Product Requirements and Specifications Document (PRSD)
Portable Ruggedized Fluid Pump

Approvals

Title	Print	Signature	Date

Revision History

Revision	Summary of Change	Originator
X0	New Document	UTSA-ECE
X1	Updated Version 1: Format changes requested by Dr. Jonathan Votion & Prof. August Allo	Green Engineers

1. Introduction

This document contains the system requirements for the ***Portable Ruggedized Fluid Pump***. These requirements have been derived from several sources.

1.1 Purpose of This Document

This document is intended to guide development of the ***Portable Ruggedized Fluid Pump***. It will go through several stages during the course of the project:

1. **Draft:** The first version, or draft version, is compiled after requirements have been discovered, recorded, classified, and prioritized.
2. **Proposed:** The draft document is then proposed as a potential requirements specification for the project. The proposed document will be reviewed by several parties, who may comment on any requirements and any priorities, either to agree, to disagree, or to identify missing requirements. Readers include end-users, developers, university faculty, course instructor, and any other stakeholders.
3. **Validated:** Once the various stakeholders have agreed to the requirements in the document, it is considered validated.
4. **Approved:** The validated document is accepted as an appropriate statement of requirements for the project. The developers then use the requirements document as a guide to implementation and to check the progress of the project as it develops.

1.3 Scope of the Product

The Portable Ruggedized Fluid Pump is envisioned as a compact, versatile, and ruggedized medical device designed to deliver multiple fluids simultaneously with configurable flow rates in high-stress scenarios such as military combat zones and pre-hospital care. It prioritizes reliability, user-friendliness, and adherence to stringent regulatory standards. It's remote control capabilities empower healthcare providers and medics, optimizing patient care. Our vision is to set new industry standards, surpass potential barriers, and provide a lifeline to those operating in the most challenging environments, starting with military healthcare providers and first responders, with future expansion into other healthcare sectors.

1.4 Case for the Product (Need)

The Portable Ruggedized Fluid Pump is indispensable to our clients, including military medical units and first responders, as it fulfills their critical goals of saving lives, optimizing resource utilization, and enhancing national defense and public safety. Its rapid and precise fluid infusion capabilities are vital in stabilizing patients suffering from severe hemorrhage, a life-saving intervention required in combat zones and pre-hospital care. By delivering multiple fluids simultaneously and accommodating configurable flow rates, the fluid pump not only improves patient outcomes but also reduces the strain on medical resources, aligning with resource optimization objectives. Furthermore, it enhances national defense by ensuring rapid and effective fluid infusion in challenging operational settings, making it an invaluable asset for military forces and emergency response teams engaged in disaster relief and humanitarian missions.

2. General Description

Our project, the Portable Ruggedized Fluid Pump, is a pioneering medical device designed to be a lifeline in the most challenging and critical situations. In simple terms, it is a compact, user-friendly, and robust infusion pump that delivers fluids precisely and rapidly. Whether it's a military combat medic administering life-saving fluids on the battlefield or a paramedic treating a severe injury in a pre-hospital setting, the fluid pump is engineered to save lives. Its capabilities go beyond traditional infusion pumps, offering remote control for real-time adjustments, making it adaptable to a wide range of medical scenarios. The Portable Ruggedized Fluid Pump is not just a device; it's a solution that empowers our heroes on the front lines of healthcare and defense, ensuring that timely and accurate fluid delivery is never a concern when every second counts.

2.1 Product Perspective

The client has chosen to develop the Portable Ruggedized Fluid Pump in response to a critical need in the medical and military sectors. The fluid pump addresses the urgent need for a reliable and adaptable fluid infusion solution in high-stress scenarios, such as military combat zones and pre-hospital care. The primary stakeholders include military medical units, combat medics, and first responders, who require immediate and precise fluid infusion to save lives. The project is being developed by a dedicated team of engineers, medical experts, and advisors, all driven by the common goal of creating a life-saving medical device. Ultimately, the finished product will benefit those on the front lines of healthcare and defense, enhancing patient outcomes, conserving resources, and contributing to national defense and public safety.

2.2 Product Functions

The Portable Ruggedized Fluid Pump is a multifunctional medical device designed to provide life-saving fluid infusion capabilities. Users can perform a range of critical activities while using the pump, including the precise and rapid delivery of multiple fluids simultaneously, which is vital for stabilizing patients suffering from severe hemorrhage. The device offers configurable flow rates, allowing users to adapt to varying medical requirements with ease. Additionally, the fluid pump boasts remote control capabilities, enabling healthcare providers to make real-time adjustments for optimal patient care. Its robust design, user-friendly interface, and adherence to stringent medical standards make it a versatile and indispensable tool for military healthcare providers, combat medics, first responders, and medical professionals across various healthcare settings.

2.3 User Characteristics

We anticipate that the Portable Ruggedized Fluid Pump will be primarily used by military healthcare providers, combat medics, first responders, and medical professionals in various healthcare settings. These users possess diverse technical backgrounds, ranging from medical training to military education, depending on their specific roles. Their motivation to use the device is rooted in the critical need for immediate, accurate, and adaptable fluid infusion to save lives, particularly in high-stress scenarios like combat zones or pre-hospital care. While the pump's user-friendly interface is designed to minimize obstacles, users may need training to operate the device effectively, especially in remote-controlled settings. Specialized skills may

include understanding the device's interface, interpreting vital signs, and adapting the fluid pump to varying medical needs and environmental conditions.

2.4 General Constraints

In the development of the Portable Ruggedized Fluid Pump, we are working under several constraints. One significant constraint is the need to ensure the device's compatibility with existing medical and military systems and standards. This requires rigorous adherence to regulatory requirements, such as FDA standards for medical devices and military protocols. We also have to consider the rugged operational environments in which the pump will be used, which influences design decisions regarding durability and resistance to extreme conditions. These constraints necessitate a highly specialized and interdisciplinary development approach, involving medical experts, engineers, and advisors to meet the project's objectives effectively.

2.5 Assumptions and Dependencies

In the development of the Portable Ruggedized Fluid Pump, we make several assumptions to guide the project effectively. We assume that the device's primary deployment environment is military combat zones, pre-hospital care settings, and various healthcare facilities, and that it needs to operate reliably in these challenging conditions. Additionally, we assume that the device's users have access to necessary training to operate the device, and that healthcare professionals and military personnel have basic technical skills to understand and use its interface effectively. Furthermore, we assume that the device's compatibility with existing medical and military systems and adherence to regulatory standards are crucial to its success. These assumptions influence our design and development decisions to ensure that the fluid pump meets the needs and expectations of its users and stakeholders.

