# Trima Accel<sup>®</sup> Automated Blood Collection System



**Service Manual** 

#### **TERUMO**BCT

## Trima Accel® Automated Blood Collection System Service Manual

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### **Preface**

The Trima Accel Automated Blood Collection System Service Manual provides the information needed to service and troubleshoot the system. This manual applies to versions 5.1.0 and higher. For version 5.0 systems, see the Trima Accel Automated Blood Collection System Service Manual PN 777821-113, RN 704111-003.

#### **Who Should Read This Manual**

This manual is intended for Terumo BCT service technicians and employees, trained and qualified customer technical staff, and Terumo BCT service partners. Only these trained personnel are permitted to service the device and replace parts.

#### **How to Use This Manual**

This manual is divided into sections that can be read and used separately.

Title	Description
Operational Description	Describes the function and location of certain device systems and components.
System Description	Describes the functional and electronic principles of certain device systems and components.
Software Description	Describes the software that the device uses to operate.
Alarms	Provides alarm text and alarm information.
Troubleshooting	Describes non-alarm troubleshooting.
Maintenance and Calibration	Describes maintenance and service procedures for the device.

# 1

# **Operational Description**

#### **System Directory**

The Trima Accel system consists of several major subsystems, such as the display, the pump panel, the centrifuge chamber, and the electronics box (e-box).

The system directory shows the names and locations of some major systems and components in relation to the whole device. There are figures showing front views and rear views with callout lists to identify components in each figure. Some figures may not show a callout in the front view, but it will be present in the rear view. Components that are not called out in the system directory are explained in detail in their respective Operational Description sections.

#### **Trima Accel Device Exterior**

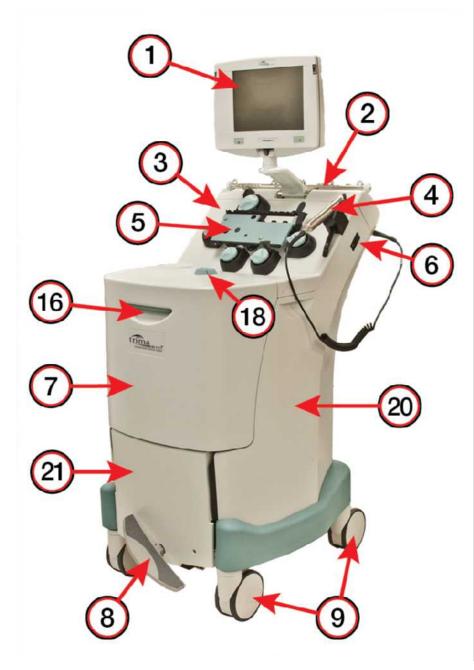


Figure 1-1: The Trima Accel system, front view

- 1 Display
- 2 IV pole
- 3 Pump panel
- 4 Seal Safe system
- 5 Cassette plate
- 6 Power switch
- 7 Centrifuge door
- 8 Brake pedal
- 9 Swivel caster
- 10 Handle wheels
- 11 System serial number
- 12 IV pole button
- 13 Power cord
- 14 Power cord holder
- 15 Ethernet connection
- 16 Door latch handle
- 17 Circuit breaker
- 18 Loop damper
- 19 Handheld barcode reader outlet
- 20 Side panel
- 21 Front panel
- 22 Rear panel
- 23 Linear actuator screw access hole



Figure 1-2: The Trima Accel system, rear view

- 1 Display
- 2 IV pole
- 3 Pump panel
- 4 Seal Safe system
- 5 Cassette plate
- 6 Power switch
- 7 Centrifuge door
- 8 Brake pedal
- 9 Swivel caster
- 10 Handle wheels
- 11 System serial number
- 12 IV pole button
- 13 Power cord
- 14 Power cord holder
- 15 Ethernet connection
- 16 Door latch handle
- 17 Circuit breaker
- 18 Loop damper
- 19 Handheld barcode reader outlet
- 20 Side panel
- 21 Front panel
- 22 Rear panel
- 23 Linear actuator screw access hole

Table 1-1: Trima Accel system components

	Component	Function
1	Display	Allows you to communicate with the system through audio, visual, or touch-screen interfaces.
2	IV pole	Contains hooks for hanging bags and containers. Adjusts up and down for transport.
3	Pump panel	Holds the pumps, valves, sensors and detectors.
4	Seal Safe system	Seals the lines of the tubing set.
5	Cassette plate	Holds the tubing set cassette in place.
6	Power switch	Allows you to turn power to the system on and off.
7	Centrifuge door	Allows access to the centrifuge chamber.
8	Brake pedal	Allows you to adjust the direction of the swivel casters for moving the system or to lock the swivel casters in place so that the system does not roll.
9	Swivel casters (4)	Used to transport the system.
10	Handle wheels (2)	Facilitates transport of the system in a horizontal position.
11	System serial number	Unique number that identifies the system.
12	IV pole button	Allows you to lower the IV pole by pressing the button.
13	Power cord	Connects the system to a power source.
14	Power cord holder	Secures the power cord during transport.
15	Ethernet connection	Allows the service computer to communicate with the device.
16	Door latch handle	Allows you to open the centrifuge door.
17	Circuit breaker	Protects the system from an electrical surge. Secondary power switch used to power the system on and off.
18	Loop damper	Reduces the vibration of the disposable tubing set during a procedure.
19	Handheld barcode reader outlet	Connects the optional barcode reader assembly.
20	Side panel	Covers and protects the internal components from damage, provides containment in case of catastrophic failure, and is a cosmetic feature.
21	Front panel	Covers and protects the internal components from damage, provides containment in case of catastrophic failure, and is a cosmetic feature.

Table 1-1: Trima Accel system components (continued)

	Component	Function
22	Rear panel	Covers and protects the internal components from damage, holds the power cord, vents heat from inside the device, and allows access to the screw that is used to manually raise the cassette plate (used during power failure).
23	Linear actuator screw access hole	Allows tool access to manually raise the cassette plate to allow the operator to unload a disposable tubing set if power is lost during a procedure.

#### **Trima Accel Device Interior**



Figure 1-3: The Trima Accel system with no panels, front view

- 1 Centrifuge motor
- 2 E-box
- 3 Lower compartment cooling fan 1
- 4 Upper compartment cooling fan 2
- **5** E-box cooling fan 3 (inside e-box)
- 6 Linear actuator screw
- 7 Leak detector CCA
- 8 Top cap assembly
- 9 ESD service strap

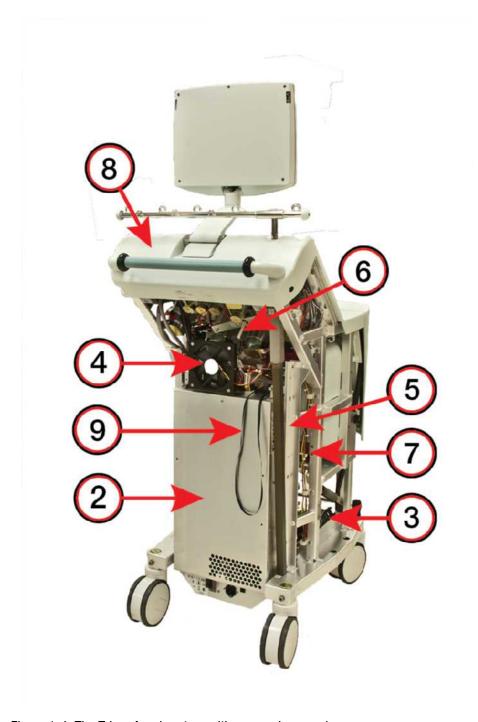


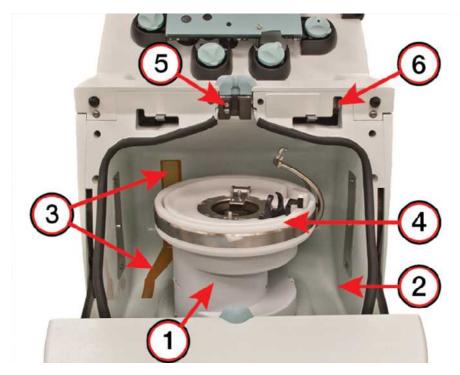
Figure 1-4: The Trima Accel system with no panels, rear view

- 1 Centrifuge motor
- 2 E-box
- 3 Lower compartment cooling fan 1
- 4 Upper compartment cooling fan 2
- **5** E-box cooling fan 3 (inside e-box)
- 6 Linear actuator screw
- 7 Leak detector CCA
- 8 Top cap assembly
- 9 ESD service strap

**Table 1-2: Trima Accel system components** 

	Component	Function
1	Centrifuge motor	Spins the disposable tubing set channel that is used to separate blood into its components.
2	E-box	Contains CCAs for the safety and control systems, the hard drive, the motor drive systems, and the power supply.
3	Lower compartment cooling (fan 1)	Provides airflow that is used to cool the centrifuge motor and basin.
4	Upper compartment cooling (fan 2)	Provides airflow that is used to cool the pump and valve motors.
5	E-box cooling (fan 3)	Provides airflow that is used to cool the e-box electronics.
6	Linear actuator screw	Raises or lowers the cassette plate when the motor is activated.
7	Leak detector CCA	Contains the leak detector circuitry.
8	Top cap assembly	Contains the display arm assembly, the handle, the Seal Safe connector, and the barcode reader connector and interfaces with the IV pole. This is a replaceable component.
9	ESD service strap	Provides a secondary ESD (electrostatic discharge) strap if the service technician does not have a primary ESD strap.

#### **Trima Accel Centrifuge Basin**



- 1 Centrifuge
- 2 Basin
- 3 Leak detector
- 4 Filler assembly
- 5 Upper hex holder
- 6 Door lock with sensors

Figure 1-5: The Trima Accel basin

**Table 1-3: Trima Accel basin components** 

	Component	Function
1	Centrifuge	Spins the disposable tubing set channel that is used to separate blood into its components.
2	Basin	Provides protection from catastrophic centrifuge failure and contains fluid leaks.
3	Leak detector	Senses fluid in the basin from leaks in the channel or tubing.
4	Filler assembly	Holds the disposable tubing set channel where blood component separation occurs.
5	Upper hex holder	Holds and locks disposable tubing when the centrifuge door is closed.
6	Door lock with sensors	Ensures that the centrifuge door cannot be opened while the centrifuge is spinning.

#### **Boot Sequence**

This section describes the boot sequence and when to interrupt that sequence for troubleshooting and maintenance purposes.

When it is turned on, the Trima Accel device performs a low-level memory check, generating an alarm if this check fails. If this check is successful, the device moves on to the boot sequence.

It is possible to interrupt the boot sequence for three different scenarios.

The first scenario is to enter Single-Step mode, which is used to connect the device to STS with an FTP connection, usually after the safety computer fails to boot and dlogs need to be recovered. To enter Single-Step mode, press and hold the pause button after the memory check until the screen shows that the pause button is detected. Then press the pause button to advance through each step of the boot sequence. Stop at the message line "press and release pause button to initialize serial port driver."

In FTP mode, STS does not auto-discover the Trima Accel device. To connect, select device type **Trima** from the drop-down menu and enter the serial number, or enter the IP address 172.21.127.255 to connect to a new hard drive. Accept any FTP warnings that appear.

The second scenario is to enable the software load installation script, which is used after new software has been loaded and needs to be installed. To run the installation script, press and hold the pause and stop buttons after the memory check, a few seconds after the power is on, and hold the buttons until the message line "Installation script found—release buttons to execute." Wait for another message line reading "Installation complete—cycle power to restart." Then boot to the two-button donor screen, and check to make sure the changes took place.



**Note:** The device allows only **one** chance to interrupt the normal boot sequence to install new files or software. All calibration and software data is lost if the device boots to the two-button donor screen after uploading files to the device. If this installation script is not activated on the first boot, then calibration and software transfer must be performed again.

The third scenario is to enter Service mode, which is used for software installations, updates, device maintenance, and device troubleshooting. To enter Service mode, press and hold the pause and stop buttons after the screen shows the volume checks, and do not release the buttons until the screen prompts you to do so.

After the boot sequence is finished, the device then checks the power supply voltages, performs valve position tests, checks the leak detector voltage, and tests the door lock functionality. Without errors to any of these items the software is then loaded into Procedure mode (two-button donor screen).

#### **Blood Collection Process**

This section describes the blood collection process.



**Note:** This section describes the blood collection process from the standpoint of the device electronics for field service personnel. See the Operator's Manual for detailed procedural information for the operator.

The Trima Accel system operates automatically when it is in Procedure mode. Pumps control the flow of inlet blood, anticoagulant, platelets, plasma, and return blood. Centrifugal force and the inlet pump control the red blood cell (RBC) flow. Donor data that is entered at the beginning of the procedure helps the Trima Accel system perform software calculations (algorithms) that control operations. This donor data—height, weight, and gender—is used to calculate the total blood volume (TBV) of the individual. Once the Trima Accel system accumulates this data, it recommends optimal procedures or combinations of products, and the operator chooses a procedure based on donor time limits. When the Trima Accel system receives procedure instructions, it can set pump flow rates and centrifuge speed. Automatic control of the RBC/plasma interface optimizes blood separation.

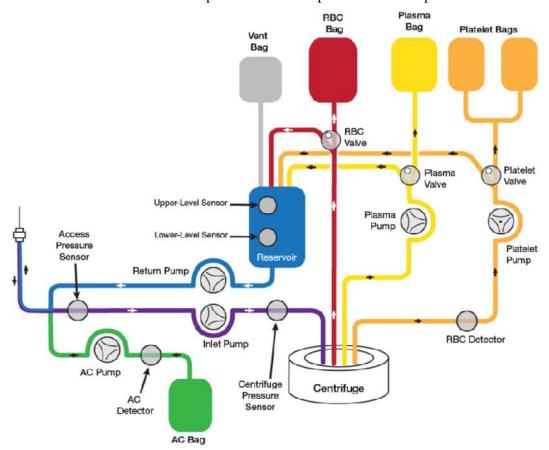


Figure 1-6: Trima Accel fluid flow diagram

First, the disposable tubing set is loaded onto the Trima Accel system. Once the cassette is loaded, the Trima Accel system prompts the operator to clamp both the needle line and the sample bag line. The anticoagulant (AC), return, and inlet pumps are run to pressure test the tubing set. If the tests are not successfully completed, alarms are generated.

The Trima Accel system prompts the operator to prime the system by connecting the AC bag. The AC pump forces anticoagulant through the inlet line to the access and return lines. The operator then performs the venipuncture and opens the clamp on the needle line. The return pump (rotating in reverse) pulls blood into the return line until blood reaches the lower-level sensor in the return reservoir. At this point, the initial priming sequence initiates.

The procedure starts with the inlet pump drawing blood into the Trima Accel system through the single-needle access. Anticoagulant, pumped by the AC pump at a configured ratio, is infused into the system close to the needle. The inlet pump continues to pump blood into the centrifuge, which has started rotation. The centrifuge accelerates at controlled rates, then holds at 2,000 rpm for 2 minutes before accelerating to its final commanded speed. At this point, the Trima Accel system enters run mode and the pumps accelerate to their commanded run mode speeds.

The control and safety computers monitor several items during startup of the procedure. The first return cycle is monitored closely due to the high amount of AC in the Trima Accel system during startup. An over-delivery of volume during the first return cycle results in a safety shutdown of the Trima Accel system for this reason. Once the startup phase is complete, return cycle volume problems can cause alarms, but the procedure can be continued.

The actual separation of blood components occurs inside the channel portion of the tubing set. Whole blood enters into the channel and is separated into its various components by centrifugal force.

Three valves divert the blood components that are being collected—which may include plasma, platelets, and/or RBC—into collect bags. If any of these components are not being collected, the valves route them to the return reservoir located on the front panel of the Trima Accel system. When the reservoir contains an appropriate volume (approximately 55 mL), the upper-level reservoir sensor triggers and activates the return pump. The return pump interrupts the incoming flow of blood to the cassette by pushing return blood back through the single-needle access until the reservoir empties (reaches the lower-level sensor). The inlet pump remains at a constant speed during this entire cycle. This causes a small amount of return blood to re-circulate back through the inlet pump and into the channel, maintaining continuous blood flow to the interface. The AC pump shuts off during the return cycle. The return pump turns off after the reservoir empties.

#### **Pump System**

The Trima Accel device uses five pumps to move anticoagulant, blood, and blood components through the disposable tubing set using peristaltic action.

Each pump consists of a pump motor, a pump rotor, a seal, and a raceway housing. The platelet pump spins at a significantly slower rate than the rest of the pumps, so it needs two magnets in the rotor to properly measure speed. The platelet pump rotor is marked with a black dot for recognition. The return pump, which has a larger diameter, is the only pump able to spin in both directions; all other pumps spin in a counterclockwise direction.

#### **Pump Locations**

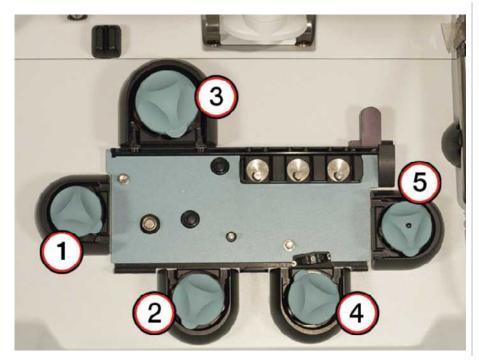


Figure 1-7: Pump locations (front)

- 1 AC pump
- 2 Inlet pump
- 3 Return pump
- 4 Plasma pump
- 5 Platelet pump

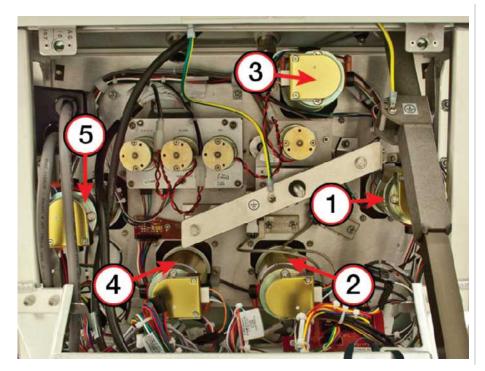
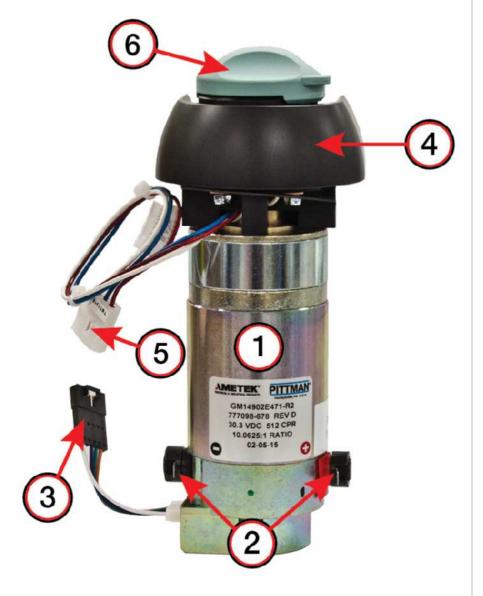


Figure 1-8: Pump locations (rear)

- 1 AC pump (behind IV pole)
- 2 Inlet pump
- 3 Return pump
- 4 Plasma pump
- 5 Platelet pump

#### **Pump Assembly**



- 1 Pump motor
- 2 Drive terminals
- 3 Encoder connector
- 4 Pump raceway housing
- 5 Hall-effect sensor connector
- 6 Pump rotor

Figure 1-9: Pump system components

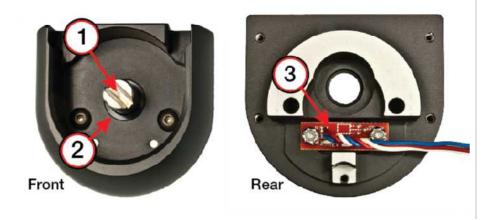
**Table 1-4: Pump system components** 

	Component	Function
1	Pump motor	Turns the rotor to move fluids through the disposable tubing set.
2	Drive terminals	Connect the pump to 24 V power.
3	Encoder connector	Sends pump speed encoder data from the pump motor to the e-box.

**Table 1-4: Pump system components (continued)** 

	Component	Function
4	Pump raceway housing	Mounts the pump motor and the Hall-effect sensor. It also has a machined raceway that is designed to accept the disposable tubing set.  Note: The pump motors can be removed without removing or loosening any of the pump raceways. If a pump raceway is removed or loosened, an alignment tool is necessary to reinstall it.
5	Hall-effect sensor connector	Sends pump speed pulses from the raceway to the e-box.
6	Pump rotor	Attaches to the pump motor shaft and uses two spring-loaded rollers to provide the peristaltic action in the disposable tubing set.

#### **Pump Raceway**



- 1 Pump motor shaft
- 2 Pump seal
- 3 Hall-effect sensor

Figure 1-10: Pump raceway housing components

**Table 1-5: Pump raceway housing components** 

	Component	Function
1	Pump motor shaft	Transfers rotation to the pump rotor. The shaft has a one-quarter-turn slot that is used to attach the rotor.
2	Pump seal	Prevents fluid from entering the device. It is a rubber seal between the pump motor shaft and the pump raceway housing.
3	Hall-effect sensor	Senses pump speed by detecting when the magnet in the pump rotor passes over it.

#### **Pump Rotor**



- 1 Rotor cap
- 2 Roller
- 3 Roller spring
- 4 Magnet
- 5 Rotor washer

Figure 1-11: Pump rotor components

**Table 1-6: Pump rotor components** 

	Component	Function
1	Rotor cap	Catches the disposable tubing with a tab when the set is loading to ensure that the tubing line is drawn down into the raceway housing.
2	Roller	Pushes against the tubing to create the peristaltic action of the pump.
3	Roller spring	Applies force to the roller to enable it to pinch the tubing closed as the pump rotates.
4	Magnet	Activates the Hall-effect sensor in the raceway housing as it passes over the sensor. The platelet pump rotor (indicated with a dot on the rotor cap) is the only rotor with two magnets; all of the other rotors have only one magnet.
5	Rotor washer	Decreases clicking noises during rotation. It is a clear plastic washer.

#### **Sensor System**

The sensor system is made up of multiple sensors and detectors that monitor pressure, fluid levels, leaks, door position, lock status, and platelet line composition.

The input for sensor systems consists of variable analog information, and the input for detector systems consists of binary on/off information.

The sensor system is made up of the following:

- Two pressure sensors
- Two reservoir level sensors
- The RBC detector
- The anticoagulant (AC) detector
- The leak detector

#### **Motion Feedback Systems**

Optical encoders and Hall-effect sensors are used in various subsystems as a feedback loop. These sensor systems are often paired together, where the primary signal is obtained from one sensor and must match the secondary signal obtained from the other sensor.

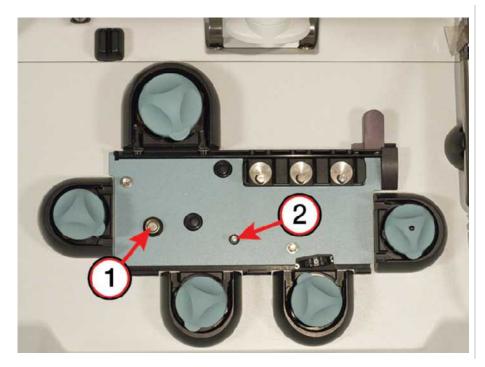
Optical encoders are used by the pumps, the valves, the centrifuge, and the door lock system. All of these are monitored by the control system except for the door lock system, which is monitored by the safety system. They function by sensing interruptions in a light beam, counting these interruptions, and sending that data to the feedback system.

Hall-effect sensors are used as part of the feedback loops for the safety system, and one is used to give door position information. The Hall-effect sensors are used in the centrifuge motor, the pump housing raceways, and the door closed sensor. All of these are monitored by the safety system except for the door closed sensor, which is monitored by the control system. The Hall-effect sensors function when a transducer senses a magnetic field and then converts that field sensing to an electrical signal that is sent to the feedback system. The safety system counts these pulses to compare against what the control system sees with the optical sensors.

There are closed loop and open loop conditions to the feedback systems. Closed loop is the default condition that uses sensor-derived feedback to directly control the system. An open loop condition removes the sensor-derived information from the feedback loop.

#### **Pressure Sensors**

There are two pressure sensors on the front panel of the Trima Accel system, which monitor the draw/return donor access pressure and the centrifuge pressure.



- 1 Access/return pressure sensor
- 2 Centrifuge pressure sensor

Figure 1-12: Pressure sensor locations (front)

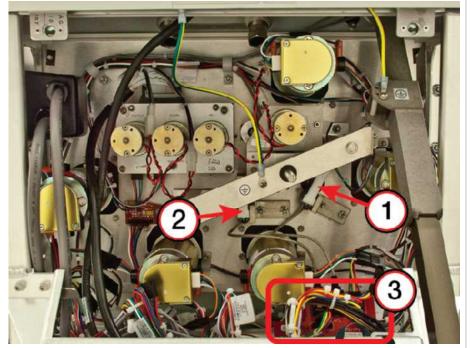


Figure 1-13: Pressure sensor locations (rear)

- 1 Access/return pressure sensor
- 2 Centrifuge pressure sensor
- 3 Adapter CCA

**Table 1-7: Pressure sensor system components** 

	Component	Function
1	Access/return pressure sensor	Monitors the fluid pressure that is either coming from or going to the donor.
2	Centrifuge pressure sensor	Monitors the fluid pressure inside the centrifuge channel.
3	Adapter CCA	Connects the pressure sensor connectors to the wiring harness connectors.

#### **AC Sensor**

The anticoagulant (AC) sensor indicates the presence of AC.

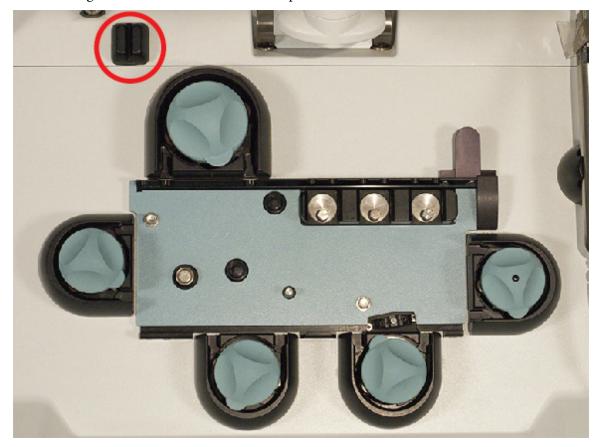
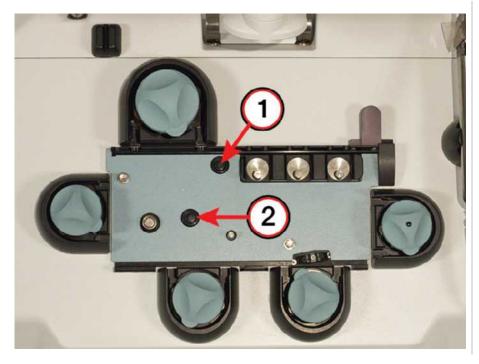


Figure 1-14: The AC sensor

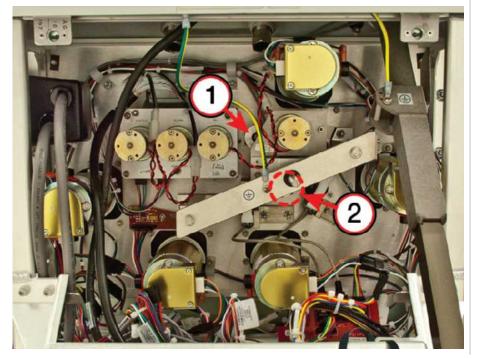
#### **Reservoir Level Sensors**

The reservoir level sensors are used to read the fluid level in the reservoir, which is used to toggle the device between draw and return cycles.



- Upper-level reservoir sensor
- Lower-level reservoir sensor

Figure 1-15: Reservoir level sensor locations (front)



sensor

Lower-level reservoir sensor (not visible, located behind the linear actuator assembly)

Upper-level reservoir

Figure 1-16: Reservoir level sensor locations (rear)

**Table 1-8: Reservoir level sensor system components** 

	Component	Function
1	Upper-level reservoir sensor	Monitors the fluid level at the upper limit of the disposable tubing set casette reservoir chamber. This signal triggers the system to toggle between draw and return cycles.
2	Lower-level reservoir sensor	Monitors the fluid level at the lower limit of the disposable tubing set casette reservoir chamber. The lower-level sensor also detects the introduction of air to the donor.

#### **RBC Detector**

The RBC detector is used to detect RBC in the platelet line, indicating a spillover.

The RBC detector is also used to identify disposable set type. It can sense whether a black or white stamp is on the cassette.

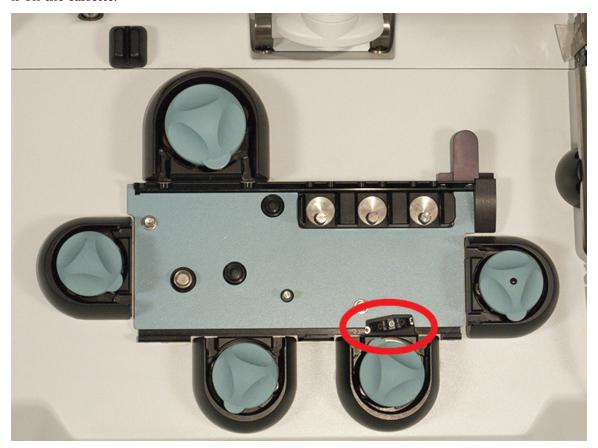


Figure 1-17: RBC detector location (front)

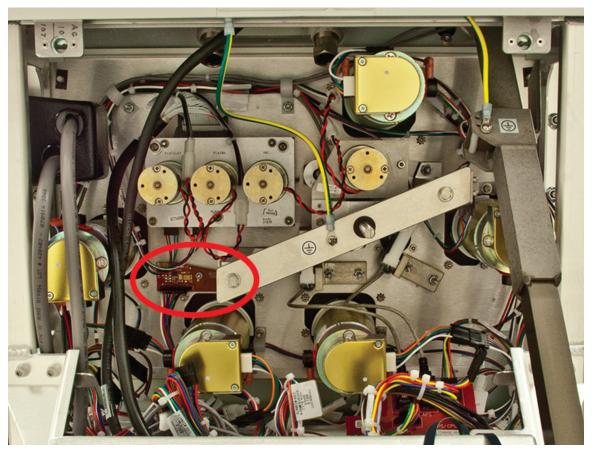


Figure 1-18: RBC detector location (rear)

#### **Leak Detector**

The leak detector is a resistive sensor used to detect leaks in the centrifuge basin.

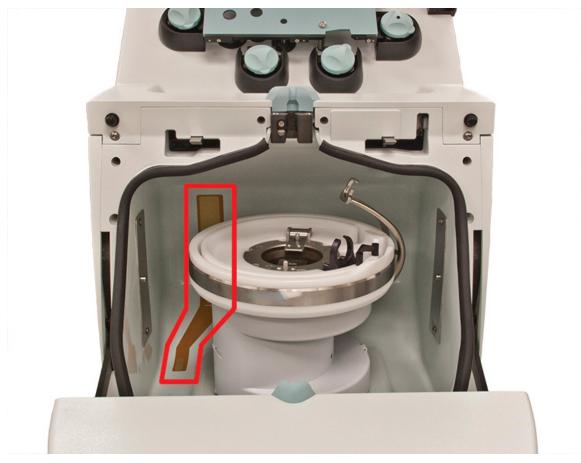


Figure 1-19: The fluid leak detector

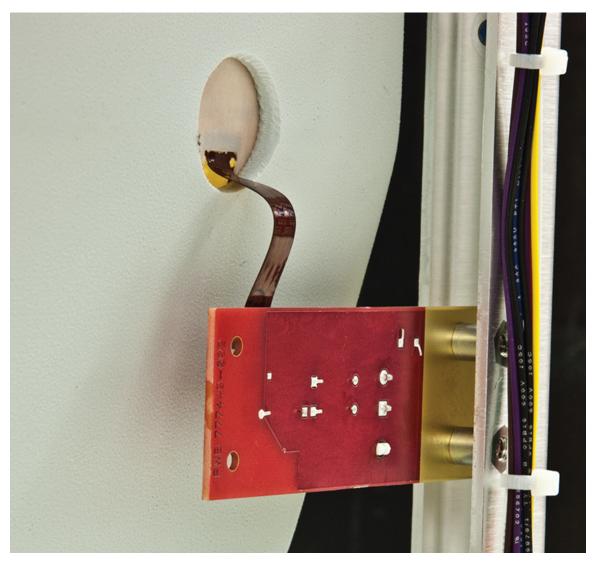


Figure 1-20: The fluid leak detector connection and the leak detector CCA (rear)

#### **Centrifuge System**

The centrifuge is used to separate blood into its components.

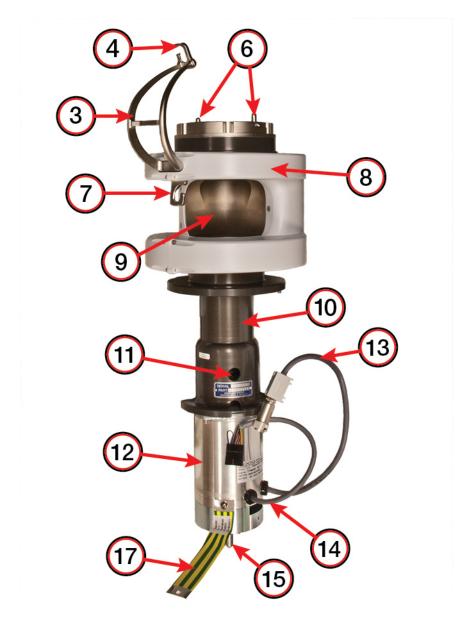
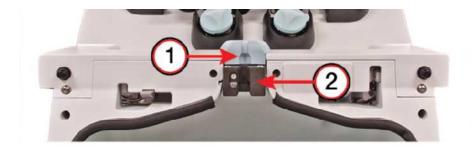


Figure 1-21: Centrifuge assembly components

- 1 Loop damper
- 2 Upper hex holder
- 3 Loop arm
- 4 Upper bearing holder
- 5 Filler assembly (not pictured)
- 6 Filler retainers
- 7 Lower bearing holder
- 8 Gear shrouds
- 9 Loading port
- 10 Gear train assembly
- 11 Motor coupler
- 12 Centrifuge motor
- 13 Power cable
- 14 Centrifuge Hall-effect sensor cable
- 15 Precession damper pin
- 16 Precession damper
- 17 Ground strap
- 18 Centrifuge motor controller
- 19 64 V switch



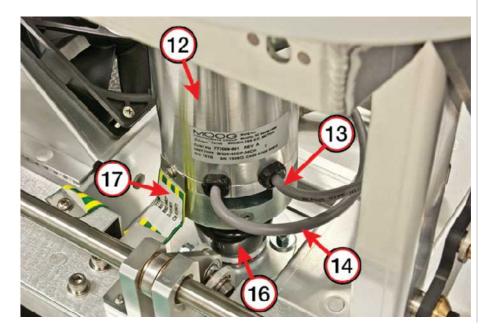
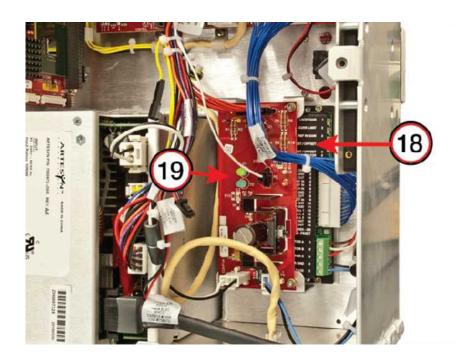


Figure 1-22: Centrifuge system components

- 1 Loop damper
- 2 Upper hex holder
- 3 Loop arm
- 4 Upper bearing holder
- 5 Filler assembly (not pictured)
- **6** Filler retainers
- 7 Lower bearing holder
- 8 Gear shrouds
- 9 Loading port
- 10 Gear train assembly
- 11 Motor coupler
- 12 Centrifuge motor
- 13 Power cable
- **14** Centrifuge Hall-effect sensor cable
- 15 Precession damper pin
- 16 Precession damper
- 17 Ground strap
- 18 Centrifuge motor controller
- 19 64 V switch



- 1 Loop damper
- 2 Upper hex holder
- 3 Loop arm
- 4 Upper bearing holder
- 5 Filler assembly (not pictured)
- 6 Filler retainers
- 7 Lower bearing holder
- 8 Gear shrouds
- 9 Loading port
- 10 Gear train assembly
- 11 Motor coupler
- 12 Centrifuge motor
- 13 Power cable
- **14** Centrifuge Hall-effect sensor cable
- 15 Precession damper pin
- 16 Precession damper
- 17 Ground strap
- 18 Centrifuge motor controller
- 19 64 V switch

Figure 1-23: Centrifuge system components in ebox

**Table 1-9: Centrifuge system components** 

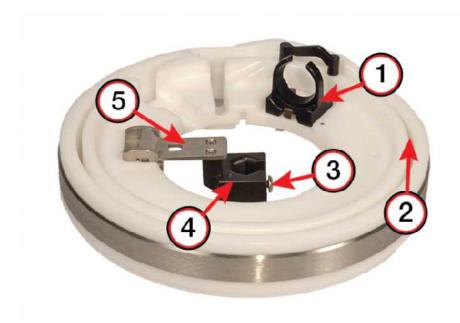
	Component	Function
1	Loop damper	Reduces the vibration of the disposable tubing set during a procedure.
2	Upper hex holder	Holds and locks disposable tubing when the centrifuge door is closed.
3	Loop arm	Holds the disposable tubing set loop.
4	Upper bearing holder	Provides a connection point for the disposable tubing set's upper bearing to attach to the loop arm.
5	Filler assembly (not pictured)	Holds the disposable tubing set channel where blood component separation occurs.
6	Filler retainers	Hold the filler to the centrifuge assembly. These are spring-loaded latches, and both must be actuated to release the filler.
7	Lower bearing holder	Provides a connection point for the disposable tubing set's lower bearing to attach to the loop arm.
8	Gear shrouds	Cover and protect the gear assembly of the centrifuge. These shrouds can be removed for cleaning.

**Table 1-9: Centrifuge system components (continued)** 

	Component	Function
9	Loading port	Opening in the centrifuge used to route the disposable tubing set from the loop arm to the filler.
10	Gear train assembly	Consists of the centrifuge gear assembly and the rotating part of the centrifuge.
11	Motor coupler	Connects the centrifuge motor to the gear assembly.
12	Centrifuge motor	Spins the disposable tubing set channel to separate blood into its components.
13	Power cable	Provides 3-phase 64 V DC voltage to the centrifuge motor.
14	Centrifuge Hall-effect sensor cable	Connects three Hall-effect sensors inside the motor to the safety stack in the e-box. These sensors are used to read the speed of the motor shaft.
15	Precession damper pin	Connects the precession damper to the centrifuge assembly.
16	Precession damper	Prevents precessional movement of the centrifuge while changing rotation speed.
17	Ground strap	Provides a common ground point between the centrifuge assembly and the device chassis.
18	Centrifuge motor controller	Provides 3-phase power signals to the centrifuge motor.
19	64 V switch	Controls the power available to the centrifuge motor.

## **Filler Assembly**

The filler assembly holds the channel portion of the disposable tubing set in place for centrifugation.



- 1 LRS chamber bracket
- 2 Channel
- 3 Locking pin
- 4 Collar holder
- 5 Filler latch

Figure 1-24: The filler assembly

**Table 1-10: Filler assembly components** 

	Name	Function
1	LRS chamber bracket	The LRS chamber bracket holds the LRS chamber in place.
2	Channel	Secures the channel and the connector in the filler.
3	Locking pin	Locks the hex collar in place.
4	Collar holder	Holds the hex collar of the rotating centrifuge loop in place while the centrifuge spins.
5	Filler latch	Swings up to facilitate loading of the channel. The filler latch lowers over the filler latching pin to lock the filler in place.

# **Door System**

The centrifuge door allows access to the centrifuge basin, and the door lock system ensures that the centrifuge door cannot be opened while the centrifuge is moving.

## **Centrifuge Door System**

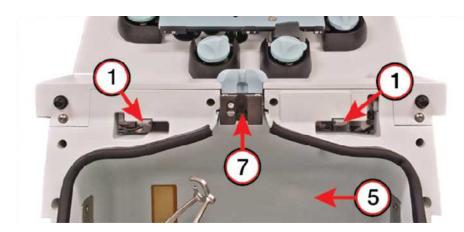


Figure 1-25: Centrifuge door components (frame side)

- 1 Latch hooks
- 2 Latch plate
- 3 Latch magnet
- 4 Latch holes
- 5 Centrifuge basin
- 6 Door liner
- 7 Upper hex holder
- 8 Striker plate
- 9 Locking shaft hole

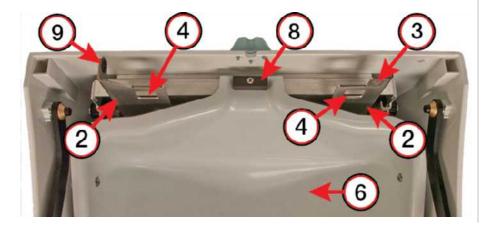


Figure 1-26: Centrifuge door components (door side)

- 1 Latch hooks
- 2 Latch plate
- 3 Latch magnet
- 4 Latch holes
- 5 Centrifuge basin
- 6 Door liner
- 7 Upper hex holder
- 8 Striker plate
- 9 Locking shaft hole

**Table 1-11: Centrifuge door components** 

	Component	Function
1	Latch hooks	Engages the latch holes in the latch plate used to hold the door closed.
2	Latch plate	Spring-loaded plate that is moved by the door latch handle. This plate holds the latch magnet and the locking shaft hole and provides a surface that is used to activate the door closed plunger.

**Table 1-11: Centrifuge door components (continued)** 

	Component	Function
3	Latch magnet	Activates the door position Hall-effect sensor using the south-pole side of the magnet. It is both glued and taped into the latch plate.
4	Latch holes	Two holes in the latch plate that catch on the latch hooks that hold the door closed.
5	Centrifuge basin	Contains any fluid leaks from the disposable tubing set and contains any damage from catastrophic centrifuge failure.
6	Door liner	Presses against the door gasket to contain fluid in the basin and holds the striker plate.
7	Upper hex holder	Holds and locks the disposable tubing set when the centrifuge door is closed.
8	Striker plate	Presses against the upper hex holder locking pin to secure the disposable tubing set.
9	Locking shaft hole	Retains the locking shaft used to lock the door and physically prevents the door from opening when the shaft is engaged.

# **Door Lock System**

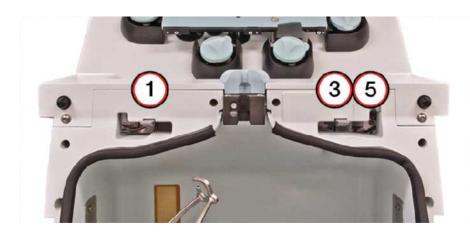


Figure 1-27: Door lock component locations with covers

- 1 Door position Halleffect sensor
- 2 Door lock solenoid
- 3 Solenoid position optical sensor
- 4 Locking shaft
- 5 Door position optical sensor

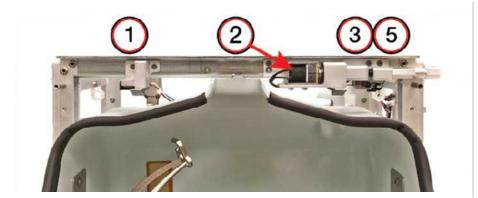
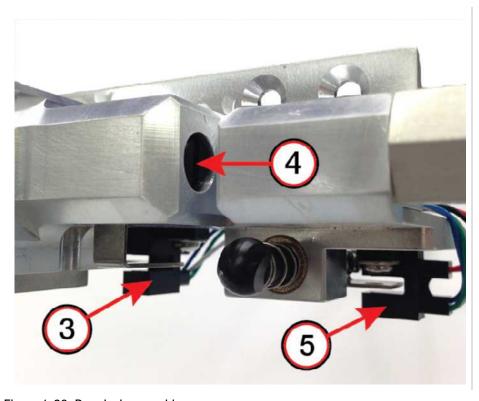


Figure 1-28: Door lock component locations without covers

- 1 Door position Halleffect sensor
- 2 Door lock solenoid
- 3 Solenoid position optical sensor
- 4 Locking shaft
- 5 Door position optical sensor



1 Door position Halleffect sensor

- 2 Door lock solenoid
- 3 Solenoid position optical sensor
- 4 Locking shaft
- 5 Door position optical sensor

Figure 1-29: Door lock assembly

**Table 1-12: Door lock system components** 

	Component	Function
1	Door position Hall- effect sensor	Determines whether the centrifuge door is open or closed by sensing the presence of a south-pole magnet on the door latch assembly when the door is closed.
2	Door lock solenoid	Engages the locking shaft that locks the centrifuge door closed using a momentary 24 V bi-directional pulsed signal.

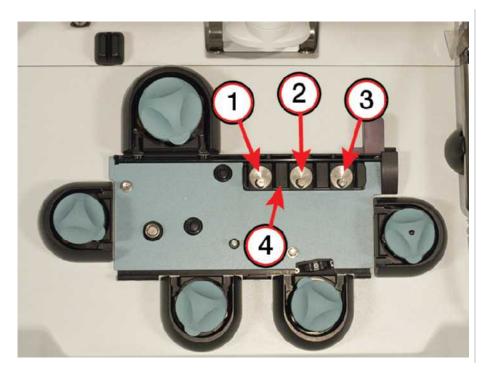
Table 1-12: Door lock system components (continued)

	Component	Function
3	Solenoid position optical sensor	Senses the locked or unlocked position of the locking shaft. The sensor determines this state when a flag that is attached to the locking shaft interrupts the light.
4	Locking shaft	Engages the latch plate on the centrifuge door to lock or unlock the door. It is moved by the door lock solenoid.
5	Door position optical sensor	Senses the open or closed position of the centrifuge door. A spring-loaded plunger interacts with the centrifuge door, and the sensor determines this state when a flag attached to the plunger interrupts the light.

# **Valve System**

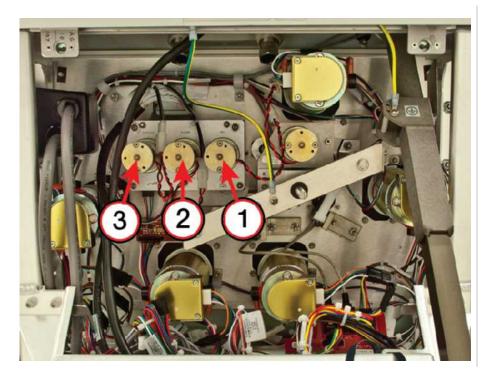
The valves are used to divert blood components to collection bags or back to the donor.

## **Valve Locations**



- 1 RBC valve
- 2 Plasma valve
- 3 Platelet valve
- 4 Valve housing

Figure 1-30: Valve locations (front)



- 1 RBC valve
- 2 Plasma valve
- 3 Platelet valve

Figure 1-31: Valve locations (rear)

**Table 1-13: Valve functions** 

	Component	Function
1	RBC valve	Directs the flow of RBC to either the RBC collection bag or the return reservoir.
2	Plasma valve	Directs the flow of plasma to either the plasma collection bag or the platelet line.
3	Platelet valve	Directs the flow of platelets to the platelet collection bag. It also directs the flow of platelets and plasma to the return reservoir.
4	Valve housing	Provides a surface for the valve rollers to compress the tubing against. It provides a base to which the valve assembly can be mounted and includes stop pins that limit valve rotation.

# **Valve System**



- 1 Valve housing
- 2 Valve housing stop pin
- 3 Valve post
- 4 Valve body
- 5 Valve motor

Figure 1-32: Valve system components

**Table 1-14: Valve system components** 

	Component	Function
1	Valve housing	Provides a surface for the valve rollers to compress the tubing against. It provides a base to which the valve assembly can be mounted and includes stop pins that limit valve rotation.
2	Valve housing stop pin	Provides a stopping point that inhibits valve rotation when the valve reaches functional limits.

**Table 1-14: Valve system components (continued)** 

	Component	Function
3	Valve post	Pinches the tubing closed. It contains a roller assembly that allows the valve post to roll smoothly over the tubing to prevent damage.
4	Valve body	Contains the valve post and a flag assembly that is used by the optical encoders to provide valve position feedback. It is attached to the motor shaft.
5	Valve motor	Drives the valve body to the left, right, or center position. There is no feedback mechanism in the motor.

## **Valve Assembly**



- 1 Valve post
- 2 Valve post bearing
- 3 Optical sensors (3 per valve)
- 4 Optical sensor window
- 5 Lowered cassette position sensor connector (J3)
- 6 Raised cassette position sensor connector (J2)
- 7 Drive terminal
- 8 Valve motor
- 9 Valve CCA
- 10 Valve 0-ring seal
- 11 Valve assembly connector

Figure 1-33: Valve assembly components

**Table 1-15: Valve assembly components** 

	Name	Function
1	Valve post	Pinches the tubing lines closed by pressing against the valve housing surface.
2	Valve post bearing	Rotates to help pinch the tubing lines closed without damaging them.

Table 1-15: Valve assembly components (continued)

	Name	Function
3	Optical sensors	Determines the left, center, and right positions of the valves and communicates the positions to the control CCA.
4	Optical sensor window	Allows light to pass to one position sensor while blocking light to the other two position sensors.
5	Lowered cassette position sensor connector (J3)	Provides a pass-through connection for the lowered cassette position sensor.
6	Raised cassette position sensor connector (J2)	Provides a pass-through connection for the raised cassette position sensor.
7	Drive terminal	Connects switched 24 V power and ground to the valve motor from the motor driver CCA.
8	Valve motor	Rotates the valve body.
9	Valve CCA	Contains the optical sensors mounted on the CCA and pass-through circuitry for the cassette position sensors.
10	Valve O-ring seal	Prevents fluid from entering the electronics inside the device.
11	Valve assembly connector	Connects the valve assembly to the e-box.

# **Linear Actuator**

The linear actuator system raises and lowers the cassette plate.

