



Medical

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Redefining the Business of Blood

Maximizing the Use of Whole Blood Donations for Improved Plasma Yields and Increased Platelet Availability



Redefining the Business of Blood

Today's Healthcare Environment

New discoveries, new technologies, therapeutic changes, new protocols, medical advances, and stricter regulations constantly dictate the necessity to change. The world of blood supply is without exception. It too, must stay at the pinnacle of quality care and maintain economic viability while confronted with:

- ▶ Increasing demand for high quality components to support therapeutic innovation.
- ▶ Higher costs of implementing a safer blood supply.
- ▶ Growing requirements for quality and safety measures among customers.
- ▶ Emerging global infectious threats to our blood supply.
- ▶ Stricter regulatory requirements for the manufacturing of blood products.
- ▶ Labor and logistical implications of providing products to an ever increasing number of patients, e.g. shrinking donor pool.

Facing the challenges of change, blood centers must make smarter decisions to maximize their business potential and at the same time enhance their ability to provide the highest quality blood transfusion product.



What does 'Redefining the Business of Blood' mean?

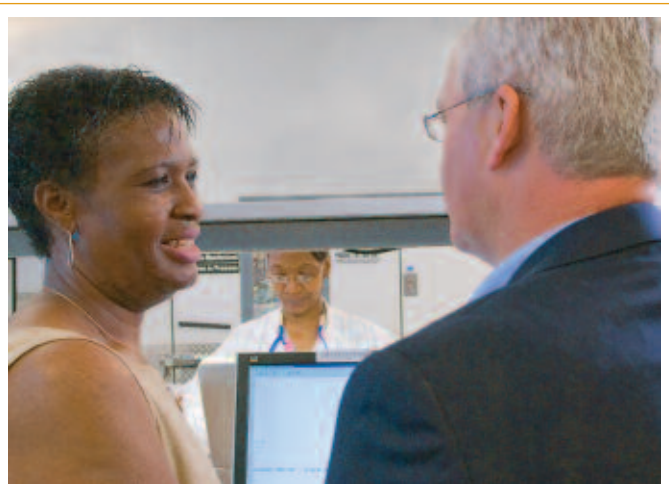
It's taking a fresh look at your operation to pinpoint the "high-return" areas in which to invest your time, finances, and resources to optimize your business. Using this valuable insight, you can decide where product availability can be improved and revenue income can be generated.

Pall Medical is committed to providing its expertise to help you optimize your business potential every step of the way.

Taking the First Step

Business optimization starts with knowing where your center is headed and understanding the challenges you will face in getting there. When you look at your overall business, what are the issues that concern you most?

- ▶ Is importing product an issue for your center? In what ways?
- ▶ Do you have an opportunity to export product? If so, could this be an important part of your business?
- ▶ Are there competitors moving into the area? Who are your main competitors? In what ways have they affected your business? Are you competing primarily for more donors or for more customers?
- ▶ Is expanding your center's business and customer base a major concern?
- ▶ Are you concerned about collection issues such as recruitment, staffing, processing, and so on?
- ▶ How frequently do you talk to your customers about issues that concern them? What plans do you have to change the products you offer to help meet your customers' needs?
- ▶ How does the need to leukoreduce product affect your center's planning, if at all, such as collections space and staffing, lab space and staffing, inventory, etc.?



Get More from Manual Whole Blood Donations

Over fourteen million units of whole blood are collected in the United States from an ever shrinking pool of eligible donors. Whole blood is such a valuable resource that it needs to be maximized to its fullest potential. A blood collection facility that approaches whole blood donation with this in mind, has the greatest potential to redefine their blood business to achieve their goals and satisfy their customer's needs.

Plasma... a resource in high demand. After a period of market fluctuations in the value of plasma earmarked for further manufacturing, the demand for plasma is on the rise.

Whole blood (WB)-derived platelets... an untapped resource. Based on a 2005 survey, platelet concentrates were prepared from only 30.3% of whole blood donations.¹ Though single-donor platelets made up the difference in platelet transfusion needs, the margin between supply and demand is small.



Maximizing plasma yields and increasing platelet availability through WB donations gives your facility the ability to adequately supply leukoreduced RBCs (red blood cells) and address:

- ▶ Supply issues due to donor restrictions related to TRALI (Transfusion Related Acute Lung Injury).
- ▶ High operational costs driven by market economics and regulatory requirements.

As you can see in the table below, all WB and RBC filtration systems can help you achieve your plasma needs. Choosing the appropriate system depends on tradeoffs between plasma yields and workflow efficiency. Only an RBC or RBC/PLT (red blood cell/platelet) in-line filtration system coupled with a platelet pooling system truly maximizes product yields from WB donations. The path you take to achieve business optimization is unique to your facility.

Reviewing Your Options – Leukoreduced RBCs With A...