2.6 Objectives

The primary objective is to enhance battlefield medical care by providing a portable, ruggedized fluid pump system that significantly improves the speed and efficiency of fluid infusion in far-forward military environments. Additionally, the project aims to optimize resource utilization by enabling the simultaneous infusion of multiple fluids for varied medical needs. User-friendly operation is a crucial focus, ensuring ease of use in high-stress situations, with the added benefit of remote control capabilities. Lastly, the project emphasizes compliance with rigorous medical and safety standards to guarantee the PRFP's quality, safety, and reliability.

1. Enhance Battlefield Medical Care:
   Improve the speed and efficiency of fluid infusion in far-forward military environments, addressing the critical need for rapid resuscitation in combat casualty care. The primary objective is to provide a portable, ruggedized fluid pump system that significantly enhances medical support for wounded soldiers, ultimately saving lives on the battlefield.
2. Optimize Resource Utilization:
   Enable combat medics and military healthcare providers to administer multiple fluids simultaneously at adjustable rates, supporting precise fluid management. The modular design allows the connection of multiple pumps, optimizing resource utilization by accommodating the infusion of different fluids for multiple patients or varied medical needs in challenging operational settings.

3. Ensure User-Friendly Operation:
   Design the Portable Ruggedized Fluid Pump (PRFP) to be user-friendly, particularly in high-stress situations commonly encountered in combat zones. The objective is to provide military healthcare professionals with a device that is easy to operate, allowing for quick and effective fluid delivery without compromising accuracy. Remote control capabilities further enhance usability, allowing adjustments and monitoring from a distance.
4. Compliance with Standards and Safety:
   Adhere to strict medical and safety standards, including FDA regulations and relevant industry standards. The objective is to ensure the PRFP meets the highest standards of quality, safety, and reliability. By complying with established regulations, the product aims to instill confidence in users, contribute to the overall safety of medical interventions, and facilitate seamless integration into existing military healthcare systems.

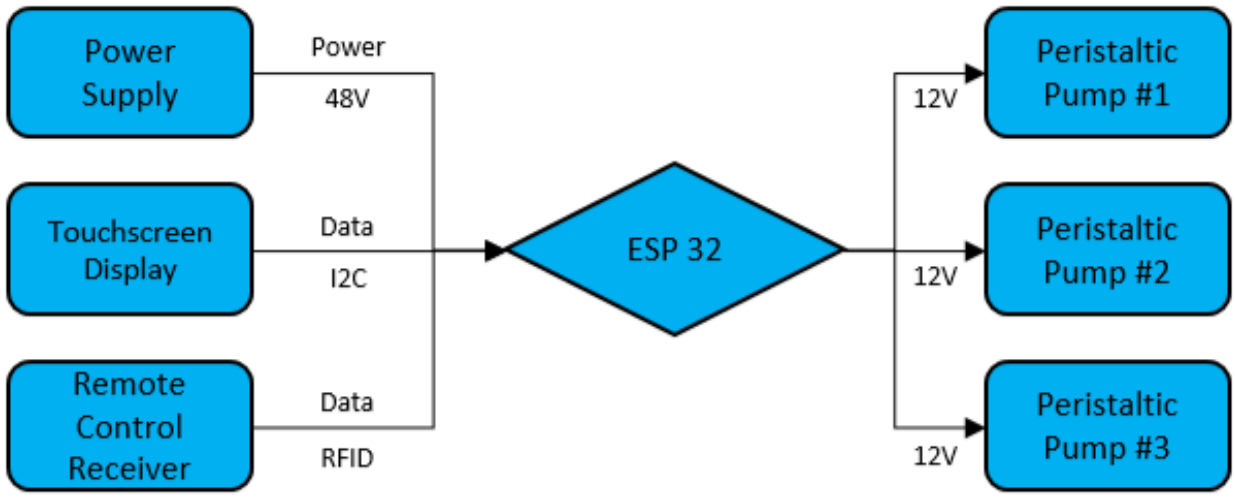

Figure 1:Function Block Diagram

2.7 Plan

In developing the Portable Ruggedized Fluid Pump, our team will implement a five phase plan encompassing research, design, prototyping, testing, and the final refinements. The research phase will delve into existing technologies and user needs, guiding subsequent design decisions. The design phase will translate these insights into a detailed plan, setting the stage for prototype development. Through rigorous testing, we will validate the PRFP's functionality, safety, and adherence to standards. The final touches phase will refine the device based on feedback,

ensuring it not only meets technological benchmarks but also serves as a user-friendly and reliable tool for military healthcare and emergency responders.

- **Research**
  In the research phase, the team will extensively explore existing technologies, medical device standards, and user needs related to fluid infusion in combat and emergency medical scenarios. This phase involves literature reviews, consultations with medical professionals and military experts, and a comprehensive analysis of available peristaltic pump technologies. The aim is to establish a solid understanding of the requirements, challenges, and potential solutions within the context of portable and ruggedized fluid pumps for combat casualty care.
- **Design**
  In the design phase, the team will translate the insights gained from research into a detailed plan for the Portable Ruggedized Fluid Pump (PRFP). This involves specifying the system architecture, selecting materials, designing the casing, and choosing peristaltic pumps with the necessary capabilities. The user interface, remote control features, and compliance with medical and safety standards will be key considerations. The design phase will culminate in a comprehensive blueprint that guides the subsequent stages of prototype development.
- **Prototyping**
  With the design specifications in hand, the team will move on to the prototype phase. This involves the physical realization of the PRFP, including the assembly of the casing, integration of pumps, implementation of the user interface, and incorporation of remote control functionalities. The modular design will be put into practice, allowing multiple units to be connected for simultaneous fluid infusion. This phase requires close collaboration between engineering and design teams to ensure that the prototype aligns with the established design principles.
- **Testing**
  The test phase is critical for validating the functionality, durability, and safety of the PRFP. Rigorous testing protocols will be employed to evaluate the performance of peristaltic pumps, assess the user interface's intuitiveness, verify remote control capabilities, and ensure compliance with medical standards. Testing will be conducted under simulated battlefield conditions and high-stress scenarios to simulate real-world usage. Any identified issues will trigger iterative improvements, ensuring that the PRFP meets the highest standards of reliability and precision.
- **Final Touches**
  In the final phase, the team will focus on refining the PRFP based on feedback from testing. This includes making adjustments to the user interface for enhanced usability, optimizing the modular design for seamless connectivity, and addressing any issues related to the remote control system. Documentation, including compliance records and user manuals, will be finalized. The goal is to ensure that the PRFP is not only a technologically advanced solution but also a user-friendly and reliable tool for combat medics, military healthcare providers, and emergency responders.

2.8 Schedule Requirements

The project schedule for the development of the project encompasses a series of critical tasks and milestones. These include design and prototyping phases, rigorous testing, regulatory compliance assessments, and ongoing refinement of the device. The schedule accounts for milestones such as the first draft of the final report, which is estimated to be due approximately one month before finals, and the first demonstration of the fluid pump prototype, scheduled about three weeks before finals. We have established a structured timeline that allocates time to each task, ensuring that we meet deliverable dates and adhere to the project's established objectives.

