125-009



# INDEX INSTRUMENT SERVICE ADVISORY

01-JUL-1999

PRODUCT: AEROSET (TM) (125)	DATE: <b>05-AUG-1999</b>
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ISA#	SUBJECT	EFFECTIVITY DATE

125-007	Touchscreen Alignment Disk	09-AUG-1999
125-005	Reagent Arm Tubing Guides	01-JUL-1999
125-004	Installation of the Aeroset External Water Delivery Kit	28-JAN-1999
125-003	Installation of the Optional External Waste Pump for Aeroset	05-FEB-1999
125-002	Installation System Verification	15-OCT-98
125-001A	Aeroset (TM) Assay Configuration Modifications	18-OCT-98
125-001	Aeroset (TM) Assay Configuration Modifications	OBSOLETE

Wash Nozzle Mounting Plate and Dry Nozzles

**PENDING -** ISA index number has been reserved for a future ISA.

**CANCELLED -** ISA index number is cancelled.

**INCORPORATED -** ISA was incorporated into another document or manual.

OBSOLETE - ISA no longer applies.
COMPLETE - ISA is complete.

#### **END OF DOCUMENT**



SUBJECT: Reagent Arm Tubing Guides	ISA#: 125-005
ORIGINATOR: Mark Holohan	PRODUCT: AEROSET® (125)
APPROVED: Christie McCain 01-JUL-1999	EFFECTIVITY DATE: 01-JUL-1999

Aeroset® is a registered trademark of Abbott Laboratories.

#### I. Distribution:

Worldwide

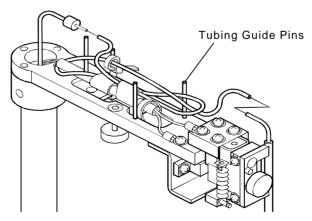
## II. Purpose:

The purpose of this document is to introduce the addition of four tubing guide pins to the configuration of the R1A and R2A Reagent Arms. The new guide pins minimize the possibility of crushing the Reagent Arm tubing between the Arm head assembly and the cover attachment screws when replacing the Reagent Arm cover. (See figure below)

#### III. Parts:

The part numbers for the Reagent Arms will not change. Continue to use 2-89012-01 for R1A and 2-89014-01 for R2A. Existing stock will be used until depleted. The new style Reagent Arms with the tubing guide pins will be incorporated into instrument S/N A8612051 and above.

**Note:** The new style Reagent Arms will be replaced only as a next failure item. The arms are fully backward compatible. No changes have been made to the arm covers, mounting hardware or Removal/Replacement procedures.



Reagent Arm 1A and 2A Head Assembly END OF DOCUMENT



SUBJECT: Touchscreen Alignment Disk	ISA#: 125-007
ORIGINATOR: Mike Schuchmann	PRODUCT: AEROSET® (125)
APPROVED: Christie McCain 04-AUG-1999	EFFECTIVITY DATE: 09-AUG-1999

Aeroset® is a registered trademark of Abbott Laboratories.

#### I. Distribution:

Worldwide

## II. Purpose:

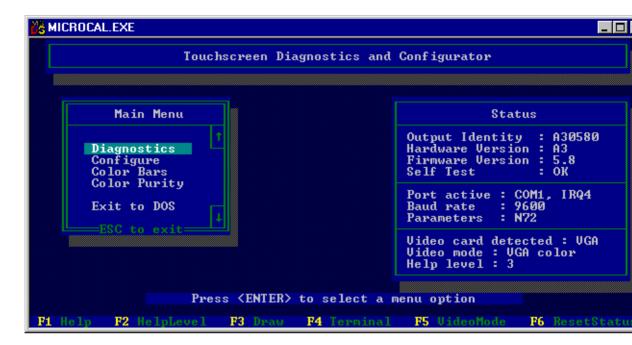
This document describes the Aeroset Touchscreen Alignment Procedure. This procedure must be performed after replacing the SCC monitor to ensure proper function and alignment of the touchscreen assembly.

#### III. Parts:

Touchscreen Alignment Disk - Catalog Number 2-89883-01.

## IV. Procedure:

- 1. Log off and power down the analyzer.
- 2. Insert the touchscreen alignment disk in the floppy drive on the SCC computer.
- 3. Power up the analyzer.
- 4. At the A:\> prompt, type the word "microcal" and press the enter key. The system will load the Microcal<sup>™</sup> "Touchscreen Diagnostics and Configurator" application.



- 5. Select the "Diagnostics" function from the menu and press the enter key.
- 6. Select "Calibration" function and press the enter key. The following warning will appear:



Press the Y key to continue.

7. A target mark will appear on the lower left corner of the touchscreen. Touch the center of the mark on the screen. Another mark will then appear on the right upper corner. Touch the center of the mark. This will calibrate the touchscreen.

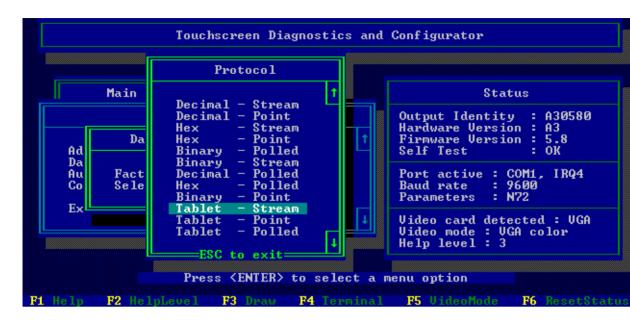


- 8. After adjusting, select "Exit to main menu" and press enter to return to the main menu.
- 9. Select the "Configure" function from the menu and press enter to customize the touchscreen.
- 10. Select "Adjust Sensitivity" and press enter.
  - a. Select "Normal" and press enter.
- 11. Select "Data Protocol" and hit enter. The following warning will appear:



Press the Y key to continue.

- 12. Select "Select Protocol" and press enter.
  - a. Select "Tablet Stream" and press enter.



- 13. Select "Auto Baud Detection" and press enter.
  - a. Select "Disable" and press enter. The following warning will appear:



Press the Y key to continue.

- b. Select "9600" and press enter.
- 14. Select "Communication Parameters" and press enter.
  - a. Select "N81" and press enter. The following warning will appear:



Press the Y key to continue.

- 15. Select "Exit to Main Menu" and press enter to return to the main menu.
- 16. Select "Exit to DOS" and press enter. The following message will appear:

- 17. Press the Y key to return to the DOS prompt.
- 18. Turn off power to the analyzer and remove the floppy disk. Wait 15 seconds, then turn on power again and log in. The touchscreen should now be properly aligned. Select various fields and buttons on the touchscreen to ensure alignment and operation.

End of procedure.

