# **COULTER<sup>®</sup> TQ-Prep<sup>™</sup> Workstation**

Instructions For Use





PN 4237396BA (June 2010)





# 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.

Issue A 8/97

Software Version 1.1.

**Issue B, 6/03** Changes were made to,

- comply with the EU IVD Directive (98/79/EC).
- change the company name from Coulter Corporation to Beckman Coulter Inc.

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

#### Issue BA, 06/10

Updates were made to the company corporate 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.

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This introductory section contains the following topics:

- How to use your COULTER<sup>®</sup> TQ-Prep<sup>™</sup> Workstation manuals
- About the Operator's Guide
- Conventions

### HOW TO USE YOUR COULTER TQ-PREP WORKSTATION MANUALS

Use the **Reference** manual for in-depth information about:

- What the instrument does
- The methods it uses
- Its specifications
- Information about installation.

A Master Index is included at the back which lists entries from the entire documentation set.

Use the Operator's Guide for the day-to-day running of your instrument:

- To run a gravimetric validation test
- To clean, to replace or adjust a component
- To troubleshoot the instrument.

Read the Controls and Indicators chapter to become familiar with the different parts of your system. Then go through the detailed step-by-step procedures of daily startup, processing samples and shutdown. The calibration chapter contains the gravimetric validation and precision tests. The following chapters contain the cleaning, replacement and adjustment procedures and troubleshooting tables. A Master Index is included at the back which lists entries from the entire documentation set.

Use the **Operating Summary** after you are trained and familiar with using the system. It contains a brief summary of the daily startup, sample processing and shutdown procedures, and descriptions of the touch screen.

See the Documentation page on the back cover of this manual for the contents of each manual. It can help you to determine which manual contains the information that you need.

# ABOUT THE OPERATOR'S GUIDE

Your TQ-Prep Workstation Operator's Guide is a source of information on what the system does.

This information is organized as follows:

■ Chapter 1, Controls and Indicators

Illustrates the parts of the instrument used during normal operation. Describes the software screens that appear on the touch screen.

- Chapter 2, Startup Details the daily startup routine.
- Chapter 3, Sample Processing

Describes how to load the samples into the carousel, the carousel onto the instrument and how to request sample processing.

Chapter 4, Shutdown

Describes the normal daily shutdown procedure and the long-term shutdown procedure.

- Chapter 5, Calibration
   Describes the gravimetric validation test and the precision test.
- Chapter 6, Cleaning Procedures

Provides cleaning procedures for the instrument.

■ Chapter 7, Replace/Adjust Procedures

Provides procedures for replacing or adjusting parts.

■ Chapter 8, Troubleshooting

Describes how to troubleshoot the instrument with the troubleshooting icons that appear on the screen. Additional troubleshooting tables are included.

■ Index

This is a Master Index that contains entries from all manuals in the documentation set.

### **CONVENTIONS**

- All figures showing reagent containers on the software screens or in the instrument include the OPTION reagent.
- Within text and instructions, screen buttons and icons appear as they do on the touch screen:
  - Screen button example:
  - Troubleshooting icon example:

# 1.1 WORKSTATION COMPONENTS



# 1.2 SAMPLE PROCESSING AREA



# 1.3 REAGENT STORAGE AND DISPENSE AREA



#### **TOUCH SCREEN SOFTWARE FLOWCHART** 1.4



# 1.5 SOFTWARE SCREENS, ICONS AND BUTTONS

# Main Screen and Buttons



Button/Icon	Function/Description
	Gravimetric Validation Test button. Performs a Gravimetric Validation test on all tubes in a carousel. See Chapter 5 for test details.
	<ul> <li>Cycle Counter button Accesses the Cycle Counter screen, which displays:</li> <li>The total number of instrument cycles run by the system.</li> <li>The remaining number of reagent tests in the current reagent containers.</li> </ul>
	• which performs a new reagent prime and resets the reagent test counter to 300.
	<b>User-Prime</b> button Primes the tubing from the reagent bottles to the syringes and from the syringes to the dispensing head with 100 µL reagent. Used during troubleshooting to remove air bubbles. Do not use unless bubbles are present.
	Note: Does not function when troubleshooting icon appears on the touch screen. (See Table 8.1 for a description of the troubleshooting icon.)
88	Reagent Mode/Empty Syringes button
	<ul> <li>Empties the syringes and leaves their plungers in the fully up position. This is used during the syringe replacement or the long-term shutdown procedures.</li> </ul>
	• Selects the reagent mode needed for sample processing: three reagents or four reagents. The displayed mode is the active mode. This function only applies if you have the LALS OPTION.

1	
-	

Button/Icon	Function/Description
	<b>Preincubation/Run Cycle</b> button Performs a 10-minute preincubation and then automatically begins a run cycle.
	Run Cycle button Begins a run cycle immediately.

# Gravimetric Screen, Icons, and Buttons



Button/Icon	Function/Description
	<ul> <li>Stop button</li> <li>Stops Gravimetric Validation testing immediately. (If pressed during reagent dispensing, processing stops at the end of the dispensing. If pressed during mixing, processing stops at the end of mixing.)</li> </ul>
	• After pressing :
	<ul> <li>Press to return to the Main screen.</li> </ul>
	<ul> <li>Or, press to continue processing.</li> </ul>
5	<ul> <li>Exit button</li> <li>Only appears after you press .</li> <li>Exits this screen and returns to the Main screen.</li> </ul>
$\Box$	<ul> <li>Run Cycle button</li> <li>Only appears after you press .</li> <li>Starts Gravimetric Validation testing on the next unprocessed sample tube.</li> </ul>
	Sample tube. Animation indicates mixing.
01, 02, 03 32	The carousel position of the sample tube currently being processed. Appears below the sample tube icon.

Button/Icon	Function/Description
ABCO	<ul> <li>Reagent container.</li> <li>A, B, and C represent ImmunoPrep A, B, and C.</li> <li>O represents the OPTION reagent for the LALS OPTION.</li> </ul>
	Indicator that appears under the A, B, C, or O reagent container icon to show which reagent is currently being dispensed.

# **Prime Screen and Icons**



Button/Icon	Function/Description
ABCO	<ul> <li>Reagent container.</li> <li>A, B, and C represent ImmunoPrep A, B, and C.</li> <li>O represents the OPTION reagent for the LALS OPTION.</li> </ul>
	Indicator that appears under the A, B, C, or O reagent container icon to show which reagent is currently being dispensed.

# Cycle Counter Screen, Icons, and Buttons



Button/Icon	Function/Description
$\square$	Exit button Exits this screen and returns to the Main screen.
	New Reagent Prime/Test Counter button Performs a new reagent prime and resets the reagent test counter to 300. Use it after replacing the ImmunoPrep <sup>™</sup> reagents or after replacing a syringe. Note: Button does not function while troubleshooting icon or appears on the touch screen. (See Table 8.1 for a description of the troubleshooting icons.)
	Example reagent counts appear in the left column for each bulleted condition below:
© 300	Appears next to the maximum number of tests remaining in the ImmunoPrep reagent containers.
5 <sub>301</sub>	<ul> <li>If  has not appeared and the count reaches 0, the next test count is 301. It continues to count up until you replace the reagents and press</li> </ul>
25 [32]	<ul> <li>Once the troubleshooting icon, D, appears on the touch screen, an additional test counter appears in brackets next to the reagent test count. This count starts at [32] and counts down to [0]. When the countdown from [32] reaches [0], the system will not process any more</li> </ul>
	samples until you change the reagents and press
	Total number of instrument cycles. You cannot reset this number

# Preincubation Screen, Icons, and Buttons



Button/Icon	Function/Description
	<ul> <li>Stop button</li> <li>Cancels the request to run samples after the 10-minute preincubation. The timer continues to count down to 00:00. Then the timer changes to</li> </ul>
	10:01 and continues counting until you press $\bigcirc$ or $\bigcirc$ .
	After pressing
	<ul> <li>Press by to return to the Main screen.</li> </ul>
	<ul> <li>▶ Or, press → to continue processing.</li> </ul>
4	Exit button
	• Appears after you press or if the sample processing lid is open and the preincubation time is 10:01 or higher.
	• Exits this screen and returns to the <b>Main</b> screen.
	Continue Preincubation/Run Cycle button
_>Σ	Only appears after you press
	Starts the run cycle after the timer counts down to 00:00.
	• Starts the run cycle immediately if the timer displays 10:01 or more.