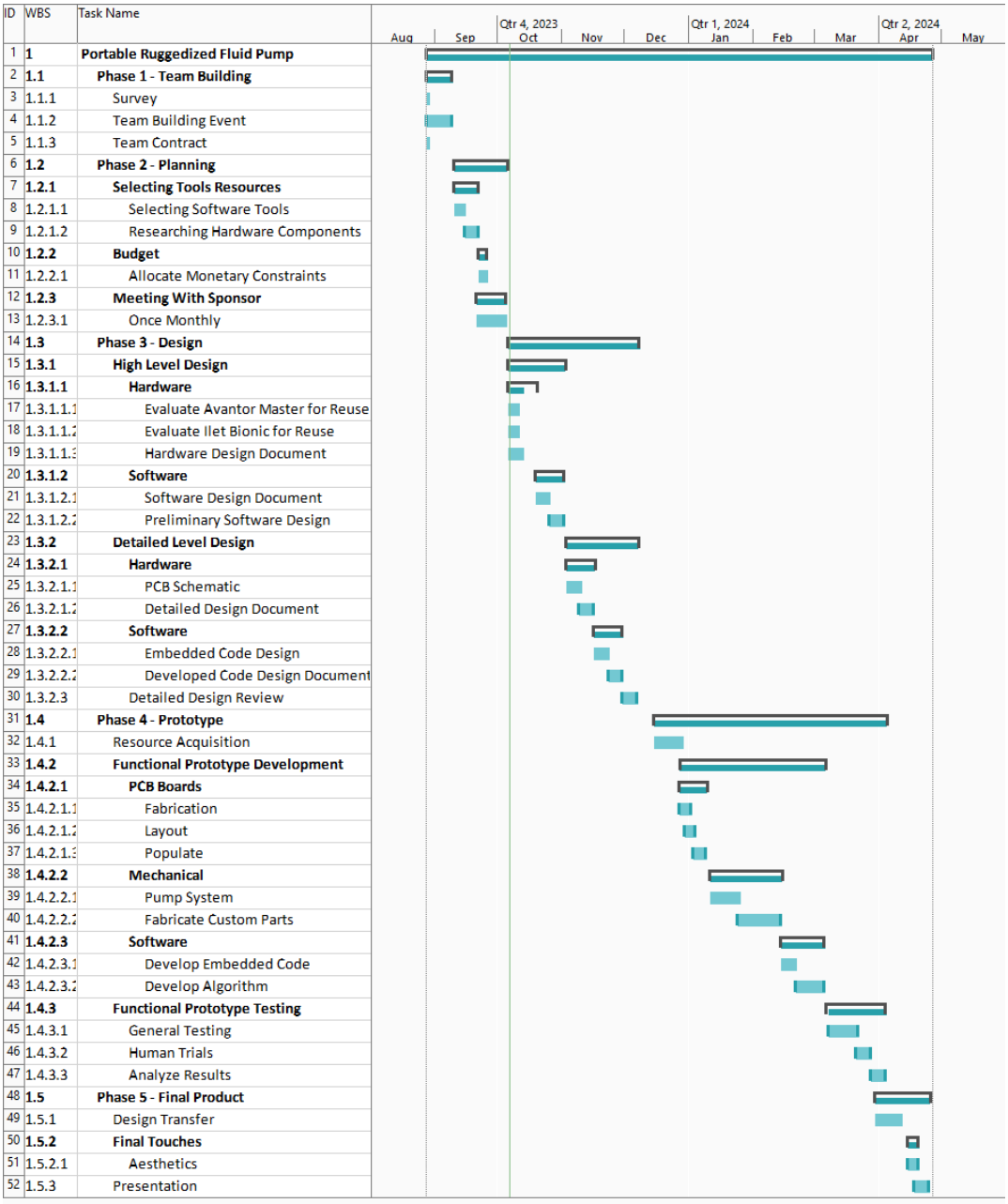

Figure 2: Gantt Chart

3. Specific Requirements and Specifications

This section of the document lists specific requirements and specifications for the Portable Ruggedized Fluid Pump. Requirements and specifications are divided into the following sections:

1. User requirements and specifications. These are requirements and specifications written from the point of view of end users, usually expressed in narrative form.
2. System requirements and specifications. These are detailed requirements and specifications describing the functions the system must be capable of doing.
3. Interface requirements and specifications. These are requirements and specifications about the user interface, which may be expressed as a list, as a narrative, or as images of screen mock-ups.

3.1 User Requirements and Specifications

3.1.1 User interface

- 3.1.1.1 The user interface must feature a rugged touchscreen display with a minimum size of 5 inches for easy readability and operation in challenging environments.
- 3.1.1.2 It will provide an intuitive and user-friendly interface that allows quick access to key functions without extensive training.
- 3.1.1.3 The touchscreen display must be daylight-readable, ensuring visibility even in bright sunlight to facilitate outdoor use.
- 3.1.1.4 The interface will incorporate a simple navigation menu for seamless access to different operational modes and settings.
- 3.1.1.5 It must include a visual indicator for battery status, ensuring users are aware of the remaining power for reliable operation.
- 3.1.1.6 The touchscreen will support gloved and wet operation to accommodate various environmental conditions.
- 3.1.1.7 The user interface must offer configurable settings for fluid infusion parameters, allowing healthcare providers to adjust rates based on patient needs.
- 3.1.1.8 The display will be customizable, enabling users to prioritize and arrange information based on their preferences and workflow.
- 3.1.1.9 The user interface must support remote control capabilities, allowing users to adjust settings and monitor the system from a distance, enhancing operational flexibility.

3.1.2 Ergonomics

- 3.1.2.1 The device must have a compact and lightweight design, weighing no more than 5 pounds, to facilitate easy portability by healthcare providers in challenging environments.
- 3.1.2.2 It will feature an ergonomic handle or grip for comfortable and secure one-handed operation during fluid infusion procedures.
- 3.1.2.3 The device casing will be ruggedized and impact-resistant to withstand harsh conditions in military and pre-hospital settings.
- 3.1.2.4 The tubing connectors, including Luer Lock fittings, must be easily accessible and designed for quick and secure attachment to standard IV systems.

3.1.2.5 The ergonomics will support both tabletop and handheld use, providing flexibility in different medical scenarios.
3.1.2.6 The device will have a low noise level during operation, minimizing disruption in quiet or sensitive environments.
3.1.2.7 It must be designed with an integrated cable management system to prevent entanglement and ensure safe and organized use.
3.1.2.8 The tubing and connectors will be color-coded or labeled for easy identification, reducing the risk of errors during fluid administration.
3.1.2.9 The device will be compatible with standard medical equipment, such as IV stands and mounts, for seamless integration into existing healthcare setups.

