M4Knick >

PLASMA FRACTIONATION

In the Pharmaceutical Industry

рн **SE 555**

Holder SENSOGATE WA 130H

Transmitter
PROTOS 4400

Controller
UNICAL 9000



Facts about Fractionation

- Proteins can be extracted from human plasma through fractionation and used to treat a range of medical conditions
- These proteins can also be used as a source material for plasma-derived pharmaceutical products
- Even small errors in pH measurements can result in massive product loss or compliance setbacks

Automating pH Control for Ensured Accuracy

The plasma fractionation process plays a critical role in medicine and demands unmatched accuracy. pH control in this process is one of the most crucial factors for its success. Technicians must measure pH to ensure the successful extraction of certain proteins and compounds.

Components found in blood, like albumin and immunoglobulin, are pH reactive, meaning their optimal fractionation states fall within specific pH and temperature ranges. Operators must measure pH at various points along the fractionation process line—from clarification to sterile filtration—while considering specific temperatures, to ensure the plasma has been optimally compartmentalized.

Problems can manifest in several ways in such a sensitive application. The demand for real-time monitoring, manual interference with the process, buffer interference, and temperature moderation can all threaten the accuracy of pH control.

While maintaining the integrity of pH accuracy is paramount in biotech processes like blood fractionation, so is sterility. Hygienic connections are designed to minimize contamination risks and bolster the safety and quality of pharmaceutical products. Furthermore, by digitizing critical data, information security is improved, eliminating manual transcription errors.

Introducing cCare

The Knick cCare system is designed to extend sensor life by providing automatic retraction, cleaning, calibration, and insertion of inline process sensors. cCare systems address sensor performance issues in challenging processes that demand accuracy and consistency.

Fully digital Memosens pH sensors like the SE 555 eliminate noise found in traditional analog systems. Designed for hygienic applications, the SE 555 can withstand CIP & SIP cleaning methods.

The Sensogate WA 130H pnuematic holder automatically retracts the pH sensor. It allows steam delivery directly into the calibration chamber, ensuring sterilization of the sensor. This maintains a closed system, meeting FDA compliance.

The Unical 9000 controller is responsible for the delivery of air to drive the pneumatic holder and the application of cleaning and calibration solutions. Safe for hazardous locations, fully automatic, modular, low-wear, and low-maintenance. The Protos 4400 transmitter provides diagnostics for the controller and SE 555 pH electrode. It is expandable to fieldbus communication and operation with Memosens, digital and analog electrodes.

Return on Investment

Fully Automated Process

The Unical 9000 fully automates the cleaning, calibration, sterilization, and retraction of the sensor. This vastly reduces human error due to manual calibrations, and significantly minimizes sensor replacement costs and process downtime.

Minimize Manual Error

cCare is purpose-built for applications looking focusing on sterility and minimizing manual intervention. The digitized and repeatable efficiency of the system is precisely the solution engineers strive for.

Intuitive Knowledge

Memosens technology allows technicians to observe sensor conditions using onboard diagnostics of the cCare system. This provides an additional verification that the sensor is healthy and reading accurately.