



अखिल भारतीय आयुर्विज्ञान संस्थान (एम्स) कल्याणी
All India Institute of Medical Sciences (AIIMS) Kalyani
(स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार के तत्वावधान में एक सांविधिकनिकाय)
(A Statutory Body under the Aegis of Ministry of Health and Family Welfare, GOI)
राष्ट्रीय राजमार्ग – 34, बसन्तपुर, सागुना, कल्याणी, ज़िला – नदिया, पश्चिम बंगाल - 741245
NH-34 Connector, Basantapur, Saguna, Kalyani, District Nadia, West Bengal 741245

WEB CHALLENGE NOTICE

Dispatch No. 2287/P-13036/1/22-23/Blood Bank

Dispatch Date:19/11/2022

The notice is being uploaded on the web site www.aiimakalyani.edu.in and CPPP.

Sub: Verification and Justification of proprietary nature of the items through 15 days WEB Challenge on the official website of AIIMS, Kalyani and CPPP before Procurement Automated Blood Processing System against proprietary article certificate of the manufacturer.

Inviting Comments thereon.

Department of Blood Bank & Transfusion Medicine, AIIMS, Kalyani has raised an indent for procurement of Automated Blood Processing System.

The Original Equipment Manufacturer (OEM) M/s. Terumo BCT Inc., 10811 West Collins Avenue, Lakewood, CO 80215, United States has declared in the Proprietary Certificate provided in their company's letter head that the above mentioned Automated Blood Processing System (Automated Blood Component Separation Device) is the proprietary product manufactured by M/s. Terumo BCT Inc., 10811 West Collins Avenue, Lakewood, CO 80215, United States and this OEM also appoint an authorized distributor in India, for marketing, selling and technical services their product range.

The notice is being uploaded for general information of prospective Manufacturer/ Authorized Distributor/Dealer to submit their objection/ comments, if any, on proprietorship of the Automated Blood Processing System (Automated Blood Component Separation Device), Make: M/s. Terumo BCT Inc., 10811 West Collins Avenue, Lakewood, CO 80215, United States, they may submit their proposal along with specifications, supported by all documentary evidence and a price quotation for the above said items.

The objection/proposal/comments, if any should be sent in sealed cover to the office of Chairperson, Procurement Cell, AIIMS, Kalyani, P.O.- Ghoragacha, NH 34 Connector, Basantapur, Suguna, Kalyani, District- Nadia, West Bengal 747245. Or through email to e-tender@aiimskaiyani.edu.in, so as to reach on or before Dated. on 04/12/2022. Failing which it will be presumed that no other firm is interested to offer comments/protest/object and case will be decided on its merits.

The "Ref No. 2287/P-13036/1/22-23/Blood Bank, due on 04/12/2022 should be superscripted on sealed envelope

Enclosures:

- 1.) Proprietary Certificate of Manufacturer M/s. Terumo BCT Inc., 10811 West Collins Avenue, Lakewood, CO 80215, United States.

Note from pre-page

Copy to:

1. Indenting Officer : For kind information please.
2. PS To ED : For kind information please.
3. FIC Website : For kind information please.

Sd/-

Chairperson of the Procurement Cell
AIIMS, Kalyani.

26 September 2020

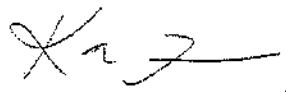
Proprietary Certificate

To Whomsoever it may concern

This is to certify that the equipment "Automated Blood Component Separation Device" having Make Terumo BCT & Model Reveos - 23000 as per attached technical specification is the proprietary product of M/s. Terumo BCT Inc., 10811 West Collins Avenue, Lakewood, CO 80215, United States. No other Company/Manufacturer with given specification manufactures the equipment in the world. Its accessories and consumables are equipment specific and proprietary in nature.

The items include:

- Reveos Device (Catalogue 23000) with Reveos System Manager Software Application
- Reveos 3 Component Set
- Platelet Pooling Set



Authorized Signatory

Name: Karen Lowitz

Designation: Regulatory Affairs Manager

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Shinjuku-ku, Tokyo 163-1450.
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WHOLE BLOOD AUTOMATION DEVICE

1. The Centrifuge System should be able to Automated to perform the following process steps for up to 4 units of Whole blood within a cycle- balancing, centrifugation, sedimentation, expression, and tube sealing.
2. The system should provide procedure and process data- per unit and per cycle.
3. The centrifuge device should have software to transfer procedure and process data to and from the device.
4. System should be a Fixed bucket (minimum 4/device) technology for Whole Blood sedimentation and separation
5. The system should have Integrated sealing heads (3/bucket) to seal the components during the processing cycle.
6. The device should have a Touch Screen Display with Graphical User Interface
7. Should be provided with a Temperature Controller system
8. Processing buckets should be equipped with a bucket sensor to detect the component interface.
9. The device should have a line/tubing sensor to detect the component interface for each WB processed
10. The device should have a built in expression system (hydraulic) which allows for consistent component expression during processing.
11. Should have an inbuilt balancing system which would eliminate the need for a manual balancing device.
12. Should be able to process the following components from each unit of Whole Blood, in one centrifuge cycle- Red Blood Cells, Leukoreduced Plasma, Residual Leukocytes and Platelets.
13. System should work on an integrated processing set which should be able to be used for collection and processing of whole blood.
14. The system should have a pooling set that is designed to allow the pooling, leukoreduction and storage for 3-6 IPUs for transfusion.

Copy for Store.