3.1.3 Training or skills required
3.1.3.1 The device will be designed with an intuitive user interface, minimizing the need for extensive training and enabling healthcare providers to operate it with basic proficiency.
3.1.3.2 Training materials, including user manuals and online resources, must be comprehensive and easily accessible to facilitate quick onboarding of new users.
3.1.3.3 The training materials must cover device troubleshooting procedures, empowering users to address common issues independently.
3.1.3.4 The system will include a user authentication feature with different access levels, ensuring that only trained personnel can operate advanced settings.
3.1.3.5 The device will support remote training sessions or webinars to provide ongoing education and updates to healthcare providers.
3.1.3.6 Regular training and certification programs will be available, either online or through organized sessions, to keep healthcare providers up-to-date with the device's features and best practices.
3.1.3.7 The device will have a user-friendly error messaging system, providing clear and actionable information to assist users in identifying and resolving issues promptly.
3.1.3.8 The device will be designed to align with established medical protocols and standards, reducing the learning curve for healthcare providers already familiar with industry norms.

3.2 System Requirements and Specifications

3.2.1 Physical Characteristics
3.2.1.1 The device, designed for portability, will be compact and lightweight, fitting comfortably within a rucksack, with dimensions not exceeding 14 inches in length, 10 inches in width, and 6 inches in height.
3.2.1.2 Constructed with robust and impact-resistant materials, the device will meet military-grade standards, ensuring durability and protection of internal components during transportation and field use.
3.2.1.3 The device casing must achieve an IP67 or higher rating for dust and water resistance, safeguarding its functionality in diverse environmental conditions and when exposed to the elements

3.2.1.4 The rucksack-contained device will feature a user-friendly touchscreen display of at least 5 inches, with anti-glare technology for optimal visibility in outdoor and high-light scenarios.
3.2.1.5 The tubing and connectors must be made from medical-grade, sterilizable materials, ensuring compatibility with standard IV systems and maintaining hygiene within the confined space of the rucksack.
3.2.1.6 It will have an ergonomic design, facilitating easy access to essential controls, and incorporating a secure and comfortable grip for one-handed operation by healthcare providers in the field.
3.2.1.7 The integrated cable management system is crucial to prevent entanglement and ensure safe and organized use within the limited space of the rucksack.
3.2.1.8 The overall weight of the device, including the battery and essential components, will not exceed 30 pounds, considering the capacity and comfort of the healthcare provider carrying the rucksack.
3.2.1.9 The system will support easy integration with the rucksack, allowing for secure attachment and stability during movement, ensuring the safety of both the device and the healthcare provider.

3.2.2 Material Requirements

3.2.2.1 All external casing materials must comply with military-grade standards, providing durability and impact resistance to protect internal components in field conditions.
3.2.2.2 The device's external surfaces and components will be resistant to common cleaning agents and disinfectants used in medical environments, ensuring easy and effective sterilization.
3.2.2.3 Tubing and connectors must be made from medical-grade materials compatible with standard IV systems, facilitating hygienic fluid delivery and preventing adverse reactions.
3.2.2.4 All internal electronic components will be designed with military-grade specifications to withstand temperature variations, vibration, and shocks experienced in combat and field environments.
3.2.2.5 The touchscreen display will feature scratch-resistant and anti-glare materials, ensuring optimal visibility and usability in outdoor and high-light conditions.
3.2.2.6 All materials used in the device construction must be free from hazardous substances, meeting relevant environmental and safety regulations.
3.2.2.7 The rucksack housing the device will be made from water-resistant and durable materials, providing additional protection during transport and field use.
3.2.2.8 Materials used for cable management within the device will be flexible, durable, and resistant to wear, ensuring long-term functionality in confined spaces.
3.2.2.9 The battery housing will be constructed with fire-resistant materials to enhance overall safety during operation and transport in various environments.

3.2.3 Electrical Requirements

3.2.3.1 The device will be powered by a rechargeable battery with a voltage capacity of 48V, providing a minimum of 8 hours of continuous operation to meet field-use demands.
3.2.3.2 Electrical components must comply with military-grade standards for reliability and durability, ensuring consistent performance in challenging environmental conditions.
3.2.3.3 The device will include a built-in power management system to optimize energy efficiency and extend battery life during operation.
3.2.3.4 The battery will support both AC outlet recharging and alternative power sources for versatility in charging options, accommodating varied field conditions.
3.2.3.5 All electrical connections and components must be insulated and protected to prevent electrical malfunctions or safety hazards during operation.
3.2.3.6 The touchscreen display will be equipped with efficient backlighting to ensure visibility in low-light conditions without compromising battery life.
3.2.3.7 The electrical system will feature fail-safe mechanisms to prevent damage in case of power surges, fluctuations, or unexpected voltage variations.

3.2.4 Abilities

3.2.4.1 The device will have the ability to simultaneously deliver multiple fluids at configurable flow rates, ensuring versatile and precise fluid management in combat and emergency medical scenarios.
3.2.4.2 It must be capable of remote control operation, allowing healthcare providers to adjust settings and monitor the device from a distance, enhancing flexibility and adaptability in the field.
3.2.4.3 The system will support modular expansion, enabling the connection of multiple devices to accommodate the simultaneous treatment of multiple patients or the infusion of different fluids.
3.2.4.4 The device must offer a user-friendly interface on the touchscreen display, allowing for intuitive and efficient operation by healthcare providers in high-stress environments.
3.2.4.5 It will have the ability to integrate with existing military medical systems and protocols, ensuring seamless compatibility and efficient incorporation into broader healthcare infrastructure.
3.2.4.6 The device will be designed with an ergonomic interface, facilitating easy one-handed operation by healthcare providers in challenging field conditions.
3.2.4.7 The device will incorporate a robust cable management system to prevent entanglement and ensure safe and organized use during operation and transport.
3.2.4.8 It will have the ability to operate quietly, emitting minimal noise to maintain a low acoustic profile in the field and avoid unnecessary attention in sensitive operational settings.
3.2.4.9 The system will feature automated alarms and notifications to alert healthcare providers to any abnormalities or issues, enhancing overall safety and awareness during operation.

3.2.5 Limitations

3.2.5.1 The device will not exceed a weight limit of 20 kilograms, ensuring portability and compliance with military carry-load standards for healthcare providers operating in the field.
3.2.5.2 The maximum dimensions of the device will not exceed 30 cm x 20 cm x 15 cm, facilitating easy storage within a standard military-issue rucksack without occupying excessive space.
3.2.5.3 The device will be designed to operate within a temperature range of -20°C to 50°C, ensuring functionality in both extreme cold and hot environments commonly encountered in military operations.
3.2.5.4 The touchscreen display will have an operating limit for ambient light conditions, maintaining optimal visibility in outdoor settings with up to 10,000 lux.
3.2.5.5 The rechargeable battery will not exceed a weight of 10 kilograms and a size of 15 cm x 10 cm x 5 cm, ensuring it remains lightweight and portable while providing a minimum of 8 hours of continuous operation.
3.2.5.6 The device's remote control system will have a specified range of at least 100 meters, maintaining effective communication between the device and the healthcare provider in the field.
3.2.5.7 The system's electrical components will be designed to minimize electromagnetic interference, complying with MIL-STD-461G to prevent disruptions to nearby electronic equipment.
3.2.5.8 The device will not compromise patient safety, with features in place to prevent over-infusion, under-infusion, or other risks associated with fluid delivery, adhering to ISO 14971 risk management standards.

