AU2700® and AU5400® Chemistry Analyzer

Reaction Profile Check for Cuvette Overflow Detection

PN B06960AA
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Beckman Coulter, Inc.
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BECKMAN COULTER

AU2700® and AU5400® Chemistry Analyzer
Reaction Profile Check for Cuvette Overflow Detection
PN B06960AA (March 2012)

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CHAPTER 1

Introduction

This addendum is a separate document containing changes and additions to the AU2700 and AU5400 User's Guides. The changes and additions in this addendum pertain to the Cuvette Overflow Modification using the Reaction Profile Check (RPC) method.

This chapter describes the principle of the RPC and how to operate effectively with the RPC method.

1.1 Reaction Profile Check (RPC) Description

1.2 Cuvette Overflow Detection Principle

1.3 Operation with Reaction Profile Check

1.1 Reaction Profile Check (RPC) Description

A cuvette overflow occurs when fluid spills onto the outside of the cuvette. This may affect the accuracy of subsequent test results.

The purpose of the RPC cuvette overflow detection method is to detect a cuvette overflow so appropriate corrective actions can be taken immediately.

The principle of the RPC method is a new software algorithm used specifically with System Monitoring Solution (SMS) to detect abnormal reaction kinetics caused by a cuvette overflow by running an SMS test.

Beckman Coulter recommends manually requisitioning and running the SMS test at regular intervals defined by Standard Operating Procedures of each laboratory. It is possible to requisition the SMS test through the LIS.

The SMS test detects abnormal reaction kinetics which are indicative of a cuvette overflow. The cuvette overflow check is only performed during the measurement of the SMS test. If abnormal reaction kinetics are detected, the SMS test generates a flag (*), and an audible alarm message is generated to indicate a possible cuvette overflow, or other analyzer error.

1.1.1 Cuvette Overflow Alarms

The alarm message "4064 REACTION PROFILE CHECK ERROR (aa, bbbb, cc, ddddd, e, ffff, ggg..gg) hhh....hh" is generated, followed by a second alarm "4065 REACTION PROFILE CHECK CONSECUTIVE JUDGEMENT ERROR". The system goes to *Stop* mode.

The following describes the two alarms:

- 4064 REACTION PROFILE CHECK ERROR (aa, bbbb, cc, ddddd, e, ffff, ggg...gg) hhh...hh

aa:	Sample Type
bbbb:	Sample Number
cc:	Kind Number (Quality Control, Calibrator)
ddddd:	Item Name
e:	Unit Number (AU2700: 1, AU5400: 1, 2, or 3)
fffff:	Cuvette Position (Inner or Outer)
ggg..gg:	Condition 1-8
hhh..hh:	Sample ID

- 4065 REACTION PROFILE CHECK CONSECUTIVE JUDGEMENT ERROR (a, bbbb)

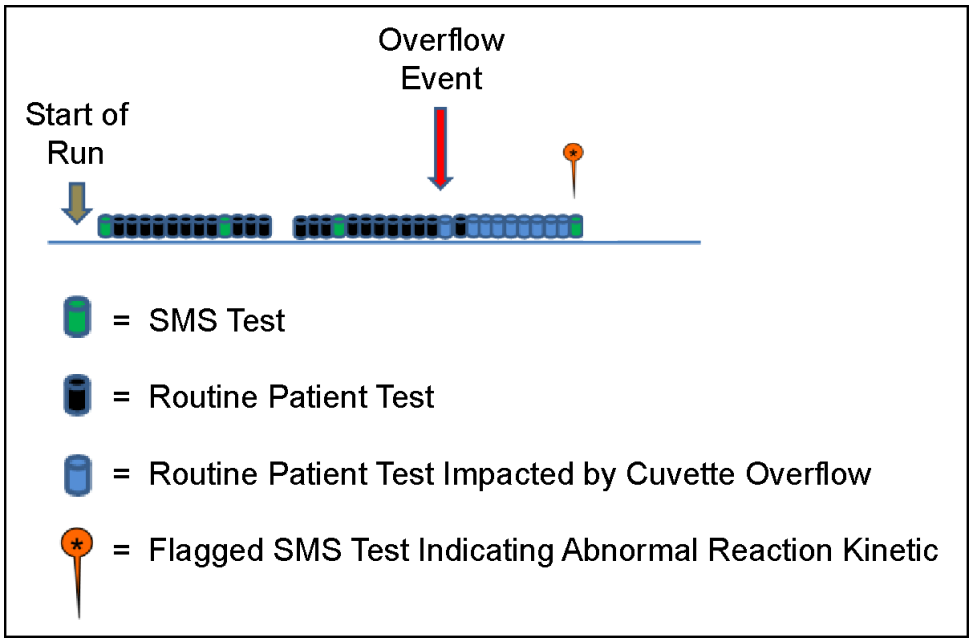
a:	Unit No. (AU2700: 1, AU5400: 1, 2, or 3
bbbb:	Cuvette Position (Inner or Outer)

1.1.2 Cuvette Overflow Detection Concept

The SMS test is run to detect abnormal reaction kinetics that can be caused by a cuvette overflow. Beckman Coulter recommends the SMS test be performed during daily operations at a frequency based on the Standard Operating Procedures and workflow of the laboratory.

- In Figure 1.1, the green cuvettes show where the SMS test takes place during a routine run on an AU system.
- The (*) indicates that the analyzer has detected an abnormal reaction kinetic.

Figure 1.1 Cuvette Overflow Detection Concept



TIP If the analyzer goes to *Stop* mode before the requisitioned SMS test is complete, include troubleshooting for a cuvette overflow as part of the investigation. Run the SMS test once the analyzer is functional.

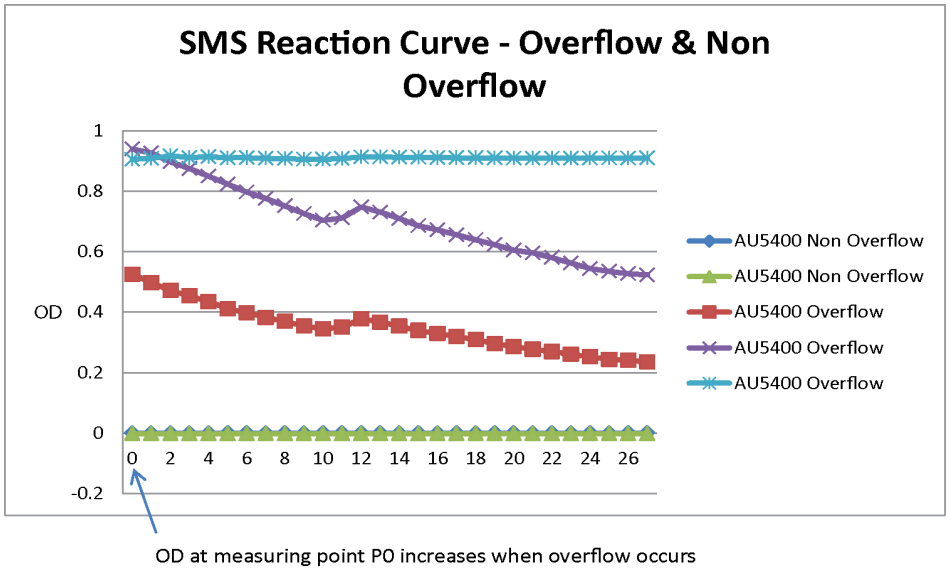
1.2 Cuvette Overflow Detection Principle

Detection of abnormal reaction kinetics is based on flagging the elevated optical density (OD) measured at P0 of the SMS test, which occurs during a cuvette overflow. P0 is the first available photometric measuring point.

The OD at P0 of the SMS test is approximately 0.0000 OD when the AU is operating without a cuvette overflow. This is due to the formulation of the SMS test without a reactive component at the measured wavelength (800 nm).

The OD at P0 and subsequent measuring points of the SMS test becomes unstable when a cuvette overflow occurs. This is due to the light being scattered, reflected, or refracted by the overflow. Figure 1.2 demonstrates the typical unstable OD values throughout the reaction for overflow reaction kinetics with the SMS test.

Figure 1.2 SMS Reaction Curve: Non Overflow and Overflow



1.3 Operation with Reaction Profile Check

1.3.1 System Monitor Solution Assay Protocol

The RPC method to detect abnormal reaction kinetics caused by a cuvette overflow is performed only on the SMS test. The SMS reagent part number B15601 is the only product specifically designed to flag abnormal reaction kinetics caused by a cuvette overflow.

Beckman Coulter recommends the SMS test be performed during daily operations at a frequency based on the Standard Operating Procedures and workflow of the laboratory, and at the beginning and ending of each sample run. An example is to run the SMS test before patient samples are measured, as part of routine QC, at regular sample intervals, and after the patient sample run is complete.

It is necessary to run the SMS test on the Inner and Outer cuvette wheel.

The following sample types may be used as sample material for the SMS test:

1. DI water
2. Quality control material

Beckman Coulter recommends performing the SMS test as QC from the green rack on the AU2700/AU5400 or from the STAT table on the AU2700. The SMS test can also be performed from a routine (white rack) sample.

The SMS assay requires a reagent blank with every new lot number of reagent.

CHAPTER 2

Parameters

This chapter describes the parameters for the System Monitoring Solution (SMS) test.

The SMS Test Parameters and Reaction Profile Check Parameters are defined by Beckman Coulter. Use the SMS Test parameter sheet to program the SMS Test parameters.

2.1 Common Test Parameters

2.2 Specific Test Parameters

2.3 QC Test Parameters (Optional)

2.4 Calibration Specific Test Parameters

2.5 Reaction Profile Check (RPC) Parameters

2.1 Common Test Parameters

Refer to the AU2700 or AU5400 User's Guides for how to program test parameters. In the US and AP markets, refer to *Parameter Menu Operation* in Chapter D, part 3. In the EU market, refer to *Configuring Tests* in Chapter 4.

There are two options for programming and running the SMS test. Beckman Coulter recommends performing the SMS test using QC from the green rack on the AU2700/AU5400 or stat table on the AU2700.

1. SMS Test as a QC Test (Green Racks on the AU2700/AU5400, or the Stat Table QC on the AU2700)
2. SMS Test as a Routine Test (White Racks)

2.1.1 SMS Test as a QC Test (Green Racks on the AU2700/AU5400, or the Stat Table QC on the AU2700)

1 Select **Parameter** > **Common Test Parameters** > **Test Name**.

Test Name:	SMS
Long Name:	System Monitor
Reagent ID:	220
Use Cuv.:	Both
Alarm Shots:	32

For the AU5400, a bottle of SMS must be placed on each unit.

2 Select **Parameter > Common Test Parameters > Round**. Select SMS for all rounds and all units.

2.1.2 SMS Test as a Routine Test (White Racks)

1 Select **Parameter** > **Common Test Parameters** > **Test Name**.

Test Name:	SMS*
Long Name:	System Monitor
Reagent ID:	220
Use Cuv.:	**
Alarm Shots:	32

* AU2700: It is necessary to program an SMS test for the Inner and Outer cuvette wheel, for example SMSI and SMSO.

* AU5400: It is necessary to program an SMS test for the Inner and Outer cuvette wheel and each unit, for example 1SMSI, ISMSO, 2SMSI, 2SMSO, 3SMSI, and 3SMSO.

** The SMS test must be programmed on both the Inner and Outer cuvette wheel for the AU2700, and for the Inner and Outer cuvette wheel and each unit for the AU5400.

2 Select **Parameter** > **Common Test Parameters** > **Round**. Select SMS for all rounds and all units.

2.2 Specific Test Parameters

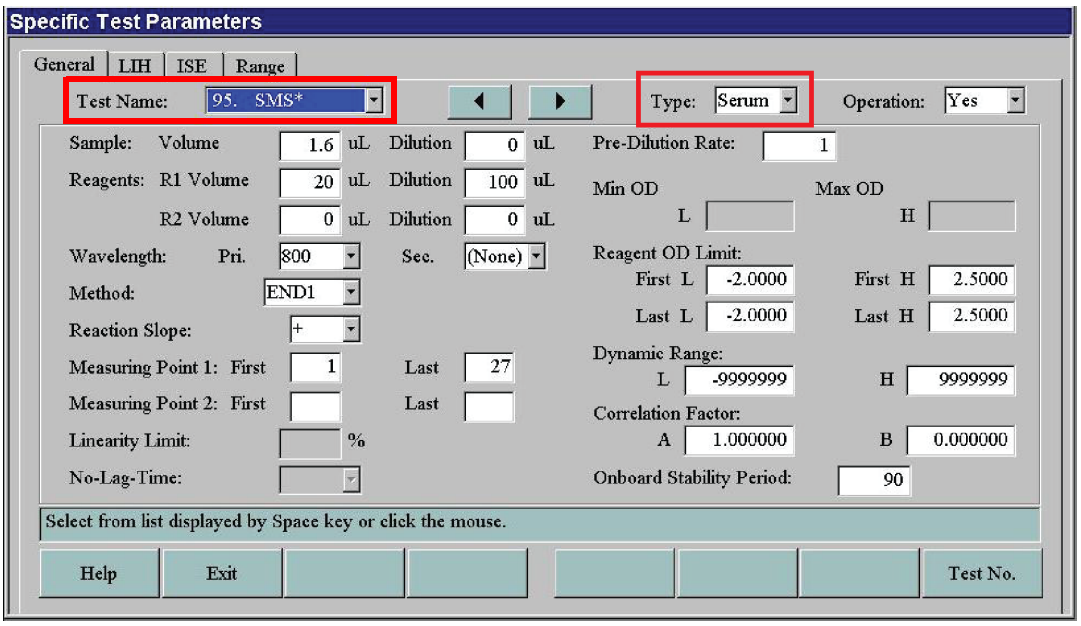
Program the Specific Test Parameters.

1 Select **Parameter** > **Specific Test Parameters**.

2 Program the SMS test according to the SMS parameter sheet.

Enter the values according to the screen shot below.

Figure 2.1



- Test Name is user-defined depending on the option (1 or 2) selected for programming and running the SMS test. Option 1 and 2 are described in section 2.1 Common Test Parameters. Examples for Option 1 and 2:

Option 1 AU2700 and AU5400 Test Name:	SMS (1 test is programmed)
Option 2 AU2700 Test Name:	SMSI and SMSO (2 tests are programmed)
Option 2 AU5400 (2 units) Test Name:	1SMSI, ISMSO, 2SMSI, 2SMSO (4 tests are programmed)
Option 2 AU5400 (3 units) Test Name:	1SMSI, ISMSO, 2SMSI, 2SMSO, 3SMSI, 3SMSO (6 tests are programmed)

- The SMS sample type is user-defined. Select the sample type in use at the "Type" drop-down list.

2.3 QC Test Parameters (Optional)

Programming the SMS as a QC sample or test is optional, based on selecting option 1. SMS Test as a QC Test (Green Racks on the AU2700/AU5400, or the Stat Table QC on the AU2700) in 2.1 Common Test Parameters. Beckman Coulter recommends performing the SMS test using QC from the green rack on the AU2700/AU5400, or the stat table on the AU2700.

The QC sample for the SMS test may be an existing QC material, or an SMS QC Sample using DI water can be programmed. Following is an example for programming an SMS QC Sample using DI water for the SMS test.

