Users Guide Vol. 2

AU400e®/AU400®

Chemistry Analyzer

For *In Vitro* Diagnostic Use

CE

BM400V2 AB
JUNE 2013

Beckman Coulter, Inc.
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Brea, CA 92821 U.S.A.

BECKMAN COULTER®

AU400e® /AU400® Chemistry Analyzer
User's Guide
PN BM400V2AB (JUNE 2013)

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Introduction

This chapter includes detailed information about the maintenance required for each system component. To ensure data is accurate, perform maintenance on schedule, and keep a record on the maintenance/inspection check lists provided in this chapter.

Caution

Follow laboratory safety guidelines when performing maintenance procedures. Observe all warning and caution instructions listed in the following procedures. Also, do not place any body parts in the path of moving equipment, unless you are certain that the analyzer is in Stop or Standby and that diagnostic functions are not activated.

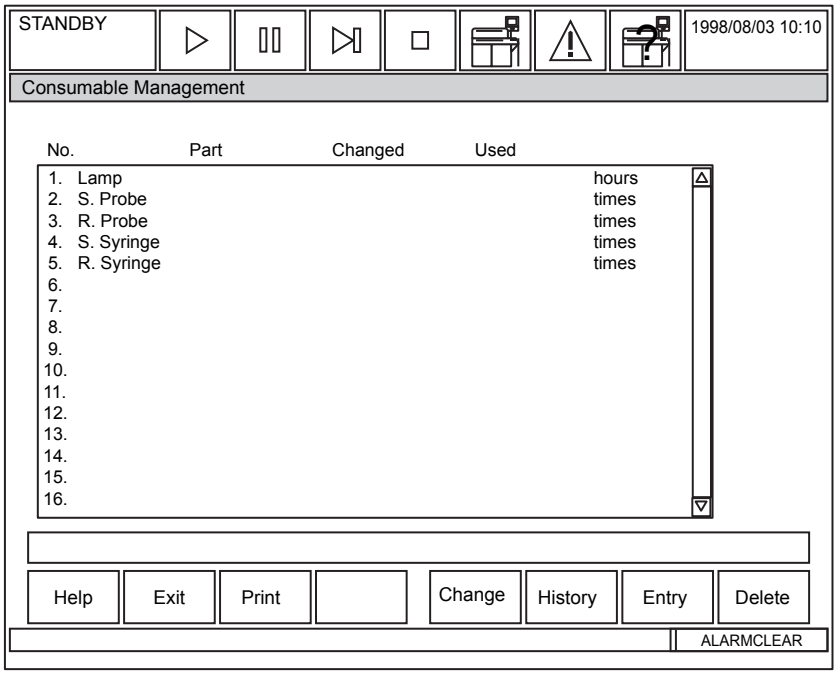
Chapter F Maintenance

1. Maintenance Schedules and Preparation

Periodic Maintenance

- Record on-line maintenance records in [Maintenance], [Periodic Maintenance].
- To display a maintenance schedule, select F5 Grid Display.
- To update the maintenance schedule, place the cursor on a maintenance item and select F5 Execute. The analyzer must be in a standby mode.
- To display the last 10 dates maintenance was performed and the next date due, select F6 History.
- To add additional maintenance items to the Periodic Maintenance schedule, select function key F7 Entry. Beginning with line 37, scroll to a blank line and click to highlight it. Select F7 Entry and type in the name of the maintenance item. Select the scheduled interval (days, weeks, months, or years) from the pull-down menu called “period unit.” Enter a number in the period option for the assigned time. To add another maintenance item, select the ►button and repeat the previous steps. When all maintenance items are added, select the close button.
- To obtain a printout of the maintenance records, select F3 Print.

Consumable Management



- Track critical components through Consumable Management for timely warranty replacement.
- Record consumable items on-line in [Maintenance], [Consumable Management].
- Place the cursor on a consumable item to update. The item is highlighted in blue. Select F5 Change. The consumable management window displays. At the prompt “Renewal OK?” select OK for the changed item. A record of the time period an item is used is then tracked.
- To view a listing of the last 10 times an item was changed and how long the item was used, select function key F6 History

- To add additional consumable items to Consumable Management, select F7 Entry. Beginning with line 14, scroll to a blank line and select it. Select F7 Entry, then type in a consumable name. Next, select a time unit (days, weeks, months, or years) from the pull-down menu called "unit." Enter a number in the lifetime option for the assigned time. To add another consumable item, select the ► button and repeat the previous steps. After all consumable items are added, select the close button.
- To obtain a printout listing the last 10 dates an item was changed, select F3 Print.

Additional Instruction

- Please see additional instruction on maintenance procedures in the maintenance videos available within online help.

Preparation of Solutions for Maintenance Procedures:

Bleach (Sodium hypochlorite) and Beckman Coulter Wash Solution are recommended for all cleaning procedures related to the Beckman Coulter Chemistry-Immuno systems. Deviations from related procedures or use of any other solutions should be evaluated by the institution to ensure proper performance and compatibility with Beckman Coulter systems.

Bleach

For the purposes of maintenance procedures on Beckman Coulter Chemistry-Immuno systems, undiluted bleach is defined as 5-10% Sodium hypochlorite, and may also contain up to 0.5-1% Sodium hydroxide. Many brands of liquid household bleach contain impurities or lack sufficient concentration of sodium hypochlorite for cleaning. Consequently, only the following should be used. Do not use scented formulations of these products:

- Clorox®
- Javex-5™
- Reagent grade or other purified preparations of sodium hypochlorite

Prepare working concentrations by mixing bleach and DI water in the following proportions:

Concentration	Volume of Clorox		Volume of DI Water
10%	10	+	90
20%	20	+	80

NOTE: *Sodium hypochlorite quickly loses its germicidal action upon exposure to light, therefore, all dilutions should be made daily and in an area away from direct light. A 24-hour preparation of this solution under an average fluorescent light environment is not sufficient to cause degradation of the solution, provided the solution is placed into a closed container. Clear containers are suitable for 24-hour storage of this solution.*

Beckman Coulter Wash Solution

The catalog numbers for this product are OSR0001 and ODR2000.

Prepare working concentrations by mixing wash solution and DI water in the following proportions:

Concentration	Volume of Wash Solution		Volume of DI Water
1%	1	+	99
2%	2	+	98
20%	20	+	80

Month _____ Year _____

DAILY ANALYZER	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
2.1 Inspect Sample and Reagent Syringes for leaks																															
2.2 Check Wash Solution Rolling Pump for leaks																															
2.3 Inspect concentrated wash solution level																															
2.4 Inspect and clean Sample & Reagent probes and Mix Bars																															
2.5 Inspect the Stability of the Upper Cover																															
2.6 Inspect printer and paper																															
2.7 Prepare for a Sample Probe wash																															
2.8 Change DI water in the pre-dilution bottle																															
DAILY ISE	**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**
7.1.1 Inspect the ISE Reagent Syringe for leaks																															
7.1.2 ISE Cleaning																															
WEEKLY ANALYZER	**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**
3.1 Perform a W2																															
3.2 Perform a Photocal																															
3.3 Perform a Photometer Check																															
3.4 Wash the Sample Pre-Dilution Bottle																															
WEEKLY ISE	**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**
7.2.1 Perform a Selectivity Check for the Na/K Electrodes																															

Month _____ Year _____

EVERY TWO WEEKS ISE	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
7.3 Clean the Mix Bars, Liquid Level Lensors, Sample Pot and Sample Pot tubing.																															
MONTHLY ANALYZER	**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**
4.1 Clean Sample and Reagent Probe Wash Wells																															
4.2 Clean Mix Bar Wash Wells																															
4.3 Clean Wash Nozzle, DI Water Tank and Filter, and Sample Probe Filter.																															
EVERY THREE MONTHS ANALYZER	**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**
5.1 Replace Wash Solution Rolling Tube																															
5.2 Clean Air Filters																															
EVERY THREE MONTHS ISE	**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**
7.4.1 Replace Mixture & Mid-standard Pump Roller Tubing (Part of 6 month PM. User must perform procedure alternately.)																															
7.4.2 Replace Valve Tubing (Part of 6 month PM. User must perform procedure alternately.)																															

Month _____ Year _____

AS NEEDED ANALYZER	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
6.1 Replace Cuvettes																															
6.2 Replace the Sample and Reagent Probes																															
6.3 Replace Mix Bars																															
6.4 Replace the Wash Nozzle Joint Tubes																															
6.5 Replace Sample and Reagent Syringes																															
6.6 Replace DI Water Filter (Part of 6 month PM)																															
6.7 Replace Sample Probe Filter (Part of 6 month PM)																															
6.8 Replace Photometer Lamp (Part of 6 month PM)																															
6.9 Clean the Cuvettes and the Cuvette Wheel (Part of 6 month PM)																															
6.10 Clean or Replace Individual Cuvettes																															
6.11 Perform a W1 Procedure																															
6.12 Clean Rack Feed Areas																															
6.13 Clean Wash nozzle unit																															
6.14 Clean Deionized-Water Tank																															
6.15 Clean Deionized-Water Filter																															
6.16 Clean Sample Probe Filter																															

Month _____ Year _____

AS NEEDED ISE	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
7.5.1 Replace the Reference Electrode																															
7.5.2 Add Reference Electrode Solution																															
7.5.3 Replace Reagents																															
7.5.4 Replace the Na, K, or Cl Electrode																															
7.5.5 ISE Cleaning Procedure																															

2. Daily Maintenance

To obtain accurate results and optimum system performance, be sure to perform the following daily maintenance procedures. Record maintenance on the schedules located at the beginning of this chapter. *Maintenance items can also be recorded on-line in the [Periodic Maintenance] screen.*

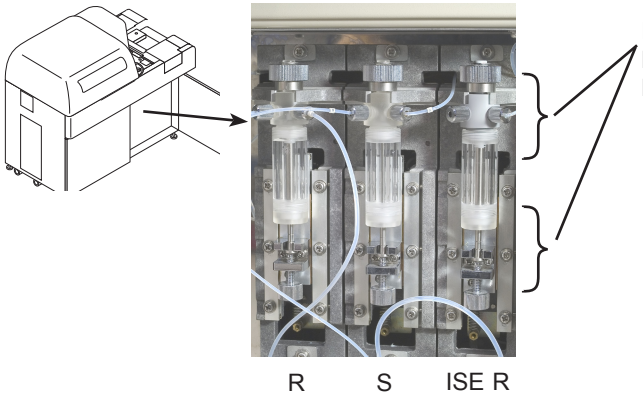
Caution

Do not place any body parts in the path of moving equipment, unless you are certain that the analyzer is in Stop or Standby and that diagnostic functions are not activated.

Contents

2.1 Inspect Sample and Reagent Syringes for Leaks

Before starting daily analysis, be sure to check the sample and reagent syringes for leaks or condensation on the syringe case. If condensation is present, check for proper installation and operation of the syringe. Check the sample and reagent syringes in the same procedure.



If condensation or leaks are visible, perform the following steps:

Caution

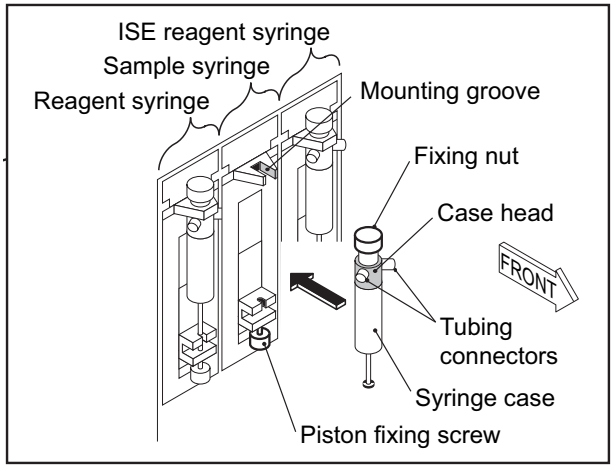
Do not place any body parts in the path of moving equipment, unless you are certain that the analyzer is in Stop or Standby and that diagnostic functions are not activated.

Daily Procedure

Prepare the following:

- Dry, clean cloth

1. Open the right front cover.
2. Check the following areas for leaks: bottom of the syringe cases, the case head, syringe case, area around the fixing screws and the tubing. (Also make sure the tubing is not crimped.)



See Also

For information about replacing and troubleshooting syringes, refer to the" As Needed Maintenance" section of this Chapter and the Troubleshooting Chapter.

Caution

If your skin comes in contact with liquid, immediately rinse it with water.

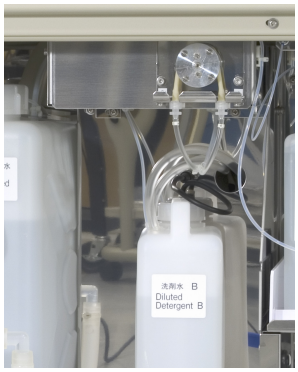
3. Check the two fixing screws on the case head. If necessary, tighten them by turning them clockwise.
4. Verify that the bottom screw fits securely against the piston.
5. Visually check for leaks inside the syringe case. *Replace any damaged component.*

To perform syringe verification for troubleshooting, perform the following steps:

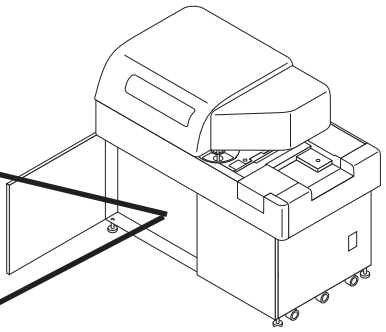
6. Loosen the bottom fixing screw *first*, then the top fixing nut. Pull the syringe and case forward.
7. Verify that the syringe provides a smooth, resistant pull by pulling on the piston.
8. Turn the syringe case by hand. *If the syringe case is loose, turn it clockwise toward the case head to tighten.*
9. Visually check each case head for cracks. *If there are cracks on the case head, replace the case head.*
10. Pull the syringe from the case head and verify that there is one O-ring, and that it is not damaged.
11. Re-install the syringe and secure the top fixing nut first, and then the bottom fixing screw. **Note:** Verify that the correct size syringe (reagent or sample) is placed in the appropriate position. To replace a syringe, refer to the "As Needed" section of this chapter.
12. Close the right front cover.

2.2 Check the Wash Solution Rolling Pump for Leaks

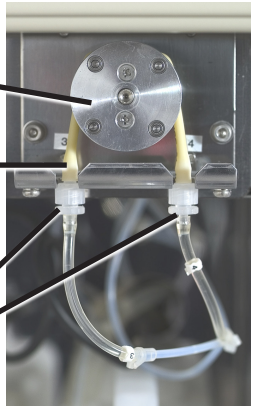
The wash solution rolling pump supplies concentrated wash solution to the wash solution tank. If the pump leaks, the concentrated wash solution may not be diluted properly. Check the wash solution rolling pump every day before starting analysis.



AU400e



AU400



Daily Procedure

Prepare the following:

- Dry, clean cloth

1. Place the analyzer in standby or stop.
2. Open the front left cover.

Caution

If your fingers come into contact with any liquid, immediately wash them with water. The wash solution pump dispenses concentrated wash solution.

3. Blot the pump with the dry clean cloth. If the pump is wet, blot until completely dry.
4. Visually check the wash solution rolling tube for cracks.
5. If cracks or other damage is found, replace the wash solution rolling tube.
6. Verify that the labels on the tube match the labels on the pump.

See Also

For rolling tube replacement procedures, refer to the section called "Maintenance Every Three Months."

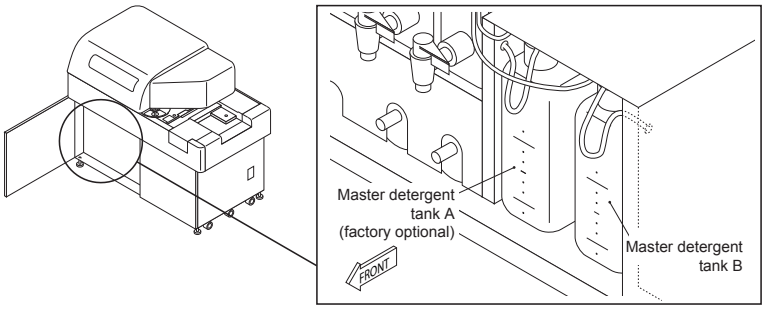
7. Check the tube connector. If it is loose, turn clockwise and make sure it is finger tight. Check for leaks again. If the tube still leaks, replace it.
8. Close the left front cover.

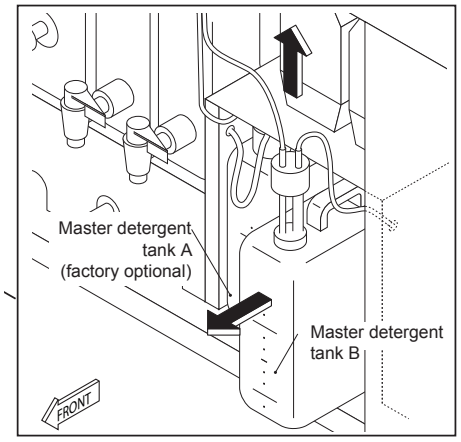
Note

AU400 analyzers contain two Wash Solution Rolling Pumps. AU400e analyzers contain one pump.

2.3 Inspect the Concentrated Wash Solution Level

Before starting daily analysis, check the wash solution level of the concentrated wash solution tank. Add an appropriate amount of concentrated wash solution to refill the tank. *If wash solution becomes low or empty during analysis, an alarm is generated and the analyzer shifts to a Pause Mode.*





Daily Procedure

Prepare the following:

- •

  Wash Solution (#OSR0001) for tanks A (factory optional) & B

1. Open the right front cover.

2. Visually check the wash solution level in tank A (AU400 only) and B (AU400 and AU400e). The concentrated wash solution should be replenished daily. The following consumption chart is based on 2,000 tests per day:

   Concentrated wash solution:

   Approx. 0.40 L/day

Adding Concentrated Wash Solutions

1. Pull the concentrated tank forward.

Warning

When removing the cap from the concentrated wash solution tank, do not allow your hands and clothing to come into contact with the wash solution. If contact occurs, immediately wash your hands with water for at least fifteen minutes and refer to the MSDS sheet. If wash solution comes into +contact with your eyes or it is ingested, immediately rinse with water, avoid vomiting and consult the MSDS sheet.

2. Loosen the wash solution tank cap, then pull out the liquid-level sensor and the cap.
3. Take out the concentrated wash solution tank.

Warning

- If the wash solution spills, wipe it up immediately with a dry cloth. If the wash solution is not wiped up, a toxic gas may be generated and system components could corrode.
- Be sure to use the correct wash solution (OSR0001).

4. The capacity of each bottle is 2 liters. Either replace the bottle with a new one, or add concentrated wash solution to the existing bottle if it is not completely empty.
5. Insert the liquid-level sensor into the concentrated wash solution tank and tighten the cap.
6. Push the tank back into position.
7. Close the right front cover.

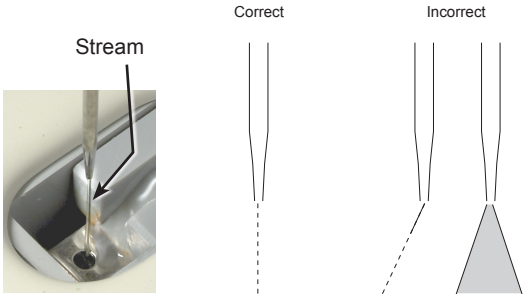
2.4 Inspect and Clean Sample Probe, Reagent Probe, and Mix Bars

If problems are found with the sample probe, reagent probe, or mix bars, performance may be affected. Before starting daily analysis, check that the sample probe, reagent probe, and mix bars are operating properly. Also check the outside of each part for stains and crystallization. Clean the parts with an alcohol wipe if necessary.

Daily Procedure

■ **Inspect for Normal Operation**

1. Open the upper cover.
2. Put the analyzer in Warm-up or standby.
3. Select [Maintenance], [ANL Maintenance].
4. Select “F/Prime Washing-line.”
5. Press the STAT ROTATION/DIAG button. The DI water will be dispensed from each probe. *The mix bars are washed and rinsed, the wash nozzle unit will do a sequence.*
6. Observe the stream of DI water coming from the sample and reagent probes. Verify that the wash wells fill with water. *If DI water sprays or does not dispense in a straight line from the probe tips, clean the probe tip with an Alcohol Prep pad. A Stylet may be used if problems still occur* ***after*** *wiping reagent probe tip.*



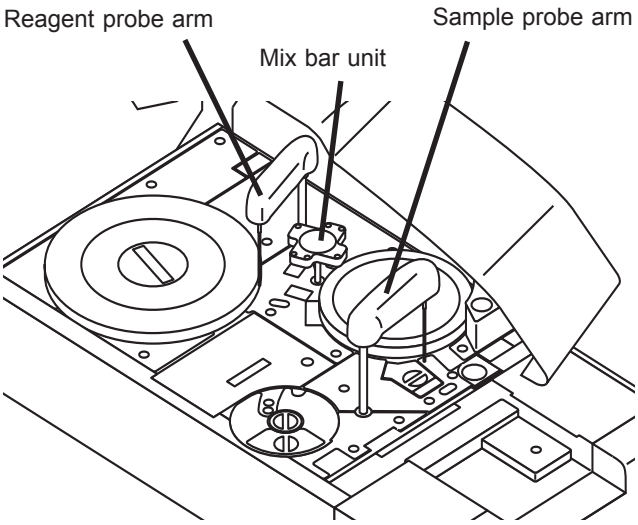
7. Close the upper cover.
8. Optional Step: For inspection and cleaning procedures, refer to the following.

See Also

For replacement procedures, refer to the "As Needed Maintenance" section of this chapter.

■ **Inspecting and Cleaning the Sample Probes, Reagent Probes, and Mix Bars**

1. Inspect the probes and mix bars. If there is staining or crystallization on the outside of the sample probe, reagent probe, or mix bars, clean the part with an Alcohol Prep.



Instruction

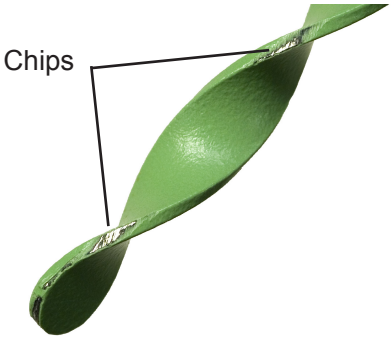
Exercise care not to bend the sample probe, reagent probe, or mix bars during cleaning.

2. Visually check the sample probe, reagent probe, and mix bars for bends or scratches.

   If they are bent or scratched, replace them.

Caution

Replace the mix bar if there are chips in the teflon coating. Chipped Mix Bars can cause carry-over and inaccurate results.

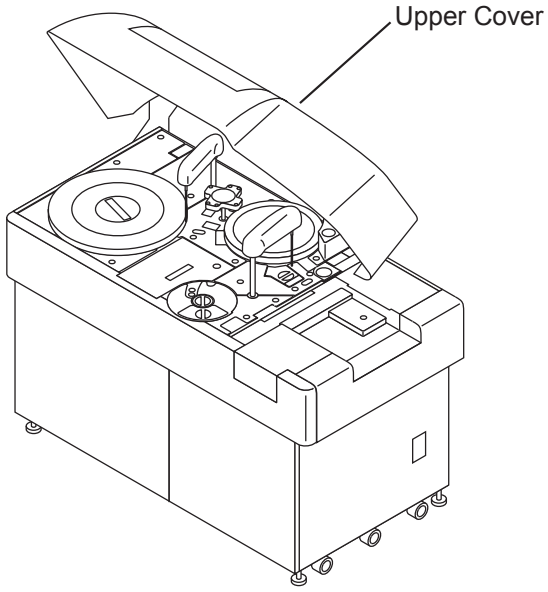


See Also

For information about how to replace the sample or reagent probe or mix bars refer to the "As Needed Maintenance” section of this chapter.

2.5 Inspect the Stability of the Upper Cover

Before starting daily analysis, check the stability of the upper cover of the analyzer to verify that it is stable and remains in the upright position when raised. If the upper cover starts to descend when opened, have the cover supports inspected and replaced by Beckman Coulter authorized personnel.



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2.6 Inspect the Printer and Paper

Before starting daily analysis, check the amount of paper in the printer. Check that the printer is on and paper is loaded. If the printer paper is depleted during analysis, or if the power to the printer is turned off, an error will result. During the error, data transferred to the printer will not be printed.

See Also
For information about how to use the printer, refer to the operator's manual supplied with the printer.

Daily Procedure

Prepare the following:

- Printer paper

1. Check that the printer is on. *If not, turn on the power to the printer. Make sure that the printer is online.*
2. Check that the paper is loaded correctly and that a sufficient amount of paper remains. If the paper is not loaded correctly, reload it.

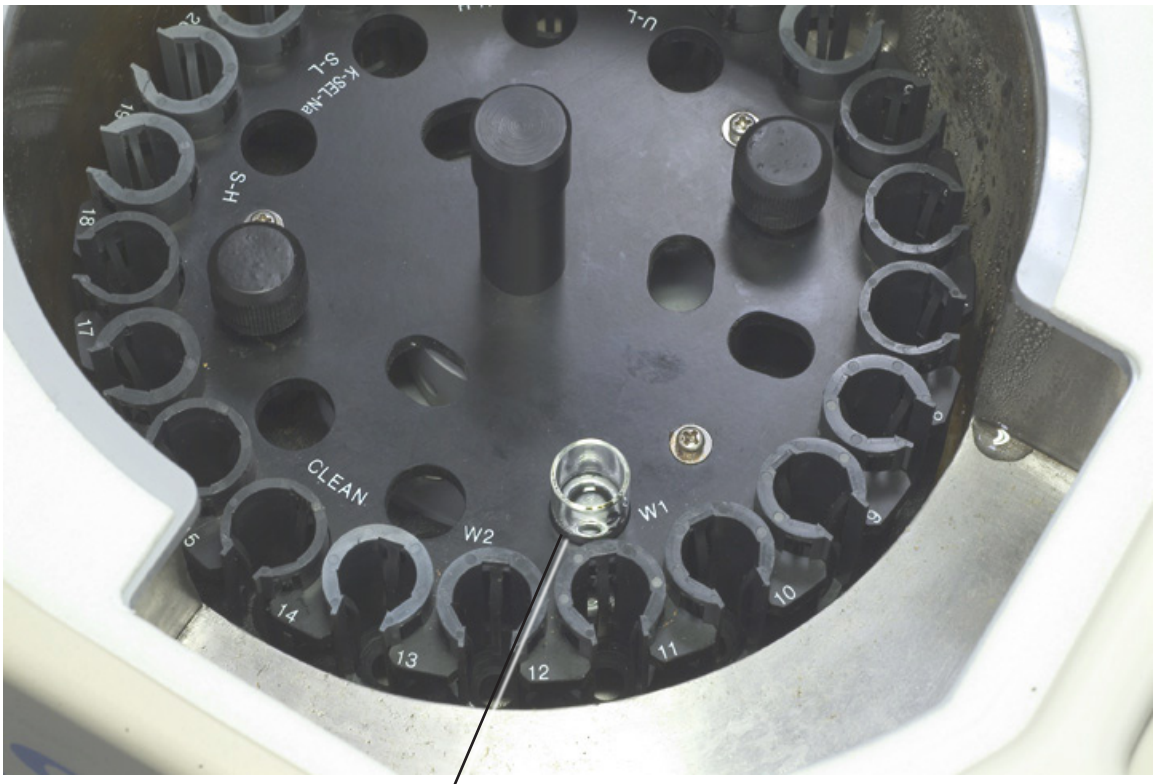
See Also
For information about remedies for printer problems and how to load the paper, refer to the operator's manual supplied with the printer.

2.7 Prepare for a Sample Probe Wash

Place a tube of 2% diluted wash solution (product number OSR0001) in the W1 (Wash 1) position on the STAT table. *When the analyzer shifts from Standby to Measure 1, the sample probe will automatically go into the wash solution tube 5 times to be cleaned. If wash solution is not on the STAT table in the W1 position, a "Sample Probe Detergent Short" alarm will be generated. The probe is cleaned during the Measure 4 Mode after analysis is complete.*

Note:

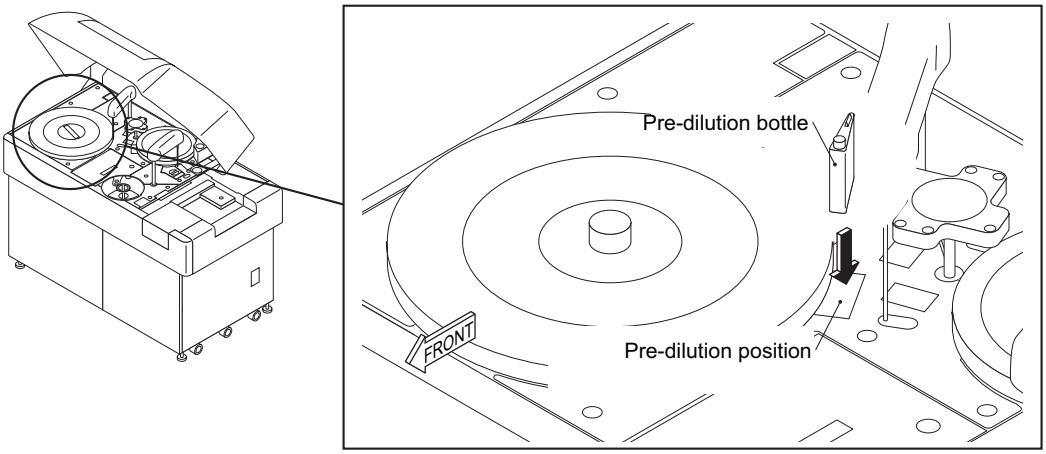
By following good lab practice and ensuring a clean, sealable container is used, diluted OSR0001 can be prepared ahead of time. Diluted OSR0001 is good for 6 months from the date of preparation.



W1 Position

2.8 Change DI water in the Pre-dilution Bottle

Before starting daily analysis, rinse the sample pre-dilution bottle with DI water twice then fill it with fresh DI water.



Caution

Place the bottle in the compartment so it does not protrude above the surface of the analyzer top. If it is not placed properly, reagent probe crashes could occur. Also, do not place the cap on the bottle when it is on the analyzer, This also causes probe crashes.

3. Weekly Maintenance

To obtain accurate results and optimum system performance, be sure to perform the following weekly maintenance procedures. Record maintenance on the schedules located at the beginning of this chapter. *Maintenance items can also be recorded on-line in the [Periodic Maintenance] screen.*

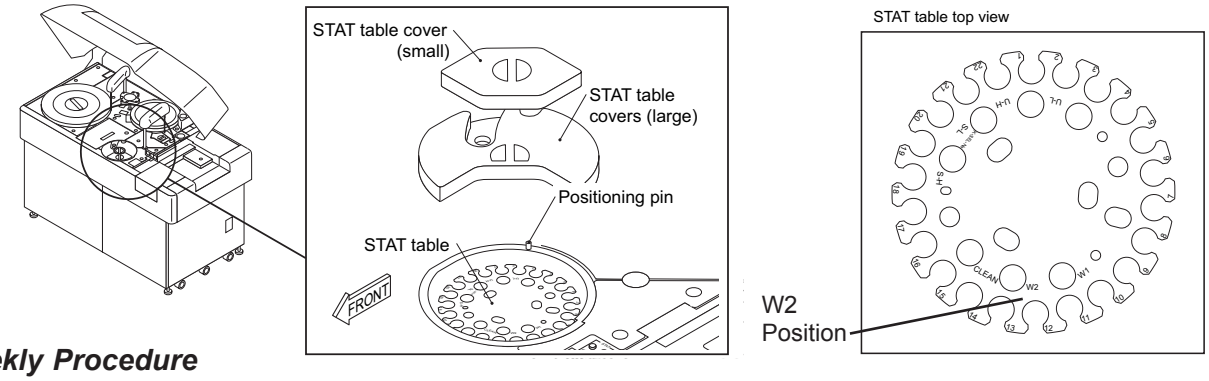
Contents

3.1 Perform a W2 (Washes Cuvettes, Mix Bars, Reagent Probes, and Waste Lines)

If the sample probes, reagent probes, mix bars, and cuvettes are contaminated, appropriate analysis results will not be obtained. The W2 prepares the cuvettes for the photocal by thoroughly cleaning them. Perform a photocal to check the integrity of the cuvettes. The photocal can be performed after the W2 automatically by selecting this option when executing the W2.

Note

The W2 can be performed in conjunction with an End Process. Start the W2, wait until W2 displays in the mode area. Verify that the system does not indicate “insufficient detergent? by allowing the timer to reach 24 minutes. Exit System Status to Main Menu, then select the End Process key. The system can be programmed to perform an automatic on with a Photocal, or a photocal can be performed immediately after a W2.



Weekly Procedure

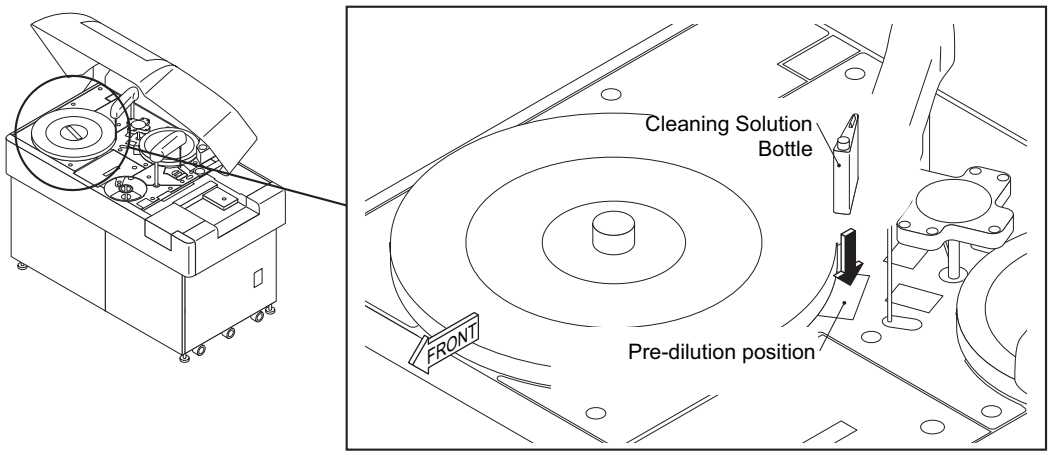
Prepare the following:

- Cleaning solution bottle (Empty 60ml reagent bottle.)
- Sample containers for W2 position on Stat Table (part #ZM0062).
- 60 mL 1N HCl or
  60 mL of 10% bleach
  ISE Cleaning Solution: Optional for performing Daily ISE Cleaning procedure during the W2 process.
- A W2 requires approximately 25 minutes to be performed. Alternate the cleaning solution each week using a freshly prepared 10% bleach solution one week, and 1N HCl the next week.

Warning

- Be careful to use the correct cleaning solution before performing a W2. Do not mix an acid cleaning solution and an alkaline cleaning solution. If they are mixed, a toxic gas may be generated. Prepare different bottles for each cleaning solution and note the cleaning solution name on each bottle to prevent them from accidentally being mixed.
- Do not allow your skin and clothing to come into contact with cleaning solution. If your hands or clothing come into contact with the cleaning solution, immediately wash them off with water. If a cleaning solution comes into contact with your eyes or it is ingested, immediately rinse with water, avoid vomiting, and consult the MSDS sheet.
- Do not spill the cleaning solution on the system. *If cleaning solution spills onto the system, wipe it off with a cloth or paper towel dampened with water, then wipe 2 or 3 times using a dry cloth.*
- Do not mix the cleaning solution with other chemicals. *If it has been mixed with another chemical, discard it after performing an appropriate neutralization process.*

1. Fill a sample tube (ZM0062) for the W2 with at least 3 mLs of HCl or bleach. *If HCl was used previously, then use bleach this time.*
2. Remove the two STAT table covers.
3. Set the sample container in the “W2” position on the STAT table.
4. Replace the two STAT table covers.
5. Fill a 60 ml reagent bottle (OE63093) with 60 mLs of the specified HCl or bleach. *If HCl was used the previous time, then use bleach this time. Do not fill the cleaning solution into the neck of the reagent bottle or level sensing errors could result.*



Caution

Be careful not to spill cleaning solution while handling the bottles. If cleaning solution spills onto the system, immediately wipe it off with a cloth or paper towel dampened with water. Then wipe 2 or 3 times using a dry cloth.

6. Set the cleaning solution bottle in the pre-dilution position.

7. Make sure the system power is on.
8. Select the [System Status] icon. *The System Status screen will appear.*
9. Press function key F6 (W2 start). *The W2 Start window will appear. This window allows ISE cleaning during the W2. Place a container of ISE cleaning solution in the "Clean" position on the STAT table. "Start W2? Yes" will start the W2 and ISE cleaning.*
10. Select "YES," then press enter. *The system will start a W2. The operation will end after 25 minutes. The time will count down in the mode display area.*

Important

11. After completing the W2 operation, replace the cleaning solution bottle with the pre-dilution bottle. On the STAT table, remove the sample tubes of cleaning solution from the W2 and Clean positions.

12. Close the upper cover.
13. Perform a photocal measurement.

See Also

For information about how to perform a photocal, refer to the "Weekly Maintenance" section in this chapter.

3.2 Perform a Photocal (after the W2)

The photocal procedure verifies the integrity of the cuvettes. Cuvettes that are dirty or scratched will not pass the photocal procedure. Cuvettes that fail the photocal procedure could affect analysis results, and they need to be cleaned or replaced. This procedure can also be programmed to start automatically after an end Process and Auto-On. This is programmed in [Parameters], [System], [Auto Power On]. The settings in system maintenance must be on for this automatic maintenance setting to work. Additionally, a photocal can be performed with a W2 (see 'Perform a W2' in this chapter).

Weekly Procedure

Caution

To obtain accurate analysis data, do not start a photocal until the photometer lamp has stabilized (approximately 20 minutes).

1. Make sure the system is in the Standby Mode.
2. Select the [System Status] icon. *The [System Status] screen will appear.*
3. Press function key F7 (Photocal Start). *The Photocal Start window will appear.*
4. Select “YES,” then press enter. *The system will start a photocal (takes 20 minutes). When the photocal is complete, the system moves to Standby.*

Checking Results

1. Select [System Status], [Cuvette Status]. Verify that a range of 0.03 for the mean check and a range of 6.5 for the absolute check is set as a default. If not, enter the ranges of 0.03 and 6.5 in the appropriate fields. *When function key F5 (check start) is selected in this screen, the absolute check, cuvette check and mean check are performed. Only the mean check data is analyzed for routine operation. The absolute check (or base check) cuvette data is not utilized for routine operation.*

Important

The Absolute check prompt must be set to 6.5 to max out the absolute check range. The absolute check will compare the OD of a cuvette to the last saved OD of the same cuvette. If the absolute check prompt is left at 0.0 when function key F5 (check start) is selected, all cuvettes will fail the absolute check, and appear in blue on screen. The analyzer can be operated within specification if the mean check and cuvette check are within the acceptable range. The absolute check is not a scheduled maintenance procedure.

2. Press function key F5 (check start). *Any cuvette that fails the mean cuvette check will be listed in the "Error Cuvette No. List" window in red. A cuvette failing the internal cuvette check is listed in green.*
3. Optional: Print a list of defective cuvettes by selection function key F3 (print). Note: The internal cuvette check range is 0.01 and cannot be changed.
4. Remove and clean all defective cuvettes on the list. *For information on cleaning individual cuvettes, refer to the "As Needed" maintenance section in this chapter.*
5. Repeat the photocal procedure after cleaning or replacing any cuvettes. *If an error occurs after cleaning the cuvettes, replace them.*
6. *Select function key F6 (save) to save photocal data after a successful photocal.*

3.3 Perform a Photometer Check

The photometer check is performed to check the integrity of the lamp. A cuvette will be checked for the 0% and 100% transmittance of light through the cuvette. The lamp is also checked when the analyzer goes from Standby to a Measure Mode.

A new lamp, at 100% values, will be closer to 0.01 then move toward 1.7 as the lamp ages. It is normal to see the 340 wavelength at a slightly higher reading than the other 12 wavelengths.

Weekly Procedure

Prepare the following:

- DI water

Caution

To obtain accurate results, do not start a photometer check until the photometer lamp has stabilized after system start-up (approximately 20 minutes).

Instruction

The analyzer must be in the Stop mode to enter diagnostics.

1. Transfer the unit to the Stop Mode, then select [Maintenance], [Maker Maintenance], [ANL DIAG].
2. Select the "Combination" tab located at the top of the screen.
3. Select "Photometer Check A/0-100%."
4. Select the "Print" check box to print the results.
5. Select a cuvette number (1-88) to perform the check.
6. Add approximately 500 ul of DI water to the cuvette number selected with a pipet.
7. Select "Yes" at the Start Measure prompt.
8. The 0% and 100% values will display on the screen.

   Acceptable Ranges: 0% = -5 to 25

   100% = 0.01 to 1.7

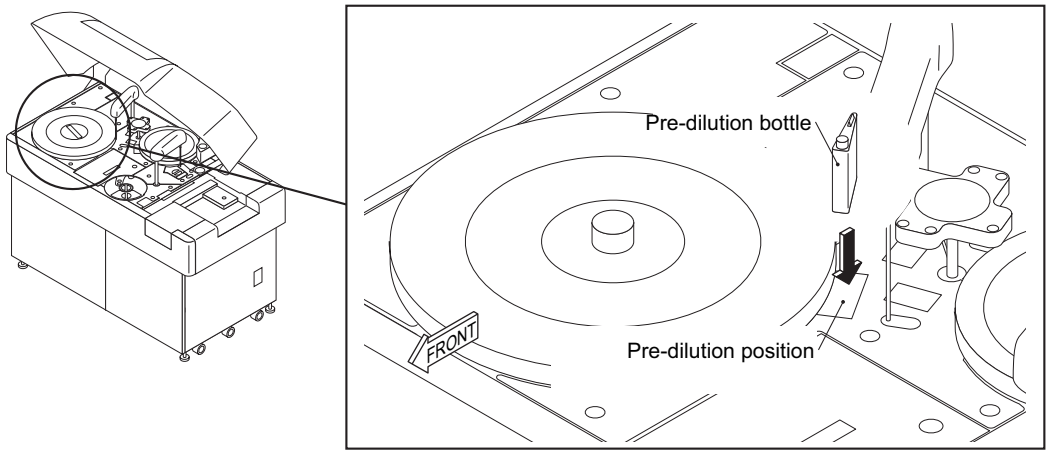
   If the numbers exceed these ranges, replace the photometer lamp and perform a photocal. ***After the lamp is replaced, the operator must repeat a photocal with the new lamp. Refer to the replace Lamp procedure in the As Needed Maintenance section.***

Instruction

The water will automatically be removed from the cuvettes during the next wash or start process.

3.4 Wash the Sample Pre-dilution Bottle

The pre-dilution bottle must be cleaned weekly with bleach to prevent bacteria from growing inside which could affect analysis results.



Weekly Procedure

Prepare the following:

- DI water
- Freshly prepared 10% bleach solution

1. Remove the pre-dilution bottle from the analyzer and empty it.
2. Rinse the bottle with a freshly prepared 10% bleach solution and empty it.

Caution

Do not leave any bleach residue in the bottle! Residue will adversely affect analysis results.

3. Rinse and empty the bottle with DI water twice.
4. Fill the bottle with fresh DI water and place the bottle in the pre-dilution position on the analyzer.

Caution

Place the bottle in the compartment so it does not protrude above the surface of the analyzer top. If it is not placed properly, reagent probe crashes could occur. Also, do not place the cap on the bottle when it is on the analyzer, this also causes probe crashes.

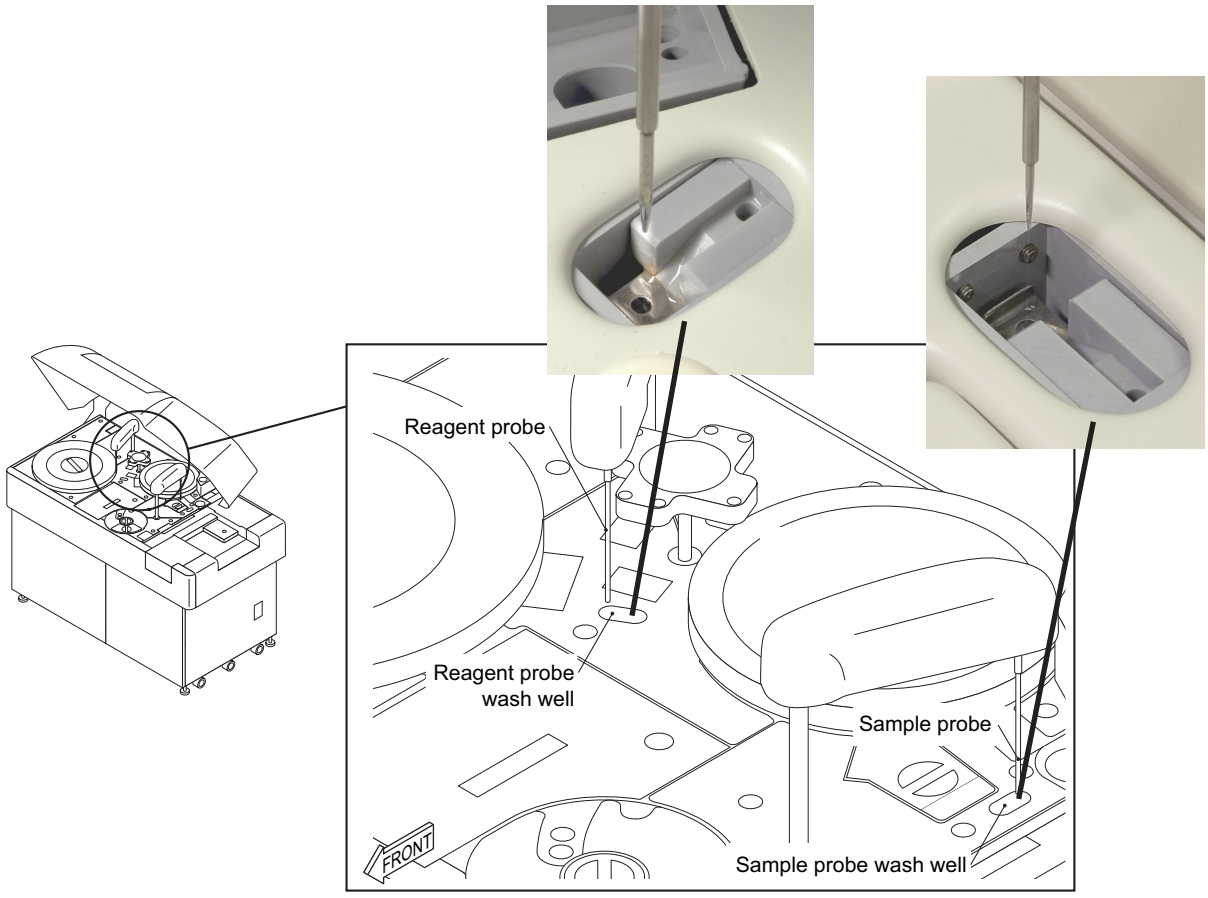
4. Monthly Maintenance

To obtain accurate results and optimum system performance, be sure to perform the following monthly maintenance procedures. Record maintenance on the schedules located at the beginning of this chapter. *Maintenance items can also be recorded on-line in the [Periodic Maintenance] screen.*

Contents

4.1 Clean the Sample Probe and Reagent Probe Wash Wells

If the sample or reagent probe wash wells are not cleaned regularly, they will become increasingly difficult to clean. Stains may cause contamination and reduce the reliability of analysis data. A stained sample probe may also contaminate samples. To keep analysis data reliable, and to prevent samples from being contaminated, clean the sample and reagent probe wash wells every month.



Monthly Procedure

Prepare the following:

- Squirt bottle with freshly prepared 10% bleach solution
- Cotton swab

1. Open the upper cover.
2. Verify that the analyzer is in the Warm-up or Standby Mode.
3. Select [Maintenance], [ANL Maintenance].
4. Select "D/Cleaning Wash Wells."
5. Press the STAT ROTATION/DIAG button. *The sample and reagent probes move to the cuvette wheel position.*

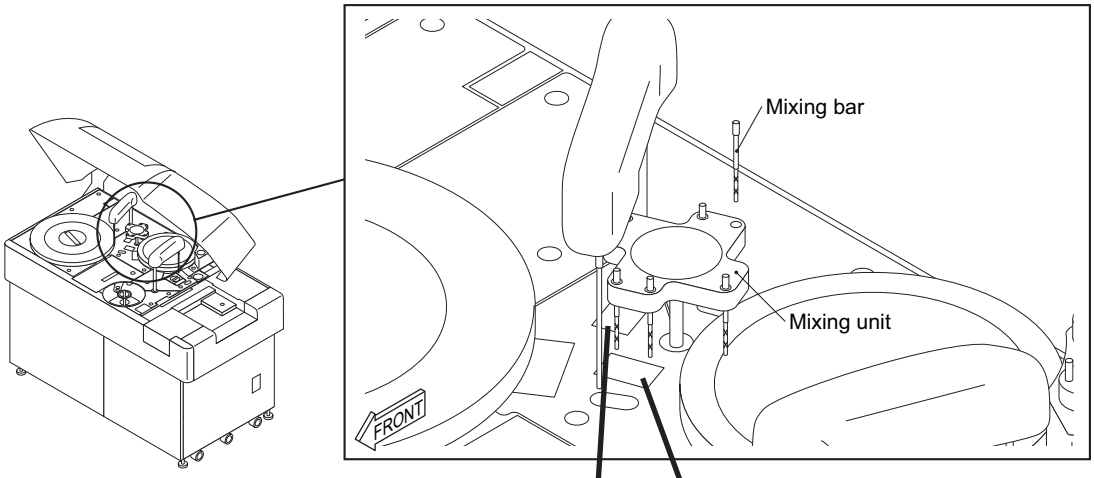
Caution

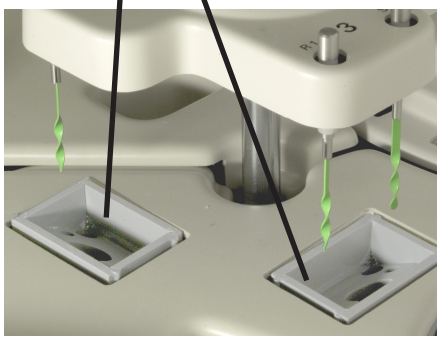
If bleach spills, immediately wash the affected area with water.

6. Squirt the 10% bleach solution into each wash well while cleaning the inside with a cotton swab. During cleaning, be careful not to damage the sample and reagent probe tips.
7. Press the stat rotation/diag button. The sample and reagent probe will return to its home position over the wash well.
8. Select "F/Prime Washing-line" on the [Maintenance], [ANL Maintenance] screen.
9. Press the STAT ROTATION/DIAG button. *The DI water is dispensed from the sample and reagent probes into the wash wells.*
9. Close the upper cover.

4.2 Clean the Mix Bar Wash Wells

If the mix bar wash wells are not cleaned regularly, deposits may form in them. This causes contamination and reduces the reliability of analysis data. The stained mix bars may contaminate samples. To maintain the reliability of analysis data, and to prevent samples from being contaminated, clean the mix bar wash wells every month.





Monthly Procedure

Prepare the following:

- Squirt bottle with freshly prepared 10% bleach solution
- Cotton swab

1. Open the upper cover.
2. Verify that the analyzer is in the Warm-up or Standby Mode.
3. Manually turn the mix bar units so the mix bars are not over the wash wells.
4. Squirt the 10% bleach solution into each wash well while cleaning the inside with a cotton swab.
5. Realign the mix bar unit as closely as possible to avoid errors.

Caution

Do not spill the bleach solution outside the mix bar wash well. If it spills, immediately wipe it up.

6. Select “F/Prime Washing-line” on the [Maintenance], [ANL Maintenance] screen.
7. Press the STAT ROTATION/DIAG button. *The mix bars will go through one wash sequence.*
8. Close the upper cover.

4.3 Clean the Wash Nozzle Unit, Deionized-Water Tank and Filter, and Sample Probe Filter..

The following four procedures share several steps, so it is most efficient to perform them together. If only one procedure is required while troubleshooting a particular problem, locate the procedure in the As Needed section of this chapter.

Wash Nozzle Unit

The wash nozzle unit is equipped with a total of eight nozzles. The unit consists of six wash nozzles (three-part nozzle) for mixture aspiration, wash solution/deionized-water (DI-water) dispensing, and wash solution/DI water overflow aspiration, and one nozzle each for aspiration and drying. If a nozzle is clogged, or the O-ring on the tube mounting joint manifolds are damaged, flattened, twisted or missing, the function of the nozzle does not work properly. This results in a cuvette wheel overflow or problems with the analysis data. To prevent an overflow and abnormal analysis data, clean the wash nozzle unit every month.

Deionized-Water Tank

Regular cleaning prevents the accumulation of deposits or bacteria that could affect analysis.

Deionized-Water Filter

If the deionized-water filter is dirty, the system may generate abnormal analysis data.

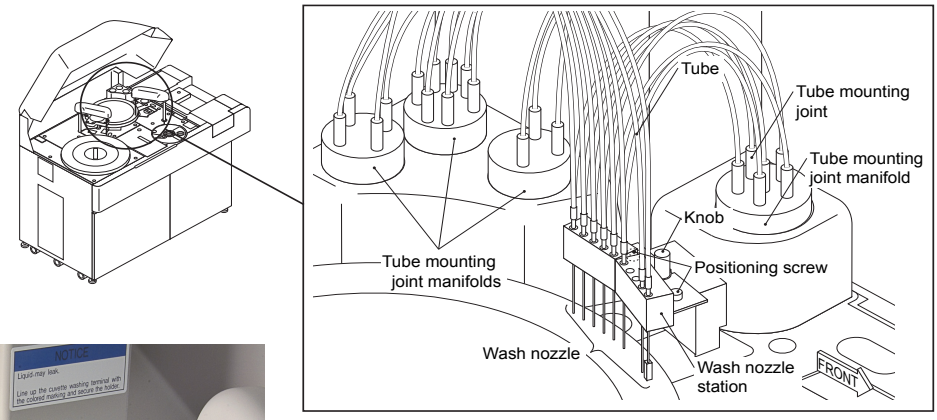
Sample Probe Filter

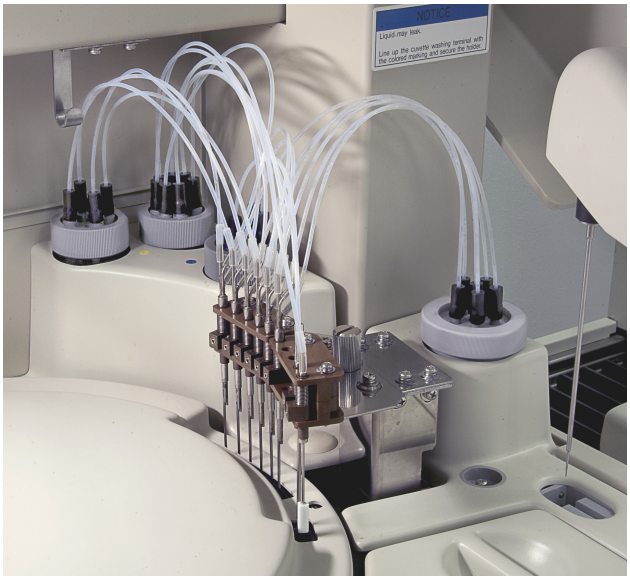
If the sample probe filter is dirty, the system may generate abnormal analysis data.

Monthly Procedure

Prepare the following:

- Dry, clean cloth
- Sonicator filled with DI water
- Basin
- Freshly prepared 20% bleach
- Extra DI tank (In start-up kit)





Remove and Clean the Wash Nozzle Unit

1. Open the upper cover.
2. Verify that the analyzer is in the Warm-up or Standby Mode.
3. Select [Maintenance], [ANL Maintenance].
4. Select "E/Replacing Wash Nozzle."
5. Press the STAT ROTATION/DIAG button. *The liquid in the tubing on the wash nozzle unit is drained.*
6. Open the rear cover.
7. Remove the four tube mounting joint manifolds from the wash nozzle unit.

Instruction

- When handling the wash nozzles, be careful not to scratch them.
- When loosening the knob on the wash nozzle unit, do not loosen the positioning screws on both sides of the knob. These screws are used for positioning the wash nozzle unit.

