

COULTER[®] A^C ● T diff[™] COULTER[®] A^C ● T diff 2[™]

HEMATOLOGY ANALYZER

ROUTINE OPERATION

EASY REFERENCE GUIDE

PN A35926AB (December 2009) Beckman Coulter, Inc. Miami Education Center

READ ALL PRODUCT MANUALS BEFORE ATTEMPTING TO OPERATE INSTRUMENT

This document is not intended to replace the information in your instrument Instructions for Use manual. Information in the Instructions for Use manual supersedes information in any other manual.

Beckman Coulter urges our customers to comply with all national health and safety Laboratory protocol such as the use of barrier protection. This may include, but is not limited to, protective eyewear, gloves, and suitable laboratory attire when operating or maintaining this or any other automated laboratory analyzer.

HAZARDS AND OPERATIONAL PRECAUTIONS AND LIMITATIONS

WARNINGS, CAUTIONS, and IMPORTANTS alert you as follows:

WARNING: CAUTION: IMPORTANT: Might cause injury Might cause damage to the instrument Might cause misleading results

SAFETY SYMBOLS



Consider all materials (specimens, reagents, controls, etc.) as being potentially infectious.

Wear standard laboratory attire and follow safe laboratory procedures when handling any material in the laboratory



The probe is sharp and may contain biohazardous materials, including controls and calibrators.

Avoid any unnecessary contact with the probe and probe area.



Electrical shock hazard

Possibility of electrical shock when instrument is plugged in to the power source

Before continuing, unplug the A^c•T diff / A^c•T diff 2 analyzer from electrical outlet

SUMMARY OF ICONS

Before you begin, familiarize yourself with some of the instrument screen icons





Calibration Assigned Values

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$COULTER^{\ensuremath{\mathbb{R}}} A^{\ensuremath{\mathsf{C}}} \bullet T diff / A^{\ensuremath{\mathsf{C}}} \bullet T diff 2$

Routine Operation

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DAILY OPERATION / STARTUP

STARTUP

Do this procedure daily.

- 1. At Main screen, touch Startup icon.
- 2. Review results on Startup screen.

- 3. If all parameters *PASS*, touch **Print** icon.
 - Go to Running 4C-ES[®] Cell Control on page 4.
- 4. If any parameters *FAIL*, repeat Startup up to **two times**.
 - If Startup continues to fail, refer to A^C•T diff or A^C•T diff 2 Operator's Guide, Service and Maintenance chapter; Troubleshooting.







DAILY OPERATION / RUNNING CONTROLS

RUNNING COULTER[®] 4C PLUS/4C-ES[®] CELL CONTROLS

<u>NOTE</u>: You may use either "COULTER 4C-ES Cell Control" or "4C Plus Cell Control" on your AC•T diff /diff 2 analyzers. We will refer to all acceptable control material as 4C-cell control throughout this document.

- 1. Remove control vials from refrigerator.
 - Confirm that *lot numbers* and *expiration dates* on vial match information on the Table of Expected Results.
 - Warm at room temperature 10 15 minutes.
- 2. At Instrument Main screen
 - Touch QA icon.
 - Select correct control level:
 - L low N - normal H - high

Make sure that level of control you are testing matches the one selected (L, N, or H)





4C Run icon



- 3. Verify control cap is secure.
- Mix each control vial 8 x 8 x 8 times according to package insert instructions.



• Inspect vial contents to ensure uniform cell distribution. If contents are not well distributed, repeat this mixing procedure.



Cover top of control vial with lint-free tissue and remove cap.

Place well-mixed vial under probe. Press the aspirate switch.

When you hear the beep remove the vial and recap it.



A^c●T diff 2

Place well-mixed vial in Cap Pierce tube holder and close door.

When tube holder door opens, remove vial.



DAILY OPERATION / RUNNING CONTROLS

- 5. Results appear on screen.
 - Review control results.
 - Refer to Quality Control section for review procedures.
 - To reject a result, touch
 Trash icon.
 - Control results are automatically stored (unless results are nonnumeric).
 - If Autoprint is OFF, manually print results.
- 6. Repeat <u>steps 3 through 5</u> for each required control level.
- 7. Return control vials to refrigerator within 30 minutes of removing them.
- 8. Refer to **QUALITY CONTROL REVIEW** in this document.
- 9. Review out-of-limits control results according to your laboratory's protocol.



DAILY OPERATION / RUNNING SAMPLES

RUNNING PATIENT SAMPLES / WHOLE BLOOD MODE



- 2. Mix sample **thoroughly** according to your laboratory's protocol.
- 3. Be sure you are in Whole Blood mode.

A ^c ●T diff				
ID:0000	00001	1117	4-22-99)
WE	3		4 13:46	
WBC	9.2	LY	40.0	
RBC	3.6	MO	9.8	•뭥
Hgb	10.0	GR	49.8	
Hct	370	LY#	37	
MCV	83.1	MO#	09	+省
MCH	32.5	GR#	46	1.2. 7
MCHC	35.6	RDW	34.6	1 - S
Pt	215.	MPV	25.4	
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	A	∙T	dif	f 2
10 0000 CU	100002 VB	111	4-22- 13:46)	99 02
VBC RBC Hgb Hct MCU MCH MCHC Plt	9,2 3,6 13,2 37,0 93,1 29,6 35,6 215	L V GR L V# MC# GR# RDV MPU	406 9.0 49.8 37 09 46 12.9 7.8	
1				D 888888883

DAILY OPERATION / RUNNING SAMPLES

4. $A^{c} \bullet T$ diff

Place a lint-free tissue over the top and remove cap. Place well-mixed sample at probe and press aspirate switch. Remove tube when you hear the beep.