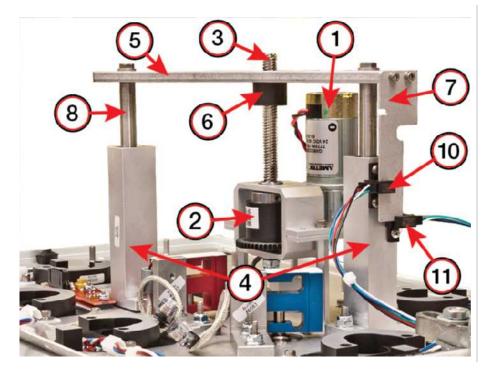


Figure 1-34: The linear actuator

Figure 1-35: The cassette plate

- Linear actuator motor
- 2 Slip clutch
- Lead screw
- **Bearing blocks**
- Tie bar assembly
- Lead screw drive nut 6
- 7 Sensor flag
- Tie bar shafts
- Cassette plate
- 10 Raised cassette position sensor
- 11 Lowered cassette position sensor

- Linear actuator motor
- 2 Slip clutch
- Lead screw
- Bearing blocks
- Tie bar assembly
- Lead screw drive nut
- Sensor flag
- Tie bar shafts
- Cassette plate
- 10 Raised cassette position sensor
- 11 Lowered cassette position sensor

**Table 1-16: Linear actuator system components** 

	Component	Function			
1	Linear actuator motor	Drives the slip clutch and the lead screw to move the cassette plate up and down. This is part of the linear actuator assembly.			
2	Slip clutch	Allows the lead screw to slip when the motor is in danger of being over-driven. This prevents damage to the linear actuator motor if the cassette plate cannot fully travel up or down. This is part of the linear actuator assembly.			
3	Lead screw	Moves the tie bar assembly, the tie bar shafts, and the cassette plate. This is part of the linear actuator assembly.			
4	Bearing blocks	Contain bearings to ensure that the tie bar shafts slide freely, are used to ensure that the cassette plate stays aligned, and provide a base to which t cassette position sensors are mounted. DO NOT loosen or move the beari blocks. They are aligned with a special tool, and their alignment is criticall important. If you suspect that the blocks need to be moved or replaced, contact your regional customer support representative. DO NOT lubricate. T bearings inside do not require any lubrication.			
5	Tie bar assembly	Contains the tie bar, the drive nut for the lead screw, and the flag used to sense when the cassette plate is in the lowered position.			
6	Lead screw drive nut	Connects the tie bar to the threads of the lead screw. This connection enables the linear actuator motor to raise and lower the cassette plate.			
7	Sensor flag	Provides cassette plate position information by using spaces in the flag shape to trigger the position sensors on or off depending on the sensor flag position.			
8	Tie bar shafts	Connect the tie bar assembly to the cassette plate. The shaft end that has the flat side is the end that connects to the tie bar assembly, and it must be tightened first. The tie bar shafts require Loctite® adhesive and a specific torque.			
9	Cassette plate	Holds the disposable tubing set cassette during loading, the procedure, and unloading. The cassette is held by a spring latch at the top of the cassette plate. The cassette plate requires Loctite adhesive and a specific torque.			
10	Raised cassette position sensor	Determines whether the cassette plate is fully raised. This is an optical sensor that senses a notch in the flag to indicate cassette position. This sensor connects to J2 (the left-side connector, as viewed from the rear of the device) on the valve CCA.			
11	Lowered cassette position sensor	Determines whether the cassette plate is fully lowered. This is an optical sensor that senses the end of the flag to indicate cassette position. This sensor connects to J3 (the right-side connector, as viewed from the rear of the device) on the valve CCA.			

# E-Box

The e-box contains the CCAs for the safety and control computer systems, the hard drive, the motor driver and centrifuge drive systems, and the power supply.

The enclosure offers EMI protection. The e-box also serves as an electrical connection point to all systems.

## **Python E-box Version**

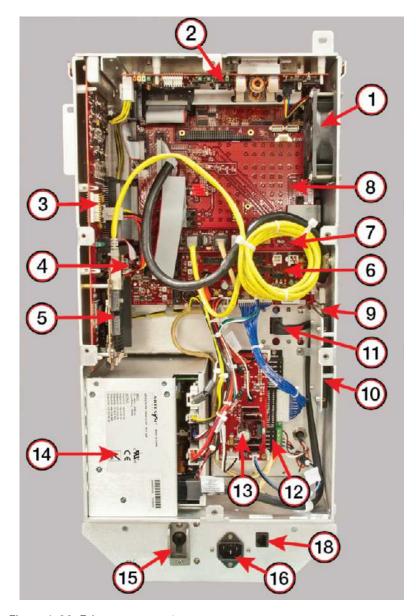
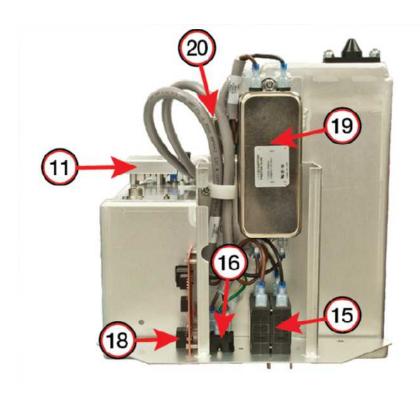


Figure 1-36: E-box components

- 1 E-box cooling fan
- 2 Motor driver CCA
- 3 Safety CCA
- 4 Safety interface CCA
- 5 Safety computer
- 6 Control CCA
- 7 Control computer
- 8 Control interface CCA
- 9 Hard drive interface CCA
- 10 Hard drive
- 11 Seal Safe system power supply
- 12 Centrifuge motor controller
- 13 64 V switch
- 14 Power supply
- 15 Circuit breaker
- 16 Power receptacle
- 17 Power cord clamp (not shown)
- **18** Service Ethernet port
- 19 High frequency filter
- 20 General line filter
- 21 E-box cover (not shown)



- 1 E-box cooling fan
- 2 Motor driver CCA
- 3 Safety CCA
- 4 Safety interface CCA
- 5 Safety computer
- 6 Control CCA
- 7 Control computer
- 8 Control interface CCA
- 9 Hard drive interface CCA
- 10 Hard drive
- 11 Seal Safe system power supply
- 12 Centrifuge motor controller
- 13 64 V switch
- 14 Power supply
- 15 Circuit breaker
- **16** Power receptacle
- 17 Power cord clamp (not shown)
- **18** Service Ethernet port
- 19 High frequency filter
- 20 General line filter (behind cables)
- 21 E-box cover (not shown)

Figure 1-37: E-box components (bottom)

**Table 1-17: Centrifuge system components** 

	Component	Function			
1	E-box cooling fan	Provides airflow to cool the e-box components.			
2	Motor driver CCA	Provides drive power to the pump motors, the valve motors, the linear actuato motor, and the centrifuge door lock solenoid.			
3	Safety CCA	Monitors system functions to make sure they are within safe limits.			
4	Safety interface CCA	Connects the device harnesses to the new safety CCA connectors.			
5	Safety computer	Monitors system functions and communicates with the control computer to make sure they are within safe limits.			
6	Control CCA	Responsible for operator, procedure, and hardware control.			
7	Control computer	Responsible for operator, procedure, and hardware control and communicates with the safety computer to make sure they are within safe limits.			

**Table 1-17: Centrifuge system components (continued)** 

	Component	Function				
8	Control interface CCA	Connects the device harnesses to the new control CCA connectors.				
9	Hard drive interface CCA	Connects the hard drive SATA connector to the IDE harness connector.				
10	Hard drive	High-capacity, self-contained electronic storage device containing a read-write mechanism inside a sealed unit.				
11	Seal Safe system power supply	Provides the RF energy to the Seal Safe system.				
12	Centrifuge motor controller	Provides three-phase power signals to the centrifuge motor.				
13	64 V switch	Controls the power available to the centrifuge motor.				
14	Power supply	Converts the AC input voltage into DC voltage required for the device system				
15	Circuit breaker	Protects the system from an electrical surge. This is also a secondary powe switch that is used to power the device on and off.				
16	Power receptacle	Input point where the main AC power enters the device through the power cord.				
17	Power cord clamp (not pictured)	Prevents accidental power cord disconnection.				
18	Service Ethernet port	Allows the service computer to communicate with the device.				
19	High frequency filter	Removes higher frequency electrical noise from the input AC power.				
20	General line filter	Removes electrical noise from the input AC power.				
21	E-box cover (not pictured)	Provides physical and ESD protection to the electronics in the e-box. The foam backing on the cover presses on the CCAs, preventing intermittent connections.				

## **Versalogic/Ampro E-box Version**

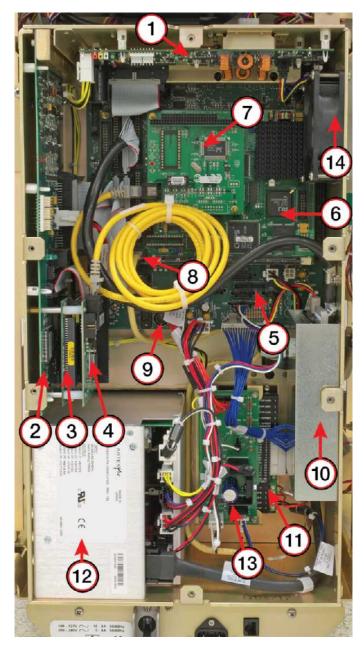


Figure 1-38: The Trima Accel system e-box

- 1 Motor driver CCA
- 2 Safety/ultrasonics CCA
- 3 Safety computer
- 4 Safety Ethernet CCA
- 5 Control CCA
- 6 Control computer
- 7 Control Ethernet CCA
- 8 External Ethernet connector
- 9 Keyboard connector
- 10 Hard drive
- 11 Centrifuge motor controller
- 12 DC power supply
- 13 64 V switch CCA
- 14 E-box fan

# **Display System**

The display system is the interface between the device and the operator.



Figure 1-39: Display components (front)

- 1 Front display housing
- 2 Rear display housing
- 3 Display matrix
- 4 Touch-screen display
- 5 Touch-screen display cable
- 6 Stop button
- 7 Stop button cable
- 8 Pause button
- 9 Pause button cable
- 10 Alarm LEDs
- 11 Trim tape
- 12 Rubber bumper
- 13 Display arm
- 14 Display arm cable
- 15 Display CCA
- 16 Flex harness
- 17 LED power cable
- 18 Grounding straps
- 19 Display plate
- 20 Speaker

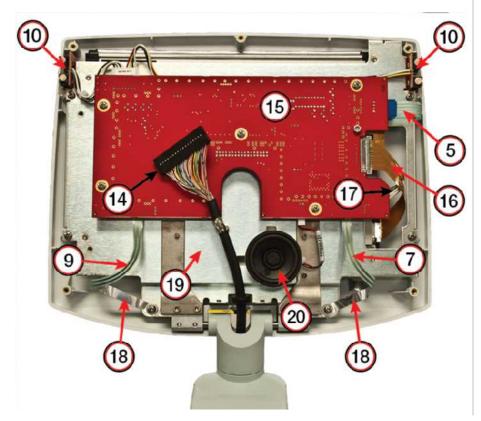


Figure 1-40: Internal display components (rear)

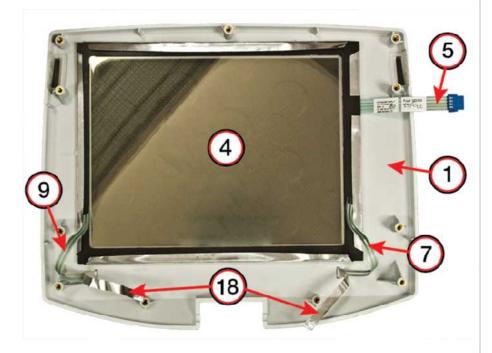


Figure 1-41: Internal display components (front)

- 1 Front display housing
- 2 Rear display housing
- 3 Display matrix
- 4 Touch-screen display
- 5 Touch-screen display cable
- 6 Stop button
- 7 Stop button cable
- 8 Pause button
- 9 Pause button cable
- 10 Alarm LEDs
- 11 Trim tape
- 12 Rubber bumper
- 13 Display arm
- 14 Display arm cable
- 15 Display CCA
- 16 Flex harness
- 17 LED power cable
- **18** Grounding straps
- 19 Display plate
- 20 Speaker
- 1 Front display housing
- 2 Rear display housing
- 3 Display matrix
- 4 Touch-screen display
- 5 Touch-screen display cable
- 6 Stop button
- 7 Stop button cable
- 8 Pause button
- 9 Pause button cable
- 10 Alarm LEDs
- 11 Trim tape
- 12 Rubber bumper
- 13 Display arm
- 14 Display arm cable
- 15 Display CCA
- 16 Flex harness
- 17 LED power cable
- 18 Grounding straps
- 19 Display plate
- 20 Speaker

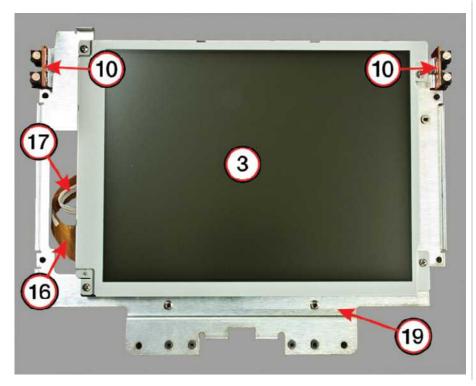


Figure 1-42: Internal display components (front)

- 1 Front display housing
- 2 Rear display housing
- 3 Display matrix
- 4 Touch-screen display
- 5 Touch-screen display cable
- 6 Stop button
- 7 Stop button cable
- 8 Pause button
- 9 Pause button cable
- 10 Alarm LEDs
- 11 Trim tape
- 12 Rubber bumper
- 13 Display arm
- 14 Display arm cable
- 15 Display CCA
- 16 Flex harness
- 17 LED power cable
- 18 Grounding straps
- 19 Display plate
- 20 Speaker

**Table 1-18: Display system components** 

	Component	Function
1,2	Display housings	Protect the display components. Both housings have sealed alarm LED windows that prevent fluid from entering the display (when the back housing is replaced, the alarm LEDs can catch on these windows). The trim tape must be removed before the rear housing can be removed.
3	Display matrix	Provides the visual interface between the operator and the device. It is a color LCD with an internal white LED backlight. The matrix communicates with the display CCA through the flex harness.
4	Touch-screen display	Determines where the operator has touched the display interface. It monitors and measures two voltages corresponding to horizontal and vertical position that are converted to x-y coordinates and sent to the display CCA.
5	Touch-screen display cable	Connects the touch-screen display to the display CCA. Impedance measurements from the pins on this connector correspond to horizontal and vertical edge-to-edge resistances and can be used to help in troubleshooting.
6	Stop button	Stops centrifuge and pump movement when pressed while in Procedure mode.

Table 1-18: Display system components (continued)

	Component	Function				
7	Stop button cable	Connects the stop button to the display CCA using a low-insertion-force connector.				
8	Pause button	Stops pump movement when pressed while in Procedure mode.				
9	Pause button cable	Connects the pause button to the display CCA using a low-insertion-force connector.				
10	Alarm LEDs	Alerts the operator that an alarm condition is present and communicates that alarm's status. LEDs off = safe operating condition; LEDs blinking = operator-recoverable alert (control-generated alarm); LEDs on = non-recoverable alarm (safety-generated alarm).				
11	Trim tape	Seals the front and rear display housings together and prevents fluid from entering the display. The tape also conceals the seam between the housings for cosmetic purposes.				
12	Rubber bumper	Prevents damage when the display housing is moved into the display arm.				
13	Display arm	Holds the display in position during operation and transport. The display arm connects to the display plate and contains the display cable.				
14	Display arm cable	Connects the display CCA to the e-box. This cable is the only connection between the display and the device, and it carries power, video signals, touch-screen inputs stop/pause button inputs, alarm LED signals, and speaker output signals.				
15	Display CCA	Drives the display matrix and coordinates all other display functions with the ebox. This CCA also powers the LED backlight in the display matrix, computes touch-screen coordinates, de-bounces push button signals, and drives the alarm LEDs.				
16	Flex harness	Carries EMI-filtered video signals between the display CCA and the display matrix.				
17	LED power cable	Sends power to the LED backlight in the display matrix and sends the blank screen signal.				
18	Ground straps	Provide a grounding path for static discharge from the stop and pause buttons. They attach to the display plate.				
19	Display plate	Provides a mounting surface for the display components and attaches the display assembly to the display arm.				
20	Speaker	Generates audio tones for alerts, alarms, and other operational sounds.				

# **Power System**

The power system transforms AC input into DC outputs for the subsystems.

The power system consists of the power switch, the circuit breaker, filters, and the power supply. The filters are for AC line noise suppression. The power supply outputs 5, ±12, 24, and 64 volts DC. The 5 volts is used for logic circuits; 12 volts is used for op amp reference, the speaker, the display backlight, and the display matrix; –12 volts is used for op amp reference and the RBC detector; 24 volts is used for pump and valve motors, alarm lights, fans, and the door lock solenoid; and the 64 volts is used by the centrifuge motor. There is also a 12.7 volt output for the Seal Safe system, if that is installed.

## **Mechanical Systems**

There are several subsystems that do not have electronic components to them and are purely mechanical.

The IV pole uses a lever system to bind the pole at the desired height position. To move the pole, a button is pushed that releases this binding, allowing for free movement. A square block inside of the IV pole tube keeps the IV pole from rotating.

The brake pedal has three positions: 360-degree caster rotation with rolling wheels, no caster rotation with rolling wheels, and no caster rotation with locked front wheels. The casters are adjustable for braking purposes.

The display arm has two versions: the newer version uses two adjustable ball detents to keep the display arm in position, and a previous version uses a push button to adjust the display arm position.

The front door latch plate is adjustable to ensure a seal with the basin front edge.

The body panels are removable to allow access to device systems and parts. There are two side panels, a front panel, and a back panel.

# **2**System Description

## **Pump System**

The pumps control the flow of inlet blood, anticoagulant, plasma, platelets, and return blood.

Each pump has a brushed direct current (DC) gear motor with a permanent magnet design and a built-in encoder, which generates 20,608 encoder counts per revolution. The motor-gear ratio is 10.062:1. The number of encoder pulses per revolution is calculated as the gear ratio multiplied by the 512 line encoder multiplied by 4 samples. The encoder tracks the direction of the motor. The pumps are driven by the 24 V power supply.

Each pump rotor has a Hall-effect sensor mounted in its raceway housing that acts as a redundant speed monitor (monitored by the safety computer CCA) independent of the encoder monitor circuit (monitored by the control computer). If the encoder reading and the Hall-effect sensor reading are significantly different, the system generates a pump error alarm. The pump rotors have a bottom-mounted magnet to signal the Hall-effect sensor when movement occurs.

Due to the platelet pump's unique spring mounting, the platelet pump has two magnets in its rotor, which differentiates it from other rotors.

All pumps have three quick-disconnect connectors. Two connectors, the power and ground connectors, attach to the motor through the brush assemblies. The third connector is the encoder harness. Each pump raceway also has a Hall-effect sensor CCA mounted to it with a quick-disconnect terminal.



**Note:** The pump motors can be removed without removing or loosening any of the pump raceways. If a pump raceway is removed or loosened, an alignment tool is necessary to reinstall it.

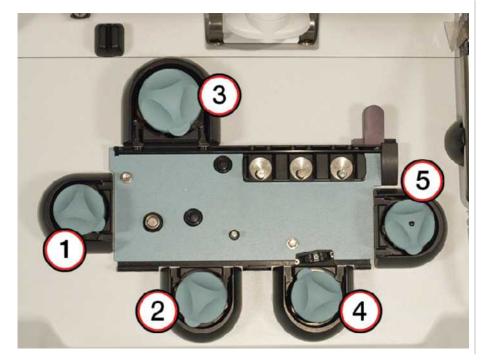


Figure 2-1: Pump locations (front)

- 1 AC pump
- 2 Inlet pump
- 3 Return pump
- 4 Plasma pump
- 5 Platelet pump

**Table 2-1: Pump system components** 

Pump	Name	Function
1	AC pump	The AC pump supplies anticolagulant to the access manifold. The AC pump runs only during the draw cycle. For safety reasons, the maximum AC pump flow rate is limited to a value based on the patient's total blood volume (TBV).
2	Inlet pump	The inlet pump draws whole blood and AC into the system and pumps it into the centrifuge channel.
		The maximum speed of the inlet pump can be configured to fast (142 mL/min), medium (120 mL/min), or slow (100 mL/min). The maximum inlet pump speed can also be limited based on the TBV limits that are configured.
3	Return pump	The return pump returns blood and blood components to the patient. The pump can run in both forward and reverse directions to aid in priming, and during a safe cassette load and unload. The return pump motor is a different assembly than the rest of the pump motors. The direction of the return pump is constantly monitored during the procedure for safety reasons. The return pump returns blood to the patient during the return cycle until air is detected at the lower-level sensor, signaling the logic to switch back to the draw cycle. This pump has a larger rotor than the other four pumps.
4	Plasma pump	The plasma pump is used to collect plasma or recirculate plasma to the platelet line for addition to the platelet product or to the reservoir, depending on the position of the platelet valve. The speed of the plasma pump is varied to control the interface in the channel.
5	Platelet pump	The platelet pump is used to collect platelets or move recirculated plasma to the platelet product or reservoir. The platelet pump is also used to add replacement fluid for the donor during a dRBC run. The platelet pump rotor is not interchangeable with the other rotors.

# Pump System

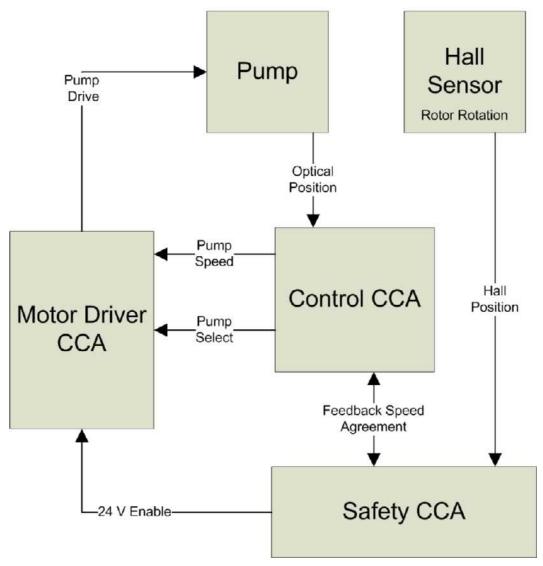
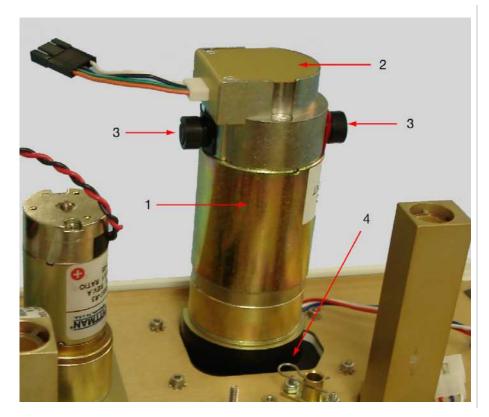


Figure 2-2: Pump system block diagram

The control CCA selects the pump and sends pump speed signals to the motor driver CCA. The safety CCA enables the 24-volt power. The motor driver CCA sends a 24-volt pulse-width-modulated drive signal to the selected pump motor. As the pump rotates, an internal optical encoder is counting rpm, and that position information is sent to the control CCA to complete the feedback loop. At the same time, the rpm of the pump rotor magnet is being read by a Hall-effect sensor, and that position information is sent to the safety CCA. The pump rotations seen by both the safety CCA and the control CCA must agree, otherwise an alarm is generated, and the safety CCA cuts 24-volt power to the motor driver CCA.

## **Pump Assembly**

The five pumps control the flow of inlet blood, anticoagulant, plasma, collected components, replacement fluid, and return blood. The pumps get their drive commands from the motor driver CCA.



- 1 Pump motor
- 2 Optical encoder
- 3 Drive terminals
- 4 Hall-effect sensor

Figure 2-3: The pump assembly

**Table 2-2: Pump assembly components** 

Pump	Name	Function				
1	Pump motor	The pump motor is a 24 V DC brushed motor that drives the pump rotor.				
2	Optical encoder	The optical encoder provides speed feedback by reporting the pump speed to the control CCA. The encoder is attached directly to the motor shaft.				
3	Drive terminals	The drive terminals connect switched 24 V power and ground from the motor driver CCA to the pump motor.				
4	Hall-effect sensor	The Hall-effect sensor acts as a redundant speed monitor by reporting the pump speed to the safety CCA. The sensor is mounted to the pump raceway.				

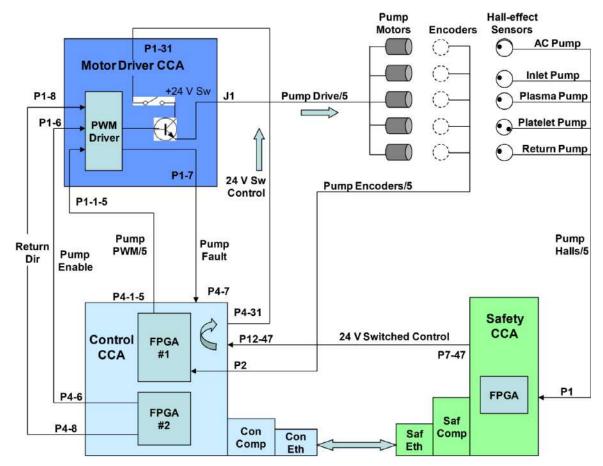


Figure 2-4: Pump interconnect diagram

# **Sensor System**

The sensor system is made up of multiple sensors that monitor pressure, fluid levels, leaks, door position, lock status, and platelet line composition.

The sensor system is made up of

- Two pressure sensors
- Two fluid level sensors
- The RBC detector
- The AC detector
- The leak detector

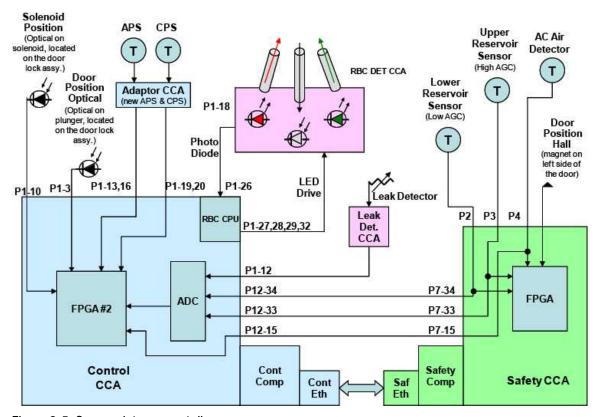
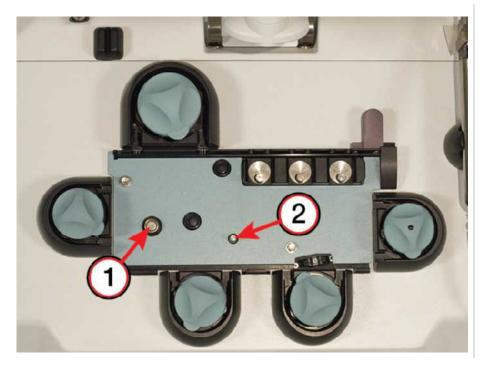


Figure 2-5: Sensors interconnect diagram

## **Pressure Sensors**

The pressure sensors (2) measure access, return, and centrifuge pressures.



- 1 Access/return pressure sensor
- 2 Centrifuge pressure sensor

Figure 2-6: Pressure sensor locations (front)

**Table 2-3: Pressure sensor components** 

Sensor	Name	Function
1	Access/return pressure sensor	The access/return pressure sensor monitors the pressure of the donor access during the draw and return cycles.
		This sensor signals the logic to shut off the pumps if pressures exceed predetermined alarm safety limits. If the pressure returns to normal range after the pumps have stopped, the pumps automatically restart. This can occur for two consecutive alerts within the allotted time. If a third pressure alert occurs within 3 minutes, the pumps stop and operator attention is required to continue the run. The <b>Continue</b> button is not activated if the pressure remains in the alarm range. The pressure sensor automatically engages when the cassette lowers. The transducer for this sensor is a strain-gauge load cell that is magnetically coupled to a metal disk on the cassette. There is a magnet built in to the sensor.  The access/return pressure sensor is also used to monitor the pressure of the RBC in-line filter during storage solution addition.
		prossure of the ribo in line litter during storage solution addition.
2	Centrifuge pressure sensor	The centrifuge pressure sensor senses pressure inside the centrifuge channel. It is also used during the addition of additive solutions and to monitor the pressure of the filter during in-line filtration of RBC products.
		This sensor stops the pumps and centrifuge when the pressure exceeds 1,350 mmHg; the sensor automatically engages when the cassette lowers.
		<b>Note:</b> Overly high centrifuge pressures are usually the result of line occlusions or an air block.

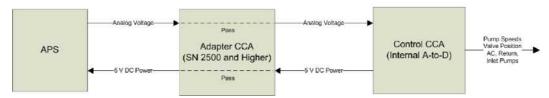


Figure 2-7: APS sensor block diagram

The APS is powered by 5 V from the control CCA. All lines pass through the valve CCA (just straight pass-through only). Output is a variable DC voltage, positive or negative, depending on the direction of force exerted on the sensor. The control computer performs analog-to-digital conversion for its processing. The control computer sends that feedback information to adjust the AC, return, and inlet pump speeds.

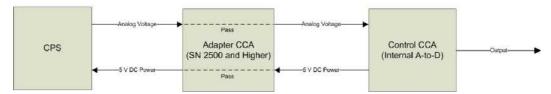
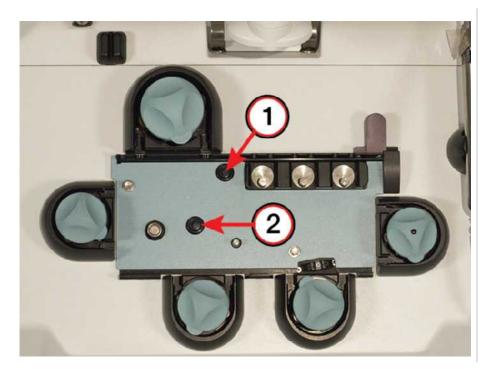


Figure 2-8: CPS sensor block diagram

The CPS is powered by 5 V from the control CCA. All lines pass through the valve CCA (just straight pass-through only). Output is a variable positive DC voltage, depending on the amount of force exerted on the sensor. The control computer performs analog-to-digital conversion for its processing. The control computer sends that feedback information to adjust the plasma, platelet, and inlet pump speeds.

#### **Reservoir Level Sensors**

The upper-level and lower-level reservoir sensors control the draw and return cycles by sensing the upper and lower limits of fluid in the return reservoir.



1 Upper-level reservoir sensor

2 Lower-level reservoir sensor

Figure 2-9: Reservoir level sensor locations (front)

The return cycle starts when both sensors detect fluid. The return pump starts, pumping fluid out of the reservoir. When both sensors detect air, the return pump stops and the draw cycle starts.

If the lower-level sensor detects air (while the return pump is running) for an extended period of time, an alarm occurs and the return pump stops. This blocks the return line and prevents air from being returned to the donor.

The lower-level and upper-level reservoir sensors are identical and connect to the safety/ultrasonics CCA.

Table 2-4: General fluid level states

State	Lower-Level Sensor	Upper-Level Sensor		
Full	Detects fluid	Detects fluid		
Mid	Detects fluid	Detects air		
Empty	Detects air	Detects air		
Error	Detects air	Detects fluid		

**Table 2-5: STS fluid level states** 

Loaded Cassette: Saline and Sensor States			STS Status and Control			Dlog Column	
Saline Level in Reservoir	Lower- Level Detects	Upper- Level Detects	Safety Level	Control Level	AGC Lo Volts	AGC Hi Volts	Reservoir Status
Full ~ 70 mL	Fluid	Fluid	Mid *	High	0.15 to 0.55	0.15 to 0.55	H (high)
½ <b>Full</b> ~ 35 mL	Fluid	Air	Mid *	Mid	0.15 to 0.55	0.75 to 0.95	L (low)
Empty 0 mL	Air	Air	Empty	Empty	0.75 to 0.95	0.75 to 0.95	E (empty)
Full with Error	Air	Fluid	Empty	Error	0.75 to 0.95	0.15 to 0.55	F (fail)

<sup>\*</sup> The safety system does not look at the upper-level sensor

#### Level Sensors

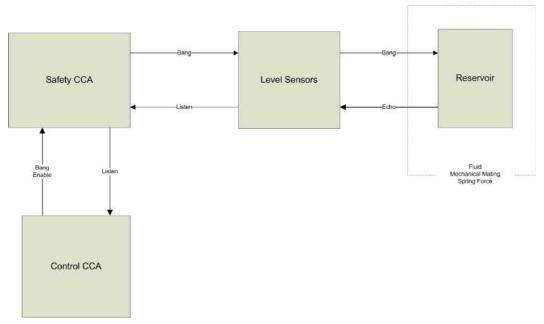


Figure 2-10: Level sensor block diagram

The safety CCA sends out a bang and then listens for the return every 250 microseconds. The safety CCA automatic gain control (AGC) circuitry increases gain as the fluid in the reservoir decreases, because the signal transmits more easily through fluid in the reservoir than through air. As the fluid level in the reservoir increases, the gain decreases, and vice versa. The bang generated from the safety CCA waits for the control CCA to trigger it. The safety CCA splits off the listen signal to both control and safety systems. The signal comparison happens on the safety CCA.

If the lower-level sensor sees air, this is a bad safety condition. If this occurs, the safety system removes the control system's command ability by removing the 24 volts.

Donor safety: During a return cycle, if the lower-level sensor detects air too early or too late, the safety system removes the 24 volts to the motor driver CCA, which removes pump power so the pumps do not run even if commanded to do so by the control system. This prevents air from being returned into the donor.

### **AC Sensor**

The AC sensor detects the presence of anticoagulant (AC).

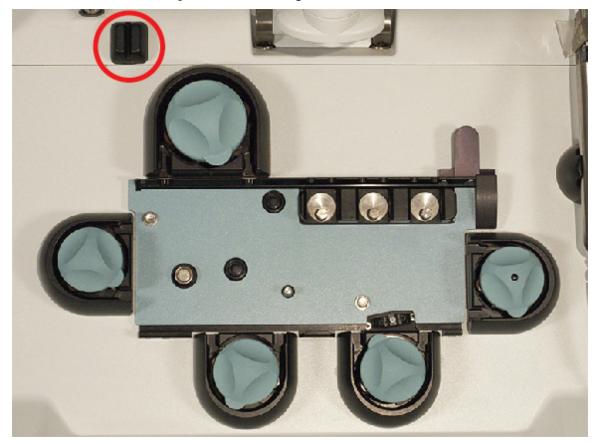


Figure 2-11: The AC sensor

The AC fluid sensor detects the presence of anticoagulant (AC) in the anticoagulant line with an ultrasonic 2 MHz signal.

### AC Detector System

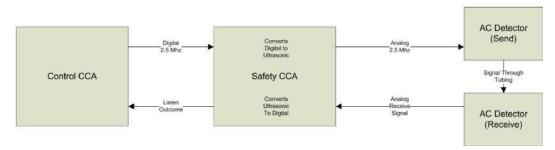


Figure 2-12: AC detector block diagram

The control CCA sends a digital clock signal to the safety CCA, which converts that to an analog ultrasonic signal. The "send" side of the AC detector transmits this signal through the tubing to the "receive" side of the detector. The signal transmits through fluid but does not transmit through air. The listen signal is received by the safety CCA, and the safety CCA sends this outcome (either fluid or no fluid) to the control CCA for normal awareness purposes.

### **RBC Detector**

The RBC detector is used to detect RBC contamination in the platelet line, detect the tubing set type, and detect gross differences between predicted and collected platelet products.



Figure 2-13: RBC detector location (front)

The RBC detector is mounted in a small CCA under the front panel. It uses green and red LEDs to perform the following tasks:

- The RBC detector measures the shade or color of the collected product to check for RBC contamination (RBC spillover). If RBC contamination is present in the platelet line, the system generates an alarm.
- The RBC detector detects the type of tubing set that is loaded by measuring the light reflected from the stamp on the back of the cassette. If the tubing set cannot be identified, the system generates an alert.
- The RBC detector detects gross differences between the predicted platelet collection and the actual collected platelet product. If a gross difference is detected, the system generates a Verify Platelet Product message at the end of the procedure.

### **RBC** Detector System

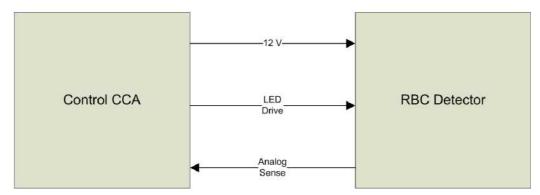


Figure 2-14: RBC detector block diagram

The control CCA sends 12 V and the drive signal to the RBC detector. A sense line comes from the RBC detector to the control CCA. When the sense line is detecting RBC contamination, the signal is low when RBC is not sensed and high when RBC is sensed. When the sense line is detecting cassette type, the signal is a low number for a black stamp, which absorbs more light, and a higher number for a white stamp. These numbers are recorded in the dlog file. This number can be calibrated and is used to adjust the duty cycle for the LEDs to adjust light intensity. Every time a cassette is loaded, the RBC detector auto-calibrates, storing a number in a register on the control CCA to balance the red/green ratio at 1. This number adjusts the duty cycle of the LEDs to balance the reflectance (these numbers are also in the dlog file). When RBC contamination is detected, the device generates an alarm that can be cleared and adjusts the valve position and the pump speed to purge the line of RBC and continue on.

### **Leak Detector**

The leak detector senses fluid leaks from the disposable tubing set. It is mounted on the back wall of the centrifuge basin.

The leak detector consists of a printed wiring board (PWB) with traces that act like a variable resistor. When fluid is deposited on the leak detector, a change in resistance is detected, and an alarm is generated by the control system. The normal voltage range of the leak detector is 2.0 V to 3.0 V. Below 2.0 V indicates a fluid leak. Above 3.0 V indicates an open circuit. During startup tests and prior to loading a tubing set, the system checks the ability of the leak detector to operate normally.

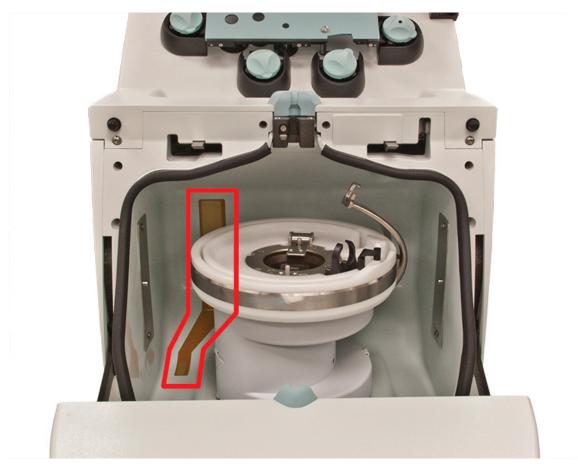


Figure 2-15: The leak detector

## Leak Detector System

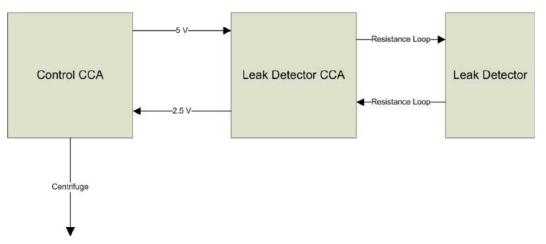


Figure 2-16: Leak detector block diagram

The control CCA sends 5 V to the leak detector CCA and is looking for 2.5 V coming back. The control CCA reads the difference between the two voltages. A range near 2.5 V is defined as good. Any voltage below that indicates a leak in the basin. This leak condition causes the control CCA to remove the 64-volt power to the centrifuge motor, causing the centrifuge to stop.

# **Centrifuge System**

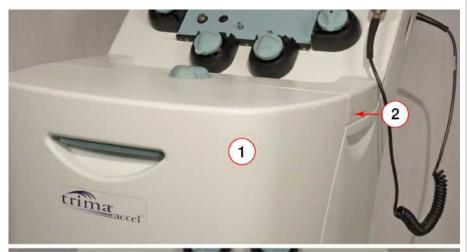
The centrifuge system is made up of the centrifuge, filler, and drive assembly.

The centrifuge separates the whole blood into components by spinning the blood inside the disposable channel. The centrifuge has the following characteristics:

- The centrifuge is driven by a beveled gear train.
- The filler has a diameter of 12.5 in (31.8 cm).
- The centrifuge is designed to rotate at speeds up to 3,000 rpm. If the centrifuge exceeds 3,100 rpm, drive power to the motor is shut off. If the centrifuge exceeds 3,200 rpm, the safety system generates an alarm.
- The centrifuge has a front door panel that rotates down, providing easy access to the centrifuge and tubing holders.
- The centrifuge contains an open port for loading the disposable channel, which occupies the middle of the gear train hub.



Note: The Spectra Optia and Trima Accel centrifuge basins are not interchangeable.



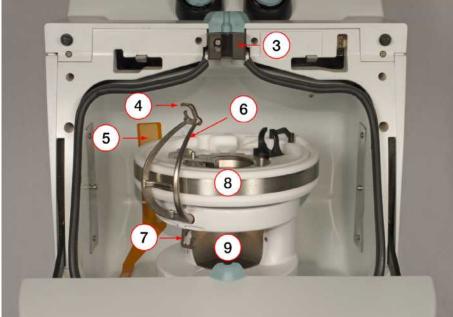


Figure 2-17: The centrifuge door and basin

- 1 Centrifuge door
- 2 Centrifuge door lock release
- 3 Upper collar holder
- 4 Upper bearing holder
- 5 Leak detector
- 6 Centrifuge arm
- 7 Lower bearing holder
- 8 Filler
- 9 Centrifuge loading port

**Table 2-6: Centrifuge door and basin components** 

	Name	Function
1	Centrifuge door	The centrifuge door separates the centrifuge from the patient and the operator. When the centrifuge door is closed and the centrifuge is spinning, the door is held in the locked position by an interlock solenoid located at the top right of the basin/door opening. This solenoid, driven by the motor driver CCA, engages a plunger to activate the lock.
		There are two sensors that monitor that the door is closed (an optical sensor and a Hall-effect sensor) and an optical sensor to monitor that the door is locked. The door automatically unlocks at centrifuge speeds less than 60 rpm. An optical switch on the frame assembly behind the front door (monitored by the safety/ultrasonics CCA) tells the system when the front door opens and closes. A Hall-effect sensor (monitored by the control CCA) and a magnet mounted on the front door also monitor the door. The system prevents the operator from opening the door while the centrifuge is running at more than 60 rpm or from running the centrifuge when the door is open. An optical switch (monitored by the control and safety/ultrasonics CCAs) located on the solenoid lock assembly tells the system whether or not the solenoid is in the locked position. The solenoid is not spring-loaded and will not move if power is removed.
2	Centrifuge door lock release	The centrifuge door lock release manually unlocks the centrifuge door when the centrifuge door key is inserted through the centrifuge door key opening to depress the solenoid plunger.
3	Upper collar holder	The upper collar holder attaches the upper end of the centrifuge tubing to the frame above the centrifuge. The operator loads the upper end of the tubing by inserting the upper tubing with the collar below the holder, aligning the collar to the holder, and pulling up until the collar fully seats in the holder. When the door closes, the collar locks in place.
4	Upper bearing holder	The upper bearing holder holds the centrifuge tubing in place at the upper end of the centrifuge arm.
5	Leak detector	The leak detector senses fluid in the basin from leaks in the channel or tubing. The leak detector is mounted on the back wall of the centrifuge basin. The leak detector consists of a printed wiring board (PWB) with traces that are configured to act like a variable resistor. During startup tests and prior to loading a tubing set, the system checks the ability of the leak detector to operate normally. A small circuit card is mounted on the frame near the back of the basin. The leak detector plugs into this circuit card and the output of the circuit card goes to the control CCA.

Table 2-6: Centrifuge door and basin components (continued)

	Name	Function
6	Centrifuge arm	The centrifuge arm holds the rotating centrifuge tubing in place while the centrifuge spins.
7	Lower bearing holder	The lower bearing holder holds the centrifuge tubing in place at the lower end of the centrifuge arm.
8	Filler assembly	The filler assembly holds the channel portion of the tubing set in place.
9	Centrifuge loading port	The centrifuge loading port provides an opening in the centrifuge housing for loading the channel.

### Centrifuge System

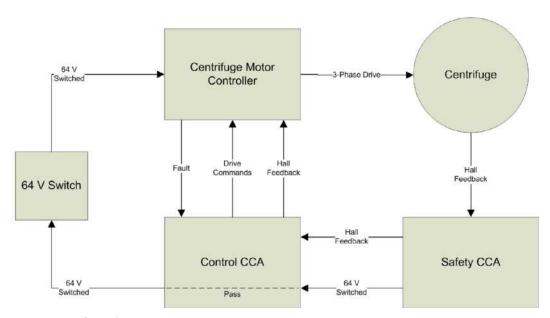


Figure 2-18: Centrifuge system block diagram

Starting with an input signal, the control CCA sends a drive command to the centrifuge motor controller (CMC) after the safety CCA has turned on the 64-volt switch to make centrifuge drive voltage available to the CMC. The conditions that must be met for the safety CCA to enable the 64-volt switch include: the door lock solenoid must be unpowered, the door closed sensors must read closed, and the leak detector must be dry. The control CCA sends a DC voltage (0 V to 5 V) to the CMC as a drive command. The CMC then converts that voltage into 3-phase drive by superimposing a duty cycle onto the raw 64-volt-switched voltage on each line, causing the centrifuge motor to spin. Hall-effect sensor feedback is sent directly to the safety CCA, the control CCA, and the CMC through simple splitting. The safety and control CCAs have to agree within a certain range of rpm or time, or the centrifuge drive power is cut. The Hall-effect sensor output is a pulse voltage. If voltage, current, or something in processing is wrong in the CMC, it sends a fault signal (commutation, direction, or processing) to

control as a bit code signal. This fault is seen in STS. Fault bit, 64-volt raw and switched, centrifuge commanded/actual (Hall-effect feedback) are all columns in the dlog file. Centrifuge braking circuitry is in the CMC.

## **Centrifuge Drive Assembly**

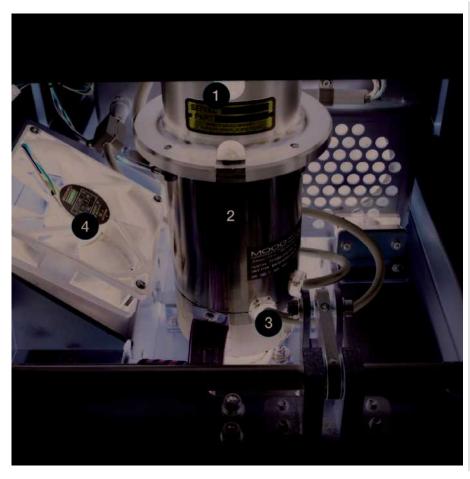


Figure 2-19: The centrifuge drive assembly and motor

- 1 Gear assembly
- 2 Centrifuge motor
- 3 Hall-effect sensor
- 4 Cooling fan

Table 2-7: Centrifuge drive assembly components

	Component	Function
1	Gear assembly	The gear assembly allows the filler to spin at the commanded speed and the centrifuge arm to spin at half the commanded speed. This speed difference, combined with other aspects of the system's design, prevents the centrifuge loop from twisting.
2	Centrifuge motor	The centrifuge motor runs the centrifuge. The motor is a three-phase, brushless, DC motor rated at ¼ horsepower. The three phases are in a wye configuration. Two legs of the wye are alternately energized (one leg attached to V+ and the other to ground) to achieve rotation. Each set of legs must be energized twice in sequence before one centrifuge revolution is complete.
3	Centrifuge Hall-effect sensors	Three centrifuge Hall-effect sensors mounted inside the motor casing sense the speed of the motor shaft. These sensors send a feedback signal to the control and safety/ultrasonics CCAs to regulate centrifuge speed. A quick-disconnect connector is used to facilitate the removal and replacement of the centrifuge motor and gear train. Another cable carries the drive signals generated by the centrifuge motor controller to the centrifuge motor and connects at the rear of the e-box.
4	Cooling fan	The fan cools the centrifuge motor and geartrain. The 24 V DC fan has a built-in Hall-effect sensor to detect fan operation.

### **Centrifuge Motor Controller**

The centrifuge motor controller provides power to the three-phase centrifuge motor.

The control computer calculates the necessary drive for the centrifuge motor (based on algorithms) and converts this drive signal to an analog voltage. The voltage is then amplified and sent to the centrifuge motor controller. The motor controller controls the timing for the phasing of the three-phase centrifuge motor. It uses feedback from the three Hall-effect sensors mounted inside the centrifuge motor to determine the phasing sequence and timing. Both the safety computer and the control computer also monitor the Hall-effect sensor signals to ensure that no sensor has failed. If a sensor has failed, a centrifuge hardware failure alarm generates. When the centrifuge stops, due to either a command or an alarm condition, the control system and the safety system can command the motor controller to brake the centrifuge motor.

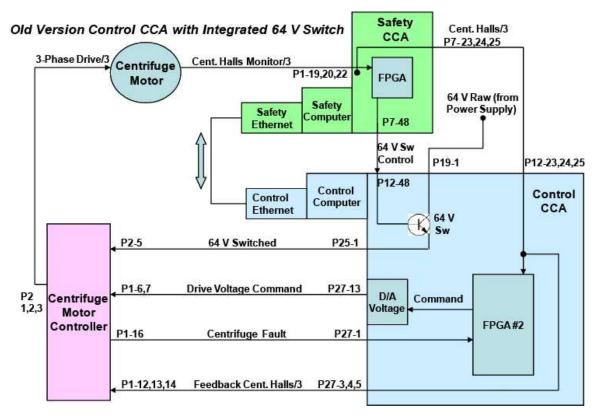


Figure 2-20: Centrifuge motor controller (old version)

#### New Version with Separate 64 V Switch CCA P7-48 P12-48 Safety 64 V Switched Control Control CCA CCA P1-19,20,22 **FPGA** FPGA#2 Cent. Halls Monitor/3 P7-23,24,25 Cent. Halls/3 P12-23,24,25 Command Centrifuge Motor Safety Computer D/A Control Safety Control 3-Phase Computer Voltage Ethernet Ethernet Drive/3 P27-3,4,5 P27-13 P27-1 P32-4 P2 P1-12,13,14 Feedback Cent. Halls/3 P1-16 **Drive Voltage Command** Centrifuge P1-6,7 Centrifuge Motor Fault Controller 64 V Raw (from P3-1 Power Supply) P1-4 64 V Switched 64 V Sw P2-5 P4-1

CCA

# Figure 2-21: Centrifuge motor controller (new version)

# **Door System**

The centrifuge door assembly allows access inside the centrifuge basin, and the centrifuge door lock system ensures that the centrifuge door cannot be opened while the centrifuge is spinning.

