segment [58]. To do this, a modular variant specification matrix is created to link the different modules to the product properties for each market segment. Module variants must exist to meet the needs of a specific market segment and should only be created to satisfy customer needs. Module variants add complexity to the product design and therefore should be given sufficient consideration before defining them. After the module variants are defined, these modules can be configured to create a generic product structure for each different market segment based on the customer needs and module variants.

Confirm Architecture Feasibility

The MFD process is largely circular and before the product architecture can be fully defined, it must be validated for feasibility. To do so, each step of the process must be revisited and evaluated to determine if the product architecture truly accomplishes the company goals, customer needs, and technical feasibility. It is during this final step that each of the four voices (customer, engineering, business, and modularity) are combined to build the final modular product architecture. However, due to the circular nature of the MFD process, the architecture is continually improved as the product is developed based on future planning of changing technology and developing customer needs.

2.3. Product Lifecycle Management

Having a standardized way to manage a product from concept, through manufacturing, to product retirement is critical to the products success. Product lifecycle management (PLM) creates a platform for cross-functional teams to coordinate which in turn helps reduce delays and errors. PLM can be separated into three phases: product design and development, manufacturing, and distribution [61].

2.3.1. Product Design and Development

During the development phase, key information about the product will be stored in a PLM system. This will often be documentation such as technical product requirements, customer needs, market segments, design iterations, prototypes, and the final design [61]. For modular products it is important to consider how design revision will be handled. Modules that have multiple variants will be treated as separate parts in the PLM system but will share a common interface with the system [62]. Depending on how a company plans to configure their product, it can become very cumbersome to deal with module variant revisions for multiple baselines and potential configurations of a single product. Due to this, adopting a PLM system that works with a modular product architecture is paramount for the successful lifecycle management of a modular product.

2.3.2. Manufacturing

Before the product design is finalized, collaboration between the product developers and those responsible for manufacturing the product must take place. This is done to ensure that the final parts can be manufactured to meet the technical specifications defined during the development phase [61]. It is also at this stage of the product lifecycle that materials and resources are produced to ensure manufacturing can sustain the required levels of production to meet sales. This stage of the manufacturing process requires collaboration with procurement specialist and business analysist to plan the volume of manufacturing and timeline for the parts to be completed, assembled, and added to inventory.

2.3.3. Distribution

With the product design finalized and manufacturing started, the distribution phase of the product lifecycle can begin. This phase focuses on projecting sales, controlling inventory, and distributing the product to distributors or directly to end users [61]. Inventory management has an added level of complexity for modular systems as balancing the number of module variants on hand with the expected sales of product baselines that match those module variants is important to avoid distribution delays and added cost of excess inventory.

2.4. Product Development

2.4.1. Product Planning

Prior to starting development of a product, planning must be done for the entire product portfolio by taking into account potential changes in the industry based on advancements in technology, market

feedback, and competitor innovations. The product planning often takes place with senior management and is done so to ensure the company remain efficient by avoiding poor market coverage, mistimed product launches, and misallocation of resources [53]. Specifically, this process can be visualized in the following five steps.

1. **Identify Opportunities**: This process starts by identifying opportunities in the market for future product development. Referred to by Karl Ulrich and Steven Eppinger as the "opportunity funnel" [53], this step enables companies to compile input from all corners of the market and identify the most promising opportunities.
2. **Project Prioritization**: Using the ideas collected from the "opportunity funnel" this step eliminates impractical ideas and allows the company to pursue only to the most promising projects. The four perspectives shown below are used for evaluating and prioritizing ideas compiled in the funnel [53].
    - **Competitive Strategy**: A company's competitive strategy is an approach used to relate current market trends and products with that of its competitors. This perspective is guided by perspectives such as development of new technologies, keeping market costs competitive, customer needs, and future market trends. With these perspectives in mind, a company is able to generate their strategy for staying competitive in the free market.
    - **Customer Segmentation**: By group customers into segments a company is able to visualize how their current product portfolio meets the needs of specific market segments and knowing where there is room for new products either from the company or its competitors. This allows the company to anticipate weaknesses in their product portfolio which can help with prioritization for future projects.
    - **Technological Trends**: For companies with products supported by advanced technologies, a discussion on when to adapt the newest technological trend into future (or even current) products needs to be discussed. Implementing new technologies can have a high development cost both monetarily and with time but can also give large market advantages.
    - **Product Platform Organization**: For a company with a large product portfolio ensuring there is little to no overlap between technical solutions increases efficiency and allows the company to focus more resources on keeping or increasing their market share.
3. **Resource Allocation and Market Planning**: With the "opportunity funnel" narrowed down to feasible ideas, the company must choose which ones to peruse by determining available resources and analyzing market trends [53]. This step helps solidify that the chosen ideas will be profitable for the company.
    - **Resource Allocation**: Providing a new project with adequate resources while maintaining the resource allocation of existing project is critical for success of both current and future projects. If the same resources become allocated over multiple projects, the likelihood of delays in project timelines and decreases in productivity increases. Companies must be cautious when accepting new projects as overallocation of resources can significantly decrease their market share.
    - **Market Timing**: Another way to determine which projects are feasible is to analyze market trends. Appropriately timing product launches with market needs can further ensure that the product produces profit for the company.
4. **Pre-Product Planning**: After a project has been approved, sufficient front end planning must be done prior to starting development. It is during this stage that the project team will decide on project goals, consumer markets, potential assumptions and constraints, and who will be

a stakeholder for the project. Diligent planning at this stage, especially for assumptions and constraints can have a big impact on the efficiency of development.

5. **Reflection**: Finally, before launching into the true product development, the team must ask themselves if their product plan aligns with company goals, consumer markets, and technical feasibility.

2.4.2. Product Specifications

Product specifications are used to bridge the gap between customer needs which are largely qualitative into technical requirements that are quantitative. To do this, the product team must remove as must subjectivity as possible by setting specific requirements that a product can be design for and validated against [4]. For more complex projects, broad target specifications are set to not stifle creativity during the concept generation process. After the team has landed on one or multiple promising concepts, the specifications are redefined with more pointed values to guide the next stage of development. It is at this stage that technical feasibility and cost need to be taken into account as both areas carry risk in making the product impossible to produce or too expensive to sell for a profit.

2.4.3. Concept Generation

With target specifications set, the next step in the product development process is the act of concept generation. Usually this process is very efficient for the project as it takes a relatively small amount of the project budget and time but produces the foundation for the next steps of the development process [53]. Karl Ulrich and Steven Eppinger propose a five step process for concept generation that breaks down the large task of generating concepts into smaller, more manageable subtasks [53].

1. **Clarify the Problem**: Prior to generating concepts, the team must first fully understand what value the product is bringing to the customer. This is done by analyzing the customer needs and fully grasping the target specifications. From here the team can break down the product into smaller pieces that can be ranked by criticality to help visualize what problems need to be addressed first.
2. **Seach Externally**: With the product decomposed into smaller sub components, concepts that solve these problems can be searched for externally by analyzing existing technical solutions to the problem that already exist.
3. **Seach Internally**: Alternative to existing solutions, brainstorming sessions both as a team and individually should be used to generate new concepts.
4. **Explore Systematically**: Using both the external and internal concepts generated in the two previous steps, the team can then group them together by subproblem. Combining these concepts by subproblem in a table allows for visualization of how each concept can be linked together to solve the entire problem. This method of systematically evaluating the subproblems and associated concepts makes a technical product much more manageable.
5. **Reflect**: Finally, the team must reflect on the concepts and ask questions to determine if these concepts still serve the overall purpose the product is trying to achieve. While placed last in this list, it can be done multiple times during the process to ensure that the concepts stay focused on the scope of the problem.

2.4.4. Concept Selection

Once a sufficient number of concepts are generated that address the problem the product is aiming to solve, a single concept must be chosen for further development. While there are many methodologies that can be implemented to accomplish this, Karl Ulrich and Steven Eppinger suggest using a two stage process where the concepts are first “screened” and then “scored” [53].

1. **Concept Screening**: This step is used to quickly narrow down the list of concepts and improve those concepts that show promise. Often times this can be done using a matrix where the concepts are ranked against a reference concept based on a set list of selection criteria. These concepts are then ranked if they are better than, equal to, or worse than the set reference. Once the concepts are ranked, the team can more easily decide which concept(s) should be further explored and revised based on the findings of the screening matrix. This approach is known as the "Pugh concept selection" [63] method and is the suggested method for concept screening as outlined in *Product Design and Development* by Ulrich and Eppinger [53].
2. **Concept Scoring**: With the initial concepts narrowed down, a concept scoring matrix can be implemented to decide which of the screened concepts should be developed. Much like the screening matrix, the concepts are scored against a selection criteria. However, instead of ranking the concepts against a reference. Each criteria is given a weight percentage based on importance. Each concept is rated for each criteria and multiplied by the weight percentage. The sum of each concept is then ranked and the highest ranking concept is then chosen for further development.

2.5. Prototyping and Testing

Prototyping is an important part of the product development process and provides critical information about how the concept performs given the technical and user requirements. Prototypes can be split into two main categories, physical and analytical [4]. These categories can be further segmented into levels of fidelity that are related to cost and time to create. Low fidelity physical prototypes are often used in the early stages of concept generation and selection as they can be created quickly and for low cost but lack robustness and polish. On the other end of the spectrum, high fidelity physical prototypes closely resemble the finished product. They are expensive to manufacture but show a strong correlation to what the final product will resemble. Analytical prototypes follow the same convention as physical prototypes but exist within a non-physical world such as a CAD model or FEA simulation. Prototyping is an iterative process that along with concept testing improves the final product by ensuring all technical and user requirements are met.

After a prototype of the concept is created, it must be tested to validate if it meets the technical requirements and customer needs that were first defined during the planning stage [4]. To get a holistic understanding of how the concept performs, both user and technical testing needs to be performed. As product development is an iterative process, the results of concept testing are important for improving the concept prior to more testing and eventual product release.

3. Methodology

3.1. PALMA Software

PALMA is a proprietary software developed by Modular Management. This tool is used to develop and manage modular product architecture. The heart of PALMA is the 'HUB' where all tools can be accessed. A condensed version of the 'HUB' where tool are grouped into four 'voices' of the MFD process [58] is shown in Figure 8. Each of these 'voices' are used to ensure a balanced product architecture. Starting the MFD process with the voice of the customer guarantees the modular product architecture is grounded in customer needs, critical to the success of the product as customer satisfaction drives sales. Figure 8 only shows the PALMA tools relevant to the four voices, more tools were used for this thesis and are listed below, and highlighted later in Figure 11. There are many tools in PALMA that were not used for this thesis as there is not sufficient cost, marketing, or business strategy information available to fully utilize them. Were the modular product architecture proposed in this thesis implemented by Laerdal, overtime, these tools would be used as the product architecture grows and adapts alongside the product lifecycle. The PALMA tools used in this thesis and the methodology behind how they are used is described in the subsequent sub-sections below.

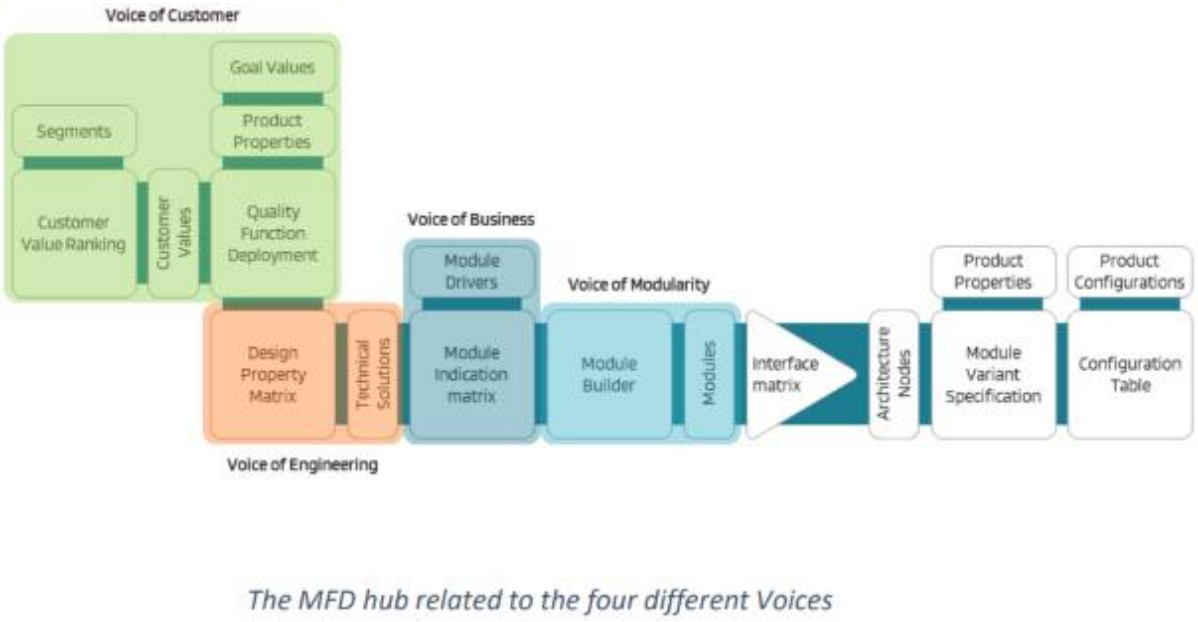


Figure 8 – From: A 5-step Guide to Develop a Modular System [58]

3.1.1. Customer Value Ranking (CVR)

The Customer Value Ranking (CVR) tool is used to understand the importance of different customer values across the different market segments. The following methodology describes how this matrix was created and used.

- Establishing the Matrix Structure:
  - List the market segments horizontally along the top of the matrix as column headers.
  - List the customer values vertically along the side of the matrix as row headers.

The weight these market segments carry can be adjusted based on the excepted market share each segment will control [59]. While not necessary, adjusting the weight of the market segments can help produce a more accurate CVR.

- Filling in the matrix:

Each cell of the matrix is given a score from 1 to 5; with 1 meaning the customer value is not important to the market segment and 5 meaning the customer value is very important to the market segment [64]. This scoring should be based on data from each market segment, whether than be from interviews, surveys, or a mix of both. Scoring can be rather subjective as it is hard to give quantitative values to qualitative results. To help simplify this, the average thoughts from each market segment should be used and edge cases ignored. As long as the scores given to each market segment are done in a consistent manner, then the actual numbers given are less important.

- Analyzing the Results:

To verify the ranking has been done consistently, the sum of scores for each market segment should be similar. If one market segments has a higher or lower sum than others it means that the CVR has been skewed in favor, or against that market segment. This can lead to inaccuracies down the line in the MFD process or indicate that the market segments are not well defined.

The resulting CVR ranking is used to weigh the customer values from 1 to 5 for the combined market segments, with 1 meaning the customer value is not significant to the entire market and 5 meaning the customer value is critical to the entire market. The CVR matrix determines this ranking based on the average score given to each customer value from each market segment and then ranks the customer values based on the average score. Due to this, a customer value of medium importance (average score of 3) can receive a weighted rank of 1 if the other customer values are all of high importance (average score of 4.5 or higher). It is possible to normalize this 'outlier' customer value to a rank of 3, but this then normalizes the rest of the values. In certain scenarios, this could be appropriate. The ranking of customer values is then imported into the Quality Function Deployment matrix which is used in the next step of the MFD process.

3.1.2. Quality Function Deployment (QFD)

The Quality Function Deployment (QFD) tool is used to visualize the relationship between customer values and product properties [65]. The methodology for creating this matrix is as follows:

- Identifying Product Properties:

This can be done by identifying what functionality the product must have to meet the market segments and customer needs. These are not defined functions of the product, but rather characteristics that functions will enable the product to perform. For example, if a customer value is 'easy management of fluids' then the product requires a fluid system that can be filled and emptied. This could mean some product properties are 'fluid system' and 'fluid exchange' as they support the customer value. The function would then be something that enables the product to have a fluid system that can be filled and emptied. Each product property is also given a classification and accompanying goal values. These classifications are used when defining variants of the product as they can be listed as "base" meaning the product property occurs in all variants; "option" meaning the product property will or will not occur depending on the product variant; and "variance" meaning the product property has multiple options which correspond to specific variants [61]. Using the example above the product properties 'fluid system' and 'fluid exchange' are given the "option" classification and the yes/no goal values. This will correlate with product variants where the fluid system is included or not included, if there is no fluid system in the product then by default there cannot be any exchange of fluid. The size of the fluid system could be classified as "variance" and the goal values could match the simulator size of newborn, baby, child, and adult.

- Establishing the Matrix Structure:
    - List the product properties horizontally along the top of the matrix as column headers.
    - List the customer values vertically along the side of the matrix as row headers.
- Filling in the matrix:

QFD ranking is done using three symbols: ● (Filled Circle), ◐ (Half-filled Circle), and ○ (Empty Circle). These symbols are then assigned values: filed circle = 9, half-filled circle = 3, and empty circle = 0; which are then summed to give two scores, one for customer values, and one for product properties [65]. If a customer value does not have a relationship with a product property then the cell is left blank. This scoring system is again rather subjective, but when done consistently throughout the entire matrix the results are still valuable.

- ● **(Filled Circle):** Indicates a strong positive relationship between a customer value and a product property. Full circle means the product property has a clear and undisputable positive impact on fulfillment of the customer values, recognized by all customers.
- ◐ **(Half-filled Circle):** Represents a medium positive relationship. The product property moderately addresses the customer value. Half circle means the product property has a positive impact on fulfillment of the customer value in most cases but it might not be recognized by all customers.
- ○ **(Empty Circle):** Denotes a weak positive relationship. The product property has a slight influence on the customer value. Open circle means the product property has a positive impact on fulfillment of the customer value in special cases and it will not be recognized by all customers.
- Analyzing the Results:

This matrix is used to help visually organize which product properties are linked to which customer values. The customer value score, which is the other scoring done in the QFD matrix, is used to indicate which product properties are relevant to a specific customer value. This score can be used to visualize which customer values are most relevant to the product properties as a whole. These customer values can indicate a focus that should be taken during development of the product.

The product property score, which is used to indicate the customer values that are linked to a specific product property. This score can be used to visualize the product properties that are most important to the customers; meaning they are crucial to product success and should be prioritized during the development process. While product properties that do not have a high product property score are not viewed as directly impacting the customer values; they still can be important to the product as a whole. Due to this, product properties with a low product property score should not be overlooked but rather investigated for how they affect the product system. The product property score is used to weigh the product properties in terms of market relevance in the Design Property Matrix (DPM).

3.1.3. Design Property Matrix (DPM)

The Design Property Matrix (DPM) is a tool used to map the relationship between functions and accompanying technical solutions of the product with product properties. Using a simplified scoring system, the DPM quantifies the strength of these relationships and identifies an estimated level of variance required for each technical solution needed to meet market demands.

- Define Functions and Technical Solutions:

Product functions are concrete representations of product properties and the technical solutions are different ways the product can implement said function. Using the product properties defined prior to starting the QFD, a list of product functions and then proposed technical solutions can be created. Expanding on the example given previously for the customer value of 'easy management of fluids', if we think of a grouping of product properties that support this customer value as 'fluid system' and 'fluid exchange'. The function(s) would then be something that enables the product to have a fluid system that can be filled and emptied such as 'ability to refill/empty fluids' and 'ability to store fluids'. At this stage the technical solutions do not have to be fully defined and multiple solutions should be listed to avoid limit potential product concepts before development begins. For these functions, a quick connect fluid connection could be used as a technical solution that allows the user to easily connect a syringe or external pump to the manikin to refill/ empty the fluids. These fluids could be stored in some internal reservoir such as a flexible or rigid plastic bladder. The technical solutions are then later refined using a concept scoring matrix.

- Establishing the Matrix Structure:
    - List the product properties horizontally along the top of the matrix as column headers.
    - List the functions and respective technical solutions vertically along the side of the matrix as row headers.
- Filling in the Matrix:

The DPM scoring is done using three symbols: ● (Filled Circle), ◐ (Half-filled Circle), and ○ (Empty Circle). These symbols are then assigned values: filed circle = 9, half-filled circle = 3, and empty circle = 0 [66]. If a function does not have a relationship with a product property then the cell is left blank. This scoring system is again rather subjective, but when done consistently throughout the entire matrix the results are still valuable.

- ● **(Filled Circle):** This signifies a strong positive relationship between a function and a product property. The function is significant in achieving the desired property.
- ◐ **(Half-filled Circle):** This symbol represents a moderate positive relationship between a function and a product property. The function somewhat contributes to the product property.
- ○ **(Empty Circle):** This denotes a weak positive relationship between a function and a product property. The function has a slight effect on the product property.
- Analyzing the Results:

The finished matrix gives three scores, the variance count prediction score, the functions score, and the product property sum [66]. The variance count prediction is used to estimate the number of variants needed in the product for a given function. If the variance count prediction score is much higher than other functions it can indicate the need for at function to be broken up into smaller functions. This score is calculated based on the strength of relationship to product properties and the number of goal values each product property has. The functions score relates the functions based on how interconnected to the product properties they are. A function with stronger relationship to multiple product properties rates higher than a function that is only related to one product property. The function score is used to rank the importance of functions; an important tool for when assigning resources during the development phase. Similarly, the product property sum scores the product properties based on how many functions they are connected to. The functions and product properties scores are used to organize and visualize the interconnections between the functions and product properties.

3.1.4. Module Indication Matrix (MIM)

The Modular Indication Matrix (MIM) is a strategic matrix that aligns module drivers with product functions. Module drivers are pre-defined for the MFD process based on the research that modular management was founded on [58], [60]. These module drivers were previously discussed in Section 2.2.3 *Modular Function Deployment (MFD) Process*.

The MIM creates function groupings based on module drivers and is used when building the modules to ensure there are no conflicting strategies by highlighting groups of functions that share the same module strategy. An example of a conflicting function strategies would be having carry over (a function that will be re-used without change for the whole product life) and technology push (a function that will change during the product life) for the same function. As you can see this causes an obvious clash in strategy. If conflicting strategies do occur, it requires the function to be broken up into smaller functions to avoid conflicts.

- Establishing the Matrix Structure:
    - List the module drivers horizontally along the top of the matrix as column headers.
    - List the functions and respective technical solutions vertically along the side of the matrix as row headers.
- Filling in the Matrix:

Scoring is again done using three symbols: ● (Filled Circle), ◐ (Half-filled Circle), and ○ (Empty Circle). These symbols are then assigned values: filed circle = 9, half-filled circle = 3, and empty circle = 0 [67]. If a function does not have a relationship with a module driver then the cell is left blank. This scoring system is again rather subjective, but when done consistently throughout the entire matrix the results are still valuable.

- ● **(Filled Circle):** This signifies a strong positive relationship between a function and a module driver. The function is significant in achieving the module driver.
- ◐ **(Half-filled Circle):** This symbol represents a moderate positive relationship between a function and a module driver. The function somewhat contributes to the module driver.
- ○ **(Empty Circle):** This denotes a weak positive relationship between a function and a module driver. The function has a slight effect on the module driver.
- Analyzing the Matrix:

The only result from this matrix is a sum for the module drivers. This sum can be used to understand the distribution of the overall product strategy between Operational Excellence, Customer Intimacy, and Product Leadership as described previously in Section 2.2.3 *Modular Function Deployment (MFD) Process*. The product strategy distribution is important as it should align with the companies 'big picture' business strategy.

3.1.5. Module Builder (MB)

PALMA uses the module builder to create clusters of functions based on the relationships defined between functions and product properties in the DPM and function and module drivers in the MIM. These clusters can then be generated into modules that can be manually refined later. This tool has three columns consisting of: functions, modules, and clusters. A completed module builder will have all of the functions from the left column distributed into the modules in the central column [68]. When generating the modules, PALMA implements clustering algorithms that can help refine the generated modules. Given the proprietary nature of the algorithms that are used in the module builder, specifics have not been added to this thesis, per the request of Modular Management. For

this project, due to the interconnectivity of the system, the modules were created manually based on recommendations given by the basic clustering algorithm.

3.1.6. Module Strategy Matrix (MSM)

The Modular Strategy Matrix (MSM) is similar to the MIM but instead of characterizing the relationship between product functions and module drivers; the MSM defines the relationship between modules and module drivers. The results of the MSM matrix help validate the proposed modules align with the strategic goals of the company, it also exposes any strategy conflicts that would require the modules reevaluated. With the MSM completed, each module will have a product strategy assigned to it based on that modules relationship to the module driver.

- Establishing the Matrix Structure:
  - List the module drivers horizontally along the top of the matrix as column headers.
  - List the functions and respective technical solutions vertically along the side of the matrix as row headers.
- Filling in the Matrix:

The MSM is setup with module drivers on the top (column) and modules on the side (rows) of the matrix. Scoring is again done using three symbols: ● (Filled Circle), ◐ (Half-filled Circle), and ○ (Empty Circle). These symbols are then assigned values: filed circle = 9, half-filled circle = 3, and empty circle = 0 [69]. If a module does not have a relationship with a module driver then the cell is left blank. This scoring system is again rather subjective, but when done consistently throughout the entire matrix the results are still valuable. Below is a description of when each score should be used:

- ● **(Filled Circle):** This signifies a strong positive relationship between a module and a module driver. The module is significant in achieving the module driver.
- ◐ **(Half-filled Circle):** This symbol represents a moderate positive relationship between a module and a module driver. The module somewhat contributes to the module driver.
- ○ **(Empty Circle):** This denotes a weak positive relationship between a module and a module driver. The module has a slight effect on the module driver.
- Analyzing the Matrix:

The sum and score of the MSM should be checked to ensure there are no zeros which indicate that the module or module driver has no relationship. Ideally all modules and module drivers will form some relationship but it is not necessary for creating a working modular product architecture. More important is there are no strategic conflicts. Non compatible module strategies and drivers can be found in Figure 9 which is provided on the PALMA guide for the MSM Tool [69]. This figure is based on the foundational MFD research [60] as previously mentioned. The MSM provides a check to ensure the modules align with the company product strategy focus. This validates the voice of the business in the modular product architecture and allows easy visualization of module relevance within the product architecture.

Strategy	Non-compatible Module driver
Product Leadership	Carry over, Planned Development
Operational Excellence	Technology push, Planned development, Technical Specification
Customer Intimacy	Common Unit

Figure 9 – From: PALMA Guide for Module Strategy Conflicts [64]

3.1.7. Interface Matrix (IM) and Diagram

The interface matrix is used to classify the type of interface between modules. These categories can vary product to product but typically for physical hardware the following categories would be expected: attachment (physical), spatial, control, field (magnetic, electrical), transfer (air, liquid, force, power, data) and environment [70].

- Establishing the Matrix Structure:
    - List the modules horizontally along the top of the matrix as column headers.
    - List the modules vertically along the side of the matrix as row headers.

As modules cannot have an interface with the same module the diagonal and upper triangle of the matrix are greyed out, this leaves the bottom triangle of the matrix to be filled out.

- Filling in the Matrix:

Letters that correspond to the categories are entered into the module cell, an example of this would be the fluid management module has a mechanical and fluid transfer interface with the IV module, therefore at the cell where those two modules meet, the letters A (attachment) and Tf (fluid transfer) would appear.

- Analyzing the Matrix and Creating the Interface Diagram:

While the interface matrix does an adequate job of mapping out the interfaces between modules it is hard to visualize the modular system with its interfaces from a matrix. The interface diagram solves this problem but providing an easy to read visualization of module interfaces for the entire modular system. For simple products, an interface matrix might be sufficient in understanding the interconnectivities of the modular system. But for a complex system, the interface diagram is crucial for understanding how a modular system interacts with other modules within the modular hierarchy [62], [71], [72].

The style used to design the interface diagram was inspired by those shown in *Interface diagram: Design tool for supporting the development of modularity in complex product system* [71]. This paper first defines the interface diagram by creating boxes for each module. From these boxes, color coded lines (color coded boxes are used in the paper [71]), for example a blue line to represent a fluid interface, is drawn from one module box to the other interfacing box. As you can imagine, for a complex system this can become a very densely populated diagram. The interface diagram can be further improved by organizing the modules within their modular hierarchy defined by the generic product structure, which will be discussed in a later section.

3.1.8. Module Variant Specification (MVS)

The module variant specification is the first tool used as part of product configuration planning.

- Define Module Variants:

Candidates for module variants can be identified through analysis of the DPM. By grouping the functions with their associated module and using the variance count prediction score from the DPM, an idea of what modules require module variants can be found. From here, modular variants are proposed based on what specific product properties are needed to meet each specific market segment.

- Establishing the Matrix Structure:
    - List the product properties horizontally along the top of the matrix as column headers.

    - List the functions and respective technical solutions vertically along the side of the matrix as row headers.
- Filling in the Matrix:

The MVS is used to ensure that each product property goal value is met by each module and its variants. In line with the other PALMA matrix tools, the scoring system is done using three symbols: ● (Filled Circle), ◐ (Half-filled Circle), and ○ (Empty Circle). These symbols are then assigned values: filed circle = 9, half-filled circle = 3, and empty circle = 0 [73]. If a module variant does not have a relationship with a product property then the cell is left blank. This scoring system is again rather subjective, but when done consistently throughout the entire matrix the results are still valuable. Below is a description of when each score should be used:

- ● **(Filled Circle):** This signifies a strong positive relationship between a module variant and a product property. The module variant is significant in achieving the product property.
- ◐ **(Half-filled Circle):** This symbol represents a moderate positive relationship between a module variant and a product property. The module variant somewhat contributes to the product property.
- ○ **(Empty Circle):** This denotes a weak positive relationship between a module variant and a product property. The module variant has a slight effect on the product property.
- Analyzing the Matrix:

For quality assurance, the sum for each product property should be greater than zero, the tool also indicates if any goal values are not being used by modules. This is a good check to ensure that the modules and its variants fully encompass the product properties as that is essential for meeting customer needs for all market segments.

3.1.9. Generic Product structure (GPS)

The generic product structure is used to organize the modules into a hierarchy within the product. Not all product baselines will have every module or variant, but by organizing the generic structure of the product it becomes easier to visualize how different product baselines and potential configurations will be built up. PALMA refers to this module hierarchy as a 'node' structure when working in the HUB as seen in Figure 8. The module hierarchy is determined by where modules exist within the product. For example, the fluid management module is a system level module, but because it interacts with many modules in the system, it will not have any sub-level modules directly assigned to it. Another example would be the IV module, this is sub-level because it is contained within the detachable arm top-level module. Figure 10 is a visual representation of this module hierarchy approach.

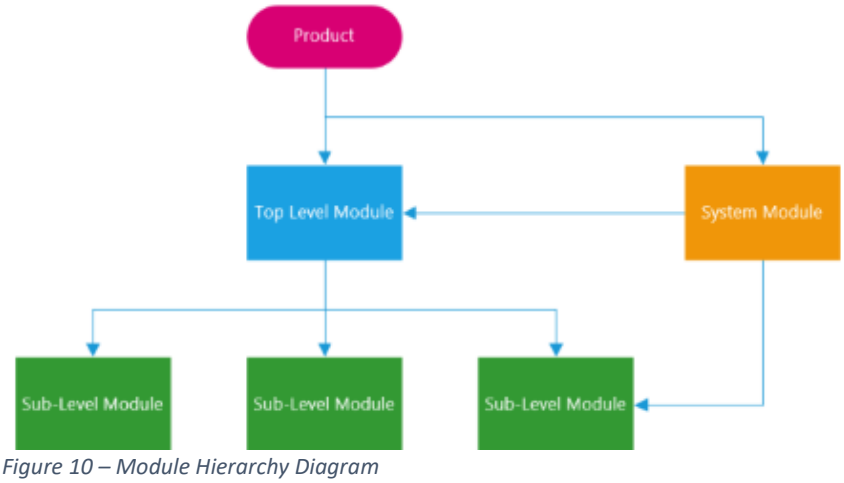


Figure 10 – Module Hierarchy Diagram

While there are plenty of other ways module hierarchy can be defined, logically this representation fits well with the modules that are used to build medical patient training solutions. To my

knowledge, the way I have chosen to define the module hierarchy is unique to the product being developed for this thesis.

After the module hierarchy is defined, each node can be given characteristics. These characteristic limit how the product can be configured. If a module will only occur in some baselines and or configurations, that node will be labeled as 'optional' [74]. Similarly, if a module will always occur but with different variants in some baselines, that node will be labeled as 'variable' [74]. Rules are then defined to constrain which module variants will occur based on which product property goal values they meet. The generic product structure gives a good visualization of how the modules fit into the product, this is a crucial step in product configuration as it gives shape to the modules instead of listing them in rows as initially done in the module builder. This allows for critical thought into how the product will be laid out and if any adjustment need to be made to the modules or module variants before moving forward in the MFD process.

3.1.10. Configuration Interface (CI)

The configuration interface is used to setup what input fields will be available in the product configuration tool. PALMA generates three default tabs: commercial properties, system properties, and product structure, but does allow for custom input fields to be created. For this product, the configuration tool will be used to select which modules and module variants will occur in each product baseline. Knowing this, the default product structure tab is used and a new tab for product attribute configuration is added [75]. These two tabs give the best representation of how the product baselines will be configured by the customer. As an important customer value is 'easy to choose the product that I need', it is important that the product configuration is easy to understand. Although the way the customer chooses and customizes which product baseline they want to use in their custom product configuration will look different than the product configuration tool in PALMA, it is important to define the product baselines and configuration options in an intuitive way.

3.1.11. Configuration Lab (CFG)

The configuration lab is where the product baselines are created and configuration rules visualized. The tool consists of tabs across the top and drop down lists under each tab [76]. These lists are for the different features the product will have and contain any feature variants that could be possible for different configurations based on the chosen product baseline. The methodology that is implemented for this tool is found below:

- Feature selection:
    - Select which feature variants will occur in the specific product baselines from the lists provided under each tab.
- Compatibility Rules Color Coding:
    - The compatibility of features within the same product baseline is color coded as follows:
        - Green: The selected feature variant is compatible with all previously chosen functions.
        - Yellow: The selected feature variant is not compatible with one or more previously selected functions, but compatibility can be achieved by altering previous selections.
        - Red: The selected feature variant is incompatible with the current configuration and cannot be made compatible regardless of changes to previous selections.

This approach will ensure that the product baseline and potential configurations meet the compatibility rules and that no conflicting functions have been added to any of the configurations.

3.1.12. Product Specification Matrix (PSM)

With how the configuration interface and configuration lab were setup, the product specification matrix is used to define which global attribute customization is available for which product baseline and potential configurations. Once the customer has chosen a product baseline, they have the ability to customize that baseline with a set number of module and attribute configurations. This customization is limited because offering 'engineered-to-order' products is far to complex to be sustainable given the business strategy Laerdal Medical uses. However, not offering any user driven customization would be an under utilization of the modular product architecture, therefore a balance between customization and complexity with logistics, such as assembly and storage or parts, must be created. Creating this balance is an iterative process and something that is not controlled by the product specification matrix and is done after the draft product architecture has been created. The methodology for creating this matrix is as follows:

- Establishing the Matrix Structure:
    - Arrange the names of the product baselines horizontally along the top of the matrix as column headers.
    - List the attributes of the customizable configuration vertically along the side of the matrix as row headers.
- Filling in the matrix:
    - List the customization parameters available to the applicable module for each product baseline.
- Documenting and Reporting:
    - Document the matrix in a clear manner so that it can be easily understood by project stakeholders.
- Updating and Maintenance:
    - Keep the matrix up-to-date with the most recent iteration of the modular product architecture as product development progresses.

Following this methodology enables the product specification matrix to be used effectively to manage the global attribute customization for the potential arm configurations.

3.1.13. Product Configuration Matrix (PCM)

The product configuration matrix is used to manage the product configurations that were created in the configuration lab [77]. The methodology used for this matrix is outlined in the steps below:

- Establishing the Matrix Structure:
    - Arrange the names of the product baselines horizontally along the top of the matrix as column headers.
    - List the nodes of the generic product structure vertically along the side of the matrix as row headers.
- Filling in the matrix:
    - Assign the specific module variants to the appropriate module for each product baseline.
    - When modules are not used, indicate this either with N/A or leave the cell blank
- Documenting and Reporting:
    - Document the matrix in a clear manner so that it can be easily understood by project stakeholders.
- Updating and Maintenance:
    - Keep the matrix up-to-date with the most recent iteration of the modular product architecture as product development progresses.

This methodology provides a systematic way to manage the complexity of multiple product baselines and their potential configurations that adapts to changes made during development.

3.2. Computer Aided Design (CAD) Software

3.2.1. Siemens NX

Siemens NX, a computer-aided design (CAD) software, will be used through the product development and prototyping phase of this thesis. NX will be used to modify existing parts for module interfaces, design new parts for the modules and their variants, and assemble the different product baselines defined from the modular product architecture. The following is an outline of the workflow for how Siemens NX will be used to achieve the thesis objectives.

- Initial Assessment and Preparation:
  - Begin by importing the existing CAD models of the SimMan left arm into an assembly in Siemens NX.
  - Analyze the current design to plan where new module interfaces should be located to avoid interference with the existing structure that must remain.
- Design Modification:
  - Modify existing parts of the SimMan arm in NX to create new interfaces that will allow for the modular components to be integrated into the existing SimMan arm frame.
- Module Creation:
  - Design new modular components within NX that will interface with the modified SimMan arm frame.
  - Ensure that all variants within the same module share the same interface with the modified frame.
- Iteration:
  - Iterate on the modules and interfaces design based on rapid prototyping done during the development phase.
- Assembly of Arm Baselines:
  - Create CAD assemblies in NX for each product baseline of the modular arm to create digital prototypes for each baseline.
- Documentation and Output:
  - Generate drawings from the NX assemblies that visualize the different modules found in each product baseline.
  - Export CAD files from one product baseline to STL for 3D printing the final parts that will be used to assembly the physical prototype.

By following this methodology, Siemens NX will serve as a vital tool for the development of a functional prototype arm for the full-size medical patient training solutions. The software's capabilities will be used to create a modular design that aligns with the strategic objectives of Laerdal Medical and the aims of the thesis.

3.2.2. Microsoft Visio

Microsoft Visio will be used to graphically represent the interfaces, fluid and electrical layouts, and various other figures within the thesis. The following methodology outlines the steps for using Visio to support the thesis objectives.

- Preparation and Planning:
  - Gather all necessary data and specifications related to the modular arm baselines, including interface requirements, and fluid/electrical component specifications.

- Creating Interface Diagrams:
    - Develop interface diagrams that map the mechanical, data, power, and fluid interactions between the modules in the arm.
- Designing Fluid and Electrical Layouts:
    - Create schematic diagrams for the fluid and electrical systems of each arm baseline.
    - Rate each solution based on how likely the technical solution is to change from draft architecture to final product.
- Developing Figures for the Thesis Report:
    - Design various figures within Visio that will be incorporated into the thesis report. These figures may include flow charts and process diagrams that help the reader better visualize the content of the thesis.
- Integration and Documentation:
    - Import the completed Visio diagrams and figures into the thesis report.
    - Ensure that all Visio outputs are of high resolution and quality suitable for publication.

This methodology ensures that Microsoft Visio will be effectively used to create informative visual material that enhances the communication of the thesis content. The software's diagramming capabilities will contribute to a more comprehensive and understandable presentation of the modular design and product baselines of the arm.

3.3. Technical Specification

Developing a simplified technical specifications is used to communicate to the users the functionalities of each product baseline. This methodology outlines the process for creating this specification in a way that is user-friendly and informative.

- Identification of Key Functionalities:
    - Review each product baseline to identify its core features.
    - Determine which functions are most relevant to the user's understanding for selecting a product that fits their needs.
- Simplification of Technical Details:
    - Translate the technical functions into features that are usable and known by the customer.
- Structuring the Specification Document:
    - Organize the technical specifications into a logical structure, grouping related functionalities together.

This approach to creating the simplified technical specifications will enable the users to understand the functionalities offered with each product baseline. This methodology prioritizes user readability and ensures that technical information is accessible, relevant, and geared towards informed decision-making.

3.4. Bill of Materials (BOM)

A Bill of Materials (BOM) is a list used to detail the quantity of parts, components, and assemblies used in a product. As the arm developed in this thesis is only a first draft, a comprehensive BOM cannot be created. Instead, a BOM for both the fluid and electrical systems for each product baseline was created in Microsoft Visio. The methodology behind how these BOMs were created is as follows:

- Identification of Components:
    - Review the fluid and electronic system diagrams for all product baselines to identify all components required for each system.

- Quantification of Materials:
    - Count the number of each component that occurs for each system for all product baselines.
- Compilation of BOM:
    - Create a BOM for each product baseline using the components and quantities found in the previous steps.
- Updating and Maintenance:
    - Update and maintain the BOM as a living document through the entire product development and manufacturing cycle.

The BOM is an important document that ensures each product baseline and customized configuration is manufactured using the right components. By following this methodology, mistakes made when creating the BOM can be avoided.

3.5. Cost Analysis

It is hypothesized that a modular product architecture will reduce the cost of the product. This cost reduction can appear in many ways, but this comparison is focusing on the aspect of replacing a module within the product. This comparison will be done on the 'Realistic IO w/ IM' variant of the 'IO Module' will be compared to the IO functionality on the SimMan 3G PLUS arm. With the monolithic architecture used to develop SimMan 3G PLUS, it is theorized that replacing the IO functionality would be more expensive than replacing an IO module in a modularized simulator arm. This comparison only looks at the material cost and does not take into consideration other costs associated with repairing and/or replacing parts.

- Identification and Quantification of Components:
    - Compile a list of the quantity of components used in both the IO module variant and the SimMan 3G PLUS arm.
- Data Collection:
    - Determine the cost to Laerdal Medical of each component.
- Calculation of Module Cost:
    - Sum the resulting costs of each part in the system to calculate the total module cost.
- Comparison of Results:
    - Compare the cost of the IO module variant to the IO functionality in the SimMan 3G PLUS arm.
- Documentation and Reporting:
    - Document the assumptions, calculations, and results of the cost analysis.
    - Report the results of the cost analysis highlighting the % change in cost between the IO module and SimMan 3G PLUS arm.

A modular product architecture can decrease the cost of a product in many ways. By following this methodology, the analysis performed will show whether or not this modular product architecture will reduce the material cost associated with replacing a module.

3.6. Sustainability Analysis

To compare the sustainability of the modular product architecture to a monolithic product architecture, a carbon equivalent analysis for materials will be used. Instead of comparing the entire product, the 'Realistic IO w/ IM' variant of the 'IO Module' will be compared to the IO functionality on the SimMan 3G PLUS arm. This comparison will test the hypothesis that using a modular product

architecture will improve the sustainability of Laerdal Medical training solutions. The methodology for this process is as follows:

- Identification and Quantification of Components:
  - Compile a list of the quantity of components used in both the IO module variant and the SimMan 3G PLUS arm.
  - Identify what materials each component is manufactured from.
- Data Collection:
  - Determine the mass of each component.
  - Collect data for the carbon equivalent for each material using a Life Cycle Inventory (LCI) dataset.
- Calculation of CO_2 Equivalent:
  - Multiply the carbon equivalent of the material by the weight of that material for each part.
  - Sum the resulting carbon equivalent of each part in the system to calculate the total carbon equivalent.
- Comparison of Results:
  - Compare the total carbon equivalent of the IO module variant to the IO functionality in the SimMan 3G PLUS arm.
- Documentation and Reporting:
  - Document the assumptions, calculations, and results of the sustainability analysis.
  - Report the results of the sustainability analysis highlighting the % change in carbon emissions between the IO module and SimMan 3G PLUS arm.

A modular product architecture is expected to increase the sustainability of a product. By following this methodology, the analysis performed will be done in a structured way to avoid errors that can skew the results.

3.7. Product Lifecycle Management (PLM) Software

3.7.1. Siemens NX TeamCenter

Siemens NX TeamCenter has the ability to act as a Product Lifecycle Management (PLM) system, providing an interface between CAD software used for product design and the Enterprise Resource Planning (ERP) system used for business management. While Laerdal Medical does not currently have the 'Product Configurator' license that is meant for products with multiple different baselines and potential configurations (such as a modular product), there are plans to test this software in the future [78]. For this thesis I was unable to test the functionality of this Siemens NX TeamCenter package but based on research I have done into managing a modular system with a PLM software, the 'Product Configurator' license within Siemens NX TeamCenter seems like a strong candidate. Therefore, I have chosen to outline the methodology behind this despite not testing it during the thesis. The methodology that Siemens NX TeamCenter 'Product Configurator' add-on package is as follows:

- Revision of Items:
  - Item revisioning is used to save the state of a part at a specific point, allowing for the tracking of changes as the item progresses through its lifecycle stages.
- Integration with CAD Systems:
  - Teamcenter is integrated with NX CAD allowing for structures and attributes between NX and Teamcenter to be synchronized, with master data held in Teamcenter.
- Integration with ERP Systems:

- Teamcenter's product structures can be transferred to ERP systems, along with BOMs directly from the CAD models.

3.8. Customer Satisfaction

Gauging customer satisfaction through surveys is an important step in determining if the modular product architecture has been developed correctly. While a modular product architecture improves many aspects of a product, if customers are not willing to buy the product then the product is doomed to fail. For this thesis, no actual customers were interviewed. Rather, product and sales managers were interviewed as these are the positions that know best what the customer needs and what they are willing to buy. The methodology for this process is as follows:

- Survey Design:
  - Design a survey that includes both qualitative and quantitative questions that a focused on gauging customer satisfaction of the modular product architecture.
- Selection of Participants:
  - Identify employees within Laerdal who have a deep understanding of customer needs and the markets medical training solutions are sold in.
- User Testing with Participants:
  - Interview the participants by showing them the modular product architecture and physical prototype of the modular arm.
  - Have participants fill out the survey during the interview.
- Collection and Analysis of Responses:
  - Analyze the responses to identify trends in what can be improved about the modular product architecture.
- Improvement of Modular Product Architecture:
  - Improve the modular product architecture based on the feedback gained from the survey filled out during user testing.

Ensuring the modular product architecture will be well received by the desired markets is crucial for the success of the product. Prior to development of the product, the modular product architecture should be tested with potential customers. The methodology described above aims to gauge how successful the modular product will be.

4. Modular Product Architecture

The modular product architecture for the arm developed in this thesis was designed in the PALMA software created by Modular Management. The PALMA tools used to develop the modular product architecture for the modular arm are highlighted in blue on the 'HUB', or main menu in PALMA, shown in Figure 11. The MFD process is inherently iterative; using the first draft architecture, rapid interface prototyping and meetings with project stakeholders within Laerdal Medical were conducted. The feedback and knowledge gained from rapid prototyping and brief update meetings was then used to improve the architecture to a second draft. This second draft was used to develop the module arm and build the single physical prototype and digital prototypes for each product baseline that is then configured by the customer. User testing was performed using the second draft architecture and the physical prototype, the feedback from this testing was then used to improve the second draft architecture to the final architecture that is presented in this chapter. Given the scope of this thesis, further iteration on the proposed architecture will be left to future work. Modular product architecture should be treated as a living document that changes and adapts during the product development phase and to market trends during the lifecycle of the product.

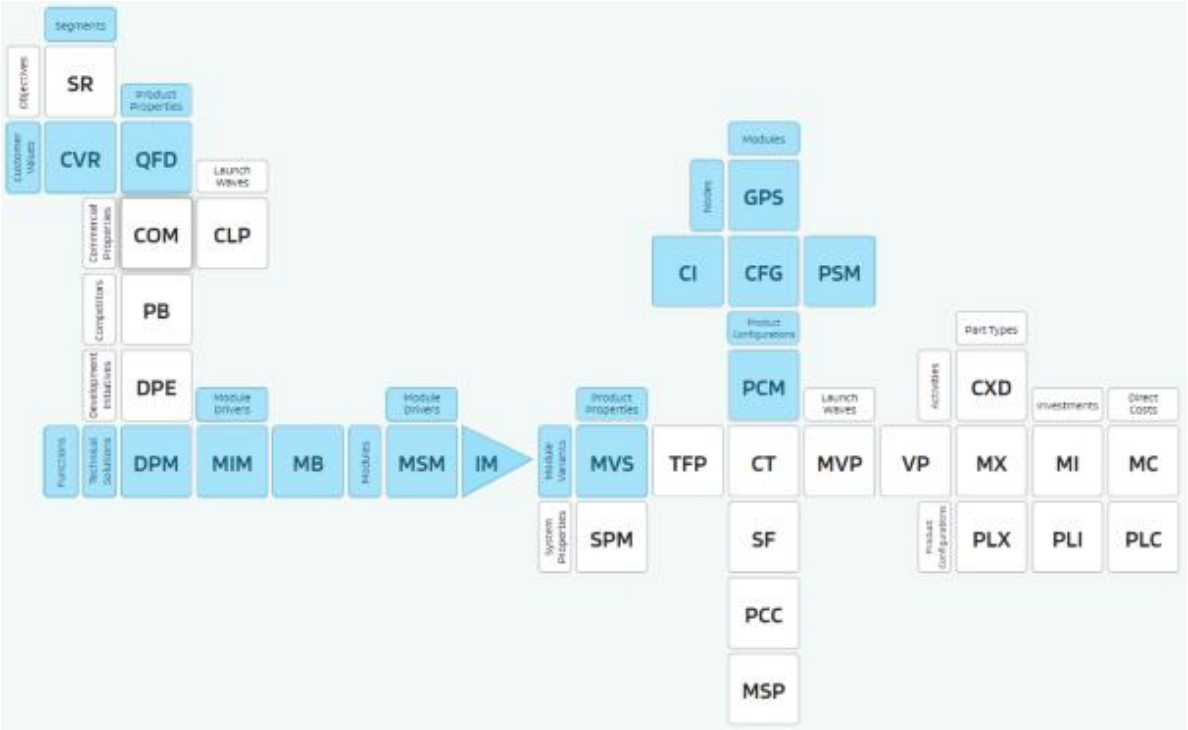


Figure 11 – HUB from PALMA with Tools used in Thesis Highlighted

4.1. Voice of Customer

The proposed modular product architecture fully encompasses the market segments and customer values for Laerdal's medical training solutions. This validates the voice of the customer, a critical voice if the product is going to be successful in the market. Knowing this improves the confidence that the modular product architecture will be well received by the target markets. Two PALMA tools, the customer value ranking and quality function deployment were instrumental in voicing the customer needs. Using these tools at the start of the MFD processes ensured decisions made when developing the modular product architecture were centered around meeting customer needs for all market segments. The foundation for a successful product is customer satisfaction, developing the modular product architecture using the MFD process guarantees that voice of the customer will be heard.

