

AU680 New Test Configuration



For Training Purposes Only

This job aid is a shortened version of the procedures found in the sources below. Information in the job aid is correct as of the date published. Verify you have the most current version.

Source:

- AU680 Instructions for Use, PN B04779AB, June 2015
Chapter 3: System Setup
- AU680 Reference Manual, PN B63158AA, August 2015
Chapter 2: Parameters

Note: In order to complete the new test configuration, you will need the reagent instruction for use (IFU), chemistry setting sheet, AU680 contamination avoidance parameters, online test data if the test will be transmitted through a laboratory information system or middleware, calibrator and quality control information.

Use beckmancoulter.com for documentation required for Beckman Coulter reagents. Select **Support > Technical Documents**:

- **Document Category:** select **Consumable IFU/CIS/Setting Sheet** for reagent IFUs and chemistry setting sheets
- **Document Category:** select **Instrument IFU/Manual** for contamination avoidance

AU680 Chemistry Analyzer

WARNINGS AND PRECAUTIONS

Read all product manuals and consult with Beckman Coulter-trained personnel before attempting to operate the instrument.

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

INTENTION FOR USE

This document is not intended to replace the information in the Instructions for Use (IFU) or Reference Manual (RM). Information in the Instructions for Use and the Reference Manual supersedes information in any other manual.

REVISION STATUS

Version 1.0 (September 2016)

Based on:

- AU680 Chemistry Analyzer Software version 4.0
 - AU680 Instructions for Use, PN B04779AB (June 2015)
 - AU680 Reference Manual PN B63158AA (August 2015)
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TRADEMARKS

AU680 Chemistry Analyzer

New Test Configuration

Enter Common Test Parameter Information

Menu List > Parameters > Common Test Parameters > Test Name

Enter the Test Name:

- Find an available position to add the new test (open positions are 103-120). You may need to use the scroll bar. Tests are processed in the test number order (1-120) with some exceptions
CAUTION: If you choose to use a position that had a previous test name, be aware of the following:
 - Changing a test name affects all results associated with that test number
 - Any previously reported results (with the old test name) are assigned the new test name
 - Use an available position (without a previously assigned test) when possible
- Select **Edit (F1)**
 - Name: Enter a maximum of 6 characters
 - Long Name: (Optional) Enter a maximum of 20 characters
 - Reagent ID: Enter the first 3 digits of the reagent ID, or refer to the chemistry setting sheet for the reagent ID 3-digit code
 - Alarm Shots: Enter the number to generate a "Reagent Short" alarm (default = 32)
 - Multi Reagent Switch: Select **Yes**. Selecting Yes allows the instrument to switch to a new sequence from the current set (sequence 1) of reagent bottles when either the R1 or R2 becomes empty
- Verify the information and select **Confirm (F1)**

Add the test to a Group of Tests:

- Select the **Group of Tests** button
- Select Group 1, 2 or 3 from the **Group** drop-down list
- Select **Edit (F1)**
- Select **Test Setting (F5)**
- Select the test to add to the Group. The test name will highlight in blue. Select **Close**
- To change the print order: Select the test, then select **Forward (F2)** or **Backward (F3)**
- Verify the information and select **Confirm (F1)**

Add the test to a Profile (Optional):

- Select the **Profile** button
- Select **Sample, RB/Calibration** and **QC** tabs as needed to add the test to any required profiles
- Select **Edit (F1)**
- Select the sample type from the **Type** drop-down list
- Select a profile from the **Profile Name** drop-down list
- Select the test. The selected test highlights in blue
- Verify the information and select **Confirm (F1)**

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Enter Specific Test Parameter Information

Menu List > Parameters > Specific Test Parameters > General

Enter the general test information:

- Select **Edit (F1)**
- Select the test from the **Test Name** drop-down list
- Select the sample type from the **Type** drop-down list
- Select **Yes** from the **Operation** drop-down list
- Enter the specific test parameters from the chemistry setting sheet. Entering the information correctly is critical to the performance of the test
- Verify the information and select **Confirm (F1)**

