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ADD

INDEX
INSTRUMENT SERVICE ADVISORY

PRODUCT:	DATE:
LCx® Probe System (69)	**07-JUL-98**

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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

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SUBJECT: **LCx® Service Manual**	ISA#: **69-013**
ORIGINATOR: **Eric Tormos**	PRODUCT: **LCx® Probe System (69)**
APPROVED: **Jack B. Hall 7/7/98**	EFFECTIVITY DATE: **07-JUL-98**

I. DISTRIBUTION:
Worldwide

II. PURPOSE:
This ISA is to notify the field of a revised LCx® Probe System Service Manual Total Service Call Procedure. This procedure has been developed from customer site visits made to correct various customer issues. The purpose of this new procedure is to reduce the number of preventive maintenance procedure requirements, while continuing to maintain optimum performance of the instrument.

The Total Service Call Procedure makes sure that the three major subsystems, i.e., temperature, photo and dispense, are checked. Solving an error on one of the subsystems should result in checking the other two as well.

III. PARTS:
None.

IV. PROCEDURE:

6.1 PM/TOTAL SERVICE CALL PROCEDURE

Suggested PM/Total Service Call Procedure

1. Verify proper TSB level.
2. Obtain printout of System Parameters 1, 2, 4, 37, and 38.
   - System
   - Files
   - 1
   - Print
   - Obtain a printout of Sys Log file and review for problems
3. Clean Air Heater and Thermistor with compressed air.
   a. Remove Boom Shroud Assembly (RR2.3).
   b. Remove Air Duct Cover (RR2.6).
   c. Clean dust for heater coils and thermistor with compressed air.
   d. Check ground connections at air heater fan, reagent heater block and liquid heater (<10 hm).
   e. Clean reagent receiver and carousel receiver.
4. Inspect instrument and accessories for wear and leaks in tubing or multivalve block.
5. Clean Power Supply Fan with compressed air.
6. Run boom check.
7. Run temperature check (only if it was not yet requested as a verification procedure).
8. Run photo check (only if it was not yet requested as a verification procedure).
9. Run dispense check (only if it was not yet requested as a verification procedure).
10. Run performance panel of customer's choice.
11. Obtain printout of System Parameters 1, 2, 3, 4, 37 and 38.

6.2 PM/TOTAL SERVICE CALL CHECKLIST
Suggested PM/Total Service Call Procedures Performed

1.		Verify proper TSB level.

2.		Obtain printout of System Parameters 1, 2, 3, 4, 37, and 38. ● System ● File ● 1 ● Print ● Obtain a printout of Sys Log file and review for problems
3.		Clean Air Heater and Thermistor with compressed air. a. Remove Boom Shroud Assembly (RR2.3). b. Remove Air Duct Cover (RR2.6). c. Clean dust for heater coils and thermistor with compressed air. d. Check ground connections at air heater fan, reagent heater block and liquid heater (<10 hm). e. Clean reagent receiver and carousel receiver.
4.		Inspect instrument and accessories for leaks in tubing or multivalve block.
5.		Clean Power Supply Fan with compressed air.
6.		Run boom check.
7.		Run temperature check (only if it was not yet requested as a verification procedure).
8.		Run photo check (only if it was not yet requested as a verification procedure).
9.		Run dispense check (only if it was not yet requested as a verification procedure).
10.		Run performance panel of customer's choice.
11.		Obtain printout of System Parameters 1, 2, 3, 4, 37 and 38.

END OF DOCUMENT

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SUBJECT: **HIISIM ASTM Simulator**	ISA#: **69-012**
ORIGINATOR: **Eric Tormos**	PRODUCT: **LCx® Probe System (69)**
APPROVED: **Jack Hall (6/15/98)**	EFFECTIVITY DATE: **09-JUN-98**

I. Distribution:

Worldwide

II. PURPOSE:

The Purpose of this ISA is to inform the field that the LCx Analyzer Version 2.1, when interfaced with COMPAQ PROLINEA 4/33 computers to run HIISIM ASTM Simulator program may delete the ASTM loadlist from the LCx. The HIISIM Software package is used to simulate an ASTM host. The LCx misses the EOTcharacter from the HIISIM, although the EOT being sent can be verified. This issue is unique to the COMPAQ PROLINEA 4/33 computer.

The issue has not been observed with other computer systems. The cause of this issue has not been determined.

III. PARTS:

None.

END OF DOCUMENT

ABBOTT ADD	INSTRUMENT SERVICE ADVISORY

SUBJECT: **LCx Analyzer Version 2 Software and Incompatibility with LCx Diagnostic Software Version 1.0.0**	ISA#: **69-011**
ORIGINATOR: **Kyle Hranitzky**	PRODUCT: **LCx® Probe System (69)**
APPROVED: **Bob Schabel**	EFFECTIVITY DATE: **25-AUG-97**

I. Distribution:

International and USA

II. PURPOSE:

The purpose of this ISA is to inform the World Wide Field Service Organizations that due to the restructuring of the LCx Analyzer Version 2 Software, the LCx Diagnostic Software Version 1.0.0 cannc be used as a diagnostic tool when servicing the LCx Analyzer.

For troubleshooting boom, optics, temperature, bar code, liquid level sense, analog board and RS-232 problems refer to the appropriate section of the LCx Analyzer Service Manual (3-47277-01) or to TSB 69-005 (LCx Analyzer Version 2 Software Upgrade).

A version of diagnostic software compatible with the LCx Analyzer Version 2 Software is under development. Notification will be conveyed to the World Wide Field Service Organizations when this software is released.

ABBOTT ADD	INSTRUMENT SERVICE ADVISORY

SUBJECT: **Error Codes 166, 197, 198 and 199**	ISA#: **69-010**
ORIGINATOR: **Kyle Hranitzky**	PRODUCT: **LCx® Probe System (69)**
APPROVED: **Bob Schabel 15/Jan/97**	EFFECTIVITY DATE: **15-JAN-97**

I. DISTRIBUTION:

Worlwide

II. PURPOSE:

The purpose of this ISA is to provide an overview of Error Codes 166 (Read Error), 197 (Calibrator Too High), 198 (Calibrator Too Low) and 199 (Average Out of Range).

Background on: Code 166 Read Error generation. A Code 166 Read Error is declared when an instrument specific limit is exceeded. This instrument limit is set by the equation: threshold = [(HV*60) + 850]500/1000; where HV is the Photomultiplier Tube (PMT) High Voltage set during MEIA Optics Photo Calibration. When a patient sample is read and the raw counts (PMT signal) generated from that sample exceeds the determined threshold value, a 166 error is generated. Each sample is read multiple times to establish the linearity of the reads. If any of the reads exceeds the threshold value, an internal flag is generated. This in turn triggers a printed 166 error, specific for that particular sample, on the data tape. There are several factors, that in the right combination, can lead to an increased probability of generating a 166 error:

a. An occasional patient sample may contain high concentrations of the target DNA. When these targets are amplified through thermal cycling the resultant high counts may exceed the threshold limit.

b. If reagents are released near the upper end of the manufacturing specifications, then there is an opportunity for higher rate counts to be generated. This case, combined with an elevated patient sample, will increase the likelihood of a 166 error.

c. From the above equation it is obvious that the PMT High Voltage (System Photo Parameter 38.28 MEIA CAL VOLT) is the major contributor in determining what the threshold limit will be. In-house testing has shown that an MEIA Optics Assembly with a PMT High Voltage value greater than 550 Volts is less likely to generate a Code 166 Read Error than an MEIA Optics Assembly with a PMT High Voltage less than 550 Volts. The lower the threshold value, the increased probability that a high patient sample will trigger a 166 error.

Recommendation:

If normal troubleshooting suggestions, such as those listed in Isolation Procedure 66 as found in the LCx® Analyzer Service Manual, have not resolved the issue AND the MEIA Cal Voltage is less than 550 Volts, consider replacing the MEIA Optics Assembly. Remember that a 166 error can be an indication of a hardware problem other than with the MEIA Optics Assembly. It is important to follow normal troubleshooting suggestions prior to replacing the MEIA Optics Assembly. Finally, remember that an occasional 166 error may occur, particularly if the sample is from an area where there is a high incidence of a given disease state. If this occurs, have the customer contact their respective Customer Service representative for additional instructions.

Background on: Code 197 Calibrator Too High, Code 198 Calibrator Too Low and Code 199 Average Out of Range Error generation. Error codes 197 Calibrator Too High, 198 Calibrator Too Low and 199 Average Out of Range are error codes that may arise on the LCx Analyzer

when specific criteria are met:

a. The overall efficiency of the amplification process on the LCx® Thermal Cycler can be affected by the ramping rate during the 3 phases of a single cycle of amplification. The ramping rate determines how fast target temperatures are reached when going from one step of the amplification cycle to the next. Ramping efficiency that is above or below nominal ramping rates can result in calibrator rates that are above or below pre-established assay validity specifications. When this occurs and the calibrator rates or average of the calibrator rates fall outside of their guardbands an error condition exists and the corresponding error code is generated.

b. The MEIA Optics Assembly can also be a contributor to error codes 197 and 199. The higher the ALS (Anode Luminous Sensitivity) rating of the PMT (Photomultiplier Tube) located in the MEIA Optics Assembly, the increased susceptibility to higher invalid calibrator rates. Once a PMT is assembled into an MEIA Optics Assembly there is no easy way to determine what the ALS rating is of the PMT. In-house engineering has determined an association between ALS rating of the PMT and the PMT High Voltage set during MEIA Optics Photo Calibration. An MEIA Optics Assembly with a PMT High Voltage greater than 550 Volts is less likely to generate a code 197 or 199 error message than an MEIA Optics Assembly with a PMT High Voltage less than 550 Volts.

Recommendation:

Troubleshooting should include verifying that the correct volume of Activation Reagent is delivered to the Calibrator vial upon activation and that the Calibrator vial is vortexed to ensure proper mixing. If the incorrect volume of Activation Reagent is pipetted or sufficient vortexing is not accomplished these error conditions could result. A different lot of reagent should be tried.

The Chiller and Heater Tests should be performed on the LCx® Thermal Cycler to ensure that the cycler is operating within nominal specifications. If either of these tests fails replace the LCx Thermal Cycler.

Finally, if the PMT High Voltage (System Photo Parameter 38.28 MEIA CAL VOLT) is less than 550 Volts, consider replacing the MEIA Optics Assembly.

END OF DOCUMENT

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SUBJECT: **Liquid Level Sensing and the LCx® Analyzer**	ISA#: **69-009**
ORIGINATOR: **Kyle Hranitzky**	PRODUCT: **LCx® Probe System (69)**
APPROVED: **Mark Slater 9/9/96**	EFFECTIVITY DATE: **09-SEP-96**

I. DISTRIBUTION:
Worldwide

II. PURPOSE:
The purpose of this ISA is to provide an overview of the liquid level sensing used on the LCx Analyzer. This ISA is divided into two main subject areas; liquid level sense theory and troubleshooting.

III. PROCEDURE:
Liquid Level Sensing and the LCx Analyzer

Liquid Level Sense Theory

The Liquid Level Sense (LLS) system is designed to detect liquid at the point when a singular conductive probe touches the liquid. This is done so that the Z Boom Step location of the liquid can be reported to and memorized by a microprocessor. The purpose is for determining the Z Boom Step where liquid is sensed and compared to set reference values. The singular probe is necessary so that the amplification vial may be punctured to access the liquid.

An alternating voltage source (sine wave oscillator) operates at a frequency within the lower end of the RF spectrum. The oscillator voltage is applied to a conductive probe. The probe interfaces with a liquid vessel filled with conductive material. There are two conductive sensing plate(s) (carousel and reagent receivers), stationed in close proximity to the reagent pack or reaction cell. The receivers are connected to an electronic circuit to amplify and condition the amplitude modulated voltages, produced by the interaction between the probe and the receiver(s). The voltage signals are quantified by an analog to digital converter (ADC). The resulting values are interpreted by a microprocessor.

The combination of probe, liquid and sensing plate form a capacitor. When the probe touches liquid, capacitance increases as the AC signal on the probe passes through the ions in the liquid, through the receiver plates and then to the LLS PCB. By definition, when the probe is out of liquid the AC signal is small. As the probe gets closer to liquid, the signal gradually increases until liquid is sensed and the AC signal (Delta) is large. Each level sensing location has a hard coded delta value in the software which when met or exceeded will indicate that liquid has been sensed.

The liquid level sense board has six functional blocks (reference the attached Block Diagram):

1. A function generator circuit, U8 and U9 (120 kHz Oscillator) provides the alternating voltage to drive the conductive probe. U9 provides additional gain so that the output voltage approaches +/- 15 Volts.
2. U1 and U2 Buffer Amp, Shield Drivers function as shield drivers, buffering the sensed voltage back onto the cable and sensor shields. This provides a virtual ground for the purpose of shielding the sensing plates and the cable shields.
3. Static electricity discharges are rich in high frequency impulse energy. The low pass filters allow the sensors to act as a capacitor to high frequency signals. This will cause signals above the operating frequency that appear on the sensor plates, to be coupled through to the virtual ground of the shield buffers output. The amount of impulse energy passed to the filter amplifiers will therefore be reduced.

4. U6, a summing amplifier, allows matching the high input impedance desired for the sensing capacitor plate(s) with the low source impedance needed by the filter stage which follows. The input voltages from the two sensors are inverted and summed at U6's inverting input junction.
5. The Bandpass Amplifier (U4 and U5) provides amplification to the low signals provided by the sensing plate, thus allowing the 120 kHz signal produced by the oscillator to be amplified, while filtering out undesirable signals.
6. The Full Wave Bridge Rectifier (U3) converts the amplified 120 kHz voltage signals from the bandpass filter into a DC voltage which varies as the magnitude of the 120 kHz voltage. The filter stage removes changes in modulation occurring above 600 Hz (noise).
7. In addition, an analog switch (U7) allows doubling the gain for input voltages, affording level sensing at greater distances between the probe and sensing plate. This function is currently not used.