Signature: *[Signature]*
 Date: 11/7/22
 Dr. K. K. Chatterjee
 M.D., B.D., D.M., Dip. Path (UK) FRSPH (UK)
 Dir. (Infectious Diseases) (AIIMS Delhi)
 Associate Professor, Department of Microbiology
 AIIMS (All India Institute of Medical Sciences)
 Kalyani, West Bengal, India
 Regn. No. 23576 (NB/17C)



Signature: *[Signature]*
 Date: 11/7/22
 OFFICE OF THE
 MEDICAL SUPERINTENDENT
 AIIMS, KALYANI-741245
 Dr. Kapan Kumar
 Assistant Professor
 Dept. of Transfusion Medicine
 & Blood Bank
 AIIMS, Kalyani, West Bengal



Signature: *[Signature]*
 Date: 11/7/22
 Dr. Samrat Kumar
 Additional Professor of Blood Bank
 Dept. of Transfusion Medicine & Blood Cent
 AIIMS, Bhubaneswar-751019

C-12

15. Cost of all accessories required for the full functioning of the system should be included with the price courted.
16. Price of All consumables (Leuco- depleted blood bag set and platelet pooling set) should be fixed for the period of 10 years.
17. Compatible UPS should be provided with minimum 120 min back up and should be maintained (including batteries) for entire period of warranty and CMC
18. Bidder should provide upgraded version of equipment (Hardware/ software) free of cost during the lifecycle of the equipment
19. Bidder should provide a backup system of the same/ upper version to ensure uninterrupted work during the breakdown/ maintenance/ or any other scenario when one machine is off.
20. The necessary IQ, OQ, PQ and calibration certificate should be provided from time to time as and when required
21. Comprehensive warranty for 5 years and 5 years CMC after warranty
22. The CMC will include repair & replacement of every defective part or accessories of the equipment and regular calibration of the equipment at 6 months or after major breakdown and repair
23. Comprehensive training for lab staff and support services till familiarity with the system
24. User/Technical/Maintenance manuals to be supplied in English
25. Miscellaneous item for complete operationalization of the equipment which are not mentioned here but required shall also be provided by the vendor.

Sayan
 Sayan
 M.D., D.M., D.M.C. (DIP) FRCM (UK)
 D.I. (Infectious Diseases) (AIIMS Delhi)
 Associate Professor, Department of Microbiology
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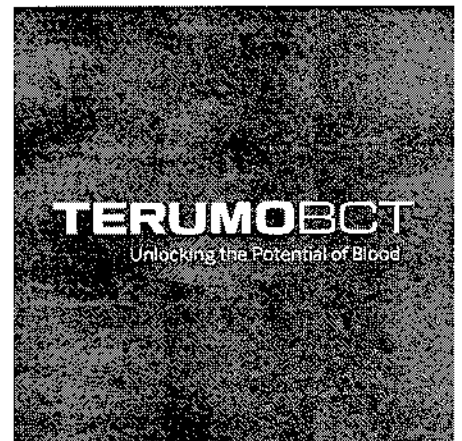
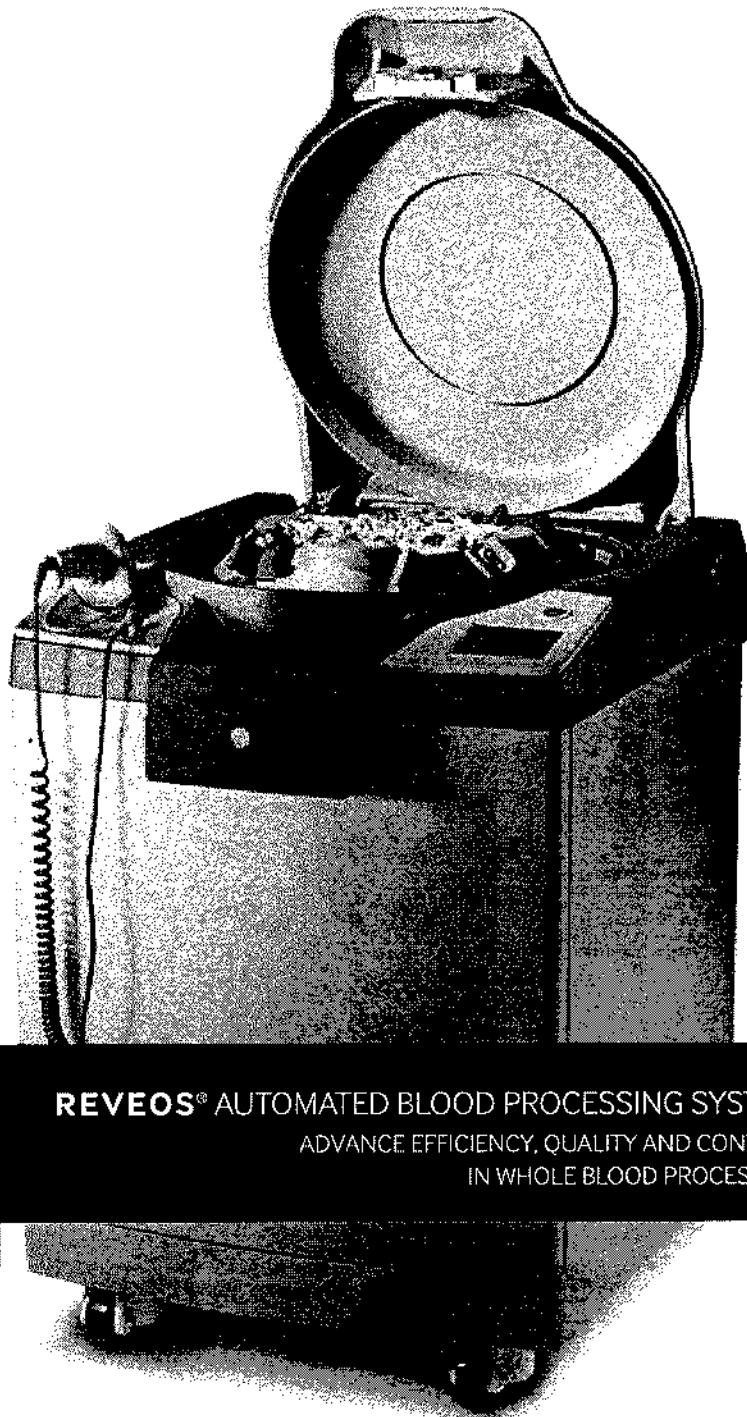
Copy for same

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Signature
 OFFICE OF THE
 MEDICAL SUPERINTENDENT
 AIIMS, KALYANI-741245
 Dr. Karan Kumar
 Assistant Professor
 Dept. of Transfusion Medicine
 & Blood bank
 All India Institute of Medical Sciences, West Bengal



Signature
 Dr. Somnath
 Additional Professor
 Dept. of Transfusion Medicine
 AIIMS, Bhubaneswar-751019
 09/07/22



REVEOS® AUTOMATED BLOOD PROCESSING SYSTEM
ADVANCE EFFICIENCY, QUALITY AND CONTROL
IN WHOLE BLOOD PROCESSING

THE REVEOS® AUTOMATED BLOOD PROCESSING SYSTEM IS NOT CLEARED FOR SALE IN THE U.S. IT IS AVAILABLE IN SELECT MARKETS.