Latching the centrifuge door closed involves engaging two latch hooks attached to the frame above the front of the basin that grab onto two latch holes in the latch plate of the centrifuge door. These two latch hooks have sensors associated with them that indicate whether the door is open or closed. To lock the door, the solenoid engages the door lock shaft into a hole in the latch plate. This shaft has a sensor that indicates whether the door is locked or unlocked. When the door latch handle is pressed, it mechanically levers the latch plate in the door off the latch hooks on the frame, which opens the door. When the door is locked, the handle does not move when it is pressed.

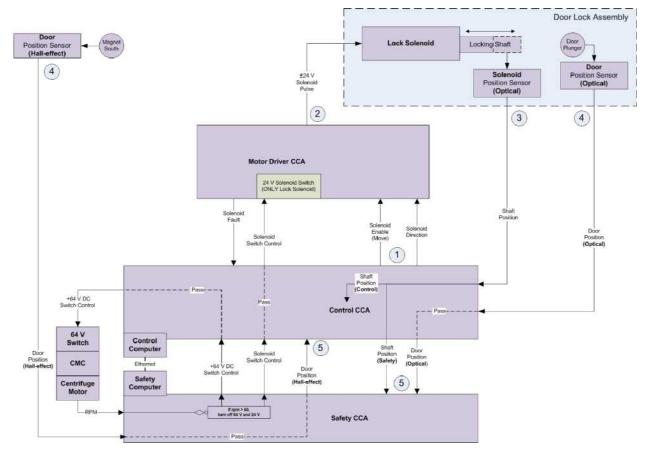


Figure 2-22: Door lock system block diagram

### Prerequisites

The door lock system must meet the following electronic prerequisites for normal operation:

- 24 V DC source from the power supply must be within a 19.2 V DC to 28.8 V DC range
- 24 V DC switched from the motor driver CCA must be within a 19.2 V DC to 28.8 V DC range
- Safety CCA reset of 24 V shutdown (digital) indicates run or no reset (low)
- Safety CCA must activate the 24 V DC switch (digital) on the motor driver CCA

- 24 V current sense line (DC voltage) from the motor driver CCA must not trigger the solenoid fault line
- Safety CCA must turn off the 64 V switch
- Lock solenoid power must be enabled
  - Safety system controls the lock solenoid power and turns off the solenoid power if the centrifuge spins over 60 rpm
  - For safety reasons, it is not possible to have both the solenoid energized and the centrifuge motor powered up (64 V switched)
  - During boot-up, a T1 door lock test is performed that locks and unlocks the door solenoid

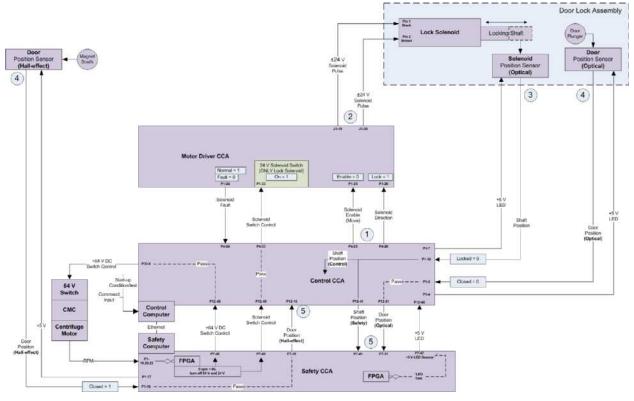


Figure 2-23: Door lock system diagram

### Control Computer

Door lock movement is initiated when the device software or STS tells the control computer to lock or unlock the door. The control computer tells the control CCA field-programmable gate array (FPGA) to actuate the door lock solenoid and also informs the safety computer what it told the control CCA FPGA through an Ethernet connection. This is a redundant system used to ensure that the device fails in a safe state. An alarm is generated if the safety computer notices a difference between the control and safety conditions.

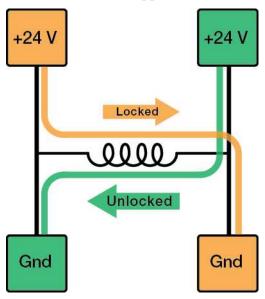
### Control CCA (Beginning)

The control CCA FPGA translates the orders given by the control computer into the necessary logic bits that are sent to the motor driver CCA to energize the lock solenoid. The control CCA generates a lock solenoid direction bit and a lock solenoid enable bit that are sent to the motor driver CCA. The direction bit sets the voltage polarity presented to the lock solenoid, and the enable bit applies the voltage to the lock solenoid.

The control CCA also monitors the position of the locking shaft and the Hall-effect door position sensor (it does not monitor the optical door position sensor; the safety system does).

#### Motor Driver CCA

The lock solenoid is driven by +24 V DC that is applied to the solenoid using H-bridge circuitry located on the motor driver CCA. The direction bit (1=lock, 0=unlock) determines how the H-bridge power circuit presents the voltage across the lock solenoid. The +24 V DC is toggled between the two sides of the H-bridge, which toggles the direction of the current flow through the solenoid coil. +24 V DC from one direction is used to extend the locking shaft (locked), and +24 V DC from the opposite direction is used to retract the shaft (unlocked).



The enable bit is used to connect the power from the H-bridge to energize the lock solenoid (bit 0 = energize, bit 1 = de-energize). The lock solenoid is energized until the sensor reports the correct position, waiting a maximum of 1 second. There is a 1-second non-powered pause between each attempt to move the lock solenoid.

There are two separate +24 V switches on the motor driver CCA. There is one switch just for the lock solenoid, and another switch for the valves, pumps, and linear actuator. The lock solenoid has a dedicated +24 V switch so that the power to the lock solenoid can be disabled without interfering with the power to other systems. The concept behind using switched 24 V is to provide a safety mechanism to keep the door from being opened while the centrifuge is moving. The safety and control systems have to agree on certain centrifuge door conditions, and the safety system can remove the power using the switch if there is no agreement between the two systems.

The motor driver CCA monitors the power to the lock solenoid for problems. If there is an undervoltage or over-current problem, it sends a solenoid fault bit (1=normal, 0=fault) to the control CCA. This fault is logged in the STS fault screen.

### Door Lock Assembly (Lock Solenoid and Optical Door Position Sensor)

The lock solenoid is magnetically latching, which means that when the shaft is pulled into the lock solenoid, it is held there by magnetic force (shaft in), which overcomes the spring force that holds the shaft in the locked position (shaft out). There is an access hole that can be used to push in the locking shaft to manually unlock the door if power is lost.

The locking shaft has an attached flag that triggers the optical solenoid position sensor. The optical sensor sends its output to both control and safety CCAs (an alarm is generated if these two do not agree). In the unlocked position, the IR light is blocked by the flag, sending a "1" bit to both control and safety CCAs; in the locked position, the IR light shines through a hole in the flag, sending a "0" bit to both systems.

The door position optical sensor is activated by a flag attached to a plunger that moves to trigger the sensor when the door latch plate moves the plunger. In the open position, the IR light is blocked by the flag, sending a "1" bit to just the safety system; in the closed position, the IR light shines through a hole in the flag, sending a "0" bit to safety only (because the other set of doorposition data is from the Hall-effect sensor on the other side of the door).

### Hall-Effect Door Position Sensor

The Hall-effect door position sensor is on the left (IV pole button) side of the device. This is one of two door position sensors, one on each side of the device, used for redundancy and to help indicate when the door has not closed evenly. On the left (IV pole button) side is the Hall-effect sensor, and on the right (power switch) side is the optical sensor.

The south-pole side of a magnet in the latch plate triggers the feedback signal. When the door is closed, the magnet is detected and the sensor outputs a "1" bit to the control CCA. When the door is open, the magnet is not detected and the sensor outputs a "0" bit. The sensor is powered by 5 V that comes from a different source than the LED light voltage in the optical sensors (because of the LED test that occurs every 60 seconds).

### Control CCA (End)

The control CCA receives the feedback position bits from the locking shaft position sensor and the door position Hall-effect sensor. The shaft position sensor gets split and goes to both the control and safety CCAs. The control CCA reports these two items to the control computer only.

The control and safety systems are both looking for the position sensor bit to confirm the position of the locking shaft. They must both agree on the position, or an alarm is generated. As a redundant safety mechanism, the control CCA is monitoring one half of the door position output (Hall-effect) and sends this data to the control computer. The safety CCA is monitoring the other half of the door position output (optical) and sends this data to the safety computer. The two computers compare this data through an Ethernet connection, and the two sets of sensor data must agree, or an alarm is generated.

After a door lock or unlock command is given, the control system sends the enable bit and waits 1 second for the shaft feedback signal. If the shaft position is reported as locked, it toggles the enable bit to **off** for one second and tries the process again. If, after a third cycle, there is still no shaft detection, a fault bit is generated on the control CCA and sent to the motor driver CCA, which disables the H-bridge circuit until the device is powered off. The fault bit overrides the enable bit. This works the same way during a door unlock cycle as well.

### Safety CCA

The safety CCA performs a lock solenoid power test once before every procedure. The solenoid power is turned off and the solenoid is commanded to lock. The system should report an unlocked position because there is no power to the lock solenoid. The solenoid power is then turned back on to prepare for a procedure.

The position sensor LED power is generated on the safety CCA. The FPGA on the safety CCA performs an LED test at start-up and every 60 seconds during a run. The test is as follows:

- 1. Turn off LED power.
- 2. Wait 3 ms.
- 3. Check all LED position sensors. All must be unknown.
- 4. Turn on LED power.

### **Safety Computer**

The safety system monitors the state of the 64 V power and the centrifuge rpm every 0.5 seconds. Either the +64 V switch or the +24 V door lock switch can be enabled at any one time, but they cannot be enabled at the same time. The safety computer turns off the lock solenoid power if the centrifuge is spinning at more than 60 rpm or the +64 V switch is enabled. The safety computer turns on the lock solenoid power if the centrifuge is spinning at less than 60 rpm. When the lock solenoid power is disabled, the solenoid position cannot be changed.

A T1 test is performed on the door lock solenoid to ensure system integrity. The T1 test is performed once before a procedure.

T1 tests are completed by the safety computer before the first time it uses the power switches (+24 V, +64 V, or both). The safety computer verifies that the door is locked and closed at the time of the T1 test. For certain versions of software, a T1 test failure on the lock solenoid may not have an alarm at the time of failure, but may alarm at the donor connection step instead.

# **Valve System**

The valve system operates by rotating valves in the valve assembly to pinch tubing closed between the valve post bearing and the valve housing.

Each valve motor rotates the valve post to one of three positions: right, center, or left. When the valve post is in the right or left position, it is pinching a section of the disposable tubing set between the valve post bearing and the valve housing, which closes that part of the disposable tubing set. When the post is in the center position, both sections of tubing are open. Only one valve moves at a time.

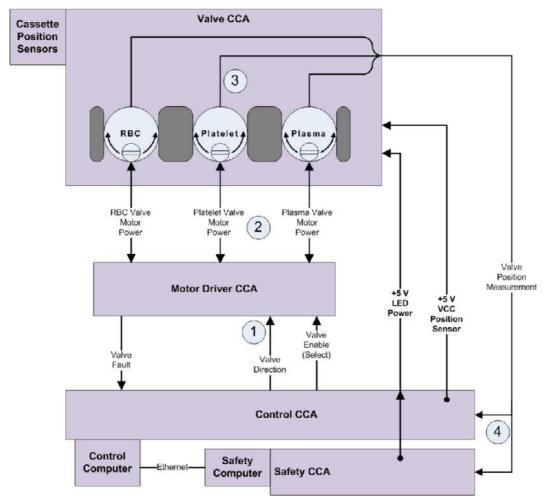


Figure 2-24: Valve system block diagram

### Prerequisites

The valve system must meet the following electronic prerequisites for normal operation:

- 24 V DC source from the power supply must be within a 19.2 V DC to 28.8 V DC range
- 24 V DC switched from the motor driver CCA must be within a 19.2 V DC to 28.8 V DC range
- Safety CCA reset of 24 V shutdown (digital) indicates run or no reset (low)
- Safety CCA must activate the 24 V DC switch (digital) on the motor driver CCA

- 24 V current sense line (DC voltage) from the motor driver CCA must not trigger the valve fault line
- Valve fault line (digital) from the motor driver CCA indicates normal, no fault (high)
- Position sensor VCC on the valve CCA must be within a 4.75 V DC to 5.25 V DC range
- Sensor LED power must be within range; 5.05 V DC maximum (switched on the safety CCA)
- Start-up test must pass
  - All LEDs off: Valves must show unknown for all positions
  - All LEDs on: Valves must be seen in every position while rotating through all positions

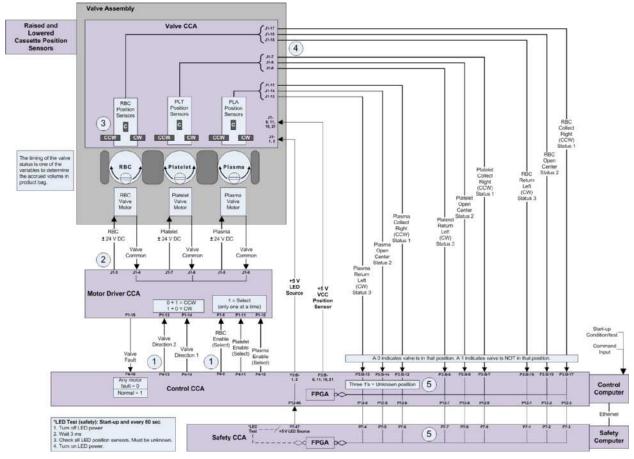


Figure 2-25: Valve system diagram

### **Control Computer**

Valve movement is initiated when the device software or STS tells the control computer which valve to move and in which direction. The control computer tells the control CCA FPGA to execute the valve movement and also informs the safety computer what it told the control CCA FPGA through an Ethernet connection. This is a redundant system used to ensure that the device fails in a safe state. If the safety computer notices a significant difference between the control and safety conditions, the device is shut down with an alarm or reboot.

### Control CCA (Beginning)

The control CCA FPGA translates the orders given by the control computer into the necessary logic bits that are sent to the motor driver CCA to move a valve. The control CCA generates two valve direction bits and the valve enable bit that are sent to the motor driver CCA. The two valve direction bits set the valve motor voltage polarity on the motor driver CCA. There is a separate valve enable bit for the RBC enable, the platelet enable, or the plasma enable function. Only one of these enable bits is generated and used at one time.

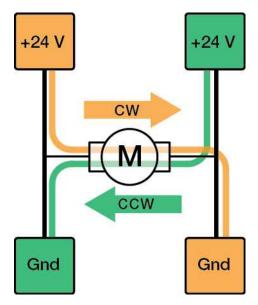
#### Motor Driver CCA

The valve motors are driven by voltage that is applied using H-bridge circuitry located on the motor driver CCA. The two valve direction bits from the control CCA create four different bit combinations. Two of the combinations are used to move the valve, and two of the combinations are used to hold the valve in position. The valve enable bit determines which valve motor will use the power from the H-bridge power circuit. The valve motor does not rotate until the selected valve enable bit is sent.

**Table 2-8: Valve direction bit combinations** 

Valve Motor Direction	Valve Direction 2	Valve Direction 1	Voltage Across Motor
CW	1	0	+24 V DC
CCW	0	1	-24 V DC
Stopped	0	0	0 V DC
Stopped	1	1	0 V DC

The valve direction bits determine how the H-bridge power circuit presents the voltage polarity across the valve motor. Each motor shares a powered line called the valve common (this is not a ground line). The voltage for the valve common is determined by the valve direction 2 bit. The other powered line is independently controlled for each motor and is the voltage differential relative to the valve common line. The voltage for the powered line is determined by the valve direction 1 bit. The polarity of the relative voltage between the valve common and powered lines is what rotates the motor in the following directions: +24 V DC is used for clockwise (CW) rotation, -24 V DC is used for counterclockwise (CCW) rotation, and 0 V DC is used to hold position and resist rotation.



The motor driver CCA monitors the power of all the valve motors for problems. If there is an under-voltage or over-current problem on any one motor, it sends a valve fault bit to the control CCA. Normal operation is a "1" and a fault is "0." This fault is logged in the STS fault screen.

### Valve CCA and Assembly

With the valve direction selected and the valve enabled, the +24 V DC switched is connected to the valve motor to rotate the valve body. The valve CCA has three position sensors and three LEDs per valve, for a total of nine position sensors and nine LEDs. There are three measured positions: return, open, or collect. All the LEDs are continuously on and shine on the valve body housing. There is a window in the valve body housing, and as the valve rotates the LED light shines through this window and is detected by one of three position sensors. This detection creates a position bit "0" for that specific position. The other two positions create a position bit "1" because the LED light is blocked from reaching the sensor. When all three positions create a "1," the position of the valve is unknown. The position sensor bit is read by control and safety every 10 ms. This code is also in the dlog file labeled as "valve position." See the *Troubleshooting* chapter for more detail on dlogs.

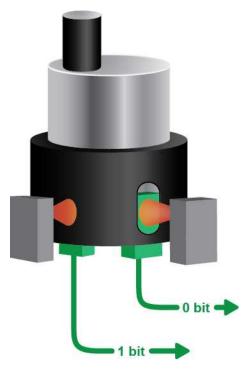


Figure 2-26: Valve position sensor window and infrared LED light

Not related to normal valve function, but could impact function: The raised cassette and lowered cassette position sensor signals pass through the valve CCA; however, the +5.0 V LED power and +5 VCC are shared lines with the valve position sensors and LEDs.

### Control CCA (End)

The valve position bits are sent to the control CCA FPGA and the safety CCA FPGA, where the system identifies the measured position. When the commanded position is reached, the control computer stops the valve movement by toggling the enable bit of the selected valve to **off**, which removes the power connection from the H-bridge circuit to the motor.

The control and safety systems are both looking for the position sensor bit to confirm the position of the valve. They must both agree on the position, or an alarm is generated. As a redundant safety mechanism, the control and safety systems are also calculating the time between when the valve starts moving (enable bit is sent) and when it stops moving (position bit is received). The timing of when the valve reaches its commanded position is also one of the variables used to determine the accrued volume in a product bag.

### Safety CCA

The position sensor LED power is generated on the safety CCA. The FPGA on the safety CCA performs an LED test at start-up and every 60 seconds during a run. The test is as follows:

- 1. Turn off LED power.
- 2. Wait 3 ms.
- 3. Check all LED position sensors. All must be unknown.
- 4. Turn on LED power.

### **Safety Computer**

The safety computer monitors the movement commands sent by the control computer and the position information sent from the position sensors on the valve CCA, and removes power to the valves when these data sets disagree. The safety computer controls the 24-volt switch that provides power to the valve motors. This is a safety function; the +24 V DC switched power is enabled when all safety related inputs are good.

The safety computer and control computer communicate with one another using a dedicated Ethernet connection. Both the safety system and the control system can decide to shut down power or reboot the device if something is wrong, but it is the safety computer that always performs the action of turning off the 24-volt switch.

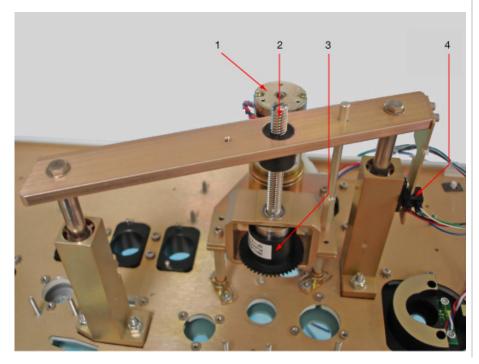
The safety computer also monitors the prerequisites and removes power if any of these are missing or incorrect.

# **Linear Actuator System**

A 24 V DC motor drives the linear actuator system. Two optical sensors sense the cassette tray location and signal the logic to disable the linear actuator motor when the correct position is achieved. The optical sensors are connected to the valve sensor CCA. If the optical sensors do not detect the commanded linear actuator position after 8.0 seconds, the system generates an alarm. A slip clutch allows for overdrive in the system without damaging the motor.



Note: Only one valve or linear actuator motor is driven at a time.



1 Linear actuator motor

- 2 Lead screw
- 3 Slip clutch
- 4 Optical sensor and sensor flag

Figure 2-27: The linear actuator

**Table 2-9: Linear actuator components** 

	Name	Function
1	Linear actuator motor	A 24 V DC brushed motor that drives the linear actuator.
2	Lead screw	The lead screw raises or lowers the cassette tray when the motor runs.  The lead screw can be turned manually through an access hole in the rear door to raise or lower the cassette tray if there is a power failure.  See the operator's manual for details.
3	Slip clutch	The slip clutch stops the linear actuator in case of a jam or finger entanglement.

**Table 2-9: Linear actuator components (continued)** 

	Name	Function
4	Optical sensor and sensor flag	The two optical sensor assemblies detect when the cassette tray is in the up and down positions using the sensor flag.

### Linear Actuator

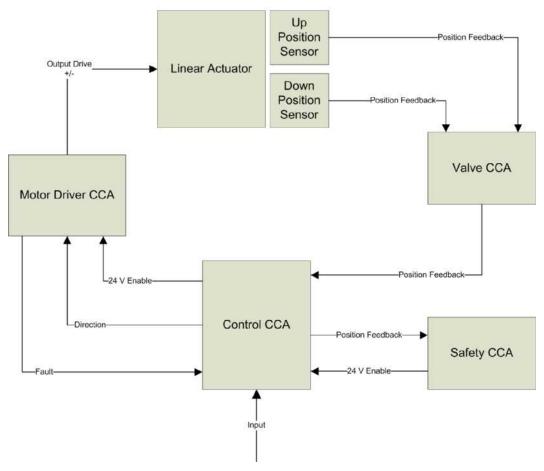


Figure 2-28: Linear actuator block diagram

Cassette plate position optical sensors (feedback) for the linear actuator go through the valve CCA. Input command is received at the control CCA, which sends this input command to the motor driver CCA. The motor driver CCA converts and applies the pulse-width modulated drive signal (polarity equals direction) to the linear actuator motor. The motor is driven until the position sensors (flags on the linear actuator assembly) detect the final position desired. The optical sensors light power (5 V) comes from the control CCA but passes through the valve CCA. The optical sensors are always on. The linear actuator flag interrupts the light to detect position. If the device is turned on and the position reads "down," the safety system shuts down all 24 V. If cassette is "down" on startup, this is a bad safety condition. The safety CCA removes the control CCA's command if this occurs. When the control CCA sees zero feedback volts, the drive signals shut off. The fault line is current sense; if the current goes too high, it shuts off the drive voltage.

# **E-Box and Computer Systems**

The computer system is made up of control and safety computers plus several CCAs that interface with the pumps, valves, sensors, centrifuge, and display. The computer system components are located in the e-box.

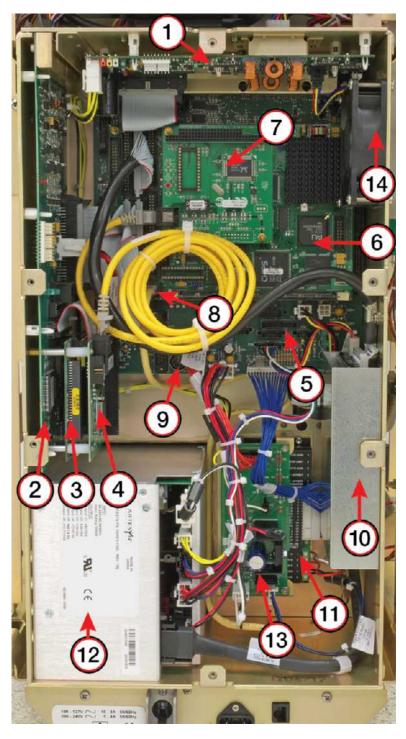


Figure 2-29: The Trima Accel system e-box

- 1 Motor driver CCA
- 2 Safety/ultrasonics
- 3 Safety computer
- 4 Safety Ethernet CCA
- 5 Control CCA
- 6 Control computer
- 7 Control Ethernet CCA
- 8 External Ethernet connector
- 9 Keyboard connector
- 10 Hard drive
- 11 Centrifuge motor controller
- 12 DC power supply
- 13 64 V switch CCA
- 14 E-box fan

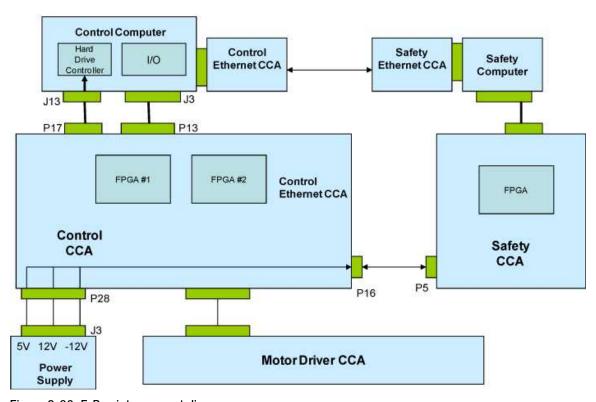


Figure 2-30: E-Box interconnect diagram

### **Control and Safety Functions**

The system has two computers: the control computer and the safety computer. The control computer is responsible for the graphical user interface (GUI) and controls most of the hardware. The safety computer is responsible for monitoring the safety system, including sensors. The control and safety computers continually exchange information about pump speeds, centrifuge speeds, and motor and valve positions to ensure safe operation through Ethernet and direct ribbon cable connection. Both computers interface to gate arrays using their ISA buses.

Both computers calculate donor limits and available products. Independent tasks on both computers ensure donor safety. The control computer is responsible for operator, procedure, and hardware control. The safety computer ensures that the control computer is operating within the donor's safety constraints. Figure 2-31 shows how the control and safety computers communicate via Ethernet. The following functions are controlled/monitored by the control computer and monitored by the safety computer:

- Pumps
- Centrifuge
- Valves
- Door sensors
- Cassette position

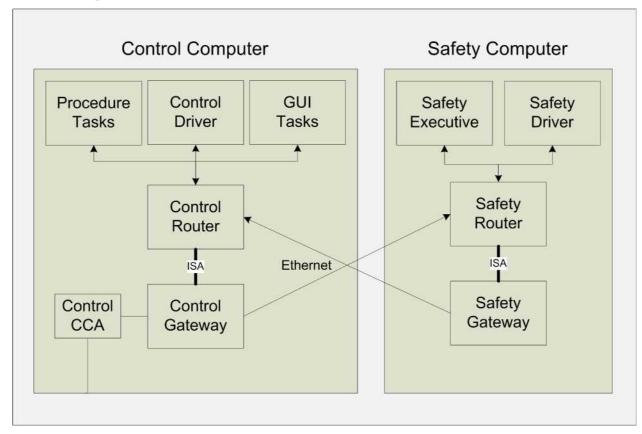


Figure 2-31: Control and safety communication

### **Control CCA**

The control CCA runs the main electromechanical functions of the system. This includes commanding the pump speeds, centrifuge speed, and valve positions to perform the procedure.

The control CCA receives commands from the control computer, receives sensor information, and coordinates operations with the safety computer. The control CCA interfaces with the motor driver CCA to command the pumps, valves, and linear actuator. The control CCA interfaces with the centrifuge motor controller to command the centrifuge motor. The control CCA contains the amplifier circuit for the display speaker, the LVDS circuit for communicating with the GUI display, and the two control gate arrays that interface with the motor driver CCA and various sensors.

There are two styles of the control CCA. Serial numbers 1281 and below were manufactured with the old-style control CCA. On the previous control CCA, the 64 V switch is located on the control CCA. On the new control CCA, the 64 V switch is located on a separate circuit board. It is possible to upgrade a machine to the new-style control CCA.



Figure 2-32: The control CCA

### **Control Functions**

Two FPGAs are responsible for communications between the control computer and sensors. The gate arrays interface to the industry standard architecture (ISA) computer bus. The gate arrays regulate the following control functions of the control CCA.

Control Functions	Related Hardware Component
Enables and sends direction commands to the valve and linear actuator motors	Motor driver CCA
Enables the centrifuge door-lock solenoid	
<ul> <li>Enables the speed commands for all pumps. An 8-bit pulse-width-modulation (PWM) signal for each pump generates the speed commands</li> <li>Enables the direction of the return pump</li> </ul>	
<ul><li>Enables the audio alarm speaker</li><li>Enables the alarm lights</li></ul>	Display module
Receives data on the computed centrifuge speed and generates the centrifuge speed command	Centrifuge motor controller

### **Monitor functions**

The control CCA also monitors various sensors via the FPGAs.

Monitor Functions	Related Hardware Component
Monitors patient inlet and return pressures	Inlet pressure sensor, return pressure sensor
Monitors centrifuge pressure for occlusions	Centrifuge pressure sensor
Monitors centrifuge door position	Centrifuge door position Hall-effect sensor
Monitors valve positions	Valve position sensors
Monitors for leaks in the disposable tubing set	Leak detector
Monitors for the presence of anticoagulant	AC air detector
Monitors the reservoir level	Upper- and lower-level reservoir sensors
Monitors centrifuge speed	Centrifuge Hall-effect sensors
Monitors pump speeds	Pump motor encoder signals

### **LVDS Display Circuit**

A low-voltage differential system (LVDS) carries all communication to the liquid crystal display (LCD). The LVDS receives input from the control computer flat-panel interface and sends its data directly to the display. The LVDS circuitry multiplexes the 32-TTL (transistor-transistor logic) signals from the control computer into 8 low-voltage differential lines for signal fidelity. The LVDS signals are converted back to TTL signals on the display CCA.

### **Control Computer**

The control computer is responsible for operator, procedure, and hardware control.

It controls the GUI software responsible for the graphical user interface and contains the interface for the flat panel LCD display. It contains four serial ports used by the touch-screen interface and RBC microcontroller. The control computer boots from the hard disk drive and runs on the  $VxWorks^{@}$  operating system.

The control Ethernet is connected directly to the control computer. The barcode scanner also uses one of the serial ports.



Figure 2-33: The control computer

### **Control Ethernet CCA**

The control Ethernet CCA, mounted on top of the control computer, communicates information from the control computer to the safety computer via the safety Ethernet CCA mounted on the safety computer. The control computer and safety computer continually exchange information about pump speeds, centrifuge speeds, and motor and valve positions to ensure safe operation.

The control Ethernet CCA is used to transfer software to the safety computer from the hard drive during the boot sequence. The control and safety Ethernet CCAs are connected using a crossover Ethernet cable.



Figure 2-34: The control Ethernet CCA

# **Safety CCA**

The safety CCA contains the safety/ultrasonic gate array, the control for the switches for the 24 V and 64 V power supplies, and the ultrasonic transmitter and receiver circuits for the AC level detector and the upper-level and lower-level sensors.

The safety CCA also powers the alarm LEDs.



Note: The safety CCA is sometimes referred to as the ultrasafe CCA or the ultrasonic CCA.

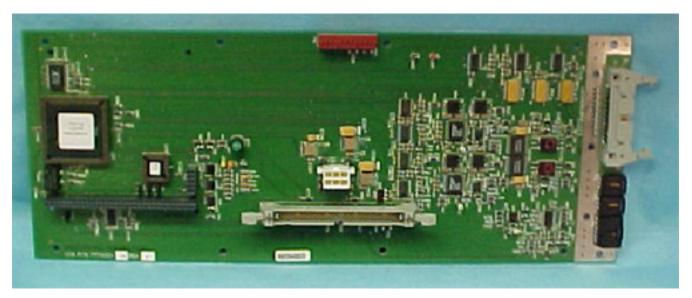


Figure 2-35: The safety CCA

## Safety/ultrasonics gate array

	Monitor and Control Functions	Related Hardware Component
•	Monitors pump speeds, via the pump Hall-effect sensors, matching them with pump encoder signals to ensure that they agree.	Motor driver CCA
•	Monitors the safety-critical lower-level sensor, generating an alarm if it doesn't sense fluid or air at the proper times.	
•	Monitors the centrifuge Hall-effect sensors, watching for over-speed and speed out-of-range conditions.	
•	Monitors the valve-position sensors, generating an alarm if they sense unsafe positions.	
•	Monitors the centrifuge door position optical sensor, generating an alarm if it is in an unsafe position.	
•	Monitors the outputs of the cassette position optical sensors.	
•	Controls 24 V and 64 V switches.	
•	Controls power to the door lock solenoid via a separate 24 V switch on the motor driver CCA.	
•	Controls LED power to the optical sensors (valve, linear actuator, door lock).	
•	Controls the transmitter and receiver circuits for the air detectors.	
•	Enables alarm light for safety alarms.	Display module
•	Monitors pressing of the stop or pause buttons on display module.	

# **Power Supply Switches**

The safety CCA controls the 24 V and 64 V switches. The two physical 24 V switches are located on the motor driver CCA, and the physical 64 V switch is located on the 64 V switch CCA.

#### **Ultrasonic Circuits**

The ultrasonic transmitter and receiver circuits for the fluid detectors and the upper-level and lower-level reservoir sensors are housed on the safety/ultrasonics CCA.

# **Safety Computer**

The safety computer monitors the pumps, valves, volumes, and flows to ensure the system is operating within safe limits.

The safety computer monitors the system functions to make sure they are within safe limits. It verifies the pump and centrifuge speeds by comparing data from the Hall-effect sensors to the speeds seen by the control computer. The safety computer monitors the lower-level sensor for fluid and air to ensure patient safety. It also monitors the AC detector. If any error is deemed "unsafe," the safety computer will generate an alarm and place the machine into the "safe state" by switching off the +24 V and +64 V switched power supplies. The safety computer interfaces through the internal network to boot from the hard drive by requesting the data from the control computer.



Figure 2-36: The safety computer

# **Safety Ethernet CCA**

The safety Ethernet CCA communicates information from the safety computer to the control computer via the control Ethernet CCA. The safety Ethernet CCA is identical to the control Ethernet CCA, except that the safety Ethernet CCA has a boot ROM chip and a different network ID. The safety computer boots using the boot ROM on the safety Ethernet CCA. The control computer and safety computer continually exchange information about pump speeds, centrifuge speeds, and motor and valve positions to ensure safe operation.



Figure 2-37: The safety Ethernet CCA

## **Motor Driver CCA**

The motor driver CCA runs the five pump motors, the three valve motors, the linear actuator motor, and the centrifuge door-lock solenoid. The motor driver CCA contains two 24 V switches: one is for the pumps, valves, and linear actuator, and the other is dedicated to the door-lock solenoid.

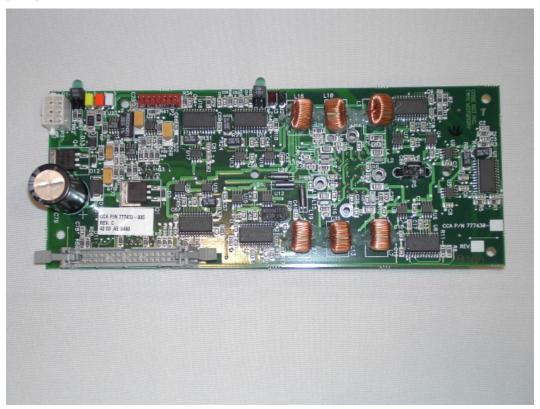


Figure 2-38: The motor driver CCA

#### **Pump Motors**

All five pumps receive pulse-width-modulation (PWM) drive from the motor driver CCA. The drive signal originates at the control computer, passes through the control CCA, and is then converted to PWM at the motor driver CCA. The return pump can turn in both directions, while the other pumps can only turn counter-clockwise.

Optical encoders, located in the back of the motors, sense motor speed. These signals are sent to the control CCA and used for feedback. Redundant Hall-effect sensors are mounted in the raceway housing of each pump. These signals are sent to the safety CCA and monitored to ensure safe limits.

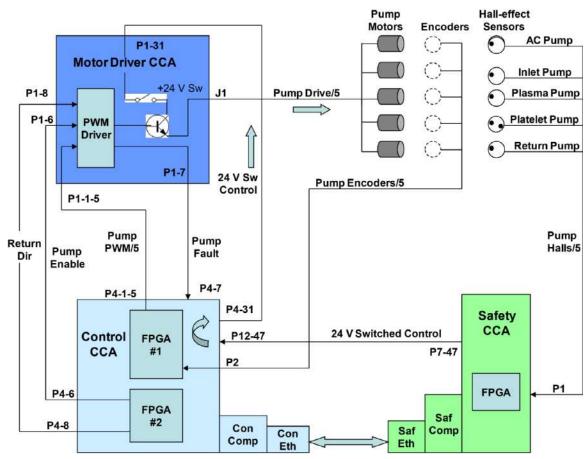


Figure 2-39: Pump interconnect diagram

#### **Valve Motors**

All three valves receive enable and direction commands from the motor driver CCA. These commands are generated by the control computer and routed through the control CCA to the motor driver CCA. The valves are driven full **on** or **off** with no speed control. Three optical sensors for each valve assembly (all located on the valve sensor CCA) sense valve position. The signals are sent back to the control CCA. When the control computer detects that the valve is in the commanded position, the drive signal is shut off. The LEDs for the valve optical sensors are activated and sensed at one-minute intervals by the safety computer to ensure that they are operational and functional.



**Note:** Only one valve motor is driven at a time. This includes the linear actuator.



**Caution:** The connectors for the display and valve cables are identical. If these cables are accidentally swapped, electronic components will be damaged. Make sure these cables are plugged into the correct sockets.

#### **Linear Actuator**

The linear actuator uses two optical sensors to detect the position of the cassette. The sensors are mounted on the cassette shaft housing. This signal is sent back to the control CCA and transferred to the safety CCA for redundant monitoring. When the control computer detects that the cassette plate is in the commanded position, the drive signal is shut off.

## **Centrifuge Door-Lock Solenoid**

The centrifuge door-lock solenoid ensures that the centrifuge door cannot be opened while the centrifuge is spinning. It is a bi-directional solenoid: pulsed in one direction, it locks the door; pulsed in the opposite direction, it unlocks the door. The solenoid moves only when pulsed. To ensure safety, while the door is locked and the centrifuge is spinning, the safety system disables the 24 V solenoid power. The centrifuge door-lock solenoid has its own 24 V power switch on the motor driver CCA. The control system monitors the solenoid position as it attempts to lock the door. It will try five times to lock the door in two-second increments.

#### 64 V Switch CCA

The 64 V switch CCA enables and disables power to the centrifuge motor controller. The 64 V switch CCA is controlled by the safety computer.

The 64 V switch is either located on the control CCA or mounted separately on a bracket over the centrifuge motor controller, depending on the revision of the control CCA. Systems below serial number 1282 were manufactured with the 64 V switch integrated on the control CCA. An upgrade spare, including the separate 64 V switch CCA, required bracket, and additional cabling is available to upgrade this component.

Here are some helpful test point measurements to take:

- Use test points J1 and J4 to measure the switched 64 V.
- Use test points J1 and J2 to measure the power supply 64 V.
- Use test points J1 and J3 to measure a quick pulse from the over-voltage protection (OVP) signal.



Figure 2-40: The 64 V switch CCA

# **Cooling Fans**

There are three  $24\,\mathrm{V}$  DC cooling fans. Each fan has a Hall-effect sensor that is monitored by the control CCA.

If the fan has stopped or the Hall-effect sensor line is open, the device reboots before reaching the twobutton screen.

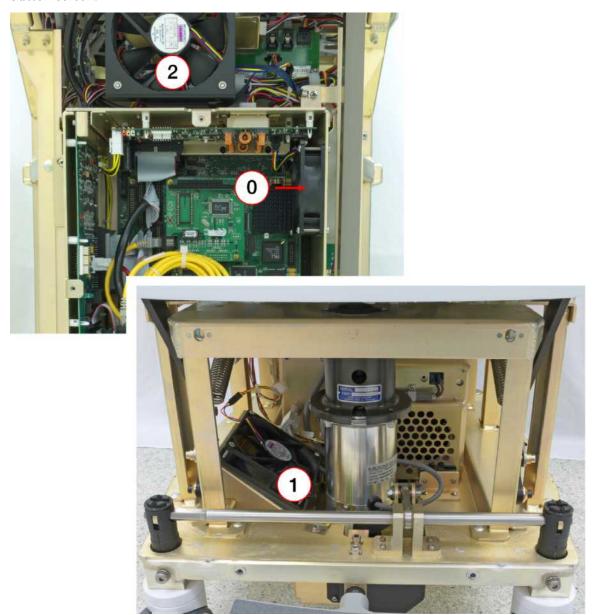


Figure 2-41: Cooling fan locations

# **Table 2-10: Cooling fan locations and functions**

Fan	Location	Function
0	Inside the e-box	Cools the e-box components by pulling air through the e-box.
1	Bottom of the machine	Cools the centrifuge motor and gear train.
2	Above the e-box	Cools the pump panel components.

# **Display System**

The touch-screen display system shows system information relayed from the control computer and serves as the user interface for the system.



- 1 Alarm lights
- 2 Display matrix
- 3 Touch-screen overlay
- 4 Stop button
- 5 Pause button
- 6 Trim tape
- 7 Display console arm

Figure 2-42: The display console

**Table 2-11: Display system components** 

	Component	Function
1	Alarm lights	The four red alarm lights, located on the top corners of the display console, indicate alarm status.
		See Table 2-12.
2	Display matrix	The display matrix shows the current system information and status. The screen is a 10.4-inch diagonal, active thin-film transistor (TFT) liquid crystal display (LCD). The display is backlit by a single, field replaceable, cold-cathode fluorescent tube (CCFT) assembly.
3	Touch-screen overlay	The touch-screen overlay is a thin film that covers the display screen. Pressing the screen causes a change in resistance between two film layers. The change in resistance is converted to X-Y coordinates representing the touch location by a micro-controller on the display CCA. These coordinates are conveyed to the control CCA, as if from a mouse.
4	Stop button	The stop button stops the centrifuge and the pumps.
5	Pause button	The pause button pauses the pumps during normal operation.

Table 2-11: Display system components (continued)

	Component	Function
6	Trim tape	The trim tape seals the front and rear shells of the display console case from fluid spills. The trim tape also has an electro-magnetic shielding effect. The trim tape must be replaced if the case is disassembled.
7	Display console arm	The display console arm supports the display console. It allows the display to move up, down, left, and right. It also allows the display to tilt.

# Table 2-12: Alarm light states

Light State	Alarm Status		
Off	Safe operating condition.		
Lights on, flashing	Operator-recoverable alert condition, control generated.		
Lights on, solid	Non-recoverable alarm condition, safety generated. The non-recoverable alarm status supersedes the operator-recoverable alert status.		

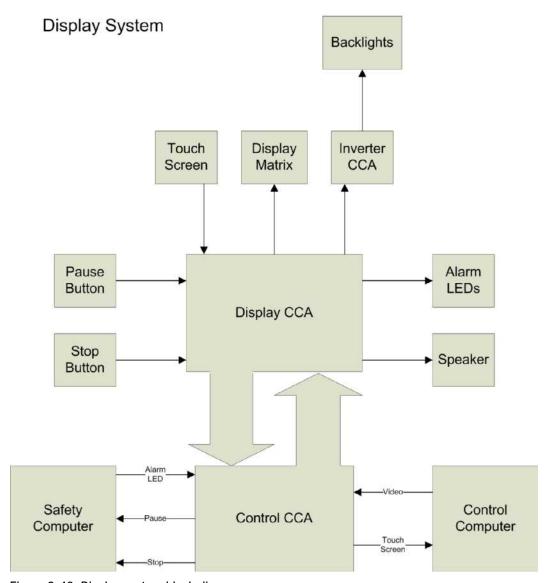


Figure 2-43: Display system block diagram

The stop and pause buttons are both normally open switches that read 5 V when open and 0 V when closed (pressed). The alarm LEDs are 24-volt lights that display either a control-generated alert flashing light or a safety-generated alarm solid light.

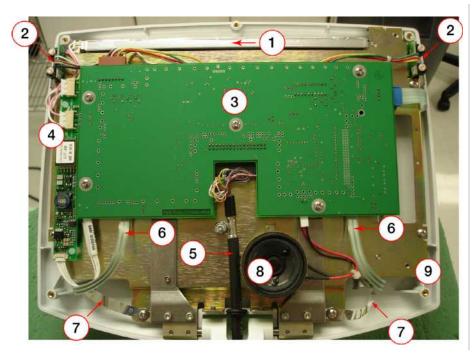
The touch screen reads resistive coordinates where touched and sends that information to the display CCA, where it is converted to a digital signal and sent to the control computer. The analog speaker audio is generated on the display CCA, where the speaker driver signal comes from the control CCA.

The display matrix video signals are generated in the control computer, converted to LVDS format on the control CCA, and then buffered and sent/received by the display CCA.

The inverter CCA converts low-voltage signals from the control CCA to high-voltage, high-frequency signals to drive the fluorescent lighting used to illuminate the display matrix.

# **Display Assembly**

The display assembly is accessed by removing the back shell of the display console case. The display assembly includes the display CCA, circuitry, and wiring that drive the touch-screen display.



- 1 LCD backlight
- 2 Alarm lights
- 3 Display CCA
- 4 Power inverter card
- 5 Arm cable
- 6 Button cables
- **7** Grounding straps
- 8 Speaker
- Backing plate

Figure 2-44: The display internal assembly

Table 2-13: Display internal assembly components

	Component	Function
1	Cold-cathode fluorescent tube (CCFT) assembly	The cold-cathode fluorescent tube (CCFT) assembly backlight provides a light source for the touch-screen display.
2	Alarm lights	The alarm lights illuminate (flashing or solid) to indicate an alert or alarm status. The alarm lights consist of two sets of four red LEDs.
3	Display CCA	The display CCA drives and coordinates all touch-screen display functions. It also connects all other components in the display to the control CCA.
4	Power inverter card	The power inverter card supplies power to the LCD backlight for the touch-screen display.  Warning: High voltage is present in the power inverter card.
5	Arm cable	The arm cable carries power, video signals, touch-screen input, and stop and pause button input from the display CCA to the control CCA.
6	Button cables	The button cables connect the stop and pause buttons to the display CCA using low-insertion force connectors.

Table 2-13: Display internal assembly components (continued)

	Component	Function
7	Grounding straps	The grounding straps suppress static discharge from the stop and pause buttons. The grounding straps attach to the backing plate.
8	Speaker	The speaker conveys sound from the amplifier on the control CCA.
9	Backing plate	The backing plate mounts the display assembly on the arm.

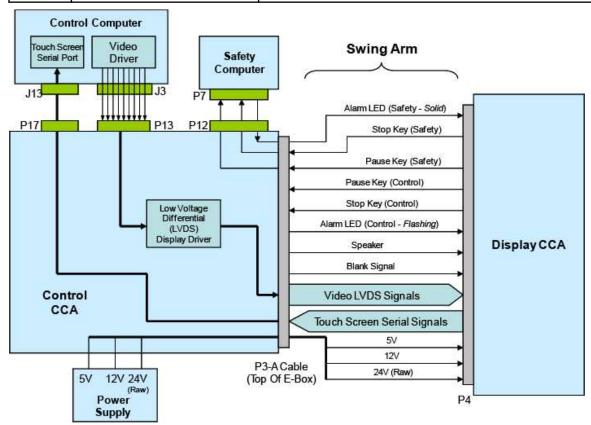


Figure 2-45: Display CCA interconnect diagram

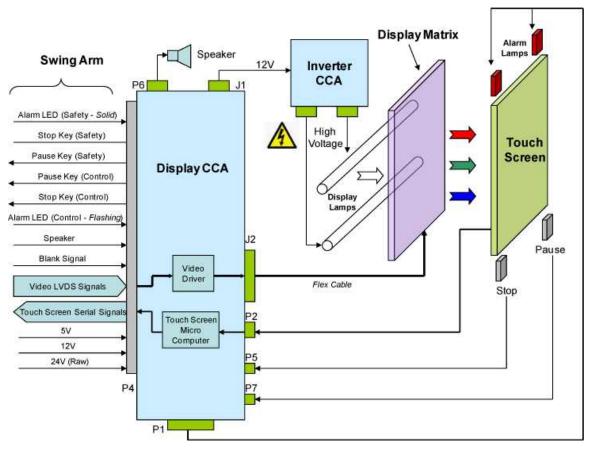


Figure 2-46: Display head interconnect diagram

# **Display CCA**

The display CCA is a graphical user interface (GUI) system that allows the operator to communicate with the system via the touch screen. The display CCA resides in the display console case mounted on the display console arm.

The display CCA drives and coordinates all display functions, including:

- Communicating directly through the control CCA and the control computer via a low voltage differential signal (LVDS) multiplexer to process all video signals.
- Processing signals to and from the touch-screen display using a micro-controller.
- Driving the alarm lights on the outside of the display console case.
- Processing signals from the stop and pause buttons.
- Driving the audio speaker that warns the operator of alarm/alert conditions.



**Caution:** The connectors for the display and valve cables are identical. If these cables are accidentally swapped, electronic components will be damaged. Make sure these cables are plugged into the correct sockets.



Figure 2-47: The display CCA

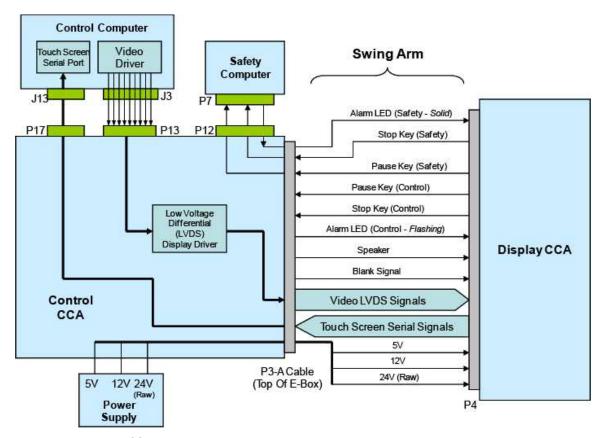


Figure 2-48: Display CCA interconnect diagram

# **Power System**

#### **Power Switch and Circuit Breaker**

The power switch, a toggle switch near the top of the right side panel, directs line current to the primary side of the power supply. The main line circuit breaker has a black toggle handle and is located in the bottom rear of the machine near the power entry. The circuit breaker is a magnetic system for greater accuracy. If line voltage is 220 V AC to 250 V AC, the circuit breaker trips at 4 amperes. If line voltage is  $100 \, \text{V}$  AC to  $125 \, \text{V}$  AC, the circuit breaker trips at  $10 \, \text{amperes}$ . The power entry is IEC-320, compatible with a cord-retaining hood.