4.1.1. Customer Value Ranking (CVR)

As stated previously, both the customer values [14] and market segments [7] were defined prior to the start of this thesis. This work was done internally by MoSAic with the help from product managers of Laerdal medical training solutions. While defining the market segments and customer values is not my work, the ranking done in the CVR was done as part of this thesis work. A discussion with members from MoSAic team was held after the CVR was completed to ensure it aligned with their understanding of what market segments valued which customer values most. There are two important results that come from the CVR matrix shown in Figure 12, the sum of points for each market segment (found on the row below the matrix) and the average score for each customer value (found in the first column on the right side of the matrix).

Segments	Emergency Medical Services - Advanced	Military - Combat Medic	Emergency Medical Services - Intermediate	Military - Military Hospital	Healthcare Education - Advanced	Clinical - Emergency Room	Clinical - Intensive Care Units	Healthcare Education - Intermediate	Emergency Medical Services - Basic	Healthcare Education - Basic		1-5	
Customer Values													
Easy management of fluids	5	5	5	5	5	5	5	5	5	5	5.0	5	10
Accessible consumables	5	5	5	5	5	5	5	5	5	5	5.0	5	10
Easy to learn how to use the product	5	5	5	5	5	5	5	5	5	5	5.0	5	10
Easy of running/operating/controlling training	5	5	5	5	5	5	5	5	5	5	5.0	5	10
Easy to choose the product that I need	5	5	5	5	5	5	5	5	5	5	5.0	5	10
Easy to set up (preparation)	5	5	5	5	5	5	5	5	5	5	5.0	5	10
Easy to clean	5	5	5	5	5	5	5	5	5	5	5.0	5	10
Ease of maintenance	5	5	5	5	5	5	5	5	5	5	5.0	5	10
Easy to understand product disposal	5	4	5	4	5	5	5	5	5	5	4.8	4	8
Realism in human-like product	5	5	5	4	5	4	4	5	5	5	4.7	4	7
Training of basic patient related skills	5	5	5	5	5	3	3	5	5	5	4.6	4	8
Training of advanced patient related skill	5	5	4	5	5	5	5	4	3	3	4.4	3	6
Easy to customize	5	5	4	5	5	5	5	4	3	3	4.4	3	6
Use with real equipment	5	5	5	5	3	5	5	3	4	3	4.3	3	6
Long lasting product	4	4	4	4	5	4	4	5	4	5	4.3	3	3
Effective trauma training	5	5	5	5	5	5	5	3	2	2	4.2	3	7
High level of functional fidelity	4	3	4	3	5	4	4	5	4	5	4.1	3	3
Use in special environments	5	5	5	5	2	2	2	2	5	2	3.5	1	5
Sum	88	86	86	85	85	82	82	81	80	78			

Figure 12 – CVR Matrix from PALMA for the Modular Arm

As mentioned in the methodology, the sum of point for each market segment should be similar to eliminate the possibility of skewing the product architecture towards or away from certain market segments. Although the sum ranges from a score of 78 for the *Healthcare Education – Basic* market segment to 88 for the *Emergency Medical Servies – Advanced* market segment; I do not feel this skews the product architecture away from the *Healthcare Education – Basic* market segment. When analyzing the CVR, it can be seen that the *Healthcare Education – Basic* market segment only scores a two out of possible five points for both the *Effective trauma training* and *Use in special environments* customer values. As the *Healthcare Education – Basic* market segment is limited to training certified nursing assistants whose main role is to communicate between patients and registered nurses and the extent of their care is narrowed to maintaining patients hygiene, it makes sense we would see a low score for both the *Effective trauma training* and *Use in special environments* customer values as this market segment will likely not need to train for trauma situations or in special environments such as an ambulance, helicopter, or outside. The *Use in special environments* customer value

specifically lowers the score of five of the ten market segments, if this score was normalized we would see a smaller scoring range that is indicative of a balanced approach to the market segments. However, normalizing scores removes the little differentiation between customer values needed to rank their importance, therefore no normalization of scores was done in the CVR.

The average score for each customer value is used in the Quality Function Deployment matrix to weigh the score the customer values give when scored against the product properties. Having a more broad weight to the score from 3.5 to 5 as seen in Figure 12 gives more value to understanding what customer values and linked product properties are most important for the product. If normalization of the scoring was done, this weighed range would decrease which would limit the ability to visualize trends in the data, reducing the effectiveness of the CVR and QFD matrices for planning importance of functions in the product. In line with what was seen when analyzing the sum of the market segments, the *Use in special environments* customer value has the lowest average score across the market segments. However, this does not mean that this customer value is less important than the others as it still is highly important to half of the market segments. This knowledge is used to better design the functions critical to the market segments this customer value is important to by ensuring the technical solution is robust enough to work in special environments.

Quickly visualizing how these market segments align with customer values can be difficult when looking at a matrix. To combat this, PALMA has created the 'Customer Canvas' shown in Figure 13. While better used on PALMA where market segments can be toggled on and off which hides their respective color, this figure can still be more easily analyzed then the CVR matrix found in Figure 12. Looking again at The *Use in special environments* customer value, there is a large gap between the curves, indicating an inconsistency between market segments with this customer value. This gap

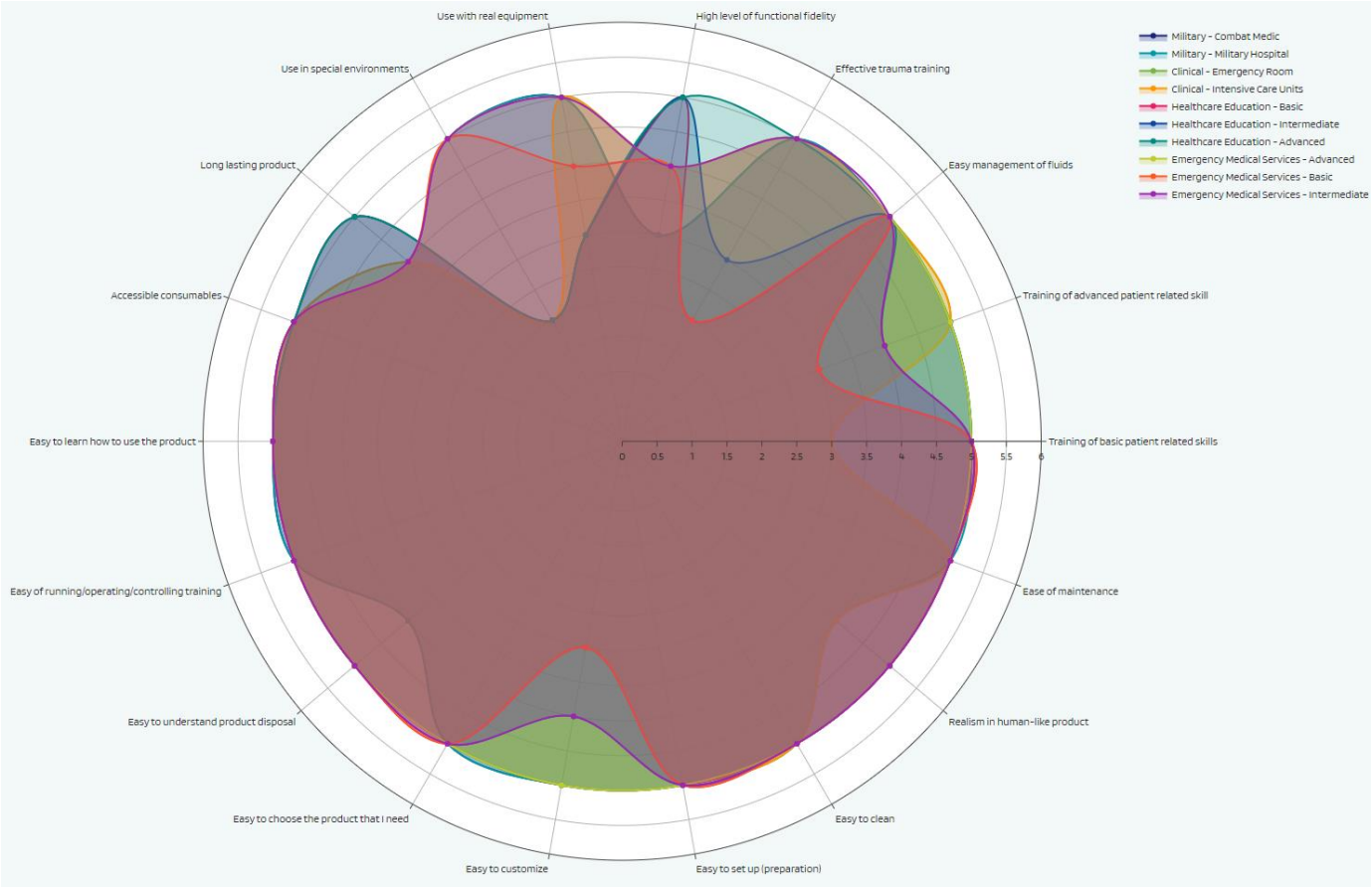


Figure 13 – Customer Canvas from PALMA for Modular Arm

correlates to the low average score seen when analyzing the matrix. As described previously, this misalignment is to be expected due to only half of the market segments requiring training solutions to be used in special environments. While harder to determine the exact score given by each market segment to each customer value when looking at the 'Customer Canvas' it is much easier to spot trends such as misalignment between market segments. Understanding these trends is critical in creating modules, product baselines, and user-driven configuration to meet all market segments. One obvious trend that can be easily seen is the misalignment in customer that value *Effective trauma training*. Knowing this, we can plan for having a dedicated trauma module and product baseline to allow those customers that need to simulate trauma without forcing the customers that will never use this module to pay the added cost of having it in their product. Understanding this trend and implementing modules to segment the product to target specific market segments highlights the benefits of a modular product architecture when compared to a monolithic one.

The results from the CVR are used as the foundation for the entire modular product architecture. Although the ranking may seem insignificant, its use with weighing the customer values in the QFD matrix has large downstream effects on shaping both the modular product architecture and development of the product. Ensuring that the product properties and linked functions align with the customer values and market segments are critical for creating a product that will be well received by the customer. At its core, the CVR helps ground the product architecture, it can be far to easy to add unnecessary functionality to a product, increasing its complexity and cost, without adding value to the customer. By aligning the modular product architecture with customer values from the start, this pitfall can be avoided to a large extent.

4.1.2. Quality Function Deployment (QFD)

The QFD matrix is used to link relationships between customer values and product properties. Prior to filling out the matrix, the product properties must be defined. The product properties were defined prior to the start of this thesis by the MoSAic team for the entire manikin [79]. These pre-defined product properties were condensed to only include those relevant to the arm being

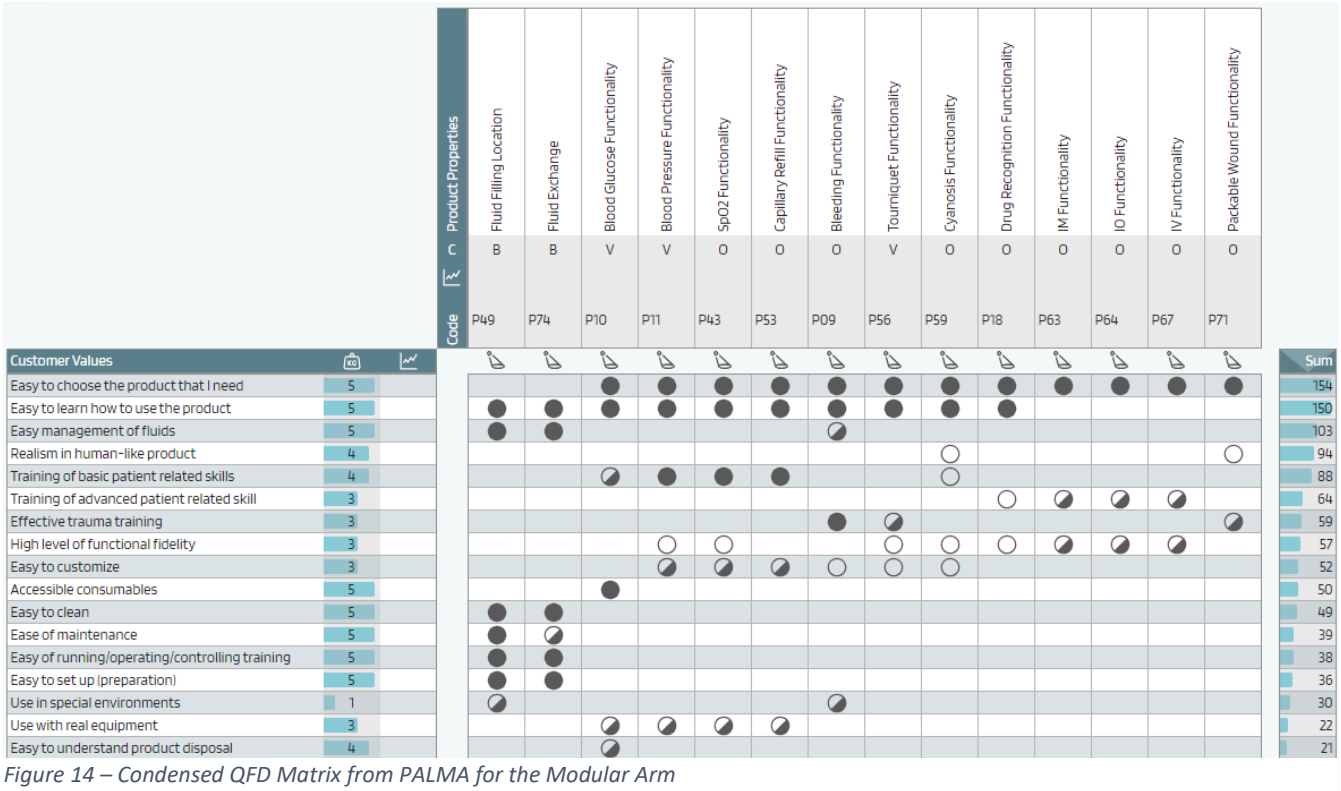


Figure 14 – Condensed QFD Matrix from PALMA for the Modular Arm

developed in this thesis. From this initial list, product properties were iterated by me as the modular product architecture for the thesis was developed. In the end, the list of product properties found in Appendix A.1 is a culmination of work done by the MoSAic team and my original work for this thesis.

A condensed version of the QFD matrix is presented in Figure 14 to provide a readable example of how the QFD was used to link customer values to product properties. The full QFD matrix can be found in Appendix A.2, the symbols have been replaced with their equivalent numerical values (as explained in the methodology section). This condensed QFD matrix shows 14 of the 72 product properties and provides a range of sums which allows for visualization of trends in how certain product properties relate to more or less of the customer values; only those that relate directly to functionality of the product were chosen. Two results from the QFD matrix are generated, the first and most important is the weighted sum of the product properties found at the bottom of the matrix. This weighed sum is used in the Design Property Matrix to add weight based on importance to the function scores. The less important score can be found to the right of the matrix, where the sum for each customer value can be seen. This sum does not necessarily correlate to the importance of the customer value, which is shown as the weighted score of one to five on the left of the matrix, but rather an indication of how many product properties are linked to that specific customer value.

Again using the *Effective trauma training* customer value as an example, the product properties relevant to this customer values have been linked. In later steps these product properties get linked to product functions which are then distributed into modules. With this understanding of the MFD process, the usefulness of the QFD matrix for grouping product properties into potential modules becomes evident. On a larger scale, the QFD matrix can be used to rank product properties by importance. The product properties *Fluid Filling Location* and *Fluid Exchange* have the highest score because they interconnected with the most customer values. Having effective technical solutions to enable these product properties is therefore crucial to the success of the product as they encompass all market segments and will likely be properties of every product baseline and configuration offered.

4.2. Voice of Engineering

The voice of engineering is used to map how the customer centric product properties will be solved by technical solutions within the product. This portion of the MFD process bridges the gap from conceptual product properties that the customers need to physical solutions that can be implemented into the product. By having the voice of engineering after the voice of the customer, only the essential product functions are considered. This reduces complexity of the product ensuring the customer receives what they need and nothing more.

4.2.1. Design Property Matrix (DPM)

The DPM is used to link product properties to product functions. Prior to filling out the DPM, the product functions must be defined. Before starting this thesis, MoSAic had mapped out functions and various technical solutions, both currently implemented and new concepts, for the whole simulator [80]. For the thesis, these functions and technical solutions were condensed based on relevance to the arm. The list of functions found in Appendix A.3

is not fully my original work as it has been adapted from the work done prior to starting the thesis by the MoSAic team.

A condensed version of the DPM for increased readability is presented in this section. This DPM uses the same product properties shown in the condensed version of the QFD matrix to bring consistency to the analysis and trends described. The full DPM can be found in Appendix A.4 where every function and product property have been linked. Three results from the DPM are given from the matrix, the sum found at the bottom of the matrix is linked to how many functions the product property interacts with. This result can be used to compare the sum of product property interactions created by the QFD matrix. This comparison, while difficult to analyze, can be used to refine the importance ranking of the product properties. An easier way to determine the importance of the function to customer values is to use the score found in the second column on the right side of the matrix. This score links the customer values to product function through the product properties by

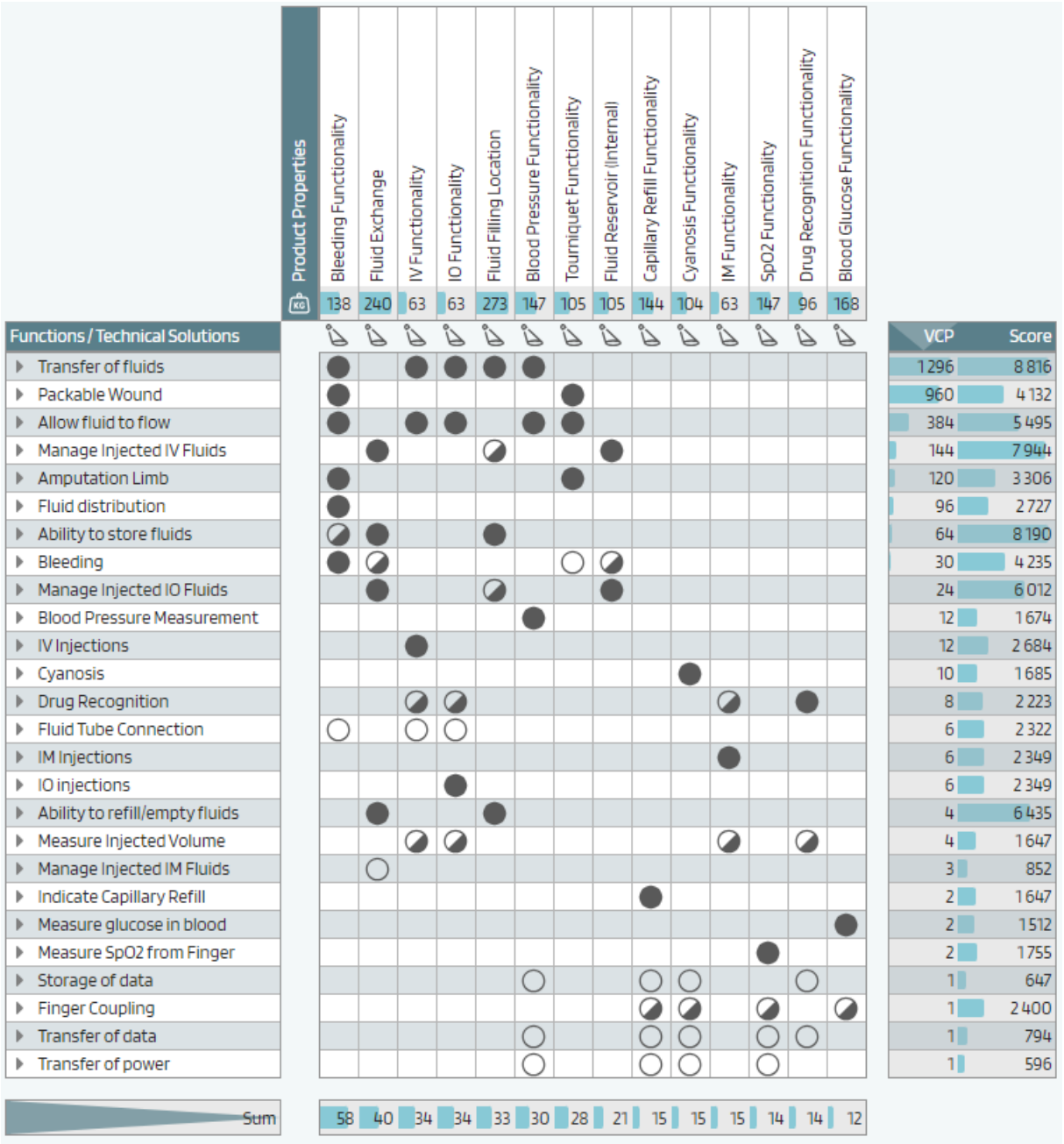


Figure 15 – Condensed DPM from PALMA for the Modular Arm

using the importance weight for the product properties created in the QFD matrix. Similarly, to the value of knowing which product properties are most important, knowing which functions are most

important is critical to the success of the product by focusing resources on functions that will appear in all product baselines. Looking at the condensed version of the DPM found in Figure 15, six of the functions all have a significantly high score, while the exact value of this score is not relevant, these six functions have a much higher score than most other functions. This indicates that these functions are more important for meeting all market segments than the other functions. Logically, this makes sense as all six of these functions deal with how fluids are managed by the product and user, a customer value that scored a full five out of five in the CVR for all market segments. Knowing this, designing a robust and easy to use fluid system is directly linked to product success. When comparing these results to the QFD, we also see direct alignment as the product properties *Fluid Filling Location* and *Fluid Exchange* had the highest score due to their relevance to the customer values. Fluid management in the product is only one example of a trend that has been realized after analysis of the QFD matrix and confirmed by the DPM matrix. The third result from the DPM is used to map how much variance is required for each technical solution to meet the goal values of the product properties, this result is known as the variance count predictor (VCP) and can be found in the first column to the right of the matrix. The higher the VCP, the more variance is being linked to the technical solution from the product property. In essence, a higher VCP for a technical solution means more complexity is needed to meet the customer needs. Sometimes, technical solutions with a high VCP can be split into multiple smaller ones, other times, like with this thesis, high VCP score technical solutions are kept as one due to how they fit into modules. The transfer of fluids function is organized with the fluid management module, a system level module that is interconnected with many other modules. In a less complex system, the function could likely be separated to fit into multiple modules each that are self-controlled.

When creating the modular product architecture for the thesis, this process of finding relationships between customer values, product properties, and functions was performed for each grouping of product properties. Each tool is meant to be used iteratively and refined after each subsequent step of the MFD process. The DPM finalizes the relationship between customer needs and product functions that is needed to create a modular product architecture that is grounded in customer values and encompassing of all market segments.

4.3. Voice of Business

The voice of business is used to ensure that the modular product architecture aligns with the companies business strategies. PALMA divides these business strategies into three categories: operational excellence, product leadership, and customer intimacy [58], [60] to simplify and focus the business strategy of modular product architecture.

4.3.1. Module Drivers

The module drivers used for the MFD process were developed by Gunnar Erixon in the paper “Modular Function Deployment (MFD), Support for Good Product Structure Creation” [60]. For this thesis, the module drivers outlined in that paper were used, as they are the default module drivers used in PALMA. The descriptions for these module drivers are the default for what appears in PALMA and are therefore not my original work but the work of Modular Management [81] based on that of

Gunnar Erixon [60].

Name	Description	Type
Carry Over	Parts that are re-used in future improvements of the product as they are planned to have a long lifecycle.	Improvement
Technology Push	Parts that will likely change during the product life cycle due to technology advancements.	Improvement
Planned Development	Features that are planned to be improved in the future.	Improvement
Technical Specification	Parts that control aspects of the technical specification, often vary across different product variants.	Variance
Styling	Parts that contribute to the design language of the product.	Variance
Common Unit	Parts that are universally used across different product variants.	Variance
Process & Organisation	Parts that have specialized processes or resources that require organization for continued procurement.	Process
Separate Testing	Parts that functions can be tested separate from the rest of the modules.	Process
Black box Engineering	Parts that can be manufactured and delivered to the company as a completed module by a partner.	Process
Service & Maintenance	Parts that are detachable are easier to repair.	Process
Upgrading	Parts that are easily interchanged makes it easier to upgrade the product after production.	Process
Recycling	Parts that are made of multiple materials should be easy to recycle.	Process

Figure 16 – Module Drivers from PALMA as defined by Modular Management [75]

These module drivers are split into three types: improvement, variance, and process [81]. These are groupings defined by Modular Management for use in PALMA. By grouping the module drivers, it helps to eliminate conflicting strategies, as was described previously in Section 3.1.6. The module drivers help to organize the product functions into the three types. Modules are created based on the grouping of the functions, and then the module drivers are again used to ensure no modules have conflicting strategies. Grouping functions and modules with the module drivers ensures alignment of modules with the modular principles. If a module consists of parts that are both *carry over* and *planned development* there will be a clash in module strategy and the resulting module would not align with the pillars of modular product architecture. Just like the QFD and DPM were used to ensure product properties and functions align with customer needs, modular drivers ensure that modules align with the modular principles and company business strategy.

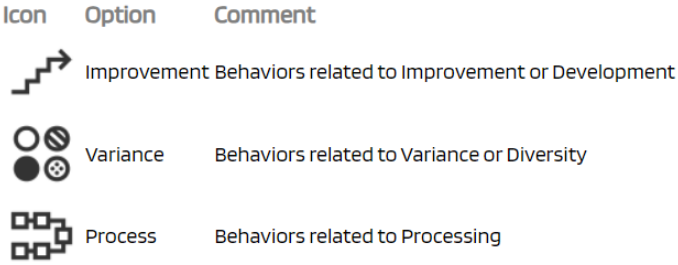


Figure 17 – From: PALMA Guide for Module Drivers [75]

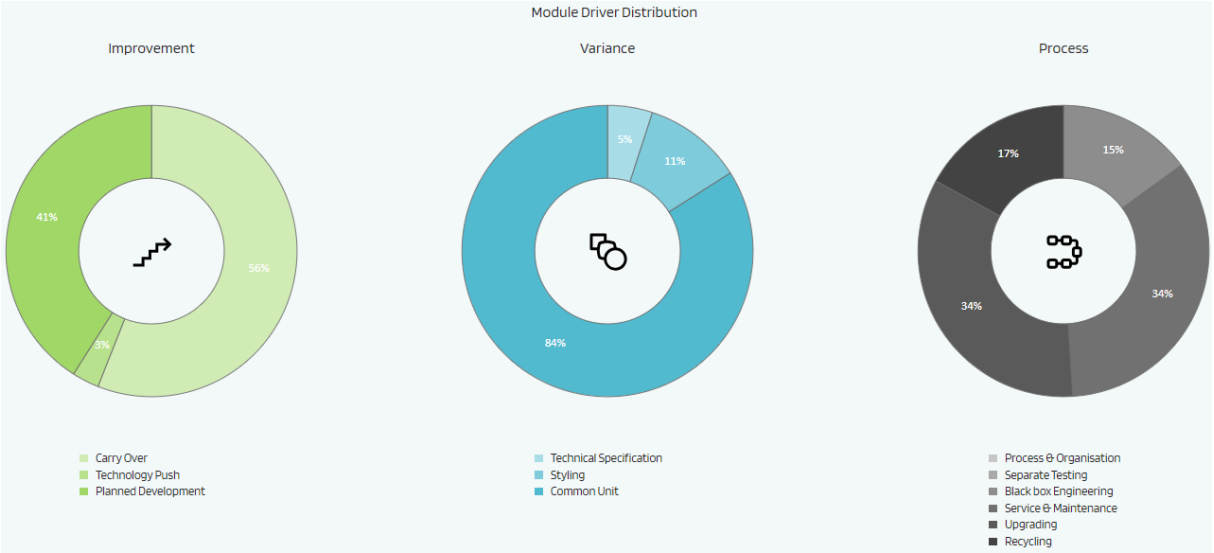


Figure 18 – Module Driver Distribution Report from PALMA

After the module drivers are linked to the modules, a distribution report becomes available in PALMA. This report, shown in Figure 18, is generated within PALMA to show the distribution of the modules within the three module driver categories: improvement, variance, and process. This report

provides a nice visual representation for analyzing how the modules are distributed within each module driver category. For example, in the improvement section, close to half of the modules are going to require technology advancement during the lifecycle of the product as 44% of the improvement category is associated with planned development and technology push. Reports like this generated by PALMA help stakeholders quickly visualize the strategy of the product from a bigger picture without having to sort through and analyze multiple different matrices.

4.3.2. Module Indication Matrix (MIM)

Using the default module drivers and product functions, the modular indication matrix is used to group together functions by module driver type. Grouping the module functions together allows for analysis of which functions should be combined together to create a module. Given there are 50 product functions, the full MIM is too large to visually present in the body of the thesis. Instead, the full MIM can be located in Appendix A.5. In this section, a condensed version of the MIM is presented to share insight into how the results of the matrix were used to aid in the creation of modules for the modular arm focused on in this thesis. The condensed MIM, as seen in Figure 19 only shows 17 of the 50 product functions. These functions focus on the core features of the arm and the fluid system to align with the functions and product properties shown in the other condensed matrices.

Analyzing the matrix shows that the product functions *Ability to store fluids* and *Ability to refill/empty fluids* should be grouped together in the same module as they are both linked to the module drivers *Carry over* and *Common Unit*. For the product functions *Cyanosis* and *Drug Recognition*, these are product functions that should be grouped in separate modules as the module drivers *Technology Push* and *Planned Development* have a strategic misalignment. However, just because the product functions have the same module drivers do not necessarily mean they should be placed in the same module. The product functions *IM injections, IO injections,* and *IV injections* all share the *Carry over, Service & Maintenance,* and *Upgrading* module drivers. Without analyzing what customers need

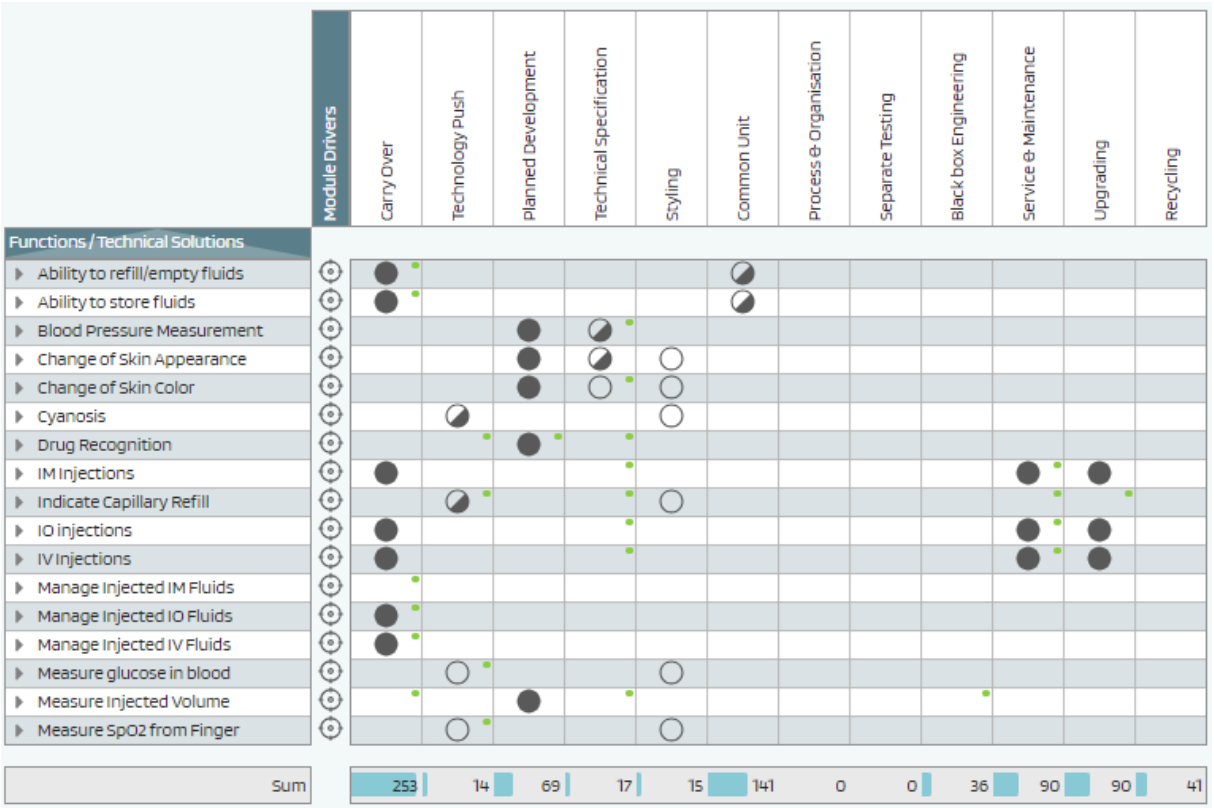


Figure 19– Condensed MIM from PALMA for the Modular Arm

these functions and where these functions are located within the arm, it seems perfectly logical that all three product functions could be grouped into one module. While this grouping would work, it unnecessarily increases the complexity of the modular system. A better way to group these functions into module is to group them based on where the procedure is performed within the arm and then created module variants based on the different customer needs. Both IO and IM injections are performed in the shoulder, therefore the functions associated with them should be grouped into one module. The IV injections are performed in three locations all in the lower arm. As no other functions directly align with the *IV injections* product function, it should be grouped into its own module. Splitting the injection functions up into two separate modules reduces the complexity of the modular system by limiting the functionality of a module to a specific area in the product and then linking them together with a system module such as the *Fluid Management* module.

The MIM provides valuable information for how to group product functions into modules However, PALMA alone cannot make decisions about how the modular system should be designed. Critical thinking and a deep understanding of the product goals is required to make informed decisions based on the results presented by PALMA. Iterations to the MIM and all matrices must be made continuously, it is impossible to fully understand the interconnectivity of the modular system from the start. The injections functionality is a great example of this as both grouping methods work but with a better understanding of how the whole modular system should interact, it becomes clear one method is better than the other.

4.4. Voice of Modularity

The voice of modularity is the culmination of the previous voices (customer, engineering, and business) into dedicated modules that adhere to the principles developed previously. The modules are created to organize these customer focused functions into modules and variants of modules in a way that meets market demands in a flexible way. Without the voice of modularity, the product architecture is no different from that of a monolithic approach. This unique organization of functions into modules is the foundation for the inherent customization offered in product developed with a modular architecture.

4.4.1. Modules and Variants

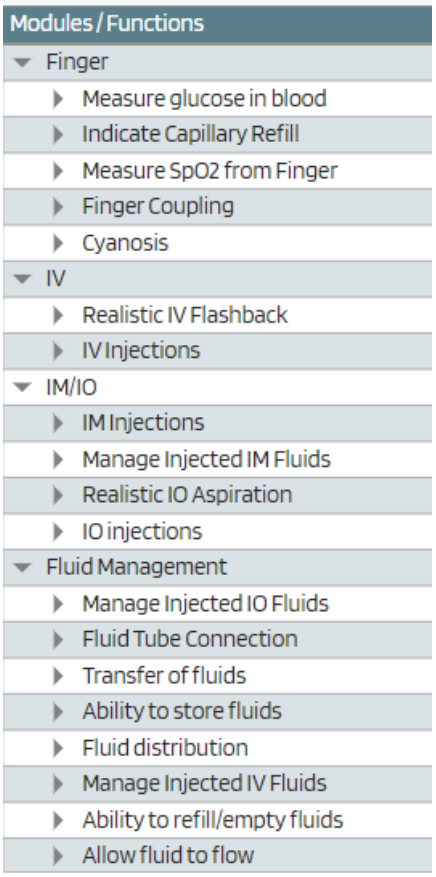


Figure 20 – Condensed version of modules and their associated functions grouped using the module builder tool in PALMA

Using the module builder tool in PALMA, the product functions were grouped into modules. A condensed module builder interface can be seen in Figure 20, the list of modules and associated functions was too long to present within the thesis body but can be found in Appendix A.6. The modules and functions presented in Figure 20 give a good representation to the type of product functions that are associated with each module.

Product functions were grouped into modules using the insight gained from the MIM where the product functions were associated with module drivers. These module drivers grouping helped to create a sense of organization to the functions as certain module drivers, such as *carry over* and *technology push* cannot be grouped together in the same module. Some product functions were easy to group into modules, such as the *realistic IV flashback* and *IV injections* product functions going into the IV module. Having an idea of the desired function of the modules can aid in grouping the product functions into module, for example, the product function *manage injected IV fluids* could be apart of the IV module as it is directly related to the IV functionality. However, given how the system is intended to work with all fluids being managed by the fluid management module, it made more sense to associate the *manage injected IV fluids* function with the fluid management module.

After all of the product functions were grouped into modules, the variants for each module were defined. These variants are used to differentiate between functionality that is not required by all customers to help cover all market segments using different configurations of product baseline. Defining the modules and variants provides the foundation for the product baseline to be built on. The following sub-sections explain the function and variants (when applicable) of each module for the product architecture created in this thesis that was used to develop the modular arm. These modules follow the module hierarchy defined in Section 3.1.9.

Arm Connector

The arm connector module is a system level module that defines the interface between the shoulder frame module and the detachable arm frame module. This module provides a detachable mechanical, fluid, and power/data connection between the two interfacing modules. The intention of this module is to allow different detachable arm configurations to be attached to the shoulder module which is permanently attached to the torso of the manikin. No module variants have been created for the arm connector as it will appear in all product configurations of the modular arm. Regardless of the fluid or power/data connection being utilized by the specific product configuration it must be present in all product configurations to allow for any detachable arm configuration to be attached to the shoulder module. This module provides the customer with added customization to their full body medical patient training simulator making it a versatile and essential module from the consumers point of view.

Frame – Shoulder

The shoulder frame module is a top level module that will be permanently connected to the torso of the manikin. The frame will house the shoulder joint that will provide three degrees-of-freedom to allow for realistic movement. The shoulder frame module will interface with the IM/IO module, part of the fluid management system module, part of the drug recognition module, part of the skin appearance module, the upper half of the arm connector module, and the shoulder skin module. The detachable arm module can be connector and disconnected from the shoulder module because of the arm connector module that interfaces both modules. The module itself has little functionality and rather provides an interface for multiple modules. As the shoulder frame will be consistent for all full body medical patient training simulators, there are no module variants for this module.

Frame – Detachable Arm

The detachable arm frame module is a top level module that can be detached from the shoulder frame module because of the arm connector module. The detachable arm frame module contains the joints for the elbow, forearm, and wrist which allows for realistic movement of the lower arm. Depending on the product configuration, the detachable arm module will interface with the and hand frame modules and some or all of the following sub-level modules: detachable arm skin, IV (cubital fossa and cephalic vein sites), pulse, finger, blood pressure, and seizure. The detachable arm module will also interface in part with the drug recognition and skin appearance modules as these are spread over both shoulder and detachable arm modules. Given the need for trauma limbs to satisfy all market segments, the detachable arm frame module has been divided into three module variants.

Module Variants:

- Base Detachable Arm Frame

This module variant is used for the non-trauma product baselines and contains all joints, and interfaces mentioned above.

- Amputee Arm Frame

This module variant is used for the trauma: amputee arm product baseline. The amputation occurs below the elbow so forearm rotation and the hand frame module are not part of this variant. This variant will always contain an interface for the amputee variant of the trauma module.

- Large Wound Arm Frame

This module variant is used for the trauma: large wound product baseline. The large wound occurs on the forearm but full arm joint and wrist articulation are present in this module variant. This variant will always contain an interface for the large wound variant of the trauma module.

Frame – Hand

The hand frame module is a top level module that interfaces to the base detachable arm frame and large wound arm frame module variants of the detachable arm frame module. The interface occurs at the wrist joint which allow for full realistic articulation. The hand frame module interfaces with the dorsal vein site of the IV module, the finger module at all sites (index, middle, ring), and the detachable arm skin. This module provides a frame to interface other modules with, it does not have any module variants but does not occur with the trauma: amputee product baselines.

Skin – Shoulder

The shoulder skin module is a sub-level module that provides a realistic interface to the customer with the product. This module interfaces with the shoulder frame module and can be removed and replaced due to damage or with a different color or skin demographic. This module is only used to enhance the interaction between the customer and the product. Due to the IM/IO module, there are two module variants associated with the shoulder skin module.

Module Variants:

- Base Shoulder Skin

The base shoulder skin variant will cover the shoulder frame module and have a cutout to allow for the realistic IM and Realistic IO with IM variants of the IM/IO module to interface with the shoulder frame module. These module variants have their own skin, a small seam will be seen on the skin at the module interface.

- Exposed IO Shoulder Skin

The exposed IO shoulder skin variant will cover the shoulder frame module and have a cutout to allow for the exposed IO variant of the IM/IO module to interface with the shoulder frame module. This module variant will have its own skin, a small seam will be seen on the skin at the module interface. The IO injection point for the exposed IO module variant is much smaller therefore less skin needs to be replaced. Using a second module variant to account for this specific IM/IO module variant reduces the amount of plastic waste associated with changing the IM/IO module after use.

Skin – Detachable Arm

The detachable arm skin module is a sub-level module that provides a realistic interface to the customer with the product. This module interfaces with the detachable arm frame module and can be removed and replaced due to damage or with a different color or skin demographic. This module is only used to enhance the interaction between the customer and the product. Due to the trauma module, there are three module variants associated with the shoulder skin module.

Module Variants:

- Base Detachable Arm Skin

The base detachable arm skin variant is used for all product baselines except the two trauma arm configurations. There are holes in this arm skin variant that interface with the IV and finger modules which both have their own skin. At theses interfaces, a small seam will occur.

- Amputee Arm Skin

The amputee arm skin variant is used for the trauma: amputee product baseline. It will interface with the trauma module and will show the details of an amputee wound below the elbow.

- Large Wound Arm Skin

The large wound arm skin variant is used for the trauma: large wound product baseline. It will interface with the finger module and the trauma module which will show the details of the large wounds on the lower arm.

Finger

The finger module is a sub-level module that interfaces with the hand frame module, detachable arm skin module, and electronics management module. The finger module provides three fingers sites,

index, middle, and ring, that can be exchanged by the customer adds increased product customization at a relatively low level of complexity to Laerdal. Each finger will have skin that will show a seam when interfaced with the detachable arm skin module. Four functional finger variants: SpO_2, capillary refill, blood glucose, and cyanosis along with one function free finger variant can be mixed and matched by the user to better encompass their training needs. Following the solution used in SimMan 3G PLUS, the thumb and pinky have remained as non-functional fingers that are placed inside the arm skin. This helps eliminate the risk of broken parts as these fingers are most likely to be caught in doors or snagged on hospital beads. While only having three functional fingers does reduce the immersion of the product, especially when simulating cyanosis in the fingers, this is a necessary tradeoff required to make a more robust product.

Module Variants:

- Blood Glucose Finger

The blood glucose finger variant will allow the user to take reading of blood glucose using a real glucometer by pricking the tip of the finger. The finger will be filled with a red colored sugar water solution that can be diluted to different blood glucose levels. To fill/empty the finger with the solution, a tube and syringe will be attached to the base of the finger. The technical solution has only been conceptualized but that will be the intended functionality of this finger variant.

- SpO_2 Finger

The SpO_2 finger variant will allow the user to take blood oxygen reading from the finger using a real pulse oximeter. This function is available on the SimMan 3G PLUS, the technical solution is intended to be reused but will need to be modified to fit a modular interface that can be attached and detached.

- Cyanosis Finger

The cyanosis finger variant will turn blue at the fingertip to indicate cyanosis. These fingers will likely be used in sets of three, so they will be offered as an add-on packaged.

- Capillary Refill Finger

The capillary refill finger variant will allow the user to test the capillary refill time by pressing on the back of the finger and determining how long it takes for the finger to turn from white back to normal.

- Dummy Finger

The dummy finger variant is used as a placeholder to increase realism of the product for the lower cost product baselines that will not have functions in the fingers. This dummy finger solution can be found on SimMan 3G PLUS but they are not removable without taking apart the hand frame.

IV

The IV module is a sub-level module that interfaces with both the detachable arm frame and skin modules. This module interfaces at three sites: cubital fossa, cephalic vein, dorsal vein, along the arm frame. This module is used to provide IV functionality for medicine injection and blood draw at various sites commonly used by healthcare professionals. Due to the different needs of the customers, two module variants have been created to help encompass all market segments. Both module variants will provide blood flashback to the user which indicated correct IV needle placement. This module will be interfaced with the fluid management module and an internal and optional external reservoir can be used to store fluids for use of the IV function.

Module Variants:

- Pre-Ported

The pre-ported IV variant is used for customers that do not need to train on the initial insertion of am IV needle but rather the care and continued used associated with an already inserted IV catheter. The pre-ported IV variant is exposed on the skin to guide the user to where the needle should be inserted. This solution is currently implemented on SimMan 3G PLUS, although in a non-modular way.

- Hidden

The hidden IV variant is used for customer that want to train on initial IV needle insertion. Aside from the split line seen at the module interface with the skin, there will be no opening to guide the user as to where the needled should be placed. Instead, a vein will be shown to indicate the region that the IV should be inserted in. The hope is that the hidden IV variant will mimic the process and feel used when inserting an IV needle into a real patient. A similar solution is current implement on SimMan Critical Care in a non-modular fashion.

IM/IO

The IM/IO module is a sub-level module that interfaces with both the shoulder frame and skin modules and fluid management module. This module is intended to provide IM and IO functionality to the user at the deltoid muscle and humeral head locations used in real world medical emergency situations. Due to the differing customer needs, three module variants were created to ensure that customer could pick the training solution they need and no pay for any unneeded features.

Module Variants:

- Realistic IM

This module variant provides a realistic experience to the customer for performing IM injections in the deltoid muscle on the shoulder. Skin to match the surrounding shoulder skin module will be used to create visual consistency and eliminate a “bullseye” for where to inject. Foam and a plastic bone are used to simulate the muscle and humeral head in the shoulder. An absorbent pad is located within the module to absorb the injected fluid and insure no fluid leaks into the manikin. This solution matches what is found on SimMan 3G PLUS.

- Exposed IO without IM

This module variant provides a “bullseye” IO experience to the customer when performing IO injections. Some customers do not require the high realism associated with the realistic IO with IM variant. This variant is aimed to be a lower cost IO function. The skin interface is different than for that of the other two IM/IO variants so the “bullseye” where the IO drilling is done is a smaller surface area, this saves money and material waste as the exposed IO cap is a consumable part. Aspiration is provided to the user during IO injection to indicate the needle is in the correct location, this is used to mimic the bone marrow that is aspirated during a real IO injection. This variant is connected to the fluid management system to allow injected fluid to be stored in the internal or optional external reservoir.

- Realistic IO with IM

This module variant provides a realistic experience to the customer for performing IM/IO injections in the deltoid muscle and humeral head on the shoulder. Similar to the Realistic IM variant, skin to

match the surrounding shoulder skin module will be used to create visual consistency and eliminate a "bullseye" for where to inject. The same foam and a plastic bone from the Realistic IM variant are used to simulate the muscle and humeral head in the shoulder. An absorbent pad is located within the module to absorb the injected fluid and insure no fluid leaks into the manikin. Similar to the Exposed IO without IM variant, aspiration is provided to the user during IO injection to indicate the needle is in the correct location, this is used to mimic the bone marrow that is aspirated during a real IO injection. The IO bone is connected to the fluid management module so injected fluid is contained within the internal or optional external reservoir. This solution matches what is found on SimMan 3G PLUS.

Pulse

The pulse module is a sub-level module that interfaces with the detachable arm frame module and electronics management module. The pulse module is located at two sites on the detachable arm, at the brachial and radial pulse locations. This module is intended to give the user the ability to check the pulse of the patient at two different sites on the arm. To meet the different customer needs, two module variants have been defined. The proposed technical solution will use the same solution found in SimMan 3G PLUS with some software modifications made to meet the two module variants.

Module Variants:

- Basic Pulse

The basic pulse variant allows for centralized pulse palpation, meaning that the pulse strength and rate will be consistent at each site.

- Advanced Pulse

The advanced pulse variant allows for localized pulse palpation, this means that the pulse strength and rate can be changed at each site which can indicate certain medical conditions wanted for simulation by some customers.

Blood Pressure

The blood pressure module is a sub-level module that interfaces with the detachable arm frame, electronics management module, and fluid management module, and with a pump located elsewhere (i.e. not in the arm) in the full body medical patient training solution. The module gives the user the ability to non-invasively measure the blood pressure of the patient. Two module variants are required to satisfy the customer needs and market segments. The technical solution for the blood pressure module will need to be further developed prior to implementation as the current solutions do not provide the required functionality needed for the two module variants.

Module Variants:

- Basic Blood Pressure Cuff

The basic blood pressure cuff module variant allows the user to measure the blood pressure on the arm using a blood pressure cuff provided by Laerdal. The basic blood pressure cuff only mimics the use of an automatic blood pressure cuff. The basic blood pressure functionality cannot be used with real automatic blood pressure cuffs.