A^c•T diff 2

Place well-mixed sample in tube holder at Cap Pierce Station and close door.

Remove tube when door opens.



 Instrument automatically saves results. Results appear on screen.



- If Autoprint is ON, results print automatically.
- If Autoprint is OFF, touch **Print** icon.

To review Codes & Flags or Histograms refer to DATA REVIEW section of this document.





SHUTDOWN

Perform Shutdown daily.

- 1. At Main screen, touch **Shutdown** icon.
- 2. To abort Shutdown cycle, press Stop || icon.



Allow A^c•T Rinse to remain in the instrument for <u>30 minutes.</u>

At end of Shutdown cycle, you receive a screen prompt to perform Startup.

3. To perform Startup, touch **Continue** icon.



QUALITY CONTROL REVIEW

NOTE: Non-numeric control results are not stored.

If control results are within expected ranges, proceed to run the next control level.

Reviewing control results

- 1. Review control results as they are run.
- 2. Rerun any controls not within expected ranges.
 - If rerun control is still out of range, follow your laboratory's protocol for troubleshooting out-of-range controls
 - Reject the control, if necessary.
- 3. If a control is run in the *wrong* file
 - Delete it **immediately** or all control results for that file are invalid for IQAP reporting.
 - IQAP information must then be entered manually using eIQAP so that the invalid run can be excluded.
- 4. If no more storage space is available for one or more 4C-control files, Control file full icon _____ appears at bottom of screen.
- 5. If control is *expired*, do not use it. icon appears at bottom of screen.



Deleting and Printing 4C Series cell control files

NOTE: Once deleted, control files cannot be recovered. Be sure you have all control information you need before deleting any files.

- 1. If your laboratory participates in IQAP, download all control data for IQAP before proceeding to step 2.
 - If your laboratory does not participate in IQAP, go to step 2.



- 5. To delete control files for the level selected in step 4,
 - Touch Trash icon.

Delete Confirmation screen appears.

OR

• Touch Trash icon again.

ē ā

• Touch Return icon deleting.

to return to pervious screen without

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IMPORTANT INFORMATION ABOUT 4C-ES Cell Control

- 4C-ES cell control is an Extended Stability control. A set of lot numbers can be used for 90 days.
- **Open vial stability** defines the maximum # of events that can occur with a control vial.
- An event occurs each time a vial is taken out of the refrigerator, warmed and refrigerated again.
- 4C-ES cell control has a maximum of 20 allowable events within 35 days
- IQAP is a free program offered by Beckman Coulter that compares your laboratory's submitted control results to all other laboratories using the A^C •T diff or A^C •T diff 2 analyzer and the same 4C-ES cell control lot numbers. Your Beckman Coulter Representative can help you enroll into IQAP and provide you with information about eIQAP (electronic IQAP).

PARTICIPATING IN IQAP (INTERLABORATORY QUALITY ASSURANCE PROGRAM)

Stored 4C-Series cell control results can be returned for inclusion in the IQAP program. For additional information about the IQAP program, see the *IQAP Procedure* Manual and Addendum for Beckman Coulter Instruments assayed for 4C-ES- Cell Control or visit our website at www.BeckmanCoulter.com

Save used reagent management cards from your A^C•T diff Series reagent to use for this procedure.

NOTE: Only A^c•T diff reagent management cards should be used.

NOTE: Prior to downloading your data, ensure that your IQAP participant number has been entered into your instrument.

Without the IQAP participant number, your data cannot be automatically processed.

Attach the IQAP identification label to a used reagent management card, using care not to cover up the microchip (gold square).

- 1. Review the control summary printout that contains the individual control runs, mean, 2SD, N (number of runs). Ensure that:
 - The controls were analyzed in a correct file.
 - The control files contain the correct lot number.
 - The control files contain only one *month's* worth of data points.

If the control files meet these criteria, go to Step 2.

If the control files do not meet these criteria, do not continue this procedure because the control files cannot be processed from the IQAP download onto the reagent management card.

If you identify any erroneous data identifed above, you will need to submit your data using the following.

- The Electronic Interlaboratory Quality Assurance Program (eIQAP); visit <u>http://www.beckman.com/eiqap</u>
- Remove the current A^C T diff reagent management card and insert a <u>used</u> reagent management card into the instrument.
- 3. At the Main screen
 - Touch **QA icon**.
 - Touch 4C Management icon.
- 4. At the 4C Management screen:
 - Select A (all levels of control).
 - Touch IQAP icon to download the data to the card.
- 5. Touch the Print Summary icon to print control summaries. Keep a copy of the control file data for your records.
- 6. Place the reagent card with stored control data and attached label into the pre-addressed mailer, using care not to cover up the microchip (gold square)

Return the mailer to Beckman Coulter's IQAP department.

7. To submit your data electronically, visit http://www.beckman.com/eiqap.







4C

- 8. After completing the IQAP download, delete the control files:
 - Select (A)for All files.
 - Touch $\sqrt{2}$.icon The Delete Confirmation screen appears.
 - Touch icon again to delete the files.

OR

- Touch [] to return to the previous screen without deleting the files.
- 9. Enter your next set of controls by entering the new assigned values, expected ranges, lot numbers and expiration dates.

