Power Express Hematology Automation SystemTechnical Procedure #1501.t

Principle

The Beckman Coulter Power Express Hematology Automation Line is a sample tube processing system that automates pre-analytical, analytical, and post analytical processes. The system consists of a dynamic inlet unit, a centrifuge, a duel specimen decapper, a rack builder DxH connection unit, an ambient storage unit, outlet unit, and a Cennexus and line controller computer. The dynamic inlet unit allows for loading Hematology and Coagulation samples with minimal operator labor. The transfer arm will pick up individual samples with grippers and place the sample into radio frequency identification (RFI) sample carriers to be transported around the automation line track. The carrier moves to a bar code reader where the samples are sorted by tests ordered. The Hematology samples are routed to the DxH 2401 and the Coagulation samples are routed to the centrifuge, decapper, and the ACL TOP 750 LAS analyzers.

The Hematology side of the PE Automation System consists of DxH 2401 analyzer (3 DxH 800s and 1 SMS), Rack Builder, a 3000 specimen ambient Storage, and an Outlet unit. After the CBC specimen is run it is sent to the Storage or Outlet Unit, sorted using user defined criteria.

The Coagulation side of the PE Automation System consists of a centrifuge, a duel specimen decapper, ACL 750 TOP LAS analyzers, and an Outlet Unit. Specimens are sent from the Inlet Unit to the centrifuge. When centrifugation is complete the specimens are decapped and sent onto the automation line track. The sample stops at the TOP analyzer. The LAS arm swings out to the line and samples the specimen on the track. The specimen never boards the TOP analyzer. After sampling, the uncapped specimen moves to the Outlet Unit where it is sorted into complete or user defined sections.

Only 13x75 sized tubes can be put on the PE system. MAPP tubes cannot be loaded onto the PE line and must be front loaded onto the DxH 2401 using defined A cassette racks.

Components

□ Dynamic Inlet Unit

The Dynamic Inlet module has a transfer arm with 5 grippers and two 5 position sample holder sets, which alternately transfers five sample tubes from the Inlet racks onto five sample tube carriers on the automated track systems for processing: Blue, Red, Yellow and White racks with 50 sample holes are used. Blue racks are for routine samples. Red racks are for STAT samples and will interrupt routine loading. Yellow racks are for sample remapping (sending completed samples to the Storage or Outlet unit). White racks are for spun samples to bypass the centrifuge. The power ON and OFF buttons are located on the Inlet Unit.

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□ The Error Lane

Samples that are not received, have no test request information, unreadable bar codes, multiple tubes, unacceptable specimens (i.e. PFA, chemistry samples), or the sample was not loaded with a proper rack load will be sent to the error lane which is part of the Dynamic Inlet Unit. After three samples are in the error lane a flashing beacon and audible alarm will activate.

□ Centrifuge

Temperature Controlled Centrifuges processes up to 40 coagulation samples at a time at a temperature of $22-25^{\circ}$ C prior to sampling by the ACL TOP 750 LAS Analyzer. The centrifuge can be operated manually. The white button on the centrifuge will power off the centrifuge only, not the entire automation line.

□ Duel Decapper Module

The Decapper mode contains two assemblies that remove Hemaguard and Grainier tube caps from sample tubes. If a cap is not removed the system stops and activates an audible alarm and flashing beacon.

□ Direct Track Sampling Module

Direct Track Sampling is used with the ACL TOP 750 LAS analyzers. It samples the uncapped Coagulation specimen from a "point in space" where the LAS arm swings out from the analyzer to the sample on the automation line, aspirates the amount of sample needed for testing ordered, then pipettes into cuvettes inside the analyzer.

□ Rack Builder Module

The Rack Builder module uses transfer arms to remove sample tubes from the carrier and place them into A+ cassette racks. Only 19 racks can be in the rack builder que. When an A+ cassette is full or load time out is reached, the A+ cassette is moved onto the analyzer by elevator. When the A+ cassette is finished running on the DxH 2401 analyzer it will unload by elevator to the PE. The unload transfer arm removes the sample tubes from the cassette and places them in sample tube carriers on the track. Samples are directed to storage or outlet by sort codes.