- Advanced Blood Pressure Cuff

The advanced blood pressure cuff module variant allows the user to measure the blood pressure on the arm using a blood pressure cuff provided by Laerdal. The advanced blood pressure cuff mimics

the use of an automatic and manual blood pressure cuff by providing Korotkoff sounds to the user when measuring the blood pressure manually. The basic blood pressure functionality cannot be used with real automatic blood pressure cuffs.

Seizure

The seizure module is a sub-level module that interfaces with the detachable arm frame and electronics management module. This module gives the user the ability to simulate a seizure occurring in the patient by visually showing seizure symptoms in the arm such as shaking and uncontrolled movements. The technical solution for this needs to be further developed as the solution used in SimMan 3G PLUS is very large and according to product managers is mistaken by the users as hypothermia due to the minimal limb shaking provided by the function. To account for the varied customer needs, two module variants were used.

Module Variants:

- Basic Seizure

The basic seizure variant only allows for shaking in the arms to simulate a seizure, as this function will occur with a full body medical patient training solution, the arm shaking would be accompanied by features in other parts of the body.

- Advanced Seizure

The advanced seizure variant includes the shaking of the basic variant but adds a level of realism by locking the joints to indicate loss of movement control in the patient. Again, the seizure function would be accompanied by other indicators in the rest of the body to help with the realism of the seizure.

Joint Stiffness

The joint stiffness module is a system level module that interfaces with the shoulder frame, detachable arm frame, hand frame, and electronics management module. This module is intended to allow the user to lock the articulation of the arm into a desired position. This module adds a level of realism to improve immersion into the medical simulation. This feature is only desired by some customers due to this it is only found in one product baseline and does not have any module variants. The advanced seizure module variant requires the joint stiffness module to be present in the product baseline to work.

Drug Recognition

The drug recognition module is a system level module that interfaces with the IM/IO module, IV module, fluid management module, and electronics management module. This module is intended to provide the user feedback to which drug and what volume was injected into the patient. Two module variants have been chosen to provide customers with an ability to decide what level of fidelity they need. This functionality is currently available in SimMan 3G PLUS but will need to be improved to meet the modular product architecture requirements.

Module Variants:

- Basic Drug Recognition

The basic drug recognition variant will tell the user what drug was injected into the modular arm at either the IM/IO or IV module.

- Advanced Drug Recognition

The advanced drug recognition variant has the same function as the basic variant but will also tell the user the amount of fluid, to a 1mL accuracy, that was injected into either the IM/IO or IV module.

Skin Change

The skin change module is a system level module that interfaces with the detachable arm frame and skin modules, and the electronics management module. This module is intended to give the user visual cues by changing the appearance of the skin to indicate certain medical conditions. To provide this functionality to a wider range of customer at different price points, two module variants have been created. Currently, there is no technical solution in Laerdal medical that enables this function. A solution that meet the requirement for both solutions must be developed if the proposed modular architecture is to be used.

Module Variants:

- Basic Skin Change

The basic skin change module variant changes the color of the skin to pale, yellow, red, or blue to indicate to the user of potential medical conditions associated with certain skin color changes. Such as yellowing of the skin indicating jaundice (liver failure).

- Advanced Skin Change

The advanced skin change module variant changes the appearance of the skin by indicating burns, bruises, and rashes. It also has the same functionality as the basic variant.

Trauma

The trauma module is a system level module that interfaces with the corresponding detachable arm frame and skin modules, fluid management module, and electronics management module. The trauma module provides the user with the ability to train on trauma scenarios that focus on stopping bleeding through the use of wound packing and or a tourniquet as both can be simulated on the trauma module. Two module variants have been created to give the user two distinct trauma scenarios to train on. The trauma module is only used for the trauma product baselines. SimMan 3G PLUS has trauma limbs, however the technical solution will need to be adapted to better align with the modular principles.

Module Variants:

- Large Wound

The large wound module variant is aimed at providing the user a trauma scenario to train on that mimics that of a large laceration, gunshot, or puncture wound. This module variant can simulate both venous and arterial bleeding and bleeding from the wound sites can be stopped though wound packing or tourniquet application above the elbow.

- Amputee

The amputee module variant is aimed at providing the user a trauma scenario to train on that mimics that of an amputee occurring below the elbow. This module variant can simulate both venous and arterial bleeding and bleeding from the amputee site can be stopped though tourniquet application above the elbow.

Fluid Management

The fluid management module is a system level module that controls the flow of fluids in the entire module arm. All modules that use fluids interface to the fluid management module which allows the

fluid to flow in or out from internal or optional external reservoirs. To fit the needs of the different modules, two module variants for the fluid management module have been defined.

Module Variants:

- Basic Fluid Management

The basic fluid management module variant only allows fluid flow into the module arm from either the IV or IM/IO modules.

- Advanced Fluid Management

The basic fluid management module variant has the same functionality of the basic variant but adds the ability for fluid to flow out of the module arm by using a pump located somewhere in the rest of the full body medical patient training solution.

Electronics Management

The electronics management module is a system level module controls all of the power and data that is required to run some of the module variants. The electronics management module is powered by an internal battery found in the torso of the manikin and the data transfer is stored on a master CPU module that transmits the data to the user. Each module that interfaces with this electronics management module has its own dedicated PCA which the electronics management module interfaces to and controls.

4.4.2. Module Strategy Matrix (MSM)

The module strategy matrix is very similar to the MIM that was used to identify product function groupings for potential modules. In the MSM, modules are sorted into three categories based on the module strategies defined by PALMA: product leadership, operational excellence, and customer integrity [69]. For this thesis a balance was kept between each of the modular strategies, however depending on the company business strategy, modules could be created with the goal of skewing the strategies more towards one category. The MSM is also critical for ensuring that no modules are chosen with conflicting strategies, as described in Section 3.1.6. By analyzing the MSM, shown in

Figure 21, the strategy for each module can be seen along with the accompanying module drivers.

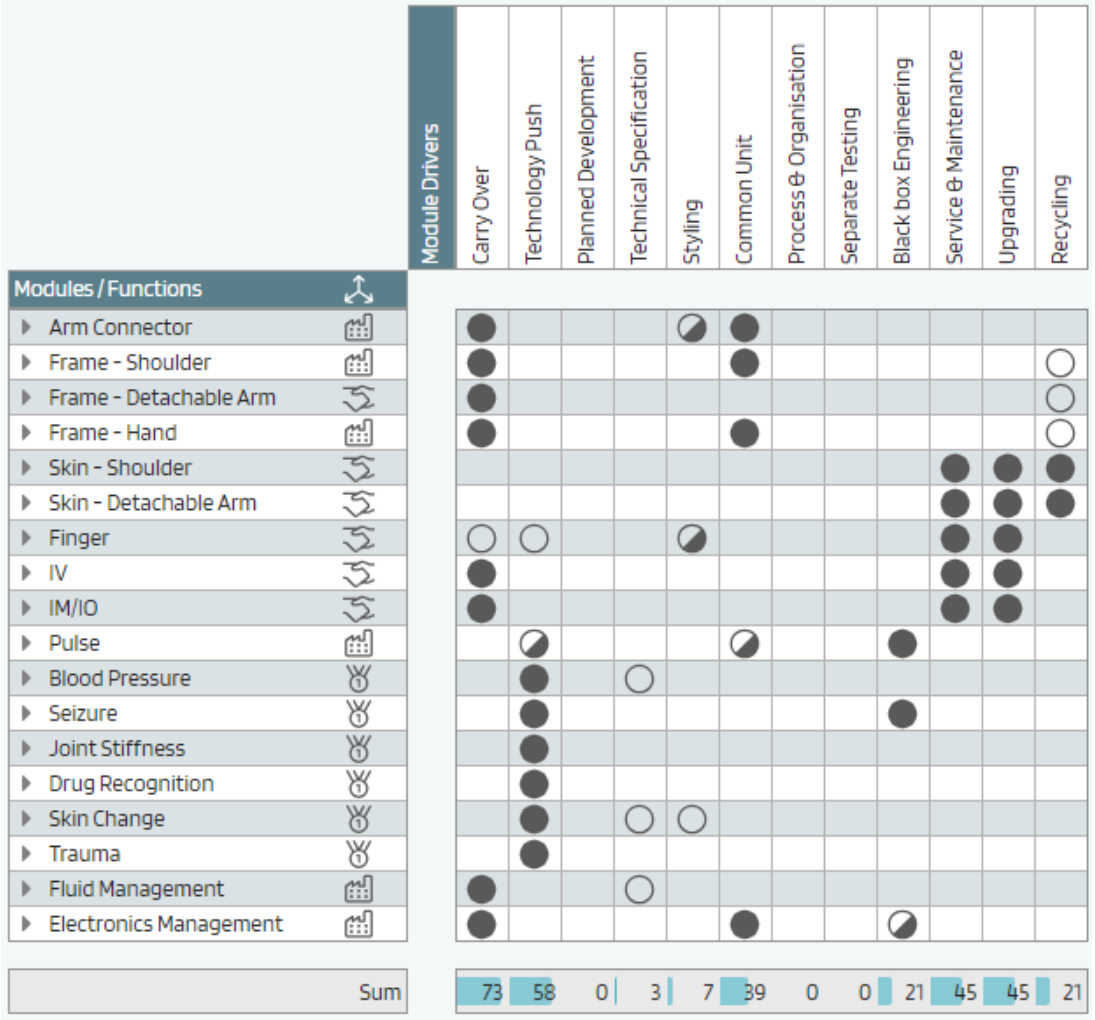


Figure 21 – MSM from PALMA for the Modular Arm

The module strategy helps create a development plan for the module. Modules, like the arm connector, that are have the operational excellence strategy are linked to the module drivers *carry over* and *common unit* and are planned to stay the same for the entire product lifecycle. These modular drivers indicate that the module should have robust technical solutions with limited module variants so the solution is consistent through the product baselines. Analyzing the MSM, we see that along with the arm connector module, the shoulder frame, hand frame, pulse, fluid management, and electronics management modules all fall into this category. Although the pulse and fluid management modules do have module variants, the variant across the product baselines is limited. For the pulse module, the two module variants are controlled by software and the physical pulse module is the same for all product baselines. Similarly, the fluid management module does have two performance steps but the fluid pump associated with the higher performance step is located outside of the arm, therefore the infrastructure for the fluid management module is the same for both modules within the arm.

Modules that use the customer intimacy strategy have a high number of module variants to meet the various customer needs of an entire market. Modules with this strategy can be linked to module drivers like *service and maintenance* and *upgrading* as the ability to customize, easily repair, and upgrade these modules increases customer satisfaction. Consequently, these modules tend to be limited to a single function to enable user driven customization. For the module arm, the following

modules fall into the customer intimacy strategy: shoulder skin, detachable arm frame, detachable arm skin, finger, IV, and IM/IO. All of these modules has the ability to be exchanged on the manikin by the user to increase the number of medical training scenarios possible on one modular arm, or one torso when swapping detachable arm modules, with, for example, a large wound modular arm configuration. These modules directly improve the customer experience and reach of a single product family through the baselines and customization provided by these modules.

The final module strategy is called product leadership, this strategy aims to differentiate a company from its competitors through the solutions it offers that my not be available, or as advanced, in competitor products. These modules are typically associated with the *technology push* module strategy as they usually rely on the newest technology to implement them into a product. These modules need to be available in the first product release and will likely improve with technological advancements over the lifetime of the product therefore it is important not to group these modules with drives such as *carry over* or *planned development* as this is a direct strategy clash.

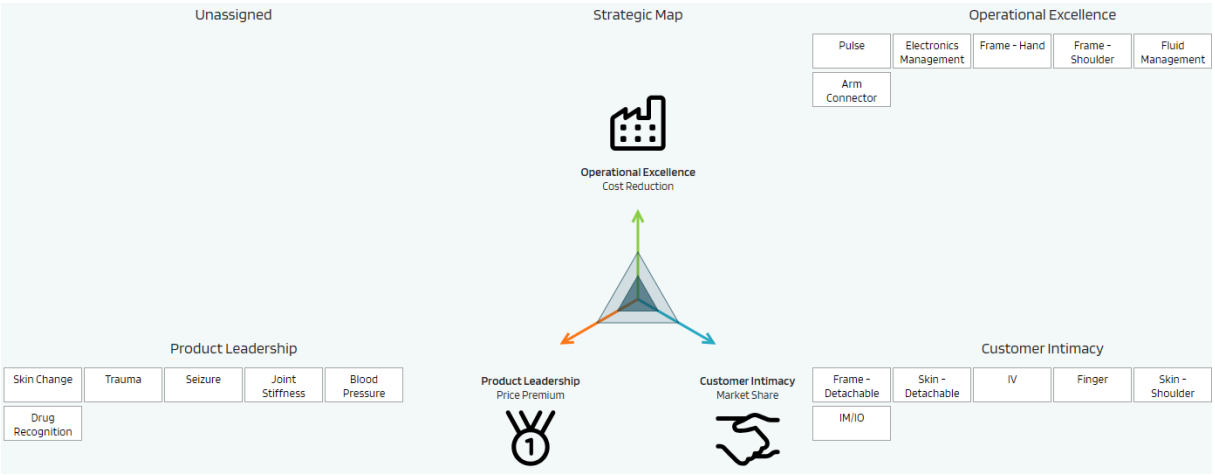


Figure 22 – Strategic Map for Modular Arm generated by PALMA

The strategic approach for the modular arm was to balance each module strategy to avoid skewing the product towards one of the three strategies. PALMA generates a "strategic map" report after the MSM has been filled out. This report, as seen in Figure 22, provides a easy to read visualization of which modules are grouped with which strategy. The three arrows in the middle give a visual representation of the balance (or lack of balance) between the three strategies. If the module arm had an unbalanced strategy then the middle triangle in Figure 22 would be skewed towards the strategy that has the most modules associated with it. Overall, the MSM matrix helps confirm alignment of the modules with the business strategy of the company by ensuring no conflicting strategies exist within each module and that the overall strategy aligns with the companies goals for that product.

4.4.3. Module Interface Matrix (IM) and Diagram

The interface matrix is an important tool for planning how the product system will be designed. By mapping out the interactions between modules prior to starting development, plans can be made for module interfaces. Knowing if a module requires an electrical and fluid interface or only a mechanical interface can help reduce complexity and uncertainty with the system design. The interface matrix uses letters abbreviations to link module interfaces together as shown in Figure 23. These interfaces are defined for each project in PALMA, for the modular arm, the following interfaces were chosen with descriptions of each found in Figure 23: attachment, transfer of force, transfer of power, transfer of data, transfer of liquid, control, and spatial. These interfaces account for all expected

module to module interfaces that will exist within the modular arm.

Name	Description	Abbreviation
Attachment	Physically connection between modules.	A
Transfer - force	Transfer of force between modules	Tm
Transfer - power	Transfer of power between modules	Tp
Transfer - data	Transfer of data between modules	Td
Transfer - liquid	Transfer of liquid between modules	Tf
Control	Communication/control of states between modules.	C
Spatial	Spatial shape and location between modules.	S

Figure 23 – Interface types used in the interface matrix in PALMA

The completed interface matrix can be used like a legend where the interfaces between each module can be visualized. However, this visualiztion is rather limited as abbreviations on a matrix can be hard to interpret into a system desing for the entire product. The full interface matrix can be found in Appendix A.7. A condensed version of the interface matrix that looks at the module interaction between the arm connector, detachable arm frame, and detachable arm skin modules can be seen in Figure 24. Analyzing the matrix, we can see which modules have a physical and spatial interface with the detachable arm frame module. This will aid design by knowing that spatially, a combination of those modules defined by the product baselines must fit within the detachable arm frame. For the arm connector module, the interface matrix indicates that a fluid and electrical connection is required along with a mechanical interface with the shoulder frame and detachable arm frame moudles.

As the interface diagram does not do an adequate job at visualizing the interfaces for the modular system, an interface diagram was created. This interface diagram was split into two diagram one for the shoulder module to arm connector and one for the arm connector to detachable arm module. This diagram uses colored lines to link interfaces to modules that are represented as boxes. A black line is used to represent a mechanical interface, blue line to represent a fluid interface, red for power, and orange for data. The interface diagrams are presented as Figure 25 and Figure 26 on the following pages as full page illustrations. Using the interface matrix as a basis. The interface diagram elevates the readability of the modular system.

Code	Modules	Arm Connector	Frame - Detachable Arm	Skin - Detachable Arm
		M32	M09	M11
M32	Arm Connector			
M03	Frame - Shoulder	A, S, Tm		
M09	Frame - Detachable Arm	A, S, Tm		
M29	Frame - Hand		A, S, Tm	
M04	Skin - Shoulder			
M11	Skin - Detachable Arm		A	
M28	Finger			S
M10	IV		A, S, Tm	S
M05	IM/IO			
M08	Pulse		A, S	
M07	Blood Pressure		A, S	
M20	Seizure		A, S	
M25	Joint Stiffness		A, S	
M17	Drug Recognition		A, S	
M18	Skin Change		A, S	
M33	Trauma		A, S	
M16	Fluid Management	Tf	A, S	
M23	Electronics Management	Td, Tp	A, S	

Figure 24 – Condensed interface matrix from PALMA for the modular arm

Interface Diagram – Shoulder Module

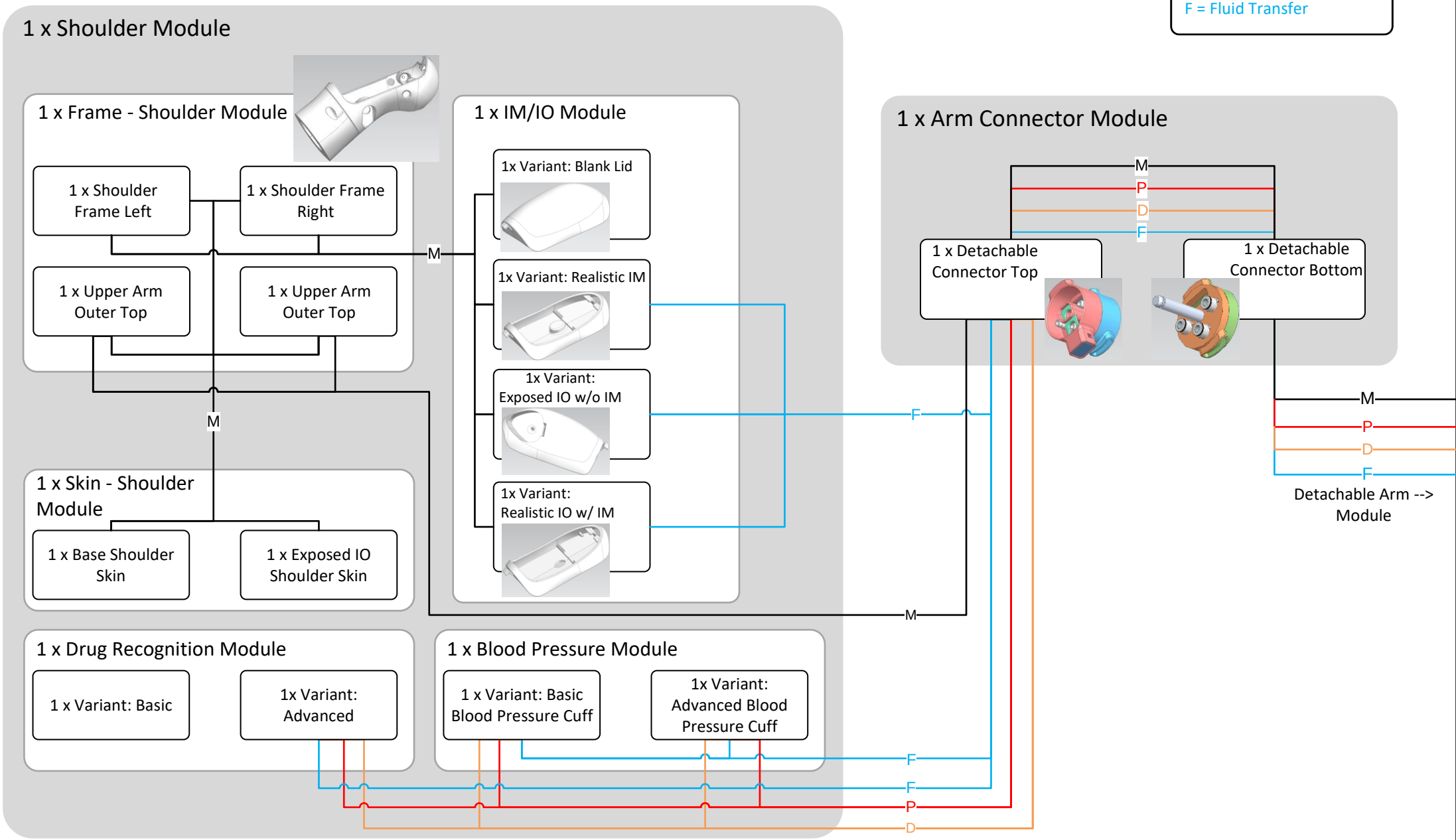


Figure 25 - Interface Diagram of Shoulder Module

Interface Diagram – Detachable Arm Module

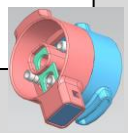
Interface Legend

M = Mechanical Interface
P = Power Transfer
D = Data Transfer
F = Fluid Transfer

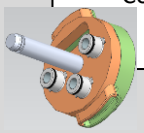
1 x Arm Connector Module

M
P
D
F

1 x Detachable Connector Top



1 x Detachable Connector Bottom



M
P
D
F
<-- Shoulder Module

F P D

1 x Detachable Arm Module

1 x Frame – Detachable Arm Module

1 x Upper Arm Inner Bottom

1 x Upper Arm Outer Bottom

1 x Elbow Inner

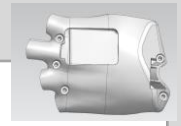
1 x Elbow Outer

1 x Lower Arm Inner

1 x Lower Arm Outer

M

1 x Frame – Hand Module



1 x Hand Frame Top

1 x Hand Frame Bottom

M

1 x Skin – Detachable Arm Module

1 x Variant: Normal Arm Skin

1 x Variant: Amputee Arm Skin

1 x Variant: Puncture Wound / Laceration Arm Skin

M

M

1 x Drug Recognition Module

1 x Variant: Basic

1x Variant: Advanced

1 x Blood Pressure Module

1 x Variant: Basic Blood Pressure Cuff

1x Variant: Advanced Blood Pressure Cuff

1 x Pulse Module

1 x Variant: Basic

1x Variant: Advanced

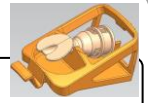
1 x Skin Appearance Module

1 x Variant: Basic Skin Change

1 x Variant: Advanced Skin Change

3 x IV Module

1 x Variant: Blank Lid



1 x Variant: Pre-Ported

1 x Variant: Hidden w/ Flashback

3 x Finger Module

1 x Variant: Dummy Finger

1 x Variant: Blood Glucose

1 x Variant: SpO2

1 x Variant: Cyanosis

1 x Variant: Capillary Refill

1 x Seizure Module

1 x Variant: Basic

1 x Variant: Advanced

Figure 26 - Interface Diagram of Detachable Arm Module

4.4.4. Module Variant Specification (MVS)

Using the module variant specification, the module variants were linked to the goal values of the relevant product properties. This matrix is one of the tools used to define the configuration rules that will be used when creating configurations of product baselines in the last step of the MFD process. The full matrix is too large to present in the body of the thesis so a condensed version is presented in Figure 27. The full MVS matrix can be found in Appendix A.8.

The condensed MVS only shows three modules and their associated variant along with the product properties they are linked with. When analyzing the matrix, the differentiation between the module variants becomes clear. For the IV module, both variants fulfill the goal values for all of the associated product properties except *IV port type*, this is where the differentiation between the module variants is realized within PALMA. This rule could later be used to restrict which IV module variant can be chosen if a product configuration was to only allow the *hidden* goal value for the *IV port type* product property. Similarly, the IM/IO module creates a differentiation between the module variants with the *fluid exchange, IM functionality,* and *IM/IO patch type* product properties. In the product configurator, if a configuration requires IM functionality then the *Exposed IO without IM* module variant cannot be selected.

Modules / Variants	Blood Pressure Functionality	Blood Pressure Range	Fluid Exchange	IM Functionality	IM Reservoir Volume (Internal)	IO Aspiration	IO Functionality	IM/IO Patch Type	IO Reservoir Volume (Internal)	IV Flashback	IV Functionality	IV Port Type	IV Reservoir Volume (Internal)	IV Sites
IV														
Pre-Ported										Yes	Yes	Pre-Po...	*	*
Hidden										Yes	Yes	Hidden	*	*
IM/IO														
Realistic IM				Yes	*	No	No	Hidden	*					
Exposed IO w/o IM			Yes	No	*	Yes	Yes	Exposed	*					
Realistic IO w/ IM			Yes	Yes	*	Yes	Yes	Hidden	*					
Blood Pressure														
Basic Blood Pressure Cuff	Autom...	*												
Advanced Blood Pressure Cuff	Manual...	*												
Sum	13	1	15	6	1	3	21	3	2	9	11	16	4	4

Figure 27 – Condensed MVS from PALMA for the modular arm

Setting these parameters for all modules and associated variants aids when defining the product baseline by ensuring that each baseline meets the requirements specified by the product architecture. For complex systems like the modular arm, this tool is valuable in ensuring that the customization offered to product baselines creates a large enough function spread to cover all market segments and customer needs.

4.5. Product Configuration

4.5.1. Generic Product structure (GPS)

The generic product structure organizes the hierarchy of the modular system by determining which modules will be system level, top level, and sub-level. The modular hierarchy presented in section 3.1.9 is based on how the product structure was designed in this thesis project for the modular arm. This generic product structure is shown in Figure 28. The entire arm assembly is treated at the product, therefore every module in the system appears underneath it. The modules directly under the arm assembly are the system level modules, these modules interact independently of the two main level modules (shoulder and detachable arm). The shoulder and detachable arm modules are connected by the arm connector module, another system level module. The remaining modules are sub-level modules that are dependent on their associated top level module, such as the IV module is dependent on the detachable arm module. This generic product structure, linked with the interface diagram provide a system design for the modular arm, an important planning step prior to starting design on the modular arm.

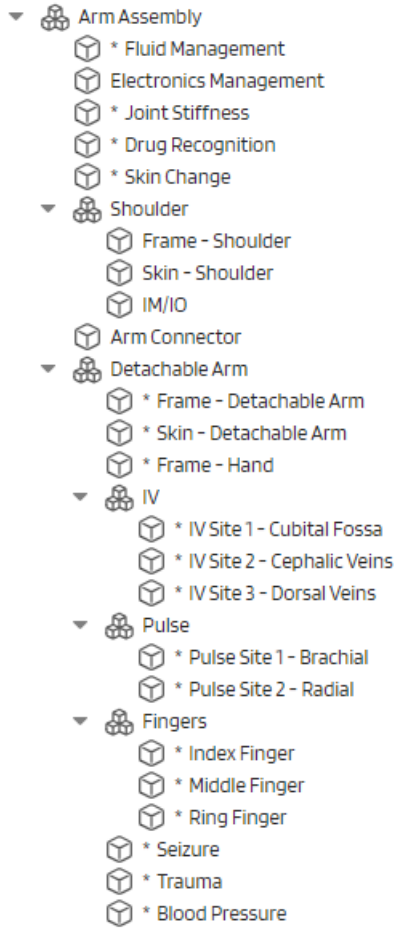


Figure 28 – Generic product structure from PALMA for the modular arm

After the generic product structure has been defined, rules that supplement those defined in the MVS can be created for each module. All the modules seen in Figure 28 with an asterisk near their name have special rules associated with them that were created in the generic product structure tool. These rules are used when creating product baselines and determining the level of user driven customization offered to each baseline by defining what grouping of modules and module variants can occur together in the same product configuration. An example of the rules given to the fluid management module variants can be seen in Figure 29. This matrix is a tool available in the generic product configuration tool and is used to define rules for each module variant. For the fluid management module, rules have been set for which product properties are available to the basic and advanced fluid management module variants. For example, the bleeding functionality product property is only available with the advanced fluid management module variant because it requires a pump.

Case	Qty	Product Properties: Measure Injected Volume	Bleeding Functionality	Blood Pressure Functionality	Drug Recognition Functionality	Fluid System	Wound Type
		Code: P83	P09	P11	P18	P26	P35
Not Included	☐ 0	No	No	None	No		None
Basic	☑ 1	Yes	No	None	Yes	Yes	None
Advanced	☑ 1	Yes	Yes	Manual Cuff an...	Yes	Yes	AmputeeGuns...

Figure 29 – Configuration rule matrix for the fluid management module from PALMA for the modular arm.

The fluid pump is only available with the advanced fluid management module variant. Similarly, the blood pressure functionality is only available with the advanced fluid management module variant for the same reason. Rules like these were defined for many of the modules and variants to ensure none of the defined product baselines are created with groupings of module variants that do not work, for example a basic fluid management system with blood pressure functionality.

The generic product structure tool is one of the final tools used in PALMA before the products baselines defined to give representation to the modular product architecture in a product. This tool is critical in defining the intended structure of the modular product as without this, the modules are only represented as lines on a spreadsheet.

4.5.2. Configuration Interface (CI)

The configuration interface defines what functions for the product can be chosen using the product configurator. For the modular arm, the generic product structure was chosen as the primary way to define the product baselines. A second tab was created that is used to represent the global attribute customization available to the user. These attributes do not affect the functionality of the product baselines but rather give customization options to the customer for creating a personalized product configuration. Both tabs of the configuration interface can be seen in Figure 30. The customer will not have full 'engineered to order' customization but they will have access to attribute customization such as the color and material of the arm skin as well as some module variant customization options for the IV and IM/IO module. Giving the customer this amount of configuration on top of the product baselines is theorized to increase customer satisfaction in the product without adding complexity cost to Laerdal medical.

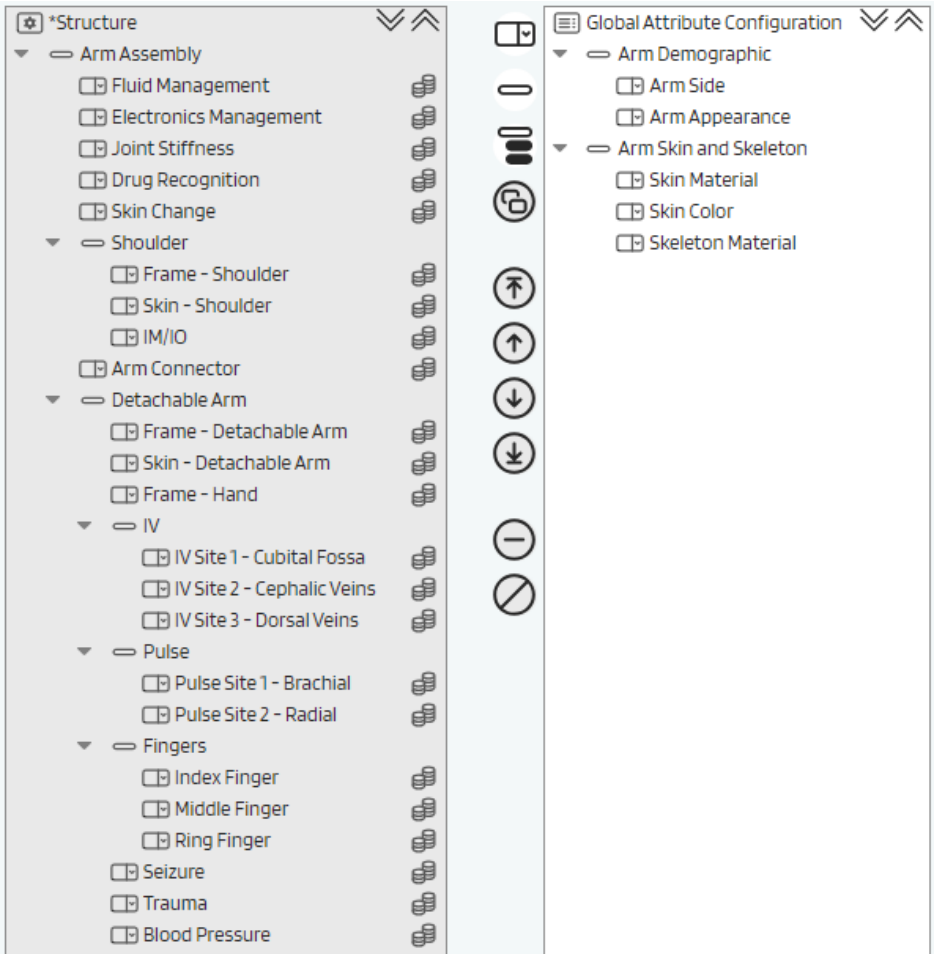


Figure 30 – Configuration interface tool from PALMA for the modular arm

4.5.3. Product Configuration Matrix (PCM) and Product Specification Matrix (PSM)

The product baselines are created in a PALMA tool known as the *configuration lab*. The configuration lab uses the tabs setup in the configuration interface tool to allow module variants to be grouped together. Each baseline is saved, and that data is used to populate the product configuration and product specification matrices in PALMA. The data from these matrices was imported into excel where a spreadsheet was created to visualize both matrices in one place. This excel spreadsheet lists the four main product baselines, two trauma baseline and the customization and add-ons available to the user for configurating a personalized product constructed from one of the baselines. These product baselines can be viewed in Figure 31, a full page illustration found at the end of this section. Defining the product baselines and configuration rules is the last step of the MFD process and results in a realization of the modular product architecture within modular baselines and executed configurations that meet the market segments. All product configurations will have an internal fluid reservoir, an optional external fluid reservoir, detachable arm connector, removable skin, and full joint articulation. As the arms are intended to be used as part of the full body training solution, customers will have the choice to create different configurations for each arm baseline to further customize the full body training solution to meet their needs.

Below each product baseline is explained and linked to the expected market segments it will satisfy. The user driven configuration elevates these baselines to account for all customer needs across all market segments. It is impossible to give every customer the exact product they need with only six baselines, hence the user driver configurations inherent to a modular product architecture.

Manikin – Intermediate

This is the most basic baseline of the modular arm, it has limited clinical functionality, only including IM and IV as available medical procedures. This product baseline is aimed at customers with a small budget that only need to train with the most basic medical procedures. This product will still provide full joint articulation and removable skin. It is expected the following market segments would purchase this product baseline.

- Emergency Medical Services – Basic
- Healthcare Education – Basic
- Healthcare Education – Intermediate

Simulator – Basic

This product baseline is one step above the manikin intermediate and could also be considered the manikin advanced product baseline as within Laerdal Medical, there is no defined performance step between an advanced training manikin and a basic training simulator. This product baseline will be more expensive than the manikin intermediate baseline but will still be a cost-effective solution aimed at providing the user with the ability to train on basic and one limited advanced medical procedures such as IO, IV, basic pulse palpation, SpO_2, and capillary refill. The following market segments are expected to purchase this product baseline.

- Emergency Medical Services – Basic
- Emergency Medical Services – Intermediate
- Healthcare Education – Basic
- Healthcare Education – Intermediate

Simulator – Intermediate

The simulator intermediate product baseline is the first baseline that implements some of the more technologically advanced modules. Due to this, a larger price gap than between the first two product

baseline is expected. The simulator intermediate baseline offers a wide range of medical procedure functionality to cover a large number of market segments. However, due to the expected price premium associated with this baseline, some of the market segments that only require the basic functions may not be willing to pay for some unnecessary features. This baseline has basic drug recognition, basic skin change, IO, IV, advanced pulse palpation, SpO_2, capillary refill, blood glucose, basic seizure, and basic blood pressure measurement. Due to the large number of functions available in this baseline, it is expected that if price is not an obstacle, most of the market segments could use this product configuration to meet their needs.

- Emergency Medical Services – Basic
- Emergency Medical Services – Intermediate
- Emergency Medical Services – Advanced
- Military – Military Hospital Personnel
- Clinical – Emergency Room Personnel
- Clinical – Intensive Care Unit Personnel
- Healthcare Education – Basic
- Healthcare Education – Intermediate
- Healthcare Education – Advanced

Simulator – Advanced

The simulator advanced product baseline is the most advanced, and therefore more expensive of the four main product baseline. This baseline has the same medical procedure functionality as the simulator intermediate baseline but at a higher level of fidelity for almost every module. This baseline gets all of the most advanced technology available in a Laerdal product and is expected to be only used by the least price limited customers. This baseline has joint stiffness control, advanced drug recognition, advanced skin change, IO, IM, IV, advanced pulse palpation, SpO_2, capillary refill, blood glucose, advanced seizure, and advanced blood pressure measurement. It is expected that due to the large amount of basic, intermediate, and advanced medical procedures available to this baseline that most market segments could use this product to meet their needs if price is not a concern.

- Emergency Medical Services – Basic
- Emergency Medical Services – Intermediate
- Emergency Medical Services – Advanced
- Military – Military Hospital Personnel
- Clinical – Emergency Room Personnel
- Clinical – Intensive Care Unit Personnel
- Healthcare Education – Basic
- Healthcare Education – Intermediate
- Healthcare Education – Advanced

Trauma: Large Wound

The trauma large wound product baseline is one of two trauma focused baseline. This baseline is used to help simulate trauma control for large wounds such as lacerations, puncture wounds, or gunshot wounds. Aside from the IO function found in the shoulder, the large wound baseline can only simulate pulse palpation and trauma through wound packing and tourniquet application. This product baseline has a more limited market segment usage but is required to fully meet the needs of the market segments for those that require training in trauma situations. It is likely that a customer

needing this arm baseline would also buy one of the other arm baseline found above to train procedures on one arm while the other arm is limited to trauma situations.

- Emergency Medical Services – Advanced
- Military – Combat Medics
- Military – Military Hospital Personnel
- Clinical – Emergency Room Personnel
- Healthcare Education – Advanced

Trauma: Amputee

The trauma amputee product baseline is last of two trauma focused baseline. This baseline helps simulate trauma control for an amputation that has occurred below the elbow. Aside from the IO function found in the shoulder and a brachial pulse site, the amputee baseline can only trauma through tourniquet application. Like the trauma large wound product baseline, the trauma amputee **configuration** has a more limited market segment usage but is required to fully meet the needs of the market segments for those that require training in trauma situations. If a customer buys the trauma amputee arm, it is likely that they will also buy one of the four non trauma libs to pair with the full body medical training solution.

- Emergency Medical Services – Advanced
- Military – Combat Medics
- Military – Military Hospital Personnel
- Clinical – Emergency Room Personnel
- Healthcare Education – Advanced

Global Customization

Once the customer has chosen one of the baseline arms listed in the product baseline above, they will be given the choice to configure the baseline to better meet their training needs. Although the amount of configuration decisions available to the customer is somewhat limited, it is theorized that the options provided will increase customer satisfaction and help satisfy the edge cases of the market segments without adding large amounts of complexity to Laerdal from a manufacturing, logistics, or cost point of view. The configuration options offered to the customers can be seen below.

- Arm side
  - Left/right
- Arm skin color
  - Light/medium/dark
- Arm skin appearance
  - Base/obese/geriatric
- Arm skin material
  - TPE/Silicone
- Arm frame material
  - PTE/POM
- IV function performance level
  - Pre-ported/hidden
- IM/IO function performance level
  - Realistic IM/exposed IO/realistic IO w/ IM
- Finger

- Dummy/SpO_2/capillary refill/blood glucose/cyanosis

Add-on Packages

Taking inspiration from the modular automobile industry, add-on packages will be offered to the customer after they have configurated the baseline arm. These add-on packages focus on offering more of the consumable modules that were available for configuration in the global customization step. These add-on packages that can be purchased at any time giving the user the ability to extend the life of their product by purchasing more of the consumable modules such as IM/IO, IV, and fingers. Listed below are the add-on packages offered to the customer:

- Cyanosis fingers pack
  - Sold in packs of three
- Additional fingers
  - Sold individually for each variant
  - Sold in 'blood glucose' pack with three blood glucose fingers
  - Sold is 'function pack' with SpO2, capillary refill, and blood glucose
- Additional IV ports
  - Solid in packs of three for each variant
- Additional IM/IO ports
  - Sold individually for each variant

Modules / Arm Baselines	Manikin - Intermediate	Simulator - Basic	Simulator - Intermediate	Simulator - Advanced
Fluid Management	Basic Fluid Management	Basic Fluid Management	Advanced Fluid Management	Advanced Fluid Management
Electronics Management	-	Basic Electronics Management	Basic Electronics Management	Basic Electronics Management
Joint Stiffness	-	-	-	Base
Drug Recognition	-	-	Basic Drug Recognition	Base w/ Volume Measurement
Skin Change	-	-	Basic Skin Change	Advanced Skin Change
Arm Skeleton Material	PET	POM	POM	POM
Arm Skin Material	TPE	TPE	TPE	Silicone
Arm Skin Color	Light	Light	Light	Light
Arm Connector	Detachable	Detachable	Detachable	Detachable
Shoulder Module				
Frame - Shoulder	Base Shoulder Frame	Base Shoulder Frame	Base Shoulder Frame	Base Shoulder Frame
Skin - Shoulder	Base Shoulder Skin	Base Shoulder Skin	Exposed IO Shoulder Skin	Base Shoulder Skin
IM/IO Variant	Realistic IM	Exposed IO	Exposed IO	Realistic IO w/ IM
Detachable Arm Module				
Frame - Detachable Arm	Base Detachable Arm	Base Detachable Arm	Base Detachable Arm	Base Detachable Arm
Skin -Detachable Arm	Base Detachable Arm Skin	Base Detachable Arm Skin	Base Detachable Arm Skin	Base Detachable Arm Skin
Frame - Hand	Base Hand Frame	Base Hand Frame	Base Hand Frame	Base Hand Frame
IV Port Variant	Pre-Ported	Pre-Ported	Pre-Ported	Hidden
IV Sites	Cubital Fossa / Cephalic Veins / Dorsal Veins	Cubital Fossa / Cephalic Veins / Dorsal Veins	Cubital Fossa / Cephalic Veins / Dorsal Veins	Cubital Fossa / Cephalic Veins / Dorsal Veins
Pulse Sites	-	Radial, Brachial	Radial, Brachial	Radial, Brachial
Pulse Variant	-	Basic	Advanced	Advanced
Index Finger	Dummy Finger	SpO2	SpO2	SpO2
Middle Finger	Dummy Finger	Capillary Refill	Capillary Refill	Capillary Refill
Ring Finger	Dummy Finger	Dummy Finger	Blood Glucose	Blood Glucose
Seizure	-	-	Basic Seizure	Advanced Seizure
Trauma	-	-	-	-
Blood Pressure	-	-	Basic Blood Pressure Cuff	Advanced Blood Pressure Cuff

Modules / Arm Baselines	Trauma: Large Wound	Trauma: Amputee
Fluid Management	Advanced Fluid Management	Advanced Fluid Management
Electronics Management	Basic Electronics Management	Basic Electronics Management
Joint Stiffness	-	-
Drug Recognition	-	-
Skin Change	-	-
Arm Skeleton Material	POM	POM
Arm Skin Material	TPE	TPE
Arm Skin Color	Light	Light
Arm Connector	Detachable	Detachable
Shoulder Module		
Frame - Shoulder	Base Shoulder Frame	Base Shoulder Frame
Skin - Shoulder	Base Shoulder Skin	Base Shoulder Skin
IM/IO Variant	Exposed IO	Exposed IO
Detachable Arm Module		
Frame - Detachable Arm	Puncture Wound / Laceration Arm	Amputee Arm
Skin -Detachable Arm	Puncture Wound / Laceration Arm Skin	Amputee Arm Skin
Frame - Hand	Base Hand Frame	-
IV Port Variant	-	-
IV Sites	-	-
Pulse Sites	Radial, Brachial	Brachial
Pulse Variant	Advanced	Advanced
Index Finger	Dummy Finger	-
Middle Finger	Dummy Finger	-
Ring Finger	Dummy Finger	-
Seizure	-	-

Global Customization	Configurations
Arm Side	Left/Right
Arm Skin Color	Light/Medium/Dark
Arm Skin Appearance	Base/Obese/Geriatric
Arm Skin Material	TPE/Silicone
Arm Frame Material	PET/POM
IV Function Performance Level	Pre-Ported/Hidden
IM/IO Function Performance Level	Realistic IM/Exposed IO/Realistic IO w/ IM
Fingers	Dummy/SpO2/Capillary Refill/Blood Glucose/Cyanosis

Add-on Packages	Contents
Cyanosis	3x Cyanosis Fingers
Additional Fingers	
Additional IV Ports	
Additional IM/IO Ports	

Figure 31 - Product baselines and configuration options for modular arm

5. Product Design

Building on the modular product architecture developed in the first phase of the thesis, the product design phase of the product development process brings the functionality of each module from an idea to a physical solution. Keeping with the focus of the modular product architecture, the arm was designed using a user centric approach focusing on how the user will interact with the various functions as this has a direct impact on the efficacy of the arms use as a medical patient training solution.

From initial drawn module interface concepts to prototype ready CAD models created in Siemens NX, this section will clarify how a modular product architecture built of matrices and excel spreadsheets is used to create a physical product. The final arm developed reaches the proof-of-concept level of product readiness. To best help Laerdal Medical, the scope of arm developed was limited to visualizing how modules fit spatially into the constraints given by the arm geometry and designing how these module interfaces interact with the users and surrounding modules. This provides Laerdal with a solid foundation to continue developing the arm using the proposed modular product architecture without the risk associated with an untested product architecture.

The skin is a vital and complicated part of medical training solutions, given the time constraints of the project, the scope was narrowed to exclude design of the skin interface with the modules and modular arm. Suggestions for how these interfaces could be accomplished technically has been included in the modular product architecture but the physical design of this skin was not included. To make the current SimMan 3G PLUS skin fit the new modular design, a complete redesign, including creating a new surface model in Siemens NX created from an imported model of a human arm would have been required, there was simply not enough time to do this properly. Instead of trying to design every aspect of the modular arm which would have likely resulted in unfinished designs, it was decided the design focus would be on module interfaces and the spatial configuration of parts within the existing arm geometry as this provides more value to Laerdal than incomplete designs do.

5.1. Concept Generation

Deciding to reuse the existing geometry of the SimMan 3G PLUS arm reduced the amount of concepts that needed to be generated. For the concept generation phase of the product development process, the interface for the removable IM/IO and IV modules was focused on. Having the module be removable by the customer as a requirement for the interface was a driving influence on the form of the design. The sketch found in Figure 32 shows the chosen concept for the interface between the listed modules and the arm frame. A snap fit style attachment was chosen as it provides easy and intuitive removal to the customer. The pockets along the edge of the interface are intended to be the interface

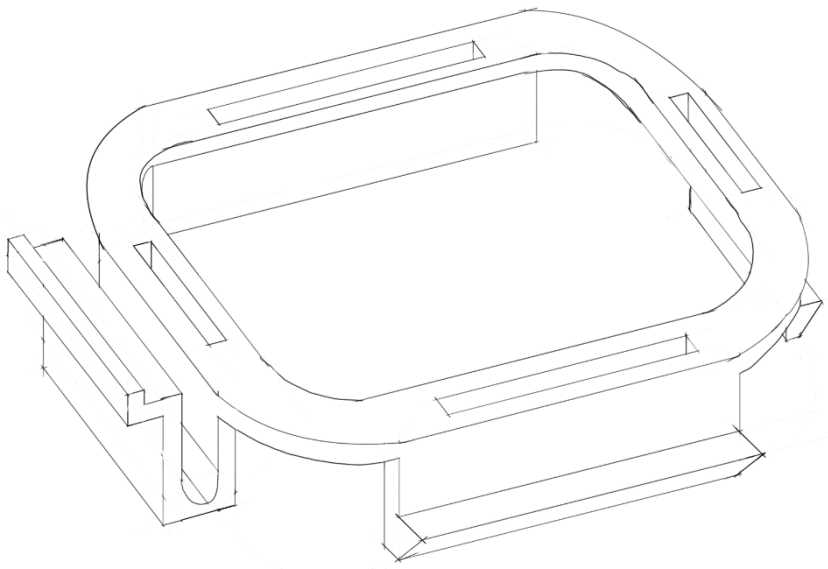


Figure 32 – Concept Sketch of Interface for IM/IO Module and IV Module

between the skin and the module. Given the scope of the thesis, the skin attachment concept was not further developed. The concept sketch provided a rough outline for the CAD models of the IV interface to be built on. Although the IM/IO module interface is curved to fit the geometry of the shoulder, the same design principle was used to create the snap lock to the arm frame.

5.2. Concept Development

The modular arm design was done in Siemens NX and utilizes the SimMan 3G PLUS arm frame, designed previously by the SimMan Team at Laerdal Medical. This decision was made to reduce the time required to model the arm geometry from scratch ensuring the form of the arm aligns with Laerdal's design principles. Modifications to the SimMan 3G PLUS are were made based on the modular product architecture to transition the arm from its monolithic base to the modular arm presented in this thesis.

Using the module interface concepts created in the concept development phase, CAD modules were created using the concept sketches to guide the form of the module. Each module was iterated several times using 3D printing to rapidly prototype and test the function and interface of each module to the arm frame, these iterations can be found in Appendix B.1 where needed improvements were tracked alongside images used to show how the form of each module developed through each iteration. As the modular arm is only a proof-of-concept, it is recommended that future development of the modular arm be done from the ground up using the proposed modular product architecture. It proved difficult to modify the existing SimMan3G PLUS arm to fit the modular product architecture as design decisions made using the monolithic original architecture created interface and space constraints.