Button/Icon	Function/Description
X	Hourglass. Animation indicates that the timer is counting.
10:00 00:00	Preincubation timer counts down from 10:00 minutes to 00:00 minutes, then sample processing begins. Note: If you press , the timer continues counting down to 00:00. Then it changes to 10:01 and continues counting up to display the total preincubation time for the samples. Counting continues until you press or continues or continues counting continues until you press or continues.

# Run Screen, Icons, and Buttons



Button/Icon	Function/Description
	<ul> <li>Stop button</li> <li>Stops sample processing immediately. (If pressed during reagent dispensing, processing stops at the end of the dispensing and sample processing is incomplete. If pressed during mixing, processing stops at the end of mixing.)</li> </ul>
	After pressing
	<ul> <li>Press to return to the Main screen.</li> </ul>
	<ul> <li>Or, press to continue processing.</li> </ul>
	Pause button
	• Pauses sample processing after completing the current sample tube. No sample is lost. Use this when you want to remove or add samples to the carousel in process, or whenever you need to interrupt sample processing of the carousel without possibly ruining a sample.
	After pressing
	<ul> <li>Perform whatever action you need to take.</li> </ul>
	<ul> <li>Press to start processing the next unprocessed sample.</li> </ul>
	<ul> <li>Or, press to return to the Main screen.</li> </ul>
	Exit button
$\square$	Only appears after you press or .
	• Exits the current screen and returns to the Main screen.

Button/Icon	Function/Description
	<ul> <li>Run Cycle button</li> <li>Only appears after you press or .</li> <li>Starts sample processing on the next unprocessed sample tube.</li> </ul>
	Sample tube. Animation indicates mixing.
01, 02, 03 32	The carousel position of the sample tube currently being processed. Appears below the sample tube icon.
ABCO	<ul> <li>Reagent container.</li> <li>A, B, and C represent ImmunoPrep A, B, and C.</li> <li>O represents the OPTION reagent for the LALS OPTION.</li> </ul>
	Indicator that appears under the A, B, C, or O reagent container icon to show which reagent is currently being dispensed.
ABCO	<ul> <li>Reagent that was being dispensed when you pressed</li> <li>Only one reagent container icon appears dark.</li> <li>A, B, and C represent ImmunoPrep A, B, and C.</li> <li>O represents the OPTION reagent.</li> </ul>
\$	Sample tube has not been completely processed. The carousel position of the ruined sample tube appears below this icon.
	shows that processing stopped after mixing of the previous reagent but before this reagent was dispensed.

### **Troubleshooting Icons**

See Table 8.1 in Chapter 8 for the description and action you need to take for each troubleshooting icon.



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### Other Icons That Can Appear on Screens

Icon	Function/Description
X	Hourglass. Indicates that the system is busy with other tasks and you cannot request a function.

# 1.6 SYSTEM SOUNDS

Number and Type	Indication
1 short beep	Sounds as positive feedback when you press a touch screen button.
1 long beep	Sounds at the completion of these functions:
	Sample processing of a carousel
	Gravimetric validation testing of a carousel.
3 short beeps	• Sounds when an error condition occurs. Beeps repeat every 3 minutes for 2 hours or until the error condition is corrected.
	• A corresponding troubleshooting icon appears on the touch screen. See Table 8.1 in Chapter 8 for the action needed.
	Note: If you replaced the reagents and forgot to press , these beeps occur and no troubleshooting icon appears on the touch screen when you press , , , or .

CONTROLS AND INDICATORS SYSTEM SOUNDS At the start of the work day, perform the appropriate startup routine:

- Daily Startup if you performed a daily shutdown
- Startup After Long-Term Shutdown if you performed a long-term shutdown.

## 2.1 DAILY STARTUP

Perform this startup procedure if you performed a daily shutdown.

**Turning On Power** 

Turn on the power switch if it is off.

Note: If you performed a long-term shutdown procedure, turn on the system per Heading 2.2, Turning on System (After Long-Term Shutdown), at the end of this chapter.





When the Main screen appears, check for any troubleshooting icon.

- If **D** or **D** appears, proceed to the next heading, Checking the Reagent and WASTE containers.
- If any of the other troubleshooting icons appears, refer to Table 8.1.



# **Checking Reagent and WASTE Containers**

- $1 \qquad \text{If } \mathbf{\bar{O}} \text{ or } \mathbf{\bar{\Omega}} \text{ appears:}$ 
  - When **T** appears, empty the waste container per the Emptying WASTE Container procedure in Chapter 7.
  - When **D** first appears, you have enough reagents to continue to run for 32 tests. Replace reagents per the Replacing Reagents procedure in Chapter 7.
    - Press to see how many more tubes can be run before replacing reagent. The number of test remaining appears within brackets [].
    - When the Cycle Counter screen displays [0] reagent tests left, the system stops processing.





2

Remove the reagent cover.





If you have the LALS OPTION, check the OPTION reagent level. Fill with distilled or deionized water if empty.





Check reagent expiration dates.

If expired, replace per the Replacing Reagents procedure in Chapter 7.



1

# Testing QualityControl (QC)

Loading the QC Sample

Open the sample processing area lid.



2 To check red cell lysis, put a fresh, whole-blood QC sample into the first position of the carousel.



3

Place the carousel onto the indexing base:

Note: To correctly secure the carousel, line up the arrow on the carousel above the hub key on the indexing base before placement.





Close the sample processing area lid.



### Processing the QC Sample





**IMPORTANT** If you open the sample processing area lid during processing, the sample in progress

might not be processed completely and  $\bigotimes$  appears on the touch screen. Opening the lid stops all movement in the sample processing area and does not start it again until you close the lid, and press



Do not open the lid during sample processing.

2

Look through the sample processing area lid to check that vortex mixing occurs at the dispensing head.



At the end of the carousel run:

- One long beep sounds.
- The Main screen appears.
- The carousel moves to the home position. (Position 10 is under the dispensing head.)



Checking and Recording QC Sample



Open the sample processing area lid.





Remove and inspect the sample. Cell lysis is complete if the sample is transparent, so that lettering can be seen through the sample.



3

Close the sample processing area lid.



# 4

Monitor the light-scatter histograms from the flow cytometer you used to run the samples.

Partially lysed samples display heavy or aberrant leukocyte light-scatter populations.

Note: The exact scatter pattern depends on the configuration of your flow cytometer. Follow the flow cytometry procedure correctly.



If you suspect incomplete lysis based on the scatter patterns:

- a. Centrifuge the sample at 400 x g for 5 minutes.
- b. Inspect the pellet for red cells. Red cell staining of white cell pellet indicates insufficient lysing activity.
- c. If incomplete red cell lysing is indicated, repeat the QC test.

6

5

All QC results must be acceptable before processing specimens and before reporting results.

7

Enter results in the Maintenance and Operational Checks Log. See Appendix A in the Reference manual.




For any abnormal system functions, go to Table 8.2, Hardware and Result Problems in Chapter 8. If problem persists, call your Coulter Representative.

## 2.2 STARTUP AFTER LONG-TERM SHUTDOWN

Turn on the system using this procedure if you performed the long-term shutdown.

