

**ABBOTT
ADD****INDEX
INSTRUMENT SERVICE ADVISORY**

PRODUCT:

ALCYON (TM) 300 Rev 0 (121)

DATE:

10-FEB-1999

ISA #	SUBJECT	EFFECTIVITY DATE
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121-002	Software Issue in LIS List Loading and List Run Modes
121-001	Temperature Verification and Adjustment Procedure

09-FEB-1999
21-SEP-98

PENDING -
CANCELLED -
INCORPORATED -
OBSOLETE -
COMPLETE -

ISA index number has been reserved for a future ISA.
ISA index number is cancelled.
ISA was incorporated into another document or manual.
ISA no longer applies.
ISA is complete.

END OF DOCUMENT



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SUBJECT: Software Issue in LIS List Loading and List Run Modes	ISA#: 121-002
ORIGINATOR: Gary Tompkins	PRODUCT: ALCYON (TM) 300 Rev 0 (121)
APPROVED: Christie McCain 10-FEB-1999	EFFECTIVITY DATE: 09-FEB-1999

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An issue has been identified with Alcyon System Software Ver 261095/0142 in the List Loading and List Run Modes. This issue may allow for samples pipetted from one patient to be reported as the results of a different patient, i.e., mismatching the results. The potential for this mismatch occurs ONLY when the ALCYON is used in the LIS List Loading and List Run Modes. This problem will be resolved in the next release of system software, currently scheduled for later this year. See below for the workaround options for this issue.

Products Affected:

ALCYON 300 (110V) Analyzer LN 04D66-01

ALCYON 300 (220V) Analyzer LN 04D67-01

ALCYON Software Version Ver 261095/0142 LN 05D64-01

Issue:

A patient sample may be pipetted from one sample tube and be reported as the results of a different patient. The potential for this to occur exists only under following combination of conditions:

1. The List Loading and Run Mode is selected to download the work list from the laboratory computer to the ALCYON Analyzer.

AND

2. The ALCYON Analyzer is configured to use two or more Reagent Carousels.

AND

3. No Chemistry test is ordered for a patient sample on the current carousel.

NOTE: If the customer is not currently operating under these conditions, the patient results are not impacted.

Necessary Actions To Be Taken:

1. Do not use the List Loading and Run Mode.

2. If the Alcyon software is configured as noted above: Presently, the only workaround is to reconfigure the Alcyon to use one of the two modes listed below. It may be necessary to contact the customer's LIS vendor to determine which of the options listed below are compatible with their LIS. Specific changes to ALCYON parameters will need to be determined by the LIS vendor.

ID Mode Run (Query mode)- In this mode, the Sample ID is either manually entered on the Analyzer (for non-bar coded tubes or cups) or is read from the bar code label on the tube. Using the Sample ID, the Analyzer then queries the laboratory computer for the tests to be run. The laboratory computer downloads the tests; the Analyzer runs the tests, then the results are uploaded to the laboratory computer.

The instructions for using the ID Mode can be found in the ALCYON Operations Manual, Section 5, *Operating Instructions: Running Tests Downloaded from a Laboratory Computer* in the section titled ID Mode Run.

Unidirectional Mode - When using the Unidirectional Mode, the Sample IDs and tests are manually entered on both the ALCYON Analyzer and the laboratory computer. The Analyzer runs the tests, then uploads the results upon completion. The instructions for using the Unidirectional Mode can be found in the ALCYON Operations Manual, Section 5, *Operating Instructions: Ordering and Running Tests* in the section titled *Entering Tests Manually (Deferred and STAT)*.

If you have any questions regarding this Instrument Service Advisory please contact your Area Specialist or WWCS CSE.

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SUBJECT: Temperature Verification and Adjustment Procedure	ISA#: 121-001
ORIGINATOR: Gary V. Tompkins/Emile Diou	PRODUCT: ALCYON (TM) 300 Rev 0 (121)
APPROVED: Christie McCain 9/21/98	EFFECTIVITY DATE: 21-SEP-98

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I. DISTRIBUTION:

Worldwide except United States.

