EFFECTIVITY



IMPLEMENTATION

INDEX TECHNICAL SERVICE BULLETIN

PRODUCT: DATE: 13-JUL-1999

SUBJECT

| 135 # | IMITELIMENTATION | 3003201 | DATE |
|----------|------------------|---------------------------------------|-------------|
| | | | |
| 119-009A | M-See TSB | Alcyon (TM) System Software 1.6 Recal | 26-MAY-1999 |
| 119-009 | CANCELLED | NUMBER WILL NOT BE USED | CANCELLED |
| 119-008 | N - See TSB | Alcyon® Hardware Upgrade 2 | |
| 119-007 | N - See TSB | Alcyon (R) Instrument Labels | 09-JUL-1999 |
| 119-005 | N - See TSB | ALCYON (TM) System Software Ver 1.5 | OBSOLETE |
| 119-004 | N - See TSB | ALCYON (TM) System Software Ver 1.40d | |
| 119-003B | I - See TSB | ALCYON (TM) 300 Hardware Upgrade | 18-SEP-98 |
| 119-003A | I - See TSB | ALCYON (TM) Hardware Upgrade | OBSOLETE |
| 119-003 | I - See TSB | ALCYON (TM) Hardware Upgrade | |
| 119-001 | N - See TSB | | 26-JUN-98 |
| | | | |

PENDING -

TSR #

CANCELLED TSB index number is cancelled.

INCORPORATED - TSB was incorporated into another document or manual.

OBSOLETE -

COMPLETE - TSB implementation is complete.



ABBOTT ADD

TECHNICAL SERVICE BULLETIN

Alcyon (TM) System Software 1.6 Recall

Mark Holohan/Gary Tompkins/Emile Diou ORIGINATOR: APPROVED: Dan Armstrong 26-MAY-1999

TSB#: 119-009A

PRODUCT: ALCYON (TM) 300 Rev 1 (119)

REF. ECN: 14245-002

Trademark: ALCYON (TM) is a trademark of Abbott Laboratories.

IMPLEMENTATION: Mandatory O Next Service Call Optional Instruments Requiring Modification: See Administrative TSB Part/Kit #: N/A TSB Part(s) Availability: N/A TSB Tracking by Serial # required (MANDATORY TSB's ONLY)

> YES \bigcirc NO

Upgrade Time: 1.0 VerificationTime: 0.5

Total Mod. Time: 1.5

NOTE The instrument must be at TSB Level n/a prior to performing this TSB.

DISTRIBUTION:

Worldwide

II. PURPOSE:

Notes

An issue has been identified with Alcyon System Software Ver. 1.6 in the printing routine. This issue may produce incorrect test results or reference ranges when printing the "Complete Report (Header)", "Incomplete Report (Draft)" and the "Control Results printout" as referenced in the Alcyon Operations Manual. These reports may **print** the test result or reference range incorrectly.

Test results displayed on the Alcyon screen using the Complete and Archived Files are correct. Patient result flagging of High/OK/LOW on the Complete Report (Header) also functions correctly, since these flags are generated using the actual test result stored in memory.

Immediate discontinued use of Alcyon Analyzers using software version 1.6 is required. Before resuming operation, the current hard disk drive containing software version 1.6 will need to be replaced with a new hard disk drive and software version 1.5 loaded on the new hard drive.

III. ADMINISTRATIVE NOTES:

The following instrument serial numbers require immediate implementation of this TSB:

| Serial | Customer Site | |
|--------|---------------------|--|
| Number | | |
| 1741 | Augusta, GA. | |
| 1626 | Urbana, IL. | |
| 1490 | Lincoln, NE | |
| 1629 | Dayton, OH | |
| 1496 | Erie, PA. | |
| 1312 | Austin, TX. | |
| 1499 | Corpus Christi, TX. | |
| 1436 | Sacramento, CA. | |
| 1437 | Sacramento, CA. | |
| 1623 | Stockton, CA. | |
| 1919 | Delkenheim, Germany | |
| 1921 | Delkenheim, Germany | |
| 1924 | Delkenheim, Germany | |

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| 1925 | Delkenheim, Germany |
|------|---------------------|
| 1926 | Delkenheim, Germany |

IV. SPECIAL TOOLS:

Standard tool kit

V. PARTS:

Hard Drive Assy Catalog number 2-85279-01

REPLACED PARTS:

Label software version 1.6 disks and old hard disk drive with instrument serial number, FSR ID and account name and return via FedEx to:

Matthews Skariah MS 1-8 Abbott Diagnostics Division 1921 Hurd Dr. Irving, TX 75038

Remove the version 1.6 Alcyon Operations Manual text pages (leave binder and tabs) and Alcyon Quick Reference Guide version 1.6 from the customer site. A new version 1.5 Operations Manual will be shipped directly to the customer.

COMPATIBILITY:

Alcyon System Software Ver. 1.5 <u>must not</u> be loaded on hard disk drive previously loaded with software version 1.6. A new hard disk drive must be installed before loading software version 1.5.

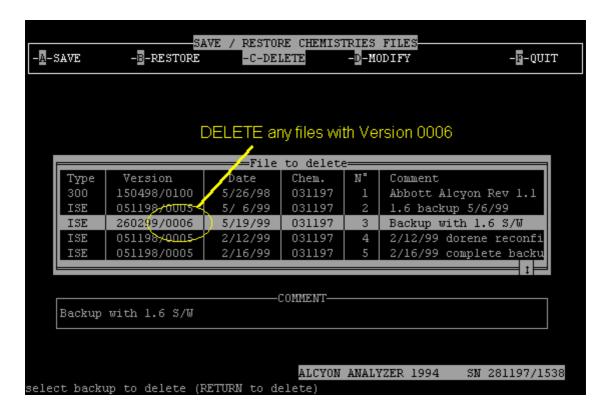
VI. PROCEDURE:

Before removal of hard disk drive:

- 1. Verify that customer has reviewed all results printed with software version 1.6 against stored results in the Complete and Archived files as per telephone protocol.
- Verify Methods disk has a software version 1.5 backup file that is acceptable to the customer for use later when restoring the Methods. (Version 1.6 backup files CANNOT be used to restore the Methods.)
 - a. Perform Shutdown (VP-01)
 - b. Insert Alcyon Methods Disk in floppy disk drive.
 - c. Turn Main Power Switch on. The system will load the program from the disk.
 - d. When the language screen is displayed, select the appropriate language. The Save/Restore Files Screen is displayed.
 - e. Select the option, -D- MODIFY and review the displayed files for software version 1.5 Methods backup files. The 1.5 backup files can be identified by noting the revision number in the Version field. (Example, xxxxxx/0005 designates a backup file for software version 1.5.)
 - f. Verify that one of the version 1.5 backup files will be acceptable to customer for Methods Restore on the new hard disk drive. This file will be used <u>LATER</u> in this procedure when restoring the Methods. After verifying this file is present exit this screen by selecting ESC, Quit, select option 6 DOS, then cycle power to reboot.
 - g. Print the System Configuration and Header Editor files and label each as Ver. 1.6.
 - h. If no acceptable version 1.5 backup file is available, print the following Configuration information. This information will be used later when manually restoring Methods and Configurations to the new hard disk drive. Label each printout as Ver. 1.6.
 - Normal ranges for all assay files
 - Q.C. ranges
 - Dilution/Rerun limits
 - Calibration configurations
 - System configuration- print all options
 - Reagent carousel
 - Header

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- 3. Deleting Methods files saved with Ver. 1.6 System Software
 - a. Highlight the Ver. 1.6 file to be deleted. See figure below. Version 1.6 backup files can be identified by xxxxxx/0006.
 - b. Select the delete option, **-C-DELETE** and press <ENTER>. The entire file is automatically deleted from the disk.
 - c. Verify that the file is deleted.
 - d. Repeat for each file saved with the Ver. 1.6 software.
 - e. When finished, proceed to MODFICATION STEPS.



MODIFICATION STEPS:

Hard Disk Drive Removal:

NOTE: It may be necessary to remove the CPU Board in order to replace the Hard Drive. If so, upon boot-up, verify CMOS configurations are correct per ISA 119/120-005.

- 1. Remove all patient Samples from Sample Carousel.
- 2. Perform Shutdown. (VP-01)
- 3. Remove Rear Cover.
- 4. Remove Card Cage Cover.
- 5. Disconnect the following cables from the Hard Drive:
 - a. Power P159, W39
 - b. Data P161, W30
- 6. Remove mounting screws (3) from Hard Drive.
- 7. Slide Hard Drive down and remove.

Hard Disk Drive Replacement:

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1. Install in reverse order.

Verification:

1. Ensure that the Hard Drive is detected upon initialization during **Version 1.5 Software Installation and Methods Restoration**.

Version 1.5 Software Installation and Methods Restoration:

- 1. Insert Installation Disk # 1 in Floppy Drive.
- 2. Turn instrument power ON. The analyzer will automatically start the installation of the new software from Disk #1. Data will be displayed as the files are loaded from the floppy drive to the hard drive. The first disk will take between 2 and 3 minutes to load.
- 3. When the message, "Please insert Disk 2 of 2 then press any key to continue" appears, remove Disk #1 and insert Disk #2. Press <Enter>. The analyzer will install Disk #2. Data will be displayed as the files are loaded from the floppy drive to the hard drive. The second disk may take up to 10 minutes to load.
- 4. When the message, "Install complete, remove floppy disk from disk drive" appears, remove Disk #2.
- 5. Turn instrument power OFF; wait 5 to 10 seconds, then turn power back ON. If the Analyzer was previously setup for a non-English language, interrupt the boot-up sequence and select the appropriate language. Otherwise, if no language selection is made, the analyzer will initialize and the Main Menu will appear in English Language.
- From the Main Menu select <Configuration>, <System Configuration>, then <Display SW Version>.
- 7. Verify that the software version is **1.50**.
 - a) If the software version is CORRECT, print the screen (**Prt Sc** key) and label with Abbott representative name, instrument serial number and date. Send printout to Mathews Skariah along with software version 1.6 disks and old hard disk drive. (See Replaced Parts section of this document.) Press <Esc> three times, to return to the Main Menu.
 - b) If software version is INCORRECT, repeat Steps 1 through 6. If, after repeating, the version is still INCORRECT, contact Abbott Technical Support.

