MOBILE REFERENCE GUIDE

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SECTION 1

INTRODUCTION

1.1 PREFACE

The U.S. population is growing, aging, and shifting ethnically. Although our rapidly changing demographics already present a challenge to blood centers, experts predict these forces will increasingly impact the health care and blood banking industries.

To meet the growing demand for blood created by the aging population—the demographic most likely to require surgeries and less likely to be able to donate—blood donations must come from younger generations and at a higher percentage. But younger donors are dropping out of the donation pool at an alarming rate. To meet the changing demand created by expanding minority racial and ethnic populations, blood centers must find ways to collect more of the blood types once considered rare, from a donor base they have traditionally struggled to recruit.

Each day, blood centers strive to cost-effectively collect the right components to match patient needs while also managing product outdates. For many, going directly to donors and having the flexibility to collect the most needed components through mobile drives is a promising solution. Adding automated collections to mobile practices can help centers collect more of the right product, at the right time, to meet ever-changing demands and improve mobile drive profitability.

1.2 CONTENT OVERVIEW

This guide is intended to offer information that may help blood centers develop and implement a mobile program that incorporates the Trima Accel system. It was created with the knowledge that most centers already conduct mobile drives, and many include apheresis systems in these operations. This guide will help assist customers who already use the Trima Accel system for in-center collections and are extending use to mobile operations. This guide should be considered as a reference only and provides a focus specifically on considerations that are unique to the mobile environment. The Trima Accel System Operator's Manual and System Administrator's Guide are the best resources for technical device operations.

This reference guide offers the following information for your consideration:

- Good Manufacturing Practices (GMP) and process control references
- Code of Federal Regulations (CFR) references
- Trima Accel system physical and environmental specifications
- Site assessments and set-up for mobile coach and inside set-up
- Suggested best practices for optimal product quality and process control
- Donor and staff scheduling and collection time considerations

SECTION 2

GETTING STARTED

2.1 GMP AND PROCESS CONTROL CONSIDERATIONS

Two types of mobile blood collection operations are:

- Mobile coach: a collection operation conducted on a self-contained coach
- Inside set-up: one in which all the equipment, supplies, and staff are transported to a remote collection location, set up, and removed at the end of day

A mobile blood drive operates under the Food and Drug Administration (FDA) registration of the facility, or home base, from which it is dispatched. If supplies or equipment are permanently stored at a collection location, the collection operation should be considered a fixed-site operation and be registered as such with the FDA.

Operations for mobile blood collections are similar to operations for fixed-site collections, but because they are mobile, there are additional considerations that need to be addressed.

Table 1 summarizes many of these considerations, including:

1. Storage of reagents (if platelet counts will be performed), supplies (disposable tubing sets, solutions and other materials), and equipment between mobile operations; because the mobile coach or truck used to transport these items may not be temperature-controlled when the vehicle is not in use, staff must know what can be left in the vehicle overnight and what must be removed
2. Assurance of adequate supplies and equipment during the mobile operation
3. Frequency and availability of preventive maintenance for equipment that is routinely transported to and from the mobile operation
4. Ready-access to medical consultation/coverage and standard operating procedures (SOPs) during mobile deployment
5. Instructions on how to correctly pack and move equipment

Table 1 – Mobile Blood Center Considerations

GMP/PROCESS CONTROL	ITEMS TO ADDRESS
Trima Accel System Handling	■ Establish device storage between mobile drives ■ Define proper loading/unloading procedures; consider loading the system closest to front of truck/nearest cab ■ Arrange for transport of the Trima Accel system, such as a box truck, van, or coach ■ Train staff and driver in proper handling and transportation ■ Ensure security; limit access during storage, transport, and throughout the mobile drive
Ancillary Equipment ■ Trima Accel System Disposable Tubing Sets ■ Hemoglobin and Hematocrit (H&H) Equipment, Cell Counters ■ Platelet Incubator and Agitator ■ Scales	■ Arrange storage between mobiles ■ Define proper loading/unloading procedures ■ Arrange for transport of equipment ■ Assure quality prior to use ■ Ensure security; limit access during storage, transport, and throughout the mobile drive
Product and Samples from Products	■ Ensure proper handling at collection site ■ Define storage at collection site ■ Define packing of product and supplies ■ Establish transport to blood center ■ Define labeling/label control
Reagents/Supplies ■ Trima Accel System Disposable Tubing Sets ■ Quality Control (QC) Reagents	■ Ensure adequate storage space and conditions during and between mobile drives ■ Ensure usage and storage SOPs are in place