- Code 2 goes to the Problem section of the Outlet
- Code 3 goes to the Critical section of the Outlet
- Code 4 goes to the Clot Check section of the Outlet
- Code 5 goes to the No Slide section of the Outlet

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□ Storage Module

The ambient storage holds 3000 completed Hematology samples. These samples are available for retrieval for additional testing. The samples are in the line controller computer data base as received status until a proper rack load is performed to remove the samples from the storage unit. Samples are then 'processed' status.

Outlet Unit

The Outlet Unit has 8 racks and can have up to 15 user defined rows for sorting of completed samples. Samples are removed using proper rack load procedure. Completed coagulation racks are exchanged and assigned a Rack ID to allow for easy sample location. Rack IDs consisted of rack number, letter C, and date (ie 7C013118)

- □ Cennexus Computer
 - The Cennexus computer receives sample programming from the LIS and then downloads routing information to the line control computer.
 - Sample Query will search for samples using unique six digit barcode numbers or "HP" numbers.
 - *Detail* will give the status and location of the sample.
 - *Location* will show on the Line Controller computer the general location with a dark blue box.
 - *Manual Retrieve* will move samples to '*Retrieve*' portion of the Outlet.
- □ Line Controller Computer

Manages the Units on the automation line. Modules can be disabled from the Line Controller.

- When the PE is operational the System Status will be "Active" and the Host Communication will be "Online".
- When the PE is in Shutdown the System Status will be "Ready" and the Host Communication will be "Offline".
- □ Module Control Panels
 - Control Panel Button descriptions are listed in IFU booklets.

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- Control panel colors: White is setup or maintenance; Green is running; Yellow is paused or alarming; Red is stopped or malfunction.
- Control Panel can be changed from Auto to Manual. Function codes can be used in Manual mode.
- □ White Button.

This button is the Emergency Stop and turns off power to the entire automation line. DO NOT PUSH THIS BUTTON! ONLY USE IF IN DANGER OF BODILY HARM!

- □ Sample Tube Carriers **RFID** (radio frequency identification) carriers. Carriers hold only 13x75 tubes.
- □ Track.

Green Belts move constantly when the automation line is powered on.

□ Barcode Readers.

All barcode readers are labeled BRO1 or BRO2, etc.. The barcode reader communicates to the Line Computer.

- \Box Sensors are labelled **SN**
 - Hall Effect Sensors

Small black sensors detect the metal carriers. A red light on the side of the sensor will light up when it detects metal.

• Fiber Optic Sensors

Detect the presence or absence of sample tubes by emitting a light beam that is reflected off the sample tube. These can be adjusted by increasing or decreasing the intensity of light using the amplifier. When adjusting the amplifier look at the blood not label on sample tube.

Photo Optic Sensors

Are located inside the Connection Unit to determine the location of cassettes. These sensors send light from a transmitter to a receiver. The cassettes interrupt the beam and are detected.

Opto Isolator Sensors

These detect the home position of transfer arms.

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□ Cylinders

Driven by air and perform some type of motion. Controlled by solenoids and labelled **SL**.

• Gripper Fingers and pads

These have up and down motion, swinging motion, and open and close motion.

Stoppers

Stoppers are located underneath the track. They move up and down to stop RFID carriers. Occasionally a carrier will get stuck. Gently twist (never push) the carrier to remove. Rough handling may bend stoppers.

Diverter Gates

Move in and out to direct the carriers along the track.

- DxH automation Cassette Racks labelled **A**+.
- □ Yellow lights

Lights flash when an error is triggered.

Operation

Operating the automation line begins with Start Up of the PE. The Line Controller will enable the Connection Units. Hematology and Coagulation samples are loaded onto the Dynamic Inlet Unit using proper rack load procedure. The PE Automation System will move samples along the track, sorting between Coagulation and Hematology sides. The specimens will be load balanced between the analyzers for maximum efficiency. When analysis is complete, the specimens will be sorted to the Storage or the Outlet Units.