The software also contains several routines which help to ensure valid level sensing. Once fluid is sensed, guardband software parameters are referenced to ensure that fluid was sensed within specified limits. A second software routine ensures the stability of each level sense reading so that positive and negative electrical spikes, as well as bubbles will be ignored.

Level Sense Troubleshooting

General Troubleshooting Level Sense problems.

1. Make sure that all tubing connections are secure.
2. Make sure that the probe is aligned vertically. If the probe is out of vertical alignment or bent the probe may strike the side of the vial as it descends to level sense. If the probe is bent, replace it. If the probe is still not aligned vertically, replace the boom assembly.
3. Clean the contact area between the probe and the probe clip with ethanol. Remember that the probe serves as the transmitter and a clean contact between the probe and probe clip contributes to proper transmission.
4. Clean any buffer spills or dried buffer from both of the carousel and reagent receiver plate surfaces. Salt buildup can lead to a highly resistive short to analog ground.
5. Make sure that the probe clip connector P1 (green), reagent receiver connector P5 (blue) and the carousel receiver connector P4 (red) are securely attached to the LLS board.
6. Ensure that the AC air heater fan and reagent heater block are grounded properly. Poor grounding can lead to excessive noise. Resistance should be less than one ohm.
7. Check to ensure that the input AC voltage is not noisy. Excess noise can lead to unstable level sense readings.
8. Perform a boom calibration/check to ensure proper setting of the Z-ASP LIM parameters for each of the dispense locations.

Level sense error codes 47, 52 and 99

1. Follow Isolation Procedure IP-22 as outlined in the LCx Analyzer Service Manual.
2. Error Code 47 Reagent Insufficient/Empty may occur during the prologue of the assay run, prior to any aspiration or dispense commands. This error can be initiated by several scenarios:
    a. Reagent tracking (test counter) indicates that the reagent pack lacks sufficient reagent required to perform the assay run.
    b. The fluid level at a specific location may be too low. This could be due to actual usage, spillage or a factory short-fill of the amplification vial.
    c. The LLS board gain and/or delta value at a specific location fail to meet specification. Determine the LLS board gain as outlined below.
3. Error Code 52 Level Sense Not Found occurs during the assay run. There are several reasons that could account for this error to be displayed:
    a. The Delta value for a specific location is too low. Determine the Delta value for the specific location as outlined below.

b. The LLS board gain is marginal or too low. Determine the LLS board gain as outlined below.
c. Consider changing the probe, probe clip and/or analog board. These components are integral to successful level sensing.

4. Error Code 99 Level Sense Hardware Error. This error may be generated when a stable level sense cannot be read. This error can also occur during the aspiration command. As the probe dives in liquid, the software verifies that the probe is in liquid.

   a. Excessive noise on the AC input line can cause this error. You may want to verify that the customers input voltage is clean.
   b. Improper grounding of the AC air heater fan can also cause this error. Verify that there is no corrosion around the screw used to attach the ground lead to the fan.
   c. This error can also be caused by improper function of the following hardware components: boom assembly, motor driver board, LLS board, analog board, CPU and power supply.

LLS Board Gain

1. On the LLS board move the jumper JU-1 from NOR to CAL. (Reference the attached block diagram.)
2. Connect the positive lead of the multimeter to TP2 and the ground lead to TP8. This simulates an "out of liquid condition". Record the voltage Vdc to the third decimal point if possible.
3. Press and hold the SW1 switch on the LLS board with a NON-CONDUCTIVE object for 10 seconds.

   NOTE: DO NOT USE YOUR FINGERS! Record the voltage from the multimeter to the third decimal place before releasing the button. This simulates an "in liquid minimum condition".
4. Calculate the gain:

   GAIN = (Step 3 voltage - Step 2 voltage) * 28.28427

   The gain should be between 90 and 100.
5. Remove the multimeter.
6. Reset JU-1 from CAL to NOR!
7. Replace the LLS board if the gain was not between 90 and 100.

Determination of Delta (DL)

1. Pipet 1 mL of System Diluent into each of the first 3 bottles of the buffer reagent pack.
2. Pipet 5 mL of System Diluent into bottle 4 (the large vial) of the buffer reagent pack.
3. Pipet 50 uL into an empty amplification vial and the reaction/specimen well of the reaction cell.
4. Press MONITOR, HND CTRL, OTHER, OTHER, LS.
5. Press the NEXT BL key to move the boom to each of the positions that you placed diluent into.

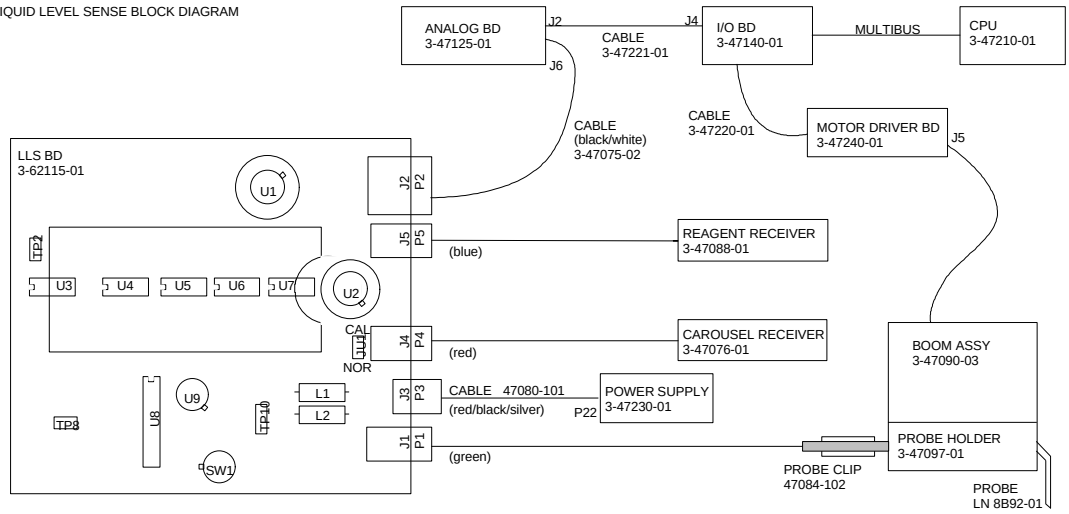
   a. For the reagent pack the display will show:
   INRT, MUP, CONJ, UPAR
   b. For the reaction cell the display will show:
   MTRX, VIAL, LCRW
6. Press LS to sense liquid. Record the DL (Delta) value.
7. The DL (Delta) over each position of the reagent pack should be >/= 90.
8. The DL (Delta) over the reaction well/specimen well (LCRW) should be >/= 55.
9. The DL (Delta) over the vial should be >/= 75.
10. If the DL (Delta) value(s) fail to meet the above criteria consider:

    a. Cleaning the probe clip where it contacts the probe.
    b. Replacing the probe.
    c. Making sure that the connectors from the reagent receiver and the carousel receiver are

connected to the LLS board.

d. Replacing the LLS board.
e. Replacing the Analog board.

LIQUID LEVEL SENSE BLOCK DIAGRAM



END OF DOCUMENT

ABBOTT ADD	INSTRUMENT SERVICE ADVISORY

SUBJECT: **Error Codes 163 (NRMSE too high) or 164 (Correlation Coefficient too low) on Chlamydia**	ISA#: **69-008**
ORIGINATOR: **Kyle Hranitzky**	PRODUCT: **LCx® Probe System (69)**
APPROVED: **Mark Slater 6/3/96**	EFFECTIVITY DATE: **03-JUN-96**

I. DISTRIBUTION:

International and USA

II. PURPOSE:

This ISA provides for modification to LCx® Assay Module 1, Version 2.

The Min Rate parameter (#31) for the LCx Chlamydia Assay (#11) will be increased from 10 to 40.

The Min Rate parameter specifies the lowest rate for which the NRMSE and Correlation Coefficient parameters will be checked. The NRMSE and Correlation Coefficient parameters are both indicators of variability in the reads taken at the optics station. At low rates, these calculations have been found to be unreliable indicators of variability within the read, causing invalid results for which there is no functional cause.

Customers using LCx Assay Module 1, Version 2.0 who are experiencing Code 163 (NRMSE too high) or Code 164 (Correlation Coefficient too low) errors on the Chlamydia assay for which no functional cause can be identified are candidates for modification to the Min Rate parameter.

III. PROCEDURE

1. Enter the Superuser code for the day in the following format: ".XXXX.", where XXXX is the Superuser code. "SUPER" will appear in the Ready Menu display.
2. Press [ASSAY].
3. Press [ASSAY _ FILES]
4. Enter 11.31.
5. Press [DISPLAY].
6. Enter 40.
7. Press [STORE].
8. Press [EXIT].
9. Press [PRINT]. Verify that the Min Rate parameter (#31) has been changed to 40.
10. Exit the Superuser mode by entering the Superuser code as in step 1 above.

END OF DOCUMENT

ABBOTT ADD	INSTRUMENT SERVICE ADVISORY

SUBJECT: **Manufacturability Improvement of the LCx® Boom Assembly**	ISA#: **69-007**
ORIGINATOR: **Kyle Hranitzky**	PRODUCT: **LCx® Probe System (69)**
APPROVED: **Mark Slater 3/11/96**	EFFECTIVITY DATE: **11-MAR-96**

I. DISTRIBUTION:

Worldwide

II. PURPOSE:

This ISA provides the World Wide Field Service Organization notice of the possibility of the Z-Boom Motor connector interfering with a support rib in the instrument.

The Z-Boom Motor is rigidly mounted to the Boom Assembly and moves radially with the boom throughout normal instrument operation. Field Service personnel in Europe and Japan reported that the five-wire connector, that is mechanically attached to the Z-Boom Motor and is located beneath the Boom Assembly platform can interfere with a support rib in the instrument. This interference is manifested as a clicking sound at a specific location of R-Boom rotation. In rare cases, the problem results in actual failure of the connector or in Z-Boom Failed Home or Z-Boom Missing Steps error messages.

The resolution to this potential problem is the removal of the Z-Boom Motor Connector and terminals, with direct wiring to the boom connector (C/N 3-47090-03).

Boom Assemblies will not be modified in the field. Boom Assemblies (C/N 3-47090-02) that are in kits or depot inventory will be reworked in-house to the -03 configuration.

Boom Assemblies (C/N 3-47090-02) that are currently in instruments will be replaced on a NEXT FAILURE basis of the Boom

Assembly (Reference TSB 69-003).

END OF DOCUMENT

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SUBJECT: **LCx® Diagnostic Software Version 1.0.0**	ISA#: **69-006**
ORIGINATOR: **Michael Mowen / Kyle Hranitzky**	PRODUCT: **LCx® Probe System (69)**
APPROVED: **Mark Slater 3/11/96**	EFFECTIVITY DATE: **11-MAR-96**

I. DISTRIBUTION:

USA. and International

II. PARTS:

1 ea. C/N 3-79228-01 LCx® Diagnostic Software (Version 1.0.0)
International Service Sites and USA FSR's should order/forecast parts via their regular spare parts channels.

THIS DIAGNOSTIC SOFTWARE IS CONFIDENTIAL MATERIAL AND IS DESIGNATED FOR ABBOTT FIELD SERVICE USE ONLY. DO NOT GIVE TO A CUSTOMER!!!!!!

III. PURPOSE:

To inform the World Wide Field Service Organizations of the release of Version 1.0.0 LCx® Diagnostic Software. These diagnostics allow the FSE/FSR to perform R-Boom, Z-Boom, LLS, Bar Code, Boom Life test, RS-232 check (IMx®, TDx®, and TDxFLxTM), CV calculations, MEIA Optics tests, and Analog PCB tests by connecting a computer via a cable to the LCx Analyzer. In the months ahead, more diagnostic tests will be released. This software is a troubleshooting tool designed to aid the FSE/FSR in "Decision Support" while troubleshooting.

Software problem/change reports (2 ea.) will be included at the end of this ISA so that you can report any problems. These forms can also be used to request changes or addition of new diagnostics. Your input is greatly welcomed. A brief description of how to fill out the forms and where to send them will be at the end of this ISA.

This ISA will serve as the User's Manual for the Diagnostics package.

When To Use: It is recommended that you use these diagnostics on LCx Analyzer service calls that involve R-Boom and Z-Boom problems, MEIA Optics, Temperature, Bar Code, LLS errors, and Analog Bd. problems. The RS-232 check will work on the system listed in the RS-232 software, but not the LCx Analyzer because the port 2 is not active at this time.

System Setup:
The System setup includes both software and hardware. Software is defined as the laptop diagnostics program supplied to you on a 1.44 Meg floppy disk. Hardware is defined as the serial cable that has to be connected from the COM port of the laptop Computer to the COM1 port of the LCx System. This software will run in the Windows environment only.

Running WINDOWS™:
From the FieldWatch Main Menu, select **Windows**. If you are starting from a DOS prompt, which may look like C:\>, type **WIN** to open the Windows application. Once in Windows, use the mouse to select **FILE** from the menu bar and then select **RUN**.

Place the laptop Diagnostics disk in the A Drive. Ensure that the Command Line in the Dialog box says "a:\setup.exe". If it does not say this, type **a:\setup.exe**. Move the mouse pointer to the OK button and click the left mouse button once. The setup program will automatically create a program group for Diagnostic Software and install two Icons inside this program group for the actual diagnostic application and a separate RS-232 check). All tests, including the RS-232 can be run out of the LCx Diagnostic Software V1.0.0 ICON. The RS-232 ICON can be used if that is the only check you want to run. A message will appear that states a successful completion of the installation.
If the software is not installed properly, the following message will appear:

> LCx Diagnostic Software is not properly installed. Please re-run setup at a later time to install the test application properly.

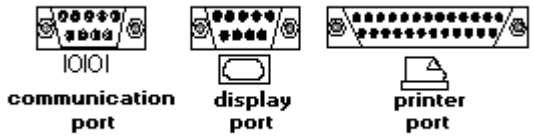
If you have tried to install this software at least three times and still have not been successful, contact the X SYSTEMS® CSE group to report it. We will try to resolve your problem and/or see that you get another copy of the software to install.