## **END OF DOCUMENT**



SUBJECT: Wash Nozzle Mounting Plate and Dry Nozzles	ISA#: 125-009
ORIGINATOR: Albert Blanco	PRODUCT: AEROSET® (125)
APPROVED: Christie McCain 30-JUN-1999	EFFECTIVITY DATE: 01-JUL-1999

AEROSET® is a registered trademark of Abbott Laboratories

#### I. PURPOSE:

The Wash Nozzle Mounting Plate and Dry Nozzles have been redesigned to simplify Dry

Nozzle alignment and to clarify orientation of the Dry Tips during replacement.

Part Number 2-89271-01 will no longer be available and upgrade kit 2-89881-01 (Nozzles,

Dry, Incl. baseplate, upgrade) must be used when replacing the Wash Nozzle Mounting Plate and Dry Nozzles.

#### II. TOOLS:

The following tools are recommended to install the Wash Nozzle Mounting Plate and Dry

#### Nozzles:

- 1. Robotics alignment tools.
- 2. Triangle Ruler with right angle.

## III. PARTS:

1. 2-89881-01 Nozzles, Dry, Incl. baseplate, upgrade kit includes:

Description Qty.
Wash Nozzle Mounting Plate. 1

Dry Nozzles with Dry Tips. 2

Screws. 13

## **REPLACED PARTS:**

Dispose of per local regulation.

#### IV. PROCEDURE:

Note: Wear gloves, lab coat, and safety glasses while in the laboratory.

Note: Refer to the Parts Lists (PL), Verification Procedures (VP), and Removal and Replacement Procedures (RR) in the Aeroset Service Manual as noted.

## MODIFICATION STEPS:

- 1. Remove the Cuvette Washer Cover.
- 2. Remove the Cuvette Wash Head from the Cuvette Wash Elevator by unscrewing the Cuvette Wash Head Mount Knob.
- 3. Remove the tubing from each nozzle.
- 4. Remove the Cuvette Washer Cover Bracket from the Wash Nozzle Mounting Plate.
  Loosen the two screws and slide the Cuvette Washer Cover Bracket up with all of the nozzle tubing still attached.
- 5. Remove the Wash Nozzle Mounting Plate from the Cuvette Washer Base Plate by removing the 2 screws.
- Remove all the nozzle pairs and the Dry Nozzles from the existing Wash Nozzle Mounting Plate.
- 7. Mount all of the existing nozzle pairs on the new Wash Nozzle Mounting Plate included in the ISA Kit.

Note: Do not reinstall the old style Dry Nozzles on the new Wash Nozzle Mounting Plate included in the ISA Kit.

Note: Be sure to replace nozzle pairs in the correct order.

8. Place the triangle ruler on the bottom of the Wash Nozzle Mounting Plate to confirm that each nozzle is perpendicular to the Wash Nozzle Mounting Plate. Perform this check from two or more directions perpendicular to each nozzle (Figure 1).

Note: If a Nozzle is bent, adjust the Nozzle by bending in the opposite direction, so that it is perpendicular to the Wash Nozzle Mounting Plate. Use the Triangle Ruler as a reference.

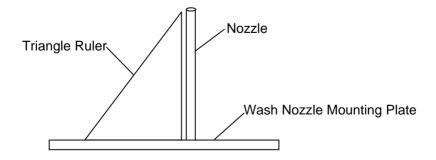


Figure 1. Nozzle Alignment.

- Install the new style Dry Nozzles included in the ISA Kit on the new Wash Nozzle Mounting Plate (Figure 2).
- 10. Orient the A-line Dry Nozzle so the large end of the white plastic block is toward the back of the Wash Nozzle Mounting Plate.
- 11. The B-Line Dry Nozzle should be oriented so the large end of the white plastic block is toward the front of the Wash Nozzle Mounting Plate.

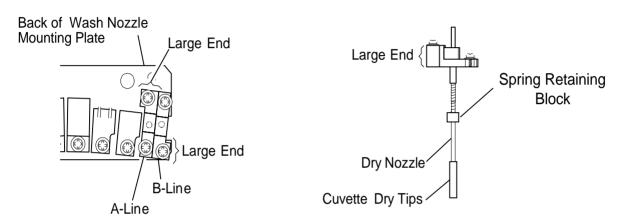


Figure 2. Orientation of new style Dry Nozzles on the Wash Nozzle Mounting Plate.

12. Slide the Cuvette Dry Tips on the Dry Nozzles. Orient each Cuvette Dry Tip in the direction of the Spring Retaining Block (Figure 3)

Note: Do Not touch the Cuvette Dry Tips with fingertips.

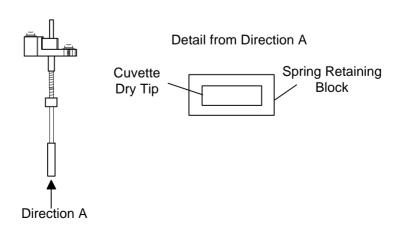


Figure 3. Orientation of Cuvette Dry Tip to the Spring Retaining Block

- 13. Install the Wash Nozzle Mounting Plate onto the Cuvette Washer Baseplate.
- 14. Install the Cuvette Washer Cover Bracket onto the Wash Nozzle Mounting Plate.

15. Reattach all the tubing that was removed earlier.

Note: The aspiration line sleeve tubing is denoted by a green stripe. Aspiration nozzles are located toward the front of the Wash Nozzle Mounting Plate and water nozzles are to the back of the Wash Nozzle Mounting Plate.

- 16. Replace the Cuvette Washer Standoffs from the old style Cuvette Washer Baseplate to the new Cuvette Washer Baseplate.
- 17. Align the Cuvette Washer using the Cuvette Washer Adjustment Procedure (VP-36) in Aeroset Service Manual.

Note: The Cuvette Dry Tips must not deviate sideways when they enter the cuvette (Fig 4).

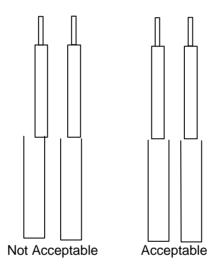


Figure 4. Positions of Cuvette Dry Tips and Cuvettes.

17. Mount the Cuvette Washer Cover.

#### CHECKOUT:

- From the Maintenance Utilities Screen, step the Cuvette Washer down by pressing the
- Step Down button.

Check the alignment of the each nozzle pair. The Cuvette Dry Tips should go into the cuvette very precisely, with little or no lateral movement

Perform a "Start-Up" using the Wash Cuvettes option only.

Note: If alignment is needed refer to the Cuvette Washer Adjustment Procedure (VP-36) in the Aeroset Service Manual

#### **END OF DOCUMENT**



SUBJECT: Installation of the Aeroset External Water Delivery Kit	ISA#: 125-004
ORIGINATOR:	PRODUCT:
Steve Lincoln	AEROSET (TM) (125)
APPROVED:	EFFECTIVITY DATE:
Christie McCain 1/27/98	28-JAN-1999

Aeroset (TM) is a trademark of Abbott Laboratories

#### I. Distribution:

World Wide.

## II. Purpose:

This document describes the procedure for installing the Aeroset (TM) External Water Delivery Kit.