	Category A Focus on Plasma ONLY Workflow Considerations	Category B Focus on Plasma and LR WB-derived Platelets Improving Product Yields	Category C Focus on LR WB-derived Platelets ONLY Improving Safety and Availability
OPTION 1	Leukotrap® RC System with RC2D Filter	Leukotrap RC with RC2D Filter with Acrodose™ PLus Systems	Leukotrap RC PL and Acrodose PL Systems
OPTION 2	Leukotrap WB with SAVE System	Leukotrap SC RC with Acrodose™ PLus Systems and Standard Collection Bag	Leukotrap PL and Acrodose PL Systems with Leukotrap SC RC System
OPTION 3	Leukotrap SC RC System		Leukotrap RC with RC2D Filter with Acrodose PLus Systems
OPTION 4			Leukotrap SC RC with Acrodose PLus Systems and Standard Collection Bag

Category A | Focus on Plasma:

Workflow Considerations

Production Logistics

Every year recruitment goals increase to meet the growing demands for blood donations. To achieve these goals, blood drives must sometimes take place at locations distant from the processing center and run for longer periods of time. Blood Centers may be facing the need for component production growth and longer drive hours, while keeping an eye on overhead costs.

Option #1: Business Optimization Using the Leukotrap® RC System with RC2D Filter designed to provide:

- ▶ Improved plasma yields by as much as 10% over WB in-line systems.
- ▶ Greater flexibility for component staff scheduling with ample timing for filtration – up to 72 hours when stored at 1-6 °C.
- ▶ Superior filtration performance across a broad range of processing conditions with reduced filter plugging.
- ▶ Fast flow rates and filtration times that can increase production throughput.
- ▶ Adaptability to semi-automatic processing.
- ▶ Streamlined inventory management from one system that is capable of both hard spins for plasma or soft spins for platelet/plasma production.

Option #2: Business Optimization Using the Leukotrap WB with SAVE System designed to provide:

- ▶ Improved ergonomics from the patented SAVE System to reduce staff injury and accommodate flexibility in staff scheduling.
- ▶ Adaptability to mobile and laboratory settings.
- ▶ Fast flow rates and filtration times.
- ▶ Improved workflow efficiency over dockable systems by 7-fold.²

Choosing the **Leukotrap WB with SAVE System** doesn't mean you have to compromise your plasma production needs. In a study comparing plasma yields with a competitive WB in-line system, the plasma yield was significantly higher after a 24-hour cold hold when using the **Leukotrap WB with SAVE System**.³

Option #3: Business Optimization Using the Leukotrap SC RC System with BPF4™ Filter:

Though RBC dockable systems are inherently more labor intensive than in-line systems for producing leukoreduced RBCs and plasma, using the right dockable system can streamline and improve the workflow efficiency of dockable processing.

The Leukotrap SC RC System is designed to provide maximum flexibility with:

- ▶ Improved ergonomics from the patented SAVE System to reduce staff injury and accommodate flexibility in staff scheduling.
- ▶ Fast flow rates and filtration times.
- ▶ Bulk packaging to reduce set-up and preparation times.



Leukotrap RC System with RC2D Filter

Now there's no compromise between increasing component production and maintaining optimal operational efficiency when producing leukoreduced RBCs and plasma.

Category B | Focus on Plasma and Platelets:

Improving Product Yields

Production Logistics

In order to maximize plasma yield, whole blood is centrifuged under hard spin conditions. In addition, the plasma is often expressed until the red cells begin to exit the main collection bag. The result – RBCs that have a high hematocrit that may cause filter plugging and slow flow when filtered.

The production of WB-derived platelets has been steadily decreasing while the patient need for platelets has grown exponentially. Despite the growth of single-donor platelet production, platelet availability is still an issue. Single-donor platelets also have eroded profit margins and increased overhead due to their significantly higher disposable and capital equipment costs.

Blood collection facilities can capitalize on the clinical benefits of single-donor platelets with the availability of whole blood platelets to meet increasing platelet transfusion requirements. Non-leukoreduced WB-derived platelets made with **Leukotrap® RC System with RC2D Filter** can be pooled and leukoreduced using the **Acrodose™ PPlus System** to make a transfusion-ready, therapeutic dose of platelets that are clinically equivalent to a single-donor platelet, an AcrodoseSM platelet.



Acrodose PPlus System

Option #1: Business Optimization Using the Leukotrap RC System with RC2D Filter and the Acrodose PPlus System

Whether you need to maximize plasma yield or increase platelet availability, now you can collect whole blood in one system and produce leukoreduced RBC platelets and non-leukoreduced plasma for planned or emergent product needs.

The Leukotrap RC System with RC2D Filter may be the only WB collection system you need to:

- ▶ Increase your plasma yield and revenue by as much as 10% over WB in-line systems with more flexibility to handle RBCs prepared under extreme spin conditions, or
- ▶ Increase platelet availability by making non-leukoreduced platelets and processing them using the Acrodose PPlus System to make value-added Acrodose Platelets.

Option #2: Business Optimization Using the Leukotrap SC RC System with BPF4™ Filter and the Acrodose PPlus System

Though RBC dockable systems are inherently more labor intensive than in-line systems for producing leukoreduced RBCs, the combination of a standard blood collection set and dockable leukoreduction system may be the best solution to achieve your platelet and plasma needs. WB can be collected in standard trade bags – Nutricel® Additive System or CPDA-1 Blood Collection Sets. The RBCs can be processed using the Leukotrap SC RC System with BPF4™ Filter. When the non-leukoreduced platelets are processed using the Acrodose PPlus System, you have the value-added availability of Acrodose Platelets.