3.2.6 Equipment or materials required to use the product
3.2.6.1 The device requires medical-grade tubing made of biocompatible materials, compliant with ISO 10993 standards, to ensure safe and sterile fluid delivery to patients.
3.2.6.2 Luer Lock connectors must be used to connect the device to standard IV systems, ensuring a secure and standardized interface for fluid transfer.
3.2.6.3 The touchscreen display will be made of shatterproof and scratch-resistant materials, meeting MIL-STD-810H standards for durability in military environments.
3.2.6.4 The remote control system will include RFID technology for secure and user-friendly communication with the device, enhancing operational flexibility in the field.
3.2.6.5 The rucksack housing the device will be constructed from ruggedized and water-resistant materials, providing protection against environmental factors during transport and storage.
3.2.6.6 The rechargeable battery must be swappable and comply with industry standards, allowing easy replacement and ensuring compatibility with the device's power requirements.
3.2.6.7 The peristaltic pumps will be lightweight and compact, constructed from durable materials capable of withstanding the demands of military field operations.

3.2.6.8 All external components, including buttons and connectors, will be sealed against dust and moisture, meeting IP67 standards to enhance the device's resilience in challenging environments.

3.2.7 Equipment interface requirements

3.2.7.1 The device will have USB and Ethernet ports for data transfer and connectivity with external devices, following industry standards for versatility in communication.

3.2.7.2 The touchscreen display must support multi-touch functionality and provide a user-friendly interface with intuitive navigation, enhancing the interaction between the healthcare provider and the device.

3.2.7.3 The remote control system will have a secure wireless interface using RFID technology, allowing seamless communication with the device within a specified range.

3.2.7.4 The device will be compatible with standard medical connectors, such as ISO 80369 Luer Locks, ensuring interoperability with existing medical equipment and systems.

3.2.7.5 The microcontroller will have communication ports compatible with common protocols like UART, SPI, and I2C, enabling integration with various sensors and components.

3.2.7.6 The device's data interface must comply with relevant military communication standards, ensuring secure and reliable data transmission in military environments.

3.2.7.7 The remote control system will feature a user-friendly interface with tactile buttons and visual indicators, allowing healthcare providers to control the device efficiently in the field.

3.2.8 Handling and storage requirements

3.2.8.1 The device must be stored within a temperature range of -40°C to 60°C, ensuring functionality in diverse environmental conditions.

3.2.8.2 The device will withstand humidity levels between 10% and 90% during both operation and storage, maintaining reliability in varied climates.

3.2.8.3 The system must be designed to endure transportation vibrations and shocks, adhering to military standards for resilience during movement in field conditions.

3.2.8.4 The rucksack housing the device must provide secure and padded compartments for each component, minimizing the risk of damage during transportation and storage.

3.2.8.5 The device's touchscreen display will incorporate a protective cover or case for safe storage, preventing scratches or damage to the screen when not in use.

3.2.8.6 All electronic components, including the microcontroller and pumps, must be securely mounted within the device to resist damage caused by impact during handling and transportation.

3.2.8.7 The device will be resistant to electromagnetic interference (EMI), ensuring stable operation in environments with potential electronic disturbances.

3.2.8.8 The rucksack must be water-resistant, safeguarding the device from environmental elements and ensuring its functionality in rain or wet conditions.

3.2.8.9 The device's internal components, such as the battery and pumps, will have specific storage conditions outlined in their respective manuals to prolong their lifespan and performance.

3.2.9 Cleaning and Sterilization

3.2.9.1 All external surfaces of the device, including the touchscreen display and housing, must be resistant to common cleaning agents, allowing for easy and effective decontamination.

3.2.9.2 The device's medical-grade tubing and connectors will be designed for sterilization using standard methods such such as autoclaving or chemical sterilants, meeting medical hygiene standards.

3.2.9.3 The device's user interface components, such as buttons and touch surfaces, must be constructed from materials that can withstand regular cleaning and disinfection procedures without degradation.

3.2.9.4 The rucksack housing the device will be made from materials that allow for easy cleaning and decontamination, ensuring that it remains sanitary in field environments.

3.2.9.5 The device's user manual will provide clear instructions on recommended cleaning and sterilization procedures, ensuring proper maintenance and adherence to medical hygiene standards.

3.2.10 Product maintenance and serviceability

3.2.10.1 The device will have a modular design that allows for easy replacement of individual components, facilitating swift maintenance and minimizing downtime in the field.

3.2.10.2 All components, including pumps, will be easily accessible for routine maintenance tasks such as inspection, cleaning, and replacement if necessary.

3.2.10.3 The device's battery will be designed for straightforward removal and replacement, ensuring uninterrupted operation with minimal service disruption.

3.2.10.4 The device will be equipped with self-diagnostic features to identify potential issues, enabling proactive maintenance and reducing the risk of unexpected failures.

3.2.10.5 The device's housing will be designed with durability in mind, minimizing wear and tear to extend the overall lifespan and reduce the frequency of maintenance needs.

3.2.10.6 Critical components, such as the microcontroller, will have firmware upgrade capabilities, allowing for the installation of software updates to enhance performance and address potential issues.

3.2.10.7 The device's tubing and connectors will be designed for easy replacement, ensuring quick and efficient repairs in the event of wear, damage, or contamination.

3.2.10.8 The device's user manual will include clear and detailed instructions on routine maintenance procedures, empowering users to perform basic tasks without extensive technical expertise.

3.2.10.9 The device's maintenance schedule will be outlined in the user manual, specifying recommended intervals for routine checks and servicing to ensure long-term reliability and performance.

3.2.11 Operating parameters

3.2.11.1 The device will operate within a temperature range of -20°C to 50°C, ensuring functionality in diverse environmental conditions encountered in military and pre-hospital settings.

3.2.11.2 The operating humidity range for the device will be 10% to 90%, allowing reliable performance in various climates without compromising internal components.

3.2.11.3 The device's tolerance to transportation vibration will adhere to military standards, ensuring stability and functionality during transport in rugged conditions.

3.2.11.4 The device will be designed to operate at altitudes ranging from sea level up to 15,000 feet, meeting the requirements for use in diverse geographic locations.

3.2.11.5 The device will be impact-resistant, capable of withstanding falls from a height of at least 5 meters without compromising its functionality.