## III. Parts

External Water Delivery Kit LN 09D60-01

A. This kit contains the following parts:

1. Auto Fill Cap	89701-101	1ea
a. This part number includes:		
110 VAC AC/DC Converter	(used in U.S. o	only)
In-line Filter	(not used)	
Remote cable	(not used)	
2. Carboy, 20 Liter	14241-011	1ea
3. Fitting, 1/2" to 3/8" Reducer	14603-204	1ea
4. Tubing, .5 ID	14370-138	5ft
5. Clamp, Hose, 5/16"- 7/8"	11096-205	4ea
6. Pwr Sup, Linear, EUR 5V	14114-062	(for countries
		where 220 volts is
		used)
7. Fitting, Tube-Pipe, Nipple, 1/4"	14603-220	1ea
8. Fitting, Tube-Pipe, 3/8" X 1/4"	14603-221	1ea
9. Line Cord, 220v	14355-059	(for countries
		needing this cord

configuration)

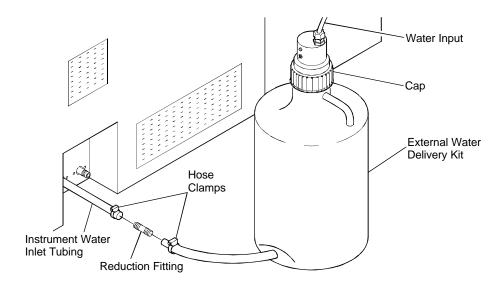
## IV. Administrative notes:

## V. Special Tools:

Standard Tool Kit.

## VI. Procedure:

- 1. Unpackage the External Water Kit.
  - A. Select the appropriate AC/DC converter for the power available in the lab (110 vac for the U.S., 220 vac for "220" volt labs). Discard the AC/DC converter that is not needed.
  - B. Discard the remote cable and the in-line filter that are supplied with the kit.
- 2. Attach the piece of tubing (14370-138) supplied in the kit to the exit port at the bottom of the water reservoir (14241-011).
- 3. Attach the instrument water inlet tubing to the exit tubing on the water reservoir using the 1/2" to 3/8" reduction fitting (14603-204) and hose clamps (11096-205) supplied with the kit.
- 4. Using either the 1/4" ( 14603-220) or the 3/8" fitting (14603-221) supplied with the kit attach the incoming water line to the cap (89703-101) of the water Carboy (14214-011).
- 5. Plug the DC plug of the AC/DC converter into the cap.
- 6. Plug the AC/DC converter into the correct AC outlet.



- 7. Adjust the incoming water pressure to 40 PSI (or 3 bar depending on the type of gage that is being used) using the regulator provided by the laboratory.
- 8. Turn the main water valve on and ensure there is water flow from the inlet port in the cap.
  - A. Allow the water to flow for approximately one minute in order to clear any debris from the cap.

- 10. Push the float switch on the cap up and ensure that the water shuts off and the valve in the cap does not vibrate.
- 11. Attach the cap to the water Carboy and allow the bottle to fill.
- 12. Ensure the water shuts off when the water Carboy is full and that the valve in the cap does not vibrate.
  - A. If the valve vibrates during shut off, turn the water off, readjust the incoming water pressure down and repeat step 11 and 12.



SUBJECT:	ISA#:
Installation of the Optional External Waste Pump for Aeroset	125-003
ORIGINATOR:	PRODUCT:
Steve Lincoln	AEROSET (TM) (125)
APPROVED:	EFFECTIVITY DATE:
Christie McCain 2/5/1999	05-FEB-1999

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#### I. Distribution:

World Wide.

## II. Purpose:

This document describes the correct procedure for the installation of the optional Aeroset (TM) External Waste Pump.

## III. Parts

1. External Waste Pump kit LN 09D61-01

## A. This kit includes:

1. 89839-102	Waste Pump
14370-141	Tubing, Reinforced PVC, .625 ID, 20 feet
14370-140	Tubing, PVC, .5 ID, 1 foot
14603-224	Fitting, Tube-Tube, insert 1/2", 3 ea
14603-223	Fitting, Tube-Tube, insert 5/8", 2 ea
14603-222	Fitting Reducer, 1/2" to 1/4", 1 ea
14331-018	Clamp, Hose, Snap, 15/32", 1 ea
14331-019	Clamp, Hose, Snap, 3/4", 4 ea
14331-020	Clamp, Hose, Snap, 7/8", 2 ea
14355-059	Line Cord, 220 Volt
14325-001	Line Cord, 120 Volt

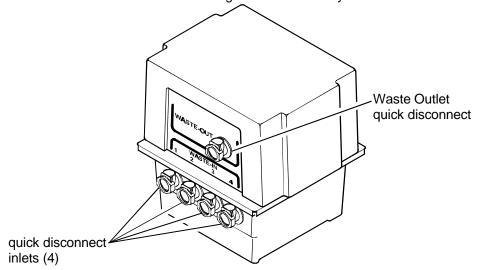
## IV. Administrative notes:

N/A

## V: Special Tools:

#### VI. Procedure:

- 1. Waste Pump Placement.
  - A. Place the Waste Pump Assembly within 3' of the back of the analyzer.
  - B. Ensure that the inlet ports of the Waste Pump are no more than 4" above the floor.
- 2. Attach Tubing to Waste Pump Assembly.
  - A. Insert the 5/8" quick disconnect fitting (p/n 14603-223) to the waste outlet tubing (p/n 14370-141, 20' supplied with the kit) and secure it with a hose clamp.
  - B. Connect the male end of the fitting to the Waste Outlet quick disconnect on the waste pump assembly.
  - C. Insert the other end of the outlet tubing into the laboratory waste drain.

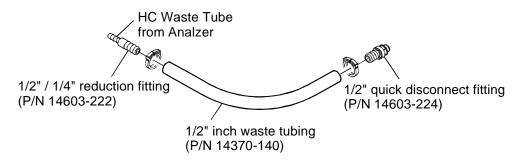


- D. Insert a 1/2" quick disconnect fitting (p/n 14603-224) into the analyzer OVERFLOW tubing and secure using a hose clamp.
- E. Insert the OVERFLOW tubing into any one of the four quick disconnect inlet fittings on the waste pump assembly.
- F. Insert a 1/2" quick disconnect fitting (p/n 14603-224) into the analyzer BATH DRAIN tubing and secure using a hose clamp.
- G. Insert the BATH DRAIN tubing into a quick disconnect inlet fitting on the waste pump assembly.
- H. Insert a 5/8" quick disconnect fitting (p/n 14603-223) into the analyzer DRAINAGE tubing and secure using a hose clamp.
- I. Insert the analyzer DRAINAGE tubing into a quick disconnect inlet fitting on the waste pump assembly.

Note: The High Concentration waste tubing from the analyser is to be attached to the External Waste pump only if local regulations allow draining into the laboratories drain system.