Facility	■ Check environmental controls
	  ■ Temperature
	  ■ Ventilation
	  ■ Electrical supply
	  ■ Protect or avoid carpeted or difficult-to-clean surfaces
	■ Ensure donor confidentiality (during interview and of donation records)

Table 1 – Mobile Blood Center Considerations (continued)

GMP/PROCESS CONTROL	ITEMS TO ADDRESS
Donor Safety	■ Define medical coverage during mobile drive ■ Identify procedures for managing donor reactions ■ Establish a system to track donor blood loss ■ Ensure access to testing, historical donations, and pre-donation data needed to qualify donor

Staffing and Staff Safety	■ Define process to ensure safe work practices at mobile site
	  ■ Ensure personal protective supplies are available
	  ■ Confirm exposure control processes are in place
	  ■ Enforce safety rules
	  ■ Ensure adequate staffing levels
	  ■ Verify availability of hand-washing facilities or alternative method of decontamination
	■ Define process to assure compliance with labor laws

Biohazardous Material Control	■ Define process for storage, transport, and disposal
	  ■ During mobile drive
	  ■ After mobile drive

SOP	■ Ensure access to SOPs during mobile drive
Training	■ Train staff about issues unique to mobile operations (for example, verification of donor eligibility and procedure documentation, sample collection handling, holding, packing, and transport) ■ Verify competency for testing performed by mobile staff
Error/Accident/Event Reporting	■ Define process to initiate and route ■ Define process to assure FDA Blood Product Deviation reports are generated and reported per regulation
Records Management ■ Procedure Report ■ QC Reports – Equipment	■ Define process to stock and maintain adequate inventory at remote site ■ Define process to initiate, route, and archive completed records

Table 1 — Mobile Blood Center Considerations (continued)

GMP/PROCESS CONTROL	ITEMS TO ADDRESS
Regulatory	■ Verify collection site is truly a mobile versus fixed-site operation ■ Define "home base" for the mobile drive ■ Assure review of test results by Clinical Laboratory Improvement Amendments (CLIA)-qualified staff for tests performed on donors ■ Report addition of mobile coach in FDA annual report

2.2 CFR REFERENCES

21 CFR 210 and 211	Current Good Manufacturing Practices (cGMP) Regulations
21 CFR 601 Subpart C	Biologics Licensing
21 CFR 600 Subpart D	Reporting Adverse Experiences
21 CFR 607	Establishment Registration and Product Listing for Manufacturers of Human Blood and Blood Products
21 CFR 610	General Biological Product Standards
21 CFR 630	General Requirements for Blood and Blood Components and Blood Derivatives
21 CFR 640	Additional Standards for Human Blood and Blood Products

Other useful references:

AABB Publications

- *Blood Bank Regulations A to Z*
- *AABB Standards for Blood Banks and Transfusion Services*
- *AABB Technical Manual*

2.3 TRIMA ACCEL SYSTEM CONSIDERATIONS

The Trima Accel system is the leading platform for platelet, red blood cell (RBC), and plasma collection—effective in both in-center and mobile applications. It is the only system on the market today with the versatility to perform automated mobile collections of platelets, RBCs, and plasma—one solution to collect any blood component in any combination. The Trima Accel system was designed with wheels, enabling ease of portability, and quick loading and unloading. Following are items to be considered when adopting this system into mobile operations.

Trima Accel system weight and dimensions

The Trima Accel system weighs 187.7 pounds with the Trima Accel Seal Safe System installed. When the monitor and IV pole are folded down, system dimensions are similar to those of a typical office chair:

	TRIMA ACCEL SYSTEM	EXAMPLE: OFFICE CHAIR
Depth	32.0 inches	20 inches
Width	20.75 inches	26 inches
Height	41.9 inches	45 inches

Trima Accel system physical and environmental specifications

The physical and environmental specifications for the Trima Accel system (device and disposable tubing sets) and the electrical requirements for operation are outlined in the specifications chapter of the Operator's Manual for each Trima Accel system:

- Trima Accel System Version 5.0-5.1, Chapter 10
- Trima Accel System Version 6.0, Chapter 10

