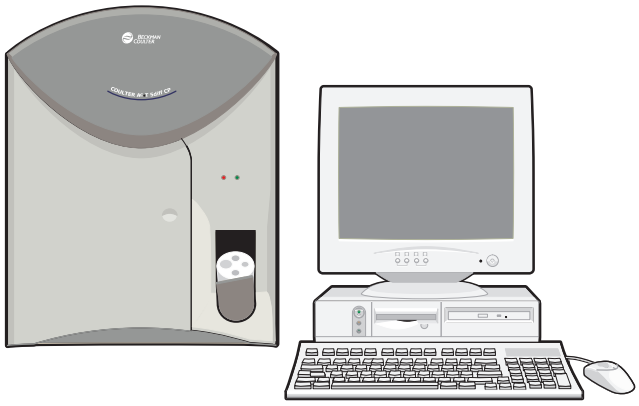
COULTER®
A^{C}•T™ 5diff Cap Pierce Hematology Analyzer

Addendum



CE

PN 773075AE (July 2016)

Manufactured for
Beckman Coulter, Inc.
250 S. Kraemer Blvd.
Brea, CA 92821 U.S.A.

Rx Only in the U.S.A.

BECKMAN COULTER

WARNINGS AND PRECAUTIONS

READ ALL PRODUCT MANUALS AND CONSULT WITH BECKMAN COULTER-TRAINED PERSONNEL BEFORE ATTEMPTING TO OPERATE INSTRUMENT. DO NOT ATTEMPT TO PERFORM ANY PROCEDURE BEFORE CAREFULLY READING ALL INSTRUCTIONS. ALWAYS FOLLOW PRODUCT LABELING AND MANUFACTURER'S RECOMMENDATIONS. IF IN DOUBT AS TO HOW TO PROCEED IN ANY SITUATION, CONTACT YOUR BECKMAN COULTER REPRESENTATIVE.

HAZARDS AND OPERATIONAL PRECAUTIONS AND LIMITATIONS

WARNINGS, CAUTIONS, and IMPORTANTS alert you as follows:

WARNING - Can cause injury.
CAUTION - Can cause damage to the instrument.
IMPORTANT - Can cause misleading results.

BECKMAN COULTER, INC. URGES ITS CUSTOMERS TO COMPLY WITH ALL NATIONAL HEALTH AND SAFETY STANDARDS SUCH AS THE USE OF BARRIER PROTECTION. THIS MAY INCLUDE, BUT IT IS NOT LIMITED TO, PROTECTIVE EYEWEAR, GLOVES, AND SUITABLE LABORATORY ATTIRE WHEN OPERATING OR MAINTAINING THIS OR ANY OTHER AUTOMATED LABORATORY ANALYZER.

WARNING Risk of operator injury if:

- All doors, covers and panels are not closed and secured in place prior to and during instrument operation.
- The integrity of safety interlocks and sensors is compromised.
- Instrument alarms and error messages are not acknowledged and acted upon.
- You contact moving parts.
- You mishandle broken parts.
- Doors, covers and panels are not opened, closed, removed and/or replaced with care.
- Improper tools are used for troubleshooting.

To avoid injury:

- Keep doors, covers and panels closed and secured in place while the instrument is in use.
- Take full advantage of the safety features of the instrument. Do not defeat safety interlocks and sensors.
- Acknowledge and act upon instrument alarms and error messages.
- Keep away from moving parts.
- Report any broken parts to your Beckman Coulter Representative.
- Open/remove and close/replace doors, covers and panels with care.
- Use the proper tools when troubleshooting.

CAUTION System integrity might be compromised and operational failures might occur if:

- This equipment is used in a manner other than specified. Operate the instrument as instructed in the Product Manuals.
- You introduce software that is not authorized by Beckman Coulter into your computer. Only operate your system's computer with software authorized by Beckman Coulter.
- You install software that is not an original copyrighted version. Only use software that is an original copyrighted version to prevent virus contamination.

IMPORTANT If you purchased this product from anyone other than Beckman Coulter or an authorized Beckman Coulter distributor, and, if it is not presently under a Beckman Coulter service maintenance agreement, Beckman Coulter cannot guarantee that the product is fitted with the most current mandatory engineering revisions or that you will receive the most current information bulletins concerning the product. If you purchased this product from a third party and would like further information concerning this topic, call your Beckman Coulter Representative.