#### Installing the Reagents



Power should already be off.



2

Remove the reagent cover.



Open a new ImmunoPrep Reagent System. The reagents need to be at room temperature before they are placed in the instrument.

Note: If you are using the same reagents that you removed from the system before shutdown, check that the original date when they were opened is still within the open bottle stability limits.





Remove the reagent containers filled with water.



5

Discard the water from the Reagent A, B, and C containers. Dry, cap and save the empty containers for future use.



Place the ImmunoPrep reagents onto the system.

Reagent container fitting color code:

- Green Reagent A
- Blue Reagent B
- Yellow Reagent C
- Red WASTE
- White OPTION Reagent.













Place the filled OPTION reagent container in the system.





Replace the reagent cover.



### Turning On Power, Priming and Testing



Turn on the power switch.





Prime the instrument with the new reagents.

a. Press on the Main screen.



b. Press to prime and reset the reagent test count.



Note: If you installed the **same** partially filled reagent containers that you removed from the instrument before long-term shutdown, AND you do not want to reset the reagent test counter to

300, press 10 times to prime. (Reagent count cannot be at [0] on the Cycle Counter screen.)





Perform a Gravimetric Validation test. See Chapter 5.





Check the reagent and WASTE containers as described in Heading 2.1, Daily Startup.





Run a whole-blood quality control sample as described in Heading 2.1, Daily Startup.



### **STARTUP** *STARTUP AFTER LONG-TERM SHUTDOWN*

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If a troubleshooting icon appears at any time during sample processing, see Table 8.1 for the appropriate action to take. Figure 3.1 shows where the troubleshooting icons appear on the screen.



Figure 3.1 Troubleshooting Icons

## 3.1 PREPARING AND LOADING SAMPLE TUBES

Collect, label, and store samples according to your laboratory's standard procedures.

- Prepare the sample per the appropriate antibody package insert or system guide instructions.
- Use straight 12 x 75 (+1/-2) mm tubes for samples.

12 x 75 mm

1

- Tubes with defects might cause a tube, dispensing head or carousel jam. Use another brand of tubes if jams occur frequently.
  - Tubes with a ring on the bottom (A) can cause a jam if you leave the next carousel position empty.
  - Tubes that are deformed/bent (B), have an excessive lip (C), or have a large protrusion on D) might cause jams.

Place the sample tubes into the carousel.

Note: Do not skip more than one space between sample tubes. Two consecutive openings without sample tubes causes the system to stop processing the carousel.

Note: If using the COULTER EPICS<sup>®</sup> XL-MCL (multitube carousel loader), do not skip more than one space between sample tubes.

Note: If using SYSTEM II<sup>™</sup> software, load the sample tubes in the carousel to match the worklist.



## 3.2 LOADING THE CAROUSEL

Open the sample processing area lid.





1

Remove carousel, if present.



3

Place your prepared carousel onto the indexing base.

Note: To correctly secure the carousel, line up and place the arrow on the carousel over the hub key on the indexing base.



Close the sample processing area lid.



## 3.3 RUNNING SAMPLES IMMEDIATELY

If a power failure occurs, discard the sample in process.

**CAUTION** Moving the Reagent A, B, or C container during sample processing can cause a level sense probe

to falsely detect a low reagent condition, display **U** and start the 32-test countdown. Only check the reagent containers when the instrument is not processing samples. Use the **Cycle Counter** screen to check the available number of tests.

If your system has the LALS OPTION, select the correct reagent mode (3 or 4 reagents).









**IMPORTANT** If you open the sample processing area lid during processing, the sample in progress

might not be processed completely and  $\bigotimes$  appears on the touch screen. Opening the lid stops all movement in the sample processing area and does not start it again until you close the lid, and press



Do not open the lid during sample processing.



The unit processes the samples, skipping any single empty test tube positions. The screen displays:

- The number of the tube in process.
- An arrow below the reagent being dispensed.





If you need to pause or stop the carousel during processing, see Heading 3.5, Pausing and Stopping.



After processing all of the samples in the carousel:

- One long beep sounds.
- The Main screen appears.
- The carousel moves to the home position.



Open the sample processing area lid.





Remove the carousel.





Store samples according to your laboratory's standard procedures. Samples are ready for the flow cytometer.

## 3.4 RUNNING SAMPLES WITH 10-MINUTE PREINCUBATION

If a power failure occurs, discard the sample in process.

Use this procedure to include an automatic 10-minute incubation time before sample processing begins.

CAUTION Moving the Reagent A, B, or C container during sample processing can cause a level sense probe

to falsely detect a low reagent condition, display **Q**, and start the 32-test countdown. Only check the reagent containers when the instrument is not processing samples. Use the **Cycle Counter** screen to check the available number of tests.

If your system has the LALS OPTION, select the correct reagent mode (3 or 4 reagents).





X

1



The timer counts down starting at 10:00 minutes. After 10 minutes, sample processing begins automatically.

Note: See Heading 3.5, Pausing and Stopping, if you need to:

- Start sample processing before the 10-minute incubation is done.
- Delay sample processing for an incubation time of more than 10 minutes.
- Exit the incubation screen.
- Stop processing.
- Pause sample processing in progress.



**IMPORTANT** If you open the sample processing area lid during processing, the sample in progress

might not be processed completely and  $\bigotimes$  appears on the touch screen. Opening the lid stops all movement in the sample processing area and does not start it again until you close the lid, and press



. Do not open the lid during sample processing.



The unit processes the samples, skipping any single empty test tube positions. The screen displays:

- The number of the tube in process.
- An arrow below the reagent being dispensed.







After processing all samples in the carousel:

- One long beep sounds.
- The Main screen appears.
- The carousel moves to the home position.





Open the sample processing lid.



Remove the carousel.





Store samples according to your laboratory's standard procedures. Samples are ready for the flow cytometer.

## 3.5 PAUSING AND STOPPING

#### Pausing During Sample Processing

During processing, you can pause the carousel in progress whenever you need to add or remove samples. Any sample in progress is completed when you pause sample processing.





To resume processing on the next unprocessed tube:

- a. Open the sample processing area lid.
- b. Add or remove samples as needed.
- c. Close the sample processing area lid.



#### Stopping During Sample Processing

During processing, you can stop processing immediately.





To resume processing on the next unprocessed tube:

- a. Open the sample processing area lid.
- b. Correct the problem condition.
- c. Close the sample processing area lid.

١.



4

#### **Stopping During Preincubation**

During the 10-minute preincubation, you can cancel the request to start processing when 00:00 is reached. However, the counter does not stop counting. After stopping, you can then request any of these tasks:

- Exit the screen and end preincubation countdown.
- Start processing immediately.
- Start processing after more than 10 minutes.
- Rerequest processing to automatically start after the 10-minute preincubation. (In case





2

- a. The screen changes but the timer continues to count down.
- b. After 00:00 appears, the timer changes to 10:01 and continues to count higher.
- c. Perform step 3, 4, or 5 as needed.





<-

G>₿



5

To start processing after more than 10 minutes:

a. Wait until the timer displays the incubation time you want.



To rerequest processing to start when the timer displays 00:00:



Note: If you press this button after the timer displays 10:01 or higher, processing begins immediately.



## 4.1 DAILY SHUTDOWN

Turn off the power switch, if required.



## 4.2 LONG-TERM SHUTDOWN

If you need to shut down the instrument for 10 days or more:





Remove the reagent cover.



Empty the WASTE container. See Heading 7.3, Emptying Waste Container, in Chapter 7.





Remove ImmunoPrep A, B, and C.

Note: If the containers still have reagent in them and you want to save them, cap and store them at **room temperature** until you start up the system again.



5

Place containers filled with distilled water into the Reagent A, B, and C openings.

Note: You received empty reagent containers with your system.