Temperature and environmental specifications

CHARACTERISTICS	PERFORMANCE
Trima Accel system	
Ambient operating temperature	15.5° to 27.7° C (60° to 82° F)
Ambient operating humidity	8% to 80% relative humidity (RH), non-condensing
System storage temperature	0° to 60° C (32° to 140° F)
Disposable tubing sets	
Long-term storage temperature range	0° to 60° C (32° to 140° F)
Shipping temperature range	-29° to 60° C (-20° to 140° F)
ACD-A and AS-3 solutions	
Recommended storage	Room temperature 25° C (77° F) Protect from freezing Avoid excessive heat
Physical specifications	
Floor space required	4.61 ft^2
Floor slope	less than 5 degrees

Power requirements and interruption recovery

Trima Accel system requires a clean power supply and ground integrity to operate safely.

CHARACTERISTICS	PERFORMANCE
Total Maximum Power Required	1,000 watts with Seal Safe 700 watts without Seal Safe
Input Current	100 to 127 Vac: 10 to 8 A 50/60Hz 200 to 240 Vac: 5 to 4 A 50/60Hz

Information regarding power interruption recovery is located in the Operator's Manual:

- Trima Accel system 5.0-5.1, Chapter 6
- Trima Accel system 6.0, Chapter 6

For site considerations beyond Trima Accel system specifications, see Section 2.4 "Other Mobile Considerations: Mobile Coach Versus Inside Set-up" in this guide.

Transporting the Trima Accel system

Instructions for how to prepare the Trima Accel system for transport and how to set it up at a donation site can be found in the Operator's Manual:

- Trima Accel system 5.0-5.1, Chapter 1
- Trima Accel system 6.0, Chapter 1

Prior to and during transport, the Trima Accel system should be secured to prevent potential damage—the leuokoreduction filter bracket, Trima Seal Safe System, and bar code reader should be disconnected and stored separately from the device. The IV pole and touch-screen display panel should be lowered. To lower the IV pole, press the IV pole release button on the left side of the system while holding and slowly lowering the pole. To lower the display panel, gently push down on the neck of the display panel then tilt the display panel forward.

To further protect your device, a heavy-duty cover (PN 704250-000) is available and recommended for use when transporting the Trima Accel system within the mobile environment. The cover includes a tethered monitor cover for additional protection of the display panel.

Secure the Trima Accel system in place before and during transportation by setting the wheel pedal (located on the front of the system below the centrifuge door) to the locked position. Using your foot, turn the pedal to the right to brake the system securely, and to the left to release the brake. To avoid possible injury or potential damage to the system, do not lift the Trima Accel system by the brake or side bumpers.

For more detailed transportation instructions, an additional reference resource titled "Transporting the Trima Accel System in a Mobile Environment" is included in the appendix of this guide.

Additional transportation considerations:

- Solutions and disposable tubing sets
- Ancillary equipment
  - Thermometer
  - Hemoglobin and hematocrit equipment
  - Platelet incubator and agitator
  - Cooler/refrigerator for RBC and plasma storage
  - Tube sealer
- Staffing

System qualifications prior to use

The Trima Accel system is designed for portability. Every time you perform a collection procedure, the system goes through a series of self-diagnostic tests: power on, tubing set, AC detector, and level sensor. If the system detects a problem, it will display an alert or an alarm. If no alert or alarm is displayed, the system has passed its functional checks and there is no need for additional system qualifications. A detailed list of the system self-diagnostic tests can be found in the Operator's Manual:

- Trima Accel system 5.0-5.1, Chapter 1
- Trima Accel system 6.0, Chapter 1

Trima Accel system operation

Supplies

The following supplies are necessary to perform a collection using the Trima Accel system:

- Trima Accel system
- Trima Accel system Operator's Manual
- Disposable tubing sets appropriate for the collection type
- Solutions
  - ACD-A anticoagulant
  - Saline and AS-3, if performing RBC collections
- Method for determining donor hematocrit and platelet count (see best practices in Table 2)
- Venipuncture site preparation materials
- Blood pressure cuff
- Hand squeezers and warming blankets (customary for apheresis donors)
- Tube sealer or grommets
- Scales, if processing products at the collection site

Donor information

The following donor information is required to perform a collection using the Trima Accel system:

- Gender
- Height
- Weight
- Hematocrit or hemoglobin

If performing a platelet collection, a donor platelet count is also required. In a mobile operation, platelet count options can include: day of platelet count (if a cell counter is available), an average of previous platelet counts, the last platelet count, or a default platelet count. See Table 4 for suggested platelet count and hematocrit methods in Section 3 "Best practices" of this guide.