8. Loosen the knob on the wash nozzle unit, then remove the wash nozzle unit along with the tubing.

Caution

After placing the wash nozzle unit in the sonicator with DI water, verify that the tips of the wash nozzle do not rest on the bottom of the sonicator. When the sonicator is running the wash nozzle to vibrate and can damage the tips.

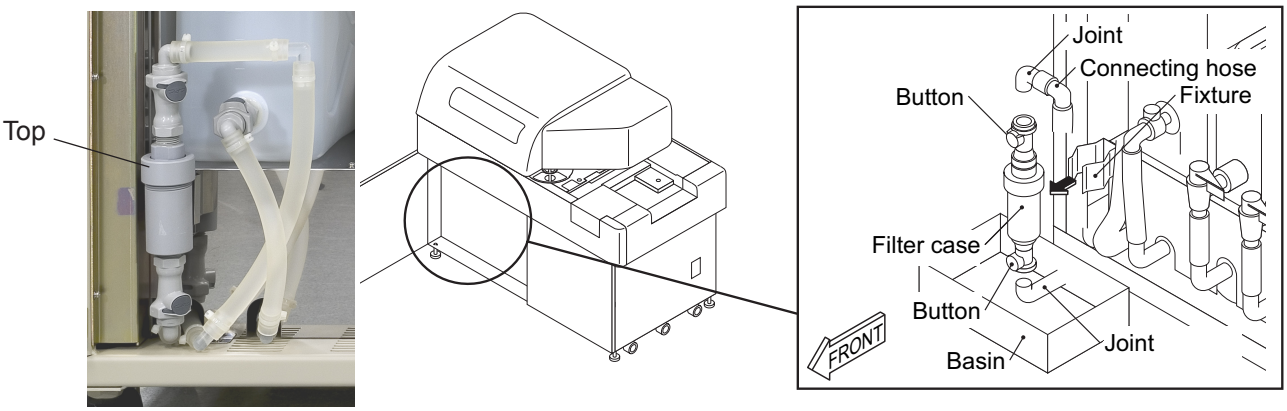
Instruction

- When cleaning the wash nozzle unit using a sonicator, be careful not to scratch the wash nozzles.
- Do not scratch or tear the joints and tubes. A leak may result from the scratched part and the cuvette wheel may overflow.

Tips

The sonicator is the optimal device for cleaning the wash nozzles. If a sonicator is not available, use DI water. While pouring water into the wash nozzles, clean each nozzle hole using the supplied stylet. Rinse the nozzles in DI water, then dry them with a soft cloth.

9. Clean the tips of the nozzles for 15 minutes using DI water in a sonicator. No wash solution is required.
   Do not submerge the springs on top of these nozzles - only submerge the tips of the wash nozzles, including the shortest nozzles tips.



Remove and clean the Sample Probe Filter

Instruction

Perform an End Process before removing the Sample Probe Filter, DI-Water Filter, or DI-Water Tank. If this procedure is performed with the system sub-power on, water could spill from tubing and tanks.

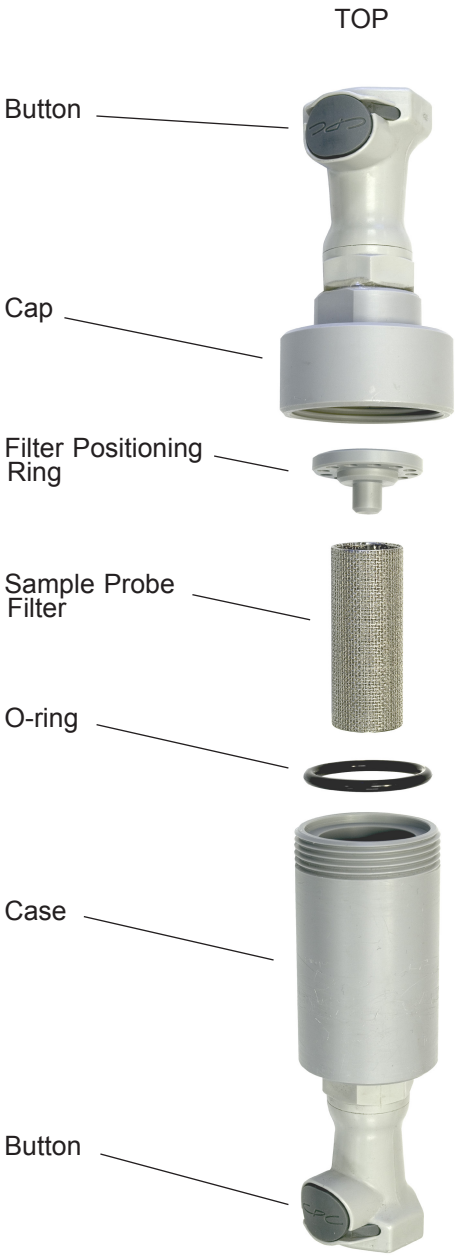
1. Confirm that an End Process was performed.
2. Open the left front cover.
3. Position a basin to catch any liquid that spills from the deionized-water drain hose.
4. Pull the Sample Probe Filter Case forward to remove it from the metal clip.
5. While pressing the button at each end of the sample probe filter case, disconnect the hose joints.

Instruction

Loosen the filter case over the basin. The deionized water in the filter case will drain from the joint. If water spills onto the system, immediately wipe it up with a dry, clean cloth.

When removing the sample probe filter, be careful not to lose the O-ring or the filter positioning ring.

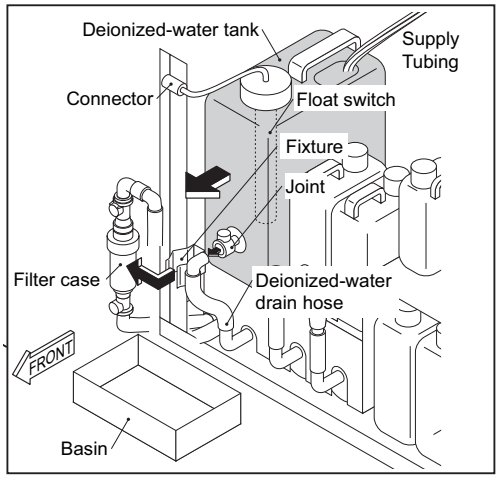
6. Unscrew the Sample Probe Filter Case and remove the sample probe filter.
7. Clean the Sample Probe Filter for 10 minutes, using DI water in a sonicator. *If a sonicator is not available, rinse in DI water. While pouring DI water onto the filter, scrub it with a toothbrush.*
8. Inspect the O-ring, Filter Positioning Ring, and the inside of the case. Remove any accumulations with a damp towel.



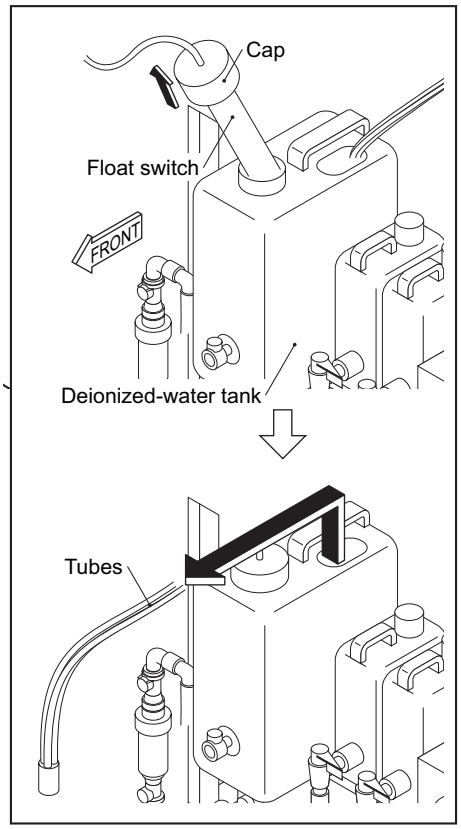
Remove the Deionized-Water Tank

Tip

If low-quality deionized water is obtained from the main water source, the two Diluted Wash Solution Tanks may require cleaning in addition to the Deionized-Water Tank. For detailed information, contact Beckman Coulter Technical Services.



1. Unplug connector #240.
2. Disconnect the joint of the deionized water drain hose from the tank by pressing the gray Quick Disconnect button.
3. Pull the DI water tank forward while removing the tubes inserted in the tank. Lay the tubes in the basin.
4. Remove the deionized-water tank from the instrument.
5. Loosen the water tank cap and remove the float switch.

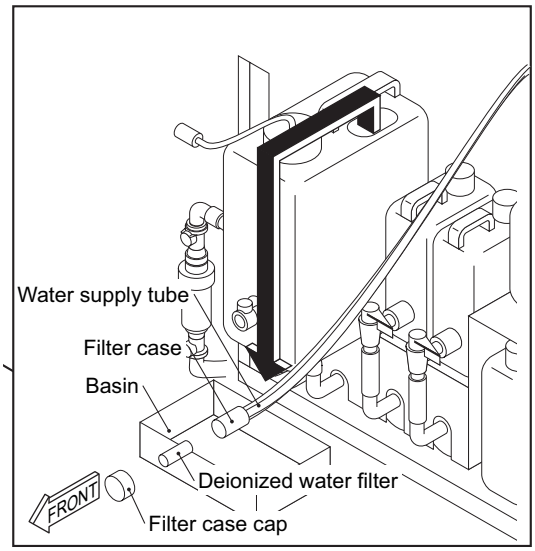


Remove the Deionized-Water Filter

Instruction

Loosen the DI-Water Filter case over the basin. The deionized water in the filter case will drain from the joint. If the deionized water spills onto the system, immediately wipe it off with a dry, clean cloth.

1. Turn the DI-Water Filter case cap to remove it.
2. Remove the deionized-water filter from the filter case.



Clean both filters and the Deionized-water Tank

1. Clean the deionized-water filter for 10 minutes in DI-water using a sonicator. *If a sonicator is not available, pour DI water over the filter while scrubbing it with a toothbrush.*
2. Rinse the tubes and inside of the tank with a fresh 20% bleach solution and rinse thoroughly with deionized water.
3. Store the tank where it can air dry.

Re-install the Deionized-water filter

1. Rinse the DI-water Filter in deionized water.
2. Insert the DI-water Filter into the filter case.
3. Replace the Filter Case cap and hand-tighten.

Install the spare Deionized-water Tank

1. Fill the spare DI tank at least half full with DI water and install the tank. Alternate the tanks so each one can dry thoroughly between cleaning.

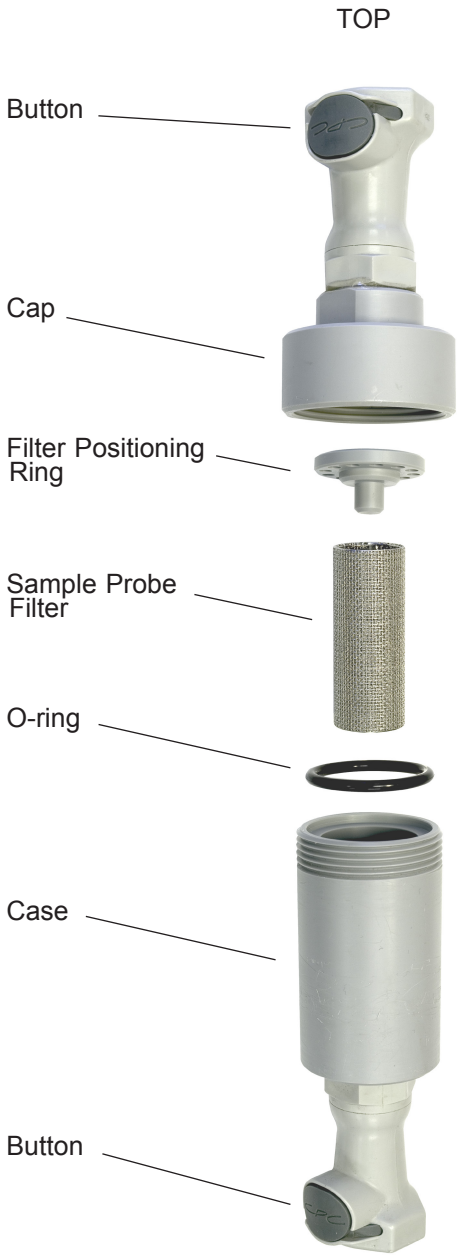
Caution

If the tank is empty, and the pump runs without water, the pump may be damaged.

2. Insert the the Float Switch and water supply tubes into the Deionized-water Tank. Tighten the cap.
3. Replace the DI-water Tank in the system. Verify that the tubing is fully inserted in the DI-water Tank.
4. Reconnect the joints on the deionized-water tank. *Push each joint until a click is heard.*
5. Reconnect connector #240. When reconnecting the #240 connector, do not force the connection or the pins can be damaged. Turn the connector gently until it slides into the connection easily and without force.

Re-install the Sample Probe Filter

1. Rinse the Sample Probe Filter in deionized water.
2. Insert the Sample Probe Filter into the filter case.
3. Position the O-ring correctly on the filter case.
4. Place the Filter Positioning Ring over the filter.
5. Assemble the top of the filter case (cap) and hand-tighten. Ensure the button at the top of the filter case (cap) faces the same direction as the bottom button of the filter case.
6. Refer to the illustrations and verify that the top of the filter case is pointed upward and connect the two hoses to the filter case fittings. *Push each hose connector into the filter case until a click is heard.*



Re-install the Wash Nozzle Unit

1. Remove the wash nozzle unit from the sonicator and wipe with a soft cloth.
2. Using a gauze dampened with water, wipe any foreign matter from O-rings such as dust or detergent residue. If foreign matter remains, remove the O-ring with tweezers, wash with water, and re-insert.
3. Place the O-ring inside the depense manifold. If any O-ring is scratched or damaged, replace with O-ring MU9638.

Caution

If O-rings are used without cleaning for an extended period of time, or if the cover on the jount unit is closed without any O-ring set in the groove, detergent crystals will collect and could scratch the O-rings. Check the O-rings during Monthly mainteance. For more reliable maintenance, replace the O-rings once a year.

Instruction

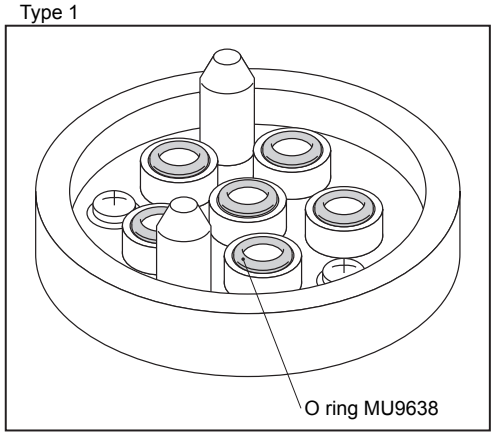
Be sure to attach the tube mounting joint manifolds in their original places. If a manifold is attached incorrectly, normal analysis cannot be performed.

4. Match the two positioning holes on the wash nozzle unit with the positioning screws, then secure the station by finger-tightening the knob.
5. Attach the manifolds, hand tighten them firmly. When attaching the manifolds, match the color connections and tighten them firmly. *For information about the tube mounting joint positions, refer to the drawing on the following page. Make sure the O-rings are in place on each manifold and not damaged.*
6. Close the rear cover.

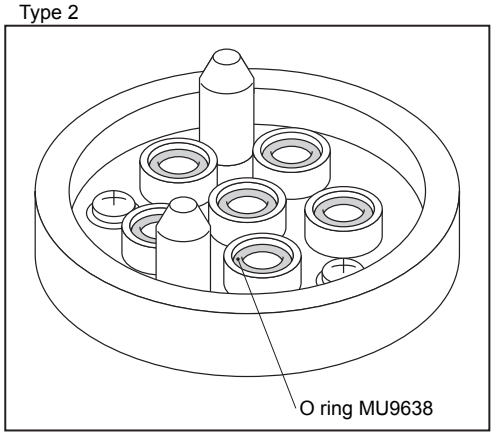
Check the system

1. Press the Green power button to apply power to to the system.
2. After initialization, select [Maintenance], [ANL Maintenance].
3. Select "F/Prime Washing-line."
4. Press the STAT ROTATION/DIAG button.
   - Observe the DI-Water and filter tubing. *The deionized water will flow through the tube and then the air in the DI-Wiater tubing will be released. This prime may need to be performed 2-3 times to ensure that all of the air is out of the tubing.*
   - Observe the Wash Nozzle Unit. *Verify that air in the tubing of the wash nozzle unit is released. Verify the movement is smooth and complete.*
5. Repeat the previous step two or three times until the air in the affected tubing is completely removed.
6. Close the left front cover and the upper cover.

Type 1

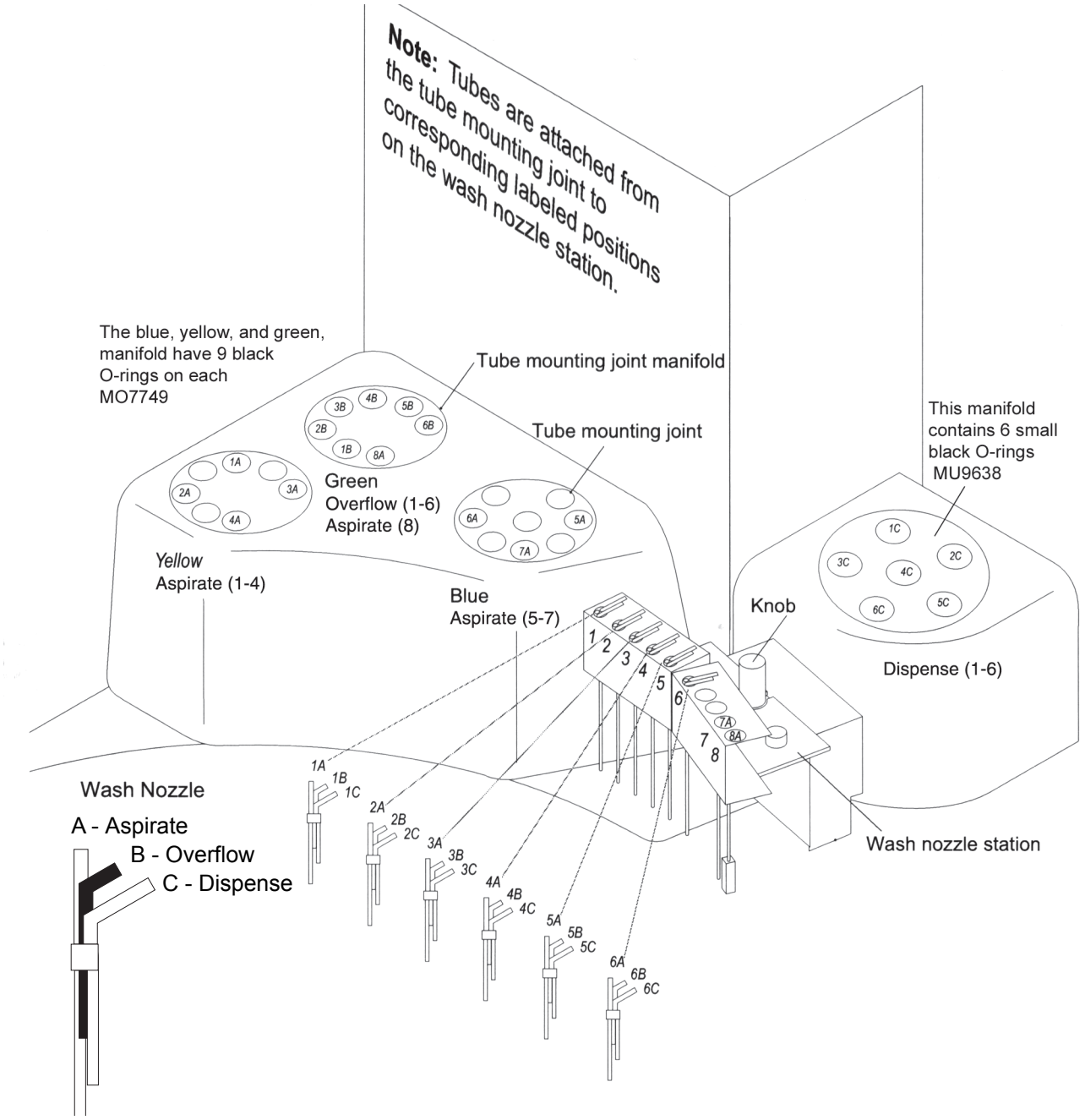


Type 2



Tubing Diagram of the Wash Nozzles and Tube Mounting Joints

In order to distinguish individual connecting positions easily, follow the tubing diagram below:



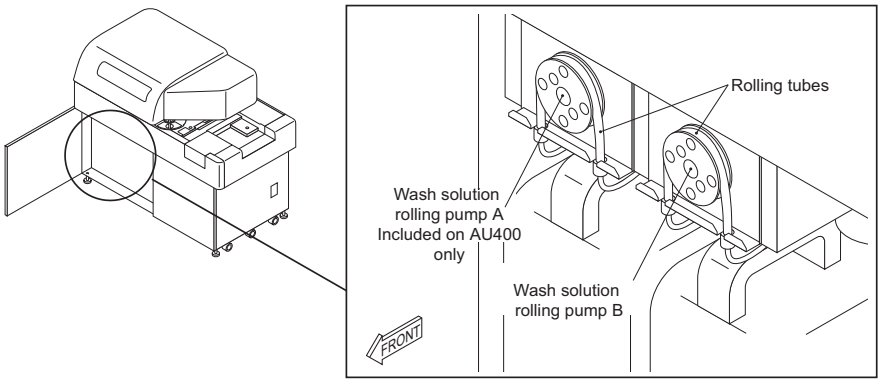
5. Maintenance Required Every Three Months

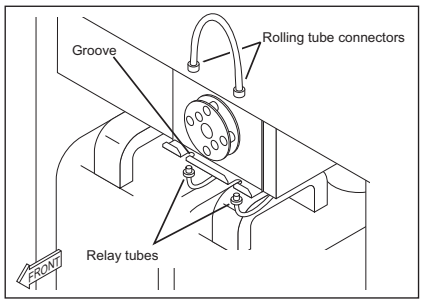
To obtain accurate results and optimum system performance, perform the following maintenance procedures every three months. Record maintenance on the schedules located at the beginning of this chapter. *Maintenance items can also be recorded on-line in the [Periodic Maintenance] screen.*

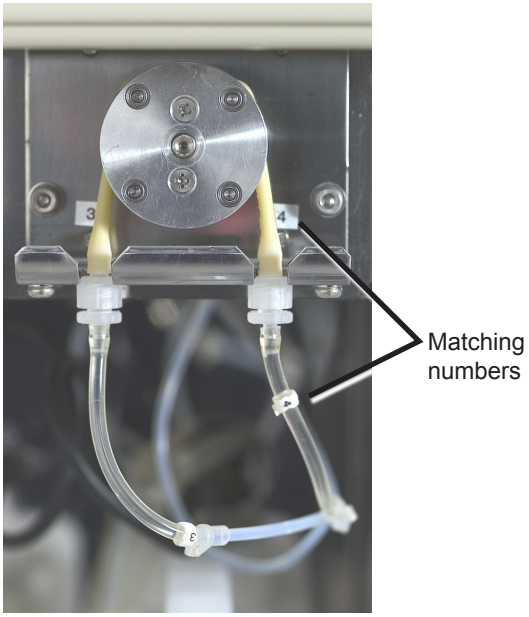
Contents

5.1 Replace the Wash Solution Rolling Tube

The rolling tube will wear and break if it is used for an extended period of time.







Every Three Months

Prepare the following:

- New tubing MU9623

1. Place the analyzer in Warm-up or Standby.
2. Open the left front cover.
3. Select [Maintenance], [ANL Maintenance].
4. Select "G/Replace Detergent Tube."
5. Press the STAT ROTATION/DIAG button. *The pump rotates in reverse. The concentrated wash solution in the tube returns to the tank.*

Note

The AU400 includes two pumps. The AU400e only contains one pump.

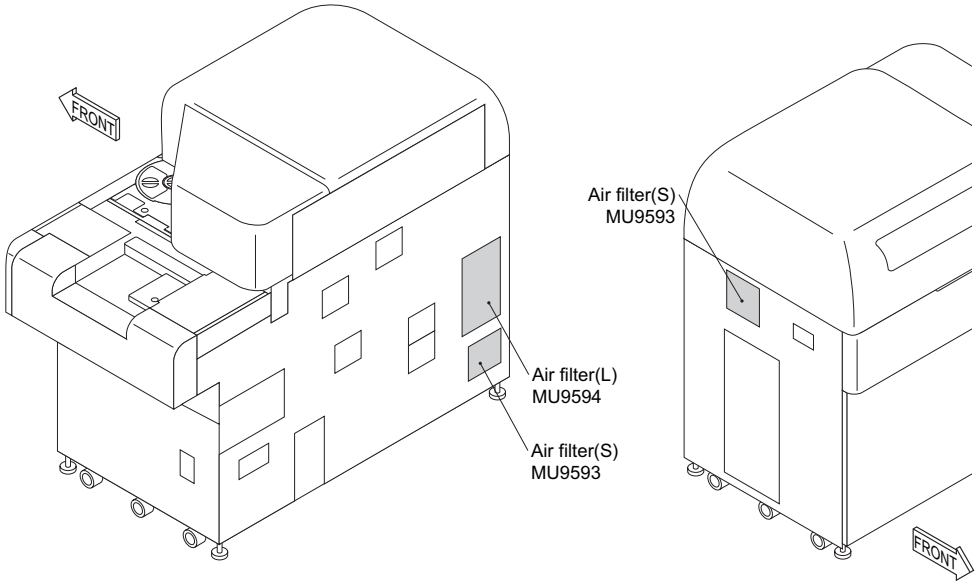
Caution

Handle the tubing with care or wash solution could splash on skin. If wash solution splashes on your skin, immediately wash the area with water.

6. Remove rolling tube A (factory optional) and B shown in the illustration above. Remove the tubes by unscrewing the connectors of each tube.
7. Connect the new tubing and rotate the connectors to tighten them.
8. Stretch the tubing around the rolling pump. Slip the tube into the groove as shown in the illustration. **Note:** The numbers on the tube should match the numbers on the side of the pumps.
9. Press the STAT ROTATION/DIAG button. *The pump rotates counterclockwise. The concentrated wash solution fills the tubing.*
10. Check for leaks in the tubing then close the left front cover.

5.2 Clean Air Filters

If the air filters on the system are used for an extended period of time, they may become clogged with dust and dirt. This reduces the cooling performance in the inside of the system. Clean the air filters every three months.



Every Three Months

Prepare the following:

- Vacuum

Caution

Do not clean the air filters with water. Moisture could enter the system and damage the internal electronics.

1. Confirm that the system is is in Standby mode.
2. Remove the three air filters as shown in the figure.
3. Vacuum the air filters thoroughly.
4. Place the air filters back in their original locations.

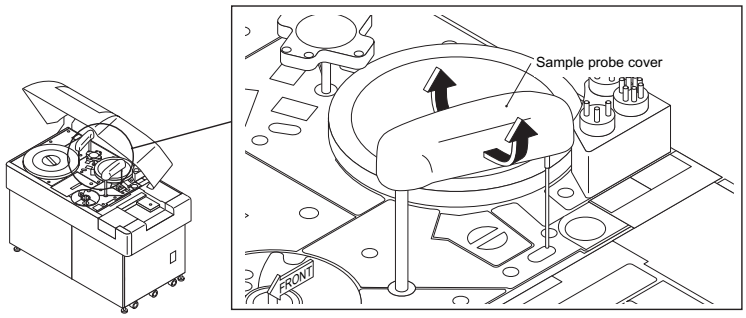
6. As Needed Maintenance

To obtain accurate results and optimum system performance, perform the following maintenance procedures as needed. Record maintenance on the schedules located at the beginning of this chapter. *Maintenance items can also be recorded on-line in the [Periodic Maintenance] screen.*

Contents

6.1 Replace the Sample and Reagent Probes

If the sample or reagent probes are damaged or have occlusions that cannot be removed, replace them.

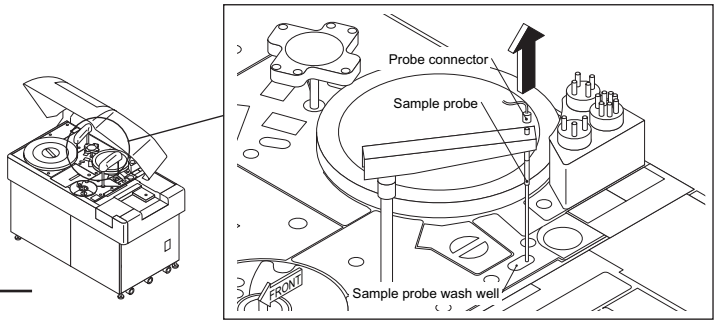


As Needed

Sample Probe Replacement Procedure

Prepare the following:

- Sample probe MU9934



Instruction

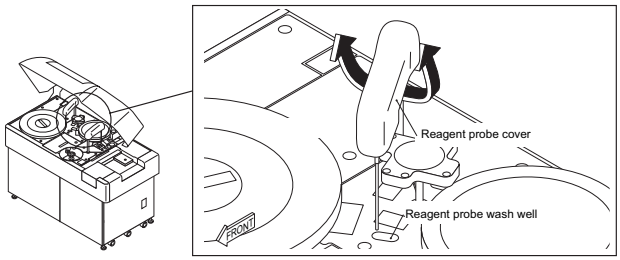
Check that the sample probe is positioned over the wash well before replacing it. Liquid will drip during probe replacement.

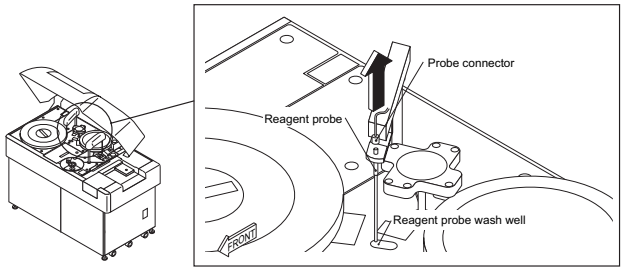
1. Verify that the analyzer is turned on and is in the Warm-up or Standby Mode.
2. Open the upper cover.
3. Select [Maintenance], [ANL Maintenance].
4. Select "A/Replace S Probe & Syringe."
5. Press the STAT ROTATION/DIAG button. *Water will drain from the sample probe tubing.*
6. Remove the sample probe cover. *The probe cover has wedges inside the cover. While spreading both sides of the cover from the inside by hand, lift the cover to remove it from the probe arm.*
7. Disconnect the probe connector.

Instruction

When replacing the sample probe, be careful not to bend or scratch the probe tip.

8. While holding the probe connector, pull the sample probe upward.
9. Place a new sample probe through the top of the holder.
10. Tighten the probe connector to secure the sample probe. *Tighten the connector firmly.*
11. Replace the sample probe cover. *First place it on the arm from the probe side. A click should be heard.*
12. From [Maintenance], [ANL Maintenance] select "F/Prime Washing-line."
13. Press the STAT ROTATION/DIAG button. *The DI water will be dispensed from the probe tip. Check that the DI water is dispensed in a thin straight stream. It should not spray or dispense at an angle.*
14. Close the upper cover.





As Needed

Reagent Probe Replacement Procedure

Prepare the following:

- Reagent probe MU9958

Instruction

Check that the reagent probe is positioned over the wash well before replacing it. Liquid will drip during probe displacement.

1. Verify that the analyzer is turned on and is in the Warm-up or Standby Mode.
2. Open the upper cover.
3. Select [Maintenance], [ANL Maintenance].
4. Select "B/Replace R Probe & Syringe."
5. Press the STAT ROTATION/DIAG button. *Water will drain from the reagent probe tubing.*
6. Remove the reagent probe cover. *The probe cover has wedges inside the cover. While spreading both sides of the cover from the inside by hand, lift the cover to remove it from the probe arm.*
7. Disconnect the probe connector.

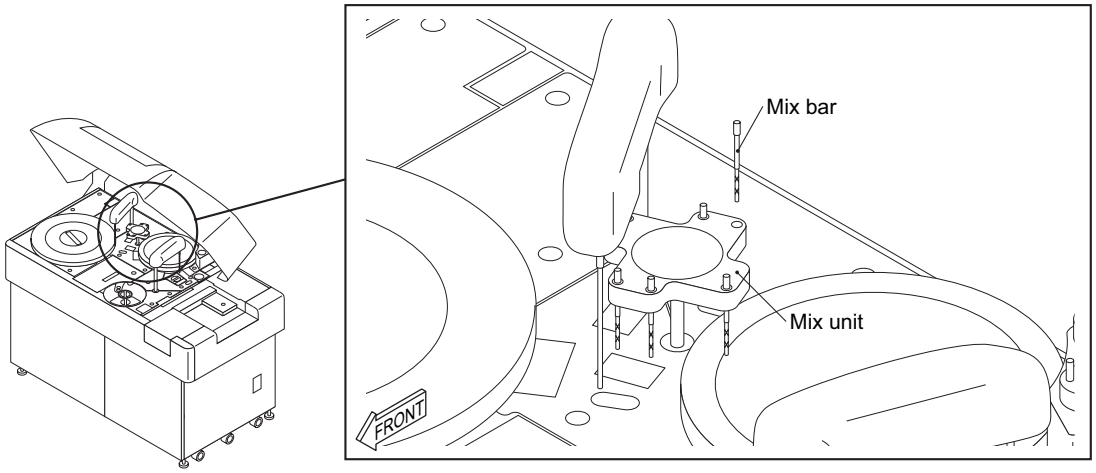
Instruction

When replacing the reagent probe, be careful not to bend or scratch the probe tip.

8. While holding the probe connector, pull the reagent probe upward.
9. Place a new reagent probe through the top of the holder.
10. Tighten the probe connector to secure the probe. *Tighten the connector firmly.*
11. Replace the probe cover. *First place it on the arm from the probe side. A click should be heard.*
12. From [Maintenance], [ANL Maintenance], select "F/Prime Washing-line."
13. Press the STAT ROTATION/DIAG button. *The DI water will be dispensed from the probe tip. Check that the DI water is dispensed in a thin straight stream. It should not spray or dispense at an angle.*
14. Close the upper cover.

6.2 Replace Mix Bars

Replace the mix bars if they are stained, damaged, or if the teflon coating is chipped.



As Needed

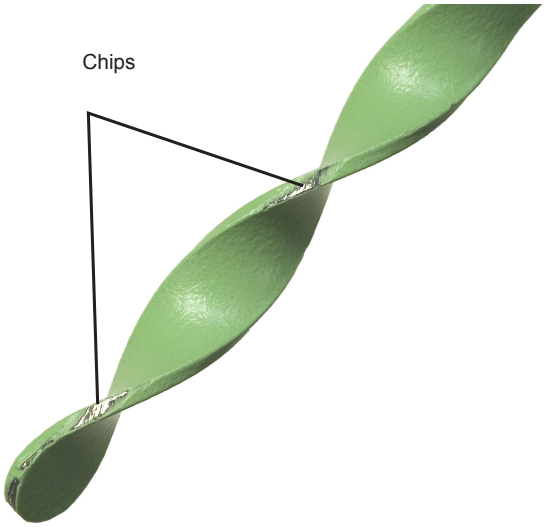
Prepare the following:

- New Mix Bar MU9599

Caution

Replace the mix bars while the mix unit drive is not operating. Personal injury may result if replacement of a mix bar is attempted during operation of the mix unit.

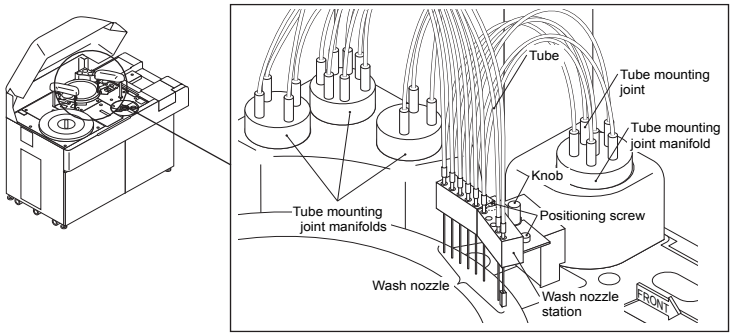
1. Verify that the analyzer is turned on and is in the Warm-up or Standby Mode.
2. Open the upper cover.
3. Pull out the mix bar to be replaced.
4. Insert a new mix bar into the mix unit from the top. *Be careful not to sctatch the mix bar when inserting it into the mix unit. While inserting the mix bar, rotate it slightly to engage the flat portion of the bar with the gear of the mix unit.*

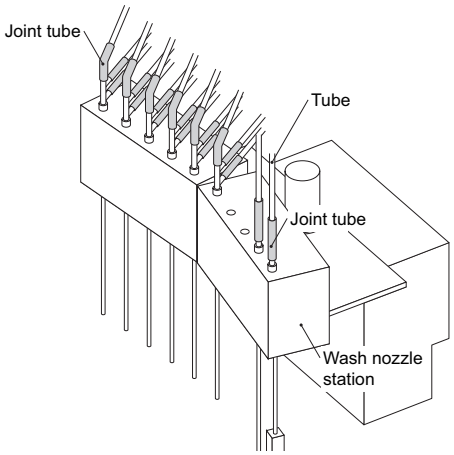


5. Select [Maintenance], [ANL Maintenance].
6. Select "F/Prime Washing-line."
7. Press the STAT ROTATION/DIAG button. *Observe the mix bars during the wash sequence.*
8. Close the upper cover.

6.3 Replace the Wash Nozzle Joint Tubes

If a wash nozzle tube is scratched or cracked or liquid drips from nozzles, liquid could remain in the cuvettes, or the dripping could cause an overflow. This may result in an analysis data error. To prevent analysis data errors, immediately replace the damaged tube.





As Needed

Prepare the following:

- New joint tube ZM1131 (3 pieces per set)

1. Open the upper cover.
2. Verify that the analyzer is turned on and is in the Warm-up or Standby Mode.
3. Select [Maintenance], [ANL Maintenance].
4. Select "E/Replacing Wash Nozzle."
5. Press the STAT ROTATION/DIAG button. *The liquid is drained from the tubing.*
6. Open the rear cover.
7. Remove the four tube mounting joint manifolds from the wash nozzle unit.

Instruction

- When handling wash nozzles, be careful not to scratch them.
- When loosening the knob on the wash nozzle unit, do not loosen the positioning screws on both sides of the knob. These screws are used to position the wash nozzle unit.

8. Loosen the knob on the wash nozzle unit, then remove the wash nozzle unit along with the tubing. Put it on a flat working surface.
9. Remove the tubes to be replaced.

Caution

Replace tubes one by one. If a wrong nozzle and tube are connected, problems could occur. *Refer to the drawing on the next page for correct tube and nozzle positions.*

10. Place the new joint tube on the mounting joint and on the other end of the wash nozzle unit. Both ends of the tubing should be centered. Allow approximately 1mm between the ends of the tube and nozzle as shown in the drawing.

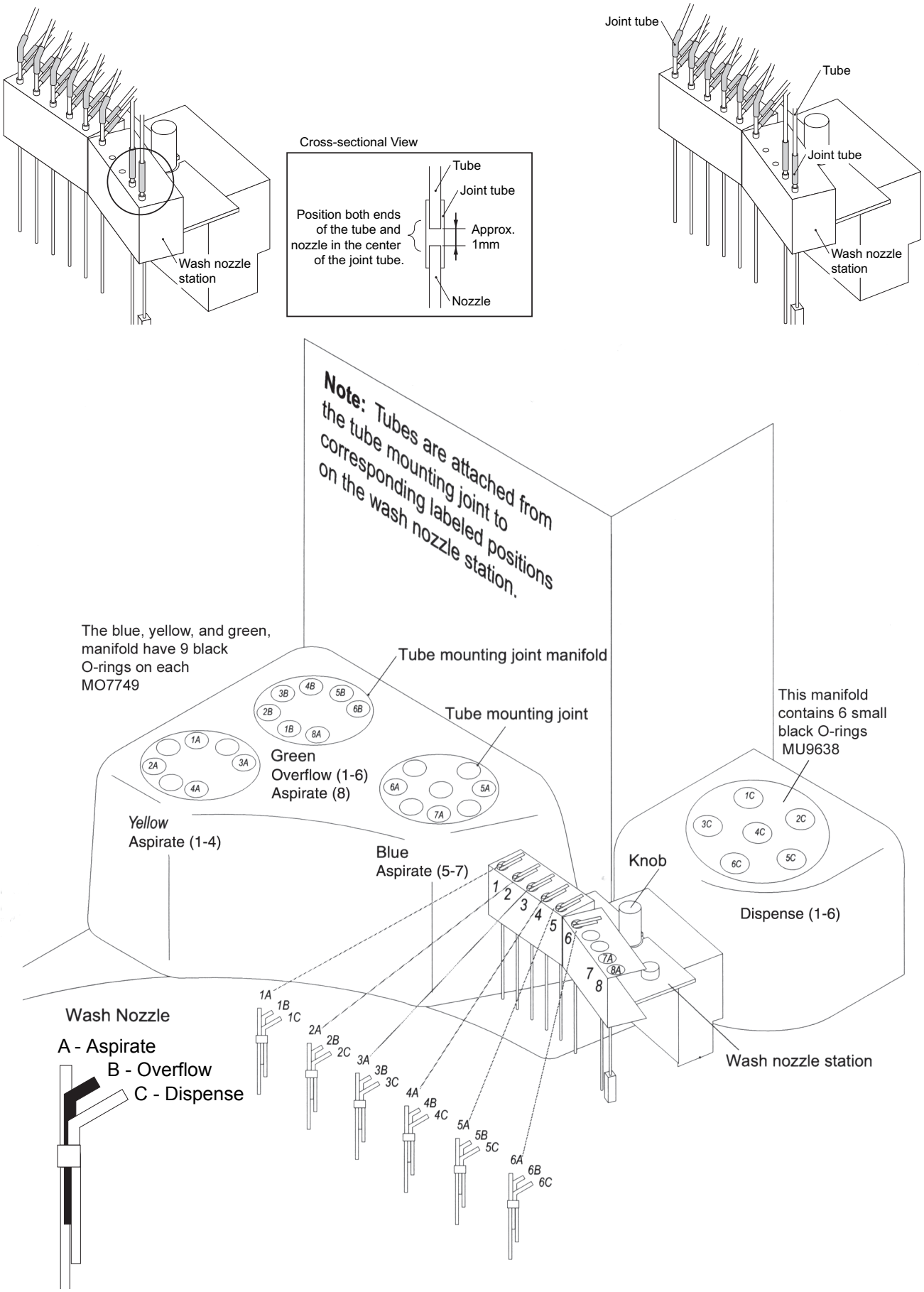
Instruction

Be sure to attach the tube mounting joint manifolds in their original places. If a manifold is attached incorrectly, normal analysis cannot be performed.

14. Replace the wash nozzle unit and reconnect the four tube mounting joint manifolds. When attaching the manifolds, match the color connections and tighten them firmly.
15. Close the rear cover.

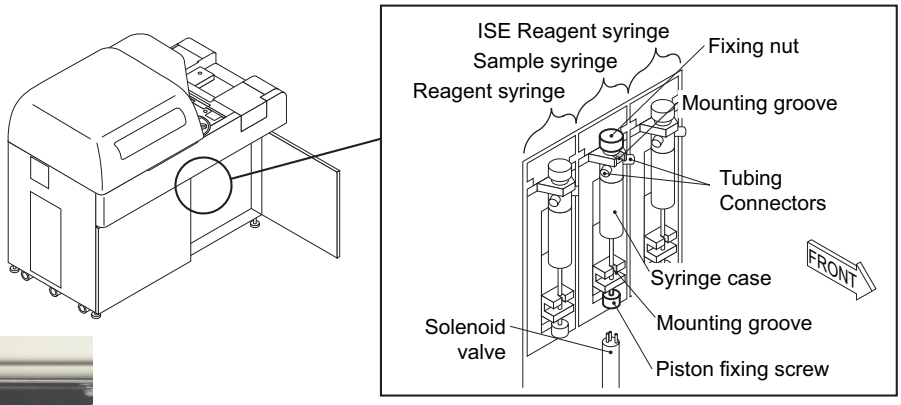
Check the system

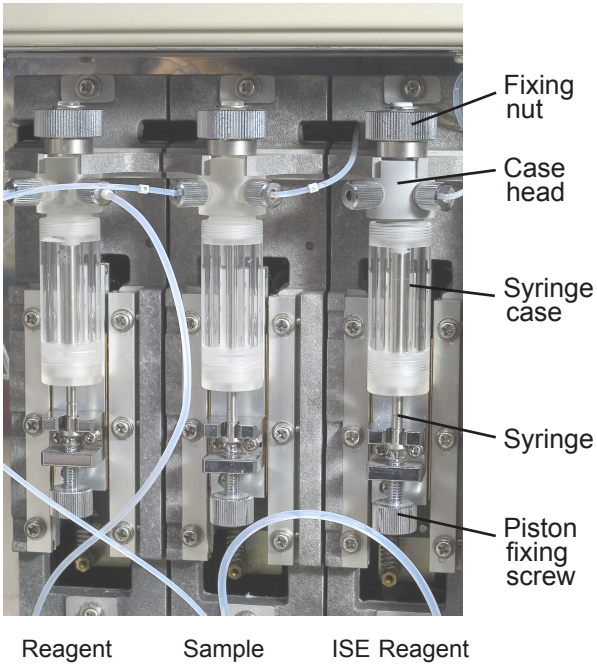
1. Select [Maintenance], [ANL Maintenance]. Select "F/Prime Washing-line."
2. Press the STAT ROTATION/DIAG button. *The deionized water flows through the tube and the air in the tube is removed.*
3. Close the upper cover.


Wash nozzle station
Cross-sectional View
Tube
Joint tube
Position both ends of the tube and nozzle in the center of the joint tube.
Approx. 1mm
Nozzle
Joint tube
Tube
Joint tube
Wash nozzle station
Note: Tubes are attached from the tube mounting joint to corresponding labeled positions on the wash nozzle station.
The blue, yellow, and green, manifold have 9 black O-rings on each MO7749
Tube mounting joint manifold
Tube mounting joint
This manifold contains 6 small black O-rings MU9638
Green
Overflow (1-6)
Aspirate (8)
Yellow
Aspirate (1-4)
Blue
Aspirate (5-7)
Knob
Dispense (1-6)
Wash Nozzle
A - Aspirate
B - Overflow
C - Dispense
Wash nozzle station

6.4 Replace Sample and Reagent Syringes

Replace the syringe when: 1. Pulling on the piston, there is no longer a smooth, resistant pull. Instead, the syringe is very hard or loose when pulling, or it is not a smooth movement. 2. The teflon tip is worn or damaged. 3. There are leaks around the syringe even after proper installation. 4. The head of the syringe is cracked.





As Needed

Use the following procedure to replace the sample syringe and reagent syringes.

Prepare the following:

- New sample syringe ZM0111
- New reagent syringe ZM0112
- (Same for ISE Reagent [Buffer] syringe.)

Remove and Replace Syringes

1. Open the right front cover.
2. Verify that the analyzer is turned on and is in the Warm-up or Standby Mode.
3. Select [Maintenance], [ANL Maintenance].
4. Select one of the following menu items according to the type of syringe to be replaced. To replace the sample syringe, select "A/Replace S Probe & Syringe." To replace the reagent syringe, select "B/Replace R Probe & Syringe."
5. Press the STAT ROTATION/DIAG button. *Liquid is drained from the tube of the selected syringe.*

Caution

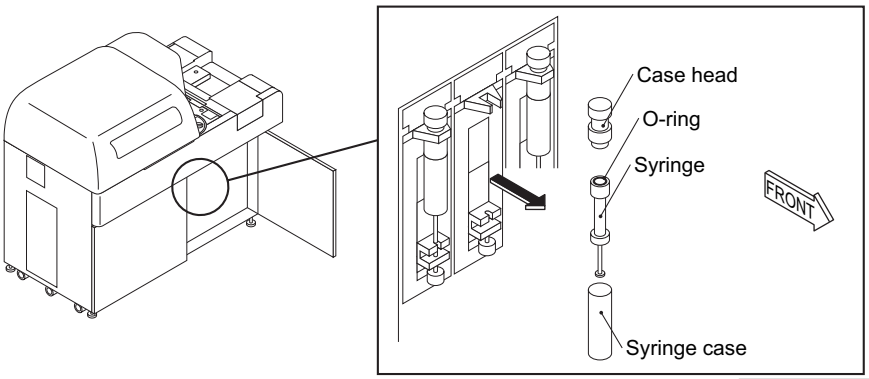
Do not place any body parts in the path of moving equipment, unless you are certain that the analyzer is in Stop or Standby and that diagnostic functions are not activated.

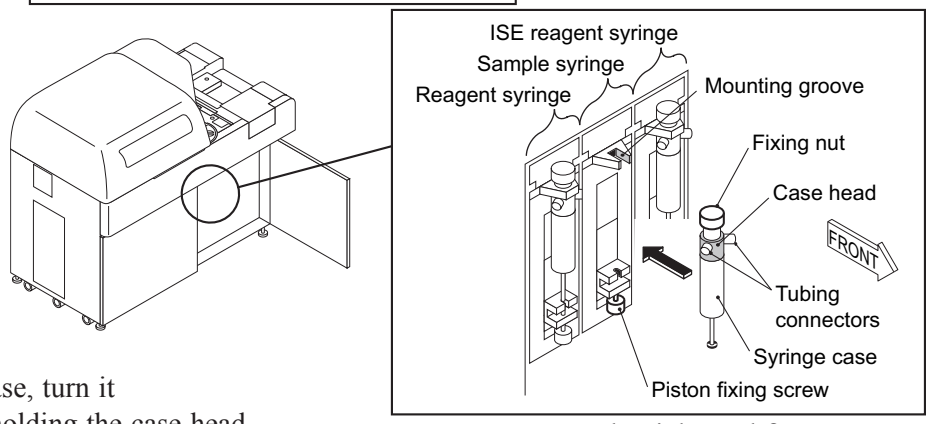
6. Loosen the bottom fixing screw *first*, then the top fixing nut. Pull the syringe and case forward.

Caution

- Do not apply excessive force to the fixing screws when removing the syringe case. This can cause damage to the syringe case. Do not use pliers when tightening the screws.
- If the relay tubes are disconnected from the solenoid valve during syringe case removal, screw the relay tubes onto the connectors.

7. Tilt the syringe head and case upside down before replacing the syringe. This will prevent air from entering the tubing lines and keeps the water that collects in the head of the syringe from leaking.

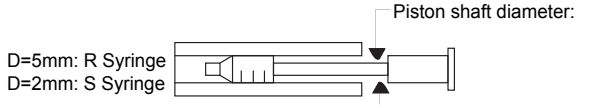




8. To remove the syringe case, turn it counterclockwise while holding the case head.
9. Pull the syringe out from the case head. If the O-ring remains in the case head, carefully remove it with tweezers to prevent scratching the case head.

Warning

Verify that the correct size syringe is being replaced (sample or reagent). The S and R syringe have different piston shaft diameters.



Do not pull the piston out of a new syringe. This could cause the syringe to be inaccurate even if it is replaced.

10. Insert the new syringe into the case head without dumping the existing water from the head of the syringe. Water may escape on the side of the syringe head. Dry the excess water. Completely dry the syringe and syringe case to prevent condensation from forming on the case.
11. Tilt the syringe head upward without twisting the tubing lines. Screw the syringe case clockwise onto the case head.
12. Re-install the syringe and secure the top fixing nut *first*, and then the bottom fixing screw.

Note: Top screws must be tightened first to ensure proper syringe alignment on the analyzer.

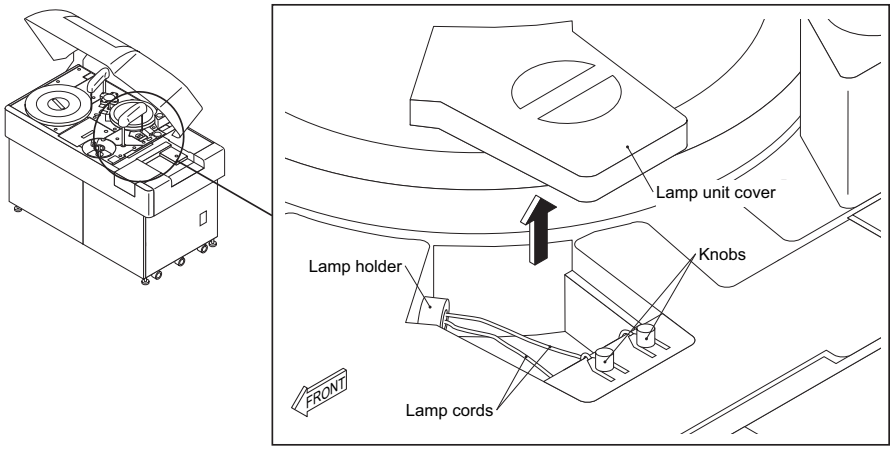
13. Tighten the piston fixing screw (bottom screw) finger tight only. Do not use pliers.

Check the system

1. Perform the following as required:
   - •If a sample syringe is replaced, select “H/S Syringe Prime" on the [ANL Maintenance] screen. This takes approximately 25 minutes to complete. Selecting F2 Exit stops the prime and exits the menu.
   - •If a reagent syringe is replaced, select “F/Prime Washing-line" on the [ANL Maintenance] screen. Repeat this step five or six times until the air in the tube is completely removed. *If the ISE Reagent (Buffer) Syringe was replaced, select [System Status], [ISE Status], F6 Prime, D/Buffer Prime.*
2. Press the Stat Rotation/Diag button. *For Sample or Reagent Syringes, DI water flows through the probe, removing air from the probe. On the ISE Buffer syringe, buffer flows through the tube and “J” nozzle, removing the air.*
3. Close the right front cover.

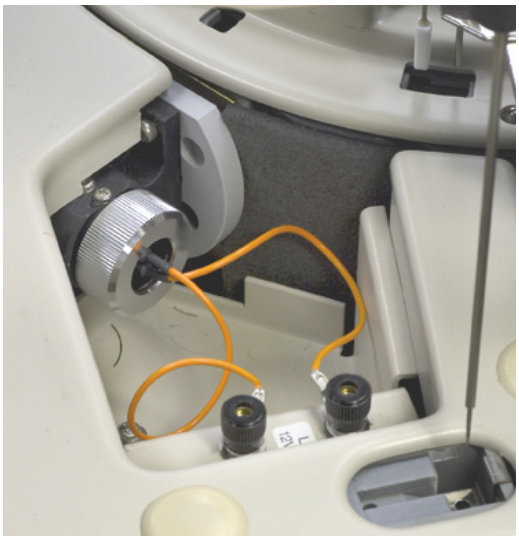
6.5 Replace the Photometer Lamp

Photometer lamps are under warranty for 1,000 hours. If the photometer lamp deteriorates, appropriate analysis results will not be obtained. Replace the photometer lamp every six months, or when the photometer check is out-of-range, or when alarms occur. After replacing the photometer lamp, perform a photocal to obtain accurate data.



Warning

- To prevent electric hazards, be sure to perform an End Process before replacing the photometer lamp.
- Wait 5 minutes or more after the End Process is completed. Do not touch the lamp with bare hands until the photometer lamp has cooled down completely. The lamp is very hot and can cause burns.
- Never touch the glass of the photometer lamp with bare hands or gloves! Oil from skin or fingerprints changes the light intensity of the lamp and decreases the measuring accuracy or cause premature failures.
- If the photometer lamp is stained, perform an End Process and wait at least 5 minutes. Check that the photometer lamp has cooled down completely, then wipe off the stain with a soft cloth dampened with alcohol.



Instruction

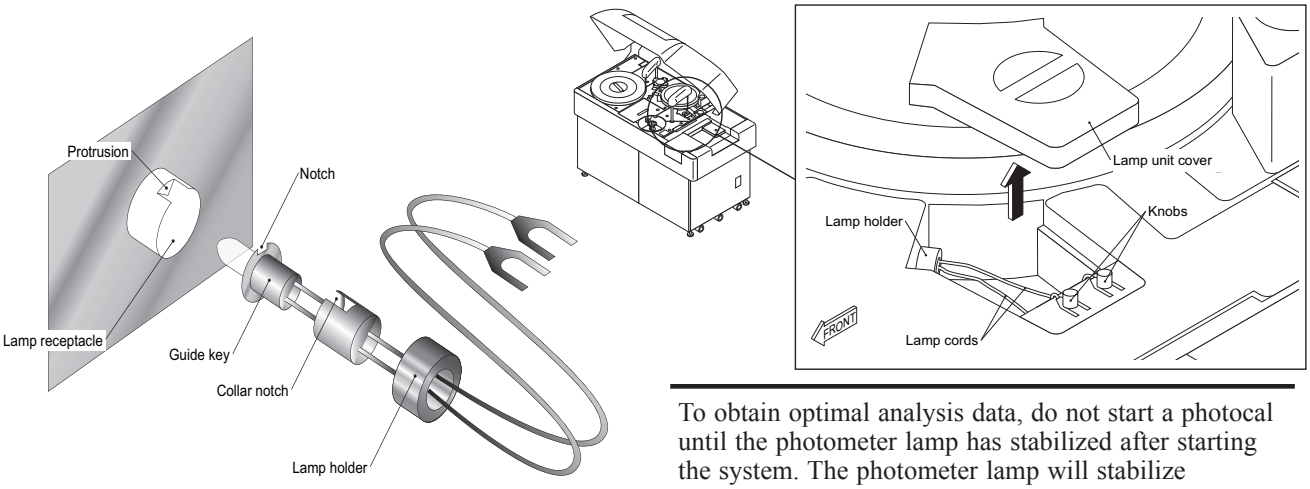
When removing the lamp unit cover, be careful not to bump the cover against the sample probe.