Enter all the necessary Ranges using the reagent instructions for use (IFU) and your laboratory protocol:

- Select the **Range** button
- Select the test from the **Test Name** drop-down list
- Select the sample type from the **Type** drop-down list
- Select **Edit (F1)**
- Select **Set Decimal Places (F5)**. Select 0-4 for the appropriate decimal place for the results. Select **Close**
- From the **Value/Flag** drop-down list
 - Select **Flag** to access **Level** to set a positive limit (P flag) or negative limit (N flag); used for drugs of abuse testing
 - Select **Value** to access **Specific Ranges** to set high (H flag) and low ranges (L flag)
 - Check 1-6 to enter a range based on sex and age
 - 7: Standard demographic: Enter generic information to be used when no demographic information is available
 - 8: Not within expected values: Enter information to be used when the patient demographic information does not meet the values entered for 1-6
- For Panic Value (optional), enter a range to generate a panic low (pl flag) or panic high (ph flag)
- Enter units in the **Unit** box to be printed on reports
- Verify the information and select **Confirm (F1)**

Enter Repeat Specific Parameters

Menu List > Parameters > Repeat Parameters > Repeat Specific

Note: Perform the following steps if the Auto Repeat feature is going to be used. The reagent IFU will identify if it is appropriate to dilute the sample with the onboard diluent.

Enter the auto repeat values:

- Select **Edit (F1)**
- Select the test from the **Test Name** drop-down list
- Select the sample type from the **Type** drop-down list
- Make a selection for one of the following:
 - **Normal Repeat** (same as first run): the values are from the chemistry setting sheet
 - **Repeat with diluent:** enter user defined values to either lower Sample Volume OR select a Pre-Dilution Rate from drop-down list. Do not make changes to both
 - **Repeat with condense:** enter user defined values
- **Repeat Decision Range:** enter user defined values for **Low** and **High** limits
- (Optional) **Reflex Range:** enter user defined values for **Low** and **High** limits
- **Note:** To use the reflex feature, enter the **Deciding Test** and **Related Test** selections at **Menu List > Parameters > Repeat Parameters > Repeat Common > Group**
- Select **Confirm (F1)** when all required repeat parameters have been entered

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Enter Calibrator Information

Menu List > Parameters > Calibration Parameters > Calibrators

Note: This step is only required if this is new calibrator material. If this test is using calibrator material already in use, continue with the next step “Enter Calibration Specific Information”.

Enter calibrator information:

- Select **Edit (F1)**
- Select an available position (for the correct sample type) to enter the Calibrator Name, ID (if calibrator bar codes are in use), Lot No. and Expiration date
- Verify the information and select **Confirm (F1)**

Enter Calibration Specific Information

Menu List > Parameters > Calibration Parameters > Calibration Specific

Enter the calibration specific information:

- Select **Edit (F1)**
- Select the test from the **Test Name** drop-down list
- Select the sample type from the **Type** drop-down list
- Refer to the chemistry setting sheet to select the **Calibration Type** from the drop-down list
- For all Calibration Types except MB, use the chemistry setting sheet to enter:
 - Formula, Slope Check, Factor Range, Allowable Range Check, Advanced Calibration, Lot Calibration and Stability
 - Counts: enter the number of replicates to be performed (1,2,3 or 4)
 - Select the calibrator from the **Calibrator** drop-down list
 - For **Conc.**, enter the calibrator concentration from the calibrator package insert
- For the Calibration Type MB, use the chemistry setting sheet to enter:
 - Formula, Allowable Range Check, Advanced Calibration, MB Type Factor and Stability
 - Counts: enter the number of replicates to be performed (1,2,3 or 4)
- Verify the information and select **Confirm (F1)**

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Enter Quality Control (QC) Information

Menu List > Parameters > QC Parameters > Controls

Note: This step is only required if this is new QC material. If this test is using QC material already in use, continue with the next step "Enter QC Specific Information".