Restoring Methods from the back-up disk:

- a. Select <Stop/Shutdown>, then <Shutdown Instrument>.
- b. Select CONFIRM and press <Enter>.
- c. Turn the power OFF at the main switch.
- d. Place the Alcyon Methods Disk in the disk drive.
- e. Turn the power ON. The analyzer will load the program from the floppy disk.
- f. Select the appropriate language version and press <Enter>.
- g. Select <Restore> and press <Enter>.

NOTE: Use the Complete option for restoring Methods onto the new Hard Drive.

To Perform a Complete Restore:

- 1. Select < Complete > and press < Enter >.
- 2. Highlight the file to be loaded into the Alcyon Analyzer memory (acceptable Ver. 1.5 Methods backup file) and press <Enter>. This option will load Methods, reagent tray configurations, profiles, calibrators, controls definitions and validation rules. The message "Restaure?? OK (Strike any key)" will appear at the bottom of the screen when the Restore is complete. Press <Esc> twice.
- 3. Select Quit to exit. The screen returns to the Language Choice screen.
- 4. Select #6 D.O.S.
- 5. When the A:\> appears:
 - a) Remove the floppy disk and store in a safe place.

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- b) Turn power OFF.
- c) Wait 5-10 seconds, then turn the power ON.

Any changes made will be present when the instrument has initialized.

Manually Restoring Configurations:

- 1. Manually enter the Configuration information obtained in Step 2 of the PROCEDURE section above in each appropriate file:
 - Normal ranges for all assay files
 - Q.C. ranges
 - Dilution/Rerun limits
 - Calibration configurations
 - System configuration- print all options
 - Reagent carousel
 - Header

CHECKOUT:

- 1. Print the System Configuration and Header Editor files and label each as Ver. 1.5. Verify that each printout matches the Ver. 1.6 printout from Step 2 g in the PROCEDURE section.
- 2. If a manual restoration of Methods and Configurations was performed, print the following configuration information and label each printout as Ver. 1.5.
 - Normal ranges for all assay files
 - Q.C. ranges
 - Dilution/Rerun limits
 - Calibration configurations
 - System configuration- print all options
 - Reagent carousel
 - Header

Verify that each printout matches the Ver. 1.6 printout from Step 2 g in the PROCEDURE section.

- 3. Calibrate all customer assays and run controls. Verify operations with customer.
- 4. Ensure software version 1.6 disks, old hard disk drive, and copy of Display Software Version screen are returned to address listed in the REPLACED PARTS section of this document.
- 5. Perform VP-18 Save/Update Methods.

MODIFICATION CONTROL STICKER UPDATE:

Mark off number 9 on the modification control sticker upon completion of this procedure. The TSB modification control sticker is located behind the front display panel.

END OF DOCUMENT

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TECHNICAL SERVICE BULLETIN

Alcyon® Hardware Upgrade 2

ORIGINATOR: Emile Diou

APPROVED: Christie McCain 30-JUN-1999

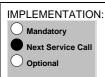
TSB#: **119-008**

PRODUCT: ALCYON® 300 Rev 1 (119)

REF. ECN: See Reason and Justification

for Change document

Trademark: ALCYON® is a registered trademark of Abbott Laboratories



Instruments Requiring Modification: s/n 2125 and below, excluding 1986, 1987, 1993, and 1994 TSB Part/Kit #: 2-83746-01

TSB Part(s) Availability: 06-JUL-1999

TSB Tracking by Serial # required (MANDATORY TSB's ONLY)



Upgrade Time: 5 hrs
VerificationTime: 2 hrs
Total Mod. Time: 7 hrs

NOTE The instrument must be at TSB Level <u>n/a</u> prior to performing this TSB.

I. DISTRIBUTION:

Worldwide

II. PURPOSE:

This TSB adddresses:

Optical Alignment Software and Procedure

The optics alignment software will aid the FSR through the a) the alignment of the reaction carousel and b) the vertical alignment of the optics assembly. This alignment procedure requires the use of optical alignment tools ("black cuvettes"). These optical alignment tools also have probe target holes to assist in the probe alignments.

Tube/Cup Detector Alignment Procedure

The tube/cup detector on some instruments may not be properly aligned. A probe crash may result if a tube is detected when a cup is present. The alignment eliminates the chance of this problem from occuring.

Transfer Mechanism Up Sensor Adjustment

The up sensor on both transfer mechanisms may not be positioned properly. Incorrect position of this sensor will result in errors #3 and/or #4. A procedure is now released to properly adjust the up sensor to reduce the occurance of these errors.

Wash Pump Volume Verification

The pump volumes can drift until the pump has been run for several hours. Verify the pump volumes are within specifications and make adjustments if necessary.

Liquid Level Sense Cable Inspection

Some cables in the factory were found to have a short center conductor that does not make good contact, resulting in intermittent liquid level sense errors.

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Syringe Drive Upgrade

The syringe drive will be upgraded to improve the alignment of the syringe piston to the glass barrel. This upgrade will improve the life of the syringe pistons.

New Syringe Assemblies

The syringe assemblies will now be supplied by Kloehn. These new syringes reduce the manufacturing inconsistencies from the old syringe supplier.

• New Sample Probe Clamp

The new clamp improves the consistency of the sample probe mounting to provide more reliable/repeatable mixing action.

Power Measurement Requirements

Power requirements are defined for proper ground continuity and Neutral to Hot voltages.

Enhanced Optics PCB

The electronic potentiometers on the optics PCB may drift during instrument initialization. Pull-up resistors have been added to the PCB to eliminate the possibility of drift.

Metallic Label on Video Display PCB

A metallic label on this PCB may become loose and short circuit onto the CPU PCB. This label should be removed from all PCB's to prevent the occurance of this problem.

III. ADMINISTRATIVE NOTES:

International Service Managers should send forecasts requirements to their responsible logistic organization based on the number of affected instruments in their respective areas.

Special tools and parts described below should be ordered in advance of performing this TSB.

IV. SPECIAL TOOLS:

NOTE: The following special tools should be received in advance of performing this TSB. The following catalog number provides the special tools and cables required to perform this TSB:

| Catalog Number | Description | Qty |
|----------------------|-------------------------------|-----------------------|
| 2-83745-01 | Pre-TSB Tools & Parts | 1 |
| | | |
| This Pre-TSB Tools & | Parts includes the following: | |
| 2-82600-01 | Optic Alignment Tools | 1 (3 tools/catalog #) |
| | | |
| 2-83743-01 | Optics Alignment Software | 1 |
| 2-83737-01 | Pump Adjustment Tool | 1 |
| 2-84116-01 | Syringe Alignment Tool | 1 |
| 2-85204-01* | Cable, Sample Arm LLS | 1 |
| 2-85205-01* | Cable, Reagent Arm LLS | 1 |

^{*}These cables may be in the FSE kit and Depot locations. Verify the reliability of these cables following the procedure described below.

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V. PARTS:

| Catalog Number | Description | Qty |
|----------------|------------------------------|-----|
| 2-83746-01 | Alcyon Hardware Upgrade 2Kit | 1 |

The following parts will be included in the Alcyon Hardware Upgrade 2 Kit:

| Part Number | Description | Qty |
|---|--|-----|
| n/a | Syringe Drive Upgrade kit | 1 |
| n/a 2-83848-01 LN 01G87-01 LN 01G86-01 | This syringe upgrade kit includes the following: hardware for the lower support lower syringe support (2x) Reagent Syringe - 500 ul Sample Syringe - 50 ul | |
| 2-82810-01 | Sample Probe Clamp | 1 |
| 2-85010-01 | Bd, Optics | 1 |
| LN 7F70-02 | ISE Reference Tubing 0-0 | 1 |
| LN 7F71-02 | ISE Reference Tubing 9-9 | 1 |
| 2-84105-01 | ISE Reference Tubing #8 | 1 |
| LN 6F68-02 | Customer Letter and Operations Manual Insert | 1 |

The ISE tubing is packed in the TSB kit but is only to be installed on ISE instruments. For non-ISE instruments, these parts will not be used.

NOTE: The following catalog part numbers are no longer available.

2-83348-01 (Tubing, Reference Sol. Supply, Pump) has been replaced by 2-84105-01 ISE Reference Tubing #8

2-83347-01 (Tubing, Ref. Sol. Return w/check valve) has been replaced by LN 7F70-02 ISE Reference Tubing 0-0

2-83349-01 (Tubing, Ref. Sol. Supply, Electrode) has been replaced by LN 7F71-02 ISE Reference Tubing 9-9

2-85282-01 (Syringe lower bracket) has been replaced by 2-83848-01 lower syringe support REPLACED PARTS:

Return the 2-85010-01 Optics PCB through normal return parts process. Discard all other parts.

COMPATIBILITY:

n/a

VI. PROCEDURE:

MODIFICATION STEPS:

1. Turn the instrument power OFF.

Perform the following from the back of the instrument

Enhanced Optics PCB

1. Remove and replace the Optics PCB per RR-E1.9.

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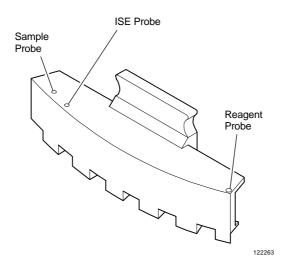
Metallic Label on Video Display PCB

- 1. Remove the Display Bd. per RR-E1.7.
- 2. Remove and discard the metallic label identified as "p/n 83272-101".
- 3. Reinstall the Display Bd. per RR-E1.7.