QUALITY CONTROL SET UP

ENTERING LOT NUMBER / EXPIRATION DATE

- 1. At Main screen, touch QA icon. At Management icon.
 - Select control Level (L, N, or H)
 - Touch Lot # field and enter lot number located on vial (up to 6 digits).
 Example: 079600
 - Touch Exp. field and enter expiration date (up to 6 digits) in MMDDYY format.
 Example: 12-23-06
 Enter in dashes between the MM-DD-YY format
 - Touch **Print** icon to print control set up information for your records.
 - Touch Save and Exit icon to save control set up information.

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• Repeat step 1 until all lot numbers and expiration dates are entered for all levels.







ENTERING ASSIGNED VALUES and EXPECTED RANGES.

2. At Main screen, touch QA icon



• At the QA screen touch one of the 4C Parameter icons





• Select the control level:



• Refer to **TABLE OF EXPECTED RESULTS** supplied with your control material for assigned values and expected ranges.



• On keypad enter the <u>assigned values</u> and <u>expected ranges</u> from TABLE OF EXPECTED RESULTS. Touch the Save icon to save the control file information.



• When you are finished entering all values for the control, touch Save and Exit icon.



- Repeat <u>step 2</u> until all assigned values and expected ranges are entered for all levels.
- To print entered values



DATA REVIEW

Refer to the A^C•T diff / A^C•T diff 2 *Installation and Training guide or the Operator's Guide* for information about patient sample collection and storage requirements, as well as instructions for handling irregular sample results. If sample is flagged, review the results per laboratory protocol.

CODES AND FLAGS

The $A^{c} \bullet T$ diff / diff 2 produces two types of flags:

- **CODES** that *replace* parameter results.
- **FLAGS** that appear *next to* parameter results. Up to two flags can be displayed for a parameter.

Replacement Flags (CODES)

For those flags that *replace* parameter results, the hierarchy in decreasing order of importance is:

- ---- (Total Voteout)
- **+++++** (Results exceed operating range)
- **XXXXX** (Aperture Alert)
- (Incomplete Computation)

Non-Replacement Flags

For those flags that *appear next to* the parameter results, the hierarchy, in decreasing order of importance, is:

- **X** (one or more Aperture Alert criteria not met)
- + (overrange result: greater than linear range but less than operating range)

WBC > 99.9 but < 150 X $10^3/\mu$ L RBC > 7.0 but < 8.00 x $10^6/\mu$ L Hgb > 25.0 but < 30.0 g/dL Plt > 999 but < 3000 x $10^3/\mu$ L

- * (occurs on parameters influenced by +++++, +, or - -)
- 1, 2, 3, 4, M (where M means multiple region failure on WBC histogram)

Flagging on the Analyzer

On the Analyzer you can set up <u>three</u> sets of **Patient Ranges (1, 2 and 3)** according to your laboratory's protocol.

You select the Range you want to use before running patient samples. The samples will be flagged with a **H** (High) when result is higher than the high patient sample limit or **L** (Low) when result is lower than the low patient sample limit.

Follow your laboratory's protocol for action to take.

Attention: Beckman Coulter does not claim to idenify every abnormality in samples and suggests using all available flagging options to optimize the sensitivity of the instrument results. All flagging options include reference ranges (H/L), codes, and flags. Beckman Coulter recommends avoiding the use of single messages or outputs to summarize specimen results or patient conditions.

Histograms



WBC differential histogram areas

The percentage of leukocytes (WBC) that fall into each of the three population categories is derived from the WBC histogram.

WBC Differential Histogram Flagging

WBC differential results (% and #) may be flagged **1**, **2**, **3**, **4**, **or M** depending on the regions that failed. **M** = multiple region failure.

WBC differential results flagged *only* with * indicates interference with differential populations.

If both WBC **and** WBC differential results are flagged with *, this indicates the 35 fL check for interference failed.

GENERAL PROCEDURES / POWER UP ANALYZER

Power Up Analyzer

1. At the back of the instrument, press the on button to turn instrument ON.

2. For the next few minutes, the instrument performs its startup process. You will see various screen displays on the touch screen.

3. Next the instrument performs a a background check and indicates a PASS or FAIL message for each parameter.









GENERAL PROCEDURES / POWER UP ANALYZER

 If PASS appears for all parameters, print the results by touching the **Print** icon. **Note:** If Autoprinting is ON, the report prints automatically.

If *FAIL* appears for any parameter, do Startup again:

- Touch the Main Screen icon.
- Touch the **Startup** icon. The instrument goes through the startup process again.
- Allow the instrument to complete the startup routine.
- If *FAIL* appears for any parameter, repeat steps a though c.
 - If, after repeating steps a through c two times, *FAIL* appears for any parameter refer to A^C●T diff Operator's Guide, Service and Maintenance chapter; Troubleshooting.
 - 2) If *PASS* appears for all parameters, print the results as described above.
- 5. After the startup report prints, touch the Main Screen icon to continue.









REPLACING REAGENTS

A change of reagents may be necessary when you see one of these icons:



Replacing the COULTER[®] A^C ● T diff Pak[™] or Tainer Reagents[™]



1. Remove the A^c•T diff Pak or Tainer reagent management card from the instrument.

NOTE: Keep used reagent management card for downloading IQAP, if applicable.



2.

A^C●T diff Pak

Obtain new A^c•T diff Pak Verify Expiration Date



A^C•T diff Tainer

Obtain new A^c•T diff Tainer Verify Expiration Date



3. $A^{C} \bullet T$ diff Pak

Pull the perforated cardboard from the reagent container box, and remove the management card.



4. Insert A^c●T diff Pak reagent management card from new reagent container into slot at front of instrument.



5. Place new A^c • T diff Pak reagent container next to empty container.



 $A^{C} \bullet T$ diff Tainer

Remove the new reagent management card from the sleeve on the reagent container.



