

# **Title-Assessment of Equipment Programming Efficiency for Blood Component Preparation to Enhance Accuracy in Service Settings**

## **1. Introduction and Background**

Component preparation plays a crucial role in blood center services, requiring adherence to standardized procedures for optimal outcomes. The introduction of CPD solution for blood collection has notably enhanced the viability of whole blood, facilitating standard component preparation processes<sup>1</sup>. Utilizing specialized equipment like refrigerated centrifuge machines, which operate on centrifugal and centripetal forces, has been pivotal since the inception of the single-step heavy spin centrifugation method in the 1960s<sup>2</sup>. Over time, component preparation techniques have evolved from manual methods to fully automated centrifuge cryocentrifuge systems, categorized into first to third generations, each continually improving in performance. The fundamental principle underlying all generations is the utilization of centrifugal and centripetal forces to separate components, departing from conventional whole blood holding methods<sup>3</sup>. Foreign reaction in the recipient is natural tendency of blood products. To avoid this always rational use of blood product is always necessary. So component separation is need of hours for the blood transfusion. The success of component preparation hinges on various factors, with proper instrument programming being paramount. Quality outcomes are achievable only through optimal programming, ensuring standardized products. The aim of the above study Evaluating programming's impact on centripetal and centrifugal forces, acceleration, deceleration, and time intervals is crucial in selecting the most effective program to elevate standards.

## **2. Methodology**

Although component preparation is an evolving science. The present study was observational study carried out in a tertiary care institute in eastern India over three months. Evaluation of 20 each as pilot samples for both equipment has been selected. Performance run carried out according to standard operative procedure of the equipment.

There were present (working programmes) of both equipment e.g 1. Thermofisher cryocentrifuge 2. Rota Silenta Agile were modified with five closely matched programs and their performance was observed.

### **1. Present program for Thermofisher cryocentrifuge**

RPM (2350/3450), RCF(1048x2/2054x2), Acceleration (9), Deceleration(10) and Mid interval(8).

### **2. Present program for Agile centrifuge**

RPM(2190/3250) ,RCF(671x2/1509x2),Acceleration (7),Deceleration(9) and Mid interval(9).

3. Parameters such as acceleration, deceleration, mid-interval time, RPM, relative centrifugal force (RCF), and gravitational force (G) were studied.

4. The quality and frequency of prepared blood products of modified programs (PRBC, FFP, PC, and WBC) were assessed using a Fully Automated Hematology Analyzer<sup>2</sup>.

## Modified/AppliedCroyocentrifuge(programs)

PROGRA MME	RPM- Hard spin/So ft spin	RCF	DIAMET ER	TIM E	MI D- TIM E	ACCELE RATION	DEACCELA RATION
<b>Thermofis her</b>	3450/23 50	2054X2/104 80X2	30/29				
P1	do	do	do	21	9	8	4
P2	do	do	do	19	8	8	3
P3	do	do	do	20	9	8	3
P4	do	do	do	24	10	10	4
P5				25	10	10	5
<b>Rota silenta</b>	3250/21 90	1509X2/671 X2	29.5/28. 5				
PI	do	do	do	23	12	8	3
P2	do	do	do	20	11	7	2
P3	do	do	do	21	12	7	2
P4	do	do	do	25	13	8	4
P5	do	do	do	27	13	9	5

The module of the different programs estimated over RCF,RPM,MID-INTERVAL,ACCELERATION and ACCELERATION.