Initial Issue, 12/06
Software version 2A

Issue AA, 03/09
Software Version 2A

An update was added to page 6.

Issue AB, 01/10
Software Version 2A

Common updates were made to:

- Remove instructions to affix updated labels to a printed manual because these files are now placed on the BCI website.
- Replace the manufacturer's symbol on the cover page to show the Brea, CA address.

Data updates made are indicated by change bars on the left-side page margin of Chapter 2, Performance Characteristics.

- Added the Reference Range Studies section under the Performance Characteristics section.
- Added a statement indicating that text will be removed from SUBMITTING CONTROL RESULTS FOR IQAP (INTERLABORATORY QUALITY ASSURANCE PROGRAM) on page 7-11, of the Instructions for Use manual, once the manual is updated.

Issue AC, 06/10
Software Version 2A.

Updates were made to the company corporate address.

Issue AD, 03/2016
Software Version 2A

The following section was modified:

- A CE mark statement was added to Chapter 2.

Issue AE, 07/2016
Software Version 2A

The following address was changed:

- EC Rep address

Note: Changes that are part of the most recent revision are indicated in text by a bar in the margin of the amended page.

This document applies to the latest software listed and higher versions. When a subsequent software version changes the information in this document, a new issue will be released to the Beckman Coulter website. For labeling updates, go to www.beckmancoulter.com and download the most recent manual or system help for your instrument.

REVISION STATUS

DOCUMENT OVERVIEW

Purpose

This Addendum contains important product update information that was not available when the product manuals for your COULTER® A^{C}•T 5diff Cap Pierce (CP) Hematology Analyzer were created. Make sure all operators for the A^{C}•T 5diff CP Hematology Analyzer are aware of the information in this Addendum.

Affected Documents

The following A^{C}•T 5diff CP Hematology Analyzer documents are affected by these updates:

- Instructions for Use, PN 624021
- Training Guide, PN 4277205
- Host Transmission, PN 4277065
- Online Help, PN 4237650

Keep this Addendum with your current product documentation.

UPDATE INFORMATION

Updates are described in detail in the next section of this Addendum. The location of the changed information is identified by chapter name, heading name, and/or procedure name and step number, as appropriate.

Each update includes detailed instructions concerning how to handle that update in the A^{C}•T 5diff CP System Help.

If an Update Affects the System Help

If an update involves the A^{C}•T 5diff CP System Help:

1. Locate the information that needs to be updated as instructed in this Addendum.
2. Review each change for impact to your standard operation procedures and retain this Addendum as part of your Quality System documentation.

NCCLS

Name Change

Effective January 2005, the NCCLS (National Committee for Clinical Laboratory Standards) changed its name to CLSI (Clinical and Laboratory Standards Institute).

Impact on References

All NCCLS documents, publications, guidelines, and standards referenced in the COULTER® A^C•T 5diff Cap Pierce (CP) System Help and printed manuals were published prior to this name change and, therefore, do not need to be changed.

Impact on the List of Abbreviations

Add CLSI acronym to the LIST OF ABBREVIATIONS.

KNOWN INTERFERENCE STATEMENT

Add Statement to RBC Information

If hemolysis is occurring in vivo, the instrument RBC may be flagged as low, reflecting the true circulating cells. If, however, the hemolysis is in vitro, the specimen may give falsely low RBC results. Cell counts due to in vitro hemolysis do not represent the number of circulating red blood cells.

How to Handle the Update

- In the System Help (PN 4237650):
  - Under Section 3.5, INTERFERING SUBSTANCES, locate the RBC Parameter heading.
  - Review this change for impact to your standard operation procedures and retain this Addendum as part of your Quality System documentation.

REAGENT REPLACEMENT PROCEDURES

The expiration date field represents the open container stability date for all reagents. Refer to the Storage, Stability, and Disposal Section of the package insert for each reagent for the open container expiration dating and proper temperature storage.