If your system has the OPTION reagent, check the container. If it is empty, add distilled or deionized water.





Replace the reagent cover.



8

Request a new reagent prime if you did NOT save partially filled reagent containers for use at the next startup:



a.

Press at the Main screen.





After priming, turn off the power switch.



9

#### 5.1 GRAVIMETRIC VALIDATION, ACCURACY AND PRECISION TESTING NEEDED

You do not need to calibrate the instrument.

Perform the Gravimetric Validation testing of the delivery system with reagent (\*density of distilled water = 1.0 g/mL), to do a quick check of the accuracy of the syringes and dispensing system.

\* The density of ImmunoPrep A and C is insignificantly different from distilled water. The density of ImmunoPrep B is 1.04 g/mL.

Perform the Accuracy and Precision testing of the delivery volume using distilled or deionized water (accuracy/mean =  $\leq 5\%$ , precision/CV =  $\leq 5\%$ ), to do a more complete check of the accuracy and precision of the syringes and dispensing system.

#### 5.2 PERFORMING GRAVIMETRIC VALIDATION TESTING

#### When to Perform

Perform the Gravimetric Validation test procedure:

- After the initial power up at instrument installation, before running any sample.
- After power up from a long-term instrument shutdown, before running any sample.
- Once every 6 months.
- When you perform major preventive maintenance or replace a critical part, such as a syringe.
- When your laboratory calibration verification schedule indicates you should perform more frequent validation.
- When there is an indication that the instrument volume delivery is out of calibration, such as failing the daily QC check. Indications might be:
  - ► Failure of red blood cells to lyse completely. (Not enough Reagent A, lysing reagent, was dispensed.)
  - Eventual formation of brownish coloring in the sample. (Not enough Reagent B, stabilizing reagent, was dispensed.)
  - ► Loss of scattering characteristics to cells in storage. (Not enough Reagent C, fixing reagent, was dispensed.)

#### Preparing and Loading the Sample Tubes



Turn the power on if it is off.



2

3

- Label three 12 x 75 mm, clean, dry test tubes as 1, 2, 3.
- If you have the OPTION reagent option, label another 12 x 75 mm, clean, dry test tube as 4.



Using a balance capable of weighing to the nearest milligram, individually tare weigh the tubes and record their weights in Table 5.1.



4

Place the test tubes, in order, in the first three (or four) openings of the carousel.





Open the sample processing area lid.



6

Place the carousel onto the indexing base:

Note: To correctly secure the carousel, line up and place the arrow on the carousel over the hub key on the indexing base.



7

Close the sample processing lid.



#### Processing the Sample Tubes

If you have the LALS OPTION, select the reagent mode needed (3 or 4 reagents).

CAUTION Moving the Reagent A, B, or C container during sample processing can cause a level sense

probe to falsely detect a low reagent condition, display **Q**, and start the 32-test countdown. Only check the reagent containers when the instrument is not processing samples. Use the **Cycle Counter** screen to check the available number of tests.

# 2



- The indexing base rotates to the first tube.
- The dispensing head extends and dispenses one test volume of a single reagent into a test tube.





The touch screen displays the dispense order of the reagents by their syringes:

- A into tube 1
- B into tube 2
- C into tube 3
- OPTION Reagent into tube 4 (if LALS OPTION is present and the four-reagent mode was selected).





When processing is done:

- One long beep sounds.
- The Main screen appears.
- The carousel moves to the home position.



### **Recording and Checking Results**

1

2

Weigh each tube and record its weight in Table 5.1.



Subtract each tube's tare weight from its	
weight with the dispensed reagent.	

Weight After Test (g)	Weight Before Test (g) Tare Weight	Weight of Dispensed Liquid (g)
3.359	2.762	0.597
3.036	2.761	0.275
2.908	2.808	0.100
1		

Check that the weights of the dispensed reagents are within the acceptable weight ranges given in Table 5.1.

(	Weight After Test (g)	Weight Before Test Tare Weight	9	Weight of Dispensed Reagent (g)	Acceptable Weight Range (g)
Į	3.359	2.762	Γ	0.597	0.570-0.630
	3.036	2.761		0.275	0.262-0.289
	2.908	2.808	L	0.100	0.095-0.105
I	(				0.450-0.550
1					$\nearrow$

4

If the weights are acceptable, record them in the Maintenance and Operational Checks Log. See Appendix A in the Reference manual.



# 5

If the weights are not within the stated ranges:

- Check for air bubbles in the tubing. See the Checking for Air Bubbles procedure in Chapter 8 for details.
- If no bubbles are present, repeat the entire Gravimetric Validation test.
- If you have already run the Gravimetric Validation testing twice, perform the Accuracy and Precision test.

Tube No.	Reagent	Weight After Test (g)	Weight Before Test (g) Tare Weight	Weight of Dispensed Reagent (g)	Acceptable Weight Range (g)
1	А				0.570-0.630
2	В				0.262-0.289
3	С				0.095-0.105
4	OPTION				0.450-0.550

#### Table 5.1 Gravimetric Validation Test Worksheet

### 5.3 ACCURACY AND PRECISION TESTING

#### Frequency

Check the Accuracy and Precision (reproducibility) of the system with distilled water whenever one or more reagents fail the Gravimetric Validation test twice.

Note: If **D** appears during this procedure, one test is subtracted from the remaining 32 reagent test count for each dispensed SET of reagents (which equals 3 or 4 tubes).

#### Replacing the Reagents with Water



Turn the power on if it is off.





Press or or to empty reagent out of the syringes.



Remove the reagent cover.





Remove ImmunoPrep A, B, and C. Cap and store them at **room temperature**.



5

Place containers filled with distilled water into the Reagent A, B, and C openings.

Note: You received empty reagent containers with your system.





If your system has the LALS OPTION, and the OPTION reagent container is empty, add distilled or deionized water.





00
a. Record the current reagent test count if you need to track reagent usage.

b. Press to prime the system and reset the reagent test count to 300.



Preparing and Loading the Sample Tubes

1

9

Label 12 x 75 mm, clean, dry test tubes.

- Label 30 tubes (1-30) if you only have Reagents A, B, and C.
- Label 32 tubes (1-32) if you also have the OPTION reagent.



2

Using a balance capable of weighing to the nearest milligram, individually tare weigh the tubes and record their weights.

- Use Table 5.2 if you only have Reagents A, B, and C.
- Use Table 5.4 if you also have the OPTION reagent.





Place the test tubes, in order, into the carousel.





Open the sample processing area lid.



5

Place the carousel onto the indexing base.



Close the sample processing area lid.



### Processing the Sample Tubes

If you have the LALS option, select the reagent mode needed (3 or 4 reagents).



CAUTION Moving the Reagent A, B, or C container during sample processing to check the amount of

reagent can cause a level sense probe to falsely detect a low reagent condition, display **U**, and start the 32-test countdown. Only check the reagent containers when the instrument is not processing samples.

2



- The indexing base rotates to the first tube.
- The dispensing head extends and dispenses one test volume of a single reagent into a test tube.





Test tubes receive the reagents in this order repetitively until all the tubes receive a reagent:

- A into tube 1
- B into tube 2
- C into tube 3
- OPTION reagent into tube 4 (if you have the LALS OPTION and you selected the four-reagent mode).



4

When processing is done:

- One long beep sounds.
- The Main screen appears.
- The carousel moves to the home position.



**Recording and Checking Results** 

1

Weigh each tube and record its weight next to its tube number in Table 5.2 or 5.4, as appropriate.



Subtract each tube's tare weight from the weight of the tube with the dispensed reagent.



3

Calculate the Means and CVs.

- Check that the Means of the dispensed reagents are within the acceptable ranges given in Table 5.3 or 5.5.
- Check that the CVs of the dispensed reagents are within the acceptable CV ranges given in Table 5.3 or 5.5.