2.4 OTHER MOBILE CONSIDERATIONS: MOBILE COACH VERSUS INSIDE SET-UP

When introducing the Trima Accel system into mobile operations, other details in addition to device specifications should be considered. Site specifications and mobile preparation will vary between the two types of mobiles: mobile coach and inside set-up at a remote collection location.

Mobile coach considerations

Consider the following when designing a drive using a mobile coach

- What are the coach specifications: height (H), length (L), and width (W)?
- How much space is needed for parking?
- Will the coach transport staff?
- What is the best bed configuration? Should this be strictly a Trima Accel system coach or Trima Accel system plus whole blood coach?
- How many whole blood and/or Trima Accel system beds are needed?
- What is the appropriate number of medical history screening areas?
- Will donor registration take place on the coach?
- Will the canteen be on the coach?
- Ensure canteen is separate from blood collection activities.
- Do you need a refrigerator for canteen food?
- What types and quantities of ancillary equipment and supplies are needed?
- What are the specifications for each piece of ancillary equipment and additional supplies? Consider dimensions, power, storage, floor slope, ambient operating temperature, and relative humidity.
- What size generator is needed to support the electrical equipment?
- How much storage is necessary?
- Do you need phone lines or uplink capabilities?
- How much surface area do you need?
- Do you want mountable items to conserve surface area?
- What type of flooring is best?
- What type of cabinets?
- What type of counter tops?
- What are the desired amenities?
- Do you want a TV/DVD player?

- Do you want a stereo system?
- Do you want windows with shades?
- Do you want an awning?
- What interior colors are best?
- What are CDL driver license requirements?
- How much and what kind of storage space do you need for collected blood?
- Do you have proper storage conditions for collected blood?

Calculating mobile coach generator power requirements

When operating Trima Accel systems on a mobile coach, ensure the generator is powerful enough to run all the equipment necessary for a mobile coach operation. To determine generator requirements, you must calculate the total maximum power required to operate all devices that require electricity. When calculating power consumptions, you must also consider duty cycles. Maximum power is defined as the watts required for the device to function. If the power rating doesn't specify watts, look for voltage (V) and current or amperage (A) information and multiply these two numbers together to obtain the watts needed to operate that device.

V x A = WATTS

To calculate total maximum power, look at the power rating on the device label and multiply the watts (W) for an individual device with the device quantity (X).

W x X = TOTAL MAXIMUM POWER

To help compute the total maximum power in watts needed for a generator, complete the following worksheet:

DEVICE	VOLTAGE (V)	AMPS (A)	WATTS (W)	DEVICE QUANTITY (X)	TOTAL MAXIMUM POWER
TRIMA ACCEL SYSTEM					
AIR CONDITIONER					
HEATER					
H&H EQUIPMENT					
TUBE SEALER					
MICROWAVE					
REFRIGERATOR					
COMPUTER					
TELEVISION					
DVD PLAYER					
TUBE ROCKERS					
CELL COUNTERS					
PLATELET INCUBATORS AND AGITATORS					
TOTAL					

Mobile coach site assessment

In addition to considering how to configure your mobile coach, it is important to assess in advance the site where the coach will be parked to make sure the location meets specified requirements. In addition to general requirements for a mobile blood drive, consider the following:

- Are there enough parking spaces for the coach and donors?
- Are there overhangs on the way to or at the mobile site?
- Is the designated parking spot in a fire lane?
- Does the designated parking spot require a permit?
- Are there any other special arrangements for the designated area?
- Where will donor registration and canteen be located if not on the coach?
- How will the registration and/or canteen be staffed if not on the coach?
- If canteen and/or registration are not on coach, what type of volunteer training is needed?
- If canteen and/or registration are not on coach, how will the volunteers communicate with staff?
- Where are the nearest restrooms?
- Where is the nearest telephone?
- If there is an emergency, how will it be handled?
- Do you have medical emergency contact information?
- Do you have proper storage space and conditions for the products that will be collected?
- Are there any collection-time restrictions?
- Will there be product pickups for this mobile? If so, at what time(s)?
- Are there any special product handling instructions for this mobile?
- What supply/reagent inventory is necessary for each drive?