1 Select **Parameter** > **QC Control** > **QC Common > Control**.

Control Name:	SMS QC Sample
Control ID:	User Defined
Expiration:	User Defined
Lot No.:	No Entry: DI water
Multi Rack check box:	Check if the multi-rack option is in use for other QC samples (only available on the AU5400)

2 Select **Parameter > QC Control > QC specific > Preset.**

Control Name:	SMS Sample
Multi/Single:	Single
Mean:	0.0
SD:	1
Range:	4

2.4 Calibration Specific Test Parameters

1 Select **Parameter** > **Calibration** > **Calibration Specific.** Refer to the SMS (B15601) IFU.

Test Name:	SMS
Type:	User Defined
Calibration Type:	MB
MB Type Factor:	0
Count:	1
Advanced Calibration:	No
Calibration Stability Period:	Empty

2 Select **Inner/Outer (F6)** to program the MB Type Factor (0) for both the inner and outer cuvette wheel.

3 For the AU5400, select **Unit No.** and program the MB Type Factor (0) for the Inner and Outer wheel on each unit.

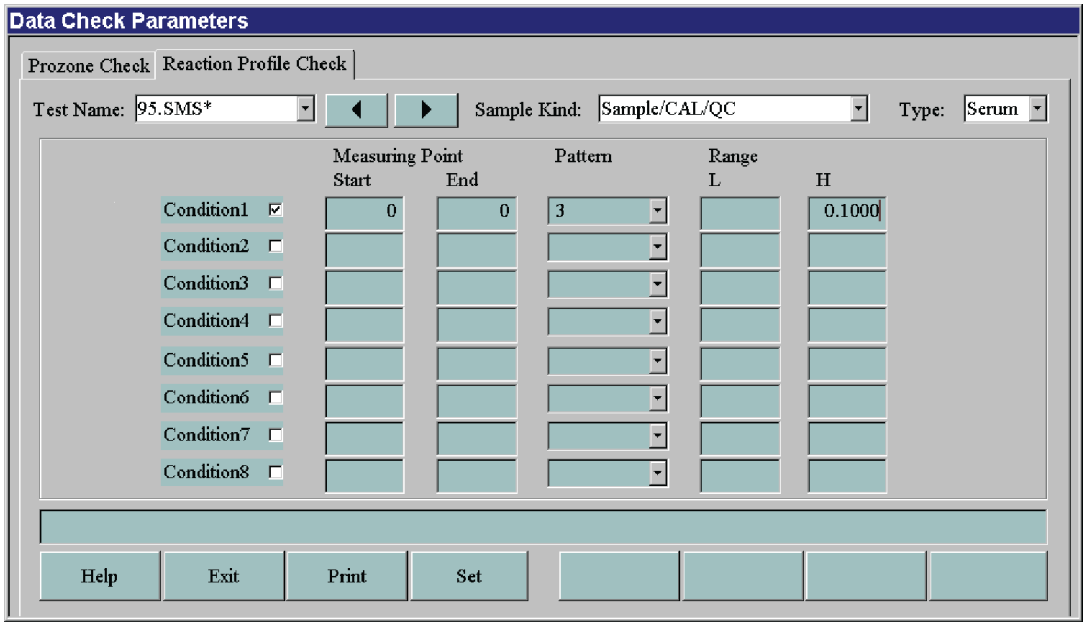
2.5 Reaction Profile Check (RPC) Parameters

The Reaction Profile Check Parameters for SMS are defined by Beckman Coulter and are located in the SMS IFU. For detailed procedures, contact Beckman Coulter Technical Services.

1 Select **Parameter** > **Special** > **Data Check Parameters** > **Reaction Profile Check.**

2 Select **Set (F4).**

Figure 2.2



3 Select **SMS** from the "Test Name" drop-down list.

4 Select **Sample/CAL/QC** from the "Sample Kind" drop-down list

5 Select the user-defined sample type from the "Type" drop-down list.

6 Enter the RPC parameters by referring to the SMS IFU.

7 Select **Exit (F2).**

CHAPTER 3

Troubleshooting

This Chapter contains new information on how to confirm a cuvette overflow, what can cause a cuvette overflow, how to recognize an overflow, and corrective actions for how to recover from the overflow. The possible causes and corrective actions if a cuvette overflow did not occur are described.

3.1 Confirm a Cuvette Overflow Has Occurred

3.2 Recovering from a Cuvette Overflow

- 3.2.1 What Causes an Overflow?
- 3.2.2 Recognizing an Overflow
- 3.2.3 Items to Check when Recovering from an Overflow
- 3.2.4 After the Overflow is Fixed

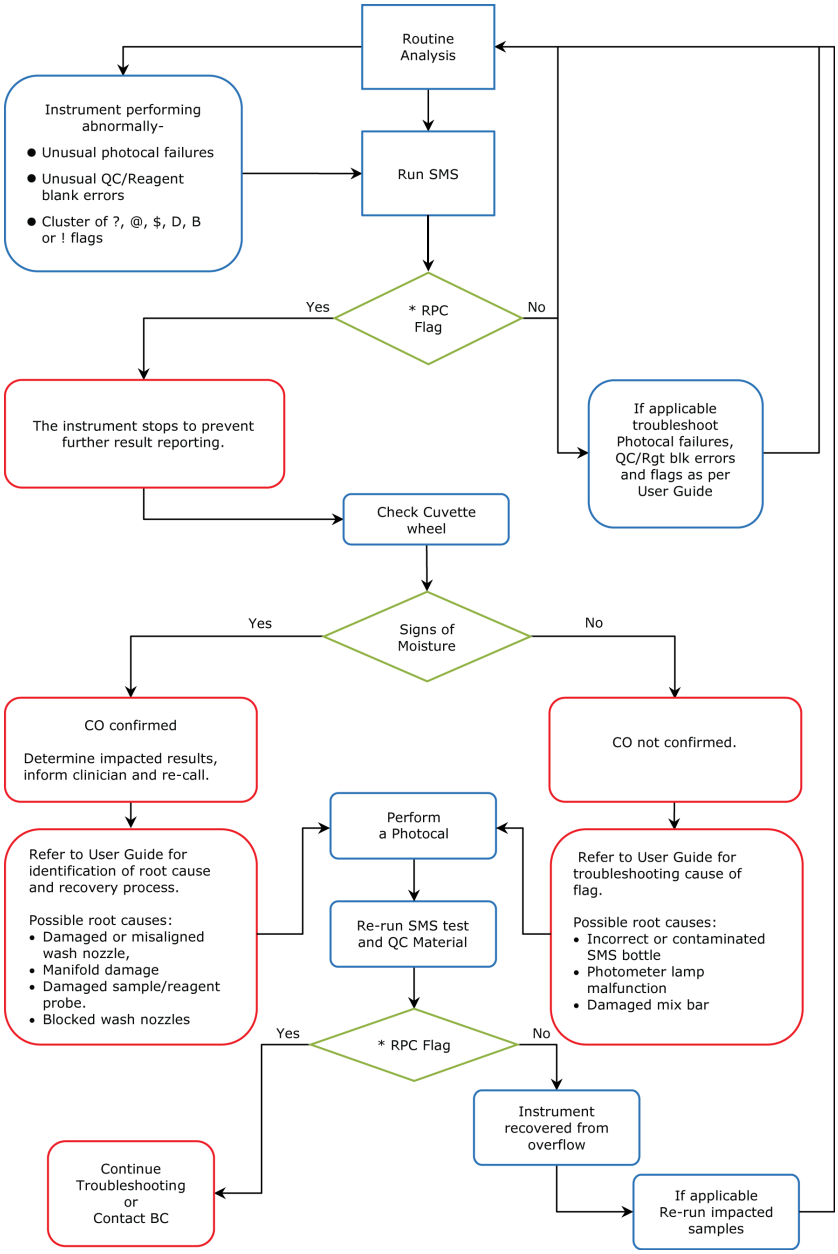
3.3 Troubleshooting When a Cuvette Overflow Did Not Occur

3.1 Confirm a Cuvette Overflow Has Occurred

A cuvette overflow may have occurred before the SMS test that generated the "*" flag and 4064 REACTION PROFILE CHECK alarm message. Refer to the flowchart to confirm a cuvette overflow has occurred.

To confirm a cuvette overflow has occurred, remove the cuvette wheel cover. The cuvettes should appear frosty or white. If the cuvettes appear dark, black, or are wet when removed, a cuvette overflow has occurred.

Figure 3.1



3.2 Recovering from a Cuvette Overflow

The following procedure explains what can cause an overflow, how to recognize an overflow, and corrective actions for how to recover from the overflow.

TIP Performing scheduled maintenance correctly reduces the chances of a cuvette overflow. For more information about maintenance for each system component, refer to the Maintenance Chapter in the AU2700 or AU5400 User's Guide.

3.2.1 What Causes an Overflow?

A cuvette overflow may be caused by any of the following:

- A wash nozzle is clogged or partially clogged. When this happens, liquid is not aspirated from the cuvette completely and eventually liquid spills over the side. This can occur when the wash nozzles are not cleaned properly, or when particles such as glass are aspirated into the nozzle.
- A wash nozzle is bent or damaged.
- There are damaged or missing o-rings on the tube mounting joint manifold.
- The reagent probe is bent. A bent probe could be dispensing outside of the cuvette.
- The sample probe is bent. A bent probe could be dispensing outside of the cuvette.
- Cuvettes are chipped or cracked due to alignment problems with the reagent probes or wash nozzles.
- The wash nozzle tubing is not connected to the nozzle.

3.2.2 Recognizing an Overflow

A "4064 Reaction Profile Check Error" alarm and a "4065 Reaction Profile Check Consecutive Judgment Error" alarm are generated.

For detailed instructions, refer to section 4.1 Identifying and Re-analyzing Samples after a Cuvette Overflow in chapter 4 of this addendum.

The cluster of error flags *, ?, @, $, D, B, and ! may indicate a cuvette overflow. The data, alarms and/or flags will vary depending on the severity of the overflow. One or all tests could be affected by an overflow. Items to check:

- QC error flags or alarms
- Reagent blank error flags
- Analyzer not performing as normal operation
- Numerous cuvettes fail after photocal
- Run an SMS test to confirm a cuvette overflow

3.2.3 Items to Check when Recovering from an Overflow

⚠ WARNING

Immediate attention should be given to an overflow. If nothing is done to fix the problem, the wheel will continue to overflow. Contact Beckman Coulter Technical Services for assistance with performing these checks.

- The wash nozzle should be aligned over the cuvettes. Visually inspect and ensure the wash nozzles are centered over the cuvettes and check the alignment.
- Sonicate and clean the wash nozzles with a stylus to remove any debris. Refer to the *Maintenance* Chapter, *Clean the Cuvette Wash Nozzle* procedure in the AU2700 or AU5400 User's Guide.
- Check the reagent and sample probes to be sure they are properly aligned. Rotate the sample and reagent probes over the cuvette wheel.
- Check for chipped or cracked cuvettes. Replace them if necessary.

  For information about replacing cuvettes, refer to section 5.1 Clean the Cuvettes, Cuvette Wedges, and the Cuvette Wheel after an Overflow in chapter 4 of this Addendum.
- Verify the wash nozzle tubing connections are secure.
- Verify the o-rings on the manifolds are in place and not damaged.

3.2.4 After the Overflow is Fixed

After the cuvette overflow is fixed, refer to section 5.1 Clean the Cuvettes, Cuvette Wedges, and the Cuvette Wheel after an Overflow in chapter 4 of this addendum.

After the cuvettes, cuvette wedges, and cuvette wheel are clean, perform the following:

1. Perform a Photocal. Refer to the *Maintenance* Chapter in the *AU2700 or AU5400 User's Guide*.
2. Run an SMS test to verify the overflow is fixed.
3. The results from the previous non-flagged SMS test and the SMS test that generated the "*" flag and 4064 Reaction Profile Check alarm are invalid and must be analyzed again. Refer to 4.1 Identifying and Re-analyzing Samples after a Cuvette Overflow for the appropriate procedure.

3.3 Troubleshooting When a Cuvette Overflow Did Not Occur

If the analyzer is performing abnormally, and the SMS test did not generate an "*" flag, review analyzer data by looking at the following items:

1. Photocal and Photometer Lamp Check: Perform a photocal and photometer lamp check to verify the integrity of the cuvettes and lamp. Refer to the AU2700 and AU5400 User's Guides, *Maintenance* Chapter.
2. Reagent Blank, Calibration, and QC Data: Review reagent blank, calibration, and QC data for accuracy and precision. Refer to the *Troubleshooting and Software* Chapters in the AU2700 and AU5400 User's Guides.
3. ?, @, , $, D, B, and ! Error Flags: Review data for one or more of the listed error flags. Refer to the *Error Flags* Chapter in the AU2700 or AU5400 User's Guide for a description and corrective action for the flags.

If it is confirmed that a cuvette overflow did not occur but the SMS test generated a "*" flag and the analyzer went to *Stop* mode, the possible root cause of the analyzer abnormality could be a contaminated SMS reagent bottle, a deteriorating lamp, or a damaged mix bar.

1. SMS Reagent

   Replace the SMS reagent and perform a reagent blank.
2. Lamp

   Try to confirm how long the lamp has been in use. If the lamp has been in use over 1,000 hours, replace the lamp.

   Refer to the AU2700 or AU5400 User's Guide, *Maintenance* Chapter to replace the lamp.
3. Mix Bar

   Refer to the AU2700 or AU5400 User's Guide, *Maintenance* Chapter to replace the mix bar.

CHAPTER 4

Monitoring Results

This chapter describes how to identify samples affected by a cuvette overflow. Results from samples affected by an overflow are invalid and must be analyzed again.

4.1 Identifying and Re-analyzing Samples after a Cuvette Overflow

4.1.1 Searching for Samples if the SMS test is a QC Sample for Condition A

4.1.2 Searching for Samples if the SMS test is a QC Sample for Condition B

4.1.3 Searching for Samples if the SMS test is a Routine Sample for Condition A

4.1.4 Searching for Samples if the SMS test is a Routine Sample for Condition B

4.1 Identifying and Re-analyzing Samples after a Cuvette Overflow

A cuvette overflow may have occurred before SMS test that generated the "*" flag and 4064 REACTION PROFILE CHECK alarm message.

If a cuvette overflow is confirmed, the results obtained from the previous non-flagged SMS test and the SMS test that generated the "*" flag and 4064 REACTION PROFILE CHECK alarm are invalid and must be analyzed again.

There are two options with two conditions to search for samples affected by the cuvette overflow described in procedures 4.1.1, 4.1.2, 4.1.3, and 4.1.4.

NOTE It is only necessary to follow **one** procedure, based on the Option (1 or 2) and Condition programmed and in use in the laboratory.

1. Running the SMS as a QC sample. There are two conditions:

   Condition A:

   - Barcode analysis mode and realtime Online requisition
   - Sequential analysis mode

   Use the 4.1.1 Searching for Samples if the SMS test is a QC Sample for Condition A procedure.

   Condition B:

   - Barcode analysis mode and batch online or manual requisition
   - Rack No. analysis mode

   Use the 4.1.2 Searching for Samples if the SMS test is a QC Sample for Condition B procedure.

2. Running the SMS as a routine sample. There are two conditions:

   Condition A:

   - Barcode analysis mode and realtime Online requisition
   - Sequential analysis mode

   Use the 4.1.3 Searching for Samples if the SMS test is a Routine Sample for Condition A procedure.

   Condition B:

   - Barcode analysis mode and batch online or manual requisition
   - Rack No. analysis mode

   Use the 4.1.4 Searching for Samples if the SMS test is a Routine Sample for Condition B procedure.