II. PURPOSE:

This ISA provides the Temperature Verification and Adjustment Procedure for the Rev. 0 ALCYON Analyzer. This procedure is a Field Service procedure. Customers are not trained to perform this procedure.

III. PROCEDURE:

The **Temperature Verification and Adjustment Procedure** is dependent on the proper version of firmware located in the Temperature Controller. All analyzers with serial numbers 1639 and greater should have Eurotherm Temperature Controller Model 2116 with firmware version 1.2 will use the procedure below. Procedures for other firmware versions are not supported. As necessary, refer to the *Verify Firmware Version* section in this document.

Materials Required:

- Calibrated Digital Thermometer
- Cuvettes (9)
- DI Water

Procedure:

1. Ensure All covers are installed on instrument.
2. Perform System Startup. (VP - 01)
3. Allow system temperature to stabilize for 15 minutes.

- 4. While instrument temperature stabilizes, perform the following setup:
 - a. Access Reglages.
 - b. From the Main Menu:
 - B - REACTION WHEEL
 - H - WHEELS DISENGAGING
 - F - WHEEL ROTATION SEVERAL STEPS
- 5. Set the parameters to:

DIRECTION (0= to Home)	1
NUMBER OF STEPS	1000
SPEED	300
BACKWARD & FORWARD	Y
STOP ACTIVE (Y/N)	N
- 6. Dispense 300 microliters of DI water into each cell of a reaction cuvette segment.
- 7. Manually rotate to access position 4 of the Reaction Carousel.
- 8. Place the cuvette with water in position 4.
- 9. Place empty cuvettes into all other sectors of the Reaction Carousel.
- 10. Manually rotate cuvette position 1 to the unloader position. This will cause the water-filled cuvette to incubate next to the Colorimeter during Step 11.
- 11. Rotate the Reaction Wheel:
 - a. [F10] - to continuously rotate Reaction Wheel.
 - b. Allow the wheel to rotate for six (6) minutes.
 - c. S - to stop Reaction wheel rotation.
- 12. Manually rotate cuvette position 4 to the unloader position.
- 13. Measure the liquid temperature of cells 1, 4, 8, and 12. (1 is toward the back of the instrument.)
- 14. Remove cuvette #4 to allow it to cool.
- 15. Calculate the Mean and Standard Deviation:
 - a. Specifications : Mean = $36.5 \pm .1^{\circ}\text{C}$
SD $\leq 0.1^{\circ}$
 - b. Subtract the Mean value from 36.5 to derive offset adjustment value, to be used later in procedure.
- 16. At the Temperature Controller front panel, (Figure 1) execute the procedure in Table 1.

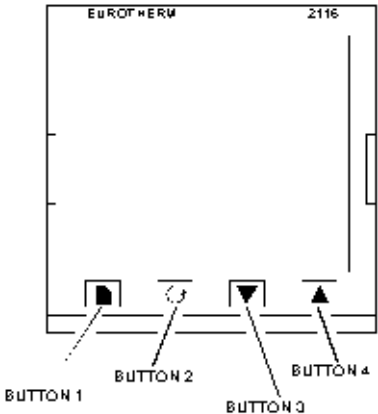


Figure 1: Temperature Controller Front Panel

NOTE: When programming Temperature Controller, if display does not respond as noted in these tables, verify the Temperature Controller firmware version as indicated in the *Verify Firmware Version* section of this document.