PUT AUTOMATION TO WORK FOR YOU

IMPROVE YOUR LAB EFFICIENCY, BLOOD COMPONENT QUALITY
AND PROCESS CONTROL.

AUTOMATED WHOLE BLOOD (WB) PROCESSING, FOUR UNITS AT A TIME

The Reveos system is an easy-to-use platform that automates and integrates the manual steps involved in WB processing.

Quick and efficient, the Reveos system processes four units of WB at a time. Use your Reveos system to produce red blood cells (RBCs), leukoreduced plasma, interim platelets for pooling and residual leukocytes with a single centrifugation step.

AUTOMATION DESIGNED FOR EASY ADOPTION

While the prospect of automating your process may seem daunting, we have helped many blood centers around the world successfully upgrade their labs. And that number continues to grow. Today, blood banks in more than 25 countries have adopted our WB automation technologies.

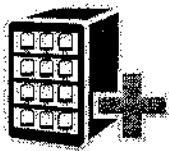
These blood centers benefit from the rewards of automation. And you could, too. Put our knowledge and expertise to work to improve your WB process.

Let's take a look.



THE VALUE OF AUTOMATION*

THE BENEFITS OF AUTOMATION INCLUDE IMPROVEMENTS IN THESE AREAS:



PRODUCTIVITY

- The platelet yield index (PYI) feature can help you create more pools of platelets from your daily collections of WB
- One shift and four Reveos devices can process approximately 70,000 units of WB annually**



COMPLIANCE

- Reveos System Manager (RSM) automatically records processing steps



EFFICIENCY

- The Reveos system reduces the need for resources, including staff time, equipment, space, standard operating procedures (SOPs) and training
- In a single run, the system integrates the functions of centrifugation, sedimentation, separation and sealing of four WB units, resulting in multiple blood components



QUALITY

- The Reveos system is designed to create consistent products, using fixed-bucket technology and integrated processing steps
- The PYI feature allows for estimating/predicting the platelet yield of platelet pools
- Plasma is automatically leukoreduced

*As compared with manual processing

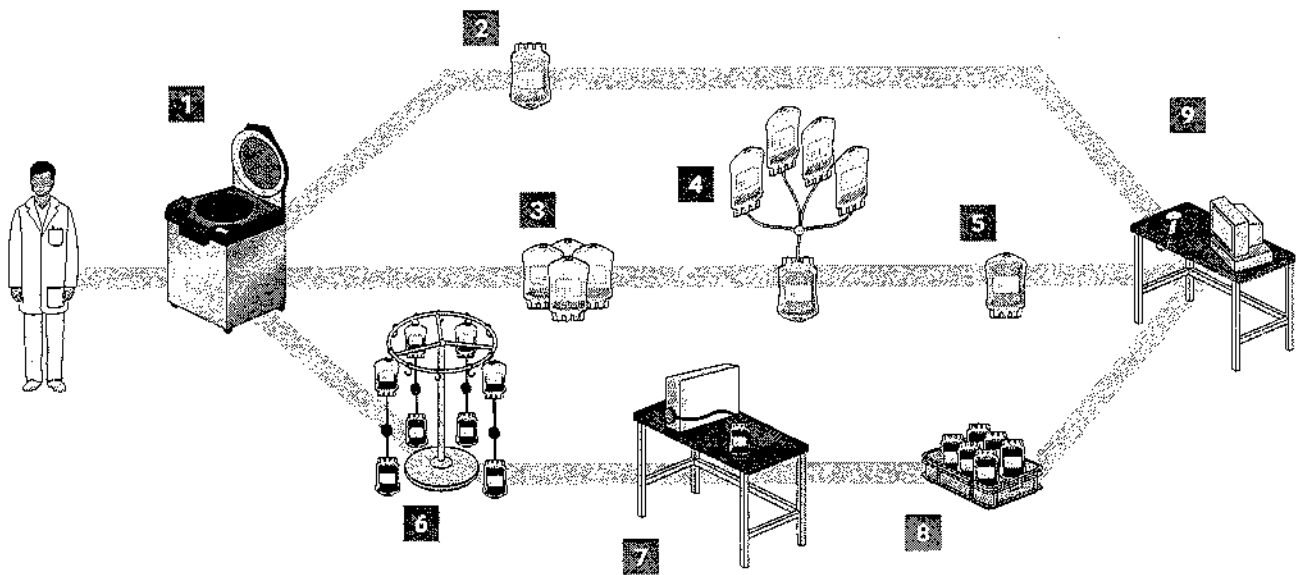
**See the assumptions listed in the improved throughput table on page 9

COMPARE YOUR PROCESS TO THE REVEOS SYSTEM PROCESS PROCESS FOUR UNITS OF BLOOD AT A TIME

THE REVEOS SYSTEM PROCESS: 3 COMPONENT (3C) PROTOCOL AND PLATELET POOLING

The Reveos system process requires far fewer steps than manual processing.

- | | |
|------------------------------------|---|
| 1 Operate Reveos system | 6 Leukoreduce red blood cell (RBC) units |
| 2 Leukoreduced plasma unit | 7 Seal RBC units |
| 3 Interim platelet units | 8 Store leukoreduced RBC units |
| 4 Pool platelets | 9 Enter data |
| 5 Therapeutic platelet dose | |