If the Means or CVs are outside the acceptable range, contact your Coulter Representative.

5

Record test results in the Maintenance and Operational Checks Log. See Appendix A in the Reference manual.



**Returning Reagents to the Instrument** 



Remove the reagent cover.





Remove the reagent containers filled with water.



3

Discard the water from the Reagent A, B, and C containers. Dry, cap and save the empty containers for future use.



Screw the cap assembly securely into the corresponding reagent container.

Reagent container fitting color code:

- Green Reagent A
- Blue Reagent B
- Yellow Reagent C
- Red WASTE
- White OPTION Reagent.





Place ImmunoPrep A, B, and C onto the system.



6

If your system has the LALS OPTION, check that the OPTION reagent container is not empty.













- a. Record the current reagent test count if you need to track reagent usage.
- b. Press to prime the system and reset the reagent test count to 300.

Note: The reagent test count will not reflect the true test count until you replace the reagents and request a new reagent prime.



Tube No.	Syringe	Weight After Test (g)	Weight Before Test (g) Tare Weight	Weight of Dispensed Liquid (g)
1	А			
2	В			
3	С			
4	А			
5	В			
6	С			
7	А			
8	В			
9	С			
10	А			
11	В			
12	С			
13	А			
14	В			
15	С			
16	А			
17	В			
18	С			
19	А			
20	В			
21	С			
22	А			
23	В			
24	С			
25	A			
26	В			
27	С			
28	А			
29	В			
30	С			

Table 5.2 Accuracy and Precision Test Worksheet - 3 Reagents

Syringe A Tube No.	Weight of Dispensed Liquid (g)	Syringe B Tube No.	Weight of Dispensed Liquid (g)	Syringe C Tube No.	Weight of Dispensed Liquid (g)
1		2		3	
4		5		6	
7		8		9	
10		11		12	
13		14		15	
16		17		18	
19		20		21	
22		23		24	
25		26		27	
28		29		30	
Total		Total		Total	
SD		SD		SD	
Mean		Mean		Mean	
Acceptable Mean	*0.570-0.630	Acceptable Mean	*0.251-0.278	Acceptable Mean	*0.095-0.105
CV		CV		CV	
Acceptable CV	≤5%	Acceptable CV	≤5%	Acceptable CV	≤5%

Table 5.3 Accuracy and Precision Calculation Worksheet - 3 Reagents

\* These ranges are for distilled or deionized water. If you use ImmunoPrep A, B, and C, adjust the range for ImmunoPrep B to 0.262-0.289. The density of ImmunoPrep A and C is insignificantly different from distilled water.

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Tube No.	Syringe	Weight After Test (g)	Weight Before Test (g) Tare Weight	Weight of Dispensed Liquid (g)
1	А			
2	В			
3	С			
4	OPTION			
5	А			
6	В			
7	С			
8	OPTION			
9	А			
10	В			
11	С			
12	OPTION			
13	А			
14	В			
15	С			
16	OPTION			
17	А			
18	В			
19	С			
20	OPTION			
21	А			
22	В			
23	С			
24	OPTION			
25	А			
26	В			
27	С			
28	OPTION			
29	А			
30	В			
31	С			
32	OPTION			

Table 5.4 Accuracy and Precision Test Worksheet - 4 Reagents

Syringe A Tube No.	Weight of Dispensed Liquid (g)	Syringe B Tube No.	Weight of Dispensed Liquid (g)	Syringe C Tube No.	Weight of Dispensed Liquid (g)	OPTION Syringe Tube No.	Weight of Dispensed Liquid (g)
1		2		3		4	
5		6		7		8	
9		10		11		12	
13		14		15		16	
17		18		19		20	
21		22		23		24	
25		26		27		28	
29		30		31		32	
Total		Total		Total		Total	
SD		SD		SD		SD	
Mean		Mean		Mean		Mean	
Acceptable Mean	*0.570-0.630	Acceptable Mean	*0.251-0.278	Acceptable Mean	*0.095-0.105	Acceptable Mean	0.450-0.550
CV		CV		CV		CV	
Acceptable CV	≤5%	Acceptable CV	≤5%	Acceptable CV	≤5%	Acceptable CV	≤15%

Table 5.5 Accuracy and Precision Calculation Worksheet - 4 Reagents

\* These ranges are for distilled or deionized water. If you use ImmunoPrep A, B, and C, adjust the range for ImmunoPrep B to 0.262-0.289. The density of ImmunoPrep A and C is insignificantly different from distilled water.

**CALIBRATION** ACCURACY AND PRECISION TESTING

## 6.1 EXTERNAL SURFACES OF INSTRUMENT

## Routine Cleaning

For routine cleaning, wipe all surfaces, as needed, with a clean cloth moistened with distilled water.

## Decontaminating

To decontaminate or to clean blood from the external surfaces, wipe all surfaces, as needed, with a clean cloth moistened with an acceptable cleaning solution such as:

- Four parts water, and
- One part high quality, fragrance-free bleach (5% sodium hypochlorite - available chlorine).





1

Dispose of contaminated cleaning material properly.



## 6.2 CLEANING SPILLED BLOOD OR BROKEN SAMPLE TUBE

Check the drip tray in the sample processing area for spilled blood and broken test tubes, as needed.

We recommend the use of plastic sample tubes to avoid broken glass.

Follow your laboratory's safety procedures and any local, state or federal regulations that apply.

**WARNING** Possible biohazardous condition. Handle broken sample tube with care. Avoid skin puncture. Dispose of all contaminated cleaning materials and sample tube pieces (sharps) in accordance with your local regulations and acceptable laboratory procedures.

Clean up any blood spill or broken sample tube as quickly as possible.



2

Use a clean cloth moistened with a cleaning solution capable of inactivating the Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV) and Hepatitis B Virus (HBV).

To make an acceptable cleaning solution, mix:

- Four parts water, and
- One part high quality, fragrance-free bleach (5% sodium hypochlorite available chlorine).











Clean up any spilled blood or pieces of a broken sample tube.



5

Dispose of the contaminated material and broken sample tube pieces properly.



Close the sample processing area lid.



## 7.1 OPERATOR REPLACEABLE PARTS

- Fuses
- Reagents:
  - TQ-Prep/ImmunoPrep Reagent System (ImmunoPrep A, B, C)
  - OPTION reagent (distilled or deionized water) for LALS OPTION
- Syringes
- WASTE container's:
  - Full contents
  - ► Level sense probe.

## 7.2 REPLACING FUSES

Only use 250 V, 6 A, SLO-BLO, 3 AG fuses on the TQ-Prep Workstation.

If either fuse burns out (is open), the system shuts down.



Turn off the power switch.





Unplug the power cord.



Find the fuses at the back of the system.





3

Use a screwdriver to unscrew the fuse cap. Remove fuse cap from system.



**CAUTION** Using the wrong fuse in the instrument could produce a fire hazard. Only replace fuses with ones of the same type and rating.

**5** Remove the fuse from the cap and inspect it. If the fuse is burned out, replace it with a new one of the same type and rating.

Note: If the first fuse is not burned out, put it back in and check the other fuse.





Discard defective fuse.





Insert the new fuse into the cap.





Put the fuse and cap into the system and then screw in the fuse cap.





Plug in the power cord.



# Turn on the power switch.



WARNING Do not try to replace a fuse if it fails shortly after its replacement. This could cause shock to the user and possible system damage. Turn off the power and unplug the power cord from the instrument if a fuse fails shortly after its replacement. Call your Coulter Representative.