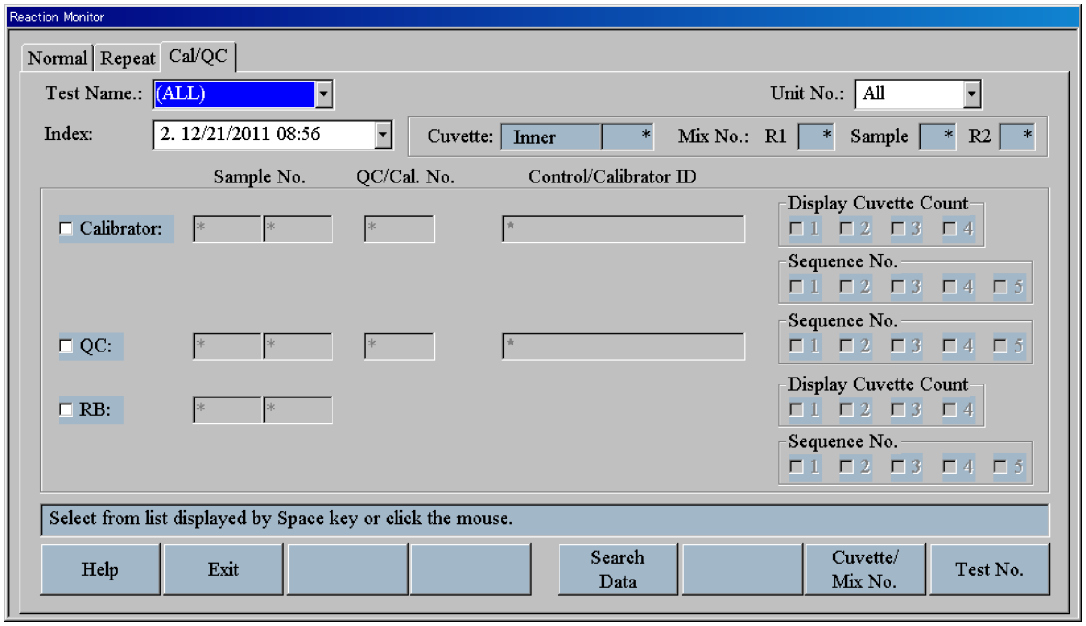
WARNING

If a cuvette overflow is confirmed, all samples measured after the previous nonflagged SMS test and before the SMS test that generated the "*" flag and 4064 REACTION PROFILE CHECK alarm are invalid and must be analyzed again. If these results have already been transferred to the Host Computer or reported, take corrective actions according to the facility Standard Operating Procedures.

4.1.1 Searching for Samples if the SMS test is a QC Sample for Condition A

1 Select **Routine** > **Reaction Monitor** > **Cal/QC**.

Figure 4.1



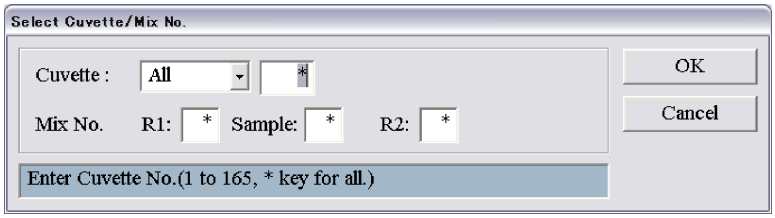
2 Select **SMS** from the "Test Name" drop-down list.

3 For the AU5400 only, select the unit number that generated the 4064 alarm from the "Unit No." drop-down list.

4 Select the last Index from the "Index" drop-down list.

5 Select **Cuvette/Mix No. (F7)**. The Select Cuvette/Mix No. window appears.

Figure 4.2

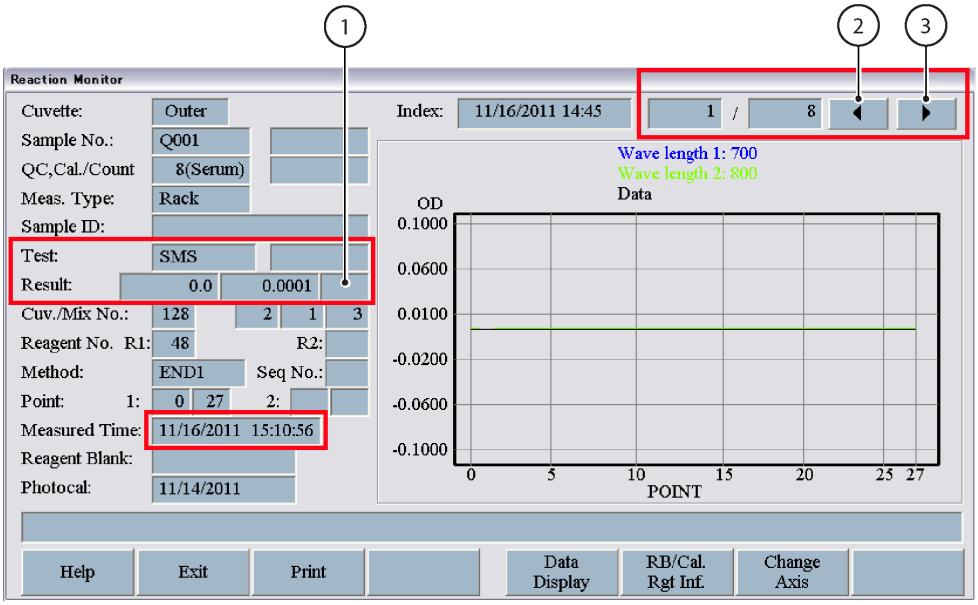


6 Select **Inner** or **Outer** that generated the 4064 alarm from the "Cuvette" drop-down list, then select **OK**.

7 Select (check the box) for QC.

8 Select **Search Data (F5)**. The Reaction Monitor window appears.

Figure 4.3



1. Flag Display field
2. Backward arrow
3. Forward arrow

9 Select the forward arrow button to go to the last result (SMS test with the "*" flag). In this example, go to result 8/8.

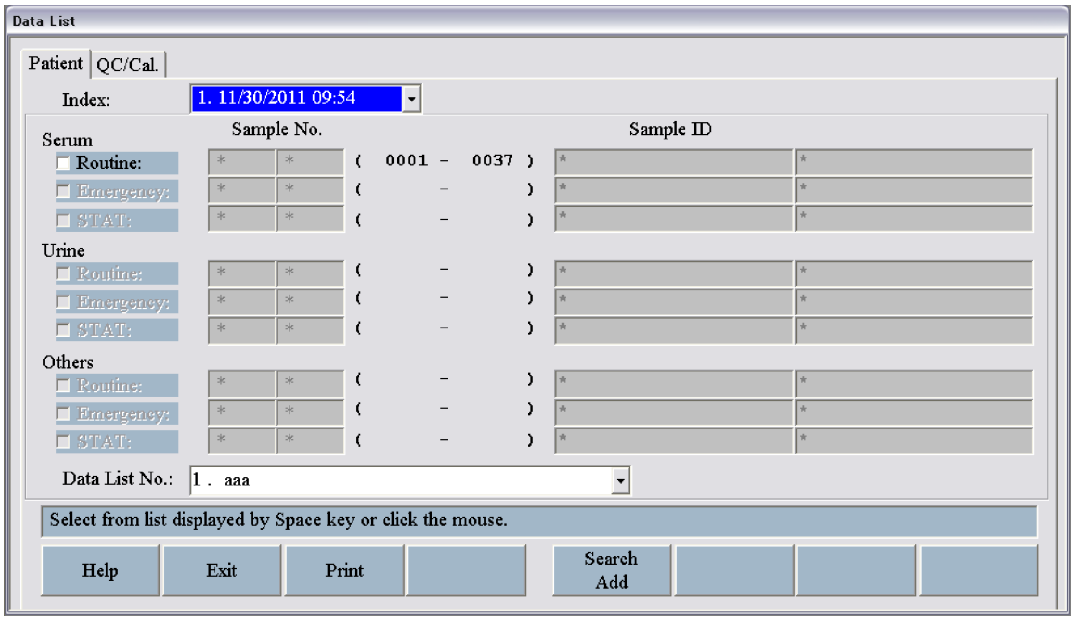
10 Select the backward arrow button to go to the previous SMS test that did not have a "*" flag. The "*" flags displays after the Result.

11 Note the date and time from the **Measured Time** field.

12 Select **Exit (F2)**.

13 Select **Routine** > **Data Report** > **Data List** > **Patient**.

Figure 4.4

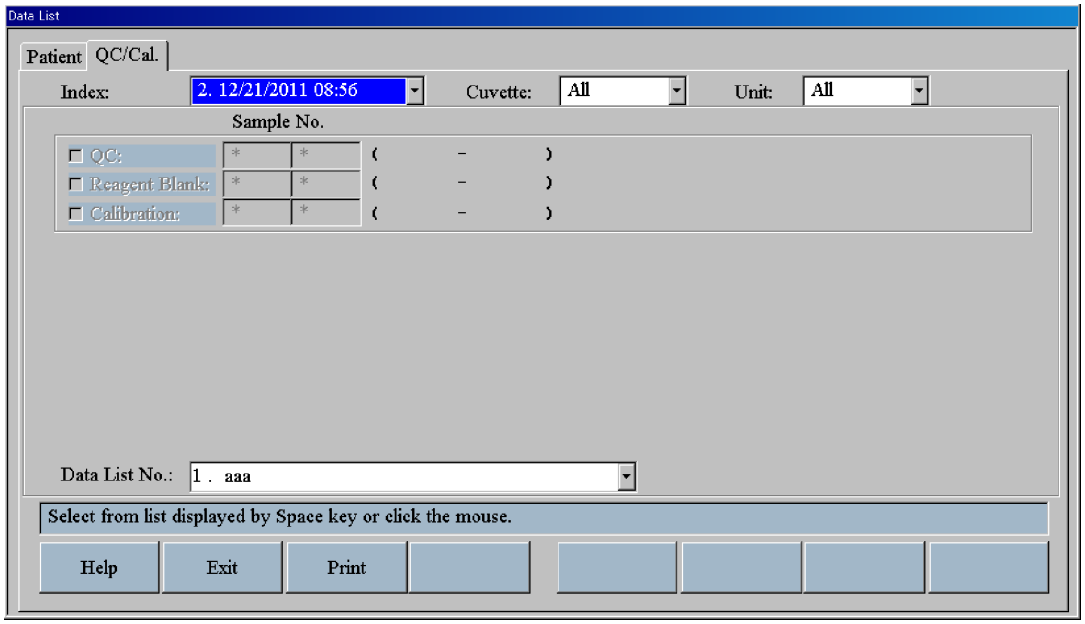


14 Select the index containing the 4064 alarm that was generated from the "Index" drop-down list.

Note the sample numbers of each sample kind (Routine, Emergency, or STAT) for Serum, Urine, or Others measured in the index. STAT is applicable only for the AU2700.

15 Select **Routine** > **Data Report** > **Data List** > **QC/Cal**.

Figure 4.5



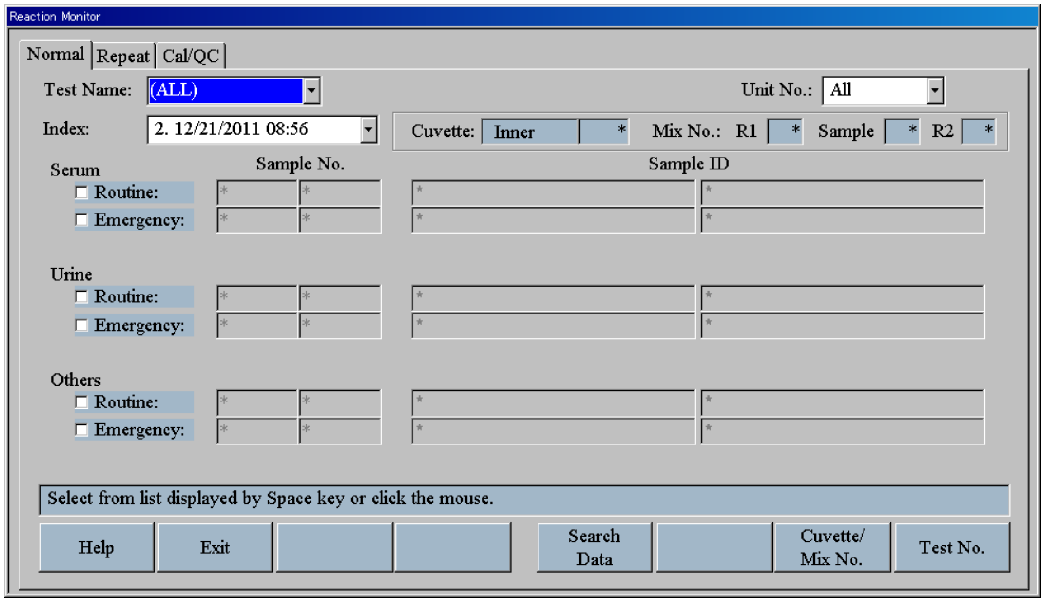
16 Select the index containing the 4064 alarm that was generated from the "Index" drop-down list.

Note the sample numbers of all QC, reagent blank, and calibration samples analyzed in the index.

17 Select **Exit (F2)**.

18 Select **Routine** > **Reaction Monitor**.

Figure 4.6



19 Select the following fields:

Test Name: (All).

Unit No.: Only for the AU5400. The unit number that the 4046 alarm generated.

Index: The index that the 4064 alarm generated.

Check box: Check one sample kind (Routine, Emergency, or STAT) for Serum, Urine, or Others measured in the index. STAT is applicable only for the AU2700.

Sample No.: First column: "*" or approximate sample number.

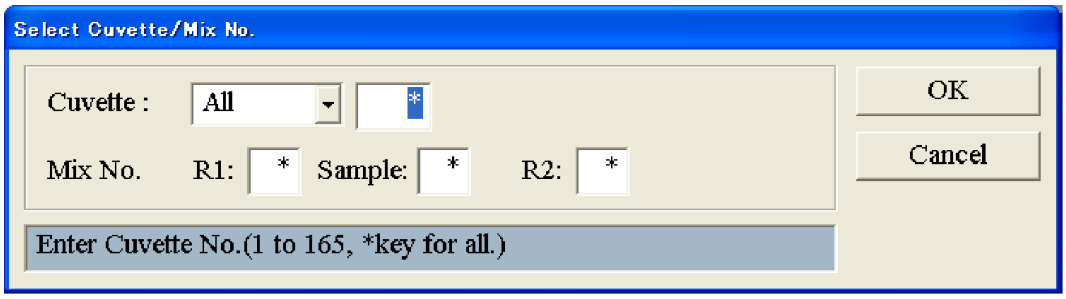
Second column: "*" or approximate sample number.

TIP Check only one sample kind at a time so it is easier to identify the approximate first Sample No. required to search. Perform this check one sample kind at a time for all the sample kinds measured in the index.

TIP If there is a large number of samples in the sample kind checked to search, the search takes a long time. Enter an approximate starting (first column) and ending (second column) Sample No. to search to reduce the search time. For example, the maximum number of photometric tests per 60 minutes is 1600. If the average number of tests per sample is 8, the approximate number of samples processed per 60 minutes is 200 samples. Searching the last 220 samples (200 plus 10%) should be sufficient to find the results. If the search does not contain samples measured for 60 minutes before the 4064 alarm was generated, it is necessary to increase the range of samples to search and perform the search again.