Insert A^c•T diff Tainer reagent management card from new reagent container into slot at front of instrument.



Unscrew the three white plastic caps from the $A^c \bullet T$ diff Tainer reagent container and remove seals to expose each opening.





6. $A^{C} \bullet T$ diff Pak

Remove cap and seal for tube number 1 on A^c•T diff Pak container.



A^C•T diff Tainer

Open reagent compartment door and remove empty A^c●T diff Tainer reagent container.



IMPORTANT Risk of misleading results if the pickup tubes are contaminated. Ensure that the reagent pickup tubes remain clean and free of contamination. Avoid contact with lab surfaces or your gloved hands.

7. $A^{C} \bullet T$ diff Pak

Remove reagent pickup tube 1 from empty reagent container.



A^C•T diff Tainer

Remove pickup tube 1 from reagent container:

- a. Unscrew the cap
- b. Pull reagent tube 1 from container



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- A^C•T diff Pak
- 8. Insert reagent pickup tube 1 into New container and tighten cap.



9. Repeat <u>steps 7 and 8</u> for reagent with pickup tube 2.



A^C•T diff Tainer

Connect pickup tube 1 to the new reagent container box:

- a. Insert cap end of pickup tube 1 into opening 1 of reagent container
- b. Screw cap to container.



Repeat <u>steps 7 and 8</u> for reagent pick up tubes 2 and 3 and place container with tubes attached in reagent compartment. Close compartment door.



10 8888 (U) ()	88882 VB	! !!!	4/22/05 13:46:02	
WBC RBC Hgb Hot	92 36 132 370	LV MO GR LV#	40.6 9.8 49.8 3.7	
MCH MCHC P1t	296 35.6 215	GR RDV MPU	4 16 12:9 7.18	
		<u> </u>	ø	990069963

10. Touch Lyse Prime icon, if displayed.

11. Touch Diluent Prime icon, if displayed.

10 0000	00002	E.C.	4,62,0	05	
CU	WB		³⁴ 13.46	02	
VBC	9.2	LV	40.6		
RBC	3.5	MO	9.B		•8
Hgb	13.2	BR	49.B		
Hct	370	LVI	3 T		_
MCU	931	MC#	6.0		I+≦
MCH	29.6	GRe	4.6	1	12.1
MCHC	35.6	RDV	12.9	I	100 0
Plt	215	MPU	7.B		
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		, 			
	U BC RBC Hgb Hct MCU MCHC Plt	10 00000002 CUUB MBC 92 RBC 36 Hgb 132 Hct 370 MCU 951 MCH 296 MCHC 356 Plt 215	ID BERGEREZ Image: Constraint of the second se	1) BEBEBBBBEZ 1) 1346 (UWB 1346 MBC 9.2 LV 405 RBC 3.6 MO 9.8 Hgb 13.2 GR 49.8 Hct 37.0 LV4 37 MCU 93.1 MCE 80 MCU 93.1 MCE 80 MCU 93.1 MCE 40.8 MCH 29.6 GRA 4.6 MCHC 35.6 RDV 12.9 P1t 215 MPU 7.8	I) B00000002 IIIII 40205 (UWB 134602 VBC 9.2 LV 406 RBC 3.5 MO 9.8 Hgb 13.2 DR 49.8 Hct 37.0 LV4 3.7 MCU 93.1 MC6 8.9 MCU 93.1 MC6 8.9 MCU 93.1 MC6 8.9 MCU 93.1 MC4 8.9 MCH 29.6 GRN 4.6 MCH 35.6 ROV 12.9 P1t 215 MPU 7.8

12. Touch AcT Rinse Prime icon if displayed



13. Follow your laboratory's protocol for recording reagent lot numbers and expiration dates of the new A^C•T diff Pak / A^C•T diff Tainer reagents.

REPLACING A^C ●T Rinse[™] Shutdown Diluent (with PAK only)



Replace Rinse container when you see this screen:



1. Open reagent compartment door and remove Rinse container with tubing still attached.



A^c●T diff 2



- 2. Remove pickup tube from Rinse container:
 - a. Unscrew cap
 - b. Pull tube from container



IMPORTANT Risk of misleading results if the pickup tubes are contaminated. Ensure that the reagent pickup tubes remain clean and free of contamination. Avoid contact with lab surfaces or your gloved hands.

- 3. Connect pickup tubes to new Rinse container:
 - a. Insert pickup tube into Rinse container
 - b. Screw cap to bottle
- 4. Place new Rinse container into reagent compartment and close door.



A^c•T diff 2



5. Touch Continue icon to prime Rinse.



GENERAL PROCEDURES SCHEDULE

Procedure	Frequency	Situation
Clean the baths	When necessary	 Before any type of calibration Increased voteouts, MCV values, X flags Decreased cell counts Failure to recover control values Erratic MCV, RBC, and WBC counts Aperture alerts not remedied by zapping the apertures
Replace Hydrophilic Diluent Filters	At least every 6 months or 5,000 cycles	 When you get platelet background failures When you get chronic "Diluent Empty" messages
Replace peristaltic pump tubing (A ^c • T diff)	Every 12 months or every 10,000 cycles	 <u>When you replace diluent filters</u> When you get excessive diluent empty messages When tubing is worn to the extent that it looks almost worn through
Replace diluent filters (A ^c •T diff)	When necessary	 <u>When you replace peristaltic pump tubing</u> When you get excessive diluent empty messages When a filter is clogged
Replace syringe pistons and seals (A ^c • T diff)	Every 12 months or every 10,000 cycles	 Excessive fluid leaks You see build-up around a syringe