5.2.1. IV Modules and Variants

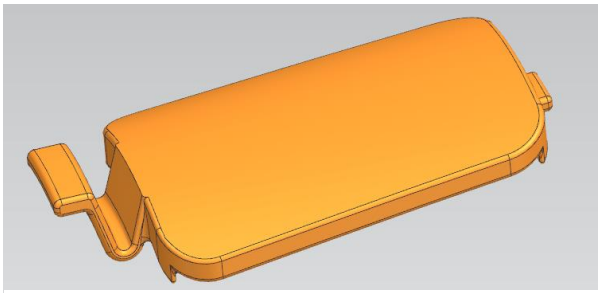


Figure 33 – CAD Model of IV interface used as a placeholder design for the Hidden variant of the IV module.

The form the IV module interface was adapted from the concept sketch shown previously in Figure 32. Changes were made to the IV module interface through a few iterations that were recorded in the iteration log. The final IV module interface, as shown in Figure 33 resembles the initial design by retaining the snap fit principles chosen during the concept development phase.

Designing the part with a focus on modularity from the start will elevate the level of product modularity. The IV module is a good example of this, in the presented design, each IV site has the same modular interface design but due to the existing surface geometry of the SimMan 3G PLUS arm, each IV site is a separate part. For this thesis, only the frame for the *pre-ported* IV module variant was developed and was designed to allow for use with the existing pre-ported IV technical solution found on multiple Laerdal medical patient training solutions, including SimMan 3G PLUS. As illustrated in Figure 34, each of the *pre-ported* IV module variant sites has a different geometry but share the same interface design principle of a snap fit on the front with a tab on the back to guide insertion into the frame. On the modular arm frame, the interface has been designed to ensure the IV module does not fall into the internals of the arm to limit problem associated with assembly of the IV module. Each interface on the modular arm frame follows the same design principle but due to the constraints of the existing geometry each IV site is different. Ideally, each IV site would share the same geometry to limit the number of unique parts IV module variant. With the current design, three unique parts for each IV module variant would need to be developed, controlled, and manufactured,

unnecessarily increasing cost and reducing modularity of the system. Designing the arm geometry with a plan for three modular IV sites gives priority to ensure each site for the IV module shares the same geometry and interface to reduce the number of unique parts required for the modular arm. For the *hidden* IV module variant, a blank lid placeholder was used as the solution currently used on Laerdal medical training solutions for a hidden IV will need a full redesign to fit a modular system. This redesign would also need to focus on designing one part with a universal interface that can be used at all three IV sites.

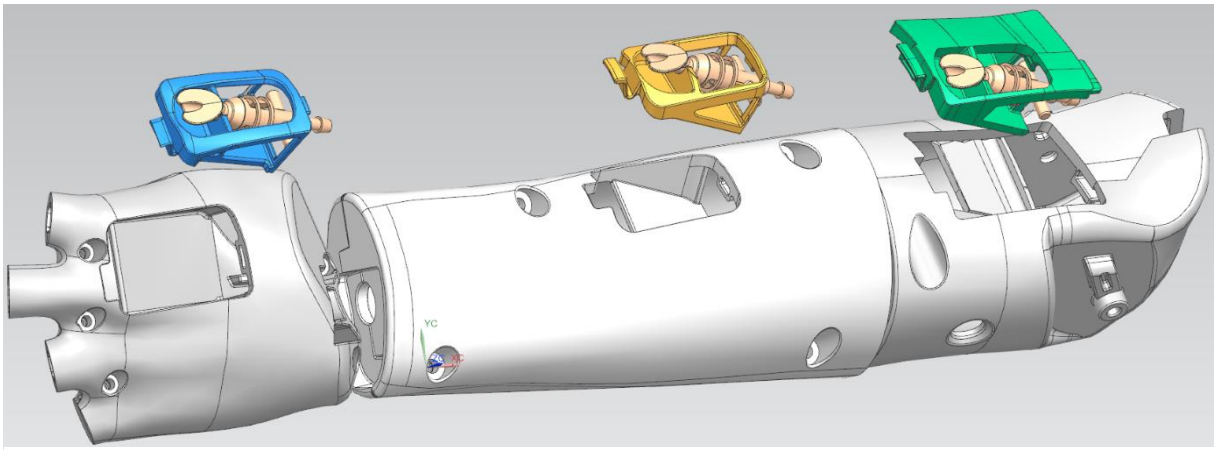


Figure 34– CAD Model Assembly of the Pre-Ported IV Module Variant and Interface with Arm Frame For All Three IV Sites (Dorsal Veins – Left, Cephalic Veins – Middle, Cubital Fossa – Left). The Pre-Ported IV frame includes the Pre-Ported IV Part Currently Used in Laerdal Medical Patient Training Solutions

5.2.2. IM/IO Module and Variants

For the IM/IO module, the existing IM and IO functionality found in the shoulder of the SimMan 3G PLUS arm were adjusted to fit the principles of modular design while keeping the snap fit principle chosen during concept development. These modifications were made to create a universal interface for the different IM/IO module variants. This interface was created below the existing interface for the IO bone, absorbent pad, IO plate, and IM foam to insure all of the existing parts would fit with the new module. The *Realistic IM* and *Realistic IO w/ IM* module variants reuse the existing parts

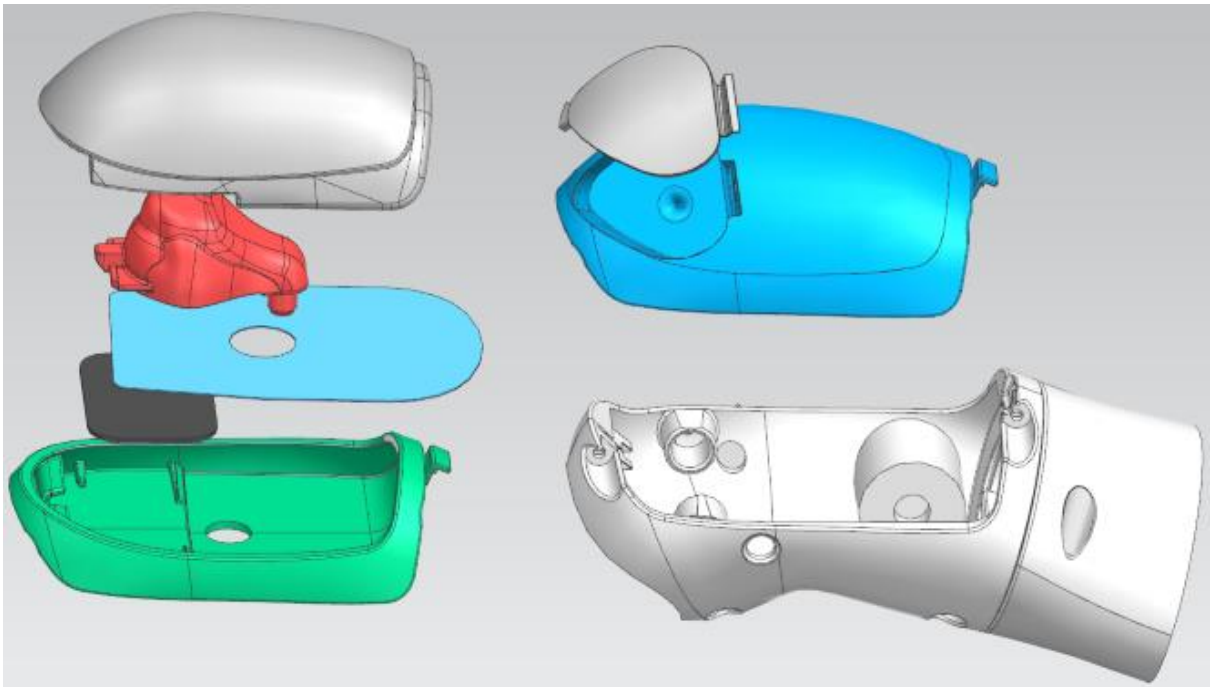


Figure 35 – IM/IO Module Variants: Realistic IO with IM (Left) and Exposed IO (Right) with Interface to Shoulder.

found in the IM and IO functionality for SimMan 3G PLUS with the main difference between the two variants being the *Realistic IM* fluids are contained within the module and not interfaced with the fluid management module like the *Realistic IO w/ IM* module. A third and less expensive module variant was added called *Exposed IO* that removes the realism of the first two module variants by having a "bullseye" type insert indicating where the IO needle should be inserted. All three of these module variants share the same interface as shown in Figure 35 with the shoulder frame enabling them to be easily be swapped out for different module variants by the user. Potentially the largest improvement to the IM and IO functionality has to do with the skin. In the current SimMan 3G PLUS arm, the entire arm skin must be removed and replaced once the skin at the shoulder has become worn down from repeated IM or IO needle injections. This creates a lot of silicone waste and increases the cost, the proposed solution integrates a separate skin directly to the IM/IO module that then interfaces with the remaining arm skin with a small cut line. It is theorized that this solution will decrease cost and increase sustainability associated with degradation to the skin from IM and IO use. The IO bone needle holes still need to be filled with superglue after each use to ensure no liquid leaks during subsequent injections, but the improved modular design makes this process much easier. Instead of unzipping and moving the entire arm skin, the proposed design only requires the skin be removed from the IM/IO module to access the IM foam and IO bone below. As mentioned previously, the skin interfaces were only theorized so there has been no physical development done to validate this proposition.

5.2.3. Arm Connector Module

The detachable arm connector was developed to give the user the ability to swap arm configurations on a full body medical patient training solution. The shoulder module will be fixed to the torso of the full body training solution while the detachable arm module can be exchanged with different configurations of that module, such as one of the two trauma limb baseline. The design for this connector was inspired by previous work done by the hardware technology research and development team at Laerdal Medical. That initial design concept was created for a junior sized training solution, it was redesigned using the same pin lock design principle and interfaced with the shoulder module and detachable arm module to create a streamlined connection between the two, as shown in Figure 36. One fluid and one power/data connection along with the center pin exists in the arm connection module to provide the mechanical connection and the fluid power/data transfer

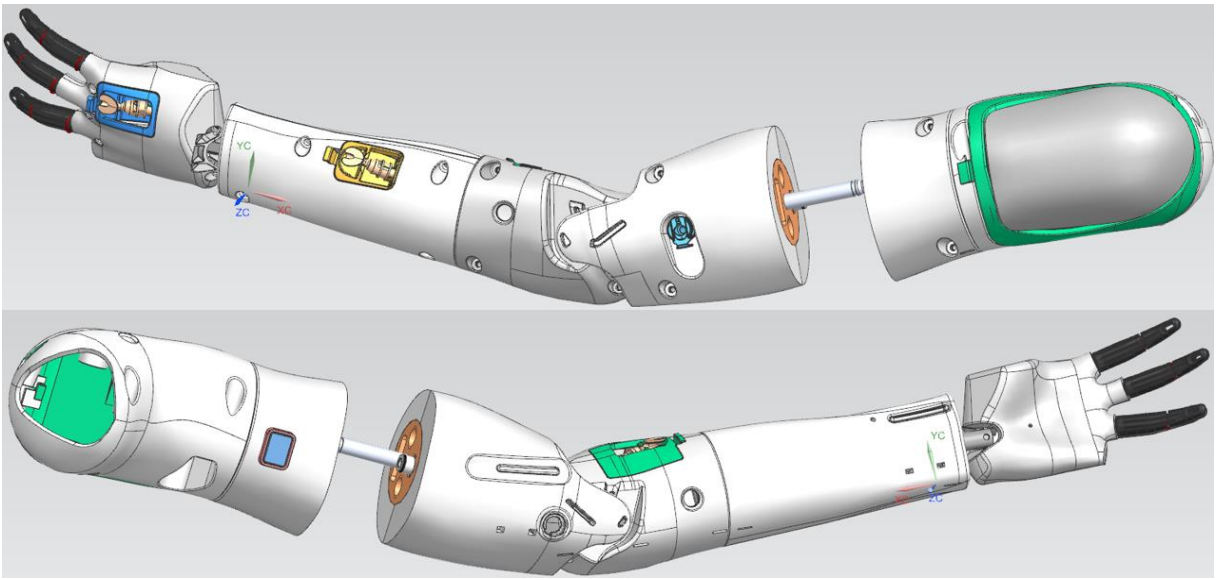


Figure 36 – CAD Model of modular arm showing the front (top) and back (bottom) of the detachable arm module being removed from the shoulder module.

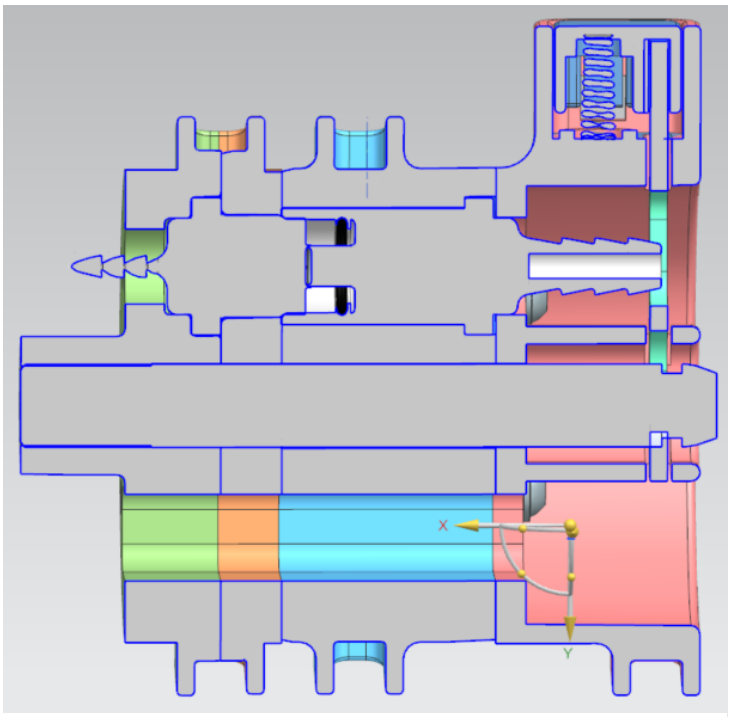


Figure 37 – Section view of locked arm connector module.

between sub-modules found in the detachable arm module and shoulder module. The connector is actuated by pressing a button on the inside of the detachable arm as seen in the bottom illustration in Figure 36.

The central pin creates the main mechanical lock using a sliding plate mechanism. The chamfered end of the pin is followed by a notch. When the pin is inserted into the upper part of the arm connector, the chamfered end pushes the plate up until the notch is reached. A spring in the button brings the plate back down and the notch locks in the center pin constraining the mechanism from opening again. Pressing the button compresses the spring moving the plate allowing the center pin to be removed, detaching the arm. When connected, the fluid and electronic male and female halves are paired to allow transfer between the two modules.

The locking mechanism and interface between the two halves of the arm connector module is visualized as a section in Figure 37. Here the button used to actuate the spring that controls the plate can be seen in the top right corner.

The full assembly of both top and bottom parts of the arm connector module is shown in Figure 38. The top part of the arm connector module contains the button and plate used lock and unlock the center pin, the female ends of the fluid and electronics connector are also located on this half. The two parts of the upper arm connector are screwed together and then connected to the upper arm portion of the shoulder module using the pocketed tabs below and opposite the button. When the two halves of the upper arm connector are screwed together the upper half of the upper arm module are locked into place. Similar to the upper half, the bottom half of the connector is screwed together than connected to the upper arm portion of the

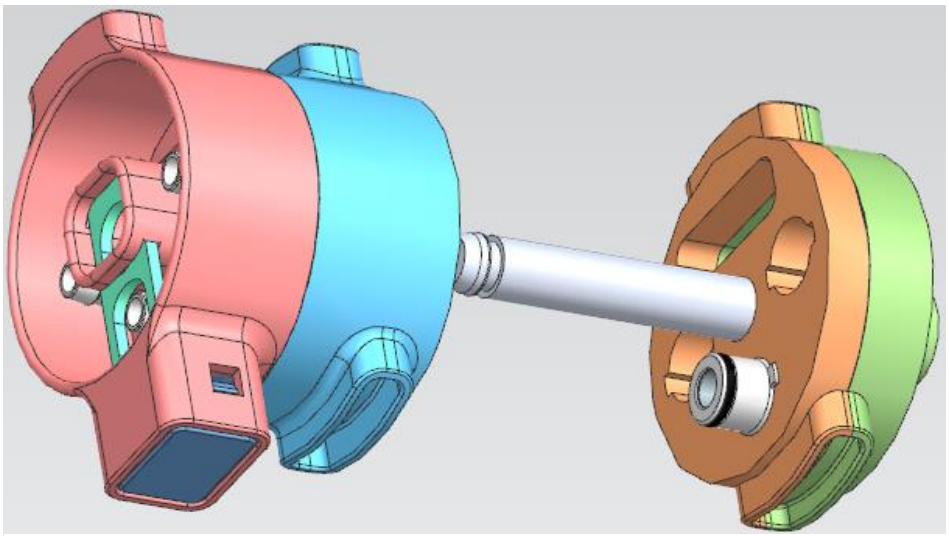


Figure 38 – Exploded view of arm connector module with top (left) and bottom (right)

detachable arm module using the pocketed tabs shown in Figure 38.

When considering the whole medical patient training solution, the arm connector module is what in part enables the modular product architecture to be customizable at the customer level. This is done by increasing flexibility to the amount of patient scenarios that can be trained by connecting different arms to the same torso. It is product customization like this that drives companies to the front of an industry by providing a “one stop shop” for all training needs where the customer can buy one torso and multiple arms and/or legs to meet all of their patient training needs.

5.2.4. Finger Module Connection

The finger module connection design needed to be robust and intuitively changed by the customer. For this, a simple press fit type connection was used. Inside the hand frame is a notch that allows the O-ring around the end of the finger to slip into. This notch can be seen on the middle finger in Figure 39. When in place, the finger cannot accidentally fall out but can still be easily removed by the customer. This module interface likely contains the most risk as none of the functional finger variants were prototyped and therefore a small, easy to connect power and data connector was not tested with the finger connection design. This is again one place where designing the hand and finger frames with the focus of a modular interface is critical and adapting the existing SimMan 3G PLUS hand frame and fingers to fit the modular product architecture proved challenging.

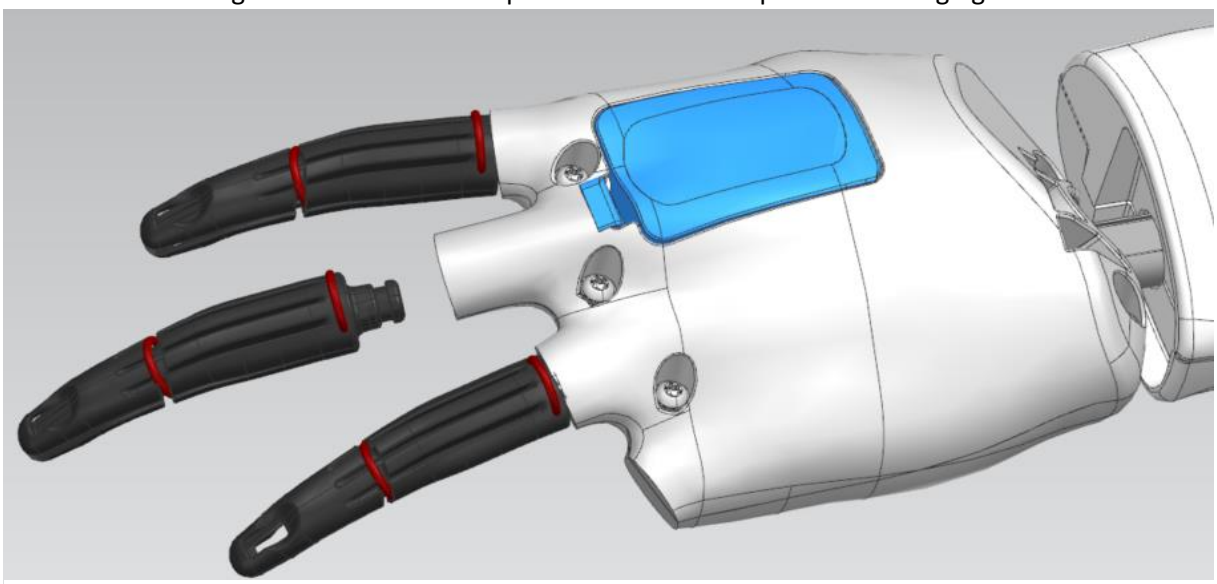


Figure 39 – CAD model of the dummy finger, finger module variant shown interfacing with the hand frame module

5.2.5. Fluid Management Module Fluid Exchange

The fluid management module is self-contained within the modular arm, however, certain procedures and functions require more fluid volume than what is provided with the internal fluid reservoirs. Customers also need the ability to empty or fill these internal reservoirs, to account for both these cases, two fluid connectors have been placed in the modular arm, one in the shoulder module and one in the detachable arm module as shown in Figure 40. An off the shelf quick connect dripless fluid connector was chosen due to its simple, usable, design. Using off the shelf parts for more complex assemblies reduces complexity to Laerdal as parts must only be procured and managed instead of manufactured and assembled. To drain the internal reservoirs, the user can connect an empty syringe to the male connector (not shown in Figure 40) and then insert the male connector into the female connector attached to the manikin. The liquid is then removed by pulling the syringe open, drawing fluid out of the reservoir and into the syringe. To add additional reservoir volume, a male connector is inserted into the female connector found on the module arm. Once the

internal reservoir is filled, the external reservoir will then start to fill as water flows out of the manikin through the fluid connector. Simple solutions like this help decrease cost and increase usability which further elevates the quality of the product in the eyes of the customer.

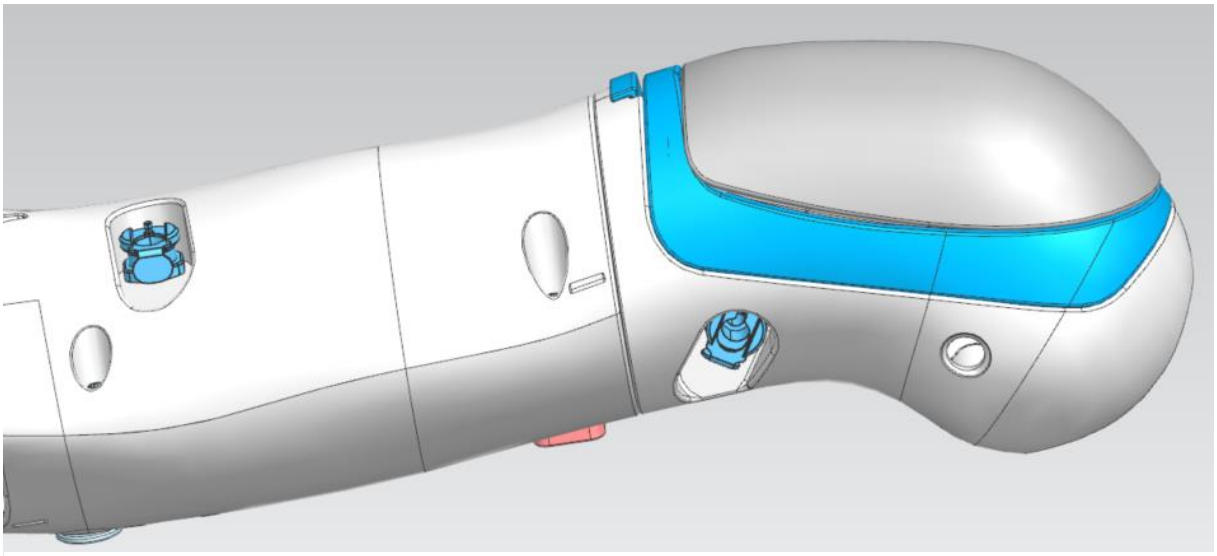


Figure 40 – Quick connect fluid connectors for filling/emptying of internal fluid reservoirs or for connecting external fluid reservoirs. The connection points are located in both the shoulder module (right) and detachable arm module (left)

5.3. System Diagrams and BOM

As the arm is not designed to a product ready level, a full BOM was not used. Instead, a BOM linked to the system diagrams for the fluid management and electronics management modules was created. System diagrams for all arm baselines were created starting with the *Simulator Advanced* product baseline to spatially test the layouts as this is the most feature dense baseline. The *Simulator Advanced* product baseline system diagrams and associated BOMs are presenting in the section with the system diagrams and BOMs for the remaining baseline found in the Appendix B.2 through B.11.

The system diagrams were instrumental to the success of prototyping as it allowed for spatial layouts and logic to be iterated quickly without committing to a full prototype. The risk of each technical solution found in the system diagrams is color coded based on the confidence I have that the solution can be used when the arm is further developed by Laerdal. The color coding appears on the BOM and is as follows: green – high level of confidence, yellow – medium level of confidence, red – low level of confidence. The BOM also includes part numbers to indicate if a part is currently used in Laerdal product or not.

Graphics were added to the system diagrams to increase readability for the reader to help them visually like modules to physical technical solutions found inside the arm prototype. Overall, the system diagrams were used to spatially visualize the generic product structure for each product baseline which allowed for a more streamlined prototyping process.

5.3.1. Fluid System Schematics

The fluid system schematics were created in Microsoft Visio and used to visualize the interactions between the system level fluid management modules and the sub-level modules that are connected to it. These sub-level modules were placed appropriately in the arm as shown in Figure 41 for the *Simulator Advanced* product baseline, and in Appendix B.2 through B.11 for the other product baselines. This fluid system schematic builds on the work done in the interface diagram by further defining the fluid interfaces and placement of modules within the arm. The fluid system diagram also defines the logic behind how fluid is allowed to flow through the system.

Drip-free quick connectors (illustrated as note 2 and 3 on the fluid system schematic) were used to define the interface for the IV and IM/IO modules with the fluid management module. Using a drip-free quick connector allows the user to detach the IV and IM/IO modules from the fluid management module while ensure fluid still held within the fluid management module does not leak. Check valves (illustrated as note 4 on the fluid system schematic) were included in the fluid management module after the quick connector to ensures that all fluid put into the system from the IV or IM/IO modules flows into the internal reservoir instead of out another IV site or floods the IO bone. The quick connector that is used to attach an external reservoir or fill/empty the internal reservoir is located behind the last check valve only allowing fluid to flow from that port into or out of the internal reservoir. When an external reservoir is attached, fluid will first fill the internal reservoir and then start flowing into the external reservoir.

The blood pressure module utilizes the existing technical solution found within the SimMan 3G PLUS where air is pumped into a custom blood pressure cuff to simulate the change in arterial pressure used to measure blood pressure. This air pump is located somewhere else in the manikin so the exact location is outside the scope of this thesis.

The advanced drug recognition module variant requires that injected volume is measured to an accuracy of 1 mL. The created architecture proposes this be done using an off the shelf in-line flow meter as depicted in the photo associated with note 5 on the fluid system diagram.

The fluid system schematic and accompanying BOM for the *Simulator Advanced* product baseline can be found on the following pages as full page illustrations in Figure 41 and Figure 42.

Fluid Diagram – Simulator Advanced Baseline

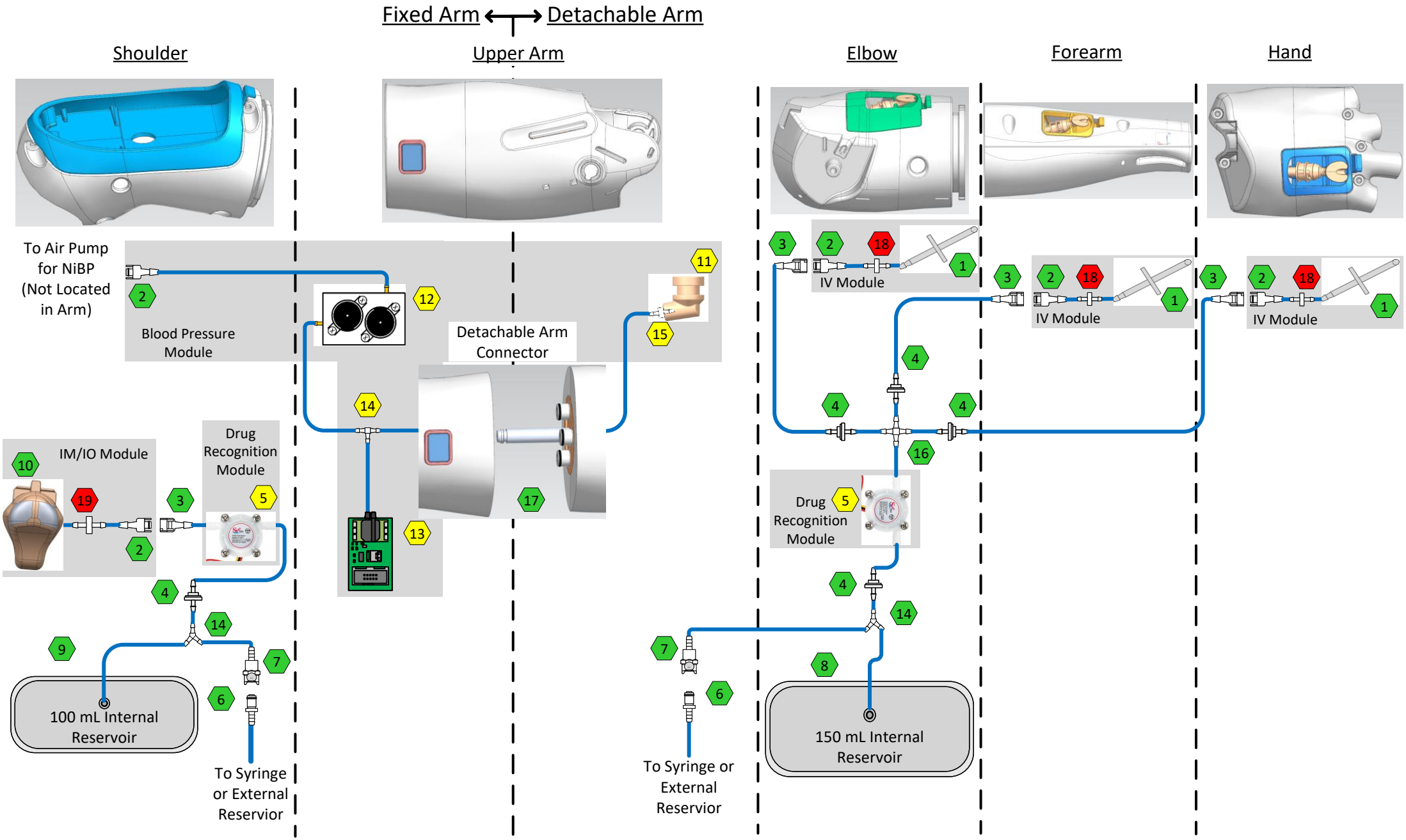
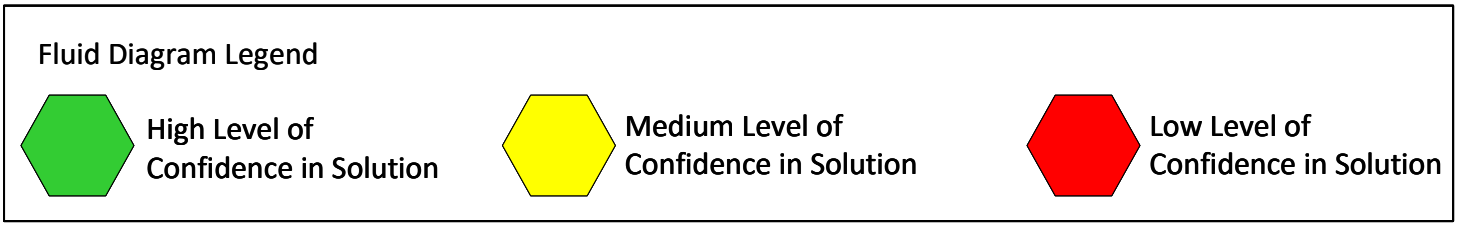


Figure 41 - Fluid management module schematic for Simulator advanced arm baseline

Fluid System BOM – Simulator Advanced Baseline



NOTE	PART NO.	DESCRIPTION	QUANTITY
1	20-17551	Pre-Port IV Body	3
2	N1226	Male Quick Conn. 3mm Barb	5
3	N1201	Female Quick Conn. 3mm Barb	4
4	20-14565	Check Valve 2.4mm	5
5	-	Inline Flow Meter	2
6	20-06199	CPC Quick Connector (Female)	2
7	-	CPC Quick Connector (Male)	2
8	-	150 mL Plastic Reservoir	1
9	-	100 mL Plastic Reservoir	1
10	20-17496	IO Bone	1
11	20-18246	NiBP Cuff Arm Connector	1
12	50-02305	Dist. Unit 2xlowpro	1
13	-	PCA	1
14	-	Fitting T barb 1/8"	2
15	-	Fitting Barb 1/8"	1
16	-	Fitting Cross Barb 1/8"	1
17	-	Detachable Arm Connector	1
18	-	IV Flashback Reservoir	3
19	-	IO Filter	1

Figure 42 - Fluid management module BOM for Simulator advanced arm baseline

5.3.2. Electronic System Schematics

Similar to the fluid system schematics, the electronic system schematics were created in Microsoft Viso using the same format. As my educational background is in Mechanical Engineering, I only have a fundamental knowledge of electronic systems, therefore the electronic system presented only shows a basic layout of where PCAs (printed circuit board assemblies), connecting ribbon cables, and basic electronic powered functions will be located in the arm.

The electronic system schematic is used to visualize how the electronics management module interfaces with the other modules located in the arm that require power and data interfaces. Like the fluid system schematic, the electronic system schematic uses the interface diagram as the basis for the design. Elevating the colored lines used to indicate power and data interfaces to the physical parts and functions that are expected to be used in the modules within the arm. The electronic system schematic was used to map where the technical solutions used in the modules will be located within the arm. This map was then used when creating the digital prototypes of all the arm baselines to confirm the spatial constraints given by the arm geometry allow for each product baseline to be assembled.

In this section, the electronic system schematic and accompanying BOM for the *Simulator Advanced* product baseline is presented on the following pages as full page illustrations in Figure 43 and Figure 44. The remaining electronic system schematics and BOMs can be found in Appendix B.2 through B.10.

Electronics Diagram – Simulator Advanced Baseline

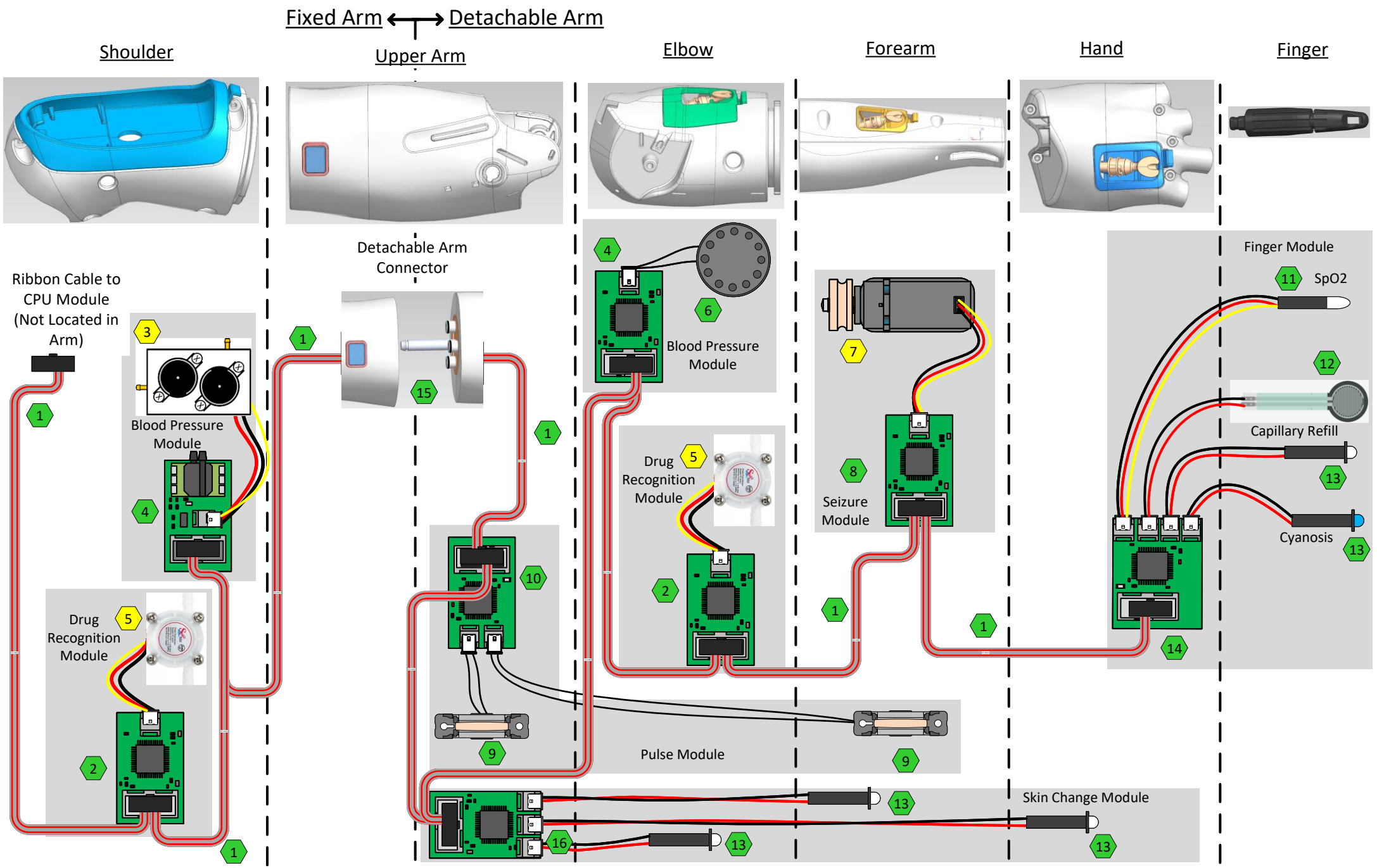
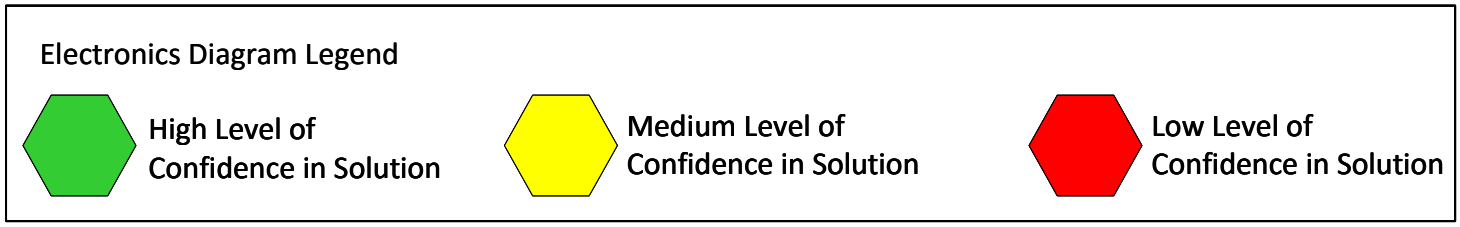


Figure 43 - Electronics management module schematic for Simulator advanced arm baseline

Electronics System BOM – Simulator Advanced Baseline



NOTE	PART NO.	DESCRIPTION	QUANTITY
1	-	Ribbon Cable	1
2	-	Drug Recognition PCA	2
3	20-18246	Dist. Unit 2xlowpro	1
4	-	Blood Pressure PCA	2
5	-	Inline Flow Meter	1
6	-	Speaker	1
7	-	Seizure Motor	1
8	-	Seizure PCA	1
9	20-11599	Pulse	2
10	-	Pulse PCA	1
11	50-02720	SpO2 Finger	1
12	-	Pressure Sensor	1
13	-	RBG LED	5
14	-	Hand PCA	1
15	-	Detachable Arm Connector	1
16	-	Skin Change PCA	1

Figure 44 - Electronics management module BOM for Simulator advanced arm baseline

5.4. Product Specification and Analysis

This section will detail the technical functionality associated with each product baseline along with validating two of the prior hypotheses assumed about a product designed using a modular product architecture. Analyzing the product for cost and sustainability effectiveness against the SimMan 3G PLUS provides a direct comparison to the improvements a modular product architecture has when compared to a monolithic product architecture.

5.4.1. Technical Specification

The technical specification was created to give customers an understanding of the technical functionality provided universally for all baseline, what is specific to each baseline, and what configuration decisions to the baselines they can make. This technical specification was inspired by what can be found about SimMan 3G PLUS on Laerdal's website, an example of what is included in the technical specification can be found below. This specification uses the *Simulator – Advanced* product baseline because it is the most feature dense baseline. In Appendix B.11 the full technical specification can be found.

Simulator – Advanced

- Durable and recyclable plastic skeletal frame (Polyoxymethylene- POM)
- Replaceable and realistic soft plastic skin (Silicone)
- Stiffness controlled joint movement
- Realistic humeral IO access
- Deltoid IM injection site
- Realistic vein IV access at Cubital Fossa, Cephalic Veins, and Dorsal Veins
- Pulse palpation at radial and brachial sites
- Pulse strength variable and independent of site
- SpO2 measurement in finger compatible with pulse oximeter
- Capillary refill in finger
- Blood glucose measurement in finger compatible with glucose meter
- Arm movement and locking joint seizure simulation
- Drug recognition through RFID enabled medicine vile
- Injected drug volume measurement
- Skin color change to represent pale, yellow, or red skin
- Skin appearance change to represent rashes, bruising, and burns
- Non-invasive automatic cuff blood pressure measurement
- Non-invasive manual cuff blood pressure measurement with Korotkoff sounds

This technical specification does not include information about the modular product architectures structure as this information is not relevant to the customer. However, when looking at the structure of the modular product architecture, links can be made to the product functions shown in the technical specification and modules defined in the product architecture. The product function *Realistic humeral IO access* and *Deltoid IM Injection site* are both realizations of the realistic IO w/ IM variant of the IM/IO module, similarly *Drug recognition through RFID enable medicine vile* and *Injected drug volume measurement* are the functions associated with the advanced drug recognition variant of the drug recognition module. The technical specification does its job of communicating the differences between product baselines in an easy to understand way to ensure the customer buys the product they need, a realization of a customer value.

5.4.2. Cost Assessment

For the cost assessment, the realistic IO w/ IM variant of the IM/IO module was chosen for a direct cost comparison with the IM and IO functionality of the SimMan 3G PLUS. Only the cost to Laerdal Medical of the parts was used in this comparison, these direct costs were provided by the financial analysis team at Laerdal Medical. The cost comparison makes several assumptions:

The cost/g of POM (material used for the frame of the arm) and silicone (material used for the arm skin) was extrapolated from the total cost and weight of the parts found on SimMan 3G PLUS. This cost/g equivalent was then used to calculate an estimated cost for the POM module frame and silicone arm material used on the module, all other parts were reused directly from SimMan 3G PLUS therefore the same cost was used. The sum of each part in both solutions was calculated to determine the cost of each solutions. A percentage change between the two solutions was then calculated to create a direct comparison between the cost of the two solutions.

It is also assumed that the entire silicone arm skin will be replaced once during the lifecycle of SimMan 3G PLUS. Based on internal testing documentation done for IM and IO needle injection on the silicone material used in the SimMan 3G PLUS arm skin, the material does degrade visually after use with the IO needle but not with the IM needle. A 25G needle was used for IM and after 2000 injections, there was no visible material degradation until the material was significantly stretched, something that would not occur during normal operation use. However, after only 50 injections with the 15G needle used for IO injections, there was visible degradation to the arm skin, and significant degradation after 100 injections. Of course, after this many injections, the IO Bone and potentially IM foam pad would need to be replaced. As both the proposed module and existing functionality on SimMan 3G PLUS use the same parts, the cost associated with replacing these parts was not included.

The realistic IO w/ IM variant of the IM/IO module has a dedicated arm skin that is only used on the module. The full arm skin remains but is not punctured during use of the IM/IO module. Using the assumption presented above, this change was calculated to have a cost savings of 880.7 NOK, largely due to the significant reduction of silicone that must be replaced once worn out from use of the IM and IO functionality. This cost savings equates to a 74.15% reduction in assumed lifetime cost associated with the IM and IO functionality. Although assumptions had to be made to create the cost analysis, this proves the hypothesis that when compared to a monolithic product, a modular product has a reduced operating cost enabled by inexpensive exchange and repair of modules instead of an interconnected system. A breakdown of the full cost assessment can be found in Appendix B.12.

5.4.3. Sustainability Assessment

The sustainability assessment was also performed for the realistic IO w/ IM variant of the IM/IO module and directly compared to SimMan 3G PLUS. An LCI Dataset from Ecoinvent version 3.10 [82] (updated in 2023) was used, which implements environmental footprint (EF) method 3.1 as defined by the European Platform on Lifecycle Analysis [83], to collected the kg CO_2 equivalent for each material used in the IM and IO functionality for the modular arm and SimMan 3G PLUS. The sustainability team at Laerdal Medical was responsible for using the Ecoinvent software to collect the kg CO_2 equivalent data. The description for each material found in the full sustainability assessment located in Appendix B.13 was taken from the Ecoinvent database and the sustainability team. While the calculations done are my original work, the kg CO_2 equivalent and material descriptions are not. To calculate the embodied kg CO_2 in each part that comprises the IM and IO functionality in both SimMan 3G PLUS and the modular arm, the kg CO_2 equivalent taken from the database and the weight of each part were multiplied. The resulting embodied kg CO_2 for each part was then summed

to determine the total amount of embodied kg CO_2 for each solution. A percentage change was then calculated to determine the difference in CO_2 emissions between the two solutions.

Similar to the cost assessment, the sustainability assessment also assumes that over the lifetime of SimMan 3G PLUS, the arm skin will need to be replaced once from degradation associated with use of the IM and IO functionality. The validation to this assumption was described in the cost assessment section based on internal testing of the silicone skin material done at Laerdal Medical. Once again, the potential replacement of other parts such as the IO bone or IM foam pad is ignored as this replacement would be required for both SimMan 3G PLUS and the IM/IO module at the same time.

Taking into consideration the assumptions above, the realistic IO w/ IM variant of the IM/IO module provided a kg CO_2 savings of 2.4 kg, this equates to a percentage reduction of 68.77% between the two solutions. This analysis validates the assumption that when compared to a product developed using a monolithic architecture, a modular product architecture improves the sustainability during the lifecycle of the product. Modules allow for smaller parts of the product to be replaced or repaired reducing the amount of waste commonly associated with interconnected system, as shown in this sustainability analysis.

5.5. Product Lifecycle – Module Interface Management

When designing a product using a modular product architecture, the module interfaces must be controlled in a way that updates to one interface results in the same update to all of the interfaces. For example, if the IV module interface on the arm frame is changed, this change should be automatically updated downstream for all variants of the IV module. For this thesis, the workflow behind how this can be done in Siemens NX was investigated. This section will present the CAD workflow developed during this thesis using an example part to confirm it works as needed. This workflow can be visualized in the flowchart found in Figure 45. Starting with a master CAD part, which for the modular arm was the arm frame, a modeling decision is made to use either a linked CAD body or linked sketch. Next, an intermediate CAD part is created from either the linked body or sketch, this part is the interface the module variants will be created from. Finally, the geometry needed for each module variant is created from the linked intermediate CAD part. If this workflow is followed, changes to the geometry of the master CAD part update the intermediate part which then updates all module variants. Depending on the extend of the changes made to the master geometry, some features will need to be redefined, but no remodeling needs to be done to the intermediate or module variants.

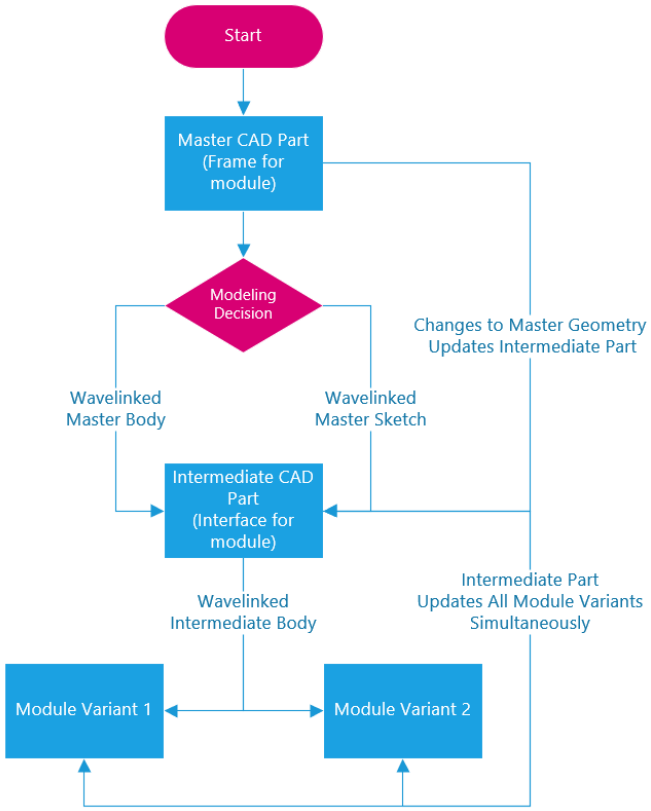


Figure 45 – Flowchart for CAD workflow used to manage module interfaces.

This workflow was tested using a simple surface that was thickened to create a solid body. A simple interface was then extruded from the center using a single sketch. After the intermediate CAD part for the module interface was created, and the subsequent two module variants created, the initial surface was modified with the interface sketch remaining the same. Both the original surface and updated surface can be seen in Figure 46.