Perform the following from the front of the instrument

Optical Alignment Procedure

NOTE: The following procedure will replace VP-39, Reaction Carousel Alignment, from the Service Manual.



Optics Alignment Tool

Alignment of the Reaction Carousel

- 1. Perform VP-01 to shut down the instrument.
- 2. Insert the Optics Alignment Software disk into the floppy drive.
- 3. Turn the instrument power ON. The instrument will boot to the optics alignment software.
- 4. Enter the appropriate information regarding instrument serial number and operator name.
- 5. Load at least 9 new cuvettes on the cuvette loader, and press <Enter> when prompted. The instrument will load cuvettes in positions 1 8, then check the alignment of each cuvette position with respect to the optics assembly.

NOTE: The specification for the movement of the reaction carousel home sensor either clockwise or counterclockwise should be less than or equal to 0.38mm

The specification for the position of the cuvette with respect to the light beam must be less than the absolute value of 0.51.

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NOTE: To index the carousel to view the results of the next cuvette location, select "I" - Ignore.

If the alignment fails...... then..... Then..... in one or more cuvette adjust the home sensor either select "R" - Rerun. This will locations. CW or CCW according to the repeat the alignment test again. Note: To view the results of the direction displayed on the next cuvette location, select "I" screen. Ignore. in one cuvette location only select "V" - View. This will bring 1. Adjust the down sensor on the cuvette to the unload side of the cuvette loader to ensure the cuvette loader. proper cuvette loading. 1. Verify the cuvette is properly 2. Replace and report any seated in the carousel. cuvettes with physical 2. Remove and inspect the abnormalities. cuvette for breakage or physical 3. Adjust the abutments to abnormalities. proper cuvette holding. 3. Inspect the abutments for proper settings. Then select "R" - Rerun. This will repeat the alignment test

If the alignments passes..... then..... Then..... the software will automatically the instrument will unload the a report will be printed showing the pass criteria for all nine begin the alignment part of the cuvettes, and prompt the user to location. Maintain this printout install the optic alignment tools optics assembly. for verification that this ("black cuvettes") in positions 1. procedure has been completed. 4, and 7. Follow the screen prompts to manually install the black cuvettes. The system will now monitor the lamp intensity. Wait until the lamp is stable before proceeding. It may take approximately 15 minutes for the lamp to become stable.

again.

Alignment of the Optics Assembly

TOOL REQUIRED: 10mm box wrench and 3mm allen wrench.

When the lamp is stable, the system will calculate the gains for each wavelength.

The specifications for gains are as follows:

| Wavelength | Gain Specifications | |
|------------|---------------------|--|
| 340nm | 20 - 80 | |
| 380nm | 10 - 70 | |
| 405nm | 30 - 90 | |
| 500nm | 30 - 90 | |
| 550nm | 20 - 80 | |
| 600nm | 10 - 70 | |

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If the gains fail......

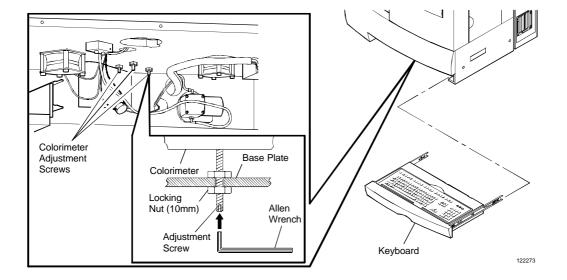
then.....

| Verify the lamp is seated properly. | Repeat the gain test. |
|--|-----------------------------|
| 2. Clean the fiber optics bundle. | s representation game recom |
| Measure the lamp voltage and adjust if | |
| necessary | |

If the gains pass, the system will index positions 1, 4, and 7 in front of the optics assembly and print a report identifying optical counts for front and back of the optical alignment tool for all wavelengths. The front and back of the optical alignment tool is identified as Position 1 and Position 2 respectively.

The optical count specification for all wavelengths is 10000 - 23000 counts.

The optics assembly will need to be adjusted if the optical counts are outside the specification. Locate the three adjustment screws as shown in figure below.



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If the optical counts fail,

Select A - Align. This will index the carousel to the first failed position. The front (Position 1) of the optical alignment tool will be positioned with front of optics assembly.

- Adjust one screw at a time. Loosen the lock nut and adjust the set screw using a 3mm allen wrench. Rotate CW to raise the counts, or CCW to decrease the counts.
- Adjust the screws to have approximately the same number of counts on all 6 wavelengths.
- Select O Offset to +32. This will index the carousel 32 steps to position the back (Position 2) of the optical alignment tool to be in front of the optics assembly.
- 4. Repeat steps 1 and 2.
- 5. Tighten the jam nuts when the adjustment is complete.

NOTE: The light beam is considered perpendicular to the alignment tool when the average counts from the FRONT and BACK are within range and are close to each other.

Then.....

Select T - Test. This will rerun the alignment test and print a report identifying optical counts for front and back of the optical alignment tool for all wavelengths.

When the alignment is complete, retain a copy of the final printed report as verification that the optics assembly has been properly aligned.

NOTE: To exit the alignment software program without making adjustments to the optics assembly select I - Ignore. Follow the screen prompts to remove the optical alignment tools from the reaction carousel.

Tube/Cup Detector Alignment Procedure

Tube/Cup Detector Verification

- 1. Install several tubes in random locations on the sample carousel.
- 2. From the Main Menu in Reglages, select:
 - E SAMPLE WHEEL
 - F DYNAMIC TEST TUBE/CUP

The system will automatically read the tube/cup status of each position and display the results.

- 3. Compare the displayed results with the tube position for correctness.
- 4. Press any key to stop.

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Tube/Cup Detector Alignment

Perform this procedure to align the detector and adjust the controller to properly detect a tube or cup.

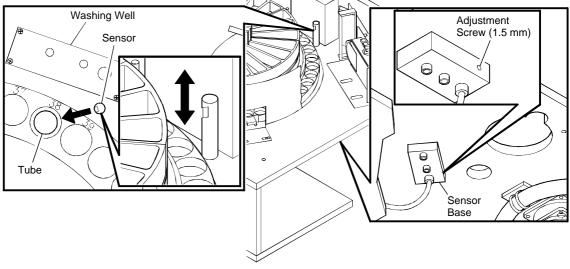
- 1. Place a 10 ml tube in position 38 of the sample carousel and position this tube in front of the tube/cup detector by selecting:
 - E SAMPLE WHEEL
 - A WHEEL INITIALIZATION
- 2. On the Tube/Cup Controller, adjust the following:
 - a) HYS (hysteresis) poteniometer fully clockwise. **NOTE: Rotate this poteniometer carefully. This poteniometer is easily broken.**
 - b) SENS (sensitivity) poteniometer fully clockwise.

Verify the **ORANGE LED** is ON.

- 3. Remove the tube and verify the **ORANGE** and **GREEN** LEDs are ON.
- 4. Re-insert the tube and adjust the SENS poteniometer counter-clockwise until the **RED** LED is ON and the **ORANGE** LED is OFF when the tube is removed.
- 5. With the tube installed, adjust the HYS poteniometer counter-clockwise until the **GREEN** LED is just coming ON (flashing) and the **ORANGE** LED is ON.

| | ORANGE LED | GREEN LED | RED LED |
|------|------------|--------------|---------|
| TUBE | ON | OFF/FLASHING | OFF |
| CUP | OFF | ON | ON |

6. Adjust the tube/cup detector either up/down or rotationally to optimize the signal to the controller as illustrated below. Tighten the adjustment screw when the alignment is correct.



122270

7. Repeat the verification to ensure tubes and cups are properly detected.

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Transfer Mechanism Up Sensor Adjustment

This procedure is written for the Sample Transfer Arm, but the same procedure can be performed for the Reagent Transfer Arm. The illustrations will identify the specific test point for each transfer mechanism.

- 1. Initalize the Sample Transfer Arm by selecting:
 - C Sample Transfer
 - B Complete Initialization of Module
 - C Preprogramed Up and Down Movements

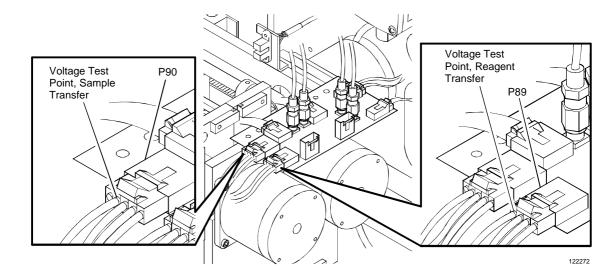
Set ABOVE to (A) Washing

Set Backward and Foreward to N (No)

Set First Movement to U (Up)

Press F10 to confirm

2. Measure the voltage for the up sensor PCB at connector P90 pin number 4. Measure the voltage throughout the entire procedure. When the arm is up, the voltage should be >3.0 volts, and the screen should display "Transfer Up".



Sensor Test Point

- 3. Step the transfer arm DOWN 1 step at time by selecting:
 - G Movement Up/Down by Steps, and enter the following information;

Set 'direction' = 1

Set 'number of steps' = 1

Set 'speed' = 100

Set 'backward/forward' = N

Set 'stop active' = Y

Press F10 to Confirm.