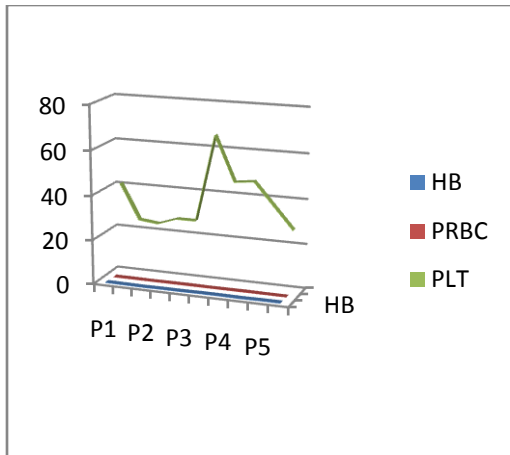
### 12. Results

The HERAEUS Thermofisher cryocentrifuge 16 Centrifuge outperformed the ROTA Silenta 630 RS. The optimal programming for the HERAEUS CRYOFUGE involved acceleration (8 minutes), deceleration (8 minutes), mid-interval (3 minutes), and RPM (2350 and 3450), with calculated RCF values of 2096 and 4018. This programming resulted in the highest platelet yield (287ug/dl), minimal FFP contamination by RBC and platelets (0.01 and 24ug/dl, respectively), PRBC with a hematocrit of 69%, RBC concentration of 9.6ug/dl, and platelet contamination of 186ug/dl.

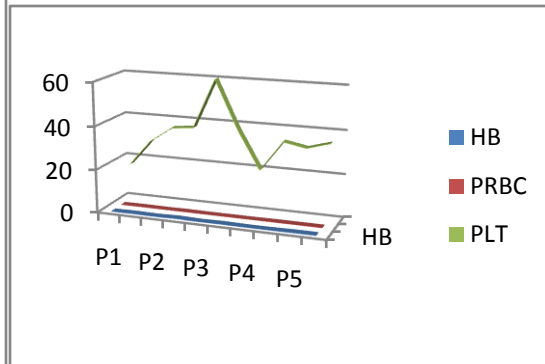
In comparison to applied programming (P2) to present programs, the present program observed inferior platelets yield (189ug/dl), FFP-contamination by RBC and platelets observed (.02 and 26Ug/dl) respectively).

For the ROTA Silenta, the best programming included acceleration (8 minutes), mid-interval (3 minutes), deceleration (4 minutes), RPM (2190 and 3250), with a radius of 29.5cm and computed RCF values of (1342 and 3018), respectively, resulting in the highest quality products.

Comparison to applied programming (P4) of ROTA present programs also observed platelets yield (198ug/dl) FFP Contamination by RBC and platelets (.02 and 24Ug/dl) respectively.



**Fig-1FFP(Thermofisher)**



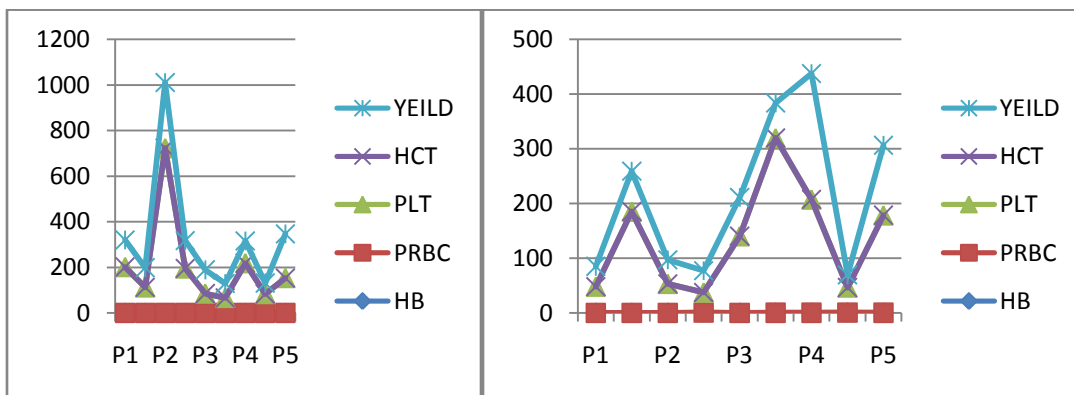
**Fig-2 FFP( Rota)**

**Fig1, (Thermofisher)**

[above graphical presentation of the outcome of programs of cryocentrifuge which represent HB and PRBC lies over the lower side while contamination of prepared FFP products is highest noted with platelets. P2 was associated with the lowest contamination of HB and PRBC (.1) and (.01) respectively. platelets was 24u/dl in P2. The highest contamination of HB, PRBC and platelets was in P3 (.2), (.01) and (27) respectively.