J. Connect the HIGH CONCENTRATION WASTE tubing from the analyzer

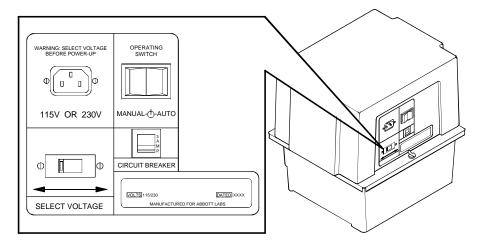
- 1') using the 1/2" to 1/4" reduction fitting (p/n 14603-222) and secure using a hose clamp.
- K. Connect the 1/2" quick disconnect fitting (p/n 14603-224) to the assembled waste tubing using a hose clamp to secure it. Then insert the waste tubing connector into a quick disconnect inlet fitting on the waste pump assembly.



1. Ensure that the High Concentration waste sensor cable is not connected to the analyser.

Note: Do not connect the system refrigerator drain line to the external waste pump.

- 2. Pump Set Up.
  - A. Place the voltage select switch on the waste pump assembly to the correct position (115 VAC for the U.S., 230 VAC for "230" volt countries).
  - B. Attach the correct line cord to the waste pump assembly (p/n 14325-001 115 VAC for U.S., p/n 14355-059 220 VAC for countries using this cord configuration).
  - C. Plug the waste pump assembly into an appropriate wall outlet.



#### 3. Check Out.

- A. Press the OPERATING select switch to the "Manual" position and ensure that the pump begins to run.
  - The OPERATION select switch will return to the "off" position when released.
- B. Place the OPERATING select switch to the "AUTO" position.

- C. Run a system **START UP** and select the following options:
  - 1. Change Water in Bath
  - 2. Wash Cuvettes
  - 3. Flush Water Lines
- B. Ensure that:
  - 1. The pump switches on when the pump reservoir is full.
  - 2. Water is pumped into the laboratory waste drain.
  - 3. There are no leaks.
  - 4. The pump stops when the pump reservoir is empty.

## VII. Periodic Maintenance.

1. No periodic maintenance is required for the External Waste Pump assembly.

## VIII. Cleaning for Service.

- 1. No service of electronics is performed at this time.
- 2. Decontaminate the outside surface of the Waste Pump assembly.
- 3. If failure analysis / or return to the vendor is required the External Waste Pump assembly must be cleaned and decontaminated.

## Note: Protective gloves must be worn when working inside the Waste Pump assembly.

- A. Empty the bottom half of the tub and rinse with a 5% solution of chloride bleach, then rinse with water.
- B. Rinse the bottom of top pump housing with a 5% solution of chloride bleach then rinse again with water.
- C. Dry the entire assembly using absorbent wipe.

## **END OF DOCUMENT**



SUBJECT: Installation System Verification	ISA#: 125-002
ORIGINATOR: Mike Schuchmann	PRODUCT: AEROSET (TM) (125)
APPROVED: Christie McCain 14-OCT-98	EFFECTIVITY DATE: 15-OCT-98

Aeroset (TM) is a trademark of Abbott Laboratories.

**DISTRIBUTION: World Wide** 

**PURPOSE:** To inform the field of the procedure to be performed on all Aeroset installations. The

test is used verify system performance immediately after installation at the customer

site.

## **III. CONTENT:**

## **Materials Required**

**AST** 2 cartridges of R1 & R2 LD 2 cartridges of R1 & R2 2 cartridges of R1

Total Protein (TP)

ICT Reference Sol. 1 bottle **ICT Sample Diluent** 1 cartridge

ICT Serum Calibrator 1 bottle of each calibrator (L and H)

**ICT Module** 1 module ICT Cleaning Fluid 1 kit Acid Wash Sol. 1 bottle Alkaline Wash Sol. 1 bottle Water Bath Additive 1 cartridge

Multiconstituent Calibrators 1 bottle for each calibrator level

**Control Material** 2 bottles (2 X 10ml) control material to have values in the following

ranges:

AST (136 - 258 U/L) (309 - 526 U/L) LD TP (3.7 - 5.3 g/dL)(126 - 163 mmol/L) Na (5.5 - 7.9 mmol/L)K CI (83 - 109 mmol/L)

Note: Control material can be customer laboratory control or Abbott Control.

## Storage and Preparation of the Reagents/Calibrators/Controls

#### **CAUTION**

The reagents/calibrators/controls must be stored and prepared according to the instructions provided in Table 5-9 below.

Table 5-9: Reagent Preparation

Name of material	Reagent	Reagent Preparation	Reagent Storage
Total Protein	Color solution	Use as is. (R1)	Room temperature
AST	Enzyme	Use as is. (R1)	2 to 8 degrees C.
	Substrate solution	Use as is. (R2)	2 to 8 degrees C.
LD	Coenzyme	Use as is. (R1)	2 to 8 degrees C.
	Substrate Solution	Use as is. (R2)	2 to 8 degrees C.
ICT	ICT Sample Diluent	Use as is. (R1)	Room Temperature
	ICT Reference Solution	Use as is.	Room Temperature
	ICT Serum Calibrator	Use as is.	2 to 8 degrees C. (After opening)
	ICT Cleaning Fluid (for Start Up ONLY)	Reconstitute with 12ml of the solvent and gently mix for 15 minutes.	2 to 8 degrees C. (After reconstituting)
Multiconstituent Calibrators	N/A	Use as is.	2 to 8 degrees C.
Control Material	N/A	Prepare according to manufacturers instructions.	Store according to manufacturers instructions.
Water Bath Additive	N/A	Use as is (R1, position C9)	Room Temperature

CAUTION: Wear a lab coat, safety glasses and gloves while handling all materials.

## **Load Configuration and Assay Disks**

- 1. Perform steps 2 5 if not previously performed.
- 2. From the Main Display, select:

Maintenance Utilities (icon)

SCC (tab)

- 3. Place the System Configuration disk in the disk drive, then select:
  - "Restore from Disk "Config"
- 4. Place the Assay Disk in the disk drive, then select:
  - "Restore from Disk Assay 1-50"
- 5. Cycle power to the SCC and analyzer when completed.

## **Perform START UP**

- 1. Perform a START UP for 24 hour operation using the following options:
  - a. Change Water Bath
  - b. Wash Cuvettes
  - c. Wash Probes with 1% Alkaline Wash Solution
  - d. Wash ICT with ICT Cleaning Fluid and ICT Reference Solution
  - e. Drain and fill the IRef Cup
  - f. Flush Water Lines
- 2. Flush the ICT Module with ICT Reference Solution. Select:

"START UP"

- a. Deselect all the options except Wash ICT with IRef
- b. Start the activity, select:

"Start"

c. When finished, flush one more time. Select:

"Start"

## Assay Set Up

1. Access the Assay Screen.

"ASSAYS"

2. From the ASSAYS screen, select:

**AST** 

3. In the ASSAY STATUS screen, select:

"Config"

4. Access the Export dialog window, select:

"EXPORT"

5. Press the arrow button to the right of the Drive field, then select:

"Hard Disk"

- 6. Close the list by selecting the return arrow.
- 7. In the File Name field, enter the file name "AST2" then select:

"OK"

8. The system will automatically add the appropriate file extension. The Export confirmation dialog window is displayed, select:

"OK"

9. Exit the screen to the Main Display.

"CANCEL" (two times)

- 10. Press the ASSAYS button.
- 11. In the ASSAYS screen, select any blank assay button.
- 12. In the Select Reaction Mode screen, confirm "Photometric" has been checked. If not:
  - a. Touch the circle to check it.