GENERAL PROCEDURES / SCHEDULE

Procedure	Frequency	Situation
Clean Dust Filter (A ^c • T diff 2)	Approximately every 6 months	Dust is visible on filter
Replace waste filter	Every 12 months or every	Waste does not drain from the baths and
(A ^c •T diff 2 only)	10,000 cycles	Baths overflow
Replace Vacuum Fluid Barrier	As required based on vacuum readings	Repeated vacuum errors
Replace RBC Diluent Filters	Every 6 months or every	Chronic Platelet Background Failures
(A°•T diff 2 only)	5,000 cycles	

GENERAL PROCEDURES / ZAPPING THE APERTURES

GENERAL PROCEDURES

This section documents the most common A^C•T diff Series general procedures, including cleaning and replacement procedures.

Performing these procedures ensures product performance. Document all procedures performed in the maintenance log included with the *Reference Manual*.

For additional information consult the chapters in A^C•T diff *Operator's Guide* (PN 4237416), or A^C•T diff 2 *Operator's Guide* (PN 4237495): Troubleshooting; Cleaning Procedures; and Replacement Procedures.

CLEANING PROCEDURES

ZAPPING THE APERTURE

Perform this procedure when instrument produces

- increased Aperture Alerts, Voteouts, or MCV values
- decreased cell counts
- erratic MCV, RBC and WBC counts

OR

• fails to recover control values

1. At Main screen


CLEANING (BLEACHING) THE BATHS

NOTE: This procedure must be performed before Calibration. Otherwise, perform the procedure as needed by referring to A^C•T diff / A^C•T diff 2 *Operator's Guide*.

- 1. Fill a tube with more than 1 mL of high-quality, fragrance-free, gelfree bleach (5 to 6% solution of sodium hypochlorite - available chlorine).
- At Main screen
 touch Diluter Functions icon. Clean Baths icon
- 3. Place tube of bleach at probe so that tip is well into bleach, and press aspirate switch. The instrument cleans the baths.
- 4. The cleaning procedure takes approximately **15 minutes** to complete

NOTE: To cancel cleaning procedure before 15 minute cleaning period ends, touch Stop icon. ||||



5. On Diluter Functions screen, touch **Exit** icon.





GENERAL PROCEDURES / DUST FILTER

<u>CLEANING THE FAN'S DUST FILTER</u> (A^C•T diff 2)

The fan is located on the back panel, and the filter is inside the fan's housing.

Clean the filter every 6 months unless the laboratory is in a dusty environment. Then more frequent cleaning is recommended, depending on conditions.





- 1. Turn instrument OFF and unplug from power source.
- 2. Remove grill and filter.



4. Replace filter and grill.



- 6. Plug instrument into power source.
- 7. Turn instrument ON and resume normal operation.

GENERAL PROCEDURES / VACUUM FLUID BARRIER

REPLACEMENT PROCEDURES

REPLACING VACUUM FLUID BARRIER

Vacuum Fluid Barrier PN 6232803



- 1. Turn instrument OFF and unplug from power source.
- 2. Open right compartment door.



- 3. Locate vacuum fluid barrier. A^c•T diff A^c•T diff 2
- 4. Remove vacuum fluid barrier from the tubing:
 - Twist off top connector.
 - Twist fluid barrier off bottom connector.



GENERAL PROCEDURES / VACUUM FLUID BARRIER

- 5. Properly dispose of used fluid barrier.
- 6. Connect a new fluid barrier to tubing by inserting tubing end into filter and turning connector until secure.
 - Repeat above procedure to connect other end of fluid barrier.

7. Close right door.

- 8. Plug instrument into power source and turn Instrument ON to resume normal operation.
- 9. Cycle a sample with known results to verify instrument performance.





REPLACING PERISTALTIC PUMP TUBING (A^C•T diff only) Peristaltic Pump Tubing PN 3213214

IMPORTANT! Risk of misleading results. Worn or damaged peristaltic pump tubing can cause misleading results. To avoid misleading results, replace the peristaltic pump tubing <u>every 12 months or 10,000 cycles</u>. Replace Diluent Filters when replacing tubing.

To optimize instrument performance, replace the peristaltic pump tubing when you get excessive diluent empty messages. In addition, check periodically for defects or twists in the tubing or for pump rollers that are not rotating properly, as these things may cause the tubing to wear more quickly.



WARNING! Possible injury to hands. The peristaltic pumps rotate at various intervals during a normal run. To avoid injury, do not put your hands in the area while instrument is cycling.

- 1. Turn instrument OFF and unplug from power source.
- 2. Open <u>right</u> compartment door.



GENERAL PROCEDURES / PERISTALTIC PUMP TUBING

3. Locate biohazard waste pump and diluent/rinse pump.

- WARNING Risk of biohazard. The waste filter can contain biohazardous material that could cause contamination. Handle and dispose of filter according to acceptable laboratory laboratory protocol.
- 4. Pull tubing from top groove and stretch tubing over pump.
- 5. Disconnect pump tubing by pulling it apart from the fitting.
 - Note: When disconnecting the permanent tubing mark them as lower and upper, this will aid when installing the new peristaltic tubing in step 12.
- 6. Pull tubing from bottom groove.









GENERAL PROCEDURES / PERISTALTIC PUMP TUBING

- 7. Disconnect pump tubing by pulling
- 8. it apart from the other fitting.