**Fig-2FFP (Rota)**

The above graphical presentation of the outcome of programs of cryocentrifuge which represent HB and PRBC lies over the lower side while contamination of prepared FFP products is highest noted with platelets. P2 was associated with the lowest contamination of HB and PRBC (.04) and (.01) respectively. Platelets were 36u/dl P2 at the lowest in P4 (20)ul/dl. Highest contamination of HB, PRBC and platelets was in P3 (.3)gm/dl, (.1)ul/dl and (60)ul/dl respectively.



**Fig-4**

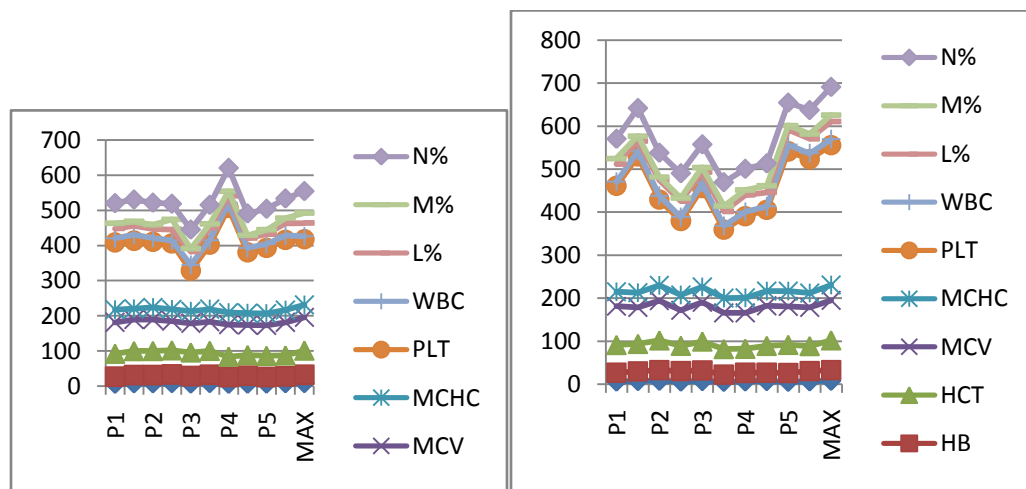
**FigG-3PLT (Thermocentrifuge)**

**Fig 3 (Thermocentrifuge)**

Above graphical presentation of the outcome of programs of cryocentrifuge which represent HB,PLT,HCT,YEILD and PRBC. Here PRBC lies over the lower side while contamination of prepared PLT products is highest noted with PRBC and negligible with WBC(.1)ul/dl. P2 was associated with the lowest contamination of HB and PRBC (.2) and (.02) respectively. Platelets were 722u/dl in P2. The highest contamination of HB, PRBC and HCT was in P1 (.4),(.04)and (.3)respectively. The highest yield of PLT was achieved in P2 (288)and the lowest was P4(48).

**Fig-4PLT (Rota)**

Above graphical presentation of the outcome of programs of cryocentrifuge which represent HB,PLT,HCT,YEILD and PRBC. Here PRBC lies over the lower side while contamination of prepared PLT products is highest noted with PRBC and negligible with WBC(.1)ul/dl. P1 was associated with the lowest contamination of HB and PRBC (.2)ul/dl and (.02)ul/dl respectively. Platelets were 319u/dl in P3. The highest contamination of HB, PRBC and HCT was in P4 (.4),(.04)and (.3)respectively. The highest yield of PLT was achieved in P4 (230)and the lowest was P3(74).



**Fig-6.**

**Fig-5.PRBC (Thermocentrifuge)**

Fig 5 Thermo[above graphical presentation of the outcome of programs of cryocentrifuge which represent HB, PLT, HCT, MCV,MCHC,WBC,L%,M%,N% and RBC. Here concentrated PRBC lies over the lower side(8.4)ul/dl while contamination of prepared PRBC products Lowest noted with PLT,HCT and WBC(186)ul/dl, (68.8%)and (8.25)ul/dl in P2. Maximum MCV and MCH were in P5 and P3 respectively.