Inside set-up considerations

Inside set-up at a remote collection location differs slightly from set-up on a mobile coach. Below are a few questions to consider when defining a standard for inside mobile set-up:

- What is the optimal bed configuration? How many beds are needed and what type (whole blood or automated collections using the Trima Accel system)?
- Should Trima Accel system beds and whole blood beds be separated or combined?
- Do you want a recovery bed?
- What is the appropriate number of medical history screening areas?
- What is the best set-up for donor- and work-flow?
- What types and quantities of ancillary equipment and supplies are needed? (See Section 2.3 "Trima Accel System Considerations" in this guide)
- What are the environmental and physical specifications for the Trima Accel system and other pertinent ancillary equipment? (See Section 2.3 in this guide)
- What is the minimum room size required?
- What are the minimum electrical requirements for the room?
- What are the requirements for temperature control?
- What are the requirements for humidity control?
- What are the requirements for ventilation?
- What are the requirements for lighting?
- What type of flooring is acceptable?

- Do you need phone lines or uplink capabilities?
- Does the entrance into the building present any challenges in transporting the Trima Accel system? For example, is the pathway or parking lot gravel or cobblestone?
- Are there any employee restrictions on lifting, including number of stairs?
- How will the equipment and supplies be transported? (See Section 2.3 in this guide)
- How will the equipment and supplies be loaded and unloaded from the transportation vehicle?
- How will the equipment and supplies be secured during transport and on site?
- How will the equipment and supplies be packaged to avoid damage?
- How will the equipment and supplies be stored to meet specifications?

Inside set-up site assessment

It is important for a location to meet all necessary requirements before setting up a mobile drive using the Trima Accel system. When planning for a remote inside set-up, consider completing a site assessment prior to scheduling the mobile drive:

- Does the room meet minimum size requirements?
- Is there adequate room to allow for privacy during donor screening?
- Identify the electrical outlet locations. Are they placed appropriately for your equipment configuration? Do you have enough outlets and electrical current requirements?
- Does the room meet minimum requirements for temperature, lighting, and ventilation?
- Is the lighting near the electrical outlets acceptable?
- Does the mobile meet surface, transporting and lifting requirements?
- Identify the donor registration and canteen locations.
- How will the registration and/or canteen be staffed?
- If canteen and/or registration are not in the same room as the drive, what type of training is needed for volunteers?
- If canteen and/or registration are not in the same room as the drive, how will the volunteers communicate with staff?
- Who will supply the chairs and tables? How many chairs and tables are needed? How will they be arranged and who will set them up?
- Where are the nearest restrooms?
- Where is the nearest telephone?
- If there is an emergency, how will it be handled?
- What type of products will be collected?
- Are there any collection-time restrictions?
- Will there be product pickups for this mobile? If so, at what time(s)?
- Are there any special product handling instructions for this mobile?
- What inventory is necessary for each drive?
- Do you have the site contact name and his/her phone number?
- Do you have location information and driving directions?

SECTION 3

BEST PRACTICES

3.1 OPTIMAL PRODUCT QUALITY AND PROCESS CONTROL

This section discusses best practices for optimal product collection and good overall process control, or minimal variation. While all processes contain sources of variation, the aim of this section is to identify common sources and explain recommended practices associated with the pre-collection, collection, and post-collection processes in an effort to minimize variation.

The degree of process variation is measured statistically based on yield data. A coefficient of variation (CV) is calculated from the average and the standard deviation of yield ratios. The Yield Scaling Factor (YSF) and yield and concentration targets are calculated from the same yield data. In order to obtain consistent products, all Trima Accel systems on the mobile should be configured the same way. Your local sales representative or implementation consultant can assist in assessing machine configurations.

Pre-collection

The main source of process variation during the pre-collection phase is accuracy of donor pre-counts. Product quality, platelet yields, and RBC dose are directly influenced by the accuracy of donor pre-counts as depicted in Tables 2 and 3.

Table 2 – The Effect of Platelet Pre-counts on Platelet Products

PLATELET PRE-COUNT	EFFECT ON PLATELET PRODUCT
Count too high	Low concentration/yield
Accurate count	Desired concentration/yield
Count too low	High concentration/yield Procedure disqualification

Table 3 – The Effect of HCT on Platelet and RBC Products

HCT	EFFECT ON PLATELET PRODUCT	EFFECT ON RBC PRODUCT
HCT too high	High CV, low yield	Low dose
Accurate HCT	Desired yield	Desired dose
HCT too low	Spillover, count message	Potential product disqualification

If you are performing a platelet collection, a donor platelet count is required. Recommended platelet count and hematocrit methods are included in Table 4.