"OK"

13. Access the Import dialog window.

"IMPORT"

14. Press the arrow button to the right of the Drive field. Select:

"Hard Disk"

- 15. Close the list by selecting the return arrow.
- 16. Press the arrow button to the right of the File Name field, select:

"AST2"

- 17. Close the list by selecting the return arrow.
- 18. Select "OK"
- 19. The Import confirmation dialog window appears which contains the text:

"Import Assay Parameters - This will overwrite any information in this file".

Select "OK".

20. While in the ASSAY STATUS/CONFIGURATION screen, change the Assay

Name from AST to AST2, then highlight the "Assay #" field and enter the number 900.

- 21. Observe the checkmark next to "A Line Outer" or "B Line Inner" circles on the screen.
  - a. If the A line already has a check by it, then check the B line by touching the circle.

If the B line already has a check by it, then check the A line.

b. Save and exit:

"OK"

22. Exit the screen to the Main Display:

"CANCEL"

- 23. Repeat the procedure for creating LD2 (use Assay #901) and TP2 (use Assay #902) files using Assay Set Up steps 1-22.
- 24. Select:

"Cal/Control", then:

"MCC1" button

- 25. In the TP and TP2 fields enter in the value stated from the MCC calibrator value assignment list and press OK. Ensure that Aeroset values are entered. Do not use Alcyon values.
  - a. Repeat the same procedure for MCC2.
- 26. Press the "Water" button.
- 27. Enter "0" for AST2, LD2, and TP2 or select the "zero set" button to set all to zero.
  - a. Confirm the entry.

"OK"

- b. Verify there is a "0" entered for AST, LD, and TP.
- 28. Select the "Run" button, then select the "SysCfg" button to display the SYSTEM CONFIGURATION screen.
  - a. Check the following options:

"Smart Sampling" (deselect the option)

"Saving Mode" (should be selected)

b. Save the selections.

"OK"

- 29. Load the reagents as specified in Table 5 10.
- 30. Scan the reagent cartridges (ensure all R2 reagents have their bar code labels facing the bar code reader prior to scanning):

"Rgt Scan"

31. Verify reagent cartridges and bottles were correctly read.

"Reagents"

Select the appropriate tab.

32. Select SmartWash for LD using the following steps:

"Assays"

"LD"

"Config"

"SmartWash" (tab)

33. From the first "Reagent" column, select the down arrow to access the selection list:

a. Select: "TP00061"

1) Close the list:

"Return Arrow"

b. From the "Wash" column select the down arrow to access the selection list:

Select: "AcidW"

1) Close the List:

"Return Arrow"

c. In the "Vol" column enter the number "345". Confirm and save the entry:

"OK" (2 times)

34. Perform steps 32 and 33 for LD2.

Table 5-10: Loadlist

MATERIAL	TEST	CAROUSEL (Position)	CONTAINER (Type)
TOTAL PROTEIN	TP (B-Line)	R1, position D-6	R1 cartridge
	TP2 (A-Line)	R1, position A-2	R1 cartridge
AST	AST (A-Line)	R1, position A-3	R1 cartridge
		R2, position A-3	R2 bottle
	AST2 (B-Line)	R1, position D-3	R1 cartridge
		R2, position D-3	R2 bottle
LD	LD (B-Line)	R1, position D-5	R1 cartridge
		R2, position D-5	R2 bottle
	LD2 (A-Line)	R1, position, A-4	R1 cartridge
		R2, position, A-4	R2 bottle
ICT	ICT Sample Diluent	R1, position A-1	R1 cartridge
	ICT Reference Solution	Dedicated position	2L bottle
	ICT Serum Calibrators	C/C carousel #40 (L)	Sample cups
		C/C carousel #41 (H)	
	ICT Cleaning Fluid (for	C/C carousel #43	Sample cup
	Start Up Only)		
Multiconstituent	Level 1	C/C Carousel #1	Sample cups
Calibrators	Level 2	C/C carousel #2	
Control Material	Control with specified	Sample Carriers 1-4 (20	Sample cups
	values.	positions total)	
Water Bath Additive	Used for Start Up Only	R1, position C-9	R1 cartridge

## Run Set Up

1. From the Main Screen, select:

"DATABASE"

"ORDER"

"C/P" - (Carrier/Position)

a. Enter the Carrier and Position Number.

Select the left field:

Enter "1"

b. Select the right field:

Enter "1"

2. Select the following assays:

Na, K, Cl, AST, AST2, LD, LD2, TP, TP2

a. Select the copy number.

"COPY"

Enter "19"

b. Confirm the selection.

"OK"

c. Exit the screen.

"OK"

3. Display the RUN OPTIONS screen.

"RUN"

a. Select:

"Patients"

b. Order calibrations:

"Calibration"

"ORDER"

- c. Select the assays listed in step 2 above.
- d. Confirm the selections.

"OK"

- 4. Put 20 empty sample cups in Sample Carriers #1-4 and place them into a Sample Carrier Tray.
  - a. Place empty Sample Carriers #5-10 into the Tray.

NOTE: The extra carriers are to test the pull in and push out operation of the

Sample Carriers from the Sample Carrier Tray.

- b. Pipette 500ul of control material into the 20 sample cups.
- c. Place the Sample Carrier Tray on the FastTrack.
- 5. Pipette 500ul of MCC1 and MCC2 in cups 1 and 2 respectively on the C/C carousel.
- 6. Pipette 500ul of ICT "Level 1" Serum Calibrator and "Level 2" Calibrator in cups.
  - a. Place the cups in positions #40 and #41 respectively on the C/C Carousel.
- 7. Begin the run.
  - "START"
- 8. After the run completes, verify the calibrations passed for each of the assays. If the calibration PASSED, the assay button "text" in the ASSAYS screen will be green. If the calibration did not pass the "text" will be yellow. A calibration Error Code will be displayed in the ASSAY STATUS screen. To view this code from the ASSAY/CONFIGURATION screen: "Status"
- 9. Print the calibration results for each of the assays.

"Cal Summary"

"Print"

10. To view the patient results, select:

"DATABASE"

- 11. Press the right arrow key located at the bottom of the right-hand column.
  - a. Continue to press the right arrow button until the results of the desired assay is displayed. The assay names are listed at the top of the database screen.
- b. Print the screen for each of the assays by pressing the PRINT SCREEN key. Verify the results

meet the acceptance criteria stated in Table 5 - 11.