20 If **Inner** or **Outer** displays in the Cuvette field, select **Cuvette/Mix No. (F7)**.

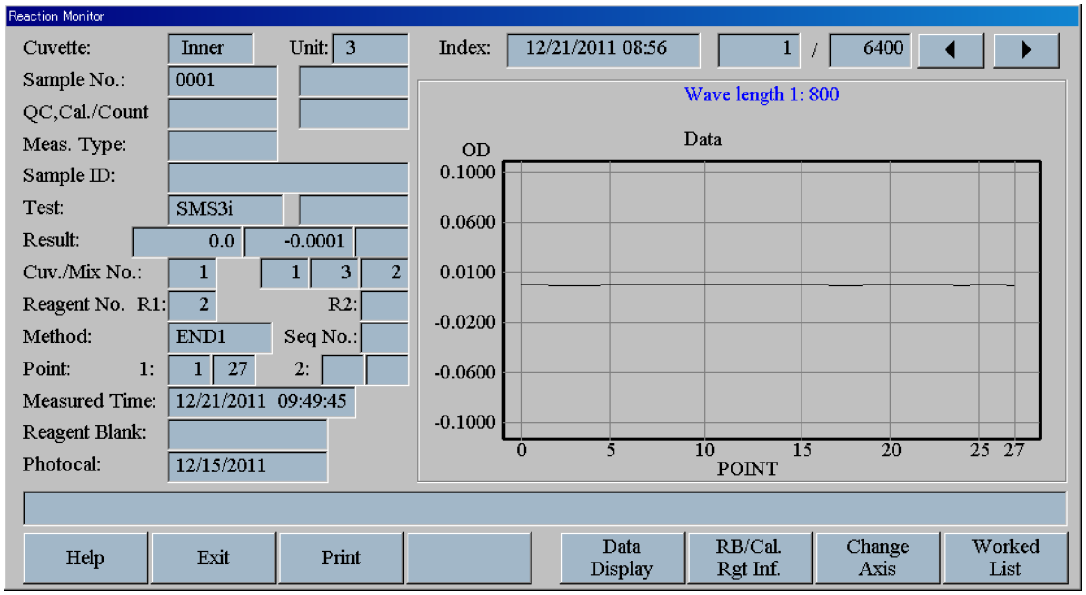
Figure 4.7



- Select **All** from the "Cuvette" drop-down list.
- Do not change the "*" at Mix No. for R1, Sample, and R2.
- Select **OK**.

21 Select **Search Data (F5)**.

Figure 4.8



22 Use the arrow buttons and look at the Measured Time to find the first Sample No. measured after the time obtained in step 10.

23 Note the Sample No.

24 Repeat steps 18 through 23 for all the sample kinds (Routine, Emergency, or STAT) for Serum, Urine, Others, QC, reagent blank, and calibration.

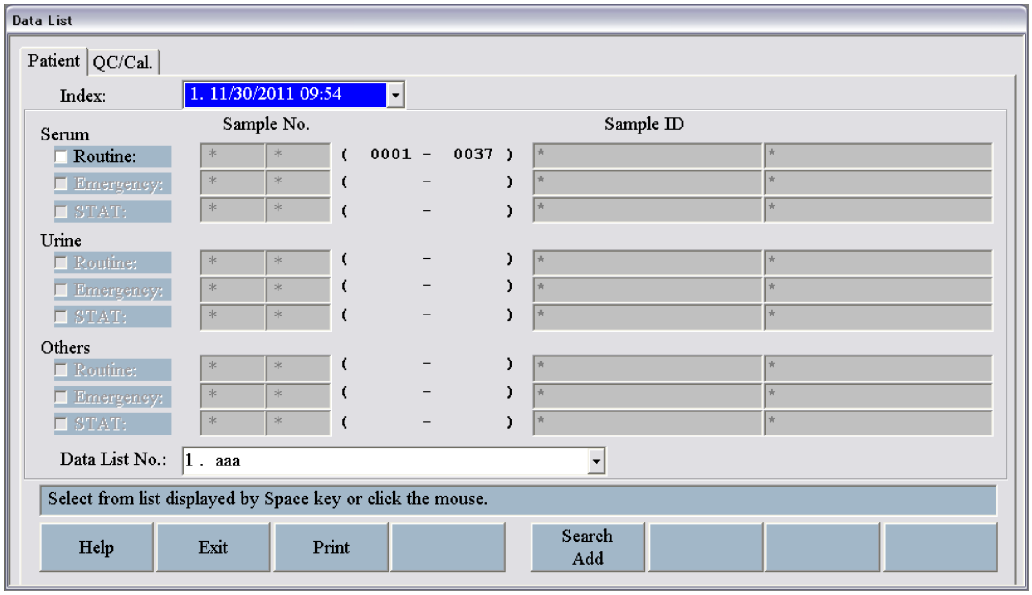
TIP It is necessary to select the **Cal/QC** tab to search for reagent blank, calibration, and QC results.

25 Select **Exit (F2)** to go back to the Reaction Monitor screen.

26 Select **Exit (F2)**.

27 Select **Routine** > **Data Report** > **Data List**.

Figure 4.9



28 Select the check box for all the sample kinds (Routine, Emergency, or STAT) for Serum, Urine, and Others measured in the index. STAT is applicable only for the AU2700.

29 Enter the first Sample No. (first column) identified in the previous steps for each sample kind. Keep "*" as the last Sample No. (second column).

30 Select **Print (F3)**.

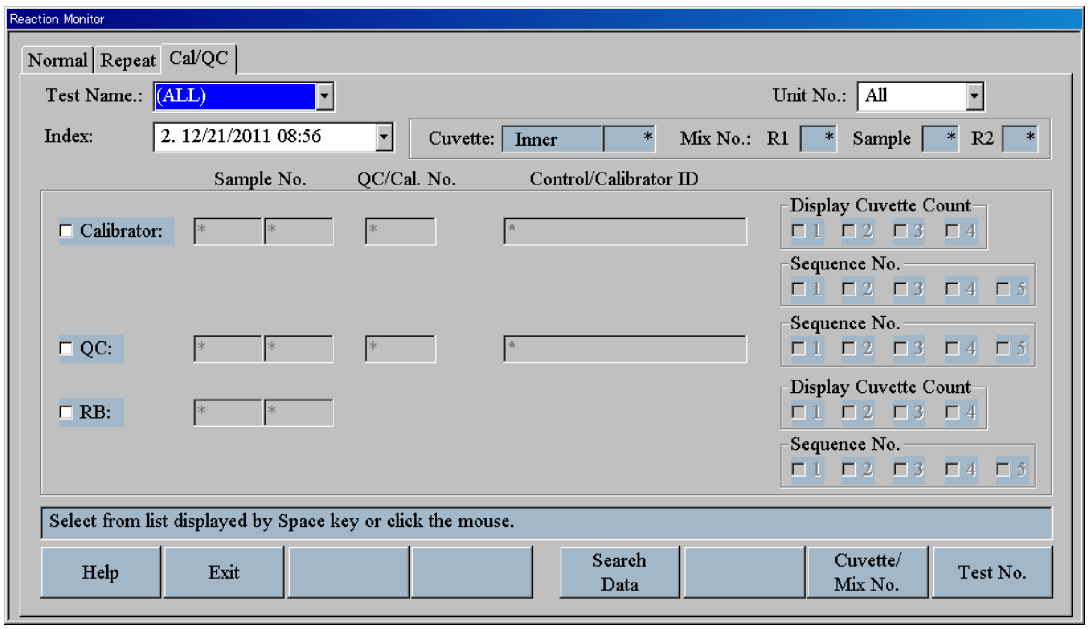
The results measured after the previous SMS test before the SMS test that generated the "*" flag and 4064 REACTION PROFILE CHECK alarm print. These results may be affected by the cuvette overflow and are invalid. Analyze these samples again.

31 Select **Routine > Data Report > QC/Cal** tab and repeat steps 27 through 30.

4.1.2 Searching for Samples if the SMS test is a QC Sample for Condition B

1 Select **Routine > Reaction Monitor > Cal/QC.**

Figure 4.10



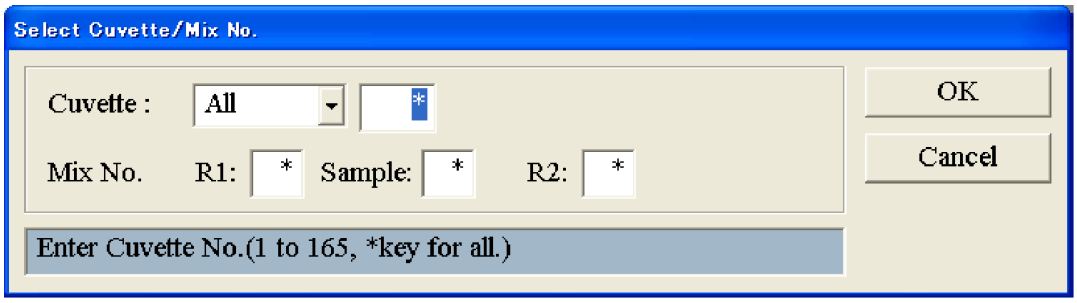
2 Select **SMS** from the "Test Name" drop-down list.

3 For the AU5400 only, select the unit number that generated the 4064 alarm from the "Unit No." drop-down list.

4 Select the last Index from the "Index" drop-down list.

5 Select **Cuvette/Mix No. (F7).** The Select Cuvette/Mix No. window appears.

Figure 4.11

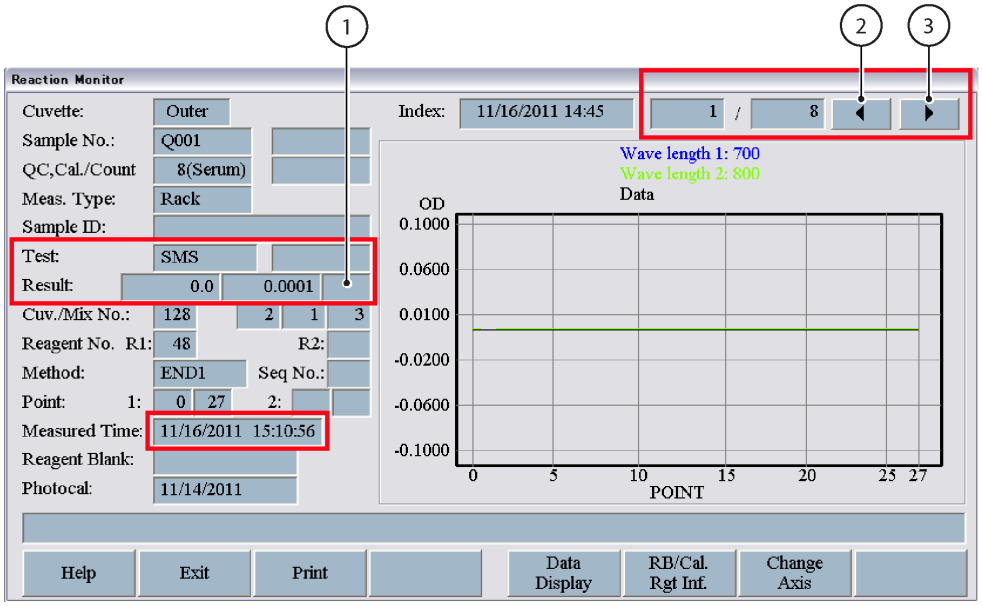


6 Select **Inner** or **Outer** that generated the 4064 alarm from the "Cuvette" drop-down list, then select **OK**.

7 Select **QC**.

8 Select **Search Data (F5)**. The Reaction Monitor window appears.

Figure 4.12



1. Flag Display field
2. Backward arrow
3. Forward arrow

9 Select the forward arrow button to go to the last result (SMS test with the "*" flag). In this example, go to result 8/8.

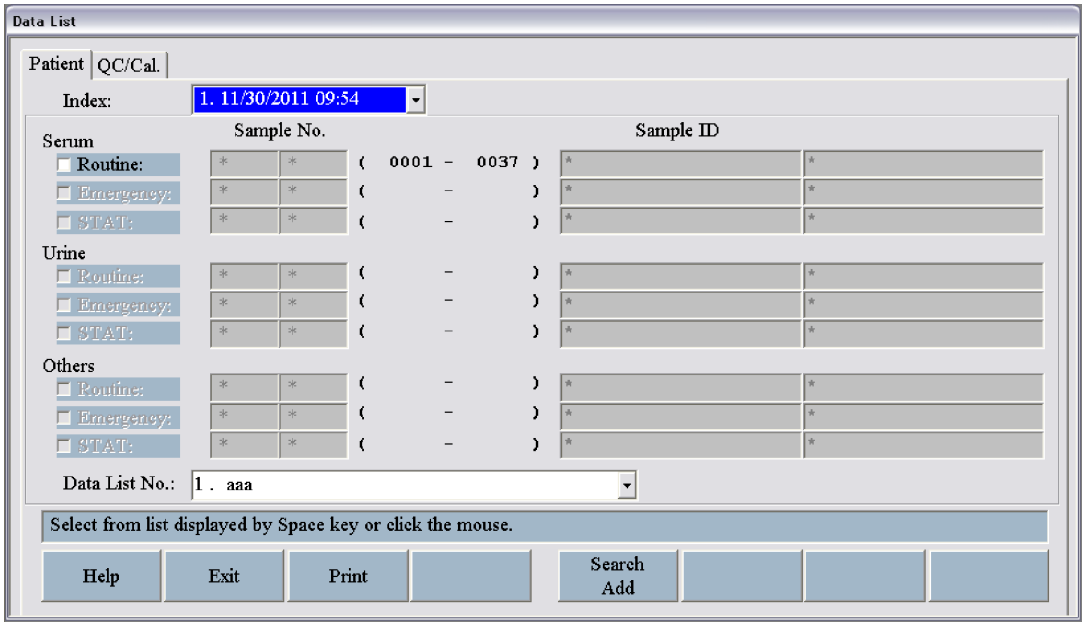
10 Select the backward arrow button to go to the previous SMS test that did not have a "*" flag. The "*" flags displays after the Result.

11 Note the Measured Time.

12 Select **Exit (F2)**.

13 Select **Routine** > **Data Report** > **Data List** > **Patient**.

Figure 4.13

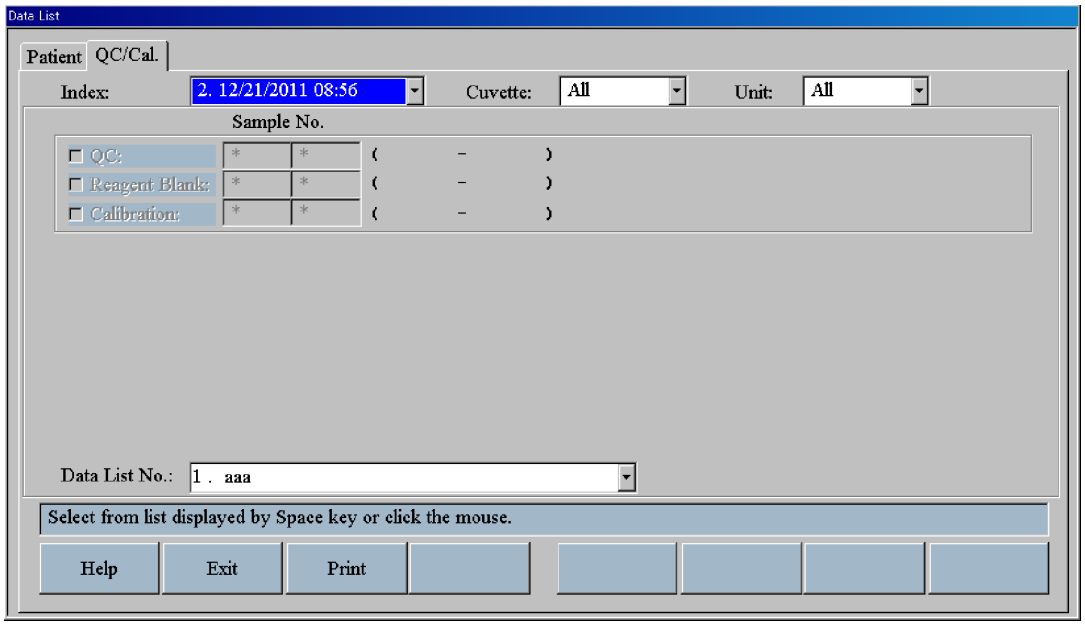


14 Select the index containing the 4064 alarm that was generated from the "Index" drop-down list.

Note the sample numbers of each sample kind (Routine, Emergency, or STAT) for Serum, Urine, or Others measured in the index. STAT is applicable only for the AU2700.