WHAT TO DO IF THE COMMUNICATION INTERFACE FAILS:
During software operation, if the interface is lost, the software will notify you with the appropriate error message. The operation will be terminated upon acknowledgement of the error. You will need to re-start the application.

WHAT TO DO IF THE APPLICATION WILL NOT EXECUTE:
If the application will not execute, due to missing or corrupted file(s), re-install the application as described above. If still unsuccessful, contact the X SYSTEMS CSE group to report it. We will assist you and/or see that you get another copy of the software to install.

RUNNING THE APPLICATION:
NOTE: Disable your screen saver before running these diagnostics. If you are level sensing and the screen saver activates, it could show incorrect LLS numbers.

NOTE: Before running the Laptop Diagnostics program, connect the A/T to Modem cable to the COM port of the laptop Computer (see illustration below) and the COM1 port of the LCx System (RS-232 connection closest to the Main power On/Off switch). Turn the power switch of the LCx analyzer to the ON position.



Using the mouse on your computer, double click the mouse on the LCx Diagnostic Software (ICON just created). A Screen Saver Advisory will appear prompting you to disable any screen saver program.

Printing Test Results:
You can print the results of the Bar Code test by choosing the **Print** button on the bottom of the display. The software allows for printing. The printer is the local printer. What ever printer you have connected to the computer will be used. This will print out the display exactly as it looks on the screen. The LCx printer is disabled for this release of diagnostic software.
After selecting the **Print** button on the display with the mouse, a prompt, Select Printer appears Choose **Select Printer**.
Select **Local Printer** to print to the printer connected to your computer. Local printer will print the screen as it appears.

NOTE: The LCx printer is disabled for this release of Diagnostic Software until new LCx system software is developed.

Saving Test Results:
You can also save the test results by using the **Save** button. When you elect to save test results, type in the serial number, even the -96 if it is present. If the S/N is 1243-96, then type in 1234-96 and

select the **Ready** button. The software will create a file based off of the serial number. The next time you store tests using that particular serial number, the file will be added to the end of the previous file. This way, a history of the instrument test results can be preserved.

Viewing Test Results:
Viewing files that were saved during running of the LCx Diagnostic Software:

You can view the files by getting into Windows and opening the Accessories group menu and double clicking on the text edit or called "Write".

Click once on "**File**" menu item.
Click once on "**Open**" menu item.
Type "***.69**".
Click once on "**OK**".

Change to directory that the files are stored (usually BOOM directory).
Double click on the file you want to open (ex. 11567-96.60).
Click once on "**Convert**" to convert to write formatting.

You can now view the file contents. The file begins with the name of the test. An example would be ZFHT for Z Boom Flag Height Test. Then the Date the test was run is next. Then the results of the test are shown. Any test run after this one would follow the same layout of test name, date and test results.

To exit the editor:

Click once on **File**.
Click once on **Exit**.
Click once on "**NO**" to the question of "save current

Tests

There are five main menus to select from. The main subject headings and sub-topics are as follows:

I. Perform Tests (gives pass/fail results)
- **A. Boom**
  1. **Bar Code Reader -** determines integrity of the Bar Code Reader.
  2. **Z Boom Flag Height** - tests Z-Home flag height.
  3. **Boom Z/R/LLS** - checks Z and R - Home alignment, reads reagent Bar Code and performs liquid level (LLS) checks.
- **B. MEIA Optics**
  1. **PMT Light Leakage** - checks PMT for susceptibility for light leakage.
  2. **MEIA Lamp Stability** - measures MEIA lamp current stability.
  3. **PMT/Photodiode Noise** - monitors PMT and Photodiode for susceptibility to noise.
  4. **MEIA Optics Gain** - monitors response of analyzer to elevated gain settings.
  5. **Fluorescence Background** - helps determine if excessive fluorescence is reflecting from the chamber surfaces under the MEIA Optics.
  6. **Do All Test** - replicates all tests under the MEIA Optics heading.
- **C. Analog Board**
  1. **PMT Noise** - insures that PMT readings are within set guard bands and within set limits for precision.
  2. **Thermistors** - monitors liquid heater, remote thermistor, air heater and reagent heater.
  3. **High Voltage Power Supply** - determines if HVPS responds linearly to increases in applied voltage.
  4. **Buffer/Waste Sensors -** checks functionality of buffer and AVR sensors.
  5. **Do All Test** - repeats all tests under the Analog Board heading.

II. Perform Checks (results are operator interpreted).
- **A. Boom**
  1. **Life Check -** a more strenuous testing of boom functionality.
- **B. RS-232 -** aids in troubleshooting the RS-232 Communications (COM) port.

III. Options
- **A. Am/SD/%CV Calc -** use this function to calculate the arithmetic mean, standard deviation and % coefficient of variation of inputted data.

IV. Exit - allows termination from the program.

V. Help - provides information about the tests, checks and options.

Using the mouse on your computer, click on the OK button of the screen saver advisory and the following menu items will be displayed:

Perform Tests Perform Checks Options Exit Help

I. Perform Tests

A. Boom

1. Bar Code Reader

Select the **Boom** item with the mouse from the menu. A submenu appears.
Select **Bar Code Reader** from the sub-menu and the following screen appears:
Use the mouse to choose **Select PC Com Port**.
Choose the appropriate communication port
Verify that the LCx COM 1 port is setup to 1200 baud, 8 bits, 1 stop and 0 parity as follows:

NOTE: *REMEMBER TO RE-EDIT ORIGINAL PARAMETERS BACK WHEN DIAGNOSTIC TESTING IS COMPLETE*D

Press	SYSTEM FILES 1.6 DISPLAY to show COM1 baud (If necessary, press 1200 using the LCx keypad then STORE) FWD to display COM1 chr len (If necessary, press 8 using the LCx keypad then STORE) FWD to display COM1 stop bit (If necessary, press 1 using the LCx keypad then STORE) FWD to display COM1 parity (if necessary, press 0 using the LCx keypad then STORE) EXIT EXIT to return to the READY menu

If any system files were edited, you must perform the Assay Module Shutdown procedure to activate these values. The procedure is as follows:

Press	UTILITY SHUTDOWN START When "130 READY TO CHANGE MODULES" appears, lift the assay module from its connector and reseat it. The LCx will re-boot and return to the READY menu.

Use the mouse to click on the **OK** button in the dialog box. The program will connect to the LCx analyzer and the main menu window will be displayed briefly while the Diagnostic Software is connecting to the LCx Analyzer.

Follow the screen prompt and place an MEIA carousel and buffer pack with a known good bar code label into the instrument. Choose **OK**. The test will begin by verifying carousel installation, homing the carousel and Boom assembly and then asking you to adjust the bar code reader for maximum counts. A Bar Code Reader test screen appears.

Manually position the bar code reader LED's over a white portion of the bar code label nearest vial #4 and adjust the reader for maximum counts. Using the mouse, click on **Ready** when done. The display then asks you to move the bar code reader LED's over a white portion of the bar code label nearest vial #1. Using the mouse, click on **Ready** when done.

Manually position the bar code reader LED's on the black portion of the bar code label nearest vial #1 and click on the **Ready** button when positioned properly. Then move the bar code reader LED's so

that they are over the red portion of the carousel label. Click on the **Ready** button when positioned properly.

The software then calculates the WHITE to WHITE difference of the Reagent Pack (the absolute value of the white counts near vial #4 minus the white counts near vial #1) and the WHITE to BLACK difference over the reagent pack. The specifications checked are:

White counts left - White counts right	<=10
White counts - Black counts	>30
White counts	>80
Carousel counts	>80

The software then automatically takes 5 readings forward and 5 readings backwards on the reagent pack label and then 5 reads of the carousel label. It times the actual reads for both reagent pack and carousel label. We want to pass all the reads. The specifications are:

	Success forward	= 5 of 5
	Success backward	= 5 of 5
	Success carousel	= 5 of 5
Bar code time:	Reagent pack	<=2.2 seconds
	Carousel	<=2.5 seconds

If the test fails:
If one of the test fails, a message box will come up offering suggestions as to where to begin troubleshooting. This is not meant to replace the LCx Service Manual. These suggestions are made only to facilitate the troubleshooting process. Always refer to the LCx Service Manual when in doubt.

If the White counts on reagent pack label are < 80 counts:

If LED's are not lit: Suspect boom, Analog BD, bar code cable between Analog PCB and CPU is put on backwards or is offset by a pin, and CPU PCB.
Clean reader with distilled water and dry thoroughly.
Check the reader height adjustment. If adjustment can not be made, replace the boom.
Replace Motor Driver PCB.
Replace the Analog PCB.
Replace the CPU PCB.

If the White counts on the carousel label are < 80 counts but reagent pack counts >80:

Check the carousel label for any defects.
Clean the carousel label.
Check seating of boom shroud, redo reader adjustment if reseated.
You may have to detune reader height over reagent pack or carousel.
If not, replace boom.

If White to White counts on reagent pack are >10:

Check the label for any defects.
Clean the label.

Insure the reagent pack is snapped together properly.
Check the boom shroud for proper seating.
Replace the boom.

If White to Black counts on reagent pack are <30:

Check the label for any defects.
Clean the label.
Check seating of boom shroud, redo reader adjustment if reseated.
Clean reader with distilled water and dry thoroughly.
Check the reader height adjustment. If adjustment can not be made, replace the boom.

If successful reagent pack label reads are less than 5 of 5:

Check the label for any defects.
Clean the label.
Check seating of boom shroud, redo reader adjustment if reseated.
Clean reader with distilled water and dry thoroughly.
Check the reader height adjustment. If adjustment can not be made, replace the boom.

If reagent reader time is > 2.2 seconds:

Insure nothing is obstructing bar code reader movement.
Replace boom assembly.
Replace Motor Driver PCB.
Replace I/O PCB.

If carousel reader time is > 2.5 seconds:

Insure nothing is obstructing carousel movement.
Replace carousel assembly.
Replace Motor Driver PCB.
Replace I/O PCB.

To rerun the Bar Code Test you can select the **Redo** button. Selecting the **Cancel** button returns you to the main menu.

I. Perform Tests

A. Boom

2. Z Boom Flag Height

Z Boom Flag Height tests Z-Home flag height (FSE/FSR adjusts to 265 +/- 2 steps, if necessary) and performs 10 LLS and calculates the average steps and range (range <=3).
Select the **Z Boom Flag Height** test.
The test begins by homing the Z and R Boom motors of the Boom assembly. A dialog box appears with instructions to install the MEIA carousel with one clean blank cell in position number one.
Click on the **OK** button to proceed to the next step.
A dialog box will appear if the manual AVR is over the carousel or if the manual AVR sensor has failed and tells the system the manual AVR is over the carousel.
If you answer **OK** to the prompt, the software will recheck the manual AVR. If you select **CANCEL** then the software will exit.
Click on the **OK** button and the display will ask you if a good Boom Calibration is stored in the analyzer.
Click on the **YES** button if the boom has been calibrated. (Click on the **NO** button if a boom calibration needs to be performed.) The Z Boom Flag Height Test is initiated.

If a failure occurs, a message box will come up offering suggestions as to where to begin troubleshooting. This is not meant to replace the LCx Service Manual. These suggestions are made only to facilitate the troubleshooting process. Always refer to the LCx Service Manual when in doubt.

Two failure modes are possible, first is the Z-Flag height. The LCx System allows levels of 258 to 272 to pass. For the FSR, acceptable levels for the Z-Flag are 263 to 267 (we want to insure that the flag is set near the mid point of 265). A Z-Flag height outside of this range requires adjustment. If adjustment is not possible, replace the Boom. Second is the level sense range, which must be 3. Level sense failure indicates a dirty/bad probe assembly or a bad Boom.

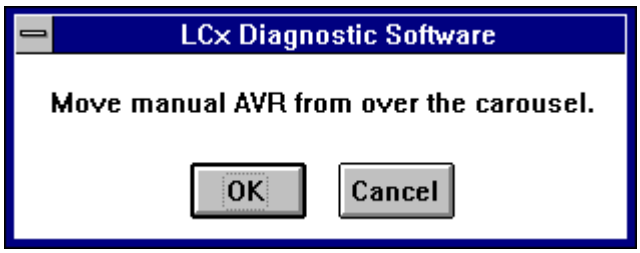
I. Perform Tests

A. Boom

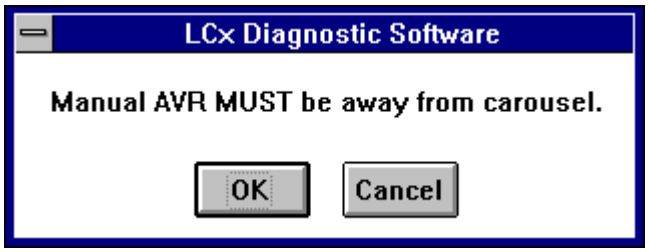
3. Boom Z/R/LLS

This test performs 5 functions such as Z boom home alignment check, R Boom home alignment check, reads reagent pack bar code, LLS checks on the reagent pack vials (simulates an hCG assay run), and does 30 LLS checks in vial 2.
To start this test, select the **Perform Tests**, **Boom**, then the **Boom Z/R/LLS** item. A dialog box will be displayed prompting you to place a MEIA Buffer Pack (with 6 mL of buffer in vial #4 and 1 mL in the other vials) into the Reagent Heater Block. The volumes for the vials were picked so as to stress the Z-Boom travel. After removing the carousel and placing a MEIA buffer pack in the instrument, select **OK**.

A dialog box will prompt you to answer if a good Boom Calibration been performed. If you answer **YES** to this question, the software will use the boom settings presently stored in the various system files. If you answer **NO**, the program will exit back to the MAIN menu. The following will appear after you answer **Yes** to the question**:**



This message box will only come up if the Manual AVR arm is over the carousel or the sensor says it is over the carousel. If the sensor is working, after moving the manual AVR and clicking **OK** or if the manual AVR was not over carousel then the following message box will appear.