Record the fuse change in the Maintenance and Operational Checks Log. See Appendix A in the Reference manual.

	co	ULTER®	TQ-PREP	M MAINT	ENANCE A	ND OPERATIONAL CHECKS LOS
	Dail	y		as N	eeded	As No
Startup/	QC check	Shutdov	vn/Clean	Gravi Valio	metric dation	Indica
Date	Tech	Date	Tech	Date	Tech	Procedure
						Replaced fuses

### 7.3 **REPLACING REAGENTS**

**IMPORTANT** Using pooled reagents might cause contamination which could produce erroneous results. Replace a reagent with a new, full container of the same reagent. Never pool partially filled containers or containers with different lot numbers or different expiration dates.



appears:

- The system continues with and completes whatever function is in progress (sample • processing, gravimetric validation or priming).
- [32] appears next to the reagent test count on the Cycle Counter screen because the system • can only run a maximum of 32 more test cycles.

• The [32] reagent test count decreases by one for each test run after **Q** appears. When the reagent test count inside the brackets displays [0] tests, the system will not process

any more tests until the reagents are replaced and you press

• Replace ALL three (or four) of the reagents at the same time.

Note: Replacing ImmunoPrep A, B, and C individually instead of all three as a reagent system invalidates the reagent test counter. The system resets the reagent test counter to 300 when you request a New Reagent prime after replacing the reagents. If reagents are not replaced as a system, the reagent test counter does not reflect the true test count. When replacing reagents, you must replace all three reagents at the same time.

Installing the New Reagent Containers

Open a new ImmunoPrep Reagent°CSystem. Make sure the reagents are at30room temperature before they are16placed on the system.16



2

1

Remove the reagent cover.



Open the appropriate new reagent container.







5

4

Lift ImmunoPrep A, B, or C container up and out.



Unscrew the cap assembly from the empty reagent container. Check the cap assembly for crystal buildup. Use a clean, damp cloth to remove any crystal buildup.

Note: The cap, sensor wire and tubing remain connected to the system.





8

6

Each cap assembly fitting is color coded for each container:

- Green Reagent A
- Blue Reagent B
- Yellow Reagent C
- White OPTION Reagent
- Red WASTE.



11

Place the new reagent container onto the system.



**10** Replace the other two ImmunoPrep reagents in the same way, using the reagents from the same ImmunoPrep Reagent System.



 Discard any unused reagents according to your standard laboratory procedures and local chemical waste regulations.

• Discard used containers and recycle whenever possible.



12 If your system has the OPTION reagent, remove the container as above, fill it with distilled or deionized water and return it to the system.







## Priming, Checking and Recording









Note: This resets the count to 300.



Check for air bubbles. See Checking for Air Bubbles in Chapter 8 for details.





Record the appropriate information in the Reagent Log. See Appendix A in the Reference manual.

	COULTER® TQ-PF	REP™ REAGENT LOG	
	TQ-Prep/Immu	noPrep Reagent Kit	
Date Opened	Lot Number	Expiration Date	chniei
4-1-97	123456K	12-24-97	

## 7.4 REPLACING SYRINGES

Change a syringe when:

- The syringe is still leaking after checking and correcting its fittings for leaks.
- The syringe delivery volume does not meet specification based on the gravimetric accuracy and precision tests and no other cause can be found, such as a leak.
- And you have confirmed with your Coulter Representative that you should change the syringe.

Note: If your system is kept in a safety cabinet/laminar flow hood, you can remove the system from the safety cabinet/laminar flow hood for this procedure.

## Preparing to Remove the Syringe







## Removing the Defective Syringe

1

Completely loosen the two thumbscrews on the syringe holder.

Note: You cannot remove the thumbscrews.



**IMPORTANT** Using tools to unscrew the tubing connectors could crack the connectors and cause leaking at the syringe fittings. A leaking syringe can cause erroneous results by delivering an incorrect amount of reagent to the sample and the leaked reagent can cause damage to the instrument. Manually unscrew the tubing connectors.



Unscrew top and side tubing connectors from the syringe by hand.

Note: You can simply turn the plastic outer locking mechanism to the right (clockwise) to unscrew the top tubing connector.





Grab the syringe holder by the thumbscrews and slide off the syringe assembly and holder from the system.





Remove the syringe holder from the syringe assembly.





Discard the old syringe assembly.



## Installing the New Syringe

1

- Assemble the two sections of the new syringe assembly.
- Visually check for cracks. Do not use a cracked syringe.



2

Place the new syringe assembly into the syringe holder.



3

Before you push the syringe assembly and holder onto the system, be sure these parts are lined up:

- The holes behind the thumbscrews with the metal pins
- The white OFF valve with the same-shaped opening
- The base of the syringe plunger with its retainer.





Push the syringe assembly and holder onto the system. Tighten the two thumbscrews.



**IMPORTANT** Overtightened tubing connectors can cause leaking at the syringe fittings. A leaking syringe can cause erroneous results by delivering an incorrect amount of reagent to the sample and the leaked reagent can cause damage to the instrument. Manually tighten the tubing connectors "finger tight," do not over tighten them.



Screw on the tubing connector to the top fitting:

- a. Screw the connector for the tubing from the dispensing head onto the top fitting.
- b. Secure this connector by turning the plastic outer locking mechanism to the left (counterclockwise).



Ensure that there is a small plastic cone-shaped part (ferrule) inside the side fitting.



7

Screw the connector for the tubing from the reagent container onto the side fitting.





Replace the reagent storage and dispense cover.





Plug in the power cord.



## 10

Turn on the power switch.



## Priming, Checking, and Recording





- a. Record the current reagent test count if you need to track reagent usage.
- b. Press to prime the syringes and reset the reagent test count to 300.

Note: The reagent test count will not reflect the true test count until you replace the reagents and request a new reagent prime.





2

Check for air bubbles. See Checking for Air Bubbles in Chapter 8 for details.



4

Perform the Gravimetric Validation test. See Chapter 5.





Record the appropriate information in the Maintenance and Operational Checks Log. See Appendix A in the Reference manual.

	CO	ULTER®	TQ-PREP	™ MAINT	ENANCE A	ND OPERATIONAL CH	IECKS LOP	
	Dail	y		Every 6 as N	Months or eeded	As	Ne	$\square$
Startup/	Dail QC check	y Shutdov	wn/Clean	Every 6 as N Gravi Valio	Months or eeded metric dation	As	: Nr	D
Startup/ Date	Dail QC check Tech	y Shutdov Date	wn/Clean Tech	Every 6 as N Gravi Valio Date	Months or eeded metric dation Tech	As Indical Procedure		

7396009A

## 7.5 EMPTYING WASTE CONTAINER

Empty the WASTE container when  $\mathbf{\hat{\Omega}}$  appears.



Remove the reagent cover.


Lift the full WASTE container up and out.



3 Unscrew the cap assembly from the full WASTE container.

Note: The cap, sensor wire and tubing remain connected to the system.





Wipe the level sense probe with a clean paper wipe.





Place the cap assembly in the WASTE container opening.





Discard the contents of the WASTE container according to your standard laboratory procedures and local chemical waste regulations.



7

Screw the empty WASTE container securely into its cap.

Note: The WASTE cap assembly has a red fitting.



Place the WASTE container back into its opening on the instrument.





Check that the red WASTE level sense cable is connected.



**10** Replace the reagent cover.



#### 7.6 REPLACING LEVEL SENSE PROBE ASSEMBLY ON WASTE CONTAINER

Replace the level sense probe on the WASTE container:

- When  $\mathbf{\overline{M}}$  appears on the touch screen and both of the following conditions exist:
  - The WASTE container is not full.
  - The WASTE container has not been shaken (that can prematurely trigger the level sense probe).
- And you have confirmed with your Coulter Representative that you should change the level sense probe

Note: As a quick check you can dry the waste level sense probe and place it back in the

WASTE container. If **1** no longer appears on the touch screen, you do not need to replace the level sense probe.





2

Hold the rough surface area of the red WASTE level sense connector and pull back on it to disconnect it.