3.2.11.6 The device's pressure resistance will comply with medical safety standards, ensuring integrity and performance during operation in various scenarios.

3.2.11.7 The device's fluid infusion rates will be adjustable within 50 to 200 mL/min, allowing for precise control tailored to different medical requirements.

3.2.12 Repeatability and reproducibility

3.2.12.1 The device will demonstrate a high level of repeatability, consistently delivering fluids within a narrow margin of the set flow rate under various operating conditions.

3.2.12.2 Reproducibility of fluid delivery will be maintained across different devices, ensuring consistency in performance and allowing for interchangeability of components.

3.2.12.3 The device's user interface will provide real-time feedback on fluid delivery parameters, allowing users to monitor and verify the repeatability of the infusion process.

3.2.12.4 The pumps will be designed to minimize variations in fluid flow, especially during changes in environmental conditions such as temperature and humidity.

3.2.12.5 The device's calibration process will be well-defined and easily repeatable, ensuring accurate and consistent fluid delivery across multiple uses.

3.2.12.6 The device will undergo rigorous testing for repeatability and reproducibility during the prototype and validation phases, ensuring it meets established performance standards.

3.2.12.7 Regular calibration checks and maintenance routines will be outlined in the user manual, providing users with guidelines to maintain optimal repeatability over the device's lifespan.

3.2.13 Reliability

3.2.13.1 The device will demonstrate high reliability, with a low probability of failure during critical operations, ensuring consistent performance in demanding military and emergency medical scenarios.

3.2.13.2 All electrical components, including the microcontroller and power supply, will be designed for robustness and reliability in harsh environmental conditions.

3.2.13.3 The pumps' mechanical components, such as tubing and connectors, will undergo rigorous testing to ensure durability and resistance to wear, contributing to the overall reliability of the fluid delivery system.

3.2.13.4 The device will include redundant safety features to mitigate the impact of potential failures and ensure uninterrupted fluid delivery in emergency situations.

3.2.13.5 Regular self-diagnostic checks will be integrated into the device's firmware, providing continuous monitoring of key components and identifying potential issues before they compromise reliability.

3.2.13.6 The device's design will incorporate fail-safe mechanisms to prevent catastrophic failures, ensuring that critical functions are maintained even in the presence of component malfunctions.

3.2.14 Mechanical safety features

3.2.14.1 The device will incorporate a robust and tamper-resistant housing to protect internal components from physical damage and unauthorized access, ensuring the safety and integrity of the system.

3.2.14.2 All mechanical components, including pumps, tubing, and connectors, will be designed to withstand impact forces and vibrations typical in military and emergency medical environments, preventing potential failures due to mechanical stress.

3.2.14.3 The device will include fail-safe mechanisms in the pump system to automatically halt fluid delivery in the event of mechanical malfunctions, minimizing the risk of injury to patients and preventing unintended fluid administration.

3.2.14.4 The device will undergo thorough mechanical testing, including impact resistance and durability assessments, to ensure it meets established safety standards and can withstand the rigors of field use.

3.2.14.5 All mechanical components that come into direct contact with patients, such as connectors and infusion sets, will be designed with smooth surfaces and rounded edges to prevent abrasions or injuries during use.

3.2.14.6 The device's housing will be constructed from materials that comply with relevant safety regulations and standards for medical devices, ensuring biocompatibility and patient safety.

3.2.14.7 The pump system will include protective features to prevent overpressure or excessive force during fluid delivery, minimizing the risk of damage to vascular structures and enhancing overall patient safety.

3.2.15 Electrical safety features

3.2.15.1 The device will incorporate electrical components and wiring that adhere to established safety standards, such as IEC 60601, to ensure electrical safety and compliance with medical device regulations.

3.2.15.2 All electrical connections and interfaces will be designed with safety mechanisms, such as insulation and shielding, to prevent electrical leakage and reduce the risk of electrical shocks to users or patients.

3.2.15.3 The device will include built-in protection circuits and fail-safe mechanisms to detect and respond to electrical faults, automatically shutting down the system in the event of malfunctions to prevent potential hazards.

3.2.15.4 All power supplies and electronic components will be enclosed within the device's housing, providing insulation and protection against environmental factors, minimizing the risk of electrical failures due to exposure to moisture or dust.

3.2.15.5 The electrical design will incorporate grounding and bonding techniques to ensure proper electrical continuity and reduce the risk of electrostatic discharge, enhancing overall safety during operation.

3.2.15.6 The device will undergo rigorous electrical safety testing, including insulation resistance and dielectric strength assessments, to verify compliance with applicable safety standards and regulations.

3.3 Interface Requirements and Specifications

3.3.1 Graphical User Interface (GUI):

3.3.1.1 The GUI will provide a clear and intuitive layout, presenting essential information such as fluid infusion rates, system status, and alarms in a visually accessible format for quick comprehension by users.

3.3.1.2 The GUI will include configurable settings, allowing users to customize parameters such as flow rates, volume limits, and alarm thresholds, ensuring flexibility to adapt to various medical scenarios and patient needs.

3.3.1.3 Interactive touch elements on the GUI, such as buttons and sliders, will be appropriately sized and spaced to facilitate precise input, minimizing the risk of user errors, particularly in high-stress situations or when wearing gloves.

3.3.1.4 The GUI will incorporate a color-coded system for visual alerts and alarms, using distinct colors and symbols to convey different levels of urgency and facilitate rapid decision-making by users.

3.3.1.5 To enhance user engagement, the GUI will support multi-language options, enabling medical personnel from diverse linguistic backgrounds to operate the device efficiently.

3.3.1.6 The graphical elements and text on the GUI will be legible, even in varying lighting conditions, ensuring optimal visibility and reducing the likelihood of misinterpretation in both indoor and outdoor settings.

3.3.1.7 The interface will feature a secure login system with user authentication to restrict access to authorized personnel only, ensuring patient data privacy and preventing unauthorized adjustments to critical settings.

3.3.1.8 To streamline the user's workflow, the GUI will offer a history log or event log, displaying a record of recent actions, alarms, and system events, aiding in troubleshooting and facilitating a comprehensive overview of device usage.

3.3.1.9 The GUI will incorporate a timer or countdown display during fluid infusion, allowing users to monitor the progress and estimate the time remaining for the completion of the infusion process.

3.3.1.10 Accessibility features, such as adjustable font sizes and contrast settings, will be implemented in the GUI to accommodate users with varying visual abilities and preferences, promoting an inclusive and user-friendly design.

3.3.2 Touchscreen Display:

3.3.2.1 The touchscreen display will be of rugged design, featuring durable materials and a protective layer to withstand harsh environmental conditions, including potential impacts, scratches, and exposure to moisture or contaminants.

3.3.2.2 The display interface will be user-friendly, with an intuitive touch response that allows for easy navigation and operation, facilitating quick access to essential functions without causing user confusion or frustration.