- □ System Operation.
 - Inlet rack exchange. The dynamic inlet control panel is yellow when ready for a rack exchange. Two drawers of 4 racks are below the panel. To load samples onto the PE automation line touch the icon on the control panel for right or left hand side of the drawers then open the drawer. Place the rack into to drawer. The dynamic inlet does not need to have all racks present to operate. When the rack is placed the control panel will show the type of rack present:
 - **E** empty rack

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- **ST** stat red rack
- **RT** routine blue rack
- **RM-R** remap refrigerated proxy unit (coag samples in outlet)
- **RM-A** remap to storage unit (heme samples)
- Touch 'play' icon and the samples will be loaded onto the automation line.
- Samples will load on two sides of the track with a 5 sample gripper. The samples are placed into RFID carriers, the barcode is read and the sample is sorted to Coag, Heme or the error lane.
- Remapping yellow racks. Hematology and Coag samples that need to be filed are placed into *separate* yellow racks. Coag samples go to the Outlet into complete coag racks. RM-R is the default setting. It will send Coag tubes to the Outlet. Touch the RM-R icon to change to RM-A which will send hematology samples to the Storage Unit.
- Error lane holds 3 samples. A flashing yellow light and audible alarm activate. On the control panel touch the 'alarm' icon to silence, and then touch the 'lock' icon to unlock the door. Press the door and it will swing out. Remove the samples, and hit the '*play*' icon to continue. The samples must be checked for receipt by SARC and given to Heme if needed.
- Rack Loader will put all Heme EDTA tubes into cassettes to run on the DxH 2401. 19 cassettes with ID of A+ are in the rack loader. These will be loaded onto the DxH 2401 by an elevator. The samples will run and be unloaded back to the rack loader. The samples are taken out of the cassette racks and placed into RFI carriers. The samples will then be filed in the storage or outlet units by user defined sort cods.
- Outlet Unit has 2 drawers of 4 racks. All racks must be present for operation. Heme samples are on the right hand side and Coag samples are on the left hand side. To rack exchange touch the icon for the correct side of the outlet. The 'alarm' icon will flash. Touch icon to silence alarm, this will also unlock the drawer. Open the drawer, remove desired rack and replace with an empty rack with the same sample sort locations. The outlet must have all racks present to run.
- Complete coagulation racks in the outlet are rack exchanged then assigned a rack ID at the Cennexus computer. On the Cennexus screen touch '*samples*' then touch the '*rack assignment*' tab. Find proper rack list, most recent are on the bottom, and assign number using number of rack-C-date (ex 7C013018). These racks will delete after 5 days.

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- All coag tubes must be scanned for completion in Beaker. Then parafilm and label the rack with the rack ID from above. Samples are stored off-line in sample refrigerator for 24 hours. Most coagulation tubes that are front loaded can be remapped to be stored in these racks.
- System Initiated Storage Unit rack exchange will alarm when the Storage Unit is full. The Control Panel will show by icon which rack is full. Silence the alarm, open the storage unit, press down on white horizontal piece, remove and dump the samples. Then replace with an empty rack. Select 'Restart' arrow icon and 'Exit' back arrow icon on the control panel. The control panel must be green.
- □ Off line sampling for DxH 2401 and ACL TOP 750 LAS
 - The DxH 2401 can be front loaded or run in single tube presentation at any time.
 - The ACL TOP 750 LAS can be front loaded at any time.
- Temperature Controlled Centrifuge operates at 22-25° C. It can hold up to 40 coag tubes and has 5 balance tubes. It can be operated in automation or manual mode. The centrifuge is set to achieve platelet poor plasma of <10/ul³ at the TOP analyzers. The speed is measured in 100 RPM units. The time is measured in 10 second units.
 - Manual Centrifugation is controlled on the D lane control panel. Select '*Manual*' icon and '*OK*' checkmark.
 - From the Centrifuge control panel select 'Top Unlock' to unlock the cover. Select and hold the 'Unlock' icon to unlock the centrifuge lid.
 - Manually place tubes into centrifuge holders. Load balance if needed. Close centrifuge lid.
 - Select 'Maintenance' on the D lane control panel. Select the number filed to display the onscreen keyboard. Enter function code 80, select 'Restart' to start centrifuge.
 - When the cycle is complete hold '*Unlock*' to unlock the centrifuge lid. Open the cover, then lid. Unload tubes. Close lid and cover.
 - ^o From D lane control panel select 'Enter' and 'Exit'. Select 'Auto' and 'OK'.