As Needed

Prepare the following:

- New photometer lamp MU9888

1. Check that an End Process was performed and allow at least 5 minutes for the lamp to cool after system shut down.
2. Open the upper cover.
3. Remove the lamp unit cover.
4. Loosen the two knobs on the terminals, then disconnect the two lamp cords from the terminals.
5. Loosen the lamp holder by turning it counterclockwise, then pull the photometer lamp from the receptacle.



6. Remove the lamp from the lamp holder and collar. Insert the new lamp into the collar and lamp holder.
7. Insert the lamp into the lamp receptacle. Be sure to match the notch on the guide key and the collar notch of a new photometer lamp unit with the protrusion on the lamp receptacle.

Caution

Tighten the lamp holder securely. If the lamp holder is loose, accurate analysis data cannot be obtained.

8. Turn the lamp holder clockwise to secure the photometer lamp.
9. Connect the two lamp cords to each terminal, then tighten the two knobs. *The cords can connect to either terminal.*
10. Replace the lamp unit cover.
11. Close the upper cover.

To obtain optimal analysis data, do not start a photocal until the photometer lamp has stabilized after starting the system. The photometer lamp will stabilize approximately 20 minutes after system start-up.

2. The mode changes from Warm Up to Standby after 20 minutes.
3. Optional: Perform a photometer check to make sure the lamp was installed properly.
4. Perform the Weekly Photocal procedure.

Caution

After replacing the photometer lamp, be sure to perform the photocal measurement to obtain accurate data.

See Also

For information about performing a photocal, refer to the "Weekly Maintenance" section of this chapter.

Tips

If errors occur as a result of the photocal measurement, try the following:

- For numerous errors, check that the photometer lamp was installed correctly, or the new photometer lamp may be defective:
  A. Install the photometer lamp again.

  B. Perform a photometer check.

- For few errors, the photometer lamp was replaced correctly, but some cuvettes may be stained:

  A. Clean the cuvettes that caused the error.

  B. If the error is not corrected even after cleaning, replace the problem cuvettes and perform a new photocal. Verify that photocal results are in range.

6.6 Clean or Replace Individual Cuvettes

If a cuvette is stained or scratched, a photometric error will result. To obtain accurate analysis results, replace cuvettes that have stains which cannot be removed by cleaning, or have scratches. Also, replace cuvettes that have error messages as a result of the photocal, or if cuvettes cannot pass a photocal even after sonicating them. The following procedure explains how to replace and clean individual cuvettes.

As Needed

Prepare the following:

- New cuvette ZM0634
- This procedure requires using Neutrad. *The wash solution can be ordered by calling 1-800-766-7000. The catalog number is Fisher #0435510. The wash solution can be ordered in 1 liter or 1 gallon bottles.*
- Cotton tipped applicators

1. Put the analyzer in Standby.
2. Open the rear cover of the analyzer.
3. Loosen the knob on the wash nozzle unit. Remove the wash nozzle unit and hang it on the hook.
4. Turn the mix units clockwise approximately 60 degrees by hand to move the mix bars away from the cuvette wheel.

Instruction

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

5. Gently lift and remove the cuvette wheel cover.
6. Using two cotton tipped applicators, gently insert them in the cuvette to be removed and pull up.

7. **To Replace Individual Cuvettes:** Insert the new cuvette(s) into the wheel. Gently push the cuvette completely into the wheel or problems with analysis could occur.

   To Clean Individual Cuvettes: Sonicate cuvettes in a 2% Neutrad solution for 15 minutes. If a sonicator is not available, soak them in a 5% Neutrad solution overnight. Allow the cuvettes to dry completely on the outside (overnight or with heat under 50 degrees C. A hair dryer works well). .

Instruction

Be sure to replace all cuvettes removed from the wheel. If not, the mixture, reagent, and wash solution will spill causing an overflow around the wheel. When removing cuvettes, be careful not to scratch them. Never touch the photometric face of a cuvette. If the photometric face is stained in any way the photometric data will be inaccurate.

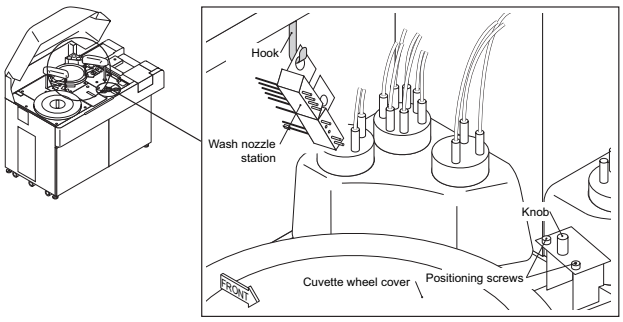
8. Replace the cuvette wheel cover.
9. Turn the mix bar unit back to its original position.
10. Remove the wash nozzle unit from the hook and screw it back into position.
11. Select [Maintenance], [ANL Maintenance].
12. Select "F/Prime Washing-line."
13. Press the STAT/Rotation Diag. button. *The wash nozzle tubing is primed with DI water.*
14. Repeat the previous step several times until air is removed.
15. Close the upper cover.
16. Perform another photocal procedure prior to running the analyzer. *All cuvettes must pass the photocal before analysis can take place.*

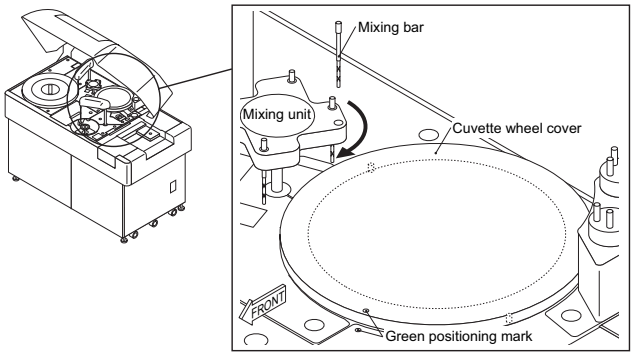
See Also

For information about how to perform a photocal, refer to the "Weekly Maintenance" section in this chapter.

6.7 Clean the Cuvettes and the Cuvette Wheel (Part of 6 month PM)

If the cuvettes and cuvette wheel are not cleaned for an extended period of time, reagents can build up on the cuvettes and wheel resulting in photometric error. Wash the cuvettes and cuvette wheel every six months. If a wheel overflow occurs, please refer to "Cleaning Cuvettes and the Cuvette Wheel after a Cuvette Wheel Overflow" located in the As Needed section of this manual.





As Needed (Part of Six Month PM)

Prepare the following:

- This procedure requires using Neutrad. *The wash solution can be ordered by calling 1-800-766-7000. The catalog number is Fisher #0435510. The wash solution can be ordered in 1 liter or 1 gallon bottles.*
- Cotton tipped applicators

Removing the cuvette wheel & cuvettes

1. Put the analyzer in Standby.
2. Open the rear cover of the analyzer.
3. Loosen the knob on the wash nozzle unit. Remove the wash nozzle unit and hang it on the hook.
4. Turn the mix units clockwise approximately 60 degrees by hand to move the mix bars away from the cuvette wheel.

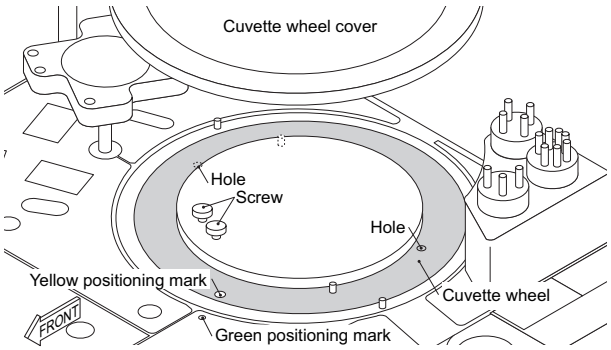
Instruction

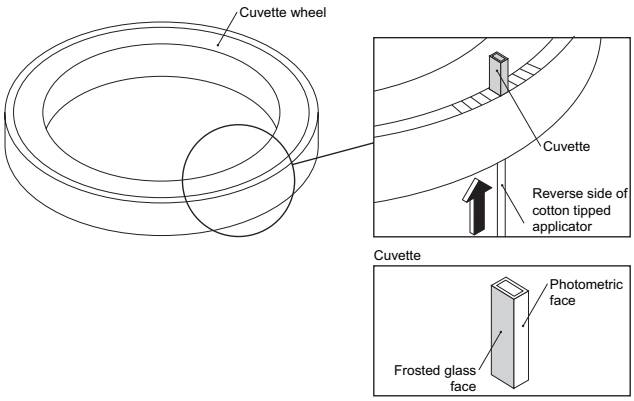
When removing the cuvette wheel cover, be careful not to scratch or bump the sample probe, reagent probes, and mix bars.

5. Gently lift the cuvette wheel cover and remove it.
6. Remove the two screws on the inner circumference of the cuvette wheel. Tighten the screws into the two specified holes shown in the drawings on the following page.
7. Use caution when removing the wheel. Bumping other devices could cause damage. Hold the two screws you placed on the wheel and lift.
8. Turn the wheel upside down and use the reverse end of a cotton tipped applicator to gently push the cuvette out from the bottom of the cuvette wheel.
9. Remove all 88 cuvettes from the wheel. *Replace any cuvettes that have obvious scratches.*

Clean and Replace the Cuvettes

1. Sonicate the cuvettes in 2% Neutrad solution for 15 minutes, or soak the cuvette in 5% Neutrad solution overnight.
2. Thoroughly rinse the cuvettes in deionized water, or sonicate them in deionized water for 10 minutes to remove any residual detergent.
3. Allow the cuvettes to dry completely. Use one of the following methods:
   - Allow cuvettes to dry naturally.
   - Use an oven with the heat set under 50 degrees Celsius. (A hair dryer works well.)
   - Use a Kimwipe.
4. Rinse the cuvette wheel with DI water and dry thoroughly with a clean cloth.



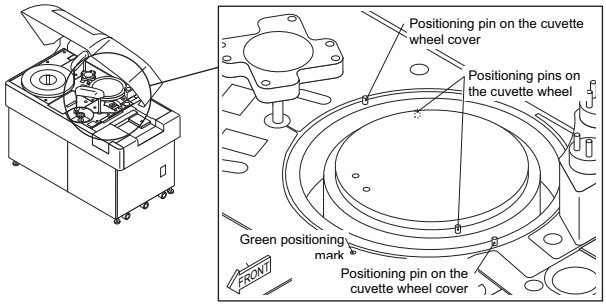


5. Insert the cuvettes back into the wheel. Ensure the cuvette is gently pushed down completely into the wheel, or problems with analysis could occur.

Instruction

Be sure to replace all cuvettes removed from the wheel back onto the wheel. If not, the mixture, reagent, detergent, etc., will spill on the wheel causing an overflow. When removing cuvettes, be careful not to scratch them. Never touch the photometric face of a cuvette. If the photometric face is stained by fingerprints, etc., the photometric data will be inaccurate.

6. Replace the cuvette wheel. Match the positioning pins as shown in the illustration below.



7. Remove the screws and place them in their original position.
8. Replace the cuvette wheel cover.
9. Turn the mix bar unit back to its original position.
10. Remove the wash nozzle unit from the hook and screw it back into position.

Check the system

1. Select [Maintenance], [ANL Maintenance].
2. Select "F/Prime Washing-line."
3. Press the STAT/Rotation Diag button. The wash nozzle tubing is primed with DI water.
4. Repeat the previous step several times until air is removed.
5. Close the upper cover.
6. Perform another photocal procedure prior to running the analyzer. *All cuvettes must pass the photocal before analysis can take place.*

See Also

For information about how to perform a photocal, refer to the "Weekly Maintenance" section in this chapter.

6.7a Clean the Cuvettes and Cuvette Wheel after a Cuvette Wheel Flood

Erroneous data is generated if the cuvettes become wet on the outside (cuvette wheel 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 Tab in the AU400/400e User's Guide.

As Needed

Prepare the following:

- Neutrad (Catalog #0435510 available through ThermoFisher at 1-800-766-7000)
- Cotton Tipped Applicators
- #2 Phillips head screwdriver.

Remove the cuvette wheel & cuvettes

1. Verify that the analyzer is in Warm up or Standby.
2. Open the large analyzer cover.

Caution

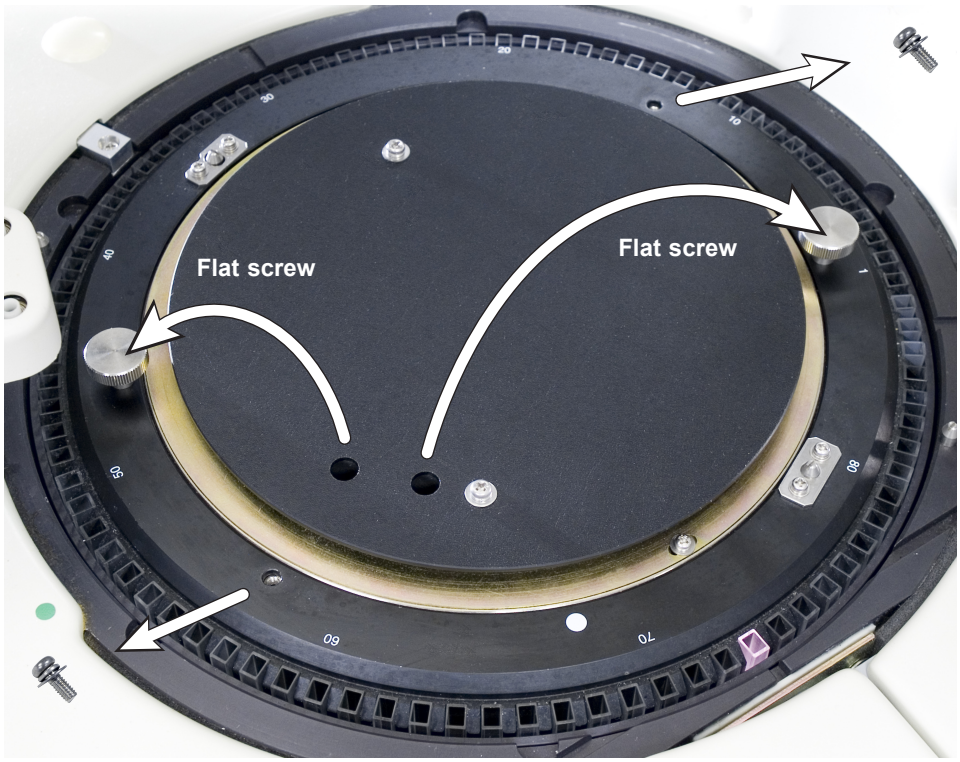
Ensure the cover is open and secured before leaning over the wash nozzle station.

3. Loosen the knob on the wash nozzle station. Support the wash nozzle when removing it from the base so that it does not hit the cuvettes. Remove the wash nozzle station and hang it on the hook.
4. Remove any mix bars positioned over the cuvette wheel. Pull the mix bars up and out. Be careful not to scratch the mix bars.
5. Gently remove the cuvette wheel cover.

Note:

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

6. Locate the 2 large, flat screws on the black plate in the center of the cuvette wheel.
7. Pull these two flat screws out of the black plate. No tools are needed to remove these screws! These screws are used as "handles" to remove the entire cuvette wheel from the incubation bath.



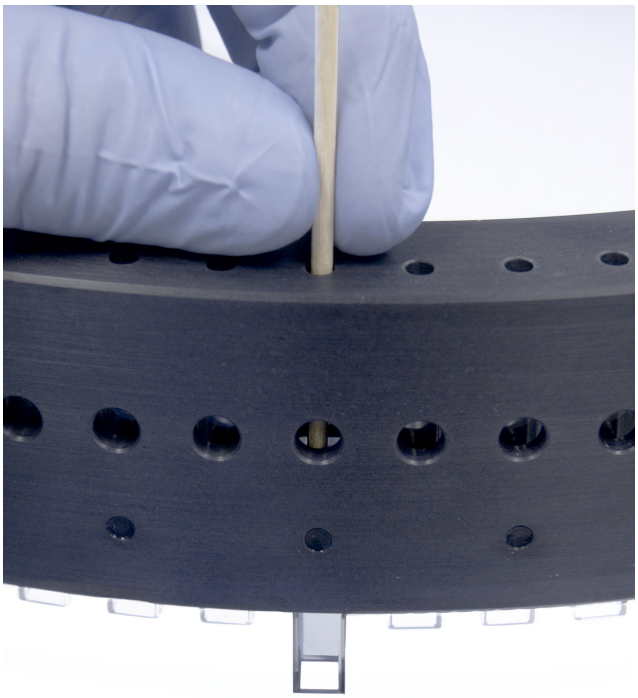
8. Attach the flat screws to the cuvette wheel. Place one of the screws into the opening on the cuvette wheel in front of cuvette number 1. Place the other screw into the opening on the cuvette wheel in front of cuvette number 46. Firmly tighten each screw into the cuvette wheel.
9. Remove the 2 Phillips screws that secure the cuvette wheel in the incubation bath using a #2 Phillips head screwdriver. These screws are located in the cuvette wheel in front of cuvette number 13 and cuvette number 57. Set these screws aside.
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 wheel slightly to clear the mix unit.

Note:

Do not touch the cuvette window.

Caution

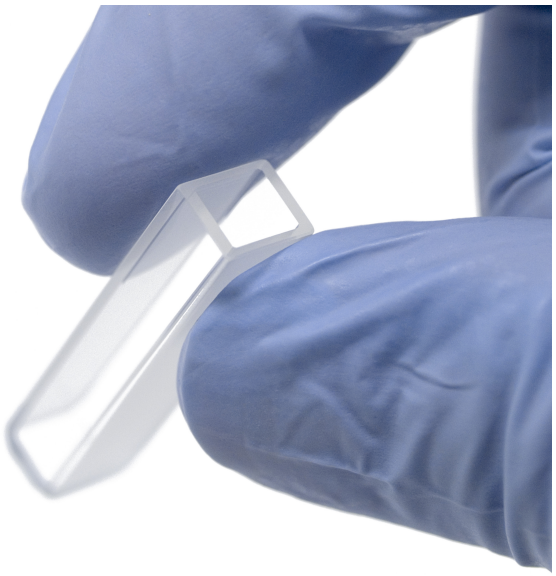
Use care when removing the cuvette wheel to avoid bumping or scratching other components.



11. Place the cuvette wheel upside down on a protected surface to remove the cuvettes. Use the reverse end of a cotton- tipped applicator stick to gently push the cuvettes out of the wheel. Remove all 88 cuvettes. Exercise caution during this procedure! The cuvettes may be scratched when they are removed from the cuvette wheel and subsequently will not pass the photocal.

Note:

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



Clean and Replace the Cuvettes

1. Sonicate the cuvettes in 2% Neutrad solution for 15 minutes, or soak the cuvette in 5% Neutrad solution overnight.
2. Thoroughly rinse the cuvettes in deionized water, or sonicate them in deionized water for 10 minutes to remove any residual detergent.
3. Allow the cuvettes to dry completely. Use one of the following methods:
   - Allow cuvettes to dry naturally.
   - Use an oven with the heat set under 50 degrees Celsius. (A hair dryer works well.)
   - Use a Kimwipe.
4. Rinse the cuvette wheel with DI water only. Do not use any cleaners or detergents as this may ruin the finish on the metal. Dry the wheel thoroughly with a lint free cloth.

Note:

In the event of a cuvette wheel overflow, dry the incubation bath with a lint free cloth. Do not use any cleaners or detergents to clean the incubation bath.

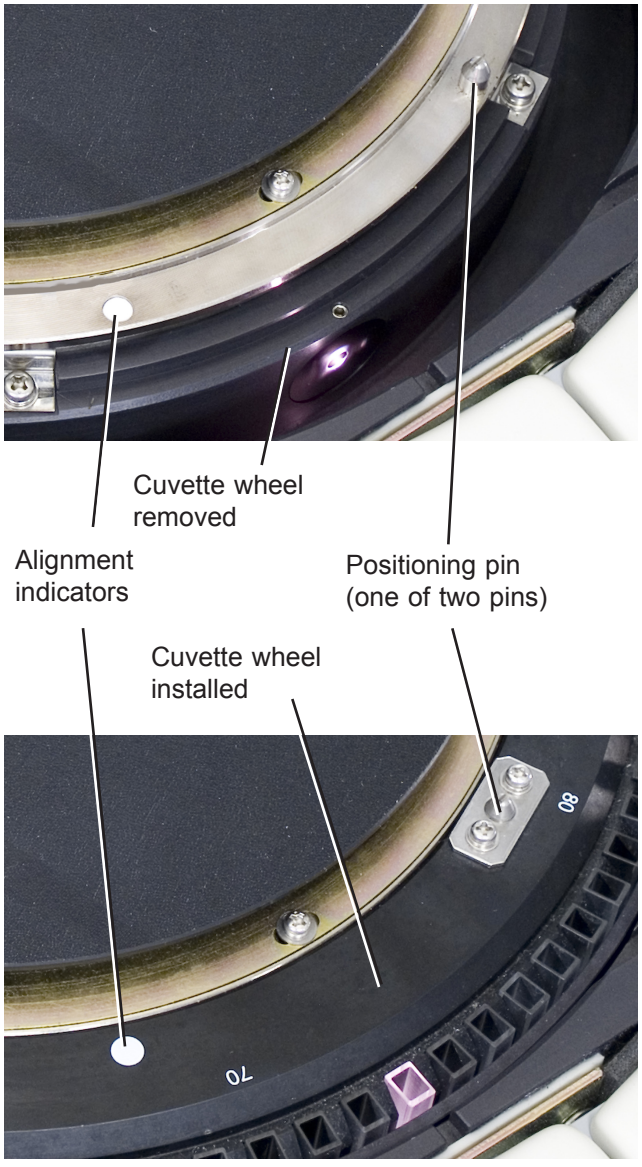
Replacing the Cuvettes and Cuvette Wheel

1. Replace all 88 cuvettes (with the open end facing up) back into the cuvette wheel.

Note:

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

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



4. Replace the 2 Phillips screws to secure the cuvette wheel in the incubation bath. These screws are located in the cuvette wheel in front of cuvette number 13 and cuvette number 57.
5. Loosen the two “handles” (large, flat screws) and set them in the openings on the black plate in the center of the cuvette wheel.
6. Replace the cuvette wheel cover by matching the green dot on the cover with the green dot on the analyzer.
7. Remove the wash nozzle station from the hook and place it on the base. Support the wash nozzle station when replacing it on the base so that it does not hit the cuvettes. Align the holes on the wash nozzle unit 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 for correct tubing placement in case any lines are disconnected.
8. Replace any mix bars that were removed. 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. Do not force the mix bar into the unit! Damage to the gears may occur.

Note:

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

Check the System

1. Select [Maintenance], [ANL Maintenance].
2. Select "F/Prime Washing-line."
3. Press the STAT/Rotation Diag button. The wash nozzle tubing is primed with DI water.
4. Repeat the previous step several times until air is removed.
5. Close the upper cover.
6. Perform the photocal procedure prior to running the analyzer. *All cuvettes must pass the photocal before analysis can take place.*

See Also

For information about how to perform a photocal, refer to the "Weekly Maintenance" section in this chapter.

6.8 Perform a W1 Procedure

Perform a W1 (Cuvette Wash) on an as needed basis. The W1 cleans all cuvettes with 2% wash solution using the wash nozzle unit, and the sample probe with the 2% wash solution in the W1 position on the stat table. The reagent probe and mix bars are cleaned in the wash wells.

As Needed

This procedure takes 9 minutes. View the upper left corner of the screen for procedure progress. The system counts down the remaining time.

Perform this procedure when either of the following is true:

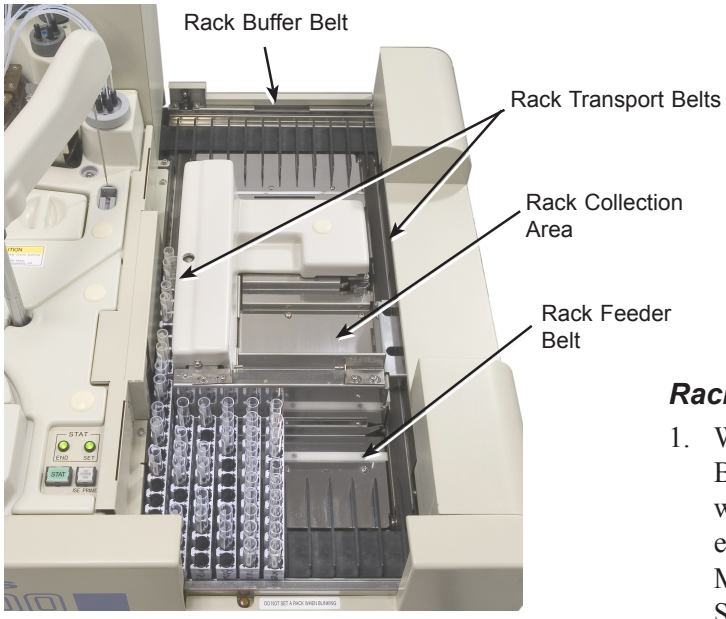
a. Stop is selected in the middle of a run, and analysis is not started again immediately.

b. Power was lost to the system during analysis, and not recovered in a short period of time.

1. From Standby, select the [System Status] icon.
2. Select function key F5 (W1 Start). *The system counts down the remaining time.*

6.9 Clean Belts and Rack Feed areas

To prevent possible rack jams, clean the following areas using a clean lint free cloth dampened with water. DO NOT USE ALCOHOL OR DETERGENT.



As needed

Prepare the following:

- Clean lint-free cloth.

Rack Transport Belts:

1. Place the analyzer in STOP mode.
2. Open the analyzer cover. Remove the unattached dark covers from the rack transport areas.
3. From the Main Menu, Select Maintenance, Maker Maintenance, (A) ANL DIAG, Sample set Unit tab, Rack Reed, (N) Normal.
4. Select "Yes" at the start Measure prompt.
5. Press the Stat Rotation/DIAG button to activate the diagnostic function.
6. To clean, hold a damp cloth to the moving belts. NOTE: *Never use alcohol to clean belts.*
7. After completing the diagnostic function, the system generates a "3150 No Rack" alarm. Clear the alarm.
8. Select Close at the Start screen.

Rack Collection Area:

1. Use a clean lint-free cloth dampened with water to clean the rack collection area.

Rack Feeder Belt:

1. Wipe the bottom and sides of the Rack Feeder Belt with a clean lint-free cloth dampened with water. If it is necessary to move the belt for ease of cleaning, Select [Maintenance], [Maker Maintenance], [Anl Diag]. Click the Sample Set Unit tab at the top of the screen. Select "Q/Forward" and then press the white, Stat rotation/Diag button on the top of the instrument panel. This advances the belt for ease of cleaning. Dry the area with a dry lint-free cloth when completed.

Rack Buffer Belt:

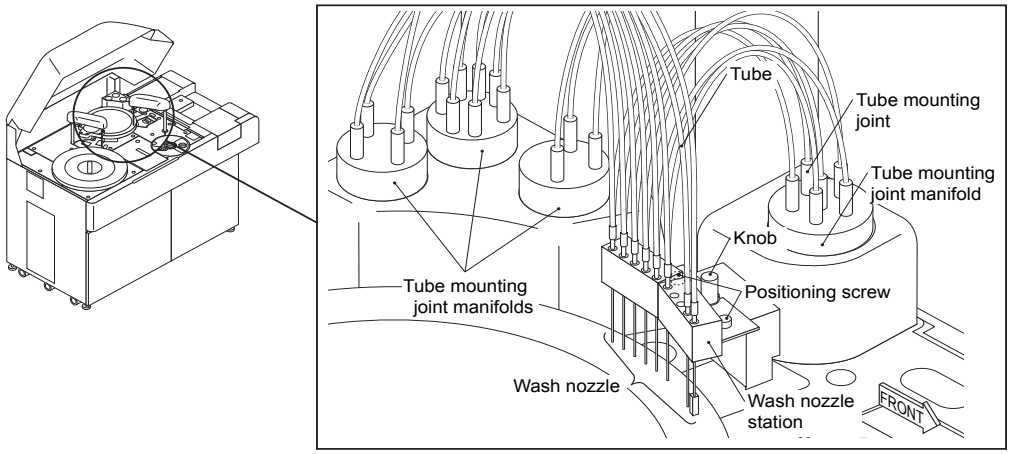
1. Wipe the bottom and sides of the Rack Buffer Belt with a clean lint-free cloth dampened with water.
2. If it is necessary to move the belt for ease of cleaning, select [Maintenance], [Maker Maintenance], [Anl Diag]. Click the Mix/Wheel/Nozzle tab at the top of the screen. Select "T/Forward" and then press the white, stat rotation/diag button on the top of the instrument panel. This advances the belt forward for ease of cleaning. Dry the area with a dry lint-free cloth when completed.

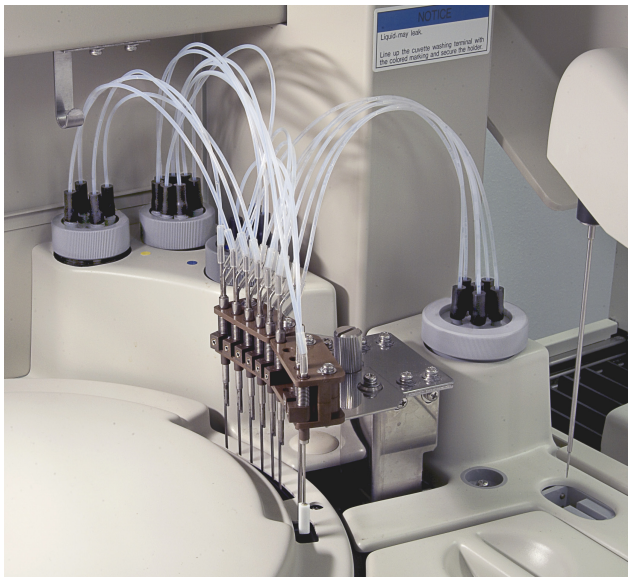
Finish

1. Select F2 EXIT to return to the Main Menu.
2. Click the STOP icon or press the STOP/Standby key to return the analyzer to the standby mode.
3. Replace the dark covers over the rack transport areas.
4. Close the large analyzer cover.

6.10 Clean the Wash Nozzle Unit

The wash nozzle unit is equipped with a total of eight nozzles. The unit consists of six wash nozzles (three-part nozzle) for mixture aspiration, wash solution/deionized-water (DI-water) dispensing, and wash solution/DI water overflow aspiration, and one nozzle each for aspiration and drying. If a nozzle is clogged, the nozzle function is weakened. This results in a cuvette wheel overflow or problems with the analysis data. To prevent an overflow and abnormal analysis data, clean the wash nozzle unit every month. This procedure is also included in the monthly procedure, Clean the wash nozzle unit, Deionized-Water Tank and Filter, and Sample Probe Filter.





As Needed Procedure

Prepare the following:

- Dry, clean cloth (KIMWIPE)
- Sonicator filled with DI water

Remove the Wash nozzle unit

1. Open the upper cover.
2. Verify that the analyzer is in the Warm-up or Standby Mode.
3. Select [Maintenance], [ANL Maintenance].
4. Select "E/Replacing Wash Nozzle."
5. Press the STAT ROTATION/DIAG button. *The liquid in the tubing on the wash nozzle unit is drained.*
6. Open the rear cover.
7. Remove the four tube mounting joint manifolds from the wash nozzle unit.

Instruction

- When handling the wash nozzles, be careful not to scratch them.
- When loosening the knob on the wash nozzle unit station, do not loosen the positioning screws on both sides of the knob. These screws are used for positioning the wash nozzle unit.

8. Loosen the knob on the wash nozzle unit, then remove the wash nozzle unit along with the tubing.

Clean and replace the Wash nozzle unit

Caution

After placing the wash nozzle unit in the sonicator, verify that the tips of the wash nozzle do not rest on the bottom of the sonicator. When the sonicator is running the wash nozzle to vibrate and can damage the tips.

Instruction

- When cleaning the wash nozzle unit using a sonicator, be careful not to scratch the wash nozzles.
- Do not scratch or tear the joints and tubes. A leak may result from the scratched part and the cuvette wheel may overflow.

Tips

The sonicator is the optimal device for cleaning the wash nozzles. If a sonicator is not available, use DI water. While pouring water into the wash nozzles, clean each nozzle hole using the supplied stylet. Rinse the nozzles in DI water, then dry them with a soft cloth.

9. Clean the wash nozzle unit along with the tubing for 15 minutes, using DI water in a sonicator. No wash solution is required.
10. Take out the wash nozzle unit from the sonicator, then wipe up the water drops using a soft cloth.
11. Using a gauze dampened with water, wipe any foreign matter from O-rings such as dust or detergent residue. If foreign matter remains, remove the O-ring with tweezers, wash with water, and re-insert.
12. If any O-ring is scratched or damaged, replace with O-ring MU9638.

Caution

If O-rings are used without cleaning for an extended period of time, or if the cover on the jount unit is closed without any O-ring set in the groove, detergent crystals will collect and could scratch the O-ring. Check the O-rings during Monthly mainteance. For more reliable maintenance, replace the O-rings once a year.

Instruction

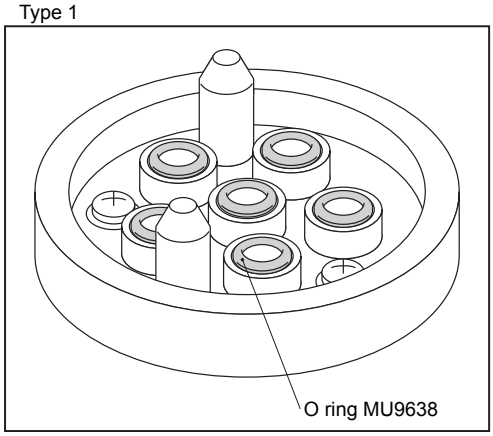
Be sure to attach the tube mounting joint manifolds in their original places. If a manifold is attached incorrectly, normal analysis cannot be performed.

13. Attach the manifolds, tighten them firmly. When attaching the manifolds, match the color connections and tighten them firmly. *For information about the tube mounting joint positions, refer to the drawing on the following page.*
14. Match the two positioning holes on the wash nozzle unit with the positioning screws, then fix the station by tightening the knob.
15. Close the rear cover.

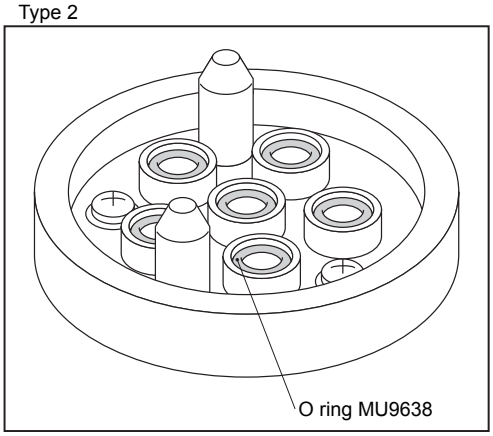
Check the system

1. Select “F/Prime Washing-line” on the [Maintenance], [ANL Maintenance] screen.
2. Press the Stat Rotation/DIAG button. *The air in the tubing of the wash nozzle unit will be released.*
3. Close the upper cover.

Type 1

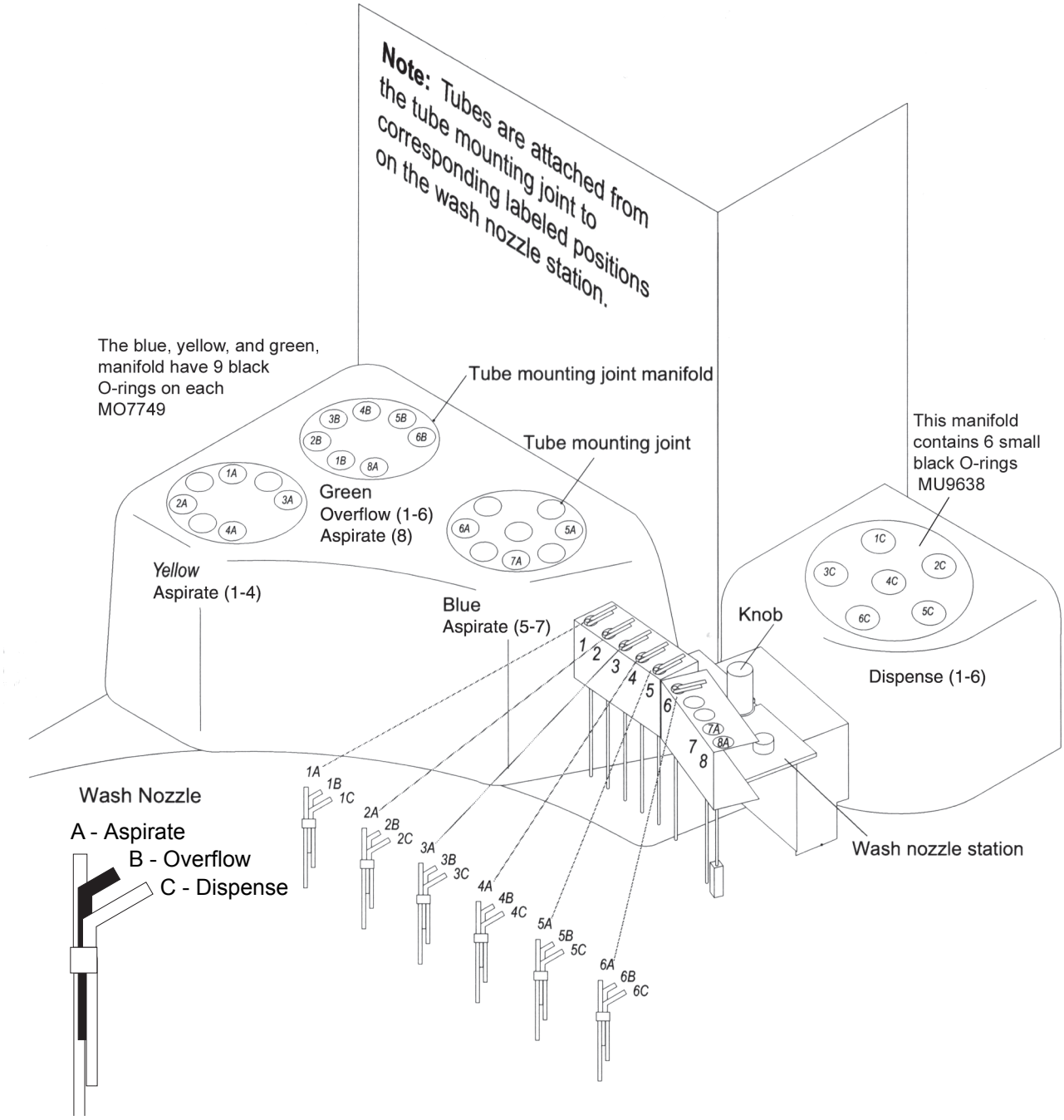


Type 2



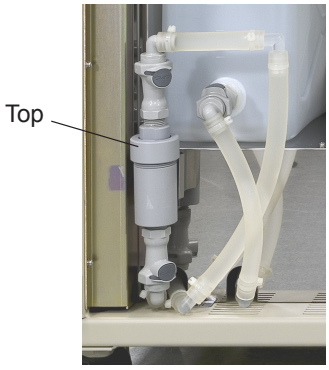
Tubing Diagram of the Wash Nozzles and Tube Mounting Joints

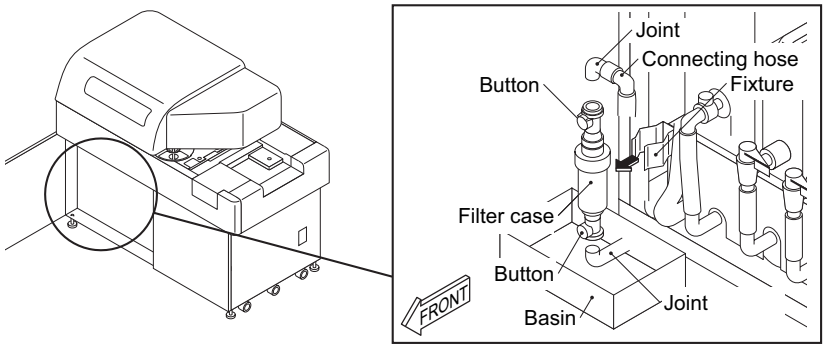
In order to distinguish individual connecting positions easily, follow the tubing diagram below:



6.11 Clean or Replace the Sample Probe Filter

If the sample probe filter is dirty, the system may generate abnormal analysis data. This procedure is also included in the monthly procedure, Clean the Wash nozzle unit, Deionized-Water Tank and Filter, and Sample Probe Filter.





As Needed Procedure

Prepare the following:

- Dry, clean cloth
- Basin
- Sonicator filled with DI water
- New water filter ZM3079 (if needed)

Removing the sample probe filter

Instruction

Perform an End Process before performing this procedure. If this is performed with the sub-power to the system turned on, water could spill from tubing and tanks.

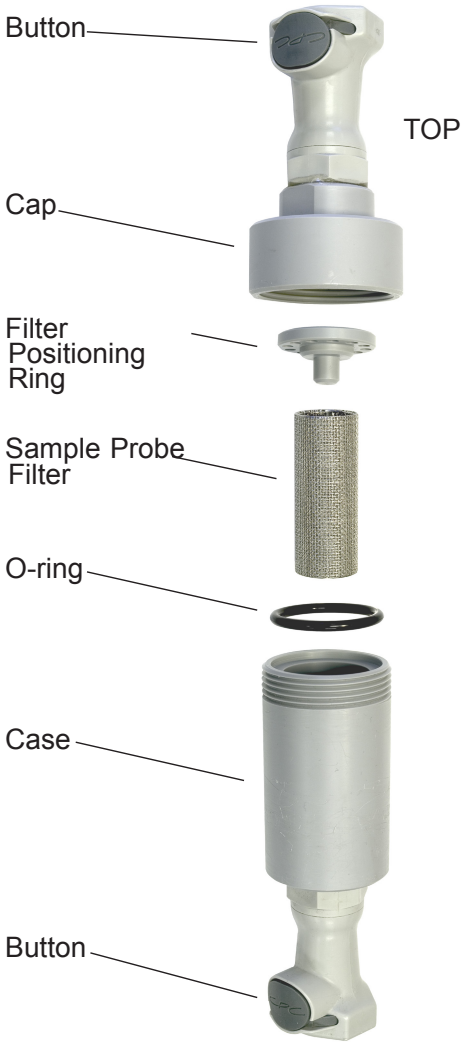
1. Confirm that an End Process was performed.
2. Open the left front cover.
3. Position a basin to catch any liquid that spills from the deionized-water drain hose.
4. Pull the Sample Probe filter case forward to remove the case from the fixture.
5. While pressing the buttons, disconnect the joints at each end of the sample probe filter case.

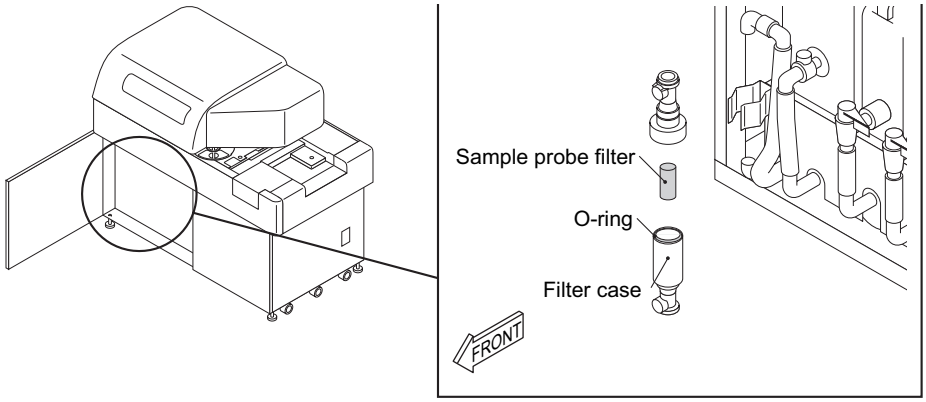
Instruction

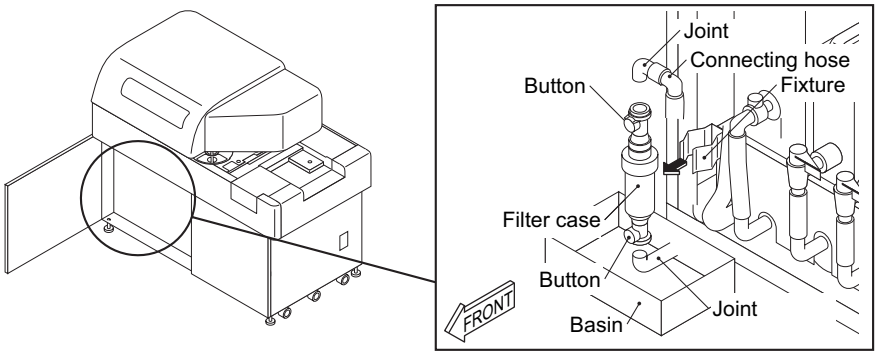
Loosen the filter case over the basin. The deionized water in the filter case will drain from the joint. If water spills onto the system, immediately wipe it up with a dry, clean cloth.

When removing the sample probe filter, be careful not to lose the O-ring or the filter positioning ring.

6. Unscrew the case and remove the sample probe filter.







Cleaning and replacing the Sample Probe Filter

1. Clean the Sample Probe Filter for 10 minutes, using DI water in a sonicator. *If a sonicator is not available, rinse in DI water. While pouring DI water onto the filter, scrub it with a toothbrush.*
2. If necessary, replace the filter with part number ZM3079.
3. Inspect the O-ring, Filter Positioning Ring, and the inside of the case. Remove any accumulations with a damp towel.
4. Rinse the Sample Probe Filter in deionized water.
5. Insert the Sample Probe Filter into the filter case.
6. Position the O-ring correctly on the filter case.
7. Place the Filter Positioning Ring over the filter.
8. Assemble the top of the filter case and tighten.
9. Refer to the illustrations and verify that the top of the filter case is pointed upward and connect the two hoses to the filter case fittings. *Push each hose connector into the filter case until a click is heard.*
10. Push the Sample Probe Filter Case into the metal clip.
11. Check for leaks. If no leaks are present, remove the basin.

Check the system

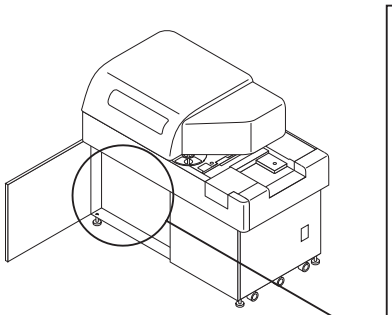
1. Press the Green power button to apply power to to the system.
2. After initialization, select [Maintenance], [ANL Maintenance].
3. Select "F/Prime Washing-line."
4. Press the STAT ROTATION/DIAG button.
   - Observe the DI-Water and filter tubing. *The deionized water will flow through the tube and then the air in the DI-Wiater tubing will be released. This prime may need to be performed 2-3 times to ensure that all of the air is out of the tubing.*
5. Repeat the previous step two or three times until the air in the affected tubing is completely removed.
6. Close the left front cover and the upper cover.

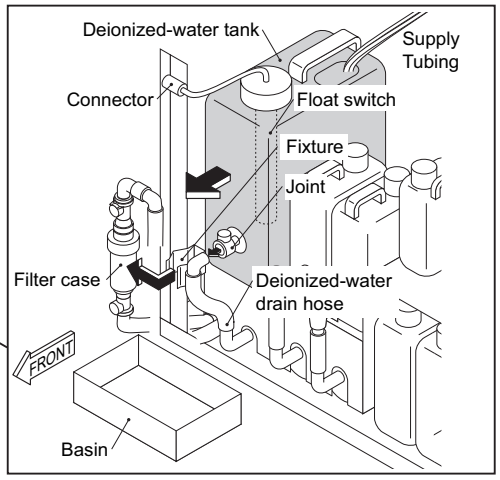
6.12 Clean the Deionized-Water Tank

Regular cleaning prevents the accumulation of deposits or bacteria that could affect analysis. This procedure is also included in the monthly procedure, Clean the Wash nozzle unit, Deionized-Water Tank and Filter, and Sample Probe Filter.

Tips

If low-quality deionized water is obtained from the main water source, the two diluted wash solution tanks may need to be cleaned in addition to the deionized-water tank. For detailed information, contact Beckman Coulter Technical Services.





As Needed Procedure

Prepare the following:

- Dry, clean cloth
- Basin
- Freshly prepared 20% bleach
- Extra DI tank (In start-up kit)

Instruction

Perform an End Process before performing this procedure. If this procedure is performed with the sub-power to the system turned on, the float switch in the deionized-water tank will activate and excess water will drain from the tubing.

Remove and clean the Tank

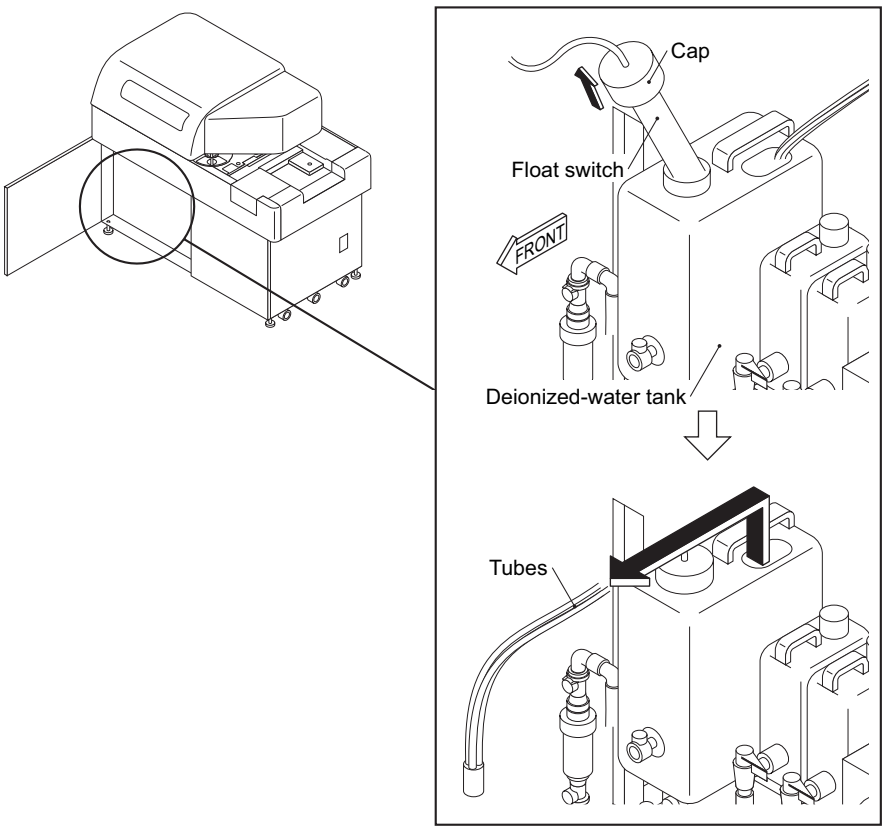
1. Confirm that an End Process was performed.
2. Open the left front cover.
3. Unplug connector #240.
4. Position a basin under the deionized-water drain hose on the floor.
5. Pull the Sample Probe Filter Case forward to remove it from the metal clip.
6. While pressing the button, disconnect the joint of the deionized water drain hose from the tank.
7. Pull the DI water tank forward while removing the tubes inserted in the tank. Lay the tubes in the basin
8. Remove the deionized-water tank from the instrument.
9. Loosen the water tank cap and remove the float switch.
10. Rinse the inside of the tank and tubes with a fresh 20% bleach solution and rinse thoroughly with deionized water.
11. Let the tank air dry.

Install the spare tank

1. Fill the spare DI tank at least half full with DI water and install the tank. Alternate tanks so each one can dry thoroughly between cleaning.

Caution

If the tank is empty, and the pump runs without water, the pump may be damaged.



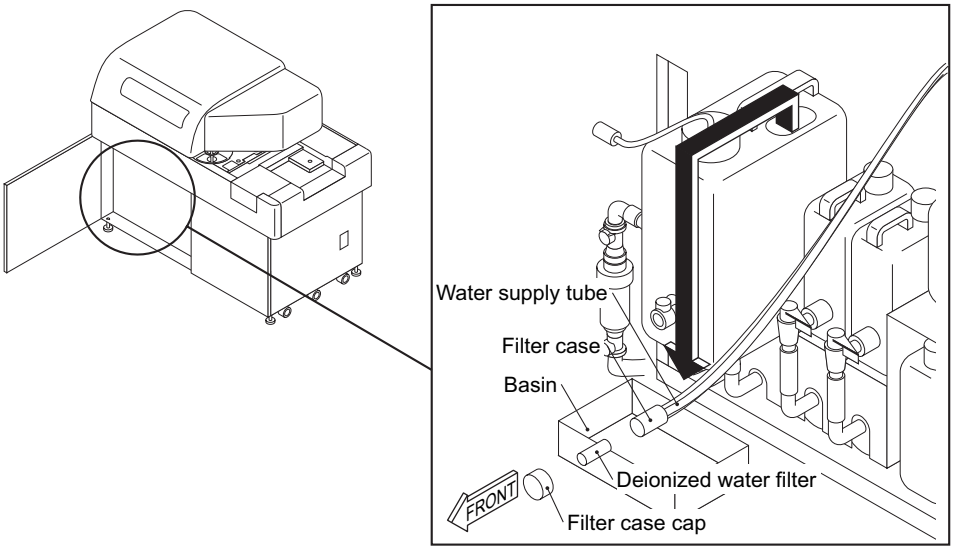
2. Insert the float switch and the water supply tubes into the deionized-water tank.
3. Replace the DI-water Tank in the system. *Verify that the tubing is fully inserted in the DI-water Tank.*
4. Reconnect the joints on the deionized-water tank and Sample Probe Filter Case. *Push each joint until a click is heard.*
5. Tighten the cap.
6. Reconnect connector #240. When reconnecting the #240 connector, do not force the connection or the pins can be damaged. Turn the connector gently until it slides into the connection easily and without force.
7. Push the Sample Probe Filter Case into the metal clip.
8. Remove the basin.

Check the system

1. Press the Green power button to apply power to to the system.
2. After initialization, select [Maintenance], [ANL Maintenance].
3. Select "F/Prime Washing-line."
4. Press the STAT ROTATION/DIAG button.
   - Observe the DI-Water and filter tubing. *The deionized water will flow through the tube and then the air in the DI-Wiater tubing will be released. This prime may need to be performed 2-3 times to ensure that all of the air is out of the tubing.*
5. Repeat the previous step two or three times until the air in the affected tubing is completely removed.
6. Close the left front cover and the upper cover.

6.13 Clean or Replace the Deionized-Water Filter

If the deionized-water filter is dirty, the system may generate abnormal analysis data. This procedure is also included in the monthly procedure, Clean the Wash nozzle unit, Deionized-Water Tank and Filter, and Sample Probe Filter.



As Needed Procedure

Prepare the following:

- Dry, clean cloth
- Basin
- Sonicator filled with DI water

Removing the deionized-water filter

Instruction

Perform an End Process before performing this procedure. If this procedure is performed with the sub-power to the system turned on, the float switch in the deionized-water tank will activate and excess water will drain from the tubing.