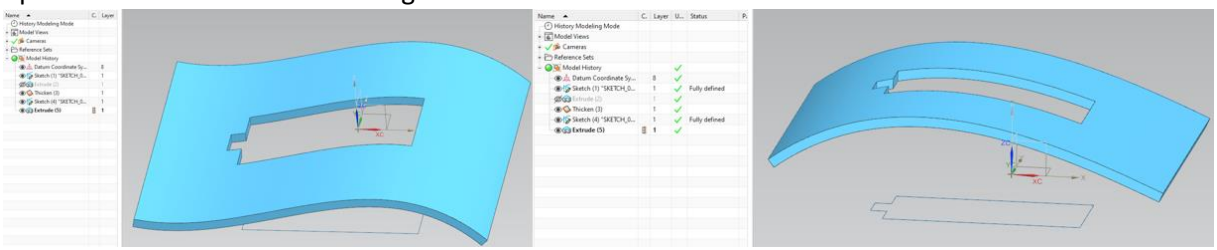


Figure 46 – Master CAD parts used to test the proposed CAD workflow. The original master part is shown on the left and the modified master part is shown on the right.

The intermediate part and module variants were then inspected to determine how much of the changes made to the master part were automatically updated. For each part, faces had to be redefined. Although this process did not work perfectly, after the broken links were redefined, the

parts updated as expected. While this process is not fully automated, it does ensure that the changes made to the master part are consistent and no modeling changes needed to be made, crucial as this can create errors in the module interfaces.

The intermediate part was created in two ways to confirm either decision made according to the workflow flow cart is valid. One part was made by linking the master CAD body and then modeling was done using the internal faces for the interface pocket. The other part was made by linking the master CAD sketch and linked surface. Using this sketch the interface was modeled and then constrained using the linked surface. Both intermediate models that represent the module interface can be seen in Figure 47.

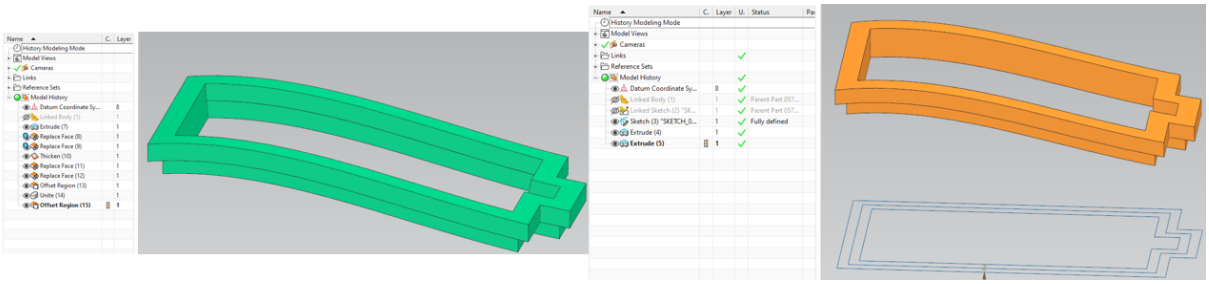


Figure 47 – Intermediate CAD parts created using both workflow decisions. The part on the left was created only using the linked body of the master part. The part on the right was created using the linked sketch and top surface of the master part.

The module variant parts were then created using a linked CAD body of the intermediate CAD part created in the previous step. Module variants one and two were created using the same linked body from the intermediate CAD part. These variants were created to validate the workflow methodology by using an intermediate interface part used to create the module variants from. This intermediate part would not be manufacture but it would still need to be revision controlled in a PLM software as this intermediate part is what dictates the interface between the master CAD part and the module CAD part. Although this does add an extra part to revision control, it ensure no mistakes are made when updating module interfaces. If an intermediate part was not used, each interface for each module variant would potentially need to be remodeled in the same way for each revision.

In Figure 48, both module variants can be seen, slight differences are included to visually differentiate between them. As shown in the figure, both module variants share the same interface but have different geometries, as would occur in a real part being designed using a modular product architecture.

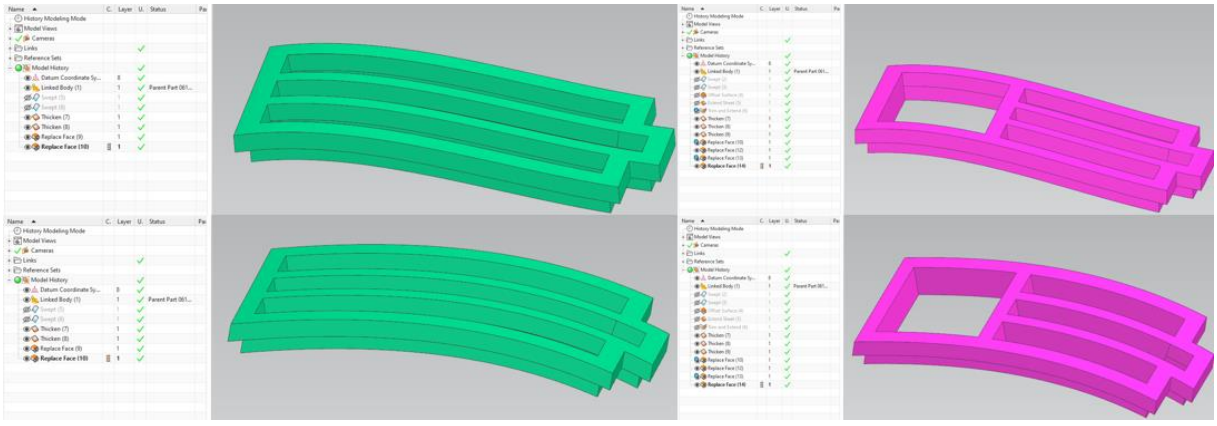


Figure 48 – Module variants showing initial and updated geometry based on master CAD part. The parts on the left are module variant one with the initial geometry on top and the updated geometry on the bottom. The parts on the right are module variant two with the initial geometry on top and the updated geometry on the bottom.

6. Product Prototype and User Testing

Prototyping is a realization of both the modular product architecture and the design of the product baseline completed in the first two phases of the thesis work. This phase of the thesis focuses on the development of physical and digital prototypes used to confirm the feasibility of the product design, and the execution of user testing used to validate the market appeal for the modular product architecture.

The physical prototyping process materializes the CAD models created to design the product baselines helping to bridge the gap between design and reality. Physical prototypes serve as a tool to validate design assumptions made when designing the modular interfaces by refining the engineer and designers' knowledge of how the product meets the technical and user interaction requirements.

The digital prototyping procedure serves as a visualization tool for understanding how the modules spatially interact with each other within each arm baseline. This crucial step validates the product baselines by ensuring all modules fit within the constraints of the arm geometry for each baseline.

The user testing step validates the theorized market appeal and customer satisfaction of the modular product architecture through interaction with the physical prototype, and a walk through of the buying process from baseline product selection to user driver configuration of the chosen baseline. The feedback gained from the user testing will then be used to improve the modular product architecture.

Overall this final phase of the thesis work is used to validate and improve the work done in the two previous phases.

6.1. Physical Prototype

The physical prototype was mainly manufactured using 3D printed PLA to create a low cost 1:1 scale materialization of the CAD model that users could physically interact with. The arm connector module utilized both laser cutting, for the sliding locking pate, and a manual lathe, for the center pin to manufacturing a working prototype that allows the shoulder and detachable arm modules to be disconnected from each other. The manufacturing of the arm connector prototype was performed by me in the workshop at Laerdal Medical. The 3D printing was done at Laerdal Medical using Prusa MK3s. Given the large number of parts the workload for printing the prototype was split between me and a 3D printing technician at Laerdal Medical. The 3D printing technician printed the larger frame module parts in the 3D printing lab while I printed the smaller parts in the makerspace near my workspace, this was done to ensure 3D printers near my workspace were available to other engineers as some of the large parts took nearly 24 hours to complete.

Based on the limited scope of the physical prototype for the thesis, the simulator basic product baseline was chosen to be prototyped. Time was not given to creating prototype with a working electronics or advanced fluid management module. Instead, the physical prototype focused on the modules the users will directly interact with such as the arm connector, IM/IO, IV, and fingers. All variants of the IM/IO and IV module were also prototyped to allow the users a chance to test how easy and intuitive it was to exchange these modules on the physical prototype. These module variants also showed a visualization of the customization options available to the user after choosing to buy the simulator basic arm baseline.

Preliminary tests were conducted on the fluid system implemented into the physical prototype, this was done to confirm that the system proposed in the fluid system diagrams worked as expected to

route fluid one way towards the reservoirs from the multiple IV ports. During this testing, it was determined that the fluid line layout could be improved to eliminate kinking of tubes that occurred with re-inserting the IV modules after removal. It was also noted that rigid internal bladders would be better suited for the modular arm as when the flexible bladders were inflated, they interfered with other parts inside the arm. Having a rigid bladder that takes up the same space regardless of how much fluid is inside will solve this issue.

Overall, the physical prototype was successful in allowing users to interact with exchanging of the modules and detaching of the detachable arm from the shoulder. The remainder of this section is dedicated to pictures seen in Figures 46-49 of the physical prototype to help provide visualization to what was just previously discussed.

Figure 49 – Physical prototype of IM/IO module. Realistic IO with IM module variant seen on left and exposed IO module variant seen on right. Realistic IM module variant not shown as it highly resembles the realistic IO with IM module with the absence of a fluid line.

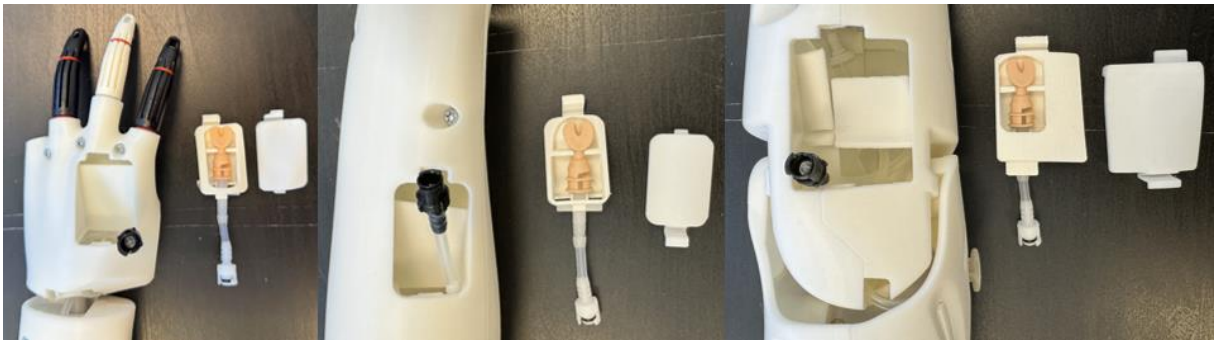


Figure 50 – Physical prototype of IV module with pre-ported and hidden (placeholder design) module variants. Dorsal veins IV site on left, cephalic veins IV site in middle, and cubital fossa IV site on the right.

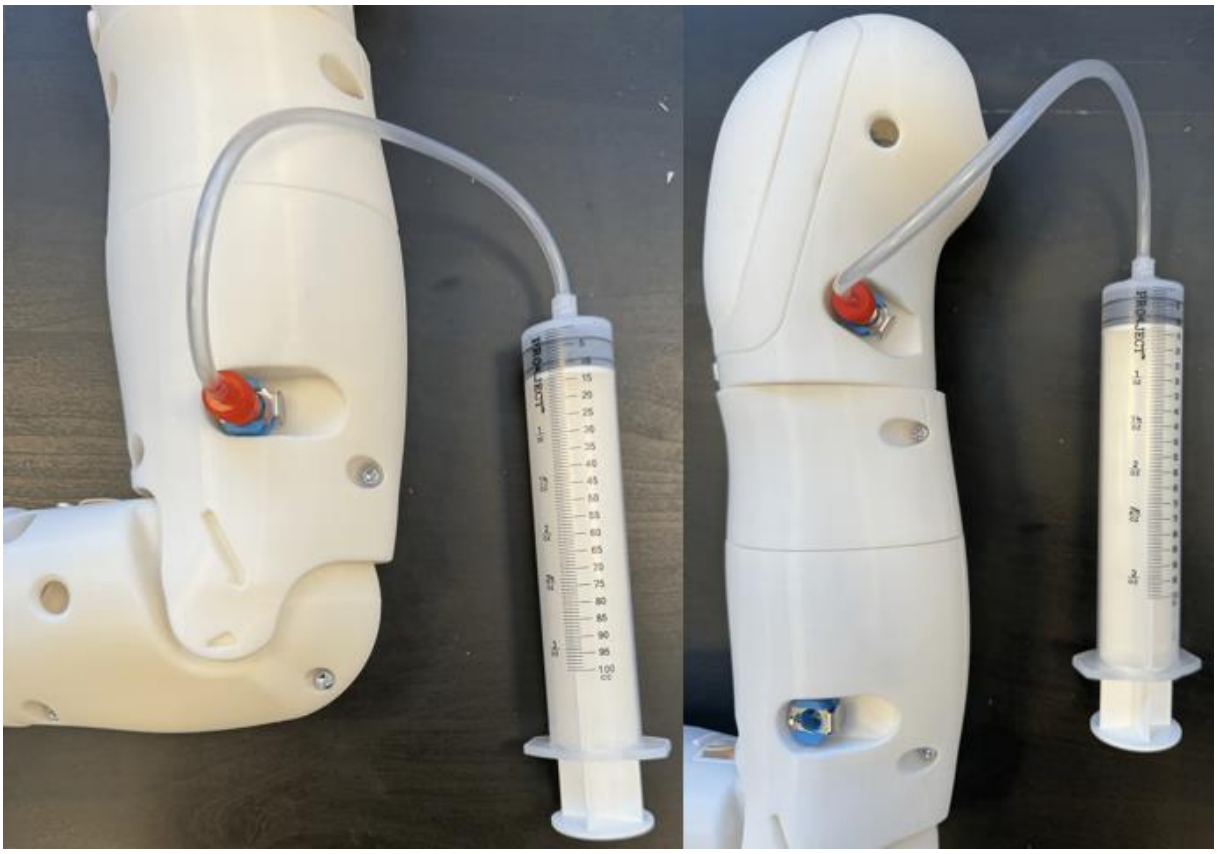


Figure 51 – Physical prototype of fluid exchange system. Fluid exchange for IV reservoir on left, and the fluid exchange for the IM/IO module on the right.

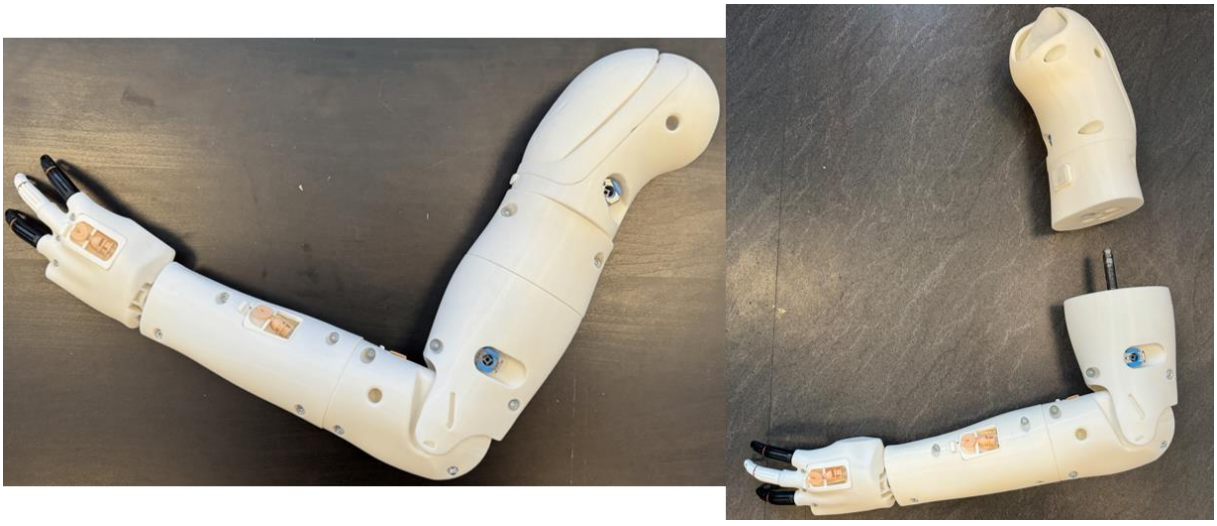


Figure 52 – Physical prototype of simulator basic baseline for modular arm with detachable arm module shown detached from shoulder module on the right.

6.2. Digital Prototypes

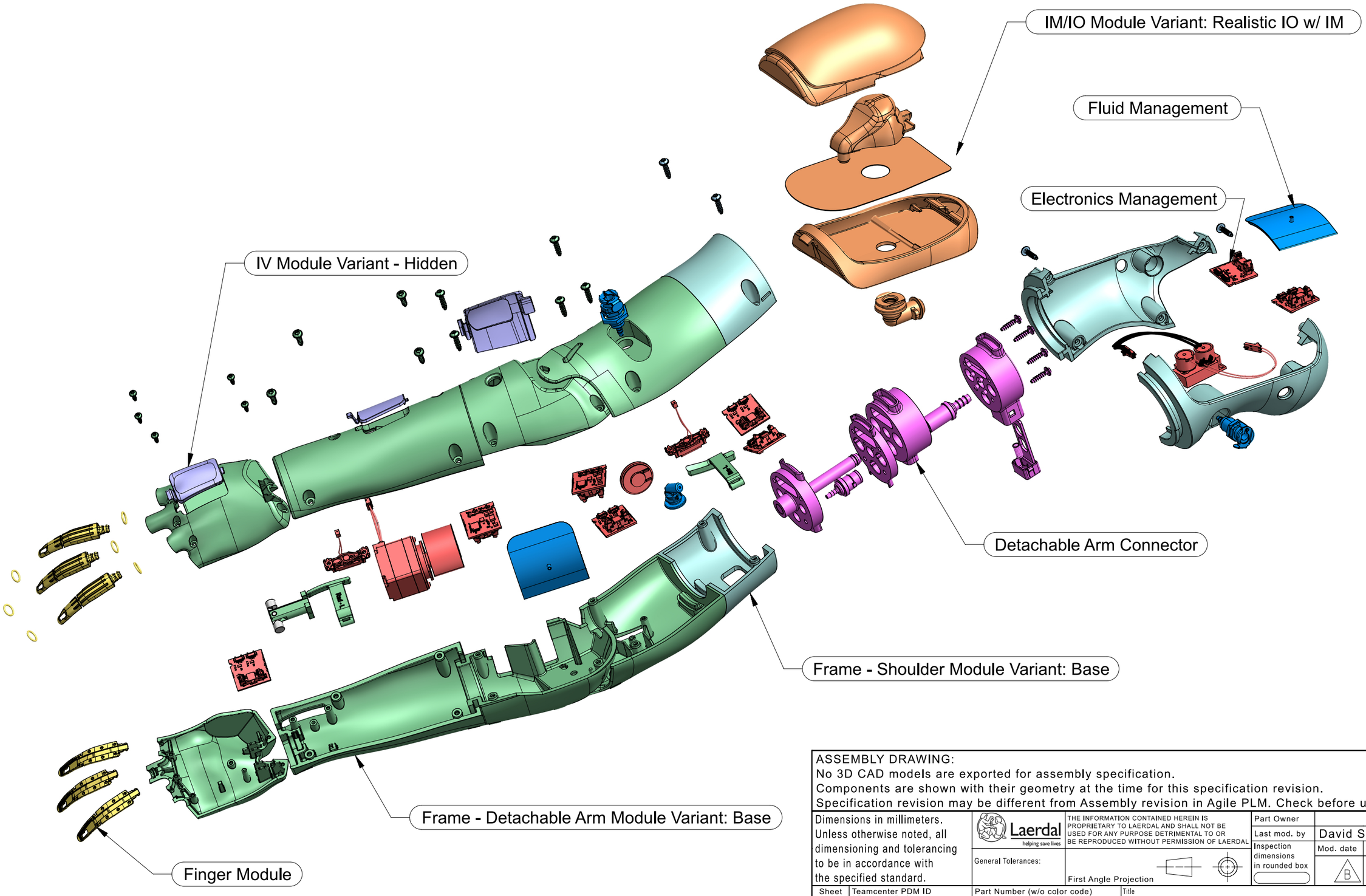
The digital prototypes were created as assemblies in Siemens NX. Starting with the simulator advanced product baseline, all components of each module were added to an assembly where they were placed in the arm according to the generic product structure created during the MFD process. The simulator advanced baseline was chosen as the first digital prototype as it is the most densely populated product baseline. All other digital prototypes could then be created by removing specific modules as dictated by the modular arm product baselines. The digital prototypes were used to

confirm that the modules could be spatially located within the modular arm, this was a critical step in ensuring the validity of the product architecture. If the modules cannot be spatially configured as shown in the product baselines than that configuration will not work. It was identified that the seizure module found in both the simulator advanced and intermediate baselines will need to have a smaller eccentric load to fit with the cephalic vein IV site. This insight can be used for when designing an improved version of the seizure module and could also be used to make the IV modules more space efficient. As this thesis only was taken to the proof-of-concept phase, the baselines were not reorganized due to this spatial conflict. The seizure module had previously been identified as one of the modules that needs to be redesigned to better meet the function provided by the seizure module. Knowing there are added size constraints associated with this module can be added as a technical requirement when redesigning the module in the future.

The digital prototypes are presented as exploded views that are color coded by module. This visualization helps show which modules are present in which product baselines. In the body of this thesis, only the exploded view from the digital prototype of the simulator basic is shown to show a comparison between the physical prototype presented in the previous section. This exploded view is presented as a full page illustration in Figure 53 on the next page and the remaining exploded views are be found in Appendix C.1 through C.5.

Overall, the digital prototypes were successful in planning how the modules would be spatially organized within the different product baselines for the modular arm. These prototype would be iteratively updated during the development process to ensure that no new spatial conflicts are created.

Rev.	Description of Change:
02	New Specification



ASSEMBLY DRAWING:
No 3D CAD models are exported for assembly specification.
Components are shown with their geometry at the time for this specification revision.
Specification revision may be different from Assembly revision in Agile PLM. Check before use!

Dimensions in millimeters. Unless otherwise noted, all dimensioning and tolerancing to be in accordance with the specified standard.	Laerdal helping save lives	THE INFORMATION CONTAINED HEREIN IS PROPRIETARY TO LAERDAL AND SHALL NOT BE USED FOR ANY PURPOSE DETRIMENTAL TO OR BE REPRODUCED WITHOUT PERMISSION OF LAERDAL	Part Owner	
			Last mod. by	David Shapiro
	General Tolerances:	First Angle Projection	Inspection dimensions in rounded box	Mod. date: 25-Apr-2024
			B	Letter in triangle shows point of revision-change

Sheet size	Teamcenter PDM ID / Revision Reference:	Part Number (w/o color code)	Title	
A3	061427/02	061427	Modular Arm Assembly - Simulator Advanced	
Sheet scale 1:3	Prototype revs. (01, A01 etc.) in Teamcenter PDM only Design revisions (A, B etc.) data uploaded to Agile PLM	Document Number in Agile PLM: 061427	Attachment to Doc.: Sheet 1 of 1	Doc. Rev.: 02

Figure 53 - Exploded view CAD model of digital prototype for Simulator advanced baseline

6.3. User Testing

User testing was conducted with three product managers, one marketing manager, and one member of the MoSAic team. The same survey was given during each user test to ensure consistency for the quantitative data being collected. Ultimately, some user tests ran over the hour allocated for each so the less relevant questions were glossed over depending on the user. In the end, each user gave valuable insight into what works with the modular product architecture and what they felt could be improved. This data, mainly qualitative, was used to improve the product architecture for the final draft that was presented in this thesis report. While the quantitative data was used to track how well each user felt the modular product architecture satisfied market and customer needs in a way that could be compared with the other users.

Along with the survey that is available in Appendix C.6, supplemental information was provided and explained to the user prior to testing. This information described the different market segments and customer values the modular product architecture aimed to satisfy. Before interacting with the physical prototype, it was explained to the user which product baseline the physical prototype was configured from and the other modules available in the different product baselines were described. Interacting with the physical prototype was not guided to ensure the quantitative questions relating to the intuitiveness of swapping modules on the physical prototype were not skewed.

The results from the user testing were mainly positive indicative that the modular product architecture will be received well by the market segments. The quantitative results are compiled and shown in Table 1. The user testing was broken into three topics: user interaction where the user tested with the physical prototype, customer value where the user considered value of offering user-driven customization and add-on packages, and market segments and business strategy where the user examined how well the modular product architecture meet the market and business needs.

Table 1 – User testing quantitative results for modular arm

User / Question	Marketing Manager	Product Manage (SimMan)	Product Manager (SimJunior)	Product Manager (ResusciAnne)	Mosaic Team Member	Average Score
Topic: User Interaction						
IV Module - Dorsal Veins	4	5	TBD Testing soon	4	3	4
IV Module - Cephalic Veins	4	5		4	4	4.25
IV Module - Cubital Fossa	4	5		4	5	4.5
IO Module	4	5		4	5	4.5
Detachable Arm Connector	5	5		5	5	5
Finger Connector	2	3		3	3	2.75
Fluid Connector	4	4		5	5	4.5
Topic: Customer Value						
Arm Skin Color (Baseline)	=	=	=	=	=	N/A

Arm Skin Appearance	+	+		=	+	N/A
Arm Skin Material	+	+		=	-	N/A
IV Port Type	+	+		-	=	N/A
IV Sites	+	-		-	=	N/A
IO/IM Type	+	+		+	+	N/A
Fingers	+	+		-	+	N/A
Additional Finger (Baseline)	=	=	=	=	=	N/A
Cyanosis Package	+	+		-	+	N/A
Advanced Bleeding	+	-		-	+	N/A
Additional IV Ports	+	+		+	-	N/A
Additional IO Ports	+	+		+	-	N/A
Topic: Market Segments and Business Strategy						
Baseline coverage	5	5		3	4	4.25
Configuration coverage	5	5		3	4	4.25
Align to business strategy	5	5		5	5	5
Perceived impact on market	5	5		5	5	5
Overall satisfaction	5	5		5	5	5
How likely to adopt into your product?	N/A	5		3	N/A	4

Analyzing Table 1, specifically the average score column, all the averages for the user interaction scored above a four out of possible five except for the finger connector which scored an average of 2.75. This indicates that the technical solution used for the finger connector needs improvement in the next design iteration to improve the user experience. The qualitative comments associated with the finger connector focused on how it was hard to know if the finger was correctly attached and that the solution did not feel robust.

Many qualitative comments also mentioned the lack of need for blank lid module variants for both the IV and IM/IO modules, stating that the cost associated with maintaining more parts will likely outweigh the added cost of having IV and IM/IO module variants in all product baselines. It was

decided that the blank lid module variants for both the IV and IM/IO modules would be removed in the final product architecture and the product baselines originally using the blank lid variants would instead use the least expensive variants. This decision reduces complexity to Laerdal without adding much cost to the product baselines.

Other comments relating to the user interaction with the modules questioned the need for the user to remove the IV modules and fingers or if that should be limited to technicians. This is something that will need consideration for future iterations of the arm product architecture. Not allowing the customer to replace the modules themselves does reduce the modularity of the product but at the same time increases the robustness of the product. Potentially there can be a compromise made to offer some service of the module to the user without requiring a service technician.

The feedback regarding the value added from user-driven customization was fairly mixed across all users. Based on the quantitative results presented in Table 1, and qualitative results given by each user two changes were made to the final product architecture. First, the option to choose which IV site was used on the arm was removed to reduce complexity for Laerdal during product configuration, this change results in every product baseline using all three IV sites, with an exception made to the trauma limbs that have no IV sites as they use different variants of the detachable arm frame module. The second change made was to make advanced bleeding standard in both the trauma limb baseline as it was commented that this functionality is required in all trauma scenarios so should not be an optional add-on.

Lastly, the users largely agreed that the market segments and Laerdal business strategies were met by the proposed modular product architecture. This signifies that despite some small shortcomings of the product architecture, it will be successful when implemented into a product. The user testing signified the end of the thesis work and provided validation to the assumptions made when developing the modular product architecture. Overall, the users were satisfied with the product architecture signifying a successful development of the modular product architecture.

7. Conclusion

As the work done in this thesis developed a modular product architecture and a proof of concept modular arm prototype, the conclusion to this report provides a good opportunity to reflect on the work done, knowledge gained, and recommendations for continued development of the modular arm. The main goal of this thesis was to explore the theorized advantages and limitation of incorporating a modular product architecture for Laerdal Medical's future medical patient training solutions. Focusing on the development of a modular product architecture for the arm of a full body medical patient training solution, this thesis served as a functional feasibility study for Laerdal's internal product architecture team. Specifically by providing valuable insight into the materialization of a modular product architecture into configurable product baselines for a function dense area of a full body medial patient training solution.

The specific focus outlined in the scope that was guided by the research questions was substantiated through accomplishment of the following thesis milestones:

Development of a modular product architecture:

- A modular product architecture for the arm of a full body medical patient training solution was successfully produced. This product architecture, which is centered on customer values and market segment coverage, demonstrates the feasibility of using modules to build configurable product baselines, thus achieving increased product offerings with less standalone products.

Creation of a proof-of-concept modular arm design:

- A proof-of-concept modular arm design for all product baselines was achieved by integrating existing parts from current adult Laerdal manikins and simulators, with modified components and novel parts. The final design focused on creating universal interfaces for module variants and spatial configuration of modules within the constraints of the arm geometry.

Analysis of modular arm design for cost and sustainability improvements:

- The realistic IO with IM module variant of the IM/IO module in the modular arm was used for a direct cost and sustainability analysis with the IM and IO functionality found in SimMan 3G PLUS. The cost analysis showed a 74.15% reduction in lifetime cost associated with the IM and IO functionality when implemented with the modular product architecture verses implementation with a monolithic product architecture.
- Similarly, the sustainability analysis showed a 68.77% reduction in embodied CO_2 emissions when the IM and IO functionality is implemented in the proposed modular product architecture.

Production of a physical and digital prototypes of modular arm baselines:

- The physical and digital prototypes were created to test the functionality of the arm baselines both for configuration potential and spatial availability within the arm geometry constraints. The physical prototype showed the practicality of user configuration from a arm baseline, while the digital prototypes validated that the modules could be configured within the arm geometry as defined in the arm baselines.

User testing to gauge customer satisfaction and market coverage of the modular product architecture.

- The user testing performed internally at Laerdal helped gauge how the customers are expected to react to the launch of a modular full body medical training solution. Through interaction with the physical prototype and testing of the product configuration possibilities, the users scored various aspects of the modular product architecture. The results were overwhelmingly positive with a few important suggestions that were immediately implemented into the product architecture.

The thesis work has successfully answered the research questions and stayed within the boundaries set by the project scope to present Laerdal with an extensive feasibility study grounded in the insight gained from this research. This thesis contributes a valuable perspective for how modularity in Laerdal products can increase market share through enhanced customer satisfaction at a lower cost without sacrificing sustainability commitments.

The remainder of this section will touch on recommendations for future work and scope adjustments from the pre-study project plan that were implemented to ensure a successful completion of the project.

7.1. Recommendations for Future Modular Product Architecture Design

Having now completed the MFD process once, a few things standout that could be improved when working through the MFD process again. To enchance the results of future modular product architecture, it is recommended to:

Follow a more iterative process with a focus on continual improvement and refinement of the modular product architecture at each stage of the MFD process and during the product development phase. This will ensure that the final product architecture does not conflict with the product design.

Carefully define product properties that are organized into commercial and system properties. Doing this makes working with the DPM and MVS easier due to the grouping of the product properties. It also enables the commercial offerings matrix (COM) and system properties matrix (SPM) to be used which helps elevate the business side of the MFD process. However as this thesis did not focus on the business aspects of the MFD process, these tools were not used.

Fully define the voice of the customer prior to moving forward in the MFD process. While the MFD process is meant to be iterative, it is important that the voice of the customer is completed prior to moving to the voice of engineering or doing any iterations as the voice of the customer provides the foundation for the entire MFD process.

7.2. Deviations from Pre-Study Project Plan

During the thesis project, several deviations from the project plan presented in the pre-study report, as seen in Appendix D, occurred. These changes were necessary as the project evolved due to continued learning that happened while working through the MFD process. These changes ensured that the project adhered to the time constraints while still answering all research questions. In the end, these changes did not affect the success of the project as all research questions were thoroughly answered by the thesis work. The following are the key changes and an explanation to why they were made:

The MFD process was more iterative than anticipated. To adjust for this, early prototyping was done to test module interfaces and spatial configurations of modules within the modular arm frame. The findings from this prototyping was used to iterate and improve the modular product architecture.

The BOM scope was limited to the fluid management and electronics management modules for each product baseline. As the product development was only taken to a proof-of-concept level, a full BOM

was not provided and instead a more in-depth design of the fluid management and electronics management modules was done to test the functionality of the system level module.

The technical specification focus was shifted to provide the customer with technical features provided in each product baseline and the configuration available to them. Similar the BOM scope adjustment, it was determined that this provided more value than a traditional technical specification that would list all technical product requirements such as part materials or flow and voltage requirements.

The cost and sustainability analysis scope was condensed from the entire arm to the IM and IO functionality. As the arm prototype was only a proof-of-concept and did not contain all parts that the final product will, the module with the most overlap to SimMan 3G PLUS was used. The analysis on a single module still accomplished the goal of comparing the modular product architecture to a monolithic product architecture.

7.3. Expanding Learnings from Arm to Full Manikin

The modular product architecture presented in this report was built for the arm of a full body medical training simulator, however the principles used and knowledge gained can be used for development of a modular product architecture for the entire manikin. Specifically, the product structure, modules and variants, arm baselines, and configuration possibilities could be easily adapted to fit the full body training solution product architecture. Given the functions of the arm are mostly disconnected from the rest of the body, the arm architecture developed for this thesis could largely be re-used for the arms.

7.4. Future Work

Given the time constraints associated with the thesis, future work has been identified as a way to build-off the work done in this thesis and improve the modular product architecture and product development process using modular principles for full body medical training simulators. Using this thesis as the foundation, the following are potential future tasks that could be explored:

Skin attachment:

- The attachment of the skin to the shoulder and detachable arm frame modules should be explored using the product properties and customer values associated with the arm skin identified in the proposed modular product architecture.
- The attachment of skin to the IV and IM/IO module variants and how the skin interacts with the skin from the other modules should also be explored.

Refinement of proposed modular arm architecture:

- The proposed modular product architecture for the arm should be refined after integrated into the modular product architecture for the full body. How functions interact with other parts of the body will need to be evaluated, and potentially new modules or variants will be created from this insight.

PLM for a modular product

- PLM and ERP systems that work with a modular product architecture and interact with Siemens NX is critical for offering configurable products to the customer. This along with proper CAD model management for product baselines and potential configurations is required for a smooth implementation of a modular product archecitreu.

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Appendix A.1 - Product Property Names and Goal Values

Measure Injected Volume
No
Yes

Fluid Reservoir (External)
No
Yes

Fluid Reservoir (Internal)
No
Yes

Anatomical Landmarks
Humeral head
Ulnar styloid
Humeral Lateral Epicondyle

Arm Appearance
Base
Geriatric
Obese

Arm Attachment Type
Detachable

Arm Side
Left
Right

Arm Size and Weight
Newborn
Baby
Child
Adult

Arm Skeleton Material
Engineering Plastic
Commodity Plastic

Arm Skin Material
Silicone
TPE

Bleeding Functionality
No
Yes

Bleeding Type
Arterial
Venous

Blood Glucose Functionality
None
Low/Normal/High

Blood Pressure Functionality
None
Manual Cuff and Stethoscope
Automated Cuff

Blood Pressure Range
Baby Range
Child Range
Adult Range
Newborn Range

Capillary Refill Functionality
No
Yes

Capillary Refill Time
0 - 10 sec

Change in Skin Appearance
None
Burns
Bruises
Rash

Change in Skin Color
White (Pale)
Yellow (Jaundice)
None
Blue
Red

Control of Joint Stiffness
No
Yes

Cyanosis Functionality
No
Yes

Drug Recognition Functionality
No
Yes

Elbow Articulation
1 DOF

Finger Connector
Detachable

Finger Placement
Middle
Index
Ring

Fluid Color
Red

Fluid Exchange
Yes

Fluid Filling Location
At Each Module

Fluid Flow Rate (Bleeding)
5 - 30 mL/min
30 - 120 mL/min
300 - 600 mL/min

Fluid Flow Type
Static Flow
Dynamic Flow

Fluid System
No
Yes

Fluid System Size (External)
100 mL
200 mL
500 mL
1000 mL

Fluid System Size (Internal)
25 mL
50 mL
125 mL
250 mL

Fluid Tube Diameter
6 mL
4 mL
3 mL

Screw Size
3 mL
4 mL

Fluid Tube Material
TPE
TPU
Silicone

Fluid Type
Purified, deionized water

Forearm Rotation
1 DOF

IM Functionality
No
Yes

IM Reservoir Volume (Internal)
1 mL
3 mL
4 mL

Bleeding Reservoir Volume (Internal)
25 mL
30 mL
75 mL
150 mL

IO Aspiration
No
Yes

IO Functionality
No
Yes

IM/IO Patch Type
Blank Lid
Exposed
Hidden

IO Reservoir Volume (Internal)
20 mL
50 mL
100 mL

IV Flashback
No
Yes

IV Functionality
No
Yes

IV Port Type
Blank Lid
Pre-Ported
Hidden

IV Reservoir Volume (Internal)
25 mL
30 mL
75 mL
150 mL

IV Sites
Cubital Fossa
Dorsal Veins
Cephalic Veins

Leak Resistant
Yes

Wound Type
None
Amputee
Gunshot Wound
Puncture Wound
Laceration

Packable Wound Functionality
No
Yes

Power Distribution Area
Central

Power Type
Electrical

Pulse Rate
0 - 300 bpm

Pulse Sites
None
Radial
Brachial

Pulse Strength
Low/Normal/High
Adjustable

Pulse Distribution
Centralized
Localized

Realism in Touch and Feel
Basic
Advanced

Recyclability Labeling
Yes

Seizures
None
Shaking
Limb Movement

Shoulder Articulation
3 DOF

Simulator Demographic
Newborn
Baby
Child
Adult

Skin Color
Dark
Medium
Light

Skin Removal
Yes

SpO2 Functionality
No
Yes

SpO2 Level
0 - 100%

Tourniquet Functionality
No
Yes

Tourniquet Sites
Upper Arm

Wound Care
No
Yes

Wrist Articulation
2 DOF

Appendix A.2 - Full QFD Matrix

| Customer Values | Weight | Measure Injected Volume | Fluid Reservoir (External) | Fluid Reservoir (Internal) | Anatomical Landmarks | Arm Appearance | Arm Attachment Type | Arm Side | Arm Size and Weight | Arm Skeleton Material | Arm Skin Material | Bleeding Functionality | Bleeding Type | Blood Glucose Functionality | Blood Pressure Functionality | Blood Pressure Range | Capillary Refill Functionality | Capillary Refill Time | Change in Skin Appearance | Change in Skin Color | Control of Joint Stiffness | Cyanosis Functionality | Drug Recognition Functionality | Elbow Articulation | Finger Connector | Finger Placement | Fluid Color | Fluid Exchange | Fluid Filling Location | Fluid Flow Rate (Bleeding) | Fluid Flow Type | Fluid System | Fluid System Size (External) | Fluid System Size (Internal) | Fluid Tube Diameter | Screw Size | Fluid Tube Material | Fluid Type | Forearm Rotation | IM Functionality | IM Reservoir Volume (Internal) | Bleeding Reservoir Volume (Internal) | IO Aspiration | IO Functionality | IM/IO Patch Type | IO Reservoir Volume (Internal) | IV Flashback | IV Functionality | IV Port Type | IV Reservoir Volume (Internal) | IV Sites | Leak Resistant | Wound Type | Packable Wound Functionality | Power Distribution Area | Power Type | Pulse Rate | Pulse Sites | Pulse Strength | Pulse Distribution | Realism in Touch and Feel | Recyclability Labeling | Seizures | Shoulder Articulation | Simulator Demographic | Skin Color | Skin Removal | SpO2 Functionality | SpO2 Level | Tourniquet Functionality | Tourniquet Sites | Wound Care | Wrist Articulation | Sum |
|---|---|---

Appendix A.3 - Functions and Technical Solutions

Transfer of fluids	IM Injections	Skin Mounting Upper Arm
Flexible tubes	Foam in PVC pocket	Zipper
Packable Wound	Foam in TPE pocket	Studs and Holes
Wound Packing w/ Bleeding	Foam in Silicone pocket	Indicate Capillary Refill
Allow fluid to flow	Skinned PUR foam	Switch and LED (that fades)
Active Valve	IO injections	Pressure sensor and LED (that fades)
Manage Injected IV Fluids	Anatomical bone, with soft tissue foam	Measure glucose in blood
Internal, fixed local reservoir	Plate bone	Blood fluid with glucose in fingertip
Drained, external reservoir	Fluid Tube Connection	Hand Chassis
Amputation Limb	Fixed Connector	End-exoskeleton Hybrid
Tourniquet w/ Bleeding	Lure Lock Connector	Realistic IO Aspiration
Fluid distribution	Realistic IV Flashback	Local reservoir, pressurized fluid
Local fluid pump	Local reservoir, pressurized fluid	Sponge
Air over fluid, valves	Sponge	Simulated in syringe
Bladder, pressurized by filling	Simulated in syringe	Finger Coupling
Ability to store fluids	Change of Skin Color	Bayonet ez-fix
Rigid tank	RGB LEDs	Lure Lock Style
Flexiable Bladder	Skin color controlled by temperature changes	Arm Coupling Lower
Bleeding	Ability to refill/empty fluids	HTP Standard connector
Purified, deionized water (red color)	Quick connector	Arm Coupling Upper
Manage Injected IO Fluids	Measure Injected Volume	HTP Standard connector
Internal, fixed local reservoir	Flow meter in line	Transfer of data
Drained, external reservoir	Change of Skin Appearance	Ribbon Cable
IV Injections	Removable Patch	Transfer of power
Pre-ported lure lock, drain	RGB LEDs	Ribbon Cable
Pad, with 3 veins, blood flashback	Skin appearance controlled by temperature changes	Skin Split Line Lower
Semi pre-ported with small silicone ball	Joint Stiffness Control	Horizontal Split
Blood Pressure Measurement	Inflatable Bladders	Vertical Split
Modified blood pressure cuff	Disk Brake	Skin Split Line Upper
NiBP device with tubing kit	Rim Brake	Horizontal split
Arm Chassis Lower	Manage Injected IM Fluids	Vertical split
End-exoskeleton Hybrid	Absorbent Pad	Elbow Articulation
Arm Chassis Upper	Pulse Palpation	Hinge Joint
End-exoskeleton Hybrid	Electrical, small	Shoulder articulation
Adjustable Pulse Strength	Skeleton Landmarks Lower	Hinge Joint
Centralized adjustment, all sites adjusted at the same time (grouped)	Incorporated into Frame	Rotation Joint
De-centralized, different sites adjusted individually	Skeleton Landmarks Upper	Double Hinge Joint
Cyanosis	Incorporated into Frame	Shoulder Ball Joint
LEDs, blue illuminating	Arm Seizure	Wrist articulation
Drug Recognition	Rotating eccentric load	Double Hinge Joint
Antenna, preconfigured RFID tags	Measure SpO2 from Finger	Radius/Ulna Rotation
Antenna, programmable RFID tags	IR Sensor and Transmitter + LEDs (works with real PulseOx)	Rotation Joint
Bluetooth BLE	Skin Mounting Lower Arm	Storage of power
	Zipper	Centralized Battery
	Studs and Holes	Storage of data
		SSD

Appendix A.4 - Full DPM Matrix

| Functions | Weight | Measure Injected Volume | Fluid Reservoir (External) | Fluid Reservoir (Internal) | Anatomical Landmarks | Arm Appearance | Arm Attachment Type | Arm Side | Arm Size and Weight | Arm Skeleton Material | Arm Skin Material | Bleeding Functionality | Bleeding Type | Blood Glucose Functionality | Blood Pressure Functionality | Blood Pressure Range | Capillary Refill Functionality | Capillary Refill Time | Change in Skin Appearance | Change in Skin Color | Control of Joint Stiffness | Cyanosis Functionality | Drug Recognition Functionality | Elbow Articulation | Finger Connector | Finger Placement | Fluid Color | Fluid Exchange | Fluid Filling Location | Fluid Flow Rate (Bleeding) | Fluid Flow Type | Fluid System | Fluid System Size (External) | Fluid System Size (Internal) | Fluid Tube Diameter | Screw Size | Fluid Tube Material | Fluid Type | Forearm Rotation | IM Functionality | IM Reservoir Volume (Internal) | Bleeding Reservoir Volume (Internal) | IO Aspiration | IO Functionality | IM/IO Patch Type | IO Reservoir Volume (Internal) | IV Flashback | IV Functionality | IV Port Type | IV Reservoir Volume (Internal) | IV Sites | Leak Resistant | Wound Type | Packable Wound Functionality | Power Distribution Area | Power Type | Pulse Rate | Pulse Sites | Pulse Strength | Pulse Distribution | Realism in Touch and Feel | Recyclability Labeling | Seizures | Shoulder Articulation | Simulator Demographic | Skin Color | Skin Removal | SpO2 Functionality | SpO2 Level | Tourniquet Functionality | Tourniquet Sites | Wound Care | Wrist Articulation | VCP | Score |
|---|---|---

Functions	Module Drivers	Carry Over	Technology Push	Planned Development	Technical Specification	Styling	Common Unit	Process & Organisation	Separate Testing	Black box Engineering	Service & Maintenance	Upgrading	Recycling
Storage of data		9					9			9			
Ability to store fluids		9					3						
Ability to refill/empty fluids		9					3						
Adjustable Pulse Strength			3										
Allow fluid to flow		9			3								
Amputation Limb													
Arm Chassis Lower		9											1
Arm Chassis Upper		9					9						1
Arm Coupling Lower		9				3	9						
Arm Coupling Upper		9				3	9						
Arm Seizure				9						9			
Bleeding				3									
Blood Pressure Measurement				9	3								
Change of Skin Appearance				9	3	1							
Change of Skin Color				9	1	1							
Cyanosis			3			1							
Drug Recognition				9									
Elbow Articulation		9					9						
Finger Coupling		1				3					9	9	
Fluid distribution		9			3								
Fluid Tube Connection		9			3		3						
Hand Chassis		9					9						3
IM Injections		9									9	9	
Indicate Capillary Refill			3			1							
IO injections		9									9	9	
IV Injections		9									9	9	
Joint Stiffness Control				9									
Manage Injected IM Fluids													
Manage Injected IO Fluids		9											
Manage Injected IV Fluids		9											
Measure glucose in blood			1			1							
Measure Injected Volume				9									
Measure SpO2 from Finger			1			1							
Packable Wound				3									
Pulse Palpation			3				3			9			
Radius/Ulna Rotation		9					9						
Realistic IO Aspiration		9									9	9	
Realistic IV Flashback		9									9	9	
Shoulder articulation		9					9						
Skeleton Landmarks Lower		9					9						
Skeleton Landmarks Upper		9					9						
Skin Mounting Lower Arm											9	9	9
Skin Mounting Upper Arm											9	9	9
Skin Split Line Lower											9	9	9
Skin Split Line Upper											9	9	9
Storage of power		9					9			9			
Transfer of data		9					9						
Transfer of fluids		9			1		3						
Transfer of power		9					9						
Wrist articulation		9					9						
Sum		253	14	69	17	15	141	0	0	36	90	90	41

Appendix A.6 - Modules and Functions

Arm Connector	IM/IO
Arm Coupling Upper	IM Injections
Arm Coupling Lower	Manage Injected IM Fluids
Frame - Shoulder	Realistic IO Aspiration
Arm Chassis Upper	IO injections
Skeleton Landmarks Upper	Pulse
Shoulder articulation	Pulse Palpation
Frame - Detachable Arm	Adjustable Pulse Strength
Elbow Articulation	Blood Pressure
Skeleton Landmarks Lower	Blood Pressure Measurement
Radius/Ulna Rotation	Seizure
Arm Chassis Lower	Arm Seizure
Wrist articulation	Joint Stiffness
Amputation Limb	Joint Stiffness Control
Frame - Hand	Drug Recognition
Hand Chassis	Measure Injected Volume
Skin - Shoulder	Drug Recognition
Skin Split Line Upper	Skin Change
Skin Mounting Upper Arm	Change of Skin Color
Skin - Detachable Arm	Change of Skin Appearance
Skin Mounting Lower Arm	Trauma
Skin Split Line Lower	Bleeding
Finger	Packable Wound
Measure glucose in blood	Fluid Management
Indicate Capillary Refill	Manage Injected IO Fluids
Measure SpO2 from Finger	Fluid Tube Connection
Finger Coupling	Transfer of fluids
Cyanosis	Ability to store fluids
IV	Fluid distribution
Realistic IV Flashback	Manage Injected IV Fluids
IV Injections	Ability to refill/empty fluids
	Allow fluid to flow
	Electronics Management
	Transfer of data
	Transfer of power
	Storage of power
	Storage of data

Appendix A.7 - Full IM

Modules	Arm Connector	Frame - Shoulder	Frame - Detachable Arm	Frame - Hand	Skin - Shoulder	Skin - Detachable Arm	Finger	IV	IM/IO	Pulse	Blood Pressure	Seizure	Joint Stiffness	Drug Recognition	Skin Change	Trauma	Fluid Management	Electronics Management
Arm Connector																		
Frame - Shoulder	A, S, Tm																	
Frame - Detachable Arm	A, S, Tm	A, Tm																
Frame - Hand			A, S, Tm															
Skin - Shoulder		A																
Skin - Detachable Arm			A	A	S													
Finger				A, S, Tm		S												
IV			A, S, Tm	A, S, Tm		S												
IM/IO		A, S			S													
Pulse			A, S															
Blood Pressure			A, S															
Seizure			A, S															
Joint Stiffness		A, S	A, S									A, Td						
Drug Recognition		A, S	A, S					A, Tf	A, Tf									
Skin Change		A, S	A, S															
Trauma			A, S															
Fluid Management	Tf	A, S	A, S	A, S				A, Tf	A, Tf		A, Tf				A, Tf		A, Tf	
Electronics Management	Td, Tp	A, S	A, S	A, S			Td, Tp			A, C, Td, Tp	A, C, Td, Tp	A, C, Td, Tp	A, C, Td, Tp	A, C, Td, Tp	A, C, Td, Tp	A, C, Td, Tp	A, C, Td, Tp	