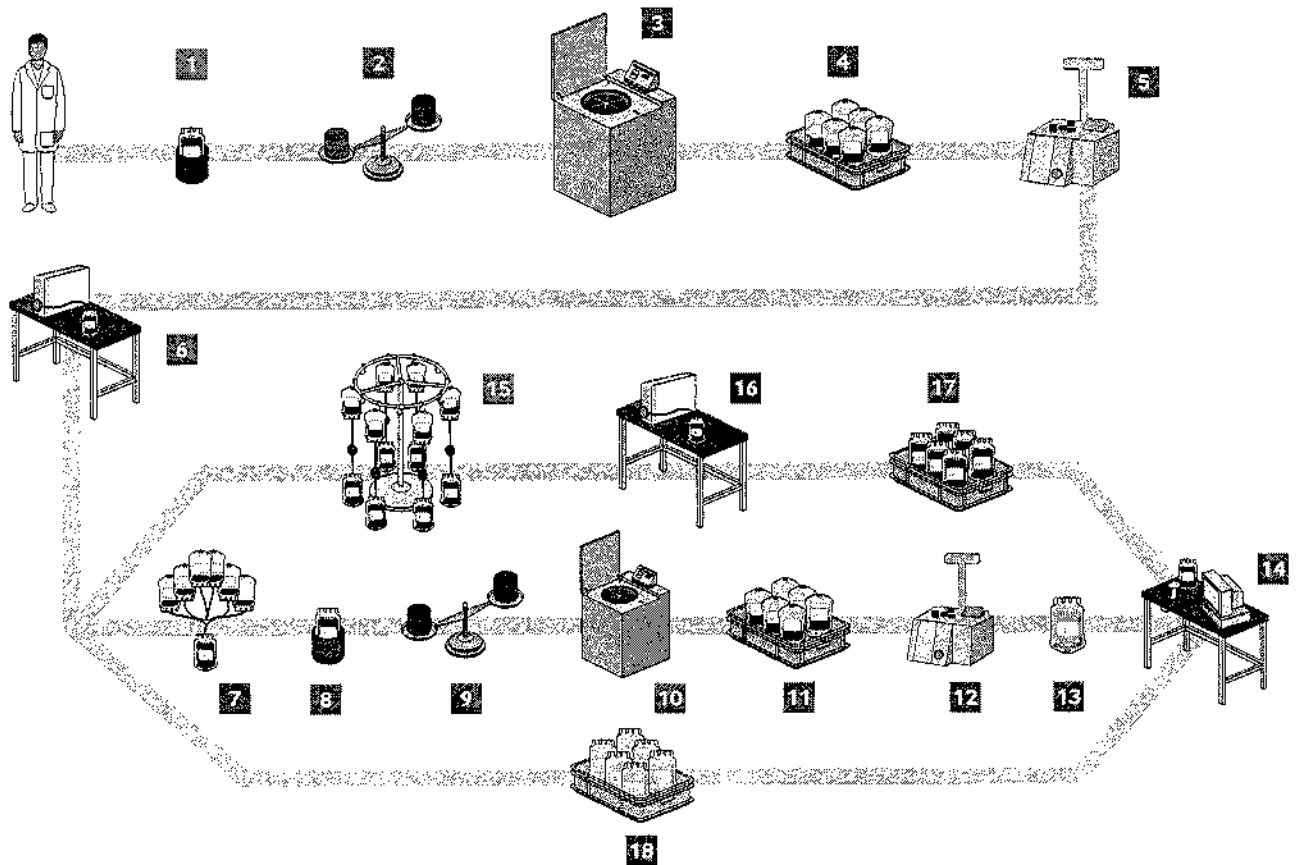


MANUAL WB PLATELET PROCESS

THERE ARE MANY STEPS IN THE MANUAL PROCESS.
EACH ONE CAN AFFECT THE QUALITY OF YOUR FINAL COMPONENTS.