15 Select **Routine > Data Report > Data List > QC/Cal**.

Figure 4.14



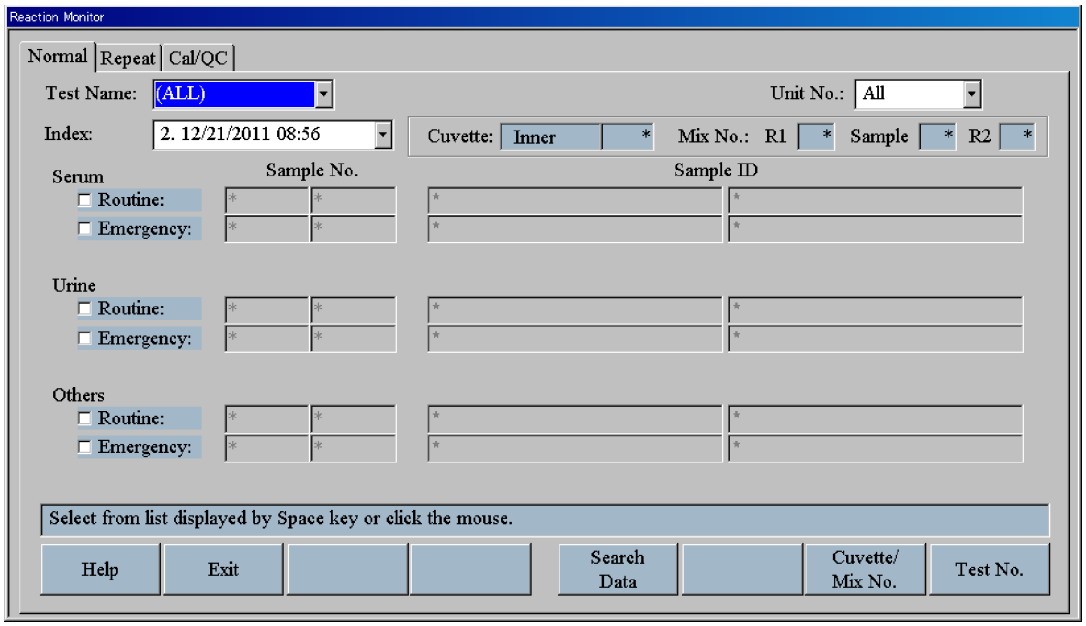
16 Select the index containing the 4064 alarm that was generated from the "Index" drop-down list.

Note the sample numbers of all QC, reagent blank, and calibration samples analyzed in the index.

17 Select **Exit (F2)**.

18 Select **Routine** > **Reaction Monitor**.

Figure 4.15



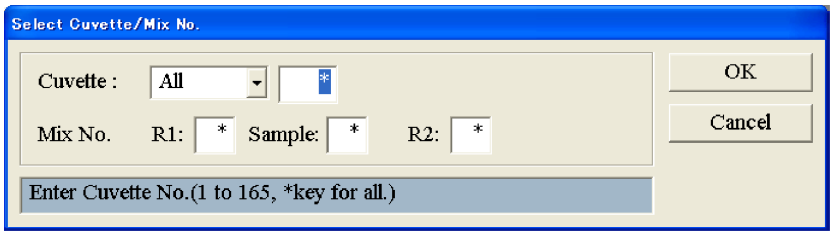
19 Select the following fields:

Test Name:	(All).
Unit No.:	Only for the AU5400. The unit number that the 4046 alarm generated.
Index:	The index that the 4064 alarm generated.
Check box:	Check one sample kind (Routine, Emergency, or STAT) for Serum, Urine, or Others measured in the index. STAT is applicable only for the AU2700.
Sample No.:	First column: "*" Second column: "*"

TIP Check only one sample kind at a time so it is easier to identify the approximate first Sample No. required to search. Perform this check one sample kind at a time for all the sample kinds measured in the index.

20 If **Inner** or **Outer** displays in the Cuvette field, select **Cuvette/Mix No. (F7)**.

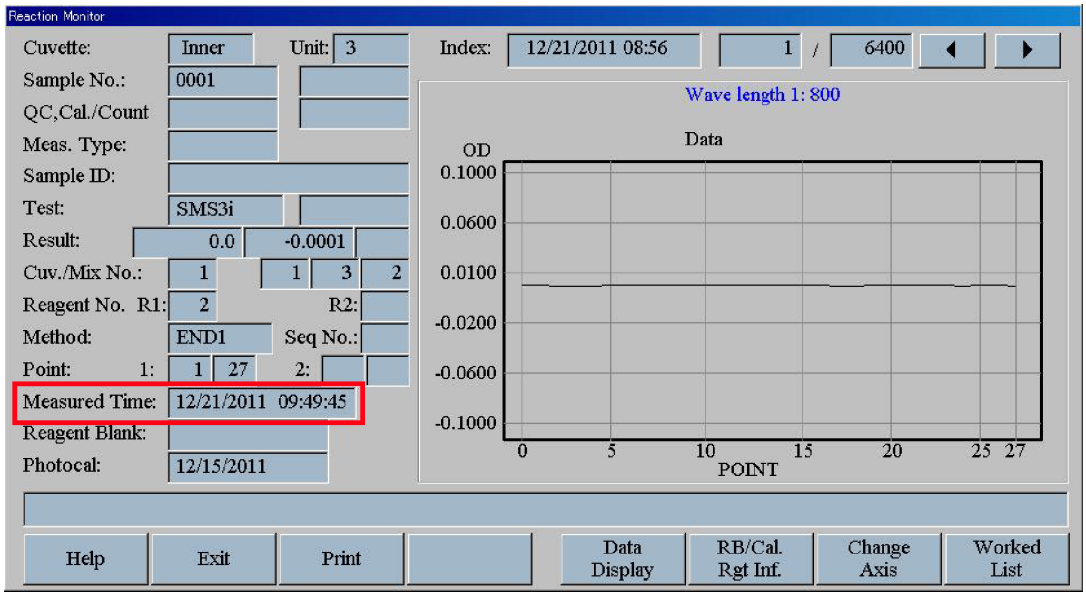
Figure 4.16



- Select **All** from the "Cuvette" drop-down list.
- Do not change the "*" at Mix No. for R1, Sample, and R2.
- Select **OK**.

21 Select **Search Data (F5)**.

Figure 4.17



22 Use the arrow buttons and look at the Measured Time to find the first test measured after the time obtained from step 10. Note the sample number, test name, and sample ID.

23 Select the forward arrow button to go to the next test. Note the sample number, test name, and sample ID.

24 Repeat step 23 up to the last result. In this example, the last result is 6400/6400.

25 Select **Exit (F2)**.

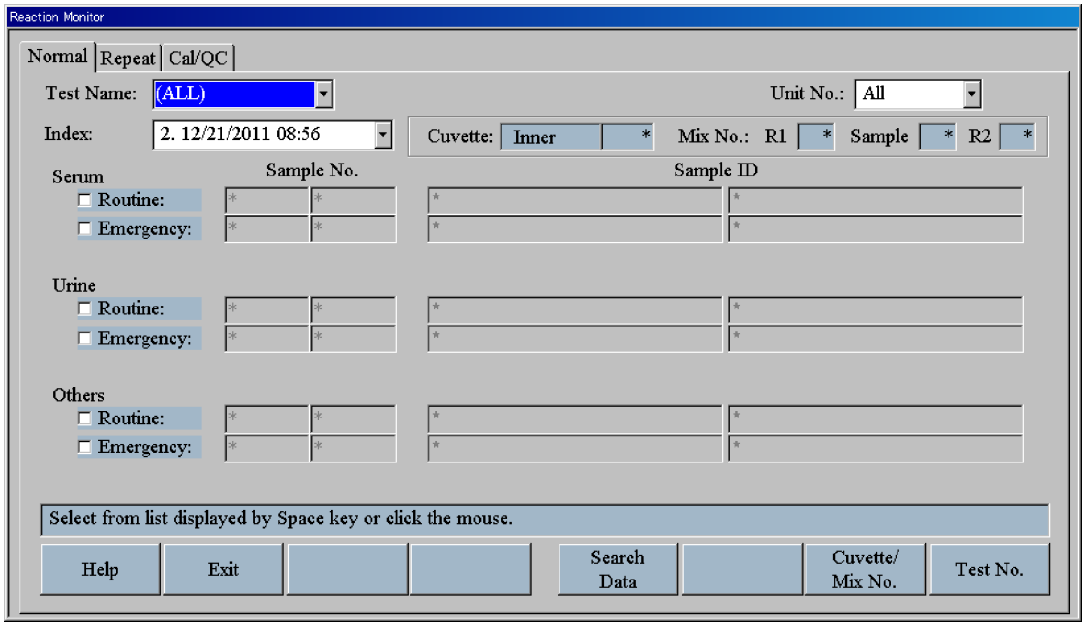
26 Select **Routine > Reaction Monitor > QC/Cal** and repeat steps 18 through 25.

27 All results from samples identified in this procedure are invalid and must be re-analyzed.

4.1.3 Searching for Samples if the SMS test is a Routine Sample for Condition A

1 Select **Routine > Reaction Monitor > Normal**.

Figure 4.18



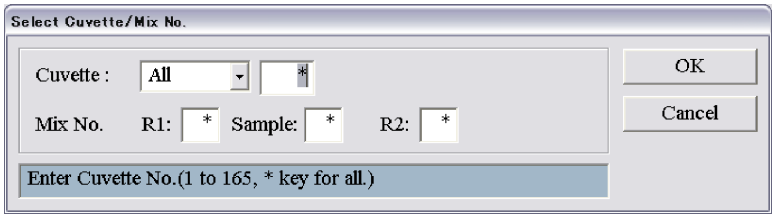
2 Select the SMS test that generated the 4064 alarm from the "Test Name" drop-down list.

3 For the AU5400 only, select the unit number that generated the 4064 alarm from the "Unit No." drop-down list.

4 Select the last Index from the "Index" drop-down list.

5 Select **Cuvette/Mix No. (F7)**. The Select Cuvette/Mix No. window appears.

Figure 4.19

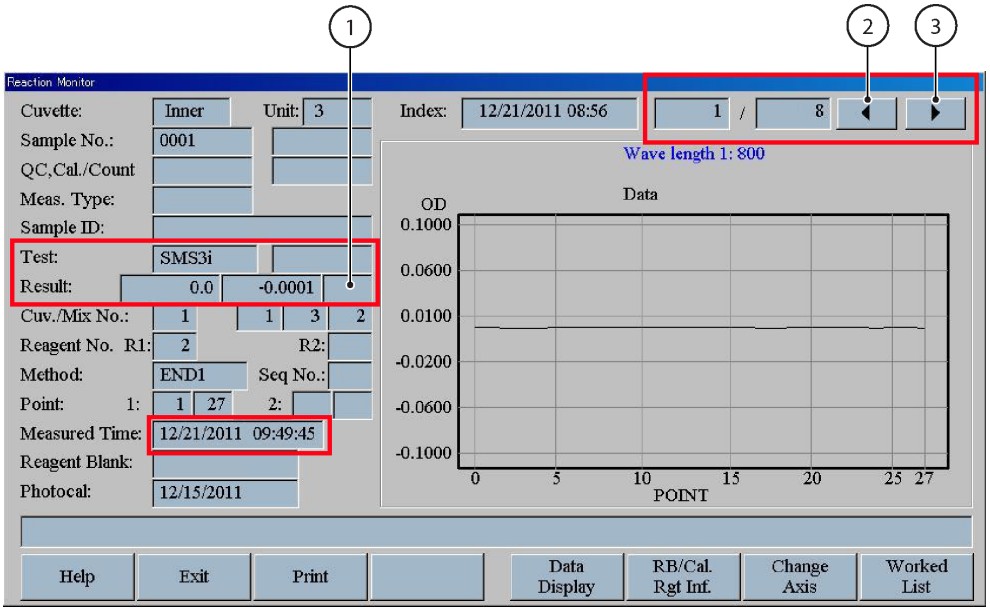


6 Select **Inner** or **Outer** that generated the 4064 alarm from the "Cuvette" drop-down list, then select **OK**.

7 Select (check the box) for Routine for the user-defined SMS sample type in use.

8 Select **Search Data (F5)**. The Reaction Monitor window appears.

Figure 4.20



1. Flag Display field
2. Backward arrow
3. Forward arrow

9 Select the forward arrow button to go to the last result (SMS test with the "*" flag). In this example, go to result 8/8.

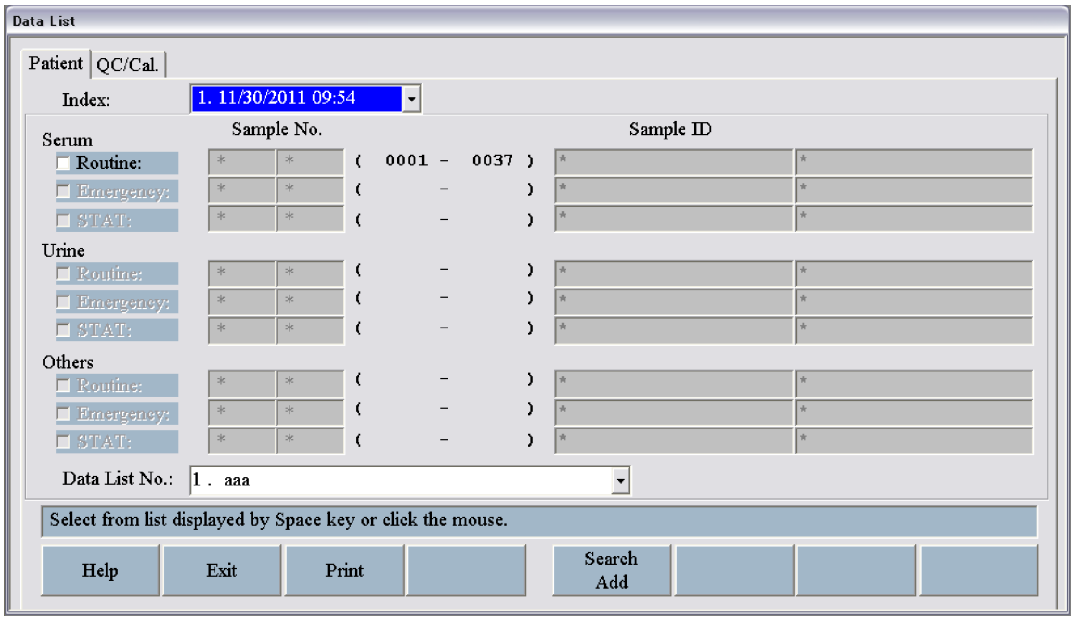
10 Select the backward arrow button to go to the previous SMS test that did not have a "*" flag. The "*" flags displays after the Result.