Legend	
A	Physical Interface
S	Spatial Interface
C	Control Interface
Tm	Transfer of force
Tf	Transfer of fluids
Td	Transfer of data
Tp	Transfer of power

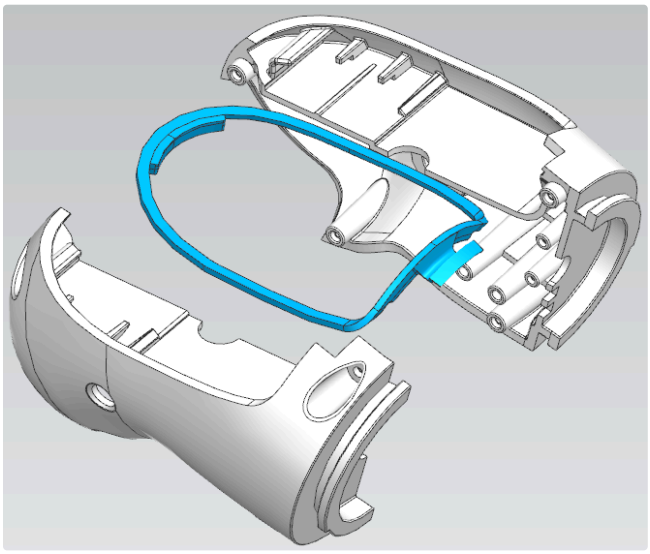
Appendix A.8 - Full MVS

| Modules / Variants | Wrist Articulation | Wound Type | Wound Care | Tourniquet Sites | Tourniquet Functionality | SpO2 Level | SpO2 Functionality | Skin Removal | Skin Color | Simulator Demographic | Shoulder Articulation | Seizures | Screw Size | Recyclability Labeling | Realism in Touch and Feel | Pulse Strength | Pulse Sites | Pulse Rate | Pulse Distribution | Power Type | Power Distribution Area | Packable Wound Functionality | Measure Injected Volume | Leak Resistant | IV Sites | IV Reservoir Volume (Internal) | IV Port Type | IV Functionality | IV Flashback | IO Reservoir Volume (Internal) | IO Functionality | IO Aspiration | IM/IO Patch Type | IM Reservoir Volume (Internal) | IM Functionality | Forearm Rotation | Fluid Type | Fluid Tube Material | Fluid Tube Diameter | Fluid System Size (Internal) | Fluid System Size (External) | Fluid System | Fluid Reservoir (Internal) | Fluid Reservoir (External) | Fluid Flow Type | Fluid Flow Rate (Bleeding) | Fluid Filling Location | Fluid Exchange | Fluid Color | Finger Placement | Finger Connector | Elbow Articulation | Drug Recognition Functionality | Cyanosis Functionality | Control of Joint Stiffness | Change in Skin Color | Change in Skin Appearance | Capillary Refill Time | Capillary Refill Functionality | Blood Pressure Range | Blood Pressure Functionality | Blood Glucose Functionality | Bleeding Type | Bleeding Reservoir Volume (Internal) | Bleeding Functionality | Arm Skin Material | Arm Skeleton Material | Arm Size and Weight | Arm Side | Arm Attachment Type | Arm Appearance | Anatomical Landmarks | VCP | Score |
|---|---|---

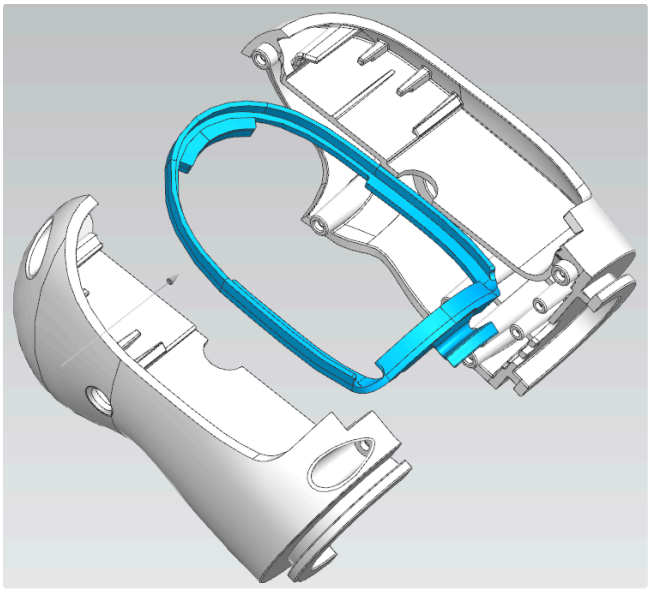
Appendix B.1 - Design Iteration Log

Product Design - Iteration Log

Iteration Log



Iteration A



Iteration B

IM/IO Module

IM/IO Module - Iteration A (Proof of Concept) - Completed Feb 22, 2024

- Shoulder Front - 056928
- Shoulder Back - 056929
- IO/IM Frame - 056959

Improvements for next iteration:

- ~~Increase length of snap lock~~
- ~~Make more robust~~

Notes:

- Snap tolerance is good and proof of concept works, now the part needs to be further developed to better interface with the foam and skin

IM/IO Module - Iteration B - Completed Mar 18, 2024

- Shoulder Front - 056928
- Shoulder Back - 056929
- IO/IM Frame - 056959

Improvements for next iteration:

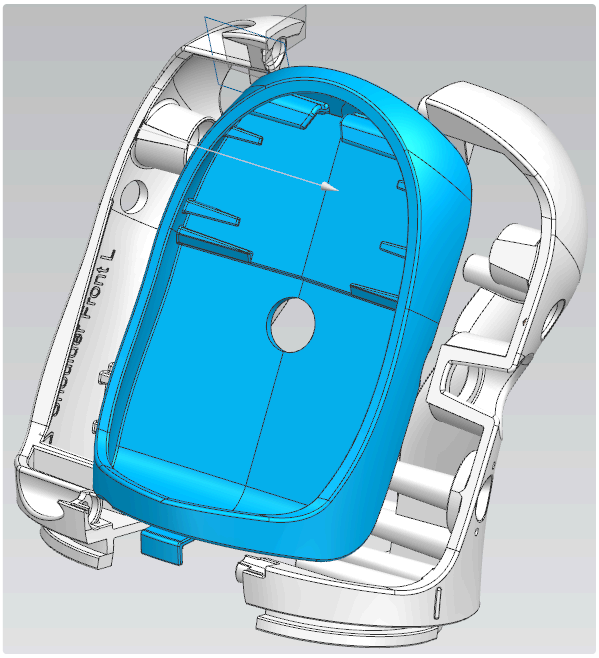
- ~~Interface with foam~~
- Interface with skin
  - replaceable
- ~~Blank Lid Variant~~
- ~~Exposed Variant~~

IM/IO Module - Iteration C - Completed Apr 2, 2024

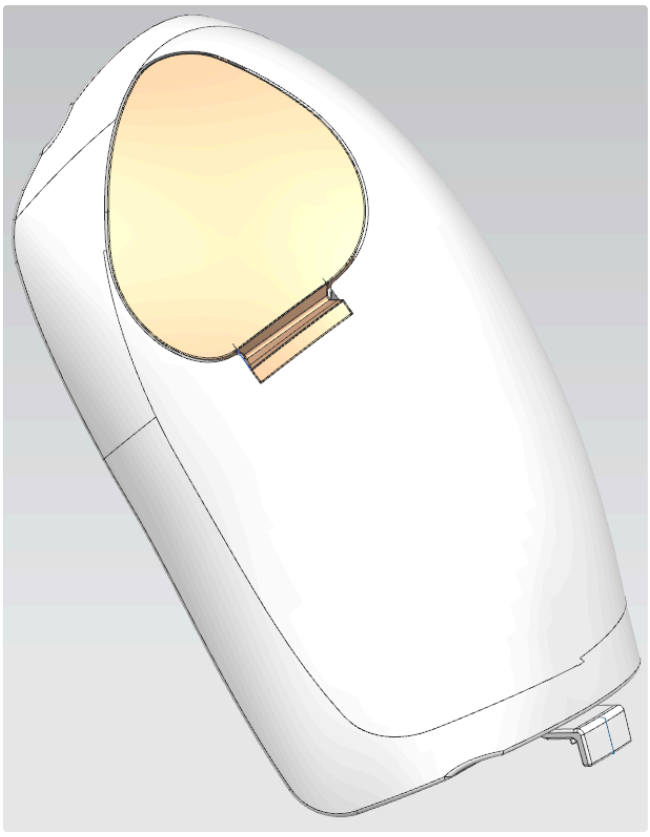
- Shoulder Front - 056928/2
- Shoulder Back - 056929/2
- IO/IM Frame - 056959/2

Improvements for next iteration:

- ~~Interface with foam~~
- Interface with skin
  - replaceable
- ~~Blank Lid Variant~~
- ~~Exposed Variant~~



Iteration C

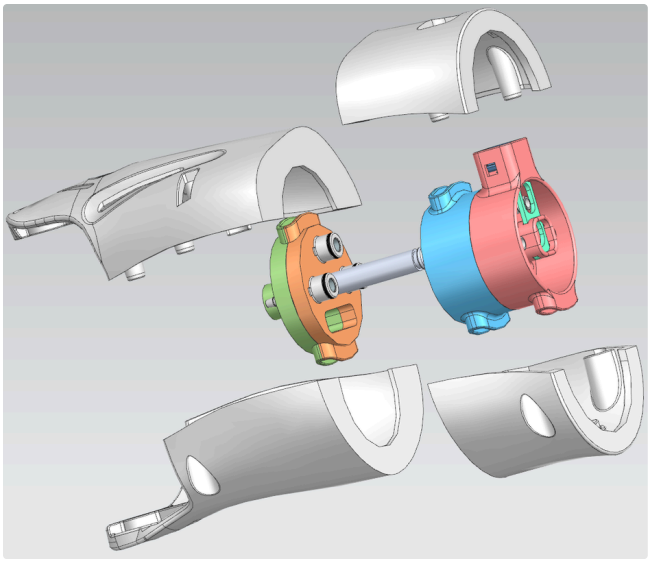


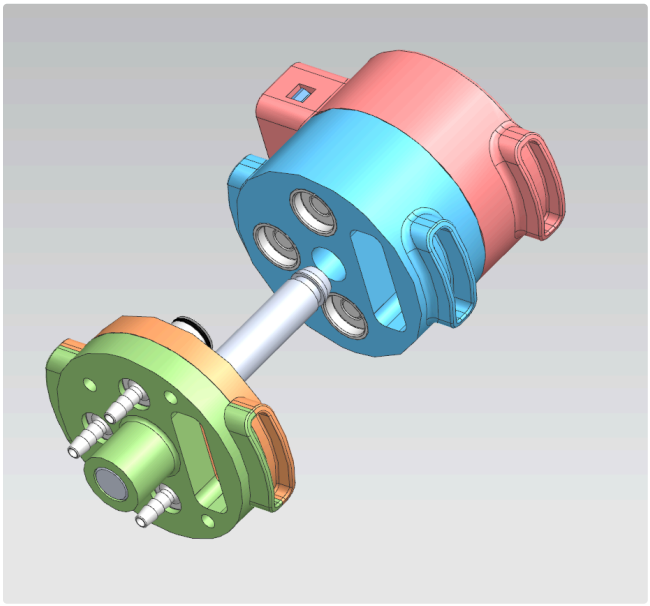
Exposed IO w/o IM - Iteration A

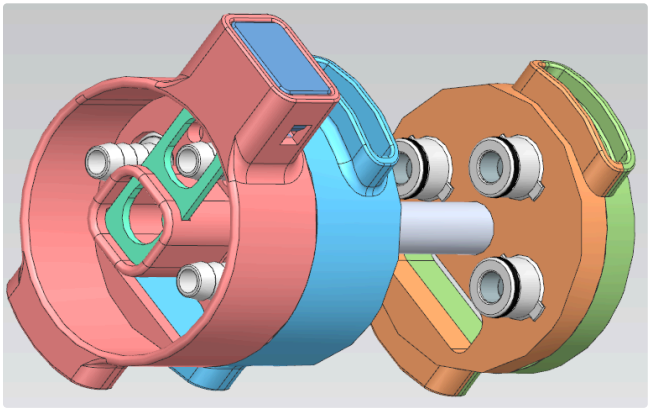
Detachable Arm Connector

Detachable Arm Connector - Iteration A (Proof of Concept) - Completed Feb 26, 2024

- Upper Arm Outer Top - 056964
- Upper Arm Inner Top - 056965







- Upper Arm Outer Bottom - 056930
- Upper Arm Inner Bottom - 056931
  - Pulse Bar Brachial L - 20-17536
  - Pulse - 20-11599
- Detachable Connector Top - 056973
  - Connector Top Housing - 056974
  - Connector Top Plate - 056975
  - Connector Button - 056997
  - Connector Pin Plate - 056998
  - Spring - 049163
  - CPC Connector (NS2D170412) x3 - 047754
  - 4x16 T20 Screw x4
- Detachable Connector Bottom - 057000
  - Connector Bottom Housing - 057001
  - Connector Bottom Plate - 057003
  - Connector Pin - 048948
  - CPC Connector (NS2D220212) x3 - 047628
  - 4x16 T20 Screw x4

Improvements for next iteration:

Interface from Connector to Upper Arm

- Add screw holes at connection interface to ensure parts stay together near connection
  - Only needed in lower arm

Connector

- Choose power/data connector and update port size accordingly
- Increase tolerance for connector in orange and green plate
  - small gap appears in there
- Determine # of fluid connectors needed from lower to upper arm
- ~~Thicken lower side to work with T4 x 16 screws~~
- ~~Make hole smaller for pin~~
- ~~increase space between plate and connector~~

Connector Pin Plate

- ~~Reduce hole for pin to create tighter fit~~

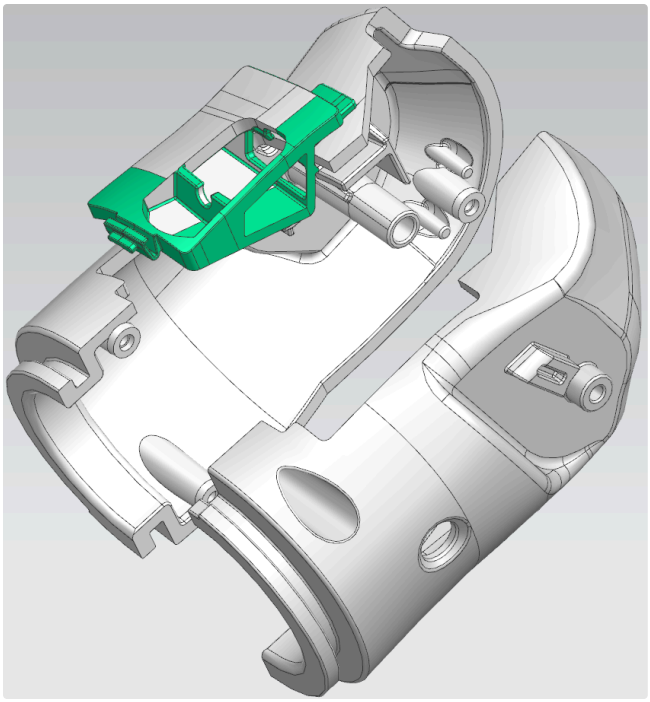
Notes:

Interface from Connector to Upper Arm

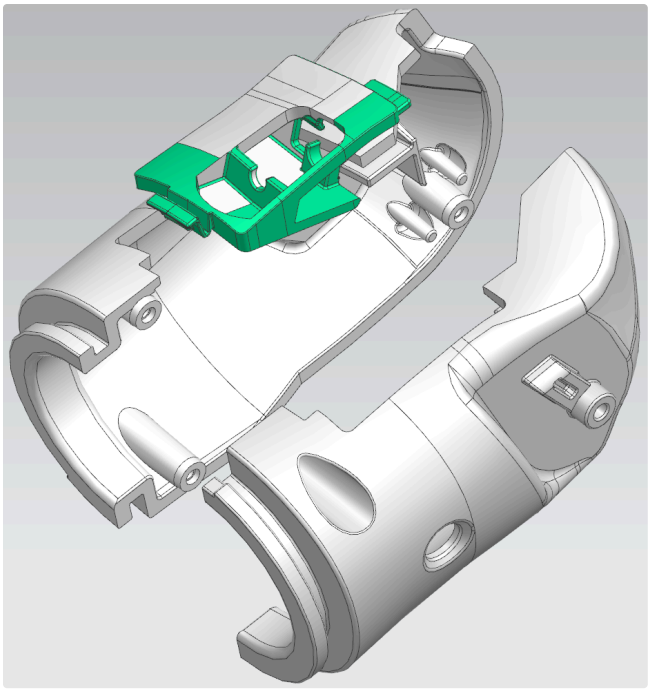
- Interface works well, but extra screws in lower arm would make the connection stronger

Connector

- 1mm gap between connectors when closed



Cubital Fossa (Pre-Ported) - Iteration A



Cubital Fossa (Pre-Ported) - Iteration B

IV Module

Cubital Fossa (Pre-Ported) - Iteration A (Proof of Concept) - Completed Feb 28, 2024

- IV Module - Cubital Fossa - Pre-Ported - 057025
- Elbow Outer L - 056933
- Elbow Inner L - 056934

Improvements for next iteration:

- ~~Fix front snap so it can be removed without a tool~~
  - ~~Cephalic Veins snap is perfect~~
- ~~Increase gap between elbow frame and IV module frame~~
- ~~Try to integrate extra clip for Pre-Ported IV part into IV module frame to eliminate need for part# 20-17498~~
  - ~~Cephalic Veins snap works for this~~

Cubital Fossa (Pre-Ported) - Iteration B - Completed Mar 20, 2024

- IV Module - Cubital Fossa - Pre-Ported - 057025
- Elbow Outer L - 056933
- Elbow Inner L - 056934

Improvements for next iteration:

- Integrate skin into module
- ~~Create blank lid version~~

Cephalic Veins (Pre-Ported) - Iteration A (Proof of Concept) - Completed Feb 28, 2024

- IV Module - Cephalic Veins - Pre-Ported - 057039
- Lower Arm Inner L - 056936

Improvements for next iteration:

- ~~Cannot remove once in place because snap is on wrong side~~
  - ~~Snap must be on same side as insertion point~~

Cephalic Veins (Pre-Ported) - Iteration B - Completed Mar 20, 2024

- IV Module - Cephalic Veins - Pre-Ported - 057039
- Lower Arm Inner L - 056936

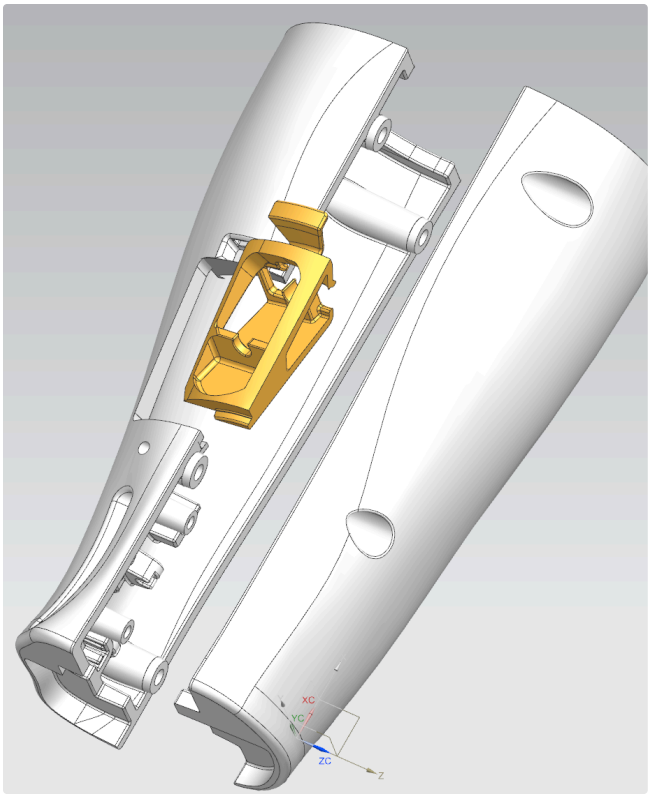
Improvements for next iteration:

- Integrate skin into module
- ~~Create blank lid version~~

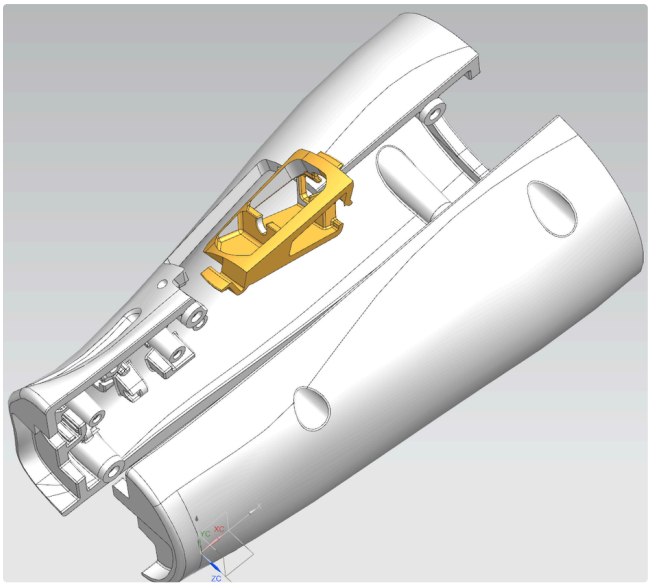
Cephalic Veins (Pre-Ported) - Iteration C - Completed Mar 28, 2024

- Changed location of IV port to better match real life placement-

---



Cephalic Veins (Pre-Ported) - Iteration A



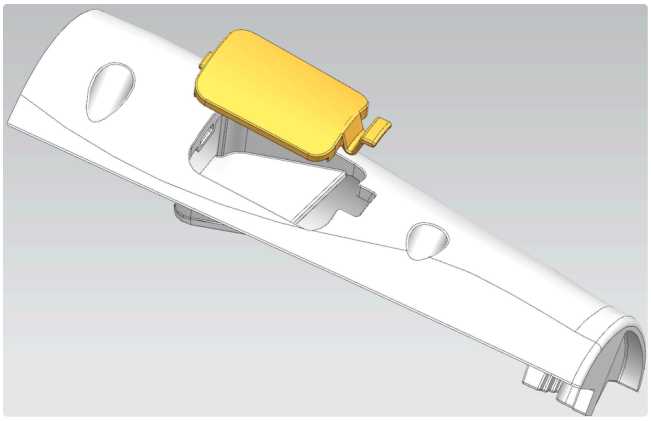
Cephalic Veins (Pre-Ported) - Iteration B

Dorsal Veins (Pre-Ported) - Iteration A (Proof of Concept) - Completed Mar 21, 2024

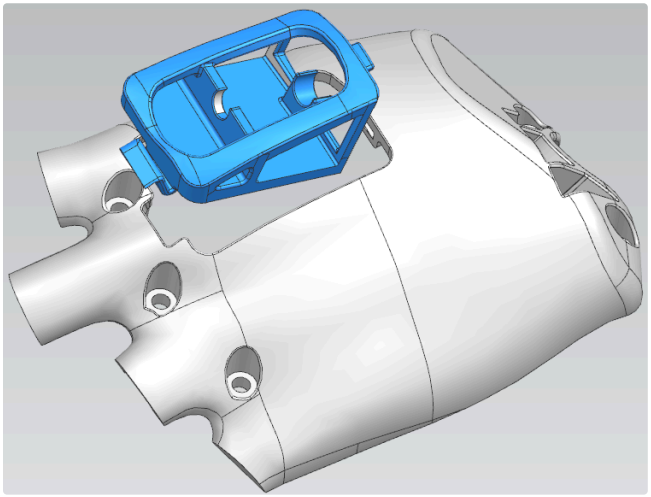
- IV Module - Dorsal Veins - Pre-Ported - 057280
- Hand Dorsal L - 056938/2

Improvements for next iteration:

- Integrate skin into module
- ~~Create blank lid version~~



Cephalic Veins (Hidden Placeholder) - Iteration C



Dorsal Veins (Pre-Ported) - Iteration A

Finger Module Interface - Iteration A

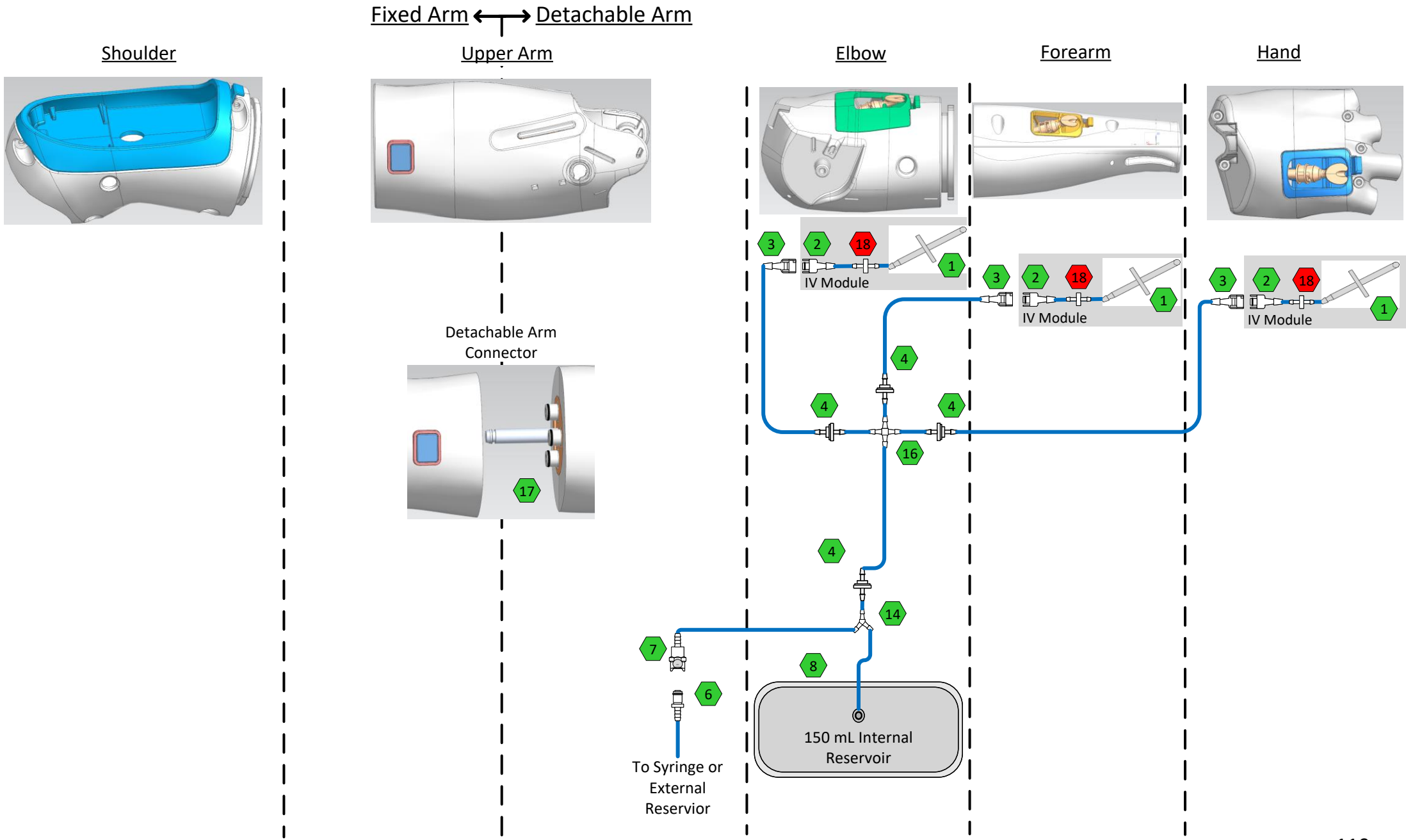
Finger Module

Finger Module - Iteration A (Proof of Concept) - Completed Mar 28, 2024

- Dummy Finger - 057291
- Dummy Finger Bottom - 057292

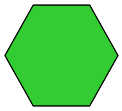
Appendix B.2

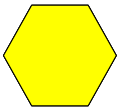
Fluid Diagram – Manikin Intermediate Baseline

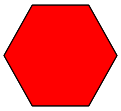


Appendix B.2 Fluid System BOM – Manikin Intermediate Baseline

Fluid Diagram Legend

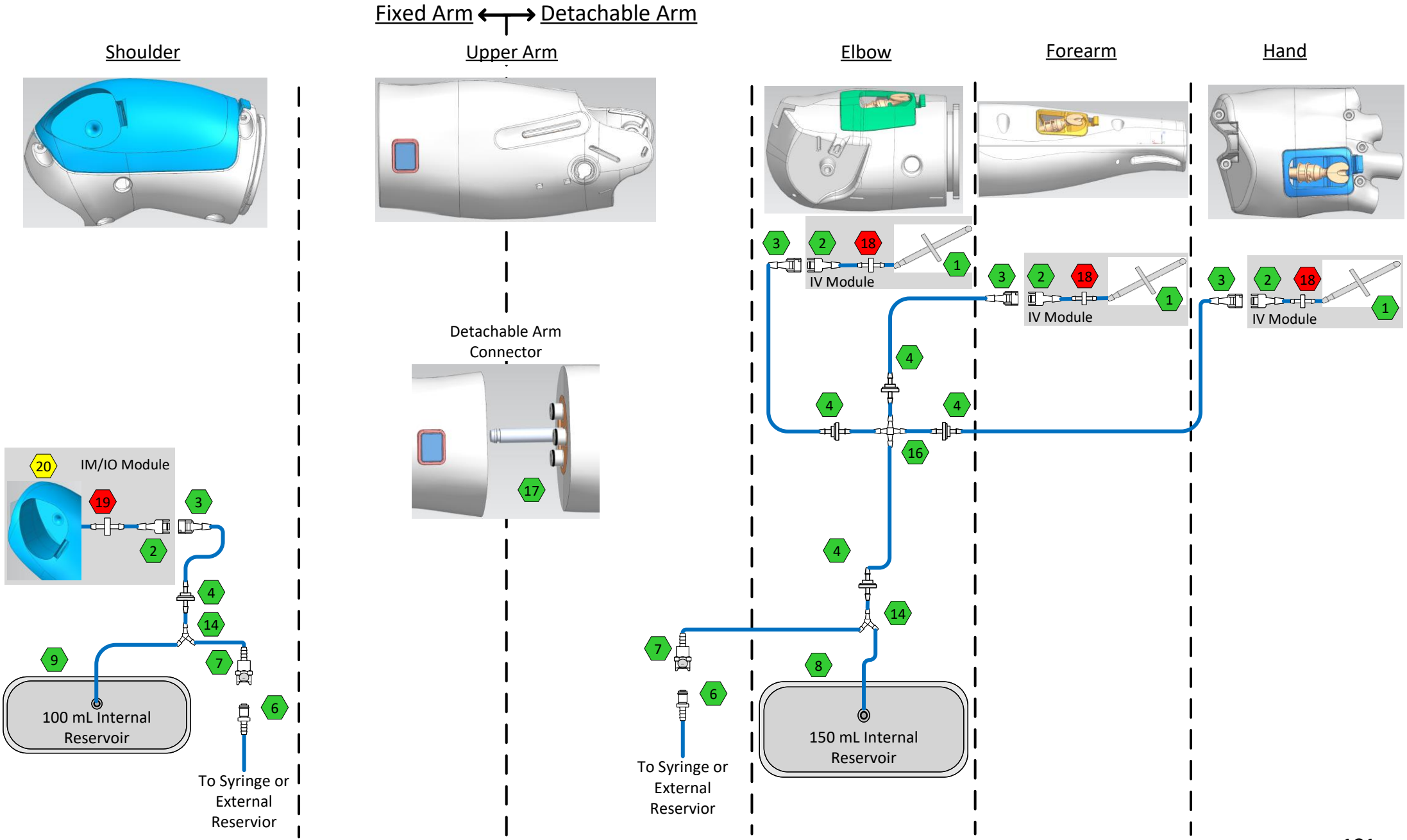

High Level of Confidence in Solution


Medium Level of Confidence in Solution


Low Level of Confidence in Solution

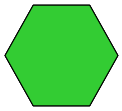
NOTE	PART NO.	DESCRIPTION	QUANTITY
1	20-17551	Pre-Port IV Body	3
2	N1226	Male Quick Connector - 3mm Barb	3
3	N1201	Female Quick Connector - 3mm Barb	3
4	20-14565	Check Valve 2.4mm	4
6	20-06199	CPC Quick Connector (Female)	1
7	-	CPC Quick Connector (Male)	1
8	-	150 mL Plastic Reservoir	1
9	-	100 mL Plastic Reservoir	1
14	-	Fitting T barb 1/8"	1
16	-	Fitting Cross Barb 1/8"	1
17	-	Detachable Arm Connector	1
18	-	IV Flashback Reservoir	3

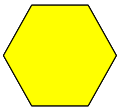
Appendix B.3 Fluid Diagram – Simulator Basic Baseline

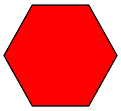


Appendix B.3 Fluid System BOM – Simulator Basic Baseline

Fluid Diagram Legend


High Level of Confidence in Solution

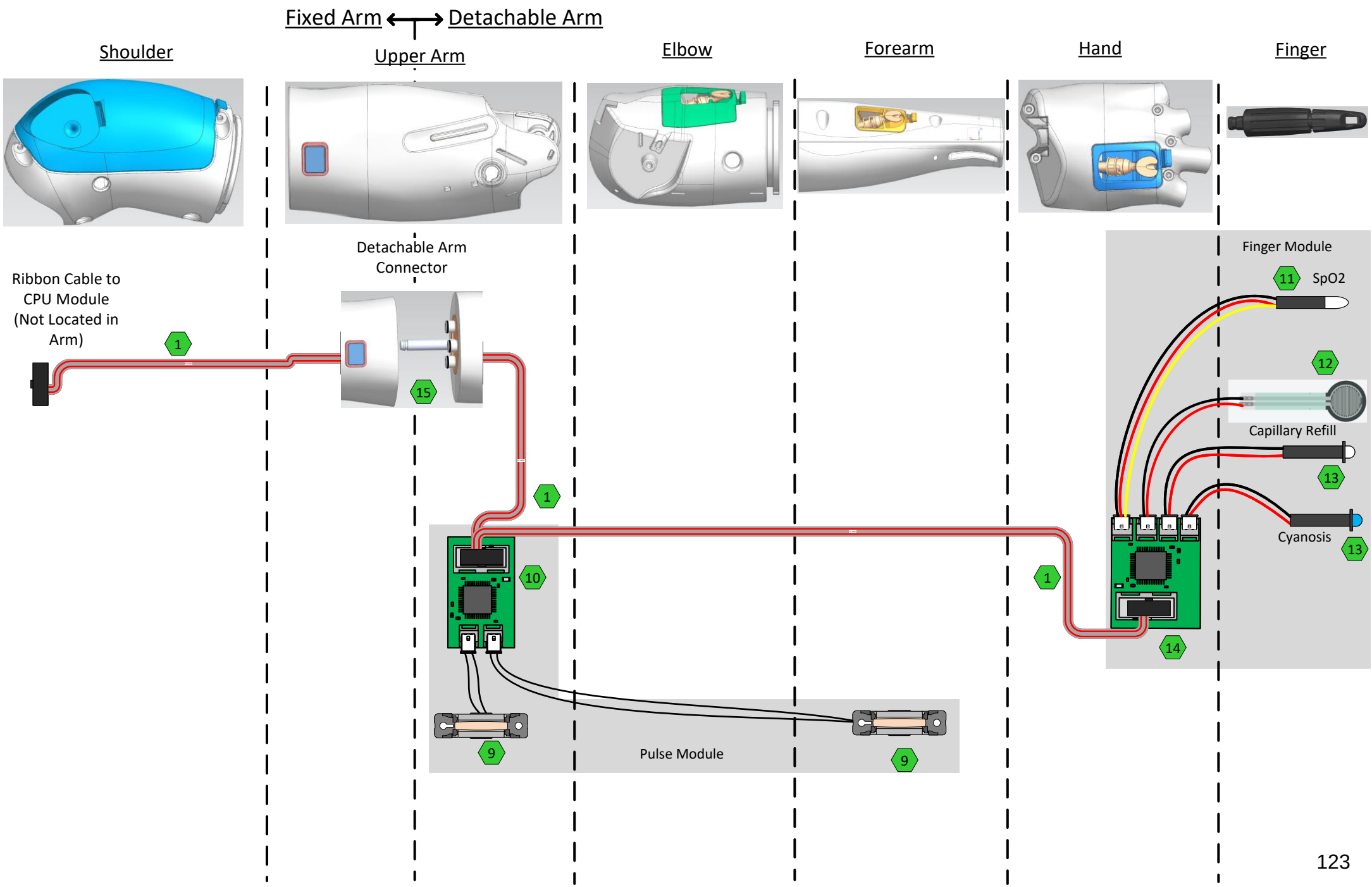

Medium Level of Confidence in Solution


Low Level of Confidence in Solution

NOTE	PART NO.	DESCRIPTION	QUANTITY
1	20-17551	Pre-Port IV Body	3
2	N1226	Male Quick Connector - 3mm Barb	3
3	N1201	Female Quick Connector - 3mm Barb	3
4	20-14565	Check Valve 2.4mm	5
6	20-06199	CPC Quick Connector (Female)	2
7	-	CPC Quick Connector (Male)	2
8	-	150 mL Plastic Reservoir	1
9	-	100 mL Plastic Reservoir	1
14	-	Fitting T barb 1/8"	2
16	-	Fitting Cross Barb 1/8"	1
17	-	Detachable Arm Connector	1
18	-	IV Flashback Reservoir	3
19	-	IO Filter	1
20	-	Exposed IO Module	1

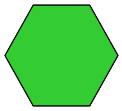
Appendix B.4

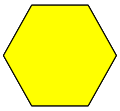
Electronics Diagram – Simulator Basic Baseline

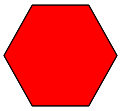


Appendix B.4 Electronics System BOM – Simulator Basic Baseline

Electronics Diagram Legend


High Level of Confidence in Solution

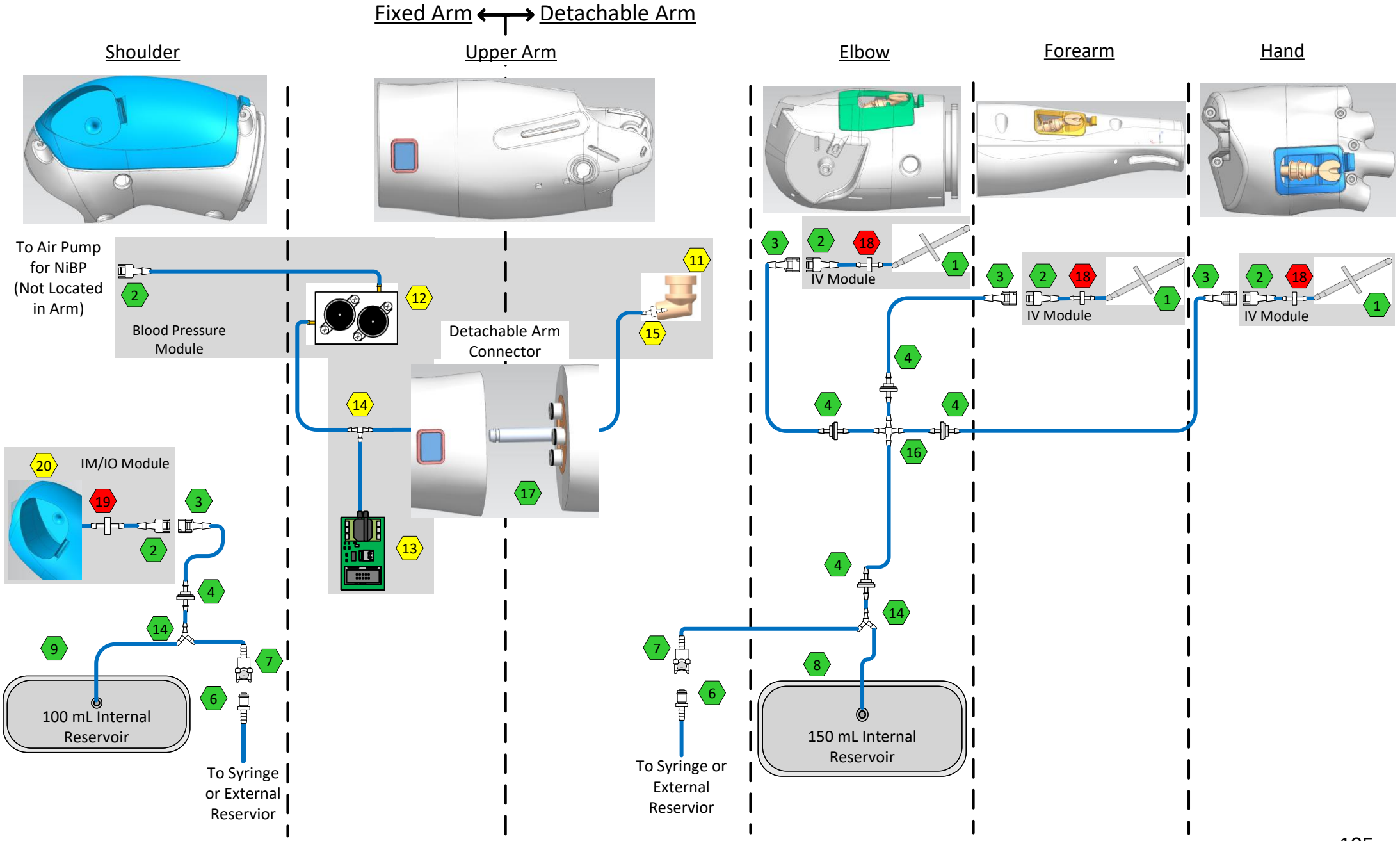

Medium Level of Confidence in Solution


Low Level of Confidence in Solution

NOTE	PART NO.	DESCRIPTION	QUANTITY
1	-	Ribbon Cable	1
9	20-11599	Pulse	2
10	-	Pulse PCA	1
11	50-02720	SpO2 Finger	1
12	-	Pressure Sensor	1
13	-	RBG LED	2
14	-	Hand PCA	1
15	-	Detachable Arm Connector	1

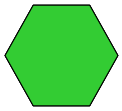
Appendix B.5

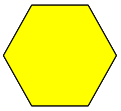
Fluid Diagram – Simulator Intermediate Baseline

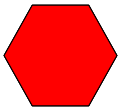


Appendix B.5 Fluid System BOM – Simulator Intermediate Baseline

Fluid Diagram Legend

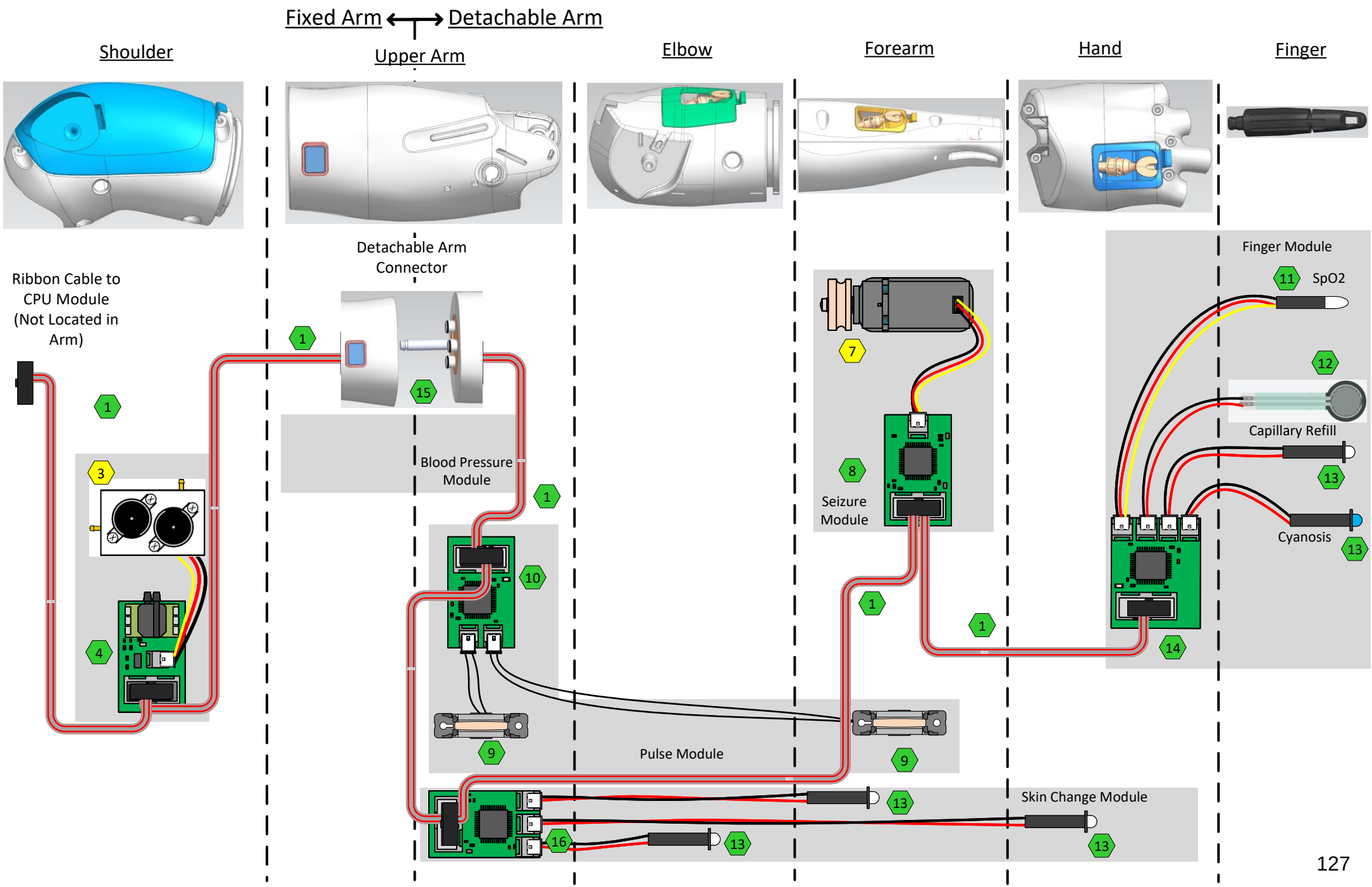

High Level of Confidence in Solution


Medium Level of Confidence in Solution


Low Level of Confidence in Solution

NOTE	PART NO.	DESCRIPTION	QUANTITY
1	20-17551	Pre-Port IV Body	3
2	N1226	Male Quick Conn. 3mm Barb	5
3	N1201	Female Quick Conn. 3mm Barb	4
4	20-14565	Check Valve 2.4mm	5
6	20-06199	CPC Quick Connector (Female)	2
7	-	CPC Quick Connector (Male)	2
8	-	150 mL Plastic Reservoir	1
9	-	100 mL Plastic Reservoir	1
11	-	NiBP Cuff Arm Connector	1
12	20-18246	Dist. Unit 2xlowpro	1
13	50-02305	PCA	1
14	-	Fitting T barb 1/8"	2
15	-	Fitting Barb 1/8"	1
16	-	Fitting Cross Barb 1/8"	1
17	-	Detachable Arm Connector	1
18	-	IV Flashback Reservoir	3
19	-	IO Filter	1
20	-	Exposed IO Port	1

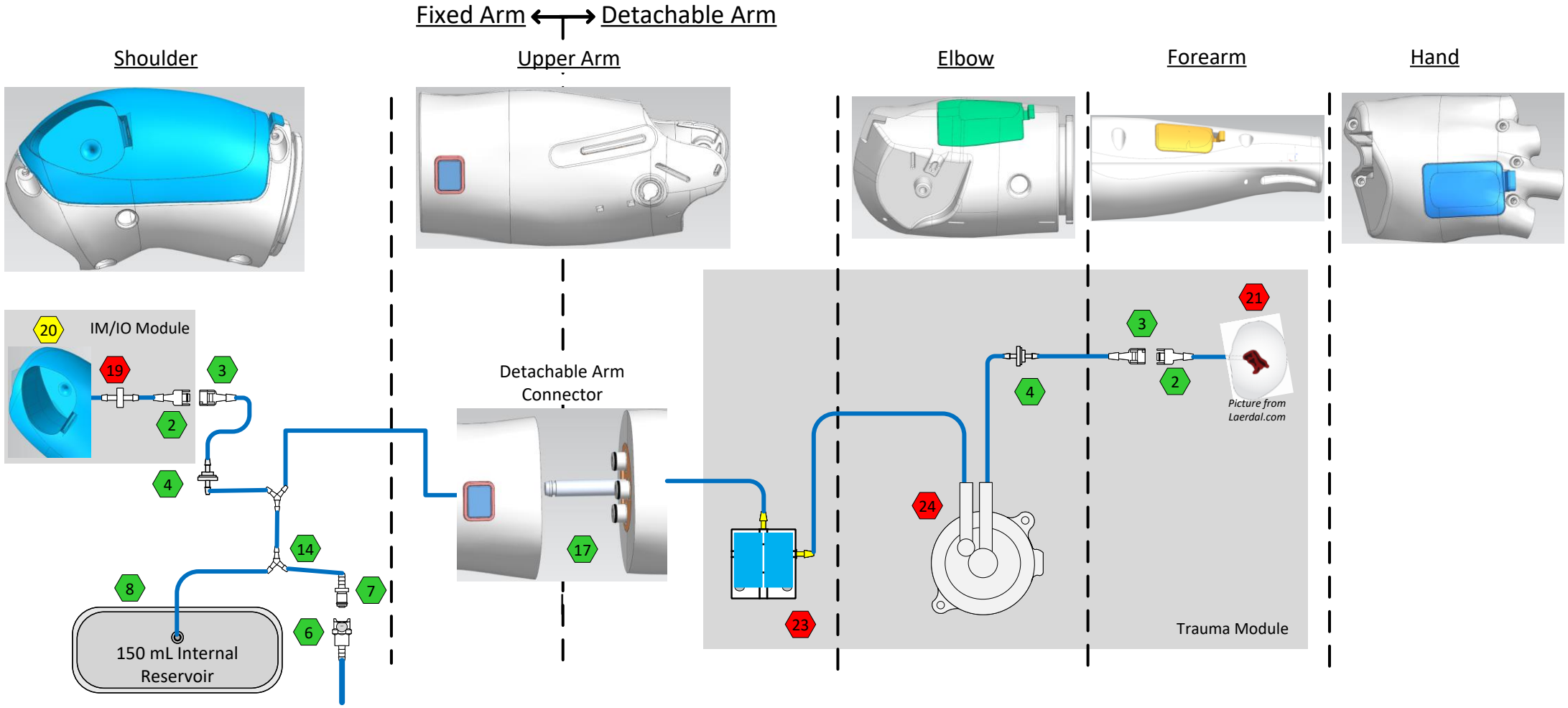
Appendix B.6 Electronics Diagram – Simulator Intermediate Baseline