- c. If the results do not pass the acceptance criteria, troubleshoot the error to correct the problem and then repeat the run.
- 12. If all the assays pass the acceptance criteria (Table 5 11), then delete the assay files AST2, LD2, TP2. Select the following:

"ASSAYS"

- a. Select the assay file to be deleted.
- b. Access the ASSAY CONFIGURATION Screen.

"Config"

"Delete"

"OK"

c. In the Select Reaction Mode screen, select:

"Cancel"

- d. Repeat the procedure and delete each of the assays listed in step 12.
- 13. Delete the library files.
  - a. From the Main Screen, select:

"Maintenance Utilities" (icon)

"SCC"

b. In Library Maintenance, select:

"ALL", and then:

"Delete"

c. Confirm the selection.

"OK"

- 14. Select the "Run" button, then select the "SysCfg" button to display the SYSTEM CONFIGURATION screen.
  - a. Check the following option:

"Smart Sampling" (should be selected)

b. Confirm and Save the selection.

"OK" (2 times)

Table 5-11: Acceptance Criteria

Name of Test	Assay	•	Acceptance Criteria Range* Less than or equal to:
	AST	20	9
	AST2	20	9

ISA#Plæsciscion Thestallation S	ystem Verification		Page 15
	LD	20	19
	LD2	20	19
	TP	20	0.22
	TP2	20	0.22
	Na	20	3.4
	K	20	0.24
	CI	20	3.0

<sup>\*</sup> Range = The difference between the highest and lowest result in the run of 20 replicates.

# **END OF DOCUMENT**



SUBJECT: Aeroset (TM) Assay Configuration Modifications	ISA#: 125-001A
ORIGINATOR: Patrick Wood	PRODUCT: AEROSET (TM) (125)
APPROVED: Christie McCain 10/23/98	EFFECTIVITY DATE: 18-OCT-98

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## I. <u>DISTRIBUTION</u>:

World Wide

## II. PURPOSE:

To inform the Field of Technical Bulletin (TB) 1037-1998. This Technical Bulletin provides additional technical information for use during the installation of the AEROSET System. Technical Bulletin (TB) 1025-1998 is replaced by Technical Bulletin (TB) 1037-1998.

## III. <u>CONTENT</u>:

TECHNICAL BULLETIN

TB 1037-1998

Issue Date: 27 August 1998

## THIS TECHNICAL BULLETIN SUPERSEEDS TB 1025-1998 ISSUED 6/29/98

<b>Product:</b>	AEROSET <sup>TM</sup> System

## **Content:**

This Technical Bulletin provides additional technical information for use during the installation of the AEROSET System. This information will assist you with the set-up of the Assay Configurations in order for the System to be configured in accordance with the assay specific AEROSET Reagent Application Sheets. Please be advised that the next release of the assay disk and future software releases will address these issues.

Information is divided into the following categories:

- 1. Assay Configuration Modifications
- 2. SmartWash Configuration Modifications
- 3. Reagent Configuration Modifications
- 4. Print Format Modifications
- 5. Software Limitations
- 6. Additional Information

The following bullet points are additional information that was not previously communicated in

- Urine applications using the "Use Fac/Blk" calibration method do not need a blank sample or blank replicate defined. These applications include Urine Amylase, Urine Calcium, Urine Magnesium, Urine Phosphorus, and Urine Uric Acid.
- Sample volumes have been defined for automated dilutions. Please refer to the assay specific application sheets for recommended diluents.
- A software limitation has been identified in the functionality of the "Max" field. Details on the limitation as well as suggested options are covered under the category "Software Limitations".
- A "#" indicates information that has been updated since the issue of the previous version of this technical bulletin

After assay disk installation do the following:

## **Assay Configuration Modifications:**

Load all bar coded reagents that will be used and select <RGT SCAN>. Configure any non bar coded reagents (ICT sample Diluent, ALT-A, etc.). Select <Assays> from the Information Access Area of the Main Display and choose the appropriate assay.

Select <Config> then select the Tab defined in the table below. Edit the current value to the new value for the Field and **press the Enter Key within thirty seconds.** After entering the new value select <Save>. When the "Save" window appears select <OK> to save the changes.

Assay	Assay Screen Name	Tab	Field	Currently	New Value
Alanine Aminotransferase	ALT#	Base	Dil 1 S. Vol	2.0	20
Alanine Aminotransferase	ALT#	Base	Dil 1 DS. Vol	0.0	5.3
Alanine Aminotransferase	ALT#	Base	Dil 1 D. Vol	0	80
Alanine Aminotransferase	ALT#	Base	Diluent Reagent Name/Position	-	Diluent
Albumin BCP	AlbP	Outline	Max	13.1	11.0
Albumin BCP	AlbP	Outline	Max Text (Untitled field to right of "Max" field)	>13.1	>11.0
Albumin BCG	AlbG	Outline	Max	11.8	11.0
Albumin BCG	AlbG	Outline	Max Text (Untitled field to right of "Max" field)	>11.8	>11.0
Ammonia *	Amm	Outline	L-Reference	11	18
Ammonia	Amm	Outline	Reference-H	32	72
Amylase	Amy #	Base	Dil 1 S. Vol	2.0	2.4

Amylase Urine	Amy-U#	Calibration	Blank Reps	3	0
Amylase Urine	Amy-U#	Calibration	Blank Sample	Water	-
Aspartate Aminotransferase activated	AST-A	Outline	Reference-H	40	50
Calcium Urine	Ca-U#	Calibration	Blank Reps	3	0
Calcium Urine	Ca-U#	Calibration	Blank Sample	Water	-
Carbon Dioxide	CO2 #	Base	Dil 1 S. Vol	2.0	25
Carbon Dioxide	CO2 #	Base	Dil 1 DS. Vol	0.0	4.8
Carbon Dioxide	CO2 #	Base	Dil 1 D. Vol	0	75
Carbon Dioxide	CO2 #	Base	Diluent Reagent Name/Position	-	Diluent
Cholesterol	Chol #	Base	Dil 1 S. Vol	2.0	25
Cholesterol	Chol #	Base	Dil 1 DS. Vol	0.0	2.4
Cholesterol	Chol #	Base	Dil 1 D. Vol	0	75
Cholesterol	Chol #	Base	Diluent Reagent Name/Position	-	Diluent
Creatine Kinase	CK #	Base	Dil 2 S. Vol	2.0	10
Creatine Kinase	CK #	Base	Dil 2 DS. Vol	0.0	4
Creatine Kinase	CK#	Base	Dil 2 D. Vol	0	90
Creatine Kinase	CK#	Base	Diluent Reagent Name/Position	-	Diluent
Creatinine	Crea	Calibration	Interval	0	24
Creatinine Urine	Crea-U	Calibration	Interval	0	24
Direct Bilirubin	DBil	Calibration	C1 Drop-Down List box C2 Drop-Down List box	Bili 1 Bili 2	Bil 1 Bil 2
Direct Bilirubin	DBil	Outline	Reference-H	0.4	0.2