# **Power Supply**

The DC power supply provides six secondary power supplies to the system. All secondary supplies have over-voltage and over-current protection. If an over-voltage occurs, the power supply generates a "Power Fail Warning" logic signal, latching the power supply outputs off. Turn the main power off and back on again to restart the power after this type of event. If an over-current condition occurs, the power supply generates a DC power bit "Not OK" signal, monitored by the control CCA. Serial Number 1T4296 and below were manufactured with the old-style power supply that requires an external tool to test the over-voltage and over-current protection. The new-style power supply is capable of performing its own over-voltage protection testing internally. There are test points for over-voltage for each secondary power supply. There are three LED indicator lights on the new power supply: the green LEDs indicate that the DCOK and ACOK signals are within specification, and the yellow LED indicates OVP detection.

**Table 2-14: Power supply voltages** 

+64 V DC	The +64 V DC secondary power supply powers the centrifuge motor. A shunt regulator circuit in the DC power supply dissipates electromotive force (EMF) from the centrifuge motor when it brakes to a stop. LEDs on the control CCA indicate the status of +64 V switched and unswitched supplies. If the LEDs are lit, the supplies are within normal range.
+24 V DC	The +24 V DC secondary power supply powers the pump motors, the valve motors, the linear actuator motor, the alarm lights, the fans, and the centrifuge door-lock solenoid. LEDs on the motor driver CCA indicate the status of the +24 V switched and unswitched supplies. If the LEDs are lit, the supplies are within normal range.
+12 V DC	The +12 V DC secondary power supply powers the audio speaker, the display backlight, and the operational amplifiers on the RBC detector CCA. It is used as a voltage reference on several cards and as the excitation voltage for the two air detector circuits. It also drives the LEDs on the RBC detector CCA. An LED on the control CCA indicates the status of the 12-volt supply. If the LED is lit, the supply is within normal range.
-12 V DC	The -12 V DC secondary power supply powers the operational amplifies on the motor driver CCA and the RBC detector CCA. An LED on the control CCA indicates the status of the -12 V DC supply. If the LED is lit, the supply is within normal range.

# **Table 2-14: Power supply voltages (continued)**

+12.7 V DC	The +12.7 V DC secondary power supply powers the Seal Safe system. An LED on the control CCA indicates the status of the +12.7 V DC supply. If the LED is lit, the supply is within normal range.
+5 V DC	The +5 V DC secondary power supply powers all the logic circuitry and serves as a voltage component control (VCC) on all the computer cards. It also powers the hard drive and the pump and centrifuge Hall-effect sensors. The 5 V system uses sense lines from the control CCA to regulate the 5 V DC. An LED on the control CCA indicates the status of the 5 V supply. If the LED is lit, the supply is within normal range. If the 5 V DC supply is out of range, a reset signal generates and reboots the control and safety computers.

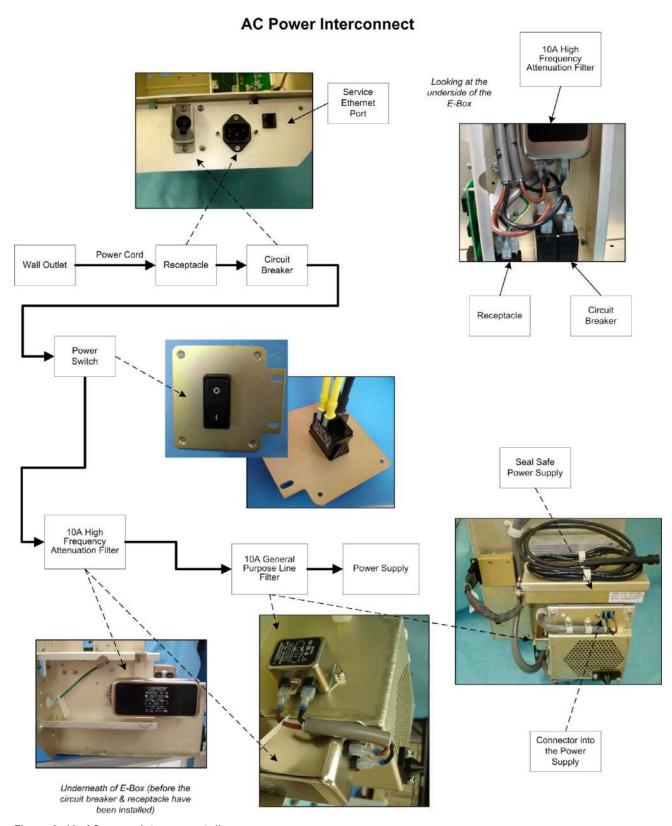


Figure 2-49: AC power interconnect diagram

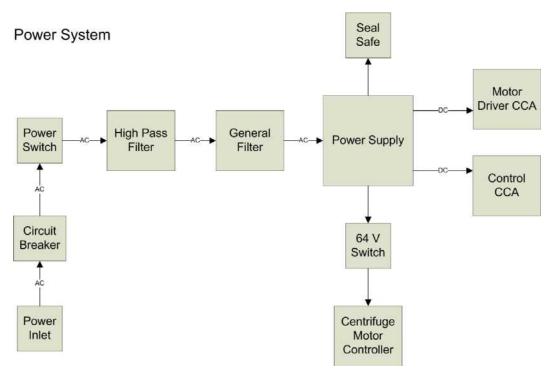


Figure 2-50: Power system block diagram

Raw AC comes into the receptacle from the power cord and goes through the circuit breaker and power switch to the high pass filter, which removes line noise from the input. From there the AC goes to a general purpose filter. From the filters the AC goes to the power supply, where it is converted to DC outputs. The power supply has various over-temperature and over-current warnings that are tested with the over-voltage protection (OVP) test box (spare).

# **Mechanical System**

## **IV Pole**

The IV pole is a system consisting of a vertical rod and a horizontal rod with hooks for bags and solutions. The IV pole can be lowered for transport. The vertical rod is held in place by a locking mechanism that is actuated by button on the left side (viewed from the front) of the device.



Figure 2-51: The IV pole

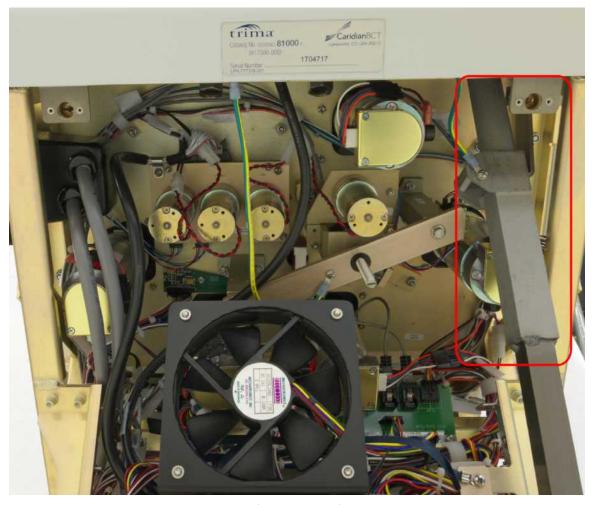


Figure 2-52: The IV pole locking mechanism (from the rear of the machine, looking up)

# **Wheel and Brake System**

The wheel and brake system consists of four caster-mounted wheels that allow the system to have full mobility. The three-position wheel pedal, located below the centrifuge door, can lock the front casters or brake the front wheels.

Pedal Position	Wheel Action
Left	Locks the front casters in the center position for directional travel. The rear casters remain unlocked and all wheels rotate freely.
Center	Allows all four casters to move freely and all wheels rotate freely.
Right	Locks the front casters and front wheels. The rear casters remain unlocked and rear wheels rotate freely.

# 3 Software Description

# **Version 5.1 Software Description**

# **Trima Accel Software Description**

This section describes the Trima Accel system software.

The Trima Accel system operates automatically, performing many individual steps to complete the entire blood component collection procedure. The collection procedure consists of separate and sequential system states, some of which contain substates. Within each substate, the system performs a series of tasks.

When an alarm or error occurs, the Data Log (DLog) file captures the system state and hardware information related to that alarm. Compare the information in the Data Log file with the information in this chapter to solve the alarm or error problem.

#### **State and Substate Overview**

The Trima Accel system version 5.1 software has twelve system states (thirteen system states including Service mode), or stages of blood collection process. During each state, the hardware continues to perform the same task or set of functions. As soon as the hardware begins a new task or set of functions, a new state begins.

**Table 3-1: Version 5.1 States and Substates** 

System State	State #	Substate	PFR?
Self Tests	1		No
Power Failure Recovery (PFR)	0	Start Protocol  Power Failure Recovery (PFR) Initialization  Power Failure Recovery (PFR)	No

Table 3-1: Version 5.1 States and Substates (continued)

System State	State #	Substate	PFR?
Startup Tests	2	CPUID Test	No
		Calib Verification	
		Power Test	
		Valves Test	
		Leak Detector Test	
		CentShutdown Test	
		Door Latch Test	
		GUI Started	
		Load Cassette	
		Start Pumps	
		Lower Cassette	
		Cassette ID	
		Stop Pumps	
		Evacuate Set Valves	
		Evacuate Bags	
		Lower Notification	
Disposable Tests	3	Close Valves	No
		Press Inlet Line	
		Inlet Press Test	
		Inlet Decay Test	
		Negative Press Test	
		Negative Press Relief	
AC Connected	4		No
AC Prime	5	AC Prime Inlet	No
		AC Press Return Line	
Donor Connected	6		Yes
			Continue or End Run
Blood Prime	7	Blood Prime Inlet	Yes, See System State -
		Blood Prime Return	PFR for details
		Evac Set Valves	
		Evac Reset Valves	

Table 3-1: Version 5.1 States and Substates (continued)

System State	State #	Substate	PFR?		
Blood Run	8	Prime Substates	Yes, See System State -		
		Prime Channel 1	PFR for details		
		Prime Channel 2			
		Prime Channel 3			
		Prime Channel 4			
		Prime Vent			
		Ramp Centrifuge			
		Prime Airout 2			
		Collection Substates			
		Channel Setup			
		Pre-Platelet Plasma			
		Pre-Platelet, No Plasma			
		Platelet Plasma			
		Plasma Only			
		PCA			
		Mid Run			
		PIR w/no plasma			
		PIR w/ plasma			
		PIR			
		Extended PCA			
		Extended Plasma			
		RBC Collect			
		Pre Rinseback			
		Recovery Substates			
		Note: Recovery substates can occur in any of the Blood Run substates. Only one recovery substate occurs at a time.  RBC Spillover			
		Pumps Pause			
		Air Block			
		Centrifuge Stop			
		Centrifuge Slow			
		Saline Bolus			
		Saline Prime			
		WBC Chamber Purge			
		RBC Chamber Purge			
		Plasma Valve Motion			
		Settle Channel			
		Clear Line			

Table 3-1: Version 5.1 States and Substates (continued)

System State	State #	Substate	PFR?
Blood Rinseback	9	Rinseback Lower Reservoir Rinseback Recirculate	Yes, Rinseback or End Run
		Rinseback Return Disconnect Prompt	
Donor Disconnect	10	Disconnect Test Open Valves Start Pumps Raise Cassette Stop Pumps	No
Post Run	11	Post Run Display	No
Service Mode			No

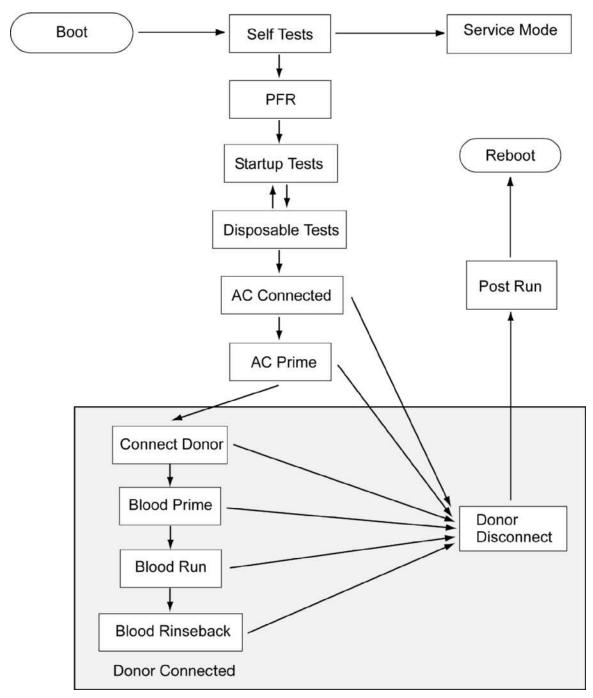


Figure 3-1: Version 5.1 software flow diagram

#### **Self Test State**

The Self Test state starts boot sequence starts with the BIOS self test. This is similar to a PC BIOS self test, and tests the major processor board components such as the CPU, interrupt controller, timer, and RAM.

If any of these tests fail, the system displays an error message and aborts the boot sequence. If all tests pass, control is passed to the boot device. The boot device then loads the vxWorks boot ROM image. The boot ROM image contains the software required for loading and starting the operating system. It provides a set of device drivers for accessing the storage device or network device through which the operating system is loaded.

When the boot ROM image is executed, it first tests for the presence of a keyboard. If a keyboard is attached, the system enables the loading of a debug vxWorks image that includes the necessary software components for using the WindRiver development and debugging tools. If the **Esc** key is pressed, the system enters an alternate boot mode in which booting is stopped immediately after loading the OS image and drivers. This is signified with a prompt that looks like an arrow: "->." Note that a login or password is not required when using the keyboard to execute commands from the command line. The login and password are required to upload files to the machine via FTP.

The OS software uses the pause and stop keys to select Single-Step boot and Service mode. In Single-Step mode, the system pauses and waits for the technician to press the pause button after each step of the boot sequence is completed; otherwise the boot proceeds normally. During Single-Step mode, the technician can login to the machine via FTP after the message "initializing network software" appears on the screen. Service mode is used for software installation, updates, and machine maintenance.

During the network initialization process, the system start mode is determined: normal boot, Service mode, or Alt Boot mode. If the system start mode is normal, then the safety board MAC address in the control computer ARP table is made permanent. This removes any possibility that an ARP update from the external network interface could overwrite it. Overwriting that MAC address would prevent the control computer from communicating with the safety computer. Note that this protection is not provided in Service mode or Alt Boot mode to aid in system troubleshooting.

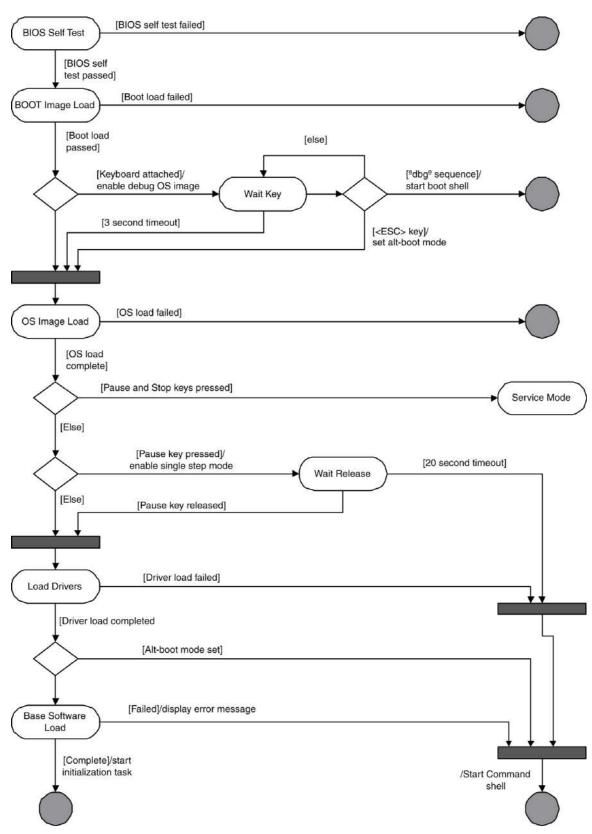


Figure 3-2: Trima Accel boot sequence

# **Power Fail Recovery State**

The PFR state allows the Trima Accel system to restore data if a power failure occurs during a procedure.

This state begins with a handshake across domain boundaries between control and safety computers. The Trima Accel system tries to restore data (in the power fail save file) from a previous procedure if there is any valid data. If there is valid data, the Trima Accel system performs the power tests that are normally performed in the Startup Tests state and then restores the previous data. After restoring the data, the Trima Accel system allows the operator a choice to continue with or discontinue the collection procedure. The rules for continuation from a power fail situation follow:

- If the power failure occurs during the Startup Tests state through the AC Prime, Rinseback, or Donor Disconnect states, recovery is not allowed. The operator must unload the set.
- If the power failure occurs during the Donor Connected state, the operator can continue or end the collection procedure.
- If the power failure occurs in the return cycle during the Blood Prime and Blood Run system states, the operator can continue, rinseback, or end the collection procedure with no time restraint.
- If the power failure occurs during the draw cycle of the Blood Run or Blood Prime states, the operator can continue, rinseback, or end the collection procedure if the PFR screen is restored within 9.5 minutes. If power is not restored within 9.5 minutes, the operator can only end the collection procedure.
- If the power failure occurs during the Rinseback state, the operator can rinseback or end the collection procedure.

Successful completion of PFR state results in the following conditions and actions.

Trima Acc Termination Condition System Condition		Trima Accel System Action			
PFR data successfully saved and restored if valid.	Pause.	If there is no valid PFR data, the Trima Accel system proceeds automatically to the startup tests in the Startup Tests state. If there is valid PFR data, the Trima Accel system proceeds to the power tests in the Startup Tests state.			

# **Startup Tests State**

The Startup Tests state performs the Trima Accel system's mandatory startup tests.

This state follows the Power Fail Recovery (PFR) state. It contains tasks that start in this state and continue until the Donor Connected state. The Startup Test state ends when all tests are successfully completed.

The startup tests are executed before a disposable tubing set is loaded and before the donor is connected. These tests ensure that the Trima Accel system is operational, that the critical safety features are in place, and that computer redundancy is functioning. During power fail recovery situations only some of the tests are performed to ensure safety of the already-connected donor. Startup tests include the following activities:

- Test if the safety system can disable power to pumps and centrifuge.
- Test the cassette position function (up and down) at both the control and safety computers.

- Test the valve position sensing (both control and safety computers) in all three positions for each valve.
- Test if the lower-level sensor registers air continuously at both the control and safety computers.
- Test if the AC level sensor registers air continuously.
- Test the safety system centrifuge rpm sensor (Halls) for commanded and zero speed.
- Test if the control computer can stop the centrifuge.
- Evacuate air from the collection bags.

Successful completion of Startup Tests state results in the following conditions and actions.

Exit Condition	Trima Accel System Condition	Trima Accel System Action		
All startup tests have passed.	Pause.	The Trima Accel system advances to the Disposable Tests state.		

## **Startup Tests Substates**

The Startup Tests state performs the Trima Accel system's mandatory startup tests.

#### **CPUID Test Substate**

First, this substate tests the available memory on the control and safety computers. If the memory is insufficient, an alarm is generated. Next, this substate checks that the control and safety CPU type matches one of those listed in the hw.dat file. If the CPU type does not match, an alarm is generated. If a valid power fail recovery condition or a new collection procedure condition is detected, the Trima Accel system advances to the Power Test substate.

#### Calib Verification (Calibration Check) Substate

This substate checks that the cal.dat file values for access pressure, centrifuge pressure, and RBC detector are different values than the defaults. If any one (or more) are the same as the default values, then a "cal.dat xxxx not calibrated" alarm is generated.

#### Power Test Substate

Prior to beginning this test, the Trima Accel system verifies that the disposable tubing cassette is in the unloaded position. If not, the Trima Accel system advances directly to the Donor Disconnect system state. If the cassette is in the unloaded position, the safety computer checks for the presence and limits of the 24-volt and 64-volt DC power supplies. The 24-volt and 64-volt DC supplies are then disabled and re-enabled to confirm safety computer's control over them. The second part of the power tests turns the 24-volt and 64-volt power supplies on, commands the pumps to zero, and ensures that they are not moving. At the end of this substate, the 24-volt switch remains ON and the 64-volt switch is turned OFF. If any test fails, an alarm is generated, and the Trima Accel system resumes at the beginning of Startup Tests. If all conditions are met, the Trima Accel system advances to the Valves Test substate.

#### Valves Test Substate

The RBC, plasma, and platelet valves are moved sequentially to all three of their possible positions. If any of the positions cannot be reached within 10 seconds, an alarm is generated and the Trima Accel system resumes at the beginning of the Startup Tests state. If this test passes, the Trima Accel system advances to the Leak Detector Test substate.

#### Leak Detector Test Substate

The leak detector output voltage is checked to verify that it is open and can detect fluid leaks. If this test fails, an alarm is generated. If this test passes, the Trima Accel system advances to the CentShutdown substate.

## CentShutdown Test (Centrifuge Shutdown) Substate

The control computer first checks the 64-volt DC to see if it is within range. Then the Trima Accel system commands the centrifuge to zero and verifies immobility for two seconds. If this test fails, an alarm is generated. If this test passes, the Trima Accel system advances to the Door Latch Test substate.

#### **Door Latch Test Substate**

These tests check that the door can be seen as both open and closed by the door lock optical and Hall sensors. The 24-volt switch dedicated to the door solenoid is also checked to ensure that it can be turned off. If these tests fail an alarm is generated. If these tests pass, the **Load System** button is enabled. There is also a test to check the ability of the software to lock and unlock the door without power. This test locks the door and waits to see if it locks even when the power is supposed to be off. If the door is in the locked state, the alarms are given and the tests are tried again.

#### GUI Started (Load System Button) Substate

This substate is not a test but instead enables the **Load System** button and waits for the operator to press it and the **Continue** button from the subsequent screen. The **Donor Info** button also activates at this time.

#### Load Cassette Substate

After the operator presses the **Load System** button, the cassette is checked for the up position as seen by the optical sensor. The valves are also commanded to the open position. If they do not achieve the open position in ten seconds, an alarm is generated.

**Table 3-2: Load Cassette Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Open	Open	Open	0

Exit Condition When the operator touches the Continue button.

## Start Pumps Substate

This substate commands the pumps on individually to minimize voltage spikes. When all pumps have reached their commanded speed (± 5 mL/min), the Trima Accel system advances to the Lower Cassette substate.

**Table 3-3: Start Pumps Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
60	60 140*	60	60	150 110*	Open	Open	Open	0 or –1

<sup>\*</sup>Versions 5.1.6 through 5.1.9

Exit Condition When the pumps are detected at the commanded speed within 10 seconds.

#### Lower Cassette Substate

In this substate the cassette is commanded down and the lower optical switch is checked to verify that the cassette achieves the loaded position. If this does not occur within 15 seconds, the "Cassette Error" alarm generates.

**Table 3-4: Lower Cassette Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
60	60 140*	60	60	150 110*	Open	Open	Open	0

<sup>\*</sup>Versions 5.1.6 through 5.1.9

Exit Condition When the cassette plate is detected in the down position.

## Cassette ID Substate

During this substate the RBC detector checks the cassette type to make sure that it is the proper cassette for the chosen collection procedure. If the cassette does not match the procedure, an alarm is generated. If the tubing set cannot be identified, but is within a valid range, a screen displays that allows the operator to choose the correct tubing set or load a new one. During this substate the Trima Accel system begins calibration of the red and green reflection strengths of the RBC detector to a ratio of one for spillover

detection purposes. If the calibration fails, an alarm is generated. If these tests pass, the Trima Accel system advances to the Stop Pumps substate. For versions 5.1.6 and 5.1.7, RBC calibration does not take place for black stamp cassettes.

**Table 3-5: Cassette ID Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
60	60 140*	60	60	150 110*	Open	Open	Open	0

<sup>\*</sup>Versions 5.1.6 through 5.1.9

Exit Condition	When the cassette stamp reflectance value is read.
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## Stop Pumps Substate

This substate commands the pumps to zero. When all pumps are zero, the Trima Accel system advances to Evacuate Set Valves substate.

**Table 3-6: Stop Pumps Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Open	Open	Open	0

Exit Condition	When the pumps are detected at the commanded speed within 10 seconds.
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#### Evacuate Set Valves (Set Valves for Evacuate) Substate

This substate changes the position of the valves in order to evacuate air from the set. For a platelet, plasma, or RBC set, the RBC valve moves to the return position and the other valves move to the open position. For all other sets, the RBC valve moves to the collect position and the plasma and platelet valves move to the open position. If the valves cannot achieve position in 10 seconds, an alarm is generated. When all valves achieve position, the Trima Accel system advances to the Evacuate Bags substate.

**Table 3-7: Evacuate Set Valves Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Open	Open	Open Return*	0

\*versions 5.1.8 and 5.1.9

**Exit Condition** 

When the valves are detected in the commanded position within 10 seconds.

## **Evacuate Bags Substate**

This substate removes air from the product bags. The return pump runs until a predetermined volume has been pumped (version specific). If the access pressure exceeds the alarm limit during this test, an alarm is generated and the Trima Accel system reverts to the previous substate. If the test passes, the Trima Accel system advances to the Lower Notification substate.

**Table 3-8: Evacuate Bags Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	90	Open	Open	Open Return*	0

<sup>\*</sup>versions 5.1.8 and 5.1.9

Exit Condition	When 140 mL is processed by the return pump.
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## Lower Notification (Cassette Position Message) Substate

This substate informs GUI of the cassette position (it should be down) to prepare for disposable tests. If the cassette is down, the Trima Accel system advances to the Disposable Tests substate.

**Table 3-9: Lower Notification Substate** 

0 0 0 0 Open Open 0	AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
	0	0	0	0	0	Open	Open	Open	0

**Exit Condition** When the cassette down message is sent.

# **Disposable Tests State**

The Disposable Tests state performs tests designed to determine whether the disposable tubing set is properly loaded and functioning.

The disposable tests include the following activities:

- Checks for the correct tubing set and the proper loading of the disposable
- Checks the integrity of the set. The access pressure sensor checks both positive and negative pressure of the disposable set to ensure its usability
- Checks for AC, inlet, and return pump tubing occlusions
- Checks for proper access pressure sensor function

Successful completion of the Disposable Tests state results in the following conditions and actions.

Exit Condition	Trima Accel System Condition	Trima Accel System Action
All disposable tests have passed.	Pause.	The Trima Accel system prompts the operator to connect the AC line.

## **Disposable Tests Substates**

The disposable tests are a sequential series of automated tests designed to ensure that the tubing set is properly loaded and functioning correctly. These tests also check the occlusions in the AC, inlet, and return pumps and the function of the access pressure sensor.

#### Close Valves (Move Valves to Return Position) Substate

This substate commands the platelet, plasma, and RBC valves to the return position. If they do not achieve the return position, an alarm is generated. When all valves reach the return position, the Trima Accel system advances to the Press Inlet Line substate.

**Table 3-10: Close Valves Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Return	Return	Return	0

# **Exit Condition** When the valves are detected in commanded position within 10 seconds.

#### Press Inlet Line (Pressurize Inlet Test) Substate

This test runs the AC pump until a version-specific predetermined access pressure is reached. If the pressure limit is not reached, an alarm is generated. If the test fails, pressing the **Continue** button repeats this test. Pressing the **End Run** button unloads the cassette and returns to the beginning of the Startup Tests state.

**Table 3-11: Press Inlet Line Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
142	0	0	0	0	Return	Return	Return	0
Exit Condition When the APS is greater than 400 mmHg before 100 mL processed by the AC pump.						C pump.		

## Inlet Press Test (Inlet Line Pressure Test) Substate

This test stops all pumps and checks that the access pressure does not drop more than a version-specific predetermined amount. If the pressure drop exceeds the exit condition, an alarm is generated. If the test fails, pressing the **Continue** button repeats this test. Pressing the **End Run** button unloads the cassette and proceeds to the beginning of the Startup Tests state.

**Table 3-12: Inlet Press Test Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Return	Return	Return	0

**Exit Condition** 

When there is less than 50 mmHg decrease in APS pressure since previous state in 3 seconds.

#### Inlet Decay Test (Pump Occlusion Test) Substate

This test commands the AC, return, and inlet pumps until each has achieved one-third of a revolution. The Trima Accel system advances to the Negative Press Test state if the exit condition is satisfied. If the test fails, pressing the **Continue** button returns to the Press Inlet Line substate. Pressing the **End Run** button unloads the cassette and returns to the beginning of the Startup Tests state.

**Table 3-13: Inlet Decay Test Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
20 20, 0*	20 20, 0*	0	0	-40 -40, 0*	Return	Return	Return	0

<sup>\*</sup>Versions 5.1.8 and 5.1.9

**Exit Condition** 

When there is greater than 50 mmHg decrease in APS pressure after the pumps rotate.

## Negative Press Test (Negative Pressure Test) Substate

This test commands the inlet pump until the access pressure sensor reading is less than a version-specific predetermined amount. If the pressure is reached before the exit condition, the Trima Accel system advances to the Negative Press Relief substate. If the test fails, pressing the **Continue** button returns to the Press Inlet Line substate. Pressing the **End Run** button unloads the cassette and proceeds to the beginning of the Startup Tests state.

**Table 3-14: Negative Press Test Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	142	0	0	0	Return	Return	Return	0

**Exit Condition** 

When the APS is less than -350 mmHg before 115 mL is processed by the inlet pump.

#### Negative Press Relief (Negative Pressure Relief) Substate

This final disposable test substate commands a pump until the access pressure sensor reading is greater than a version-specific predetermined amount. If this does not occur before the exit condition, an alarm is generated. When this pressure is achieved, the disposable tests are complete, and the Trima Accel system advances to the AC Connected state.

**Table 3-15: Negative Press Relief Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
142	0	0	0	0 90*	Return	Return	Return	0

\*Version 5.1.9 only

**Exit Condition** 

When the APS is greater than -50 mmHg before 50 mL is processed by the AC pump.

## **AC Connected State**

The AC Connected state prompts the operator to attach the AC container to the tubing set and load the AC tubing into the AC detector.

The AC Connected state ends when the operator touches the **Continue** button. Successful completion of the AC Connected state results in the following conditions and actions.

Exit Condition	Trima Accel System Condition	Trima Accel System Action
The operator touches the <b>Continue</b> button.	Pause.	The Trima Accel system advances to the AC Prime state.

If performing an RBC collection procedure, touching the **Continue** button advances the Trima Accel system to the Replacement Fluid screen, otherwise the Trima Accel system advances to the AC Prime state.

#### **AC Prime State**

The AC Prime state primes the AC line and a portion of the inlet and return lines with anticoagulant.

The AC air detector is tested for function during this state. This system state ends when all tests are successfully completed. Successful completion of the AC Prime state results in the following conditions and actions.

Exit Condition	Trima Accel System Condition	Trima Accel System Action
All tests have passed.	Pause.	The Trima Accel system prompts the operator to connect the donor.

#### **AC Prime Substates**

The AC Prime substates prime the AC line and a portion of the return line with ACD-A. AC sensor and access pressure tests are also performed.

#### AC Prime Inlet (Prime Initial AC and Inlet Lines)

In this test, the AC and inlet pumps are commanded to process AC through the AC line. If the AC-level sensor does not see AC after a version-specific predetermined volume is pumped an alarm is generated. The test repeats a second time when the **Continue** button is pressed. If the test fails again, a prime failure

alarm is generated. If ACD-A is seen at the sensor, the AC and inlet pumps continue at the same speed until a version-specific predetermined volume of AC is pumped. After successful completion of this substate, the Trima System advances to the AC Press Return Line substate.

**Table 3-16: AC Prime Inlet Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
50	50	0	0	0	Return	Return	Return	0
Exit Condition When AC is detected before 3 mL processed by AC pump.								

AC Press Return Line (Pressurize Return Line)

The AC and inlet pumps stop and the return pump is commanded to run until the access pressure sensor reads a version-specific predetermined amount. If the exit condition is not met, an alarm is generated. If pressure is achieved and the donor information is entered, the **Begin Donor Prep** button appears in the task bar at the bottom of the screen.

**Table 3-17: AC Press Return Line Substate** 

0 0 0 0 -50 Return Return 0	AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
	0	0	0	0	-50	Return	Return	Return	0

**Exit Condition** When APS is less than or equal to -50 mmHg before 7 mL is processed by the return pump.

#### **Donor Connected State**

The Donor Connected state prompts the operator to connect the donor and take a blood sample. The 64-volt switch turns on and the control computer checks the centrifuge motor controller fault bit.

**Table 3-18: Donor Connected State** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Return	Return	Return	0

Successful completion of the Donor Connected state results in the following conditions and actions.

Exit Condition	Trima Accel System Condition	Trima Accel System Action
The operator touches the <b>Continue</b> button.	Pause.	The Trima Accel system advances to the Blood Prime state.

## **Blood Prime State**

The Trima Accel system begins priming the tubing set with the donor's blood during the Blood Prime state.

The access pressure sensor alarms are enabled for the first time, the centrifuge starts, and the Trima Accel system begins updating and displaying collection procedure information. This system state ends when fluid is detected at the lower-level sensor and the centrifuge runs at the commanded speed. Successful completion of the Blood Prime state results in the following conditions and actions.

Exit Condition	Trima Accel System Condition	Trima Accel System Action
Blood Prime substates have completed.	Under algorithm control.	The Trima Accel system advances to the Blood Run state.

#### **Blood Prime Substates**

The Blood Prime state consists of four substates: Two substates prime the inlet and return lines with blood, and two substates vent pressure from the product bags.

#### Blood Prime Inlet (Blood Prime Inlet Lines) Substate

The inlet and AC pumps run at the calculated collection procedure values (Qac and Qin) for the chosen procedure with all valves remaining in the return position. The centrifuge is commanded on. When a version-specific predetermined inlet volume is pumped, the Trima Accel system advances to the Blood Prime Return substate.

**Table 3-19: Blood Prime Inlet Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	Qin	0	0	0	Return	Return	Return	200
Exit Condition		When 13 mL	is processed	by inlet pum	p and centrifu	ige reaches 2	00 rpm.	

## Blood Prime Return (Blood Prime Return Line) Substate

The return pump is commanded to run. When fluid is sensed at the lower-level sensor of the reservoir, the return pump continues running for a version-specific predetermined volume and then stops. The volume pumped by the return pump must be between version-specific predetermined amounts. When the actual centrifuge speed is within 25 rpm of the commanded speed within the exit condition time, the Trima Accel system advances to the Evac Set Valves substate.

Table 3-20: Blood Prime Return Substate

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
5.8* 2.9	0	0	0	-80* -40	Return	Return	Return	200

<sup>\*</sup>Versions 5.1 and 5.2

Exit Condition	When 5 mL is processed by inlet pump after lower-level sensor detects fluid.
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## Evac Set Valves (Vent Collect Bags) Substate

This substate moves the platelet, plasma, and RBC valves to vent pressure from the product bags built up during the previous substate. When the valves reach the open position, the Trima Accel system advances to the Evac Reset Valves substate.

**Table 3-21: Evac Set Valves Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Open	Open	Open	200

Exit Condition When the valves are detected in commanded position within 10 seconds.

## Evac Reset Valves (Move Valves to Return Position) Substate

This substate moves the platelet, plasma, and RBC valves. When the valves reach the return position, the Trima Accel system advances to the Blood Run substate.

**Table 3-22: Evac Reset Valves Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Return	Return	Return	200
Exit Condition		When the va	lves are detec	ted in comma	ınded positior	n within 10 se	econds.	

## **Blood Run State**

The Blood Run state performs the collection procedure.

Blood Run functions include

- Priming the channel and the rest of the tubing set
- Establishing the interface
- Collecting the platelet, plasma, and RBC products

The Trima Accel system performs single needle draw and return cycles and controls pump speed commands accordingly during this system state. The "RBC Spillover" alarm, all AC related alarms, and the hypovolemic alarm are activated at this time. When the Blood Run state completes, the Trima Accel system advances to the Blood Rinseback state.

Exit Condition	Trima Accel System Condition	Trima Accel System Action
All Blood Run targets are achieved, an alarm ends the collection procedure, or the operator ends the collection procedure.	Under algorithm control.	The Trima Accel system advances to the Blood Rinseback state.

#### **Blood Run Prime Substates**

This Blood Run Prime substate primes the channel and prepares the disposable tubing set for the collection.

#### Prime Channel 1 Substate

The inlet pump and centrifuge are commanded to run at version-specific predetermined speeds. If the centrifuge does not achieve commanded speed in 2 minutes, the "Hardware Failure" alarm generates. The calculated AC ratio (based on channel hematocrit) implements at this time, thus, creating a

command for the AC pump (Qac). The plasma and platelet pumps are commanded to run at version-specific speeds until a predetermined volume has been pumped into the channel. The Trima Accel system advances to the Prime Channel 2 substate.

**Table 3-23: Prime Channel 1 Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	35	5 30*	30 0*	0	Return	Return	Return	2000

<sup>\*</sup> DRBC tubing sets

Exit Condition	When 70 mL is processed by inlet pump.
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#### Prime Channel 2 Substate

The plasma and platelet pumps are commanded to zero while the AC and inlet pump speeds are maintained until a version-specific predetermined inlet volume has been pumped. The Trima Accel system then advances to the Prime Channel 3 substate.

**Table 3-24: Prime Channel 2 Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	13	2	11	0	Return	Return	Return	2500

**Exit Condition** When 15 mL is processed by inlet pump.

#### Prime Channel 3 Substate

The inlet pump continues to run at the speed from the previous substate (or Qin, whichever is less), the AC ratio changes to the ratio calculated for the collection procedure, and the AC pump speed changes accordingly. After a version-specific inlet volume has been pumped, the Trima Accel system advances to the Prime Channel 4 substate.

**Table 3-25: Prime Channel 3 Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	Qin	0	0	0	Return	Return	Return	2500

**Exit Condition** When 25 mL is processed by inlet pump.

#### Prime Channel 4 Substate

The inlet pump speed increases again to a version-specific maximum speed and the AC pump speed changes accordingly. The plasma and platelet pumps are commanded to version-specific speeds. The Trima Accel system begins checking for fluid at the upper reservoir sensor and executes return cycles as necessary. After a version-specific inlet volume has been pumped, the Trima Accel system advances to the Prime Vent substate.

**Table 3-26: Prime Channel 4 Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	Qin	15	15 0*	0	Return	Return	Return	2500

<sup>\*</sup> DRBC tubing sets

Exit Condition	When 8 mL is processed by inlet pump.
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## Prime Vent (Vent Air) Substate

This substate occurs in platelet collection procedures only. The centrifuge and pumps remain at their previous speeds and the platelet valve moves to the collect position to remove air from the channel. After a version-specific volume of plasma + platelet have been pumped, the Trima Accel system advances to the Ramp Centrifuge substate.

**Table 3-27: Prime Channel Vent Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	Qin	15	15 0*	0	Collect	Return	Return	2500

<sup>\*</sup> DRBC tubing sets

Exit Condition	When 10 mL is processed by platelet and plasma pump combined.
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## Ramp Centrifuge Substate

The centrifuge is commanded to its final calculated speed (usually 3000 rpm). If it cannot make it to its final speed in 2 minutes, a centrifuge hardware alarm is generated. The platelet valve is commanded back to the return position while the pumps and centrifuge remain at their previous speeds. When the machine goes from the first draw cycle to the first return cycle the Trima Accel system advances to the Remove Channel Air substate.

**Table 3-28: Ramp Centrifuge Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	45	12	0	0	Return	Return	Return	3000

**Exit Condition** 

When target (donor-specific) volume is processed by inlet pump.

#### Prime Airout 2 (Remove Channel Air) Substate

The AC pump turns off, and the plasma, platelet, and return pumps are commanded to version-specific speeds to remove air from the channel. When a version-specific inlet volume has been pumped, the Trima Accel system advances to the Blood Run Collection substates.

Table 3-29: Substate

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0, 3.8 0, Qac**	0, 45	0, 5	0, 10 0*	0 155, 0**	Return	Return	Return	3000

<sup>\*</sup> DRBC tubing sets \*\*Vesions 5.1.8 and 5.1.9

**Exit Condition** 

When 50 mL is processed by inlet pump.

#### **Blood Run Collection Substates**

The Blood Run state contains nineteen prime and collection substates and eleven recovery substates. This section describes the prime and collection substates.

## Channel Setup Substate

This substate continues to establish the interface until a predetermined inlet volume has been pumped. The pumps begin ramping up in speed during this substate. After completion of this substate, the Trima Accel system advances to Pre-Platelet Plasma, Pre-Platelet No Plasma, or Plasma Only substates depending upon the chosen procedure.

**Table 3-30: Channel Setup Substate** 

AC P	•	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac		Qin	Qplas	Qplat 0*	Qret	Return	Return	Return	3000

<sup>\*</sup> DRBC tubing sets

Exit Condition	When a total of 200 mL is processed by the inlet pump.
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## Pre-Platelet Plasma (Pre-Platelet, Collecting Plasma) Substate

This substate occurs only in procedures where both platelets and plasma are collected. The plasma valve is commanded to the collect position and the plasma pump speed changes to regulate the RBC line hematocrit. The AC and inlet pump speeds change to keep the AC infusion rate at the run configured value. After enough inlet volume has been processed to stabilize the LRS chamber, the Trima Accel system advances to the Platelet Plasma substate or the Pre-Platelet No Plasma substate.

**Table 3-31: Pre-Platelet Plasma Substate** 

Qac   Qin   Qplas   Qplat   Qret   Return   Collect   Return   3000	AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
	Qac	Qin	Qplas	Qplat	Qret	Return	Collect	Return	3000

<b>Exit Condition</b>	When the target (donor-specific) volume is processed by the inlet pump.
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## Pre-Platelet No Plasma (Pre-Platelet, No Plasma Collect) Substate

This substate occurs after the Channel Setup substate, in procedures where platelets, but not plasma, are collected. The AC and inlet pump speeds change to keep the AC infusion rate at the run configured value. After a predetermined inlet volume has been processed, the Trima Accel system advances to the Mid Run substate.

**Table 3-32: Pre-Platelet No Plasma Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	Qin	Qplas	Qplat	Qret	Return	Return	Return	3000

**Exit Condition** When the target (donor-specific) volume is processed by the inlet pump.

#### Platelet Plasma (Concurrent Platelet Plasma) Substate

This substate occurs after the Pre-Platelet Plasma substate in procedures where both platelets and plasma are collected. The platelet valve now opens while the plasma valve remains open until the volume target is achieved. If the plasma volume target is small, the plasma valve closes and the Trima Accel system advances to the Mid Run substate. If the volume target is large, the plasma valve remains open and the Trima Accel system advances to the Extended Plasma substate.

**Table 3-33: Platelet Plasma Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	Qin	Qplas	Qplat	Qret	Collect	Collect	Return	3000

<sup>\*</sup> DRBC tubing sets

Exit Condition When the target (procedure-specific) volume is collected in the plasma bag.

## Plasma Only (Plasma Only Collect) Substate

This substate occurs after the Channel Setup substate in plasma/RBC procedures where plasma is collected. The plasma valve opens and remains open until the plasma target volume is achieved. After completion of this substate, the Trima Accel system advances to the RBC Collect substate if RBC is chosen.

**Table 3-34: Plasma Only Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	Qin	Qplas	Qplat	Qret	Return	Collect	Return	3000
	Ī							

**Exit Condition** When the target (procedure-specific) volume is collected in the plasma bag.

#### PCA (Platelet Concentration Adjustment) Substate

This substate occurs after all plasma is collected during the Platelet Plasma substate. This substate only occurs if the Trima Accel system calculates that the volume in the platelet bag will be lower than it should be by a predetermined volume after the Mid Run substate. This usually occurs when the concurrent plasma product collected is a small or medium product. During this substate the plasma valve moves to the return position and adds plasma to the platelet bag to reach the needed volume. When the target volume is added to the platelet bag, the Trima Accel system advances to the Mid Run substate.

**Table 3-35: PCA Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	Qin	Qplas	Qplat	Qret	Collect	Return	Return	3000

**Exit Condition** When the target (donor-specific) volume is collected in the platelet bag.

## Mid Run (Platelet Only Collection) Substate

This substate occurs after the Platelet Plasma substate (and the Platelet Concentration Adjustment substate, if it occurs) to collect the remainder of the platelet product needed to reach the target yield. This substate only occurs if more collected platelets are needed after the Concurrent Platelet Plasma substate. During this substate the plasma pump runs slowly.

**Table 3-36: Mid Run Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	Qin	Qplas	Qplat	Qret	Collect	Return	Return	3000

**Exit Condition** When the target (donor-specific) volume is collected in the platelet bag.

## PIR (Platelet Inventory Recovery) Substate

This substate occurs after the Mid Run substate if the collect flow is less than a predetermined rate during Platelet Only Collection. Otherwise, the Trima Accel system skips this substate and advances to the Extended PCA substate. During Platelet Inventory Recovery the platelet pump ramps up in speed to its maximum value and continues running until predetermined platelet volume has been pumped. The Trima Accel system advances to the Extended PCA substate.

**Table 3-37: PIR Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	Qin	Qplas	Qplat	Qret	Collect	Return	Return	3000

Exit Condition When the target (donor-specific) volume is collected in the platelet bag.

## Extended Plasma (Extended Plasma Collection) Substate

This substate occurs after all platelets are collected and additional plasma is necessary to achieve the plasma target. The platelet valve closes and the plasma valve moves to the collect position. After the plasma target is achieved, the Trima Accel system advances to the RBC Collect substate if RBC is chosen.

**Table 3-38: Extended Plasma Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	Qin	Qplas	Qplat	Qret	Return	Collect	Return	3000

**Exit Condition** When the target (donor-specific) volume is collected in the plasma bag.

#### Extended Plasma (Extended Plasma Collection) Substate

This substate occurs after all platelets are collected and additional plasma is necessary to achieve the plasma target. The platelet valve closes and the plasma valve moves to the collect position. After the plasma target is achieved, the Trima Accel system advances to the RBC Collect substate if RBC is chosen.

Table 3-39: Extended Plasma Substate

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	Qin	Qplas	Qplat	Qret	Return	Collect	Return	3000

**Exit Condition** When the target (donor-specific) volume is collected in the plasma bag.

#### RBC Collect (RBC Collection) Substate

If RBC collection is chosen, this substate occurs after all platelets and plasma are collected. The RBC valve opens until the RBC volume target is achieved. The inlet flow is limited by the configured AC ratio for RBC procedures.

**Table 3-40: RBC Collect Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	Qin	Qplas	Qplat	Qret	Return	Return	Collect	3000

**Exit Condition** When the target (donor-specific) volume is collected in the RBC bag.

## Pre Rinseback (Prepare for Rinseback) Substate

This substate occurs in both platelet/plasma/RBC procedures and DRBC procedures. All valves move to the return position and all pumps are commanded to zero. When these actions successfully complete, the Trima Accel system advances to the Blood Rinseback state.

**Table 3-41: Pre Rinseback Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	Qin	Qplas	Qplat	Qret	Return	Return	Return	3000

Exit Condition	When the pumps and valves are detected at the commanded speed and position within 10
	seconds.

## **Blood Run Recovery Substates**

The Blood Run state contains eleven recovery substates. Recovery substates interrupt the procedure and suspend the procedure time clock.

When the recovery routine completes, the Trima Accel system returns to the procedure substate that it was in prior to recovery. These recovery substates can occur at any time during the Blood Run state. Only one recovery substate happens at a time. Descriptions of the recovery substates follow.

## RBC Spillover (Spillover Recovery) Substate

Spillover recovery can be entered via a command from the operator (by pressing the **Spillover** button on the Adjust screen) or automatically when detected by the RBC detector. This substate triggers the WBC Chamber Purge substate followed by the Clear Line substate (see the description for these recovery substates on next page). At the end of spillover recovery, the RBC detector checks for the presence of a spillover and regenerates the recovery procedure if a spillover persists.

#### Pumps Pause (Pause Recovery) Substate

This recovery occurs when the pumps are paused for more than 6 seconds. After the inlet pump processes a predetermined inlet volume, the pumps return to their original collection values and the Trima Accel system returns to the previous blood run substate.

#### Air Block (Air Block Recovery) Substate

This recovery is initiated when the operator presses the **Air in Plasma Line** button on the Adjust screen. The centrifuge speed lowers to a predetermined speed, all valves close, and the pump speeds lower to remove the air block. The plasma pump runs at a predetermined speed, maintaining chamber flow, until a predetermined volume of plasma has been pumped. The system then transitions to the Centrifuge Stop substate.

## Centrifuge Stop (Centrifuge Stop Recovery) Substate

This recovery procedure occurs anytime after the centrifuge stops (or drops below a predetermined speed). This recovery procedure takes precedence over the other recovery procedures. The centrifuge ramps up to its final commanded speed while the pumps are maintained at low speeds to prevent the occurrence of a spillover or air block. When the centrifuge reaches the commanded speed plus 60 more seconds, the pumps return to their normal collection speeds.

## Centrifuge Slow (Centrifuge Slow Recovery) Substate

This recovery substate occurs if the centrifuge actual speed drops below a predetermined speed, but is greater than a predetermined speed. The centrifuge ramps up to 3000 rpm and this recovery continues for 15 more seconds.

## Saline Bolus (Saline Bolus Recovery) Substate

This substate occurs whenever a saline bolus is administered. The platelet pump runs at a predetermined speed until a predetermined volume of saline bolus is delivered. At the same time the return pump runs at the same speed to keep the reservoir volume approximately even. After a predetermined volume of saline has been pumped, the Trima Accel system resumes the draw or return cycle that it was previously

#### Saline Prime (Replacement Fluid Priming Recovery) Substate

This substate occurs the first time replacement fluid is administered in an RBC/Plasma procedure. The platelet pump runs at a predetermined speed until a predetermined volume of saline is pumped to prime the replacement fluid line.

#### WBC Chamber Purge (WBC Chamber Purge Recovery) Substate

This substate occurs during any procedure where a spillover recovery occurs or a very large inlet volume is processed. The plasma pump increases in speed and the platelet pump stops, purging volume from the LRS chamber. This continues until a predetermined plasma volume is pumped through the LRS chamber.

#### RBC Chamber Purge (RBC Chamber Purge Recovery) Substate

This substate occurs during any procedure where a platelet, plasma, RBC tubing set is loaded. This recovery substate always occurs at the beginning of the Channel Setup substate. The plasma pump runs at a predetermined speed and the platelet pump stops, purging volume from the LRS chamber. This continues until a predetermined plasma volume is pumped.