Power Down

□ Power Down

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- Line controller
 - Go to Line controller. Select **Shutdown**. The shutdown screen appears "This will shut down the automation system. Are you sure?" Select "**OK**".
 - A reminder screen will appear "Sample present on the system. Please remove. Proceed with system shutdown. Are you sure?" Select "**OK**".
 - The Line controller status will be "Ready" and Host Communications will be "Offline".
 - Select "**Exit**" from main menu of Liner Controller computer. A message box will appear "This will exit to Windows. Are you sure?" Select "**OK**".
- Power on line
 - Press the red power **OFF** button on the Inlet Unit.
- Cennexus
 - Select "**Exit**" from the Cennexus computer.
- □ Power Up
 - Power
 - ^o After at least one minute press the green **ON** button on the Inlet Unit.
 - Cennexus
 - ^o Press the power button on the Computer CPU.
 - The Cennexus log on is **BEC** and no password.
 - ^o The software will launch and the Cennexus Main Menu screen will appear.
 - Note that System Alerts must not be red or the Line controller will not launch
 - Line controller
 - From the Line Controller click Start Up. Choose "**Do Not Delete**". Click '**OK**'.
 - ^o Click Start Up. Click "Do Not Delete". Click 'OK'.
 - The system status is "Active". The host communication will be "Online".
 - ^o All modules must be green status (except Dynamic Inlet will be yellow)
- \Box The PE is ready for operation.

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Maintenance

- □ Daily Maintenance
 - Shutdown Line Controller Computer.
 - Stop loading Inlet Unit and finish with all specimens on PE Automation Line. No specimens can be on the PE automation track, the Centrifuge or Rack Builder Modules.
 - ^o Confirm Outlet is empty. Perform rack exchange if needed.
 - Empty Decapper trash can.
 - From Line Controller Computer select "System **Operation**". Select "**Shutdown**". The screen will ask "Are you sure? Choose "**OK**'.
 - The doors will unlock with a loud noise.
 - The system status will be "*Ready*". The Host communication will be "*Offline*".
 - Turn the power off on the Outlet Module with the Red button. Wait 60 seconds and turn on the power with the Green button.
 - From the Line Controller Computer choose **System**, then **'Thru lanes**' to return all carriers to the Inlet queue. When complete select **''Exit**''
 - ^o Choose Start Up. Choose "Delete Processed Samples Only". Choose 'OK'.
 - The system status is "Active". The host communication will be "Online".
- □ Weekly Maintenance
 - Clean Centrifuge
 - If the control panel is Green, hit the white button. This will unlock the cover. Turn the green switch next to the button off then on
 - If the control panel is in STOP the cover will be unlocked.
 - From the Centrifuge control panel select and hold the bottom '*Unlock*' icon to unlock the centrifuge lid.
 - Wipe inside of the centrifuge with a sani-wipes.
 - ^o Close covers and put module in auto mode.

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- Clean Decapper
 - Put module in manual mode
 - ^o Open doors, touch 'lock' icon to unlock
 - Clean disposal chutes (funnel-like) by pulling out and wiping inside with sani-wipes.
 - Clean splash shields (metal) with sani-wipes.
 - Return to auto mode
- □ Monthly Maintenance
 - Check belts for dust and wear. Vacuum if necessary
 - Check grippers and clean if necessary. Use function codes listed on laminated key if needed to move or open and close the grippers.
 - ^o Inlet, Centrifuge, Decapper, Storage, Outlet and Rack Builder
 - Perform Cennexus back up (done by Specialist)

Error Recovery

The Power Express Automation Line has with *Instructions For Use* (IFU) booklets for each module. These contain descriptions, procedures, function codes, error recovery, error code tables, and sensor diagrams. Diagrams have numbered sensors and cylinders. Each IFU contains extensive Error Code definitions and Error Code tables specific to that module. Sensor Diagram Layouts are also included in each IFU. The diagrams are labelled with PS, PM, AS, SL, and SN prefixes and numbers. SL codes are cylinders and SN codes are sensors.