11 Note the date and time from the **Measured Time** field.

12 Select **Exit (F2)**.

13 Select **Routine** > **Data Report** > **Data List** > **Patient**.

Figure 4.21

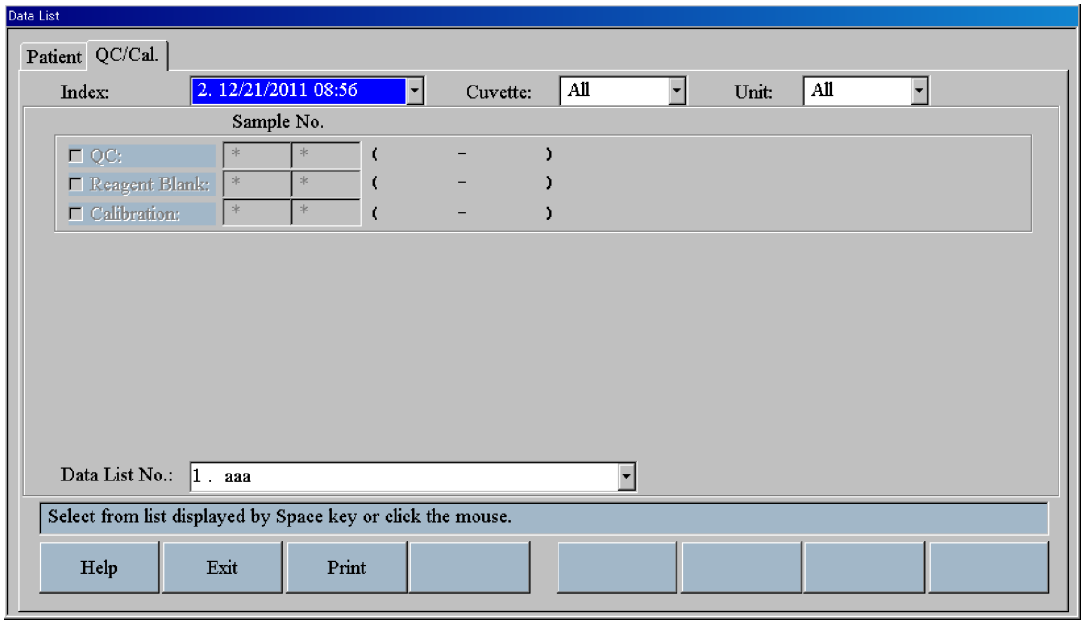


14 Select the index containing the 4064 alarm that was generated from the "Index" drop-down list.

Note the sample numbers of each sample kind (Routine, Emergency, or STAT) for Serum, Urine, or Others measured in the index. STAT is applicable only for the AU2700.

15 Select **Routine** > **Data Report** > **Data List** > **QC/Cal**.

Figure 4.22



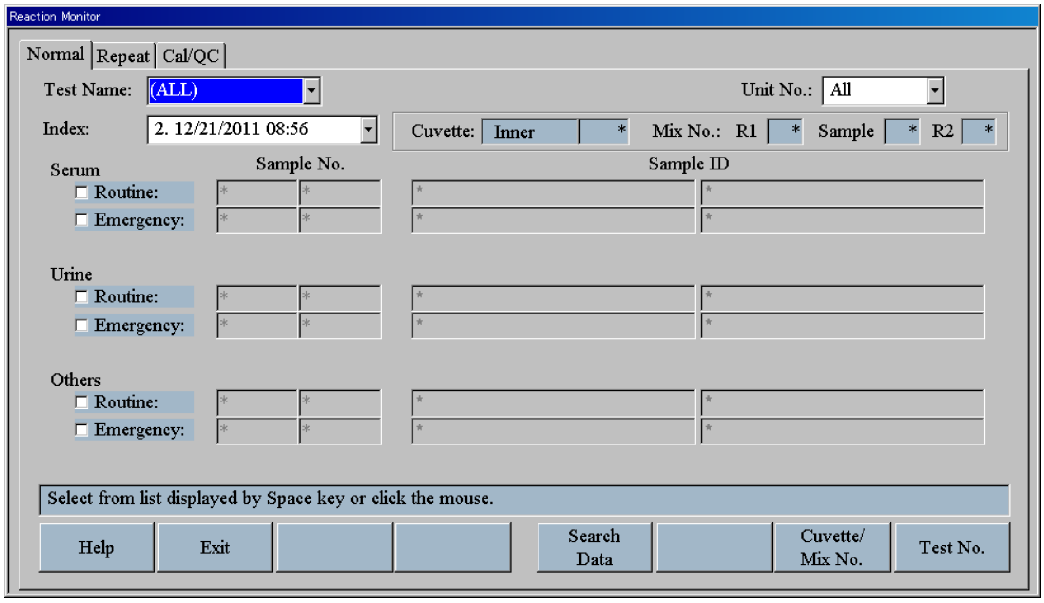
16 Select the index containing the 4064 alarm that was generated from the "Index" drop-down list.

Note the sample numbers of all QC, reagent blank, and calibration samples analyzed in the index.

17 Select **Exit (F2)**.

18 Select **Routine** > **Reaction Monitor**.

Figure 4.23



19 Select the following fields:

Test Name: (All).

Unit No.: Only for the AU5400. The unit number that the 4046 alarm generated.

Index: The index that the 4064 alarm generated.

Check box: Check one sample kind (Routine, Emergency, or STAT) for Serum, Urine, or Others measured in the index. STAT is applicable only for the AU2700.

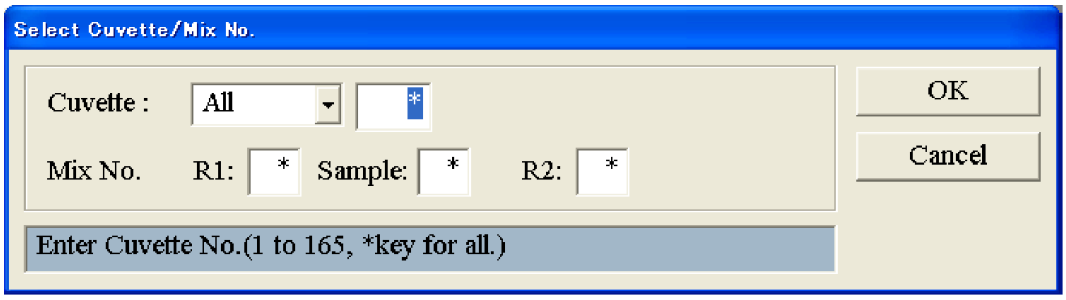
Sample No.: First column: "*" or approximate sample number.
Second column: "*" or approximate sample number.

TIP Check only one sample kind at a time so it is easier to identify the approximate first Sample No. required to search. Perform this check one sample kind at a time for all the sample kinds measured in the index.

TIP If there is a large number of samples in the sample kind checked to search, the search takes a long time. Enter an approximate starting (first column) and ending (second column) Sample No. to search to reduce the search time. For example, the maximum number of photometric tests per 60 minutes is 1600. If the average number of tests per sample is 8, the approximate number of samples processed per 60 minutes is 200 samples. Searching the last 220 samples (200 plus 10%) should be sufficient to find the results. If the search does not contain samples measured for 60 minutes before the 4064 alarm was generated, it is necessary to increase the range of samples to search and perform the search again.

20 If **Inner** or **Outer** displays in the Cuvette field, select **Cuvette/Mix No. (F7)**.

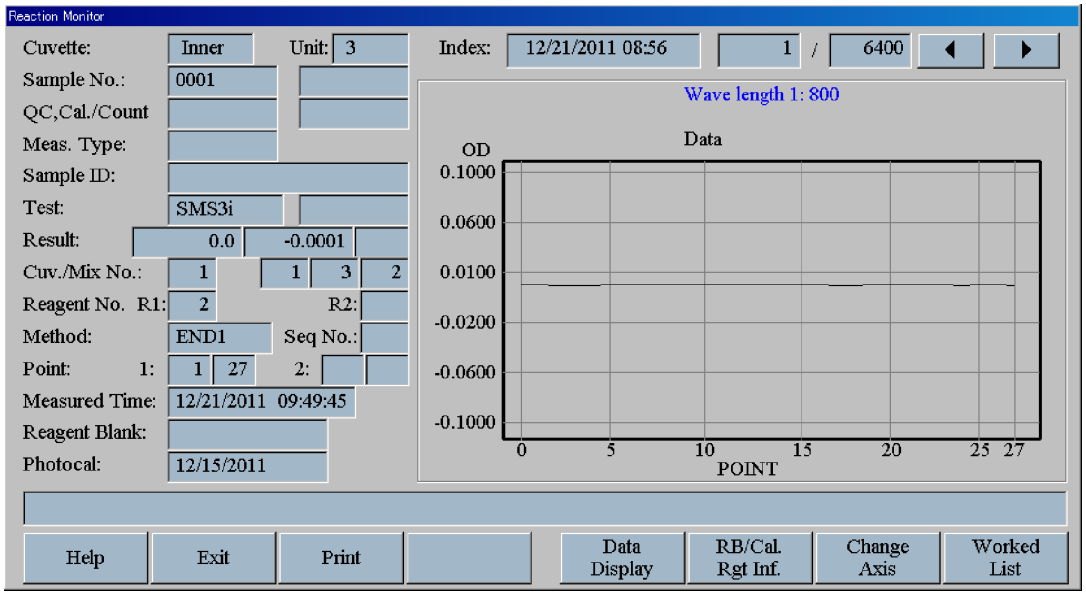
Figure 4.24



- Select **All** from the "Cuvette" drop-down list.
- Do not change the "*" at Mix No. for R1, Sample, and R2.
- Select **OK**.

21 Select **Search Data (F5)**.

Figure 4.25



22 Use the arrow buttons and look at the Measured Time to find the first Sample No. measured after the time obtained in step 10.

23 Note the Sample No.

24 Repeat steps 18 through 22 for all the sample kinds (Routine, Emergency, or STAT) for Serum, Urine, Others, QC, reagent blank, and calibration.

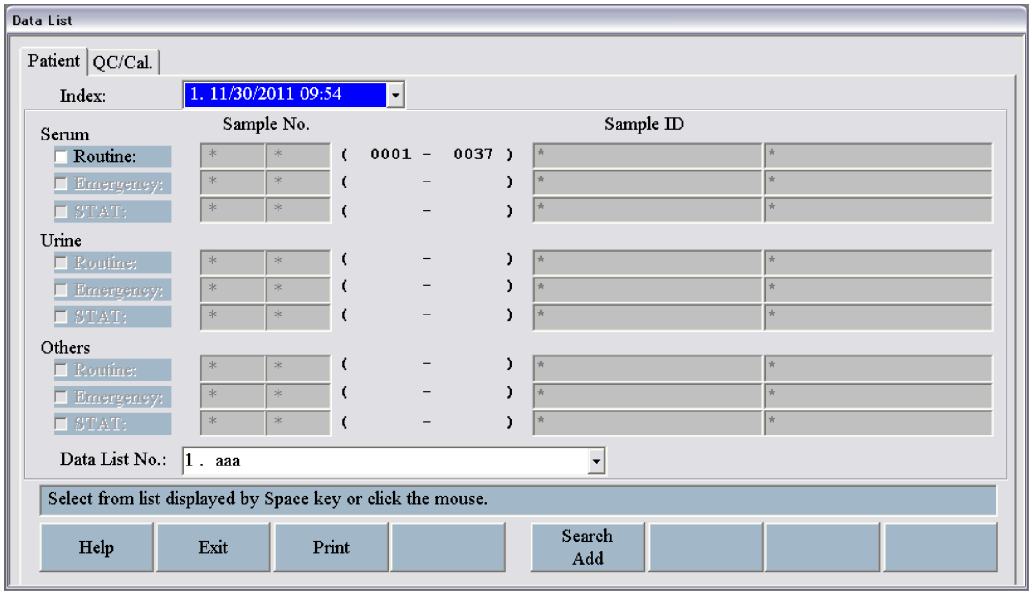
TIP It is necessary to select the **Cal/QC** tab to search for reagent blank, calibration, and QC results.

25 Select **Exit (F2)** to go back to the Reaction Monitor screen.

26 Select **Exit (F2)**.

27 Select **Routine** > **Data Report** > **Data List**.

Figure 4.26



28 Select the check box for all the sample kinds (Routine, Emergency, or STAT) for Serum, Urine, and Others measured in the index. STAT is applicable only for the AU2700.

29 Enter the first Sample No. (first column) identified in the previous steps for each sample kind. Keep "*" as the last Sample No. (second column).

30 Select **Print (F3)**.

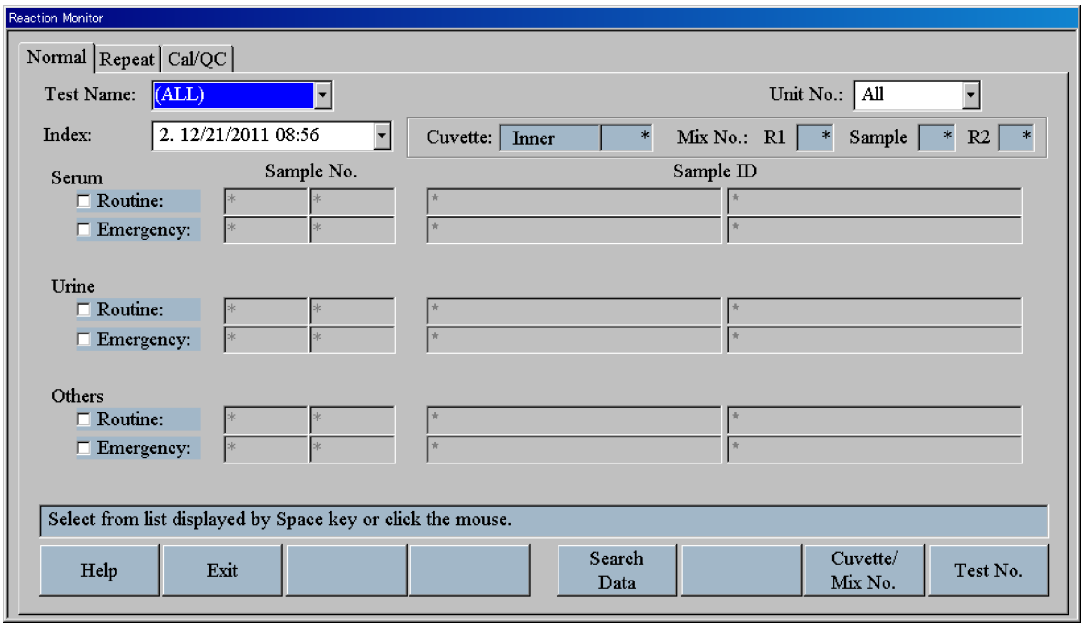
The results measured after the previous SMS test before the SMS test that generated the "*" flag and 4064 REACTION PROFILE CHECK alarm print. These results may be affected by the cuvette overflow and are invalid. Analyze these samples again.