#### Plasma Valve Motion (Plasma Valve Move Recovery) Substate

This substate occurs whenever the plasma valve changes position during a platelet collection procedure. This recovery stops the pumps for one second while the valve moves to prevent fluid from entering the plasma bag while the valve moves through the open position.

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#### Settle Channel Substate

This substate occurs only after the WBC Chamber Purge substate. This substate settles the cells in the channel prior to resuming collection. During this recovery the inlet pump flow rate decreases to less than a predetermined amount and pumps a predetermined inlet volume.

#### Clear Line Substate

This substate occurs after WBC Purge recoveries. It functions to clear RBC/WBC out of the platelet line. The inlet, platelet, and plasma pumps are limited to predetermined speeds. This substate ends when a predetermined platelet volume has been pumped.

#### **Rinseback State**

The Blood Rinseback state returns the donor's blood.

The hematocrit in the RBC line is configured to maximize blood return. This system state ends when the lower-level sensor detects air. Successful completion of the Blood Rinseback state results in the following conditions and actions.

Exit Condition	Trima Accel System Condition	Trima Accel System Action
All Blood Rinseback substates are completed.	Under algorithm control.	The Trima Accel system advances to the Donor Disconnect state.

#### **Rinseback Substates**

The Blood Rinseback state consists of four substates that evacuate the channel and return remaining blood to the donor.

#### Rinseback Lower (Rinseback Lower Reservoir) Substate

All valves are commanded to the return position and the inlet, AC, plasma, and platelet pumps are commanded to zero. The return pump runs until air is present at the lower-level sensor, or a predetermined volume of return has been pumped. The Trima Accel system then advances to the Rinseback Recirculate substate.

**Table 3-42: Rinseback Lower Substate** 

0 0 0 Qret Return Return 3000	AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
	0	0	0	0	Qret	Return	Return	Return	3000

Exit Condition When the lower-level sensor detects air or 10 mL processed by the return pump.

#### Rinseback Recirculate Substate

The inlet and return pumps are commanded to predetermined speeds to recirculate the blood in the channel before returning it to the donor. After a predetermined inlet volume is processed, the Trima Accel system advances to the Rinseback substate.

**Table 3-43: Rinseback Recirculate Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	100	Qplas	Qplat	100	Return	Return	Return	3000

**Exit Condition** When 50 mL is processed by the inlet pump.

## Rinseback (Rinseback Return) Substate

The centrifuge is commanded to zero. The inlet pump is also commanded to zero and the plasma, platelet, and return pumps run until the lower-level sensor sees air and a predetermined return volume is processed. When this occurs, the Trima Accel system advances to the Disconnect Prompt substate.

**Table 3-44: Rinseback Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	Qplas	Qplat	Qret, 0	Return	Return	Return Return, Collect*	0

<sup>\*</sup>Versions 5.1.8 and 5.1.9

Exit Condition When the lower-level sensor detects air or 20 mL processed by the return pump.

## **Disconnect Prompt Substate**

The pumps all stop and the Disconnect Prompt screen prompts the operator to press **Continue** to disconnect the donor. When the operator presses **Continue**, the Trima Accel system advances to the Donor Disconnect state. If the operator does not respond to the prompt in 10 minutes, the Trima Accel system automatically advances to the Donor Disconnect state.

**Table 3-45: Disconnect Prompt Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Return	Return	Return	0

**Exit Condition** When the operator touches **Continue** or 10 minutes have passed.

#### **Donor Disconnect State**

The Donor Disconnect state checks that the operator has correctly clamped off the donor access line prior to disconnecting the donor. When the Disconnect Test substate is complete, the cassette is unloaded.

This state ends when the disconnect test successfully passes and the cassette is unloaded, or when the test fails three consecutive times, warning the operator. Successful completion of the Donor Disconnect state results in the following conditions and actions.

Exit Condition	Trima Accel System Condition	Trima Accel System Action		
The disconnect test has passed once and the cassette has been unloaded, or the test failed three consecutive times and the cassette has been unloaded.	Paused.	The operator is prompted to continue to the Post Run state.		

#### **Donor Disconnect Substates**

The Donor Disconnect state consists of five substates: Disconnect Test, Open Valves, Start Pumps, Raise Cassette, and Stop Pumps.

#### **Disconnect Test Substate**

The inlet pump is commanded to a predetermined speed, and the Trima Accel system waits to verify that the access pressure drops by a predetermined amount within 30 seconds. Then the system checks that the pressure does not decay by more than a predetermined amount within the following 10 seconds. If

both tests fail, a disconnect test alert is displayed and the Trima Accel system repeats the test. The operator is prompted to repeat the test. If it fails twice again, a disconnect test alarm is generated and the operator is allowed to unload the cassette by pressing **Continue** and **Confirm Disconnect**.

**Table 3-46: Donor Disconnect Test Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	50, 0	0	0	0	Return	Return	Return	0

## Open Valves Substate

All valves are moved to their open positions. When the valve position sensors sense all three open positions, the Trima Accel system advances to the next substate.

**Table 3-47: Open Valves Substate** 

1	Pump L/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0		0	0	0	0	Open	Open	Open	0

Exit Condition When the valves are detected in the commanded position within 10 seconds.

## Start Pumps Substate

All pumps are commanded to their unload speeds.

**Table 3-48: Start Pumps Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
60	60 140*	60	60	150 -110*	Open	Open	Open	0

<sup>\*</sup>Versions 5.1.6 through 5.1.9

Exit Condition When the pumps are detected at commanded speed within 10 seconds.

#### Raise Cassette Substate

The cassette is commanded to the raised position while the pumps are running at their unload speeds. When the cassette is detected in the raised position, the Trima Accel system advances to the next substate.

**Table 3-49: Raise Cassette Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
60	60 140*	60	60	150 -110*	Open	Open	Open	0

<sup>\*</sup>Versions 5.1.6 through 5.1.9

Exit Condition	When the cassette plate is detected in the up position.
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## Stop Pumps Substate

The pumps are commanded to stop and the operator is prompted to press **Continue**. When the operator presses **Continue**, the Trima Accel system advances to the Post Run state.

**Table 3-50: Stop Pumps Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Open	Open	Open	0

## **Post Run State**

The Post Run state displays end-of-run statistics.

The Post Run state ends when the operator touches the **Next Procedure** button. Successful completion of the Post Run state results in the following conditions and actions.

Exit Condition	Trima Accel System Condition	Trima Accel System Action
The operator touches the <b>Next Procedure</b> button.	Paused.	The Trima Accel system reboots and advances to the Self Tests state.

# **Version 6.0 Software Description**

## **Trima Accel Software Description**

This section describes the Trima Accel system software.

The Trima Accel system operates automatically, performing many individual steps to complete the entire blood component collection procedure. The collection procedure consists of separate and sequential system states, some of which contain substates. Within each substate, the system performs a series of tasks.

When an alarm or error occurs, the Data Log (DLog) file captures the system state and hardware information related to that alarm. Compare the information in the Data Log file with the information in this chapter to solve the alarm or error problem.

#### **Self Test State**

The Self Test state starts boot sequence starts with the BIOS self test. This is similar to a PC BIOS self test, and tests the major processor board components such as the CPU, interrupt controller, timer, and RAM.

If any of these tests fail, the system displays an error message and aborts the boot sequence. If all tests pass, control is passed to the boot device. The boot device then loads the vxWorks boot ROM image. The boot ROM image contains the software required for loading and starting the operating system. It provides a set of device drivers for accessing the storage device or network device through which the operating system is loaded.

When the boot ROM image is executed, it first tests for the presence of a keyboard. If a keyboard is attached, the system enables the loading of a debug vxWorks image that includes the necessary software components for using the WindRiver development and debugging tools. If the **Esc** key is pressed, the system enters an alternate boot mode in which booting is stopped immediately after loading the OS image and drivers. This is signified with a prompt that looks like an arrow: "->." Note that a login or password is not required when using the keyboard to execute commands from the command line. The login and password are required to upload files to the machine via FTP.

The OS software uses the pause and stop keys to select Single-Step boot and Service mode. In Single-Step mode, the system pauses and waits for the technician to press the pause button after each step of the boot sequence is completed; otherwise the boot proceeds normally. During Single-Step mode, the technician can login to the machine via FTP after the message "initializing network software" appears on the screen. Service mode is used for software installation, updates, and machine maintenance.

During the network initialization process, the system start mode is determined: normal boot, Service mode, or Alt Boot mode. If the system start mode is normal, then the safety board MAC address in the control computer ARP table is made permanent. This removes any possibility that an ARP update from the external network interface could overwrite it. Overwriting that MAC address would prevent the control computer from communicating with the safety computer. Note that this protection is not provided in Service mode or Alt Boot mode to aid in system troubleshooting.

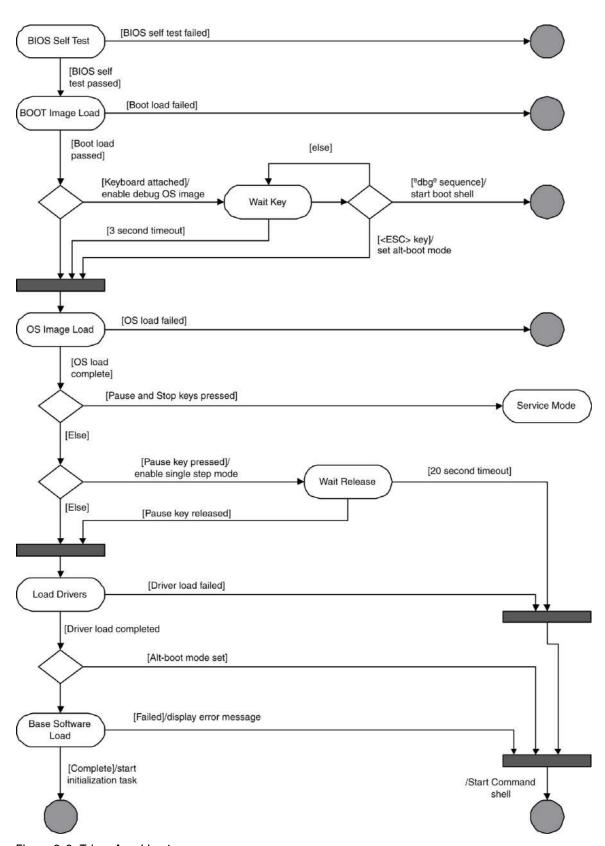


Figure 3-3: Trima Accel boot sequence

## **Power Fail Recovery State**

The PFR state allows the Trima Accel system to restore data if a power failure occurs during a procedure.

This state begins with a handshake across domain boundaries between control and safety computers. The Trima Accel system tries to restore data (in the power fail save file) from a previous procedure if there is any valid data. If there is valid data, the Trima Accel system performs the power tests that are normally performed in the Startup Tests state and then restores the previous data. After restoring the data, the Trima Accel system allows the operator a choice to continue with or discontinue the collection procedure. The rules for continuation from a power fail situation follow:

- If the power failure occurs during the Startup Tests state through the AC Prime, Rinseback, or Donor Disconnect states, recovery is not allowed. The operator must unload the set.
- If the power failure occurs during the Donor Connected state, the operator can continue or end the collection procedure.
- If the power failure occurs in the return cycle during the Blood Prime and Blood Run system states, the operator can continue, rinseback, or end the collection procedure with no time restraint.
- If the power failure occurs during the draw cycle of the Blood Run or Blood Prime states, the operator can continue, rinseback, or end the collection procedure if the PFR screen is restored within 9.5 minutes. If power is not restored within 9.5 minutes, the operator can only end the collection procedure.
- If the power failure occurs during the Rinseback state, the operator can rinseback or end the collection procedure.

Successful completion of PFR state results in the following conditions and actions.

Termination Condition	Trima Accel System Condition	Trima Accel System Action
PFR data successfully saved and restored if valid.	Pause.	If there is no valid PFR data, the Trima Accel system proceeds automatically to the startup tests in the Startup Tests state. If there is valid PFR data, the Trima Accel system proceeds to the power tests in the Startup Tests state.

## **Startup Tests State**

The Startup Tests state performs the Trima Accel system's mandatory startup tests.

This state follows the Power Fail Recovery (PFR) state. It contains tasks that start in this state and continue until the Donor Connected state. The Startup Test state ends when all tests are successfully completed.

The startup tests are executed before a disposable tubing set is loaded and before the donor is connected. These tests ensure that the Trima Accel system is operational, that the critical safety features are in place, and that computer redundancy is functioning. During power fail recovery situations only some of the tests are performed to ensure safety of the already-connected donor. Startup tests include the following activities:

- Test if the safety system can disable power to pumps and centrifuge.
- Test the cassette position function (up and down) at both the control and safety computers.

- Test the valve position sensing (both control and safety computers) in all three positions for each valve.
- Test if the lower-level sensor registers air continuously at both the control and safety computers.
- Test if the AC level sensor registers air continuously.
- Test the safety system centrifuge rpm sensor (Halls) for commanded and zero speed.
- Test if the control computer can stop the centrifuge.
- Evacuate air from the collection bags.

Successful completion of Startup Tests state results in the following conditions and actions.

Exit Condition	Trima Accel System Condition	Trima Accel System Action
All startup tests have passed.	Pause.	The Trima Accel system advances to the Disposable Tests state.

## **Startup Tests Substates**

The Startup Tests substates test the safety system, cassette and valve position function, lower-level and AC level sensors, centrifuge Hall sensor, and centrifuge control. The cassette is lowered, the tubing set type is verified, and air is evacuated from the collection bags.

#### **CPUID Test Substate**

First, this substate tests the available memory on the control and safety computers. If the memory is insufficient, an alarm is generated. Next, this substate checks that the control and safety CPU type matches one of those listed in the hw.dat file. If the CPU type does not match, an alarm is generated. If a valid power fail recovery condition or a new collection procedure condition is detected, the Trima Accel system advances to the Power Test substate.

#### Calib Verification (Calibration Check) Substate

This substate checks that the cal.dat file values for access pressure, centrifuge pressure, and RBC detector are different values than the defaults. If any one (or more) are the same as the default values, then a "cal.dat xxxx not calibrated" alarm is generated.

#### **Power Test Substate**

Prior to beginning this test, the Trima Accel system verifies that the disposable tubing cassette is in the unloaded position. If not, the Trima Accel system advances directly to the Donor Disconnect system state. If the cassette is in the unloaded position, the safety computer checks for the presence and limits of the 24-volt and 64-volt DC power supplies. The 24-volt and 64-volt DC supplies are then disabled and re-enabled to confirm safety computer's control over them. The second part of the power tests turns the 24-volt and 64-volt power supplies on, commands the pumps to zero, and ensures that they are not moving. At the end of this substate, the 24-volt switch remains ON and the 64-volt switch is turned OFF. If any test fails, an alarm is generated, and the Trima Accel system resumes at the beginning of Startup Tests. If all conditions are met, the Trima Accel system advances to the Valves Test substate.

#### Valves Test Substate

The RBC, plasma, and platelet valves are moved sequentially to all three of their possible positions. If any of the positions cannot be reached within 10 seconds, an alarm is generated and the Trima Accel system resumes at the beginning of the Startup Tests state. If this test passes, the Trima Accel system advances to the Leak Detector Test substate.

#### Leak Detector Test Substate

The leak detector output voltage is checked to verify that it is open and can detect fluid leaks. If this test fails, an alarm is generated. If this test passes, the Trima Accel system advances to the CentShutdown substate.

#### CentShutdown Test (Centrifuge Shutdown) Substate

The control computer first checks the 64-volt DC to see if it is within range. Then the Trima Accel system commands the centrifuge to zero and verifies immobility for two seconds. If this test fails, an alarm is generated. If this test passes, the Trima Accel system advances to the Door Latch Test substate.

#### **Door Latch Test Substate**

These tests check that the door can be seen as both open and closed by the door lock optical and Hall sensors. The 24-volt switch dedicated to the door solenoid is also checked to ensure that it can be turned off. If these tests fail an alarm is generated. If these tests pass, the **Load System** button is enabled. There is also a test to check the ability of the software to lock and unlock the door without power. This test locks the door and waits to see if it locks even when the power is supposed to be off. If the door is in the locked state, the alarms are given and the tests are tried again.

#### GUI Started (Load System Button) Substate

This substate is not a test but instead enables the **Load System** button and waits for the operator to press it and the **Continue** button from the subsequent screen. The **Donor Info** button also activates at this time.

#### Load Cassette Substate

After the operator presses the **Load System** button, the cassette is checked for the up position as seen by the optical sensor. The valves are also commanded to the open position. If they do not achieve the open position in ten seconds, an alarm is generated.

**Table 3-51: Load Cassette Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Open	Open	Open	0

Exit Condition When the operator touches the Continue button.

## Start Pumps Substate

This substate commands the pumps on individually to minimize voltage spikes. When all pumps have reached their commanded speed (± 5 mL/min), the Trima Accel system advances to the Lower Cassette substate.

**Table 3-52: Start Pumps Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
60	140	60	60	110	Open	Open	Open	0 or –1

Exit Condition When the pumps are detected at the commanded speed within 10 seconds.

#### Lower Cassette Substate

In this substate the cassette is commanded down and the lower optical switch is checked to verify that the cassette achieves the loaded position. If this does not occur within 15 seconds, the "Cassette Error" alarm generates.

The access pressure sensor is auto-zeroed at this point.

**Table 3-53: Lower Cassette Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
60	140	60	60	110	Open	Open	Open	0

Exit Condition When the cassette plate is detected in the down position.

#### Cassette ID Substate

During this substate the RBC detector checks the cassette type to make sure that it is the proper cassette for the chosen collection procedure. If the cassette does not match the procedure, an alarm is generated. If the tubing set cannot be identified, but is within a valid range, a screen displays that allows the operator to choose the correct tubing set or load a new one. For white stamp cassettes only: During this substate the Trima Accel system begins calibration of the red and green reflection strengths of the RBC detector

to a ratio of one for spillover detection purposes. If the calibration fails, an alarm is generated. If these tests pass, the Trima Accel system advances to the Stop Pumps substate. RBC calibration does not take place for black stamp cassettes.

**Table 3-54: Cassette ID Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
60	140	60	60	110	Open	Open	Open	0

**Exit Condition** When the cassette stamp reflectance value is read.

#### Stop Pumps Substate

This substate commands the pumps to zero. When all pumps are zero, the Trima Accel system advances to Evacuate Set Valves substate. CPS auto-zero takes place here.

**Table 3-55: Stop Pumps Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Open	Open	Open	0

Exit Condition When the pumps are detected at the commanded speed within 10 seconds.

## Evacuate Set Valves (Set Valves for Evacuate) Substate

This substate changes the position of the valves in order to evacuate air from the set. For a platelet, plasma, or RBC set, the RBC valve moves to the return position and the other valves move to the open position. For all other sets, the RBC valve moves to the collect position and the plasma and platelet valves move to the open position. If the valves cannot achieve position in 10 seconds, an alarm is generated. When all valves achieve position, the Trima Accel system advances to the Evacuate Bags substate.

**Table 3-56: Evacuate Set Valves Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Open	Open	Return	0

**Exit Condition** When the valves are detected in the commanded position within 10 seconds.

## **Evacuate Bags Substate**

This substate removes air from the product bags. The return pump runs until a predetermined volume has been pumped (version specific). If the access pressure exceeds the alarm limit during this test, an alarm is generated and the Trima Accel system reverts to the previous substate. If the test passes, the Trima Accel system advances to the Lower Notification substate.

**Table 3-57: Evacuate Bags Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	90	Open	Open	Return	0

**Exit Condition** When 140 mL is processed by the return pump.

## Lower Notification (Cassette Position Message) Substate

This substate informs GUI of the cassette position (it should be down) to prepare for disposable tests. If the cassette is down, the Trima Accel system advances to the Disposable Tests substate.

**Table 3-58: Lower Notification Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Open	Open	Return	0

Exit Condition When the cassette down message is sent.

# **Disposable Tests State**

The Disposable Tests state performs tests designed to determine whether the disposable tubing set is properly loaded and functioning.

The disposable tests include the following activities:

- Checks for the correct tubing set and the proper loading of the disposable
- Checks the integrity of the set. The access pressure sensor checks both positive and negative pressure of the disposable set to ensure its usability
- Checks for AC, inlet, and return pump tubing occlusions
- Checks for proper access pressure sensor function

Successful completion of the Disposable Tests state results in the following conditions and actions.

Exit Condition	Trima Accel System Condition	Trima Accel System Action
All disposable tests have passed.	Pause.	The Trima Accel system prompts the operator to connect the AC line.

Trima Accel version 6.0 introduces new disposables that require a different set of disposable tests than previous software versions. During the Pressurize Inlet Line substate, the system determines which type of disposable is loaded on the system based on the pressure measured at the APS. If the APS reads less than 300 mmHg the set is recognized as a "RAS" set and the new disposable test tree is used. If the pressure is greater than 500 mmHg, the set is recognized as a "non-RAS" set and the original disposable tree is used.

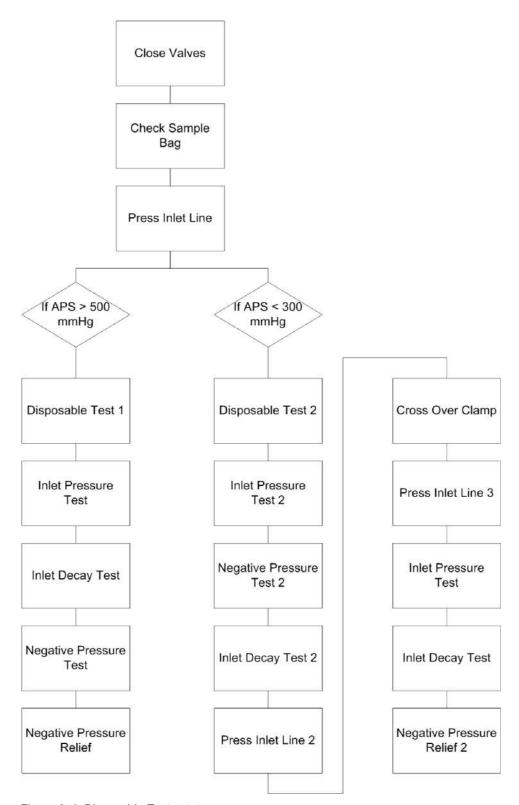


Figure 3-4: Disposable Tests state sequence

# **Disposable Tests Substates**

The disposable tests are a sequential series of automated tests designed to ensure that the tubing set is properly loaded and functioning correctly. These tests also check the occlusions in the AC, inlet, and return pumps and the function of the access pressure sensor.

# Close Valves (Move Valves to Return Position) Substate

This substate commands the platelet, plasma, and RBC valves to the return position. If they do not achieve the return position, an alarm is generated. When all valves reach the return position, the Trima Accel system advances to the Press Inlet Line substate.

**Table 3-59: Close Valves Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Return	Return	Return	0

Exit Condition When the valves are detected in commanded position within 10 seconds.

## Check Sample Bag Substate

This substate checks that the access pressure sensor is less than a predetermined value before the exit condition is met to check that the sample bag is closed.

**Table 3-60: Check Sample Bag Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Return	Return	Return	0

**Exit Condition** When the APS is greater than 50 mmHg after 10 mL processed.

## Press Inlet Line (Pressurize Inlet Test) Substate

This test runs the AC pump until a version-specific predetermined access pressure is reached. If the pressure limit is not reached, an alarm is generated. If the test fails, pressing the **Continue** button repeats this test. Pressing the **End Run** button unloads the cassette and returns to the beginning of the Startup Tests state.

**Table 3-61: Press Inlet Line Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
142	0	0	0	0	Return	Return	Return	0

**Exit Condition** When the APS is greater than 400 mmHg before 50 mL processed by the AC pump.

## Inlet Press Test (Inlet Line Pressure Test) Substate

This test stops all pumps and checks that the access pressure does not drop more than a version-specific predetermined amount. If the pressure drop exceeds the exit condition, an alarm is generated. If the test fails, pressing the **Continue** button repeats this test. Pressing the **End Run** button unloads the cassette and proceeds to the beginning of the Startup Tests state.

**Table 3-62: Inlet Press Test Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Return	Return	Return	0

**Exit Condition** When there is less than 50 mmHg decrease in APS pressure since previous state in 3 seconds.

#### Inlet Press Test 2 Substate

This substate is the same as "Inlet Press Test (Inlet Line Pressure Test) Substate" on page 3-49, except with a different exit condition.

**Table 3-63: Inlet Press Test 2 Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Return	Return	Return	0

**Exit Condition** When there is less than 50 mmHg decrease in APS pressure since previous state in 3 seconds.

# Inlet Decay Test (Pump Occlusion Test) Substate

This test commands the AC, return, and inlet pumps until each has achieved one-third of a revolution. The Trima Accel system advances to the Negative Press Test state if the exit condition is satisfied. If the test fails, pressing the **Continue** button returns to the Press Inlet Line substate. Pressing the **End Run** button unloads the cassette and returns to the beginning of the Startup Tests state.

**Table 3-64: Inlet Decay Test Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
20, 0	20, 0	0	0	-40, 0	Return	Return	Return	0

**Exit Condition** When there is greater than 50 mmHg decrease in APS pressure after the pumps rotate.

# Inlet Decay Test 2

This substate is the same as "Inlet Decay Test (Pump Occlusion Test) Substate" on page 3-50, except with a different exit condition.

Exit Condition	When there is greater than 50 mmHg decrease in APS pressure after the pumps rotate.
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# **Table 3-65: Inlet Decay Test 2 Substate**

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
20	20	0	0	-40	Return	Return	Return	0

## Press Inlet Line 2 Substate

This substate is similar to "Press Inlet Line (Pressurize Inlet Test) Substate" on page 3-49, except with a different exit condition and pump speed.

**Table 3-66: Press Inlet Line 2 Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	400	Return	Return	Return	0
Exit C	Exit Condition		PS is greater t	han 300 mml				

# Close Crossover Clamp Substate

This substate instructs the operator to close the crossover clamp on the disposable set and waits for confirmation.

**Table 3-67: Close Crossover Clamp Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Return	Return	Return	0

**Exit Condition** When the operator touches the **Continue** button.

#### Press Inlet Line 3Substate

This substate is the same as "Press Inlet Line (Pressurize Inlet Test) Substate" on page 3-49, except with a different exit condition.

Table 3-68: Press Inlet Line 3 Substate

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
142	0	0	0	0	Return	Return	Return	0

**Exit Condition** When the APS is greater than 500 mmHg before 50 mL is processed by the AC pump.

## Negative Press Test (Negative Pressure Test) Substate

This test commands the inlet pump until the access pressure sensor reading is less than a version-specific predetermined amount. If the pressure is reached before the exit condition, the Trima Accel system advances to the Negative Press Relief substate. If the test fails, pressing the **Continue** button returns to the Press Inlet Line substate. Pressing the **End Run** button unloads the cassette and proceeds to the beginning of the Startup Tests state.

**Table 3-69: Negative Press Test Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	142	0	0	0	Return	Return	Return	0

**Exit Condition** When the APS is less than -350 mmHg before 115 mL is processed by the inlet pump.

# Negative Press Relief (Negative Pressure Relief) Substate

This final disposable test substate commands a pump until the access pressure sensor reading is greater than a version-specific predetermined amount. If this does not occur before the exit condition, an alarm is generated. When this pressure is achieved, the disposable tests are complete, and the Trima Accel system advances to the AC Connected state.

**Table 3-70: Negative Press Relief Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
142 0*	0	0	0	0 -90*	Return	Return	Return	0

<sup>\*</sup>Version 6.0.3

Exit Condition	When the APS is greater than -50 mmHg before 50 mL is processed by the AC pump.
----------------	---

## Negative Press Relief 2 Substate

This substate is similar to "Negative Press Relief (Negative Pressure Relief) Substate" on page 3-52, except with a different exit condition and pump speed.

**Table 3-71: Negative Press Relief 2 Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	-50	Return	Return	Return	0

**Exit Condition** When the APS is greater than 500 mmHg before 50 mL is processed by the AC pump.

# **AC Connected State**

The AC Connected state prompts the operator to attach the AC container to the tubing set and load the AC tubing into the AC detector.

The AC Connected state ends when the operator touches the **Continue** button. Successful completion of the AC Connected state results in the following conditions and actions.

Exit Condition	Trima Accel System Condition	Trima Accel System Action
The operator touches the <b>Continue</b> button.	Pause.	The Trima Accel system advances to the AC Prime state.

If performing an RBC collection procedure, touching the **Continue** button advances the Trima Accel system to the Replacement Fluid screen, otherwise the Trima Accel system advances to the AC Prime state.

## **AC Prime State**

The AC Prime state primes the AC line and a portion of the inlet and return lines with anticoagulant.

The AC air detector is tested for function during this state. This system state ends when all tests are successfully completed. Successful completion of the AC Prime state results in the following conditions and actions.

Exit Condition	Trima Accel System Condition	Trima Accel System Action
All tests have passed.	Pause.	The Trima Accel system prompts the operator to connect the donor.

#### **AC Prime Substates**

The AC Prime substates prime the AC line and a portion of the return line with ACD-A. AC sensor and access pressure tests are also performed.

# AC Prime Inlet (Prime Initial AC and Inlet Lines)

In this test, the AC and inlet pumps are commanded to process AC through the AC line. If the AC-level sensor does not see AC after a version-specific predetermined volume is pumped an alarm is generated. The test repeats a second time when the **Continue** button is pressed. If the test fails again, a prime failure alarm is generated. If ACD-A is seen at the sensor, the AC and inlet pumps continue at the same speed until a version-specific predetermined volume of AC is pumped. After successful completion of this substate, the Trima System advances to the AC Press Return Line substate.

**Table 3-72: AC Prime Inlet Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
50 30*	50 30*	0	0	0	Return	Return	Return	0

<sup>\*</sup>If APS drops more than 20 mmHg

Exit Condition	When AC is detected before 5 mL processed by AC pump.
----------------	---

# AC Press Return Line (Pressurize Return Line)

The AC and inlet pumps stop and the return pump is commanded to run until the access pressure sensor reads a version-specific predetermined amount. If the exit condition is not met, an alarm is generated. If pressure is achieved and the donor information is entered, the **Begin Donor Prep** button appears in the task bar at the bottom of the screen.

**Table 3-73: AC Press Return Line Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	-50	Return	Return	Return	0

**Exit Condition** When APS is less than or equal to -50 mmHg before 7 mL is processed by the return pump.

## **Donor Connected State**

The Donor Connected state prompts the operator to connect the donor and take a blood sample.

The 64-volt switch turns on and the control computer checks the centrifuge motor controller fault bit.

**Table 3-74: Donor Connected State** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Return	Return	Return	0

Successful completion of the Donor Connected state results in the following conditions and actions.

Exit Condition	Trima Accel System Condition	Trima Accel System Action
The operator touches the <b>Continue</b> button.	Pause.	The Trima Accel system advances to the Blood Prime state.

#### **Door Lock Check Substate**

This substate only applies to version 6.0.3, and is entered immediately after the **Start Draw** button is touched. The system checks that the door is closed and locked. If the door is closed but not locked, the system locks the door.

**Table 3-75: Door Lock Check Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)		
0	0	0	0	0	Return	Return	Return	0		
Exit Co	ndition	When the do	When the door has been successfully locked.							

## **Blood Prime State**

The Trima Accel system begins priming the tubing set with the donor's blood during the Blood Prime state.

The access pressure sensor alarms are enabled for the first time, the centrifuge starts, and the Trima Accel system begins updating and displaying collection procedure information. This system state ends when fluid is detected at the lower-level sensor and the centrifuge runs at the commanded speed. Successful completion of the Blood Prime state results in the following conditions and actions.

Exit Condition	Trima Accel System Condition	Trima Accel System Action		
Blood Prime substates have completed.	Under algorithm control.	The Trima Accel system advances to the Blood Run state.		

#### **Blood Prime Substates**

The Blood Prime state consists of four substates: Two substates prime the inlet and return lines with blood, and two substates vent pressure from the product bags.

# Blood Prime Inlet (Blood Prime Inlet Lines) Substate

The inlet and AC pumps run at the calculated collection procedure values (Qac and Qin) for the chosen procedure with all valves remaining in the return position. The centrifuge is commanded on. When a version-specific predetermined inlet volume is pumped, the Trima Accel system advances to the Blood Prime Return substate.

**Table 3-76: Blood Prime Inlet Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	40	0	0	0	Return	Return	Return	200

**Exit Condition** When 13 mL is processed by inlet pump and centrifuge reaches 200 rpm.

## Blood Prime Return (Blood Prime Return Line) Substate

The return pump is commanded to run. When fluid is sensed at the lower-level sensor of the reservoir, the return pump continues running for a version-specific predetermined volume and then stops. The volume pumped by the return pump must be between version-specific predetermined amounts. When the actual centrifuge speed is within 25 rpm of the commanded speed within the exit condition time, the Trima Accel system advances to the Evac Set Valves substate.

**Table 3-77: Blood Prime Return Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
5.8 2.9*	0	0	0	-40	Return	Return	Return	200

<sup>\*</sup>Version 6.0.3

**Exit Condition** When 5 mL is processed by inlet pump after lower-level sensor detects fluid.

# Evac Set Valves (Vent Collect Bags) Substate

This substate moves the platelet, plasma, and RBC valves to vent pressure from the product bags built up during the previous substate. When the valves reach the open position, the Trima Accel system advances to the Evac Reset Valves substate.

**Table 3-78: Evac Set Valves Substate** 

AC Pu (mL/n	· 1	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Open	Open	Open	200

Exit Condition When the valves are detected in commanded position within 10 seconds.

# Evac Reset Valves (Move Valves to Return Position) Substate

This substate moves the platelet, plasma, and RBC valves. When the valves reach the return position, the Trima Accel system advances to the Blood Run substate.

**Table 3-79: Evac Reset Valves Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Return	Return	Return	200

Exit Condition When the valves are detected in commanded position within 10 seconds.

## **Blood Run State**

The Blood Run state performs the collection procedure.

Blood Run functions include

- Priming the channel and the rest of the tubing set
- Establishing the interface
- Collecting the platelet, plasma, and RBC products

The Trima Accel system performs single needle draw and return cycles and controls pump speed commands accordingly during this system state. The "RBC Spillover" alarm, all AC related alarms, and the hypovolemic alarm are activated at this time. When the Blood Run state completes, the Trima Accel system advances to the Blood Rinseback state.

Exit Condition	Trima Accel System Condition	Trima Accel System Action
All Blood Run targets are achieved, an alarm ends the collection procedure, or the operator ends the collection procedure.	Under algorithm control.	The Trima Accel system advances to the Blood Rinseback state.

#### **Blood Run Prime Substates**

This Blood Run Prime substate primes the channel and prepares the disposable tubing set for the collection.

#### Prime Channel 1 Substate

The inlet pump and centrifuge are commanded to run at version-specific predetermined speeds. If the centrifuge does not achieve commanded speed in 2 minutes, the "Hardware Failure" alarm generates. The calculated AC ratio (based on channel hematocrit) implements at this time, thus, creating a command for the AC pump (Qac). The plasma and platelet pumps are commanded to run at version-specific speeds until a predetermined volume has been pumped into the channel. The Trima Accel system advances to the Prime Channel 2 substate.

Table 3-80: Prime Channel 1 Substate

	Pump L/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac		35	5 30*	30 0*	0	Return	Return	Return	2000

<sup>\*</sup> DRBC tubing sets

3-58

Exit Condition	When 70 mL is processed by inlet pump.
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#### Prime Channel 2 Substate

The plasma and platelet pumps are commanded to zero while the AC and inlet pump speeds are maintained until a version-specific predetermined inlet volume has been pumped. The Trima Accel system then advances to the Prime Channel 3 substate.

Table 3-81: Prime Channel 2 Substate

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	13	2	11	0	Return	Return	Return	2500

**Exit Condition** When 15 mL is processed by inlet pump.

#### Prime Channel 3 Substate

The inlet pump continues to run at the speed from the previous substate (or Qin, whichever is less), the AC ratio changes to the ratio calculated for the collection procedure, and the AC pump speed changes accordingly. After a version-specific inlet volume has been pumped, the Trima Accel system advances to the Prime Channel 4 substate.

**Table 3-82: Prime Channel 3 Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	35	0	0	0	Return	Return	Return	2500

**Exit Condition** When 25 mL is processed by inlet pump.

# Prime Channel 4 Substate

The inlet pump speed increases again to a version-specific maximum speed and the AC pump speed changes accordingly. The plasma and platelet pumps are commanded to version-specific speeds. The Trima Accel system begins checking for fluid at the upper reservoir sensor and executes return cycles as necessary. After a version-specific inlet volume has been pumped, the Trima Accel system advances to the Prime Vent substate.

**Table 3-83: Prime Channel 4 Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	45	15	15 0*	0	Return	Return	Return	2500

#### \* DRBC tubing sets

Exit Condition	When 8 mL is processed by inlet pump.
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## Prime Vent (Vent Air) Substate

This substate occurs in platelet collection procedures only. The centrifuge and pumps remain at their previous speeds and the platelet valve moves to the collect position to remove air from the channel. After a version-specific volume of plasma + platelet have been pumped, the Trima Accel system advances to the Ramp Centrifuge substate.

**Table 3-84: Prime Channel Vent Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	45	15	15 0*	0	Collect	Return	Return	2500

<sup>\*</sup> DRBC tubing sets

Exit Condition	When 10 mL is processed by platelet and plasma pump combined.
----------------	---

# Ramp Centrifuge Substate

The centrifuge is commanded to its final calculated speed (usually 3000 rpm). If it cannot make it to its final speed in 2 minutes, a centrifuge hardware alarm is generated. The platelet valve is commanded back to the return position while the pumps and centrifuge remain at their previous speeds. When the machine goes from the first draw cycle to the first return cycle the Trima Accel system advances to the Remove Channel Air substate.

**Table 3-85: Ramp Centrifuge Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac         45         12         0         0         Return         Return         Return         3000						3000		
Exit Condition When target (donor-specific) volume is processed by inlet pump.								

# Prime Airout 2 (Remove Channel Air) Substate

The AC pump turns off, and the plasma, platelet, and return pumps are commanded to version-specific speeds to remove air from the channel. When a version-specific inlet volume has been pumped, the Trima Accel system advances to the Blood Run Collection substates.

Table 3-86: Prime Airout 2 Substate

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0, Qac	45	5	0, 10 0*	0	Return	Return	Return	3000

<sup>\*</sup> DRBC tubing sets

Exit Condition	When 50 mL is processed by inlet pump.
----------------	--

#### **Blood Run Collection Substates**

The Blood Run state contains nineteen prime and collection substates and eleven recovery substates. This section describes the prime and collection substates.

# **Channel Setup Substate**

This substate continues to establish the interface until a predetermined inlet volume has been pumped. The pumps begin ramping up in speed during this substate. After completion of this substate, the Trima Accel system advances to Pre-Platelet Plasma, Pre-Platelet No Plasma, or Plasma Only substates depending upon the chosen procedure.

**Table 3-87: Channel Setup Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	Qin	0	Qplat 0*	0	Return	Return	Return	3000

<sup>\*</sup> DRBC tubing sets

Exit Condition	When a total of 200 mL is processed by the inlet pump.
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# Pre-Platelet Plasma (Pre-Platelet, Collecting Plasma) Substate

This substate occurs only in procedures where both platelets and plasma are collected. The plasma valve is commanded to the collect position and the plasma pump speed changes to regulate the RBC line hematocrit. The AC and inlet pump speeds change to keep the AC infusion rate at the run configured value. After enough inlet volume has been processed to stabilize the LRS chamber, the Trima Accel system advances to the Platelet Plasma substate or the Pre-Platelet No Plasma substate.

Table 3-88: Pre-Platelet Plasma Substate

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	Qin	Qplas	Qplat	Qret	Return	Collect	Return	3000
Fxit Condition When the target (donor-specific) volume is processed by the inlet nump								

# Pre-Platelet No Plasma (Pre-Platelet, No Plasma Collect) Substate

This substate occurs after the Channel Setup substate, in procedures where platelets, but not plasma, are collected. The AC and inlet pump speeds change to keep the AC infusion rate at the run configured value. After a predetermined inlet volume has been processed, the Trima Accel system advances to the Mid Run substate.

**Table 3-89: Pre-Platelet No Plasma Substate** 

Qac   Qin   Qplas   Qplat   Qret   Return   Return   Return   3000	AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
	Qac	Qin	Qplas	Qplat	Qret	Return	Return	Return	3000

Exit Condition When the target (donor-specific) volume is processed by the inlet pump.

# Platelet Plasma (Concurrent Platelet Plasma) Substate

This substate occurs after the Pre-Platelet Plasma substate in procedures where both platelets and plasma are collected. The platelet valve now opens while the plasma valve remains open until the volume target is achieved. If the plasma volume target is small, the plasma valve closes and the Trima Accel system advances to the Mid Run substate. If the volume target is large, the plasma valve remains open and the Trima Accel system advances to the Extended Plasma substate.

**Table 3-90: Platelet Plasma Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	Qin	Qplas	Qplat	Qret	Collect	Collect	Return	3000

<sup>\*</sup> DRBC tubing sets

Exit Condition	When the target (procedure-specific) volume is collected in the plasma bag.
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## Plasma Only (Plasma Only Collect) Substate

This substate occurs after the Channel Setup substate in plasma/RBC procedures where plasma is collected. The plasma valve opens and remains open until the plasma target volume is achieved. After completion of this substate, the Trima Accel system advances to the RBC Collect substate if RBC is chosen.

**Table 3-91: Plasma Only Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	Qin	Qplas	Qplat	Qret	Return	Collect	Return	3000
Exit Condition When the target (procedure-specific) volume is collected in the plasma bag.								

## PCA (Platelet Concentration Adjustment) Substate

This substate occurs after all plasma is collected during the Platelet Plasma substate. This substate only occurs if the Trima Accel system calculates that the volume in the platelet bag will be lower than it should be by a predetermined volume after the Mid Run substate. This usually occurs when the concurrent

plasma product collected is a small or medium product. During this substate the plasma valve moves to the return position and adds plasma to the platelet bag to reach the needed volume. When the target volume is added to the platelet bag, the Trima Accel system advances to the Mid Run substate.

**Table 3-92: PCA Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	Qin	Qplas	Qplat	Qret	Collect	Return	Return	3000

Exit Condition

When the target (donor-specific) volume is collected in the platelet bag.

# Mid Run (Platelet Only Collection) Substate

This substate occurs after the Platelet Plasma substate (and the Platelet Concentration Adjustment substate, if it occurs) to collect the remainder of the platelet product needed to reach the target yield. This substate only occurs if more collected platelets are needed after the Concurrent Platelet Plasma substate. During this substate the plasma pump runs slowly.

**Table 3-93: Mid Run Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	Qin	Qplas	Qplat	Qret	Collect	Return	Return	3000
Fxit Co	ndition	When the tai	raet (donor-sn	ecific) volum	e is collected	in the platele	t han	

## PIR (Platelet Inventory Recovery) Substate

This substate occurs after the Mid Run substate if the collect flow is less than a predetermined rate during Platelet Only Collection. Otherwise, the Trima Accel system skips this substate and advances to the Extended PCA substate. During Platelet Inventory Recovery the platelet pump ramps up in speed to its maximum value and continues running until predetermined platelet volume has been pumped. The Trima Accel system advances to the Extended PCA substate.

**Table 3-94: PIR Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	Qin	Qplas	Qplat	Qret	Collect	Return	Return	3000
Exit Co	ndition	When the tar	get (donor-sp	ecific) volum	e is collected	in the platele	t bag.	

# Extended PCA (Extended Platelet Concentration Adjust) Substate

This substate occurs after the Platelet Plasma substate (and the Mid Run substate if it occurs) and prior to collecting additional plasma. It only occurs if the Trima Accel system calculates that the volume in the platelet bag is lower than it should be by a predetermined volume or more after the Mid Run substate. This usually occurs when the concurrent plasma product collected is a large product. During this substate the plasma valve moves to the return position and adds plasma to the platelet bag to reach the needed volume. When the target volume is added to the platelet bag, the Trima Accel system advances to the Extended Plasma substate.

**Table 3-95: Extended PCA Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	Qin	Qplas	Qplat	Qret	Collect	Return	Return	3000

**Exit Condition** When the target (donor-specific) volume is collected in the platelet bag.

#### Extended Plasma (Extended Plasma Collection) Substate

This substate occurs after all platelets are collected and additional plasma is necessary to achieve the plasma target. The platelet valve closes and the plasma valve moves to the collect position. After the plasma target is achieved, the Trima Accel system advances to the RBC Collect substate if RBC is chosen.

**Table 3-96: Extended Plasma Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	Qin	Qplas	Qplat	Qret	Return	Collect	Return	3000

**Exit Condition** When the target (donor-specific) volume is collected in the plasma bag.

RBC PTF Setup 1 Substate

**Table 3-97: RBC PTF Setup 1 Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	Qin	Qplas	Qplat	Qret	Return	Return	Return	3000

**Exit Condition** When the target volume is processed by the inlet pump.

# **RBC PTF Setup 2 Substate**

Table 3-98: RBC PTF Setup 2 Substate

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	Qin	Qplas	Qplat	Qret	Return	Return	Return	3000

**Exit Condition** When the target volume is processed by the inlet pump.

# RBC Collect (RBC Collection) Substate

If RBC collection is chosen, this substate occurs after all platelets and plasma are collected. The RBC valve opens until the RBC volume target is achieved. The inlet flow is limited by the configured AC ratio for RBC procedures.

#### **Table 3-99: RBC Collect Substate**

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	Qin	Qplas	Qplat	Qret	Return	Return	Collect	3000

**Exit Condition** When the target (donor-specific) volume is collected in the RBC bag.

# Pre Rinseback (Prepare for Rinseback) Substate

This substate occurs in both platelet/plasma/RBC procedures and DRBC procedures. All valves move to the return position and all pumps are commanded to zero. When these actions successfully complete, the Trima Accel system advances to the Blood Rinseback state.

#### **Table 3-100: Pre Rinseback Substate**

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Return	Return	Return	3000

Exit Condition When the pumps and valves are detected at the commanded speed and position within 10 seconds.

# **Blood Run Recovery Substates**

The Blood Run state contains eleven recovery substates. Recovery substates interrupt the procedure and suspend the procedure time clock.

When the recovery routine completes, the Trima Accel system returns to the procedure substate that it was in prior to recovery. These recovery substates can occur at any time during the Blood Run state. Only one recovery substate happens at a time. Descriptions of the recovery substates follow.

# RBC Spillover (Spillover Recovery) Substate

Spillover recovery can be entered via a command from the operator (by pressing the **Spillover** button on the Adjust screen) or automatically when detected by the RBC detector. This substate triggers the WBC Chamber Purge substate followed by the Clear Line substate (see the description for these recovery substates on next page). At the end of spillover recovery, the RBC detector checks for the presence of a spillover and regenerates the recovery procedure if a spillover persists.

# Pumps Pause (Pause Recovery) Substate

This recovery occurs when the pumps are paused for more than 6 seconds. After the inlet pump processes a predetermined inlet volume, the pumps return to their original collection values and the Trima Accel system returns to the previous blood run substate.

## Air Block (Air Block Recovery) Substate

This recovery is initiated when the operator presses the **Air in Plasma Line** button on the Adjust screen. The centrifuge speed lowers to a predetermined speed, all valves close, and the pump speeds lower to remove the air block. The plasma pump runs at a predetermined speed, maintaining chamber flow, until a predetermined volume of plasma has been pumped. The system then transitions to the Centrifuge Stop substate.

## Centrifuge Stop (Centrifuge Stop Recovery) Substate

This recovery procedure occurs anytime after the centrifuge stops (or drops below a predetermined speed). This recovery procedure takes precedence over the other recovery procedures. The centrifuge ramps up to its final commanded speed while the pumps are maintained at low speeds to prevent the occurrence of a spillover or air block. When the centrifuge reaches the commanded speed plus 60 more seconds, the pumps return to their normal collection speeds.

## Centrifuge Slow (Centrifuge Slow Recovery) Substate

This recovery substate occurs if the centrifuge actual speed drops below a predetermined speed, but is greater than a predetermined speed. The centrifuge ramps up to 3000 rpm and this recovery continues for 15 more seconds.

# Saline Bolus (Saline Bolus Recovery) Substate

This substate occurs whenever a saline bolus is administered. The platelet pump runs at a predetermined speed until a predetermined volume of saline bolus is delivered. At the same time the return pump runs at the same speed to keep the reservoir volume approximately even. After a predetermined volume of saline has been pumped, the Trima Accel system resumes the draw or return cycle that it was previously in.

# Saline Prime (Replacement Fluid Priming Recovery) Substate

This substate occurs the first time replacement fluid is administered in an RBC/Plasma procedure. The platelet pump runs at a predetermined speed until a predetermined volume of saline is pumped to prime the replacement fluid line.

# WBC Chamber Purge (WBC Chamber Purge Recovery) Substate

This substate occurs during any procedure where a spillover recovery occurs or a very large inlet volume is processed. The plasma pump increases in speed and the platelet pump stops, purging volume from the LRS chamber. This continues until a predetermined plasma volume is pumped through the LRS chamber.

## RBC Chamber Purge (RBC Chamber Purge Recovery) Substate

This substate occurs during any procedure where a platelet, plasma, RBC tubing set is loaded. This recovery substate always occurs at the beginning of the Channel Setup substate. The plasma pump runs at a predetermined speed and the platelet pump stops, purging volume from the LRS chamber. This continues until a predetermined plasma volume is pumped.

#### Plasma Valve Motion (Plasma Valve Move Recovery) Substate

This substate occurs whenever the plasma valve changes position during a platelet collection procedure. This recovery stops the pumps for one second while the valve moves to prevent fluid from entering the plasma bag while the valve moves through the open position.

## Settle Channel Substate

This substate occurs only after the WBC Chamber Purge substate. This substate settles the cells in the channel prior to resuming collection. During this recovery the inlet pump flow rate decreases to less than a predetermined amount and pumps a predetermined inlet volume.

## Clear Line Substate

This substate occurs after WBC Purge recoveries. It functions to clear RBC/WBC out of the platelet line. The inlet, platelet, and plasma pumps are limited to predetermined speeds. This substate ends when a predetermined platelet volume has been pumped.

## **Rinseback State**

The Rinseback state returns the donor's blood. Variations include plasma or saline assisted rinseback.

The hematocrit in the RBC line is configured to maximize blood return. This system state ends when the lower-level sensor detects air. Successful completion of the Blood Rinseback state results in the following conditions and actions.

Exit Condition	Trima Accel System Condition	Trima Accel System Action
All Blood Rinseback substates are completed.	Under algorithm control.	The Trima Accel system advances to the Donor Disconnect state.