- □ The control panel will display the error code. Silence the alarm by touching the 'alarm' icon. Use the appropriate IFU booklet to locate the error and troubleshoot the solution.
- □ Function codes are listed with the icon key for each module in each IFU booklet
- □ IFU booklets
 - Power Express General System Operation Instructions for Use (IFU), Beckman Coulter 2016

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- Power Express Centrifuge Module Instructions for Use (IFU), Beckman Coulter 2016
- Power Express Decapper and Recapper Modules Instructions for Use (IFU), Beckman Coulter 2016
- Power Express Decapper and Recapper Modules Instructions for Use (IFU), Beckman Coulter 2016
- Power Express Storage Module Instructions for Use (IFU), Beckman Coulter 2016
- Power Express Direct Track Sampling Module Instructions for Use (IFU), Beckman Coulter 2016
- Power Express Rack Builder Module Instructions for Use (IFU), Beckman Coulter 2016

Unit Bypass

- □ Each module can be bypassed using the control panel. Change from Auto to Manual. Use the *bypass* icon or function 01
- □ Connections can be paused from the Cennexus computer. Touch the Cennexus icon on the top right hand side to access correct page. Use the dropdown arrow to select *'Pause'* or *'Run'*
- □ Connections can be disabled from the Line Controller computer. Click *System Status* then *unit enable/disable*

Emergency Stop Recovery

The White Emergency Stop Button immediately shuts off power to the entire line. Recovery is time consuming to complete. Do not press this button unless injury is imminent. Once the button is pressed, do not stop the connected analyzers. The analyzers will continue to process samples on each analyzer. Reset Stop Button before beginning recovery by depressing again. Samples may be in any module.

□ Remove samples from the Rack Builder. Front load samples on the DxH 2401 that need to be run and file completed samples.

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- □ Remove any samples at the Direct Track Sampler for ACL TOP 750 LAS analyzers. Front load samples on the TOPs that need to be run and file completed samples.
- □ Remove any samples on the track, in decapper, in grippers, or anywhere on the PE Automation line.
- □ Perform a Shutdown from the Line Controller Computer
 - From Line Controller Computer select "**System Operation**". Select "**Shutdown**". The screen will ask "Are you sure? Choose "**OK**'.
 - The doors will unlock with a loud noise.
 - The system status will be "Ready". The Host communication will be "Offline".
 - ^o Turn the power off on the Outlet Module with the Red button
 - From the Line Controller Computer choose **System**, then '**Thru lanes**' to return all pucks to the Inlet queue. When complete select "**Exit**"
 - ^o Choose Start Up. Choose "**Do Not Delete**". Choose '**OK**'.
 - The system status is "Active". The host communication will be "Online".
- □ Remove samples from the Centrifuge. Hit the white centrifuge button. The cover will unlock. Turn the green switch off and on.
 - From the Centrifuge control panel select and hold the lower 'Unlock' icon to unlock the centrifuge lid.
 - Remove samples and process off line. Manual use of the Centrifuge is possible, but not recommend as the line is recovered and ready to use at this point.

LIS Down Time

When the LIS is not working the Power Express Automation Line **CANNOT** be used. The line controller computer must communicate the LIS to route specimens to proper connection units. Follow the LIS downtime procedure.

Safety Notes

The PE Hematology Automation System is a moving robotic automation line. Use care when operating and troubleshooting the automation line.

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- □ Do not wear ties, hanging badges, or hanging jewelry. These may catch on moving parts.
- □ Keep long hair pulled back.
- \Box Keep covers on all Units.
- \Box Do not remove doors.
- □ Check that the control panel is in Pause when performing error recovery.

References

- Power Express General System Operation Instructions for Use (IFU), Beckman Coulter 2016
- Power Express Centrifuge Module Instructions for Use (IFU), Beckman Coulter 2016
- Power Express Decapper and Recapper Modules Instructions for Use (IFU), Beckman Coulter 2016
- Power Express Decapper and Recapper Modules Instructions for Use (IFU), Beckman Coulter 2016
- Power Express Storage Module Instructions for Use (IFU), Beckman Coulter 2016
- Power Express Direct Track Sampling Module Instructions for Use (IFU), Beckman Coulter 2016
- Power Express Rack Builder Module Instructions for Use (IFU), Beckman Coulter 2016

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Procedure History

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02/2018	L Gandy	New	6/18/2018	L Howell MD