How to Handle this Update

In the System Help (PN 4237650):

- Under Section 11.11, REPLACEMENT PROCEDURES, locate the following:
  - Changing the Diluent Reagent, Step 14b.
  - Changing One Reagent: Fix, WBC Lyse, HGB Lyse, or Rinse Reagents, Step 16b.
  - Changing All Reagents, Step 24b.
- Review this change for impact to your standard operation procedures and retain this Addendum as part of your Quality System documentation.

FIXED FORMAT: CP SYSTEM

Results Calculation and Rounding

The sequence for the calculation of results after analysis is:

1. Raw values from parameter acquisition are sent to the calculation module within the software. These values may contain greater than six (6) digits after the decimal point.
2. The raw values are then truncated and the rounding calculation applied to the parameter values based on the internal format, these are the internal raw values. (See examples below.)
3. The results are then displayed and printed according to the user unit selection: US, SI1, SI2, SI3, SI4.

Examples of results rounding between the A^{C}•T 5diff CP display and the Host display:

1. If the internal raw value is 32.945234 and truncated to 32.945.
   32.945 is rounded, depending on the units format with 2 Digits to 32.95.
   32.951 is rounded, depending on the units format with 1 Digit to 32.9.
   - With the truncated value of 32.945, the A^{C}•T 5diff CP could display 32.9 and the transmitted data is 32.95.
2. If the internal raw value is 32.9512345 and truncated to 32.951.
   32.951 is rounded, depending on the units format with 2 Digits to 32.95.
   32.951 is rounded, depending on the units format with 1 DIgit to 33.0.
   - With the truncated value of 32.951, the A^{C}•T 5diff CP could display 33.0 and the transmitted data is 32.95.

Applying Flags and Rounding

In the A^{C}•T 5diff CP, it is the calculation module that calculates the final or rounded values and applies the flags according to the customer limit(s) selected. Flags are always based on the flag limit applied to the raw, non-truncated values.

Example of flag applied to internal raw values within the workstation.

1. The high limit to flag is set at 33.0.
   - The rounded value is 32.96. The A^{C}•T 5diff CP displays on the screen 33.0 without a flag.
   - The rounded value is 33.01 The A^{C}•T 5diff CP displays on screen 33.0 with the flag.

   Note: The flag is calculated on internal raw value and not rounded value.

Parameter Rounding and Units Selection

The example below tracks a parameter result as it is displayed and printed for all "Units" formats.

Units	Parameter	Internal Raw Value	Display and Print Format	Result Displayed and Printed	Units
US	MCHC	35.96	#0.0	36.0 HH	"g/dL"
SI1	MCHC	359.6	###0	360 HH	"g/L"
SI2	MCHC	359.6	###0	360 HH	"g/L"
SI3	MCHC	35.96	#0.0	36.0 HH	"g/dL"
SI4	MCHC	22.29	#0.0	22.3 HH	"mmoI/L"

Host Transmission Formats

All A^{C}•T 5diff Series transmit to the host in US format only. This transmission format provides for two digits after the decimal point for all parameters or a total of 5 spaces including the decimal point, XX.XX. This transmission format holds true for all parameters, excluding platelet and PCT (For Research Only. Not for use in diagnostic procedures.). The host receives the parameter values already rounded. So, it can round the results again in accordance with its configuration and obtain a different value in comparison with that displayed at the A^{C}•T 5diff workstation.

DOWNLOADING RESULTS TO DISKETTE FOR IQAP SUBMISSION

Update Supplies Needed

Under "Supplies Needed:", delete "or control diskette" from the first bullet so that it reads:

- Formatted Blank Diskette (you provide)

How to Handle this Update

- In the System Help (PN 4237650):
  - Locate Section 7.2, SUBMITTING CONTROL RESULTS FOR IQAP (INTERLABORATORY QUALITY ASSURANCE PROGRAM) ▸▸ Downloading Results to Diskette for IQAP Submission.
  - Review this change for impact to your standard operation procedures and retain this Addendum as part of your Quality System documentation.

DELETING SAMPLE RESULTS

Update Procedure

Change the second note in Step 1 to read:

- Use the **Search Results** tab view to search for and delete sample results from the current archive.