#### **Rinseback Substates**

The Rinseback substates evacuate the channel and return remaining blood to the donor.

## Rinseback Lower (Rinseback Lower Reservoir) Substate

All valves are commanded to the return position and the inlet, AC, plasma, and platelet pumps are commanded to zero. The return pump runs until air is present at the lower-level sensor, or a predetermined volume of return has been pumped. The Trima Accel system then advances to the Rinseback Recirculate substate.

**Table 3-101: Rinseback Lower Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	Qret	Return	Return	Return	3000

Exit Condition	When the lower-level sensor detects air or 10 mL processed by the return pump.
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#### Rinseback Recirculate Substate

The inlet and return pumps are commanded to predetermined speeds to recirculate the blood in the channel before returning it to the donor. After a predetermined inlet volume is processed, the Trima Accel system advances to the Rinseback substate.

**Table 3-102: Rinseback Recirculate Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	100	Qplas	Qplat	100	Return	Return	Return	3000

Exit Condition	When 50 mL is processed by the inlet pump.

## Rinseback (Rinseback Return) Substate

The centrifuge is commanded to zero. The inlet pump is also commanded to zero and the plasma, platelet, and return pumps run until the lower-level sensor sees air and a predetermined return volume is processed. When this occurs, the Trima Accel system advances to the Disconnect Prompt substate.

**Table 3-103: Rinseback Substate** 

AC Pu (mL/r	·	'   Pump	Pump	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	Qplas	Qplat	Qret, 0	Return	Return	Return	0

Exit Condition When the lower-level sensor detects air or 20 mL processed by the return pump.

# **Disconnect Prompt Substate**

The pumps all stop and the Disconnect Prompt screen prompts the operator to press **Continue** to disconnect the donor. When the operator presses **Continue**, the Trima Accel system advances to the Donor Disconnect state. If the operator does not respond to the prompt in 10 minutes, the Trima Accel system automatically advances to the Donor Disconnect state.

**Table 3-104: Disconnect Prompt Substate** 

	C Pump nL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0		0	0	0	0	Return	Return	Return	0

Exit Condition When the operator touches Continue or 10 minutes have passed.

## **Donor Disconnect State**

The Donor Disconnect state checks that the operator has correctly clamped off the donor access line prior to disconnecting the donor. When the Disconnect Test substate is complete, the cassette is unloaded.

This state ends when the disconnect test successfully passes and the cassette is unloaded, or when the test fails three consecutive times, warning the operator. Successful completion of the Donor Disconnect state results in the following conditions and actions.

Exit Condition	Trima Accel System Condition	Trima Accel System Action		
The disconnect test has passed once and the cassette has been unloaded, or the test failed three consecutive times and the cassette has been unloaded.	Paused.	The Trima Accel system proceeds to either the Post Run state or the Metered Storage Solution (MSS) state, depending on configuration.		

#### **Donor Disconnect Substates**

The Donor Disconnect state consists of five substates: Disconnect Test, Open Valves, Start Pumps, Raise Cassette, and Stop Pumps. If MSS is configured on, the cassette is **not** unloaded after the donor is disconnected.

## **Disconnect Test Substate**

The inlet pump is commanded to a predetermined speed, and the Trima Accel system waits to verify that the access pressure drops by a predetermined amount within 30 seconds. Then the system checks that the pressure does not decay by more than a predetermined amount within the following 10 seconds. If both tests fail, a disconnect test alert is displayed and the Trima Accel system repeats the test. The operator is prompted to repeat the test. If it fails twice again, a disconnect test alarm is generated and the operator is allowed to unload the cassette by pressing **Continue** and **Confirm Disconnect**.

**Table 3-105: Donor Disconnect Test Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	50, 0	0	0	0	Return	Return	Return	0

# Open Valves Substate

All valves are moved to their open positions. When the valve position sensors sense all three open positions, the Trima Accel system advances to the next substate.

**Table 3-106: Open Valves Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Open	Open	Open	0

**Exit Condition** When the valves are detected in the commanded position within 10 seconds.

# Start Pumps Substate

All pumps are commanded to their unload speeds.

#### **Table 3-107: Start Pumps Substate**

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
60	60	60	60	150	Open	Open	Open	0

Exit Condition When the pumps are detected at commanded speed within 10 seconds.

#### Raise Cassette Substate

The cassette is commanded to the raised position while the pumps are running at their unload speeds. When the cassette is detected in the raised position, the Trima Accel system advances to the next substate.

#### **Table 3-108: Raise Cassette Substate**

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
60	60	60	60	150	Open	Open	Open	0

Exit Condition When the cassette plate is detected in the up position.

# Stop Pumps Substate

The pumps are commanded to stop and the operator is prompted to press **Continue**. When the operator presses **Continue**, the Trima Accel system advances to the Post Run state.

**Table 3-109: Stop Pumps Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Open	Open	Open	0

# **Metered Storage Solution State**

The Metered Storage Solution (MSS) state administers the automatic addition of metered storage solution.

This system state begins when the Trima Accel system determines if the run is a normal metered storage run or a "salvage case." This is determined by flags during the Rinseback protocols. A "salvage case" is defined as a run where the machine does not return sufficient volume from the reservoir and channel back to the donor. If the run is a "salvage case," the machine will flag the final product for possible WBC contamination. Successful completion of the Metered Storage Solution state results in the following conditions and actions.

Exit Condition	Trima Accel System Condition	Trima Accel System Action
All MSS substates are completed.	Paused.	The Trima Accel system proceeds to the MSS Disconnect state.

#### **Metered Storage Solution Substates**

Metered Storage Solution substates administer metered storage solution to the collected product.

## MSS Setup (Metered Storage Solution Setup) Substate

This substate waits for the operator to confirm or cancel the automatic metered storage procedure. This state transitions upon receiving message to continue from the GUI task.

**Table 3-110: MSS Setup Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Return	Return	Return	0
Exit Condition When the operator touches the Continue button.								

# MSSPFR (Metered Storage Solution Power Fail Recovery) Substate

This substate recovers from a power failure. It will branch to the last substate being executed at the time of the failure. This substate generates no alarms or alerts.

**Table 3-111: MSSPFR Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Return	Return	Return	0

# Verify Closure (Verify Channel Clamps are Closed) Substate

This substate verifies that the channel clamps are closed. It runs the pumps to see if fluid can be pulled from the channel. If fluid is pulled from the channel into the reservoir, a channel clamp alert is generated and the product is flagged for WBC contamination. This alert is generated a maximum of two times in this substate. The operator is then allowed to continue after the second alert. This substate is not executed if it is a salvage case MSS run.

**Table 3-112: Verify Closure Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	27	0	18.4	27	Return	Return	Return	0

**Exit Condition** When fluid is not detected by the AC detector and APS is greater than 250 mmHg.

# Reservoir Setup Substate

This substate empties the reservoir. The return pump runs until the lower-level sensor detects air. This state is not executed if this is determined to be a salvage case MSS run. (Reservoir Setup\_2 is identical to Reservoir Setup except for the name).

**Table 3-113: Reservoir Setup Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	27, 0	0	0	27, 0	Return	Return	Return	0

Exit Condition When the lower-level sensor detects air.

#### MSS Connect Substate

This substate waits for the operator to confirm that PAS and/or RAS storage solutions are connected. This state calculates the correct amount of storage solution to be metered to the product based on the actual collected volume and the Plasma-Percent carryover. This substate also calculates the estimated storage solution used for the MSS run (prime, addition, and purging) and sends it to the GUI task. The substate will exit upon receiving message to continue from the GUI task.

**Table 3-114: MSS Connect Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Return	Return	Return	0

Exit Condition When the operator touches the Continue button.

## MSS Prime Substate

This substate primes the system with storage solution. The Trima Accel system monitors the APS during these substates. If the APS raises above the configured value, the state will pause and run the inlet pump to relieve the pressure. The MSS Prime substate consists of five subordinate substates.

# Reservoir Setup 2

This substate empties the reservoir. The return pump will run until the lower-level sensor detects air.

**Table 3-115: Reservoir Setup 2 Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	27, 0	0	0	27, 0	Return	Return	Return	0

Exit Condition When the lower-level sensor detects fluid.

# Reservoir Setup 3

This substate empties the reservoir. The return pump will run until the lower-level sensor detects air.

**Table 3-116: Reservoir Setup 2 Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	27, 0	0	0	27, 0	Return	Return	Return	0

**Exit Condition** When the lower-level sensor detects fluid.

#### MSS RBC Prime 1

This substate primes the cassette with RAS. The pumps run until the lower-level sensor detects fluid. The fluid must be detected before a version-specific predetermined amount of fluid is processed by the pumps.

Table 3-117: MSS RBC Prime 1 Substate

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
50	45, 0	0	0	45, 0	Return	Return	Return	0

**Exit Condition** When the lower-level sensor detects fluid.

# MSS PLT Prime Salvage

This substate is only executed in the event of an MSS salvage case. A salvage case is determined by the amount of fluid processed during Rinseback.

Table 3-118: MSS PLT Prime Salvage Substate

AC Pu (mL/n	•   •	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	60	60	0	Return	Return	Return	0

Exit Condition When the lower-level sensor detects fluid.

# MSS RBC Prime Salvage

This substate is only executed in the event of an MSS salvage case. A salvage case is determined by the amount of fluid processed during Rinseback.

**Table 3-119: MSS RBC Prime Salvage Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
50	0	0	0	0	Return	Return	Return	0

**Exit Condition** When the lower-level sensor detects fluid.

#### MSSPLTPrime1

This substate primes the cassette with the storage solution. The state alarms if the lower-level sensor sees fluid too soon (mss prime too soon) or too late (mss prime delay). This state will not be executed during a MSS salvage case.

Table 3-120: MSSPLTPrime1 Substate

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	54	60	60	54	Return	Return	Return	0

Exit Condition When the lower-level sensor detects fluid.

#### MSSPLTPrime2

This substate completes the priming of the storage solution through the cassette.

#### **Table 3-121: MSSPLTPrime2 Substate**

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0, 30	0	0	Return	Return	Return	0

**Exit Condition** When the target (procedure-specific) volume is processed by the platelet pump.

# MSS Parallel Processing

## **Table 3-122: MSS Parallel Processing Substate**

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	R/C*	Return	R/C*	0

<sup>\*</sup>Return, unless delivering storage solution, then closed.

# VacPurge

This substate purges the set of contaminants. It will run the vacuum purge algorithm a version-specific predetermined number of times.

## Table 3-123: VacPurge

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	Qplas	Qplat	0	Return	Return	Return	0

Exit Condition When the target (procedure-specific) volume is processed by the platelet and plasma pumps.

## **PAS Final Flow Verification**

This substate will fill the reservoir to a full state if it is not already.

## **Table 3-124: PAS Final Flow Verification**

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	110	110	0	Return	Return	Return	0

Exit Condition When the upper-level sensor detects fluid.

# VacPurgeFinal

This substate moves the platelet valve to the collect position. If it is a non-salvage case, it will flush the portion of the cassette below the platelet valve.

Table 3-125: VacPurgeFinal

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	R/0/C*	Return	Return	0

<sup>\*</sup> Commands the platelet valve slowly from return to open to closed.

# MSSPLTAdditionPause (MMS Platelet Addition Pause) Substate

This substate waits for the operator to confirm that the platelet bag has been clamped. Otherwise, the automatic metered storage solution addition is cancelled. This state transitions upon receiving message to continue from the GUI task.

Table 3-126: MSSPLTAdditionPause Substate

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Closed	Return	Return	0

Exit Condition	When the operator touches the <b>Continue</b> button.
----------------	---

## MSSPLTAddition

This substate runs the platelet and plasma pumps to deliver the calculated amount of storage solution to the platelet product.

**Table 3-127: MSSPLTAddition Substate** 

AC Pu (mL/m		Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	Qplas	Qplat	0	Closed	Return	Return	0

<b>Exit Condition</b> When the target (procedure-specific) volume is processed by the platelet and plasma pumps.
--

## **MSSRBCAddition**

This substate runs the AC pump to deliver the calculated amount of storage solution to the RBC product.

**Table 3-128: MSSRBCAddition Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Ramp to 70	0, 10	0	0	0	Return	Return	Closed	0

Exit Condition	When the target (procedure-specific) volume is processed by the AC pump.
----------------	--

#### MSS Disconnect Substate

The substate waits for the operator to confirm the storage solution is disconnected.

**Table 3-129: MSS Disconnect Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Return	Return	Return	0

Exit Condition	When the operator touches the <b>Continue</b> button.
----------------	---

# **Metered Storage Solution Disconnect State**

The MSS Disconnect state checks that the operator has correctly sealed the product and additive solution bags following the MSS state.

Upon completion of the MSS state, the Trima Accel system waits for the operator to confirm the products and storage solution have been disconnected. After the operator confirms this information, the system unloads the cassette and proceeds to the Post Run state.

Exit Condition	Trima Accel System Condition	Trima Accel System Action
The operator pressed the <b>Continue</b> button.	Paused.	The Trima Accel system prompts the operator to remove the disposable set. The Trima Accel system unloads the cassette and proceeds to the Post Run state.

#### **MSS Disconnect Substates**

Upon completion of the MSS state, the Trima Accel system waits for the operator to confirm the products and storage solution have been disconnected. After the operator confirms this information, the system unloads the cassette and proceeds to the Post Run state.

# Open Valves Substate

All valves are moved to their open positions. When the valve position sensors sense all three open positions, the Trima Accel system advances to the next substate.

**Table 3-130: Open Valves Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Open	Open	Open	0

Exit Condition When the valves are detected in the commanded position within 10 seconds.

# Start Pumps Substate

All pumps are commanded to their unload speeds.

## **Table 3-131: Start Pumps Substate**

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
60	60	60	60	-110	Open	Open	Open	0

Exit Condition When the pumps are detected at commanded speed within 10 seconds.

#### Raise Cassette Substate

The cassette is commanded to the raised position while the pumps are running at their unload speeds. When the cassette is detected in the raised position, the Trima Accel system advances to the next substate.

**Table 3-132: Raise Cassette Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
60	60	60	60	-110	Open	Open	Open	0

Exit Condition When the cassette plate is detected in the up position.

# Stop Pumps Substate

The pumps are commanded to stop and the operator is prompted to press **Continue**. When the operator presses **Continue**, the Trima Accel system advances to the Post Run state.

**Table 3-133: Stop Pumps Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Open	Open	Open	0

# **Post Run State**

The Post Run state displays end-of-run statistics.

The Post Run state ends when the operator touches the **Next Procedure** button. Successful completion of the Post Run state results in the following conditions and actions.

Exit Condition	Trima Accel System Condition	Trima Accel System Action		
The operator touches the <b>Next Procedure</b> button.	Paused.	The Trima Accel system reboots and advances to the Self Tests state.		

# **Version 6.1 Software Description**

# **Trima Accel Software Description**

This section describes the Trima Accel system software.

The Trima Accel system operates automatically, performing many individual steps to complete the entire blood component collection procedure. The collection procedure consists of separate and sequential system states, some of which contain substates. Within each substate, the system performs a series of tasks.

When an alarm or error occurs, the Data Log (DLog) file captures the system state and hardware information related to that alarm. Compare the information in the Data Log file with the information in this chapter to solve the alarm or error problem.

## **Self Test State**

The Self Test state starts boot sequence starts with the BIOS self test. This is similar to a PC BIOS self test, and tests the major processor board components such as the CPU, interrupt controller, timer, and RAM.

If any of these tests fail, the system displays an error message and aborts the boot sequence. If all tests pass, control is passed to the boot device. The boot device then loads the vxWorks boot ROM image. The boot ROM image contains the software required for loading and starting the operating system. It provides a set of device drivers for accessing the storage device or network device through which the operating system is loaded.

When the boot ROM image is executed, it first tests for the presence of a keyboard. If a keyboard is attached, the system enables the loading of a debug vxWorks image that includes the necessary software components for using the WindRiver development and debugging tools. If the **Esc** key is pressed, the system enters an alternate boot mode in which booting is stopped immediately after loading the OS image and drivers. This is signified with a prompt that looks like an arrow: "->." Note that a login or password is not required when using the keyboard to execute commands from the command line. The login and password are required to upload files to the machine via FTP.

The OS software uses the pause and stop keys to select Single-Step boot and Service mode. In Single-Step mode, the system pauses and waits for the technician to press the pause button after each step of the boot sequence is completed; otherwise the boot proceeds normally. During Single-Step mode, the technician can login to the machine via FTP after the message "initializing network software" appears on the screen. Service mode is used for software installation, updates, and machine maintenance.

During the network initialization process, the system start mode is determined: normal boot, Service mode, or Alt Boot mode. If the system start mode is normal, then the safety board MAC address in the control computer ARP table is made permanent. This removes any possibility that an ARP update from the external network interface could overwrite it. Overwriting that MAC address would prevent the control computer from communicating with the safety computer. Note that this protection is not provided in Service mode or Alt Boot mode to aid in system troubleshooting.

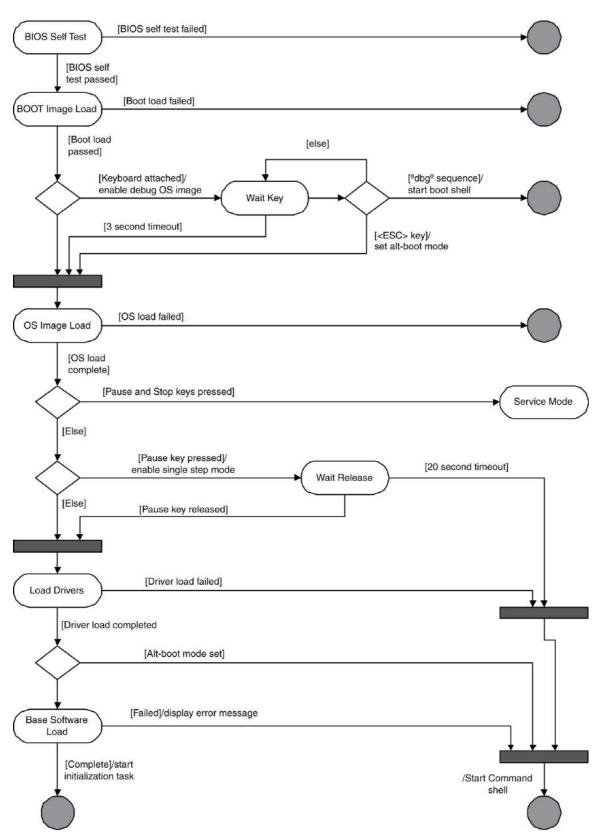


Figure 3-5: Trima Accel boot sequence

# **Power Fail Recovery State**

The PFR state allows the Trima Accel system to restore data if a power failure occurs during a procedure.

This state begins with a handshake across domain boundaries between control and safety computers. The Trima Accel system tries to restore data (in the power fail save file) from a previous procedure if there is any valid data. If there is valid data, the Trima Accel system performs the power tests that are normally performed in the Startup Tests state and then restores the previous data. After restoring the data, the Trima Accel system allows the operator a choice to continue with or discontinue the collection procedure. The rules for continuation from a power fail situation follow:

- If the power failure occurs during the Startup Tests state through the AC Prime, Rinseback, or Donor Disconnect states, recovery is not allowed. The operator must unload the set.
- If the power failure occurs during the Donor Connected state, the operator can continue or end the collection procedure.
- If the power failure occurs in the return cycle during the Blood Prime and Blood Run system states, the operator can continue, rinseback, or end the collection procedure with no time restraint.
- If the power failure occurs during the draw cycle of the Blood Run or Blood Prime states, the operator can continue, rinseback, or end the collection procedure if the PFR screen is restored within 9.5 minutes. If power is not restored within 9.5 minutes, the operator can only end the collection procedure.
- If the power failure occurs during the Rinseback state, the operator can rinseback or end the collection procedure.

Successful completion of PFR state results in the following conditions and actions.

Termination Condition	Trima Accel System Condition	Trima Accel System Action
PFR data successfully saved and restored if valid.	Pause.	If there is no valid PFR data, the Trima Accel system proceeds automatically to the startup tests in the Startup Tests state. If there is valid PFR data, the Trima Accel system proceeds to the power tests in the Startup Tests state.

# **Startup Tests State**

The Startup Tests state performs the Trima Accel system's mandatory startup tests.

This state follows the Power Fail Recovery (PFR) state. It contains tasks that start in this state and continue until the Donor Connected state. The Startup Test state ends when all tests are successfully completed.

The startup tests are executed before a disposable tubing set is loaded and before the donor is connected. These tests ensure that the Trima Accel system is operational, that the critical safety features are in place, and that computer redundancy is functioning. During power fail recovery situations only some of the tests are performed to ensure safety of the already-connected donor. Startup tests include the following activities:

- Test if the safety system can disable power to pumps and centrifuge.
- Test the cassette position function (up and down) at both the control and safety computers.

- Test the valve position sensing (both control and safety computers) in all three positions for each valve.
- Test if the lower-level sensor registers air continuously at both the control and safety computers.
- Test if the AC level sensor registers air continuously.
- Test the safety system centrifuge rpm sensor (Halls) for commanded and zero speed.
- Test if the control computer can stop the centrifuge.
- Evacuate air from the collection bags.

Successful completion of Startup Tests state results in the following conditions and actions.

Exit Condition	Trima Accel System Condition	Trima Accel System Action
All startup tests have passed.	Pause.	The Trima Accel system advances to the Disposable Tests state.

# **Startup Tests Substates**

The Startup Tests substates test the safety system, cassette and valve position function, lower-level and AC level sensors, centrifuge Hall sensor, and centrifuge control. The cassette is lowered, the tubing set type is verified, and air is evacuated from the collection bags.

#### **CPUID Test Substate**

First, this substate tests the available memory on the control and safety computers. If the memory is insufficient, an alarm is generated. Next, this substate checks that the control and safety CPU type matches one of those listed in the hw.dat file. If the CPU type does not match, an alarm is generated. If a valid power fail recovery condition or a new collection procedure condition is detected, the Trima Accel system advances to the Power Test substate.

#### Calib Verification (Calibration Check) Substate

This substate checks that the cal.dat file values for access pressure, centrifuge pressure, and RBC detector are different values than the defaults. If any one (or more) are the same as the default values, then a "cal.dat xxxx not calibrated" alarm is generated.

#### **Power Test Substate**

Prior to beginning this test, the Trima Accel system verifies that the disposable tubing cassette is in the unloaded position. If not, the Trima Accel system advances directly to the Donor Disconnect system state. If the cassette is in the unloaded position, the safety computer checks for the presence and limits of the 24-volt and 64-volt DC power supplies. The 24-volt and 64-volt DC supplies are then disabled and re-enabled to confirm safety computer's control over them. The second part of the power tests turns the 24-volt and 64-volt power supplies on, commands the pumps to zero, and ensures that they are not moving. At the end of this substate, the 24-volt switch remains ON and the 64-volt switch is turned OFF. If any test fails, an alarm is generated, and the Trima Accel system resumes at the beginning of Startup Tests. If all conditions are met, the Trima Accel system advances to the Valves Test substate.

#### Valves Test Substate

The RBC, plasma, and platelet valves are moved sequentially to all three of their possible positions. If any of the positions cannot be reached within 10 seconds, an alarm is generated and the Trima Accel system resumes at the beginning of the Startup Tests state. If this test passes, the Trima Accel system advances to the Leak Detector Test substate.

#### Leak Detector Test Substate

The leak detector output voltage is checked to verify that it is open and can detect fluid leaks. If this test fails, an alarm is generated. If this test passes, the Trima Accel system advances to the CentShutdown substate.

### CentShutdown Test (Centrifuge Shutdown) Substate

The control computer first checks the 64-volt DC to see if it is within range. Then the Trima Accel system commands the centrifuge to zero and verifies immobility for two seconds. If this test fails, an alarm is generated. If this test passes, the Trima Accel system advances to the Door Latch Test substate.

#### **Door Latch Test Substate**

These tests check that the door can be seen as both open and closed by the door lock optical and Hall sensors. The 24-volt switch dedicated to the door solenoid is also checked to ensure that it can be turned off. If these tests fail an alarm is generated. If these tests pass, the **Load System** button is enabled. There is also a test to check the ability of the software to lock and unlock the door without power. This test locks the door and waits to see if it locks even when the power is supposed to be off. If the door is in the locked state, the alarms are given and the tests are tried again.

#### GUI Started (Load System Button) Substate

This substate is not a test but instead enables the **Load System** button and waits for the operator to press it and the **Continue** button from the subsequent screen. The **Donor Info** button also activates at this time.

#### Load Cassette Substate

After the operator presses the **Load System** button, the cassette is checked for the up position as seen by the optical sensor. The valves are also commanded to the open position. If they do not achieve the open position in ten seconds, an alarm is generated.

**Table 3-134: Load Cassette Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Open	Open	Open	0

Exit Condition When the operator touches the Continue button.

# Start Pumps Substate

This substate commands the pumps on individually to minimize voltage spikes. When all pumps have reached their commanded speed (± 5 mL/min), the Trima Accel system advances to the Lower Cassette substate.

**Table 3-135: Start Pumps Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
60	140	60	60	110	Open	Open	Open	0 or – 1

Exit Condition When the pumps are detected at the commanded speed within 10 seconds.

#### Lower Cassette Substate

In this substate the cassette is commanded down and the lower optical switch is checked to verify that the cassette achieves the loaded position. If this does not occur within 15 seconds, the "Cassette Error" alarm generates.

The access pressure sensor is auto-zeroed at this point.

**Table 3-136: Lower Cassette Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
60	140	60	60	110	Open	Open	Open	0

Exit Condition When the cassette plate is detected in the down position.

#### Cassette ID Substate

During this substate the RBC detector checks the cassette type to make sure that it is the proper cassette for the chosen collection procedure. If the cassette does not match the procedure, an alarm is generated. If the tubing set cannot be identified, but is within a valid range, a screen displays that allows the operator to choose the correct tubing set or load a new one. For white stamp cassettes only: During this substate the Trima Accel system begins calibration of the red and green reflection strengths of the RBC detector

to a ratio of one for spillover detection purposes. If the calibration fails, an alarm is generated. If these tests pass, the Trima Accel system advances to the Stop Pumps substate. RBC calibration does not take place for black stamp cassettes.

**Table 3-137: Cassette ID Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
60	140	60	60	110	Open	Open	Open	0

**Exit Condition** When the cassette stamp reflectance value is read.

#### Stop Pumps Substate

This substate commands the pumps to zero. When all pumps are zero, the Trima Accel system advances to Evacuate Set Valves substate. CPS auto-zero takes place here.

**Table 3-138: Stop Pumps Substate** 

AC Pui (mL/m	•   •	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Open	Open	Open	0

Exit Condition When the pumps are detected at the commanded speed within 10 seconds.

# Evacuate Set Valves (Set Valves for Evacuate) Substate

This substate changes the position of the valves in order to evacuate air from the set. For a platelet, plasma, or RBC set, the RBC valve moves to the return position and the other valves move to the open position. For all other sets, the RBC valve moves to the collect position and the plasma and platelet valves move to the open position. If the valves cannot achieve position in 10 seconds, an alarm is generated. When all valves achieve position, the Trima Accel system advances to the Evacuate Bags substate.

**Table 3-139: Evacuate Set Valves Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Open	Open	Return	0

**Exit Condition** When the valves are detected in the commanded position within 10 seconds.

# **Evacuate Bags Substate**

This substate removes air from the product bags. The return pump runs until a predetermined volume has been pumped (version specific). If the access pressure exceeds the alarm limit during this test, an alarm is generated and the Trima Accel system reverts to the previous substate. If the test passes, the Trima Accel system advances to the Lower Notification substate.

**Table 3-140: Evacuate Bags Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	90	Open	Open	Return	0

**Exit Condition** When 140 mL is processed by the return pump.

# Lower Notification (Cassette Position Message) Substate

This substate informs GUI of the cassette position (it should be down) to prepare for disposable tests. If the cassette is down, the Trima Accel system advances to the Disposable Tests substate.

**Table 3-141: Lower Notification Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Open	Open	Return	0

Exit Condition When the cassette down message is sent.

# **Disposable Tests State**

The Disposable Tests state performs tests designed to determine whether the disposable tubing set is properly loaded and functioning.

The disposable tests include the following activities:

- Checks for the correct tubing set and the proper loading of the disposable
- Checks the integrity of the set. The access pressure sensor checks both positive and negative pressure of the disposable set to ensure its usability
- Checks for AC, inlet, and return pump tubing occlusions
- Checks for proper access pressure sensor function

Successful completion of the Disposable Tests state results in the following conditions and actions.

Exit Condition	Trima Accel System Condition	Trima Accel System Action
All disposable tests have passed.	Pause.	The Trima Accel system prompts the operator to connect the AC line.

Trima Accel version 6.0 introduces new disposables that require a different set of disposable tests than previous software versions. During the Pressurize Inlet Line substate, the system determines which type of disposable is loaded on the system based on the pressure measured at the APS. If the APS reads less than 300 mmHg the set is recognized as a "RAS" set and the new disposable test tree is used. If the pressure is greater than 500 mmHg, the set is recognized as a "non-RAS" set and the original disposable tree is used.

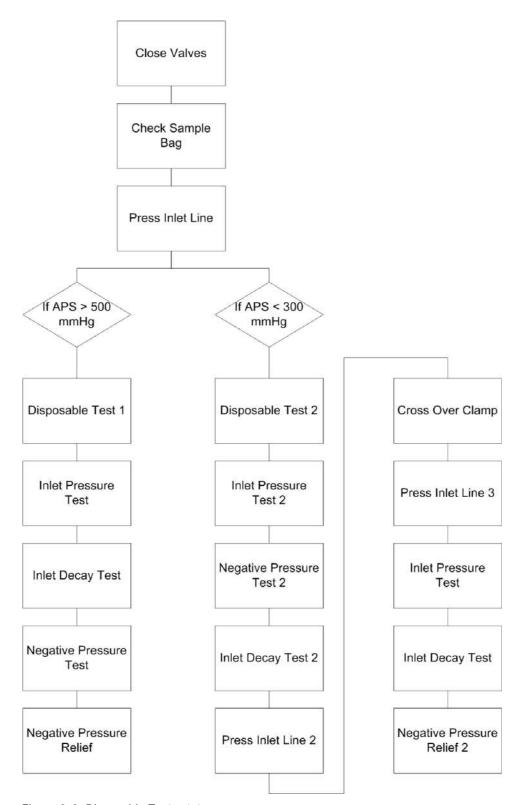


Figure 3-6: Disposable Tests state sequence

# **Disposable Test Substates**

The disposable tests are a sequential series of automated tests designed to ensure that the tubing set is properly loaded and functioning correctly. These tests also check the occlusions in the AC, inlet, and return pumps and the function of the access pressure sensor.

# Close Valves (Move Valves to Return Position) Substate

This substate commands the platelet, plasma, and RBC valves to the return position. If they do not achieve the return position, an alarm is generated. When all valves reach the return position, the Trima Accel system advances to the Press Inlet Line substate.

**Table 3-142: Close Valves Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Return	Return	Return	2000

Exit Condition When the valves are detected in commanded position within 10 seconds.

### Check Sample Bag Substate

This substate checks that the access pressure sensor is less than a predetermined value before the exit condition is met to check that the sample bag is closed.

**Table 3-143: Check Sample Bag Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Return	Return	Return	2000

**Exit Condition** When the APS is greater than 50 mmHg after 10 mL processed.

#### Press Inlet Line (Pressurize Inlet Test) Substate

This test runs the AC pump until a version-specific predetermined access pressure is reached. If the pressure limit is not reached, an alarm is generated. If the test fails, pressing the **Continue** button repeats this test. Pressing the **End Run** button unloads the cassette and returns to the beginning of the Startup Tests state.

**Table 3-144: Press Inlet Line Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
142	0	0	0	0	Return	Return	Return	2000

**Exit Condition** When the APS is greater than 400 mmHg before 50 mL processed by the AC pump.

#### Inlet Press Test (Inlet Line Pressure Test) Substate

This test stops all pumps and checks that the access pressure does not drop more than a version-specific predetermined amount. If the pressure drop exceeds the exit condition, an alarm is generated. If the test fails, pressing the **Continue** button repeats this test. Pressing the **End Run** button unloads the cassette and proceeds to the beginning of the Startup Tests state.

**Table 3-145: Inlet Press Test Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Return	Return	Return	2000

**Exit Condition** When there is less than 50 mmHg decrease in APS pressure since previous state in 3 seconds.

#### Inlet Press Test 2 Substate

This substate is the same as "Inlet Press Test (Inlet Line Pressure Test) Substate" on page 3-94, except with a different exit condition.

**Table 3-146: Inlet Press Test 2 Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Return	Return	Return	2000

**Exit Condition** When there is less than 50 mmHg decrease in APS pressure since previous state in 3 seconds.

# Inlet Decay Test (Pump Occlusion Test) Substate

This test commands the AC, return, and inlet pumps until each has achieved one-third of a revolution. The Trima Accel system advances to the Negative Press Test state if the exit condition is satisfied. If the test fails, pressing the **Continue** button returns to the Press Inlet Line substate. Pressing the **End Run** button unloads the cassette and returns to the beginning of the Startup Tests state.

**Table 3-147: Inlet Decay Test Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
20, 0	20, 0	0	0	-40, 0	Return	Return	Return	2000

**Exit Condition** When there is greater than 50 mmHg decrease in APS pressure after the pumps rotate.

# Inlet Decay Test 2

This substate is the same as "Inlet Decay Test (Pump Occlusion Test) Substate" on page 3-95, except with a different exit condition.

Exit Condition	When there is greater than 50 mmHg decrease in APS pressure after the pumps rotate.
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### **Table 3-148: Inlet Decay Test 2 Substate**

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
20	20	0	0	-40	Return	Return	Return	2000

#### Press Inlet Line 2 Substate

This substate is similar to "Press Inlet Line (Pressurize Inlet Test) Substate" on page 3-49, except with a different exit condition and pump speed.

Table 3-149: Press Inlet Line 2 Substate

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	400	Return	Return	Return	2000

Exit Condition When the APS is greater than 300 mmHg.

# Close Crossover Clamp Substate

This substate instructs the operator to close the crossover clamp on the disposable set and waits for confirmation.

**Table 3-150: Close Crossover Clamp Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Return	Return	Return	2000

**Exit Condition** When the operator touches the **Continue** button.

#### Press Inlet Line 3 Substate

This substate is the same as "Press Inlet Line (Pressurize Inlet Test) Substate" on page 3-94, except with a different exit condition.

Table 3-151: Press Inlet Line 3 Substate

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
142	0	0	0	0	Return	Return	Return	2000

**Exit Condition** When the APS is greater than 500 mmHg before 50 mL is processed by the AC pump.

### Negative Press Test (Negative Pressure Test) Substate

This test commands the inlet pump until the access pressure sensor reading is less than a version-specific predetermined amount. If the pressure is reached before the exit condition, the Trima Accel system advances to the Negative Press Relief substate. If the test fails, pressing the **Continue** button returns to the Press Inlet Line substate. Pressing the **End Run** button unloads the cassette and proceeds to the beginning of the Startup Tests state.

**Table 3-152: Negative Press Test Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	142	0	0	0	Return	Return	Return	2000

Exit Condition When the APS is less than -350 mmHg before 115 mL is processed by the inlet pump.

### **Unlock Door Substate**

This substate unlocks the centrifuge door after the disposable tests.

**Table 3-153: Negative Press Test Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Return	Return	Return	2000

**Exit Condition** When the centrifuge door lock is detected as unlocked.

### Negative Press Relief (Negative Pressure Relief) Substate

This final disposable test substate commands a pump until the access pressure sensor reading is greater than a version-specific predetermined amount. If this does not occur before the exit condition, an alarm is generated. When this pressure is achieved, the disposable tests are complete, and the Trima Accel system advances to the AC Connected state.

**Table 3-154: Negative Press Relief Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0 90*	Return	Return	Return	0

\*Version 6.1.2

**Exit Condition** When the APS is greater than -50 mmHg before 50 mL is processed by the AC pump.

### Negative Press Relief 2 Substate

This substate is similar to "Negative Press Relief (Negative Pressure Relief) Substate" on page 3-97, except with a different exit condition and pump speed.

**Table 3-155: Negative Press Relief 2 Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	-50	Return	Return	Return	0

**Exit Condition** When the APS is greater than 500 mmHg before 50 mL is processed by the AC pump.

# **AC Connected State**

The AC Connected state prompts the operator to attach the AC container to the tubing set and load the AC tubing into the AC detector.

The AC Connected state ends when the operator touches the **Continue** button. Successful completion of the AC Connected state results in the following conditions and actions.

Exit Condition	Trima Accel System Condition	Trima Accel System Action
The operator touches the <b>Continue</b> button.	Pause.	The Trima Accel system advances to the AC Prime state.

If performing an RBC collection procedure, touching the **Continue** button advances the Trima Accel system to the Replacement Fluid screen, otherwise the Trima Accel system advances to the AC Prime state.

#### **AC Prime State**

The AC Prime state primes the AC line and a portion of the inlet and return lines with anticoagulant.

The AC air detector is tested for function during this state. This system state ends when all tests are successfully completed. Successful completion of the AC Prime state results in the following conditions and actions.

Exit Condition	Trima Accel System Condition	Trima Accel System Action
All tests have passed.	Pause.	The Trima Accel system prompts the operator to connect the donor.

#### **AC Prime Substate**

The AC Prime substates prime the AC line and a portion of the return line with ACD-A. AC sensor and access pressure tests are also performed.

### AC Prime Inlet (Prime Initial AC and Inlet Lines)

In this test, the AC and inlet pumps are commanded to process AC through the AC line. If the AC-level sensor does not see AC after a version-specific predetermined volume is pumped an alarm is generated. The test repeats a second time when the **Continue** button is pressed. If the test fails again, a prime failure

alarm is generated. If ACD-A is seen at the sensor, the AC and inlet pumps continue at the same speed until a version-specific predetermined volume of AC is pumped. After successful completion of this substate, the Trima System advances to the AC Press Return Line substate.

**Table 3-156: AC Prime Inlet Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
50 30*	50 30*	0	0	0	Return	Return	Return	0

<sup>\*</sup>If APS drops more than 20 mmHg

Exit Condition	When AC is detected before 5 mL processed by AC pump.
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# AC Press Return Line (Pressurize Return Line)

The AC and inlet pumps stop and the return pump is commanded to run until the access pressure sensor reads a version-specific predetermined amount. If the exit condition is not met, an alarm is generated. If pressure is achieved and the donor information is entered, the **Begin Donor Prep** button appears in the task bar at the bottom of the screen.

**Table 3-157: AC Press Return Line Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	-50	Return	Return	Return	0

**Exit Condition** When APS is less than or equal to -50 mmHg before 7 mL is processed by the return pump.

#### **Donor Connected State**

The Donor Connected state prompts the operator to connect the donor and take a blood sample. The 64-volt switch turns on and the control computer checks the centrifuge motor controller fault bit.

**Table 3-158: Donor Connected State** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Return	Return	Return	0

Successful completion of the Donor Connected state results in the following conditions and actions.

Exit Condition	Trima Accel System Condition	Trima Accel System Action
The operator touches the <b>Continue</b> button.	Pause.	The Trima Accel system advances to the Blood Prime state.

#### **Door Lock Check Substate**

This substate only applies to version 6.1.2, and is entered immediately after the **Start Draw** button is touched. The system checks that the door is closed and locked. If the door is closed but not locked, the system locks the door.

**Table 3-159: Door Lock Check Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Return	Return	Return	0
Exit Co	ndition	When the do	or has been s	uccessfully lo	cked.			

### **Blood Prime State**

The Trima Accel system begins priming the tubing set with the donor's blood during the Blood Prime state.

The access pressure sensor alarms are enabled for the first time, the centrifuge starts, and the Trima Accel system begins updating and displaying collection procedure information. This system state ends when fluid is detected at the lower-level sensor and the centrifuge runs at the commanded speed. Successful completion of the Blood Prime state results in the following conditions and actions.

Exit Condition	Trima Accel System Condition	Trima Accel System Action
Blood Prime substates have completed.	Under algorithm control.	The Trima Accel system advances to the Blood Run state.

#### **Blood Prime Substates**

The Blood Prime state consists of four substates: Two substates prime the inlet and return lines with blood, and two substates vent pressure from the product bags.

#### Blood Prime Inlet (Blood Prime Inlet Lines) Substate

The inlet and AC pumps run at the calculated collection procedure values (Qac and Qin) for the chosen procedure with all valves remaining in the return position. The centrifuge is commanded on. When a version-specific predetermined inlet volume is pumped, the Trima Accel system advances to the Blood Prime Return substate.

Table 3-160: Blood Prime Inlet Substate

	Pump /min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac		40	0	0	0	Return	Return	Return	200

Exit Condition When 13 mL is processed by inlet pump and centrifuge reaches 200 rpm.

#### Blood Prime Return (Blood Prime Return Line) Substate

The return pump is commanded to run. When fluid is sensed at the lower-level sensor of the reservoir, the return pump continues running for a version-specific predetermined volume and then stops. The volume pumped by the return pump must be between version-specific predetermined amounts. When the actual centrifuge speed is within 25 rpm of the commanded speed within the exit condition time, the Trima Accel system advances to the Evac Set Valves substate.

**Table 3-161: Blood Prime Return Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	0	0	0	-40	Return	Return	Return	200

**Exit Condition** When 5 mL is processed by inlet pump after lower-level sensor detects fluid.

# Evac Set Valves (Vent Collect Bags) Substate

This substate moves the platelet, plasma, and RBC valves to vent pressure from the product bags built up during the previous substate. When the valves reach the open position, the Trima Accel system advances to the Evac Reset Valves substate.

**Table 3-162: Evac Set Valves Substate** 

AC Pum	•	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Open	Open	Open	200

Exit Condition When the valves are detected in commanded position within 10 seconds.

# Evac Reset Valves (Move Valves to Return Position) Substate

This substate moves the platelet, plasma, and RBC valves. When the valves reach the return position, the Trima Accel system advances to the Blood Run substate.

**Table 3-163: Evac Reset Valves Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Return	Return	Return	200

Exit Condition When the valves are detected in commanded position within 10 seconds.

### **Blood Run State**

The Blood Run state performs the collection procedure.

Blood Run functions include

- Priming the channel and the rest of the tubing set
- Establishing the interface
- Collecting the platelet, plasma, and RBC products

The Trima Accel system performs single needle draw and return cycles and controls pump speed commands accordingly during this system state. The "RBC Spillover" alarm, all AC related alarms, and the hypovolemic alarm are activated at this time. When the Blood Run state completes, the Trima Accel system advances to the Blood Rinseback state.

Exit Condition	Trima Accel System Condition	Trima Accel System Action
All Blood Run targets are achieved, an alarm ends the collection procedure, or the operator ends the collection procedure.	Under algorithm control.	The Trima Accel system advances to the Blood Rinseback state.

#### **Blood Run Prime Substates**

This Blood Run Prime substate primes the channel and prepares the disposable tubing set for the collection.

#### Prime Channel 1 Substate

The inlet pump and centrifuge are commanded to run at version-specific predetermined speeds. If the centrifuge does not achieve commanded speed in 2 minutes, the "Hardware Failure" alarm generates. The calculated AC ratio (based on channel hematocrit) implements at this time, thus, creating a command for the AC pump (Qac). The plasma and platelet pumps are commanded to run at version-specific speeds until a predetermined volume has been pumped into the channel. The Trima Accel system advances to the Prime Channel 2 substate.

Table 3-164: Prime Channel 1 Substate

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	35	5 30*	30 0*	0	Return	Return	Return	2000

<sup>\*</sup> DRBC tubing sets

Exit Condition	When 70 mL is processed by inlet pump.
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#### Prime Channel 2 Substate

The plasma and platelet pumps are commanded to zero while the AC and inlet pump speeds are maintained until a version-specific predetermined inlet volume has been pumped. The Trima Accel system then advances to the Prime Channel 3 substate.

Table 3-165: Prime Channel 2 Substate

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	13	2	11	0	Return	Return	Return	2500

Exit Condition When 15 mL is processed by inlet pump.

#### Prime Channel 3 Substate

The inlet pump continues to run at the speed from the previous substate (or Qin, whichever is less), the AC ratio changes to the ratio calculated for the collection procedure, and the AC pump speed changes accordingly. After a version-specific inlet volume has been pumped, the Trima Accel system advances to the Prime Channel 4 substate.

**Table 3-166: Prime Channel 3 Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	35	0	0	0	Return	Return	Return	2500

**Exit Condition** When 25 mL is processed by inlet pump.

# Prime Channel 4 Substate

The inlet pump speed increases again to a version-specific maximum speed and the AC pump speed changes accordingly. The plasma and platelet pumps are commanded to version-specific speeds. The Trima Accel system begins checking for fluid at the upper reservoir sensor and executes return cycles as necessary. After a version-specific inlet volume has been pumped, the Trima Accel system advances to the Prime Vent substate.

**Table 3-167: Prime Channel 4 Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	45	15	15 0*	0	Return	Return	Return	2500

#### \* DRBC tubing sets

Exit Condition	When 8 mL is processed by inlet pump.
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#### Prime Vent (Vent Air) Substate

This substate occurs in platelet collection procedures only. The centrifuge and pumps remain at their previous speeds and the platelet valve moves to the collect position to remove air from the channel. After a version-specific volume of plasma + platelet have been pumped, the Trima Accel system advances to the Ramp Centrifuge substate.

**Table 3-168: Prime Channel Vent Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	45	15	15 0*	0	Collect	Return	Return	2500

<sup>\*</sup> DRBC tubing sets

Exit Condition	When 10 mL is processed by platelet and plasma pump combined.
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# Ramp Centrifuge Substate

The centrifuge is commanded to its final calculated speed (usually 3000 rpm). If it cannot make it to its final speed in 2 minutes, a centrifuge hardware alarm is generated. The platelet valve is commanded back to the return position while the pumps and centrifuge remain at their previous speeds. When the machine goes from the first draw cycle to the first return cycle the Trima Accel system advances to the Remove Channel Air substate.

**Table 3-169: Ramp Centrifuge Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	45	12	0	0	Return	Return	Return	3000
Exit Co	ndition	When target	(donor-specif	ic) volume is	processed by	/ inlet pump.		

# Prime Airout 2 (Remove Channel Air) Substate

The AC pump turns off, and the plasma, platelet, and return pumps are commanded to version-specific speeds to remove air from the channel. When a version-specific inlet volume has been pumped, the Trima Accel system advances to the Blood Run Collection substates.

Table 3-170: Prime Airout 2 Substate

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0, Qac	Qin	5	10 0*	Qret, 0	Return	Return	Return	3000

<sup>\*</sup> DRBC tubing sets

Exit Condition	When 50 mL is processed by inlet pump.
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#### **Blood Run Collection Substates**

The Blood Run state contains nineteen prime and collection substates and eleven recovery substates. This section describes the prime and collection substates.

# **Channel Setup Substate**

This substate continues to establish the interface until a predetermined inlet volume has been pumped. The pumps begin ramping up in speed during this substate. After completion of this substate, the Trima Accel system advances to Pre-Platelet Plasma, Pre-Platelet No Plasma, or Plasma Only substates depending upon the chosen procedure.

**Table 3-171: Channel Setup Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	45	5	10 0*	0	Return	Return	Return	3000

<sup>\*</sup> DRBC tubing sets

Exit Condition	When a total of 200 mL is processed by the inlet pump.
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# Pre-Platelet Plasma (Pre-Platelet, Collecting Plasma) Substate

This substate occurs only in procedures where both platelets and plasma are collected. The plasma valve is commanded to the collect position and the plasma pump speed changes to regulate the RBC line hematocrit. The AC and inlet pump speeds change to keep the AC infusion rate at the run configured value. After enough inlet volume has been processed to stabilize the LRS chamber, the Trima Accel system advances to the Platelet Plasma substate or the Pre-Platelet No Plasma substate.

Table 3-172: Pre-Platelet Plasma Substate

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	Qin	Qplas	Qplat	Qret	Return	Collect	Return	Qcent
Exit Co	ndition	When the tai	raet (donor-sn	ecific) volum	e is processe	d by the inlet	pump.	

#### Pre-Platelet No Plasma (Pre-Platelet, No Plasma Collect) Substate

This substate occurs after the Channel Setup substate, in procedures where platelets, but not plasma, are collected. The AC and inlet pump speeds change to keep the AC infusion rate at the run configured value. After a predetermined inlet volume has been processed, the Trima Accel system advances to the Mid Run substate.

**Table 3-173: Pre-Platelet No Plasma Substate** 

Qac   Qin   Qplas   Qplat   Qret   Return   Return   Return   Qcent	AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
	Qac	Qin	Qplas	Qplat	Qret	Return	Return	Return	Qcent

Exit Condition When the target (donor-specific) volume is processed by the inlet pump.

# Platelet Plasma (Concurrent Platelet Plasma) Substate

This substate occurs after the Pre-Platelet Plasma substate in procedures where both platelets and plasma are collected. The platelet valve now opens while the plasma valve remains open until the volume target is achieved. If the plasma volume target is small, the plasma valve closes and the Trima Accel system advances to the Mid Run substate. If the volume target is large, the plasma valve remains open and the Trima Accel system advances to the Extended Plasma substate.

**Table 3-174: Platelet Plasma Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	Qin	Qplas	Qplat	Qret	Collect	Collect	Return	Qcent

**Exit Condition** 

When the target (procedure-specific) volume is collected in the plasma bag.

### Plasma Only (Plasma Only Collect) Substate

This substate occurs after the Channel Setup substate in plasma/RBC procedures where plasma is collected. The plasma valve opens and remains open until the plasma target volume is achieved. After completion of this substate, the Trima Accel system advances to the RBC Collect substate if RBC is chosen.

**Table 3-175: Plasma Only Substate** 

AC Pun (mL/mi	•	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	Qin	Qplas	Qplat	Qret	Return	Collect	Return	Qcent

**Exit Condition** 

When the target (procedure-specific) volume is collected in the plasma bag.

#### PCA (Platelet Concentration Adjustment) Substate

This substate occurs after all plasma is collected during the Platelet Plasma substate. This substate only occurs if the Trima Accel system calculates that the volume in the platelet bag will be lower than it should be by a predetermined volume after the Mid Run substate. This usually occurs when the concurrent

plasma product collected is a small or medium product. During this substate the plasma valve moves to the return position and adds plasma to the platelet bag to reach the needed volume. When the target volume is added to the platelet bag, the Trima Accel system advances to the Mid Run substate.