Appendix B.6 Electronics System BOM – Simulator Intermediate Baseline

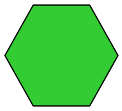
NOTE	PART NO.	DESCRIPTION	QUANTITY
1	-	Ribbon Cable	1
3	20-18246	Dist. Unit 2xlowpro	1
4	-	Blood Pressure PCA	1
7	-	Seizure Motor	1
8	-	Seizure PCA	1
9	20-11599	Pulse	2
10	-	Pulse PCA	1
11	50-02720	SpO2 Finger	1
12	-	Pressure Sensor	1
13	-	RBG LED	5
14	-	Hand PCA	1
15	-	Detachable Arm Connector	1
16	-	Skin Change PCA	1

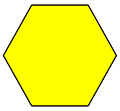
Appendix B.7 Fluid Diagram – Trauma, Large Wound Baseline

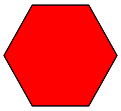


Appendix B.7 Fluid System BOM – Trauma, Large Wound Baseline

Fluid Diagram Legend

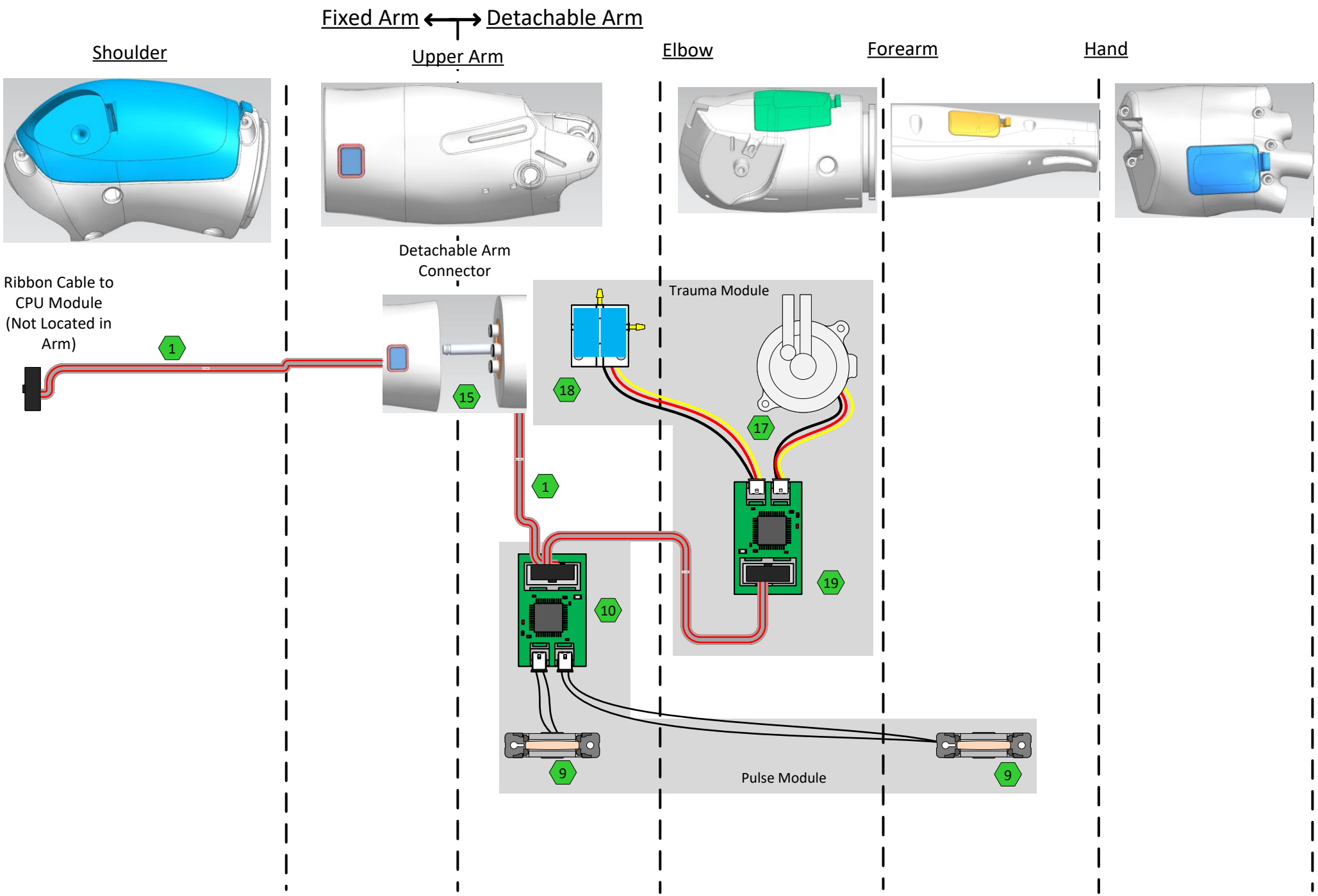

High Level of Confidence in Solution


Medium Level of Confidence in Solution


Low Level of Confidence in Solution

NOTE	PART NO.	DESCRIPTION	QUANTITY
2	20-17551	Male Quick Conn. 3mm Barb	1
3	N1226	Female Quick Conn. 3mm Barb	1
4	N1201	Check Valve 2.4mm	1
6	20-14565	CPC Quick Connector (Female)	1
7	20-06199	CPC Quick Connector (Male)	1
8	-	150 mL Plastic Reservoir	1
14	-	Fitting T barb 1/8"	1
17	-	Detachable Arm Connector	1
19	-	IO Filter	1
20	-	Exposed IO	1
22	-	Large Wound Arm Module	1
23		Valve	1
24		Disc Pump	1

Appendix B.8 Electronics Diagram – Trauma, Large Wound Baseline

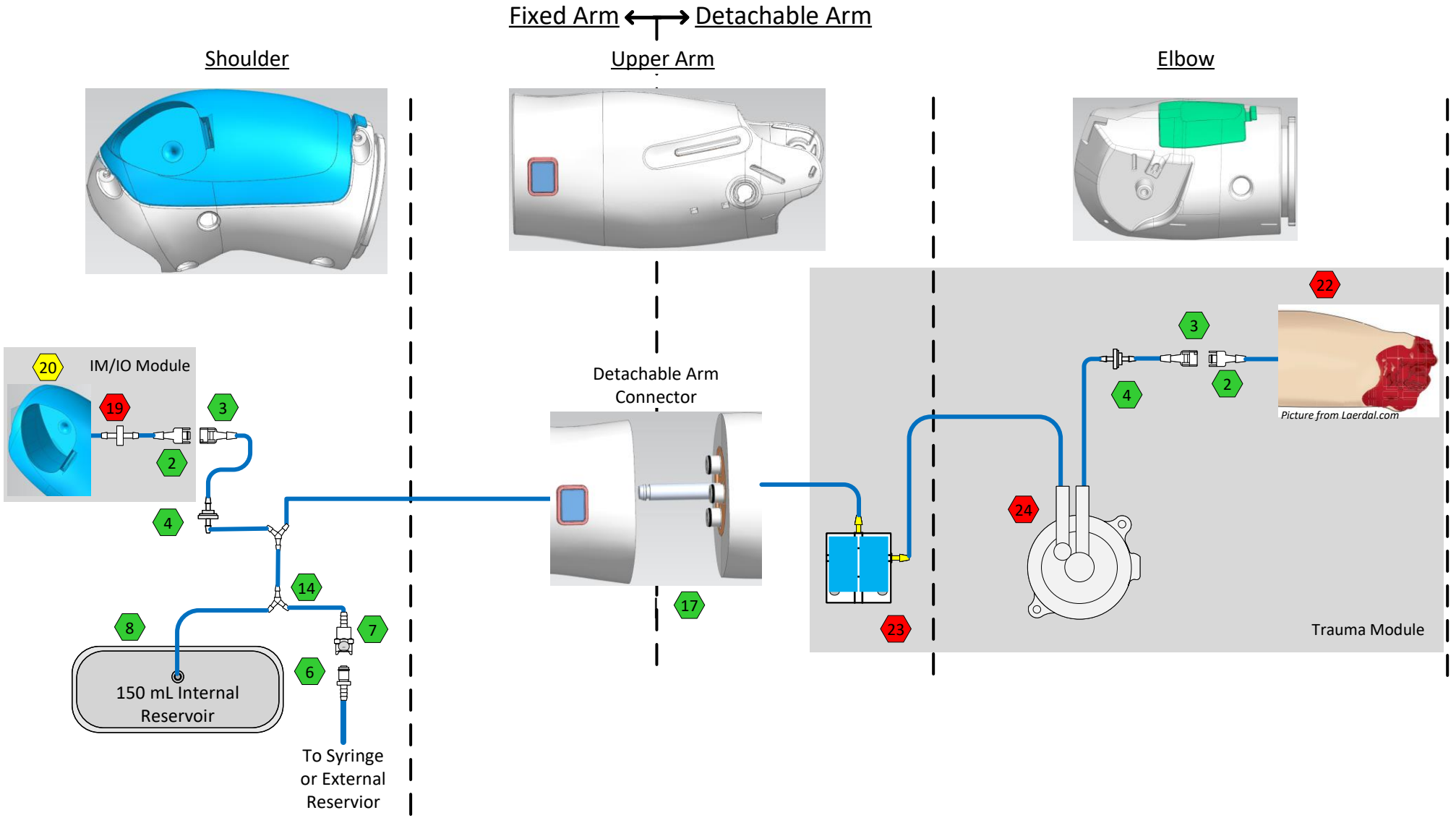


Appendix B.8 Electronics System BOM – Trauma, Large Wound Baseline

NOTE	PART NO.	DESCRIPTION	QUANTITY
1	-	Ribbon Cable	1
9	20-11599	Pulse	2
10	-	Pulse PCA	1
15	-	Detachable Arm Connector	1
17	-	Disc Pump	1
18	-	Valve	1
19	-	Trauma PCA	1

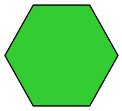
Appendix B.9

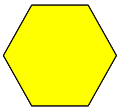
Fluid Diagram – Trauma, Amputee Baseline

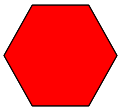


Appendix B.9 Fluid System BOM – Trauma, Amputee Baseline

Fluid Diagram Legend


High Level of Confidence in Solution

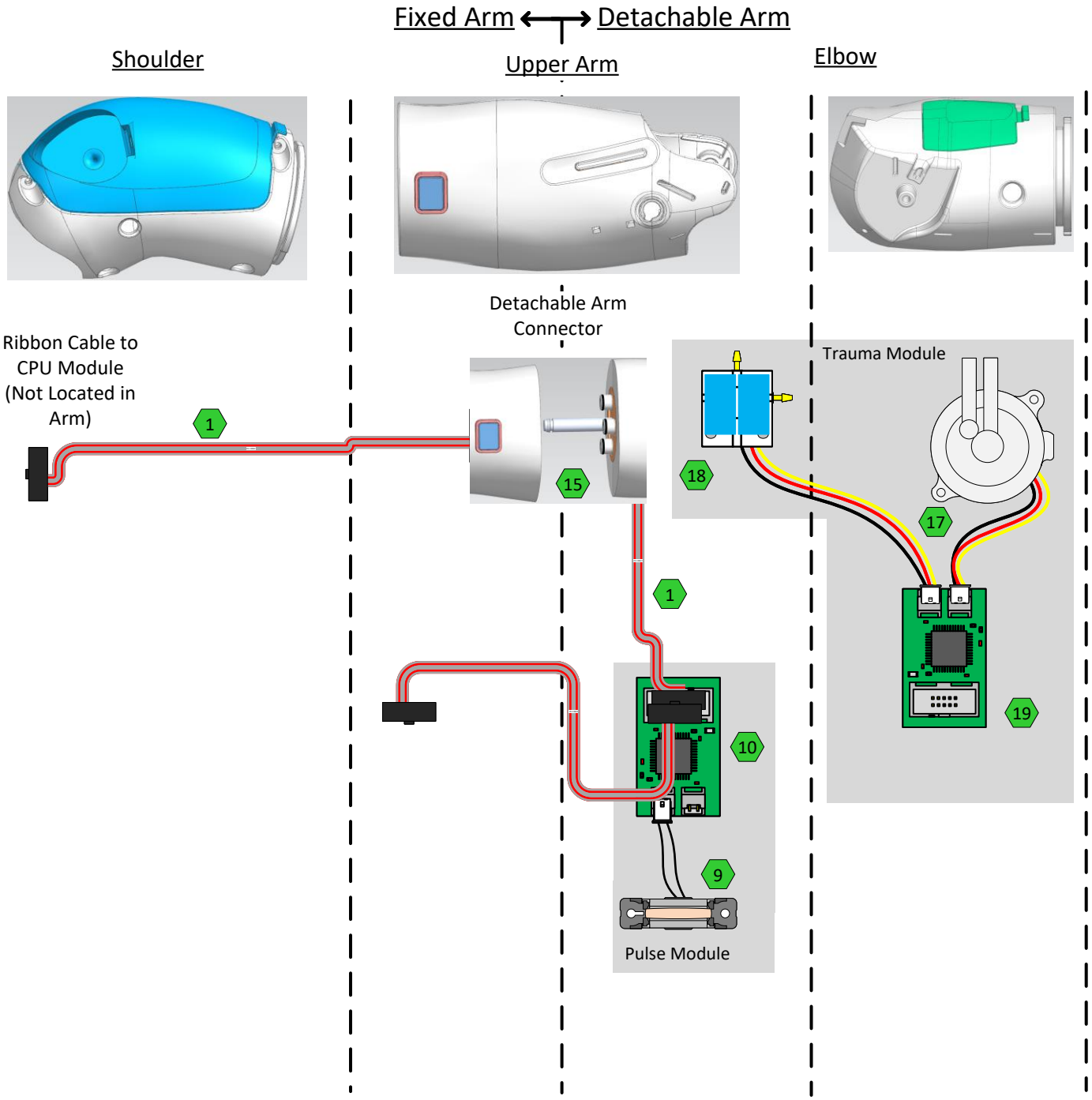

Medium Level of Confidence in Solution


Low Level of Confidence in Solution

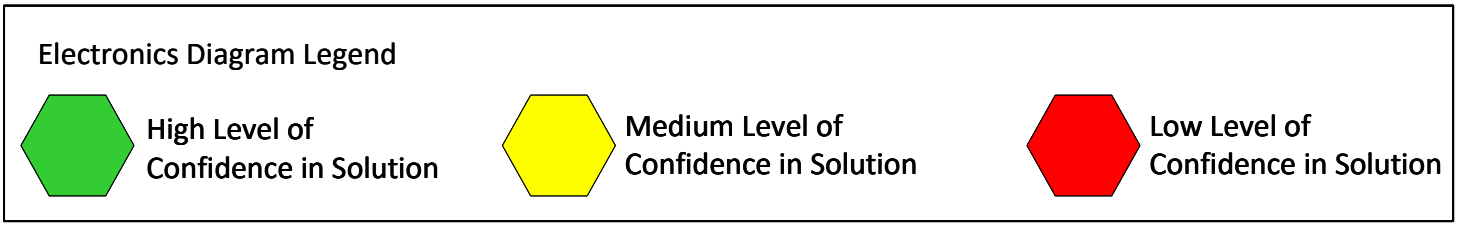
NOTE	PART NO.	DESCRIPTION	QUANTITY
2	20-17551	Male Quick Conn. 3mm Barb	1
3	N1226	Female Quick Conn. 3mm Barb	1
4	N1201	Check Valve 2.4mm	1
6	20-14565	CPC Quick Connector (Female)	1
7	20-06199	CPC Quick Connector (Male)	1
8	-	150 mL Plastic Reservoir	1
14	-	Fitting T barb 1/8"	1
17	-	Detachable Arm Connector	1
19	-	IO Filter	1
20	-	Exposed IO	1
22	-	Amputee Arm Module	1
23		Valve	1
24		Disc Pump	1

Appendix B.10

Electronics Diagram – Trauma, Amputee Baseline



Appendix B.10 Electronics System BOM – Trauma, Amputee Baseline



NOTE	PART NO.	DESCRIPTION	QUANTITY
1	-	Ribbon Cable	1
9	20-11599	Pulse	1
10	-	Pulse PCA	1
15	-	Detachable Arm Connector	1
17	-	Disc Pump	1
18	-	Valve	1
19	-	Trauma PCA	1

Appendix B.11

Technical Specification Document: Modular Arm for Medical Patient Training Simulator

1. Overview

   This document provides the technical specifications for the development of a modular arm designed for use with full-size medical patient training simulators. The modular arm will offer four different full arm baselines and two trauma arm baseline of varying performance levels fitting intermediate level manikins up to advanced level simulators. Currently this arm is only available in adult sizes but in the future the modular product architecture is planned to encompass junior and baby simulators.

2. Universal Specifications
   - Full arm joint articulation
     - 3 DOF at Shoulder Joint
     - 1 DOF at Elbow Joint
     - 1 DOF at Forearm Joint
     - 2 DOF at Wrist Joint
   - Internal fluid management system
   - Optional external fluid management system for additional fluid storage
   - Robust design allows for use in different environments
   - Detachable lower arm allows for quick customization of full manikin
   - Interchangeable skin reduces waste and downtime when damaged
3. Baseline Arm Specifications

   3.1. Manikin – Intermediate
   - Affordable and recyclable plastic skeletal frame (Polyethylene terephthalate - PET)
   - Replaceable and recyclable soft plastic skin (Thermoplastic elastomer – TPE)
   - Deltoid IM injection site
   - Pre-ported IV access at Cubital Fossa, Cephalic Veins, and Dorsal Veins

   3.2. Simulator – Basic
   - Durable and recyclable plastic skeletal frame (Polyoxymethylene- POM)
   - Replaceable and recyclable soft plastic skin (Thermoplastic elastomer – TPE)
   - Exposed humeral IO access
   - Pre-ported IV access at Cubital Fossa, Cephalic Veins, and Dorsal Veins
   - Pulse palpation at radial and brachial sites
   - SpO2 measurement in finger
   - Capillary refill in finger

   3.3. Simulator – Intermediate
   - Durable and recyclable plastic skeletal frame (Polyoxymethylene- POM)
   - Replaceable and recyclable soft plastic skin (Thermoplastic elastomer – TPE)
   - Exposed humeral IO access
   - Pre-ported IV access at Cubital Fossa, Cephalic Veins, and Dorsal Veins
   - Pulse palpation at radial and brachial sites
   - Pulse strength variable and independent of site
   - SpO2 measurement in finger compatible with pulse oximeter
   - Capillary refill in finger
   - Blood glucose measurement in finger compatible with glucose meter
   - Arm movement seizure simulation

- Drug recognition through RFID enabled medicine vile
- Skin color change to represent pale, yellow, or red skin
- Non-invasive automatic cuff blood pressure measurement

3.4. Simulator – Advanced

- Durable and recyclable plastic skeletal frame (Polyoxymethylene- POM)
- Replaceable and realistic soft plastic skin (Silicone)
- Stiffness controlled joint movement
- Realistic humeral IO access
- Deltoid IM injection site
- Realistic vein IV access at Cubital Fossa, Cephalic Veins, and Dorsal Veins
- Pulse palpation at radial and brachial sites
- Pulse strength variable and independent of site
- SpO2 measurement in finger compatible with pulse oximeter
- Capillary refill in finger
- Blood glucose measurement in finger compatible with glucose meter
- Arm movement and locking joint seizure simulation
- Drug recognition through RFID enabled medicine vile
- Injected drug volume measurement
- Skin color change to represent pale, yellow, or red skin
- Skin appearance change to represent rashes, bruising, and burns
- Non-invasive automatic cuff blood pressure measurement
- Non-invasive manual cuff blood pressure measurement with Korotkoff sounds

3.5. Trauma – Large Wound

- Durable and recyclable plastic skeletal frame (Polyoxymethylene- POM)
- Replaceable and recyclable soft plastic skin (Thermoplastic elastomer – TPE)
- Exposed humeral IO access
- Pulse palpation at radial and brachial sites
- Pulse strength variable and independent of site
- Venous bleeding at large wound site
- Packable wound site on forearm
- Tourniquet compatible above elbow

3.6. Trauma – Amputee

- Durable and recyclable plastic skeletal frame (Polyoxymethylene- POM)
- Replaceable and recyclable soft plastic skin (Thermoplastic elastomer – TPE)
- Exposed humeral IO access
- Pulse palpation at brachial site
- Pulse strength variable
- Venous bleeding at amputation below elbow
- Tourniquet compatible above elbow

4. User Driven Customization Specifications

4.1. Attribute Configuration

- Side (left/right)
- Skin color (light/medium/dark)
- Skin appearance (base/obese/geriatric)
- Skin material (TPE/silicone)
- Skeletal frame material (PET/POM)

4.2. Function Configuration

- IV function performance level (Pre-Ported/Hidden)
- IM/IO function performance level (Realistic IM/Exposed IO/Realistic IO with IM)
- Finger function (Dummy/SpO2/Capillary Refill/Blood Glucose/Cyanosis)

4.3. Add-on Packages

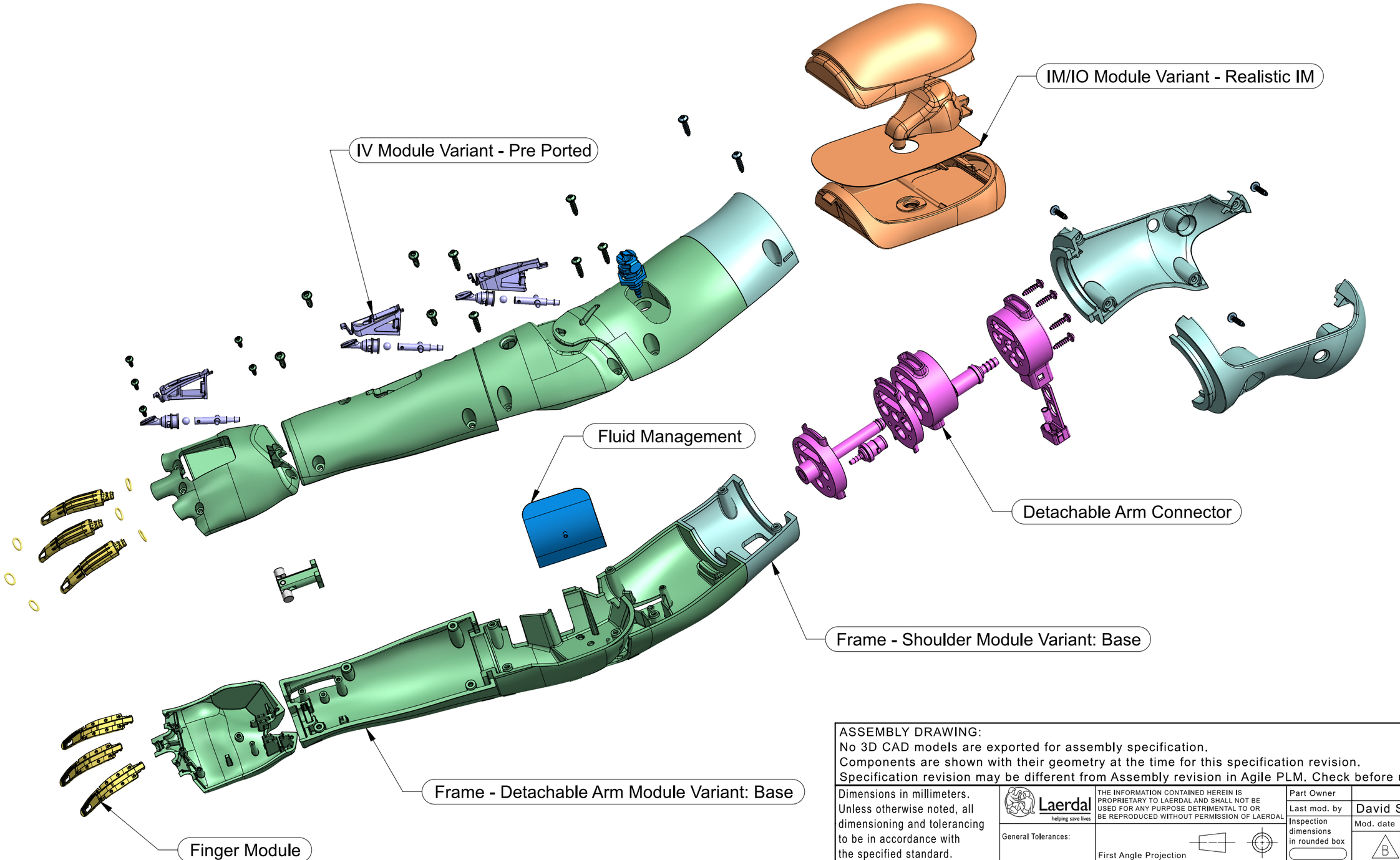
- Cyanosis package (3x Cyanosis Fingers)
- Advanced bleeding (Dynamic flow to mimic arterial bleeding)
- Additional fingers (sold individually to replace or upgrade)
- Additional IV ports (sold in packs of 3 to replace or upgrade)
- Additional IO/IM ports (sold individually to replace or upgrade)

Appendix B.12 - Cost Assessment

Part #	Part Description	Material	Cost (NOK)	Weight (g)	Cost/g
SimMan 3G Plus Solution					
20-17466	Shoulder Back L	POM	118.6	153.33377	0.773476
20-17465	Shoulder Front L	POM	108.5	131.77743	0.823358
20-17497	IO Pad Symmetric	PUR Foam	23.1	34.4	0.671512
20-17496	IO Bone Symmetric	PVC	78.2	34.1	2.293255
20-17495	IO Drain Fitting	Silicone	6.8	8.7856825	0.773987
20-17494	IO Backplate	Stainless Steel	13.9	31	0.448387
20-17828	Shoulder Absorbent Layer		5.8	1.3	4.461538
20-17504-L	SimMan Arm Skin	Silicone	832.8	573.24317	1.452787
		Total Cost (NOK)	**1187.7**		
IM/IO Module: Realistic IO w/ IM - Variant					
057610	Realistic IO w/ IM Variant Frame	POM	76.7633472	96.144428	
20-17497	IO Pad Symmetric	PUR Foam	23.1	34.4	
20-17496	IO Bone Symmetric	PVC	78.2	34.1	
20-17495	IO Drain Fitting	Silicone	6.8	8.7856825	
20-17494	IO Backplate	Stainless Steel	13.9	31	
20-17828	Shoulder Absorbent Layer		5.8	1.3	
--	Realistic IO w/ IM Variant Skin	Silicone	102.474718	70.536662	
		Total Cost (NOK) - Estimated	**307.0**		
		Cost (NOK) - Saved	**880.7**		
		Percent Reduction	**74.15%**		

Part #	Part Description	Material	LCI Dataset from Ecoinvent version 3.10 (2023) System Model: Allocation at cut-off. LCIA method: EF 3.1. (RoW = Rest of World, GLO = Global.)	Kg CO2 eq.	Kg CO2	Weight (g)
SimMan 3G Plus Solution						
20-17466	Shoulder Back L	POM	urea formaldehyde resin production. RoW **Note: This is the dataset that is also known as Polyoxymethylene (POM) urea, so it is assumed that this is the closest dataset.	3.01	0.46153466	153.3337741
20-17465	Shoulder Front L	POM	urea formaldehyde resin production. RoW **Note: This is the dataset that is also known as Polyoxymethylene (POM) urea, so it is assumed that this is the closest dataset.	3.01	0.396650066	131.7774305
20-17497	IO Pad Symmetric	PUR Foam	polyurethane production, flexible foam, TDI-based, high density. RoW	7.22	0.248368	34.4
20-17496	IO Bone Symmetric	PVC	polyvinylchloride production, suspension polymerisation. RoW.	2.94	0.100254	34.1
20-17495	IO Drain Fitting	Silicone	silicone product production. RoW.	3.65	0.032067741	8.785682499
20-17494	IO Backplate	Stainless Steel	market for steel, chromium steel 18/8. GLO	5.11	0.15841	31
20-17828	Shoulder Asorbent Layer		textile production, nonwoven polypropylene, spunbond. RoW	4.15	0.005395	1.3
20-17504	SimMan Arm Skin	Silicone	silicone product production. RoW.	3.65	2.092337585	573.2431739
			Total kg CO2		**3.495017052**	
IM/IO Module: Realistic IO w/ IM - Variant						
057610	Realistic IO w/ IM Variant Frame	POM	urea formaldehyde resin production. RoW **Note: This is the dataset that is also known as Polyoxymethylene (POM) urea, so it is assumed that this is the closest dataset.	3.01	0.289394729	96.1444283
20-17497	IO Pad Symmetric	PUR Foam	polyurethane production, flexible foam, TDI-based, high density. RoW	7.22	0.248368	34.4
20-17496	IO Bone Symmetric	PVC	polyvinylchloride production, suspension polymerisation. RoW.	2.94	0.100254	34.1
20-17495	IO Drain Fitting	Silicone	silicone product production. RoW.	3.65	0.032067741	8.785682499
20-17494	IO Backplate	Stainless Steel	market for steel, chromium steel 18/8. GLO	5.11	0.15841	31
20-17828	Shoulder Absorbent Layer		textile production, nonwoven polypropylene, spunbond. RoW	4.15	0.005395	1.3
--	Realistic IO w/ IM Variant Skin	Silicone	silicone product production. RoW.	3.65	0.257458817	70.5366623
			Total kg CO2 - Estimated		**1.091348288**	
			kg CO2 - Saved		**2.403668764**	
			% Reduction		**68.77%**	

Rev.	Description of Change:
01	New Specification



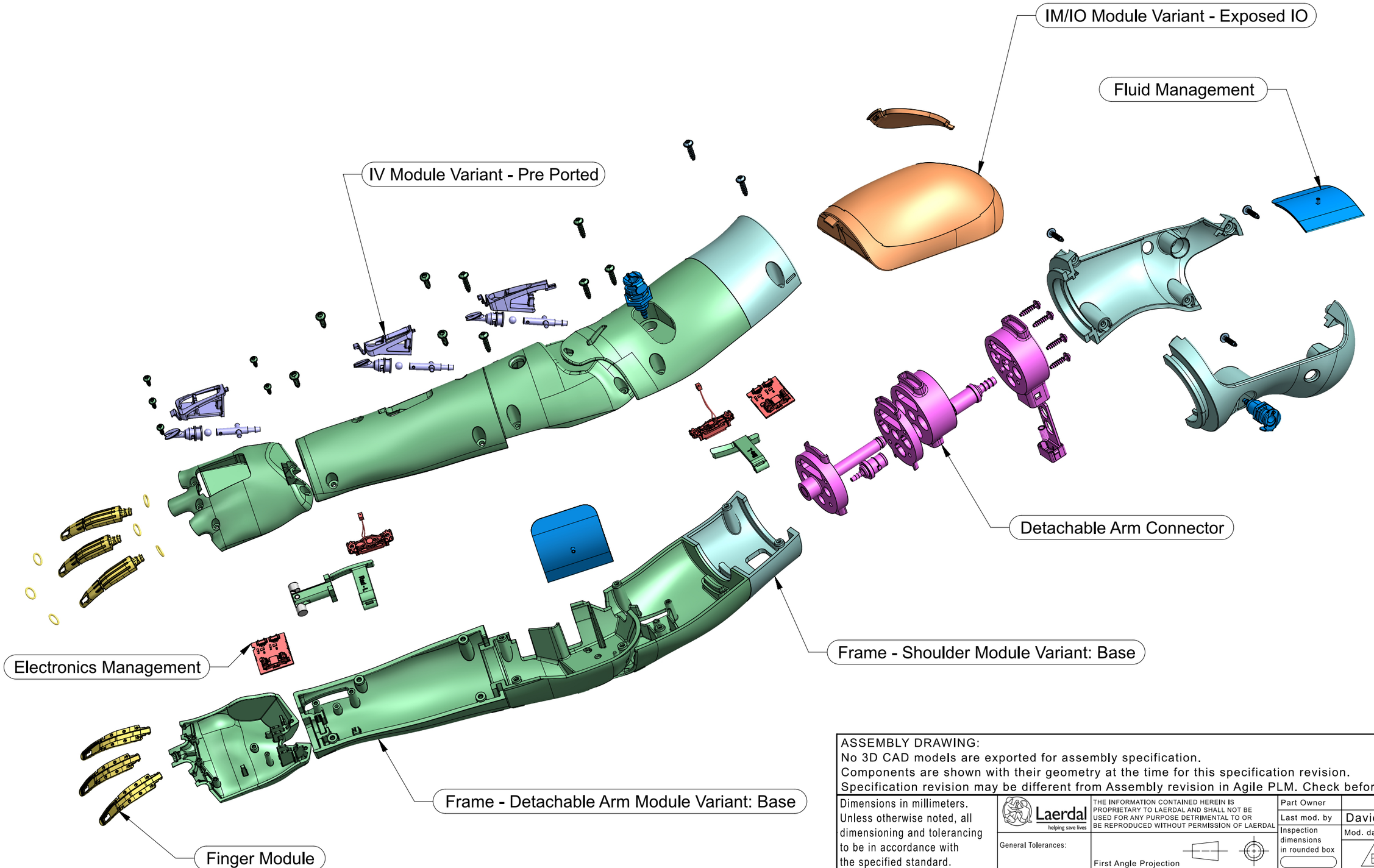
ASSEMBLY DRAWING:
No 3D CAD models are exported for assembly specification.
Components are shown with their geometry at the time for this specification revision.
Specification revision may be different from Assembly revision in Agile PLM. Check before use!

Dimensions in millimeters. Unless otherwise noted, all dimensioning and tolerancing to be in accordance with the specified standard.	Laerdal helping save lives	THE INFORMATION CONTAINED HEREIN IS PROPRIETARY TO LAERDAL AND SHALL NOT BE USED FOR ANY PURPOSE DETRIMENTAL TO OR BE REPRODUCED WITHOUT PERMISSION OF LAERDAL	Part Owner	
			Last mod. by	David Shapiro
	General Tolerances:	First Angle Projection	Inspection dimensions in rounded box	Mod. date: 25-Apr-2024
				B — Letter in triangle shows point of revision-change

Sheet size	Teamcenter PDM ID / Revision Reference:	Part Number (w/o color code)	Title
A3	062030/01	062030	Modular Arm Assembly - Manikin Intermediate

Sheet scale		Document Number in Agile PLM	Attachment to Doc.	Doc. Rev.
1:3	Prototype revs. (01, A01 etc.) in Teamcenter PDM only Design revisions (A, B etc.) data uploaded to Agile PLM	062030	Sheet 1 of 1	01

Rev.	Description of Change:
01	New Specification

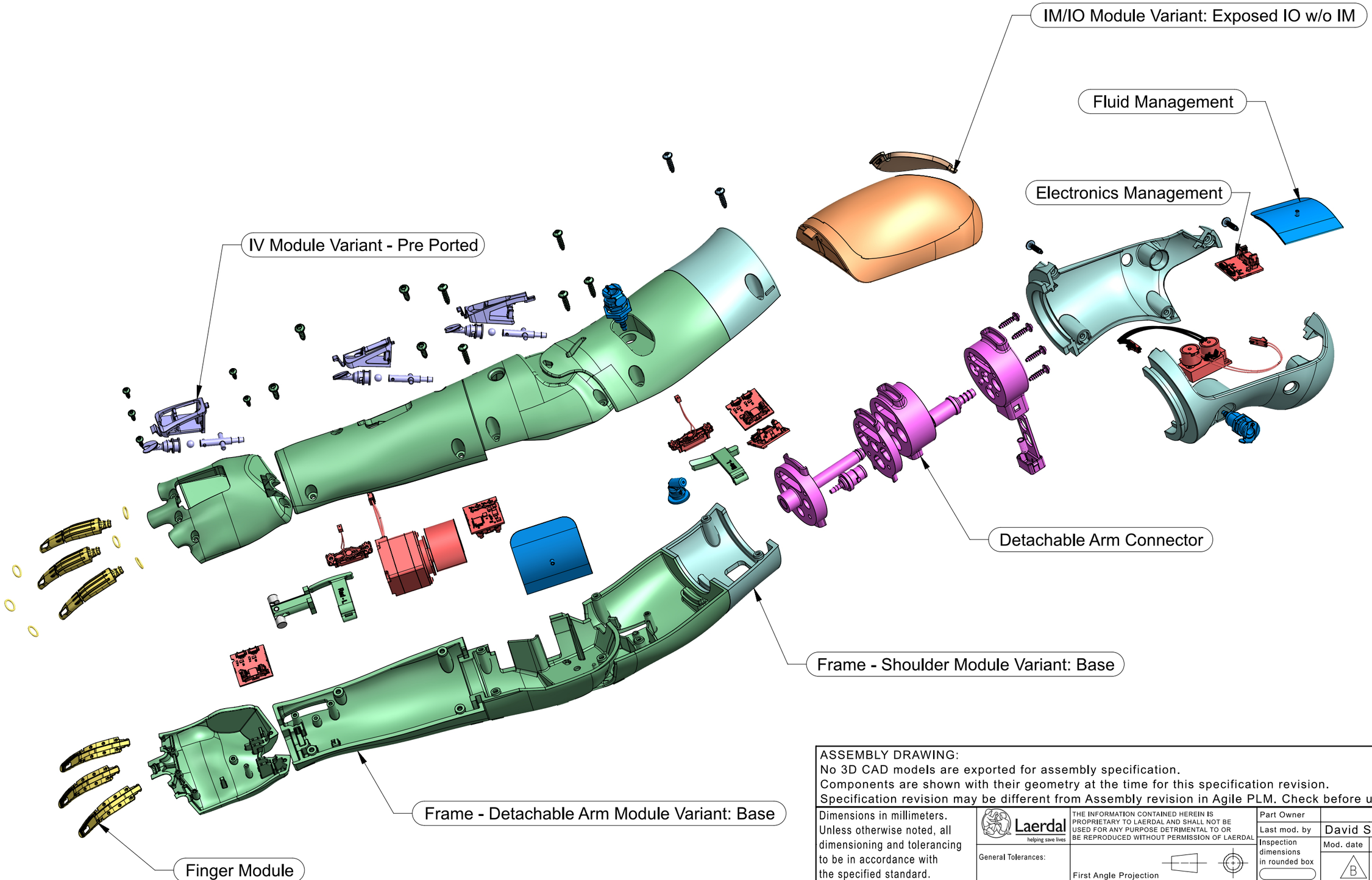


ASSEMBLY DRAWING:
No 3D CAD models are exported for assembly specification.
Components are shown with their geometry at the time for this specification revision.
Specification revision may be different from Assembly revision in Agile PLM. Check before use!

Dimensions in millimeters. Unless otherwise noted, all dimensioning and tolerancing to be in accordance with the specified standard.	Laerdal helping save lives	THE INFORMATION CONTAINED HEREIN IS PROPRIETARY TO LAERDAL AND SHALL NOT BE USED FOR ANY PURPOSE DETRIMENTAL TO OR BE REPRODUCED WITHOUT PERMISSION OF LAERDAL	Part Owner	
	General Tolerances:	First Angle Projection	Last mod. by	David Shapiro
			Inspection dimensions in rounded box	Mod. date: 25-Apr-2024
			B	Letter in triangle shows point of revision-change

Sheet size	Teamcenter PDM ID / Revision Reference:	Part Number (w/o color code)	Title	
A3	062029/01	062029	Modular Arm Assembly - Simulator Basic	
Sheet scale 1:3	Prototype revs. (01, A01 etc.) in Teamcenter PDM only Design revisions (A, B etc.) data uploaded to Agile PLM	Document Number in Agile PLM: 062029	Attachment to Doc.: Sheet 1 of 1	Doc. Rev.: 01

Rev.	Description of Change:
01	New Specification

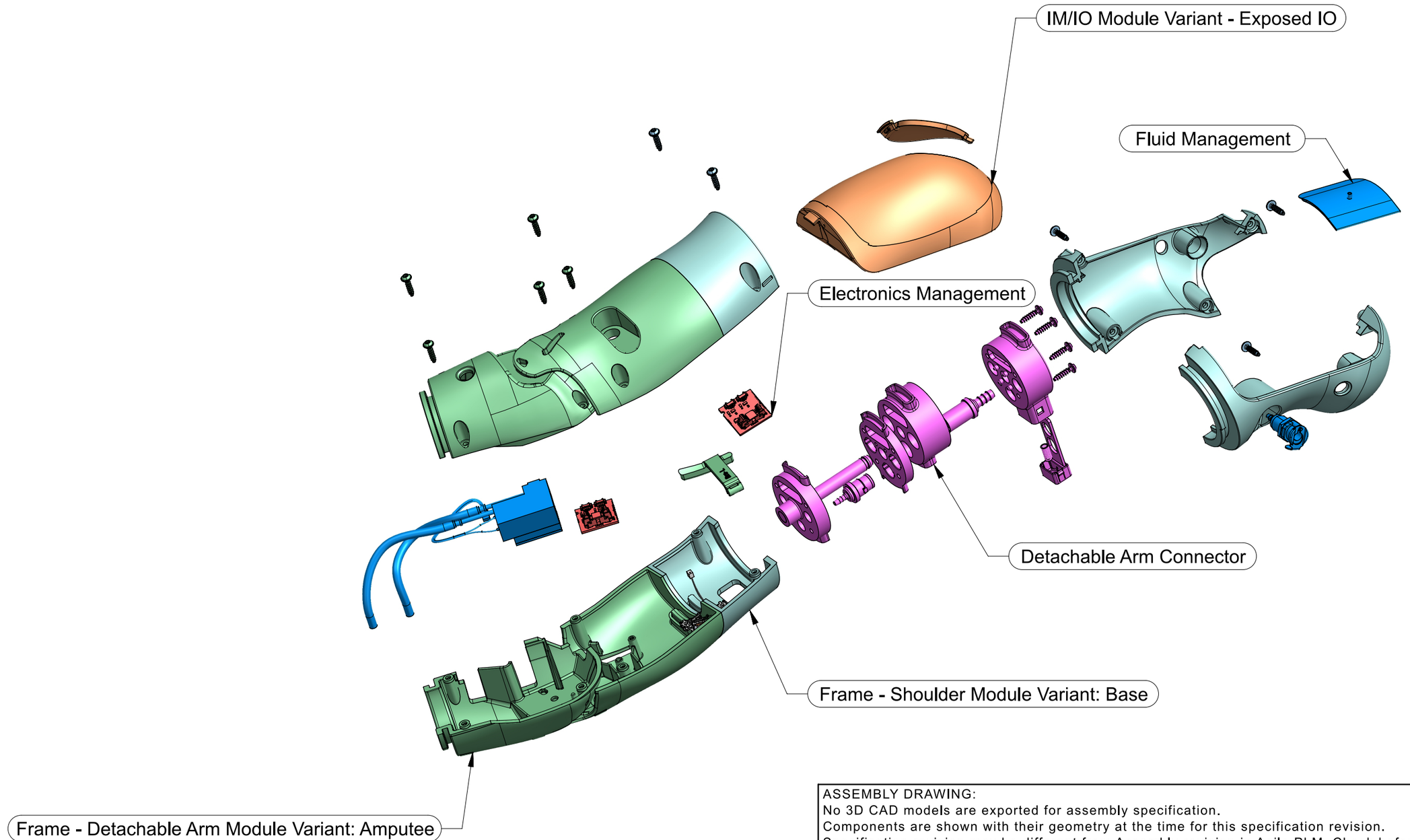


ASSEMBLY DRAWING:
No 3D CAD models are exported for assembly specification.
Components are shown with their geometry at the time for this specification revision.
Specification revision may be different from Assembly revision in Agile PLM. Check before use!

Dimensions in millimeters. Unless otherwise noted, all dimensioning and tolerancing to be in accordance with the specified standard.	Laerdal helping save lives	THE INFORMATION CONTAINED HEREIN IS PROPRIETARY TO LAERDAL AND SHALL NOT BE USED FOR ANY PURPOSE DETRIMENTAL TO OR BE REPRODUCED WITHOUT PERMISSION OF LAERDAL	Part Owner	
			Last mod. by	David Shapiro
	General Tolerances:	First Angle Projection	Inspection dimensions in rounded box	Mod. date: 25-Apr-2024
				B — Letter in triangle shows point of revision-change

Sheet size	Teamcenter PDM ID / Revision Reference:	Part Number (w/o color code)	Title	
A3	062027/01	062027	Modular Arm Assembly - Simulator Intermediate	
Sheet scale 1:3	Prototype revs. (01, A01 etc.) in Teamcenter PDM only Design revisions (A, B etc.) data uploaded to Agile PLM	Document Number in Agile PLM: 062027	Attachment to Doc. Sheet 1 of 1	Doc. Rev. 01

Rev.	Description of Change:
01	New Specification

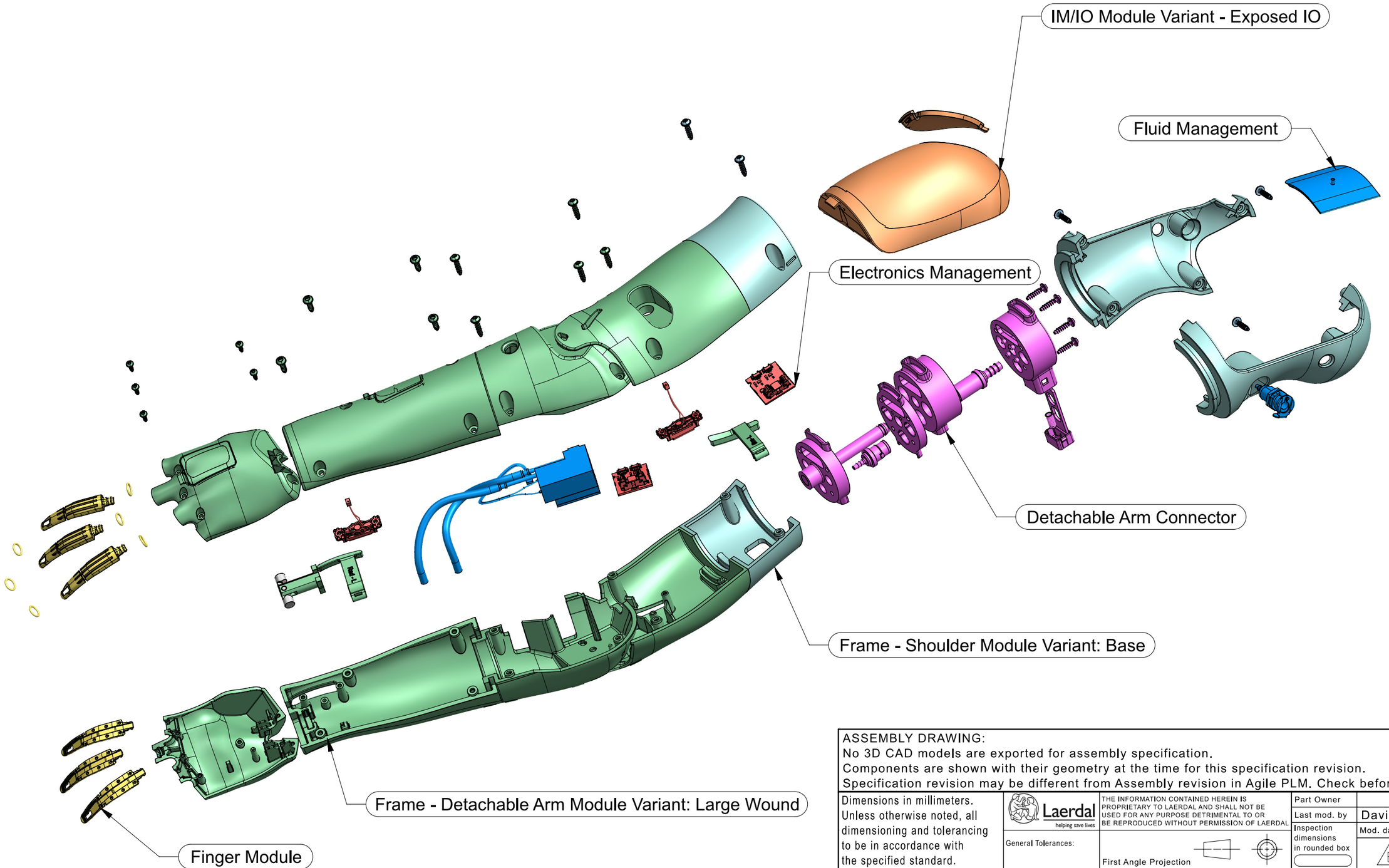


ASSEMBLY DRAWING:
No 3D CAD models are exported for assembly specification.
Components are shown with their geometry at the time for this specification revision.
Specification revision may be different from Assembly revision in Agile PLM. Check before use!