Click on the **OK** button and the test will initialize.

- Z and R boom home alignment is for checking the number of steps that the flag enters the sensor after initial detection. If one of these fails, check for proper alignment of the flag as it enters the sensor. The flag may be rubbing/hitting the sensor.

- An actual assay pipetting sequence is performed 10 times during which all reagent bottle level sense numbers are recorded and displayed. If any LLS range fails, suspect the probe/electrode assembly. Clean the probe using water and ethanol and rerun the test. If it still fails, replace the probe/electrode. If the "ave. of 4 Ranges" fails, do the same. It is possible for the LLS ranges to be in specification but the "ave. of 4 Ranges" be out. Cleaning probe usually resolves this problem.

- 30 liquid level sense operations are performed in the conjugate bottle to test for level sense accuracy.

- Test status is displayed to provide a test pass/fail result. Anytime a test fails, parameters for the failed test are displayed.

Three options are available once the test is completed: Print, Save, Cancel. To select an option, either use the mouse or press the Alt key and the underlined letter for the corresponding selection. For example, to select Print, press and hold down the Alt key then press the P key.

Print: Prints the screen contents to the LCx printer or an external printer connected to your computer.

Save: Saves the data as an ASCII file. You will be prompted to name the file as the instrument serial number, include the -96 for refurbished instruments. As you save files from the different tests, keep in mind that the files are appended to the last file saved. If you run the Z Boom Height test three times in a row and save each time, You will have all three results in the file. If you run it again and save, the results will be appended to the existing file.

Cancel: Cancels test and the program returns to the main display.

Printouts of the failed tests should be attached to the defective part and sent back to Dallas. The information on the printout can be helpful to the personnel who troubleshoot the part.
Saving the Files can be a good way of keeping a history of how the tests performed on that particular instrument. Each time you save after a test is run, the information is appended to the end of the file. If you first went to service that instrument on 1/94 and you saved the files, when you service that instrument on 6/94 and save it's file, you now have a small history of the two days of service tests performed for those dates. You can continue to append the file. In the future, when you are all on lotus notes, you can send us the files so that we can keep a database going.

Press **Cancel** to get back to the main Diagnostic menu.

I. Perform Tests
B. MEIA Optics
1. PMT Light Leakage

Select **PMT Light Leakage**.
Close the access door and select **OK**. The test proceeds to completion. The status bar shows either passed or failed and the specification that the test was compared against
If the test fails, a message box will come up offering suggestions as to where to begin troubleshooting. This is not meant to replace the LCx Service Manual. These suggestions are made only to facilitate the troubleshooting process. Always refer to the LCx Service Manual when in doubt.
Press the **OK** button then select the **CANCEL** button to get back to the main menu.

I. Perform Tests
B. MEIA Optics
2. MEIA Lamp Stability

Select **Perform Tests** , **MEIA Optics**, then select **MEIA Lamp Stability**.
After the lamp stabilizes, the test proceeds by taking 20 reads of the MEIA lamp current and compares the difference from the previous reading.
If the test fails, a message box will come up offering suggestions as to where to begin troubleshooting. This is not meant to replace the LCx Service Manual. These suggestions are made only to facilitate the troubleshooting process. Always refer to the LCx Service Manual when in doubt. Typical troubleshooting suggestions will be offered.
Press the **OK** button then select the **CANCEL** to return to the main menu.

I. Perform Tests
B. MEIA Optics
3. PMT/Photodiode Noise

Select **Perform Tests**, **MEIA Optics**, and then **PMT/Photodiode Noise**.
The test proceeds by reading the current Photodiode read and current PMT read 5 times. A results screen appears when the test has completed.
This test verifies that the readings are within a specific range and does another calculation based off of the PMT readings.
If the test fails, a message box will come up offering suggestions as to where to begin troubleshooting. This is not meant to replace the LCx Service Manual. These suggestions are made only to facilitate the troubleshooting process. Always refer to the LCx Service Manual when in doubt.
Press the **OK** button then select the **CANCEL** button to get back to the main menu.

I. Perform Tests
B. MEIA Optics
4. Optics Gain

Select **Perform Tests**, **MEIA Optics**, **MEIA Optics Gain**.
You will be directed to load an MEIA Carousel.
Insure the carousel is loaded properly and installed in the LCx and close the access door. The test proceeds to completion and the results are displayed.
If the test fails, a message box will come up offering suggestions as to where to begin troubleshooting. This is not meant to replace the LCx Service Manual. These suggestions are made only to facilitate the troubleshooting process. Always refer to the LCx Service Manual when in doubt
Press the **OK** button then the **CANCEL** button to return to main menu.

I. Perform Tests
B. MEIA Optics
5. Fluorescence Background

Select **Perform Tests**, **MEIA Optics**, **Fluorescence Background**:
After selecting **Fluorescence Background**, you will be prompted to load an MEIA Carousel.
Load the carousel as instructed and install in the LCx. Close the Access door and select **OK**. A message box comes up asking you if you have 1 or 2 white disks on your MEIA Optical standards.

Answer **NO** if you have only 1 white disk. Answer **Yes** if you have 2 white disks.
The test begins and will go to completion. This test compares the readings of the various standards and blank spots to the Matrix Detect Reference parameter 38.30
This test checks to see that no fluorescence occurs under the MEIA Optics assembly. Cleaning of the Electronic Cover or the MEIA Optics or the Carousel usually resolves the failures. If the test fails, a message box will come up offering suggestions as to where to begin troubleshooting. This is not meant to replace the LCx Service Manual. These suggestions are made only to facilitate the troubleshooting process. Always refer to the LCx Service Manual when in doubt After reading the troubleshooting suggestions, press **OK**.
Select **CANCE**L and return to the main menu.

I. Perform Tests
B. MEIA Optics
6. Do All Test

The last function under **Perform Tests**, **MEIA Optics** is the **Do All Test**. This runs all the MEIA Optics subtests in the order they appear in the main menu list. It does not all you to keep rerunning the same test over and over again. The **Do All Test** will continue on until all tests have been completed or a failure has occurred. This test is not a fully automated one. You will still have to select **OK** to certain questions so that the software knows that you have set up the instrument properly.

I. Perform Tests
C. Analog Board

The last tests under **Perform Tests** is the **Analog Board** tests.
There are four subtests under **Analog Board**: **PMT Noise**, **Thermistors**, **High Voltage Power Supply** and **Buffer/Waste Sensors**. The **Do All Test** would perform these four tests in the order they appear in the menu.
Select **Perform Tests** then **Analog Board**.

I. Perform Tests
C. Analog Board
1. PMT Noise

Select **PMT Noise** from the menu.
The PMT Noise test takes 10 readings of the PMT when the High Voltage is set at 300 Volts. It takes 10 readings with the lamp off and with the lamp on. Calculations are then performed for the mean, Standard Deviation, and the %CV of each of the 10 readings. The test will insure that individual reads are within 850 to 1150 and that the %CV is less than 1%.

If the test fails, a message box will come up offering suggestions as to where to begin troubleshooting. This is not meant to replace the LCx Service Manual. These suggestions are made only to facilitate the troubleshooting process. Always refer to the LCx Service Manual when in doubt.
Select **CANCEL** to return to the main menu.

I. Perform Tests
C. Analog Board
2. Thermistors

Select **Perform Tests**, **Analog Board**, then **Thermistors** from the menu.
Temperature readings are taken for the Liquid heater, Remote thermistor, Air Heater, Reagent Heater.
The temperature must be within the specifications noted under each of the thermistor headings. An example would be the Liquid Heater which has a specification of 34.5 to 35.5 degrees C.

If the test fails, a message box will come up offering suggestions as to where to begin troubleshooting. This is not meant to replace the LCx Service Manual. These suggestions are made only to facilitate the troubleshooting process. Always refer to the LCx Service Manual when in doubt.

Select the **CANCEL** button to return to the main menu.

I. Perform Tests
C. Analog Board

3. High Voltage Power Supply

Select **Perform Tests**, **Analog Board**, and then **High Voltage Power Supply**.
The message box tells you to go to VP-58 in the LCx Service Manual to see how to measure the High Voltage. After reviewing the VP, select **OK**. The test will ask you to measure the high voltage at the cable and have you input the voltage that you measure. ONLY ENTER IN THE NUMERICAL VALUE. As an example, if you measured 407 volts, you would enter 407 and press Enter. Do not enter 400V or 400 volts. As the computer sets the high voltage in increments of 100 (400, 500, 600.....900) you enter in the value you measured. The specification is that the value be within 10 volts of the value it sets.

If the test fails, a message box will come up offering suggestions as to where to begin troubleshooting. This is not meant to replace the LCx Service Manual. These suggestions are made only to facilitate the troubleshooting process. Always refer to the LCx Service Manual when in doubt.
Select **OK** then select **CANCEL** to return to the main menu.

I. Perform Tests
C. Analog Board
4. Buffer/Waste Sensors

Select **Perform Tests**, **Analog Board** and then **Buffer/Waste Sensors** from the menu.
Follow the instructions given such as "please remove INACTIVATION bottle and select OK." If the buffer switch is working properly, PASS will be displayed for that sensor. If it fails, FAILED appears. If the test fails, a message box will come up offering suggestions as to where to begin troubleshooting. This is not meant to replace the LCx Service Manual. These suggestions are made only to facilitate the troubleshooting process. Always refer to the LCx Service Manual when in doubt.
Select **OK** then press **Cancel** to get back to the main Diagnostic menu.

II. Perform Checks
A. Boom
Life Check
Select **Perform Checks**, **Boom**, then **Life Check** from the menu.

(NOTE: Life Check will use the system parameter for the boom)

Follow the instructions and press **OK** when finished. Level sensing will take place in the buffer pack. The Life Check is set up to run continuously in reps of 24 samples (or cycles) and keeps track of the number of level sense steps for each vial. The software also keeps track of the different ranges of level sensing for each vial. That is, how many times did it level sense within 1 step, 2 steps, 3 steps and >3 steps. Anything greater than 3 is a failure. This would indicate the probe/electrode requires cleaning or replacing, or that the boom requires calibration.
This test also keeps a running average of the 24 reps that may give us additional information as far as troubleshooting is concerned. Then the R and Z boom positions are checked. If these fail, suspect that the flag is hitting the sensor. If not able to adjust, replace the boom.
To stop the test, select the **Conclude** button. After you have selected Conclude, you can then press **Cancel** to get back to the main menu.

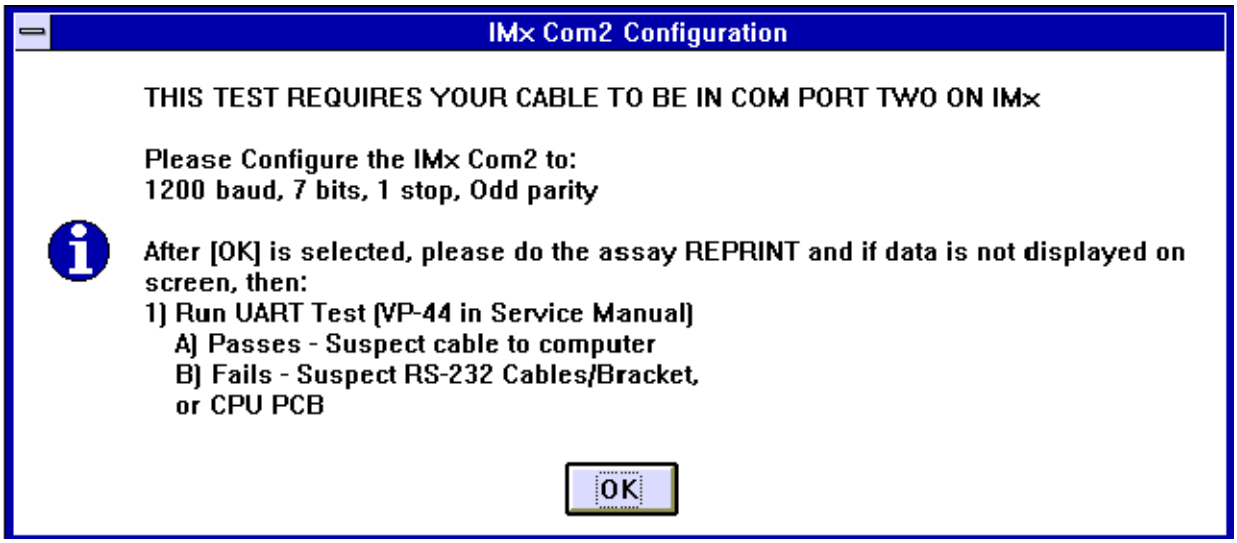
II. Perform Checks
B. RS-232 Check

Select **Perform Checks**, then **RS-232** Check from the menu.
This test allows you to verify the RS-232 operation for the IMx®, TDx® and /TDxFLx® instruments Performing the RS-232 check:

NOTE: The RS-232 port is currently not active on the LCx analyzer.
NOTE: Depending on the instrument you will be trying to verify, insure that the interface has been activated. As an example, set parameter 1.18 to 2215 in the IMx System. For TDxFLx, set parameters 2.9 and 2.10 to 1 then edit the serial number and cycle the power. For TDx, just edit the serial number and cycle the power. The cable for the TDx and TDxFLx requires that a breakout box with pins 2 and 3 crossed be attached to the AT to Modem cable.

IMx Example:
Insure the AT to Modem cable (P/N 14207-113) is connected to COM2 on the IMx Analyzer. From the

main menu, select Perform Checks, then RS-232 Check, then select PC COM Port, then select COM2 if running the GRiD® Laptop computer or select the appropriate Com port for the computer you are using.
Select "**IMx**."
The three options available are "**Send to Host**", "**Receive from X Sys**" and "**Cancel**". **Cancel** will quit the check and take you back to the main menu. **Receive from X Sys** allows you to receive information from the IMx® to your computer. **Send to Host** allows your computer to act as the IMx and send an example assay run to the Host computer, in this case DATATRAC™.
Select "**Receive from X Sys**".