**Table 3-176: PCA Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	Qin	Qplas	Qplat	Qret	Collect	Return	Return	Qcent

**Exit Condition** When the target (donor-specific) volume is collected in the platelet bag.

# Mid Run (Platelet Only Collection) Substate

This substate occurs after the Platelet Plasma substate (and the Platelet Concentration Adjustment substate, if it occurs) to collect the remainder of the platelet product needed to reach the target yield. This substate only occurs if more collected platelets are needed after the Concurrent Platelet Plasma substate. During this substate the plasma pump runs slowly.

**Table 3-177: Mid Run Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	Qin	Qplas	Qplat	Qret	Collect	Return	Return	Qcent
Exit Co	ndition	When the tar	get (donor-sp	ecific) volum	e is collected	in the platele	t bag.	

# PIR (Platelet Inventory Recovery) Substate

This substate occurs after the Mid Run substate if the collect flow is less than a predetermined rate during Platelet Only Collection. Otherwise, the Trima Accel system skips this substate and advances to the Extended PCA substate. During Platelet Inventory Recovery the platelet pump ramps up in speed to its maximum value and continues running until predetermined platelet volume has been pumped. The Trima Accel system advances to the Extended PCA substate.

Table 3-178: PIR Substate

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	Qin	Qplas	Qplat	Qret	Collect	Return	Return	Qcent
Exit Co	ndition	When the tar	get (donor-sp	ecific) volum	e is collected	in the platele	t bag.	

# Extended PCA (Extended Platelet Concentration Adjust) Substate

This substate occurs after the Platelet Plasma substate (and the Mid Run substate if it occurs) and prior to collecting additional plasma. It only occurs if the Trima Accel system calculates that the volume in the platelet bag is lower than it should be by a predetermined volume or more after the Mid Run substate. This usually occurs when the concurrent plasma product collected is a large product. During this substate the plasma valve moves to the return position and adds plasma to the platelet bag to reach the needed volume. When the target volume is added to the platelet bag, the Trima Accel system advances to the Extended Plasma substate.

**Table 3-179: Extended PCA Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	Qin	Qplas	Qplat	Qret	Collect	Return	Return	Qcent

**Exit Condition** When the target (donor-specific) volume is collected in the platelet bag.

#### Extended Plasma (Extended Plasma Collection) Substate

This substate occurs after all platelets are collected and additional plasma is necessary to achieve the plasma target. The platelet valve closes and the plasma valve moves to the collect position. After the plasma target is achieved, the Trima Accel system advances to the RBC Collect substate if RBC is chosen.

**Table 3-180: Extended Plasma Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	Qin	Qplas	Qplat	Qret	Return	Collect	Return	Qcent

**Exit Condition** When the target (donor-specific) volume is collected in the plasma bag.

RBC PTF Setup 1 Substate

Table 3-181: RBC PTF Setup 1 Substate

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	Qin	Qplas	Qplat	Qret	Return	Return	Return	Qcent

**Exit Condition** When the target volume is processed by the inlet pump.

# **RBC PTF Setup 2 Substate**

Table 3-182: RBC PTF Setup 2 Substate

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	Qin	Qplas	Qplat	Qret	Return	Return	Return	Qcent

**Exit Condition** 

When the target volume is processed by the inlet pump.

# RBC Collect (RBC Collection) Substate

If RBC collection is chosen, this substate occurs after all platelets and plasma are collected. The RBC valve opens until the RBC volume target is achieved. The inlet flow is limited by the configured AC ratio for RBC procedures.

**Table 3-183: RBC Collect Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Qac	Qin	Qplas	Qplat	Qret	Return	Return	Collect	Qcent

**Exit Condition** 

When the target (donor-specific) volume is collected in the RBC bag.

# Pre Rinseback (Prepare for Rinseback) Substate

This substate occurs in both platelet/plasma/RBC procedures and DRBC procedures. All valves move to the return position and all pumps are commanded to zero. When these actions successfully complete, the Trima Accel system advances to the Blood Rinseback state.

**Table 3-184: Pre Rinseback Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Return	Return	Return	Qcent

**Exit Condition** 

When the pumps and valves are detected at the commanded speed and position within 10 seconds.

# **Blood Run Recovery Substates**

The Blood Run state contains eleven recovery substates. Recovery substates interrupt the procedure and suspend the procedure time clock.

When the recovery routine completes, the Trima Accel system returns to the procedure substate that it was in prior to recovery. These recovery substates can occur at any time during the Blood Run state. Only one recovery substate happens at a time. Descriptions of the recovery substates follow.

# RBC Spillover (Spillover Recovery) Substate

Spillover recovery can be entered via a command from the operator (by pressing the **Spillover** button on the Adjust screen) or automatically when detected by the RBC detector. This substate triggers the WBC Chamber Purge state followed by the Clear Line state (see the description for these substates below). At the end of spillover recovery, the RBC detector checks for the presence of a spillover an regenerates the recovery procedure if a spillover persists.

# Pumps Pause (Pause Recovery) Substate

This recovery occurs when the pumps are paused for more than 6 seconds. After the inlet pump processes a predetermined inlet volume, the pumps return to their original collection values and the Trima Accel system returns to the previous blood run substate.

### Air Block (Air Block Recovery) Substate

This recovery is initiated when the operator presses the **Air in Plasma Line** button on the Adjust screen. The centrifuge speed lowers to a predetermined speed, all valves close, and the pump speeds lower to remove the air block. The plasma pump runs at a predetermined speed, maintaining chamber flow, until a predetermined volume of plasma has been pumped. The system then transitions to the Centrifuge Stop substate.

#### Centrifuge Stop (Centrifuge Stop Recovery) Substate

This recovery procedure occurs anytime after the centrifuge stops (or drops below a predetermined speed). This recovery procedure takes precedence over the other recovery procedures. The centrifuge ramps up to its final commanded speed while the pumps are maintained at low speeds to prevent the occurrence of a spillover or air block. When the centrifuge reaches the commanded speed plus 60 more seconds, the pumps return to their normal collection speeds.

### Centrifuge Slow (Centrifuge Slow Recovery) Substate

This recovery substate occurs if the centrifuge actual speed drops below a predetermined speed, but is greater than a predetermined speed. The centrifuge ramps up to 3000 rpm and this recovery continues for 15 more seconds.

# Saline Bolus (Saline Bolus Recovery) Substate

This substate occurs whenever a saline bolus is administered. The platelet pump runs at a predetermined speed until a predetermined volume of saline bolus is delivered. At the same time the return pump runs at the same speed to keep the reservoir volume approximately even. After a predetermined volume of saline has been pumped, the Trima Accel system resumes the draw or return cycle that it was previously in.

# Saline Prime (Replacement Fluid Priming Recovery) Substate

This substate occurs the first time replacement fluid is administered in an RBC/Plasma procedure. The platelet pump runs at a predetermined speed until a predetermined volume of saline is pumped to prime the replacement fluid line.

#### WBC Chamber Purge (WBC Chamber Purge Recovery) Substate

This substate occurs during any procedure where a spillover recovery occurs or a very large inlet volume is processed. The plasma pump increases in speed and the platelet pump stops, purging volume from the LRS chamber. This continues until a predetermined plasma volume is pumped through the LRS chamber.

### RBC Chamber Purge (RBC Chamber Purge Recovery) Substate

This substate occurs during any procedure where a platelet, plasma, RBC tubing set is loaded. This recovery substate always occurs at the beginning of the Channel Setup substate. The plasma pump runs at a predetermined speed and the platelet pump stops, purging volume from the LRS chamber. This continues until a predetermined plasma volume is pumped.

#### Plasma Valve Motion (Plasma Valve Move Recovery) Substate

This substate occurs whenever the plasma valve changes position during a platelet collection procedure. This recovery stops the pumps for one second while the valve moves to prevent fluid from entering the plasma bag while the valve moves through the open position.

#### Settle Channel Substate

This substate occurs only after the WBC Chamber Purge substate. This substate settles the cells in the channel prior to resuming collection. During this recovery the inlet pump flow rate decreases to less than a predetermined amount and pumps a predetermined inlet volume.

#### Clear Line Substate

This substate occurs after WBC Purge recoveries. It functions to clear RBCs/WBCs out of the platelet line. The inlet, platelet, and plasma pumps are limited to predetermined speeds. This substate ends when a predetermined platelet volume has been pumped.

### **Blood Rinseback State**

The Rinseback state returns the donor's blood. Variations include plasma or saline assisted rinseback.

The hematocrit in the RBC line is configured to maximize blood return. This system state ends when the lower-level sensor detects air. Successful completion of the Blood Rinseback state results in the following conditions and actions.

Exit Condition	1	ccel System ndition	Trima Accel System Action
All Blood Rinseback sub are completed.	ostates Under algorit	thm control.	The Trima Accel system advances to the Donor Disconnect state.

#### **Rinseback Substates**

The Rinseback substates evacuate the channel and return remaining blood to the donor.

#### Rinseback Lower (Rinseback Lower Reservoir) Substate

All valves are commanded to the return position and the inlet, AC, plasma, and platelet pumps are commanded to zero. The return pump runs until air is present at the lower-level sensor, or a predetermined volume of return has been pumped. The Trima Accel system then advances to the Rinseback Recirculate substate.

**Table 3-185: Rinseback Lower Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	Qret	Return	Return	Return	Qcent

Exit Condition	When the lower-level sensor detects air or 10 mL processed by the return pump.
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#### Rinseback Recirculate Substate

The inlet and return pumps are commanded to predetermined speeds to recirculate the blood in the channel before returning it to the donor. After a predetermined inlet volume is processed, the Trima Accel system advances to the Rinseback substate.

**Table 3-186: Rinseback Recirculate Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	100	Qplas	Qplat	100	Return	Return	Return	Qcent

Exit Condition	When 50 mL is processed by the inlet pump.

# Rinseback (Rinseback Return) Substate

The centrifuge is commanded to zero. The inlet pump is also commanded to zero and the plasma, platelet, and return pumps run until the lower-level sensor sees air and a predetermined return volume is processed. When this occurs, the Trima Accel system advances to the Disconnect Prompt substate.

**Table 3-187: Rinseback Substate** 

- 1	AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
(	0	0	Qplas	Qplat	Qret, O	Return	Return	Return	0

**Exit Condition** When the lower-level sensor detects air or 20 mL processed by the return pump.

# **Disconnect Prompt Substate**

The pumps all stop and the Disconnect Prompt screen prompts the operator to press **Continue** to disconnect the donor. When the operator presses **Continue**, the Trima Accel system advances to the Donor Disconnect state. If the operator does not respond to the prompt in 10 minutes, the Trima Accel system automatically advances to the Donor Disconnect state.

**Table 3-188: Disconnect Prompt Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Return	Return	Return	0

Exit Condition When the operator touches Continue or 10 minutes have passed.

# **Donor Disconnect State**

The Donor Disconnect state checks that the operator has correctly clamped off the donor access line prior to disconnecting the donor. When the Disconnect Test substate is complete, the cassette is unloaded.

This state ends when the disconnect test successfully passes and the cassette is unloaded, or when the test fails three consecutive times, warning the operator. Successful completion of the Donor Disconnect state results in the following conditions and actions.

Exit Condition	Trima Accel System Condition	Trima Accel System Action
The disconnect test has passed once and the cassette has been unloaded, or the test failed three consecutive times and the cassette has been unloaded.	Paused.	The operator is prompted to continue to the Post Run state.

#### **Donor Disconnect Substates**

The Donor Disconnect state consists of five substates: Disconnect Test, Open Valves, Start Pumps, Raise Cassette, and Stop Pumps. If MSS is configured on, the cassette is **not** unloaded after the donor is disconnected.

#### **Disconnect Test Substate**

The inlet pump is commanded to a predetermined speed, and the Trima Accel system waits to verify that the access pressure drops by a predetermined amount within 30 seconds. Then the system checks that the pressure does not decay by more than a predetermined amount within the following 10 seconds. If both tests fail, a disconnect test alert is displayed and the Trima Accel system repeats the test. The operator is prompted to repeat the test. If it fails twice again, a disconnect test alarm is generated and the operator is allowed to unload the cassette by pressing **Continue** and **Confirm Disconnect**.

**Table 3-189: Donor Disconnect Test Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	50, 0	0	0	0	Return	Return	Return	0

# Open Valves Substate

All valves are moved to their open positions. When the valve position sensors sense all three open positions, the Trima Accel system advances to the next substate.

**Table 3-190: Open Valves Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Open	Open	Open	0

**Exit Condition** When the valves are detected in the commanded position within 10 seconds.

# Start Pumps Substate

All pumps are commanded to their unload speeds.

**Table 3-191: Start Pumps Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
60	60	60	60	150	Open	Open	Open	0

Exit Condition When the pumps are detected at commanded speed within 10 seconds.

#### Raise Cassette Substate

The cassette is commanded to the raised position while the pumps are running at their unload speeds. When the cassette is detected in the raised position, the Trima Accel system advances to the next substate.

**Table 3-192: Raise Cassette Substate** 

	AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
I	60	60	60	60	150	Open	Open	Open	0

Exit Condition When the cassette plate is detected in the up position.

# Stop Pumps Substate

The pumps are commanded to stop and the operator is prompted to press **Continue**. When the operator presses **Continue**, the Trima Accel system advances to the Post Run state.

**Table 3-193: Stop Pumps Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Open	Open	Open	0

# **Metered Storage Solution State**

The Metered Storage Solution (MSS) state administers the automatic addition of metered storage solution.

This system state begins when the Trima Accel system determines if the run is a normal metered storage run or a "salvage case." This is determined by flags during the Rinseback protocols. A "salvage case" is defined as a run where the machine does not return sufficient volume from the reservoir and channel back to the donor. If the run is a "salvage case," the machine will flag the final product for possible WBC contamination. Successful completion of the Metered Storage Solution state results in the following conditions and actions.

Exit Condition	Trima Accel System Condition	Trima Accel System Action
All MSS substates are completed.	Paused.	The Trima Accel system proceeds to the MSS Disconnect state.

#### **Metered Storage Solution Substates**

Metered Storage Solution substates administer metered storage solution to the collected product.

### MSS Setup (Metered Storage Solution Setup) Substate

This substate waits for the operator to confirm or cancel the automatic metered storage procedure. This state transitions upon receiving message to continue from the GUI task.

**Table 3-194: MSS Setup Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Return	Return	Return	0
Exit Co	ndition	When the op	erator touches	s the Contin	ue button.			

# MSSPFR (Metered Storage Solution Power Fail Recovery) Substate

This substate recovers from a power failure. It will branch to the last substate being executed at the time of the failure. This substate generates no alarms or alerts.

**Table 3-195: MSSPFR Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Return	Return	Return	0

# Verify Closure (Verify Channel Clamps are Closed) Substate

This substate verifies that the channel clamps are closed. It runs the pumps to see if fluid can be pulled from the channel. If fluid is pulled from the channel into the reservoir, a channel clamp alert is generated and the product is flagged for WBC contamination. This alert is generated a maximum of two times in this substate. The operator is then allowed to continue after the second alert. This substate is not executed if it is a salvage case MSS run.

**Table 3-196: Verify Closure Substate** 

AC Pum (mL/mi	·   ·	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
10, 0, 30	0, 20	0	0	0	Return	Return	Return	0

**Exit Condition** When fluid is not detected by the AC detector and APS is greater than 250 mmHg.

# Reservoir Setup Substate

This substate empties the reservoir. The return pump runs until the lower-level sensor detects air. This state is not executed if this is determined to be a salvage case MSS run. (Reservoir Setup\_2 is identical to Reservoir Setup except for the name).

**Table 3-197: Reservoir Setup Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	27, 0	0	0	27, 0	Return	Return	Return	0

Exit Condition When the lower-level sensor detects air.

#### Verify Closure 3 Substate

**Table 3-198: Verify Closure 3 Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	100	60, 125	0	Return	Return	Return	0

#### MSS Connect Substate

This substate waits for the operator to confirm that PAS and/or RAS storage solutions are connected. This state calculates the correct amount of storage solution to be metered to the product based on the actual collected volume and the Plasma-Percent carryover. This substate also calculates the estimated storage solution used for the MSS run (prime, addition, and purging) and sends it to the GUI task. The substate will exit upon receiving message to continue from the GUI task.

**Table 3-199: MSS Connect Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Return	Return	Return	0

Exit Condition When the operator touches the Continue button.

#### MSS Prime Substate

This substate primes the system with storage solution. The Trima Accel system monitors the APS during these substates. If the APS raises above the configured value, the state will pause and run the inlet pump to relieve the pressure. The MSS Prime substate consists of five subordinate substates.

**Table 3-200: MSS Prime Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Return	Return	Return	0

#### Reservoir Setup 2

This substate empties the reservoir. The return pump will run until the lower-level sensor detects air.

Table 3-201: Reservoir Setup 2 Substate

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	27, 0	0	0	27, 0	Return	Return	Return	0

**Exit Condition** When the lower-level sensor detects fluid.

#### Reservoir Setup 3

This substate empties the reservoir. The return pump will run until the lower-level sensor detects air.

**Table 3-202: Reservoir Setup 2 Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	27, 0	0	0	27, 0	Return	Return	Return	0

Exit Condition When the lower-level sensor detects fluid.

#### MSS RBC Prime 1

This substate primes the cassette with RAS. The pumps run until the lower-level sensor detects fluid. The fluid must be detected before a version-specific predetermined amount of fluid is processed by the pumps.

Table 3-203: MSS RBC Prime 1 Substate

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
50	45, 0	0	0	45, 0	Return	Return	Return	0

Exit Condition When the lower-level sensor detects fluid.

#### MSS PLT Prime Salvage

This substate is only executed in the event of an MSS salvage case. A salvage case is determined by the amount of fluid processed during Rinseback.

**Table 3-204: MSS PLT Prime Salvage Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	60	60	0	Return	Return	Return	0
Exit Co	ndition	When the lov	wer-level sens	or detects flu	id.			

## MSS RBC Prime Salvage

This substate is only executed in the event of an MSS salvage case. A salvage case is determined by the amount of fluid processed during Rinseback.

**Table 3-205: MSS RBC Prime Salvage Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
50	0	0	0	0	Return	Return	Return	0

Exit Condition When the lower-level sensor detects fluid.

#### MSSPLTPrime1

This substate primes the cassette with the storage solution. The state alarms if the lower-level sensor sees fluid too soon (mss prime too soon) or too late (mss prime delay). This state will not be executed during a MSS salvage case.

Table 3-206: MSSPLTPrime1 Substate

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0, 54	60	60	0, 54	Return	Return	Return	0

**Exit Condition** When the lower-level sensor detects fluid.

#### MSSPLTPrime2

This substate completes the priming of the storage solution through the cassette.

**Table 3-207: MSSPLTPrime2 Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0, 30	0	0	Return	Return	Return	0

**Exit Condition** When the target (procedure-specific) volume is processed by the platelet pump.

#### MSS Parallel Processing

#### **Table 3-208: MSS Parallel Processing Substate**

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	R/C*	Return	R/C*	0

<sup>\*</sup>Return, unless delivering storage solution, then closed.

#### VacPurge

This substate purges the set of contaminants. It will run the vacuum purge algorithm a version-specific predetermined number of times.

#### Table 3-209: VacPurge

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	Qplas	Qplat	0	Return	Return	Return	0

**Exit Condition** When the target (procedure-specific) volume is processed by the platelet and plasma pumps.

#### **PAS Final Flow Verification**

This substate will fill the reservoir to a full state if it is not already.

**Table 3-210: PAS Final Flow Verification** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	110	110	0	Return	Return	Return	0

Exit Condition When the upper-level sensor detects fluid.

#### VacPurgeFinal

This substate moves the platelet valve to the collect position. If it is a non-salvage case, it will flush the portion of the cassette below the platelet valve.

Table 3-211: VacPurgeFinal

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	R/0/C*	Return	Return	0

<sup>\*</sup> Commands the platelet valve slowly from return to open to closed.

Exit Condition When the target (procedure-specific) volume is processed by the platelet and plasma pumps.

## MSSPLTAdditionPause (MMS Platelet Addition Pause) Substate

This substate waits for the operator to confirm that the platelet bag has been clamped. Otherwise, the automatic metered storage solution addition is cancelled. This state transitions upon receiving message to continue from the GUI task.

**Table 3-212: MSSPLTAdditionPause Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Closed	Return	Return	0

Exit Condition When the operator touches the Continue button.

#### **MSSPLTAddition**

This substate runs the platelet and plasma pumps to deliver the calculated amount of storage solution to the platelet product.

**Table 3-213: MSSPLTAddition Substate** 

AC Pum (mL/min	•	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	Qplas	Qplat	0	Closed	Return	Return	0

**Exit Condition** When the target (procedure-specific) volume is processed by the platelet and plasma pumps.

#### MSSRBCAddition

This substate runs the AC pump to deliver the calculated amount of storage solution to the RBC product.

**Table 3-214: MSSRBCAddition Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
Ramp to 70	0, 10	0	0	0	Return	Return	Closed	0

**Exit Condition** When the target (procedure-specific) volume is processed by the AC pump.

#### MSS Disconnect Substate

The substate waits for the operator to confirm the storage solution is disconnected.

**Table 3-215: MSS Disconnect Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Return	Return	Return	0

Exit Condition When the operator touches the Continue button.

## **Metered Storage Solution Disconnect State**

The MSS Disconnect state checks that the operator has correctly sealed the product and additive solution bags following the MSS state.

Upon completion of the MSS state, the Trima Accel system waits for the operator to confirm the products and storage solution have been disconnected. After the operator confirms this information, the system unloads the cassette and proceeds to the Post Run state.

Exit Condition	Trima Accel System Condition	Trima Accel System Action
The operator pressed the <b>Continue</b> button.	Paused.	The Trima Accel system prompts the operator to remove the disposable set. The Trima Accel system unloads the cassette and proceeds to the Post Run state.

#### **MSS Disconnect Substates**

Upon completion of the MSS state, the Trima Accel system waits for the operator to confirm the products and storage solution have been disconnected. After the operator confirms this information, the system unloads the cassette and proceeds to the Post Run state.

#### **Open Valves Substate**

All valves are moved to their open positions. When the valve position sensors sense all three open positions, the Trima Accel system advances to the next substate.

**Table 3-216: Open Valves Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Open	Open	Open	0
Exit Co	ndition	When the va	lves are detect	ted in the con	nmanded pos	ition within 1	0 seconds.	

#### **Start Pumps Substate**

All pumps are commanded to their unload speeds.

**Table 3-217: Start Pumps Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
60	60	60	60	-110	Open	Open	Open	0
Exit Condition		When the pu	mps are detec	ted at comma	anded speed	within 10 sec	onds.	

#### Raise Cassette Substate

The cassette is commanded to the raised position while the pumps are running at their unload speeds. When the cassette is detected in the raised position, the Trima Accel system advances to the next substate.

**Table 3-218: Raise Cassette Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
60	60	60	60	-110	Open	Open	Open	0

Exit Condition	When the cassette plate is detected in the up position.
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#### Stop Pumps Substate

The pumps are commanded to stop and the operator is prompted to press **Continue**. When the operator presses **Continue**, the Trima Accel system advances to the Post Run state.

**Table 3-219: Stop Pumps Substate** 

AC Pump (mL/min)	Inlet Pump (mL/min)	Plasma Pump (mL/min)	Platelet Pump (mL/min)	Return Pump (mL/min)	Platelet Valve	Plasma Valve	RBC Valve	Centrifuge (rpm)
0	0	0	0	0	Open	Open	Open	0

#### **Post Run State**

The Post Run state displays end-of-run statistics.

The Post Run state ends when the operator touches the **Next Procedure** button. Successful completion of the Post Run state results in the following conditions and actions.

Exit Condition	Trima Accel System Condition	Trima Accel System Action
The operator touches the <b>Next Procedure</b> button.	Paused.	The Trima Accel system reboots and advances to the Self Tests state.

# 4

## **Troubleshooting**

## **Touch Screen Troubleshooting**

- 1. Remove the back panel from the display housing.
- 2. Unplug the blue 4-wire touch screen connector from the side of the display where the IV pole is.

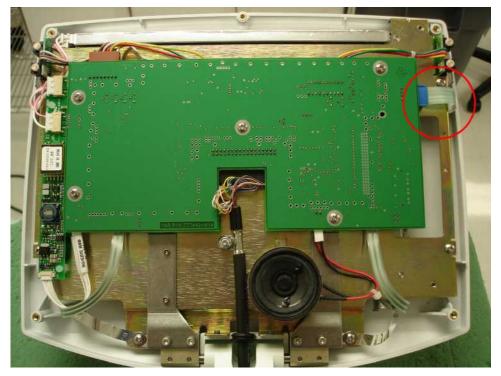


Figure 4-1: Touch screen connector (circled)

3. Access the test points for digital voltmeter (DVM) use. On some touch screens, this requires the connector to be flipped over. Be careful not to bend the harness.

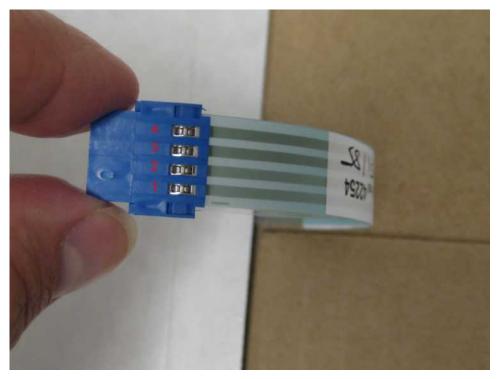


Figure 4-2: Touch screen connector test points

- 4. Measure the resistance between the pin that is closest to the LED (pin 1) and pin 2, next to it.
- 5. Verify that the resistance between pins 1 and 2 is 52  $\Omega$  ± 12  $\Omega$ .
- **6.** Measure the resistance between the other two pins (3 and 4).
- 7. Verify that the resistance between pins 3 and 4 is 90  $\Omega$  ± 20  $\Omega$ .
- 8. If the resistance measurements are within the ranges described above, measure them again while very gently moving the wire to look for intermittent connections.
- 9. If either of the resistance measurements is outside of the range described above, replace the touch screen.

## **Valve System Troubleshooting**

The intent of valve system troubleshooting is to inform the technician about where and when to measure values to help troubleshoot valve system malfunctions and how to confirm the suspected error by testing.

#### Prerequisites

Check the following electronic prerequisites for normal operation:

- 24 V DC source from the power supply must be within the 19.2 V DC to 28.8 V DC range (measure between J6 and J2 on the motor driver CCA, or check LED D14)
- 24 V DC switched voltage from the motor driver CCA must be within the 19.2 V DC to 28.8 V DC range (measure between J3 and J2 on the motor driver CCA, or check LED D1)
- Safety reset of 24 V shutdown (digital) indicates run, no reset (low)
- Safety must activate the 24 V DC switch (digital) on the motor driver CCA
- 24 V current sense line (DC voltage) from the motor driver CCA must not trigger the valve fault line
- Valve fault line (digital) from the motor driver CCA indicates normal, no fault (high)
- Position sensor VCC on the valve CCA must be within the 4.75 V DC to 5.25 V DC range
- Sensor LED power must be within range; 5.0 V DC maximum (switched on the safety CCA)
- Start-up test must pass these conditions:
  - All LEDs off: Valves must show unknown for all positions
  - All LEDs on: Valves must be seen in every position while rotating through all positions

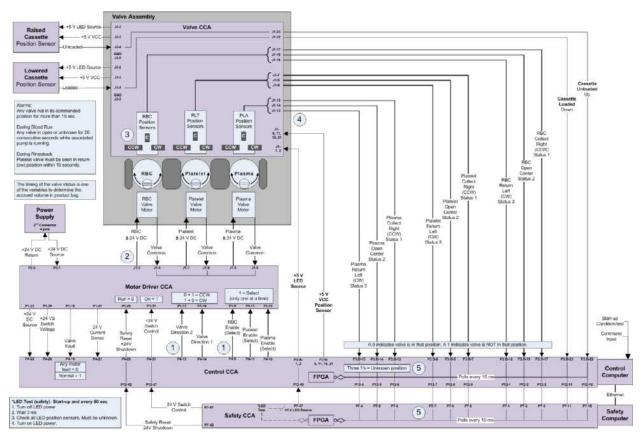


Figure 4-3: Valve troubleshooting diagram

## **Valve System Measurements**

This section indicates where to take measurements in the valve system, starting with the control CCA, moving to the motor driver CCA, the valve assembly, and finally back to the control CCA.

#### Valve Direction and Enable Bits

These bits cannot reasonably be measured in the field. Use STS to select and move the valves while using the valve motor voltage table (below) to measure the output from the motor driver CCA. If one or more valve motor connectors show proper voltage when commanded, then assume that the bits are reaching the motor driver CCA.

#### Valve Motor Voltage

Disconnect the valve motor from the power harness. Using STS in service mode, turn on the +24 V switch and then command the disconnected valve motor to move left or right. The voltage should reach the value in the table below once every second as the system attempts to find its position.

Table 4-1: Valve motor measurement points and values

Motor	From (Ground)	To (Voltage)	CW (Post to Left)	CCW (Post to Right)
Platelet	Black wire	Gray wire	+24 V DC	-24 V DC
Plasma	Black wire	Violet wire	+24 V DC	-24 V DC
RBC	Black wire	Red wire	+24 V DC	-24 V DC

#### Valve CCA +5 VCC and LED Voltage

With the valve CCA cable unplugged from the valve assembly, use the table below for measurement points and values. The LED source can be turned on and off in STS with position sensor power in the power supply section.

Table 4-2: Valve CCA connector measurement points and values

Valve CCA Cable	Ground Lead	Voltage Lead	Value
VCC for position sensors	Pin 24	Pin 6	5.05 V
LED source from safety CCA (in STS: position sensor power)	Pin 6	Pin 1	5.05 V

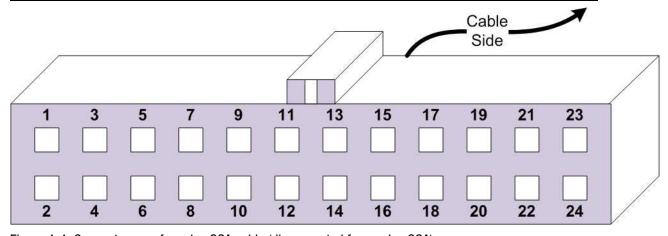


Figure 4-4: Connector map for valve CCA cable (disconnected from valve CCA)

#### Measured Position from Valves

These bits cannot reasonably be measured in the field. Use the valves section of STS to observe the control and safety status while commanding the valves. If all the valves indicate "unknown," it is possible that the +5 V LED or position sensor power is faulty. Check the +5 volt output from the safety CCA or the power supply.

#### Valve Fault Bits

These bits cannot reasonably be measured in the field. Use STS to view the faults log to determine whether a valve fault bit is being sent from the motor driver CCA.

The valve fault bit can be triggered by a momentary/persistent under-voltage or over-current problem in the motor driver CCA. The +24 V current sense line is the current of the motor driver CCA presented as a DC voltage (current sense voltage). The current is a combination of all the currents from the pump motors, the valve motors, the linear actuator motor, and the door lock solenoid. To calculate the current from the DC voltage, use the following formula: Combined Current (Amps) = Current Sense Voltage ÷ 0.51.

The value of the current is recorded in the dlog file and reported to STS; however, the system does not use this value to trigger alarms. The following values are the worst-case current values (not the alarm limits):

- Valves (×3) and linear actuator, an aggregate current limit = 1.15 A
- Pumps (×4), individual current limits = 2.30 A
- Return pump, individual current limit = 3.83 A
- Lock solenoid, individual current limit = 2.30 A
- Worst-case +24 V current, the value could be approximately 16.48 A (this assumes that all loads are active and near their individual driver circuit current limits)

## **Valve System Mechanical Failure Symptoms**

This section describes common mechanical failure symptoms for the valve system.



**Note:** Do NOT attempt to repair the valve assembly. A special tool is required to align the valve motors, the valve bodies, and the valve plate, and this alignment is performed only at the manufacturer. If a single component on the valve assembly has failed, replace the entire valve assembly. The only repair allowed to the valve assembly is to replace valve posts and bearings, if needed. The only maintenance allowed to the valve assembly is to clean the silicone grease off the valve body/housing body or valve posts/bearings and lubricate with new grease, if needed.

Table 4-3: Possible valve mechanical failures

Symptom	Possible Solution
Slow valve movement	Clean and lubricate valve body with silicone valve grease as needed. The valve bodies and o-rings should have clean grease that is able to lubricate during movement. When the grease is too old or contaminated there can be an increase in friction, which can draw too much current through the valve motor and lead to a valve fault. Increased friction could also slow the valve rotation movement and create a timeout failure when moving between positions.
Valve bearing does not rotate	Clean and lubricate valve bearing with silicone valve grease as needed. The valve posts are lubricated with valve grease and should rotate freely. Check spare parts for the correct part number for the silicone valve grease. The valve posts require tightening to a torque value of 17.0 in lb.

## **Valve System Electrical Failure Symptoms**

This section describes common electrical failure symptoms for the valve system.

**Table 4-4: Possible valve electrical failures** 

Symptom	Possible Causes
Valve motor repeatedly rotates back and forth	The valve is trying to find a position, and if the position sensors do not report all three valve positions the following list could be possible failures:  Valve CCA position sensors
	<ul> <li>Intermittent connection or wire between position sensor and control or safety CCAs</li> </ul>
	Control or safety CCA not processing the position sensor signal
Valve motor rotation is stalled, slow,	Motor driver CCA power is low or intermittent
or stuttering	Valve motor or cable/harness is failing
	Bad valve enable or valve direction bit (if stalled or stuttering)
	• Intermittent connection or wire between valve motor and motor driver CCA
	Debris or insufficient valve grease between valve housing and valve body

## **Valve System Connection Failures**

This section describes common connection problems to check for in the valve system.

**Table 4-5: Possible valve connection failures** 

Connection	Possible Connection Error
Cassette position sensors	Ensure that the raised and lowered cassette position sensors are plugged in to the valve CCA whenever the valve assembly has been removed from the device.  As viewed from the rear of the device:  Raised  Lowered
Valve assembly cable to the e-box	Plugging the valve assembly cable into the display cable connection on top of the e-box will damage the display when the device power is turned on. Ensure the proper connection, as the valve and display connectors are NOT keyed differently to prevent this confusion.    Valve Cable   P3.B   P3.A   Display Cable

## **Version 6.0.6 Dlog Information**

This is the dlog header, periodic data, and episodic data that is relevant to the valve system.

The header is the function name and/or the unit of value for the periodic data.

The periodic data is device hardware values and device software information. This data is written into the dlog every six seconds as long as the device is powered on. A row in the dlog with periodic data does not have episodic data in it.

The episodic data is detailed and coded messages from the safety or control systems. These could be values from hardware or software messages from the procedure. A row in the dlog with episodic data does not have periodic data in it.

#### **Header/Periodic Information**

**Table 4-6: Valve periodic information** 

Header Line 1	Header Line 2	Definition
CollectValveCmd	collect valve command	The commanded position of the collect valve.  Possible values are "O" (open); "C" (collecting); "R"  (returning); or "U" (unknown).
CollectValvePos	collect valve position	The measured position of the collect valve. Possible values are "O" (open); "C" (collecting); "R" (returning); or "U" (unknown).
PlasmaValveCmd	plasma valve command	The commanded position of the plasma valve. Possible values are "O" (open); "C" (collecting); "R" (returning); or "U" (unknown).
PlasmaValvePos	plasma valve position	The measured position of the plasma valve. Possible values are "O" (open); "C" (collecting); "R" (returning); or "U" (unknown).
RBCValveCmd	RBC valve command	The commanded position of the RBC valve. Possible values are "O" (open); "C" (collecting); "R" (returning); or "U" (unknown).
RBCValvePos	RBC valve position	The measured position of the RBC valve. Possible values are "O" (open); "C" (collecting); "R" (returning); or "U" (unknown).
RBC_1_AC	AC volume past the valve to RBC bag 1 (mL)	The current total amount of AC in the product inside the RBC1 bag (mL).
RBC_1_Dose	RBC dose past the valve to RBC bag 1 (mL)	The RBC1 dose at 100% HCT. For example: If the HCT of collected RBC product is configured at 80%, the "RBC dose at 100% value" ÷ "RBC collect volume" = 80%.

**Table 4-6: Valve periodic information (continued)** 

Header Line 1	Header Line 2	Definition
RBC_1_SS	SS volume past the valve to RBC bag 1 (mL)	The amount of red blood cell additive solution delivered to the RBC1 product in mL.
RBC_1_Vol	RBC volume past the valve to RBC bag 1 (mL)	The current total volume in the RBC1 bag in mL.
RBC_2_AC	AC volume past the valve to RBC bag 2 (mL)	The current total amount of AC in the product inside the RBC2 bag (mL).
RBC_2_Dose	RBC dose past the valve to RBC bag 2 (mL)	The RBC2 dose at 100% HCT. For example: If the HCT of collected RBC product is configured at 80%, the "RBC dose at 100% value" ÷ "RBC collect volume" = 80%.
RBC_2_SS	SS volume past the valve to RBC bag 2 (mL)	The amount of red blood cell additive solution delivered to the RBC2 product in mL.
RBC_2_Vol	RBC volume past the valve to RBC bag 2 (mL)	The current total volume in the RBC2 bag in mL.
Recovery	procedure recovery name	PlasmaValveMotion is a substate that occurs whenever the plasma valve changes position during a platelet collection procedure. This recovery stops the pumps for 1 second while the valve rotates through the open position to prevent fluid from entering the plasma bag.

#### **Episodic Information**

This information describes certain episodic logging associated with the valve system during normal operation. These examples are from known good runs. "X" indicates a variable valve name, so valve X could be valve RBC, valve platelet, or valve plasma. These examples do not encompass all of the possible logging that may occur.

Table 4-7: Normal episodic logging examples

Episodic Line	Definition
Config data: [PLASMA_VALVE_MOTION]	Cobe_config.dat is loading the system constants.
<ul> <li>Config data: evacuation_valve_open_dwell=5.0</li> </ul>	
<ul> <li>Config data: rinseback_v_pvalve=20.0</li> </ul>	
<ul> <li>Config data: rinseback_valve_volume=20.0</li> </ul>	
Config data: mss_plt_valve_timer=1.0	
Current monitoring status: HypOvolemia:OFF;HypERvolemia:OFF;RBC valve:OFF	Obsolete logging in "Current monitoring status" for the RBC valve. This indicates the safety system is monitoring the valve positions during rinseback to prevent hypovolemia.

Valve movement logging: The valve system produces logging that indicates the commanded valve position and the measured position. The order number indicates the commanded valve position from the software to the control CCA. The status number indicates the measured valve position from the position sensors to the valve CCA. The following are code value meanings from the episodic phrases in the table below:

- Valve: RBC, plasma, platelet
- Order: 1 = collect, 2 = open, 3 = return
- Status: 0 = unknown, 1 = collect, 2 = open, 3 = return
- Time: ttt = milliseconds

**Table 4-8: Valve movement logging** 

Episodic Line	Definition
Valve [X]: order=[1,2,3] status=[1,2,3]	The valve is commanded to a position (order) and the valve position is measured (status) before the command is sent.
Valve [X] in position: status=[0,1,2,3] time=[ttt]	The valve is now in its final measured position and it took [ttt] milliseconds for the valve to reach that position.
Valve [X] in wrong position: status=[0,1,2,3] time=[ttt]	When a valve is commanded to go from collect position to return position (1 to 3) or vice versa, the valve needs to pass through the open position (2). This logging shows that the valve is not in the final position (status) and the time it took the valve in milliseconds to get to that position.

**General episodic logging:** "Enter:" indicates that the device software has entered a specific system state or substate. See *Software Description* for more detail about specific software states. The following are examples of enter and exit logging:

- Enter:ValvesTest
- Exit:ValvesTest
- Enter:EvacuateSetValues
- Exit:EvacuateSetValues

**Table 4-9: General episodic logging** 

Episodic Line	Definition
Blink Test T1 : 1; Pass Value : VALVE_LED_TEST_NOMINAL(1)	The safety system turns off the +5 V LED power at startup and every 60 seconds after to check the position measurements in the valve system, the cassette system, and the door lock assembly. The position information is recorded in the dlog file in hex format and needs to be converted to binary to find the location of the sensor indicating the problem. During this test, each system must return an unknown position with all the bits returning a binary "1." If a binary "0" is returned during the test, that sensor is suspected to have failed, is unplugged, or has an intermittent connection. See <i>Episodic error logging</i> to decode the failures of this test.
RBCValve T1 : 14; Pass Values : ALL_VALVE_POSITIONS_VERIFIED(15) or ALL_VALVE_POSITIONS_VERIFIED_XCEPT_ UNKNOWN(14)	The measured valve positions: all the valves have cycled through all possible positions.
PseudoValve T1 : 15; Pass Values : ALL_VALVE_POSITIONS_VERIFIED(15) or ALL_VALVE_POSITIONS_VERIFIED_XCEPT_ UNKNOWN(14)	The virtual valve positions in the software: all the valves have cycled through all possible positions.
Inlet Container FlowIO; 1 ValveIO: 1 (also Return and AC) Platelet Container FlowIO: 2 ValveIO: 1 VolLimit: –1560.00000 (also Plasma and RBC)	Indicates the flow direction for each valve in relation to the bag.  • FlowIO: [0 = unknown, 1 = into the cassette, 2 = into the bag, 3 = recirculate]  • ValveIO: [0 = unknown, 1 = collect, 2 = open, 3 = return]  • VolLimit: maximum volume allowed in the bag (mL)

**Table 4-9: General episodic logging (continued)** 

Episodic Line	Definition
[X] Container flowIO=1deltaV=0.12650 accumV=174.76880 drawV=174.76880	• FlowIO: [0 = unknown, 1 = flow into set, 2 = flow into bag, 3 = flow into collect bag (recirculate), 4 = flow error (can't determine flow, set unknown)
returnV=0.00000 drawVI=174.76880 returnVI=0.00000 valveIO=1 valvePosCtI=1	<ul> <li>deltaV: [Volume of fluid accumulated in this sample]</li> </ul>
valvePosSfT=1	<ul> <li>accumV: [Volume of all fluid accumulated in bag, can be negative]</li> </ul>
	<ul> <li>drawV: [Volume of fluid accumulated in current draw cycle while valve is in return]</li> </ul>
	<ul> <li>returnV: [Volume of fluid accumulated in current return cycle while valve is in return]</li> </ul>
	<ul> <li>drawVI: [Volume of fluid accumulated in current draw cycle while bag is collecting]</li> </ul>
	<ul> <li>returnVI: [Volume of fluid accumulated in current return cycle while bag is collecting]</li> </ul>
	• valveIO: [Valve position: 0 = unknown, 1 = collect, 2 = open, 3 = return]
	<ul> <li>valvePosCtl: [Valve position as reported by control]</li> </ul>
	valvePosSfT: [Valve position as reported by safety]

## **Episodic Error Logging**

The episodic error logging section describes specific error logging of the valve system in the dlog file.

Table 4-10: Episodic error logging

Episodic Error Line	Definition
Error: [X] valve out of pos count <value></value>	The system continuously monitors the measured position of the valves, and this error occurs when the [X] valve is not measured in the commanded position after 10 seconds. The <value> is the number of 0.5-second cycles, so 20 cycles is approximately 10 seconds. The associated alarm is also reported when this is detected.</value>

Table 4-10: Episodic error logging

<b>Episodic Error Line</b>		Definition		
Blink fail: status=0x####	digit hex value that n	a valve LED blink test failure. The #### is a four- leeds to be converted to a binary value to be able to nsor is reporting a "O."		
	<ol> <li>Open the Windo</li> <li>Click <b>Hex</b> and e</li> <li>Click <b>Bin</b> to consist <b>1 0111 1111</b> 1</li> <li>Count the bits from</li> </ol>	<ol> <li>To convert hex to binary, complete the following steps:</li> <li>Open the Windows 7 calculator in Programmer view.</li> <li>Click Hex and enter the hex code; for example 17ff.</li> <li>Click Bin to convert the hex to binary, which for the example above is 1 0111 1111 1111.</li> <li>Count the bits from right to left starting with 0, then 1, then 2 and so on. The bit on the far left is number 12 and the bit on the far right is</li> </ol>		
	In the example a	bove, the 11th bit is 0, which indicates a problem		
	The position of a "0'	' bit indicates which sensor is having the problem. In be indicated. The meaning of a "0" bit in each		
	"0" Bit Position	Sensor Problem		
	0	Plasma valve return		
	1	Plasma valve collect		
	2	Plasma valve open		
	3	RBC valve return		
	4	RBC valve collect		
	5	RBC valve open		
	6	Cassette loaded		
	7	Cassette unloaded		
	8	Platelet valve return		
	9	Platelet valve collect		
	10	Platelet valve open		
	11	Door lock solenoid position		
	12	Door position (optical)		
		fail: status=0x1800," which is binary code this problem could be that the valve harness is		
	1 1111 0011 1111, 1	fail: status=0x1f3f," which is binary code this problem could be that the cassette loaded and ensors are unplugged.		

## **Door System Troubleshooting**

The intent of centrifuge door and door lock system troubleshooting is to inform the technician about where and when to measure values to help troubleshoot door position and door lock system malfunctions and how to confirm the suspected error by testing.

#### Prerequisites

Check the following electronic prerequisites for normal operation:

- 24 V DC source from the power supply must be within the 19.2 V DC to 28.8 V DC range (measure between J6 and J2 on the motor driver CCA, or check LED D14)
- 24 V DC switched from the motor driver CCA must be within the 19.2 V DC to 28.8 V DC range (measure between J3 and J2 on the motor driver CCA, or check LED D1)
- Safety CCA reset of 24 V shutdown (digital) indicates run or no reset (low)
- Safety CCA must activate the 24 V DC switch (digital) on the motor driver CCA
- 24 V current sense line (DC voltage) from the motor driver CCA must not trigger the solenoid fault line
- Sensor LED power must be within range; 5.0 V DC maximum (switched on the safety CCA)
- Lock solenoid power must be enabled

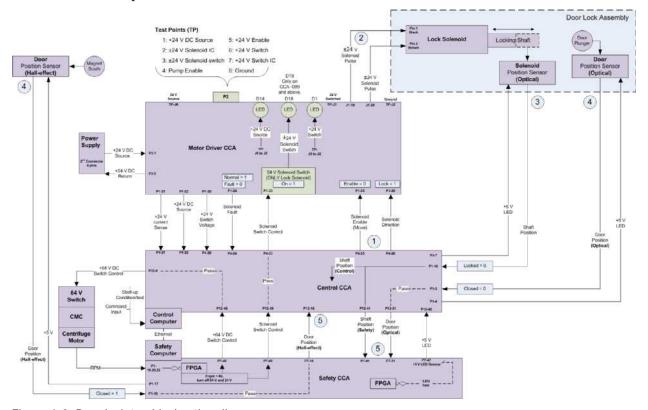


Figure 4-6: Door lock troubleshooting diagram

### **Door Lock System Measurements**

This section indicates where to take measurements in the door lock system, starting with the control CCA, moving to the motor driver CCA, the door lock assembly, and finally back to the control CCA.

#### Lock Solenoid Direction and Enable Bits

These bits cannot reasonably be measured in the field. Use STS to select and move the lock solenoid while using the lock solenoid voltage table (below) to measure the output from the motor driver CCA. If the solenoid connectors shows proper voltage when commanded, then assume that the bits are reaching the motor driver CCA.

#### Solenoid Voltage Pulse

This voltage is a momentary +24 V DC pulse. A DMM with a min/max feature will assist in capturing the voltage. If you do not have a DMM with this feature, disconnect the solenoid power harness. Insert meter probes into the device side of the solenoid power harness. Use STS to select and move the lock solenoid, and measure the solenoid pulse voltage out of the motor driver CCA.

Table 4-11: Lock solenoid voltage measurement points and values

From (Ground)	From (Ground) To (Voltage)		Unlock Direction	
Black wire	Brown wire	+24 V DC pulse	-24 V DC pulse	

#### Solenoid Coil Resistance

Measure the resistance across the solenoid coil with the harness disconnected. It should read 12.0  $\pm$  0.1  $\Omega$ .

#### Solenoid Position Optical Sensor

Measure across the solenoid position sensor connection (Pin 4 and 5) with the harness connected. The connector may be physically labeled as "Door Locked." Use STS to select and move the lock solenoid, and measure the voltage from the solenoid position sensor.

Table 4-12: Lock solenoid position optical sensor voltage measurement points and values

Pin 4	Pin 5	Reports Locked	Reports Unlocked
Blue wire	Green wire	0 V DC	+5 V DC

#### **Door Position Optical Sensor**

Measure across the door optical position sensor connection (Pin 4 and 5) with the harness connected. The connector may be physically labeled as "Door Closed." Open or close the centrifuge door and measure the voltage from the optical position sensor.

In STS, the Control Door Status section displays the status of the Hall-effect door position sensor, the Safety Door Status section displays the status of the optical door position sensor, and the Control Lock Status and Safety Lock Status sections both display the status of the door lock optical position sensor.

Table 4-13: Door position optical sensor voltage measurement points and values

Pin 4	Pin 5	Reports Open	Reports Closed
Blue wire	Green wire	0 V DC	+5 V DC

#### Door Position Hall-Effect Sensor

Measure across the door position Hall-effect sensor connection (Pin 2 and 3) with the harness connected. Open or close the centrifuge door and measure the voltage from the door position Hall-effect sensor. The south-pole magnet in the latch plate activates this sensor.

Table 4-14: Door position Hall-effect sensor voltage measurement points and values

Pin 2	Pin 3	Reports Open	Reports Closed
Blue wire	White wire	+5 V DC	0 V DC

#### 24 V Solenoid Switch

Measure across the motor driver CCA connector P2: pin 3 and test point J2 (or P2:8). Use STS to turn the door solenoid power on and off. Spinning the centrifuge more than 60 rpm does not turn off the switch in Service mode or before a procedure. It is turned off automatically only during a procedure.

#### Solenoid Fault Bit

This bit cannot reasonably be measured in the field. Use STS to view the faults log to determine whether the solenoid fault bit is being sent to the motor driver CCA.

## **Door and Door Lock System Mechanical Failure Symptoms**

This section describes common mechanical failure symptoms for the door and door lock systems.

**Latched** refers the condition where the two latch hooks on the frame catch the two latch holes on the latch plate when the centrifuge door is closed.

#### Unlatched refers to these conditions:

- The centrifuge handle is pressed and both latch hooks release and the door can be opened,
- Only one latch hook releases and the door cannot be opened.