Press:	Displayed:
Button 1	ACCS
Button 2	codE
Button 4	1, will change to: PASS, then will change to: CodE
Button 2	Goto
Button 4	ConF, will change to: Goto
Button 2	ConF
Button 4	2, will change to: PASS, then will change to: ConF
Button 1	CAL
Button 2	Adj
Button 4	YES
Button 2	OFS.L
Buttons 3 and 4	Note the value which is displayed initially when button 3 or 4 is pressed one time. Then, using buttons 3 and 4, adjust the 'Offset Low' 4 by the value noted in Step 15b above. Adjust the value more negative to raise the temperature; more positive to lower the temperature of the liquid in cuvettes. See examples below.
Button 2	OFS.H
Buttons 3 and 4	Note the value which is displayed initially when button 3 or 4 is pressed one time. Then, using buttons 3 and 4, adjust the 'Offset High' by the value noted in Step 15b above. Adjust the value more negative to raise the temperature; more positive to lower the temperature of the liquid in cuvettes. See examples below.
Button 1	ELiT
Button 4	YES

Table 1: Temperature Control Program Routine

Examples for adjusting the OFS.L & H values:

1) Assume the current OFS.L & .H values are -1.7 and the value noted in Step 15b is -.3; The value obtained in Step 15b is always subtracted from the current OFS values. Therefore, $(-1.7) - (-.3) = -1.4$ because the two minus signs together change to a plus, making it $(-1.7) + (.3) = -1.4$; so both OFS.L and OFS.H should be adjusted from -1.7 to -1.4.

2) If the current OFS values are -1.7 and the value noted in Step 15b is +.3; then $(-1.7) - (.3) = -2.0$... so both OFS.L and OFS.H should be adjusted from -1.7 to -2.0.

17. Wait 15 minutes for temperature to stabilize.
18. Repeat steps 6 through 11 until measured temperature meets specification.
NOTE: After the initial offset adjustment, the fine tuning of the temperature offset can be done in 1/10 degree intervals (UP, DOWN arrow buttons pressed once or twice etc.)
19. Once the temperature matches, return controller to operator mode, execute the procedure in Table 2 (below).
20. Allow 15 minutes to stabilize the temperature and ensure the display reads 37.

NOTE: When pressing buttons below, do not hold the button down, but press it repeatedly until the indicated word or number is displayed.

Press:	Displayed:
Button 1	ACCS
Button 2	codE
Button 4	1, will change to: PASS, then will change to codE
Button 2	Goto
Button 4	Full, will change to: Goto
Button 1	IP
Button 2	CAL
Button 4	USEr
Button 2	iP
Button 1	ACCS
Button 2	Goto
Button 3	ConF, then will change to: Goto
Button 2	ConF
Button 3	2, then will change to: PASS, then will change to ConF
Button 1	CAL
Button 2	ADJ
Button 3	no
Button 1	Elit
Button 3	YES

Table 2: Temperature Control Program Routine

Verify Firmware Version

1. Remove all patient samples from Sample Carousel.
2. Turn the instrument OFF.
3. Remove Temperature Controller. (See Figure 2.)
4. Rotate Temperature Controller to view firmware version. (See Figure 2.)
 - a. Note the appropriate firmware version
Firmware version should be:
EUROTHERM Ver. 1.20
 - b. If firmware version is any other, replace the temperature controller and notify ALCYON CSE.
5. Turn Main power switch to ON.
NOTE: When re-applying power to the analyzer, allow 15 minutes for system temperature to stabilize.

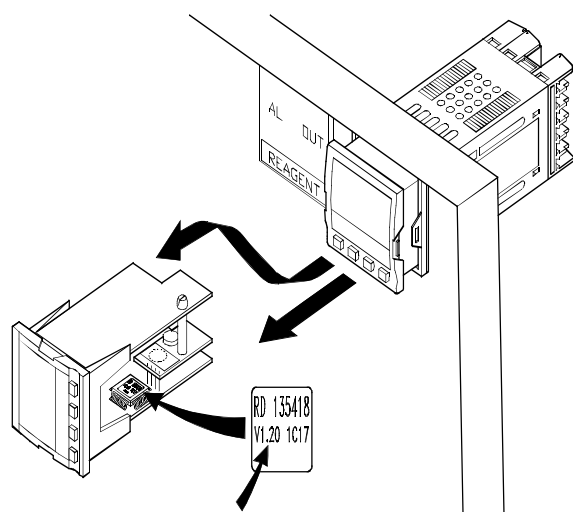


Figure 2: Firmware Revision Location

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