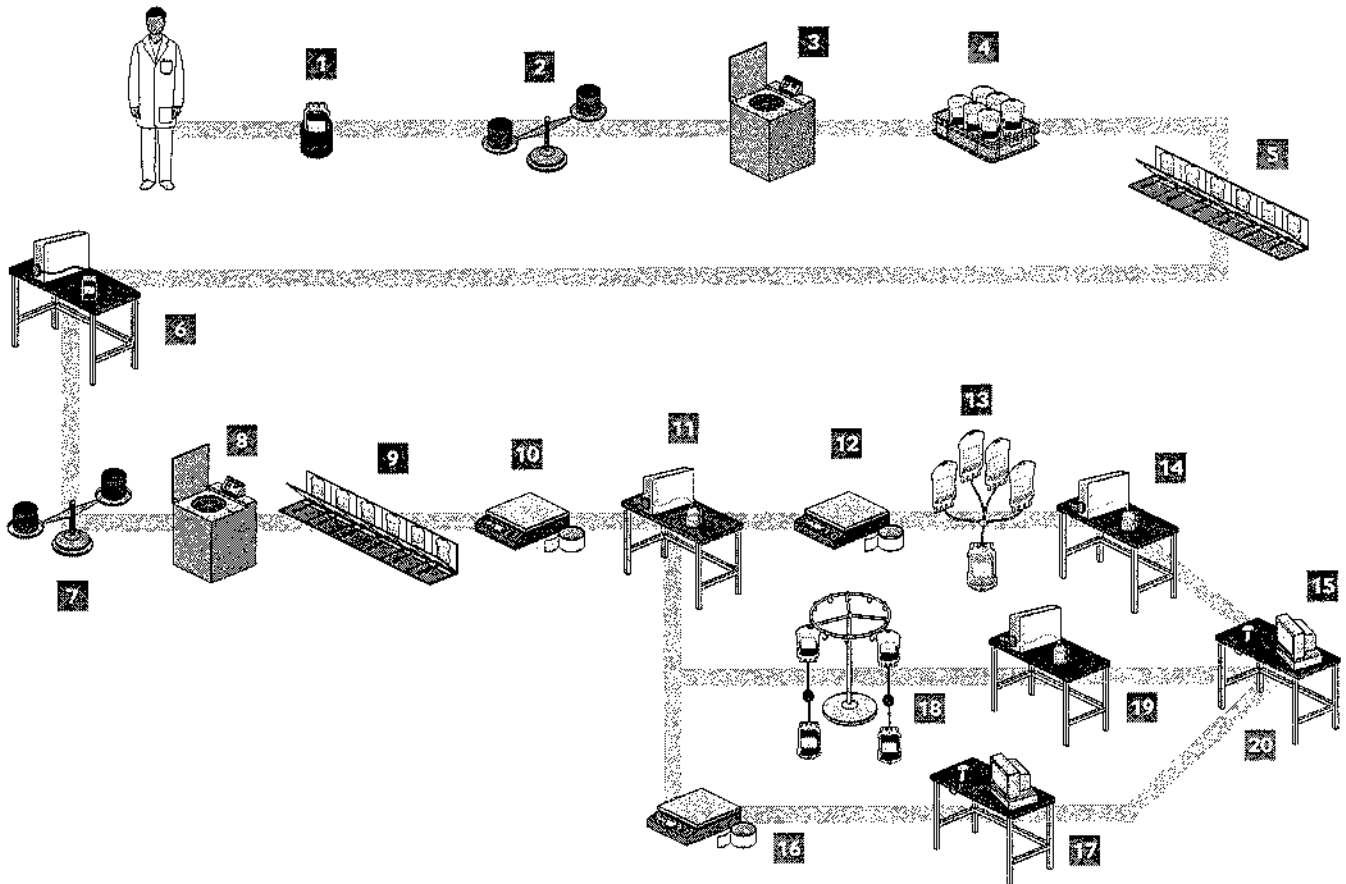
MANUAL BUFFY COAT (BC) PROCESS

- | | | |
|--|--|--|
| 1 Pack for positioning in cup | 8 Pack for positioning in cup | 15 Leukoreduce RBC units |
| 2 Balance | 9 Balance | 16 Separate RBC units from filter |
| 3 Centrifuge | 10 Centrifuge BC units | 17 Leukoreduced RBC units |
| 4 Transport units | 11 Transport units | 18 Plasma units |
| 5 Separate RBCs and plasma from BC | 12 Separate platelets from BC units | |
| 6 Seal and separate plasma, packed RBC and BC units | 13 Platelet concentrate | |
| 7 Pool and rinse BC units | 14 Enter data; store or additionally process products | |



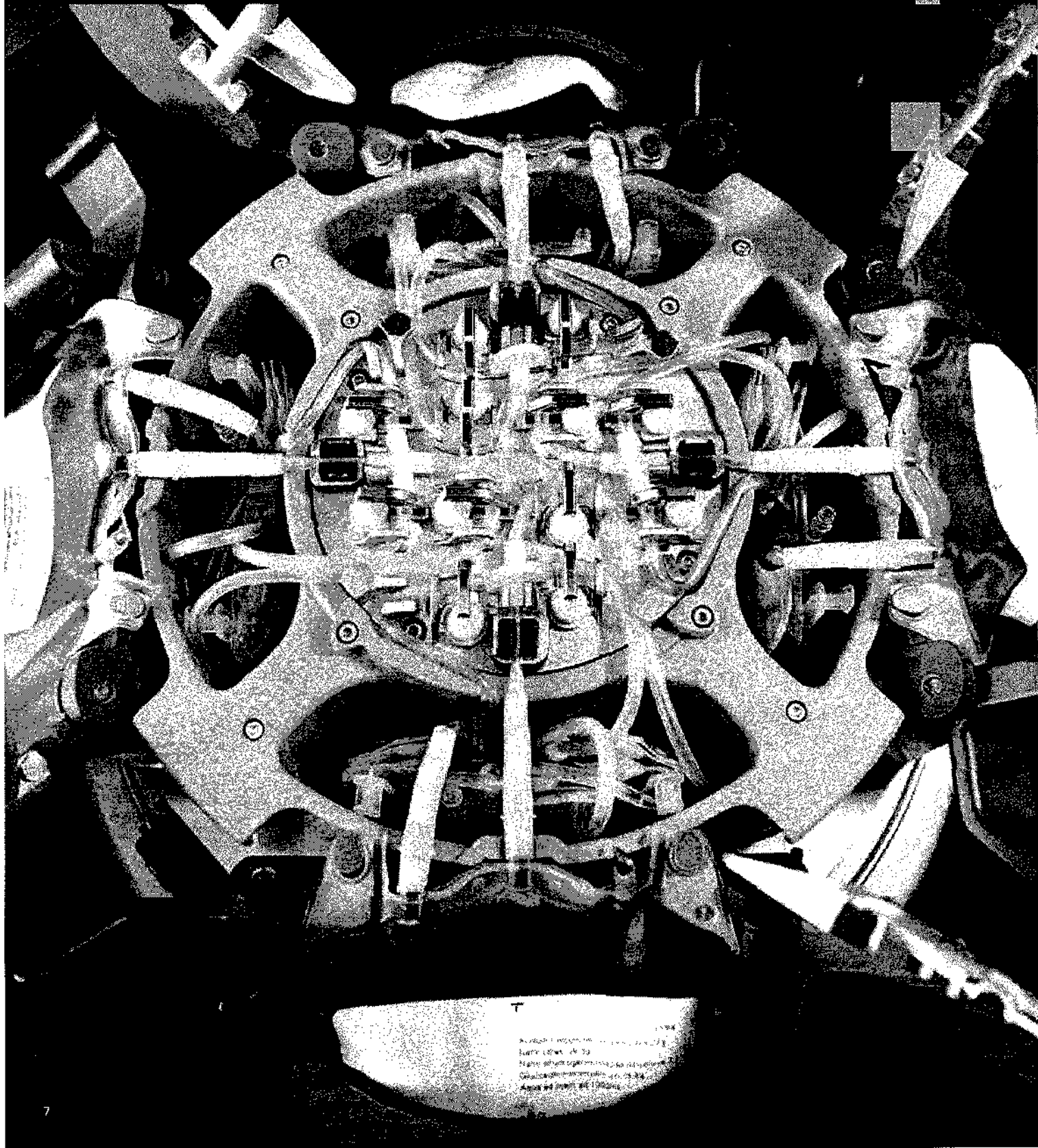
MANUAL PLATELET-RICH PLASMA (PRP) PROCESS

- | | | |
|--|--|--|
| 1 Load WB in centrifuge cups | 10 Adjust plasma volume in PC | 18 Leukoreduce RBC units |
| 2 Balance WB | 11 Seal and separate plasma from PC | 19 Seal and separate leukoreduced RBC units |
| 3 Centrifuge WB | 12 Weigh PC | 20 Enter leukoreduced RBC data |
| 4 WB is ready for PRP expression | 13 Pool and leukoreduce PC | |
| 5 Express PRP | 14 Seal and separate pooled platelets | |
| 6 Seal and separate PRP from RBCs | 15 Enter pooled platelet data | |
| 7 Balance PRP | 16 Weigh plasma | |
| 8 Centrifuge PRP | 17 Enter plasma data | |
| 9 Express plasma from platelet concentrate (PC) | | |