Table 4 – Recommended Platelet Count and Hematocrit Methods

	PRE-COLLECTION PLATELET COUNT	PRE-COLLECTION HEMATOCRIT OR HEMOGLOBIN
Best practice	Same-day venous count entered at or near initiation of the collection procedure (CV ≈ 5%)	Same-day venous count (CV ≈ 5%)
Good alternative choice	Average of the last three venous counts (CV <8% for 50% of donors, <10% for 70% of donors, <15% for 90% of donors)	Finger stick
Less preferred	Venous count from the previous donation	Using a historical count*
Least preferred	Default count (CV is about 30% or more)	Ear stick*

Note: Copper sulfate is not an acceptable method for qualifying a donor for automated collections.

*Regulations may limit use of historical count or ear stick

Consistency is as important as method. Follow your center's SOP for the method to use in obtaining platelet pre-counts while on mobile drives and adhere to this method every time.

Collection

During a mobile collection, as in a fixed-site collection setting, it is important to monitor draw and return issues, platelet clumping, and air blocks. Detailed considerations for correcting these potential problems can be found in the Operator's Manual:

- Trima Accel system 5.0-5.1, Chapter 4
- Trima Accel system 6.0, Chapter 4

Consistent collections are best achieved by monitoring the Trima Accel system and the donor frequently.

Post-collection

Considerations for processes during the post-collection phase in the mobile environment are as follows:

- Product handling and transport procedures
  - RBCs
  - Platelets
  - Plasma
- Addition of additive solution to RBCs
- Post-collection platelet sampling (if conducted at mobile site)

For post-collection procedures and handling of products, please refer to the Operator's Manual:

- Trima Accel system 5.0-5.1, Chapters 5 and 11
- Trima Accel system 6.0, Chapters 5 and 11

If post-collection platelet sampling is performed at the mobile collection site, please refer to the "Platelet Sampling Protocol" found in the Terumo BCT Knowledge Center at https://portal.terumobct.com and your center's SOP for specific sampling techniques.

SECTION 4

SCHEDULING AND COLLECTION TIMES

The following information will guide you in making decisions about equipment, staffing, and scheduling donor appointments.

4.1 STAFF AND DONOR SCHEDULING CONSIDERATIONS

In an ideal mobile blood collection scenario, a continuous flow of donors give blood. However, when you add automated blood collection to your mobile environment, donor flow will change. The most significant factor affecting the flow of donors is the length of time an automated procedure takes compared to a whole blood collection. Though considered a relatively short procedure, automated collections generally take longer than a whole blood draw. While fewer donors are accommodated in the same space per hour during automated collection, more ready-to-transfuse blood components can be drawn using automated collections.

For example, it takes the combined efforts of four to six whole blood donors to produce only one unit of platelets for transfusion. Through an automated donation, an individual can donate enough platelets in a single donation to provide one or more transfusable patient doses.

4.2 COLLECTION TIME CONSIDERATIONS

Table 5 represents an example of average collection times for a variety of automated collections procedures. This table is offered for reference as an example only, and is based on an average of donor base data and system configurations unique to one blood center; actual results will vary for each center. Please note that these times represent best-case collection scenarios and do not take into account pre- or post-collection preparation, or any adjustments made during the procedure. Your sales representative or implementation consultant can assist you in developing tables specific to your center.

Table 5 – Example Automated Collection Time by Procedure

PRODUCTS	AVERAGE COLLECTION TIME (MIN.) TRIMA ACCEL SYSTEM V6.0
Double Red Blood Cells (dRBC)	
Auto-dRBC (360 mL dose)	29
dRBC (400 mL dose)	25
Plasma Only	
1,000 mL	49
800 mL	41
600 mL	32
400 mL	23
Double Platelet Product (DPP) (7.3e11)	
DPP Only	83
DPP + PIs (200 mL)	82
DPP + Auto-RBC (180 mL dose)	90
DPP + Auto-RBC (200 mL dose)	87
Single Donor Platelet (SDP) 3.8e11)	
SDP Only	49
SDP + PIs (200 mL)	47
SDP + Auto-RBC (180 mL dose)	59
SDP + RBC (200 mL dose)	56