Lift the WASTE container up and out of the instrument.





Unscrew the cap assembly from the WASTE container.



5

Discard the contents of the WASTE container according to your standard laboratory procedures and local chemical waste regulations.







Unscrew the red fitting attached to the level sense probe assembly and remove it from the WASTE container cap.





Discard the defective level sense probe assembly.



8

Insert the new level sense probe into the opening of the WASTE container cap assembly.



10

Screw the red fitting of the level sense probe assembly into the WASTE container cap assembly.



Place the WASTE container onto the instrument.



11

Connect the WASTE level sense connector by:

- a. Lining up the two red dots:
  - Red dot on the level sense connector
  - Red dot on the red opening.
- b. Pushing the level sense connector into the red opening.



Check that the red WASTE level sense cable is connected.



13

Replace the reagent cover.



### 7.7 ALIGNING THE CAROUSEL

Perform this procedure:

- If J or appears at installation or the first time you run samples.
- The instrument pauses and beeps.



Open the sample processing area lid.



Place an empty carousel onto the indexing base:

Note: To correctly secure the carousel, line up the arrow on the carousel above the hub key on the indexing base before placement.





Close the sample processing area lid.









- 5
- The carousel moves to the tube loading position and the tube lifter moves up and down. These actions repeat for the second carousel position.
- Look through the sample processing area lid to visually check that the tube lifter comes up without touching the carousel.





After the system detects two consecutive empty carousel positions, it will stop running and return to the home position. Carousel position 10 will be under the dispensing head.



If the tube lifter touched the carousel in step 5, align the tube-position sensor:

a. Insert the Allen wrench received with the instrument into the alignment opening in the front of the instrument.



- b. Turn the Allen wrench in 1/4 in. increments as needed:
  - Turn the wrench to the **left** to move the carousel to the **right**.
  - Turn the wrench to the **right** to move the carousel to the **left**.





c. After adjustments, the tube lifter should now be centered within carousel opening 10.





Open the sample processing area lid.





Place three empty tubes into the carousel.



 $10 \qquad \qquad \text{Close the sample processing area lid.}$ 







# 12

Check that when the carousel completes processing:

- J or does not appear on the touch screen.
- The instrument does **not** pause and beep.
- If any of these conditions occurs, repeat the alignment procedure.

Turn the power OFF and then ON.



# 14

Check that after the power up self-tests are done:

- J or L does not appear on the touch screen.
- The instrument does **not** pause and beep.
- If any of these conditions occurs, repeat the alignment procedure.

## **REPLACE/ADJUST PROCEDURES** *ALIGNING THE CAROUSEL*

Review the basic operating principles described in the Reference manual so that you can more easily troubleshoot problems that may occur during normal operation or when indicated by unwanted results.

#### 8.1 TROUBLESHOOTING ICONS

Troubleshooting icons appear along the side edges of the touch screen. See Figure 8.1.

Three short beeps sound whenever one of these troubleshooting icons appears. These beeps sound again every 3 minutes for up to 2 hours or until the operator corrects the problem.



Figure 8.1 Troubleshooting Icons Location on Touch Screen

When a troubleshooting icon appears on the touch screen, locate it in the following table and perform the recommended action.

Icon	Meaning	Suggested Action	
÷	Dispense communication error	If the system does not clear the troubleshooting icon on its own, and the system locks up and stops functioning, call your Coulter Representative.	
	Dispensing head	1. Open the sample processing area lid.	
	error	2. If a test tube is jammed, gently push it down into its opening.	
		Note: If you need to remove the tube from the carousel to fix the jam, put the tube back into the carousel before continuing.	
		3. Push the dispensing head back in.	
		4. Press to continue any processing stopped in progress.	
		5. If error occurred at startup, Remains until you request sample processing, priming or Gravimetric Validation testing.	

Table 8.1 Troubleshooting Icons

Icon	Meaning	Suggested Action	
- <b></b>	Mixing speed error	If the mixing error occurred at the premixing stage before any reagent was added, you can press to request processing again on the same sample tube.	
		<ul> <li>If the mixing error occurred at the final mixing,</li> <li>appears for the current sample tube. You can press to request processing on the next sample tube.</li> </ul>	
		<ul> <li>If the system does not clear the troubleshooting icon, and the system locks up and stops functioning, call your Coulter Representative.</li> </ul>	
	Sample tube error	<ol> <li>Open the sample processing area lid.</li> <li>If a test tube is jammed, gently push it down into its opening. Note: If you need to remove the tube from the carousel to fix the jam, put back the tube before continuing.</li> <li>Push in the dispensing head.</li> <li>Press to continue any processing stopped in progress.</li> <li>If error occurred at startup, remains until you request sample processing, priming or Gravimetric Validation testing.</li> </ol>	
÷	System communication error	Do not attempt to process any samples while this icon appears on the screen. If the system does not clear the troubleshooting icon, and the system locks up and stops functioning, call your Coulter Representative.	

#### Table 8.1 Troubleshooting Icons (Continued)

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(	)
C	)

Icon	Meaning	Suggested Action	
Ţ	Carousel error	1. If this occurs at installation or the first time you run samples, perform the Aligning the Carousel procedure in Chapter 7.	
		2. If this occurs after running at least one carousel of samples:	
		<ul> <li>Open the sample processing area lid and inspect the carousel area.</li> </ul>	
		b. If a test tube is jammed, gently push it down into its opening. Note: If you need to remove the tube from the carousel to fix the jam, put the tube back in the carousel before continuing.	
		c. Remove any other possible problem or obstruction.	
		d. Push in the dispensing head.	
		e. Press to continue any processing stopped in progress.	
		<ul> <li>If error occurred at startup, Fremains on the screen until you request sample processing, priming or Gravimetric Validation testing.</li> </ul>	
	Sample processing area lid open	Close sample processing area lid. Press     to continue     any processing stopped in progress.	
		• If this appears when the sample processing lid is closed, the lid is defective. Call your Coulter Representative.	
Ō	Low reagent	<ul> <li>After D first appears, 32 tests can still be processed. Note: In the Cycle Counter screen, [32] appears after the reagent test count and then counts down to [0] tests as the system processes the remaining tests. When [0] remaining tests appear in the Cycle Counter screen, the system will not process any more sample tubes until you replace the reagents and press .</li> <li>Perform the Replacing Reagents procedure in Chapter 7 with a new ImmunoPrep Reagent System.</li> </ul>	
បិ	Full WASTE	Empty the waste container. Refer to the Emptying Waste procedure in Chapter 7. Note: The system will not perform a prime until you empty the WASTE container.	

#### Table 8.1 Troubleshooting Icons (Continued)

#### 8.2 HARDWARE AND RESULT PROBLEMS

Use the following table to troubleshoot problems not related to the troubleshooting icons. It lists the problem, the probable cause and the suggested action to take to correct the problem.

Problem	Probable Cause	Suggested Action	
Air bubbles are repeatedly in the tubing from the syringe to the dispense head.	<ul> <li>Loose tubing connections to the syringe.</li> <li>Leaks.</li> <li>Cracked syringe.</li> </ul>	<ol> <li>Perform the Checking for Air Bubbles procedure under heading 8.3, Troubleshooting Procedures.</li> <li>If problems continues, perform Gravimetric validation testing procedure in Chapter 5.</li> </ol>	
		3. If problems continues, call your Coulter Representative and replace syringe per procedure in Chapter 7.	
Beeps sound when you press	<ul> <li>The New Reagent Prime was not requested after changing the reagents.</li> </ul>	1. Press to acess the <b>Cycle</b> <b>Counter</b> screen.	
		2. Press to prime the syringes and reset the reagent test count to 300.	
Dispensing head displays resistance to manual movement when pulled out to check for air bubbles	Normal condition. With the power on, some resistance is normally felt when manually pulling out the dispensing head to check for air.	None.	
Leaks	Loose tubing connections to the syringe	IMPORTANT Overtightened tubing connectors can cause leaking at the syringe fittings. A leaking syringe can cause erroneous results by delivering an incorrect amount of reagent to the sample and the leaked reagent can cause damage to the instrument. Manually tighten the tubing connectors "finger tight," do not over tighten them. Remove and reinstall tubing connections. Tighten, but do not	
		overtighten them.	
Sample processing area lid is closed but appears. System will not process samples.	Lid is defective.	Call your Coulter Representative.	