9. Properly dispose of used pump tubing.

10. Stretch new pump tubing before connecting to the bottom fitting.

11. Place newly connected pump tubing in bottom groove.

 Stretch tubing around pump, using care not to twist or crimp tubing. Insert tubing into top groove.









GENERAL PROCEDURES / PERISTALTIC PUMP TUBING

13. Connect tubing to top connector of pump tubing.

Note: Make sure to connect permanent upper and lower tubing correctly.

14. Rotate pump <u>clockwise 4 times</u>.



- 15. Repeat steps 3 through 13 for remaining pump.
- 16. Continue with **Replacing Diluent Filters** procedure.

<u>REPLACING DILUENT FILTERS</u> (A^C•T diff only)

Diluent Filters PN 6233052

1. Locate diluent filters.

- 2. Remove diluent filter from the tubing:
 - Unscrew locking connector until completely loosened from fitting.
 - Pull tubing from diluent filter.
- 3. Repeat <u>step 2</u> at other end, twisting filter *counterclockwise* to remove.
- 4. Properly dispose of diluent filter.







5. Connect a new diluent filter to tubing by turning connectors until secure.

- Repeat step 5 to connect other end of diluent filter. 6.
- 7. Close right compartment door.

- 8. Plug instrument in to power source and turn instrument ON.
- Prime diluent lines: 9.
 - At Main screen, touch **Diluter Functions** icon. • Wet Prime • icon.
 - When instrument is finished Priming, touch Exit icon •
- 10. Cycle a sample with known results to verify instrument performance.







REPLACING SYRINGE PISTONS AND SYRINGE ASSEMBLIES

(A^c•T diff only)

Syringe Pistons

PN 2527677 (1 mL) PN 2527678 (250 μL) PN 2527679 (5 mL)



IMPORTANT! To optimize instrument performance, replace syringe pistons or syringe assemblies <u>every 12</u> <u>months or 12,000 cycles.</u> When replacing more than one syringe piston, be sure to replace them one at-a-time to ensure that you do not misplace the plungers.

NOTE: It is normal for a small amount of fluid to escape between the seal and the glass barrel. The fluid is a lubricant that helps extend the life of the syringe.

OVERVIEW



Syringe Assemblies



<u>v</u>

You need a regular, flathead screwdriver for this procedure.

- 1. Turn instrument off and unplug from power source.
- 2. Open right compartment door and locate syringes.



- 3. Remove connectors from syringes:
 - Turn connectors clockwise until loosened.
 - Pull connector from syringe fitting.
- 4. Unfasten screws securing top bracket.

- 5. Raise pistons until motor shaft coupling is visible.
 - Locate knob on bottom of motor.
 - Turn knob clockwise until motor shaft coupling is visible.
- 6. Remove syringe assembly.







7. Remove syringe from bracket.

8. Properly dispose of the old syringe.

- 9. Insert replacement syringe assembly into bracket.
 - Insert flange into groove.
 - Slide syringe all the way into bracket.

10. Repeat steps 7 through 9 as needed for the other syringes.





11. Slide syringe assembly onto screw posts and motor shaft.

Secure bracket onto posts using 12. screws you unfastened in step 4.

13. Reattach connectors to fittings and firmly tighten connectors.

14. Be sure syringes are in bracket as shown.







15. Close right compartment door.



16. Plug instrument into power source and turn instrument ON.

17.	At Main screen, touch Diluter Functions icon.
18.	After instrument finishes wet prime, touch Exit icon.

19. Cycle a sample with known results to verify instrument performance.

GENERAL PROCEDURES / WASTE FILTER

REPLACING WASTE FILTER (A^C•T diff 2 only)

Waste Filter PN 6233045

TOOLS / SUPPLIES NEEDED

- > Waste filter
- > Pliers



Be sure to wear full face protection when performing this procedure.

- 1. At instrument Main screen, touch Shutdown icon.
- 2. Turn instrument OFF *when Shutdown is completed* and unplug from power source.
- 3. Open <u>right</u> compartment door.

Locate waste filter





WARNING Risk of biohazard. The waste filter can contain biohazardous material that could cause contamination. Handle and dispose of the filter according to acceptable laboratory protocol.

GENERAL PROCEDURES / WASTE FILTER

4. Using pliers, remove tubing from waste filter.

- 5. Properly dispose of used waste filter.
- Connect tubing coming from LV 18 to port 1 of new waste filter.
 Port 1 is the end with flared outer ring.
- 7. Make sure arrow on the side of the filter points toward waste pump.

Note: The arrow on the filter is difficult to see. The picture is for illustration purpose only, your filter may be shaped differently.











LV18

- 8. Plug instrument into power source and turn instrument ON.
- 9. At instrument Main screen, touch **Startup** icon.

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10. While Startup is running, verify that there are no fluid leaks around the waste filter area.

Verify that Startup passed.

11. Close <u>right</u> compartment door and resume normal operation.



Replacing the RBC Bath Diluent Filters (A^C•T diff 2 only)

The diluent filters should be replaced under the following conditions:

- Chronic platelet background failures
- At least every 6 months or 5,000 cycles
- RBC Diluent Filters PN# A51656

TOOLS / SUPPLIES NEEDED

- > Diluent Filters (Qty. 2)
- Hemostat or similar tool
- 1. Turn the instrument off.

2. Unplug the instrument from the power source.

3. Open the right hand side compartment

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door.





Be-sure-to-wear-full-face-

procedure¶

protection when performing this



1656

4. Locate the two RBC Bath diluent fluid filters.



5. Clamp or pinch each tube connected to the bottom of the filter assembly with a hemostat or similar tool prevent draining of the RBC Bath.