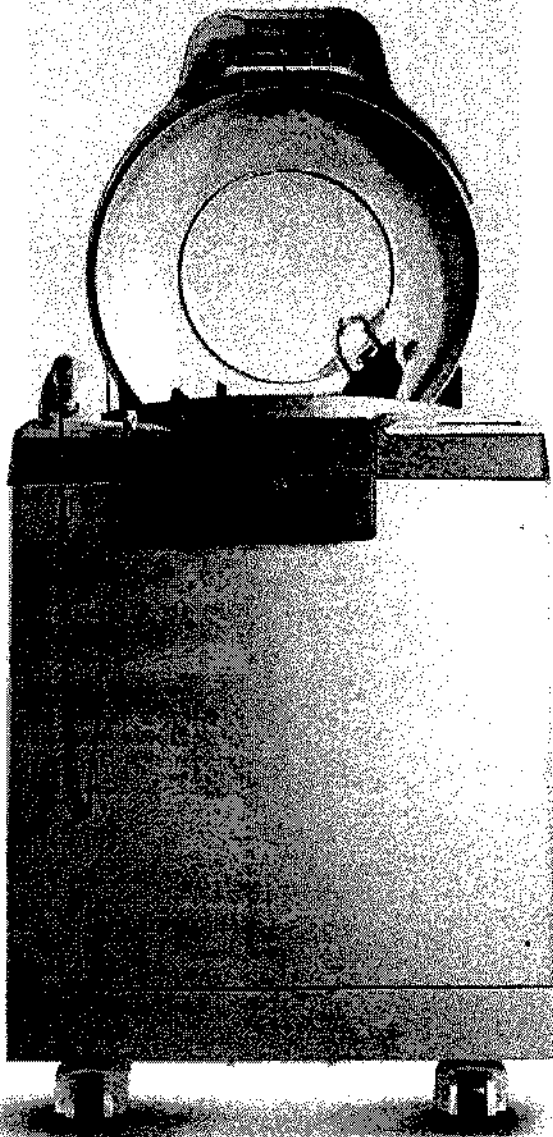


MEET THE REVEOS SYSTEM

THE REVEOS SYSTEM AUTOMATES MANY PROCESSING STEPS,
CONSOLIDATING THEM INTO A SINGLE RUN.



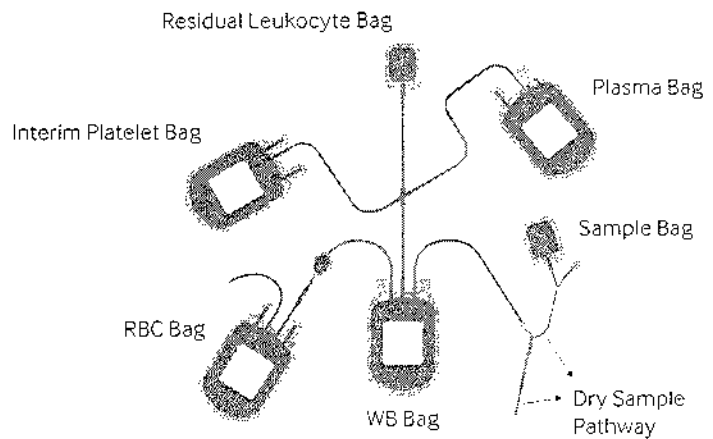
- BALANCE
- CENTRIFUGE
- EXPRESS
- SEAL
- DETERMINE PRODUCT VOLUME AND ESTIMATE PLATELET COUNT
- COLLECT DATA
- REPORT DATA



THE REVEOS SYSTEM OVERVIEW

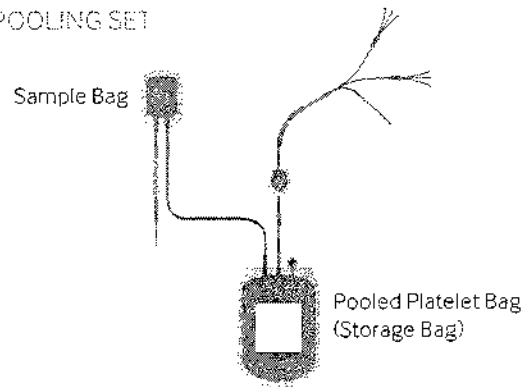
- **Reveos device**
A self-contained automated device that processes up to four units of WB at a time
- **Reveos System Manager (RSM)**
An enhanced data management system
- **Cadence® Data Collection System**
Allows us to provide enhanced customer service
- **Reveos 3C Blood Bag Set**
One set to collect and process WB into multiple components
(Intended use: The Reveos 3C blood bag set is intended to collect a unit of WB and process that unit on the Reveos device, producing blood components.)
- **Platelet Pooling Set**
Four to six interim platelet units (IPUs) are pooled to create a transfusable platelet dose
(Intended use: The platelet pooling set is intended for use with WB-derived platelets, including pooling and filtration, resulting in a Platelet product for transfusion.)

REVEOS 3C BLOOD BAG SET



Drawing may not represent current configuration

PLATELET POOLING SET



Drawing may not represent current configuration

THE ADVANTAGES OF THE REVEOS SYSTEM

LOOK WHAT YOU CAN DO WITH THE RIGHT TOOLS.

IMPROVE PRODUCT CONSISTENCY*

Achieve consistent quality with fixed-bucket technology and integrated processing steps.

OBTAIN HIGHER YIELDS*

The Reveos system may help you improve yields in several ways:

- The process is automated and consistent, resulting in fewer mistakes and fewer discarded products
- The system is highly accurate, enabling operators to obtain a higher volume of components from the same volume of WB
- The system is flexible and can be customized to your center's unique needs

The PYI is an exclusive, innovative feature that provides the operator with a prediction of the platelet yield of the processed unit. The PYI value is shown on the device display screen and recorded in RSM.

Improve throughput

THROUGHPUT POTENTIAL IN WB UNITS/YEAR				
NUMBER OF SHIFTS	1 Reveos System	2 Reveos Systems	3 Reveos Systems	4 Reveos Systems
1	18,000	36,000	54,000	72,000
2	36,000	72,000	108,000	144,000
3	54,000	108,000	162,000	216,000

Assumptions: 25 minutes/cycle, 1 cycle = 4 WB units, 250 working days/year, 7.5 hours/shift

Please contact your Terumo BCT representative for a customer-specific value analysis of the Reveos system.

Optimize your workflow:

- Reduce manual steps
- Reduce SOPs
- Reduce hands-on time
- Improve resource management

Process more than 18,000 WB units each year with these benefits: **

- Less space
- Less equipment
- Less labor
- Less time

*As compared with manual processing

**See the assumptions listed in the table above

PROCESSING EQUIPMENT	Manual Semi-Automated Method	Reveos System
Triage balance	1	0
Reveos system	0	5
Centrifuges	5	0
Expressors	18	0
Sterile connection device	2	2
Component disconnect sealers	3	1
Platelet agitators	4	4
Total	33	12
Savings	64%	

STAFF UTILIZATION	Manual Semi-Automated Method	Reveos System	Savings
First-stage separation	10	5	50%
Second-stage separation	2	0	100%
Platelet pooling	2	2	0%
Total	14	7	50%
Assumptions: 100,000 WB units/year, two-stage platelet separation			

Please contact your Terumo BCT representative for a customer-specific value analysis of the Reveos system.