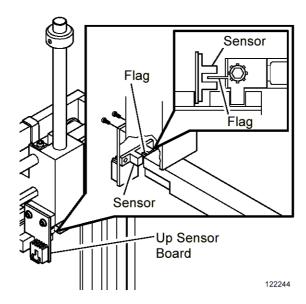
- 4. Repeat step 3 until the voltage is approximately 0.16 to 0.18 volts (the lowest value indicated by the voltmeter). Verify that "Transfer Not Up" is displayed on the screen.
- 5. Step the transfer arm UP 1 step at time by selecting:
 - G Movement Up/Down by Steps, and enter the following information:

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Set 'direction' = 0 Set 'number of steps' = 1 Set 'speed' = 100 Set 'backward/forward' = N Set 'stop active' = Y

Press F10 to Confirm

- 6. Repeat step 5 until the voltage is between 1.0 2.0 volts. Verify the screen displays "Transfer Not Up".
- 7. Repeat step 5 for one more step. The voltage should be a minimum of 3.0 volts and the screen should display "Transfer Up". If the voltage is between 2.0 - 3.0 volts and the screen displays "Transfer Up", the sensor PCB will require adjustment.
- 8. Adjust the sensor PCB by loosening the two screws that hold the sensor PCB and lightly tap the sensor PCB to reposition it, then tighten the screws. Very little movement of the sensor PCB is necessary to change the voltage to a minumin of 3.0 volts.



1. Repeat steps 1 - 8 to verify the sensor PCB is in the correct position.

^{**}Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.**

Wash Pump Volume Verification

A new tool has been released to make adjustments to the wash pump assembly easier to perform.



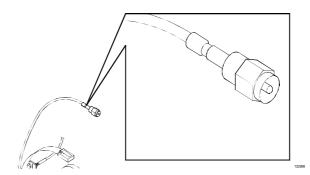
1. Perform VP - 28 Pump Volume Check to verify the proper volumes are displaced from the pump. Use the new tool and make adjustments if necessary.

Install the tool over the white adjustment knob and slide over the ribbed section for a better fit.

Liquid Level Sense Cable Inspection

NOTE: When the connector is crimped correctly, the center pin should be almost flush with the edge of the connector.

1. Inspect the liquid level sense cable for both the sample and reagent transfer arms. Unscrew the cable from the transfer connection PCB.



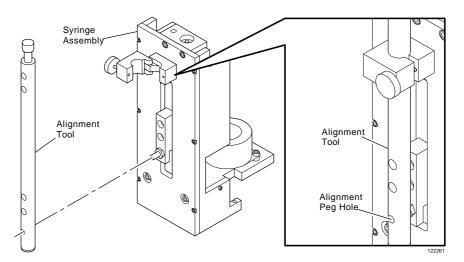
2. Gently pull the collar of each connector while holding the cable jacket. If the connector moves, the cable will need to be replaced. The transfer arm will need to be removed if the cable needs to be replaced.

^{**}Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.**

Syringe Drive Upgrade

A tool has been released to align the new lower support to the upper bracket. Before installing the lower support, verify the post is secured to the bracket.

- 1. Remove the lower bracket on the syringe drive, then install the new lower support. Do not tighten the screws.
- 2. Move the syringe drive to the bottom of its travel so that it is approximately 1.5mm (1/16") from the bottom of the slot in the front of the syringe drive. The syringe support must not contact the bottom of the slot.
- 3. Use the syringe alignment tool to align the lower bracket to the upper bracket as shown below. Tighten the screws to secure the lower bracket.

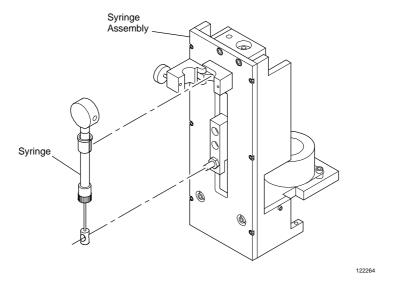


Alignment of Lower Bracket to Upper Bracket

^{**}Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.**

New Syringe Assemblies

1. Install the new syringes as shown below. Verify the circle "T" is secured to the each syringe.

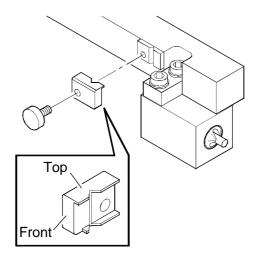


Installation of New Syringe

2. Adjust the syringe vertically with the syringe "T" so that the piston tip is 1 to 3 mm below the metallic ring.

New Sample Probe Clamp

1. Install the new sample probe clamp.



New Sample Probe Clamp

^{**}Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.**

Power Measurement Requirements

1. Verify the following power requirements at the wall outlet are met:

Line to Neutral GND to earth ground (i.e. water pipe)

For 110v 90 - 132 VAC less than 0.5 ohms For 220v 180 - 264 VAC less than 0.5 ohms

CHECKOUT:

NOTE: Use the optic alignment tool (black cuvette) in positions 1 and 9 of the reaction carousel to align the probes.

Perform the following:

- 1. Reaction Carousel Alignment per VP-39.
- 2. Reagent Transfer Arm Alignment per VP-40.
- 3. Reagent Carousel Alignment per VP-41.
- 4. Sample Transfer Arm Alignment per VP-42.
- 5. Sample Carousel Alignment per VP-43.
- 6. Mixer Adjustment per VP-44.
- 7. ISE Probe Arm Alignment per VP-i08.
- 8. ISE Electrode Offset Adjustments per VP-i09.
- 9. ISE Pump Volume Check per VP-i11.
- Perform Colorimeter Adjustment.
 From the Main Menu select Maintenance, then select Adjust Colorimeter and follow screen prompts.
- 11. Basic Run per VP-26. Perform an 18 replicate precision run on at least one non-ISE chemistry. Acceptance criteria is defined in the reagent application sheet for the control chosen. If the controls are out of range, then calibrate the assay.

MODIFICATION CONTROL STICKER UPDATE:

Mark off number 8 (eight) on the Modification Control Sticker.

END OF DOCUMENT

^{**}Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.**



ABBOTT ADD

TECHNICAL SERVICE BULLETIN

SUBJECT: TSB#: 119-007

Alcyon (R) Instrument Labels

ORIGINATOR: **Emil Jivan** PRODUCT:

APPROVED: Christie McCain 09-JUL-1999 ALCYON® 300 Rev 1 (119)

REF. ECN: none

Trademark: ALCYON (R) is a registered trademark of Abbott Laboratories.

IMPLEMENTATION:

Mandatory

Next Service Call

Optional

Instruments Requiring Modification: **See Administrative Notes**

TSB Part/Kit #: N/A

TSB Part(s) Availibility: **See Administrative**

<u>Notes</u>

TSB Tracking by Serial # required (MANDATORY TSB's ONLY)



Upgrade Time: .25 hrs

VerificationTime: .00 hrs

Total Mod. Time: .25 hrs

NOTE The instrument must be at TSB Level <u>n/a</u> prior to performing this TSB.

I. DISTRIBUTION:

Worldwide

II. PURPOSE:

The purpose of this TSB is to inform the field of serial number and extinction factor labels that have been printed using the wrong printer ribbon. The ink on the ribbon is not indelible and will cause the information on the label could be completely erased or smudged by using common laboratory disinfectants (acetone, isopropyl alcohol, or a diluent bleach solution). In some cases the printed information can be removed by scrapping or repeatedly wiping the label.

III. ADMINISTRATIVE NOTES:

The Instruments requiring this TSB include Serial Numbers enumerated in the chart below. Both labels will be packaged in a plastic bag and shipped directly to each Country Customer Service Manager. Each Country Customer Service Manager will be responsible to distribute the Label Package to the appropriate FSR per the following chart:

^{**}Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.**

| SN | Country | |
|------|-----------|--|
| 1562 | US (FL) | |
| 1563 | Hong Kong | |
| 1564 | Hong Kong | |
| 1580 | Singapore | |
| 1600 | Mexico | |
| 1601 | Brasil | |
| 1602 | Brasil | |
| 1603 | Mexico | |
| 1604 | Mexico | |
| 1605 | Brasil | |
| 1606 | Brasil | |
| 1607 | Brasil | |
| 1608 | Brasil | |
| 1609 | Mexico | |
| 1620 | Mexico | |

After this TSB has been completed destroy the old labels and mark off block # 7 on the TSB Modification Control sticker.

IV. SPECIAL TOOLS:

none

V. PARTS:

Both labels will be packaged in a plastic bag and shipped directly to each Country Manager per the above chart.

REPLACED PARTS:

none

COMPATIBILITY:

none

VI. PROCEDURE:

Verify the serial number and extinction factors on the new labels match the numbers on the labels that are to be removed.

MODIFICATION STEPS:

- 1. Remove the serial number label from the left side of the instrument.
- 2. Install the new serial number label in the same location from which the old one was removed
- 3. Remove the Extinction Factor label from inside the cuvette door.
- 4. Install the new Extinction Factor label in the same location from which the old one was removed.

CHECKOUT:

none.

MODIFICATION CONTROL STICKER UPDATE:

Mark off block #7 on the TSB Modification Control Sticker.

END OF DOCUMENT

^{**}Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.**



ABBOTT ADD

TECHNICAL SERVICE BULLETIN

SUBJECT: TSB#: 119-004

ALCYON (TM) System Software Ver 1.40d

ORIGINATOR: **Emile Diou** PRODUCT:

APPROVED: Christie McCain 9/22/98 ALCYON (TM) 300 Rev 1 (119)

REF. ECO: 12985-001

Trademark: ALCYON (TM) is a trademark of Abbott Laboratories

| IMPLEMENTATION | | |
|----------------|-------------------|--|
| C | Immediate | |
| | Next Service Call | |
| C | Next Failure | |
| C | Optional | |
| | | |

Instruments Requiring Modification:

See Administrative Notes

TSB Part/Kit #: LN 4E73-02

TSB Effectivity/

Part(s) Availability: 18-SEP-98

TSB Tracking by Serial # required (IMMEDIATE TSB's ONLY)



Upgrade Time: 0.25 hr

Validation Time: 0.25 hr

Total Mod. Time: 0.5 hr

NOTE The instrument must be at TSB Level N/A prior to performing this TSB.