1. Confirm that an End Process was performed.
2. Open the left front cover.
3. Disconnect connector #240.
4. Position a basin to avoid spilling liquid from the deionized-water drain hose onto the floor.
5. While pressing the button, disconnect the joint of the deionized water drain hose from the tank.
6. Pull the Sample Probe filter case forward to remove it from the metal clip.
7. Pull the DI water tank forward while removing the tubes inserted in the tank. Lay the tubes in the basin.
8. Remove the deionized-water tank from the instrument.

Instruction

Loosen the filter case over the basin. The deionized water in the filter case will drain from the joint. If the deionized water spills onto the system, immediately wipe it off with a dry, clean cloth.

9. Turn the DI-Water Filter case cap to remove it.
10. Remove the deionized-water filter from the filter case.

Cleaning and replacing the deionized-water filter

1. Clean the deionized-water filter for 10 minutes in DI water using a sonicator. *If a sonicator is not available, pour DI water over the filter while scrubbing it with a toothbrush.*
2. If necessary, replace the water filter with part number ZM3079.
3. Rinse the deionized-water filter in deionized water.

4. Insert the deionized-water filter into the filter case.
5. Replace the filter case cap and hand tighten.

Caution

If the tank is empty, and the pump runs without water, the pump may be damaged.

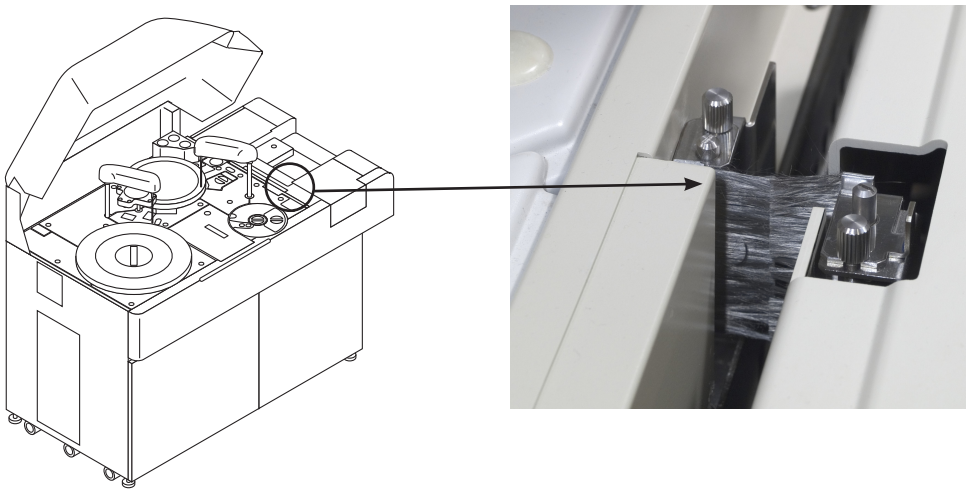
6. Replace the deionized-water tank in the system. *Verify that the tubing is fully inserted in the DI-water Tank.*
7. Connect the joints onto the DI water tank. *Push each joint until a click is heard.*
8. Reconnect connector #240. When reconnecting the #240 connector, do not force the connection or the pins can be damaged. Turn the connector gently until it slides into the connection easily and without force.
9. Push the Sample Probe Filter Case into the metal clip.
10. Remove the basin.

Check the system

1. Press the Green power button to apply power to to the system.
2. After initialization, select [Maintenance], [ANL Maintenance].
3. Select "F/Prime Washing-line."
4. Press the STAT ROTATION/DIAG button.
   - Observe the DI-Water and filter tubing. *The deionized water will flow through the tube and then the air in the DI-Wiater tubing will be released. This prime may need to be performed 2-3 times to ensure that all of the air is out of the tubing.*
5. Repeat the previous step two or three times until the air in the affected tubing is completely removed.
6. Close the left front cover and the upper cover.

6.14 Clean or Replace the Static Discharge Brushes

Static discharge brushes reduce the chance of static electricity affecting a sample reading, by allowing static electricity to discharge before sampling takes place.



Static Discharge Brush Maintenance

When sample tubes or cups are overfilled with sample, the excess sample accumulates on the static discharge brushes during analysis. This accumulation can eventually lead to a level detection error or a rack jam. To prevent these errors, users should clean soiled brushes or replace brushes that are worn or cannot be cleaned.

Cleaning or replacing the Static Discharge Brushes

Prepare the following:

- Latex gloves
- Alcohol prep
- Static Discharge Brush MU8424 (Left side).
  Static Discharge Brush MU8423 (Right side)

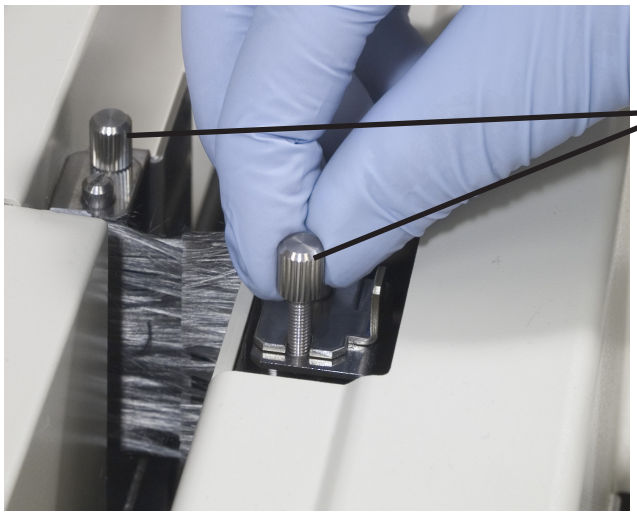
Note

Part numbers MU8424 and MU8423 include one static discharge brush, order one of each if replacing both brushes. Analyzers should have two static discharge brushes installed on each side of the rack transport. If the analyzer is equipped with only one static discharge brush contact your Field Service Engineer.

Caution

To avoid infection always wear latex gloves to clean or replace the static discharge bushes. If your hands come in contact with the static discharge brushes, wash the affected area thoroughly.

1. Select the Stop key or icon to place the analyzer in STOP mode.
2. Remove the dark acrylic cover from the rack transport area over the cup detector and barcode reader area.

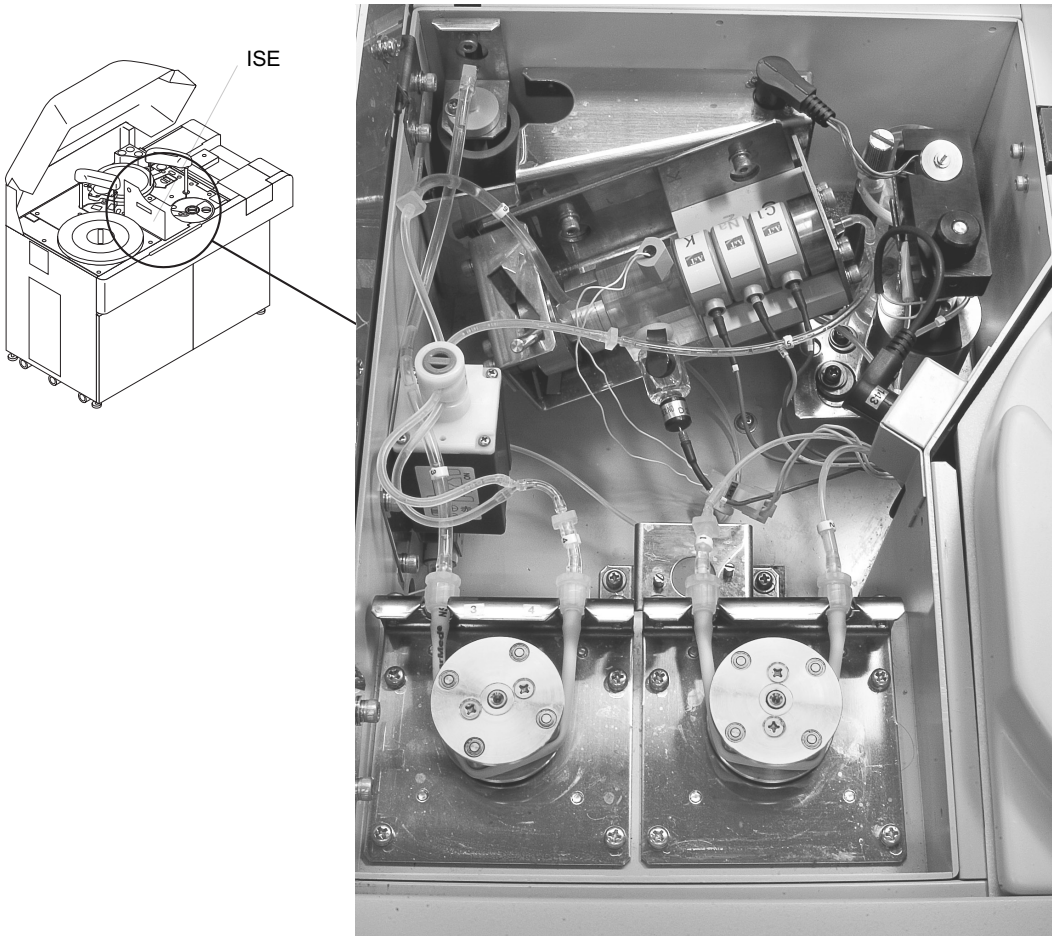


3. Loosen the static discharge brush screws by turning them gently counter clockwise until they stop turning. The screws will not come off the analyzer.
4. Lift the brush assembly out of the instrument by tilting the bottom of the static discharge brush away from the static brush housing, then, lift it up and out clearing the mounting hole for the flat mounting pin located on the side of the static discharge screw.
5. Follow the same procedure with the brush assembly on the other side of the rack transport.
6. Clean any stain on the brushes with an alcohol prep from the base to the end of the bristle tips.
7. If the static discharge brushes are still stained after cleaning or show signs of wear, replace them.
8. Dispose of the old brushes in a receptacle for biohazard waste.
9. Reinstall the clean or replaced brushes, making sure the flat mounting pins on the static discharge housing fit into the mounting holes on the brush assembly.
10. Tighten the brush screws, on each assembly.
11. Replace the dark acrylic cover from the rack transport above the cup detector and barcode reader area.
12. Select the Stop key or icon to place the analyzer in warm up or standby mode.

7. ISE Maintenance

Each part on the ISE unit requires periodic maintenance to maintain the performance of the ISE unit. This chapter gives detailed information about maintenance required for the ISE unit.

Contents

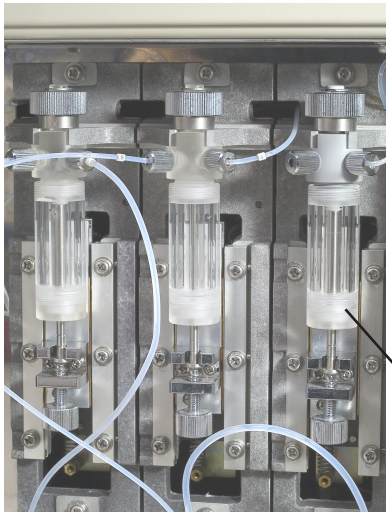


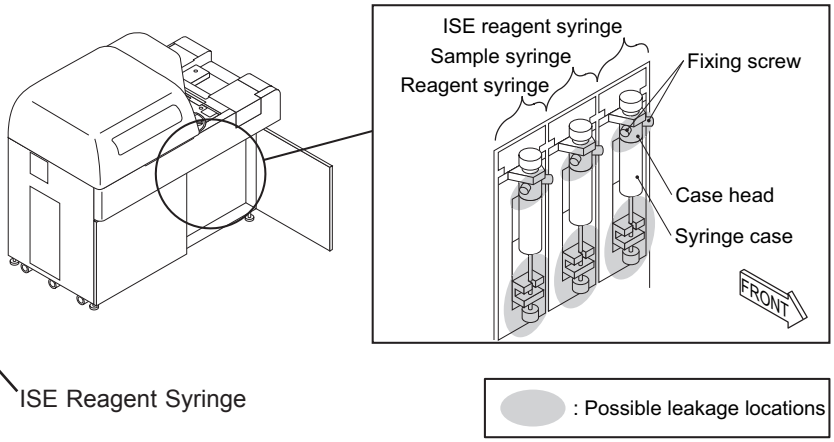
7.1 Daily ISE Maintenance

To obtain accurate results and optimum system performance, be sure to perform the following daily ISE maintenance procedures. Record maintenance on the schedules located at the beginning of this chapter. *Maintenance items can also be recorded on-line in the [Periodic Maintenance] screen.*

7.1.1 *Inspect the ISE Reagent (Buffer) Syringe for Leaks*

The ISE reagent syringe dispenses a very small amount of buffer to the sample pot. The buffer is used to make the ISE sample dilution. If liquid leaks from the syringe, incorrect amounts of buffer will be dispensed, and a problem with ISE analysis will result. Before starting daily analysis, check the ISE reagent syringe for leaks or condensation in the syringe case.





Daily Maintenance

Prepare the following:

- Clean dry cloth

1. Open the right front cover.
2. Check the following areas for leaks: bottom of the syringe cases, the case head, syringe case, area around the fixing screws, and the tubing. (Also make sure the tubing is not crimped.)

See Also

For information about replacing syringes, refer to the "As Needed ISE Maintenance" section in this chapter. For information about troubleshooting syringe problems, refer to the Troubleshooting Chapter.

Caution

If your skin comes in contact with liquid, immediately and thoroughly wash with water.

Caution

Do not place any body parts in the path of moving equipment, unless you are certain that the analyzer is in Stop or Standby and that diagnostic functions are not activated.

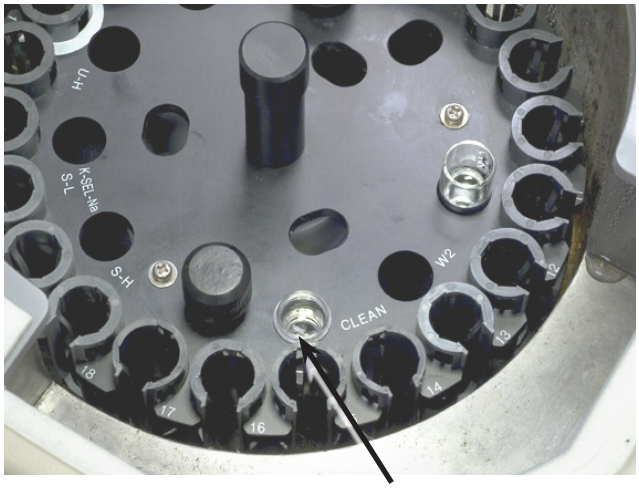
3. Check the fixing nut (top) and piston fixing screw (bottom). Tighten them if necessary.
4. Verify that the bottom screw is placed securely against the syringe piston.
5. Visually check for leaks inside the syringe case. *Replace any damaged component.*

If leaking or condensation is present, perform the following steps:

6. Loosen the top and bottom fixing screws and pull the syringe and case forward.
7. Verify that the syringe provides a smooth, resistant pull by pulling on the piston.
8. Turn the syringe case by hand. *If the case head and syringe case are loose, tighten them by turning the syringe case clockwise toward the case head.*
9. Visually check each case head for cracks. *If there are cracks on the case head, replace the case head.*
10. Remove the syringe from the case head and verify that there is one O-ring, and that it is not damaged.
11. Verify that the correct size syringe (reagent syringe) is placed in the appropriate position.
12. Close the right front cover.
13. If the previous steps are not successful, refer to the Replace Sample and Reagent Syringe procedure in the Analyzer As Needed Maintenance section.

7.1.2 ISE Cleaning

After completing daily analysis, be sure to clean the sample pot and electrode lines. Contamination or inaccurate results may occur if the cleaning cycle is not performed.



ISE Cleaning Solution

Daily Maintenance

Prepare the following:

- ISE Cleaning Solution (AUH1019)
- One ISE cup (MU9232)

1. Check that the system and the ISE unit are on and the system is in Warm-up or Standby.

Caution

If cleaning solution comes into contact with your eyes or is ingested, immediately consult your MSDS guide.

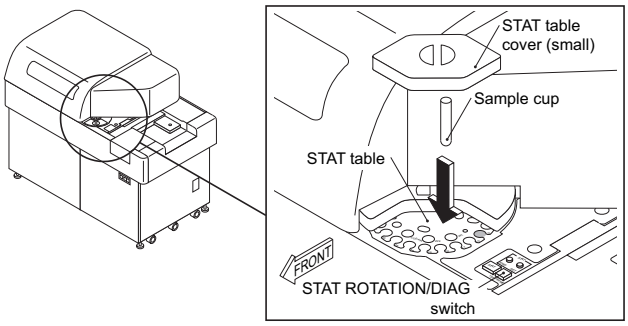
2. Fill the ISE cup with 1mL of the ISE cleaning solution.
3. Remove the small STAT table cover.
4. Rotate the STAT table by pressing the STAT ROTATION/DIAG button until the "CLEAN" position on the table can be accessed.
5. Set the sample container in the "CLEAN" position on the STAT table.
6. Press the [System Status] key. *The System Status screen will appear.*
7. Select [ISE Status] on the screen. *The ISE Status screen will appear.*
8. Press function key F5 (ISE unit start) on the [ISE Status screen]. *The window for selecting the kind of ISE single operations will appear.*
9. Select "E/Cleaning." *The window for confirming whether to start the process will appear.*
10. Select “YES.” *The system starts cleaning the sample pot and electrode line. This process requires approximately 4 minutes to complete.*
11. After the cleaning cycle is complete, press function key F2 (exit) two times. *The system returns to the Main menu.*

7.2 Weekly ISE Maintenance

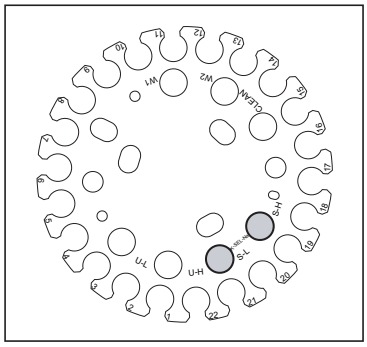
To obtain accurate results and optimum system performance, be sure to perform the following weekly ISE maintenance procedures. Record maintenance on the schedules located at the beginning of this chapter. *Maintenance items can also be recorded on-line in the [Periodic Maintenance] screen.*

7.2.1 Perform a Selectivity Check for the Na/K Electrodes

Na and K are ion-selective electrodes. If the selectivity of electrodes deteriorates, the ISE unit is affected by ions other than those to be measured and appropriate analysis results will not be obtained. To check the electrodes for deterioration, check the selectivity of the Na and K electrodes every week.



STAT Table Top View



Weekly Maintenance

Prepare the following:

- Selectivity Check Solution AUH1018
- (The set contains bottles for Na and K.)

Note

Before performing this procedure a valid ISE calibration is necessary.

1. Check that the system and the ISE unit are on and the system is in Warm-up or Standby.
2. Pour Na and K electrode check solution into different sample containers.
3. Remove the small STAT table cover.
4. Rotate the STAT table by pressing the STAT ROTATION/DIAG button until the S-H and S-L positions on the table can be accessed.
5. Place the sample containers filled with each check solution on the STAT table. Place the Na container in the “S-H” (“SEL-Na”) position. Place the K container in the “S-L” (“K-SEL”) position.
6. Press the [System Status] key. *The System Status screen will appear.*
7. Select [ISE Status] on the screen. *The ISE Status screen will appear.*
8. Press function key F5 (ISE unit start) on the [ISE Status screen]. *The window for selecting the kind of ISE single operations will appear.*
9. Select "D/Check selective." *The window for confirming whether to start the process will appear.*
10. Select “YES.” *The system starts the selectivity check process for the ISE. This process requires approximately 3 minutes to complete.*
11. Remove the sample containers from the STAT table. *Discard the remaining check solution and the sample containers.*
12. Replace the small STAT table cover.
13. After completing the check process, select the "Result Select" tab. *The selectivity check results will appear.*
14. Check the selectivity data. *For abnormal data, the background of the numeric value is displayed in yellow. The system interprets the following values as abnormal data: A value more than 160 for Na-electrode, a value more than 6.0 for K-electrode, and values of zero. If an electrode value is judged abnormal, refer to the Troubleshooting Chapter.*
15. *To remove the concentrated check solution,* Perform an M-R Prime 3 times. *Select [System Status], [ISE]. Press F6 (prime) and select M-R prime. Press the STAT ROTATION/DIAG button.*

See Also

For information on electrode replacement, refer to the "As Needed ISE Maintenance" section in this chapter.

7.3 Maintenance Every Two Weeks

To obtain accurate results and optimum system performance, be sure to perform the following ISE maintenance procedure every two weeks. Record maintenance on the schedules located at the beginning of this chapter. *Maintenance items can also be recorded on-line in the [Periodic Maintenance] screen.*

7.3.1 Clean the mix bars, liquid level sensors, sample pot and sample pot tubing.

Maintenance Every Two Weeks

Prepare the following:

- ·Alcohol Prep
- Wash Solution (OSR0001) diluted to 1%
- Sonicator

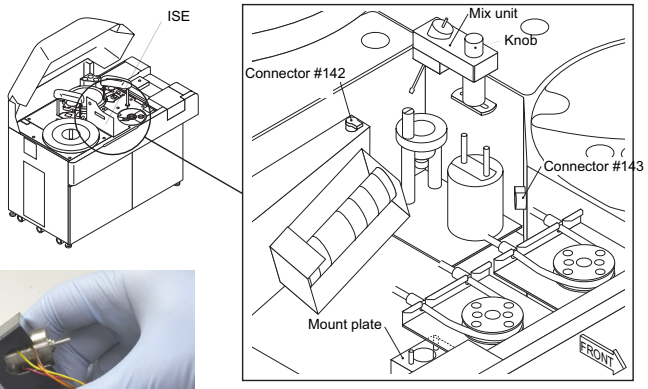
Clean the mix bar and liquid level sensors

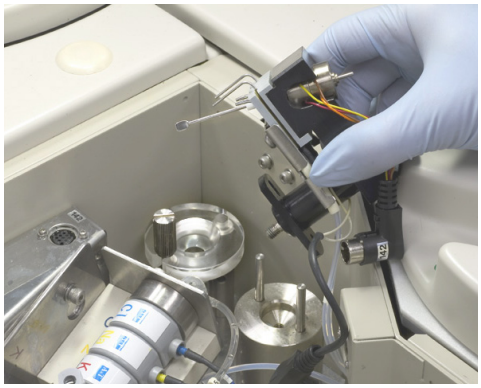
1. Verify that the analyzer is in Warm up or Standby.
2. Open the analyzer cover.
3. Select [System Status], [ISE Status], function key F6 Prime.
4. Select "A/Replace Electrode."
5. To drain the flowcell, press the Stat/Rotation Diag button on top of the instrument panel.

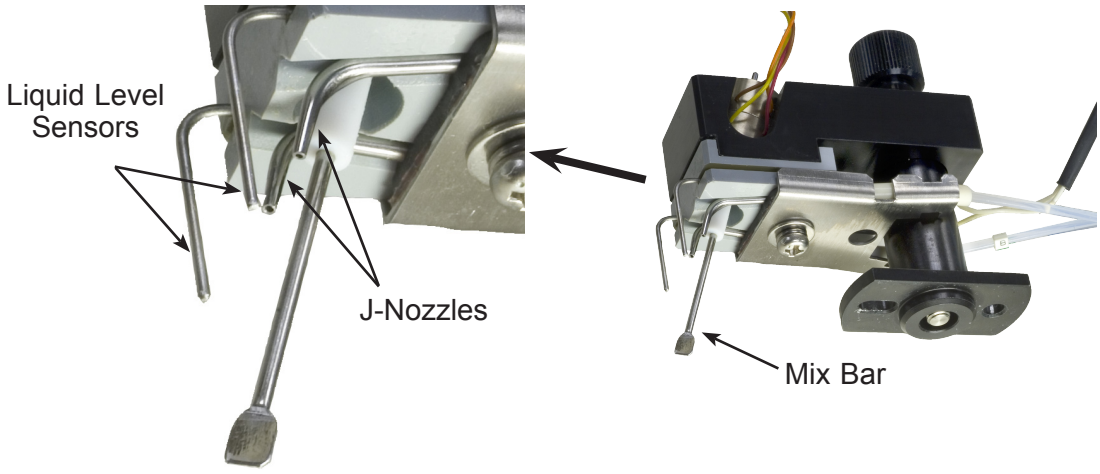
Note:

The AU400 ISE unit automatically primes the mid-standard reagent every hour of inactivity to keep the electrodes conditioned. Normally this procedure takes 20 minutes and requires removing the sample pot and tubing. To prevent a spill if the unit is apart for more than one hour, turn off the ISE switch.

6. Open the ISE unit cover.
7. Disconnect the Mix Motor connector #142 and Liquid Level Sensor connector #143.
8. Loosen the knob on the Mix Unit. Lift the unit from the positioning pins.





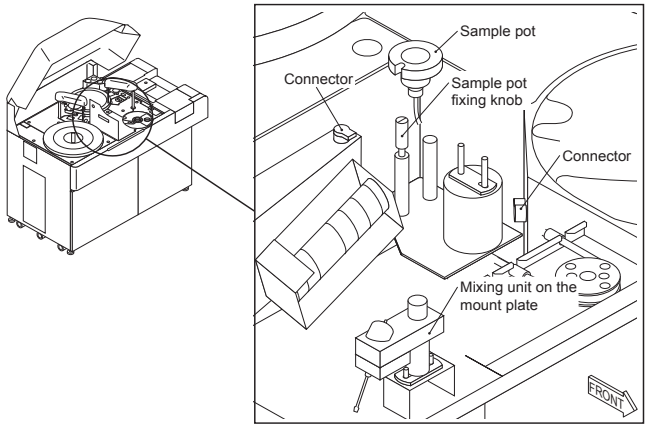


9. Carefully wipe the Mix Bar and Liquid Level Sensors with an alcohol prep using a downward stroke.

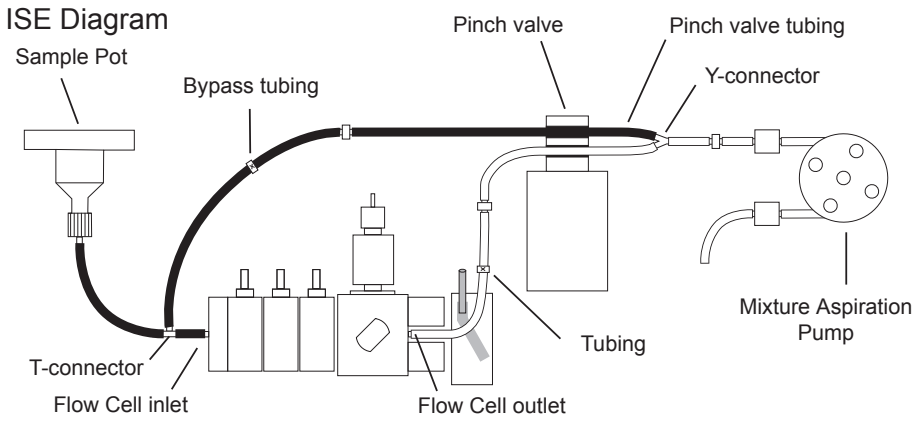
10. Set the Mix Unit aside.

Remove and clean the Sample Pot and tubing

11. Loosen the retaining knob on top of the Sample Pot. Lift the pot from the peg.



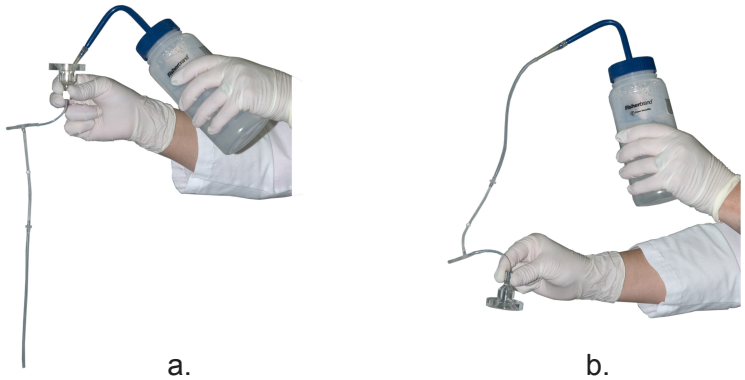
12. Hold the Sample Pot and remove the Sample Pot tubing from the inlet of the flowcell. Remove the Pinch Valve tubing from the Pinch Valve.
Disconnect the Pinch Valve tubing #5 at the Y-connector near the Mixture Aspiration Pump. The Mixture Aspiration Pump is labeled 3 and 4.



13. Using a pipette tip attached to a squeeze bottle or a syringe, fill the Sample Pot tubing, Bypass tubing, and Pinch Valve tubing with the 1% Wash Solution.
    a. Place the pipette tip or syringe inside the bottom of the Sample Pot. Force the wash solution through the Sample Pot tubing.
    b. Place the pipette tip or syringe in the Pinch Valve tubing. Force the wash solution through the Pinch Valve tubing, T-connector, and Bypass tubing.

Note:

Perform this procedure over a sink. Use caution when flushing the tubing. Position the tubing downward to avoid splashing the eyes or face.



a. b.

14. Place the Sample Pot and tubing in a beaker containing 1% Wash Solution.
15. Place the beaker in the sonicator (filled with water) and sonicate for 10 minutes.

16. Rinse the Sample Pot with DI water.
    a. Place the pipette tip or syringe at the bottom of the sample pot. Force DI water through the sample pot tubing.
    b. Place the pipette tip or syringe in the pinch valve tubing. Force DI water through the Pinch Valve tubing, line connector, and Bypass tubing. Verify that the lines are flushed thoroughly.

Note:

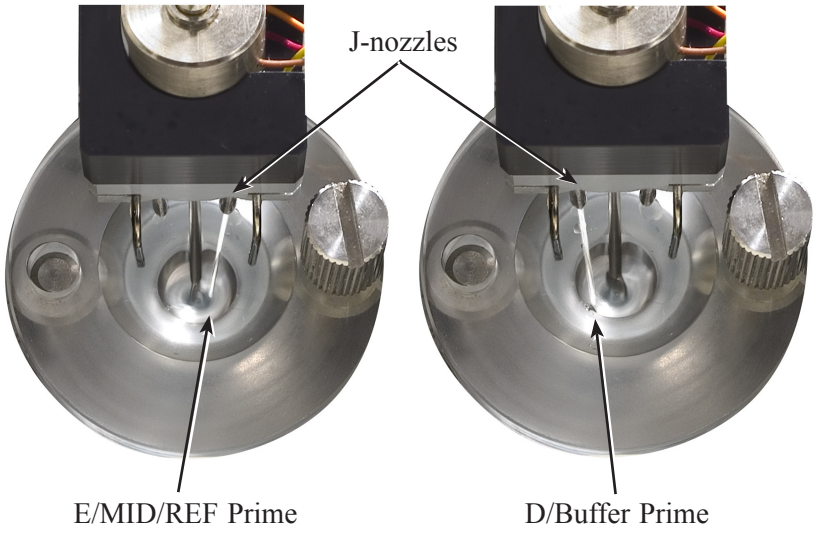
Perform this procedure over a sink. Use caution when flushing the tubing. Position the tubing downward to avoid splashing the eyes or face.

17. Dry the sample pot and tubing.

Re-install the Sample Pot and tubing

1. While holding the Sample Pot, push the Sample Pot Tubing on the inlet of the flowcell.
2. Re-install the Sample Pot. Align the hole on the top of the Sample Pot with the peg and place the screw in the slit on the opposite side. Tighten the screw.
3. Push the Pinch Valve tubing onto the Y-connector located near the Mixture Aspiration pump.
4. Push the Pinch Valve tubing into the top slot of the Pinch valve.
5. Place the Mix Unit on the two positioning pins. Tighten the knob to secure the unit. Connect the Mix Motor connector #142 and Liquid Level Sensor connector #143.
   Note: The connectors are specifically keyed to fit each plug. To avoid damage to the pins, do not force a connector into its plug. If the pins are damaged, the Mix Bar will not turn or the Level Sensors on the Mix Unit will not function properly.

Prime the ISE flowcells and tubing



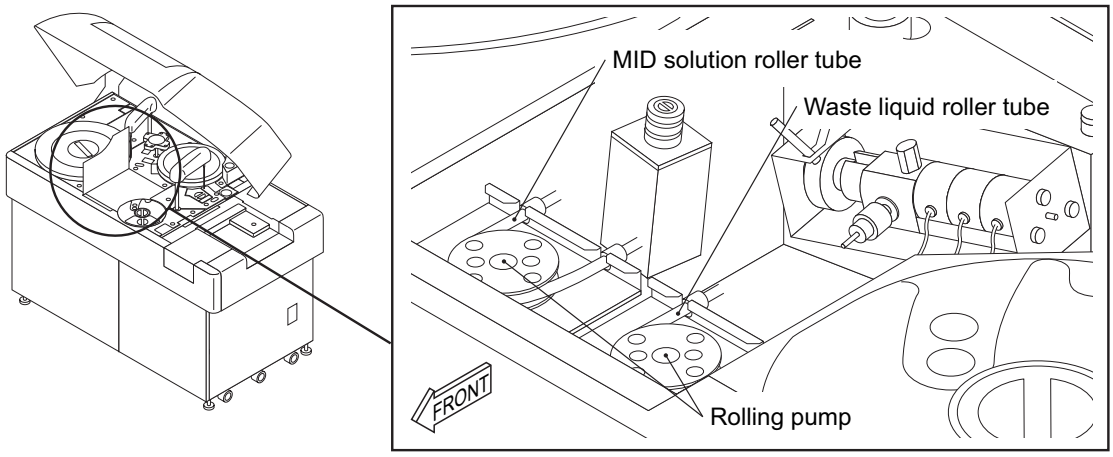
1. Select “E/MID/REF Prime.” Press the Stat/Rotation Diag button. The unit begins priming for eight cycles.
2. Observe the Mix Unit J-nozzle. Liquid should flow in a straight line from the J-nozzle into the center of the Sample Pot.
3. Observe the tubing at the outlet of the flowcell (#6). Verify that all bubbles are removed. If bubbles are present, check all tubing placement and connections and repeat steps 1 and 2. Do not calibrate the ISE until all air is removed from the flowcell.
4. Select “D/Buffer Prime”. Press the Stat/Rotation Diag button. The unit begins priming for eight cycles.
5. Verify that the Sample Pot fills and drains with buffer. Liquid should flow in a straight line from the J-nozzle into the center of the Sample Pot.
6. Close the ISE cover.
7. Use fresh standards to perform an ISE calibration and verify that a valid slope is obtained. See Chapter C Basic Operations.

7.4 ISE Maintenance Required Every Three Months

To obtain accurate results and optimum system performance, be sure to perform the following ISE maintenance procedures every three months. Record maintenance on the schedules located at the beginning of this chapter. *Maintenance items can also be recorded on-line in the [Periodic Maintenance] screen. These procedures are performed twice a year by your Field Service Engineer as a part of the preventative maintenance service. The operator is also responsible for performing these maintenance procedures twice a year.*

7.4.1 Replace the Mixture and Mid-Standard Pump Roller Tubing

The roller tubing will deteriorate due to pressure from the rolling pump and vibration. If the roller tubing is not replaced for an extended period of time, it may become flat or worn and leaks may occur. Replace the roller tubing every three months. *This procedure is performed twice a year by your Field Service Engineer as a part of the preventative maintenance service. The operator is also responsible for performing this maintenance procedure twice a year.*



Maintenance Every Three Months

Prepare the following:

- Roller tube MU9623

1. Select [System Status], [ISE Status], F6 Prime.

NOTE

Remain in the "F6 Prime" menu.

2. Select "A/Replace Electrode."
3. Press the STAT ROTATION/DIAG button. *Liquid will be drained from the tubing.*
3. Open the upper cover.
4. Open the ISE cover.

Caution

Be careful not to spill the solution on the roller tube when replacing the tube.

Instruction

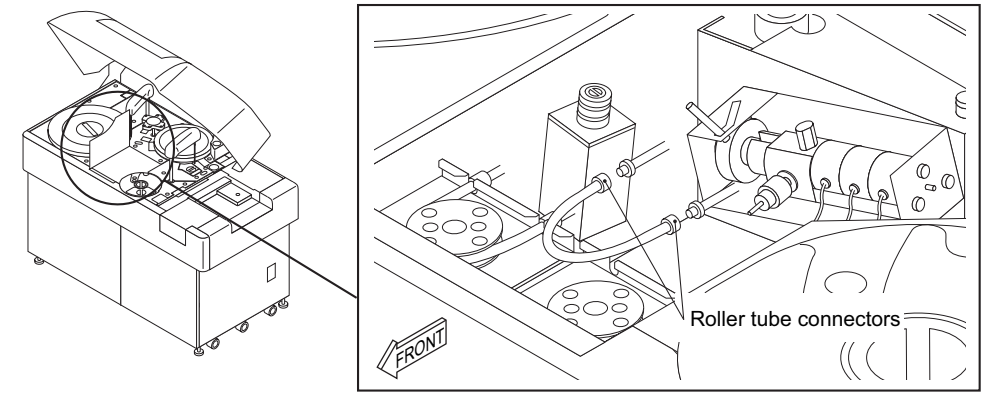
The roller tubing consists of the MID solution roller tube and the mixture roller tube. Replace these two roller tubes at the same time.

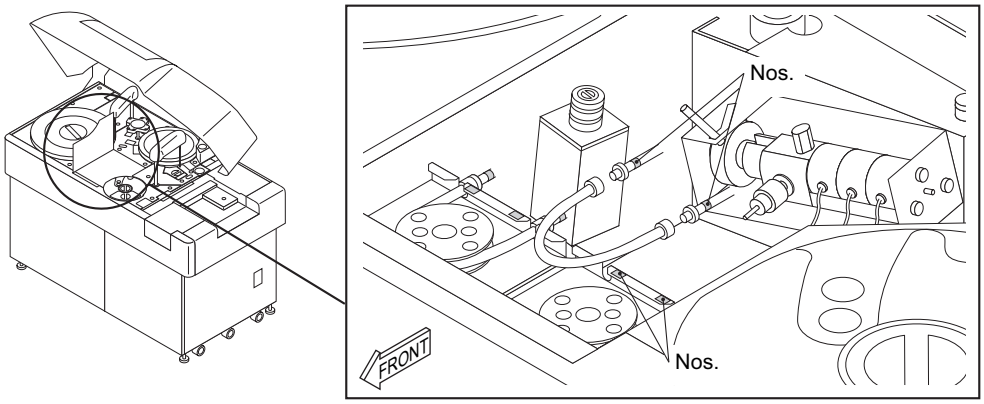
5. The MID solution and mixture roller tubes are stretched over the rolling pump cylinders. Stretch and lift tubing up and away from the rolling pump. Allow it to rest on top of the cylinders.
6. Unscrew each roller tube connector to remove the roller tube.
7. Connect a new roller tube. *Secure the connectors at both ends of the tube by screwing them hand tight.*

Instruction

Verify the tubing numbers match the labeled pump connectors. If connected incorrectly, liquid will not be supplied or drained correctly.

8. Place the roller tubes on the correct rolling pumps, then match the connectors with the notches in the vicinity of the rolling pump.

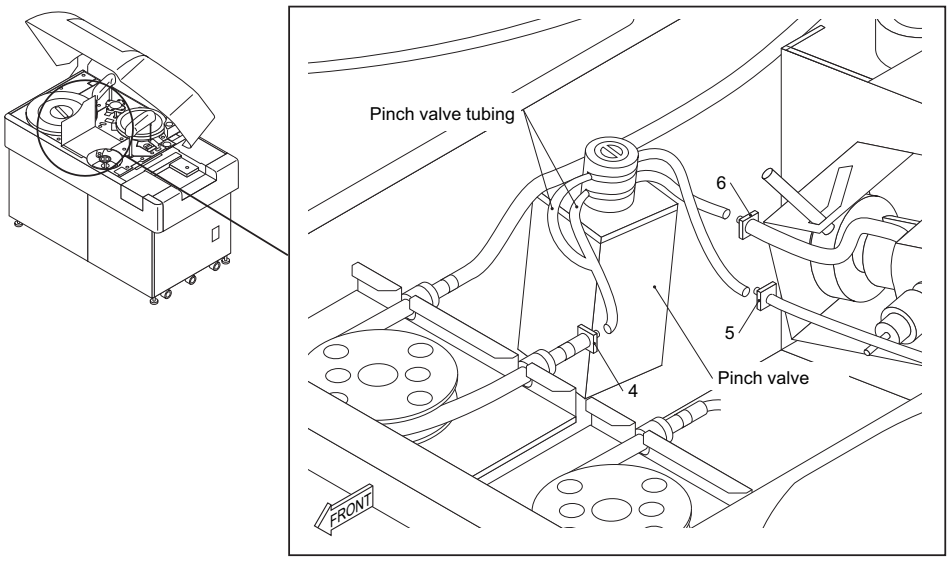


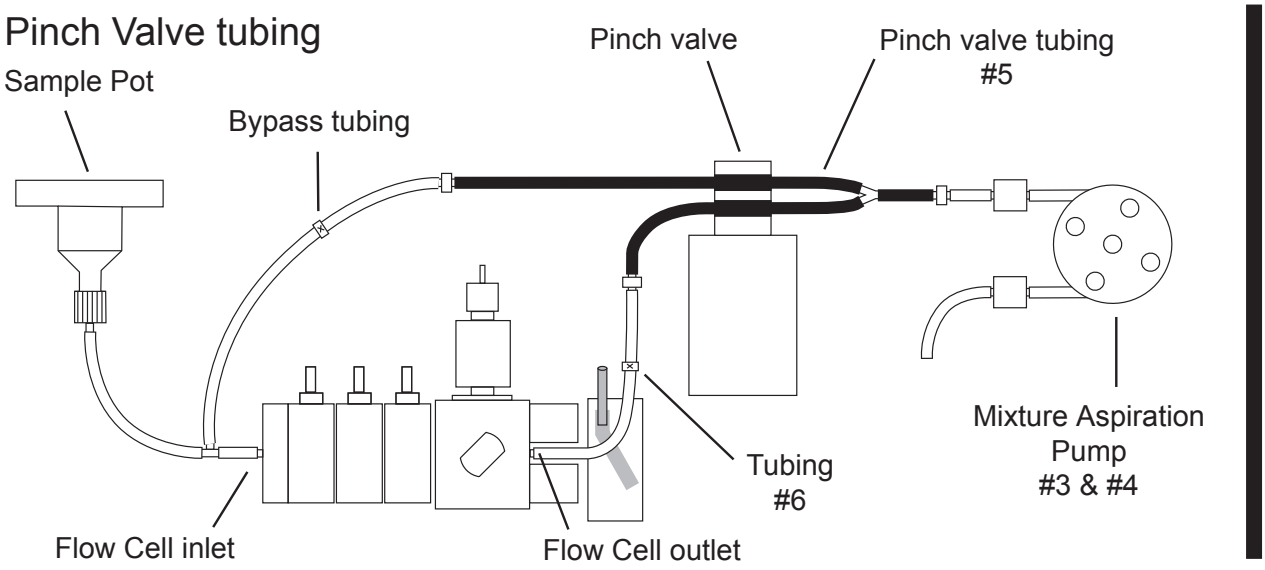


9. Press the STAT ROTATION/DIAG button. *The two rolling pumps are turned on to move the solution in each roller tube. Check that the liquid is completely aspirated from the sample pot to the electrode unit. If liquid remains in the sample pot, check the pinch valve tubing connection. Refer to the diagram located on the ISE unit door.*
10. Select Close.
11. Close the ISE unit cover.
12. Close the upper cover.

7.4.2 Replace Valve Tubing

The tubing positioned in the pinch valve may deteriorate with use over time. Replace the pinch valve tubing every three months. *This procedure is performed twice a year by your Field Service Engineer as a part of the preventative maintenance service. The operator is also responsible for performing this maintenance procedure twice a year.*





Maintenance Every Three Months

Prepare the following:

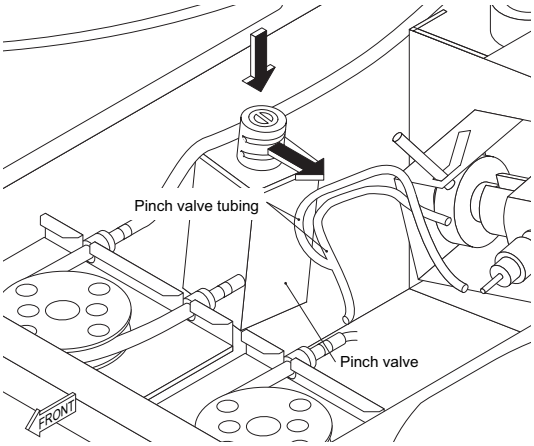
- New pinch valve tubing ZM2970

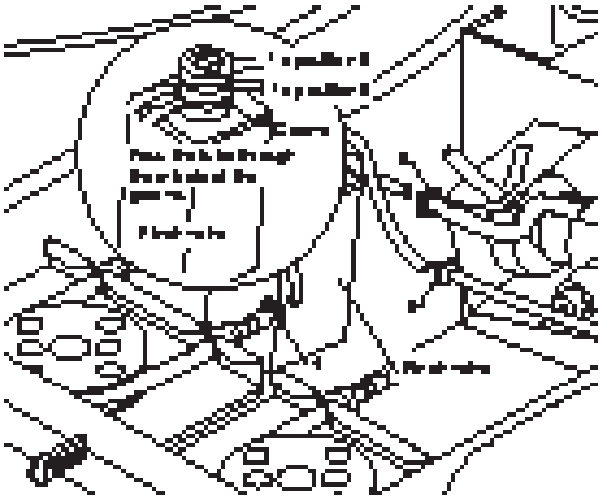
1. Select [System Status], [ISE Status], F6 Prime.

Note

Remain in the "F6 Prime" menu.

2. Select "A/Replace Electrode."
3. Press the STAT ROTATION/DIAG button. *Liquid will be drained from the tubing.*
4. Open the upper cover.
5. Open the ISE cover.
6. Disconnect the three ends of the pinch valve tubing. *Disconnect the tube ends at positions 4, 5, and 6 in the drawing above.*
7. Pull the top pinch valve tube to the right (#5 in drawing) until it is removed from the slot.





While pressing the green button on top of the pinch valve, pull the lower tube from the slot (#6 in the drawing), then release the button.

Instruction

Do not mount each branch tube in a different groove on the pinch valve. If it is mounted backwards, the liquid will not be supplied and drained correctly.

8. Mount a new section of pinch valve tubing by connecting the branches at positions 4, 5, and 6, as described above. Connect the longer Y-branched tube at position 5.

   Note: There is a diagram inside the ISE Unit cover indicating the correct positions in the pinch valve for tubing 5 and 6.

9. Replace the lower tube (#6 in the drawing) by pressing the green button on top of the pinch valve. Make sure the tube is inserted all the way into the slot. Release the green button and insert the top tube (#5 in the drawing) by pushing it all the way into the slot.

10. Press the STAT ROTATION/DIAG button. *The two rolling pumps are turned to move the solution in each roller tube. Check that the liquid is completely aspirated from the sample pot to the electrode unit. If liquid remains in the sample pot, check the pinch valve tubing connection. Refer to the diagram located on the ISE unit door.*

11. Select Close.

12. Close the ISE unit cover.

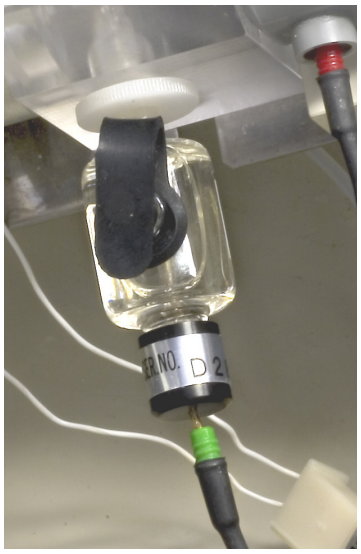
13. Close the upper cover.

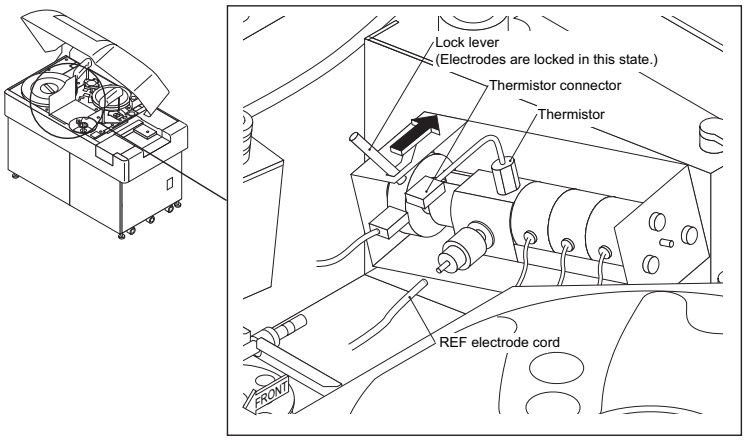
7.5 As Needed ISE Maintenance

This section describes the procedures used to perform as needed maintenance, such as those for replacing damaged parts and supplying reagents. Record maintenance on the schedules located at the beginning of this chapter. *Maintenance items can also be recorded on-line in the [Periodic Maintenance] screen.*

7.5.1 Replace the Reference Electrode

Replace the reference electrode, if calibration results are high or low for all 3 electrodes (Na, K, and Cl), or if calibration results are very unstable. Before replacing the reference electrode: check the reference packing and replace the internal reference solution. The reference electrode is under warranty one year or 300,000 samples.





As Needed Maintenance

Prepare the following:

- REF electrode MU9197
- REF electrode packing MU9202
- Internal Reference Solution AUH1017

Instruction

The reference electrode may break if excessive force is applied when replacing the electrode.

1. Check that the system and the ISE unit are on and the system is in Warm-up or Standby.
2. Open the upper cover.
3. Open the ISE unit cover.
4. Press the [System Status] key. *The System Status screen appears.*
5. Select [ISE Status] on the screen. *The ISE Status screen appears.*
6. Press function key F6 (prime) on the [ISE Status] screen. *The window for selecting prime operations appears.*
7. Select "A/Replace Electrode."
8. Press the STAT ROTATION/DIAG button. *Liquid that remains in the area of electrodes is drained.*

Tips

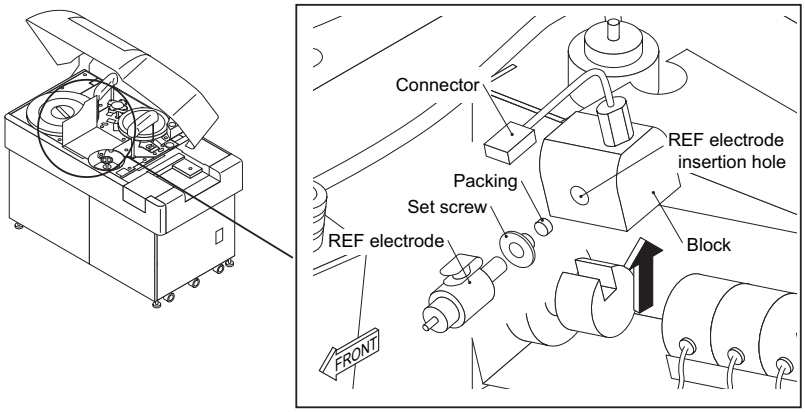
If the STAT ROTATION/DIAG button is pressed again, MID-solution will be supplied to the tube.

9. Disconnect all electrode cords. Reference is green, Na, K, and Cl are color-coded.
10. Move the lock lever to unlock the electrodes.
11. Remove the Na, K, and Cl electrodes.
12. Gently lift the block on which the REF electrode is mounted.

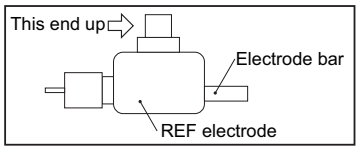
Instruction

When loosening the set screw, do not push or twist the thermistor cord, otherwise it may break.

13. Loosen the set screw, then gently remove the REF electrode along with the set screw. Gently remove the packing with a pair of hemostats.



Cross-sectional View of REF Electrode



14. Check that no air bubbles are introduced to the electrode tip on a new REF electrode.

    If air bubbles reside in the electrode tip of the new REF electrode, remove the bubbles by orienting the electrode bar downward and tapping it with a finger.

15. Replace the packing in the block.
16. Mount the new REF electrode along with the set screw on the block.
17. Tighten the set screw to secure the REF electrode.
18. Replace Na, K, and Cl electrodes based on the color-coded diagram.
19. Remount the block.
20. Move the lock lever to lock the electrodes.
21. Connect all electrode cords. Reference is green; Na, K, Cl are color-coded.
22. Press the STAT ROTATION/DIAG button. *MID-standard is supplied to the electrodes.*
23. Select "E/MID/REF Prime" on the [ISE Status] screen.
24. Press the STAT ROTATION/DIAG button again. *The two rolling pumps move the solution in each roller tube. Press the STAT ROTATION/DIAG button. The rolling pumps activate eight times. Visually check tube #6 to verify that no bubbles pass through the electrodes. Repeat this operation until there are no air bubbles in the tube. If air bubbles are present, verify that the electrodes are properly placed, the lock lever is secured, and the O-rings are in the proper position.*
25. Close the ISE unit cover.
26. Close the upper cover.
27. Wait approximately 5 minutes before performing calibration analysis.

See Also

For information about how to perform calibration, refer to the Basic Operations Chapter.

Caution

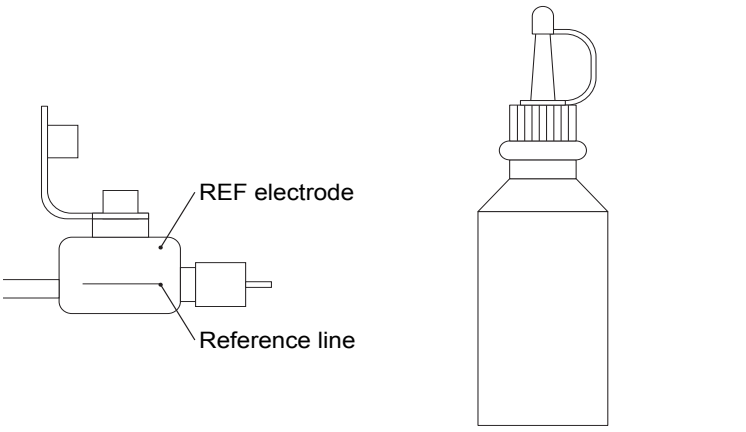
To obtain the best possible analysis data, perform two successive calibration measurements to confirm the electrode stability. If the difference between the first and second calibrations is within the following values, the electrodes are stable:

Na 0.020, K 0.045, Cl 0.025

If each difference is not within the above values, the electrode membrane may not be stabilized. Open the upper cover and the ISE unit cover. Press function key F6 (prime) on the [ISE Status] screen. Select mid-prime then repeat steps 16 to 20.

7.5.2 Add Reference Electrode Solution

Check the solution inside the REF electrode. It should be above the reference line. If the REF electrode solution is below the reference line, add more solution.



Internal Reference solution AUH1017

As Needed Maintenance

Prepare the following:

- Internal Reference Solution AUH1017

1. Remove the cap on the REF electrode.
2. Add REF electrode solution.
3. Replace the cap on the REF electrode.
4. Calibrate the ISE.

Caution

The electrode is very fragile. Be careful when adding solution so the glass does not crack or break.

See Also

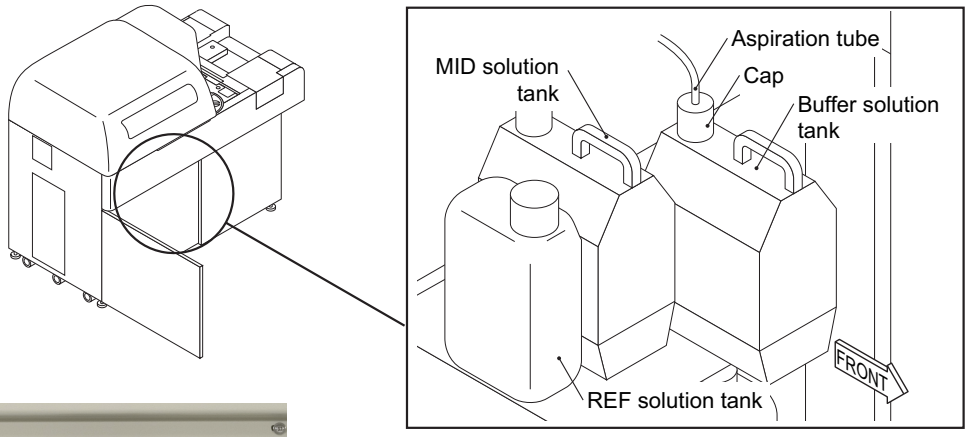
If the solution needs to be changed due to calibration problems, or the electrode requires replacement, refer to the procedure in this chapter called "Replacing the Reference Electrode."