MANAGE INFORMATION WITH EASE*

Software solutions take your system further.

- For greater control and flexibility, the Reveos system is equipped with RSM and compatible with the Cadence Data Collection System
- RSM centralizes device and operator management; it also allows interfacing with your blood bank's IT system

**As compared with manual processing*



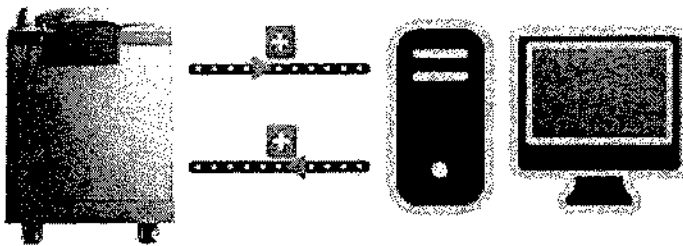
INFORMATION TECHNOLOGY (IT)

PROVIDES CONTROL AND TRACEABILITY

RSM OVERVIEW

RSM, an enhanced IT solution, is designed to effectively manage the Reveos system's day-to-day operations. RSM provides access to processing data that improves your process control and provides insight into every procedure performed on the Reveos system.

RSM can manage your devices at one site or across multiple facilities.



Data Includes:

- 🕒 Time
- 📦 Device ID
- 📊 Barcode Scans
- 🏠 Components
- 📊 Platelet Yield Index
- 📦 Volumes
- 🚨 Alarms
- ⚙️ Configurations

Data transfer from your Reveos system to RSM allows you to generate valuable reports, ensure traceability, track processes, identify areas for improvement and more.

Data transfer from RSM to multiple Reveos systems allows you to customize your Reveos system, manage your procedures and security settings and more.

RSM SEARCHES AND REPORTS

Report generation

- Schedule reports to monitor manufacturing operations
- Enable traceability of processed units, equipment and operator actions
- Identify areas for improvement
- View, print or export data to other systems for analysis
- View an intuitive graphical representation of data

Donation ID and search feature

- Find a single unit based on its donation ID, available on any page in RSM
- View donation ID search results that show processing date, component volumes, operator ID, device name and alerts or alarms that occurred during processing of the unit

INSIGHT REPORT

CHART VIEW

Operations

- Number of units processed by each Reveos device
- Average duration of procedures by operator

Production

- Average volume of each component by procedure
- Total number of components produced
- Percentage of units with a PYI within the specific range for 3C procedures

Exceptions

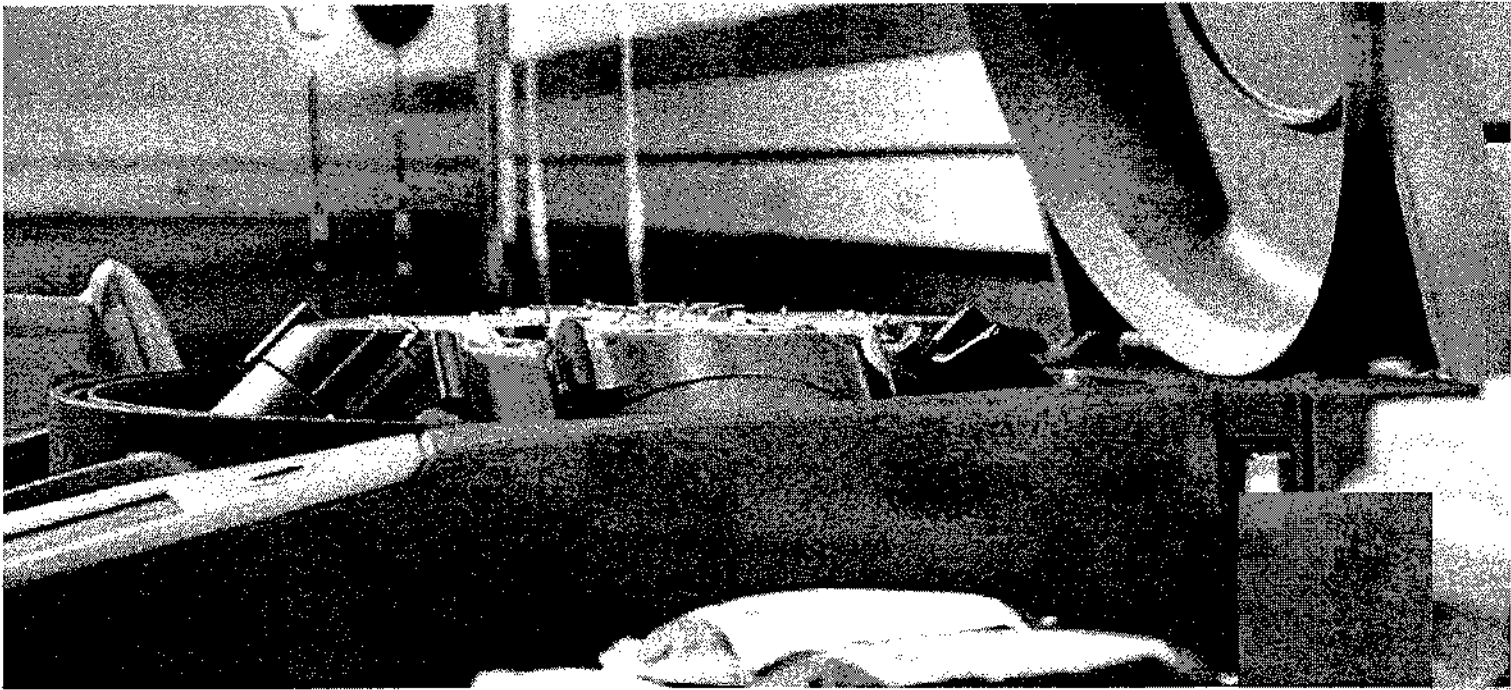
- Details about duplicated units, reprocessed units and inconclusive sealed units, as well as barcode and centrifuge temperature issues