I. DISTRIBUTION:

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

Worldwide.

II. PURPOSE:

This TSB address the release of Alcyon System Software ver 1.40d which resolves the lock-up to the instrument experienced during ISE calibration.

III. ADMINISTRATIVE NOTES:

This software is expected to be customer-installed. Field Repesentatives should verify installation of software during next service call and be sure #4 on the Modification Control Sticker is marked off.

Instruments requiring modification are: S/N: 1021-1025, 1058-1060, 1089-1093, 1122-1124, 1142, 1149, 1150, 1152, 1175-1178 and 1228.

International:

The appropriate quantities of software diskettes will be automatically shipped to each country/area. Each country/area will be responsible for translation of customer documentation and distribution and installation of the software.

U.S.A.:

Software will be shipped directly to each customer site.

IV. SPECIAL TOOLS:

N/A

V. PARTS:

^{**}Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.**

REPLACED PARTS:

N/A

COMPATIBILITY:

In the event a Hard Disc Drive, 2-85279-01, is replaced, it will be necessary to have the Rev. 1.4d software diskettes available to load the software on the new drive. The software may be ordered using the List Number above (diskettes, letter and instructions).

VI. PROCEDURE:

MODIFICATION STEPS:

Verify the Assay Configurations are correct. (Refer to Alcyon Reagent Application Manual.)

- 1. From the Main Menu, select <Configuration>, then <Assay/Diluent Config>.
- 2. Enter the Level 1 password (Found in Appendix E of the Operations Manual). Verify the Assay Configurations are correct (refer to Alcyon Reagent Application Manual).
- 3. If the Assay Configurations are not correct, restore the information from Methods Disk as described below.

Restoring Methods from Disk Procedure

- 1. Begin at the Main Menu.
- 2. Select <Stop/Shutdown>, then <Shutdown Instrument>.
- 3. Select CONFIRM and press <Enter>.

^{**}Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.**

- 4. Turn the power OFF at the main switch.
- 5. Place the Alcyon Methods Disk in the disk drive.
- 6. Turn the power ON at the main switch. The analyzer will load the program from the floppy disk.
- 7. Select the appropriate language version and press <Enter>.
- 8. Select <Restore> and press <Enter>.
- 9. There are three options for restoring assays back onto the hard drive:

- Complete

This option will load ALL methods from a previously saved file and overwrite all the methods stored on the instrument.

- Partial Manual

This option allows the operator to choose individual assays to be added to the instrument.

- Partial Auto

This option allows the instrument to automatically place a restored assay to the first free position in the list of assays.

Select **Complete or Partial (Manual or Auto)** restore. All previously saved files will be displayed. Proceed to the appropriate section below to restore the assays.

To Perform a Complete Restore

- Highlight the file to be loaded into the Alcyon Analyzer memory and press <Enter>. All assays will be loaded automatically, including all calibration and control configurations that were present when originally saved. The message "Restaure OK (Strike any key)" will appear at the bottom of the screen when the Restore is complete. Press <ESC> twice.
- 2. Select Quit to exit. The screen returns to the language choice screen.
- 3. Select #6 D.O.S.
- 4. When the A:\> appears:
 - a) Remove the floppy disk and store in a safe place.
 - b) Turn power OFF.
 - c) Wait 5-10 seconds, then turn the power ON.

^{**}Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.**

Any changes made will be present when the instrument has initialized.

To Perform a Partial Restore

- Decide whether you want the assay, when restored, to be placed at a specified number or position in the list, OR if you want the instrument to automatically assign the first free assay position. Press RESTORE and select one of the following choices:
 - Partial Manual allows the operator to define an assay number when an assay is restored to the instrument.
 - Partial Auto allows the instrument to automatically place an assay from the disk to the first free position in the list of assays on the hard drive.
- 2. Highlight the desired restore file to be loaded onto the instrument and press <Enter>.
- 3. Highlight the assay(s) to be loaded onto the instrument and press <Enter>. A list of the assays saved in this file will be displayed.
 - a) If the MANUAL option was chosen in the original method saving screen, the operator can select the position where the highlighted method will be placed. Type the desired destination number and press <Enter>.
 - b) If the AUTO option was chosen in the original method saving screen, the assay selected will automatically be added to the instrument memory at the first available position.
- 4. Press <F10> to confirm the loading of these tests. (If the error "ERROR CONVCHI7 NOT FOUND!!! on "C:\AL_300" is displayed as the bottom of the screen, press <F10> again.)
- 5. The message "Restaure OK. (Strike any key)" will appear at the bottom of the screen when the Restore is complete. Press <ESC> twice.
- 6. When finished, select Quit to exit. The screen will return to the language choice screen.
- 7. Select #6 D.O.S.
- 8. When the A:\> appears:
 - a. Remove the floppy disk and store it in a safe place.

^{**}Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.**

- b. Turn power OFF at the main switch.
- c. Wait 5 to 10 seconds, then turn the power back ON.

Any changes made will be present when the instrument has initialized.

CHECKOUT:

Verify the Assay Configurations are correct. (Refer to Alcyon Reagent Application Manual.)

- 1. From the Main Menu, select <Configuration>, then <Assay/Diluent Config>.
- 2. Enter the Level 1 password (Found in Appendix E of the Operations Manual). Verify the Assay Configurations are correct (refer to Alcyon Reagent Application Manual).
- 3. If the Assay Configurations are not correct, restore the information from Methods Disk as described below.

Restoring Methods from Diskette Procedure

- 1. Begin at the Main Menu.
- 2. Select <Stop/Shutdown>, then <Shutdown Instrument>.
- 3. Select Confirm and press <Enter>.
- 4. Turn the power OFF at the main switch.
- 5. Place the Alcyon Methods Diskette in the disk drive.
- 6. Turn the power ON at the main switch. The analyzer will load the program from the floppy diskette.
- 7. Select the appropriate language version and press <Enter>.
- 8. Select <Restore> and press <Enter>.
- 9. There are three options for restoring assays back onto the hard drive:

- Complete

This option will load ALL methods from a previously saved file and overwrite all the methods stored

on the instrument.

- Partial Manual

This option allows the operator to choose individual assays to be added to the instrument.

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

- Partial Auto

This option allows the instrument to automatically place a restored assay to the first free position in

the list of assays.

Select **Complete or Partial (Manual or Auto)** restore. All previously saved files will be displayed. Proceed to the appropriate section below to restore the assays.

To Perform a Complete Restore

1. Highlight the file to be loaded into the Alcyon Analyzer memory and press <Enter>. All assays will be loaded automatically, including all calibration and control configurations that were present when originally saved.

The message "Restaure OK (Strike any key)" will appear at the bottom of the screen when the Restore is complete. Press <ESC> twice.

- 2. Select Quit to exit. The screen returns to the language choice screen.
- 3. Select #6 D.O.S.
- 4. When the A:\> appears:
 - a) Remove the floppy disk and store in a safe place.
 - b) Turn power OFF.
 - c) Wait 5-10 seconds, then turn the power ON.

Any changes made will be present when the instrument has initialized.

To Perform a Partial Restore

- Decide whether you want the assay, when restored, to be placed at a specified number or position in the list, OR if you want the instrument to automatically assign the first free assay position. Press RESTORE and select one of the following choices:
 - Partial Manual allows the operator to define an assay number when an assay is restored to the instrument.

^{**}Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.**

- Partial Auto allows the instrument to automatically place an assay from the disk to the first free position in the list of assays on the hard drive.
- 2. Highlight the desired restore file to be loaded onto the instrument and press <Enter>.
- 3. Highlight the assay to be loaded onto the instrument and press <Enter>. A list of the assays saved in this file will be displayed.
 - a) If the MANUAL option was chosen in the original method saving screen, the operator can select the position where the highlighted method will be placed. Type the desired destination number and press <Enter>.
 - b) If the AUTO option was chosen in the original method saving screen, the assay selected will automatically be added to the instrument memory at the first available position.
- 4. Press <F10> to confirm the loading of these tests. (If the error "ERROR CONVCHI7 NOT FOUND!!! on "C:\AL_300" is displayed as the bottom of the screen, press <F10> again.)
- 5. The message "Restaure OK. (Strike any key)" will appear at the bottom of the screen when the Restore is complete. Press <ESC> twice.
- 6. When finished, select Quit to exit. The screen will return to the language choice screen.
- 7. Select #6 D.O.S.
- 8. When the A:\> appears:
 - a. Remove the floppy disk and store it in a safe place.
 - b. Turn power OFF at the main switch.
 - c. Wait 5 to 10 seconds, then turn the power back ON.

Any changes made will be present when the instrument has initialized.

MODIFICATION CONTROL STICKER UPDATE:

Mark off number 4 (four) on the Modification Control Sticker.

END OF DOCUMENT

^{**}Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.**



ABBOTT ADD

TECHNICAL SERVICE BULLETIN

SUBJECT: TSB#: 119-003B

ALCYON (TM) 300 Hardware Upgrade

ORIGINATOR: Emile Diou/Gary Tompkins
APPROVED: Christie McCain 9/18/98

PRODUCT:

ALCYON (TM) 300 Rev 1 (119)

REF. ECO: ECN#12985-004,12985-006,

12985-009,12911-060, 12985-012,

NCMR#376151, 376155

Trademark: ALCYON (TM) is a trademark of Abbott Laboratories

| IMPLEMENTATION: | TSB Part/Kit #: 2-83597-01 | Upgrade Time: 5 hrs. |
|---|--|---|
| Immediate Next Service Call | TSB Effectivity/ Part(s) Availability: 18-SEP-98 | Validation Time: 3 hrs. |
| Next Failure | TSB Tracking by Serial # required | Total Mod. Time: 8 hrs. |
| Optional | (IMMEDIATE TSB's ONLY) | **NOTE** The instrument |
| Instruments Requiring Modification: See Administrative Notes. | YES NO | must be at TSB Level <u>n/a</u> prior to performing this TSB. |

^{**}Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.**

I. DISTRIBUTION:

Worldwide.