7.5.3 Replace Reagents

If the reagents used for the ISE unit are insufficient, an alarm message will appear on the screen. If the alarm message appears, replace the corresponding reagent. After the alarm message displays, the system will be capable of analyzing approximately 150 samples. Replace the reagents before the reagent bottle is empty. The ISE on board reagent stability is specified below for the buffer solution, Mid-standard solution, and reference solution. Analysis data could be incorrect if reagents are used beyond the on board stability date.

On board stability

Check your package insert for on board stability claims.



As Needed Maintenance

Prepare the following:

- New buffer solution bottle AUH1011
- New MID solution bottle AUH1012
- New REF solution bottle AUH1013

Caution

- Never replace reagents during analysis.
- The density of the REF solution is higher than those of others. If another solution is mixed with the REF solution, analysis data will be incorrect. Never add new reagent to the remaining reagent.

1. Open the front left cover.
2. Pull out the reagent bottle that must be replaced.
3. Unscrew the cap of the reagent bottle, then take out the aspiration tube.
4. Place the new bottle on the system. Treat the old reagents in the same way as the waste liquids from the system were treated.
5. Insert the aspiration tube into the reagent bottle, then tighten the cap.

Instruction

- Push the reagent bottle in all the way until it stops. If the reagent bottle is positioned forward, the liquid-level sensor will not detect the reagent level. This may display an alarm message indicating insufficient reagent.
- If the roller tube for the mid-standard is removed from the rolling pump, the solution in the tubing flows backwards into each reagent bottle. Do not remove the roller tube for the mid-standard from the rolling pump when replacing either the mid-standard or reference.

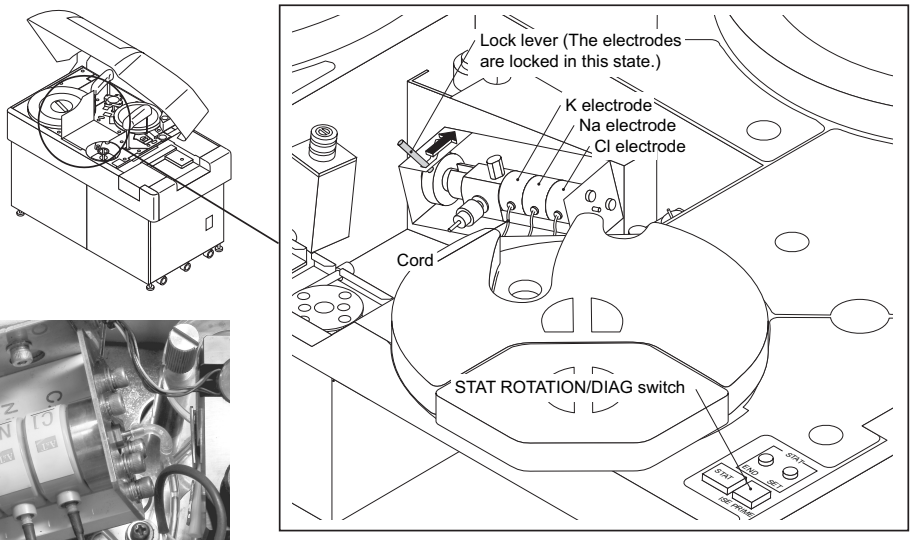
6. Push the reagent bottle to the back of the reagent shelf.
7. Select [System Status].
8. Select [ISE Status].
9. Press function key F6 (Prime).
10. Select one of the following and press enter:

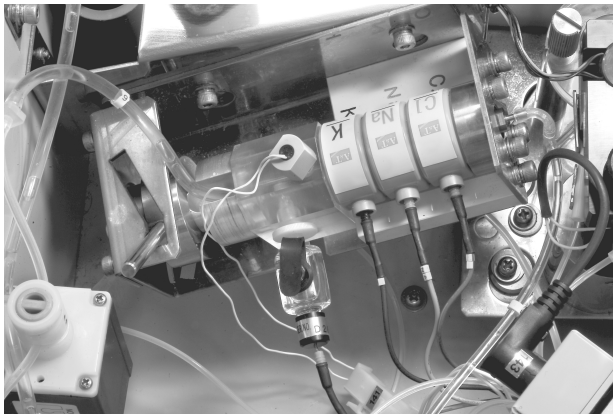
    D/Buffer Prime (Buffer reagent replaced)

    E/Mid/Ref Prime (Mid and/or Reference reagent replaced)
11. Press the STAT ROTATION/DIAG button. *Priming lasts approximately 1.5 minutes.*
12. Close the front cover.
13. Close the ISE cover.

7.5.4 *Replace the Na, K, or Cl Electrode*

If the electrodes have deteriorated, appropriate analysis results will not be obtained. Replace electrodes when calibration results are out-of-range, and troubleshooting has been performed. Electrodes are under warranty for 40,000 samples or 6 months. Replace them based on calibration and QC results.





As Needed Maintenance

Prepare the following:

- New Na electrode MU9194
- New K electrode MU9195
- New Cl electrode MU9196

1. Check that the system and the ISE are on and that the system is in Warm-up or Standby.
2. Open the upper cover.
3. Open the ISE unit cover.
4. Press the [System Status] key. *The System Status screen appears.*
5. Select [ISE Status] on the screen, then press enter. *The [ISE Status] screen appears.*
6. Press function key F6 (prime) on the [ISE Status] screen. *The window for selecting prime operations appears.*
7. Select "A/Replace Electrode."
8. Press the STAT ROTATION/DIAG button. *The liquid that remains in the region of electrodes is drained.*

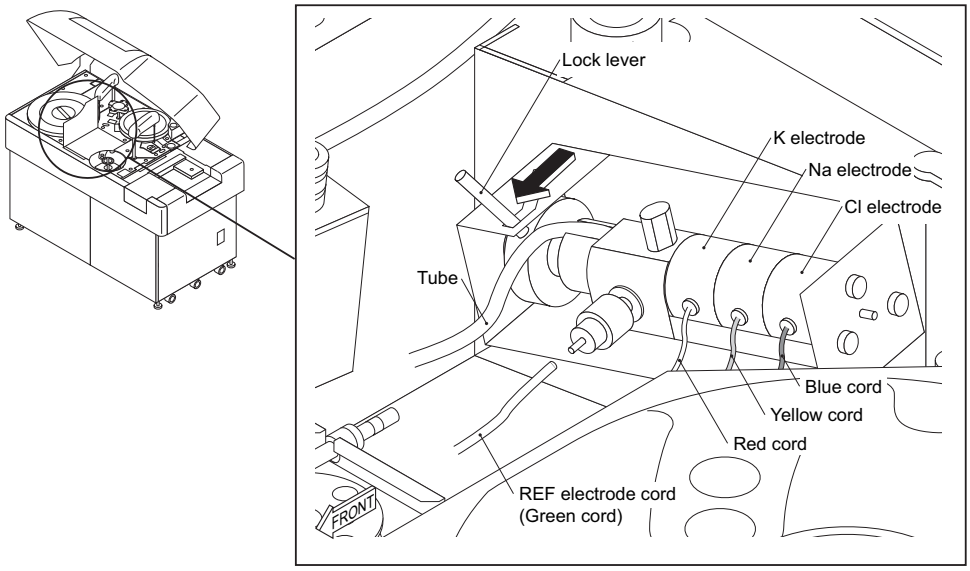
Tips

Select "A/Replace Electrode" and press the STAT ROTATION/DIAG button once. The liquid in the tube is drained. If the STAT ROTATION/DIAG button is pressed again, Mid-standard solution is supplied to the tube.

9. Disconnect the cords from the Cl, Na, or K electrode.
10. Move the lock lever to unlock the electrodes.
11. Remove the three electrodes.

Instruction

A total of four O-rings are attached to one side of three electrodes and to the metal part above the Cl electrode. Exercise care so the O-rings are not lost when removing the electrodes.



12. Mount the new electrode. Replace Na, K, and Cl electrodes based on color-coded diagram.
13. Move the lock lever to lock the electrodes.
14. Connect the appropriate cord to the corresponding electrode.
15. Press the STAT ROTATION/DIAG button. *The MID solution is supplied to the tube.*
16. Select "E/MID/REF Prime" on the [ISE Status] screen.
17. *Press the STAT ROTATION/DIAG button. The rolling pumps activate eight times. Visually check tube #6 to verify that no bubbles pass through the electrodes. Repeat this operation until there are no air bubbles in the tube. If air bubbles are present, verify that the electrodes are properly placed, the lock lever is secured, and the O-rings are in the proper position.*
18. Close the ISE unit cover.
19. Close the upper cover.
20. Wait at least 5 minutes before performing calibration analysis.

See Also

For information about how to perform calibration, refer to the Basic Operations Chapter.

Caution

To obtain the best possible analysis data, perform two successive calibration measurements to confirm the electrode stability. If the difference between the first and second calibrations is within the following values, the electrodes are stable:

Na 0.020, K 0.045, Cl 0.025

If each difference is not within the above values, the electrode membrane may not be stabilized. Open the upper cover and the ISE unit cover. Press function key F6 (prime) on the [ISE Status] screen. Select mid-prime then repeat steps 16 to 20.

7.5.5 ISE Cleaning Procedure

To help eliminate sample buildup/residue from high volume sample testing, ISE Cleaning may be necessary on an as-needed basis. This method should be used when the ISE calibration slopes are in the mid-to-low forties, or if a build-up/residue is present upon inspection of the sample pot or T-tubing. This is the ONLY ISE Cleaning Procedure recommended by Beckman Coulter.

As Needed Maintenance

Prepare the following:

- 10% bleach Solution (10mL Clorox bleach + 90mL DI H20)

1. Select [System Status], [ISE Status].
2. Select F6/Prime.
3. Select A)Replace Electrode then press the STAT Rotation/DIAG button. The flow cell will drain.
4. From the current menu, remove the mix assembly from the sample pot.
5. From the current menu, remove both pinch valve tubing's (#5 and #6) from the pinch valve.
6. For the first 2 minutes, pipette the 10% bleach solution into the ISE sample pot and manually turn the left-hand roller pump assembly clockwise until most of the bleach empties from the sample pot into the ISE tubing. Continue filling the sample pot with the bleach solution while turning the left roller pump assembly.

Note

Do not completely empty the sample pot before adding more bleach solution. Ensure the tubing is filled with the bleach solution.

7. Let the bleach solution remain in the line for the remaining five minutes.
8. Manually turn the roller pump to clear the bleach from the lines.
9. Pipette 10mL of ISE Mid-Standard Solution into the sample pot and manually turn the roller pump to clear the Mid- Standard Solution. Repeat 3-5 times.
10. Replace the mix assembly and the pinch valve tubing.
11. Press the STAT Rotation/Diag button on the analyzer.
12. Perform three to four mid-standard primes.
13. Perform a Total prime then exit the current menu.
14. Calibrate the ISE.
15. Run QC Material.

7.5.6 Replace the reagent buffer syringe

See Analyzer As-Needed Maintenance, *"6..4 Replace Sample, Reagent Syringe"*.

Chapter G
Error Flags

Introduction

If an error flag is detected during sample analysis, it is logged in the analysis data. Error flags are printed to the right of the result. Flags are also displayed on the data display screen. On the DPR display, data with a flag appears in a different color (red) than data without flags (black). The following table gives a cause and corrective action for each error flag.

Contents

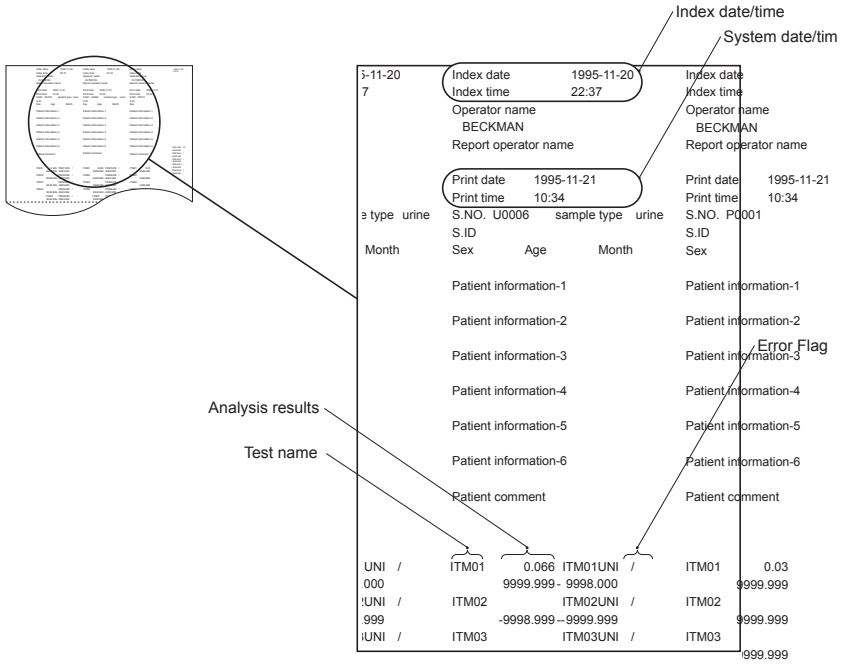
1. Checking Results

After analysis for one sample finishes, the results are immediately saved on the hard disk and a list of results are printed.

1. Look at the printout and check it for error flags. If error flags appear on the printout, perform the corrective action corresponding to that flag. For information on correcting flags, see the following pages.
2. Perform corrective actions for any alarms generated during the run. For information on correcting alarms, use the alarm on-line help function.

See Also

For information about checking results, refer to the Basic Operations Chapter, "Checking Results."



Tip

The system allows two error flags to appear on the data printout per analyte. If more than two events have occurred, the flags will be listed in priority order. The priority order of all flags are shown on the table of contents in this chapter.

2. Data Error Flags

FLAG: i (Manual dilution not calculated for ISE tests)

Cause: The i flag appears when ISE tests are requisitioned after a manual dilution rate is entered in [Routine], [Test Requisition], [Normal]. The manual dilution rate calculation is not applied to the ISE test results.

Action:

1. To obtain true electrolyte concentrations, multiply the ISE results by the dilution rate.

FLAG: d (Flags QC data that was excluded from calculation)

Cause: This flag is set in [QC Monitor], [Data Edit] by the operator to delete QC data from statistics.

Action:

1. None.

FLAG: e (Edited Data)

Cause: Data is edited from the [Data Edit] screen.

Action:

1. None.

FLAG: ((Shortage of detergent for contamination parameters in user defined detergent bottles R1 & R2)

Cause: The detergent, located in reagent compartment is empty. Reagent positions and cleaning solution types can be defined in any position. Contamination parameters will be suspended for the related cleaning solution. Carry-over may have occurred on affected tests that have this flag.

Action:

1. Fill the cleaning solution bottle in the reagent compartment.
2. Run the affected test(s) for this cleaning solution again.
3. To check contamination parameters, refer to [Parameters], [Special], [Contamination Parameters].

FLAG: R (Reagent is empty)

Cause: The reagent bottle is empty. This flag is generated when the level detectors fail to sense reagent.

Action:

1. Add more reagent and repeat analysis. For information on changing reagents, see the Basic Operations Chapter.
2. Air bubbles may be present in the reagent bottle. Remove the bubbles with a transfer pipet.
3. Wipe the moisture from the mouth of the bottle.
4. Clean the reagent probe. For information on cleaning probes, see the Maintenance Chapter.
5. Test the reagent probe for proper operation by replacing it with a new probe. For information on replacing probes, see the Maintenance Chapter. For detailed procedures on checking probes, refer to the section in this chapter called "Troubleshooting for Data Flags."

FLAG: # (Sample Level Detection Error)

Cause: The sample probe failed to detect liquid. This is most commonly caused by: A. Insufficient quantity of sample within the sample cup. B. Failure of the sample probe level detector.

Action:

1. Increase the volume of sample within the sample cup and run it again. If the volume of sample cannot be increased, transfer & run the sample as a priority STAT in a pediatric cup.
2. Wipe the sample probe with an alcohol prep and verify that the sample probe is properly attached.

3. Replace the sample probe.

FLAG: % (Clot detected)

Cause: The sample probe detected a clot in the sample.

Action:

1. Do not accept any test results from a sample with a % flag. Some test results from the sample may NOT be identified with the % flag.
2. Clean the sample probe. Refer to the Maintenance Chapter for cleaning procedures.
3. Re-run the sample that had results with the % error flag.
4. If the error still occurs, replace the sample probe.

FLAG: ? (Unable to perform calculations)

Cause: Data for this sample cannot be calculated due to one of the following:

A. The absorbance of the sample exceeds 2.5.
B. Less than three photometric readings, for a rate reaction, satisfy the assay criteria specified in the individual test parameters.
C. The Photometric data was defective.
D. The analyzer had a mechanical or electrical malfunction. The samples in progress, that cannot be completed, will have the “?” flag attached.

Action:

1. The sample may be severely lipemic, icteric, hemolytic or may contain excessively large amounts of the analyte being tested. Dilute the sample and run it again.
2. Verify the reagent. For more information see “Troubleshooting Reagents and Samples” located in the Troubleshooting Chapter.
3. The analyzer will generate error codes and/or other mechanical alarms to specify the malfunction. Once the problem is rectified, run the samples again. For detailed procedures on checking syringes, probes and calibrator material, refer to the section in this chapter called, "Troubleshooting for Data Flags ?, @, $, D, F, G, !."
4. If there is no other error flag, repeat analysis after checking the photometer lamp and the corresponding cuvette. If the system still does not recover from the error contact Beckman Coulter Technical services.
5. Check the reaction data including those processed immediately before and after the flagged data result. If any abnormality is found, check the cuvettes and cuvette wash station for an overflow, then recheck the results processed before and after the flagged data results. If the issue persists contact Beckman Coulter Technical services.
6. Check the syringes.
7. Check the probes.
8. Verify the calibrator material. Refer to "Troubleshooting for Data Flags" in this chapter for procedures.

FLAG: U (Reagent blank absorbance at last photometric point is low)

Cause: The reagent blank absorbance at the last photometric point of the assay is lower than the lower limit. Most commonly caused by:

- Reagent deterioration: On-board stability date, or reagent expiration date was exceeded.
- The reagent is in the wrong position within the reagent compartment.
- Invalid reagent OD range parameters.
- Reagent contamination.
- Incorrect reagent preparation.

Action:

1. Verify that the correct settings were programmed in [Parameters], [Specific Test Parameters].
2. Check reagent integrity. Refer to "Troubleshooting for Data Flags" in this chapter for procedures.
3. Verify that the reagent is placed in the proper position within the reagent compartment. Verify that the reagent bottles are in the correct positions.
4. Put on a new bottle of reagent and run again.
5. Verify that the reagent was made properly.

FLAG: u (Reagent blank/routine absorbance at first photometric point is low)

Cause: The reagent blank absorbance at photometer point P0 is lower than the lower limit. Most commonly caused by:

- Reagent deterioration: On-board stability date, or reagent expiration date was exceeded.
- The reagent is in the wrong position within the reagent compartment.
- Invalid reagent OD range parameters.
- Reagent contamination.
- Incorrect reagent preparation.

Action:

1. Verify that the correct settings were programmed in [Parameters], [Specific Test Parameters].
2. Check reagent integrity. Refer to "Troubleshooting for Data Flags" in this chapter for procedures.
3. Verify that the reagent is placed in the proper position within the reagent compartment. Verify that the reagent bottles are in the correct positions.
4. Put on a new bottle of reagent and run again.
5. Verify that the reagent was made properly.

FLAG: Y (Reagent blank absorbance at last photometric point is high)

Cause: The reagent blank absorbance at the last photometric point of the assay is higher than the high limit defined.

Most commonly caused by:

- Reagent deterioration: On-board stability date, or reagent expiration date was exceeded.
- The reagent is in the wrong position within the reagent compartment.
- Invalid reagent OD range parameters.
- Reagent contamination.
- Incorrect reagent preparation.

Action:

1. Verify that the correct settings were programmed in [Parameters], [Specific Test Parameters].
2. Check reagent integrity. Refer to "Troubleshooting for Data Flags" in this chapter for procedures.
3. Verify that the reagent is placed in the proper position within the reagent compartment. Verify that the reagent bottles are in the correct positions.
4. Put on a new bottle of reagent and run again.
5. Verify that the reagent was made properly.

FLAG: y (Reagent blank/routine absorbance at first photometric point is high)

Cause: The reagent blank absorbance at photometer point P0 is higher than the high limit defined.

Most commonly caused by:

- Reagent deterioration: On-board stability date, or reagent expiration date was
- exceeded.
- The reagent is in the wrong position within the reagent compartment.
- Invalid reagent OD range parameters.
- Reagent contamination.
- Incorrect reagent preparation.

Action:

1. Verify that the correct settings were programmed in [Parameters], [Specific Test Parameters].
2. Check reagent integrity.
3. Verify that the reagent is placed in the proper position within the reagent compartment. Verify that the reagent bottles are in the correct positions.
4. Put on a new bottle of reagent and run again.
5. Verify that the reagent was made properly.

FLAG: @ (Test results are too high)

Cause: In dual wavelength measurement, an error occurs if either of the two wavelengths exceeds 2.5 OD. The probable causes are:

- Specimen quality
- Incorrect placement of reagents within the reagent compartment
- Photometer lamp deterioration

Action:

1. The sample may be severely lipemic, icteric, hemolytic or may contain excessively large amounts of the analyte being tested. Dilute, then run the sample again or perform a dilution rerun. If the sample is severely lipemic, perform ultracentrifugal processing on it and then dilute it.
2. Verify all the reagent positions. An incompatible R1/R2 reagent combination often will cause absorbancies which exceed the measurable limits.
3. Perform a Photometer Check to verify lamp integrity. If the results are out-of-range, install a new lamp.

   Important: *After lamp installation, allow the lamp to stabilize, then a photocal must be performed. Repeat the Photometer Check with the new lamp installed to verify integrity. Recalibrate all tests before starting specimen analysis.*
4. Verify that the correct settings were programmed in [Parameters], [Specific Test Parameters].
5. Check the reaction data including those processed immediately before and after the flagged data result. If any abnormality is found, check the cuvettes and cuvette wash station for an overflow, then recheck the results processed before and after the flagged data results. If the issue persists contact Beckman Coulter Technical services.
6. Check syringes.
7. Check probes.
8. Verify calibrator material.
9. Verify reagent integrity and position.

See Also

For detailed procedures on checking syringes, probes and calibrator material, refer to the section in this chapter called "Troubleshooting for Data Flags ?, @, $, D, F, G, !."

FLAG: $ (Not enough data to determine linearity of reaction)

Cause: Less than three read points of a rate reaction fall within the acceptable OD range specified. In order to properly calculate a rate reaction, at least three readings must be taken prior to reaching the maximum or minimum OD limits. If the OD limits are exceeded, the reaction may have gone into substrate depletion due to either a high result, or a problem with the integrity of the reagent. The nonlinearity calculations are not made.

Action:

1. The sample may be severely lipemic, icteric, hemolytic or may contain excessively large amounts of the analyte being tested. Dilute the sample and run it again.
2. Check syringes.
3. Check probes.
4. Verify calibrator material.
5. Verify reagent integrity and position.
6. Check the reaction data including those processed immediately before and after the flagged data result. If any abnormality is found, check the cuvettes and cuvette wash station for an overflow, then recheck the results processed before and after the flagged data results. If the issue persists contact Beckman Coulter Technical services..

See Also

For detailed procedures on checking syringes, probes and calibrator material, refer to the section in this chapter called "Troubleshooting for Data Flags ?, @, $, D, F, G, !."

FLAG: D (Absorbance of reaction is greater than maximum OD range)

Cause: This flag is generated during a positive reaction or a negative reaction rate method when the OD of the photometry point FST+2 (first photometry point plus two) exceeds the OD Value Range Maximum. It is more likely that this flag will occur during a positive reaction.

OR

In addition, this flag is generated during a fixed method when the OD of a specified read point (first photometry point or last photometry point) has exceeded the OD Value Range Maximum.

Action:

1. Verify that the correct settings were programmed in [Parameters], [Specific Test Parameters].
2. The sample may be severely lipemic, icteric, hemolytic or may contain excessively large amounts of the analyte being tested. Dilute the sample and run it again or perform a dilution rerun. If the sample is severely hemolytic, collect the blood again, then repeat analysis. If the sample indicates an absorbance decrease reaction, it is assumed to be severely lipemic. If possible perform ultracentrifugal processing on it.
3. Verify reagent integrity and position. Refer to "Troubleshooting for Data Flags" in this chapter for procedures.
4. If the flag is generated for multiple assays, the lamp may need to be replaced. The integrity of the lamp can be verified by performing a photometer check. For procedures, refer to the Maintenance Chapter.
5. Check the reaction data including those processed immediately before and after the flagged data result. If any abnormality is found, check the cuvettes and cuvette wash station for an overflow, then recheck the results processed before and after the flagged data results. If the issue persists contact Beckman Coulter Technical services.

FLAG: B (Absorbance of reaction is less than minimum OD range)

Cause: This flag is generated during a negative reaction or a positive reaction rate method when the FST+2 photometry point (first specified photometry read point plus two) has an OD below the OD Value Range Minimum. It is more likely that this flag will occur during a negative reaction.

OR

When measuring a negative reaction fixed method, the OD of a specified read point (first photometry point or last photometry point) is below the OD Value Range Minimum.

Action:

1. Verify that the correct settings were programmed in [Parameters], [Specific Test Parameters].
2. The sample may be severely lipemic, icteric, hemolytic or may contain excessively large amounts of the analyte being tested. Dilute the sample and run it again or perform a dilution rerun.
3. Repeat the sample using a smaller sample volume.
4. Verify reagent integrity and position. Refer to "Troubleshooting for Data Flags" in this chapter for procedures.
5. If the flag is generated for multiple assays, the lamp may need to be replaced. The integrity of the lamp can be verified by performing a photometer check.
6. Check the reaction data including those processed immediately before and after the flagged data result. If any abnormality is found, check the cuvettes and cuvette wash station for an overflow, then recheck the results processed before and after the flagged data results. If the issue persists contact Beckman Coulter Technical services.

5. If the flag is generated for multiple assays, the lamp may need to be replaced. The integrity of the lamp can be verified by performing a photometer check.

FLAG: * (Linearity error in rate methods)

Cause: This flag is generated when the rate of a reaction is judged to be nonlinear due to exceeding the defined % variance or OD limits between photometer read points. Possible causes are:

- Contaminated reagent
- Unusually high result
- Defective cuvettes
- Electrical noise
- Dirty or defective mix bars
- Reagent dispense probe alignment problem
- Sample probe alignment

The acceptable linearity is defined in [Parameters], [Specific Test Parameters], Linearity %.

Action:

1. Verify that the correct settings were programmed in [Parameters] [Specific Test Parameters].
2. Replace reagent if contaminated or expired.
3. Perform troubleshooting or maintenance procedures listed in the bullet points above.
5. If the sample is assumed to be abnormally high, dilute the sample and repeat analysis.
6. Check the reaction data including those processed immediately before and after the flagged data result. If any abnormality is found, check the cuvettes and cuvette wash station for an overflow, then recheck the results processed before and after the flagged data results. If the issue persists contact Beckman Coulter Technical services.

FLAG: & (Prozone test data is abnormal)

Cause: This flag is generated if the data check measurement point OD of the prozone test data exceeds OD 2.5.

Action:

1. Dilute the sample and run it again or perform a dilution rerun.

FLAG: Z (Prozone error)

Cause: This flag is generated if the data check equation for either logic check 1, 2, or 3 is satisfied and the check for low concentration passes. This flag commonly occurs if the sample contains unusually high concentrations of analyte.

Action:

1. Verify that the correct settings were programmed in [Parameters], [Specific Test Parameters].
2. Dilute the sample and run it again or perform a dilution rerun.

FLAG: ! (Unable to calculate concentration)

Cause: The system has failed to calculate a result.

Action:

1. If this is a single sample issue, repeat and dilute if necessary.
2. If multiple samples are affected, review all operating parameters such as:
   - Reagent quality
   - Calibration
   - Sample integrity
   - General system issues
3. Check the reaction data including those processed immediately before and after the flagged result. In the presence of any abnormality, check the cuvettes for a possible overflow. If the issue persists, contact Beckman Coulter Technical Services.
4. If the flag is generated on Na, K, or Cl, repeat a sufficient number of samples which preceded the appearance of the "!" flag in order to verify that no incorrect results were reported. It is possible that air in the flowcell affected samples before the "!" flag was generated.
   - Perform a MID/REF Prime and verify no bubbles are in the tubing at the bottom of the flowcell to ensure there are no obstructions in the flowcell path.
   - Verify all tubing is properly connected.

See Also

For detailed procedures on checking syringes, probes and calibrator material, refer to the section in this chapter called "Troubleshooting for Data Flags ?, @, $, D, F, G, !."

FLAG:) (Cannot convert from OD to CONC)

Cause: A discrepancy between the reagent lot number and the calibrated reagent lot number was found.

Action:

1. Recalibrate the test which produced the ")" flag.
2. From the main menu select [Routine], [Data Management], [Data Correction]. This screen is used to calculate results when a calibration fails.

FLAG: a (Expired reagent or onboard stability expired)

Cause: Results using reagents with expired dating or expired on-board stability will be in concentration units with an "a" error flag attached.

Action:

1. Put on a new bottle of reagent and perform a reagent volume check.
2. The operator can choose to accept the results and remove the flag by selecting [Routine], [Data Management], [Data Edit]. Select function key F5 (Data Display), then F5 (Edit). Check the Flag box and delete the "a" flag.

FLAG: b (Calibration expired)

Cause: Results with expired calibration curves will be in concentration units with a "b" error flag attached.

Action:

1. Perform another calibration.

See Also

For detailed procedures on performing a calibration, refer to the Basic Operations Chapter.

2. The operator can choose to accept the results and remove the flag by selecting [Routine], [Data Management], [Data Edit]. Select function key F5 (Data Display), then F5 (Edit). Check the Flag box and delete the "b" flag.

FLAG: F (Results higher than the dynamic range)

Cause: The concentration of the sample has exceeded the Dynamic Range High (linearity of the reagent) limit.

Action:

1. Verify that the correct settings were programmed in [Parameters], [Specific Test Parameters].
2. If the parameters are correct, Dilute the sample and run it again. Refer to the package insert for information on dilutions.
3. Check syringes.
4. Check probes.
5. Verify calibrator material.
6. Verify reagent integrity and position. Refer to "Troubleshooting for Data Flags" in this chapter for procedures.

See Also

For detailed procedures on checking syringes, probes and calibrator material, refer to the section in this chapter called "Troubleshooting for Data Flags ?, @, $, D, F, G, !," and Chapter H Troubleshooting.

FLAG: G (Results lower than the dynamic range)

Cause: The concentration of the sample is below the Dynamic Range Low (linearity of the reagent) limit.

Action:

1. Verify that the correct Dynamic Range limits are programmed in the [Parameters], [Specific Test Parameters] screen, then repeat analysis.
2. Check syringes.
3. Check probes.
4. Verify calibrator material.
5. Verify reagent integrity and position. Refer to "Troubleshooting for Data Flags" in this chapter for procedures.
6. Follow laboratory protocol for samples with values less than the Dynamic Range low limit.

See Also

- See Chapter D, "Repeat Specific," in volume 1 of the User's Guide.
- For detailed procedures on checking syringes, probes and calibrator material, refer to the section in this chapter called "Troubleshooting for Data Flags ?, @, $, D, F, G, !," and Chapter H Troubleshooting.

FLAG: p (Out of the panic value range)

Cause: The result has exceeded the panic value limits. Limits are set in [Parameters], [Specific Parameters], "Panic Value".

Note

The AU400/AU400^{e} will generate an alarm in addition to the "p" flag for an ISE test and other tests if the panic value range is exceeded.

Action:

1. Verify the correct panic range is programmed for your lab.
2. Follow your laboratory protocol for panic results.

FLAG: T (Abnormality found in inter-chemistry check)

Cause: This flag will be attached to the data which exceeds the High/Low limits specified for the Check Parameters. The check parameters are designed to test the relationship between different analyte results on the same sample. i.e. Direct Bilirubin should be less than Total Bilirubin.

Action:

1. Review data. Verify that the correct inter-item range for your lab is programmed.
2. Follow your laboratory protocol for abnormal test results.

FLAG: P (Positive: Any value above flag level H)

Cause: The value is above flag level H in [Specific Test Parameters].

Note: This flag is not a panic value. This flag is used mainly in drug screenings to define the positive limit of a result.

Action:

1. None.

FLAG: N (Negative: Any value below flag level L)

Cause: The value is below flag level L in [Specific Test Parameters].

Action:

1. None.

FLAG: H (Result higher than normal value range)

Cause: The data has exceeded the High limit on the normal value range. The normal range is set in [Parameters], [Specific Parameters], "Normal Ranges".

Action:

1. Review data.

FLAG: L (Result lower than normal value range)

Cause: The data has exceeded the low limit on the normal value range. The normal range is set in [Parameters], [Specific Parameters], [Normal Ranges].

Action:

1. Review data.

FLAG: J (Result is higher than repeat run range)

Cause: The result has exceeded the high limit for the repeat run decision level. Repeat ranges are set in [Parameters], [Repeat Parameters], [Repeat Specific].

Action:

1. Follow laboratory protocol for repeat samples.

FLAG: K (Result is lower than repeat run range)

Cause: The result is below the low limit for the repeat run decision level. Repeat ranges are set in [Parameters], [Repeat Parameters], [Repeat Specific].

Action:

1. Follow laboratory protocol for repeat samples.

FLAG: x (Data not registered)

Cause: In multi-rule quality control, if one of the two data pairs are out of range, the other piece of data is marked with this flag.

Action:

1. This indicates that the data is not registered in the stack. Follow laboratory protocol for out-of-range QC results.

FLAG: 1 (Data exceeds QC range)

Cause: One point of QC data exceeds the control limit determined by +2SD. This is defined under [Parameters], [QC Control], [QC Common].

Note: This flag will not be generated using multi-rule to QC logic.

Action:

1. Follow laboratory protocol for out-of-range QC results.
2. Refer to the "Quality Control" section located in the Specifications Chapter for corrective actions.

FLAG: 2 (Data exceeds the 3SD control limit)

Cause: One point of QC data exceeded the +3SD limit.

Action:

1. Follow laboratory protocol for out-of-range QC results.
2. Refer to the "Quality Control" section located in the Specifications Chapter for corrective actions.

FLAG: 3 (Data continuously exceeds the 2SD control limit)

Cause: Two continuous (simultaneously high and low) QC data points exceeded the control limit of +2SD in one direction.

Action:

1. Follow laboratory protocol for out-of-range QC results.
2. Refer to the "Quality Control" section located in the Specifications Chapter for corrective actions.

FLAG: 4 (Data exceeds ^{R}4S control limit)

Cause: Two continuous QC data points exceeded the control limit of +2SD and a total range of 4SD was exceeded.

Action:

1. Follow laboratory protocol for out-of-range QC results.
2. Refer to the "Quality Control" section located in the Specifications Chapter for corrective actions.

FLAG: 5 (Data exceeds ^{4}1S control range)

Cause: Indicates that four continuous QC data points exceeded the +1SD limit.

Action:

1. Follow laboratory protocol for out-of-range QC results.
2. Refer to the "Quality Control" section located in the Specifications Chapter for corrective actions.

FLAG: 6 (Data over/under last 10 averages)

Cause: Data for 10 consecutive controls falls on the same side of the mean.

Action:

1. Follow laboratory protocol for out-of-range QC results.
2. Refer to the "Quality Control" section located in the Specifications Chapter for corrective actions.

FLAG: 7 (Data over/under range)

Cause: A control trend is indicated. Control data points to an increase or decrease in succession.

Action:

1. Follow laboratory protocol for out-of-range QC results.
2. Refer to the "Quality Control" section located in the Specifications Chapter for corrective actions.

FLAG: S (Sample repeated and original results replaced with repeat results)

Cause: A test was repeated, and the repeat result will be the final result.

Action:

1. None.

FLAG: / (Test requisition entered, but not performed)

Cause: The test was not completed even though it was requested. This error is most commonly caused by a lack of reagent available to complete the test.

Action:

1. Verify that the reagent is placed in the proper position within the reagent compartment.
2. Verify that the reagent bottle contains enough reagent to perform the test. Manually check the reagent bottle to view its contents. For more information on changing reagents refer to the Basic Operations Chapter.

FLAG: r (Data transmitted to the host computer)

Cause: The data was transmitted to the host computer.

Action:

1. None.

FLAG: c (Corrected Data)

Cause: Data was corrected in the [Data Correction] screen.

Action:

1. None.

2.1 Troubleshooting for Data Flags ?, @, $, D, F, G, !

Check the Syringes

A. Verify that the top and bottom screws are hand tight. **Note**: Do not use any mechanical instrument to tighten the screws.
B. Verify that the bottom screw is tight and flush with the piston.
C. Verify that the syringe provides a smooth and resistant pull.
D. Verify the correct size syringe is in use (reagent or sample).
E. Verify that one, undamaged O-ring is present.
F. Verify the teflon tip is not flaking or worn.
G. Check the syringe tubing for leaks or crimps. Verify that the metal tubing connectors are on correctly.

Check the Probes

A. Verify that the probes are straight with no occlusions or scratches.
B. Verify the probes are on the analyzer correctly and are not bent.
C. Verify two metal screw caps are on tightly.

Verify the Calibrator Material

A. Check the lot # and expiration date. Check the stability for storage conditions on the calibrator material (freezer, refrigerator, open bottles).
B. If using a lyophilized calibrator, check the reconstituted stability and verify that it was made correctly. Use a volumetric pipet to add the diluent.
C. Verify the calibrator material was not left at room temperature for an extended time period. Avoid prolonged exposure to air before processing, because evaporation will affect analyte concentration.
D. Verify the calibrator material was not contaminated at any point prior to or during the run. Check for indications of instability such as abnormal color, turbidity, or a precipitate. Use fresh material if necessary. Refer to the calibrator package insert.
E. Verify the calibrator material is in the correct rack position. The yellow rack with barcode #001 identifies calibrator material #1-10 in rack positions #1-10. Yellow rack with barcode #002 identifies calibrator material #11-20 in rack positions #1-10. The calibrators are identified by this system for up to 80 calibrators. Place the correct calibrator material in the corresponding position in the barcoded rack. The Cal. No. (calibrator position in the yellow rack) assigned to a test can be verified in [Parameters], [Calibration], [Calibration Specific].

Verify the Reagent Integrity

A. Check the lot # and expiration date. Check the stability for storage conditions on the reagent. Follow the directions on the package insert.
B. Verify the reagent material was not contaminated at any point prior to or during the run. Check for indications of instability such as abnormal color, turbidity, or a precipitate. Use fresh material if necessary. Refer to the package insert for preparation instructions.
C. Verify that the reagent is placed in the compartment properly and that the correct parameters were entered. Refer to the Basic Operations Chapter for procedures on placing reagents.

Verify the QC material

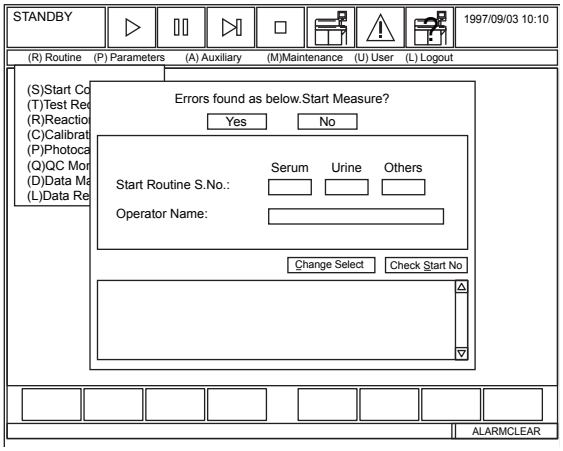
A. Check the lot # and expiration date. Check the stability for storage conditions on the QC material. Follow the directions on the package insert.
B. Use a volumetric pipet, if reconstitution is necessary. Eliminate possible errors by preparing fresh QC material.
C. Avoid prolonged exposure to air before processing, because evaporation will affect analyte concentration.
D. Verify the QC material was not contaminated at any point prior to or during the run. Check for indications of instability such as abnormal color, turbidity, or a precipitate. Use fresh material if necessary. Refer to the QC package insert.
E. Verify the QC material is in the correct rack position.
    1. Place the green rack with the control sample on the rack feeder unit. If the control is barcoded it can be placed in any position on the green rack.
    2. Start analysis.
    3. While the rack is being analyzed, check that there are no errors in the quality control data.
    4. Using [QC Monitor] from the [Routine] screen, check the daily variation chart and the day-to-day variation chart for abnormal data.

3. Non-Fatal and Fatal Errors

This section lists all possible non-fatal errors along with a description of each one.

3.1 Non Fatal Errors (Yellow)

Non fatal errors can occur during start-up. The following section gives more information on these errors and how to correct them. Non fatal means the operator can choose to start analysis anyway. If the field called "Check Non Fatal Error" located in [System Maintenance] is not checked, only fatal errors will appear when the STAT button is pressed.



See Also

For start-up procedures, refer to the Basic Operations Chapter.

Cal. error test exist:

A new test was added to the system and a calibration was not performed or failed the calibration. Check the test located in [Routine], [Calibration Monitor], [Calibration Curve] screen. Refer to "Troubleshooting for Data Flags" in this chapter for procedures on verifying calibrator material.

Cal. expired:

Calibration frequency has expired. Check the calibration stability date in [System Status], [Reagent Status]. Requisition for the expired tests in the [Routine], [Test Requisition], [Calibration] screen. Run the reagent blank and calibrate the expired tests.

Calibration: No Selected (STAT):

The STAT table is set for manual requisition and calibrator material is on the STAT table, but no requisition was performed. Requisition calibrator.

Calibration: No Selected (Rack):

No tests are requisitioned for calibration in [Routine], [Test Requisition], [Calibration]. If calibration is required, requisition for calibration before starting analysis. If calibration is not required, start analysis.

Cuvette check not performed

Following a Photocal, the results were not checked. Select F5 (Check Start) in [System Status] [Cuvette Status].

Cuvette temperature:

Temperature has exceeded standards. Call Beckman Coulter Technical Services.

Error cuvette:

A cuvette may be dirty or scratched. Check the error in [System Status], [Cuvette. Status]. Refer to the Maintenance Chapter for procedures on cleaning and/or replacing cuvettes. Perform a photocal. Also refer to the Maintenance Chapter for procedures on performing a photocal.

Incorrect reagent set:

Check the error in [System Status], [Reagent Status]. This may mean: the calibration stability expired, the reagent is empty, the on-board stability expired, or the date on the reagent bottle expired.

ISE buff. shortage:

Insufficient buffer solution.

ISE mid. shortage:

Insufficient mid-standard solution.

ISE no cal.:

1. The ISE was not calibrated for serum or urine. OR 2. An End Process was performed and "ISE no cal" occurs again when the instrument is on. You can start analysis and use the last calibration slopes obtained.

ISE not connected:

The main ISE Power Switch is off. Turn on the ISE Power Switch.

ISE ref. shortage:

Insufficient reference solution.

ISE select errors:

Refer to the Selectivity Check procedure in the ISE Maintenance section of the Maintenance Chapter.

ISE slope errors:

Refer to the ISE Calibration Errors procedure in the Troubleshooting Chapter.

ISE stop:

The ISE unit has stopped. Reset the ISE unit in [System Status], [ISE Status].

On board expired:

Reagent on-board stability has expired. Select [System Status], [Reagent Status] and check the on-board stability, if it has expired, replace the reagent. Perform a reagent volume check to update the information.

QC: No select (STAT):

The STAT table is set for manual requisition and QC material is on the STAT table, but no requisition was performed. Requisition QC.

RB error test exist:

A new test was added to the system and a reagent blank was not performed or failed. Check the test located in [Routine], [Calibration Monitor], [Reagent Blank Monitor] screen. Refer to "Troubleshooting for Data Flags" in this chapter for procedures on verifying reagent integrity.

Reagent lot no (cal):

A different reagent lot number from that used at calibration was placed on the analyzer. Calibrate the analyzer again.

Reagent lot no. (RB):

A different reagent lot number from that used for the reagent blank was placed on the analyzer. Perform another reagent blank.

Reagent temperature:

Reagent refrigerator temperature is out of the standard range. Call Beckman Coulter Technical Services.

STAT table cover open:

The STAT table cover is not on the table or is not placed properly.

Unset reagent:

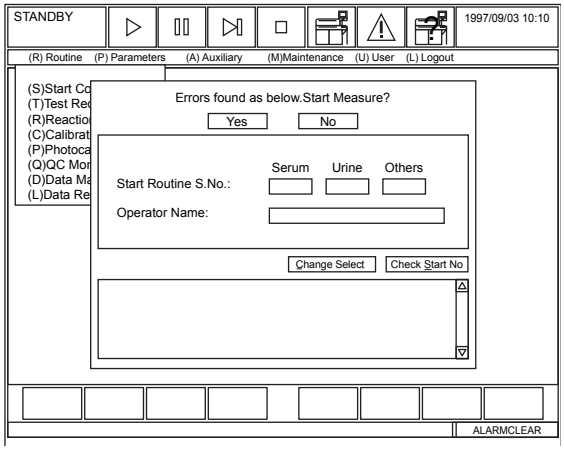
A reagent assigned to the round in use (on-board) is missing from the refrigerator. Determine what reagent is missing. Use [Reagent Status], function key F7 (Test Display) and compare with the reagents in the refrigerator. Perform a reagent volume check.

Unset STAT table:

A STAT table check is performed and calibration or QC cups assigned to positions in [Parameters] are not present on the table. When performing calibration or QC analysis, place cups in position and use the [STAT Table Status] screen to assign the positions in the software.

3.2 Fatal Errors (Red)

Fatal errors can occur during start-up. The following section gives more information on these errors and how to correct them. Fatal means the operator cannot start analysis until the problem is corrected.



See Also

For start-up procedures, refer to the Basic Operations Chapter.

Diluted washer A short:

The solution in diluted detergent tank A is low.

Diluted washer B short:

The solution in diluted detergent tank B is low.

DI water shortage:

The deionized water tank is low.

Incorrect Parameters:

A message appears on screen indicating the incorrect parameter. Open the screen containing the incorrect parameter, determine the parameter error and correct it. The parameters are saved automatically.

ISE Busy:

The ISE unit is operating. After the ISE operation is complete start analysis.

ISE cover open:

The ISE cover is open or it is not closed properly.

Rack receiver full:

The rack receiver unit is full.

Reagent cover open:

The cover to the reagent refrigerator is open.

STAT Table Unchecked:

1. The large STAT table cover was removed, or 2. A STAT Table check was not done in the [STAT Table Status] screen. OR 3. Certain [Parameter] screens were accessed. This changes the status of the STAT Table from "checked" to "unchecked." Perform a STAT Table check in the [System Status], [STAT Table Status] screen.

Unchecked Reagent:

A reagent check was not performed or the [Parameter] menu was accessed. This will change the reagent status from "checked" to "unchecked." Select the [System Status], [Reagent Status] screen and perform a reset.

Washer A shortage:

Replenish fluid in concentrated detergent tank A.

Washer B shortage:

Replenish fluid in concentrated detergent tank B.

Vacuum tank full:

The vacuum tank is full. Wait until the analyzer empties the tank. If the problem persists, contact Beckman Coulter Technical Services.

Other Errors:

A specific error name and description displays. Clear the error and restart analysis.

Chapter H Troubleshooting

Introduction

This Chapter is designed for the operator to obtain quick solutions to common problems that could occur with the AU400. The following pages provide information on general troubleshooting procedures for the analyzer and the ISE unit. Keep a history of problems and corrective actions that occur with the instrument. This helps correct a problem quickly, should it become necessary to contact Beckman Coulter Technical Services.

Chapter H Troubleshooting

To Begin Troubleshooting, Answer the Following Questions

For Data Problems

Did you interpret the data printout correctly?

See Also
For information about how to interpret the data printout, refer to the Basic Operations Chapter.

Is the data flagged?

See Also
For information about data flags, refer to the Error Flags Chapter.

Is the calibration out-of-range?

See Also
For information about how to perform a calibration, refer to the Basic Operations Chapter.

Is QC out-of-range?

See Also
For information about how to perform a QC, refer to the Basic Operations Chapter.

Is data erratic? (Have you performed scheduled maintenance?)

See Also
For information about schedule maintenance, refer to the Maintenance Chapter.

For Alarms

An alarm usually indicates a mechanical problem or a communication failure. Follow the corrective action provided in the on-line help function.

See Also
For information about how to use on-line help, refer to "Troubleshooting Using On-line Help" located in this chapter.

For an Analyzer Mechanical Error

Usually a mechanical error is associated with an alarm. Follow the corrective action provided in the on-line help function.

For Other Operational Integrity Problems

Were start-up procedures performed correctly?

See Also
For information on start-up procedures, refer to the Basic Operations Chapter.

Is the reagent stable?

See Also
For information on checking reagent stability, refer to the "Troubleshooting for Data Flags" procedure in the Error Flags Chapter.

Is there enough reagent in the bottles?

Select the [System Status] icon. Select [Reagent Status]. Press function key F5 (check start).

See Also
For information on reagents, refer to "Changing Reagents" in the Basic Operations Chapter.

Has the reagent, calibrator, and QC material been properly stored?

See Also
For information on proper storage, refer to the package insert. The "Troubleshooting for Data Flags" procedure in the Error Flags Chapter also provides general information on handling these materials.

Has the analyzer been calibrated correctly?

See Also
For information about performing calibrations, refer to "Performing Calibrations" in the Basic Operations Chapter.

Has scheduled maintenance been performed?

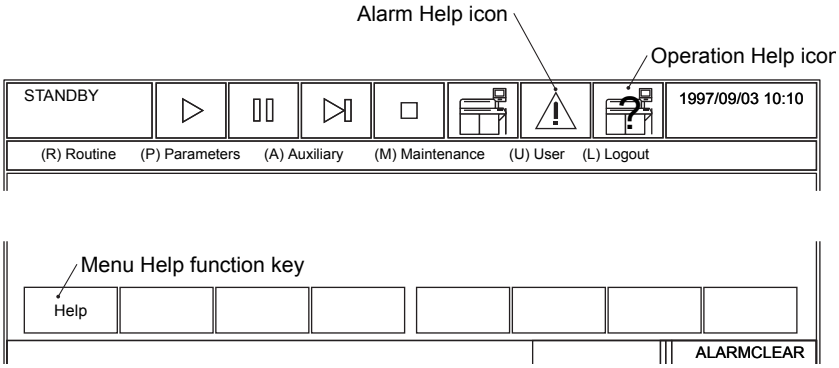
See Also
For information about schedule maintenance, refer to the Maintenance Chapter.

Has routine component replacement been performed?

See Also
For information about scheduled maintenance, refer to the Maintenance Chapter.

1. Troubleshooting Using On-Line Help

The AU400 is equipped with an on-line help function. The operator can easily obtain information on alarms, operations and software menus.



Alarm Help

Displays information about system alarms. *Press the alarm icon (as shown in the illustration above) while the alarm message is displayed. If using the mouse, move the pointer onto the alarm help icon, then press the left mouse button.*

1. The following information will be displayed on alarm help:
   - **Alarm Number** – An alarm number is associated with each alarm.
   - **Alarm Name** – Name of alarm that occurred on the system.
   - **System Status** – Describes the current state of the system or how the system responds to the alarm.
   - **User Action** – Provides steps to correct the problem and resume normal operations.
   - **Cause** – Explains why the error occurred.
   - **Additional Information** – Provides more corrective actions for advanced operators or engineers. *Do not perform these functions unless you are qualified!*
2. Follow the corrective actions provided on the screen. If the alarm is still generated after performing all recommended procedures, contact Beckman Coulter Technical Services.
3. To close the help window, select the Exit Help bookmark in the bookmark column or use the mouse to move the pointer onto the "X" enclosed in a box located at the top of the screen, then press the left mouse button.

Menu Help

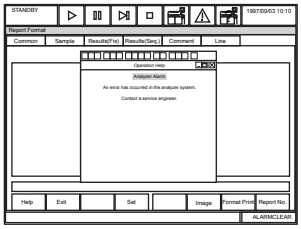
Describes the purpose of the specific software screen and how to use it. *Select a screen that you would like to know more about, press function key F1. If using the mouse, move the pointer onto the menu help icon that indicates function key F1 then click the left mouse button.*

Operation Help

Provides the same procedures found in the User's Guide. *This is an on-line guide that can be searched using Acrobat Reader.*

Window help

If the help window is displayed, use the scroll bar to view the entire message.



2. Troubleshooting the Analyzer

This section provides troubleshooting information on the analyzer for data, system, and data processor problems. Procedures for recovering from a power loss, emergency stop, and cuvette wheel flood are also provided. *Performing scheduled maintenance greatly reduces the chances of problems occurring with the analyzer. For more information about maintenance for each system component, refer to the Maintenance Chapter.*

Contents

2.1 Data Problems

Before performing detailed troubleshooting procedures, answer the following questions:

Did you interpret the data printout correctly?

See Also

For information about how to interpret the data printout, refer to "Checking Results" located in the Basic Operations Chapter.

Is the data flagged?

See Also

For information about data flags, refer to the Error Flags Chapter.

Is the calibration out-of-range?

See Also

For information about how to perform a calibration, refer to the Basic Operations Chapter.

Is QC out-of-range?

See Also

For information about how to perform a QC, refer to the Basic Operations Chapter.

Is data erratic? (Have you performed scheduled maintenance?)

See Also

For information about schedule maintenance, refer to the Maintenance Chapter.

2.1.1 Checking Abnormal Data in the Software Screens

To analyze abnormal data use the following screens:

[Routine], [QC Monitor], [Daily Control]

[Routine], [QC Monitor], [Day-to-Day Control]

[Routine], [QC Monitor], [Twin Plot]

[Routine], [Reaction Monitor]

[Routine], [Calibration Monitor], [Calibration Curve]

[Routine], [Calibration Monitor], [Calibration Trace]

[Routine], [Calibration Monitor], [Reagent Blank Monitor]

[Routine], [Photocal Monitor]

[Auxiliary], [Data Statistics]

[Auxiliary], [Histogram]

Use the [QC Monitor] Screen

Compare the test with normal QC data and identify the differences. QC parameters are set in the following screen: [Parameters], [QC Parameters]. Is the error systematic or random?

See Also

For information about the [QC Monitor] screen, refer to the Software Chapter.

Check Error Flags

Review the error flag definition. Check the data again with respect to each error flag definition.

See Also

For information about error flags, refer to the Error Flags Chapter and the "Quality Control" section in the Specifications Chapter.

Use the [Reaction Monitor] Screen

Use the [Reaction Monitor] screen to compare the normal data with the abnormal data. What differences exist between the normal and abnormal data?

See Also

For more information about the [Reaction Monitor] screen, refer to the Software Chapter.

Use the [Calibration Monitor] Screen

Use the [Calibration Monitor] screen to compare normal calibration data with abnormal calibration data. What differences exist between the normal and abnormal calibration data?

See Also

For more information about the [Calibration Monitor] screen, refer to the Software Chapter.

Use the [Photocal Monitor] Screen

Use the [Photocal Monitor] screen to check for abnormal cuvettes. The photocal procedure verifies the integrity of the cuvettes. Cuvettes that are dirty or contain scratches will not pass the photocal procedure. Cuvettes that fail the photocal procedure could affect analysis results, so they need to be cleaned or replaced.

See Also

For information about the [Photocal Monitor] screen, refer to the Software Chapter. For information about how to perform a photocal, refer to the Maintenance Chapter.

Use the [Data Statistics] Screen

After verifying the data, use the [Data Statistics] screen to obtain the mean, SD, CV, and range.

See Also

For information about the [Data Statistics] screen, refer to the Software Chapter.