Alarms and alerts

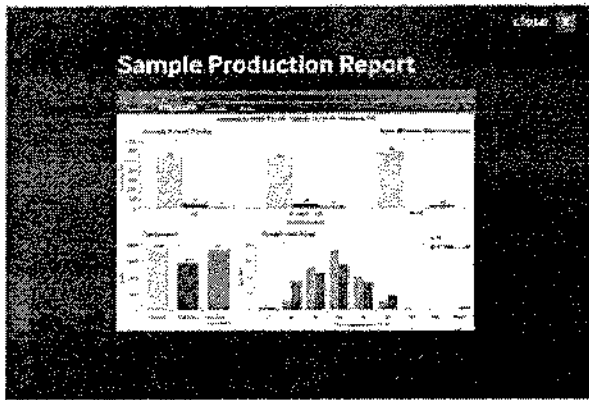
- Total number of alarms and alerts by operator and by device

DETAILS VIEW

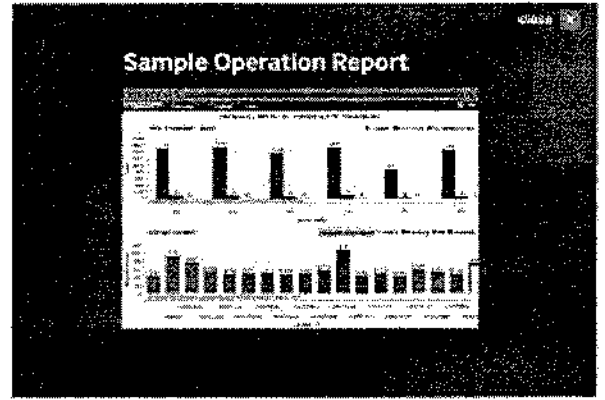
- Data from the Insight Report or a Custom Query Report in a table format



SAMPLE REPORTS



Sample Production Report



Sample Operation Report

ONE DEVICE, TWO PROTOCOLS

THE REVEOS SYSTEM	2 Component Protocol	3 Component Protocol
4 WB units	4 RBC units	4 RBC units
	4 leukoreduced plasma units	4 leukoreduced plasma units
	4 residual leukocyte units	4 leukoreduced platelet units
		4 residual leukocyte units

Please contact your Terumo BCT representative to purchase processing sets.

DEVICE AND OPERATING ENVIRONMENT SPECIFICATIONS

SPECIFICATION TYPE	VALUE
Humidity	10% to 80% RH non-condensing
Operating temperature	Recommended 18 °C to 27 °C (64.4 °F to 80.6 °F)
Storage temperature	0 °C to 60 °C (32 °F to 140 °F)
Environment	Indoor use only
Elevation	Up to 2,000 m
Rated voltage	200 V AC to 240 V AC (± 10%), 50/60 Hz
Main power circuit breaker	Characteristic C, Rated 16 A, 30 mA RCCD (European Union)
Rated input (typical)	1.2 kVA
Rated input (maximum)	6.0 kVA
Power plug	IEC 60309 2P + E, 200 V to 250 V, 50/60 Hz, 16 A IP44
Ventilation (per device installed)	Adequate to dissipate 1.0 kW in normal operation
Minimum clearance envelope (perimeter around the device)	15.2 cm (6 in)
Minimum floor area needed for installation (D × W)	99.1 cm × 114.3 cm (39 in × 45 in)
Safety standards	IEC 61010-1:2010, IEC 61010-2-20:2006
EMC standard	IEC 61326-1:2006
Ethernet connection	RJ45 CAT 5e ANSI/TIA/EIA 568 B.2
Barcode scanner connection	4-pin LEMO®
Ingress protection rating	Ordinary protection only

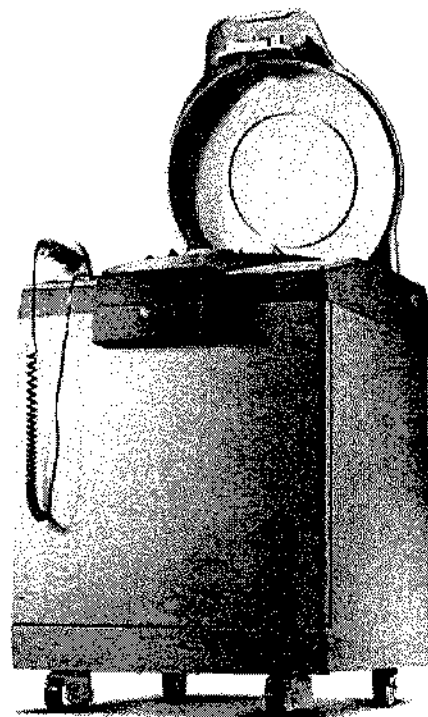
AUTOMATION IMPROVES YOUR CURRENT PROCESS

The Reveos system can help you achieve these goals:*

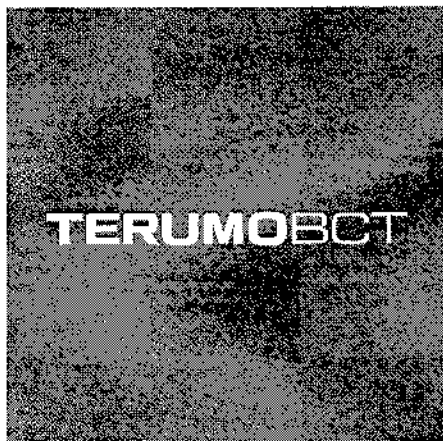
- Improve product consistency
- Obtain higher yields
- Improve throughput
- Optimize your workflow:
 - ⊖ Reduce manual steps
 - ⊖ Reduce SOPs
 - ⊖ Reduce hands-on time
- Process more than 18,000 WB units a year, with these benefits:
 - ⊖ Less space
 - ⊖ Less equipment
 - ⊖ Less labor
 - ⊖ Less time
- Manage information with ease
 - ⊖ Capture processing data electronically to support good manufacturing practice (GMP) compliance

*As compared with manual processing

FOR MORE INFORMATION ABOUT THE REVEOS SYSTEM, CONTACT YOUR TERUMO BCT REPRESENTATIVE.



As a global leader in blood component, therapeutic apheresis and cellular technologies, we believe in the potential of blood to do even more for patients than it does today. This belief inspires our innovation and strengthens our collaboration with customers.



Terumo BCT, Inc.

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UNLOCKING THE POTENTIAL OF BLOOD | TERUMOBCT.COM

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