Now there's no compromise when it comes to maximizing plasma yields and increasing platelet availability.

Category C | Focus on Platelets:

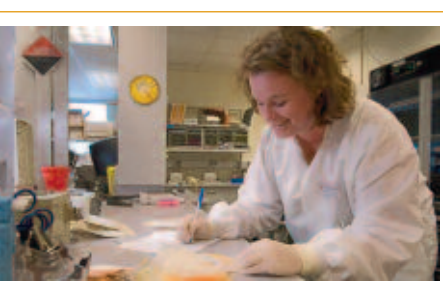
Improving Safety and Availability

Production Logistics

Now, blood collection facilities can capitalize on the clinical benefits of single-donor platelets with the availability of whole blood platelets to meet increasing platelet transfusion requirements by making AcrodoseSM Platelets. An Acrodose Platelet is a leukoreduced, pooled, ABO-matched and bacteria-tested product made from WB-derived platelets. This innovative product is designed to improve platelet safety and availability, all at a lower cost than single-donor platelets.

An Acrodose Platelet breaks down the barriers of traditional thinking that differentiate whole blood platelets from apheresis platelets by providing the highest levels of safety with no clinical sacrifice in the following critical areas:

- ▶ **Platelet Quality:** In vitro and in vivo studies suggest that pooled, stored, ABO-matched platelets are comparable in quality to single-donor platelets.⁴
- ▶ **Platelet Dosing:** Acrodose Platelets can easily be targeted to consistently meet single-donor platelet counts (at least 3.0×10^{11} platelets in a dose).
- ▶ **Bacteria Detection:** Acrodose Platelets use the same culture-based bacteria detection systems as single-donor platelets making these two products comparable.⁵
- ▶ **Donor Exposure:** Although the concern over donor exposure to viruses during pre-storage pooling is real, the advent of nucleic acid testing (NAT) has significantly reduced this risk.⁵



AcrodoseTM Systems are designed for use with either leukoreduced or non-leukoreduced platelets. There is also an option of having a pre-attached platelet bacteria detection system (Pall eBDS) with these systems.

Option #1: Business Optimization Using the Leukotrap RC PL System with the AcrodoseTM PL System is a winning combination.

All your products are leukoreduced after the WB is processed. When the leukoreduced platelets are processed using the Acrodose PL System, you have the added availability of Acrodose Platelets.

Option #2: Business Optimization Using the Leukotrap PL System with the Acrodose PL System may be the best solution for your platelet and leukoreduced RBC needs if you are not leukoreducing all of our RBCs.

When the leukoreduced platelets are processed using the [Acrodose PL System](#) you have the added availability of [Acrodose Platelets](#).

Option #3: Business Optimization Using the Leukotrap RC System with RC2D Filter and the Acrodose PPlus System:

Non-leukoreduced whole blood derived platelets made with [Leukotrap RC System with RC2D Filter](#) can be pooled and leukoreduced using the [Acrodose PPlus System](#) to make a transfusion-ready, therapeutic dose of platelets that are clinically equivalent to a single-donor platelet – an Acrodose Platelet.

Option #4: Business Optimization Using the Leukotrap SC RC System with BPF4TM Filter with the Acrodose PPlus System:

Though RBC dockable systems are inherently more labor intensive than in-line systems for producing leukoreduced RBCs, a combination of standard blood collection sets and dockable leukoreduction systems may be the best solution to obtain your platelet and plasma needs. WB can be collected in standard trade bags – [Nutricel[®] Additive System](#) or [CPDA-1 Blood Collection Sets](#). The RBC can be processed using the [Leukotrap SC RC System with BPF4 Filter](#). When the non-leukoreduced platelets are processed using the [Acrodose PPlus System](#) you have the added availability of [Acrodose Platelets](#).



Acrodose PL System



References

¹ Whitaker BI, Sullivan M (Ed.). (2005). In the 2005 Nationwide Blood Collection and Utilization Survey Report. Rockville, MD: US Dept. of Health & Human Services last accessed Sept, 2007 at <http://www.aabb.org/apps/docs/05nbcusrpt.pdf>

² Gingras A. A formula to calculate component lab workload based on time studies for the leukoreduction (LR) process. *Transfusion* 1999; 39 (Suppl):A80-P.

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⁴ Anderson NA, Gray S, Copplestone JA, Chan DC, et al. A prospective randomized study of three types of platelet concentrates in patients with haematological malignancy: corrected platelet count increments and frequency of nonhaemolytic febrile transfusion reactions. *Transfusion Medicine* 1997; 7(1):33-9.

⁵ Ortolano, GA, and Cervia, JS Pool and Store Platelets – Augmenting Quality Platelet Supply To Meet Transfusion Requirements, STRPltQty10.05, Pall Corporation, 2005.



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