3.3.2.3 The touchscreen will have an appropriate size and resolution, providing a clear and readable display of information, including fluid infusion rates, system status, and alerts, to ensure effective communication with users in both indoor and outdoor settings.

3.3.2.4 The display will incorporate a backlight or adjustable brightness settings to maintain visibility in varying lighting conditions, enabling users to interact with the device accurately and comfortably.

3.3.2.5 Touchscreen controls and buttons will be large enough to facilitate precise input, reducing the risk of accidental touches or errors, and will be responsive to accommodate users wearing gloves or in high-stress situations.

3.3.2.6 The display interface will include clear and concise graphical elements, icons, and text to convey information effectively, enhancing user understanding and minimizing the need for extensive training.

3.3.2.7 To ensure ease of cleaning and maintenance, the touchscreen will be designed with a smooth, non-porous surface that resists the accumulation of dirt, fluids, or contaminants, promoting a hygienic and sterile environment.

3.3.2.8 The touchscreen display will support multi-touch capabilities, allowing users to perform simultaneous gestures or inputs for efficient and intuitive interaction with the device.

3.3.2.9 A configurable user interface will enable customization of settings and preferences, accommodating individual user preferences and diverse operational requirements in different medical scenarios.

3.3.2.10 The display will incorporate visual indicators and alarms, using color-coded alerts, symbols, and audible signals to effectively communicate critical information, ensuring prompt user response in emergency situations.

3.3.3 Remote Control System:

3.3.3.1 The remote control system will provide a reliable wireless connection with a range of at least 10 meters, ensuring flexibility and freedom of movement for medical personnel during fluid infusion procedures.

3.3.3.2 It will feature a user-friendly interface with intuitive controls, allowing users to adjust infusion parameters, start/stop infusions, and respond to alarms efficiently, even in high-stress situations.

3.3.3.3 The remote control will include a clear and informative display or indicator for real-time feedback on the status of the fluid infusion, alarm notifications, and battery level, enhancing user awareness and facilitating quick decision-making.

3.3.3.4 To ensure security and prevent unauthorized access, the remote control system will implement secure authentication mechanisms, such as password protection or biometric verification, restricting usage to authorized personnel.

3.3.3.5 The remote control will be compact, lightweight, and designed for easy handling, accommodating the user's need for a portable and ergonomic solution that complements the dynamic nature of medical interventions in diverse environments.

3.3.3.6 It will support multi-device connectivity, allowing one remote control unit to operate multiple PRFP units simultaneously, facilitating the management of multiple patients or the infusion of different fluids.

3.3.3.7 The remote control system will be equipped with a durable and rechargeable battery, providing sufficient power for extended use without compromising the device's overall performance.

3.3.3.8 To enhance user convenience, the remote control will include a dedicated emergency stop or pause button, enabling immediate intervention in critical situations or the need for a sudden cessation of fluid infusion.

3.3.3.9 The system will have built-in safeguards against interference or signal disruption, ensuring the reliable and uninterrupted communication between the remote control and the PRFP in challenging operational environments.

3.3.3.10 The remote control system will comply with relevant medical device standards and regulations, prioritizing safety, accuracy, and reliability in its design and functionality.

3.3.4 Configurable Flow Rate:

3.3.4.1 The Portable Ruggedized Fluid Pump (PRFP) will feature a configurable flow rate with a broad range, allowing medical personnel to precisely adjust the infusion speed to match the specific needs of each patient and clinical scenario.

3.3.4.2 The configurable flow rate setting will be easily accessible and adjustable through the device's user interface, providing a straightforward and intuitive control mechanism for healthcare providers.

3.3.4.3 The PRFP will include a real-time display of the selected flow rate, ensuring immediate feedback to medical personnel and facilitating accurate monitoring and adjustment during fluid infusion procedures.

3.3.4.4 To meet diverse clinical requirements, the configurable flow rate will support both continuous and intermittent infusion modes, providing flexibility in adapting to different treatment protocols and patient conditions.
3.3.4.5 The device will incorporate preset flow rate profiles or modes for common medical applications, streamlining the configuration process and allowing quick selection of infusion parameters based on standard clinical practices.
3.3.4.6 The configurable flow rate settings will be stored in the device's memory, enabling the PRFP to retain user-defined preferences and minimizing the need for repeated adjustments during consecutive infusions.
3.3.4.7 The system will have the capability to handle simultaneous infusion of multiple fluids with independent flow rate control, enhancing its versatility in scenarios where patients require concurrent administration of different resuscitation fluids.
3.3.4.8 The PRFP will include safety features, such as audible and visual alarms, to alert medical personnel in case of flow rate irregularities, ensuring prompt response to potential issues and maintaining the safety of the infusion process.
3.3.4.9 The configurable flow rate will be adjustable in small increments or steps, allowing for fine-tuning of infusion parameters and catering to the precise requirements of diverse medical treatments.
3.3.4.10 The device's configurable flow rate functionality will comply with relevant medical device standards and regulations, ensuring that it meets the necessary safety and performance requirements for clinical use.

3.4 Environmental Conditions

3.4.1 Temperature
- 3.4.1.1 Operating
  - 3.4.1.1.1 Peristaltic Pumps: -20°C to 50°C
  - 3.4.1.1.2 Rechargeable Battery: -20℃ to 60℃
  - 3.4.1.1.3 Microcontroller: -40℃ to 85℃
- 3.4.1.2 Storage
  - 3.4.1.2.1 Peristaltic Pumps: -40°C to 60°C
  - 3.4.1.2.2 Rechargeable Battery: 20℃
  - 3.4.1.2.3 Microcontroller: -40℃ to 85℃

3.4.2 Humidity
- 3.4.2.1 Operating:
  - 3.4.2.1.1 Peristaltic Pumps: 20% to 95% RH (non-condensing)
  - 3.4.2.1.2 Rechargeable Battery: 10% to 90% RH (non-condensing)
  - 3.4.2.1.3 Microcontroller: 5% to 95% RH (non-condensing)
- 3.4.2.2 Storage:
  - 3.4.2.2.1 Peristaltic Pumps: 10% to 95% RH (non-condensing)
  - 3.4.2.2.2 Rechargeable Battery: 5% to 90% RH (non-condensing)
  - 3.4.2.2.3 Microcontroller: 5% to 95% RH (non-condensing)

3.4.3 Shipping, transportation vibration

3.4.3.1 Able to withstand vibrations typically encountered during shipping and transportation.

3.4.4 Pressure and Altitude
- 3.4.4.1 Designed to operate at sea level and up to 3,000 meters above sea level.
- 3.4.4.2 Pressure tolerance to handle variations in atmospheric pressure during air travel.

3.4.5 Electromagnetic Interference
- 3.4.5.1 Shielded against common electromagnetic interference (EMI) sources.
- 3.4.5.2 Compliance with applicable EMI standards for medical devices.