II. PURPOSE:

This TSB addresses:

- AC Cable Connector Upgrade for UL and CE Mark Requirement
 The requirement states that a tool must be used to access any area where there is exposure to AC voltage. A cable tie, requiring a tool for removal, will be added to secure the connector J198.
- New Reaction Carousel Abutments
 New Outer Abutments will improve the loading of cuvettes into the Reaction Carousel.
 Additionally, the Inner Abutments will be replaced due to inconsistent settings on the ball springs (part of the inner abutment) on existing instruments. The tension of the ball springs of the replacement abutments have been carefully preset at the Factory.
- Improved Cuvette Load/Unload Module Alignment
 A tool has been released to improve the FSE's ability to align parts of the Cuvette Load/Unload Module and improve the alignment of the Loader to the Reaction Carousel.

^{**}Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.**

Europe, Africa and the Middle East will use an BBC-1500 (LN 06E96-50) Line Conditioner provided by Delkenheim. Delkenheim will coordinate this effort.

New Probes

The Sample and Reagent probes in this TSB kit have been quality checked for proper functionality. The new sample and reagent probes are packaged with a blue sticker.

- Customer Information Package which includes:
 - 1) Alcyon Product Enhancement Kit

This customer letter informs the customer about the enhancements that are being performed by the Field Service Engineer. This customer letter also includes a "Replacement Parts Request Form" to ensure that all parts removed from the customer site will be replaced.

2) New Sample Probe Stylet

This customer letter describes the new stylet which is now released to clear any foreign objects that may be in the end of the Sample Probe. A sample probe stylet is included in this kit.

3) New Sample Probe Stylet Instructions

This customer letter describes the procedure for cleaning the Sample Probe using the Sample Probe Stylet

4) New Sample Cup Adapters and Tools

This customer letter describes the new Sample Cup Adapters and Adapter Removal Tool. It also describes the procedure for removing the adapters using the tool. New sample cup adapters and tools are included in this kit.

III. ADMINISTRATIVE NOTES:

International Service Managers should send forecasts requirements to their responsible logistic organization based on the number of affected instruments in their respective areas.

Instruments requiring modification are: S/N: 1019-1025, 1058-1060,1089-1093,1122-1124,1142,

^{**}Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.**

1149,1150,1152

For the instrument population order 2-83597-01, Alcyon 300 TSB-003 Kit.

For Service Kit and Depot Kit population, order desired quantity of parts listed below to replace current stock.

The Line Conditioners will automatically shipped to each based on instrument population.

TSB Upgrade Tracking

Each area is required to update the Alcyon Customer System Engineering group in Dallas as to the completion status of this TSB.

IV. SPECIAL TOOLS:

The special tools required are listed below. These tools are included in this TSB Kit.

| Part Number | Description | Quantity |
|-------------|--|----------|
| 2-83593-01 | Abutment Threaded Rod Tool | 1 |
| 2-83596-01 | Abutment Alignment Tool | 1 |
| 2-83440-01 | Cuvette Load/Unload Module Alignment Too | l 1 |

The following tools are recommended to perform the upgrade to the reaction carousel abutments:

- 1. #1 phillips (cross-point) screwdriver
- 2. 1/8" slotted screwdriver

V. PARTS:

^{**}Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.**

NOTE: Spare hardware has been included in this kit for the Sample Carousel top ring and the inner and outer abutments.

| Part Number | Description | Quantity |
|-------------|----------------------------------|-------------------------------|
| 2-83595-01 | Alcyon 300i TSB-003 kit | 1 |
| LN 06E99-01 | PowerVar Line Conditioner (110v) | 1 (not shipped with this TSB) |
| LN 06E99-02 | PowerVar Line Conditioner (220v) | 1 (not shipped with this TSB) |
| LN 06E96-01 | European Line Conditioner (220v) | 1 (not shipped with this TSB) |

The Alcyon 300 TSB-003 Kit includes:

| Part Number | Description | Quantity |
|-------------|---|----------------------------|
| LN 05D42-01 | Alcyon Sample Probe | 1 |
| LN 05D44-01 | Alcyon Reagent Probe | 1 |
| LN 06E65-01 | Alcyon Sample Probe Stylet (10 ea.) | 1 |
| LN 02E16-01 | Sample Cup Adapters (10 ea.) w/Tool (2 ea.) | 1 |
| 2-83593-01 | Abutment Threaded Rod Tool | 1 |
| 2-83596-01 | Abutment Alignment Tool | 1 |
| 2-82694-01 | Inner Abutment | 10 |
| 2-82695-01 | Outer Abutment | 10 |
| 2-83599-01 | Screw, Panhead, (slotted) M2.5x8 | 10 (outer abutment screws) |

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| 2-83598-01 | Screw, Panhead, (Phillips), M2.5x12 | 10 (outer abutment screws) |
|------------|-------------------------------------|--------------------------------|
| 2-83590-01 | Screw, Flat head (Phillips), M3x20 | 10 (smpl crsl top ring screws) |

n/a Cable Tie, 8.2" (21cm) 2

Service Kit and Depot Kit Impact:

DO NOT use the Alcyon Sample Probe (LN 05D42-01) and Alcyon Reagent Probe (LN 05D44-01) currently in your FSE Kit, Depot, or at the customer site. Discard these probes.

REPLACED PARTS:

Destroy all collected parts (from the customer) and replaced parts (from the instrument). Use the form in the letter account for all customer collected parts and ensure the customer receives the correct amount of replaced parts.

COMPATIBILITY:

Do not use the Alcyon Sample Probe (LN 05D42-01), and Alcyon Reagent Probe (LN 05D44-01) in your FS Kit.

VI. PROCEDURE:

NOTE: Wear gloves and safety glasses while in the Laboratory.

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

MODIFICATION STEPS:

^{**}Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.**

UPGRADES PERFORMED BEHIND THE INSTRUMENT

AC Cable Connector Upgrade

- 1. Perform Shutdown per VP-01, and remove the power cord.
- 2. Remove Rear Cover.
- 3. Install the cable tie (8.2") around connector J198 as shown in the Figure 1.

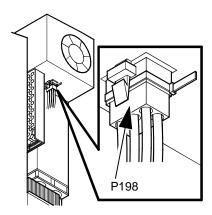


Figure 1.

^{**}Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.**

4. Cut the excess cable tie material flush with the connector.

UPGRADES PERFORMED IN FRONT OF THE INSTRUMENT

New Reaction Carousel Abutments

Replacement and Adjustment of Reaction Carousel Abutments

NOTE: During this procedure, if any object is dropped into the Reaction Area (under the Cuvette Carousel) remove it immediately. Objects can get into the Reaction Heater Fan causing it to stop turning and the instrument to overheat.

NOTE: Use the abutment tool provided in the TSB kit for only one instrument. It is made from aluminum and may be bent or damaged.

NOTE: Extra abutment hardware in included in the kit. Use if necessary.

Replacing the Abutments

- 1. From the Stop / Shutdown submenu, select Shutdown Instrument and turn instrument power OFF.
- 2. Remove the snap-on Front Cover (bezel) and right side Reaction Area Cover. Refer to PL-G1.
- 3. Remove the Top Cover and two support frames.

^{**}Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.**

- 4. Remove the Load/Unload Module per RR-A4.2.
- 5. Perform the Cuvette Carousel Support Alignment per VP-46.
- Remove all cuvettes from the Reaction Wheel.

NOTE: The following Steps must be performed at each position while located over the Cuvette Carousel Support. See Figure 2. This will prevent damage to the flexible carousel when pressing on the carousel to loosen and tighten screws.

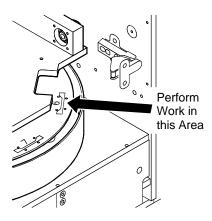


Figure 2.

7. Beginning with position 1 at the load area, remove the left screw of the Outer Abutment. Loosen

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

the right screw.

8. As shown in Figure 3, rotate the abutment and screw the threaded rod tool into the exposed hole a few turns. While holding abutment with the rod, unscrew and remove the remaining screw. Retain the screws.

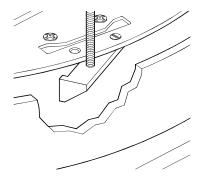


Figure 3.

- 9. Repeat the process described in Steps 6 and 7 to remove the Inner Abutment.
- 10. Refering to Figure 4, remove any burrs from the beveled edge at the outer edge of the slot in the carousel using a small flat blade screwdriver or small flat file. Do this for each position whether burrs are visible or not. Removing the burrs will create some fiberglass dust on the lower plate. Remove any of the dust from the lower plate with a damp towel.

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NOTE: Burrs left on this part of the carousel will cause cuvettes not to load properly.

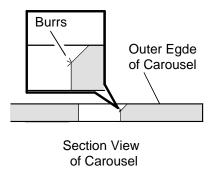
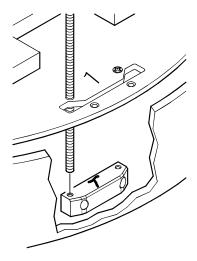


Figure 4.

- 11. Starting with position 1, carefully place one of the new Inner Abutments onto the lower plate under the Reaction Wheel with the white "T" facing UP and align the abutment under the slot in the carousel. Insert the threaded rod through the left screw hole and into the left hole of the abutment as shown in Figure 5a.
- 12. As shown in Figure 5b. Raise the abutment up to the carousel and secure with the right screw but do not tighten it. Remove the rod and install the left screw but do not tighten it.