- 6. Remove each fluid filter from the tubing
 - a Twist off the top connector



b Twist the fluid filter off the bottom connector



7. Properly dispose of the used fluid filters



8. Connect each new fluid filter to the tubing by inserting tubing end into filter and turning the filter until secure.



9. Repeat step 8 to connect the other end of the fluid filter.



10. Remove hemostats from tubing.



11. Close the right hand side door.



12. Plug the instrument into the power source.

13. Turn the instrument ON.



Perform a Startup on the instrument from the Main Menu.

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14.

- 15. Verify the Startup results "PASSED: for all parameters. If any parameter results have "FAILED" perform another Startup cycle.
- 16. Verify Calibration and run controls to verify instrument performance and resume normal operation

REPLACING HYDROPHILIC DILUENT FILTERS

Hydrophilic Diluent Filters Kit PN 6915526



Perform this procedure at least every 6 months or 5,000 cycles

- 1. At instrument Main screen, touch Shutdown icon.
- 2. Turn instrument OFF *when Shutdown is completed* and unplug from power source.
- 3. Open <u>right</u> compartment door.





Locate the two hydrophilic filters.
 A^c ●T diff

A^c•T diff 2



WARNING Risk of personal injury due to biohazard. Waste pump tubing can contain biohazardous material that could cause contamination. Handle and dispose of these components according to acceptable laboratory protocol.

4. Using a hemostat or similar tool, clamp or pinch the single tube connected to bottom of filter assembly to prevent Diluent reservoir from draining.



- 5. Remove each hydrophilic filter from the tubing:
 - Twist off top connector



• Twist off hydrophilic filter from <u>bottom</u> connector.

6. Properly dispose of used hydrophilic filters.

- 8. Connect each new hydrophilic filter to the tubing by inserting tubing end into filter and turning the connector until secure.
- 9. Repeat step 8 to connect the other end of the hydrophilic filter.

10. Remove hemostat from the tubing.

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Close <u>right</u> compartment door.
 A^c ●T diff



A^c●T diff 2



- 12. Plug instrument into power source and turn instrument ON.
- 13. If a "Diluent Empty" icon appears, touch icon to perform reagent prime.



14. Cycle a sample with known results to verify instrument performance.

PREPARATION FOR CALIBRATION

Refer to $A^{c} \bullet T$ diff or $A^{c} \bullet T$ diff 2 *Operator's Guide* for information about frequency of calibration and other reasons to calibrate the $A^{c} \bullet T$ diff / diff 2 instrument.

To prepare the instrument, before calibrating, perform

- Precalibration Checks
- Reproducibility
- Carryover

Precalibration Checks

Required maintenance has been performed on the instrument.

- ✓ Perform Cleaning (Bleaching) the Baths procedure.
- Average room temperature is within the system's operating temperature range.
- ✓ Sufficient reagent supply to complete these procedures.
- ✓ Perform Startup.

CALIBRATION / REPRODUCIBILITY

REPRODUCIBILITY

NOTE: Refer to the *Operator's Guide* for patient sample criteria for performing Reproducibility.



- 3. Thoroughly mix sample. Remember to mix sample gently between each cycle.
- 4. Analyze sample in whole blood mode for your instrument.

Trash icon appears at lower left corner of screen. You can manually delete *non-numeric results* or reject the sample, as required by touching the trash icon.



- 5. When Reproducibility sample result displays, touch **Trash** icon to delete the **first** (prime) sample manually.
- 6. Repeat <u>step 4</u> until an **N of 11** is reached. (Look at upper left corner of screen for N#)

REPROPICIBILITY										
	C783									
	Jate:	04-22-05		1	ime: 11:3	5			2	
REPERDUCTBILITY RESULTS										
3	#3C	LY.	NO.	Gă	380	RCB.	NCT	21T	ROX	KEV
1	4.89	41.50	5.00	53.50	4.786	13.48	86.29	209.9	13.28	8.45
2	5.02	41.20	5.50	52.30	4.836	13.50	86.55	198.4	12.53	8.45
3	5.11	41.80	5.20	53.00	4.919	13.79	86.73	213.8	11.22	8.65
4	5.64	41.10	6.35	52.60	4.951	13.74	85.85	201.2	12.87	8.84
5	5.14	40.40	7.30	52.30	4.940	13.88	85.49	199.0	13.15	8.65
6	5.09	41.30	6.50	52.20	4.898	13.87	85.77	206.6	13.10	8.65
7	5.11	49.10	6.30	53.60	4.879	13.66	85 97	198.1	12.75	8.45
8	5.08	40.00	7,60	52.40	4.989	13.82	85.09	195.3	13.21	8.55
9	5.13	41.20	6.90	51.99	4.916	13.93	85.94	212.2	12.69	8.45
10	5,11	40.80	6.30	52.90	4.894	13.75	85.15	201.3	12.84	8.45
11	5.16	19.00	8.20	52.80	4.855	13.92	86.09	211.1	13.05	8.65
		st	WARE STAT	ISTICS BUS	\$					
Fean	5.69	40.69	6.61	52.70	4.902	13.79	86.05	205.4	12.93	8.58
sċ	0.64	0.82	0.92	1.52	0.036	0.13	0.36	1.1	0.25	0.13
907	0.47	1 61	13.00	6.40	4.74	4.44	1.43	1.0	1.45	1.61

Verify **PASSED** for all parameters.

