

# CLAIMS

## Independent Claims

### Claim 1:

A closed-loop plasmapheresis system comprising:

1. A robotic venipuncture device with integrated imaging for real-time vein mapping and automated needle insertion.
2. A plasmapheresis unit for plasma separation, connected to the venipuncture device via sterile tubing.
3. A sterile plasma collection bottle.
4. A flow pathway maintaining sterility from vein to plasma collection, including single-use tubing and leak-proof connectors.

### Claim 2:

The system of Claim 1, wherein the robotic venipuncture device includes:

1. Ultrasound imaging and infrared sensors for vein mapping.
2. A robotic arm for automated needle insertion.
3. Safety mechanisms to detect improper vein access or collapse.

### Claim 3:

The system of Claim 1, wherein the plasmapheresis unit includes:

1. A plasma separation mechanism using centrifugation or filtration.
2. An automated return cycle for non-plasma components.
3. Integrated sterilization checks.

---

## Dependent Claims

### Claim 4:

The system of Claim 1, further comprising a biometric authentication system for donor identification and process control, wherein:

1. The biometric system uses facial recognition to verify the donor's identity.
2. The system retrieves pre-set collection parameters and program volumes based on verified donor profiles.
3. The system prevents operation if the donor identity does not match the pre-programmed parameters.

### Claim 5:

The system of Claim 4, wherein the biometric authentication system includes:

1. Integration with a centralized donor database to ensure accurate retrieval of eligibility and collection limits.
2. An auditing mechanism to log biometric verifications for compliance.
3. Deviation Integration for the automation of error reporting for further evaluation and corrective action plans.

**Claim 6:**

The system of Claim 4, wherein the facial recognition module operates in real time and incorporates redundancy mechanisms to prevent false rejections or mismatches.

---

## **DETAILED DESCRIPTION OF THE INVENTION**

### **1. Biometric Authentication Process**

The facial recognition module scans the donor's face at the start of the procedure. Verified donor profiles are cross-checked with a centralized database to retrieve pre-set collection parameters such as plasma volume limits and donation history. If the verification fails or the donor does not meet eligibility criteria, the system halts the process and notifies the operator.

### **2. Integration with the Closed-Loop System**

Upon successful authentication, the robotic venipuncture device accesses the donor's vein, and the plasmapheresis unit begins the collection process. All steps are automated and monitored to maintain sterility and safety. The biometric component ensures that the correct program volumes are used, eliminating risks associated with manual input errors.

---

## **ADVANTAGES**

1. **Error Elimination:** Prevents incorrect collection parameters or program volumes by verifying donor identity with facial recognition.
2. **Sterility and Safety:** Ensures a closed-loop process from vein to collection bottle, reducing contamination risks.
3. **Efficiency:** Enhances donor throughput by automating authentication, vein access, and plasma collection.
4. **Compliance:** Provides a robust audit trail for regulatory purposes through biometric verification logs.