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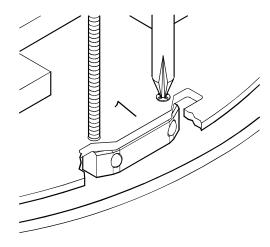
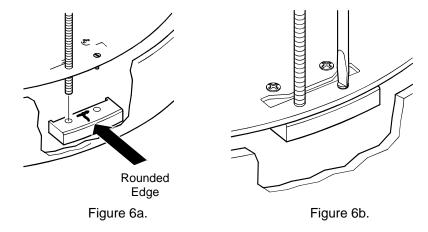


Figure 5a.

Figure 5b.

- 13. Carefully place one of the new Outer Abutments onto the lower plate under the Reaction Wheel with the white "T" facing UP and align the abutment under the slot in the carousel. Insert the threaded rod through the left screw hole and into the left hole of the abutment as shown in Figure 6a.
- 14. As shown in Figure 6b, raise the abutment up to the carousel and secure with the right screw but do not tighten it. Remove the rod and install the left screw but do not tighten it.

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15. Repeat Steps 7 through 11 for the remaining eight carousel positions.

Adjusting the Abutments for Proper Fit of Cuvette

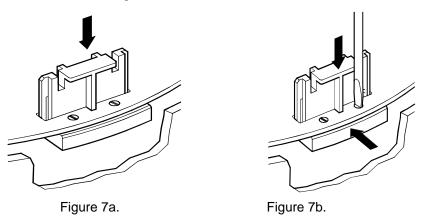
1. Install the abutment alignment tool into Position 1 as shown in Figure 7a. The tool must be seated flush with the surface of the carousel.

NOTE: When properly seated, the tool should not move from side to side. It is important that the tool remain seated in this position throughout the alignment.

2. Holding the tool straight down with the index finger, push the outer abutment inward against the

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tool with the thumb of the same hand. The tool must be remain vertical. Tighten the two outer abutment screws. Refer to Figure 7b.



click here to continue to Section 2 --> 🔝

CHECKOUT:

MODIFICATION CONTROL STICKER UPDATE:

END OF DOCUMENT

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TSB 119-003A Section 2

click here to return to Section 1 --> 🗎



3. Remove the tool and verify that the inner edge of the abutment is flush (even) with the edge of the slot as shown in Figure 8. If not, repeat Steps 1 and 2 as necessary.

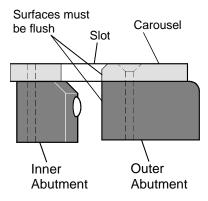


Figure 8.

4. Reinsert the alignment tool. Refering to Figure 9, insert the short end of a long "L" allen wrench (5 in/12mm) through the hole that is normally used to access the cuvette carousel support. With the

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tip of the wrench at the center of the inner abutment, pull the abutment outward with the wrench, and tighten the two screws. The tool must remain vertical.

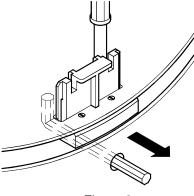


Figure 9.

- 5. Remove the alignment tool and insert a new cuvette into the slot. There should be some resistance installing the cuvette and it should not be loose once in the carousel. It should be snug, but not tight. Readjust the inner abutment as necessary to achieve a proper fit of the cuvette.
- 6. Repeat Steps 1 through 5 for the remaining eight positions.
- 7. Perform the Cuvette Carousel Support Alignment per VP-46 again to ensure the support roller has not changed during the installation of the abutments.

NOTE: If this support requires alignment, the down sensor on the Load/Unload module may

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require adjustment. See Cuvette Load/Unload Module Alignment below.

Cuvette Load/Unload Module Alignment

NOTE: Some Cuvette Load/Unload Modules have spacers (washers) behind the load side rails. If the spacers are present, remove them one at a time. After all four spacers are removed, verify that space between the rails is measures at 34mm using the Cuvette Alignment Tool. Refer to Figure 10.

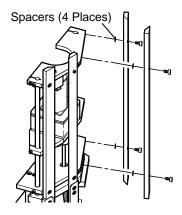


Figure 10.

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NOTE: The Cuvette Load/Unload Module Alignment Tool is used to adjust the rails to 34mm and to aid in the alignment of the Loader assembly to the reaction carousel. See Figure 11.

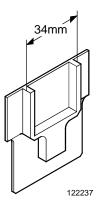


Figure 11.

1. Verify all dimensions are met as shown in Figure 12.

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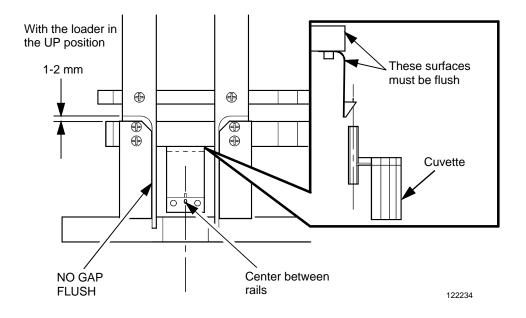


Figure 12.

Use the Cuvette Load/Unload alignment tool, to verify and adjust (if necessary) the 34mm gap
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between the unload rails as shown in Figure 13. Loosen the screws and push the rails towards the tool, then tighten the screws. Repeat this procedure at the top and bottom of the unload rails.

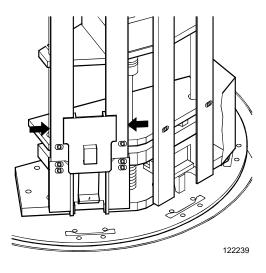


Figure 13.

3. Verify the cuvette cam pusher is centered between the load rails as shown in Figure 14.

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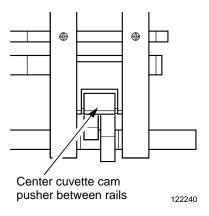


Figure 14.

4. Use the Cuvette Load/Unload alignment tool, to verify and adjust (if necessary) the 34mm gap between the load rails as shown in Figure 15. Loosen the screws and push the rails towards the tool, then tighten the screws. Repeat this procedure at the top and bottom of the load rails.

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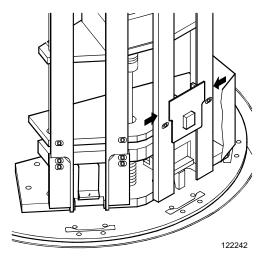


Figure 15.

Reinstallation and Alignment of Cuvette Load/Unload Module

NOTE: Prior to aligning the Cuvette Load/Unload Module, it is necessary to check the alignment of the carousel to the Optics and make any necessary adjustment using the Cuvette Carousel Home Sensor. IF ANY ADJUSTMENT IS MADE, IT WILL BE NECESSARY TO VERIFY/REALIGN THE REAGENT AND SAMPLE TRANSFER ARMS, THE ISE PROBE, THE

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REAGENT AND SAMPLE CAROUSELS AND THE SAMPLE BARCODE READER.

- 1. Reinstall Cuvette Load/Unload Module but do not tighten the mounting screws.
- 2. Perform the Reaction Carousel Alignment, VP39. Adjust as necessary. If any adjustment is made, it will be necessary to verify/realign the Reagent and Sample Transfer Arms, the Reagent and Sample Carousels, and the Sample Barcode Reader.
- 3. Once determined that the Carousel is aligned with the Optics, proceed to align the Cuvette Load/Unload Module following the Steps below.
- 4. Plug in the AC cord and turn the main power switch ON.
- 5. Enter into the Diagnostics Software (Reglages) by selecting Option 2 from the boot-up options menu.
- 6. Manually raise the Sample and Reagent Transfer Arms. The motor should already be disengaged at this time.
- 7. From the main Diagnostics main menu, select: I. CUVETTES LOADER
 - H. MOTORS DISENGAGING
 - A, WHEEL INITIALISATION the Reaction Carousel will initialize
- 8. Install the Cuvette Load/Unload Alignment Tool in the reaction carousel in the position under the loading rails. Move the Loader/Unload assembly until the load rails are flush with the tool as shown in Figure 16. Loosely tighten the screws. Remove the tool and insert into the reaction carousel in the position under the unload rails. Move the Loader/Unload assembly until the unload rails are flush with the tool.

NOTE: The rails may require additional positioning after the Load/Unload Module is installed.

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Adjust the rails and/or the entire assembly to obtain the optimum position for proper cuvette loading.

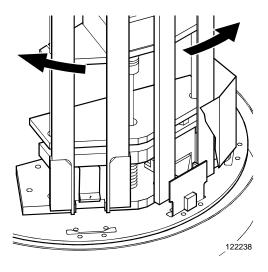


Figure 16.

9. Load one cuvette into the carousel position directly under the unload side of the Cuvette Load/Unload Module. Manually turn the shaft of the L/U Module to lower the unload hook down to the cuvette. Adjust the position of the L/U Module so the two white plastic pieces enter the cuvette

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evenly between the Vs on either side of the cuvette, being sure they do not get caught on the cuvette. Also, verify that the unload hook slips into the hole in the top of the cuvette and is centered. To raise the carriage, select C, LOADER UP. Select H, to again disengage the motor.

Insert a cuvette into the Load side rails. Again, manually turn the motor shaft to lower the cuvette into the carousel. Adjust the position of the loader so the cuvette fits into the slot without hitting the carousel.

The criteria described above must be met for both the Load and Unload sides to acheive an acceptable alignment. Further verification of the abutment modification and Cuvette Load/Unload Module positioning will be performed in the **CHECKOUT** section of this TSB.

Replacement of the Sample and Reagent Probes

1. Remove and replace the Sample and Reagent probes. Verify the streams from the sample and reagent probes are straight (i.e. not spraying or erratic).