Table 8.2	Troubleshooting	Hardware	Problems

Problem	Probable Cause	Suggested Action
Syringe, leaking	Loose tubing connections to the syringe	IMPORTANT Overtightened tubing connectors can cause leaking at the syringe fittings. A leaking syringe can cause erroneous results by delivering an incorrect amount of reagent to the sample and the leaked reagent can cause damage to the instrument. Manually tighten the tubing connectors "finger tight," do not over tighten them. Remove and reinstall tubing
		connections. Tighten, but do not overtighten them.
	Broken or defective syringe	Replace syringe.
<ul> <li>System will not run and no troubleshooting icon appears.</li> <li>System keeps beeping every</li> </ul>	The New Reagent Prime was not requested after changing the reagents.	1. Press to acess the Cycle
3 minutes (for up to 2 hours).		
		2. Press to prime the syringes and reset the reagent test count to 300.
<ul> <li>System will not run and no troubleshooting icon appears.</li> </ul>	You opened the sample     processing area lid during sample	Press     to continue
• System does not beep.	processing.	processing.
		Or, press to exit to the Main screen.
Test tube, broken	Cracked tube	Check tubes for cracks prior to use. Do not use chipped tubes. We recommend you use plastic tubes.
	Improper fit	Use 12 x 75 mm test tubes.
Touch screen is dark.	Screen has not been touched for 40 minutes so it turned off.	Touch the touch screen to redisplay it.
Touch screen is out of focus.	Incorrect viewing angle	Adjust contrast control.
Touch screen does not light when	Power cord not plugged in.	Plug power cord into outlet.
touched.	Fuse blown.	Replace the fuse per the procedure in Chapter 7.

#### Table 8.2 Troubleshooting Hardware Problems (Continued)

#### TROUBLESHOOTING HARDWARE AND RESULT PROBLEMS

Problem	Probable Cause	Suggested Action
Incomplete lysis	Blood pipetting error	Place specimen directly into bottom of sample tube. Do not let specimen run down side of tube.
	Taulty Synnige A	<b>IMPORTANT</b> Overtightened tubing connectors can cause leaking at the syringe fittings. A leaking syringe can cause erroneous results by delivering
		syringe fittings. A leaking syringe can cause erroneous results by delivering an incorrect amount of reagent to the sample and the leaked reagent can cause damage to the instrument.
		"finger tight," do not over tighten them.
		<ol> <li>Check for loose tubing connections to the syringe. Remove and reinstall tubing connections tighter, but do not overtighten them.</li> </ol>
		2. Perform the Gravimetric Validation test in Chapter 5 to check dispensing volume.
		<ol> <li>If the test fails, call your Coulter Representative and replace the syringe.</li> </ol>

#### Table 8.3 Troubleshooting Result Problems

Problem	Probable Cause	Suggested Action
Unacceptable analysis results	Air bubbles in lines	<ol> <li>Perform the Checking for Air Bubbles procedure under heading 8.3, Troubleshooting Procedures.</li> </ol>
		2. If problems continues, perform Gravimetric Validation testing procedure in Chapter 5.
		3. If problems continues, call your Coulter Representative and replace syringe per procedure in Chapter 7.
	Reagent expired	Replace all three reagents if past expiration date. Replacing Reagents procedure is in Chapter 7.
	Reagent is contaminated	<ol> <li>Check for clarity of reagents and replace reagents if any are suspect.</li> </ol>
		2. Check container cap assemblies for precipitate and clean if necessary.
		3. Cycle samples and check scatterplot.
	Syringes not dispensing proper volume.	<ol> <li>Perform the Checking for Air Bubbles procedure under heading 8.3, Troubleshooting Procedures.</li> </ol>
		2. If problems continues, perform Gravimetric Validation testing procedure in Chapter 5.
		<ol> <li>If problems continues, call your Coulter Representative and replace syringe per procedure in Chapter 7.</li> </ol>

#### Table 8.3 Troubleshooting Result Problems (Continued)

Problem Probable Cause Suggested Action	Problem
<ul> <li>You pressed during processing.</li> <li>You opened the sample processing area lid during processing area lid during processing.</li> <li>You opened the sample processing area lid during processing.</li> <li>You opened the sample processing area lid during processing area lid during processing.</li> <li>Sample tube has not been completely processed. The carousel position of the sample tube appears below this icon.</li> <li>You opened the sample processing area lid during processing area lid during processing.</li> <li>You opened the sample processing area lid during processing stopped after this reagent was dispensed but before mixing occurred.</li> <li>Shows that processing stopped after this reagent was dispensed.</li> <li>Press shows that processing stopped after mixing of the previous reagent but before this reagent was dispensed.</li> <li>Press to continue any processing with the next unprocessed tube.</li> </ul>	touch screen on the

#### Table 8.3 Troubleshooting Result Problems (Continued)

#### 8.3 TROUBLESHOOTING PROCEDURES

#### **Checking for Air Bubbles**

The TQ-Prep Workstation has been designed to prevent the formation of bubbles. Bubbles can only occur if there are loose fittings at the syringe causing leaks.

**IMPORTANT** Overtightened tubing connectors can cause leaking at the syringe fittings. A leaking syringe can cause erroneous results by delivering an incorrect amount of reagent to the sample and the leaked reagent can cause damage to the instrument. Manually tighten the tubing connectors "finger tight," do not over tighten them.

- Check that the tubing is connected to the reagent containers and syringes.
  - Check that there is no evidence of leaking tubing or loose fittings.
  - Tighten any loose fittings.



2

Check the tubing from the top of the syringes for air bubbles.

Note: An air bubble that is 0.1 in. (2.5 mm) long is equivalent to about 2  $\mu$ L of water. To determine if the bubbles in your tubing will affect delivery volume, see the accuracy specification in Chapter 4 of the Reference manual.





Replace the reagent cover.





Open the sample processing area lid.



5

Gently pull out the dispensing head.





Check the tubing at the top of the dispensing head for air bubbles.

Note: An air bubble that is 0.1 in. (2.5 mm) long is equivalent to about 2  $\mu$ L of water. To determine if the bubbles in your tubing will affect delivery volume, see the accuracy specification in Chapter 4 of the Reference manual. You can also perform the Gravimetric Validation test.







Check that the bubbles are gone.

If you want to verify that the dispense volumes are correct, you can perform the Gravimetric Validation test.

## TROUBLESHOOTING TROUBLESHOOTING PROCEDURES

This is a Master Index for the TQ-Prep Workstation Operator's Guide and Reference manual. The page number following each index entry includes an abbreviation for the manual in which it is located. These abbreviations are:

OG - Operator's Guide R - Reference Manual

#### **Symbols**

μL

definition, R GLOSSARY-2

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## COULTER TQ-Prep Workstation Documentation

Reference PN 4237395	Use and Function • Installation • Operation Principles • Specifications/Characteristics • Log Sheets • Operator Certification • References • Glossary • Index
Operator's Guide PN 4237396	Controls and Indicators • Startup • Sample Processing • Shutdown • Calibration • Cleaning Procedures • Replace/Adjust Procedures • Troubleshooting • Master Index
Operating Summary (In English) PN 4237389	Overview of daily procedures and description of screen buttons and icons.

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