Reproducibility Limits for CBC N = 10				
Parameter	%CV			
WBC	<= 3.0%			
RBC	<= 3.0%			
Hgb	<= 2.0%			
MCV	<= 3.0%			
Plt	<= 7.0%			
MPV	<= 3.0%			



 Touch the Print Summary icon to print a Reproducibility summary report for your records.



CARRYOVER

NOTE: Refer to the *Operator's Guide* for patient sample criteria for Performing Carryover. You may use 4C cell control as an alternative to normal whole-blood sample



1. At Main screen, select



- 3. Thoroughly mix sample and cycle in whole blood mode two times.
- 4. Repeat <u>steps 3</u> for the second sample.
- 5. $A^{C} \bullet T$ diff

A^C●T diff 2

Run a blank sample by pressing aspirate switch.

Run a blank sample by closing tube holder.

6. Repeat <u>step 5 twice</u> for a total of **three** blank samples.

CALIBRATION / CARRYOVER

7. Touch **Summary** icon to view carryover summary screen.



High-to-Low Carryover on the $A^c \bullet T$ diff System should meet these limits:

ALL parameters should show that Carryover is <= 2.0%



8. Touch **Print Summary** icon to print a Carryover summary report for your records.



AUTOCALIBRATION with COULTER S-CAL® CALIBRATOR



Make sure that you have performed all Precalibration Checks listed in this document.

Beckman Coulter recommends using S-CAL calibrator.

1. Prepare S-CAL calibrator according to instructions in S-CAL package insert.

Confirm that lot number and expiration date on vial match information in the Table of Assigned Values. Do use Calibrator if it has expired.



- 2. Print calibration setup report.
 - At Main screen, touch Setup icon touch Setup Report icon.
 - After calibration setup report prints, touch Exit icon. (These are the "current" calibration factors in the instrument.)
- 3. At Main screen, select



Whole Blood mode



Closed Vial Whole Blood mode

CALIBRATION

Calibration icon

0 9.0 RBC 427 Hgb 17.0

•0

87.5 Pit 208. MPV 10.5

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At Main screen, touch **QA icon**. 4.

Calibration assay screen appears.

Refer to Table of Assigned Values supplied with your calibration • material.

00000000001

215 25.4

REC 3.61 13.2 83.1

Hgb MCV

IG.

g/dL fL

а.

x10^3\LL

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- 5. On screen, use the keypad to enter values from Table of Assigned Values.
 - When you have entered all values, touch

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• The Run Screen appears.

Continue icon.

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- 6. instructions.
- Mix the S-CAL calibrator according to the package insert











7. Run S-CAL 11 times in whole blood mode.

Mix S-CAL vial gently between each cycle.

The instrument does not use the result from the first run. It performs statistics on runs 2 through 11 for a total of 10 runs. The instrument automatically saves the results.

The instrument displays but automatically rejects non-numeric result.

If you choose to reject a result, you can only reject the <u>last</u> sample analyzed.

8. After 11 acceptable results, the Summary icon will appear.

Touch the *to view the Calibration Summary screen.*

- If Autoprint is ON and you are using a graphic printer, a summary report prints automatically.
- If Autoprint is OFF, you can print a report summary by touching Print Summary icon.


- 9. Review results status on the Report Summary.
 - PASSED for <u>all</u> parameters means calibration adjustment <u>is</u> <u>not</u> required. Touch <u>Return</u> icon.
 - *NEEDED* for <u>any</u> of the parameters means calibration adjustment <u>is required</u>.

If calibration is *NEEDED*, be sure to perform the next four steps!

- Touch Save and Exit icon to automatically replace NEEDED (current) calibration factor with new calibration factor.
- > Print *new* calibration factor for your records (log book).
- At Main screen, touch Setup
 Print Setup Report icon.
- > Verify calibration by analyzing three levels of 4C-ES cell control.
- If *FAILED* appears, the % diff value and/or %CV exceeds high acceptable limit. DO NOT calibrate.
- You will not be able to save the changes for the parameters that show NEEDED
- Call your Beckman Coulter Representative for assistance.

IMPORTANT! After you have finished Calibration, be sure that you have the following printouts for your records:

- Reproducibility Summary results
- Carryover Summary results
- Current CAL factors (prior to Calibration)
- Calibration Summary results
- New CAL factors (after Calibration)

CALIBRATION

RECOGNIZE THE PRODUCTS

Take a moment to familiarize yourself with the frequently mentioned products below.



PARTS LIST

Component	Part Number (PN)
Diluent Filter (A ^c ●T diff)	PN 6233052
Peristaltic Pump Tubing (A ^c • T diff)	PN 3213214
Syringe Pistons (A ^c ●T diff)	PN 2527677 (1 mL)
	PN 2527678 (250 μL)
	PN 2527699 (5 mL)
Fluid Barrier	PN 6232803
Waste Filter (A ^c ●T diff 2)	PN 6233045
Hydrophilic Diluent Filter Kit (A ^c •T diff 2)	PN 6915526
RBC Diluent Filters (A ^c ●T diff 2)	PN A55482
Hydrophilic Diluent Filter Kit(A ^c • T diff)	PN 6915577

To order replacement parts, please contact your Beckman Coulter Representative (800) 526-7694.

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Initial Issue

A^c •T, A^c •T diff, A^c •T diff 2, diff A^c •T Pak, diff A^c •T Tainer, A^c •T Rinse, S-CAL, 4C, 4C-ES, Lin-C, COULTER, BECKMAN COULTER logo, BECKMAN COULTER, are trademarks of Beckman Coulter, Inc.

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