

BLOOD SYSTEMS (BSI): PLASMA OPTIMIZATION INITIATIVE CURRENT STATUS

The purpose of this document is to describe the status of Blood System's plasma optimization initiative. The program began in January 2011 and has reached a current state yielding on average an increase of 23 mL plasma per whole blood collection. This document outlines the program steps, as well as the average amount of plasma yielded from each separate initiative upon implementation.

| Timeline | Process Implemented | Average Plasma Yield (mL) |
|--|--|---------------------------------|
| WB to RBC In-Line System | | |
| Initiated January 2011 - 8 sites | WB in-line system to Leukotrap RC2D | |
| Initiated January 2012 - 5 sites | WB in-line system to Leukotrap RC2D | |
| Initiated January 2014 – 3 sites | Fenwal Flex system to Leukotrap RC2D | |
| Average Plasma Yield | | ~10 mL per collection |
| Haemonetics Plasma Optimization Program | | |
| Initiated January 2011 - 8 sites | Centrifuge parameters, process steps | |
| Initiated January 2012 - 5 sites | Centrifuge parameters, process steps | |
| Initiated January 2014 – 3 sites | Centrifuge parameters, process steps | |
| Average Plasma Yield | | ~5 mL per collection |
| HemoFlow 400XS with Variable Blood Volume | | |
| August 2013 – all BSI sites | Collection of up to 540 mL whole blood per donor | |
| Average Plasma Yield | | ~8 mL per collection |
| TOTAL AVERAGE PLASMA YIELD | | ~23 mL PER WB COLLECTION |

Whole Blood to Red Blood Cell In-Line Collection Systems:

Throughout 2011, BSI converted 8 sites from whole blood In-line systems to Haemonetics Leukotrap® RC System with RC2D Filter. The following year, 5 sites were converted.

BSI Implemented Plasma Optimization Techniques:

During the collection set conversion in 2011 and 2012, BSI implemented plasma optimization centrifuge parameters and process steps that were scientifically tested previously in a Haemonetics laboratory setting. These studies were subsequently documented for customer use in the Haemonetics Plasma Optimization Guide. The key to plasma optimization is total centrifugal force exerted on the whole blood collection during centrifugation and process steps such as, emptying the donor collection and plasma tubing during processing.

HemoFlow 400XS with Variable Blood Volume:

BSI has utilized the HemoFlow Blood Collection Monitor and Mixer across a majority of their whole blood collections. In August 2013, the devices were standardized to the HemoFlow 400XS and configured with the 'Variable Blood Volume' setting. The setting allows for the user to input the donor's gender, height, and weight to calculate the total blood volume. The calculation will determine the amount of blood that can be collected in the range of 460 mL – 540 mL. If the donor is not eligible for a collection above 460 mL, the user will select a preset target of 460 mL. On average, BSI has yielded an average increase of 8 mL plasma per collection.