Verify that the IMx COM 2 port is setup to 1200 baud, 7 bits, 1 stop and Odd parity as follows:
NOTE: *REMEMBER TO RE-EDIT ORIGINAL PARAMETERS BACK WHEN DIAGNOSTIC TESTING IS COMPLETED*
Press **SYSTEM** / **FILES** / **1.10** / **DISPLAY** to show COM 2 baud
(If necessary, press 1200 using the IMx® keypad then STORE)
Press **FWD** to display COM2 chr len
(If necessary, press 7 using the IMx keypad then STORE)
Press **FWD** to display COM2 stop bit
(If necessary, press 1 using the IMx keypad then STORE)
Press **FWD** to display COM2 parity
0 = none
1 = Odd
2 = Even
(If necessary, press 1 using the IMx keypad then STORE)
Press **EXIT**
Press **EXIT** to return to the READY menu.
If any system files were edited, perform the Assay Module Shutdown procedure to activate these values as follows:
Press **UTILITY** / **SHUTDOWN** / **START**
When "130 READY TO CHANGE MODULES" appears, lift the assay module from it's connector and reset it. The IMx System will re-boot and return to the READY menu.
Select **OK** to continue on. The screen now indicates:
"**Communication Status Window is Active for IMx**"
The instrument is now set up to receive data from the IMx Analyzer. Using the Reprint function of the IMx Analyzer, send information from the IMx Analyzer to your computer. Press **UTILITY**, **OTHER**, **REPRINT**. The IMx Status Window Active screen should duplicate the data that appears on the printout. If no assay data is available, the display should indicate, "NO DATA AVAILABLE".
You can Reprint the data as many times as you want. Each time the display should include the last reprint data. Select **Cancel** to return to the main menu. YOU CAN PERFORM THE SAME BASIC TEST FOR THE TDx® AND TDxFLx® instruments. Just follow the simple instructions.

If the check does not work properly:

Parity errors with COM2 usually indicate that the settings for COM2 are not correct. Insure the baud is 1200, character length is 7, stop bits are 1 and parity is set to ODD (1). If still not able to connect, run the UART Test located under Service Tests. Short pins 2,3 and 4,5 and 6,20 of the COM2 port of the IMx® Analyzer and then press UTILITY, OTHER, OTHER, SERVICE, OTHER, UART. The test should begin by testing out the COM1 port first (this will fail since the pins are not shorted) then test out COM2. If this test passes but you still have a communication problem, suspect the AT-Modem cable. If the test fails, suspect the
RS-232 cable/bracket assembly and the CPU PCB.

Send To Host:

We have set up an assay run (Ultra hTSH) that can be sent to the host computer. We mainly set this up to use with our DATATRAC™ system, but other computer setups should be able to use this example printout. Set up the DATATRAC as follows: Connect your 25 pin breakout box (P/N 14207-034 which is part of the Tool kit) to your Field Service modem cable (for use with GRiD® Cellular modem). Use 2 wires to reverse pins 2 & 3 on the connector. Set the switches on pins 2 and 3 to the OFF position. Connect 9 pin female connector to correct DATATRAC port. You will need to verify with the customer which port is set up for IMx Analyzer. All hardware connections have been made. Now set up the DATATRAC System to accept our results.

Enter the SYSTEM OPERATION section in DATATRAC™ System by selecting "1" from the main menu and then get into ENTER SAMPLE by selecting 1 and pressing enter. Enter 001 for the PID and then use the arrow keys to get over to TEST: and type in TSH. Press F1 to store data. If the system asks you for the SID number, enter the same number you used for the PID. Continue entering PIDs until you have finished entering PIDs 002, 003, 004, 005, and 006. Then press ESC to get to main menu.

Select 7, Carousel setup and press ENTER. Type 1IMX for SYSTEM and press ENTER. Under CAROUSEL enter 1; under RUN TYPE enter batch; under TEST enter TSH and under CALIBRATION RUN enter "n" for no. Press F1 to store the data. Press F2 to auto load the data then press F1 to store data. Press ESC, ESC to get back to main menu.

On your laptop, transmit data to the host computer by doing the following:

From the main menu choose Perform Checks, RS-232, Send To Host, Configure Host Com port to 1200 baud, 7 bits, 1 stop bit, odd parity then choose OK. The following information will be sent to the Host computer:

Transmitting the following sample MEIA MODE 1 Assay Test Results Output:

[

DATE: 4/06/90
TIME: 9:25:35

TECH ID : 123456789
RGNT LOT: 24682468
SERIAL #: 12345
CRSL ID : 3
CURVE : 1
CAL DATE: 4/06/90

CAL TIME: 8:23:59

ASSAY 80 ULTRA hTSH 3A62 Revision 3

MODE 1 CALIBRATOR

LOC	uIU/mL	RATE	FACTOR
1	10.0	144.0	0.926

MODE 1 CALIBRATION CURVE

CALIB	uIU/mL	AVGR
A	0.0	5.7
B	0.5	13.3
C	2.0	35.1

```
  D          10.0       144.0
  E          40.0       487.0
  F         100.0       981.4

LOC       ID          uIU/mL        RATE    NOTE
 2    CONTROL L         0.29        10.2     LOW
 3    CONTROL M         6.20        97.2


HIGH >     25.000 uIU/mL
LOW <       0.500 uIU/mL


TESTS USED TO DATE :  24

]
3
!!

Transmission Complete....
```

Watch the hard drive LED of the DATATRAC™ computer. The hard drive LED will come on when the data is accepted by the DATATRAC System. At this point you can select 9, APPROVE PATIENT RESULTS and type in the password of SUPER. Type in 1IMX for SYSTEM and press the enter key. The results should appear. If no data is available, check your cabling hookup and DATATRAC configuration. Check that the results match what was sent over. All the results should say NO DATA AVAILABLE. Press ESC until you reach the main menu on the DATATRAC System.

Press **Cancel** on the laptop computer diagnostics to get back to the main menu.

NOTE: REMEMBER TO PLEASE DELETE THE EXAMPLE FILE TRANSMITTED TO THE DATATRAC COMPUTER WHEN DIAGNOSTIC TESTING IS COMPLETED

III. Options

A. Am/SD/% CV Calc

This is the Arithmetic Mean, Standard Deviation, % Coefficient of Variation calculator. Use this function to calculate the mean, SD, % CV of assay runs.
After selecting the **Am/SD/% CV Calc** menu item you can start entering the value for each of the assay results. For example, if you ran 5 medium controls of an assay and want to find the % CV, enter the first value and press **Enter**, input the second number and press **Enter**. Continue on until all 5 values have been input. Then press **Enter** again. This forces the program to compute the mean, SD and %CV. To calculate another set of values, select **Redo** and input the new values. If you have finished with the program, select Cancel to get back to the main menu. If you missed a number, you can insert the number by selecting the **INSERT** button.
Move the highlighted line above the place where you want the number to be inserted and press the **ENTER** key.
Enter the number and press **ENTER**.
To edit a number press the **EDIT** button.
After selecting the number to be edit press the **Enter** key .
Enter the number and press the **Enter** key to continue on.
The **Delete** button works the same way as the **Edit** button.
To return to main menu select the **Cancel** button.
To exit the LCx Diagnostics from the main menu, select **Exit**. Then select **Confirm Exit**.

Software Problem/Change Report Form

Filling out the SOFTWARE PROBLEM/CHANGE REPORT form:

Send these forms to: Abbott Diagnostics
1921 Hurd Drive
M.S. 2-26 Attn: X-SYSTEMS® CSE
Irving, Tx 75038

Please complete the form for A through P.

A. Title should be the ERROR CODE description that caused this change.
B. Put X here if this is a software problem (or defect).
C. Put X here if this is a software change request.
D. Put your name here.
E. Enter revision of diagnostic software being used.
F. Put X by Customer use (since you use at customer site).
G. Put your name here (Please print).
H. Enter date here.
I. Serial number of LCx Analyzer.
J. LCx System Software revision, Type of computer being used to run diagnostics.
K. Description of the problem. You can use attachments (extra sheets) if needed.
L. Enter probable consequence of problem, if possible.
M. Put X here if attachments are being sent.
N. Put X here if attachments are not being sent.
O. Put your name here.
P. Put date here.

SOFTWARE PROBLEM / CHANGE REPORT

Report #_____Title: _____A_____
_B_Problem or_C_Change _____

Name:_____D_____
Revirian:_____E_____

FOUND DURING
___ Engineering test
___ validation
___ Manufacturing test
_F_ Customer use
___ Other:_____

DESCRIPTION Reported by:_____G_____ Date:_____H_____
Unit Serial Number(s):_____I_____
Equipment configuration and usage (e.g., system rate, error handling, hardware used):_____
_____J_____

Description of problem or change:_____K_____

Probable consequence:
_____L_____

See attached:_M_ Yes _N__ NO Originated by:_____O_____ Date:_____P_____

DIAGNOSIS
Source of problem:_____

R - Requirement/specification
I - Implementation
N/A - Not applicable

Prepared corrective action:_____

I - Immediate fix NP - Not a software problem
D - Delayed fix DP - Duplicate problem
NR - Fix not required CR - Can't reproduce
S - Spec change

Severity of probable consequence:____

Level 1: Major
Level 2: Moderate
Level 3: Minor
Level 4: Minimal

Description of prepared diagnosis / corrective action:_____

See attached:___ Yes ___ NO Diagnosed by:_____ Date:_____

FINAL RESOLUTION Revirian:_____ E.C.N.:_____ Document:_____

Affected modules:_____

APPROVALS Engineering:_____ Date:_____
Quality Assurance:_____ Date:_____

SOFTWARE PROBLEM / CHANGE REPORT

Report #:_____ Title:_____
___Problem or___Change _____

Name:_____
Revision:_____

FOUND DURING
___ Engineering test
___ validation
___ Manufacturing test
___ Customer use
___ Other:_____

DESCRIPTION Reported by:_____ Date:_____
Unit Serial Number(s):_____
Equipment configuration and usage (e.g., system rate, error handling, hardware used):_____
_____
_____
_____
Description of problem or change:_____
_____
_____
_____
Probable consequence:_____
_____
_____
See attached:___ Yes ___ NO Originated by:_____ Date:_____

DIAGNOSIS
Source of problem:____

R - Requirement/specification
I - Implementation
N/A - Not applicable

Prepared corrective action:____

I - Immediate fix
D - Delayed fix
NR - Fix not required
S - Spec change
NP - Not a software problem
DP - Duplicate problem
CR - Can't reproduce

Severity of probable consequence:____

Level 1: Major
Level 2: Moderate
Level 3: Minor
Level 4: Minimal

Description of prepared diagnostic / corrective action:_____
_____
_____
_____
_____
_____
_____
See attached:___ Yes ___ NO Diagnosed by:_____ Date:_____

FINAL RESOLUTION Revision:_____ E.C.N.:_____ Document:_____
_____
_____
Affected modules:_____
_____
_____

APPROVALS Engineering:_____ Date:_____
Quality Assurance:_____ Date:_____

END OF DOCUMENT

ABBOTT ADD	INSTRUMENT SERVICE ADVISORY

SUBJECT: **LCx® Manual Amplification Vial Retainer (AVR)**	ISA#: **69-005**
ORIGINATOR: **Kyle Hranitzky**	PRODUCT: **LCx® Probe System (69)**
APPROVED: **Bob Schabel 11/8/95**	EFFECTIVITY DATE: **16-NOV-95**

I. DISTRIBUTION:

International and USA

II. PURPOSE:

This ISA provides information for servicing LCx® analyzers equipped with the manual Amplification Vial Retainer (AVR). This information will be incorporated into the next revision of the LCx® Analyzer Service Manual.

For information about replacing an integrated Amplification Vial Retainer with a manual Amplification Vial Retainer in an LCx® Analyzer, refer to TSB 69-002: LCx® Manual Amplification Vial Retainer Retrofit: Installation and Alignment.

ISA CONTENTS

This ISA contains this information:

Introducing the Manual Amplification Vial Retainer (AVR)

Block Diagrams

- System Wiring Diagram
- Ground Cable
- LLS Cable

Isolation Procedures

This new error code is applicable to the manual Amplification Vial Retainer (AVR):
ERROR CODE 93: CAROUSEL LOCK ARM NOT LOCKED

To assist in troubleshooting AVR problems, this Isolation Procedure has been developed for Error Code 93:
IP 87: CAROUSEL LOCK ARM NOT LOCKED

Parts List Information

part number information for the manual AVR
PL illustrations including the AVR

Removal/Replacement Procedures

A new removal/replacement procedure has been developed for the manual AVR:
RR 2.11: Amplification Vial Retainer (AVR)

In addition, the use of the manual Amplification Vial Retainer (AVR) affects several removal/replacement procedures. These revised procedures are provided in this ISA:
RR 2.8 Air Duct Cover
RR 3.1 Fan & Gasket Assembly
RR 3.3 Carousel Motor Assembly
RR 3.13 Air Thermistor Assembly

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

RR 3.16 Air Heater Assembly
RR 3.18 Carousel Receiver Assembly

Verification Procedures

Two new verification procedures have been added for the manual Amplification Vial Retainer (AVR):
VP 64: Manual AVR Alignment
VP-65: AVR Sensor Check
The manual Amplification Vial Retainer affects several verification procedures for the LCx® Analyzer. These revised procedures are provided in this ISA:
VP 15: Buffer Sensor Check
(now also checks for the locked/unlocked status of the AVR)
VP 47: MEIA Performance Panel Run Procedure
(AVR must be locked and later unlocked)

Preventative Maintenance/Total Service Call Procedure

NOTE: *All IPs, PLs, RRs, and VPs mentioned in this ISA are LCx® IPs, PLs, RRs, and VPs. They are in the LCx Analyzer Service Manual unless noted otherwise.*

III. INTRODUCING THE AMPLIFICATION VIAL RETAINER

The manual Amplification Vial Retainer (AVR), when locked into position over the carousel, ensures that the amplification vial remains in place in the carousel during assay testing.