Dimensions in millimeters. Unless otherwise noted, all dimensioning and tolerancing to be in accordance with the specified standard.	Laerdal helping save lives	THE INFORMATION CONTAINED HEREIN IS PROPRIETARY TO LAERDAL AND SHALL NOT BE USED FOR ANY PURPOSE DETRIMENTAL TO OR BE REPRODUCED WITHOUT PERMISSION OF LAERDAL	Part Owner	
			Last mod. by	David Shapiro
	General Tolerances:	First Angle Projection	Inspection dimensions in rounded box	Mod. date: 25-Apr-2024
			B	Letter in triangle shows point of revision-change

Sheet size	Teamcenter PDM ID / Revision Reference:	Part Number (w/o color code)	Title	
A3	062032/01	062032	Modular Arm Assembly - Trauma Amputee	
Sheet scale 1:3	Prototype revs. (01, A01 etc.) in Teamcenter PDM only Design revisions (A, B etc.) data uploaded to Agile PLM	Document Number in Agile PLM: 062032	Attachment to Doc.: Sheet 1 of 1	Doc. Rev.: 01

Rev.	Description of Change:
01	New Specification



ASSEMBLY DRAWING:
No 3D CAD models are exported for assembly specification.
Components are shown with their geometry at the time for this specification revision.
Specification revision may be different from Assembly revision in Agile PLM. Check before use!

Dimensions in millimeters. Unless otherwise noted, all dimensioning and tolerancing to be in accordance with the specified standard.	Laerdal helping save lives	THE INFORMATION CONTAINED HEREIN IS PROPRIETARY TO LAERDAL AND SHALL NOT BE USED FOR ANY PURPOSE DETRIMENTAL TO OR BE REPRODUCED WITHOUT PERMISSION OF LAERDAL	Part Owner	
			Last mod. by	David Shapiro
	General Tolerances:	First Angle Projection	Inspection dimensions in rounded box	Mod. date: 25-Apr-2024
			B	Letter in triangle shows point of revision-change

Sheet size	Teamcenter PDM ID / Revision Reference:	Part Number (w/o color code)	Title		
A3	062031/01	062031	Modular Arm Assembly - Large Wound		
Sheet scale	Prototype revs. (01, A01 etc.) in Teamcenter PDM only Design revisions (A, B etc.) data uploaded to Agile PLM	Document Number in Agile PLM	Attachment to Doc.	Doc. Rev.
1:3		062031	Sheet 1 of 1	01

Appendix C.6

User Testing - Modular Product Architecture

Name:_____

Position:_____

Team:_____

I _____ (sign) allow my answers and feedback to be stored for internal use in Laerdal Medical and presented in a publicly accessible masters thesis report.

What are you testing:

- A physical prototype that displays the configuration potential of an arm baseline developed using a modular product architecture.
- A modular product architecture designed to showcase configuration options within product baselines.

Aim of testing:

- To evaluate the functionality and versatility of the proposed modular product architecture for future medical patient training simulators

Goals of testing:

- To determine if the proposed product architecture and product baselines encompass the customer needs of all identified market segments.
- To assess whether the proposed configuration and add-on packages to the product baselines increase customer satisfaction.
- To evaluate if giving customers the ability to easily exchange the IV and IM/IO modules adds any value to the product.

Questions

Topic: User Interaction

- Rate how it intuitive it is to exchange the following modules for different performance steps (1- hard to understand, 5 - very intuitive)
  - IV Module - Dorsal Veins _____ (1 to 5)
  - IV Module - Cephalic Veins _____ (1 to 5)
  - IV Module - Cubital Fossa _____ (1 to 5)
  - IO Module _____ (1 to 5)
  - Detachable Arm Connection _____ (1 to 5)
  - Finger Connection _____ (1 to 5)
- Do you have any comments about the value that allowing the user to exchange these modules brings to the product? Should it be a requirement that customers are able to exchange the modules?

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Topic: Customer Value

- After the customer has chosen a generic product configuration to what extend would you expect user driven customization (global customization and add-on packages) to increase customer value?
- An example of this would be the customer chooses the *Simulator - Intermediate* general configuration and then chooses they want a *Realistic IO w/ IM* instead of the *Exposed IO* that is the stock option.
  - Rate with Pugh Scoring (- / = / +)
    - Arm Skin Color: = (Baseline)
    - Arm Skin Appearance: _____
    - Arm Skin Material: _____
    - IV Port Type: _____
    - IV Sites: _____
    - IO/IM Type: _____
    - Fingers: _____
- What additional attribute customization would you suggest to further improve the product architecture? Should some of them be eliminated?

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- After the customer has chosen a generic product configuration to what extend would you expect user driven customization (global customization and add-on packages) to increase customer value?
- An example of this would be the customer chooses the *Simulator - Intermediate* general configuration and then chooses they want an additional add-on package.
  - Rate with Pugh Scoring (- / = / +)
    - Cyanosis: _____
    - Advanced Bleeding: _____
    - Additional Fingers: = (Baseline)
    - Additional IV Ports: _____
    - Additional IO/IM Ports: _____
- What additional add-on packages would you suggest to further improve the product architecture? Should some of them be eliminated?

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Topic: Market Segments

- Given your understanding of the market segments, to what extent do the product baselines encompass the market segments? _____ (1 to 5)
  - Score 1: 2 or fewer market segments met
  - Score 2: between 2 and 4 market segments met
  - Score 3: between 4 and 6 market segments met
  - Score 4: between 6 and 9 market segment met
  - Score 5: All market segments met
- If you feel that some market segments are not met, why and what baselines should be added to ensure all market segments are met?

- Given your understanding of the market segments listed above, to what extent do the configuration options help the product to encompass the market segments? _____ (1 to 5)
  - Score 1: no increase in market segments being met
  - Score 5: large increase in market segments being met
- Are there any extra add-on packages or attribute customizations that would help the product meet all market segments?

_____

_____

Topic: Business Strategy

- Considering the strategic objectives of Laerdal Medical (Data Capture, Branding, Sustainability, etc.), how well does this modular product architecture align with those objectives? _____ (1 to 5)
  - Score 1: no alignment
  - Score 5: full alignment
- Do you have any comments about how the modular product architecture could be modified to better align with the strategic objectives of Laerdal Medical?

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- How do you perceive the potential impact of this modular system on releasing a new product (time to market, total cost, risk, serviceability, etc.)? _____ (1 to 5)
  - Score 1: negative impact
  - Score 3: neutral impact
  - Score 5: positive impact
- Would you like to explain your perception?

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- Overall, how satisfied are you with the modular product architecture? (Scale from 1 to 5) _____ (1 to 5)
  - Score 1: I do not see why this is any better than the current monolithic approach
  - Score 5: I see immense value in using this in future products
- What do you find most appealing about this product architecture?

_____

_____

- What do you think need to be improved for this modular product architecture?

- How likely are you to adopt this specific modular system for your training simulators? (Scale from 1 to 5) _____ (1 to 5)
  - Score 1: I don’t see value in implementing this modular product architecture into my product (present or future)
  - Score 5: I see great value in implementing this modular product architecture into my product (present or future)
- Do you have any additional comments or feedback on the modular product architecture?

Appendix D – Pre-Study Report

Appendix D.1 – Literature Review

Appendix D.1.1 Modular Product Architecture

D.1.1.1 Fundamentals of Product Modularity – Karl Ulrich [55]

1. **Definition of Modularity**: Modularity in physical product development equates to how a product's functions are characterized by its physical components. A modular design has separable physical components that correspond directly to functional elements.
2. **Unwanted Interactions**: Minimizing accidental interactions that are not critical to the product's function. These are characterized as interactions that occur outside the specified functions of the product and cause unwanted affects to other nearby functions.
3. **Benefits of Modularity**: The potential benefits of modularity include:
    - Modularity can make development and manufacturing more efficient.
    - Modularity allows for easier customization and adaptation to changing customer needs.
    - Modularity can improve the organization and operation of complex system.
    - Modularity allows for easy upgrades of product parts without redesign of the entire product.

D.1.1.2 The Role of Product Architecture in the Manufacturing Firm – Karl Ulrich [54]

1. **Product Variety**: Product variety to match customer preferences is an important characteristic of a successful product. This can be conveyed to the customer with attributes such as variation in styling or color to provide options to customers.
2. **Interaction of Manufacturing Flexibility**: Different product architectures can contribute to increased flexibility in manufacturing by reusing standardized components with an entire product portfolio.
3. **Product Change**: Product architecture enables informed changes to individual products over their life cycle. The type of product architecture employed dictates how the changes can be implemented to the product once in production.

D.1.1.3 Modular Product Architecture – Dahmus et al. [56]

1. **Definition of Modules**: Product modules are defined as sub-systems within a product that are bundled as a unit that serve contained functions.
2. **Effective Modularity**: Effective modules can contain various characteristics, such as being:
    - Easily updated during product life cycle.
    - Created in multiple performance steps to offer product variety.
    - Easily replaced or repaired to increase product lifespan.
    - Swappable to gain added functionality after product launch.
3. **Modularity Benefits**: Product modularity benefits are enhanced when identical modules are used in different products within a companies product portfolio.
4. **Modularity Matrix**: A modularity matrix can be used to illustrates possible product modules by showing how different functions interact within a system.

D.1.1.4 Modular Function Deployment Adapted – Sonego et al. [59]

1. **Novelty and Complexity in Modular Functional Decomposition (MFD)**: High novelty projects require the full MFD process. However for low novelty projects that involve improvements to existing products the first two steps of the MFD process can be skipped because the client requirements and established technical solutions are known.

2. **Project Assessment Matrix**: A project assessment matrix can be used to gauge the levels of complexity and novelty of a company's projects. This is done by selecting the cell that best represents the project's characteristics based on one of four different MFDA (Modular Functional Decomposition Approach) configurations.
3. **Client Requirements**: Understanding client requirements enable the development team to identify basic features and variations of the product.

D.1.1.5 Product Modularity: Definitions and Benefits – Gershenson et al. [4]

1. **Complexity of Product Modularity:** Real-world products are complex, which makes it difficult to gain the full benefits of product modularity.
2. **Life Cycle Modularity:** Modules and interactions that occur throughout the product's life cycle, including development, manufacturing, service, and retirement are all part of the products life cycle modularity

D.1.1.6 A 5-step Guide to Develop a Modular System – Modular Management [58]

1. **Clarify Customer Needs**: This involves determining the importance of each customer value to each market segment to understand commonalities and differences across segments to learn what functions and variation of functions are required in the product. Understanding the customer needs is the first step of the MFD process.
2. **Identify Functions and Solutions**: Identifying functions and technical solutions for the product that align with the customers' values is the second step of the MFD process. Evaluating this requires considering both the market perspective and the company's internal criteria.
3. **Propose Modules and Interfaces**: Modules and their interfaces are proposed based on the defined functions of the product. Modules should be free of conflicting strategies and evaluated based on strategic company reasons. Proposing the modules marks the third step of the MFD process.
4. **Define Variants and Configurations**: Product variants are defined using the proposed modules and market segments to determine how many different product configurations are required to meet the needs of the entire market. This is the fourth step of the MFD process.
5. **Confirm Architecture Feasibility**: The final step of the MFD process is to confirm that the overall product architecture is feasible, which involves ensuring that the proposed modules and configurations are technically feasible and meet all customer and business needs.
6. **Module Drivers**: To gain the full benefits of the MFD process, economies of scale must be achieved. This can be done through two module drivers described below.
    - **Carry Over**: A part that remains unchanged throughout the product platform's life.
    - **Common Unit**: A part that can be used across the entire (or most of) the company’s product portfolio

Appendix D.1.2 Medical Training Simulators

D.1.2.1 The Advanced Modular Manikin Open Source Platform for Healthcare Simulation – Hananel et al. [84]

1. **Modular Connector Design Values:** Guiding technical values have been established for a modular connector that allows for limbs and the head to be detached from the torso. Using a connector in this way enable modularity within the manikin by allowing for different configurations within the same product. These design values will act as baselines when designing the technical specifications for the modular arm.
2. **Usability Study:** Potential market segments such as first responders, anesthesiologists, surgeons, nurses, and military personnel have been established and interviewed to determine customer needs required to design the modular architecture.

D.1.2.2 Advanced Modular Manikin: Final Report – Sweet [85]

1. **Module Interfacing:** Using the LEGO approach, the Advanced Modular Manikin (AMM) utilizes both digital and physical modules that are built up to create a customizable manikin. These modules have the ability to work alone for localized task training or in unison for full patient simulation training.
2. **Fluidics:** Mapping out the requirements for the fluid system allows for simplified module design as system requirements are predefined. These requirements are broken down into universal and localized as the limbs have different fluidics requirements than the head.
3. **IV Arm Module:** Based on customer needs, this module has pre-defined user requirements such as accurate heartrate reading and indication for correct IV placement. These user requirements are accomplished through physical and digital solutions where a closed loop radial pulse and IV port with fluid detection are implemented.

Appendix D.1.3 Product Development

D.1.3.1 Quality Function Deployment and Integrated Product Development – Hjort et al. [86]

1. **Consistent Approach Across Phases:** The approach to product development remains consistent across different stages with the level of detail and scope narrowing as the project progresses.
2. **Early Phases:** The early phases of development are critical. During these phases decisions are made by relying on simulations, models, and the knowledge of experienced team members and suppliers.
3. **Understanding Customers:** Understanding customer needs and delivering the right products at the right time is essential for a successful product that fills gaps in the market.

Appendix D.2 – Theoretical Framework: Project Management

Appendix D.2.1 Network Diagram and Gantt Chart

Network diagrams and Gantt charts are tools used by project managers to define project task dependencies and visualize the sequence of these activities with respect to the overall project timeline. Project tasks can either be independent (occurring in parallel with other tasks), or dependent (tasks must be performed in series) [87]. To build the Network diagram, each task is given an estimated duration, start and finish dates, and float time (the amount of time the activity can be delayed without affecting the overall project timeline). Based on the dependencies previously determined, activities are assigned one of the four primary relationship types [87]:

1. Finish-to-start: Activity A must end before activity B can begin.
2. Start-to-start: Activity B can start once A has begun.
3. Finish-to-finish: Activity A must end before B can end.
4. Start-to-finish: Activity B can end once A has begun.

With these relationships and timelines set for each task, the Network diagram can be constructed and analyzed for critical project path. Where Network diagrams are used to visualize flow between activities, Gantt charts are used to better visualize the project timeline. While useful in project planning, Gantt charts shine during the project as they allow for simple visualization of actual vs. planned project progress. For complex projects involving multiple team members, Gantt charts allow for project managers to quickly determine activities that are on the project's critical path. These critical tasks, which if delayed, will extend the total project timeline.

By representing these activities visually, project managers can focus on the most time critical aspects of the project and allocate resources accordingly. Each activity in a project is represented by a horizontal bar that corresponds to the length of the task. The position of this bar along the time axis indicates the proposed start and end times with arrows used to show the relationship between the tasks as determined by the Network diagram. Both a Network diagram and Gantt chart were created for this project using ProjectLibre, an open source project management software specializing in Gantt chart visualization. The Network diagram can be found in Appendix A6 and the Gantt chart can be found in Appendix A1-A4.

Appendix D.2.2 Work and Cost Breakdown Structure

Work and cost breakdown structures are a visual representation of the total scope and cost of work to be performed by the project team. These diagrams allow for quick visualization of project deliverables and cost associated with each stage of the project. Work breakdown structures (WBS) are visualized as a top-down representation of individual tasks that are required to complete the project. Typically, these tasks are broken down into multiple levels with the entire project being level 1, deliverables required to complete the project assigned to level 2, and the tasks required to complete each deliverable assigned to level 3 [87]. Using the Network diagram and Gantt chart, the total hours for each task is added to the WBS at level 3. These hours are then summed up for level 2 and finally level 1, which is associated with the total number of hours required to complete the project.

Similarly, a cost breakdown structure (CBS) associates an hourly rate to each task to create an estimated budget for each task, deliverable, and project as a whole. Both the WBS and CBS are important tools used by project managers to assign resources to tasks and create a budget for the project. Moreover, these structures play a crucial role in risk management by identifying critical paths and allocating contingencies for high-risk tasks. They also support quality control by clearly

defining deliverable standards at each breakdown level and facilitate schedule adherence by establishing a clear timeline for task completion.

For this project, a WBS and CBS were created as the same diagram based on the Network diagram and can be found in Appendix A5. By integrating these structures into the project management process, it is possible to ensure that the project adheres to its scope, stays within budget, and meets its quality and schedule requirements.

Appendix D.2.3 Risk Analysis

Risk analysis is a critical aspect of the project planning process as it ensures the project timeline and milestones stay aligned so that all project deliverables are delivered on time and on budget. It is impossible to predict all risks that will occur during the project. Therefore, using a risk analysis plan ensures that the anticipated risks are understood and mitigated prior to the start of the project. For this project, a risk analysis matrix was created following advice from the Smartsheet Platform, a project management software company[88].

The degree of risk is determined by the risk priority level that is calculated by multiplying the impact of the risk (on a scale of 1, low to 5, high) by the probability of the risk occurring (on a scale of 1, low to 5, high). This priority level corresponds to a probability vs impact matrix where different degrees of risk are organized using the following designations: minor (priority level of 1 to 5), moderate (priority level of 6 to 12), major (priority level of 15 to 20), severe (priority level of 25). The degree of risk is largely qualitative and fully based on assumptions, so ensuring the risk is well thought out is important. Based on the possibility and impact of the risk occurring, mitigation tactics are proposed. These mitigation tactics can then be integrated into the tasks list and Gantt chart.

The risk analysis matrix can be found in Appendix A7. Each of the risks listed has been identified as a possible moderate or major risks. Accordingly, the mitigation tactics have been implemented into the Gantt chart to help ensure the project stays on track and the milestones and timeline stay aligned.

Appendix D.3 – Goals and Milestones

To ensure the Master's thesis progresses with focus and adheres to its rigorous timeline, specific goals and corresponding milestones have been established. These milestones serve as vital checkpoints to navigate the project's three integral phases: the design of the modular product architecture, the development of modular arm variants, and the prototyping of two modular arm variants. This section will delineate the goals and milestones, providing measurable criteria to systematically evaluate the thesis's advancement. These evaluations will confirm the readiness to transition between phases, ensuring that each step brings us closer to the overarching goal of providing Laerdal Medical with a feasibility study on the use of modular product architecture to develop medical patient training simulators.

Appendix D.3.1 Phase 1 - Developing The Modular Product Architecture

Goal: Develop a modular product architecture that aligns with customer needs, market segments, company strategies, and allows for both current and future product features and variations.

Acceptance criteria:

Denotes a critical criteria, project cannot move to next phase without completion.

- **Clear Understanding of Customer Needs**
  - Segmentation of market segments based on existing customer data
  - Listing of what customers value in a Laerdal product based on existing customer data
  - Ranking of customer values in the customer value ranking (CVR) matrix
- **Defined Product Properties**
  - Listing of product properties based on existing Laerdal products
  - Goal values for these product properties based on existing Laerdal products
- **Quality Function Deployment Matrix (QFD)**
  - Input:
    - Product properties
    - Customer values
  - Output:
    - Ranking of how product properties align with customer values
- Functional Analysis
  - Listing of functions (technical solutions) that exist in current Laerdal produts
- **Design Property Matrix (DPM)**
  - Input:
    - Product properties
    - Functions (technical solutions)
  - Output:
    - Ranking of which functions accomplish which product properties
- Module Identification and Evaluation
  - Proposal and evaluation of module candidates based on the DPM
- **Modules and Interfaces**
  - Modules created from DPM results
  - Interfaces between modules defined
- **Module Variants and Configurations**
  - Listing of module variants that allow for all product properties to be met
  - Configuration of module variants into product that account for every product market
- **Space and Technical Feasibility of Architecture confirmed**

  - Potential issues addressed and architecture refined appropriately to eliminate issues that could occur in Phase 2 and 3 due to poor product architecture.

Milestones:

- Understand customer needs - February 1st
  - Completed CVR
- Identified functions and solutions – February 5th
  - Completed QFD and DPM
- Defined Modules, Interface, and Variants - February 12th
  - Completed list of modules, interfaces between modules, and variants of modules
- Defined Product Structure and Specification - February 20th
  - Generic product structure created defining which modules are required and which are optional
- Defined Product Configurations - February 23rd
  - Generic product configurations created that address all product markets
- Confirm Architecture Feasibility - March 14th
  - Product architecture compared to market segments and customer values to ensure alignment.
  - Product architecture compared to technical capability to ensure design and manufacturing is possible.

Appendix D.3.2 Phase 2 - Developing The Product

Goal: To develop a modular training simulator arm that uses scalable solutions that are sustainable, and cost-effective that can cater to different age groups (adults, juniors, babies).

Acceptance criteria:

Denotes a critical criteria, project cannot move to next phase without completion.

- **Defined Product Requirements**
  - The purpose of the arm and its functionalities are clearly defined for the arm variant(s) chosen for design
- Parts Identification
  - The existing parts that are planned to be used in the design arm variant(s) have been identified
  - The requirements for any new parts needed to create a functional product have been defined.
- **Product Design Ideas Generated**
  - Concepts for modules have been sketched and documented.
- **Concepts Developed**
  - Module concepts have been chosen for further development using a concept evaluation matrix
- **Low Fidelity Prototype to Confirm Design Feasibility**
  - Concepts prototyped to low level to confirm feasibility of concept prior to high fidelity prototyping in Phase 3.
- Design Documentation
  - Design process from idea to final concept is well-documented.
- **Technical Specification**

    - Product requirements, performance criteria, technical drawings, quality and safety standards, and testing procedures are clearly outlined and documented.
- *Bill of Materials (BOM) Created*
    - All necessary components, their quantities, part details, and assembly instructions are listed.
    - A comprehensive BOM is created and documented.
- Sustainability Assessment Completed
    - A full assessment of the arms sustainability (including environmental, social, and economic impacts) is completed using the LCA approach.
    - Recommendations for improving sustainability are developed and documented.
- Cost Assessment Completed
    - All cost elements are identified and data on each is gathered.
    - The total cost of the product is calculated.
    - Alternatives for cost reduction are considered and recommendations are documented.
- *All Documentation*
    - All the results, findings, recommendations, and other relevant information are properly documented.

Milestones:

- Design for variant(s) of modular adult arms - March 27th
    - Generation of module concepts
    - Concept Evaluation Matrix of module concept
    - Completed CAD models of chosen arm variant(s)
- Technical specification for designed modular arms - April 4th
    - Material specification supported by force calculations
    - Fluid transfer supported by flow calculations
- BOM for designed modular arms - April 10th
- *Sustainability assessment for designed modular arms – May 1st*
    - LCA completed for designed arm variant
- *Cost assessment for designed modular arms – May 7th*

* These milestone have potential to before or after set date as they are not critical for Phase 3 completion which needs to be prioritized. See Risk Analysis Plan for more information. *

Appendix D.3.3 Phase 3 - Prototyping A Variant of the Product

Goal: To successfully prototype two variants of the modular training simulator arm, ensuring it meets technical feasibility, usability, aesthetic appeal, and cost-effective production.

Acceptance criteria:

Denotes a critical criteria, project cannot move to next phase without completion.

- *Prototype Objectives Defined*
    - The objectives of the prototype, including aspects it should test such as technical feasibility, usability, and aesthetic appeal have been clearly outlined.
- *Prototyping Method Selected*

    - An appropriate prototyping method and materials have been chosen and justified, considering factors such as cost-effectiveness and the ability to accurately represent the product.
- *Test Plan Developed*
    - A comprehensive test plan has been created, detailing specific tests, procedures, and metrics for evaluating the prototype.
- Cost Estimation
    - The estimated cost for building the prototype has been calculated and documented. The cost assessment created in task 2.5.7 has been updated accordingly.
- *Prototype Built*
    - All parts required for the prototype have been accurately created using the chosen method, and the prototype has been assembled and is ready for testing.
- *Prototype Tested*
    - User testing and technical testing have been conducted, with feedback gathered on the prototype's design, functionality, performance, and reliability.
- *Test Results Analyzed*
    - Test results and user feedback have been analyzed, with areas for improvement identified.
- *Documentation*
    - Learnings from the prototyping process have been documented, providing valuable insights for future design decisions.
    - A comprehensive prototype report has been prepared, detailing the development process, testing, results, and conclusions.

Milestones:

- *Complete planning document for prototypes of two modular adult arms – April 18th*
- *Assemble both variants of modular adult arm prototypes - May 9th*
- *Test both variants of modular adult arm prototypes - May 13th*
- Documentation of both modular arm prototypes - May 17th

* These milestone have potential to be completed before or after set date as they are critical for Phase 3 completion which needs to be prioritized. See Risk Analysis Plan for more information. *

Appendix D.4 – Tasks

The tasks created for Phase 1 revolve around the development of a modular product architecture for the arm of a medical patient training simulator. This foundational phase is broken down into six stages that align with the five step process utilized in the Modular Function Deployment (MFD) methodology developed by Modular Management, a Swedish consultancy specializing in modularity. The final stage of Phase 1 is used to confirm the feasibility of the proposed modular product architecture to ensure downstream problems in Phase 2 and 3 are not created from improper product architecture. The MFD process will be employed as the product architecture methodology for this project. The tasks listed below are tailored for this project based on Modular Management's guidebook *A 5-step Guide to Develop a Modular System* [58]. This approach ensures that this project provides Laerdal Medical with a relevant feasibility study based on the specific modular product architecture methodology they are considering.

Phase 2 of the project transitions from the foundational work done during the development of the modular product architecture into the design and development phase of the product life cycle. This phase will build off the product planning done in phase 1 translating the modular thought process into tangible design solutions. During this phase, specific requirement for the adult training simulator arm variant(s) will be designed using the foundation of phase 1 to ensure the designs meet customer and company requirements. The development process is based on the outline provided in *Product Design and Development 6th Edition* By Ulrich and Eppinger [53]. The methodology used for product design has been based specifically on the introduction, product specifications, concept generation and concept selection sections found in this book. This methodology was adapted to fit a modular product architecture with the focus on delivering detailed technical specifications, full CAD models, bill of materials, sustainability analysis, and cost estimation for the chosen modular arm variants. To help mitigate risk associated with the product development, low-fidelity prototypes will be created concurrently during the product design stage. As detailed in the risk analysis plan, the prototyping of the final arm variant(s) will potentially occur prior to the completion of Phase 2 to help mitigate risk associated with prototyping a key deliverable near the project completion date.

Phase 3 represents the end of the product development process for this feasibility study, where the theoretical designs and specifications from Phase 2 are created into high-fidelity physical prototype(s). Prior to building the prototype, planning will be done to create smooth assembly and testing. This will ensure the results from testing are usable. The prototyping process is designed to be iterative, allowing for continuous improvement and optimization based on real-world testing and feedback. If time permits, the prototype designs will be adjusted and design iterations made. The end of this phase aims to deliver a physical prototype and well-documented testing plan and results. As detailed in the risk analysis plan, the prototyping of the final arm variant(s) will potentially occur prior to the completion of Phase 2 to help mitigate risk associated with prototyping a key deliverable near the project completion date.

Appendix D.4.1 Phase 1 - Developing The Modular Product Architecture

Stage 1.1 - Clarify Customer Needs

Task 1.1.1 - Identify Customer Needs

- Identify customers
    - End users
- Understand customer needs for the product based on existing product requirements and customer feedback

Task 1.1.2 - Segment the Market Based on Needs

- Identify distinct groups within target market that have specific needs or preferences
- Analyze the specific needs of each segment by values and what is required from your product

Task 1.1.3 - List Customer Values

- Compile a list of customer values by identifying what aspects or features of the product is valued by the customer most
    - Durability
    - Affordability
    - Functionality
    - etc.

Task 1.1.4 - Rank Customer Values

- Use a CVR matrix to rank customer values
    - Input:
        - Market Segments
        - Customer Values
    - Output:
        - Ranking of Customer Values

Task 1.1.5 - Refine Market Segments

- Review and refining market segments to see if merging of segments is possible.
    - If two segments have very similar value rankings, they might be merged into a single segment.

Stage 1.2 - Identify Functions and Solutions

Task 1.2.1- Identify Product Properties

- Identify necessary product properties by determining what features or characteristics the product needs to have to meet customer values.

Task 1.2.2 - Define Goal Values for Product Properties

- Determine the goal values for all product properties to cover the product range required by the market segments

Task 1.2.3 - Create Quality Function Deployment Matrix (QFD)

- A Quality Function Deployment (QFD) Matrix is used to translate customer requirements into specific product characteristics.
    - Input:
        - Product Properties and Goal Values
        - Customer Values

Task 1.2.4 - Conduct a Functional Analysis

- Meet with product managers to determine if any new features are desired in future manikins
    - Research medical procedures done in arms and pick functions that don't exist in current functions as ideas
- Analyze the main components and their respective functions in the product

- Compile functions for each product in the Laerdal simulator portfolio
- Compare functions to determine common and unique
    - within age (i.e SimMan, NursingAnne)
    - across age (i.e SimMan, SimJunior, SimBaby, SimNewB)
    - Split up functions into different performance levels (if applicable)
- Evaluate different technical solutions for the same function using existing solutions in Laerdal products using a functional decomposition diagram

Task 1.2.5 - Create Design Property Matrix (DPM)

- Document the relationships between the technical solutions and the product properties in a Design Property Matrix (DPM)
    - Input:
        - Product Properties and Goal Values
        - Functions and Technical Solutions

Stage 1.3 - Developing Modules, Interfaces, and Variants

Task 1.3.1 – Define Module Drivers

- Establish Module Drivers that align with company strategies of Operational Excellence, Customer Intimacy, and Product Leadership.

Task 1.3.2 – Create Module Indication Matrix (MIM)

- Build the Module Indication Matrix to correlate Module Drivers with technical solutions and product properties, identifying potential modules.
    - Input:
        - Functions and Technical Solutions
        - Module Drivers

Task 1.3.3 – Build Modules with Module Builder (MB)

- Create preliminary module concepts using the Module Builder tool, incorporating the insights gained from Module Drivers and the Module Indication Matrix.

Task 1.3.4 - Refine Modules using the Module Strategy Matrix (MSM)

- Refine the preliminary module concepts into defined modules based on the Module Strategy Matrix analysis.
    - Inputs:
        - Module Drivers
        - Modules

Task 1.3.5 - Develop Interface Matrix (IM)

- Define and standardize interfaces between modules using the Interface Matrix tool, based on the refined module concepts.

Task 1.3.6 - Establish Module Variants

- Determine the necessary module variants that fulfill market demands and technical requirements using insights from the defined modules and interfaces.

Task 1.3.7 - Create Module Variant Specification (MVS)

- Document and specify the identified module variants in the Module Variant Specification tool, detailing their connections to product properties.
    - Inputs:
        - Module Variants
        - Product Properties

Stage 1.4 – Developing Product Structure

Task 1.4.1 - Define Nodes

- Utilize PALMA to define nodes, which represent the logical points in the product architecture where modules will interact or integrate.

Task 1.4.2 - Create Generic Product Structure (CFG)

- Use the nodes to create a Generic Product Structure in PALMA, outlining the high-level organization of the product and how various modules will fit together.

Task 1.4.3 - Apply Configuration Interface (CI)

- Apply PALMA's Configuration Interface tool to manage and verify the connections and compatibility between different module variants within the product configuration.

Task 1.4.4 - Create Product Configuration

- Configure and validate the overall product configuration using PALMA, ensuring that the Generic Product Structure translates into a viable product layout that meets design and functional requirements.

Task 1.4.5 - Develop Product Specification Matrix (PSM)

- Develop a Product Specification Matrix using PALMA to detail the relationship between product specifications and module selections, ensuring that all technical and market requirements are comprehensively addressed.

Stage 1.5 - Define Product Configuration

Task 1.5.1 - Develop Product Configuration Matrix (PCM)

- *Use PALMA to develop a Product Configuration Matrix, which captures all possible product configurations and their components. This matrix should reflect the full range of product variants derived from the modular architecture.*

Task 1.5.2 - Create Configuration Table (CT)

- *Create a Configuration Table in PALMA that documents predefined, standard configurations for quick reference and replication. This table will serve as a guide for assembling the product variants and ensure consistency across different product lines.*

Stage 1.6 - Confirm Architectural Feasibility

Task 1.6.1 - Create Completed MFD Hub Diagram

- Create MFD hub per Modular Management MFD process step 5

Task 1.6.2 - Evaluate Space Feasibility of Interfaces and Modules

- CAD model of rough model of the arm with all modules and interfaces in place
- Prototype to allow for reorganization of modules within arm

Task 1.6.3 - Evaluate Technical and Cost Feasibility of Interfaces and Modules

- Review technical requirements of the functions each interface must perform
- Outline upper end for arm to full manikin cost percentage
- Prototype interfaces of modules to ensure existing solutions meet requirements

Task 1.6.4 - Improve and Iterate Architecture Based on Feasibility Study

- Analyze results from space and technical feasibility evaluations
- Identify issues that arose
- Iterate and implement changes to architecture to eliminate issues

Appendix D.4.2 Phase 2 - Developing The Product

Stage 2.1 - Product Design

Task 2.1.1 - Define product requirements

- Determine which product I am designing the arm for
    - Size of simulator
        - adult, junior, baby
    - Type of simulator
- What is the product intended to do
- What is the purpose of the product
- Who are the product end-users

Task 2.1.2 - Determine Existing Parts for Use

- Split up existing parts by function and sort into the defined modules
- Determine what new parts (if any) need to be developed to create working product

Task 2.1.3 - Generate Ideas for Product Design

- Sketch concepts for skeleton
    - exo vs endo skeleton
- Sketch concepts for interfaces between part and modules
- Sketch concepts for interface between modules and skeleton
- Brainstorm material for and how to manufacture skin

Task 2.1.4 - Develop Concept(s)

- Develop variant(s) of adult training simulator arms
    - Full CAD model
    - Focus on scalability
    - Focus on reuse of components across simulator sizes

Task 2.1.5 - Rough Prototype of Variant(s) for Feasibility

- Low fidelity prototype to ensure modules and interfaces will fit and interact correctly within constraints of arm

Task 2.1.6 - Design Documentation

- Compile sketches and show design process from idea to final concept

Stage 2.2 - Technical Specification

Task 2.2.1 - Tabulate Product Requirements

- Created in Task 2.1.1

Task 2.2.2 - Define Performance Criteria

- Specify what the product should be capable of achieving in terms of its function or performance.
    - Power requirements
    - Pressure requirements
    - Fluid requirements
    - Force requirements
    - Etc.

Task 2.2.3 - Create Technical Drawings

- Detail the materials to be used in each component
- Detail the manufacturing process used to create each component
- Assembly and Sub-Assembly Drawings
- Individual Component Drawings

Task 2.2.4 - Set Quality and Safety Standards

- Outline quality standards the product must meet
- Outline what regulations the product must meet and how it is met

Task 2.2.5 - Document Testing Procedures

- Describe the tests that the product must undergo to verify its functionality, durability, and safety

Task 2.2.6 - Documentation

- Create a technical specification based on results

Stage 2.3 - Create Bill of Materials (BOM)

Task 2.3.1 - Identify All Necessary Components

- Raw materials
- Parts
- Assemblies
- Sub-Assemblies

Task 2.3.2 - Determine Quantities

- Quantities for each part

Task 2.3.3 - Specify Part Details

- Include part numbers
- Part descriptions

- Part specifications

Task 2.3.4 - Organize Components

- Group components by their use or by the stage of production in which they're needed.

Task 2.3.5 - Develop Assembly Instructions

- Describe the sequence in which parts should be assembled.
- Specify which parts are to be used together in sub-assemblies.

Task 2.3.6 - Documentation

- Create a BOM with all of these results in one place

Stage 2.4 - Sustainability Assessment

Task 2.4.1 - Define Scope

- Determine which product the assessment will apply to
    - Existing product arm vs. modular product arm
- Determine which process is being evaluated and what aspects of sustainability will be included in the assessment (e.g., carbon emissions, water usage, social impacts, etc.)

Task 2.4.2 - Gather Data

- Collect data on the product or process
- Including materials used
- Energy consumption
- Waste produced
- Any social or economic impacts.

Task 2.4.3 - Conduct Life Cycle Assessment (LCA)

- An LCA examines the environmental impacts of a product or process throughout its entire life cycle, from raw material extraction to disposal.
- Identify and quantify the environmental impacts at each stage.

Task 2.4.4 - Evaluate Social and Economic Impacts

- Assess the social and economic impacts of the product or process.
    - Evaluating labor practices
    - Community impacts
    - Economic viability
    - Etc.

Task 2.4.5 - Identify Opportunities for Improvement

- Based on the assessment, identify areas where the product or process could be more sustainable, which could be as follows
    - Reducing energy use
    - Selecting more sustainable materials
    - Improving labor practices

Task 2.4.6 - Develop Recommendations

- Create specific, actionable recommendations for improving the sustainability of the product or process.

Task 2.4.7 - Documentation

- Create a document that includes results of all tasks performed

Stage 2.5 - Cost Assessment

Task 2.5.1 - Define Scope

- Determine what product the assessment will apply to
    - Existing product arm vs. modular product arm

Task 2.5.2 - Identify Cost Elements

- List all the costs associated with the product
    - Material costs
    - Labor costs
    - Overhead costs
    - Other direct or indirect costs.

Task 2.5.3 - Gather Data

- Collect data on each cost element using the following as a starting point
    - Reviewing invoices
    - Talking to suppliers
    - Or using industry benchmarks.

Task 2.5.4 - Calculate Total Costs

- Add up all the costs to determine the total cost of the product

Task 2.5.5 - Analyze Results

- Look at the results of your calculations to understand where the majority of costs are coming from.

Task 2.5.6 - Consider Alternatives

- If the costs seem too high, consider alternatives.
    - Cheaper materials
    - Improving efficiency
    - Redesigning the product or process.

Task 2.5.7 - Documentation

- Write up your findings in a cost assessment report.
    - Detailed breakdown of all costs
    - The total cost
    - Any potential alternatives or recommendations.

Appendix D.4.3 Phase 3 - Prototyping A Variant of the Product

Stage 3.1 - Planning of Prototype

Task 3.1.1 - Define Prototype Objectives

- Determine what questions the prototype should answer or what aspects of the product it should test.
    - What variant to prototype
    - Usability
    - Aesthetic appeal
    - Technical feasibility

Task 3.1.2 - Select Prototyping Method

- Choose the most appropriate method and materials for creating the prototype.
    - 3D printed models
    - Hand-crafted sculpted
    - CNC machined
    - Molded

Task 3.1.3 - Develop Test Plan

- Identify the specific tests to be performed on the prototype, outlining the procedures and metrics to be used for evaluation.

Task 3.1.4 - Develop Cost Estimation

- Estimate the cost of materials required to build the prototype
- Update cost assessment created in task 2.5.7

Stage 3.2 - Building of Prototype

Task 3.2.1 - Compile Parts for Prototype

- Using the chosen method, make all parts required for the prototype.
- Create all tooling required to mold parts of prototype.
- Mold all parts required for the prototype

Task 3.2.2 - Assemble Prototype

- Assemble the parts of the prototype, ensuring it is ready for testing.

Stage 3.3 - Testing of Prototype

Task 3.3.1 - Perform User Testing

- Conduct user testing to assess the prototype's usability and aesthetic appeal, gathering feedback on its design and functionality.

Task 3.3.2 - Conduct Technical Testing

- Perform technical tests to evaluate the prototype's performance, reliability, and technical feasibility.

Task 3.3.3 - Analyze Test Results

- Analyze the test results and feedback to identify areas of improvement.

Stage 3.4 - Documentation of Prototype

Task 3.4.1 - Document Learnings

- Keep a record of what was learned from each prototype iteration. This can inform future design decisions and provide valuable insights for the product development process.

Task 3.4.2 - Prepare Prototype Report

- Create a comprehensive report detailing the prototype development, testing process, results, and conclusions.

Stage 3.5 - Prototype of Different Variant (TIME DEPENDENT)

Task 3.5.1 - Refine Prototype Objectives

- Create new objectives for Prototype based on different variant requirements.

Task 3.5.2 - Create New Prototype Variant

- Create a new version of the prototype and prepare for the next round of testing.

Task 3.5.3 - Repeat Testing and Evaluation Process

- Repeat the testing and evaluation process with the new prototype variation.

Appendix D.5 – Deliverables

Appendix D.5.1 Phase 1 – Developing The Modular Product Architecture

- Quality Function Deployment Matrix
- Design Property Matrix
- Module Indication Matrix
- Module Strategy Matrix
- Interface Matrix
- Module Variant Specification
- Product Configuration Matrix

Appendix D.5.2 Phase 2 – Developing The Product

- CAD Model of Product Variant(s)
- Technical Specification
- Bill of Materials
- Sustainability Assessment
- Cost Assessment

Appendix D.5.3 Phase 3 – Prototyping A Variant of the Product

- Prototype of Arm Variant(s)
- Testing Results from Prototype

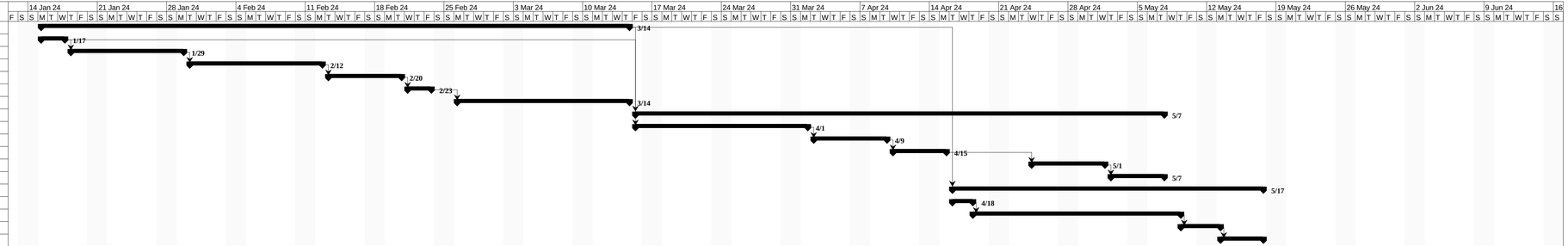
Appendix D.6 – Pre-Study Report Appendix

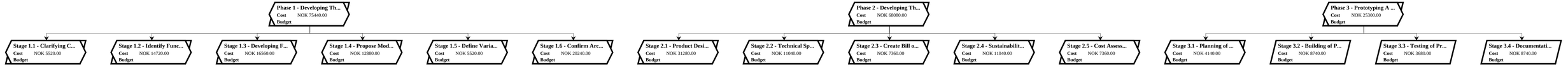
Appendix D.6.1 – Risk Analysis Matrix

RISK DESCRIPTION	IMPACT DESCRIPTION	IMPACT LEVEL	PROBABILITY LEVEL	PRIORITY LEVEL	MITIGATION NOTES
Give a brief summary of the risk.	What will happen if the risk is not mitigated or eliminated?	Rate 1 (LOW) to 5 (HIGH)	Rate 1 (LOW) to 5 (HIGH)	(IMPACT X PROBABILITY) Address highest first.	What can be done to lower or eliminate the impact or probability?
Incompatabile of module interfaces	Creates unexceptect technical issues during design phase	5	4	20	Prototype interfaces between modules
Insufficient MFD feasibilty analysis	Not all modules are able to fit into designed variant	4	3	12	Prototype space usage of modules
Scope creep	Add tasks to the project that will risk delaying the project timeline	4	4	16	Keep project focus to pre-planned task list
Misalignment of project timelines and milestones	Delays in project timeline and project deliverables	5	3	15	Regular updates of Gantt chart to make adjustments as needed
Assumption the product architecture will work	Requires significant redesign of product architecture prior to development	4	2	8	Iterate quick prototypes of modules to validate the feasability of each module
Concept development issues	Required significant redesign of concept prior to prototyping	3	3	9	Use low-fidelity prototyping to quickly test concepts to find design problems early in the process
3D Printing capabilities moving to Forus	Increase lead time to get 3D printed parts for prototype	3	2	6	Plan to print each part when the CAD model is finished to ensure all parts are done prior to the planned assembly date
3D Printing parts on specific days	Delays in prototyping assembly	3	3	9	Priorotize parts that are large, critical and take a long time to print
Testing prototype(s) on specific days	Delays in prototyping testing	3	3	9	Reserve testing equipment in advance

Appendix D.6.2 - Full Gantt Chart

	Name	Duration	Start	Finish
1	**Phase 1 - Developing The Modular Product Architecture**	**44 days**	**1/15/24 8:00 AM**	**3/14/24 5:00 PM**
2	**Stage 1.1 - Clarifying Customer Needs**	**3 days**	**1/15/24 8:00 AM**	**1/17/24 5:00 PM**
8	**Stage 1.2 - Identify Functions and Solutions**	**8 days**	**1/18/24 8:00 AM**	**1/29/24 5:00 PM**
14	**Stage 1.3 - Developing Modules, Interfaces, and Variants**	**10 days**	**1/30/24 8:00 AM**	**2/12/24 5:00 PM**
22	**Stage 1.4 - Developing Product Structure**	**6 days**	**2/13/24 8:00 AM**	**2/20/24 5:00 PM**
28	**Stage 1.5 - Define Variants and Configurations**	**3 days**	**2/21/24 8:00 AM**	**2/23/24 5:00 PM**
31	**Stage 1.6 - Confirm Architecture Feasibility**	**14 days**	**2/26/24 8:00 AM**	**3/14/24 5:00 PM**
36	**Phase 2 - Developing The Product**	**38 days**	**3/15/24 8:00 AM**	**5/7/24 5:00 PM**
37	**Stage 2.1 - Product Design**	**12 days**	**3/15/24 8:00 AM**	**4/1/24 5:00 PM**
44	**Stage 2.2 - Technical Specification**	**6 days**	**4/2/24 8:00 AM**	**4/9/24 5:00 PM**
51	**Stage 2.3 - Create Bill of Materials (BOM)**	**4 days**	**4/10/24 8:00 AM**	**4/15/24 5:00 PM**
58	**Stage 2.4 - Sustainability Assessment**	**6 days**	**4/24/24 8:00 AM**	**5/1/24 5:00 PM**
66	**Stage 2.5 - Cost Assessment**	**4 days**	**5/2/24 8:00 AM**	**5/7/24 5:00 PM**
74	**Phase 3 - Prototyping A Variant of the Product**	**24 days**	**4/16/24 8:00 AM**	**5/17/24 5:00 PM**
75	**Stage 3.1 - Planning of Prototype**	**2.25 days**	**4/16/24 8:00 AM**	**4/18/24 10:00 AM**
80	**Stage 3.2 - Building of Prototype**	**15 days**	**4/18/24 10:00 AM**	**5/9/24 10:00 AM**
83	**Stage 3.3 - Testing of Prototype**	**2 days**	**5/9/24 10:00 AM**	**5/13/24 10:00 AM**
87	**Stage 3.4 - Documentation of Prototype**	**4.75 days**	**5/13/24 10:00 AM**	**5/17/24 5:00 PM**

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Budget
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Stage 1.2 - Identify Func...
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Stage 1.6 - Confirm Arc...
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Stage 2.1 - Product Desi...
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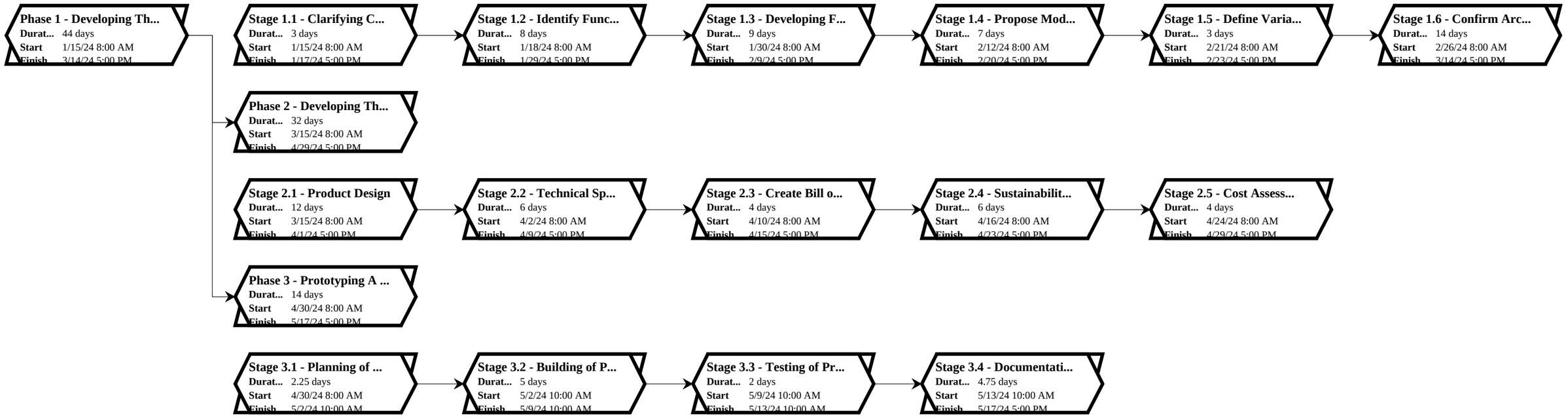
Appendix D.6.4 - Task Network