**FIG 6.PRBC Rota**

above graphical presentation of the outcome of programs of cryocentrifuge which represent HB, PLT, HCT, MCV,MCHC,WBC,L%,M%,N% and RBC. Here concentrated PRBC lies over the lower side(8.4)ul/dl while contamination of prepared PRBC products Lowest noted with PLT,HCT and WBC (153)ul/dl, (68.8%)and (69.7)ul/dl in P4. Maximum MCV and MCH were in P4 and P5 respectively.

**13.Statistical analysis**

Conducting a chi-square test, multivariate programming for component preparation was assessed. **P2** yielded the highest platelets (PLT) at 288, while P4 showed the lowest at 48 for the cytocentrifuge. In the case of Rota Silent, **P4** had the highest PLT yield at 230, with P3 having the lowest at 74. Overall, **P2** demonstrated the most significant product effect across all variables, with statistical significance at an estimated p-value of <0.05. In terms of PRBC (Rota Silent), **P4** emerged as the best-programmed choice.

programs	PLT count( $10^3/\text{ul}$ )	FFP contamination withplt( $10^3/\text{ul}$ )	Chi-square	P value at<.05
<b>P2 Thermofisher</b>	287	24	.32	
<b>Present program for Thermofisher</b>	183	26	.53	
<b>P4 Rota</b>	240	24	.05	
<b>Present programs for rota</b>	198	26	.81	
<b>P2 Thermofisher</b>	287	24	.37	
<b>P4 Rota</b>	240	24	.53	

**T-test** statics at the confidence of variance (.01) computed as (.04) with degree of freedom (18) estimated p-value obtained (.4842) which was not significant at <.05.

### 3. Discussion

To meet quality standards, any prepared component must adhere to 60 to 75% of the D&GHS advisory guideline<sup>4</sup>. Currently, our prepared components meet 60% of the standard, requiring the reprogramming or discarding of the remaining components to meet the standard. Reprogramming can be time-consuming, especially when needed for contaminated products like FFP contaminated with RBC, necessitating their disposal. Modifications in platelet preparation programming are essential for achieving higher platelet yields. For RBC preparation, selecting more concentrated PCV-RBC is necessary, achievable through program modifications. Contamination of WBC in RBC products leading to non-hemolytic febrile transfusion reactions can be reduced by selecting appropriate programs. Effective centrifugation to separate RBC from the buffy coat simplifies the process. Contamination of RBC in FFP and platelets is detrimental to RH-negative patients, mitigated by optimal program selection. Therefore, modifying programs to search for optimal programming is imperative for ideal component preparation. The conventional method of refrigerated cryo-centrifuge operation relies on centripetal and centrifugal forces, facilitating component separation based on specific gravity<sup>5</sup>. Plasticizers used significantly affect blood product quality, impacting storage lesion and product quality. Studies compared SAGM and non-SAGM blood bags, assessing RPM and RCF according to guidelines same manners as Bostan et al<sup>6,7</sup>. Dzik et al had been described a

formula over 5000/2000xg heavy and soft spin over g(gravitational force) and radius of equipment. Calculated RPM/RCF was static for the present study while changes were made to the programming of the equipment. Component preparation algorithms align with AABB and DCGH guidelines, focusing on product-specific processing and storage<sup>8,9</sup>. Heather et al and Basu et al, had described the component preparation overview similarly for product-specific processing and storage of component products<sup>9,10</sup>.

From gravitational methods to semi-automated and fully automated component separation techniques, advancements have led to improved efficiency and outcomes. While hollow fibre(Ere Sep) methods offer an alternative to centrifuge-based separation, they are more time-consuming(2hrs) and less effective in leukoreduction while above conventional separation technique took only 50 mins<sup>11</sup>. Johnson et al, has proven highest platelet yield(297.43ul/l) of their own methods while present studies highest noted with 283 ug/l of P2 programs of thermofisher. The MCV of RBC product of Ere sep methods was 92.6 femtoliter while P3 and P5 of thermofisher has shown highest MCV. The automation technique of Atrius 2C can only hold one component while the above programming can support 10 to 12 buckets of component programming<sup>12</sup>. Thomas et al, has shown in his study mean PCV of RBC (58.5%) while PCV of the applied programs{(Thermofisher(p2) } was 68% which was quite higher<sup>11</sup>. Automation technologies like Atrius 2C and Revous offer improved processing capabilities, with Revous providing high platelet yields and component pooling<sup>12,13</sup>.