Direct Bilirubin

DBil

Outline

Max

50.1

35

Direct Bilirubin	DBil	Outline	difications  Max Text	>50.1	>35
Direct Billiuolii	DBII	Outilile	(Untitled field to right of "Max" field)	>30.1	>33
Direct HDL	HDL	Outline	L-Reference	28	35
Direct HDL	HDL	Outline	Max	310	270
Direct HDL	HDL	Outline	Max Text (Untitled field to right of "Max" field)	>310	>270
Glucose	Glu#	Base	Dil 1 S. Vol	2.0	20
Glucose	Glu#	Base	Dil 1 DS. Vol	0.0	2
Glucose	Glu#	Base	Dil 1 D. Vol	0	80
Glucose	Glu#	Base	Diluent Reagent Name/Position	-	Diluent
Lactate Dehydrogenase	LD#	Base	Dil 1 S. Vol	2.0	20
Lactate Dehydrogenase	LD#	Base	Dil 1 DS. Vol	0.0	3.2
Lactate Dehydrogenase	LD#	Base	Dil 1 D. Vol	0	80
Lactate Dehydrogenase	LD#	Base	Diluent Reagent Name/Position	-	Diluent
Lactate Dehydrogenase	LD	Calibration	Interval	384	720
Magnesium *	Mg	Calibration	Interval	0	24
Magnesium, Urine *	Mg-U#	Base	Dil 1 S. Vol	2.0	15
Magnesium, Urine	Mg-U#	Base	Dil 1 DS. Vol	0.0	2.4
Magnesium, Urine	Mg-U#	Base	Dil 1 D. Vol	0	135
Magnesium, Urine	Mg-U#	Base	Diluent Reagent Name/Position	-	Diluent
Magnesium Urine	Mg-U	Calibration	Interval	0	24
Magnesium Urine	Mg-U#	Calibration	Blank Reps	3	0
Magnesium Urine	Mg-U#	Calibration	Blank Sample	Water	-

Phosphorus Urine	Phos-U#	Calibration	Blank Reps	3	0
Phosphorus Urine	Phos-U #	Calibration	Blank Sample	Water	-
TIBC	TIBC	Outline	L-Reference	225	250
Total Bilirubin	TBil	Calibration	C1 Drop-Down List box C2 Drop-Down List box	Bili 1 Bili 2	Bil 1 Bil 2
Total Protein	TP	Calibration	Interval	480	552
Triglyceride	Trig	Outline	L-Reference	50	1
Triglyceride	Trig	Outline	Male	30 - 100 32 - 148 44 - 249 50 - 321	0 - 0 0 - 0 0 - 0 0 - 0
Triglyceride	Trig	Outline	Female	35 - 110 37 - 131 36 - 144 39 - 262	0 - 0 0 - 0 0 - 0 0 - 0
Triglyceride	Trig	Outline	Age	9 19 29	0 0 0
Triglyceride	Trig	Outline	Reference-H	321	200
Triglyceride	Trig #	Base	Dil 1 S. Vol	2.0	25
Triglyceride	Trig #	Base	Dil 1 DS. Vol	0.0	2.4
Triglyceride	Trig #	Base	Dil 1 D. Vol	0	75
Triglyceride	Trig #	Base	Diluent Reagent Name/Position	-	Diluent
Urea Nitrogen	Urea	Outline	Max	234	125
Urea Nitrogen	Urea	Outline	Max Text (Untitled field to right of "Max" field)	>234	>125
Urea Nitrogen	Urea #	Base	Dil 1 S. Vol	2.0	20
Urea Nitrogen	Urea #	Base	Dil 1 DS. Vol	0.0	2.4
Urea Nitrogen	Urea #	Base	Dil 1 D. Vol	0	80
Urea Nitrogen	Urea #	Base	Diluent Reagent Name/Position	-	Diluent

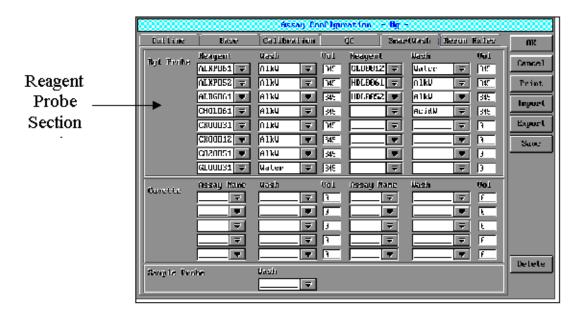
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		Cornigaration wio			1 ago 21
Uric Acid Urine *	Uric-U#	Calibration	Calibration Reps	3	0
Uric Acid Urine	Uric-U#	Calibration	Blank Reps	3	0
Uric Acid Urine	Uric-U#	Calibration	Blank Sample	Water	-
Urine/CSF Protein	UPro#	Base	Dil 1 S. Vol	2.0	4.8
Urine/CSF Protein	UPro#	Base	Dil 2 S. Vol	2.0	20
Urine/CSF Protein	UPro#	Base	Dil 2 DS. Vol	0.0	9.6
Urine/CSF Protein	UPro#	Base	Dil 2 D. Vol	0	180
Urine/CSF Protein	UPro#	Base	Diluent Reagent Name/Position	-	Diluent
Urine/ CSF Protein	UPro	Calibration	C1 Drop-Down List box	Upro 1	Upro 1
rioteni			C2 Drop-Down	Upro 2	Upro 2
			List box C3 Drop-Down	Upro 3	Upro 3
			List box C4 Drop-Down List box	Upro 4	Upro 4
			C5 Drop-Down List box	Upro 5	Upro 5

\* Note: Assays with the astrisk (Magnesium, Magnesium Urine, Ammonia, Uric Acid, and Uric Acid Urine) also require modifications to the SmartWash parameters (See next page).

## **SmartWash Configuration Modifications:**

Select <Assays> from the Information Access Area of the Main Display and choose the appropriate assay. Select <Config> and choose the SmartWash tab.



Use the following table to define SmartWash for the following reagents.

Assay	Assay Name	Tab	Section	Reagent field	WASH field	Volume field
Magnesium	Mg	SmartWas h	Reagent Probe	Reagent name for ICT Sample Diluent from the Drop-Down List box ie: "ICTDIL"	Acid	345
Magnesium Urine	Mg-U	SmartWas h	Reagent Probe	Reagent name for ICT Sample Diluent from the Drop-Down List box ie: "ICTDIL"	Acid	345
Ammonia  Note: Only required if Activated ALT reagent is used	Amm	SmartWas h	Reagent Probe	Reagent name for Activated ALT from the Drop-Down List box ie: "ALT-A"	Acid	345
Uric Acid	Uric	SmartWas h	Reagent Probe	Reagent name for DBil R1(DBILI31) and DBil R2 (DBILI12) from the Drop-Down List box	Water	300
Uric Acid Urine	Uric-U	SmartWas h	Reagent Probe	Reagent name for DBil R1(DBILI31) and DBil R2 (DBILI12) from the Drop-Down List box	Water	300

# **Reagent Configuration Modifications**

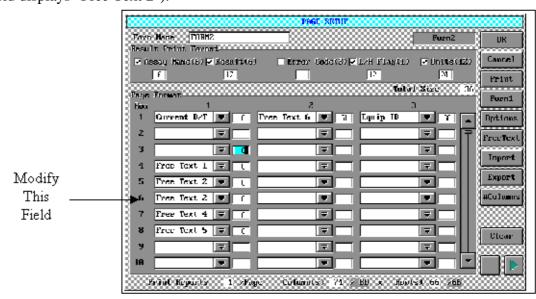
Select <Reagents> from the Information Access Area of the Main Display and choose the appropriate reagent from the Tab to change to the Cartridge size indicated in the following table. Select "Large" from the Drop-Down List box and select <Return Arrow>, <OK> to save the changes.