The manual AVR must be:

- locked during all assay testing
- unlocked during all system checks and calibrations

The locked/unlocked status is sensed by the AVR Home Sensor. The system software checks the lock sensor before and during an assay. Verify functionality of the AVR Home Sensor by using the Dispense Hand Controls.

The AVR is connected to the Analog Board via the LLS/Analog Cable Assembly.

The AVR is compatible only with Boom Assembly CN 3-47090-02. This boom assembly does not have an integrated AVR.

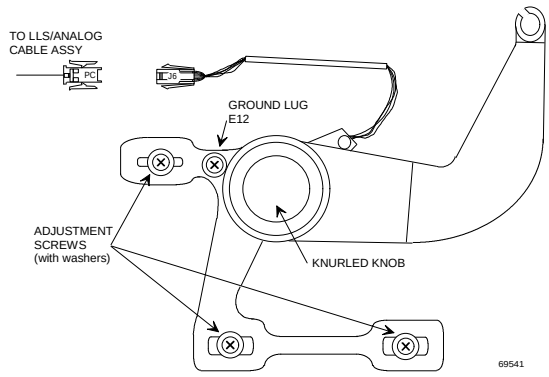


Figure ISA 69-005-1:
Manual Amplification Vial Retainer (top view)

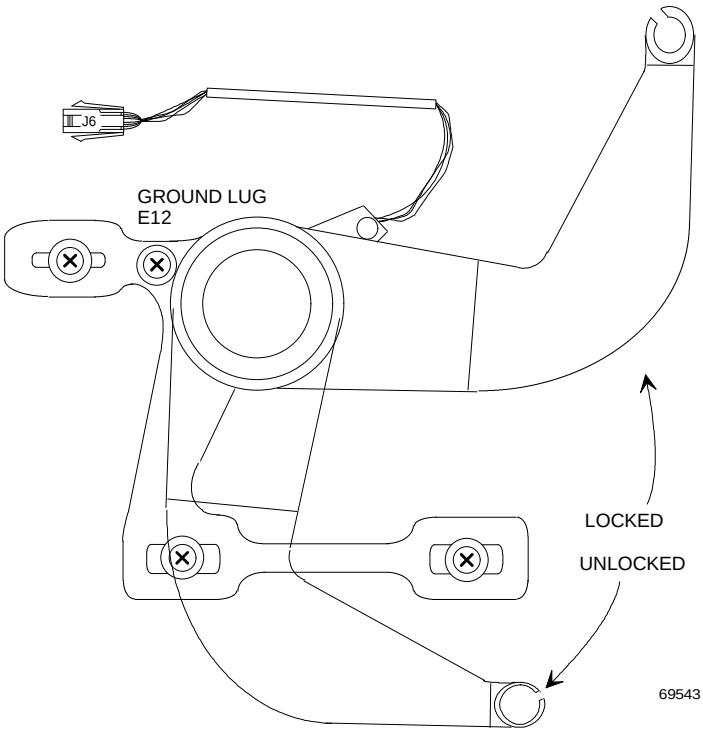


Figure ISA 69-005-2: Locked and Unlocked Positions of AVR

BLOCK DIAGRAMS

SYSTEM WIRING

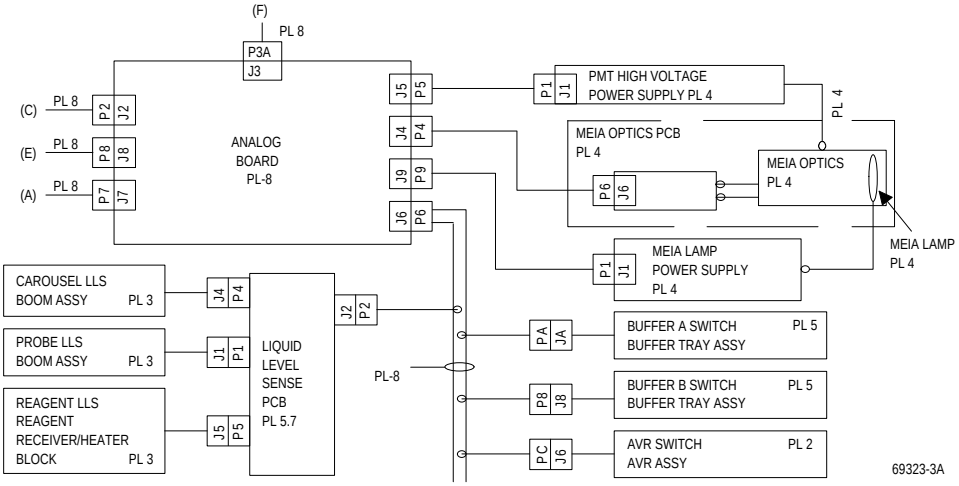


Figure ISA 69-005-3: Block Diagram: System Wiring

GROUND CABLE

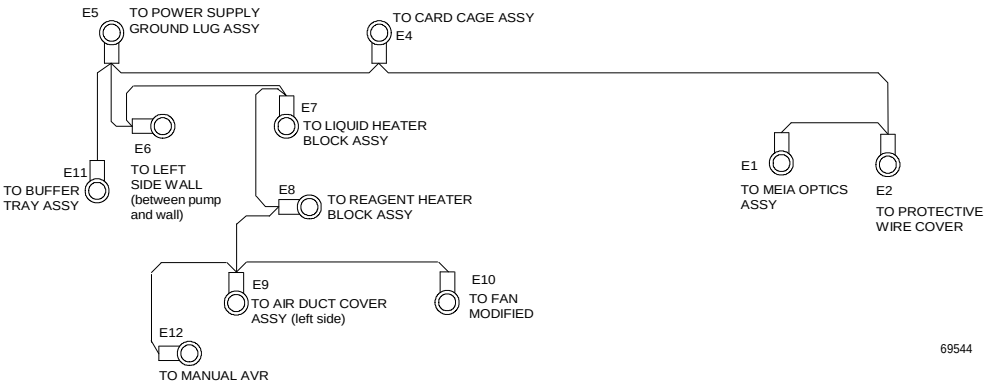


Figure ISA 69-005-4: Block Diagram: Ground Cable

LLS CABLE

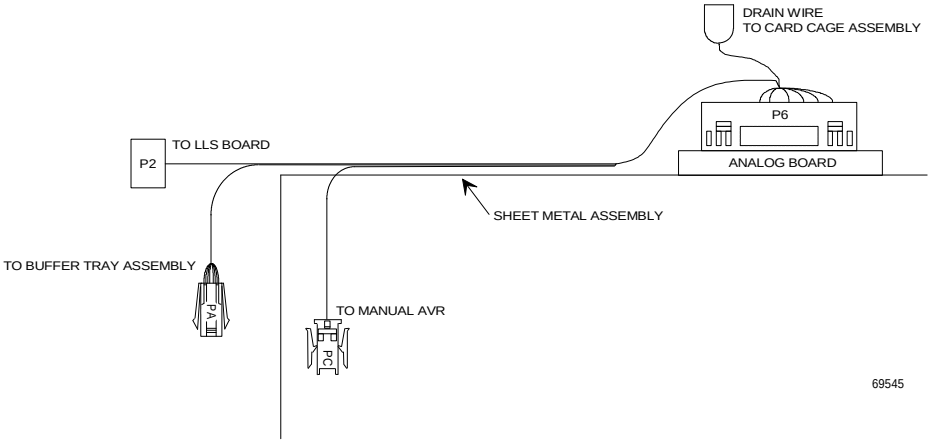
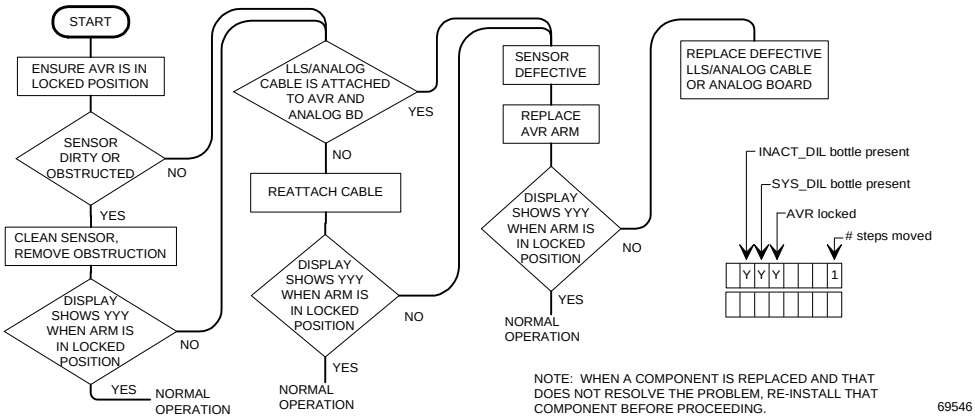


Figure ISA 69-005-5: Block Diagram: LLS Cable

ISOLATION PROCEDURES

IP 87 ERROR CODE 93: CAROUSEL LOCK ARM NOT LOCKED



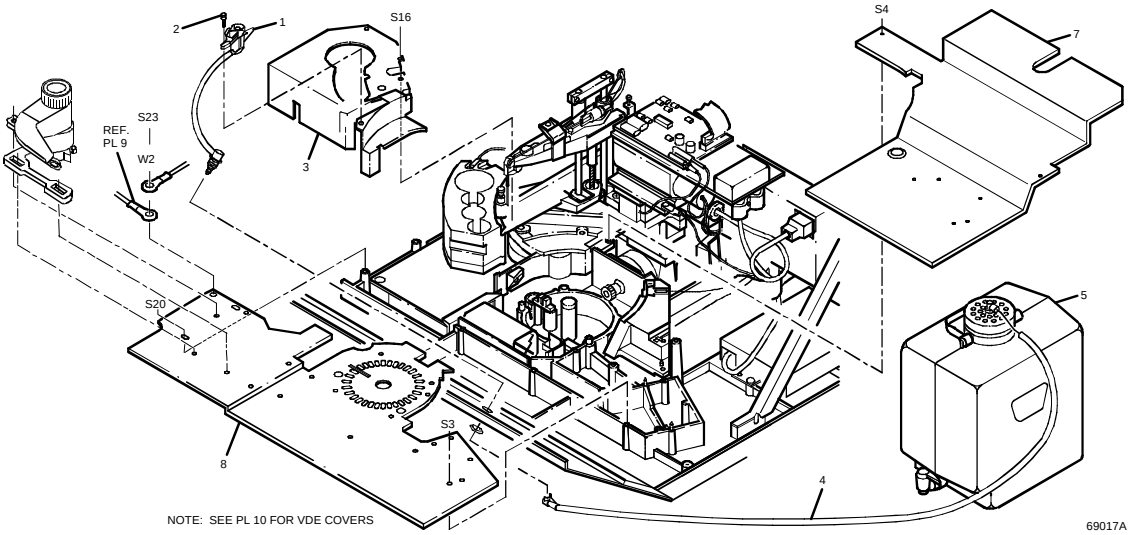
Parts List INFORMATION

Amplification Vial Retainer (AVR)	3-47002-01
with attachment hardware included:	
Screw, 6-32x0.50 Lg, CPTV (qty 3)	14494-108
(attach AVR to Air Duct Cover Assy)	
Washer, Flat #6 (qty 3)	10890-012
(attach AVR to Air Duct Cover Assy)	
Screw (qty 1)	14494-104
(attach Ground Cable Assy to AVR)	
Ground Cable Assembly	3-47077-01
LLS/Analog Board Cable Assembly	3-47075-01
LCx® AVR Positioning Tool	3-79200-01
Boom Assembly	3-47090-02

Parts Compatibility

Boom 3-47090-02, for use with the manual AVR, replaces
Boom 3-47090-01, that was used in instruments with integrated AVRs.

PL 2 INTERNAL COVERS



PL 9 GROUND CABLE

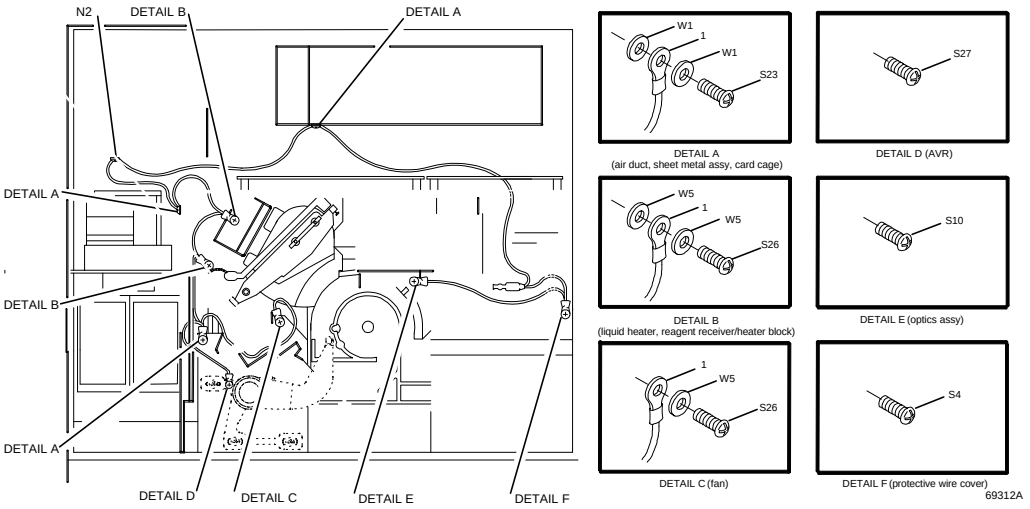
PARTS

Item	Part No.	Description	USO Location
1	47077-107	Cable, Ground Assembly	K

HARDWARE

Item	Part No.	Description	Qty.
S4	14494-105	Screw, PHP, 6-32x.312	1
S8	14489-155	Screw, PHP, 6-32x.25 LG, SS	1
S10	10854-408	Screw, PH PM CS CDPL 6-32x1/4	1
S23	10854-410	Screw, PH PM CS CDPL 6-32x5/16	3
S26	10854-508	Screw, CS CDPL 8-32x.25	2
S27	14494-104	Screw, PHP LG CPTV 6-32x.25	1
W1	10893-003	Washer, Lock Int Tooth CS CDPL #6	6
W4	14522-305	Washer, Ext Tooth SS #6	1
W5	10893-004	Washer, Int Lock, CS CDPL #8	4
N2	14422-004	Nut, Hex, 6-32	1

PL 9 GROUND CABLE



REMOVAL/REPLACEMENT PROCEDURES

RR 2.11 AMPLIFICATION VIAL RETAINER (AVR)

REMOVAL

1. Remove the Enclosure Assembly (RR 1.3).
2. Raise the Display (RR 8.1.1).
3. Remove the left VDE Cover (PL 10.2).
4. Detach the Wash Station from the Reagent Shroud.
5. Remove the Reagent Shroud (RR 2.3).
6. Remove screw from AVR ground terminal lug E12.
7. Detach cable connector J6 (from the AVR) from LLS/Analog Cable Assembly cable connector PC.
8. Remove the AVR from the Air Duct Cover Assembly (3 screws and washers).