Power Measurement Requirements

1. Verify the following power requirements at the wall outlet are met:

| | Line to Neutral | GND to earth ground (i.e. water pipe) |
|----------|-----------------|---------------------------------------|
| For 110v | 90 - 132 VAC | less than 0.5 ohms |
| For 220v | 180 - 264 VAC | less than 0.5 ohms |

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CHECKOUT:

Verification

Perform the following:

- 1. Pump Volume Check per VP-28. Verify the stream from both probes are straight (i.e. not spraying or erratic).
- 2. Cuvette Carousel Support Alignment per VP-46.
- 3. Reaction Carousel Alignment per VP-39.
- 4. Reagent Transfer Arm Alignment per VP-40.
- 5. Reagent Carousel Alignment per VP-41.
- 6. Sample Transfer Arm Alignment per VP-42.
- 7. Sample Carousel Alignment per VP-43.
- 8. Mixer Adjustment per VP-44.
- 9. Load/Unload Module Alignment per VP-45 and the Abutment and Load/Unload Module Position Verification described below.
- 10. Basic Run per VP-26. Perform a 20 replicate precision run on at least one chemistry. Acceptance criteria is defined in the reagent application sheet for the control chosen.

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Abutment and Load/Unload Module Position Verification

- 1. Cycle power to the analyzer and at the boot-up options screen (with options 1 through 5) select option 2 to enter into the Diagnostic Software.
- 2. Manually raise the Sample and Reagent Transfer Arms.
- 3. From the main Diagnostics menu, select:
 - I, CUVETTES LOADER
 - H, MOTORS DISENGAGING
 - A, WHEEL INITIALISATION the Cuvette Carousel will initialize
- 4. Fill the load side of the Load/Unload Module with cuvettes.
- 5. At the CUVETTES LOADER submenu, select:
 - J. SECTORS REPLACEMENT PROGRAMING

NOTE: During the following verification, in the event of a cuvette jam, IMMEDIATELY TURN THE MAIN POWER SWITCH OFF. Additionally, note that the cuvette full and empty sensors are not functional during this program. If any cuvettes are broken, remove the broken peices from above and below the carousel.

6. Enter values as follows: First sector 1 (press Enter)

Number of sectors 20 (press Enter)

7. Press F10 to begin the cycle. During the cycling program, transfer cuvettes from the unload side to the load side until the instrument stops after loading the 20 cuvettes. If at any time the loading or unloading does not appear to be proper (i.e., popping, crunching, etc..) press S to Stop to

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cycling.

8. Repeat Steps 6 through 8 until a total of 100 cuvettes are loaded with NO "crashes".

NOTE: It is important to observe all 100 cuvettes as they are loaded into the carousel to ensure proper loading. If any cuvette crashes occur, align and adjust the abutments and/or L/U Module until 100 cuvettes can be loaded without crashing.

9. Reinstall all the support brackets and covers previously removed.

MODIFICATION CONTROL STICKER UPDATE:

Mark off number 3 (three) on the Modification Control Sticker.

END OF DOCUMENT

Double click here to return to Section 1 --> 🛅

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ABBOTT ADD

TECHNICAL SERVICE BULLETIN

SUBJECT: TSB#: 119-003A

ALCYON (TM) Hardware Upgrade

ORIGINATOR: Emile Diou/Gary Tompkins PRODUCT:
APPROVED: Christie McCain 9/8/98 ALCYON (TM) 300 Rev 1 (119)

REF. ECO: ECN#12985-012,

NCMR#376156, 376157

Trademark: ALCYON (TM) is a trademark of Abbott Laboratories

| IMPLEMENTATION: | TSB Part/Kit #: 2-83597-01 | Upgrade Time: 5 hrs | |
|--|--|--|--|
| Immediate Next Service Call | TSB Effectivity/ Part(s) Availability: 8/24/98 | Validation Time: 3 hrs | |
| Next Failure | TSB Tracking by Serial # required | Total Mod. Time: 8 hrs | |
| Optional | (IMMEDIATE TSB's ONLY) | **NOTE** The instrument must be at TSB Level n/a | |
| Instruments Requiring | • YES | prior to performing this TSB. | |
| Modification: See Administrative Notes | O NO | | |
| | | | |

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| | DISTRIBUTION: |
|------|-----------------------|
| II. | PURPOSE: |
| III. | ADMINISTRATIVE NOTES: |
| IV. | SPECIAL TOOLS: |
| ٧. | PARTS: |
| | REPLACED PARTS: |
| | COMPATIBILITY: |

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| | | | | | _ |
|-----|----|----|----|----|----|
| VI. | PR | OC | ΕD | UR | E: |

MODIFICATION STEPS:

CHECKOUT:

MODIFICATION CONTROL STICKER UPDATE:

END OF DOCUMENT

^{**}Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.**



ABBOTT ADD

TECHNICAL SERVICE BULLETIN

SUBJECT: TSB#: 119-003

ALCYON (TM) Hardware Upgrade

ORIGINATOR: Emile Diou/Gary Tompkins
APPROVED: Christie McCain 8/21/98

PRODUCT: ALCYON (TM) 300 Rev 1 (119)

REF. ECO: ECN#12985-012,

NCMR#376156, 376157

Trademark: ALCYON (TM) is a trademark of Abbott Laboratories

| IMPLEMENTATION: | TSB Part/Kit #: 2-83597-01 | Upgrade Time: 4 hrs |
|--|---|---|
| Immediate Next Service Call | TSB Effectivity/ | Validation Time: 2 hrs |
| Next Failure | Part(s) Availability: Obsolete TSB Tracking by Serial # required | Total Mod. Time: 6 hrs |
| Optional | (IMMEDIATE TSB's ONLY) | **NOTE** The instrument |
| Instruments Requiring | • YES | must be at TSB Level <u>n/a</u> prior to performing this TSB. |
| Modification: See Administrative Notes | ONO | |
| | | |

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THIS TSB OBSOLETED BY TSB 119-003A.

| I. | DISTRIBUTION: |
|------|---------------------------------|
| II. | PURPOSE: |
| III. | ADMINISTRATIVE NOTES: |
| IV. | SPECIAL TOOLS: |
| V. | PARTS: |
| | |
| | REPLACED PARTS: |
| | REPLACED PARTS: COMPATIBILITY: |

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| | | _ | | |
|-----|----|--------|-----|------|
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| vı | PK | | -11 | IK E |
| | | | | |

MODIFICATION STEPS:

CHECKOUT:

MODIFICATION CONTROL STICKER UPDATE:

END OF DOCUMENT

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ABBOTT ADD

TECHNICAL SERVICE BULLETIN

SUBJECT:

Misaligned Cuvette Loader/Unloader Assembly

ORIGINATOR: Emile A. Diou

APPROVED: Christie McCain (7/1/98)

ALCYON (TM) 300 Rev 1 (119)

Trademark: ALCYON (TM) is a trademark of Abbott Laboratories

IMPLEMENTATION: Immediate Next Service Call Next Failure Optional

Instruments Requiring Modification: S/N 0001 thru 0074

TSB Part/Kit #: 2-82655-01

TSB Effectivity/

Part(s) Availability: 26-JUN-98

TSB Tracking by Serial # required (IMMEDIATE TSB's ONLY)



Upgrade Time: 0.5 Hr.

REF. ECN: 12774-025

TSB#: 119-001

PRODUCT:

Validation Time: 0.5 Hr.

Total Mod. Time: 1.0 Hr.

NOTE The instrument must be at TSB Level <u>n/a</u> prior to performing this TSB.

. DISTRIBUTION:

Worldwide

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II. PURPOSE:

The purpose of this TSB is to inform the field that the cuvette loaders were not properly assembled in manufacturing. As a result, the cuvettes may not be properly inserted into the reaction carousel causing cuvette crashes. The abutments used to hold the cuvettes in the reaction carousel may be too tight and may cause the cuvettes not to be inserted properly.

III. ADMINISTRATIVE NOTES:

Instrument serial numbers 1003, 1005, 1013, 1075 - 1103, 1105, 1108 and 1110 were released from the factory with correctly assembled cuvette loaders, but the TSB sticker was not marked. Mark off the block #1 on the TSB Modification Control Sticker on the next service call for these instruments.

The International Service Manager should send forecast requirements to their responsible logistic organization based on the number of instruments affected in your area.

IV. SPECIAL TOOLS:

None.

V. PARTS:

Catalog Number Description Quantity

2-82655-01 Cuvette Loader Assy. 1

SERVICE KIT IMPACT:

None.

REPLACED PARTS:

Return old cuvette loaders for rework using normal return goods channels. Mark the return ticket as TSB 119-001.

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COMPATIBILITY:

N/A

VI. PROCEDURE:

REMOVAL AND REPLACEMENT:

Remove and replace the cuvette loader/unloader per R&R A4.2 in the Alcyon Service Manual.

MODIFICATION STEPS:

1. Modify a cuvette segment by removing the top part as shown in Figure 1. This will allow you to access the abutments screws in the reaction carousel.

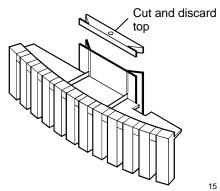


Figure 1.

2. Check the abutments in the reaction carousel by inserting the above a modified cuvette in each of the 9 locations of the reaction carousel. Adjust the abutments so the cuvettes are snug, not tight, in the carousel. See Figure 2.

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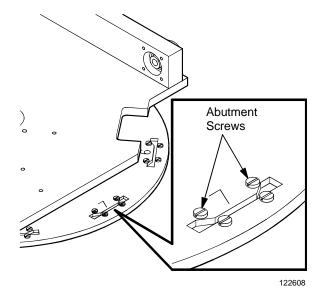


Figure 2.

CHECKOUT:

VERIFICATION:

Perform VP-45, Load/Unload Alignment, per the Alcyon Service Manual.

MODIFICATION CONTROL STICKER UPDATE:

Mark off the block #1 on the TSB Modification Control Sticker.

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END OF DOCUMENT

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