Use the [Histogram] Screen

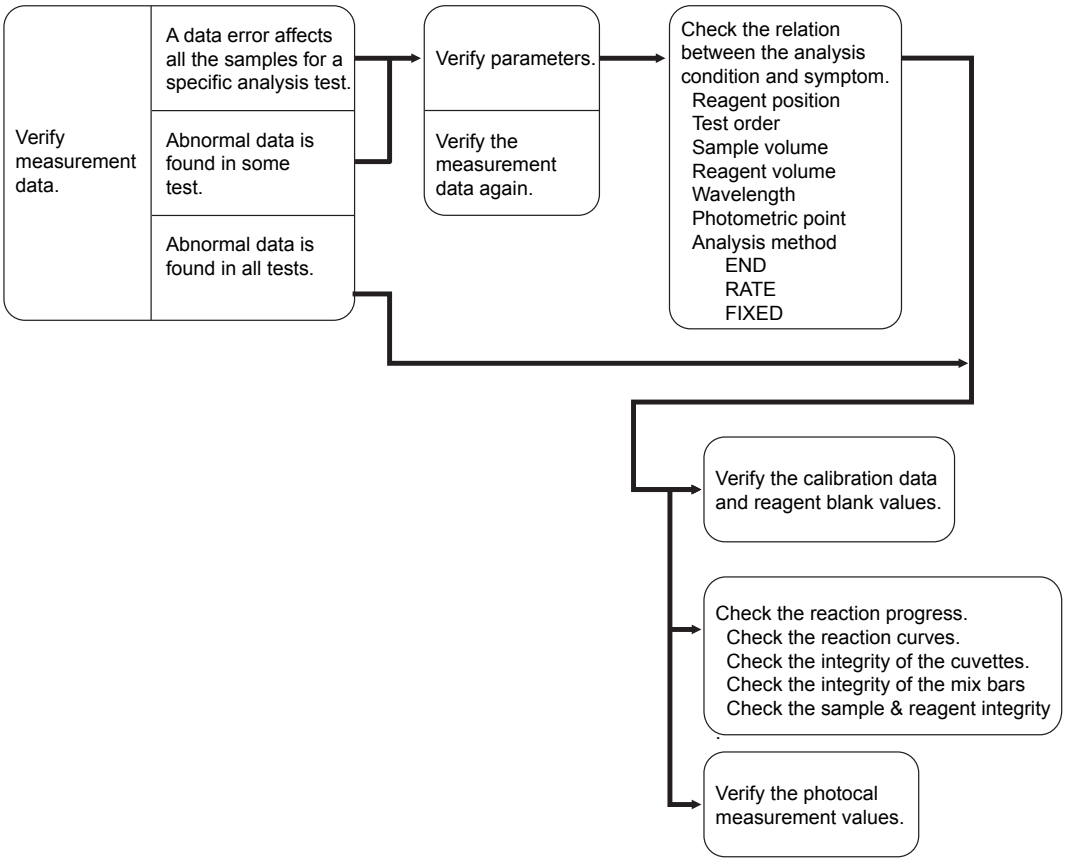
After verifying the data, use the [Histogram] screen to check the dispersion of the data.

See Also

For information about the [Histogram] screen, refer to the Software Chapter.

2.1.2 *Troubleshooting Software*

Verify parameter settings and the measurement data. Troubleshoot abnormal data by checking the items shown in the figure below:



Check Patient Data

If abnormal data is recognized:

- In a single test: If abnormal data is found in a single test or some tests, verify parameters.
- In some tests: If abnormal data is found in some tests, compare the parameters of the tests with the abnormal data to identify a common parameter(s).
- In all tests: If abnormal data is found in all patient results for a specific test, check the parameters for that test.

Check Patient Data Again

If the cause of abnormal data cannot be determined after checking parameters, try to determine if the problem occurs at certain intervals during testing. Does the problem occur after a specific reagent is used? (May indicate cross-contamination of reagents) Do the patient samples have something in common? Was a certain anticoagulant used?

Check the Calibration and Reagent Blank

Check whether the calibration or reagent blank could be causing the abnormal data.

If abnormal data is found in a single test:

Compare normal calibration data with abnormal calibration data to identify the difference between them using the [Calibration Monitor] screen. Also check the reagent blank and calibration parameters.

See Also
For information about the [Calibration Monitor] screen, refer to the Software Chapter.

If abnormal data is found in some tests:

Identify the same tests that include abnormal data between calibrators. If all abnormalities are derived from the same calibrator, the calibrator may be the cause of the abnormal data. Identify if the reagent position for the tests in question are related.

See Also
For detailed procedures on verifying calibrator material, refer to the Error Flags Chapter.

If abnormal data is found in all tests:

There is a high possibility that the calibration analysis itself may result in abnormal data.

Check the mix bars, R1 probe/syringe, sample probe/syringe, water, calibration material and common hardware.

See Also
For detailed procedures on checking the syringes, checking the probes and verifying calibrator material, refer to the Maintenance Chapter and Flags Chapter.

Check the Reaction

When a single test is performing erratically, identify where the error occurred in the data using the [Reaction Monitor] screen.

See Also
For information about how to check reaction progress, refer to the [Reaction Monitor] screen in the Software Chapter.

Check Photocal Measurement Data

Check the photocal measurement data to identify an abnormality with cuvettes or a photometer using the [Photocal Monitor] screen.

See Also
For information about how to check reaction progress, refer to the [Photocal Monitor] screen in the Software Chapter.

Check Photometer Check Data

Use to identify lamp problems. Check to see if the lamp intensity is within the acceptable range.

See Also
For information about photometer lamp replacement, refer to the Maintenance Chapter.

2.1.3 Troubleshooting Reagents and Samples

Reagents or samples may cause abnormal data. The following list describes some reagent and sample problems that can affect results.

Sample Problems Causing Abnormal Data

The following two items most commonly affect data:

1. Sample evaporation: High results may occur due to evaporation of the sample. Properly store and tightly cap samples if analysis is delayed.
2. Did not follow package insert instructions: Follow package insert instructions.

Please make note of the following sample requirements:

- This system is designed to analyze serum, urine, and cerebrospinal fluid samples. If problems are encountered when analyzing a specific test or when using a specific reagent, consult the package insert, reagent manufacturer, or distributor.
- Use serum that is sufficiently separated from blood clots and urine that is free from suspended matter or the probe may be clogged and adverse affects on analysis may result.
- Fibrin suspended in the serum may clog the probe.
- Check that the blood is sufficiently coagulated prior to serum separation. Remove the suspended fibrin before placing serum on the system.
- If any suspended matter appears in the urine to be dispensed, perform centrifugal separation to precipitate the suspended matter before testing the urine specimen.
- If a sample requires pretreatment depending on the analysis test, consult the reagent manufacturer or distributor.

Instruction

See the package insert provided by the reagent manufacturer for a list of acceptable anticoagulants.

- A minimum quantity of sample is required for analysis. Set up an appropriate quantity of sample, for correct sampling in the system, according to this guide.

See Also

For information about sampling, refer to "Sampling Specifications" in the Specifications Chapter.

- To prevent sample evaporation, do not leave samples unsealed for an extended period of time. If samples evaporate, correct analysis cannot be obtained.
- The serum is hemolyzed, lipemic, or icteric (LIH). Check the serum for the extent of LIH. See "Specific Test Parameters" in the Software Chapter for more information.
- Liquid-level sensor malfunction due to bubbles on the serum or urine surface. Remove the bubbles from the surface and repeat analysis.
- The sample cups and racks were not placed properly on the system. Place the sample cups and racks properly on the system.

See Also
For information about placing the sample cups and racks, refer to the Basic Operations Chapter.

See Also
For more information on sample requirements refer to the following: "NCCLS document (GP16-A), Urinalysis and Collection, Transportation, and Preservation of Urine Specimens: Approved Guideline," and "College of American Pathologists document, Patient Preparation & Specimen Handling, Chemistry/Clinical Microscopy (Fascicle VI)."

Reagent Problems Causing Abnormal Data

- The parameters for reagents and samples are not accurate:
  Check the parameters settings.
- To analyze serum, urine, or other samples using this system, use the appropriate reagent. For information about which products to use, consult the reagent manufacturer, the distributor, or Beckman Coulter Technical Services.
- The methods used to store the reagents, reference materials, and control serums are described in each package insert. Observe the instructions. If reagents, reference materials, and control serums are stored improperly, results will be inaccurate even if they are used within effective periods.
- Consult the package insert or reagent manufacturer or distributor for the stability of the unsealed product.
- To place the reagent on the system, follow the instructions in the package insert and in this User's Guide. Unless the reagent is placed properly, accurate results cannot be obtained and damage to the system could occur.
- Reagent interference between analysis tests: If a reagent is contaminated with another reagent during analysis, results may be affected. The actual degree of interference differs depending on the reagent. For detailed information, contact the reagent manufacturer or distributor. For information on how to check for cross-contamination between tests, contact Beckman Coulter Technical Services.
- The reagent was not prepared correctly. Replace the reagent. Refer to the package insert for preparation instructions.
- The reagent is expired. Replace the reagent.

See Also
For information about setting or replacing reagent bottles, refer to the Basic Operations Chapter.

- The liquid-level sensor malfunctioned during reagent aspiration due to bubbles in the reagent bottle. Remove the bubbles in the reagent bottle.

- Fresh reagent was added to used reagent. Replace the reagent. Do not add used reagent to fresh reagent.
- General Reagent Troubleshooting. Verify reagents are in the correct positions. Check the on-board stability.

QC & Calibrator Problems Causing Abnormal Data

- General QC and Calibrator Troubleshooting.
  - Verify the correct material is in the correct position in the rack.
  - Verify the material was made correctly.
  - Check the open bottle date and expiration dates.
  - Verify the material was not exposed to air for an extended period of time.

Abnormal Data Caused by Detergent

- The recommended detergent was not used. ***Contact Beckman Coulter Technical Services.***

Other Causes of Abnormal Data

- Periodic maintenance was not performed at the specified period. ***Be sure to perform periodic maintenance at the specified period.***

See Also
For detailed information about maintenance, refer to the Maintenance Chapter.

- Insecticide was used in the vicinity of the system.

  Insecticides can affect the cholinesterase (CHE) levels. If contamination is suspected, replace the sample cups, reagents, and reagent bottles with new ones. Also wash the sample probes, reagent probes, mix bars and cuvettes. Never use insecticide in the vicinity of the system.

See Also
For detailed information about maintenance, refer to the Maintenance Chapter.

- Water purity, electrical specifications, environmental conditions ***Check major system specifications, located in the Specifications Chapter.***

2.1.4 Troubleshooting Mechanical Problems

Abnormal data may also be caused by hardware malfunctions. Possible causes and remedies for abnormal data due to defects in hardware or accessories are described below:

Syringe(s) Problems

- Water may leak from the syringes. Hand tighten the syringe cases and case heads of the sample and reagent syringes.
- General Syringe Troubleshooting.
  - Verify the top and bottom screws are hand tight.
  - Verify that probes are not clogged.
  - Verify the bottom screw is tight up against the piston.
  - Verify there is a smooth, resistant pull.
  - Verify the correct size syringe is in use (reagent or sample).
  - Verify there is one O-ring being used, and that it is not damaged.
  - Verify the syringe is on the analyzer correctly.
  - Check the syringe tubing for crimps or leaks.
  - Check the teflon tip of the syringe for wear.
- Bubbles were generated in the syringe tubing

  Select [ANL Maintenance] from the [Maintenance] menu. After selecting "F/Prime Washing-line" press the STAT ROTATION/DIAG Switch. Air will be removed from the tubing.
- The syringe tubing is clogged.

  Remove the relay tubes, then clean each tube inside using a stylet. If the syringe tubing remains clogged after cleaning, contact Beckman Coulter Technical Services.

See Also

For information about syringe cleaning and replacement, refer to the Maintenance Chapter.

Probe Problems

- Leaks from the sample probe and reagent probe due to loose probe connectors. Remove the covers on the sample probe and reagent probe, then tighten the probe connectors.
- Leaks from the dispense tubing Remove the covers on the sample probe and reagent probe, then tighten the probe connectors. If this does not work, contact Beckman Coulter Technical Services.
- A clogged sample or reagent probe. Drain the DI water from the sample probe or reagent probe and check the way the DI water drains.
- The sample probe tip or reagent probe tip was bent or deformed. Replace the damaged sample probe or reagent probe.
- The sample aspiration position of the sample probe is incorrect. The sample probe tip is not positioned at the center of the sample cup. Visually inspect the sample probe for abnormalities. If the sample probe is bent, replace it. If the sample aspiration position is abnormal and the sample probe is not bent, contact Beckman Coulter Technical Services.

- The reagent aspiration position of the reagent probe is incorrect. The reagent probe tip touches the reagent aspiration hole in the reagent refrigerator. Visually inspect the reagent probe for abnormalities. If the reagent probe is bent, replace it. If the reagent aspiration position is abnormal and the reagent probe is not bent, contact Beckman Coulter Technical Services.
- The sample or reagent probe is not aligned over the cuvette. The sample or reagent probe tip comes into contact with cuvettes. Visually inspect the sample or reagent probe for abnormalities. If the probe is bent, replace it. If the probe is not aligned properly and it is not bent, contact Beckman Coulter Technical Services.
- The sample or reagent probe wash position was abnormal. The sample or reagent probe tip came into contact with each wash well. Visually check the sample or reagent probe for bent sections. If either of the probes is bent, replace it. If the probe wash position is abnormal although the sample or reagent probe is not bent, contact Beckman Coulter Technical Services.
- General Probe Troubleshooting.
  - Verify water can be dispensed in a straight stream.
  - Verify that the two metal cap screws for the probe connections are tight.
  - Verify that the tubing for the probes is free of air bubbles.

See Also

For information about how to replace the sample probe or reagent probe, refer to the Maintenance Chapter.

Mix Bar Problems

- The mix bars were contaminated.

  Wash the mix bars.

See Also

For information about cleaning the mix bars, refer to the Maintenance Chapter.

- The coating on mix bar was removed.

  Replace the mix bar.

See Also

For information about how to replace mix bars, refer to the Maintenance Chapter.

- While the mix bars are rotating, abnormal sounds such as rubbing, gear contact noise, or other abnormal operating sounds were generated.

  Contact Beckman Coulter Technical Services.
- The mix bar mounting position was abnormal. The mix bars came into contact with the mix bar wash well and/or cuvettes.

  Contact Beckman Coulter Technical Services.
- The wash water and detergent are not properly drained from the mix bar wash well.

  Contact Beckman Coulter Technical Services.
- Mix bars were not properly installed on the unit and the sample and reagents were not mixed properly.

  Install the mix bars again.

See Also

For information about mounting mix bars, refer to the Maintenance Chapter.

Cuvette Wheel or Wash Nozzles Problems

Scratches, fingerprints, or foreign matter is noticed on the cuvettes, or the cuvettes were stained.

See Also

For information about washing or replacing cuvettes, refer to the Maintenance Chapter.

Moisture is detected outside the cuvette(s) and the cuvette wheel.

See Also

For information about cuvette wheel floods, refer to "Recovering from a Cuvette Wheel Flood" in this chapter.

The wash water and/or detergent spills from the wash nozzles because proper draining did not occur, or the nozzles did not aspirate correctly.

Are the tube joints on the wash nozzles loose? Tighten the loose tube joints.

The wash nozzles may be clogged. Clean the wash nozzles.

See Also

For information about how to clean the wash nozzles, refer to the Maintenance Chapter.

After cleaning cuvettes, a large amount of water remains in the cuvettes.

Are the tube joints on the wash nozzles loose. Tighten the loose tube joints.

The wash nozzles may be clogged. Clean the wash nozzles.

- The tube in the concentrated detergent tank floats.

  Straighten the tube, and insert it toward the bottom of the tank so that it does not come into contact with the opening.

- The float switch in the concentrated detergent tank or diluted detergent tank malfunctioned.

  Check the float switch connector. Do not bring the tube in the tank into contact with the float switch. Check that the float switch is not directly subjected to detergent from the tube. If the float switch malfunction is not corrected by the above action, the switch must be replaced. Contact Beckman Coulter Technical Services.

See Also

For information about cleaning cuvettes, refer to the Maintenance Chapter.

For information about cuvettes replacement, refer to the Maintenance Chapter.

For information about cuvette wheel floods, refer to the Troubleshooting Chapter.

Photometer Lamp or Photometer Unit Problems

- The photometer lamp has deteriorated.
  - The photometer lamp needs to be replaced when:

    1. The check falls outside of the acceptable range.
    2. Reagent blank flags are generated (U, u, Y, y) for numerous assays.
    3. Data is inaccurate.

    Perform a photometer check and analyze results. *If the lamp is changed, a photocal must be performed.*

See Also

For information about photocal measurement results, refer to the Software Chapter.

The photometer lamp does not stay lit constantly.

- Perform the photocal measurement 2 times to check the difference between 2 sets of measurement data. If there is a discrepancy between the two sets, the photometer lamp may be defective. Replace the lamp and repeat the photocal.

See Also

For information about replacing the photometer lamp, refer to the Maintenance Chapter. *Always perform a photocal after changing the photometer lamp.*

Deionized Water Tank Problems

- The deionized water tank is dirty and stained. Water scale has formed on the inside of the tank. There are particles inside deionized water tank.
    - Clean the deionized water tank.

See Also

For information about cleaning the deionized water tank, refer to the Maintenance Chapter.

- After cleaning the deionized water tank, detergent remains.
- Clean the deionized water tank again. Rinse thoroughly with deionized water.
- Verify laboratory deionized water meets specifications.

See Also

For information about water specifications, refer to the Specifications Chapter.

Deionized Water or Dirty Filter Problems

- If Ca, Mg and Fe data are abnormal, the DI water conductivity may be greater than 2.0 us/cm.
    - Clean the deionizer. For detailed information, contact Beckman Coulter Technical Services.
- Tap water below 5 degrees C was used.
    - Supply tap water to the deionizer that is greater than 5 degrees C. For detailed information, contact Beckman Coulter Technical Services.
- The filters are stained, clogged, or have mildew on them.
    - Clean the deionized water filter and the sample probe filter. If abnormal data is not corrected after cleaning, replace the filters.

See Also

For information about how to clean or replace the deionized water filter or sample probe filter, refer to the Maintenance Chapter.

Incubation Temperature Problems

- The cuvette wheel was removed for an extended period of time and analysis was started immediately after the wheel was replaced on the system.

- If the cuvette wheel is removed for an extended period, allow one hour or more after replacing it before starting analysis.

Reagent Refrigerator Problems

- The reagent refrigerator temperature is out-of-range.
  - Press the [System Status] key to display the [System Status] screen. On the screen, check the temperature in the reagent refrigerator.
  - Open the reagent refrigerator cover and check that the reagent bottles are cool.

Rack Problems

- General Rack Troubleshooting.
  - Check barcode placement.
  - Verify sample position according to rack color.
  - Verify the correct number of magnets are present in the bottom of the rack.
  - Verify the rack was loaded correctly.

See Also

For information about racks, refer to the Basic Operations Chapter.

STAT Table Problems

- The STAT table temperature is out-of-range.
  - Make sure the two STAT table covers are on.
  - Make sure the covers are placed properly.
  - If STAT samples are placed and removed from the table frequently, and the covers are not kept in place, the temperature will increase.

2.2 System Problems

This section addresses problems that may be caused by malfunctioning hardware.

TEMP REF HIGH Alarm for the Cooling Unit

There is a problem in the reagent storage refrigeration unit. Select on-line alarm help for detailed corrective actions.

Abnormal Sound Coming from Inside the System

- Air bubbles are trapped in tubing.
    - Check the deionized water filter. If the filter is damaged, replace it.

See Also

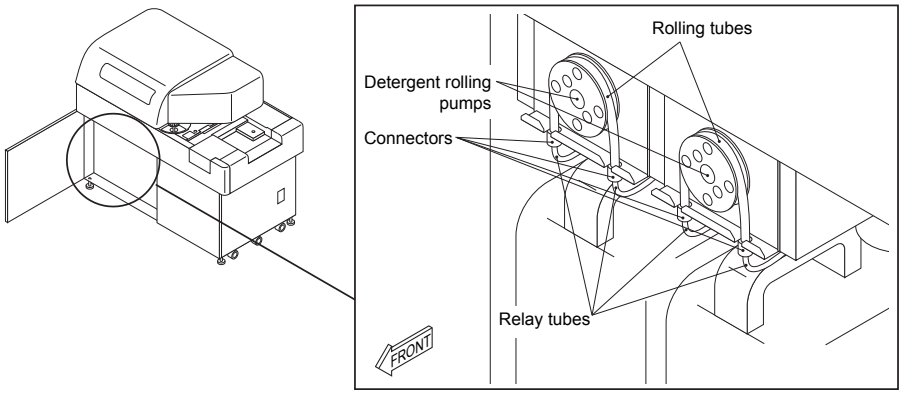
For information about replacing the deionized-water filter, refer to the Maintenance Chapter.

- Other causes
    - The circulation pump, radiator fan, lamp cooling fan, air pump, 24V power supply fan, or drying pump may be defective.
    - Contact Beckman Coulter Technical Services.

Water Supply Tank "Dilution Empty" Alarm

Select on-line help for detailed corrective actions.

Leaks in the Detergent Rolling Pump



- Any rolling tube may deteriorate.
    - Check the rolling tubes for cracks. If the tubes are deteriorating, replace them.

See Also

For information about rolling tube replacement, refer to the Maintenance Chapter.

- Are the tube connectors loose?
    - Check the connectors. If they are loose, tighten them firmly.

Barcode Errors

- The barcode labels on the sample cups or reagent bottles may be stained.
    - Check for water drops or stains on the barcode labels. If water drops are found, wipe them off. If a sample ID label is stained or damaged, replace it with a new one. If a reagent ID label is damaged, the reagent position can be fixed so the barcode will not be used.
- Barcode labels on sample cups or reagent bottles may have fallen off or were not placed properly. Refer to the Basic Operations Chapter for proper placement procedures.
- The barcode reader may be stained.
    - Wipe the window using an alcohol prep.

See Also
For information about placing barcodes, refer to the Basic Operations Chapter.

Leaks Coming from the Bottom of the Analyzer

- The wash line may be obstructed.
    - Check for obstructions in the wash wells for the sample probe, reagent probe, etc. If they are clogged, clean them.

See Also
For information about how to clean the wells, refer to the Maintenance Chapter.

- The waste line may be obstructed or it was installed improperly.
    - Does the waste line meet the system specifications?
    - Can you see any obstruction in the lines? If so, contact Beckman Coulter Technical Services.

No Detergent Supplied to the Mix Bars

- The deionized water filter may be clogged.
    - Inspect the deionized water filter. If the filter surface is dirty, the filter may be clogged. Clean the deionized water filter.

See Also
For information about how to clean the deionized water filter, refer to the Maintenance Chapter.

Reagent Alarm when Sufficient Reagent Remains in the Bottles

Select on-line alarm help for detailed corrective actions.

Sample Alarm when Sufficient Sample Remains

Select on-line alarm help for detailed corrective actions.

Detecting No Sample Cup when it is Present

- An unspecified sample cup was used.
    - Check if the specified sample cups are used for each rack.

Detecting No Sample Cup when it is Present on the STAT Table

- The related test was not selected during the requisition operation, or the requisition setup information did not meet the sample cup position on the STAT table.
  - Repeat the requisition operation.
- The wrong size adaptor was used for the sample cup set on the STAT table.
  - Check if the sample cup is set properly for the STAT table. If it is not, set the sample cup again using an adaptor appropriate for the sample cup diameter.
- An unspecified sample cup was used.
  - Check if the sample cups specified by the STAT table are used. If they are not, use the specified sample cups.

Printer is not printing or light is not on.

- The power to the printer was not turned on.
  - Check that the printer is turned on.
- The printer ribbon is old or missing.
  - Replace the ribbon.
- Make sure the on-line button is on.
- Make sure the paper is loaded properly.
- Secure the printer cables.

See Also

For information about how to replace the ribbon, refer to the printer manual supplied with the printer.

Liquid spills from the Reagent Probe Tip

- The reagent probe was not properly installed.
  - Select [ANL Maintenance] from the [Maintenance] screen. After selecting “B/ Replace R Probe & Syringe," press the STAT ROTATION/DIAG Switch. DI water will be drained from the reagent probe tip. Check if the DI water drains normally. If the DI water does not drain normally, the reagent probe may not be properly attached. Check reagent probe installation again.
- The reagent syringe case head fixing screw may be loose.
  - If the syringe case head fixing screw is loose, tighten it.

Reagent Probe not Aligned over the Cuvette

- The reagent probe may be bent.
  - Check if the reagent probe is bent. If so, replace the reagent probe.

See Also

For information about how to replace the reagent probe, refer to Maintenance Chapter.

Abnormal Data Flag # (Sample Level Detection Error) displayed in the Second Half of the Sample Dispense Operation

- The sample volume is insufficient.
    - Check the sample volume.

See Also
For information about error flags, refer to the Error Flags Chapter. For information about sample volume, refer to "Sampling Specifications" in the Specifications Chapter.

Cuvette Detergent Overflow

- The detergent aspiration nozzles may be clogged.
    - Clean aspiration nozzle using a stylet. If the problem is not resolved after cleaning the nozzle, contact Beckman Coulter Technical Services.

See Also
For information about cleaning nozzles, refer to the Maintenance Chapter.

Sample Rack Jams

- Foreign matter, such as tape, may be on the rack.
    - Check for foreign matter on the rack and remove it.
- Foreign matter may be on the bottom of the rack.
    - Check if foreign matter, such as a magnet, is incorrectly placed or jammed onto the bottom of the rack and remove it.
- Clean belts and belt area with deionized water to remove spills or sticky material.

TEMP DIL Alarm for the Wash Heat Unit

Select on-line alarm help for detailed corrective actions.

Printer Problems (Alarm "Part of data is not output yet.")

- Analysis was started while the printer was off-line or turned off.
- During analysis the printer was taken off-line or turned off.
- The printer is out of paper.
    1. Turn ON the power to the printer and make sure it is on-line.
    2. Load printer paper if necessary.
    3. Press the [System Status] key.
    4. Select "DPR Status" on the [System Status] screen.
    5. Press function key F4 (Printer Control).
    6. Select "Resume." The printer will begin printing the data that has been analyzed. After completing the printout, the system moves to the Standby mode.

2.3 Data Processor Problems

This section provides information on correcting problems with the data processor.

Menu Cannot be Selected

- The [System Status] screen is open.
  - Press the [System Status] key to close the [System Status] screen. Select the screen again.
- The selected screen does not comply with the password security level (the screen names appear in half-tone color).
  - If a half-tone color screen is selected, the temporary log-in window will be displayed. Contact your supervisor to have the password level changed.
- System Program Crashes
  1. Confirm the hard drive LED light is not on.
  2. Press the control, alt, delete keys simultaneously.
  3. When the window appears select "Shutdown.
  4. Turn the power off.
  5. Restart the system.
  6. Contact Beckman Coulter Technical Services.
- The index of the sample data file to be processed is damaged.
  - Select [Maintenance], [Retrieve Data Base]. If the problem is not corrected after executing [Retrieve Data Base], contact Beckman Coulter Technical Services.

See Also

For information about executing [Retrieve Data Base], refer to the Software Chapter.

Numeric Entry cannot be Performed from the Ten-Key Keypad

- The Num Lock is released.
  - Press the Num Lock key, then confirm that the Num Lock LED on the keyboard is lit.

Disabled Keyboard Access

- Keyboard does not respond
  - Check the keyboard cable.
- System Failure
  1. Confirm the hard drive LED light is not on.
  2. Press the control, alt, delete keys simultaneously.
  3. When the window appears select "Shutdown.
  4. Turn the power off.
  5. Restart the system.
  6. Contact Beckman Coulter Technical Services.
- Data is being saved
  - Wait until the data is saved.
- The keyboard has been affected by electrical noise.
  - Plug the keyboard cable in and out 2 or 3 times.

Inaccessible Floppy Disk

- The floppy disk was formatted differently from the specification.
- Use either of the following floppy disks:

  DOS formatted, 2HD 1.44MB

  DOS formatted, 2DD 720KB

  Format the floppy disk by selecting [Maintenance], [Data Operation], [FD Data Management]. Select the way you want to initialize the diskette: for parameters or data. Select function key F5 (start initialize).

See Also
For information about the floppy disk format, refer to the Software Chapter.

- The floppy disk was write-protected when the system attempted to write data to the disk. ***Slide the tab on the diskette to "write-enable."***
- The floppy disk is damaged.
  - Replace the floppy disk with a new one.
- **The floppy disk drive may be damaged.**
  - If the problem is not corrected after taking the above actions, contact Beckman Coulter Technical Services.

Analysis Results do not Automatically Print

- Real-time output was not set.
  - Set the real-time output of reports or data log lists from the [Printer] screen.

See Also
For information about real-time output setup, refer to the Software Chapter.

- The paper is empty.
  - Load more paper. Select [Routine], [Report], then try printing again.

See Also
For information about loading paper, refer to the printer manual supplied with the printer.

See Also
For detailed information about the [Report] screen, refer to the Software Chapter.

On-line Auto-output by Host Computer not Executed

- The I/F cable to the host computer is disconnected.
  - Connect the I/F cable correctly.
- The host I/O parameters were incorrectly modified.
  - Set the appropriate I/O parameters by selecting the [Online] screen.

See Also
For information about the [Online] screen, refer to [Routine], [Data Report], [Online] located in the Software Chapter.

No Data Stored Even Though There Is Sufficient Space on the Hard Disk

- The database in the hard disk has been destroyed.
  - Select [Maintenance], [Data Operation], [Retrieve Data Base]. Restore the analysis data that has been backed up on the floppy disk into the hard disk. If the system will not start up normally after executing [Retrieve Data Base] (the hard disk may be damaged), contact Beckman Coulter Technical Services.

See Also

For information about how to rebuild the database, refer to [Maintenance], [Data Operation], [Retrieve Database] located in the Software Chapter.

Improper Data Input/Output Between the System and Host Computer

- **The I/F cable to the host computer is disconnected.**
  Connect the I/F cable correctly.
- **The I/F cable is defective.**
  Contact Beckman Coulter Technical Services.

2.4 Recovering from an Emergency Stop or Power Loss

In the event of a power failure or an emergency stop, the main power is immediately turned off, and the power to the incubator and reagent refrigerator is also turned off. Perform the following procedure to recover from this state of power loss.

Performing an Emergency Stop

Note

The analyzer will stay in a Warm Up mode for 1 1/2 hours after an EM Stop is performed. To bypass this mode, select [Auxiliary], [Standby Set].

Caution

If the nature of the emergency compromises operator or instrument safety, press the EM Stop Switch immediately. Please be aware that pressing the EM Stop Switch without performing the other steps listed below could cause damage to the computer hard drive. Also the operating system and application files could become corrupted.

The following steps are the preferred method of shutting down during an emergency:

1. Press the following keys on the keyboard: CTRL + ALT + Delete. The Task Manager appears.
2. From the Task Manager screen, select the Shutdown button. Windows NT will close all open files and databases.
3. When the message "It is now safe to turn off your computer" appears, press the EM Stop Switch on the front of the analyzer. All power to the system turns off.

Important

In the event of a stop or an emergency stop, it is not possible to use the data. Analysis must be repeated. If analysis was in progress and a stop or an emergency stop was performed, reagent still remains in the cuvettes. This can cause damage or deterioration in the cuvettes, or may cause abnormal results. If reagent was in the cuvettes for a lengthy period of time, perform a W1 prior to restarting analysis.

Resetting the System after a power failure or an Emergency Stop

1. Press the Reset Switch on the front of the analyzer.
2. After 10 seconds, press the On Switch. The software will load. Wait approximately 20 minutes until the photometer lamp has stabilized before starting analysis. A message displays for a few minutes "Program download to analyzer." Then an alarm occurs "Power Failure Detected." Clear the alarm by pressing the "Alarm Clear" button on screen and Reset.
3. From the [Start Condition] screen, use the same index as before the emergency stop. Press function key F4 (set). Tab to the "start number" field. Set the "start number" to the next sample number after any completed data (last sample that printed results).
4. Perform a W1 to remove reagent left in the cuvettes. For detailed procedures on performing a W1, refer to the Maintenance Chapter.
5. Select [System Status], [Reagent Status]. Reset the "checked" status in the [Reagent Status] screen. Select function key F5 (Check Start), "Reset Only." Verify reagent integrity if your instrument was without power for a lengthy period of time.
6. Press start. A warning will appear "ISE No Cal." The ISE will continue to use the last ISE Cal. data performed, so answer "Yes" at the start prompt.

2.5 Recovering from a Cuvette Wheel Overflow

The following procedure explains what can cause a overflow, and how to recognize and recover from a overflow. Performing scheduled maintenance greatly reduces the chances of a cuvette wheel overflow. For more information about maintenance for each system component, refer the Maintenance Chapter.

2.5.1 What Causes a Overflow?

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.

- The wash nozzle is bent or damaged.
- Damaged or missing O-rings on tube mounting joint manifolds.
- 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.

2.5.2 Recognizing a Overflow

The error flags *, ?, @, $, D, B, ! may indicate a cuvette wheel overflow. The data, alarms and/or flags will vary depending on the severity of the overflow. One or all tests could be affected by a overflow. Here are some problems to look for:

- QC on tests are out-of-range. QC alarms have occurred.
- Reagent blank flags and alarms have occurred on one or more tests.
- Is the entire data printout incorrect?
- The analyzer is not performing as usual.
- Numerous cuvette failures after photocal.

Lift the cuvette wheel cover.

The cuvettes should appear frosty or white, if they are dark, black, or wet when removed, the cuvette wheel has overflowed.

2.5.3 Recovering from a Overflow

Instruction

Immediate attention should be given to a overflow. If nothing is done to fix the problem, the wheel will continue to overflow.

Check the following list.

- The wash nozzle station should be aligned over the cuvettes. Visually inspect and ensure nozzles are centered over cuvettes then check the alignment.
- The wash nozzles should be straight. Sonicate and clean the nozzles with a stylus to remove any debris.
- Check reagent and sample probes to be sure they are properly aligned. Rotate the sample and reagent probes over the cuvette wheel. If you require assistance performing these procedures, please contact Beckman Coulter Technical Services.

Instruction

It is very important that the probes are centered over the cuvettes.

- Check for chipped or cracked cuvettes. Replace them if necessary.

See Also

For information about replacing cuvettes, refer to the Maintenance Chapter.

- Verify the wash nozzle tubing connections are secure.
- Verify the O-rings on the manifolds are in place and not damaged.

2.5.4 After the Overflow Problem Is Fixed

Note:

Do not start cleaning cuvettes unless the cause of the overflow is determined.

Please refer to “Cleaning Cuvettes and the Cuvette Wheel after a Cuvette Wheel Overflow” located in the As Needed Section of this maintenance chapter.

3. Troubleshooting the ISE

This section provides troubleshooting information for the ISE unit. *Performing scheduled maintenance greatly reduces the chances of problems occurring with the ISE unit. For more information about maintenance for each system component, refer to the Maintenance Chapter.*

Contents

To Begin Troubleshooting the ISE, Answer the Following Questions.

For data problems

Did you interpret the data printout correctly?

See Also
For information about checking results, refer to “Checking Results” located in the Basic Operations Chapter.

Is the Data Flagged?

See Also
For information about data flags, refer to the Troubleshooting Chapter.

Is the Calibration Out-of-Range?

See Also
For information about how to perform a calibration, refer to the Basic Operations Chapter.

Is QC Out-of-Range?

See Also
For information about how to perform a QC, refer to the Basic Operations Chapter.

Is Data Erratic? (Have you performed scheduled maintenance?)

See Also
For information about schedule maintenance, refer to the Maintenance Chapter.

For Alarms

An alarm usually indicates a mechanical problem or a communication failure. Follow the corrective action provided in the on-line help function.

See Also
For information about using on-line help, refer to the Troubleshooting Chapter.

For an Analyzer Mechanical Error

Usually a mechanical error is associated with an alarm. Follow the corrective action provided in the on-line help function.

For Other Operational Integrity Problems

Were Start-up Procedures Performed Correctly?

See Also
For information on start-up procedures, refer to the Basic Operations Chapter.

Is the Reagent Stable?

See Also
For information on checking reagent stability, refer to the "Troubleshooting for Data Flags" procedure in the Error Flags Chapter.

Is There Enough Reagent in the Bottles?

An alarm will be generated when ISE reagent is low. Replenish the reagent and make sure it is in the correct position. Refer to the ISE Maintenance section of the Maintenance Chapter.

Have the Reagent, Calibrator, and QC Material Been Properly Stored?

See Also

For information on proper storage, refer to the package insert. The "Troubleshooting for Data Flags" procedure in the Error Flags Chapter also provides general information on handling these materials.

Has the Analyzer Been Calibrated Correctly?

See Also

For information about performing calibrations, refer to the Basic Operations Chapter.

Have Scheduled Maintenance and Routine Component Replacement Been Performed?

See Also

For information about scheduled maintenance, refer to the Maintenance Chapter.

3.1 ISE Sample Requirements

- The ISE is designed to analyze urine and/or serum samples. If problems are encountered when analyzing a specific test or when using a specific reagent, consult the package insert or reagent manufacturer or distributor.
- Use urine and/or serum that is free from suspended matter or the probe may be clogged and adverse affects on analysis may result.
- Exercise care when mixing chemicals (medicine, anticoagulant, preservative, etc.).
- If any suspended matter is recognized in the urine and/or serum to be dispensed, perform centrifugal separation to precipitate the suspended matter before testing the urine specimen.
- A minimum quantity of sample is required for analysis. Set up an appropriate quantity of sample for correct sampling in the system, according to this manual.
- To prevent samples from evaporation, do not leave them unsealed for an extended period of time. If samples evaporate, correct analysis cannot be obtained.

The following list describes some of the sample criteria that can affect data:

1. Properly store and tightly cap samples if analysis is delayed.
2. Follow package insert instructions.
3. High results may occur due to evaporation of the sample.
4. Halogens (bromide and iodine) may affect Cl levels.
5. A hematocrit greater than 65% may affect K levels.

Instruction

See the package insert provided by the reagent manufacturer for a list of acceptable anticoagulants.

See Also

For more information on sample requirements refer to the following: "NCCLS document (GP16-A), Urinalysis and Collection, Transportation, and Preservation of Urine Specimens: Approved Guideline," and "College of American Pathologists document, Patient Preparation & Specimen Handling, Chemistry/Clinical Microscopy (Fascicle VI)."

Other Recommendations for Accurate Data

- Use the recommended control serum
- Keep room temperature constant. Fluctuations can cause data problems.
- Verify all parameter settings.
- Perform scheduled maintenance.

3.2 Dispensing System

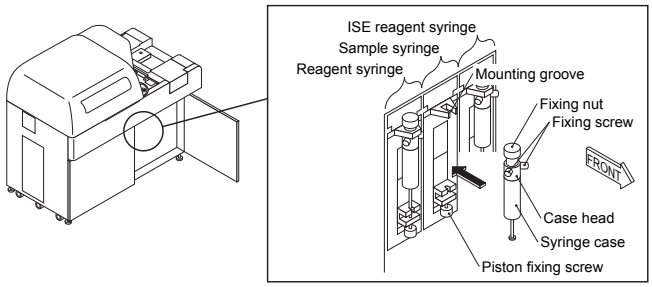
If the test results are either inaccurate or imprecise, there could be a problem with the dispensing system. The following elements make up the dispensing system:

3.2.1 Sample Probe & Syringe (Also used in photometric tests)
3.2.2 Pump Tubing
3.2.3 Mix Bar
3.2.4 Sample Pot
3.2.5 Pinch Valve Tubing

See Also
For information about cleaning or replacement procedures, refer to the Maintenance Chapter.

3.2.1 Sample Probe and ISE Reagent Syringe

The following components are used when performing ISE tests. Inaccuracy or imprecision could be caused by the problems listed below (enzymatic tests are particularly susceptible).



Problem: Worn ISE reagent syringe.

Action: Replace the syringe.

Problem: Water carry-over due to a dirty probe.

Action: Clean the probe with an alcohol prep.

Problem: Obstruction in the probe.

Action: Sonicate the probe.

Problem: Misalignment of the probe over the sample pot.

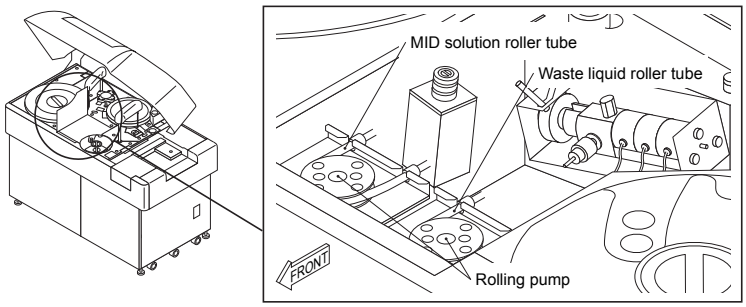
Action:
1. Confirm that the pot has been placed properly.
2. Is the probe tip bent?
3. Contact Beckman Coulter Technical Services.

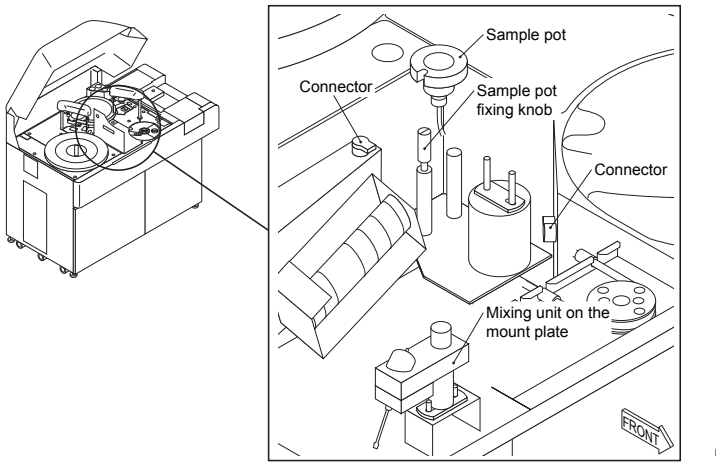
See Also

For more information on troubleshooting probes, refer to "Probe Problems" in the Troubleshooting Mechanical Problems section of this chapter.

- General Syringe Troubleshooting.
  - Verify the top and bottom screws are hand tight.
  - Verify the bottom screw is tight up against the piston.
  - Verify there is a smooth, resistant pull.
  - Verify the correct size syringe is in use (reagent or sample).
  - Verify there is one O-ring being used, and that it is not damaged.
  - Verify the syringe is on the analyzer correctly.
  - Check the syringe tubing for crimps or leaks.
  - Check the teflon syringe tip for wear.

3.2.2 Pump Tubing:





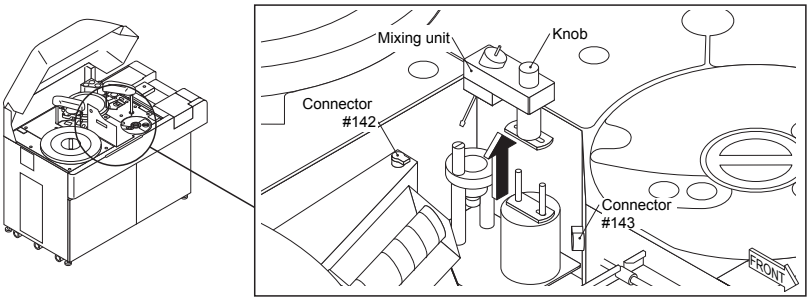
Problem: Worn or bent mixture aspiration tubing. This condition could also generate a sample pot overflow error.

Action: Observe sample pot, flowcell tubing, and bypass tubing during aspiration of calibrator or control. There must not be any air in the flowcell during the measurement period. Air will be present in the bypass tubing. If leaks occur or the tubing is worn or flat in appearance, replace the mixture pump tubing.

See Also

For procedures on replacing mixture pump tubing, refer to the Maintenance Chapter.

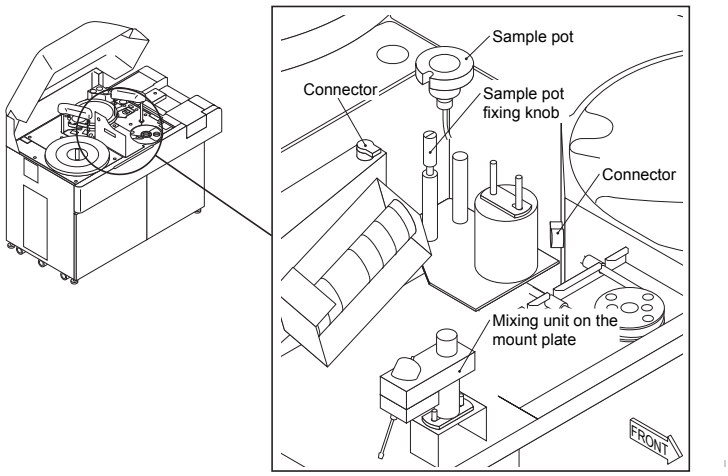
3.2.3 Mix Bar



Problem: Mix bar not rotating

Action: 1. Check power connector number 142 to the left of the mix motor.
2. Check that the mix bar is not striking the side of the sample pot. If it is, check the screws holding the motor in place.
3. Make sure the sample pot is on correctly. If it is on backwards, the mix bar can't rotate.
4. Contact Beckman Coulter Technical Services.

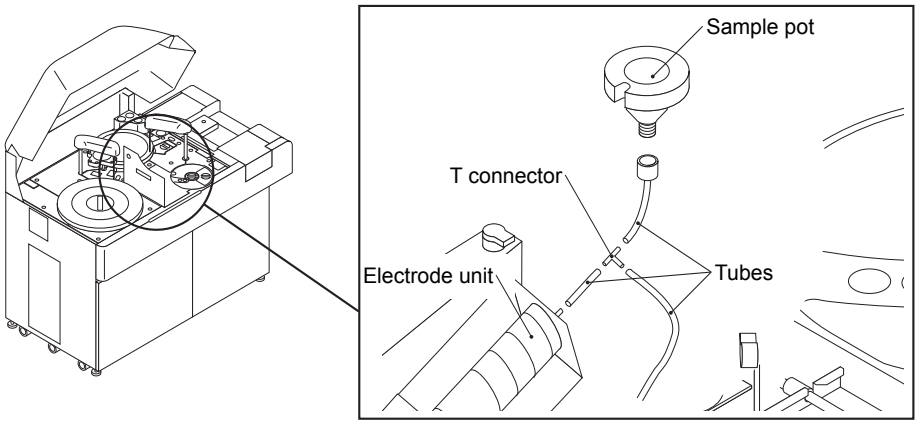
3.2.4 Sample Pot



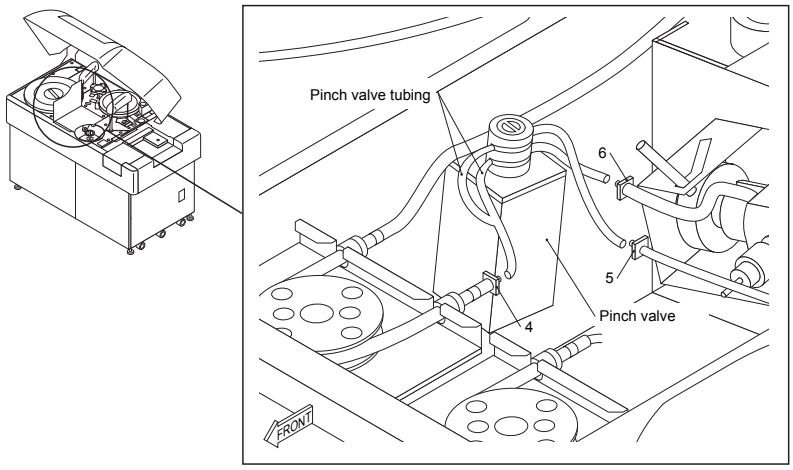
Problem: A dirty sample pot can cause calibration or QC errors.

Action:

1. Wash the sample pot daily. *Refer to the ISE Maintenance section of the Maintenance Chapter for procedures.*
2. Check the tubing and T connectors between the sample pot and electrode. If it is dirty wash it. *For information on washing the sample pot, refer to the ISE Maintenance section of the Maintenance Chapter.*



3.2.5 Pinch Valve Tubing



Problem: Calibration errors or sample pot overflow errors.

Action: Align the pinch valve tubing again so that a different part of the tube is in the valve. If the tube shows any signs of wear, replace the tube. Make sure the tubing is attached correctly. *For information about tubing replacement, refer to the Maintenance Chapter.*

3.3 Measuring Components

The following elements make up the measuring components:

- O-rings
- Electrodes
- Mixture Pump Tubing
- Thermistor
- Flowcell Block

To Determine if There Is a Flowcell Problem

1. Evaluate the calibration data.
2. Perform a Sequential Sample Measure in the [Diagnostics] screen. For more information, refer to "Sequential Sample Measure," located in the ISE Troubleshooting section of this chapter.

3.3.1 O-rings

Problem: Missing O-ring

Action: Verify that there are a total of four (4) O-rings: cell inlet block, Cl electrode, Na electrode, and K electrode.

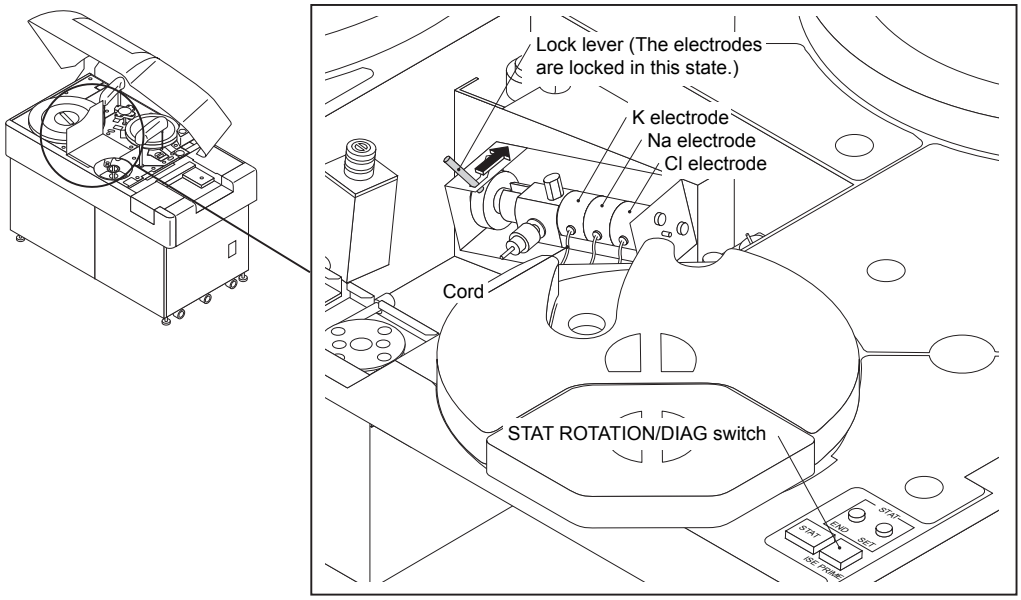
Problem: Defective O-ring

Action: The O-rings should be positioned correctly. Make sure they are not flat, bent or misshapen. Replace them if necessary.

Problem: O-ring contaminated with KCl

Action: Remove the O-ring and wash it along with the groove in deionized water to remove any residual KCl. KCl will contaminate the electrodes and affect results.

3.3.2 Electrodes



Problem: Old or obstructed Na, K, Cl, or reference electrodes

Action:

1. Remove obstructions in the flowcell path. Perform the daily cleaning procedure two or three times. Prime with mid-standard.
2. Perform a calibration.

See Also

For information about performing calibrations, refer to the Basic Operations Chapter.

3. Perform a "Selectivity Check" to verify Na and K membrane selectivity.

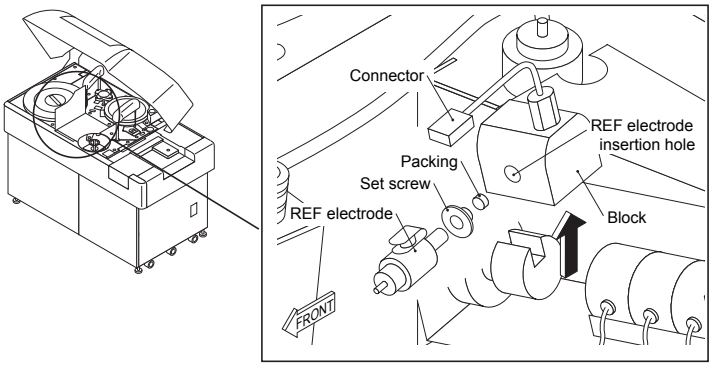
See Also

For information about performing a selectivity check, refer to the Troubleshooting Chapter.

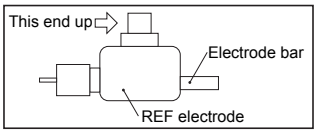
4. Try changing electrodes.

See Also

For information about replacing electrodes, refer to the "ISE Maintenance" section of the Maintenance Chapter.



Cross-sectional View of REF Electrode



Problem: Bubble in the reference electrode

Action: Check for a bubble in the reference electrode by removing and visually inspecting the electrode tip. Gently tap the tip to dislodge the bubble, then replace the electrode.

Problem: Reference electrode not installed properly

Action: Install the electrode properly by referring to the replacement procedure in the ISE Maintenance section of the Maintenance Chapter.

Problem: Broken lead wires connecting to the electrodes

Action: Call Beckman Coulter Technical Services.

Problem: Missing reference electrode packing and internal solution

Action: Reference electrode packing and internal solution can be replaced if necessary.

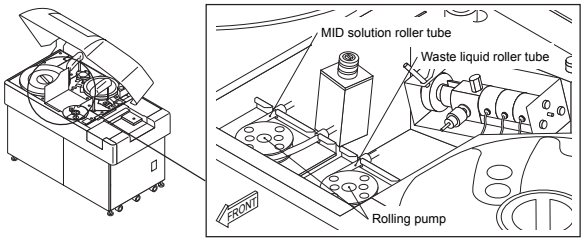
See Also

For information about adding reference electrode solution, refer to the Maintenance Chapter.

Instruction

Electrode replacement should be performed if the slope values are out-of-range, or if other troubleshooting measures don't resolve the problem. If possible, remove the suspected electrode and place it into another AU400 and perform a calibration to verify the performance of the electrode.

3.3.3 Mixture Pump Tubing



Problem: Old, worn, or crimped tubing or leaking

Instruction

Old or worn tubing will be flat (no longer round in diameter) in the area where it is pressed against the pump.

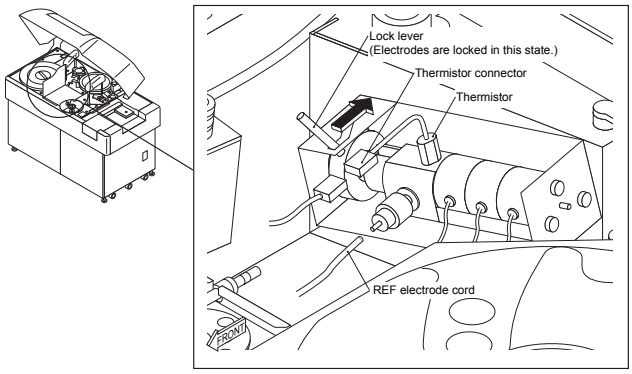
Action:

1. The mixture pump pulls the samples, calibrators, and mid-standard through the flowcell. Replace the mixture pump tubing.

See Also

For information about replacing mixture pump tubing, refer to the "ISE Maintenance" section of the Maintenance Chapter.

3.3.4 Thermistor



If the following problems occur with the thermistor, perform the action listed below:

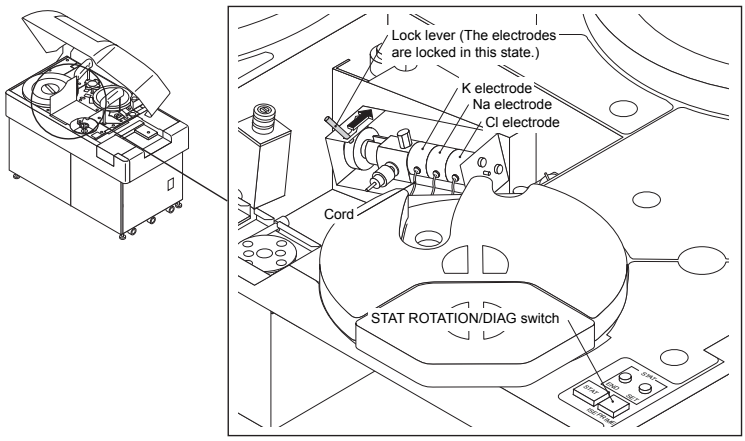
Problem:

- Defective packing
- No contact with liquid in the flowcell
- Other thermistor malfunction

Action:

1. Visually check the thermistor for liquid contact. Verify the thermistor was not forced in, and that the screw is tightened. No bubbles should be observed around the thermistor.
2. Call Beckman Coulter Technical Services if a malfunction of the thermistor is suspected.