REPLACEMENT

1. Place the manual AVR onto the Air Duct Cover Assembly.
2. Attach cable connector J6 (from the AVR) to the LLS/Analog Cable Assembly cable connector PC.
3. Attach AVR ground terminal lug E12 to the AVR with screw.
4. Loosely secure the AVR to the Air Duct Cover Assembly with 3 screws and washers.
5. Attach the Reagent Shroud (RR 2.3).
6. Secure the Wash Station to the Reagent Shroud.
7. Attach the left VDE Cover with 2 screws.
8. Reposition and secure the Display (RR 8.1.1).
9. Install the Enclosure Assembly (RR 1.3).

VERIFICATION

Perform the following procedures in the order listed:

1. Reagent Heater Block Adjustment (VP-21)
2. Boom Calibration (VP-8)
3 Level Sense Check (VP-11)
4. AVR Alignment (VP-64, procedure provided in this ISA)
5. AVR Sensor Check (VP-65, procedure provided in this ISA)
6. Buffer Sensor Check (VP-15)
7. Total Service Call Procedure

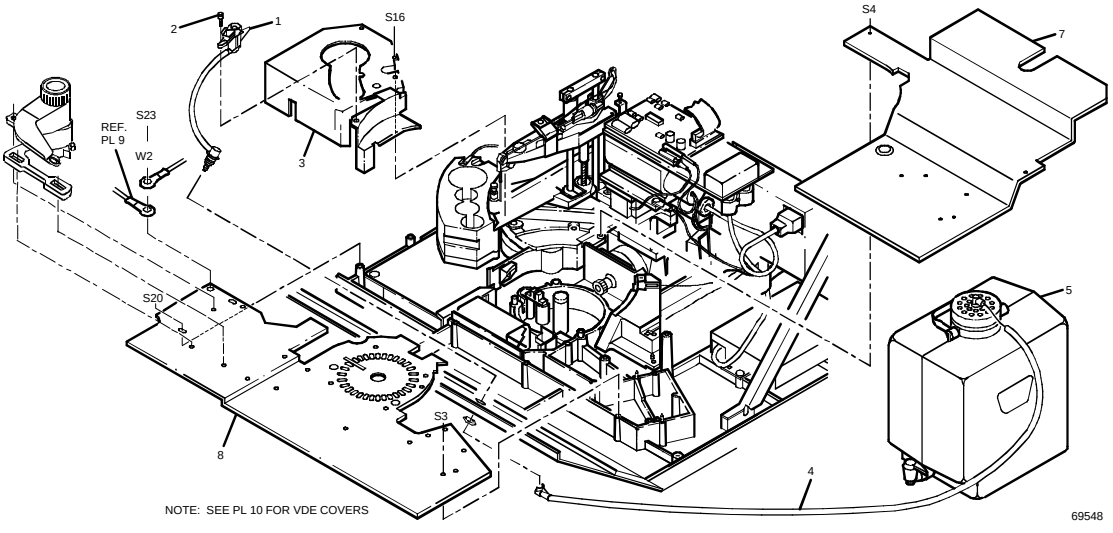


Figure ISA 69-005-6: Manual Amplification Vial Retainer

RR 2.8 AIR DUCT COVER

REMOVAL

1. Remove Enclosure Assembly (RR 1.3).
2. Remove 3 screws securing right VDE Cover to Display (PL 10.1).
3. Remove left VDE Cover (PL 10.2).
4. Remove Reagent Shroud Assembly (RR 2.3).
5. Remove AVR (RR 2.11, procedure provided in this ISA).
6. Remove Protective Wire Cover (RR 2.7).
7. Remove Air Duct Cover.
   a. Disconnect 11 mounting screws.
   b. Disconnect VDE Ground Cable.
   c. Lift off cover.

REPLACEMENT

1. Install Air Duct Cover.
   a. Connect VDE Ground Cable.
   b. Place cover over mounting holes.
   c. Secure cover with 11 mounting screws.
2. Install Protective Wire Cover (RR 2.7).
3. Install 3 screws securing right VDE Cover to display (PL 10.1).
4. Install AVR (RR 2.11, procedure provided in this ISA).
5. Install Reagent Shroud Assembly (RR 2.3).
6. Install left VDE Cover (PL 10.2).
7. Install Enclosure Assembly (RR 1.3).

VERIFICATION

1. Perform the following checks and calibrations:
   - MEIA Carousel Calibration (VP-30)
   - Boom Calibration (VP-8)
   - Level Sense Check (VP-11)
   - Bar Code Check (VP-4)
   - Temp Check (VP-28)
   - AVR Alignment (VP-64, procedure provided in this ISA)

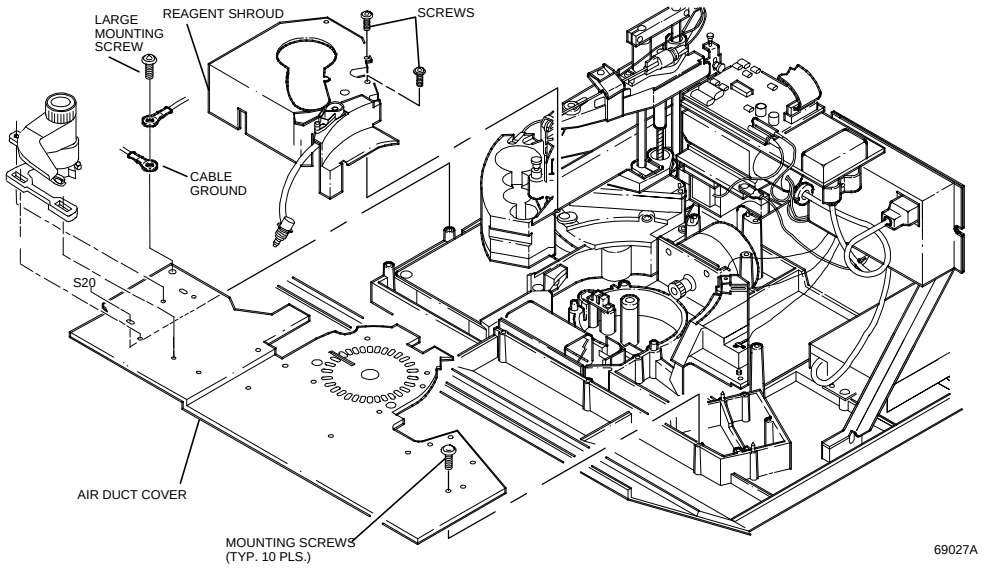


Figure ISA 69-005-7: Air Duct Cover

RR 3.1 FAN & GASKET ASSEMBLY

REMOVAL

1. Remove Enclosure Assembly (RR 1.3).
2. Raise Display to upright position (RR 8.1.1).
3. Remove left VDE Cover (PL 10.2).
4. Remove Reagent Shroud Assembly (RR 2.3).
5. Remove AVR (RR 2.11, procedure provided in this ISA).
6. Remove Protective Wire Cover (RR 2.7).
7. Remove Air Duct Cover.
8. Lift Reagent Heater Block to access mounting screws.
   a. Remove Reagent Heater Block mounting screws.
   b. Lift up assembly and set aside.
9. Lift Boom Assembly to access connector.
   a. Remove 3 screws.
   b. Remove left screw from Protective Wire Cover.
   c. Lift up assembly and set aside.
10. Disconnect Fan Cable (J34).
11. Remove Fan & Gasket Assembly.
    a. Remove 3 mounting screws.
    b. Remove assembly.

> **CAUTION:**
> Ensure Air Heater Assembly wires are not pinched when
> installing Fan & Gasket Assembly.

REPLACEMENT

1. Install Fan & Gasket Assembly.
   a. Place Fan & Gasket Assembly over mounting holes.
   b. Secure with 3 mounting screws.
   c. Connect Fan Cable (J34).
2. Install Boom Assembly (RR 3.9).
   a. Reposition Boom Assembly over mounting holes.
   b. Install 3 mounting screws.
   c. Insert left screw in Protective Wire Cover.
3. Install Reagent Heater Block Assembly (RR 3.2).
   a. Place Reagent Heater Block over mounting holes.
   b. Secure Reagent Heater Block with 2 mounting screws.
4. Install Air Duct Cover (RR 2.8).
5. Install Protective Wire Cover (RR 2.7).
6. Install AVR (RR 2.11, procedure provided in this ISA).
7. Install Reagent Shroud Assembly (RR 2.3).
8. Install left VDE Cover (PL 10.2).
9. Reposition and secure Display Assembly (RR 8.1.1).
10. Install Enclosure Assembly (RR 1.3).

VERIFICATION

1. Perform Reagent Heater Block Adjustment (VP-21).
2. Perform the following checks and calibrations:
   - MEIA Carousel Cal (VP-30)
   - Bar Code Check (VP-4)
   - Boom Calibration (VP-8)
   - Level Sense Check (VP-11)
   - AVR Alignment (VP-64, procedure provided in this ISA)
   - MEIA Temp Cal (VP-29)
   - MEIA Photo Cal (VP-27A)

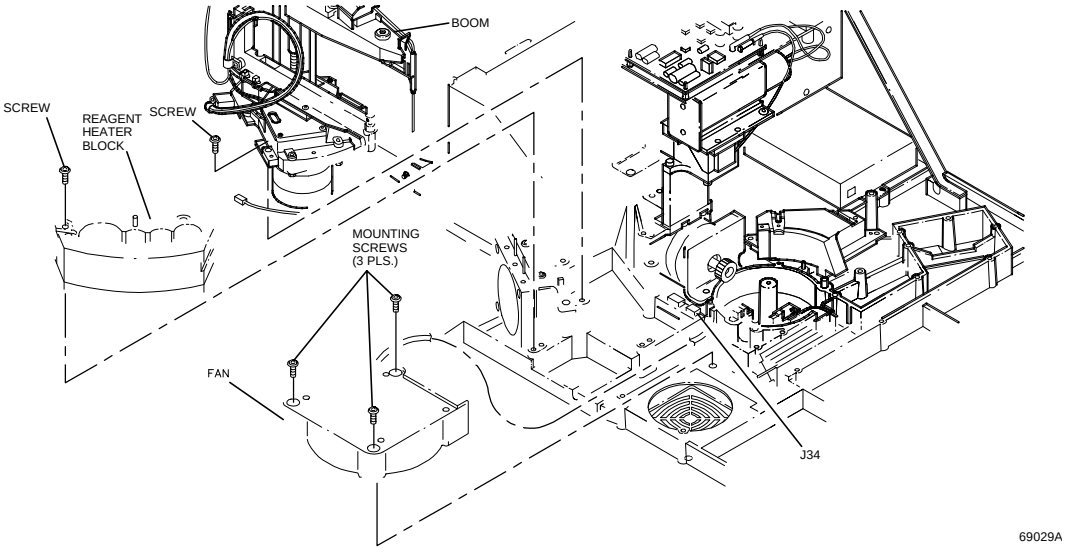


Figure ISA 69-005-8: Fan & Gasket Assembly

RR 3.3 CAROUSEL MOTOR ASSEMBLY

REMOVAL

1. Remove Enclosure Assembly (RR 1.3).
2. Raise Display to upright position (RR 8.1.1).
3. Remove left VDE Cover (PL 10.2).
4. Remove Reagent Shroud Assembly (RR 2.3).
5. Remove Amplification Vial Retainer (RR 2.11, procedure provided in this ISA).
6. Remove Protective Wire Cover (RR 2.7).
7. Remove Air Duct Cover (RR 2.8).
8. Remove MEIA Optics Assembly (RR 4.1).
9. Tilt back Card Cage (RR 8.0).
10. Disconnect Carousel Motor Assembly Cable (P4) from Motor Driver Board.
11. Remove Carousel Home Sensor.
    a. Remove 2 mounting screws.
    b. Remove Carousel Home Sensor.
12. Remove wires from cable clamps.
    a. Cut cable ties as necessary.
    b. Remove wires from clamps.
13. Lift Boom Assembly and set aside.
    a. Remove 3 mounting screws.
    b. Lift boom up and set aside.

14. Remove Carousel Motor Assembly.
    a. Remove 3 mounting screws from bracket.
    b. Remove Carousel Motor Assembly.

REPLACEMENT

1. Install Carousel Motor Assembly.
    a. Place Carousel Motor bracket over mounting holes.
    b. Secure Carousel Motor Bracket to base with 3 mounting screws.
2. Install Carousel Home Sensor.
    a. Place Carousel Home Sensor over mounting holes with embossed dot on top of sensor to the left.
    b. Secure with 2 mounting screws.
    c. Route sensor wires through notch in base rib.
3. Connect Carousel Motor Assembly Cable to Motor Driver (P4).
4. Secure wires in cable clamps.
5. Tilt Card Cage to upright position (RR 8.0).
6. Install MEIA Optics Assembly (RR 4.1).
7. Install Air Duct Assembly (RR 2.8).
8. Install Boom Assembly (RR 3.9).
9. Install Amplification Vial Retainer (RR 2.11).
10. Install Reagent Shroud Assembly (RR 2.3).
11. Install left VDE Cover (PL 10.2).
12. Install Protective Wire Cover (RR 2.7).
13. Reposition and secure Display Assembly (RR 8.1.1).
14. Install Enclosure Assembly (RR 1.3).