Tab	Position	Reagent Name	Cartridge Size (from Drop-Down List box)
R1C	# 9	Add.	Large
	10	Diluent	Large
	11	AlkW	Large
	12	AcidW	Large
R1D	18	Diluent	Large
	19	AlkW	Large
	20	AcidW	Large
R2C	11	AlkW	Large
	12	AcidW	Large
R2D	19	AlkW	Large
	20	AcidW	Large

## **Print Format Modifications:**

Default print format modifications should be performed according to the following instructions.

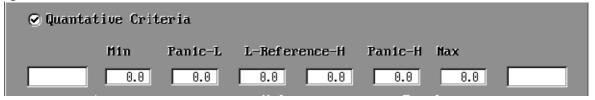
- 1 Select < Database > from the Information Access Area of the Main Display.
- 2 Select < Print> to display Print Options dialog window.
- 3 Select < Page Setup> to display Page Setup.
- 4 Select <Form2> to display the Page Setup for Form 2.
- 5 Select the Drop-Down List box for Page Format Row 6. (Currently this field displays "Free Text 2").



- 6 Select "Free Text 3" from the Drop-Down List box.
- 7 Select the Return Arrow button and select <OK> to save changes.

## **#Software Limitations**

The Outline page of the Assay Configuration screen provides the operator fields for configuring Quantitative Criteria.



The value entered in the "Max" field is the maximum value the system will report. Text entered in the "Max text" field (to the right of the "Max" field) will be reported when the result is greater than the "Max" field; i.e. >200.

There are two software limitations associated with this field.

- 1. Because the software assigns flagging (i.e.>200) after the calculations have been performed and the "Max" field is **NOT** adjusted for a dilution factor, diluted samples will always report ">Max".
- 2. The Auto Rerun feature is initiated when a Result Error Code has been configured on the Rerun page of the Assay Configuration screen. There is currently no Result Error Code associated with a result that has exceeded the "Max" field.

## **Options**

Evaluate the customer's workload and operating procedures to determine the best solution for

- 1. Since the Result Error Code "PVH" is available on the Rerun page, the "Panic-H" field can be used for entering the maximum value. This would allow the operator to Auto Rerun and report sample values over the upper linearity limit (Note: this option is available only for assays with a dilution defined in the base page).
  - a. Enter the value currently in the "Max" field into the "Panic-H" field.
  - b. In the Assay Configuration Modifications portion of this document, sample volumes were defined for automated dilutions. Enter the following "Max" values into the "Max" fields (The original "Max" values have been multiplied by the appropriate dilution factor for the assay):

Carbon Dioxide	90
Cholesterol	2820
Glucose	3820
Magnesium Urine	43.4
Urine/CSF Protein (Dil 1)	400 For CSF
Urine/CSF Protein (Dil 2)	2000 For Urine
Triglyceride	5684
Urea Nitrogen	625

- c. Select the appropriate dilution option from the Drop-Down List box for "PVH" in the Rerun Rules page.
- d. For ALT, Amy, CK, and LD (Flex rate assays with dilutions defined in the Base page):
  - i. The new **Max** values are (The "Max" value for Flex Rate Linearity, in the application sheet, has been multiplied by the appropriate dilution factor for the assay):

Alanine Aminotransferase	20567
Amylase	13108
Creatine Kinase (Dil 1)	14300
Creatine Kinase (Dil 2)	71500
Lactate Dehydrogenase	23660

- ii. Select the desired dilution option from the Drop-Down List box for the following Result Error Codes in the Rerun Rules page: "ABS", "A#0", "A#1", "A#2", and "RL%"
- 2. Samples can be diluted off-line, the manually diluted samples run and the result multiplied by the dilution factor off-line and edited into the database.
- 3. Remove the entries in the Max field for all assays. This will enable customers to report results above the Max value, however values above the linear limit will not have a Result Error Code.
- 4. To manually order the instrument to dilute, run, and report an individual result which is above the "Max" value (note: this option can be used for assays with and without a pre-configured autodilution):
  - a. **For this sample only**, reset the "Max" field to a higher value (original value times the dilution factor). This requires the supervisor level password.
  - b. Order the sample to be run in "Dil 1" or "Dil 2" mode. Note: if the dilution parameters have not been configured they must be set up at this point.
  - c. Once the sample is run, the result will be printed.
  - d. **Return the "Max" field to its original value** to ensure that results above the linearity limit are flagged.

## **Additional Information:**

• Print the Assay List to view the A-Line or B-Line configuration, to ensure correct reagent

placement in the reagent supply center. To print the Assay List, select <Assays> from the Information Access Area, then select <Print> from the ASSAYS screen. For correct use of the defined assay parameters, proper line placement is critical.

- The operator must perform a Blank daily with water as described in the Ammonia application sheet. The 336 hour calibration interval defined in the assay parameters is for the Full calibration only.
- Default reference ranges have been defined in the assay parameters for customer convenience only. It is strongly recommended that each laboratory define their own reference ranges based on their particular locale and population characteristics.
- If ALT-A and AST-A assays are used, the following configuration must be performed since the reagents are not bar code labeled:
  - 1 Define the Reagent name and location in the REAGENTS screen.
  - 2 Select the defined reagent from the Rgt Name/Pos Drop-Down List box on the Base page of the Assay Configuration screen.
- In order to protect against data loss in the event of a hard drive failure, perform a backup for the following options:

Config

Assay 1-50

Assay >50 (if assay numbers >50 have been assigned)

Refer to Additional Maintenance in section 9 of the Aeroset System Operations Manual for details.

• The ICT assay files are configured for automatic calibration when the calibration interval is exceeded. The sample probe will automatically look for calibrators without notifying the operator first. Please review the automatic calibration feature with the customer to determine if this option should be deselected.

For further information and procedures, refer to Section 2, Installation Procedures and Special Requirements in the AEROSET<sup>TM</sup> System Operations Manual.

**Contacts:** If you have any questions regarding this Technical Bulletin please contact:

- Product specific Technical Team Specialist supporting US personnel
- Worldwide Customer Service CST (Customer Support Technologist) supporting non-US personnel

**Distribution:** Worldwide

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