31 Select **Routine > Data Report > QC/Cal** tab and repeat steps 27 through 29.

4.1.4 Searching for Samples if the SMS test is a Routine Sample for Condition B

1 Select **Routine > Reaction Monitor > Normal.**

Figure 4.27



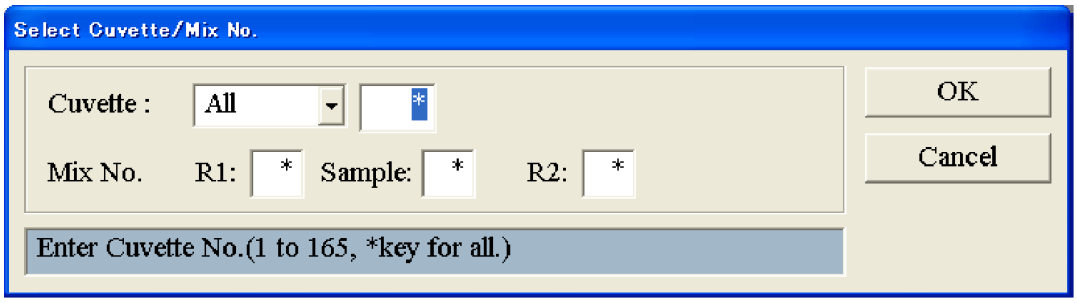
2 Select the SMS test that generated the 4064 alarm from the "Test Name" drop-down list.

3 For the AU5400 only, select the unit number that generated the 4064 alarm from the "Unit No." drop-down list.

4 Select the last Index from the "Index" drop-down list.

5 Select **Cuvette/Mix No. (F7).** The Select Cuvette/Mix No. window appears.

Figure 4.28

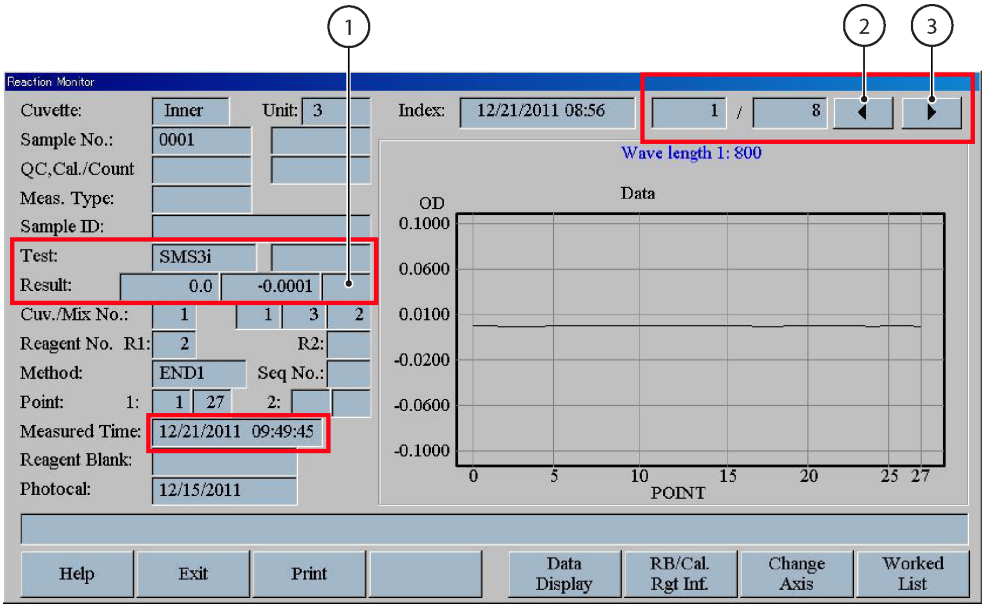


6 Select **Inner** or **Outer** that generated the 4064 alarm from the "Cuvette" drop-down list, then select **OK**.

7 Select (check the box) for Routine for the user-defined SMS sample type in use.

8 Select **Search Data (F5)**. The Reaction Monitor window appears.

Figure 4.29



1. Flag Display field
2. Backward arrow
3. Forward arrow

9 Select the forward arrow button to go to the last result (SMS test with the "*" flag). In this example, go to result 8/8.

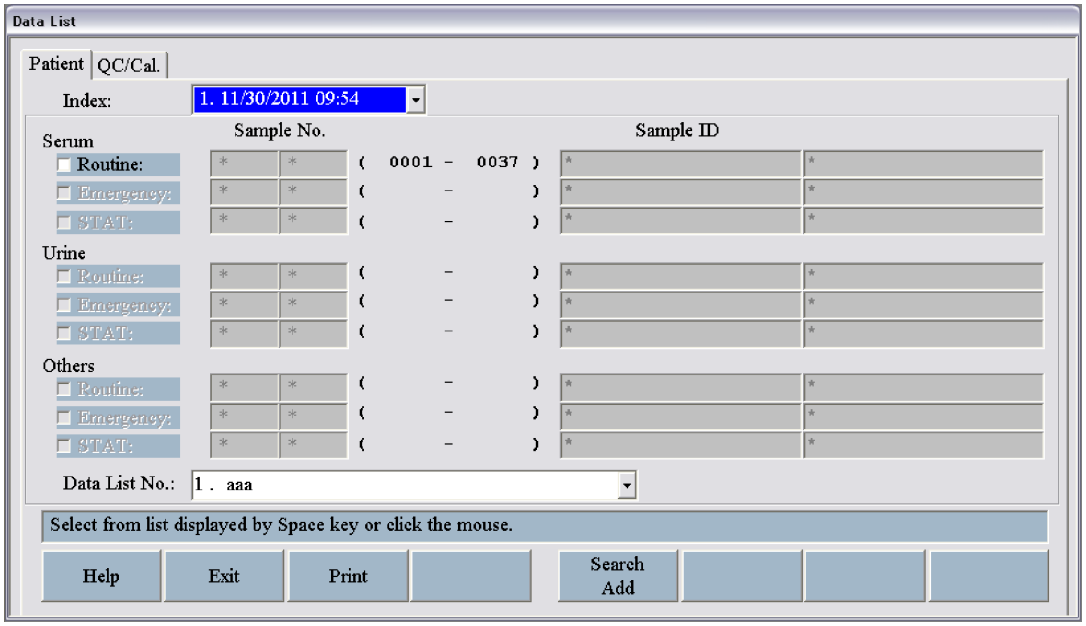
10 Select the backward arrow button to go to the previous SMS test that did not have a "*" flag. The "*" flags displays after the Result.

11 Note the Measured Time.

12 Select **Exit (F2)**.

13 Select **Routine** > **Data Report** > **Data List** > **Patient**.

Figure 4.30

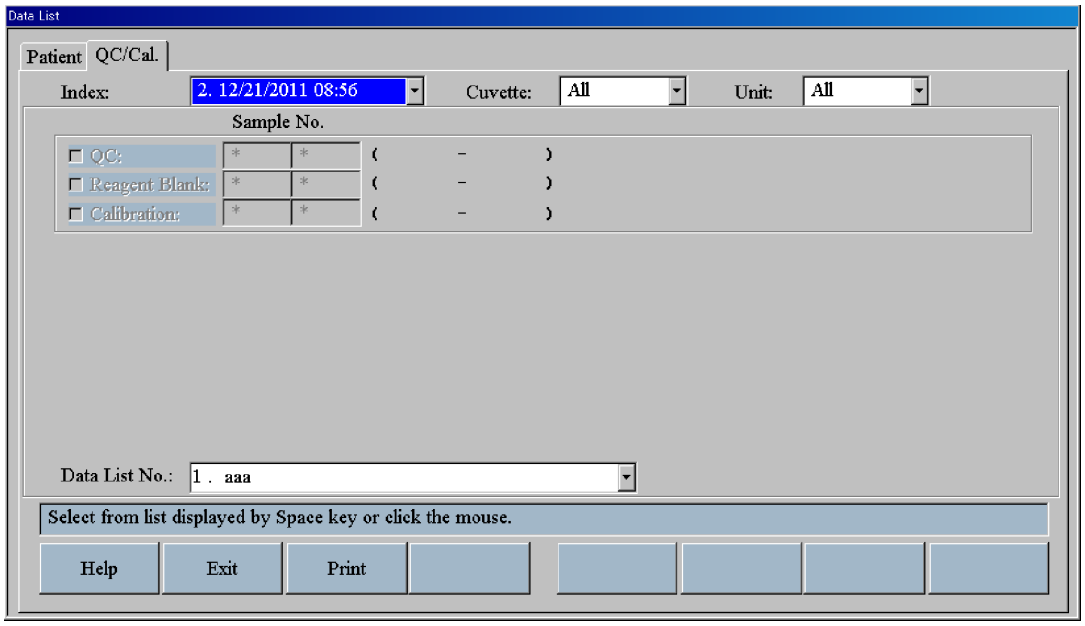


14 Select the index containing the 4064 alarm that was generated from the "Index" drop-down list.

Note the sample numbers of each sample kind (Routine, Emergency, or STAT) for Serum, Urine, or Others measured in the index. STAT is applicable only for the AU2700.

15 Select **Routine > Data Report > Data List > QC/Cal**.

Figure 4.31



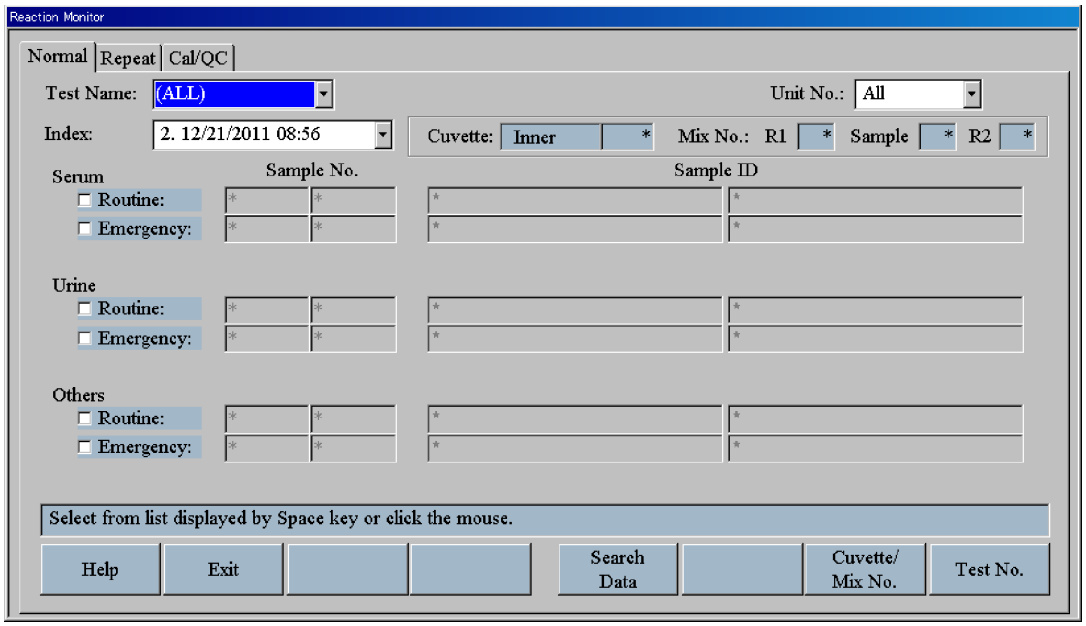
16 Select the index containing the 4064 alarm that was generated from the "Index" drop-down list.

Note the sample numbers of all QC, reagent blank, and calibration samples analyzed in the index.

17 Select **Exit (F2)**.

18 Select **Routine** > **Reaction Monitor**.

Figure 4.32



19 Select the following fields:

Test Name: (All).

Unit No.: Only for the AU5400. The unit number that the 4046 alarm generated.

Index: The index that the 4064 alarm generated.

Check box: Check one sample kind (Routine, Emergency, or STAT) for Serum, Urine, or Others measured in the index. STAT is applicable only for the AU2700.

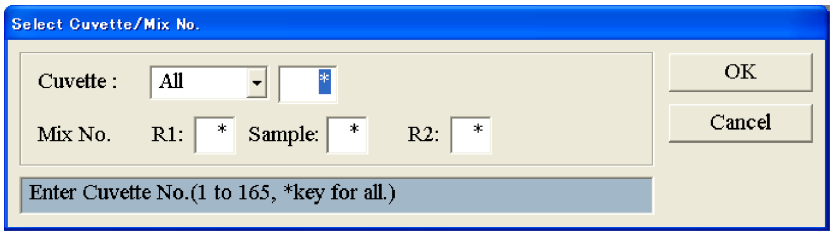
Sample No.: First column: "*"

Second column: "*"

TIP Check only one sample kind at a time so it is easier to identify the approximate first Sample No. required to search. Perform this check one sample kind at a time for all the sample kinds measured in the index.

20 If **Inner** or **Outer** displays in the Cuvette field, select **Cuvette/Mix No. (F7)**.

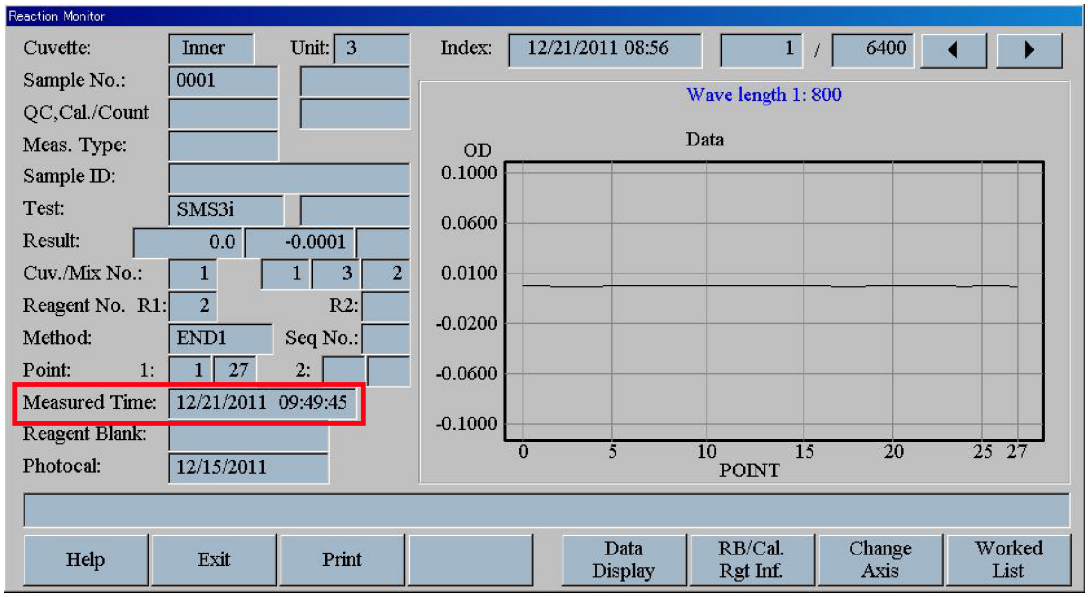
Figure 4.33



- Select **All** from the "Cuvette" drop-down list.
- Do not change the "*" at Mix No. for R1, Sample, and R2.
- Select **OK**.

21 Select **Search Data (F5)**.

Figure 4.34



22 Use the arrow buttons and look at the Measured Time to find the first test measured after the time obtained from step 10. Note the sample number, test name, and sample ID.

23 Select the forward arrow button to go to the next test. Note the sample number, test name, and sample ID.

24 Repeat step 22 up to the last result. In this example, the last result is 6400/6400.

25 Select **Exit (F2)**.

26 Select **Routine > Reaction Monitor > QC/Cal** and repeat steps 18 through 24.

27 All results from samples identified in this procedure are invalid and must be re-analyzed.

CHAPTER 5

As Needed Maintenance

This chapter contains a new as needed maintenance procedure to perform after a cuvette overflow.