How to Handle the Update

- In the System Help (PN 4237650):
  - Locate Section 9.2, AFTER LOCATING THE SAMPLE RESULTS ▸▸ Deleting Sample Results ▸▸ Step 1 ▸▸ **Notes**:
  - Review this change for impact to your standard operation procedures and retain this Addendum as part of your Quality System documentation.

WBC HISTOGRAM FLAGS

Figure 9.3 WBC/BASO Histogram Flags: CBC Panel

Figure 9.3, WBC/BASO Histogram Flags: CBC Panel should be as follows:

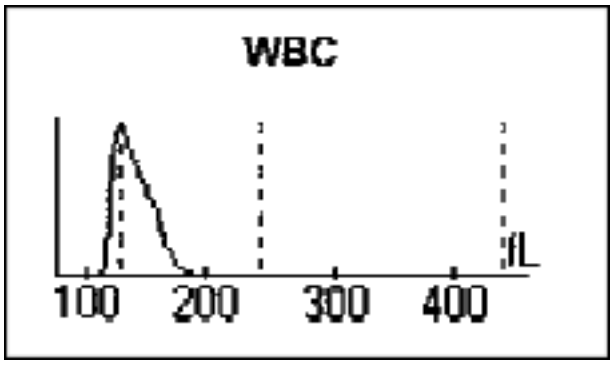
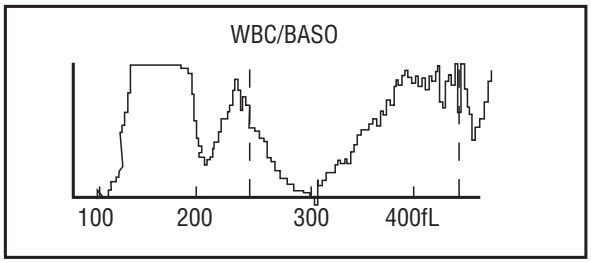


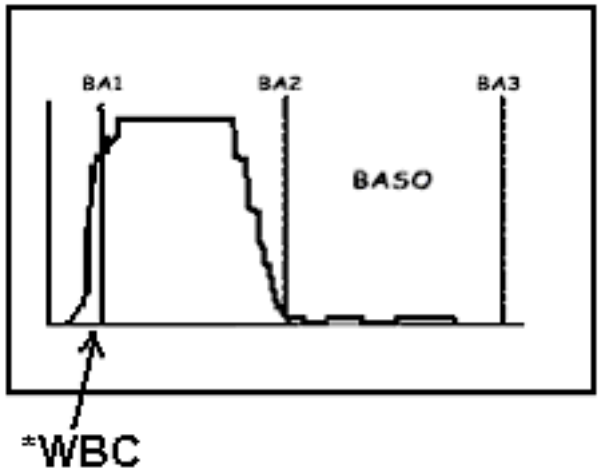
Figure 9.4 WBC/BASO Histogram Flags: CBC/DIFF Panel

Figure 9.4, WBC/BASO Histogram Flags: CBC/DIFF Panel should be as follows:



Add Figure For WBC/BASO Histogram Flags: CBC/DIFF Panel

For the WBC/BASO Histogram, *WBC flag, add the following illustration for the CBC/DIFF Panel:



How to Handle this Update

- In the System Help (PN 4237650):
  - Locate Table 9.2, WBC HISTOGRAM FLAGS.
  - Review these changes for impact to your standard operation procedures and retain this Addendum as part of your Quality System documentation.

FLAGS AND ANALYTICAL ALARMS GENERATED BY THE INSTRUMENT

Update Information

Control flags should be added to the list of instrument-generated flags.

- Note: The BA% and BA# from the A^{C}•T 5diff Control Plus cell control are reported into the control file with an "S" flag to indicate that these would normally have been suppressed if it was a patient sample.

  The high and low flags indicate recovery outside of the expected ranges. Analytical errors, other than BASO+, may require review.

How to Handle this Update

- In the System Help (PN 4237650):
  - Under Section 9.3, REVIEWING FLAGGED RESULTS, locate Flags and Analytical Alarms Generated by the Instrument ▸▸ Overview.
  - Review this change for impact to your standard operation procedures and retain this Addendum as part of your Quality System documentation.