3.3.5 Flowcell Block



If the following problems occur with the flowcell block, perform the action sequence stated below:

Problem:

- Obstruction in the flowcell inlet block
- Obstruction in the flowcell outlet block
- Defective port of flowcell inlet block
-

Action:

1. Check the expiration date of the electrodes. The expiration date is located on the box. If the electrodes have expired, do not use them.
2. Replace defective flowcell inlet or outlet blocks.
3. Perform an ISE cleaning procedure. Call Beckman Coulter Technical Services if the obstruction is not removed.

Instruction

To determine electrode integrity and on-board life, review the calibration, selectivity check, and QC results. The following calibration ranges are acceptable:

Na	38 - 65
K	38 - 65
Cl	-38 - -65
MID-STANDARD SOLUTION FACTOR RANGES:	
Na	0.80-1.20
K	0.75-1.25
Cl	0.75-1.25

Replace electrodes when results are out-of-range and other troubleshooting procedures have been performed. Electrodes are under warranty for 20,000 samples or 6 months.

3.4 Calibration Errors

Calibrate the ISE daily. If the standards were in the standard cup table for more than fifteen (15) minutes, replace with fresh standards.

See Also

For information about performing calibrations, refer to the Basic Operations Chapter. To perform a calibration from diagnostics, refer to the Software Chapter.

1. Verify calibration results.
2. Review the data daily by using the following criteria:
   A. The slopes must be in range:

Na	38 - 65
K	38 - 65
Cl	-38 - -65
MID-STANDARD SOLUTION FACTOR RANGES:	
Na	0.80-1.20
K	0.75-1.25
Cl	0.75-1.25

   B. The day-to-day slope values should be consistent for each electrode. Slopes may decrease with time. This however, does not necessarily indicate a faulty electrode.
   C. Check for trends in slope values.
3. Verify the ISE Reagent Integrity.

Instruction

A calibration failure will occur if the buffer or standard solutions become contaminated with the reference solution. The reference solution has a very high concentration of KCl and even a small amount will affect ISE results.

4. Verify the Dispensing System.
5. Verify Measuring Components.
6. Perform a calibration to obtain the electrical potential of the low, mid, and high standards.
7. If the Na and K slopes are negative and the Cl slope is positive:
   High Standard vs. Low Standard: A slope will be generated if the standards are reversed on the standard cup table. If this happens, the Na and K slope values will be negative and the Cl slope value will be positive. Pour the standards again, and place them in the correct positions on the standard cup table.

8. The Na and Cl are out-of-range:
   A possible carry-over from the K selectivity solution. Perform a calibration three (3) times and verify results.
9. The Na and K are out-of-range:
   A possible cause is contamination in the sample pot. To resolve this problem, sonicate the sample pot.
10. Na/K and Cl have a shift in the opposite direction. Check the reference electrode.

See Also

For information about replacing the reference electrode, refer to the Maintenance Chapter.

11. Na/K and Cl have a shift in the same direction:
    - Verify the integrity of the buffer reagent.
    - Visually inspect the thermistor.

See Also

For information about replacing reagents, refer to the Maintenance Chapter.

3.5 Selectivity Check

Perform a Selectivity Check for the Na/K Electrodes

The Na electrode and K electrode are ion-selective electrodes. If the selectivity of electrodes deteriorates, the ISE unit is affected by ions other than those being measured. Appropriate analysis results will not be obtained. To check the electrodes for deterioration, check the selectivity of the Na and K electrodes every week.

Instruction

A successful calibration must be achieved before performing a selectivity check.

See Also

For information about performing a selectivity check and replacing electrodes, refer to the "ISE Maintenance" section in the Maintenance Chapter.

3.6 Sequential Sample Measure

The sequential sample measure checks ISE precision. For detailed procedures, refer to [Maintenance], [Maker Maintenance], [ISE Diagnostics] in the Software Chapter. Perform a Sequence 1, 2, and 3.

1. If a value is out-of-range after performing a check, try the following:
   If only one value is out-of-range:
   - Check the corresponding electrode lead or replace the electrode.

See Also
For information about replacing the electrodes, refer to the Maintenance Chapter.

   If all three values are out-of-range in the same direction:
   - See *"3.2 Dispensing Systems"*
   - See *"3.3 Measuring Components"*
   - Replace the sample probe

   If all three values are randomly out-of-range:
   - See *"3.3 Measuring Components"*
   - Check all electrodes
   - Check reference electrode packing and internal solution

See Also
For information about replacing the solution, refer to the Maintenance Chapter.

2. Repeat the sequential sample measure until SDs are in the acceptable range.
3. Out-of-Range QC results are flagged with H or L on the printout. Verify that the range for the QC lot number is properly entered in QC parameters.

3.6.1 Shifts & Trends

Problem:

- A SHIFT is more than 7-10 QC points in a row that fall either above or below the mean.
- A TREND is 5-10 QC points in a row that are steadily increasing or decreasing.

1. Each laboratory must determine the number of QC points that define a shift or trend.
2. Shifts or trends will be flagged by the AU400 QC program.
3. Check for shifts or trends by reviewing the Daily QC Chart Output Screen
4. Preset or cumulative modes are available. The laboratory must decide what to use.
   A. Preset values are determined from the package insert.
   B. Cumulative values are calculated by indicating the start date and end date of the QC files the laboratory wants included in the calculation.

Action:

1. Verify the QC material:
   A. Check the lot number and expiration date.
   B. Check the stability for storage conditions on the QC material (freezer, refrigerator, opened bottles).
   C. If using lyophilized QC, check the reconstituted stability and verify that it was made correctly. Use a volumetric pipet to add the DI water.
   D. Verify the QC material was not left at room temperature for an extended time period. Avoid prolonged exposure to air before processing, because evaporation will affect analyte concentration.
   E. Verify that QC material was not contaminated prior to, or during the run. Check for indications of instability such as abnormal color, turbidity, or a precipitate. Use fresh material if necessary. Refer to the QC package insert for specific indications of deterioration.
   F. Verify that the QC material is mixed well.
2. If using an external calibrator (ACAL) for the electrolytes, verify the calibrator material using the same criteria as above.
3. Place the control samples in the green rack in the order of the control numbers which were set as parameters. *The control numbers correspond to the sample positions (1 to 20) in the green rack. For example, 1 to 10 are the control #s. and sample positions for the green rack of ID 1, and 11 to 20 are the control #s. and sample positions for the green rack of rack ID 2.*
4. Verify the dispensing system. (See *3.2 Dispensing Systems*)
5. Verify all reagent integrity.

See Also

For information about on board stability and reagent replacement, refer to the Maintenance Chapter.

6. Verify the integrity of the measuring components. (See *3.3 Measuring Components*)
7. Verify the software parameters.

Instruction

Check the high and low range against the package insert values. Verify that the lot number in use corresponds to these values. This range generates H and L flags on the printout.

8. If using an external calibrator (ACAL), verify that the correct calibrator concentration is entered.
9. Verify that the correct Cal No. is being used.
10. Select [Parameters], [Specific Test Parameters]. Check the factor and offset values. The factor should be 1.0 and the offset 0.0 unless results are being corrected.

3.6.2 How to Check Reagent Integrity

1. Check the lot # and expiration date. Check the stability for storage conditions on the reagent. Follow the directions on the package insert.

S***ee Also***

For information about on board stability and reagent replacement, refer to the Maintenance Chapter.

2. Verify the reagent material was not contaminated at any point prior to or during the run.
3. Check for indications of instability such as abnormal color, turbidity, or a precipitate. Use fresh material if necessary. Refer to the package insert for preparation instructions and specific indications of deterioration.
4. Verify that the reagent is placed in the compartment properly and that the correct parameters were entered. Refer to the Basic Operations Chapter for procedures on placing reagents.
5. Do not combine old reagent with fresh reagent. Always date new bottles before placing them on the unit.
6. Prime lines with fresh reagent.

Instruction

Prime the reference solution approximately five (5) times to completely fill the lines.

Chapter I
Specifications

Introduction

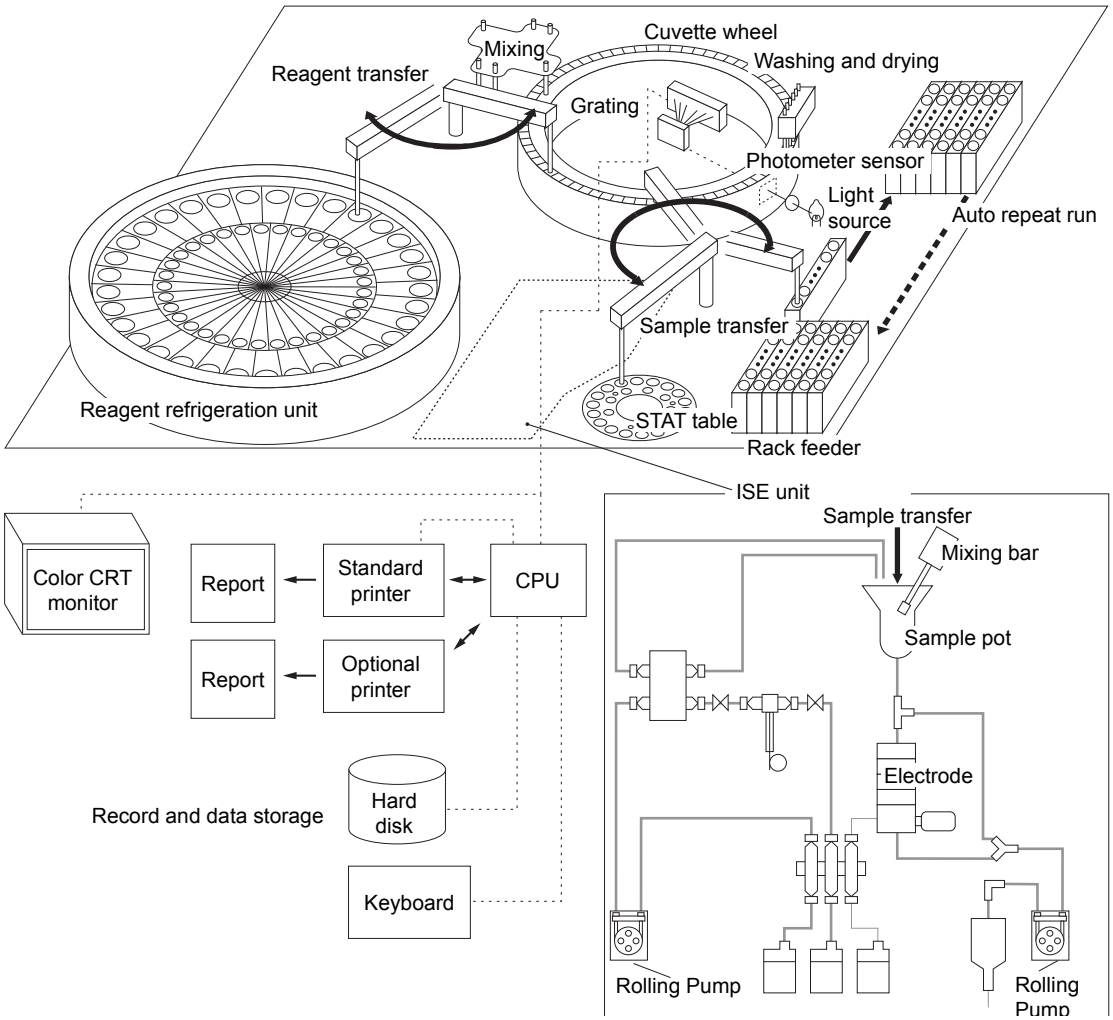
This Chapter provides an outline of system operation during analysis and hardware configuration descriptions of the analyzer. It shows the piping diagram and major specifications of this system. Also, terminology specific to the AU400 is described here.

Contents

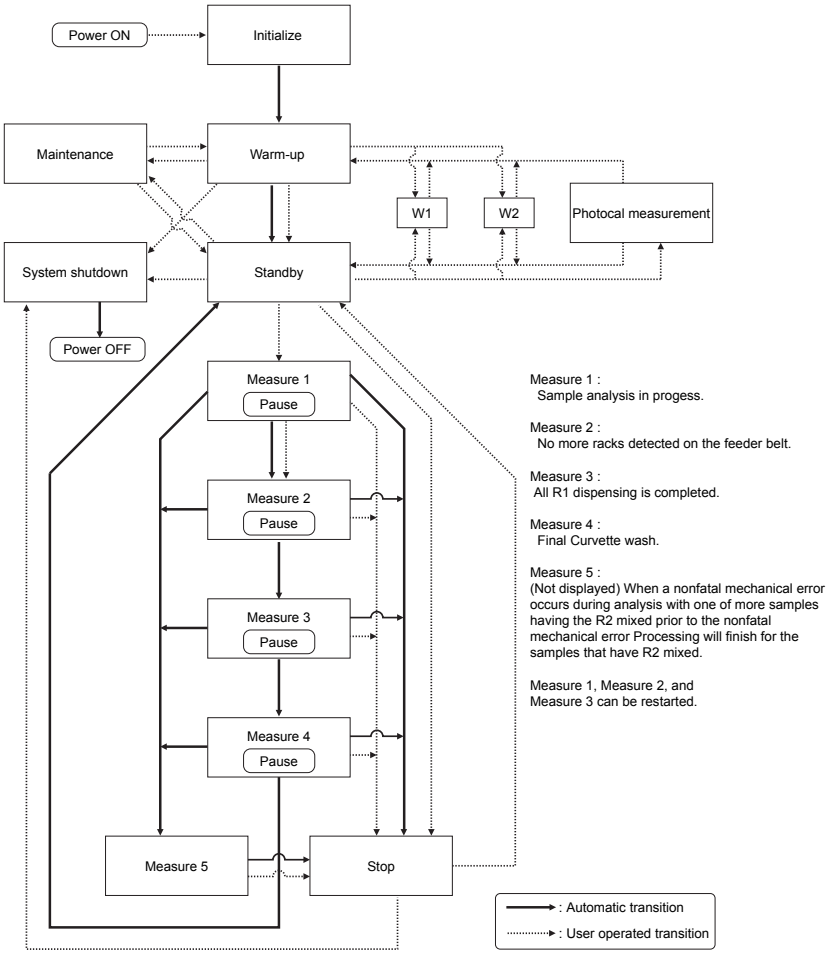
1. System Operation During Analysis

This section describes the system operation and operation modes during analysis.

Operation Process



Operation Modes



Measure 1: Sample analysis is in progress. Racks are moving from the feeder belt to the transfer belt.

Measure 2: No more racks are detected on the feeder belt.

Measure 3: All R1 dispensing is completed.

Measure End (4): Final cuvette wash.

Measure 5: ***(Not displayed)*** When a nonfatal mechanical error occurs during analysis with one or more samples having R2 mixed prior to the nonfatal mechanical error. Processing will finish for the samples that have R2 mixed.

One Touch Mode: Preprogrammed STAT analysis mode. Sample requisition is not required.

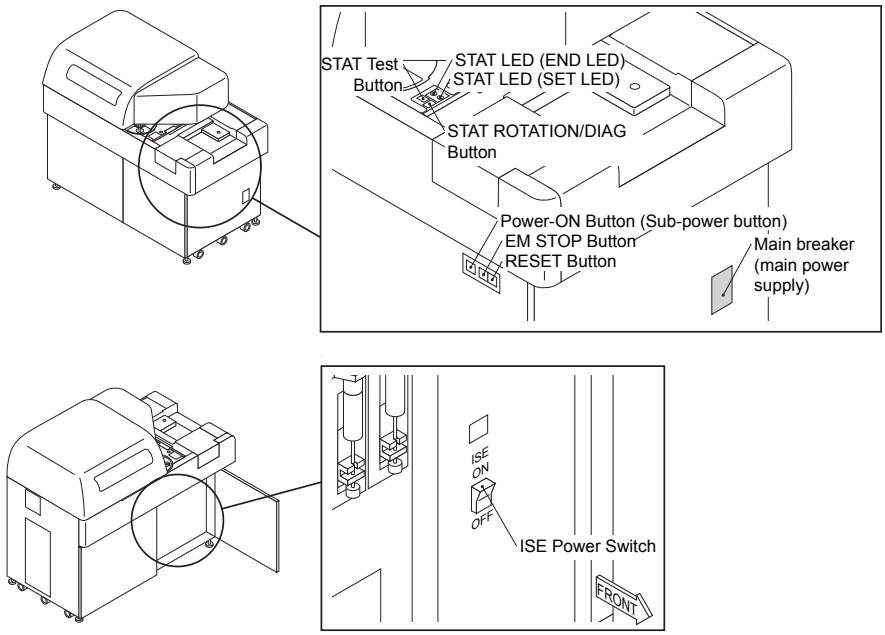
See Also

For more information on the One Touch Mode, refer to the Basic Operations Chapter.

2. Analyzer Hardware Configuration

This section describes the hardware configuration of each part of the AU400 analyzer.

Operation Switches



Power-on Button (Sub-power switch)

This button loads the software, and the lamp turns on.

STAT LED (Set LED, End LED)

SET LED: The SET LED indicates when the STAT table is ready to receive sample cups. If the light is on, it is possible to place sample cups on the table. If the light is off, sample cup placement is not possible.

END LED: The END LED indicates when the system has completed aspiration of the samples on the STAT table. If the light is on, aspiration is complete. If the light is off, aspiration is not complete.

STAT Test Button

This button starts analysis on the STAT table.

STAT ROTATION/DIAG Button

This rotates the STAT table. The STAT table rotates 1/3 of a complete rotation each time the button is pressed. Also, press this button after selecting an operational item to be performed using the [ANL Maintenance] screen or the [Diagnostics] screen. The function will begin.

See Also

For detailed information about the [ANL Maintenance] screen, refer to the Software Chapter.

This button also executes the Prime operation for discharging or supplying solution when performing ISE prime functions. Select [System Status], [ISE Status] the prime operation, and press the STAT ROTATION/DIAG button.

See Also

For detailed information about the ISE Status function, refer to the Software Chapter.

EM STOP (Emergency Stop) Button

Use this button to perform an emergency stop. In the event of a power failure, or an emergency stop, the main power is immediately turned off, including the power to the incubator and reagent refrigerator. To recover from a power loss, perform the "Recovering from an Emergency Stop or Power Loss" procedure located in the Troubleshooting Chapter.

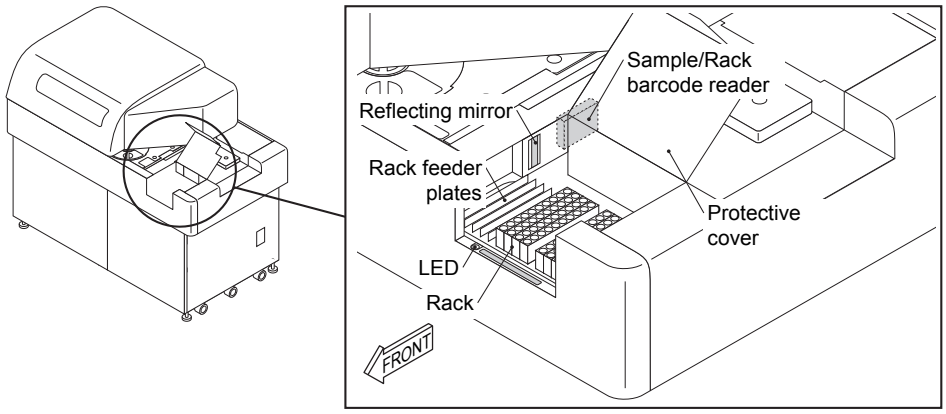
RESET (Main Power) Button

This button is used to turn on the main power after the system was stopped using the EM STOP Button. When the RESET Button is pressed, the main power (including power to the incubator and reagent refrigeration unit) turns on. *The system is equipped with a power-failure detection circuit. After power failure is detected, the circuit must be reset by pressing the RESET Button. A message displays to inform the operator of the power failure.*

ISE Power Switch

This switch is used for turning on/off power to the ISE. *When the system power is on, it is possible to turn off power to the ISE without turning off power to any other unit. The ISE Power Switch must be on if ISE analysis is to be performed.*

Rack Feeder Unit



Top view of the LED

Sample Protective Cover

Prevents dust from entering samples. It also prevents the sample from evaporating. The cover should always be closed during analysis.

Rack

Samples are placed on the rack. It is possible to set a maximum of 10 samples on one rack. The rack color differs depending on the type of analysis.

Rack Feeder Plates

Plates move the rack. The racks should be placed between the rack feed plates.

Sample Barcode Reader

Reads the sample ID on tubes.

Caution

Do not look directly at the laser beam emitted from the sample/rack barcode reader. Staring at the beam may damage your eyes.

Reflecting Mirror

Reflects the sample barcode reader laser beam onto the sample tube.

Instruction

Do not touch the mirror with your fingers or any hard materials. If the mirror is smudged or scratched, barcode reading may not be performed properly.

Rack Barcode Reader

Reads barcodes on the rack.

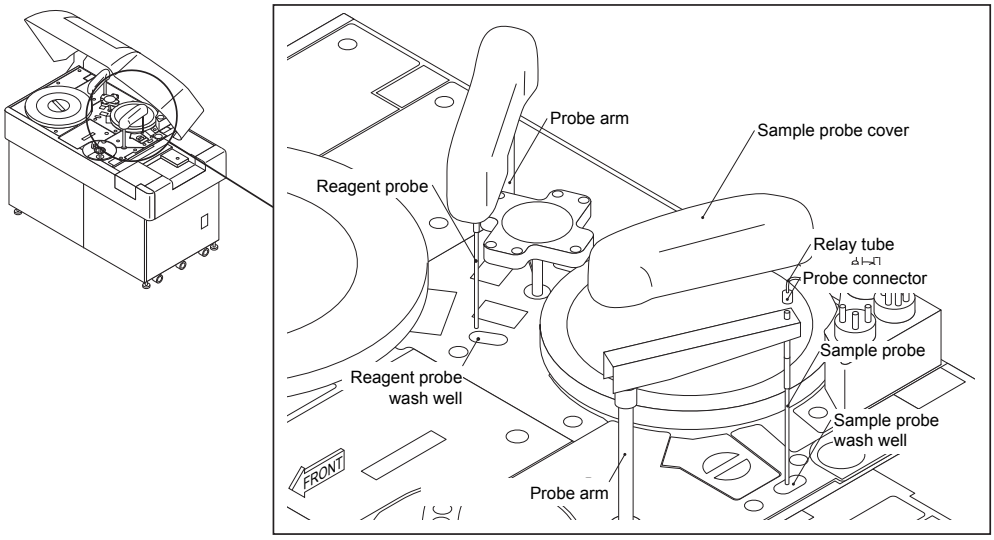
Window for Rack Barcode Reading

Where the laser comes out to read the rack ID.

Rack LED

The LED lights immediately before the rack feed plate starts moving and flashes continuously while the rack feed plate is moving. Do not set a new rack on the unit while the LED is flashing, this could cause spills on the rack unit.

Sample Probe and Reagent Probe Units



Sample probe

Dispenses a given volume of sample in a cuvette.

Reagent probe

Dispenses a given volume of reagent in a cuvette.

Probe connector

Connects the sample probe and reagent probe to the relay tube.

Probe arm

Supports the sample probe and reagent probe.

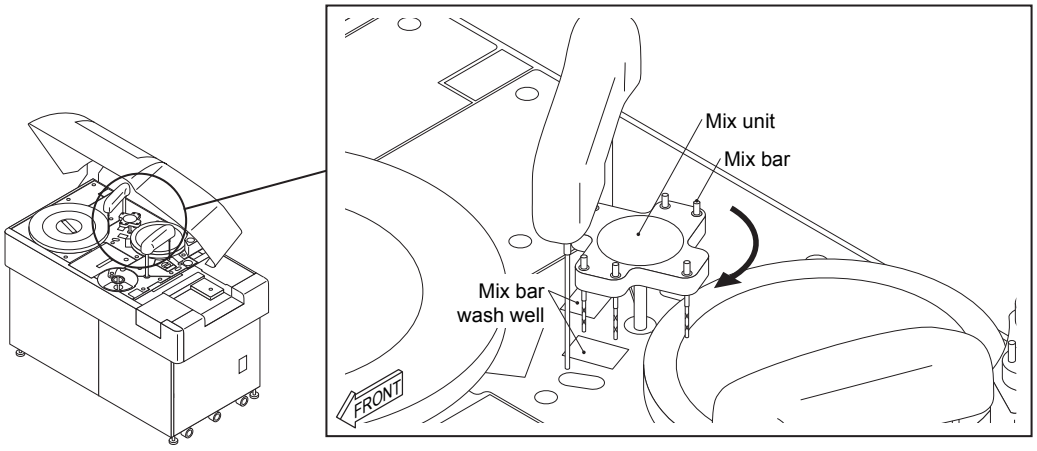
Sample probe wash well

Washes the sample probe.

Reagent probe wash well

Washes the reagent probe.

The Mix Unit



Mix Unit

This unit controls the mix bars. The sample and reagent inside a cuvette are mixed by a rotating mix bar. The mix unit also rotates the bars to the wash well. The mix unit is comprised of one mixer. There are six mix bars in the mixer.

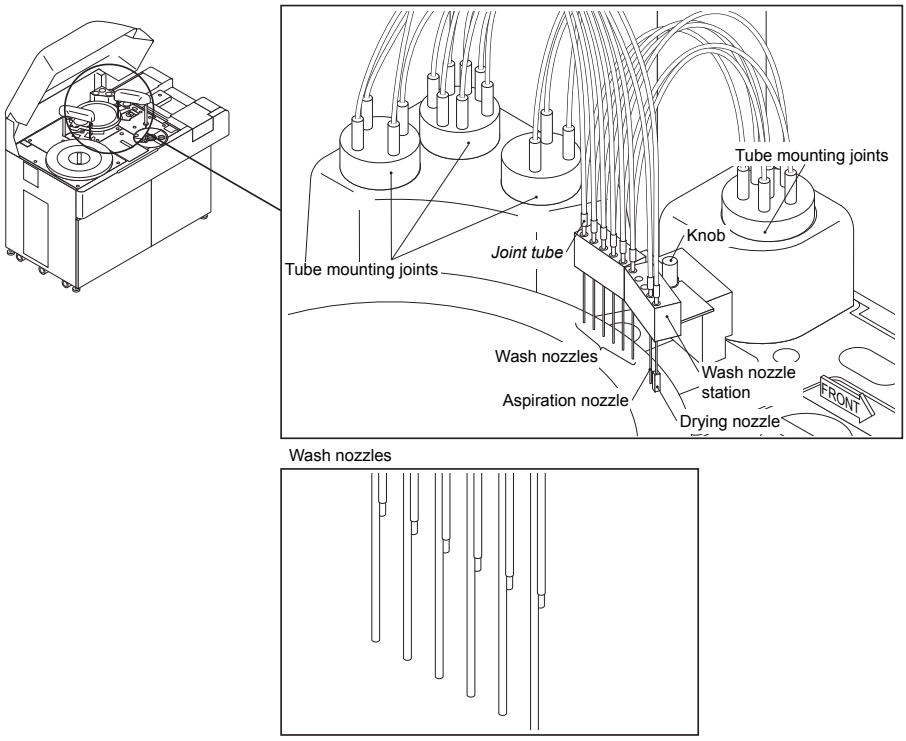
Mix Bar

After the sample and reagent have been dispensed into a cuvette, the mix bar rotates and mixes the mixture in the cuvette.

Mix Bar Wash Well

This is used for washing the mix bar after mixing.

The Wash Nozzle Unit



Wash Nozzles

Used for washing the cuvette after analysis is complete. Each nozzle is made up of three small nozzles. The longest nozzle aspirates the reaction mixture, detergent, and wash water. The next longest nozzle dispenses the detergent or wash water. The shortest nozzle aspirates any detergent or wash water that exceeds a predetermined amount.

Aspiration nozzle

Aspirates the dispensed wash water.

Drying nozzle

Aspirates the remaining drops of water inside the cuvette.

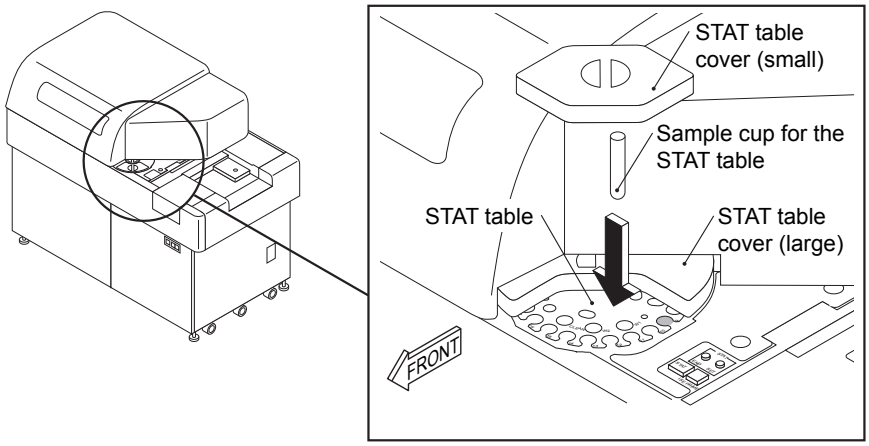
Tube Mounting Joints

Connects each of the nozzles to the internal drain tubing.

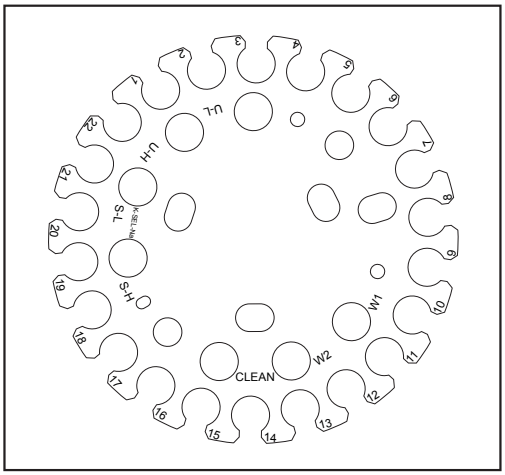
Knob

Secures the wash nozzle station.

The STAT Table



Top view of STAT table



STAT table

Used to perform urgent analysis, automatic QC and automatic calibration. There are cup positions around the inside and outside of the STAT table. The samples to be analyzed are set in the cup positions around the outside circumference of the table. Detergent or reagents used for ISE unit calibration or selectivity checks are set in the positions around the inside circumference of the table. It is possible for the system to read only the barcodes on the sample cups that are set in the outer positions on the table. *Note: The STAT table is refrigerated, after placing samples, be sure to replace the table covers. Removing the table covers frequently may cause the temperature on the table to become unstable.*

"WASH 1" Position

During normal analysis, the sample cup (containing 2% Washing Solution for washing the sample probe) is placed in this position.

"WASH 2" Position

The bleach or HCl for washing the sample probe is poured in a sample cup and placed in this position.

"CLEAN" Position

When automatically washing the ISE sample pot and electrode line, the sample cup containing the bleach is placed in this position.

"S-H" and "S-L" Positions

Used for sample cups containing calibrator solutions of serum for the ISE unit. ISE high serum standard is set in the "S-H" position, and ISE low serum standard is set in the "S-L" position. Also, use these positions to place sample cups containing the solution used in checking the ISE electrode selectivity. The solution for the Na check is set in the "S-H"("SEL-Na") position, and the solution for the K check is set in the "S-L"("K-SEL") position.

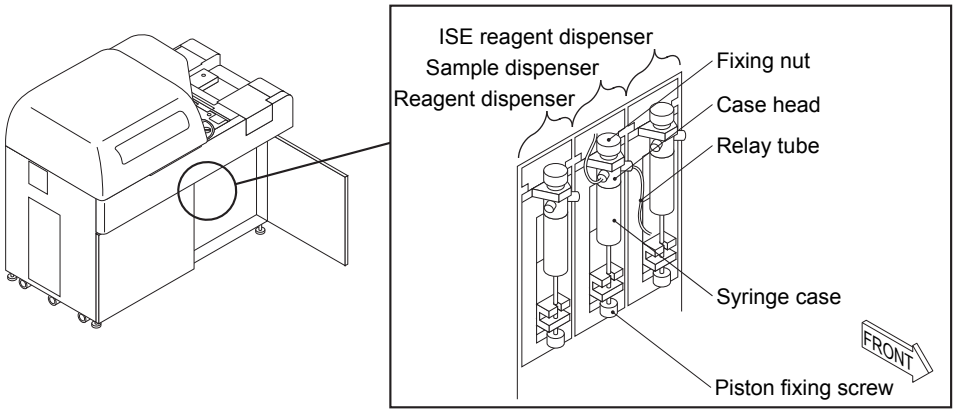
"U-H" and "U-L" Positions

Used for sample cups containing the calibration solution of urine for the ISE unit. ISE high urine standard is set in the "U-H" position, and ISE low urine standard is set in the "U-L" position.

Instruction

Do not place barcoded sample cups in the inner positions on the STAT table. Barcode read errors may occur with the sample cups placed in the inner positions.

Sample Syringe and Reagent Syringes



Sample Syringe

Used to supply a small fixed amount of sample.

Reagent Syringe

Used to supply a small fixed amount of reagent.

Fixing Nut

Attaches the syringe to the syringe unit.

Syringe Head

Secures the syringe together with the syringe case.

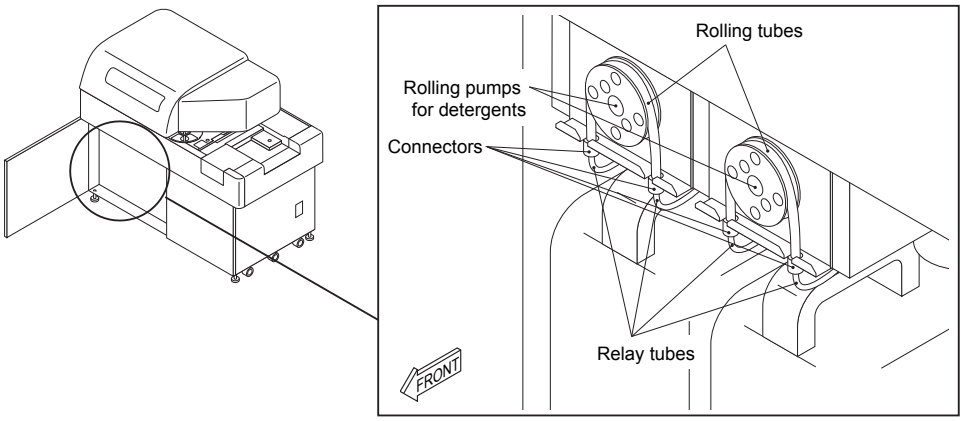
Syringe Case

This case holds the syringe.

Piston Fixing Screw

Attaches the syringe piston to the syringe drive assembly.

Rolling Pump Unit



Rolling Pump

Used to aspirate concentrated detergent and dispense it into the diluted detergent tank. There are two rolling pumps; one for detergent tank A (factory optional) and one for detergent tank B.

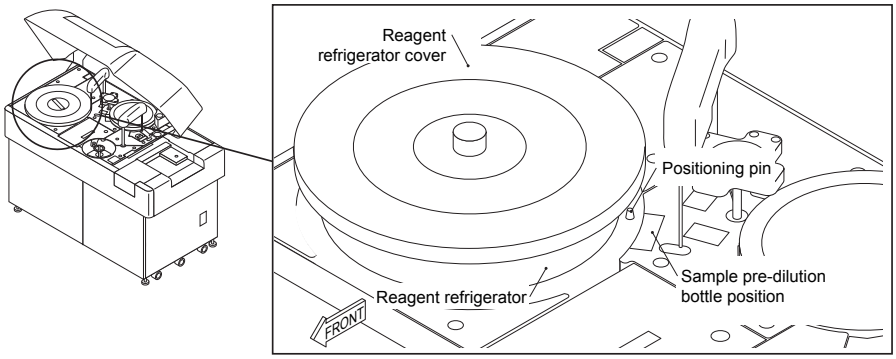
Rolling Tube

The rubber tube on the rolling pump. Detergent is supplied or drained through the tubing. There are two rolling tubes; one for detergent tank A (factory optional) and one for detergent tank B.

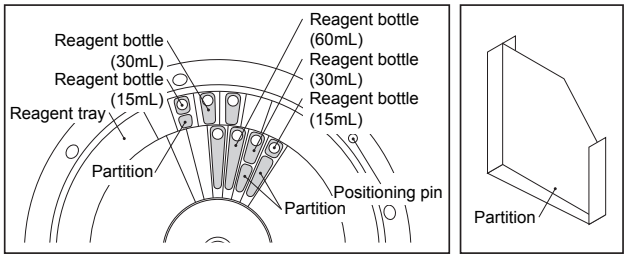
Relay Tube

The relay tubes are used to connect the rolling tubes through the connectors as shown in the illustration above.

Reagent Refrigeration Unit



Example: Top view of the reagent refrigerator
(The reagent refrigerator cover was removed.)



Reagent refrigeration unit

Refrigerates the reagent bottles. Both the first and second reagent bottles are set in the same reagent refrigerator. The refrigerators are kept between 4 and 12 degrees C.

Reagent refrigerator cover

Prevents the reagent from evaporating, and prevents dust from getting into the reagent bottle. Also, it maintains the temperature of the reagent refrigerator between 4 and 12 degrees C.

Reagent tray

Used to set reagent bottles. A maximum of 76 reagent bottles can be placed in the reagent compartment.

Reagent bottles

The reagent bottles are containers for holding reagent. Reagent bottles with a capacity of 60 mL, 30 mL or 15 mL can be placed on the reagent tray.

Use the appropriate partition when placing 15 mL reagent bottles on the outer circumference of the tray, and 30 mL or 15 mL reagent bottles on the inner circumference of the tray. Always use a partition for the 15 mL reagent bottles.

Caution

Place reagent bottles with the barcode label facing the outside of the reagent tray. If the reagent bottles are set in any other way, the reagent probe may be damaged.

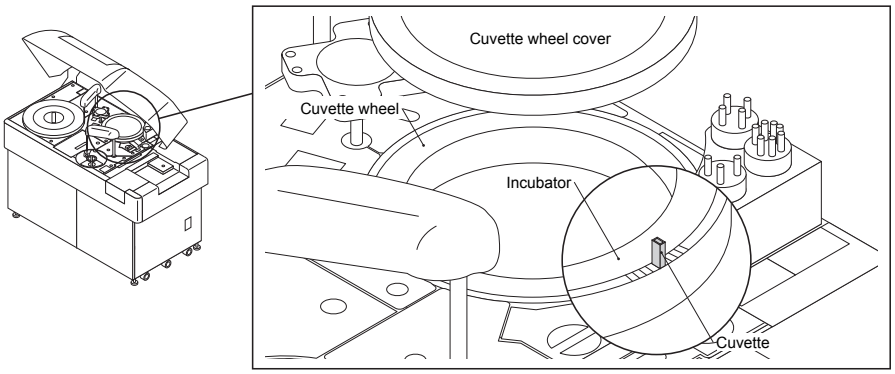
Sample Pre-dilution Bottle Position

Use this position to place the sample pre-dilution bottle filled with DI water for sample dilution.

Caution

When placing the sample pre-dilution bottle on the analyzer, be sure it does not protrude above the top analyzer surface or the reagent probe may be damaged. Do not put the cap on the bottle when it is on the analyzer, this causes the reagent probe to crash.

The Incubator



Incubator

The cuvette wheel is attached to the incubator. The mixture in each of the cuvettes in the cuvette wheel is incubated in the incubator. During analysis, the temperature in the incubator is kept at 37°C.

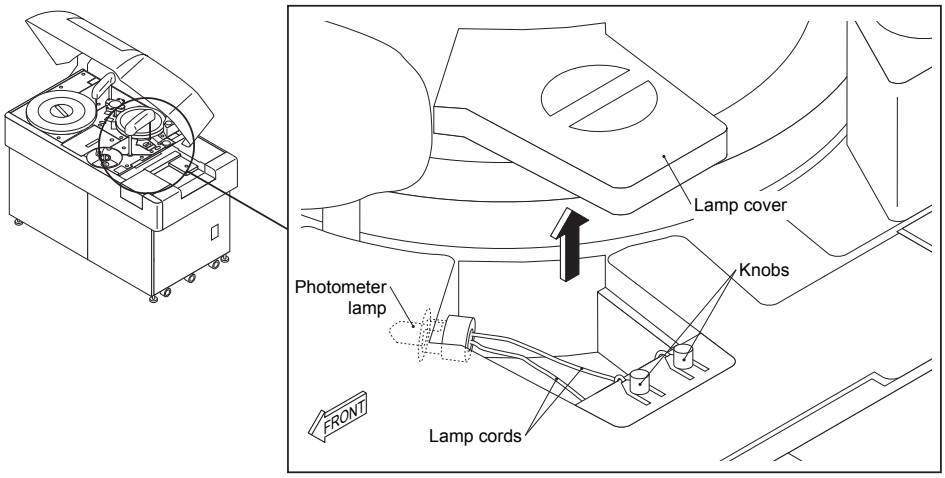
Cuvette Wheel

The cuvette wheel contains 88 cuvettes. As the cuvette wheel rotates, a series of analyses are performed from dispensing of the sample to performing photometry.

Cuvettes

These are square shaped containers made of glass used in analysis. The sample and reagent are dispensed into the cuvettes. The light path of a cuvette is 6 mm, and the capacity is 750 µl.

The Photometer Unit



Photometer Lamp

A white light source used in performing photometry on the mixture in the cuvettes.

Lamp Cover

The cover is for safety since the photometer lamp becomes very hot. Also, it prevents electric shock due to touching the terminal board of the photometer lamp, and shields the inside of the photometer unit.

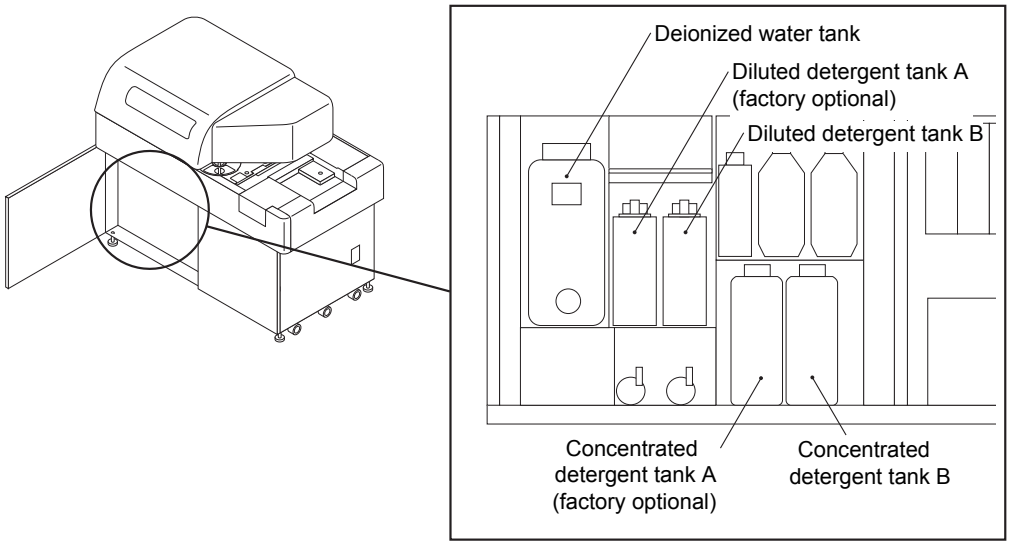
Knobs

The knobs connect the lamp cords to the terminal board. A DC voltage of approximately +12 V is output.

Lamp Cords

The lamp cords supply power to the photometer lamp.

Tank Storage



Deionized Water Tank

This tank stores the deionized water. The deionized water is produced from tap water using a deionizer. The capacity of this tank is 10 liters.

Diluted Detergent Tank A (Factory Optional)

This tank stores 2% detergent that has been diluted from the concentrated detergent A using deionized water. The capacity of this tank is 2 liters.

Diluted Detergent Tank B

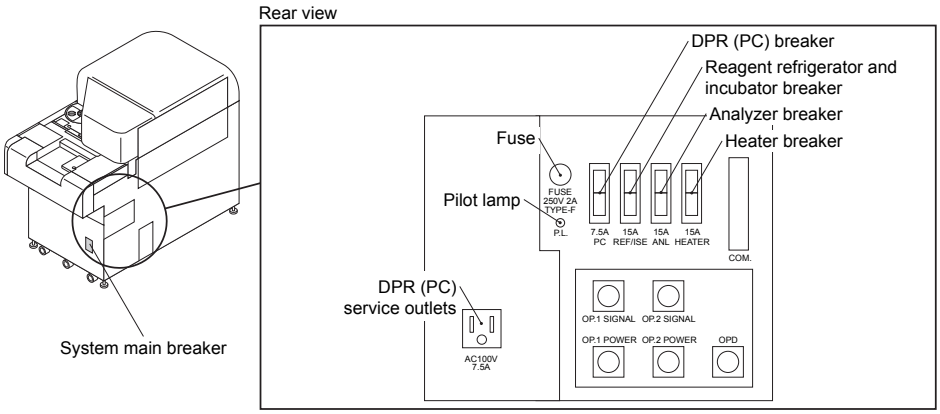
This tank stores 2% detergent that has been diluted from the concentrated detergent B using deionized water. The capacity of this tank is 2 liters.

Concentrated Detergent Tanks A (Factory Optional) and B

These tanks store concentrated extran detergent. The capacity of each tank is 2 liters. The recommended detergents are listed below.

Tank	Detergent Used	Detergent Supplied To
A (factory optional)	Extran	Cuvette wash unit
B	Extran	Cuvette wash unit & mix bar unit

Breakers and Fuse



System Main Breaker

This is the main power breaker for the entire system. 208-volt system (USA): 20 A

Analyzer breaker

This breaker is for the power source (15 A) of the analyzer drive unit and control board.

Reagent Refrigerator and Incubator Breaker

This breaker is for the power source (15 A) for the reagent refrigerator, incubator, ISE unit and some control boards.

DPR (PC) Breaker

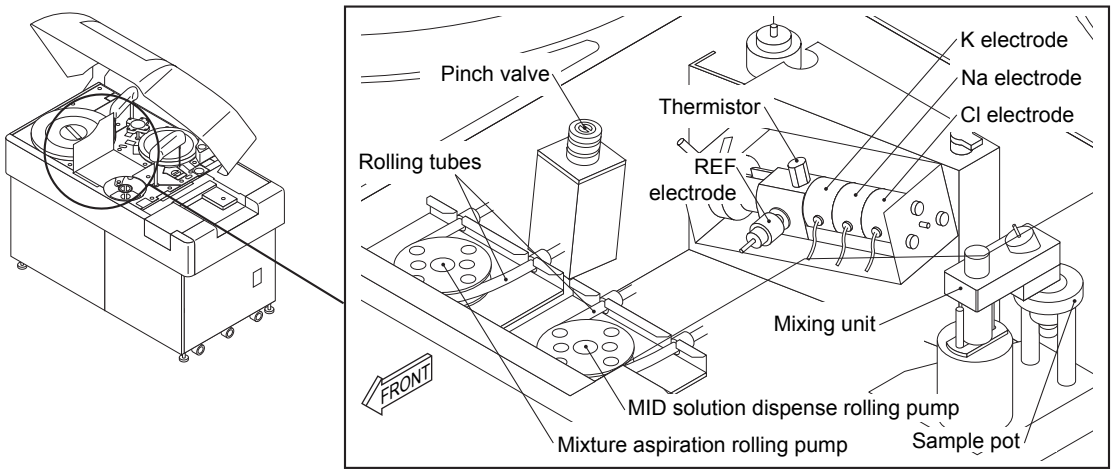
This is a 7.5-amp breaker.

Pilot Lamp

Light to indicate that the system is supplied with power.

Fuse

If the pilot lamp does not light even though the main breaker is on, the fuse may be blown. Only use the specified fuse given in the list of consumables.



Sample Pot

The sample and buffer solution are dispensed into the sample pot and mixed. The amount of dispensed sample is 20 µl of serum (fixed), 25 µl of urine (fixed), and 10 µl of DI water (fixed). The amount of dispensed buffer solution is 618 µl for serum (fixed) and 750 µl for urine (fixed).

Mixing Unit

This unit mixes sample and buffer solution dispensed into the sample pot. It is equipped with two liquid-level sensors to detect clogged tubing.

Cl Electrode, Na Electrode and K Electrode

These electrodes are used for measuring the potentials of Cl, Na and K ions in the mixture and MID solution. The concentrations of individual ions in the mixture can be calculated from the potential differences between each ion in the mixture and in the MID solution.

REF Electrode

This is the reference electrode with respect to the Cl, Na and K electrodes.

Thermistor

The potentials of the Cl, Na and K electrodes change depending on the temperature of solutions even though the concentrations are identical. To remove the effects of temperature, the output potentials are corrected by the thermistor.

Pinch Valve

This valve is used for alternately discharging the analyzed mixture and the mixture remaining in the sample pot.

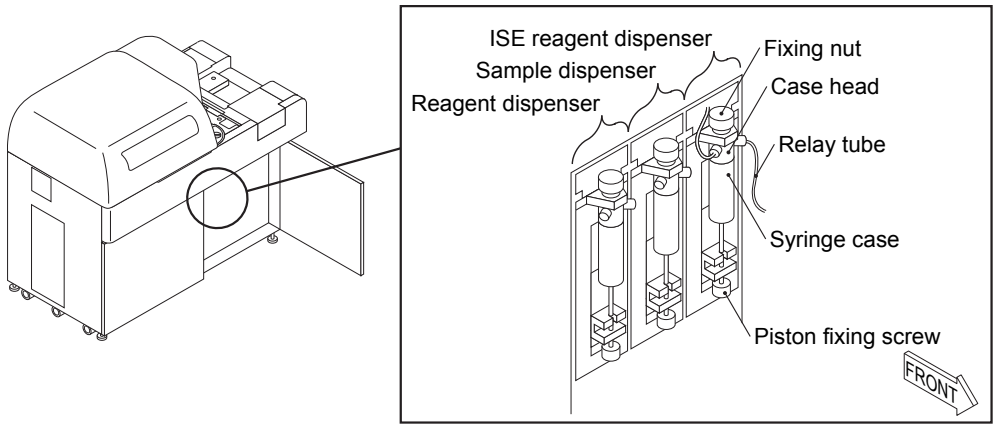
Rolling Pumps

There are two pumps; a rolling pump which aspirates the mixture solution, and a rolling pump which dispenses the MID solution.

Rolling Tubes

These tubes are made of rubber and wrap around the rolling pump. As the rolling pump rotates, the tubes are squeezed by the rollers on the pump, and solution is supplied or removed.

The ISE Reagent Syringe



Fixing Nut

Attaches the syringe to the analyzer.

Case Head

Attaches the syringe together with the syringe case.

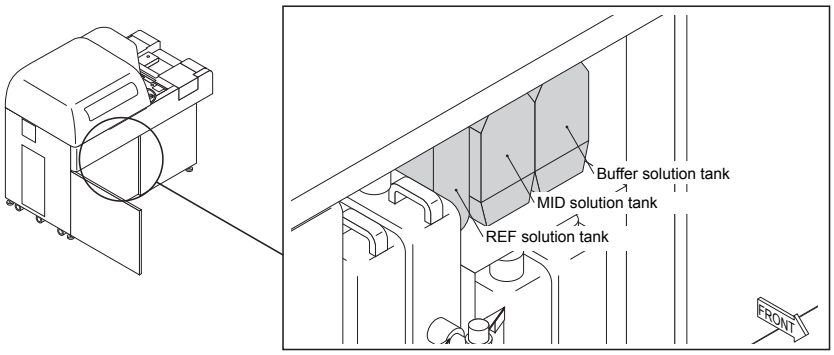
Syringe Case

Holds the syringe.

Piston Fixing Screw

Attaches the syringe piston to the syringe drive assembly.

The ISE Reagent Bottles



Buffer Solution Bottle

Stores the buffer solution used for diluting the sample. The capacity of this container is 2 liters.

MID Solution Bottle

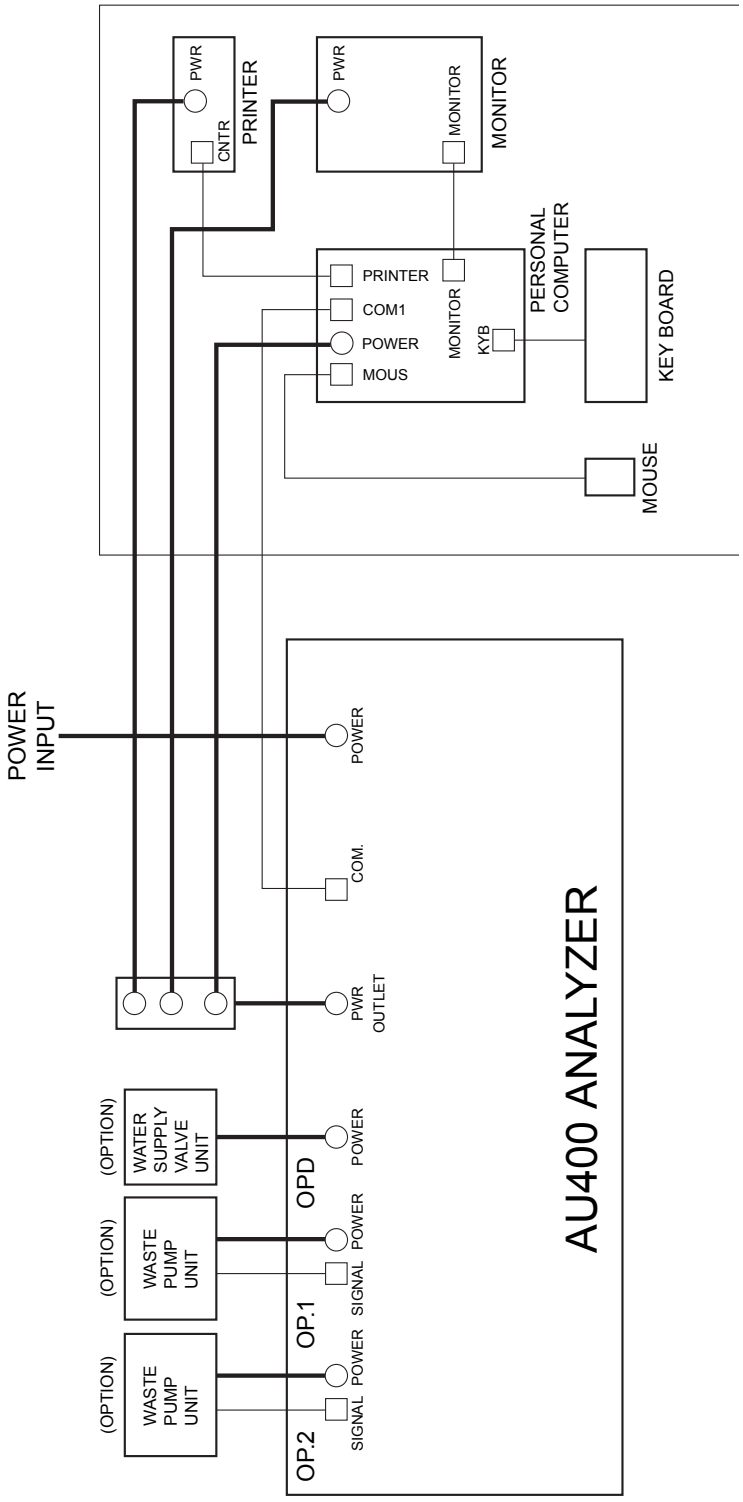
Stores the MID solution. The capacity of this container is 2 liters.

REF Solution Bottle

Stores the REF solution. The capacity of this container is 1 liter.

3. System Connections

System Connections Diagram



4. Major System Specifications

The specifications for the AU400 system are listed below.

See Also

For more information on installation environments, refer to the "Precautions on Use and Installation Environments" Chapter. *Note: Check the rating plate on the rear face of the unit for the unit type.*

Specifications Related to System Installation

Dimensions & Weight

Analyzer: (Inches)	Width 57" x Depth 30" x Height 48" Weight 924 lbs
Data processor:	Width 27.6" x Depth 27.6" x Height 62" Weight 146 lbs The data processor (DPR) includes the rack, personal computer, CRT monitor and printer.