Enter the QC information:

- Select **Edit (F1)**
- Select an available position (for the correct sample type) to enter the Control Name, ID (if QC bar codes are in use), Lot No., Expiration date and STAT Uses
- Verify the information and select **Confirm (F1)**

Enter QC Specific Information

Menu List > Parameters > QC Parameters > QC Specific

Enter the calibration specific information:

- Select the **Preset** tab
- Select the test from the **Test Name** drop-down list
- Select the sample type from the **Type** drop-down list
- Select **Edit (F1)**
- Select the control name from the **Control** drop-down list
- Select the Multi or Single from the **Multi/Single** drop-down list
- Use the QC package insert to enter:
 - QC mean value at **Mean**
 - 1 SD value at **SD**
 - Range value at **Range** (high value minus the low value)
- Verify the information and select **Confirm (F1)**

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Add the Test to Print on Reports

Menu List > System > Format > List Format

Note: Do not make any changes in Basic Condition, Print Information or Layout. Any changes will affect the format of the report.

Add the new test to all realtime reports in use:

- Select the **Test Item** tab
- Select **Edit (F1)**
- Select the report from the **List Name** drop-down list
- Select the test (blue highlight indicates it is selected)
- If the test should print on another report, make a new selection from the **List Name** drop-down list, and then select the test. Repeat this step for every report in use
- Select **Confirm (F1)** when the test has been added to all required reports

Enter Contamination Prevention Parameters

Menu List > Parameters > Misc. > Contamination Parameters

Note: This step is only required if the test is listed in the Contamination Avoidance documentation found at beckmancoulter.com.

Enter the contamination prevention information:

- Select **Edit (F1)**
- Program the Preceding Test Name, Following Test Name, Reagent Probe Cleaner Kind, Wash Count, Effective of Water Cleaning, Mixer and Cuvette
- Verify the information and select **Confirm (F1)**

Enter Data Check Parameters

Menu List > Parameters > Misc. > Data Check Parameters

Note: Program check points and decision limits to detect abnormal reaction types for prozone effects in an increasing turbidimetric assay. This step is only required if the test has Data Check parameters provided on the chemistry setting sheet.

Enter the data check information:

- Select **Edit (F1)**
- Select the test from the **Test Name** drop-down list
- Select the sample type from the **Type** drop-down list
- Select the Logic Check option (1-3) and enter the data check parameters for the test provided on the chemistry setting sheet. Only enter information from the chemistry setting sheet. Leave all other fields blank. If required, multiple data checks can be selected
- Verify the information and select **Confirm (F1)**

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Enter Online Communication Information

Menu List > System > Online > Online Test No.

Note: This step is required if the instrument is communicating with a laboratory information system (LIS) or middleware for sample programming.

Enter the Online Test information:

- Select **Edit (F1)**
- Enter the **Online Test No.** The online test number and the LIS must coincide or the data may not be transmitted correctly
- Verify the information and select **Confirm (F1)**

Save Parameters

Menu List > System > External Data Management > File Management

Save the configurations you entered to the hard drive (HD) or to a USB (External Media):

- Select **Save Files to HD** or **Save Files to External Media**
- Select **File Select (F6)**
- Select the files to be saved, select **OK**
- For saving files to HD:
 - Select **Execute (F7)**
 - Select **OK**
- For saving files to external media:
 - Select **Execute (F7)**
 - At the Execute dialog, select **External Memory Unit**, select **OK**
 - Insert the USB into the computer and select **OK**
- Select **OK** when the Execute window appears with "File save is successful"

Verify the New Test Configuration

Verify the new test was configured properly by completing the following:

- Load the reagent and any required cleaning solution
- Perform a reagent volume check for the new test
- Verify the calibration was requisitioned for the new test
- Requisition QC for the new test if it was not added to the default QC panel
- Perform a reagent blank, calibration and QC on the new test
- Review the report and verify reagent blank, calibration and QC data is acceptable for your laboratory protocol
- Perform any additional new test verification required by your laboratory protocol