**Note:** The door lock solenoid and the two optical sensors in the door lock assembly can all be replaced individually.

**Table 4-15: Possible door lock mechanical failures** 

Symptom	Inspection Points and Possible Solution	
Stuttering or sticking locking shaft movement	<ul> <li>Inspect the door lock assembly and the internal mechanisms for debris, dried spills, or damaged components. When the locking shaft is moved by hand, it should move freely once outside of the magnetic force.</li> </ul>	
	<ul> <li>Loosen the four screws holding the solenoid to the assembly, and align the solenoid to the locking shaft by feel. Replace as necessary.</li> </ul>	
	<ul> <li>Check the locking shaft hole in the latch plate to ensure that the locking shaft can go through. The hole should be an unbent, clean circle. If someone attempts to close the centrifuge door when the locking shaft is in the locked position, the latch plate impacts the locking shaft and can deform the lock hole. This may also damage the locking shaft. Check both for damage.</li> </ul>	
Centrifuge door does not latch evenly when closed	The basin position may need to be adjusted or the latch plate in the centrifuge door may need to be aligned. See the <i>Maintenance and Calibration</i> chapter in this manual for door alignment directions.	
Centrifuge door does not stay latched	<ol> <li>Note: This is a SAFETY ISSUE. Remove the device from service immediately</li> <li>Inspect the 4 door arms and the 8 shoulder screws used in mounting door arms. If one is unscrewed or broken, the door may not be able t contain a major centrifuge failure.</li> <li>Inspect the latch hooks on the frame and the latch holes in the latch plate damage or misalignment.</li> </ol>	

## **Door and Door Lock System Electrical Failure Symptoms**

This section describes common electrical failure symptoms for the door and door lock systems.

**Table 4-16: Possible door lock electrical failures** 

Symptom	Possible Causes
24 V over current STS value	Remove the door lock assembly and measure the solenoid coil resistance while gently manipulating the assembly to try and find a short in the coil.
Door position Hall-effect sensor does not report when door is closed	Inspect the south-pole magnet in the latch plate. It may be damaged or have fallen out. A diagnostic tool can be made with the latch magnet spare.

Table 4-16: Possible door lock electrical failures (continued)

Symptom	Possible Causes
Stuttering or sticking locking shaft movement, or no locking shaft	Remove the door lock assembly and measure the solenoid coil resistance while gently manipulating the assembly to try and find an open in the coil.
response to commands	<ul> <li>Measure the solenoid voltage pulse several times to ensure it is approximately ±24 V.</li> </ul>
	<ul> <li>As you measure the solenoid switch voltage, toggle the STS "Door Solenoid Power" on and off. Ensure that the solenoid switch voltage is consistent during switching.</li> </ul>
	<ul> <li>Measure the voltage of the 24 V solenoid switch, the 24 V source, and the 24 V switched on the motor driver CCA to ensure they are all approximately ± 24 V.</li> </ul>
	Check the centrifuge motor system for rpm feedback problems. If the centrifuge is reporting speeds above 60 rpm, the system will not unlock the solenoid.

**Table 4-16: Possible door lock electrical failures** 

Symptom	Possible Causes			
Motor driver CCA LEDs not lit during power on	Procedure Mode			
pono. on		24 V Power (D14)	24 V Lock (D18)*	24 V SW (D1)
	Power On	On	Off	Off
	24 V Lock Power On	On	On	Off
	24 V Lock Power Off	On	Off	Off
	T1 Test Start (D1 Blinks On/Off)	On	Off	On to Off
	- Test Lock Solenoid	On	On	On
	- Test Lock Power Control	On	Off	On
	- Test Lock Solenoid	On	On	On
	T1 Test Done – Ready for Procedure	On	On	On
		Servi	ce Mode	
	Power On	On	Off	Off
	Idle State (Before Connecting to STS)	On	Off	Off
	Idle State (Connected to STS)	On	On	Off
	Using STS, you ca to verify that signa *LED on motor dr	als are correctly re	eaching the motor	oor solenoid power) driver.

## **Door and Door Lock System Connection Failures**

This section describes common connection problems to check for in the door and door lock systems.

**Table 4-17: Possible door lock connection failures** 

Connection	Possible Connection Error
Door lock assembly position sensors	The optical solenoid position sensor and the optical door position sensor use identical sensors. Swapping these connectors will cause the solenoid position and door position to fail.

#### **STS Status and Control**

The table below contains door position and door lock troubleshooting states. You can make a tool to test the door position Hall-effect sensor using the latch magnet spare (704084-000).

**Table 4-18: STS status and control** 

Front Door Position	Door Lock Assembly (Right Side)			Door Latch (Left Side)	
and Solenoid Position	Solenoid Sensor Reported by both Control and Safety CCAs		Door Position Sensor (Optical)	Door Position Sensor (Hall- Effect)	
	Control Lock Status	Safety Lock Status	Safety Door Status	Control Door Status	
Door Open/Unlocked	Unlocked	Unlocked	Open	Open	
Door Open/Locked	Locked	Locked	Open	Open	
Door Closed/Unlocked	Unlocked	Unlocked	Closed	Closed	
Door Closed/Locked	Locked Locked		Closed	Closed	
Troubleshooting Tests					
<b>Door Open</b> Push in Door Position Plunger	N/A	N/A	Closed*	Open	
<b>Door Open</b> Magnet Tool Under Door Position Sensor	N/A	N/A	Open	Closed*	
* Sensor is being triggered					

## **Version 6.0.6 Dlog Information**

This is the dlog header, periodic data, and episodic data that is relevant to the door lock system.

The header is the function name and/or the unit of value for the periodic data.

The periodic data is device hardware values and device software information. This data is written into the dlog every six seconds as long as the device is powered on. A row in the dlog with periodic data does not have episodic data in it.

The episodic data is detailed and coded messages from the safety or control systems. These could be either values from hardware or software messages from the procedure. A row in the dlog with episodic data does not have periodic data in it.

#### **Header/Periodic Information**

**Table 4-19: Door lock periodic information** 

Header Line 1	Header Line 2	Definition		
DoorComma nd	1=door commanded locked	This contains a boolean flag for the commanded direction of the lock solenoid. 0 = door is not commanded to be locked, 1 = door is commanded to be locked.		
DoorStatus	O/C=open/close L/U=lock/unlock	·		
		Front Door Position and Solenoid Position	Solenoid Sensor	O/C=Open/Close L/U=Lock/Unlock
			Door Command	Door Status
		Door Open/Unlocked	0	0+U
		Door Open/Locked	1	0+L
		Door Closed/Unlocked	0	C+U
		Door Closed/Locked	1	C+L

#### **Episodic Information**

**Door lock movement logging:** The door lock system produces logging that indicates the commanded door lock position and the measured position.

**Table 4-20: Door lock movement logging** 

Episodic Line	Definition	
SetDoorPower Old State : [1 or 0] New State: [1 or 0]	The safety CCA is controlling the lock solenoid power. The door latch test (lock solenoid test) occurs during the T1 start-up tests. This test makes sure that the lock solenoid power can be turned off and that, when the solenoid is commanded to move, it does NOT move. The solenoid should not move because the power is off. This test also turns on the lock solenoid power and tests that, when the solenoid is commanded to move, it moves in time.	
door lock command in progress: latches= [1 or 0] direction= [1 or 0] retry count= [2]	<ul> <li>When the lock solenoid is commanded to lock in the period column "DoorCommand," this line is logged.</li> <li>Latches: 1 = Lock solenoid enable, 0 = Lock solenoid disable.</li> <li>Direction: 1 Unlock direction, 0 = Locked direction.</li> <li>Retry count: 2 = number of times tried.</li> </ul>	

**Door latch episodic logging:** "Enter:" indicates that the device software has entered a specific system state or substate. "Exit:" indicates that the device software has exited a specific system state or substate. See *Software Description* for more detail about specific software states. The following are examples of enter and exit logging:

- Enter:DoorLatchTest
- Exit:DoorLatchTest

Table 4-21: Door latch test episodic logging

Episodic Line	Definition
Enter: DoorLatchTest	Entering door solenoid test
Power Request Received: 3=ENABLE_SOLENOID_POWER	Enables +24 V solenoid switch
SafetyPowerControlTimer::PowerControlDoor (1) sending SafetyTestDoneMsg(4)	Communication log
door lock command in progress: latches=1 direction=1 retry count=2	Commanded locked
Power Request Received: 7=DISABLE_SOLENOID_POWER	Disables +24 V solenoid switch
Force DISABLE Door Power	Log of power request above
SetDoorPower Old State : 1 New State: 0	See door lock movement table above
mqueue max: 2/70	Number of messages in queue

Table 4-21: Door latch test episodic logging (continued)

<b>Episodic Line</b>	Definition
SafetyPowerControlTimer::PowerControlDoor (0) sending SafetyTestDoneMsg(PWR_CONTROL_SOLEN OID_NOMINAL)	Communication log
door lock command in progress: latches=1 direction=0 retry count=2	Commanded to unlock
solenoid fault	Attempts to unlock but cannot: Expected response
Waiting for T1 test to complete	General message
door lock command in progress: latches=1 direction=0 retry count=2	Commanded unlocked
solenoid fault	Attempts to unlock but cannot: Expected response
Power Request Received: 3=ENABLE_SOLENOID_POWER	Enables +24 V solenoid switch
SafetyPowerControlTimer::PowerControlDoor (1) sending SafetyTestDoneMsg(4)	Communication log
Cent RPM < 60 ENABLE Door Power	The centrifuge slowed down below 60 rpm Can also be: Cent RPM > 60 DISABLE Door Power The centrifuge was spun by hand faster then 60 rpm while the door was open
SetDoorPower Old State : 0 New State: 1	See door lock movement table above
door lock command in progress: latches=1 direction=0 retry count=2	Commanded to unlock
Door latch test passed	Test passed
Exit: DoorLatchTest	Exiting door solenoid test

# 5

## **Maintenance and Calibration**

#### **Aligning the Centrifuge Door**

These are instructions for aligning the centrifuge door.

The goal is to achieve an even 1/8 in (3 mm) gap between the centrifuge door and the pump panel and to apply enough pressure to the door so that it does not touch the pump panel.

1. Pull evenly on both sides of the door and compare the gap between the pump panel and the centrifuge door to the following figure. Use the following figure and table to determine the next action.

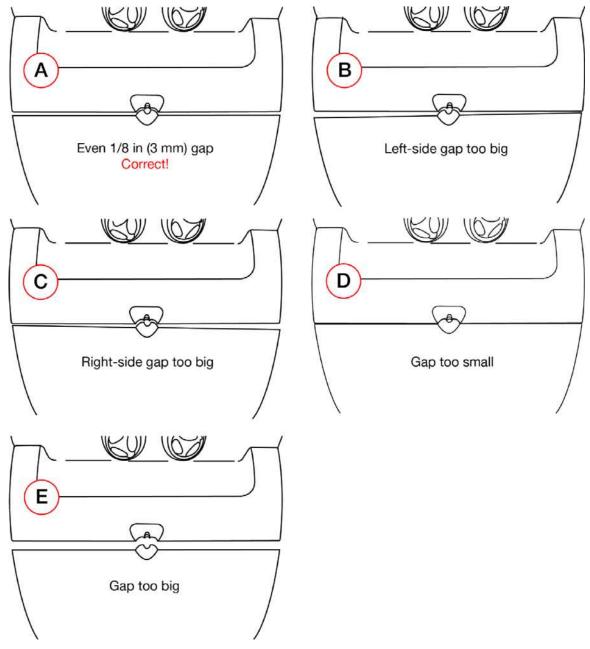


Figure 5-1: Door alignment examples

**Table 5-1: Door gap troubleshooting** 

A	If there is an even 1/8 in gap between the centrifuge door and the pump panel, there is no need to adjust the door latch.	
B, C	If the centrifuge door is misaligned, proceed to step 2.	
D	If the gap is too small (less than 3/32 in), verify that the hex screws on both sides of the pump panel are tight. Make sure you are pulling on the centrifuge door. If the problem persists, proceed to step 2.	
E	If the gap is too big (greater than 1/4 in), proceed to step 2.	

- 2. Verify there is no debris on the latches or the latch plate. If there is, clean the latches and latch plate. Proceed to step 1.
- 3. Remove the side panels. See "Removing the Side Panels" on page 5-11.
- 4. Determine how the latch plate should be adjusted using the following table, but do not make adjustments until step 7.

Measure the gap between the front door and the pump panel on the left and the right. Use the following table to determine how to adjust the latch plate.



**Tip:** Use a 1/8-inch allen wrench as a feeler gauge.

**Table 5-2: Latch plate adjustment** 

Left Side Gap	Right Side Gap	Adjustment	
Less than 3/32 in	Less than 3/32 in	Loosen all 4 screws (¼ turn) and move entire latch plate so that more latch plate is sticking further out of the door.	
Less than 3/32 in	Less than 3/16 in, but greater than 1/8 in	Leave the right screw farthest from the door edge tight, and slightly (¼ turn) loosen the other three screws that secure the latch plate Slowly rotate the latch plate around the tighter screw so that the lef side is sticking farther out of the door.	
Less than 3/32 in	Greater than 3/16 in	Leave the right screw closest to the door edge tight, and slightly (1/4 turn) loosen the other three screws that secure the latch plate. Slowly rotate the latch plate around the tighter screw so that the left side is sticking farther out of the door.	
Less than 3/16 in, but greater than 1/8 in	Less than 3/32 in	Leave the left screw farthest from the door edge tight, and slightly (¼ turn) loosen the other three screws that secure the latch plate. Slowly rotate the latch plate around the tighter screw so that the right side is sticking farther out of the door.	

**Table 5-2: Latch plate adjustment (continued)** 

Left Side Gap	Right Side Gap	Adjustment
Greater than 3/16 in	Less than 3/32 in	Leave the left screw closest to the door edge tight, and slightly (1/4 turn) loosen the other three screws that secure the latch plate. Slowly rotate the latch plate around the tighter screw so that the right side is sticking farther out of the door.
Greater than 3/16 in	Greater than 3/16 in	Loosen all 4 screws (¼ turn) and move the entire latch plate so that less of the plate is sticking out of the door.

- 5. Remove the screws holding the side of the door link arms. Support the door; it will fall to the floor when these two screws are released.
- **6.** Using a pencil, mark the corners of the latch plate. This will help you return to the starting point if you over-adjust.
- 7. Perform the adjustment determined in step 4.
- 8. Open and close the door. Verify that the door does not contact the pump panel when closing.
- 9. Open the door slightly and release it; verify that the door does not hit the rubber stops. If it does, the springs or air shocks need to be replaced.

## **Calibrating the Centrifuge Motor Controller**

This is the calibration procedure for the centrifuge motor controller.

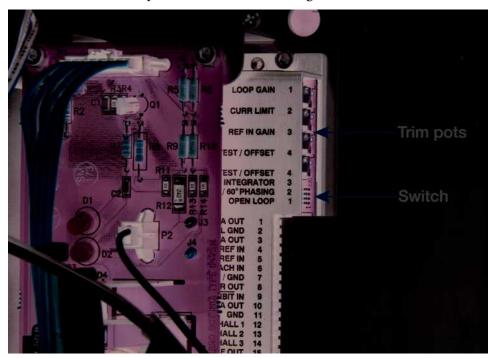


Figure 5-2: The centrifuge motor controller

Refer to the following table for the initial settings of the centrifuge motor controller.

**Table 5-3: Initial trim pot settings** 

Trim pot	Start	Then
1	14 turns <b>counterclockwise</b>	
2	14 turns <b>clockwise</b>	5.5 turns <b>counterclockwise</b>
3	14 turns <b>clockwise</b>	2 turns counterclockwise
4	14 turns <b>clockwise</b>	7 turns <b>counterclockwise</b>

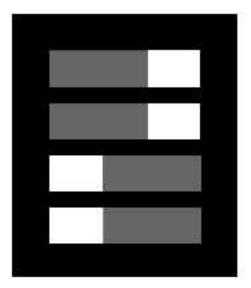


Figure 5-3: Initial switch settings

- 1. Connect the service computer to the Spectra Optia system.
- 2. Start the STS software.
- 3. Reboot the Spectra Optia system into Service mode.
- 4. Select the **Open Loop** check box in STS.
- 5. Verify that the 5 V reading is less than or equal to 5.03 V.
- 6. To prevent the centrifuge arm from rotating, place a tie wrap around the right-hand side of the chamber bracket and around the horizontal member of the loop arm. Tighten the tie wrap.
- 7. Close and lock the centrifuge door. Enable the 64 V switch.



**Caution:** Verify that the filler is installed and the hex holder is latched. The system will be seriously damaged if the hex holder is not latched.

- 8. Command the centrifuge speed to 1,000 rpm. Allow the speed to stabilize.
- 9. If necessary, adjust pot 2 until the centrifuge current reading is between 4.9 A and 5.1 A.
- **10.** Command the centrifuge speed to 0 rpm.
- 11. Disable the 64 V switch, open the centrifuge door, and remove the tie wrap.
- 12. Close and lock the centrifuge door. Enable the 64 V switch.
- 13. Command the centrifuge speed to 2,950 rpm. Allow the speed to stabilize.
- 14. If necessary, adjust pot 3 until the actual centrifuge speed reads between 2,850 rpm and 2,950 rpm.
- 15. Set the centrifuge speed to 200 rpm. Allow the speed to stabilize.
- 16. If necessary, adjust pot 4 until the actual centrifuge speed reads between 150 rpm and 250 rpm.
- 17. Repeat steps 13 to 16 until no further adjustments are needed.
- **18.** Set the centrifuge speed to 0 rpm. Verify that the centrifuge stops in 10 seconds.

19. Run Auto Test from the STS Tools menu.

#### **Positioning the Linear Actuator Sensors**

The linear actuator sensors may need to be repositioned if there are cassette alarms or if the machine fails the cassette plate test in Autotest.

The panel on the same side of the device as the IV pole must be removed.

- 1. Boot the device to Service mode and connect with the service software.
- 2. Enable the 24 V switch.
- 3. Raise the cassette plate.
- 4. The two optical sensors are mounted below the pump panel on one of the square members that house the linear actuator guides. Loosen the lower accessible screw for the top optical sensor.

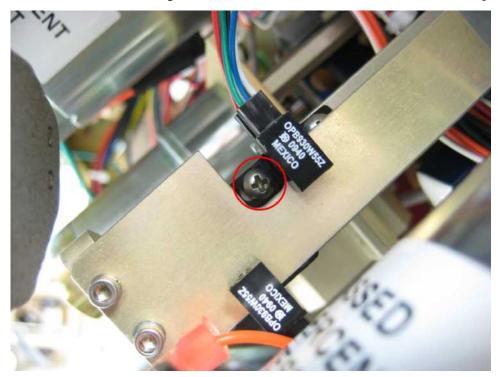


Figure 5-4: The lower accessible screw (circled)

- 5. Place a 0.035 in (0.89 mm) or 0.036 in (0.91 mm) feeler gauge under the upper left corner of the cassette plate.
- **6.** Command the cassette plate down and verify that the service software cassette position indicator status is **Unknown**.
  - If the service software cassette position indicator status is **Down**, proceed to step 7.
  - If the service software cassette position indicator status is **Up**, proceed to step 8.
  - If the service software cassette position indicator status is **Unknown**, proceed to step 9.

7. If the cassette position status is **Down**, loosen the upper accessible screw on the optical sensor and gently tap on the sensor to adjust the position until the software status is **Unknown**. Tighten the upper screw. Recheck the **Unknown** position by going to step 3.

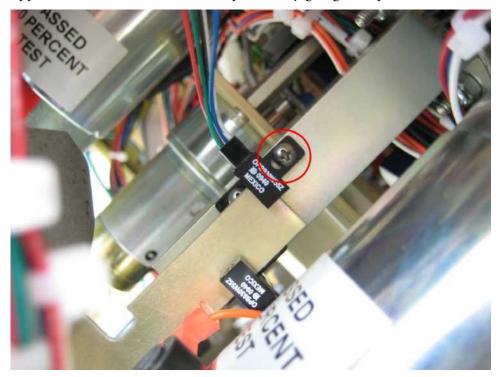


Figure 5-5: The upper accessible screw (circled)

- 8. If the cassette position status is **Up**, the two optical sensors are swapped at the valve CCA. Swap the optical sensor connectors on the bottom of the valve CCA.
- 9. Command the cassette plate up.
- 10. Place a 0.020 in (0.51 mm) feeler gauge under the upper left corner of the cassette plate.
- 11. Command the cassette plate down and verify that the service software cassette position indicator status is **Down**.
- 12. If the cassette position status is not **Down**, loosen the upper accessible screw and gently tap on the sensor to adjust the position until the status is **Down**. Tighten the upper screw.



**Note:** If any adjustment is made for the **Down** position check, you must recheck the **Unknown** position by going to step 3.

#### 13. Perform functional check below:

- 1. Command the cassette tray up and tighten the lower accessible screw.
- 2. Place a 0.035 in (0.89 mm) or 0.036 in (0.91 mm) feeler gauge under the upper left corner of the cassette plate.
- 3. Command the cassette plate down and verify that the service software cassette position indicator status is **Unknown**.
- 4. Command the cassette plate up.
- 5. Place a 0.020 in (0.51 mm) feeler gauge under the upper left corner of the cassette plate.

- **6.** Command the cassette plate down and verify that the service software cassette position indicator status is **Down**.
- 7. Command the cassette plate up and remove the feeler gauge.
- **8.** Command the cassette plate down and, without any feeler gauge, check that the cassette plate stops. Verify that the service software cassette position indicator status is **Down**.
- 9. Command the cassette plate up and verify that the cassette position status is **Up**.
- 10. If any part of the adjustment fails, restart the adjustment.
- 14. Install the side panel.

## **Removing the Side Panels**

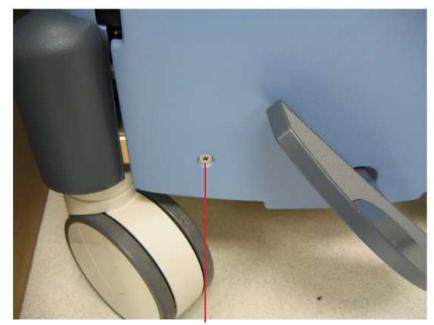
The side panels may be removed to provide access to internal components.

1. Remove the brake pedal by loosening the hex screw underneath the pedal.



Figure 5-6: Brake pedal hex screw location

2. Remove the lower front panel by removing the two hex screws.



Lower front panel hex screw

Figure 5-7: Lower front panel hex screw locations

3. Pull the two front latches upwards to release the locking mechanisms.

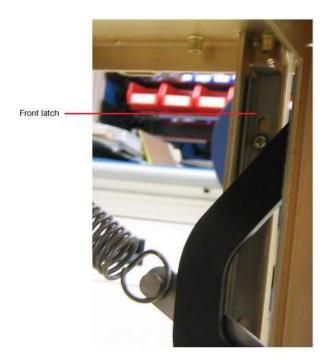


Figure 5-8: Front latch location

4. Remove the back panel by turning the six Phillips-head screws a half turn.

5. Pull the two rear latches upwards to release the locking mechanisms.

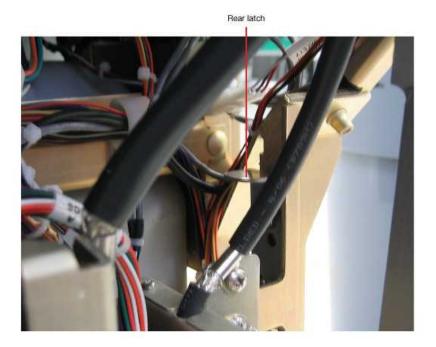


Figure 5-9: Rear latch location

- 6. Open the centrifuge door and loosen the two flat-head screws on the sides of the centrifuge basin.
- 7. Remove the side panels by pulling down on the bottom of the panel until the guides disengage from the pump panel and top cap.

Reinstalling the side panels is the reverse of removal. Begin by aligning the ridges on the top of the side panel with the pump panel and top cap. Push up on the side panels to secure them in position.

#### **Saline Run**

Ensure that all panels and doors are in place before starting the saline run.

- 1. Device setup
  - **a.** Allow the Trima Accel device to boot normally.
  - b. Verify that there are no alarms after the Trima Accel device has fully booted.
- 2. Load a disposable set
  - **a.** Load a disposable set or an appropriate test set for the saline run.
  - b. Touch the **Donor Info** button on the main screen and enter the following donor information:

Select gender	Male
Enter the height	6 ft 6 in (198 cm)
Enter the weight	250 lb (114 kg)
Blood type	A+
Hematocrit/hemoglobin	45% or 15.0 g/dL
Platelet precount	200 (× 1,000)

- c. Touch the **Confirm** button to confirm the information and continue.
- **d.** Select and confirm a product procedure for the type of disposable set used with this saline run.
- e. Touch the Load System button.
- f. Enter or accept the REF # of the disposable, if applicable. If "The REF does not match the selected procedure" is displayed, go back to the Donor Info tab and select a different procedure.
- g. Follow the on-screen instructions to load the disposable set.
- **h.** Confirm the donor information, if applicable.
- i. Connect either an anticoagulant bag or a saline bag in place of anticoagulant when prompted to connect the anticoagulant (AC) bag.
- j. Verify that the AC prime test passes without any alarms after the Priming AC screen appears.
- **k.** Touch either the **Begin Donor Prep** button or the **Prepare Donor** button and follow the instructions on the screen. The device uses the saline or AC bag as the donor.
- 1. If using a new disposable set, connect the donor needle line to the saline or AC bag, and leave the white pinch clamp on the sample bag line closed (ignore the displayed instruction to take a sample). If necessary, use tape to secure the needle and keep it from slipping out of the bag.
- m. If using a test set, connect fluid bag as appropriate for the test set.
- n. Touch the **Start Draw** button.
- **o.** The Blood Prime In Progress screen is displayed. Wait for the device to prime.
- **p.** The Draw In Progress screen is displayed.
- **q.** Verify that the device completes the first draw and return cycle without alarms.

#### 3. Stop button function test

- **a.** After two or more draw and return cycles, and when the reservoir is LESS THAN HALF FULL, press the **Stop** button on the left side of the display console.
- b. Verify that the door unlocks once the centrifuge stops spinning, and then open the door.
- c. Close the door and touch the **Continue** button on the screen.
- **d.** Verify that the door locks and the centrifuge starts spinning.
- 4. Draw pressure too low function test
  - a. During a draw cycle, clamp the donor needle line and verify that the "Draw Pressure Too Low" alarm occurs and the Trima Accel device goes into APS pause.
  - **b.** Unclamp the line and the Trima Accel device continues from APS pause.
- 5. Return pressure too high function test
  - a. During a return cycle, clamp the donor needle line and verify that the "Return Pressure Too High" alarm occurs.
  - **b.** Unclamp the line and touch the **Continue** button on the screen.
- **6.** Centrifuge pressure high function test
  - a. During a draw cycle, and when the reservoir is LESS THAN HALF FULL, close the clamp on the pink line leading from the centrifuge pressure sensor on the cassette down into the centrifuge chamber. Verify that the "Centrifuge Pressure High" alarm occurs.
  - b. Open the clamp on the line and touch the **Continue** button on the screen.
- 7. Power interrupt function test



**Note:** If the Trima Accel device is in the draw cycle when power is interrupted, the device must boot up within 10 minutes or the Trima Accel device will require the run to end without rinseback.

- a. After two or more draw and return cycles, turn off the Trima Accel device at the start of a draw cycle. Turn the power back on and allow the Trima Accel device to boot to the normal procedure.
- **b.** Verify that the "Power Interrupted" alarm is displayed.
- c. Touch the **Continue** button on the screen and verify that the Trima Accel device goes into recovery, and then resumes draw and return cycles.
- **8.** AC sensor test
  - a. Invert the AC drip chamber to introduce an air bubble that is approximately ½ inch long into the line. Do not exceed 1 inch long, and do not allow the air bubble to enter the access needle.
  - **b.** Verify that the "Air Detected at AC Sensor" alarm occurs and that the pumps stop.
  - c. Touch the **Continue** button on the screen.
- 9. End of fluid run
  - **a.** After the device has fully recovered and is at the beginning of a draw cycle, touch the **End Run** button, and then touch the **Rinseback** button on the screen. Follow the on-screen instructions to complete rinseback, disconnect the donor, and unload the disposable set.
  - **b.** Verify that the cassette unloads properly and that no alarms occur during rinseback, donor disconnect, or unloading.

# **6** Specifications

# **Physical Specifications**

**Table 6-1: Trima Accel system physical specifications** 

Characteristics	Performance	Conditions
Case material and finish	Painted structural foam panels, painted steel and aluminum; teal, gray, and black	
Floor space required	4,285 cm <sup>2</sup> (664 in <sup>2</sup> )	Floor slope less than 5 degrees.
Physical dimensions	Height:  • 106.4 cm (41.9 in) (without IV pole)  • 162.1 cm (63.8 in) (with IV pole)  Width: 52.7 cm (20.75 in)  Depth: 81.3 cm (32.0 in)	
Weight	Without Seal Safe: 84 kg (185 lb) With Seal Safe: 85.2 kg (187.7 lb)	

# **Environmental Specifications**

Table 6-2: Trima Accel system environmental specifications

Characteristics	Performance	Conditions
Ambient operating temperature	15.5 °C to 27.7 °C (60 °F to 82 °F)	
Ambient operating humidity	8% to 80% relative humidity (RH), non- condensing	
Cleanability	Unit is not damaged by 0.25% sodium hypochlorite dilute bleach or by blood spills.  Pump rotors are removable.	
	Channel leaks are contained within the centrifuge basin.	
Fluid spillage	Device passed spill test EN60601-1:44 and is electrically and performance safe.	
	Unit is not rendered unsafe by spillage over the top.	
Storage temperature: device	0 °C to 60 °C (32 °F to 140 °F)	
Storage conditions: disposable tubing set	Long-term storage temperature range: 0 °C to 60 °C (32 °F to 140 °F) Shipping temperature range: -29 °C to 60 °C	A disposable tubing set is acceptable for use as long as it has not expired and the integrity of the tubing set has not been compromised. Refer to the Preface of the Trima Accel Operator's Manual, "Warnings — Keeping Tubing Set Functionally Closed."

# **Electrical Power and Safety**

Table 6-3: Trima Accel system electrical power and safety specifications

Characteristics	Performance	Conditions
Electrical safety standards	Meets EN60601-1 General requirements for safety of medical electrical equipment and EN60601-1:19 < 500 µa AC leakage current	
Input	Power rate: 1050 VA Frequency rate: 50/60 Hz Voltage: 100-240 V	Circuit breaker overcurrent protection.
Input current	100 V AC to 127 V AC: 10 A to 8 A 50/60 Hz	
	200 V AC to 240 V AC: 5 A to 4 A 50/60 Hz	

The Trima Accel system is intended for use in the electromagnetic environment specified below. The customer or the user of the Trima Accel system should ensure that it is used in such an environment. The term "emissions" refers to the effects that the Trima Accel system machine can have on other devices in its vicinity. Based on the emissions testing listed below, the Trima Accel system should not interfere with typical mobile devices such as mobile cell phones or portable media/communication devices.

**Table 6-4: EMC emissions guidance** 

Emissions Test	Compliance	Electromagnetic Environment— Guidance
RF emissions CISPR 11	Group 1	The Trima Accel system uses high frequencies only for its internal function (e.g., computer timing signals and internal communication). The RF emissions meet the requirements of CISPR 11. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Group 2	The Trima Accel system emits RF for the Seal Safe accessory in order to perform its intended function. This is only when sealing or cutting are performed. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class A	The Trima Accel system is suitable for use in all establishments other than residential and those directly connected to the public low-voltage power supply network that supplies
Harmonic emissions IEC 61000-3-2	Class A	buildings used for residential purposes.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

The Trima Accel system is intended for use in the electromagnetic environment specified below. The customer or the user of the Trima Accel system should ensure that it is used in such an environment. The term "immunity" refers to the effects that another device may have on the Trima Accel system machine in its vicinity.

**Table 6-5: EMC electromagnetic immunity** 

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment—Guidance	
Electrostatic discharge (ESD)	± 6 kV contact	± 6 kV contact		
IEC 61000-4-2	± 8 kV air	± 8 kV air		
Electrical fast transient/burst	± 2 kV for power supply lines	± 2 kV for power supply lines	Mains power quality should be that of a typical blood center or	
IEC 61000-4-4	± 1 kV for input/output lines	± 1 kV for input/output lines	hospital environment.	
Surge	± 1 kV line(s) to line(s)	± 1 kV line(s) to line(s)	Mains power quality should be that of a typical blood center or	
IEC 61000-4-5	± 2 kV line(s) to earth	± 2 kV line(s) to earth	hospital environment.	
Voltage dips, short interruptions and voltage variations on power supply input lines			See Table 6-6	
IEC 61000-4-11				
Power frequency (50/60 Hz) magnetic field	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical	
IEC 61000-4-8			blood center or hospital environment.	

The Trima Accel system is intended for use in the electromagnetic environment specified below. The customer or the user of the Trima Accel system should ensure that it is used in such an environment. The term "immunity" refers to the effects that another device may have on the Trima Accel system machine in its vicinity.

**Table 6-6: EMC electromagnetic immunity (Voltage Variations)** 

Immunity Test	Test Level IEC 60601-1-2	Compliance Levels		Electromagnetic Environment— Guidance
		100V	230V	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% <i>UT</i> (> 95% dip in <i>UT</i> ) for 0.5 cycle  40% <i>UT</i> (60% dip in <i>UT</i> ) for 5 cycles	< 5% <i>UT</i> (> 95% dip in <i>UT</i> ) for 0.5 cycle  70% <i>UT</i> (30% dip in <i>UT</i> ) for 2 cycles	< 5% <i>UT</i> (> 95% dip in <i>UT</i> ) for 0.5 cycle  40% <i>UT</i> (60% dip in <i>UT</i> ) for 5 cycles	Mains power quality should be that of a typical blood center or hospital environment.  Interruptions of the mains supply at voltages of 100 Volts or less will result in system restart and procedure recovery as permitted by IEC 61000-4-11.
	70% <i>UT</i> (30% dip in <i>UT</i> ) for 25 cycles  < 5% <i>UT</i> (> 95% dip in <i>UT</i> ) for 5 s	85% <i>UT</i> (15% dip in <i>UT</i> ) for 25 cycles  < 5% <i>UT</i> (> 95% dip in <i>UT</i> ) for 5 s	70% <i>UT</i> (30% dip in <i>UT</i> ) for 25 cycles  < 5% <i>UT</i> (> 95% dip in <i>UT</i> ) for 5 s	If the user of the Trima Accel system is aware of frequent power interruptions at his or her facility and requires continued operation during mains power interruptions, it is recommended that the Trima Accel system be powered from a suitably rated uninterruptible power supply.

**Note:** *UT* is the AC mains voltage prior to application of the test level.

The Trima Accel system is intended for use in the electromagnetic environment specified below. The customer or the user of the Trima Accel system should ensure that it is used in such an environment. The term "immunity" refers to the effects that another device may have on the Trima Accel system machine in its vicinity.

Table 6-7: Guidance and manufacturer's declaration—electromagnetic immunity (1 of 2)

Immunity Test	Test Level IEC 60601-1-2	Compliance Level	Electromagnetic Environment—Guidance Recommended Separation Distance
			Portable and mobile RF communications equipment should be used no closer to any part of the Trima Accel system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF	3 Vrms	3 V	$d = 1.2\sqrt{P}$
IEC 61000-4-6	150 kHz to 80 MHz		For calculations based on this equation, see Table 6-9.
Radiated RF	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$
IEC 61000-4-3			80 MHz to 800 MHz. For calculations based on this equation, see Table 6-9.

Note: At 80 MHz and 800 MHz, the higher frequency range applies.

**Note:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

The Trima Accel system is intended for use in the electromagnetic environment specified below. The customer or the user of the Trima Accel system should assure that it is used in such an environment. The term "immunity" refers to the effects that another device may have on the Trima Accel system machine in its vicinity.

Table 6-8: Guidance and manufacturer's declaration—electromagnetic immunity (2 of 2)

Immunity Test	Test Level	Compliance	Electromagnetic Environment—Guidance
	IEC 60601-1-2	Level	Recommended Separation Distance
			$d=2.3\sqrt{P}$ 800 MHz to 2.5 GHz.  Where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and $d$ is the recommended separation distance in meters (m).  For calculations based on this equation, see Table 6-9.  Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. b  Interference may occur in the vicinity of equipment marked with the following symbol:

Note: At 80 MHz and 800 MHz, the higher frequency range applies.

**Note:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

<sup>&</sup>lt;sup>a</sup> Field strengths from fixed transmitters—such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast—cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Trima Accel system is used exceeds the applicable RF compliance level described above, the Trima Accel system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Trima Accel system.

<sup>&</sup>lt;sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

The Trima Accel system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Trima Accel system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Trima Accel system as recommended below, according to the maximum output power of the communications equipment.

Table 6-9: Recommended separation distance between portable and mobile RF communications equipment and the Trima Accel system

	Separation distance according to frequency of transmitter <i>m</i>		
Rated maximum output power of transmitter <i>W</i>	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

**Note:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

## **Safety Certifications**

#### **Table 6-10: Trima Accel safety certification**

Bears CSA marking with adjacent "C" and "US"

Class 1, Type BF Equipment

Certified file No. LR 114324-2

- Canadian Standards Association CAN/CSA-C22.2, No. 601-1-M90
- Power rate 1050 VA; frequency rate 50/60 Hz; voltage 100 to 240 V

UL.Std. No. 60601-1

CE-marked Notified Body: British Standards Institution

## **Performance Specifications**

**Table 6-11: Trima Accel flow rates and volumes** 

Characteristics	Performance	Conditions
AC pump volume accuracy	± 6% of the display value	Under normal operating conditions and with no line restrictions.
		Automatic loading and unloading.
Inlet pump volume accuracy	± 6% of the display value	Under normal operating conditions and with no line restrictions.
		Automatic loading and unloading.
Plasma pump volume accuracy	± 6% of the display value	Under normal operating conditions and with no line restrictions.
		Automatic loading and unloading.
Platelet pump volume accuracy	± 6% of the display value	Under normal operating conditions and with no line restrictions.
		Automatic loading and unloading.
Return pump volume accuracy	± 6% of the display value	Under normal operating conditions and with no line restrictions.
		Automatic loading and unloading.
RBC product volume	± 10% of the display volume*	As collected, after adding storage solution.
Needle flow range	Draw cycle: ≤ 142 mL/min	
	Return cycle: ≤ 302.5 mL/min	

 $<sup>^{\</sup>star}$  For validation purposes, product volume + storage solution should equal the actual volume  $\pm$  10%.

## **Product Specifications**

Table 6-12: Trima Accel system RBC storage bag specifications

Storage Parameter	Storage Ranges	Conditions
Maximum RBC storage bag volume	Up to 600 mL	Includes RBC storage solution.
Optimal RBC volume per bag	150 mL to 250 mL at 100% Hct for non- leukoreduced RBC products 128 mL to 250 mL at 100% Hct for leukoreduced RBC products	

#### Table 6-13: Trima Accel system storage bag specifications for platelets in plasma

Storage Parameter	Storage Ranges	Conditions
Platelet storage bag volume	100 mL to 400 mL	
Platelet concentration	0.7 to 2.1 × 10 <sup>6</sup> /μL	
Maximum total platelets per bag	≤5.1 × 10 <sup>11</sup> platelets	Yield = volume × concentration
Platelet storage temperature	22 ± 2 °C	

#### Table 6-14: Trima Accel system plasma storage bag specifications

Storage Parameter	Maximum Target	Conditions	Maximum Final Product Volume
Plasma storage bag volume	Up to 600 mL	If frozen	Up to 636 mL
	Up to 1,000 mL	If liquid	Up to 1,060 mL
Plasma storage bag volume, multiplasma tubing sets	Up to 400 mL	If frozen	Up to 440 mL
	Up to 600 mL	If liquid	Up to 660 mL

## **Blood Tubing Sets**

Table 6-15: Trima Accel system blood tubing set specifications

Characteristics	Performance	Conditions
AC filter, replacement fluid filter, storage solution filter	Maintain functionally closed system.	
TLR leukoreduction filter	May be used to leukoreduce RBC products by gravity filtration after the collection procedure.	
Extracorporeal blood volume (approximate)	Platelet-capable tubing sets  196 mL  RBC/plasma and plasma-only tubing sets  182 mL	
Residual volume: platelet-capable tubing sets	After rinseback  packed RBC volume = 30 mL pRBC  plasma volume = 33 mL plasma  No rinseback  packed RBC volume = 85 mL pRBC  plasma volume = 121 mL plasma	RBC and plasma volume in the tubing set will vary depending on the component being collected. Volumes represent maximum residual volumes possible for any collection ended without rinseback.
Residual volume: RBC, plasma, and plasma-only tubing sets (without LRS chamber)	After rinseback  packed RBC volume = 25 mL pRBC  plasma volume = 40 mL plasma  No rinseback  packed RBC volume = 91 mL pRBC  plasma volume = 83 mL plasma	RBC and plasma volume in the tubing set will vary depending on the component being collected. Volumes represent maximum residual volumes possible for any collection ended without rinseback.
Needle gauge	Platelet-capable tubing sets 17 gauge RBC/plasma and plasma-only tubing sets 18 gauge	
Return reservoir filter	Prevents particles (200 microns or larger) from entering the line at the bottom of the reservoir	Return reservoir prevents air from entering the return line.

## Centrifuge

#### **Table 6-16: Trima Accel system centrifuge specifications**

Characteristics	Performance	Conditions
Maximum g-force developed in channel	1,200 g	At maximum operating speed.

## **Safety**

**Table 6-17: Trima Accel system safety specifications** 

Characteristics Performance		Conditions
Alarms	Audio alarm (mutable), red flashing light, red steady light, display prompts.	
Shutdown conditions	Pumps shut down automatically under alarm conditions.	Shutdown may be initiated using the <b>Stop</b> or <b>Pause</b> button.
	Centrifuge slows down if pumps are paused for more than 1 min. Centrifuge stops if pumps are paused for more than 10 min.	
Safety	No single point failure causes donor or operator injury.	

#### Table 6-18: Trima Accel system auditory alarm signal sound levels

Characteristics	Performance	Conditions
Volume	61 dBA	Low
	69 dBA	Medium
	75 dBA	High

## **Draw/Return Pressure Sensor**

#### Table 6-19: Trima Accel system draw/return pressure sensor specifications

Characteristics	Characteristics Performance	
Operating range	-300 mmHg to +500 mmHg	
Default alarm point	-250 mmHg ± 30 mmHg (draw) +310 mmHg ± 37 mmHg (return)	
Accuracy	12% of reading or ± 20 mmHg, whichever is greater	

# **Centrifuge Pressure Sensor**

#### Table 6-20: Trima Accel system centrifuge pressure sensor specifications

Characteristics	Performance	Conditions
Operating range	400 mmHg to 1,600 mmHg	
Alarm point	1,350 mmHg	Accuracy ± 10%

## **Reservoir Level Sensors**

Table 6-21: Trima Accel system reservoir level sensor specifications

Characteristics	Performance	Conditions
High and low level sensors	Stroke volume between sensors: 54 mL ± 9 mL Sensors detect foam as air.	Level sensor requires load force of > 5 lb (2.3 kg) each ( > 10 lb [4.5 kg] total).
Time to alarm	When fluid is not detected by the low level sensor, the pumps stop before air enters the line at the bottom of the air chamber.  Return reservoir level sensor is failsafe.	An alarm is generated when the sensors do not detect fluid or air, when the appropriate volume is pumped.  System performs a safety check in a redundant manner.

### **Fluid Leak Detector**

#### Table 6-22: Trima Accel system fluid leak detector specifications

Characteristics	Performance	Conditions
Capable of detecting a 0.5 mL droplet in the centrifuge	Detects fluid leaks where moisture reaches the wall or the bottom of the basin.	

# **Anticoagulant (AC) Detector**

#### Table 6-23: Trima Accel system AC detector specifications

Characteristics	Performance	Conditions
Time to alarm	< 2 seconds after sensing the absence of fluid.	
	An alarm is generated when the sensor is unloaded after fluid is present.	

## **RBC Spillover Detector**

Table 6-24: Trima Accel system RBC spillover detector specifications

Characteristics	Performance	Conditions
Spillover detection level	> 1.5% hematocrit	Auto-divert from collected product when sensed.

## **Anticoagulant (AC) Flow Alarm**

**Table 6-25: Trima Accel AC flow alarm specifications** 

Characteristics	Performance	Conditions
Detection method	<ul> <li>AC pump off during any draw cycle</li> <li>AC pump running during return cycle, rinseback, or any donor disconnect state</li> <li>AC line occluded during draw cycle</li> </ul>	<ul> <li>AC pump movement not detected</li> <li>Improper AC pump movement detected</li> <li>AC line occluded</li> </ul>
Delay time	< 5 cycles of occlusion.	

# Anticoagulant (AC) Ratio Alarm

Table 6-26: Trima Accel system AC ratio alarm specifications

Characteristics	Performance	Conditions
Detection method	<ul> <li>Inlet pump speed/AC pump speed ratio &lt; 5</li> <li>Inlet pump speed/AC pump speed ratio &gt; 15</li> </ul>	AC ratio too low     AC ratio too high
Delay time	Alarm triggers when either of these conditions is met any time during the procedure until rinseback.	

# **Anticoagulant (AC) Infusion Alarm**

Table 6-27: Trima Accel system AC infusion alarm specifications

Characteristics	Performance	Conditions
Detection method	AC infusion to donor: > 1.3 mL/min/L TBV for three-cycle average.	AC infusion too high.
Delay time	Alarm triggers when this condition is met from the first return cycle until rinseback.	

## **Touch-Screen Display**

Table 6-28: Trima Accel system touch-screen display specifications

Characteristics	Performance	Conditions
Display housing contains the graphical user interface (GUI) display.	Pressing the screen causes a change in resistance.	The backlighting bulbs within the display can be replaced in the field.
Measures 26.7 cm (10.5 in) diagonally, 640 × 480 pixel resolution color, liquid crystal display (LCD).		
Has a touchscreen that covers the display and provides a tactile operator interface.		
Includes a speaker for alarms, alarm lights, and two external dedicated buttons with icons (the <b>Pause</b> button and the <b>Stop</b> button).		

# **Symbols and Certification**

**Table 6-29: Symbols and Certification** 

Symbol	Definition
<b>Note:</b> Some symbols appear or appear on both labels.	the Trima Accel machine label, some appear on Trima Accel disposable kit labels, and others
<b>C</b> € <sub>0086</sub>	Device is manufactured in conformance with the European Council Directive 93/42/ EEC of June 14, 1993, concerning medical devices.
	This mark with the Notified Body Number 0086 indicates the approval by the British Standards Institute for these devices within the European Community.
C US	Device is certified by CSA International in accordance with applicable U.S. and Canadian standards for conformance with the requirements of CAN/CSA-C22.2 No. 601.1-M90, CAN/CSA-C22.2 No. 1010.2.20-94, and UL 60601-1, as well as the applicable respective amendments to these standards.
*	This symbol indicates that the connection of the Applied Part, or the part of the disposable that comes in physical contact with the donor in normal use, is electrically isolated from other parts of the Medical Electrical Equipment. In such a case when any unintended voltage originating from an external source is connected to the donor (that is, applied between the donor connection and earth), this isolation is sufficient to ensure that no current higher than the allowable donor leakage current will flow.
EC REP	Indicates the European Authorized Representative of the product when accompanied by the name of the European Authorized Representative.
	Indicates the manufacturer of the product when accompanied by the name of the manufacturer.
$\sim$	Indicates the date of manufacture (or sterilization date, if the product is sterile) when accompanied by a specific date.
REF	Indicates the product catalog number when accompanied by a number.
SN	Indicates the product serial number.
$\overline{\mathbb{V}}$	This symbol indicates that consultation of the accompanying documents prior to equipment operation is critical to the safe operation of the device.
	Indicates that the equipment is subject to directive 2002/96/EC concerning waste electrical and electronic equipment (WEEE) and must be disposed of accordingly.

**Table 6-29: Symbols and Certification (continued)** 

Symbol	Definition
$\sim$	Indicates that the machine requires an alternating supply current.
	Indicates a protective earth ground. Located near chassis' main grounding location and at other protective ground points.
	Indicates the product quantity when the quantity is placed in the square.
*	Indicates the package contents.
STERILEEO	Indicates a sterile fluid pathway using ethylene oxide (EtO).
STERILE	Indicates a sterile fluid pathway using steam or dry heat.
	Indicates the expiration date of the product when accompanied by a specific date.
LOT	Indicates the product lot number when accompanied by a number.
PYRO	Indicates that the product is non-pyrogenic.
<b>S</b>	Do not vent product.
	Indicates that the user should not use the product if the package is damaged.
STERRIZE	Indicates that the product should not be resterilized.

**Table 6-29: Symbols and Certification (continued)** 

Symbol	Definition
2	<b>Not for Reuse:</b> Tubing sets manufactured by Terumo BCT bearing the not for reuse symbol are intended for single use only and are not intended to be reprocessed or reused. Terumo BCT cannot ensure the functionality or sterility of the set if it is reprocessed or reused.
ORUNE ALIZA	Indicates that the product packaging complies with European Directive 94/62/EC for packaging and packaging waste.
PHT DEHP	Indicates that the product contains phthalates, specifically Di(2-ethylhexyl)phthalate (DEHP).
IP21	Indicates that the device is protected against access by solid objects and falling water, as defined in standard IEC 60529.
<u>11</u>	Indicates correct upright position of the transport package.
¥	Stacking of the transport package is not allowed and no load should be placed on the transport package.
Ţ	Contents of the transport package are fragile therefore it shall be handled with care.
<del>*</del>	Transport package shall be kept away from rain.

## **Seal Safe System Specifications**

## **Table 6-30: Seal Safe physical specifications**

Characteristics	Performance
Physical dimensions of cutter/sealer head	Diameter: 2.5 cm (1 in) Relaxed length: ~ 1.1 m (3.7 ft)
Weight of cutter/sealer head	0.4 kg (0.9 lb)

### Table 6-31: Seal Safe environmental specifications

Characteristics	Performance
Ambient operating temperature	15 °C to 28 °C (60 °F to 82 °F)
Ambient operating humidity	8% to 80% relative humidity, non-condensing
Cleanability	Unit is not damaged by cleaning with alcohol.
Fluid spillage	Unit will not be rendered unsafe by spillage of saline over the top.
Storage temperature	0 °C to 60 °C (32 °F to 140 °F)

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### **Service Manual**

## Trima Accel® Automated Blood Collection System



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