VARIABLE TRANSMISSION FORMAT FOR SAMPLE ANALYSIS

Update Information for the Host Transmission Manual Only

The workstation transmits differential results as 0.0 to the Laboratory Information System (LIS) when the variable transmission format is selected and a sample is analyzed in the CBC mode. The A^{C}•T 5diff CP system will display and print all results correctly; this only affects the LIS receipt and interpretation of data.

Patient File Identifiers Updated

The list below consists of the parameters and identifiers if the value = A with only the CBC parameters transmitted to the LIS:

WBC	White Blood Cell or leukocyte count
RBC	Red Blood Cell or erythrocyte count
Hgb	Hemoglobin concentration
Hct	Hematocrit (relative volume of erythrocytes within the whole-blood sample)
MCV	Mean Corpuscular (erythrocyte) Volume
MCH	Mean Corpuscular (erythrocyte) Hemoglobin
MCHC	Mean Corpuscular (erythrocyte) Hemoglobin Concentration
RDW	Red Cell (erythrocyte) Distribution Width
Plt	Platelet or thrombocyte count
MPV	Mean Platelet Volume

WBC HISTOGRAM FLAGS

Replace *Default value: 3.5% or 999 particles* with **Default Values: 4% or 600 particles** in Table 9.2, WBC Histogram Flags, for **WBC/BASO** under **Description**.

How to Handle this Update

- Review this change for impact to your standard operation procedures and retain this Addendum as part of your Quality System documentation.

Performance Characteristics

Reference Range Studies

A Normal Range Study was conducted to assess the Reference Ranges for the Ac*T 5diff Cap Pierce. Whole blood samples were collected from approximately one hundred and twenty-four normal donors (males and females). The selection of donors complied with the CLSI (former NCCLS), C28-A2 guidelines.

These ranges can be used as default values for normal range flags. Your patient population Ranges may be different.

Table 2.1 Whole Blood Reference Ranges Overall

Parameter	Units	95% Confidence Low Limit	95% Confidence High Limit
WBC	$x10^3/\mu l$	3.53	9.26
RBC	$x10^6/\mu l$	3.91	5.46
HGB	g/dl	11.38	16.14
HCT	%	34.33	47.44
MCV	fL	76.06	95.16
MCH	pg	25.03	32.20
MCHC	g/dl	32.33	34.29
RDW	%	10.72	14.66
PLT	$x10^3/\mu l$	141	375
MPV	fL	7.3	10.37
LY#	$x10^3/\mu l$	1.01	3.07
LY	%	22.3	46.8
MO#	$x10^3/\mu l$	0.18	0.58
MO	%	4.0	10.0
NE#	$x10^3/\mu l$	1.79	5.51
NE	%	42.4	69.1
EO#	$x10^3/\mu l$	0.08	0.58
EO	%	1.3	10.4
BA#	$x10^3/\mu l$	0.01	0.07
BA	%	0.3	0.9

SUBMITTING CONTROL RESULTS FOR IQAP (INTERLABORATORY QUALITY ASSURANCE PROGRAM)

Next time the IFU and respective translations for the Ac*t 5 diff CP are updated, the following statement will be removed from section 7.2 titled Submitting Control Results for IQAP, on page 7-11: "As a backup, or for instruments with software versions below 2.00, summary data can be transcribed onto Intelligent Character Recognition (ICR) forms."

CE Mark

A "CE" mark indicates that a product has been assessed before being placed on the market, and has been found to meet European Union safety, health, and/or environmental protection requirements.

TRADEMARKS

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AC•T 5diff Cap Pierce Documentation

- **Instructions For Use**
  PN 624021
  Use and Function • Operation Principles • Specifications/Characteristics • Precautions/Hazards • Running Samples • Reviewing Results • Calibration • Diagnostics • Instrument Setup • Log Sheets • Manual Calibration • References • Glossary • Abbreviations • Index
- **Host Transmission Specification**
  PN 4277065
  Defines requirements for interfacing the system with a host computer.
- **Training Guide**
  PN 4277205
  Provides training information for using the CP system.
- **Daily Operations Quick Reference**
  PN 4277315
  Provides abbreviated procedures for the experienced operator.

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EC REP

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