*Based on Trima Accel Prediction Tool (Copyright 2012 Terumo BCT): Trima Accel system software = V6.0, Inlet flow = Moderate, TBV-based draw management = 4, TBV-based return = 3, Ratio = 11, Infusion rate = 4

Sources:

U.S. Trima Accel system V5.0-5.1 and V6.0 data on file with Terumo BCT

APPENDIX

TRANSPORTING THE TRIMA ACCEL SYSTEM IN A MOBILE ENVIRONMENT

NOTES

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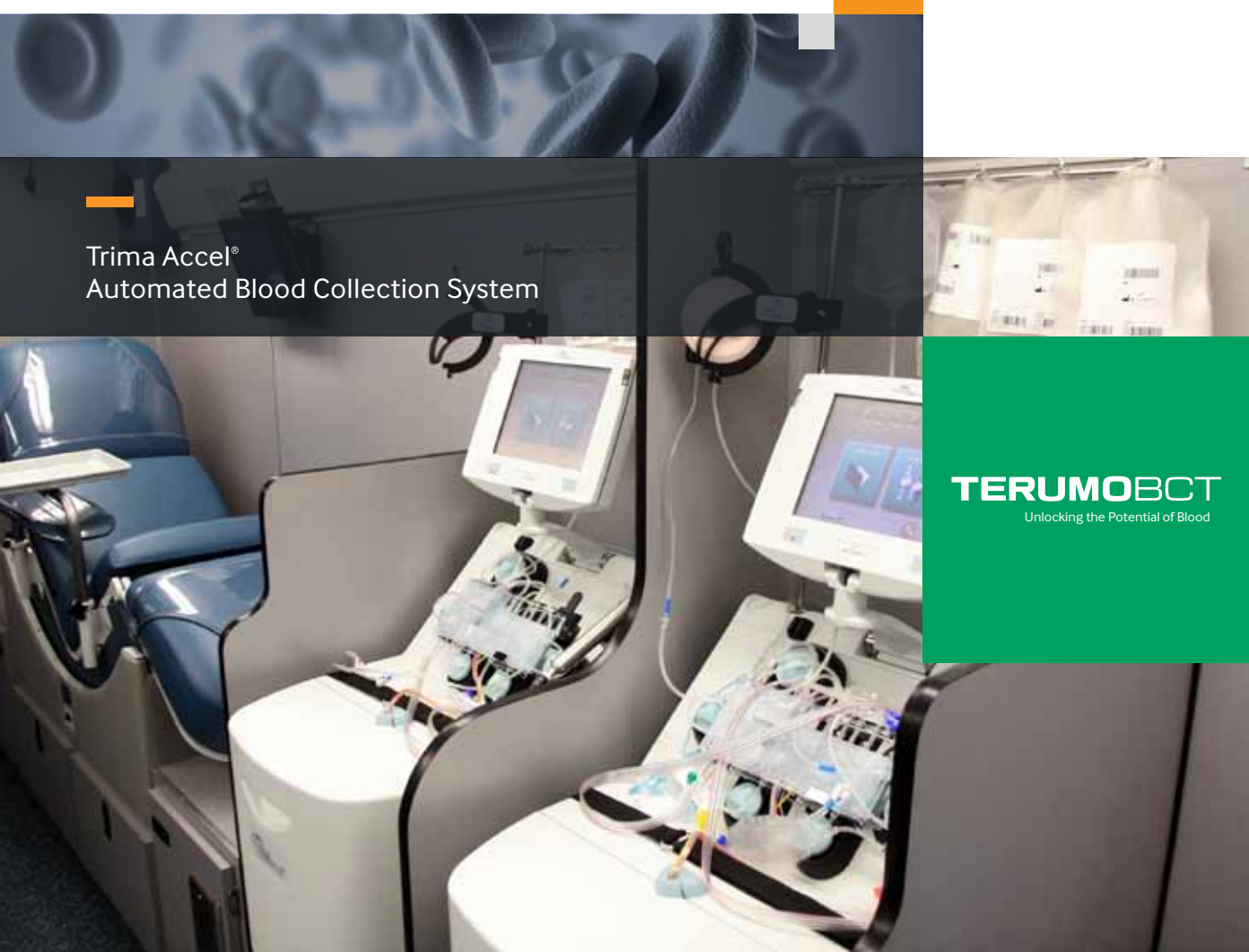
Automated Blood Collection System



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