Title: **Closed-Loop Plasmapheresis System with Robotic Venipuncture Integration and Biometric Authentication**

FIELD OF THE INVENTION

This invention relates to medical devices and blood collection systems, specifically a system and method that integrates robotic venipuncture technology with plasmapheresis devices and facial biometric authentication, enabling a fully automated, closed-loop system for plasma collection and storage, ''From the Vein to the Bottle''. The biometric component ensures accurate donor identification and eliminates errors in collection parameters or program volumes.

BACKGROUND OF THE INVENTION

Plasmapheresis is a critical medical procedure that requires precision and sterility to ensure safety and efficacy. Errors in donor identification or collection parameters can lead to adverse events, compromised plasma quality, or regulatory non-compliance. Current systems rely on manual verification processes, which are prone to human error. This invention addresses these limitations by integrating facial biometric authentication to ensure correct donor identification and pre-programmed collection parameters.

SUMMARY OF THE INVENTION

The invention provides a closed-loop plasmapheresis system that integrates robotic venipuncture technology with biometric authentication for accurate donor identification and process control. The facial recognition system verifies donor identity and retrieves pre-set collection parameters, ensuring the correct volume of plasma is collected for each individual. The robotic venipuncture device ensures precise vein access, while the closed-loop system maintains sterility from the donor's vein to the plasma collection bottle.

SPECIFICATIONS

1. Overview of the System

The invention comprises:

1. **Robotic Venipuncture Device**: A device equipped with imaging and automated needle insertion for precise vein access.
2. **Plasmapheresis Unit**: A device for separating plasma from whole blood and returning non-plasma components to the donor.
3. **Biometric Authentication System**: A facial recognition module to verify donor identity and eliminate errors in collection parameters.
4. **Closed-Loop Flow Pathway**: Sterile, disposable tubing connecting the venipuncture device to the plasmapheresis unit and plasma collection bottle.
5. **Monitoring and Control Systems**: Sensors and software for real-time monitoring and adjustment of flow rates, pressure, and sterility.

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2. Components and Features

Biometric Authentication System:

- **Facial Recognition Module**: Scans and verifies the donor's face before initiating the collection process.
- **Integration with Donor Records**: Links facial recognition data to donor profiles, retrieving pre-set parameters such as collection volume and eligibility.
- **Error Prevention Mechanisms**: Prevents operation if biometric authentication fails or does not match donor records.
- **Auditing and Compliance**: Logs all biometric verifications for regulatory compliance and auditing purposes.

Robotic Venipuncture Device:

- Integrated with imaging technologies (ultrasound/infrared) for vein mapping.
- Robotic arms for precise needle insertion and withdrawal.
- Safety features to detect vein collapse or improper insertion.

Plasmapheresis Unit:

- Plasma separation via centrifugation or filtration.
- Automated regulation of blood flow and plasma collection.
- Return cycle for non-plasma components.

Closed-Loop Pathway:

- Single-use tubing for contamination-free operation.
- Sterile connectors and integrated sterilization checks.

Monitoring and Control Systems:

- Real-time monitoring of flow rates, pressure, and plasma quality.
- Alerts for deviations or abnormalities.