Water Supply and Drainage

Water Type	Deionized CAP Type II, Bacteria Free
Water pressure	0.49 x 105 to 3.92 x 105 Pa (4-57 psig)
Water consumption: (unit type 403-02)	Average: 20 L/hour (50Hz/60 Hz) (unit type 401-02) Average: 26L/hour (50Hx/60Hz) Maximum: 0.7 L/min. (50Hz/60Hz)
Water supply hose	30 feet or less
Concentrated waste liquid hose	30 feet or less
Diluted waste liquid hose	30 feet or less
Drainage height	4 inches or less (from the installation floor) If the optional forced drainage equipment is used, it should be 4 feet or less.
Air exhaust hose	30 feet or less

Operating Environment

Temperature:	18 to 32 °C
Humidity:	40 to 80% RH (with no condensation)
Temperature fluctuation:	±2 °C or less during analysis
Conductivity of deionized water:	2.0 µs/cm or less (0.5 MΩ or greater)
Temperature of deionized water:	5 to 28 °C
Maximum altitude:	6,500 feet (2,000 M)
Pollution degree:	2
Installation category:	II

Power Supply

AC210V ±10% (U.S.A) 60Hz
AC230V ±10% (Europe) 50Hz
AC110V ±10% (Asia) 50/60Hz
AC220V ±10% (Asia) 50/60Hz
AC240V ±10% (Australia) 50/60Hz

Maximum Rated Power Consumption

3.5kVA

Electrolyte Measurement Unit (ISE)

Measures the densities of the Na, K and Cl ions using the ion-selective electrode. Throughput: 200 samples/hour

Optional Accessories

Forced Drainage Equipment	Drainage Capability Drainage Head	58 liters/hour (50 Hz) 70 liters/hour (60Hz) 4 feet
Printer	136-digit printer	

Sampling Specifications

Sampling Mechanism, Micro-Syringe Type

Clot detection function added: If a clot is detected during sample aspiration and/or sample dispense, an alarm occurs. The system cancels the sample aspiration and moves to next sample.

Crash detection function added: If the probe tip bumps against a sample cup while it is moving down, the system automatically stops the probe operation. The probe may not be able to dispense accurately in the future if it was damaged. If the probe is damaged, refer to the Maintenance Chapter for replacement procedures.

Sample Quantity Setting

2 to 50 µl/test: Can be set in increments of 0.5 µl.

Sample Dilution Quantity Setting

0 or 10 µl/test

Sample ID

Read from the barcode. One of the following barcode types can be selected: NW7, Code 39, Code 128, 2 of 5 standard, 2 of 5 interleaved, and mixed. ISBT-CODE128 can be read only if no other types are mixed.

Types of Sample Racks

Sample Rack Type The racks are visually classified according to color. The analyzer recognizes the type of rack by the placement of magnets located on the bottom of the racks.

White:	Routine sample rack
Red:	Emergency sample rack
Yellow:	Calibration sample rack
Green:	Quality control sample rack
Blue:	Reagent blank rack
Orange	Repeat sample rack

Rack No. Read from the barcode..

Sample Cup Types and Placement

Sample Cup Type	Rack	Outer STAT Ring	Inner STAT Ring	Remark
Commercial conical cup		✓	✓	
Micro sample cup		✓		Hitachi (707-0313)
Hitachi cup	✓	✓		Hitachi (716-0425)
ACA cup	✓	✓	✓	
Kendall Ezee_Nested Micro cup	✓			1270016000 1270013000
Evergreen Scientific Nested Micro Cup	✓			127-1212-010
Commercial blood collection tube *1 Inside diameter: 9mm to 15mm Outside diameter: 11.5mm to 16mm Length: 55mm to 100mm * 3	✓	✓	✓ *2	

*1: The maximum diameter of a blood collection tube should be less than 17.5mm. An adapter fitting to the outside diameter is required.
*2: Another adapter is required for tubes with a 12mm outside diameter.
*3: If the sample source is a blood collection tube, use only tubes with a total length < 100mm.

Reaction Unit Specifications

Reagent Setup Method

Turntable type

Types of Reagent

Normal-density reagent, high-density reagent

Reagent Dispense Mechanism

Micro-syringe type

Crash detection function added: If the probe tip bumps against a sample cup while it is moving down, the system automatically stops the probe operation. The probe may not be able to dispense accurately in the future if it was damaged. If the probe is damaged, refer to the Maintenance Chapter for replacement procedures.

Number of Reagent Steps

2 steps

Reagent Volume Setting Range

25 to 300 µl Can be set in increments of 1 µl.

Reagent Volume Dilution Setting Range

0, 10 to 250 µl

Mixing Method

Rotating mix bar

Reaction Container

Square, glass cuvette Capacity: 750 µl Light Path: 6mm

Incubator Temperature Control

Dry bath type

Reaction Line

Rotating disk type 88 cuvettes/line.

Photometer Unit Specifications

Optical System

Polychromatic system

Wavelength Range

340 to 800 nm	13 wavelengths:	340, 380, 410, 450, 480, 520, 540, 570, 600, 660, 700, 750 and 800 nm

Light Source

Halogen lamp	12 V/20 W Average life: 1,000 hours

Detector

Silicone photodiode array

Measurement Absorbance Range

0 to 2.5	10 mm light path conversion

Resolution of Photometry

0.0001OD

Data Processor Unit Specifications

Configuration of the Data Processor Unit

Hard disk	2 GBs or more
Memory capacity	64 MB
Floppy disk	3.5 inch (2HD 1.44 DOS format) 3.5 inch (2DD 720 kB DOS format)
Keyboard	106-key keyboard (DOS/V)
CRT	High-resolution, color
CD-ROM drive	

Printer

Standard printer: 136-digit dot matrix
Optional printer: 136 digit dot matrix

Analysis Processing Specifications

Assay Types

Single-end point assay, dual-end point assay, rate assay, fixed point assay, and electrolyte method (ISE).

Object of Analysis

Blood serum, urine, CSF, or Plasma

Measurement Items

Colorimetry	enzymes, lipids, proteins, sugars, nitrogen compounds, inorganic matters, complements, TBA, etc.
Turbidimetry	IgG, IgA, IgM, C3, C4, RF, CRP, ASO, transferrin, etc.
Latex agglutination	RF, CRP, ASO, etc.
Homogeneous EIA (EMIT)	DAU, TDM, etc.
ISE	Na, K, and Cl

Number of Tests that can be Analyzed Simultaneously

Maximum 38 tests/sample (R1 & R2)
Maximum 41 tests/sample (using ISE)

Throughput

Processing speed	400 tests/hour photometric / Maximum 800 tests/hour / ISE
Reaction Total Vol.	150 to 550 µl
Reaction time	Maximum 8 min. 37.5 sec.
Reaction temp.	37 °C
Saved samples	The capacity of sample storage on the hard disk is a maximum of 30,000 samples or 90 indexes whichever comes first. The maximum capacity of samples is 8,000 per index total including routine, emergency, repeat, priority STAT and STAT repeat (serum, urine, & other). Urine & other Sample type maximum is 999 each type per index.
Emergency serum	(E001-E999), emergency urine (UE001-UE999), & emergency other (XE001-XE999) sample type maximum is 999 each type per index.
Repeat serum	(H001-H999), repeat urine (HU001-HU999), & repeat other (HX001-HX999) sample type maximum is 999 each type per index.
Priority STAT serum	(P001-P999), priority STAT urine (UP001-UP999), & priority STAT other (XP001-XP999) sample type maximum is 999 each type per index.
STAT repeat serum	(HP001-HP999), STAT repeat urine (HUP001-HUP999), & STAT repeat other (HXP001-HXP999) sample type maximum is 999 each type per index.
RB & Cal.	Reagent Blank (R001-R999), Calibration (A001-A999) maximum is 999 samples per index.
QC	(Q001-Q999) maximum is 999 each type per index. A maximum of 300 QC indexes are saved.
A maximum of 10,000 tests are saved in [Routine], [Reaction Monitor]. The data is still present in old indexes after a new index is created, up to 10,000 tests maximum.	
Floppy disk type HD	1.44 MB stores a maximum of 250 samples or 8 indexes, whichever comes first.
Floppy disk type DD	720 KB stores a maximum of 120 samples or 8 indexes, whichever comes first.

Input/Output Specifications

Data Display

Display characters: Alphanumerics

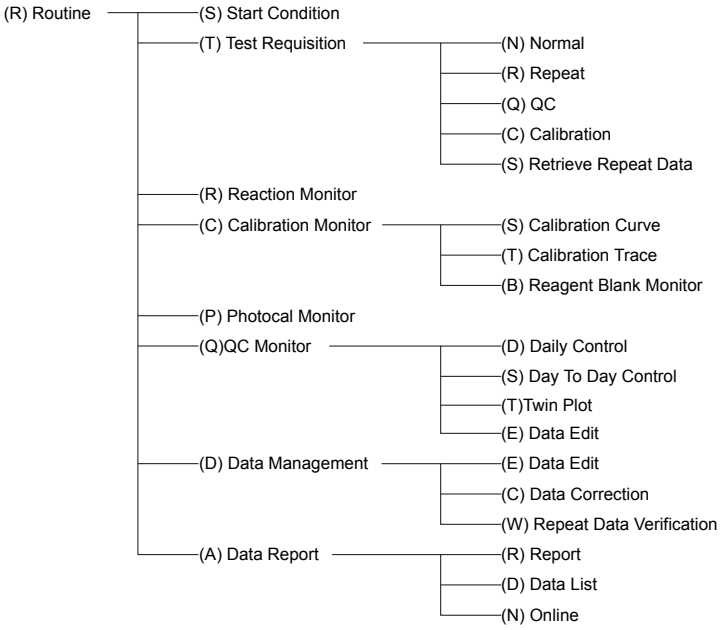
Data Input/Output to External Devices

Data exchange by RS232C or floppy disk

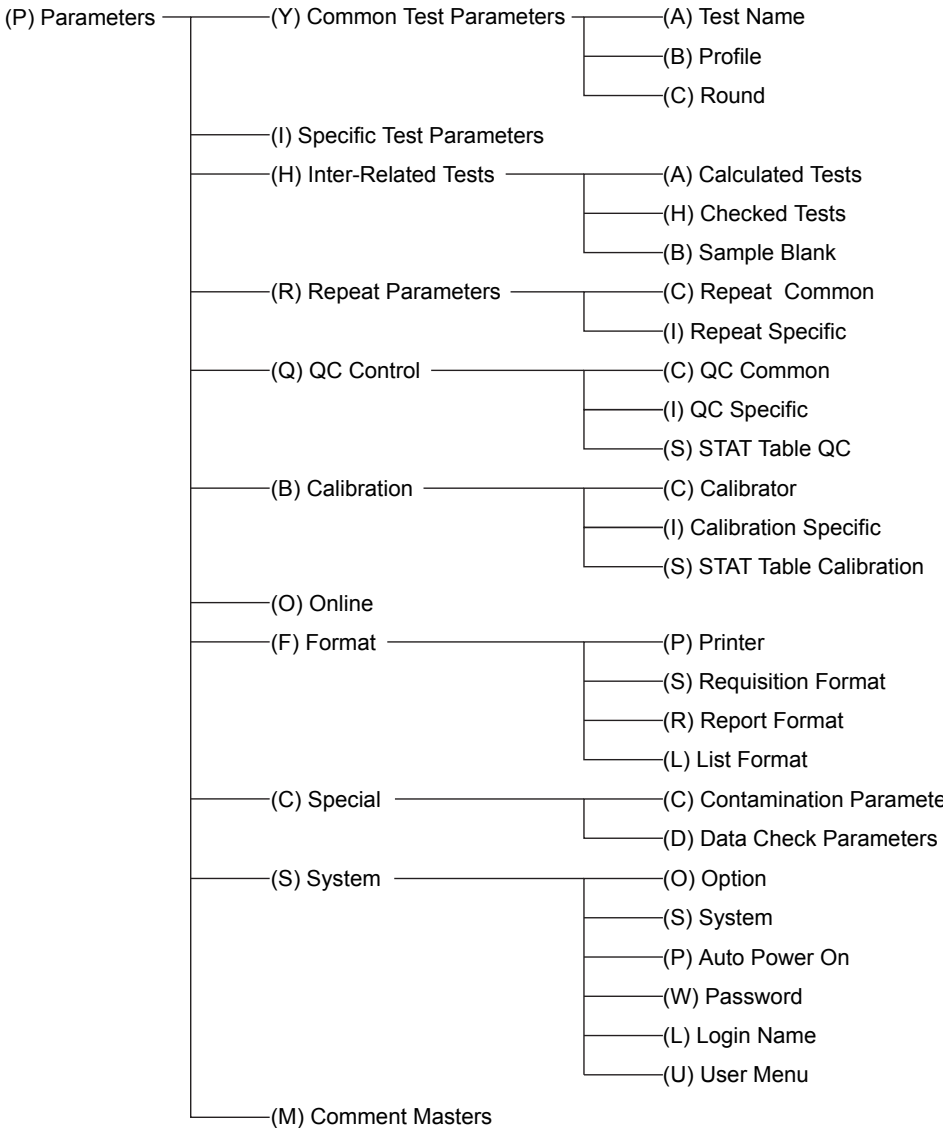
Screen Menu Items

[Routine] menu

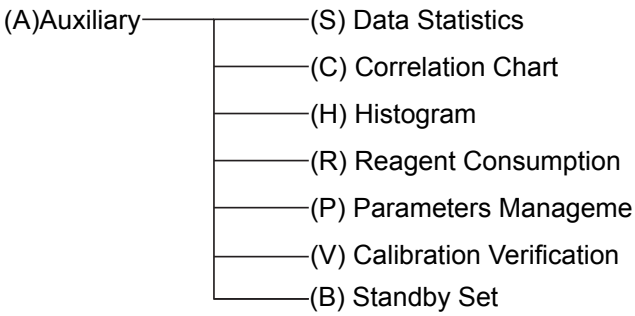
OLP4049E



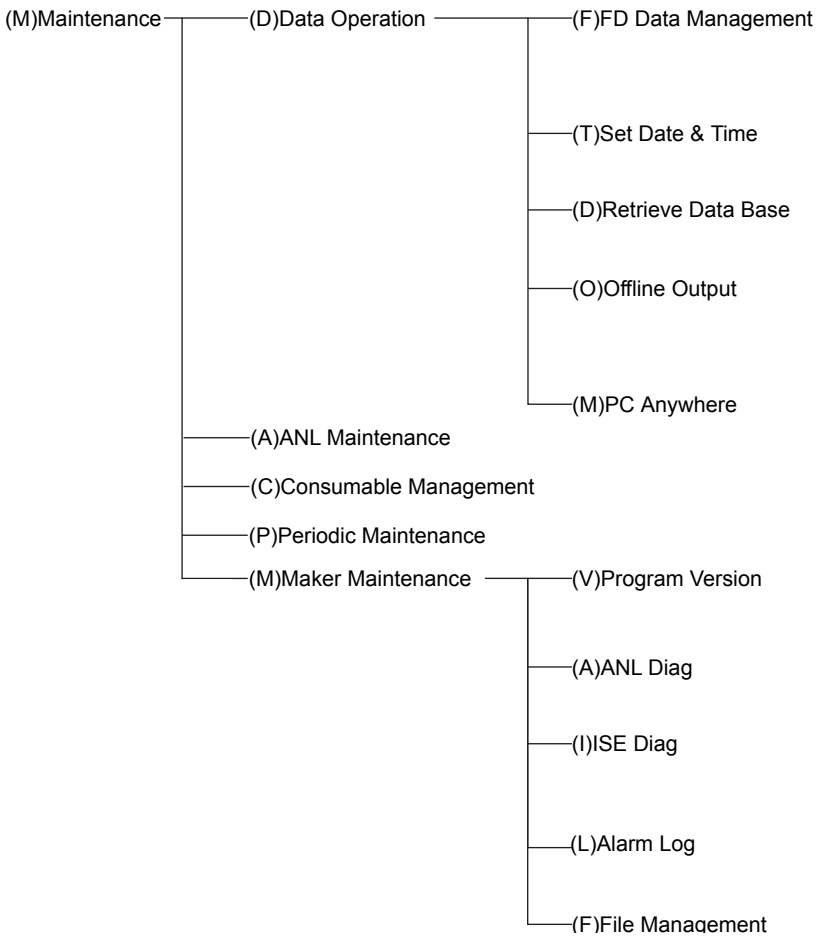
[Parameters] menu



[Auxiliary] menu



- **[Maintenance] menu**



ISE Unit Specifications

Measurement Method

Diluted ion-selective electrode method

Measurement Items

Na, K and Cl ions in serum and urine

Throughput

200 samples/hour

Dispensed Sample Amount

serum: 20 µl urine: 25 µl

Dilution

Serum: 1:32.4 times (DI water 10µl, buffer solution 618 µl)

Urine: 1:31.4 times (DI water 10µl, buffer solution 750 µl)

Measurement Range

Item	Serum	Urine
Na	50 to 200	10 to 400
K	1.0 to 10.0	2.0 to 200
Cl	50 to 200	15 to 400

Unit: mmol/l

Calibration

Auto calibration

Measures the high-density reference solution and low-density reference solution and performs two-point calibration.

Data Correction

Manual calibration correction (M-CAL) and auto calibration correction (A-CAL) are possible.

Drift Correction

Auto correction

Measures the potential of the MID solution for each sample and corrects the drift.

Electrode Type and Form

Type	Form
Na	Crown ether membrane
K	Crown ether membrane
Cl	Molecular oriented membrane
Reference electrode	Liquid junction

5. Calculations

This chapter explains the following measurement calculation methods available in this system: reagent blank (zero adjustment), end point assay, rate assay, fixed point assay, and sample blank adjustment.

5.1 Reagent Blank (Zero Adjustment)

The reagent blank (zero adjustment) method is described below.

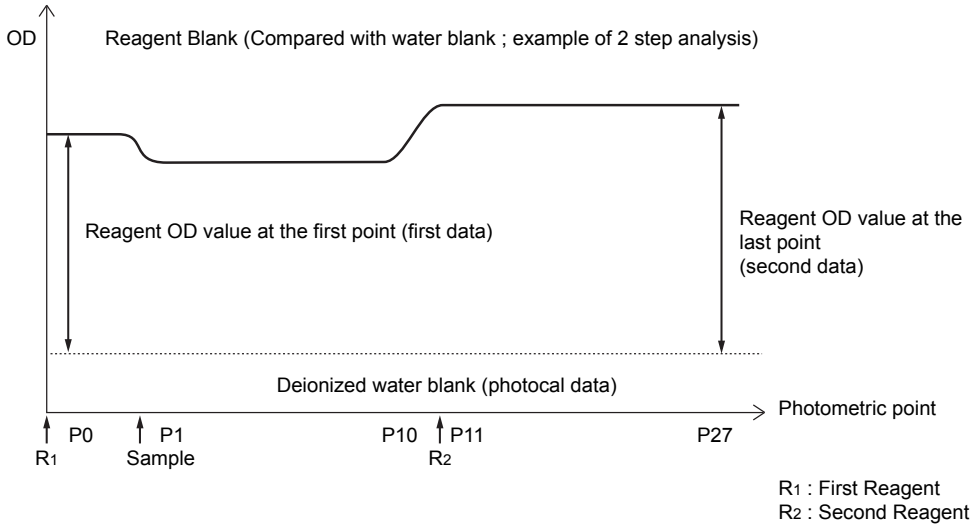
Reagent blank (Zero Adjustment)

To determine a measurement value (reaction OD), the reagent blank OD, at each photometric point, is subtracted from the measurement unless the method is End 1, Rate 1, or Fixed 1. The photocal data is subtracted from the measurement OD of a sample blank reaction that took place with the reagent.

By performing a reagent blank (RB), the OD values at all photometric points, shown in the following figure, are obtained and placed in the reagent blank table. The method parameters determine which points are used. Prepare sample cups (for serum, other & urine) filled with deionized water. Use a blue rack and place sample cups in position 1 for serum, position 4 for other and position 10 for urine. If the AU400 is used with identical reagent specifications for serum/other/urine set to "none," place only one sample cup filled with deionized water in position 1 of the blue rack.

To perform a (reagent blank) zero adjustment:

1. Set a sample cup that contains deionized water in place of a sample in the No. 1 position on the blue rack. The system assays samples from the sample cup and determines the reagent blank data (reagent blank OD value) by averaging 2 data samples, after excluding the maximum and minimum data, if replicates are set equal to 4. The system can also be set to 1, 2, 3, or 4. If one is selected, only one value is used. If two is selected, the two values are averaged. If three is selected, the two closest values are averaged.



The following describes reagent data No. 1 and No. 2 printed. The P0 reagent OD (first 0 adjustment data) and last-point reagent OD (second 0 adjustment data) after the reagent blank is completed. This is an example of a reagent blank printout.

Reagent Blank (OD)

No.	Cup Pos.	CA	TP	BUN	CREA	GLU	LD	AST
(Serum)	1 R001	0.0881	0.2330-	1.2820	0.0106	0.0664	0.3333	0.8596u
(Serum)	2 R001	0.0864	0.2332-	1.2661	0.0106	0.0646	0.3327	0.8582U
(Urine)	1 R001				0.0106			
(Urine)	2 R001				0.0107			

R001: R is the prefix for reagent blank. R001 is the first blue rack through the analyzer. The second blue rack through the analyzer prints results labeled 1R002, 2R002. The maximum number of reagent blanks per index is 999.

1R001: The OD at the first read point of the test (as set in [Parameters], [Specific Test Parameters]). Generates y (over) or u (under) flags based on an acceptable OD range entered in the individual parameter screen. For example: Data number 1 OD for serum TP is -0.2330. Note that a negative sign follows the result. Data number 1 OD for serum AST is under the acceptable range and therefore has generated a "u" flag.

2R001: The OD at the last read point of the test (as set in [Parameters], [Specific Test Parameters]). Generates Y (over) and U (under) flags based on the acceptable OD range entered in the individual parameter screen. For example: Data number 2 OD for urine CREA is 0.0107. Data number 2 OD for serum AST is under the acceptable range and therefore has generated a "U" flag.

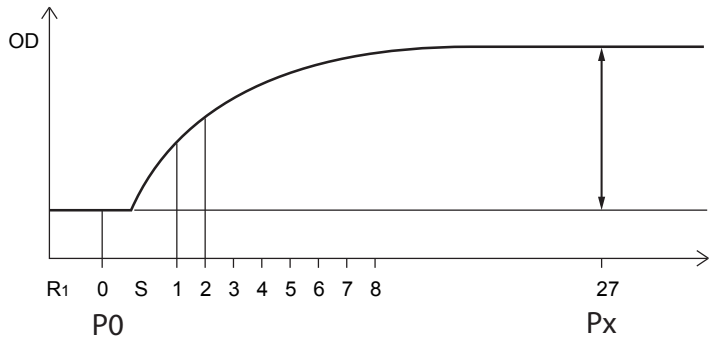
5.2 Endpoint Assay

This section describes the end point assay.

1-point Assay

This is a general end point assay that determines the reaction mixture OD from the OD measured at a specified photometric position. The diagram below illustrates the case for one reagent only with reagent volume equal to or greater than 150 μL. In this case the photometric position is 27, positions 1-27 may be used.

Reaction mixture OD = OD (at specified position) - OD0(at position 0)



ΔOD = Px (K1 X P0) when positive reaction

- {Px - (K1 X P0)} when negative reaction

where K1 = R1/(R1 + S)

P0, Px is OD at point 0 and end point

2-point Assay (self-blank method)

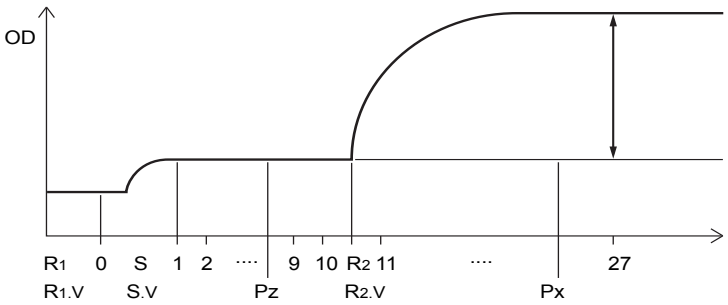
This end point assay provides a sample blank adjustment. The OD value before dispensing the second reagent is eliminated as the sample blank. The OD value adjusted by the dilution factor in the sample blank is subtracted from the OD measured after dispensing the second reagent. Thus the OD associated with the serum can be removed, and greater measuring accuracy will be obtained. The final OD value in this assay is given by the following expression:

K2 = {R1. V / (R1.V + R2.V + S.V)}

K3 = {(R1.V + S.V) / (R1.V + R2.V + S.V)}

Reaction OD value = (Px - K2 x P0) - (K3 x Pz - K2 X P0)

This calculation result is defined as the reaction OD value.



R1.V: First reagent dispense volume
R2.V: Second reagent dispense volume
P0 : Reagent OD value at the first point
Pz : Reagent OD value before dispensing the second reagent
Can be P1 - P10.
Px : Reagent OD value after dispensing the second reagent.
Can be P11 - P27.

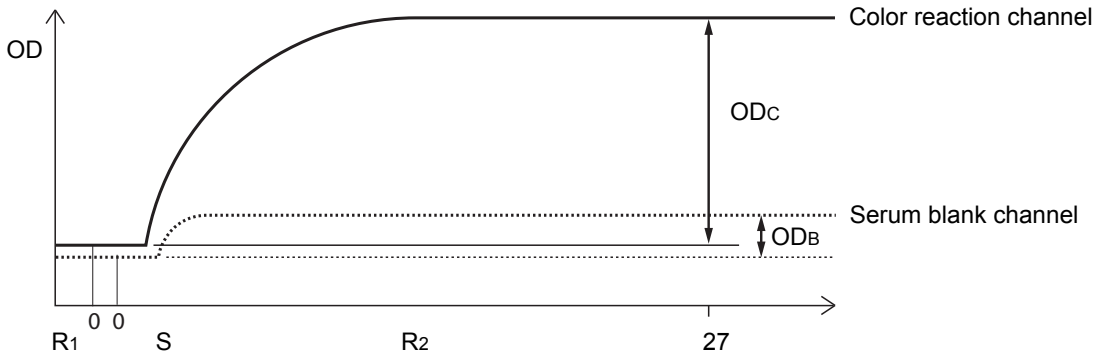
Instruction

Twenty-seven is the last read point. There are no OD values or variables after this point.

End Assay (two test: blank/color method)

This method uses a blank test to measure serum turbidity or other interfering impurities. This separate blank test OD is then subtracted from the measured OD of the color test to determine the net reaction OD. Although this uses an additional blank test and reagent, this method may improve measurement accuracy over that of some 2-point assays.

Reaction mixture OD = Color reaction channel OD (OD_C) - Serum blank channel OD (OD_B)



Instruction

To link the color reaction test and serum blank test, go to [Parameters], [H - Inter-Related Tests], and [B - Sample Blank]. Enter the test number for the color reaction test. See Section 5.5 Sample Blank for more information.

5.3 Rate Assay

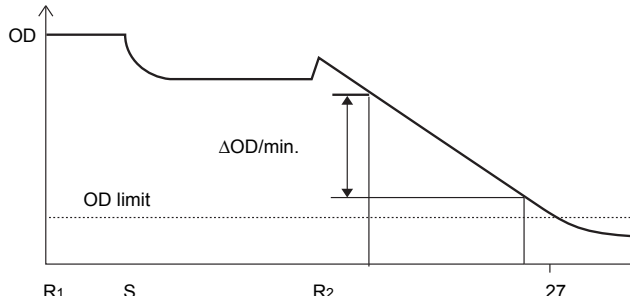
This section describes the rate assay.

Rate Assay

This assay determines the rate of absorbance variation per minute or change OD/min by calculating the slope of the change by least squares in absorbance variations for all OD values within the OD limits and included in the defined photometric points. Note at least three consecutive OD values must be within the OD range limit. If no-lag-time is defined as yes, then values before the defined first read point can be used for fast reactions.

Instruction

The Y axis is the reaction OD and the X axis is the photometric read point or time in minutes.



ΔOD = ΔPwi when the reaction is positive

-{ ΔPwi } when the reaction is negative

ΔPwi is effective points slope (OD/min) by least squares

ΔPyi is effective points slope (OD/min -- self blank points) by least squares

Double Rate Assay

This assay determines the difference in rate of absorbance variation per minute or the change in OD/min by calculating the difference in the slope of the change in absorbance variations from the start to end points. Finally the system obtains the net OD/min of the reaction by subtracting a blank rate from the reaction rate.

ΔOD = ΔPwi - (K1 X ΔPyi) when the reaction is positive

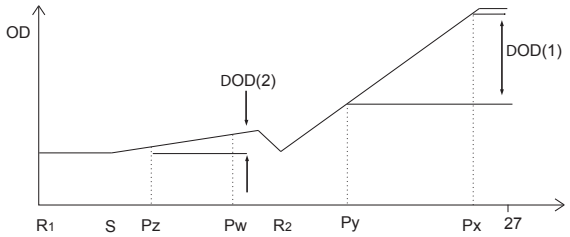
-{ ΔPwi - (K1 X ΔPyi)} when the reaction is negative

where K1 = (R1 + S)/(R1 + R2 + S)

ΔPwi is effective points slope (OD/min) by least squares

ΔPyi is effective points slope (OD/min -- self blank points) by least squares

On the methodology sheet and in the test parameters, the start (Fst) and end (Lst) photometric point for the rate, ΔOD(1)/min is defined as point 1 and for ΔOD(2)/min as point 2.



5.4 Fixed Point Assay

This section describes the fixed point assay.

Fixed Point Assay

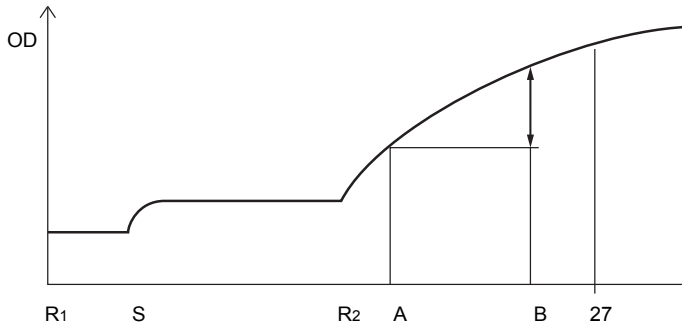
This method determines the difference between the ODs at two specified positions.

ΔOD = Px - Py when the reaction is positive

-(Px - Py) when the reaction is negative

where Px is last point OD

Py is first point OD



Double Fixed Assay (Self Blank)

ΔOD = (Px - Py) - K1 X (Pw - Pz) when the reaction is positive

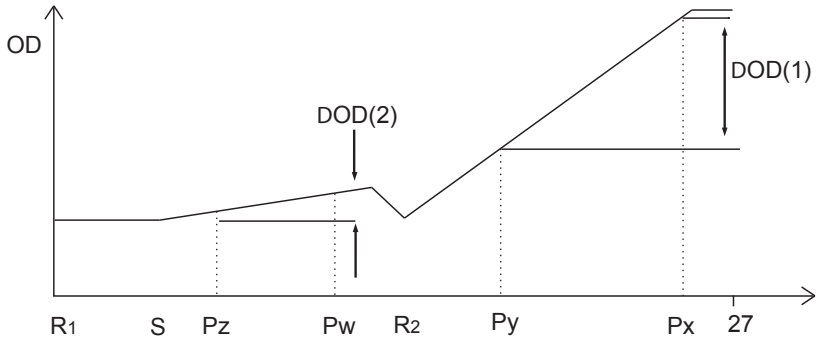
-((Px - Py) -K1 X (Pw - Pz)) when the reaction is negative

where K1 = (R1 + S)/(R1 + R2 + S)

Px, Py is OD at last and first point

Pw, Pz is OD at last and first self blank point

On the methodology sheet and in the test parameters, the start (Fst) and end (Lst) photometric point for the reaction, ΔOD(1) is defined as point 1 and the blank ΔOD(2) as point 2.



5.5 Sample Blank

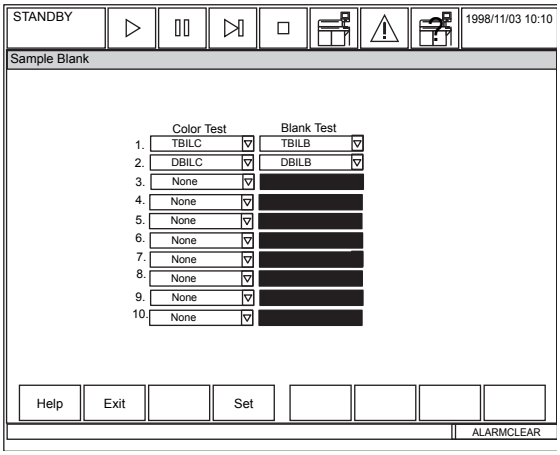
This section describes the sample blank method using two inter-related tests.

Sample Blank

The sample blank method uses the specified Color Test and Blank Test as defined in [Parameters], [Inter-related Tests], [Sample Blank].

OD calculated = color blank OD - [Reagent blank OD]

If a Color Test is selected, the Blank Test must be specified in the blank test field on the [Sample Blank] screen.



If a Color Test is selected on the screen, a corresponding Blank Test must be specified.

Once these tests are inter-related in the parameters shown above, and the Color Test is ordered, the test specified as the Blank Test will automatically be ordered.

5.6 LIH

Before the LIH level can be determined, the OD limits for each level that produce the flags must be determined and programmed. Select appropriate samples that represent the five cutoff levels of each interferant: lipemia, icterus (bilirubin), and hemolysis.

See Also

For LIH procedures, refer to [Parameters], [Specific Test Parameters] located in the Software Chapter.

Program three tests with the following wavelength pairs: 410 nm and 480 nm (P1-P0) LIH1, 570 nm and 600 nm (P2-P0) LIH2, 660 nm and 800 nm (P3-P0) LIH3 to allow the determination of the ODs at the six wavelengths used in the LIH OD calculations. These three tests may have sample volume equal to 18.0 ul, sample diluent volume equal to 0.0 and reagent 1 volume plus reagent 1 diluent volume equal to 282 ul. (It is highly recommended that these volumes be equal to the numbers programmed in LIH.) Test No. 96 LIH MUST BE selected and use normal saline as Reagent 1. Set the calibration for these three temporary tests to Cal type 1 MB with factor equal to 1000 and decimal to 1. Set the Method to End, Reaction to + and reagent OD limits to -2.0 to 2.5.

Run replicates of the cutoff levels of each type of interferant. Print the OD data for each sample and each temporary LIH test. See [Routine], [Reaction Monitor] to select "List Print of Display Data."

- To calculate the *lipemia reaction OD*, the equation is (OD 660-OD 800) both at P3 minus reagent blank OD (660-800).
- To calculate the *icterus reaction OD*, the equation is (OD 480 at P1 - OD 570 at P2) minus (OD 600 at P2 - OD 800 at P3) minus reagent blank.
- To calculate the *hemolysis reaction OD*, the equation is (OD 410 - OD 480) both at P1 minus (OD 600 at P2 - OD 800 at P3) minus reagent blank.

The final values for lipemia, icterus and hemolysis (LIH) are compared to the OD levels set in [Parameters], [Specific Test Parameters] after the following adjustment is made:

LIH check data = Reaction OD x (R1 Volume + R1 Dilution Volume + Sample Volume + Sample Dilution Volume)/(300) x 18/ (Sample Volume + Sample Dilution Volume)

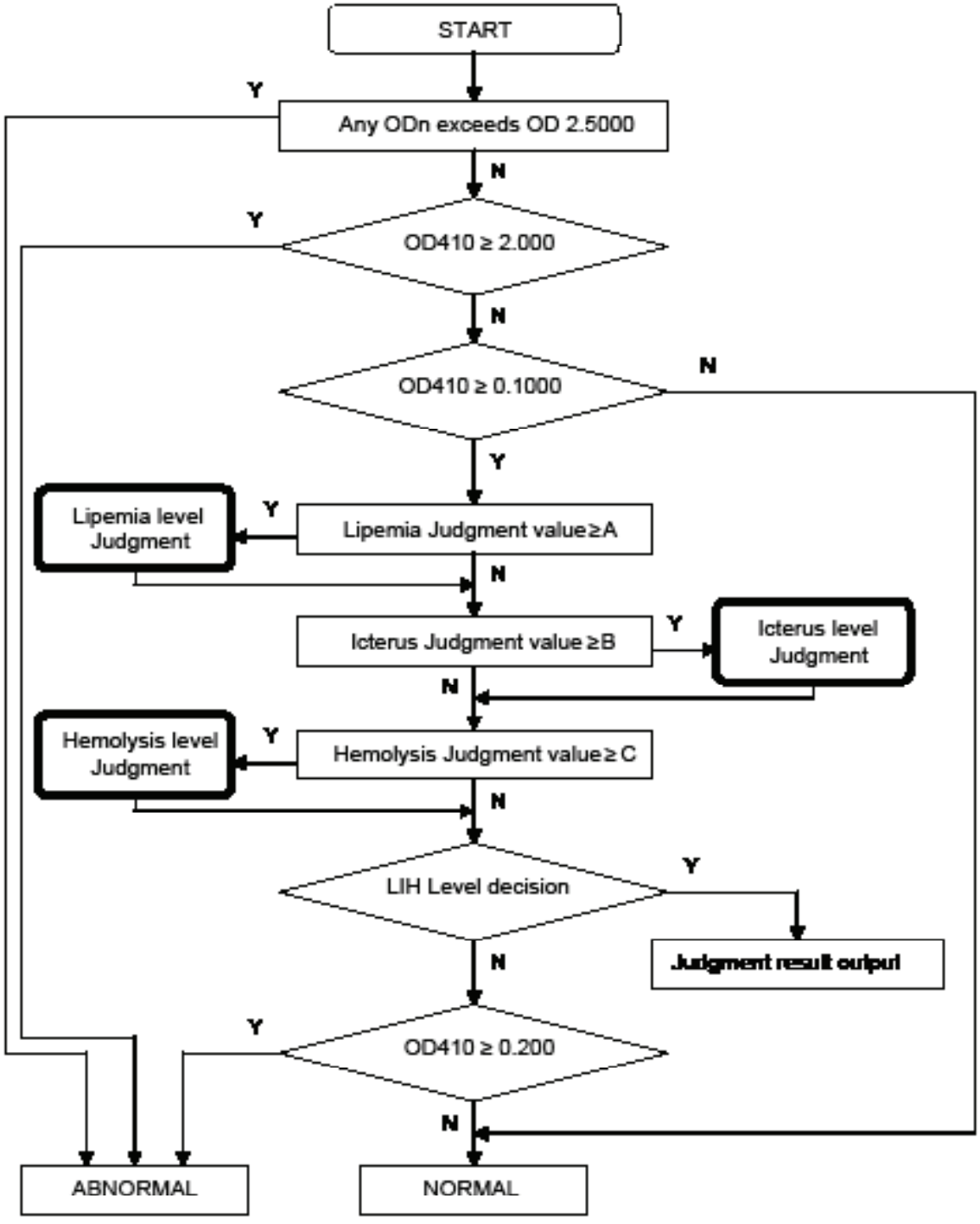
OR

$$\text{LIH check data} = \frac{\text{Reaction OD} \times \text{R1 vol.} + \text{R1 dil. vol.} + \text{sample vol.} + \text{sample dil. vol.}}{300} \times \frac{18}{\text{Sample vol.} + \text{sample dil. vol}}$$

For example: If the lipemia, icterus and hemolysis reaction ODs are less than the OD limit set for Level + for each of these, then the LIH flags are printed as LIP N, ICT N and HEM N. If a reaction OD is equal to or greater than the Level OD limit, but less than the next higher Level OD limit, then the appropriate Level flag of + to +++++ is printed. If the reaction OD limit at any of the 6 wavelengths is greater than 2.5 or if OD 410 exceeds 2.0 then ABN for abnormal is printed for Software versions up to 8.3. Software version 9.0 differentiates between ABN L for abnormal low and ABN H for abnormal high depending on how high or low the OD wavelength reaction limit is exceeded. If the sample was not analyzed for LIH it is left blank.

LIH Determination (up to version 8.3)

The following flow chart represents how the system determines detailed LIH information after analysis for software versions up to 8.3. The flags are judged N, +, ++, +++, ++++, +++++, ABN.

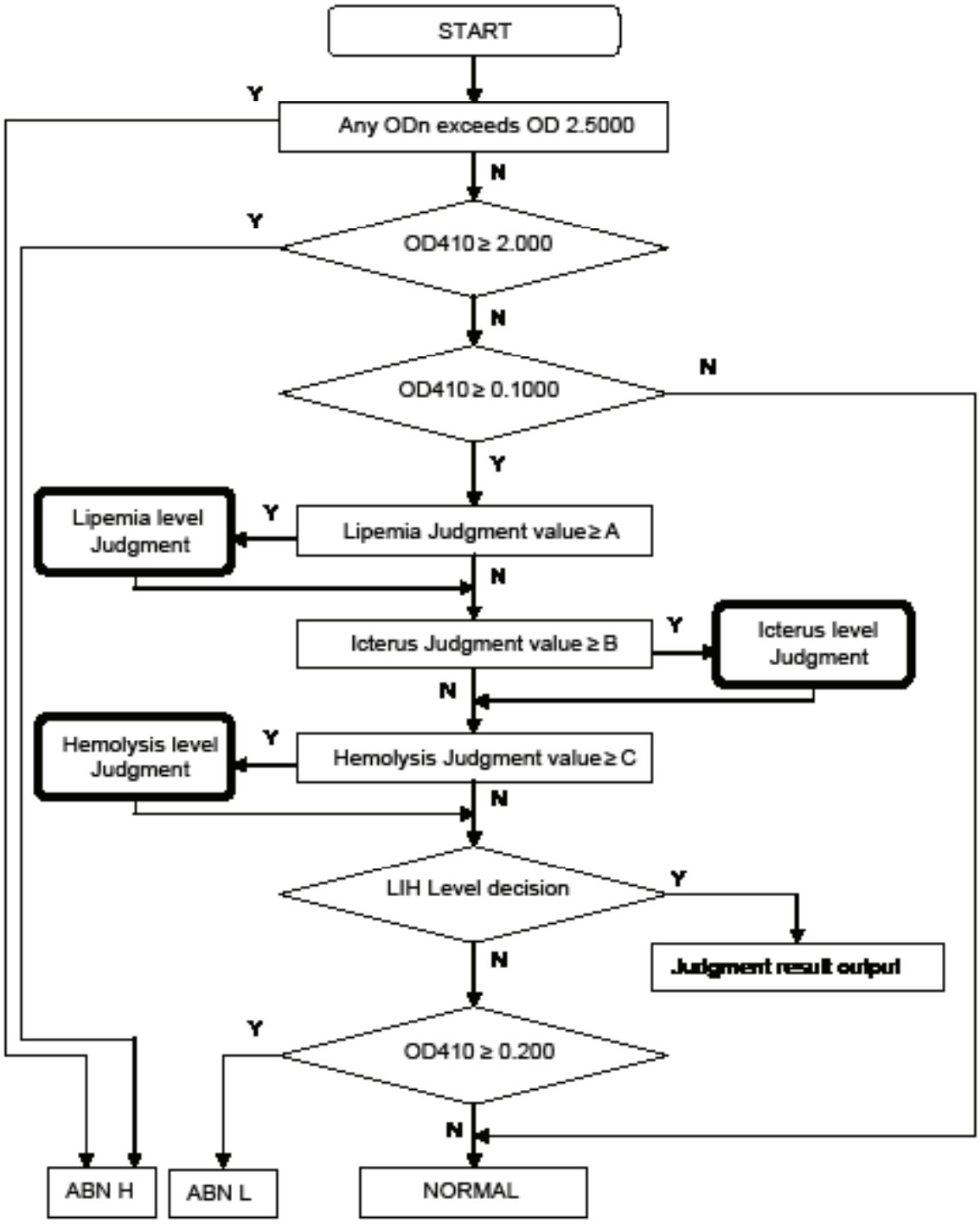


LIH Determination (Version 9.0 and later)

The following flow chart represents how the system determines detailed LIH information after analysis, if the LIH check function in software version 9.0 is enabled. The flags now report N, +, ++, +++, ++++, +++++, ABN H, ABN L.

The ABNORMAL flag in previous software versions has been extended to report ABN H (Abnormal High) and ABN L (Abnormal Low).

To upgrade to software version 9.0, and enable this function, contact your Beckman Coulter Technical Services.

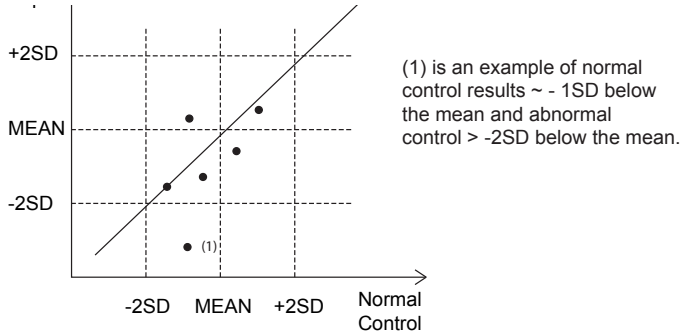


6. Quality Control

A wide variety of quality control techniques are available. On this instrument, -R control (which is the most widely used quality control technique), and multi-rule quality control (which prevents detection of insignificant errors) are designed as a part of the standard software. This section describes multi-rule control. For information about the - R control, refer to the Software Chapter.

Twin Plot Control

In quality control, usually a normal control and an abnormal control are used. The following figure shows a two-dimensional plot with the normal control on the x-axis and the abnormal control on the y-axis.

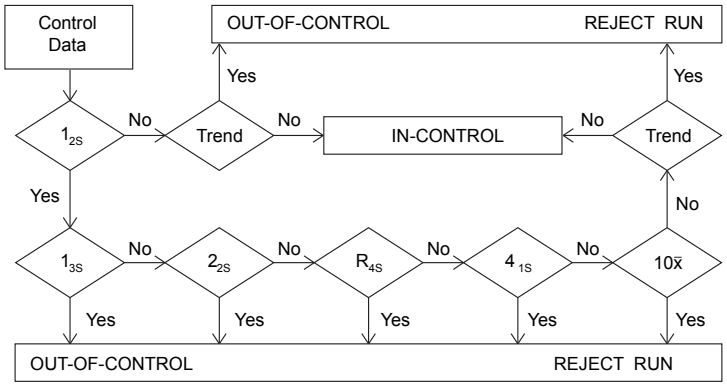


When the normal and abnormal controls are within control limits, but both controls are repeatedly biased high or low, investigate system errors by performing a reagent blank or calibration. If the problem persists reagent deterioration may be the cause; replace reagent calibrate and repeat controls.

The twin plot offers the advantage of classifying problems as either a system error or a random error. To be effective it should be combined with multi-rule control procedures to determine if drift is occurring or if the reagent is unstable.

Multi-Rule Control

In the -R control, a control error is checked by examining multiple control rules, but it is difficult if not impossible to confirm numerous tests on a real-time basis. The multi-rule control technique makes it possible to speedily cope with an error real-time, as this control method notifies the worker of just which rule an error (when generated) violates based on an error flag. When using this control technique, test samples of both the normal range and the abnormal range. Refer to the following figure:



Standard of judgement based on the multi-rule Shewhart technique.
(Logic diagram Applicable to Control Rules)

Explanation of Symbols for Multi-Rule Control and the Corresponding Error Flag:

1 Error Flag

1_{2S} is a judgment level for determining if one control result has exceeded the mean ±2 SD and that five subsequent judgment levels (shown in the table on the following page) are sequentially checked to see if there is any violation of the applicable rules.

2 Error Flag

1_{3S} is a judgment level for determining if one control result has exceeded the control limit 'mean ±3 SD.' When it exceeds the control limit, quality control has not been attained. If it does not exceed the control limit, an inquiry for judgment is made to the next judgment level 2_{2S}.

3 Error Flag

2_{2S} is a judgment level for determining if two consecutive control results have exceeded the control limit 'mean ±2 SD' in one direction. If the control limit is exceeded, then quality control has not been attained. If it does not exceed the control limit, see the next judgment level R_{4S}.

Tip

The term "consecutive" applies to either one identical control substance or a high-concentration and low-concentration control substance.

4 Error Flag

R_{4S} is a judgment level for determining if two control results, with high and low concentrations, exceed the control limit "mean + 2SD" and if the other exceeds the control limit of "mean – 2SD." If the data is out of the control limit, then quality control has not been attained. If the data is within the control limit, see the next judgment level, 4_{1S}.

5 Error Flag

4_{1S} is a judgment level for determining if four consecutive control results exceed the control limit of either 'mean +1 SD' or 'mean -1 SD.' If they have exceeded the limit, then quality control has not been attained. If they have not exceeded either control limit, an inquiry is made to the next judgment level 10 .

6 Error Flag

10 is a judgment level for determining if 7 - 10 consecutive control results fall on one side of the control mean (above or below). If they have exceeded the control limit, then quality control has not been attained. If they have not exceeded the control limit, then quality control has been attained.

7 Error Flag

Trend: Indicates that five through ten QC data points (user defined) exhibit steadily increasing or decreasing values. (A number 7 error flag is generated.)

If an error is encountered through the 6 rules described above, an abnormal data flag is printed as a list or displayed on the screen. The abnormal QC data flags and possible causes are described below:

Error Flag	Control Limit	Cause of Error
Single Rule		
1. (Data exceeds QC range in single rule)	Exceeds QC range	
Multi Rule		
2. (Data exceeds the 3SD control limit)	Exceeding 1_{3S}	Random error
3. (Data continuously exceeds the 2SD control limit)	Exceeding 2_{2S}	Systematic error
4. (Data exceeds the R4S control limit)	Exceeding R_{4S}	Random error
5. (Data exceeds 1SD control range)	Exceeding 4_{1S}	Systematic error
6. (Data over/under the last 10 averages)	Exceeding 10	Systematic error
7. (Data over/under range in multi rule)		

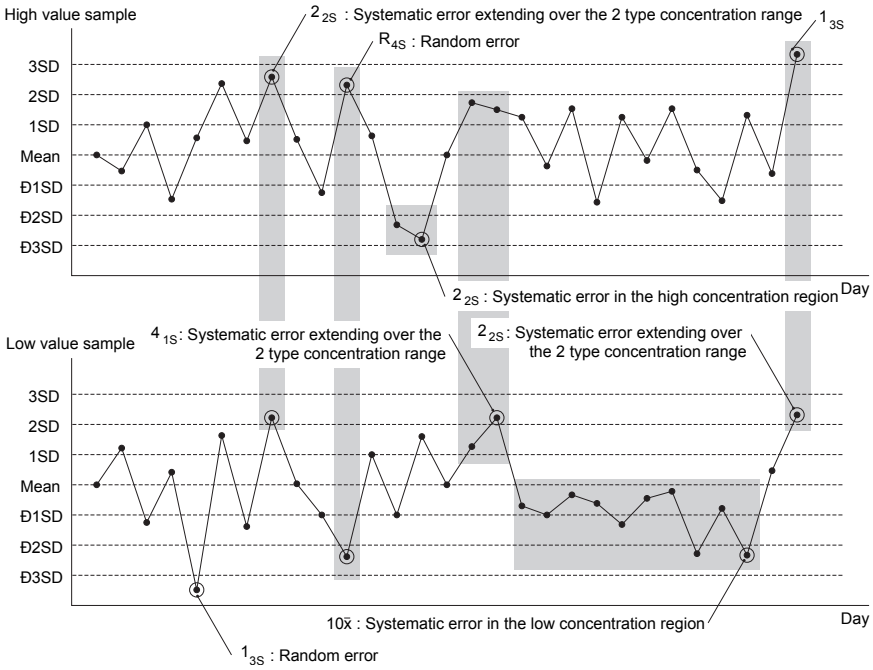
See Also

For more information on Error Flags, refer to the Error Flags Chapter.

For more information on Quality Control, many sources are available such as the following:

Tietz, N. W., ed. "Westgard Multi-Rule Control Chart," Fundamentals of Clinical Chemistry, Third Edition. Philadelphia: Harcourt Brace Jovanovich, Inc., 1987. 246-247.

Example of Control Errors According to the Multi-Rule Control are shown below



The following describes the possible causes and corrective actions for random errors and systematic errors shown in the figure above.

Random Errors

- Dispensing Problem (sample, reagent)

  For troubleshooting information refer to the Troubleshooting Chapter.

- Photometer Lamp Problem

  For troubleshooting information refer to the Troubleshooting Chapter.

- Reagent Deterioration

  For troubleshooting information refer to "Troubleshooting Data Flags" in the Error Flags Chapter.

- Poor Quality Control Sample

  Mistaken sample, different lot, etc.

See Also

For troubleshooting information refer to the Troubleshooting Chapter.

- Periodic Maintenance Not Performed Properly

  For information on scheduled maintenance refer to the Maintenance Chapter.

- Poor Mixing

  For troubleshooting information refer to the Troubleshooting Chapter.

Systematic Errors

- Incorrect Calibration

  Incorrect handling or preparation of calibration samples.

See Also

For troubleshooting information refer to "Troubleshooting Data Flags" in the Error Flags Chapter.

- **Deteriorated Reagent**

  For troubleshooting information refer to "Troubleshooting Data Flags" in the Error Flags Chapter.

- **Temperature Problems**

  For temperature specifications refer to the Specifications Chapter.

7. AU400 Terminology

Terms frequently used for the AU400 are explained below:

W1

Abbreviation for automatic wash of cuvettes. If analysis was stopped, a W1 is performed to remove the sample remaining in the cuvette and the cuvette is washed.

W2

Abbreviation for automatic wash of cuvettes and tubing. Perform a W2 weekly. After performing W2 be sure to perform the photocal measurement.

See Also

For information on performing a W2, refer to the Maintenance Chapter.

Photocal Measurement

To obtain appropriate analysis results, cuvettes are checked for stains or scratches. Confirm the photocal data obtained from a photocal measurement using the analysis status keys and the [Photocal Monitor] screen.

See Also

- For detailed information on performing a photocal, refer to the Maintenance Chapter.
- For detailed information about analysis status keys, refer to the Software Chapter.
- For detailed information about the [Photocal Monitor] screen, refer to the Software Chapter.

Profile

The profile screen sets up test panels. The individual tests are assigned for each profile. Profile No. 99 is assigned to the One Touch Mode. Therefore, this profile must be used for the most frequently used analysis tests. Set the profiles by choosing [Profile] from the [Parameters] screen.

Round

A round is a category in which a set of analysis tests used for similar analysis are grouped together so that specific analysis tests can be accessed quickly. Set the desired round by choosing [Round] from the [Parameters] screen. Example: Designate the analysis tests used for the routine analysis to Round 1, and the analysis tests used for drug analysis to Round 2. Perform routine analysis under Round 1 and switch to Round 2 for drug analysis as required.

ACAL

Abbreviation for auto-calibration. It represents the automatic creation of calibration curves. A calibration curve is automatically created using the yellow rack. It is mainly used for the analysis tests in the end point assay method.

MCAL

Abbreviation for manual calibration. It defines manual creation of calibration curves. A calibration curve is created by manually entering the individual data. It is mainly used for the analysis tests in the rate assay method.

RB

Abbreviation for reagent blank. In routine analysis the reagent blank serves as the reference value for the reagents at each photometric point of individual analysis tests. It also becomes the Y-segment first data point of calibration curves created by ACAL.

LIH Testing

Performs a test for lipemia, icteric, and/or hemolysis in serum. LIH is the symbol used for testing lipemia (L), icterus (I), and hemolysis (H). Checks the level of interference present that may make the sample analysis result abnormal.

END

This is one of the methods available for individual test parameters of the system. In the end point assay method, it defines the analysis method that uses the water blank absorbance as the reference for measurement data at each photometric point. The water blank absorbance is obtained from the photocal measurement. "END" is a method test for individual test parameters. This is another end point assay method identical to "END 1." It uses reagent blank absorbance as the reference for measurement data at each photometric point. END 1 does not use the reagent blank.

RATE

Set-up test for individual test parameters of the system. In the rate assay method, it defines the analysis method that uses water blank absorbance as the reference for measurement data at each photometric point. Water blank absorbance is obtained from the photocal measurement. "RATE" is a set-up test for individual test parameters. RATE 1 is another rate assay method identical to "RATE." RATE uses reagent blank absorbance as the reference for measurement data at each photometric point. RATE 1 does not use the reagent blank.

FIXED

Set-up test for individual test parameters of the system. In the fixed point assay method, it defines the analysis method that uses water blank absorbance as the reference for measurement data at each photometric point. Water blank absorbance is obtained from photocal measurement. "FIXED" is a set-up test for individual test parameters. This is another fixed point assay method identical to "FIXED 1." It uses reagent blank absorbance as the reference for measurement data at each photometric point. FIXED 1 does not use the reagent blank.

NO-LAG_TIME

For example, if analysis for a pathologic human sample using this system ends too quickly due to rapid reaction, two or more photometric points of effective analysis data may not be obtained. If this is the case, the system can be set-up to calculate the analysis result using the data in the lag phase. Used for one of the analysis tests in the rate assay method.