5.1 Clean the Cuvettes, Cuvette Wedges, and the Cuvette Wheel after an Overflow

5.1.1 Remove the Cuvette Wheel and Cuvettes

5.1.2 Clean the Cuvettes

5.1.3 Replace the Cuvette Wheel into the Incubation Bath

5.1 Clean the Cuvettes, Cuvette Wedges, and the Cuvette Wheel after an Overflow

Erroneous data is generated if the cuvettes become wet on the outside (cuvette overflow). The reaction of the sample and reagents takes place in a carefully controlled dry incubation bath. Water on the outside of the cuvette affects the light as it passes through the cuvette. Test results are impacted due to this change in absorbance. It is important to recognize when an overflow has occurred, determine the cause for the overflow, and follow the appropriate procedures to recover from an overflow. For additional information, refer to the Troubleshooting Chapter, 4.1 Recovering from a Cuvette Overflow in this addendum.

Materials needed for this procedure:

- 2% Wash Solution
- Cotton tipped applicators
- Sonicator
- Clean, dry lint-free cloth
- #2 Philips head screwdriver
- Large plastic containers to hold cuvette wedges
- Plastic containers to hold cuvettes in the sonicator

5.1.1 Remove the Cuvette Wheel and Cuvettes

1. Verify that the analyzer is in *Warm up* or *Standby*.

   TIP The AU2700 is a single unit system. The AU5400 has a two or three unit configuration.

2. Open the rear cover of the affected unit.

   ⚠ CAUTION

   Ensure the cover is open and secured before leaning over the wash nozzle unit.

3. Loosen the knob on the wash nozzle unit. Support the wash nozzle unit when removing it from the base so that it does not come into contact with the cuvettes, and hang it on the hook.

4. Open the upper cover of the unit.

5. Remove any mix bars positioned over the cuvette wheel. Pull the mix bars up and out. Be careful not to scratch the mix bars.

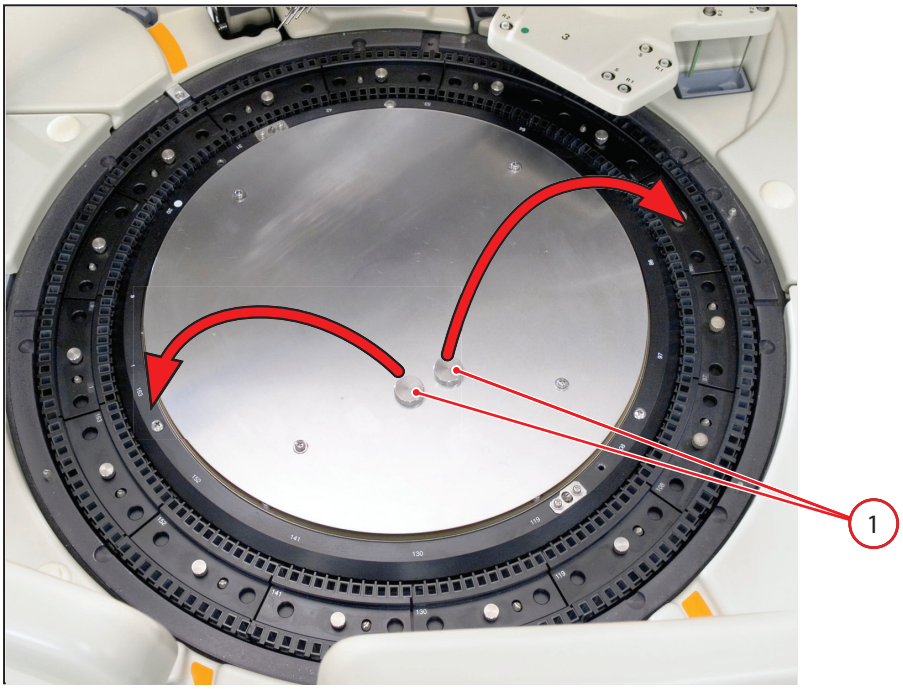
6 Remove the small cuvette wheel cover, and then remove the large cuvette wheel cover. It may be necessary to angle the cover slightly to clear the mix unit.

TIP When removing the cuvette wheel cover, be careful not to scratch or bump the sample probes, reagent probes, or mix bars.

7 Locate the 2 large, flat screws on the metal plate in the center of the cuvette wheel.

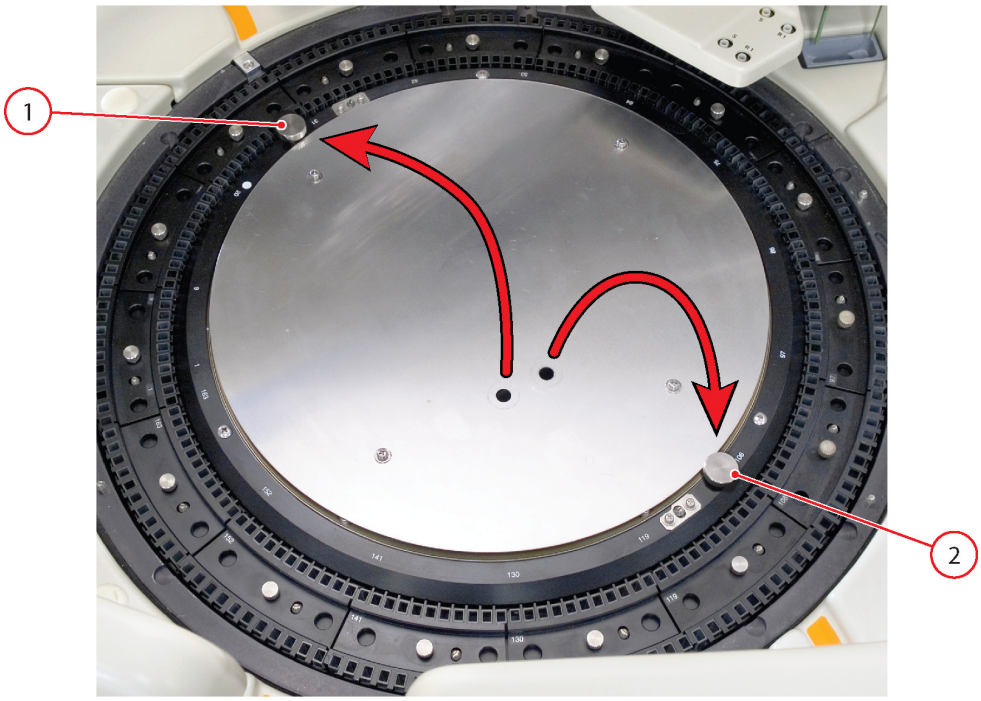
8 Remove these two large flat screws. These screws are used as "handles" to remove the cuvette wheel from the incubation bath.

Figure 5.1



1. Flat screws

Figure 5.2



1. Flat screw
2. Flat screw

9 Attach the flat screws to the frame of the cuvette wheel. Place one of the screws into the opening on the wheel in front of cuvette number 28. Place the other screw into the opening on the wheel in front of cuvette number 111. Firmly tighten each screw into the cuvette wheel.

10 Using the “handles” (large, flat screws), carefully pull the cuvette wheel off of the two metal positioning pins. It may be necessary to angle the frame slightly to clear the mix unit.

TIP Loosen the screws on all 15 wedges, and then lift out each individual wedge before removing the cuvette wheel to make the cuvette wheel lighter and easier to remove.

11 Place the cuvette wheel on a protected work surface. Loosen the screws on all 15 wedges, and then lift out each individual wedge.

⚠ CAUTION

Do not touch the photometric face (clear side) of the cuvette when removing the cuvette wedge.

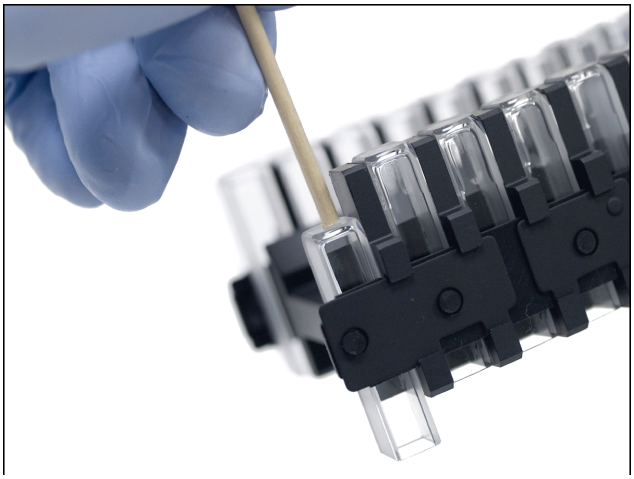
Figure 5.3

12 Place the cuvette wedge upside down on the protected surface to remove the cuvettes. Use your finger or the reverse end of a cotton-tipped applicator stick to gently push the cuvettes out of the wedge. Remove all 330 cuvettes.

⚠ CAUTION

The cuvettes may be scratched when they are removed from the wedge and subsequently will not pass the photocal.

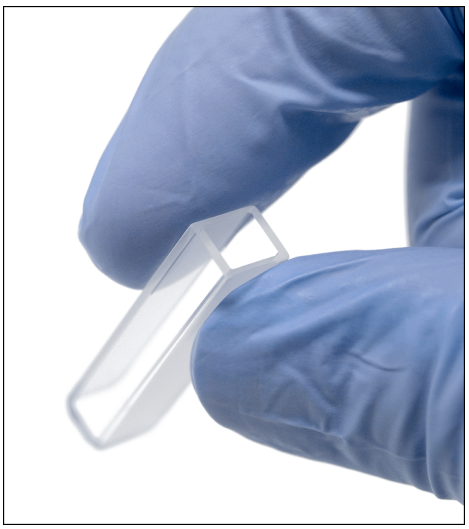
Figure 5.4



⚠ CAUTION

Do not touch the photometric (clear) side of the cuvette. Handle by the frosted side only.

Figure 5.5



5.1.2 Clean the Cuvettes

1 Submerge all cuvettes in a plastic container filled with 2% Wash Solution. If a sonicator is not available, soak the cuvettes in a 5% Wash Solution overnight.

2 Thoroughly rinse the cuvettes in deionized water, or sonicate them in deionized water for 10 minutes to remove any residual Wash Solution.

3 Allow the cuvettes to dry completely. Use one of the following methods:

- Allow cuvettes to air dry.
- Use an oven with the heat set below 50 °C (122 °F). A hair dryer works well.
- Use a lint free cloth.

⚠ CAUTION

Do not use Wash Solution or any detergent to clean the cuvette wedges or wheel. Use only DI water. The metallic plating on the wedge or wheel may be removed if Wash Solution or any other detergent is used.

4 Rinse the frame of the cuvette wheel and cuvette wedges with DI water only.

5 Dry the frame and wedges thoroughly with a lint free cloth.

6 Dry the incubation bath with a lint free cloth.

7 Replace all 330 cuvettes (with the open end facing up) back into the cuvette wedge. Ensure the cuvette is pushed down completely into the wedge.

⚠ CAUTION

Do not touch the photometric side of the cuvette. Handle by the frosted side only.

Always replace any cuvettes removed from the cuvette wedge. If a cuvette is missing, reagent and/or sample will cause an overflow in the cuvette wheel.

8 Replace all wedges into the cuvette wheel frame. Match the number on the wedge to the number listed on the frame. Match the hole on the wedge with the guide pin for proper placement.

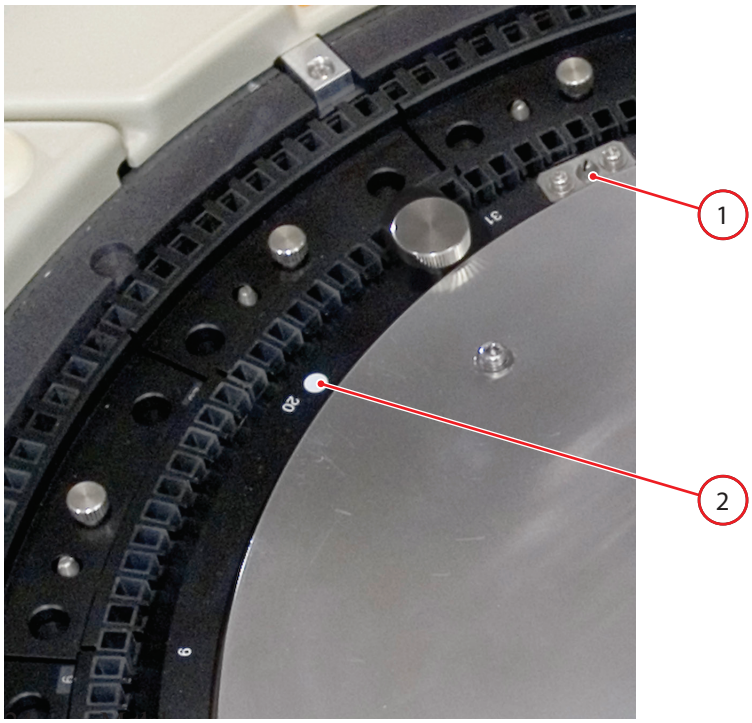
9 Screw the wedges back into place.

TIP Replace the cuvette wheel into the incubation bath before replacing the wedges into the cuvette wheel frame to make the cuvette wheel lighter and easier to replace.

5.1.3 Replace the Cuvette Wheel into the Incubation Bath

1 Use the “handles” (large, flat screws) to place the cuvette wheel back into the incubation bath. It may be necessary to angle the wheel slightly to clear the mix unit.

Figure 5.6



1. Positioning Pin
2. Alignment indicator

2 Match the white alignment indicator on the cuvette wheel with the white indicator on the analyzer unit. When the alignment is correct, the cuvette wheel can be set onto the two metal positioning pins.

3 Loosen the two “handles” (large, flat screws) and set them in the openings on the metal plate in the center of the cuvette wheel.

4 Replace the large cuvette wheel cover by matching the hole in the cover with the pin on the analyzer unit and then replace the small cover matching the green dot on the cover with the green dot on the analyzer unit.

⚠ CAUTION

Be careful not to scratch the mix bars when inserting them into mix unit.

5 Remove the wash nozzle unit from the hook and carefully place it on the wash nozzle unit base so it does not come into contact with the cuvettes. Align the holes on the wash nozzle station over the two positioning screws on the base and tighten the knob. Verify that all tubing and tube mounting joints are connected to the nozzles and joint manifolds. Refer to the "Replace the Wash Nozzle Joint Tubes" in the As Needed Maintenance section in the *AU2700 or AU5400 User's Guide* for correct tubing placement in case any lines are disconnected.

6 Replace all mix bars that were removed. Place the correct mix bars in the designated location (R2 = green dots). Insert the mix bars into the top of the mix unit. While inserting the mix bar, rotate it slightly to engage the flat portion of the mix bar with the gear of the unit.

⚠ CAUTION

Do not force the mix bar into the unit. Damage to the gears may occur.

7 Select **Maintenance** > **ANL Maintenance**.

TIP The AU2700 does not have an option to select a unit.

8 Select the appropriate analyzer unit number and **A/Prime Washing-line**.

9 Press the DIAG switch on the selected unit. The wash nozzle unit moves up and down and is primed with DI water.

10 Repeat the previous step several times until air is removed.

11 Check for leaks around the wash nozzle unit and then close the rear and upper covers.

12 Perform a Photocal on the affected unit. Refer to the Photocal procedure in the Maintenance chapter of the *AU2700 or AU5400 User's Guide*.