3.4.6 Electrostatic Discharge
- 3.4.6.1 Built to withstand electrostatic discharge (ESD) encountered in military settings.
- 3.4.6.2 Compliance with ESD protection standards, such as IEC 61000-4-2.

3.4.7 Impact Resistance
- 3.4.7.1 Designed to resist impact forces resulting from drops and rough handling.
- 3.4.7.2 Meets industry standards for impact resistance in military equipment.

3.5 Manufacturing

3.5.1 Cost
- 3.5.1.1 Peristaltic Pumps: $300
- 3.5.1.2 ESP32: $20
- 3.5.1.3 Battery: $200
- 3.5.1.4 Luer Lock Connectors: $15
- 3.5.1.5 Sterilized Tubing: $50
- 3.5.1.6 Display: $500
- 3.5.1.7 Remote Control: $150

3.5.2 Environmental requirements for production
- 3.5.2.1 A sterilized and well-ventilated environment will be needed for the production of the prototype.

3.5.3 Raw materials and suppliers
- 3.5.3.1 PETG Filament
- 3.5.3.2 Solder
- 3.5.3.3 Tubing
- 3.5.3.4 Disinfectants
- 3.5.3.5 Digikey
- 3.5.3.6 Avantor
- 3.5.3.7 Amazon

3.5.4 Test methods, standards
- 3.5.4.1 Fluid Infusion Rate Accuracy Test

3.5.4.2 Ruggedness and Durability Test
3.5.4.3 Remote Control Communication Reliability Test
3.5.4.4 User Interface Test
3.5.4.5 Battery Performance Test

3.6 Packaging

3.6.1 Packaging Configurations

3.6.1.1 Rucksack Integration: The Portable Ruggedized Fluid Pump (PRFP) will be configured to fit seamlessly within a rucksack, ensuring a compact and portable design for easy transportation in diverse operational environments.

3.6.1.2 Battery Safety Measures: The battery integrated into the PRFP must have insulating material between the contacts to prevent electrical issues and ensure safe handling.

3.6.1.3 Battery Charge Limit: The battery must be shipped with a charge level below 30% to comply with safety regulations and reduce the risk of incidents during transportation.

3.6.2 Packaging Materials

3.6.2.1 Protective Cushioning: The packaging will include Instapak expanding anti-static materials strategically placed around the PRFP, providing effective cushioning and electrostatic discharge protection.

3.6.3 Special Shipment Requirements

3.6.3.1 Hazard Labeling: The packaging will prominently display a Class 9 Battery Hazard Label to communicate the presence of batteries and associated risks.

3.6.3.2 UN 3481 Label: The packaging will feature a UN 3481 Label to indicate the classification of lithium-ion batteries for safe and regulated transport.

3.6.3.3 Shipping Restrictions: The PRFP will be designated for ground shipping only within the domestic USA to comply with safety regulations and transportation restrictions related to battery-powered devices.

3.7 Labeling

3.7.1 Detail intended use, warning, directions for use, cleaning, expiration date

3.7.1.1 The PRFP will feature prominent warning labels to address potential hazards. These include electrical hazard warnings, cautions to keep hands clear when the equipment is running, reminders about rotating machinery, and instructions not to clean or repair the machinery while in motion.

3.7.2 Identify target audience for labeling

3.7.2.1 Targeted labeling will cater to key stakeholders involved in the PRFP's operation, including transport carriers responsible for logistics, caregivers overseeing patient care, and end-users utilizing the device.

3.7.3 Language requirements

3.7.3.1 The PRFP will provide a physical manual in English for immediate reference. Additionally, a downloadable PDF manual will be made available in various languages for comprehensive understanding and usage guidance.

3.8 Regulatory

3.8.1 Clinical trials

3.8.1.1 They are crucial for gathering data to support regulatory submissions and determine if a product is safe and effective for use.

3.8.2 Submission type

3.8.2.1 Examples include new drug applications, premarket approval for medical devices, or marketing authorization applications.

3.8.3 CE mark

3.8.3.1 It allows the product to be legally placed on the market within the European Economic Area.(EEA).

3.8.4 US and international standards

3.8.4.1 The PRFP must follow FDA medical devices safety regulations.

3.8.5 Patent issues

3.8.5.1 A thorough patent search and clearance are essential to avoid legal challenges and ensure intellectual property protection.

3.8.6 Existing technology to avoid

3.8.6.1 This assessment helps navigate potential legal issues and promotes innovation within legal boundaries.

4. Appendices

N/A

5. Glossary

PRFP - The acronym for the Portable Ruggedized Fluid Pump, the main subject of the project.
Combat Casualty Care - The specialized medical care provided in combat zones to manage and treat injuries, particularly life-threatening hemorrhages.
Peristaltic Pump - A type of positive displacement pump used in medical applications, including the infusion of fluids.
Modular Design - An approach that allows components of the PRFP to be interconnected, enabling the simultaneous infusion of different fluids or the treatment of multiple patients.
User Interface - The means through which users interact with the PRFP, including the touchscreen display and remote control system.
Ruggedized - The quality of being designed and built to withstand harsh environmental conditions, such as those encountered in military settings.
IoT-Capable Microcontroller - A microcontroller with the ability to connect to the Internet of Things (IoT) for remote monitoring, control, and data transmission.

Luer Lock - A standardized connector used in medical applications to securely attach tubing to medical devices, ensuring a leak-proof connection.
FDA (Food and Drug Administration) - The regulatory body overseeing the safety and effectiveness of medical devices in the United States.
Remote Control System - A system allowing users to control and monitor the PRFP from a distance, enhancing flexibility and usability.
Prototype - A preliminary model of the PRFP built to test and validate its design and functionality.
Medical Device Standards - Regulations and guidelines that ensure the safety, quality, and performance of medical devices.
Simulated Battlefield Conditions - Controlled environments replicating the challenging conditions of a battlefield for testing and validating the PRFP's performance.
User-Friendly - Characterized by an interface and design that is intuitive, easy to understand, and accessible for users in high-stress situations.
Compliance - Adherence to established standards, regulations, and safety protocols applicable to medical devices.
Fluid Infusion - The controlled and adjustable delivery of fluids, such as blood products and intravenous fluids, into a patient's system.
EMS (Emergency Medical Services) - Services that provide pre-hospital emergency medical care, including the use of devices like the PRFP.
IoT (Internet of Things) - The network of interconnected devices capable of exchanging data and information over the internet.
Gantt Chart - A visual representation of a project schedule, displaying tasks, timelines, and dependencies.
Wireless Communication Protocol - The set of rules and conventions governing the exchange of data between devices in a wireless network, relevant for the PRFP's remote control capabilities.
GUI (Graphical User Interface) - A form of user interface that allows users to interact with electronic devices through graphical icons.

6. References

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7. Index

N/A