The FFP contamination with platelets prepared from Revous product was quite low in comparison with present study (24ul/l)<sup>12</sup>. Inappropriate programming compromises product quality and may damage blood bags, necessitating adherence to biomedical waste handling guidelines<sup>14</sup> while present study has not experienced any tear or leakage of blood bags. Overall, the study's outcomes are satisfactory, with optimal programs identified, best platelet products selected, FFP contamination minimized, and discard rates reduced. This enhances inventory management and facilitates meeting different group requirements.

The limitation of present study conducted in very small sample size although, this has been carried out in pilot study.

## **Conclusion**

Selecting the optimal programming parameters enhances product quality and meets established standards for platelet preparation, hematocrit, and PRBC preparation. FFP contamination with RBC aligns with the defined log reduction for WBC. The choice of programming can significantly improve product quality and adherence to standards. Every component laboratory should maintain to find out optimal programming, that could strengthen the blood transfusion services. Unnecessary discard of time lay out can be avoided.

**ETHICAL APPROVAL- ETHICAL APPROVAL HAS BEEN TAKEN-REF.NO-RD/AIIMS/PAT/RAC/29**

**COMPETING INTERESTS-THERE ARE NO CONFLICTS AND COMPETING INTERESTS HERE.**

**References**

1. Iloveric VA, Bryanyt j parker A; Improved quality of packed cells Med j AUST 2183-186, 1977. RTMDT-2023 ISBN No. 987-81-964676-0-9
2. A Review Article on Blood Components Preparation Saloni\*, Divyanshi Ahlawat, Sonali, Priyatosh, Mohd. Sami & Anshu Kumar Singh Department of Paramedical Sciences, Subharti Medical College, Swami, Vivekanand, Subharti, TMDT-2023 ISBN No. 987-81-964676-0-9
3. Cid J, Magnano L, Lozano M. Automation of blood component preparation from whole blood collections. Vox Sanguinis. 2014 Jul;107(1):10-8.
4. [https://naco.gov.in/sites/default/files/Drug%20%26%20Cosmetic%20Act%201940\\_0.pdf](https://naco.gov.in/sites/default/files/Drug%20%26%20Cosmetic%20Act%201940_0.pdf)
5. Prins HK, de Bruijn JCGH, Henrichs HPJ, et al; Prevention of micro aggregate formation by buffy-coats vox Sang 39;48-51, 1980.
6. Heaton WA. The quality of red blood cells. Immunological Investigations. 1995 Jan 1;24(1-2):371-90.
7. Carson JL, Grossman BJ, Kleinman S, Tinmouth AT, Marques MB, Fung MK, Holcomb JB, Illloh O, Kaplan LJ, Katz LM, Rao SV. Red blood cell transfusion: a clinical practice guideline from the AABB. Annals of internal medicine. 2012 Jul 3;157(1):49-58.
8. <https://dghs.gov.in/Uploaddata/Transfusion%20Medicine%20Technical%20Manual%202023>.
9. Harmening DM. Modern blood banking & transfusion practices. FA Davis; 2018 Nov 30.
10. Basu D, Kulkarni R. Overview of blood components and their preparation. Indian journal of anaesthesia. 2014 Sep;58(5):529.
11. Johnson L, Kwok M, Marks DC. Preparation of red blood cell concentrates and plasma units from whole blood held overnight using a hollow-fibre separation system. Transfusion Medicine. 2015 Feb;25(1):13-9.
12. Thomas S, Beard M, Garwood M, Callaert M, Waeg GV, Cardigan R. Blood components produced from whole blood using the Atrius processing system. Transfusion. 2008 Dec;48(12):2515-24.
13. Cid J, Magnano L, Lozano M. Automation of blood component preparation from whole blood collections. Vox Sanguinis. 2014 Jul;107(1):10-8.

14.Hirani DP, Villaitramani KR, Kumbhar SJ. Biomedical waste: an introduction to its management. International Journal of Innovative Research in Advanced Engineering (IJIRAE). 2014;1(8):82-7.