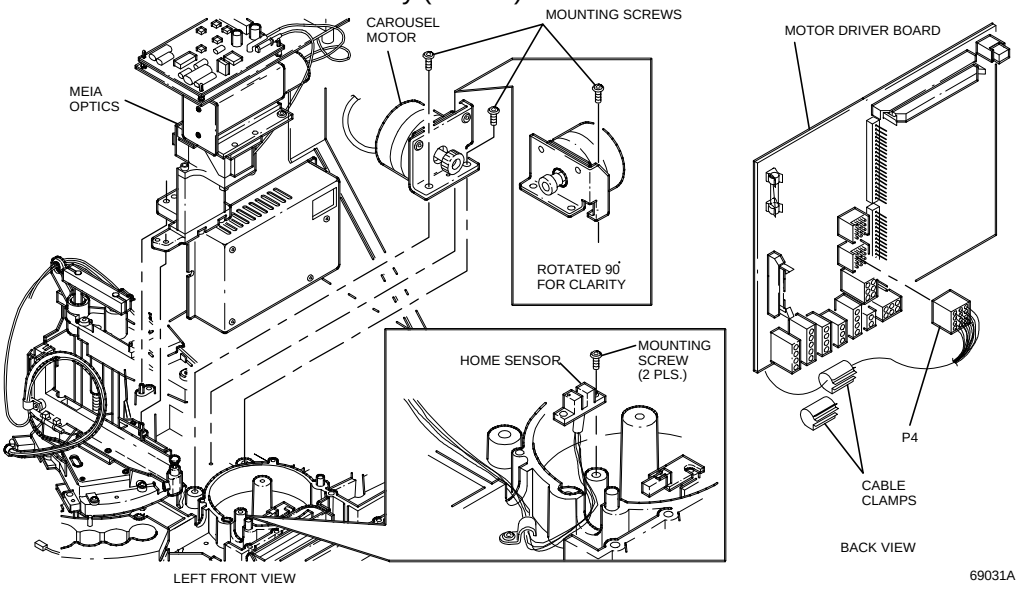


Figure ISA 69-005-9: Carousel Motor Assembly

RR 3.3 CAROUSEL MOTOR ASSEMBLY

VERIFICATION

1. Perform the following checks and calibrations:
   - Carousel Motor and Gear Adjustment (VP-19)
   - Bar Code Check (VP-4)
   - MEIA Carousel Calibration (VP-30)
   - Boom Calibration (VP-8)
   - Level Sense Check (VP-11)
   - AVR Alignment (VP-64, procedure provided in this ISA)
   - MEIA Photo Calibration (VP-27A)
   - Dispense Check (VP-13)

RR 3.13 AIR THERMISTOR ASSEMBLY

REMOVAL

1. Remove Enclosure Assembly (RR 1.3).
2. Raise Display to upright position (RR 8.1.1).
3. Remove left VDE Cover (PL 10.2).
4. Remove Reagent Shroud Assembly (RR 2.3).
5. Remove Amplification Vial Retainer (RR 2.11).
6. Remove Protective Wire Cover (RR 2.7).
7. Remove Air Duct Cover (RR 2.8).
8. Remove Air Thermistor Assembly.
   a. Disconnect Air Thermistor Assembly Cable.
   b. Remove Air Thermistor mounting screw.
   c. Remove Air Thermistor Assembly.

REPLACEMENT

1. Install Air Thermistor Assembly.
   a. Place Air Thermistor Assembly over mounting hole.
   b. Secure Assembly with mounting screw.
   c. Connect Air Thermistor Assembly Cable.
2. Install Air Duct Cover (RR 2.8).
3. Install Protective Wire Cover (RR 2.7).
4. Install Amplification Vial Retainer (RR 2.11
5. Install Reagent Shroud Assembly (RR 2.3).
6. Install left VDE Cover (PL 10.2).
7. Reposition and secure Display Assembly (RR 8.1.1).
8. Install Enclosure Assembly (RR 1.3).

VERIFICATION

1. Perform the following checks and calibrations:
   - Bar Code Check (VP-4)
   - MEIA Carousel Calibration (VP-30)
   - Boom Calibration (VP-8)
   - Level Sense Check (VP-11)
   - AVR Alignment (VP-64, procedure provided in this ISA)
   - MEIA Temperature Calibration (VP-29)
   - MEIA Photo Calibration (VP-27A)

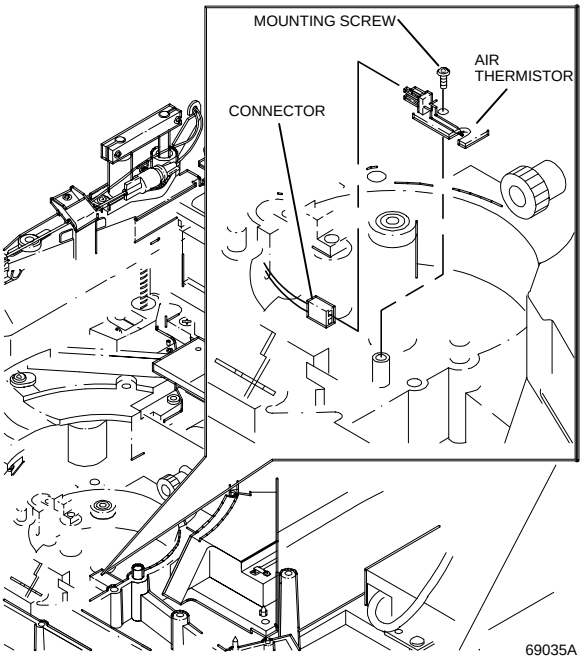


Figure ISA 69-005-10: Air Thermistor Assembly

RR 3.16 AIR HEATER ASSEMBLY

REMOVAL

1. Remove Enclosure Assembly (RR 1.3).
2. Raise Display to upright position (RR 8.1.1).
3. Remove left VDE Cover (PL 10.2).
4. Remove Reagent Shroud Assembly (RR 2.3).
5. Remove Amplification Vial Retainer (RR 2.11, procedure provided in this ISA).
6. Remove Protective Wire Cover (RR 2.7).
7. Remove Air Duct Cover (RR 2.8).
8. Lift Boom Assembly to access connector.
   a. Remove 3 mounting screws.
   b. Lift assembly and set aside.
9. Remove Air Heater Assembly.
   a. Disconnect Air Heater Assembly Cable (J1).
   b. Remove cable from cable clamps.
   c. Lift out Air Heater Assembly.
10. Remove Air Heater Insulator; set aside.

REPLACEMENT

1. Install Air Heater Assembly.
   a. Wrap Air Heater Insulator around Air Heater.
   b. Connect Air Heater Assembly Cable (J1).
   c. Place Air Heater Assembly in base and route cable.
   d. Secure cable through cable clamps.
2. Install Boom Assembly.
   a. Place Assembly over mounting holes.
   b. Secure with 3 mounting screws.
3. Install Air Duct Cover (RR 2.8).
4. Install Protective Wire Cover (RR 2.7).
5. Install Amplification Vial Retainer (RR 2.11).
6. Install Reagent Shroud Assembly (RR 2.3).
7. Install left VDE Cover (PL 10.2)
8. Reposition and secure Display Assembly (RR 8.1.1).
9. Install Enclosure Assembly (RR 1.3).

VERIFICATION

1. Perform the following checks and calibrations:
   - Bar Code Check (VP-4)
   - MEIA Carousel Calibration (VP-30)
   - Boom Calibration (VP-8)
   - Level Sense Check (VP-11)
   - AVR Alignment (VP-64, procedure provided in this ISA)
   - MEIA Temperature Calibration (VP-29)
   - MEIA Photo Calibration (VP-27A)

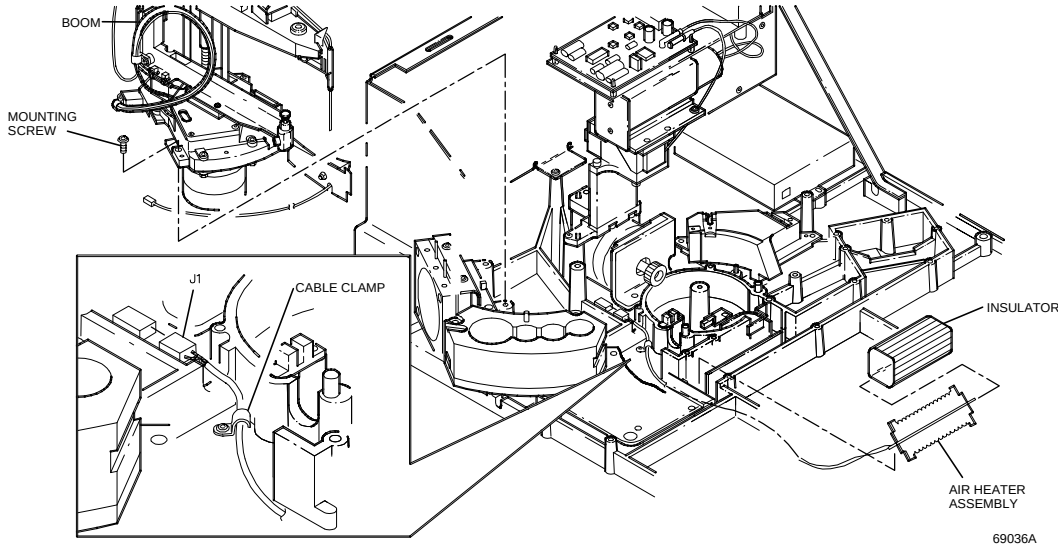


Figure ISA 69-005-11: Air Heater Assembly

RR 3.18 CAROUSEL RECEIVER ASSEMBLY

REMOVAL

1. Remove Enclosure Assembly (RR 1.3).
2. Raise Display to upright position (RR 8.1.1).
3. Remove left VDE Cover (PL 10.2).
4. Remove Reagent Shroud (RR 2.3).
5. Remove Boom Assembly (RR 3.9).
6. Remove Carousel Receiver Assembly.
   a. Disconnect Carousel Receiver Cable P4 at LLS Bd. J4.
   b. Remove mounting hardware.
   c. Remove Assembly.

REPLACEMENT

1. Install Carousel Receiver Assembly.
   a. Mount Carousel Receiver to Boom with mounting hardware.
   b. Connect Carousel Receiver Cable at LLS Bd. J4.
2. Install Boom Assembly (RR 3.9).
3. Install Reagent Shroud (RR 2.3).
4. Install left VDE Cover (PL 10.2).
5. Reposition and secure Display Assembly (RR 8.1.1).
6. Install Enclosure Assembly (RR 1.3).

VERIFICATION

1. Complete the following:
   - Reagent Heater Block Adjustment (VP-21)
   - Bar Code Check (VP-4)
   - Boom Calibration (VP-8)
   - Level Sense Adjustment (VP-12)
2. Perform Dispense Check (VP-13)

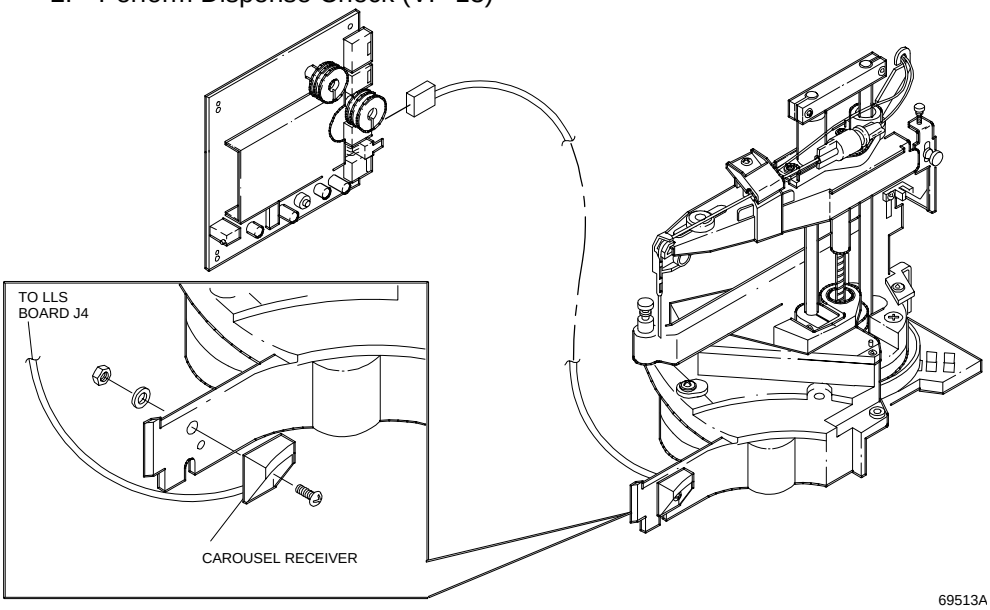


Figure ISA 69-005-12: Carousel Receiver Assembly

VERIFICATION PROCEDURES

VP-64 AVR ALIGNMENT

Time: 5 minutes
Purpose: To align the AVR over the carousel and vial.

1. Place the AVR Positioning Tool in carousel position 1 of the LCx® carousel. Lock carousel and place carousel into the analyzer.
2. Lock the AVR (turn the knob counterclockwise).
3. From the Main Menu, press:
   - MONITOR
   - HND_CTRL
   - OTHER
   - OTHER
   - LS
   - OTHER
   - OTHER
   - CR_POS1
4. Visually align the oval opening at the end of the AVR arm over the oval indentation in the AVR Positioning Tool.
5. Tighten the 3 (three) screws securing the AVR to the Air Duct Cover Assembly.
6. Press CR_POS1. Verify that the alignment has not changed. (If necessary, loosen the three screws and repeat the alignment.)

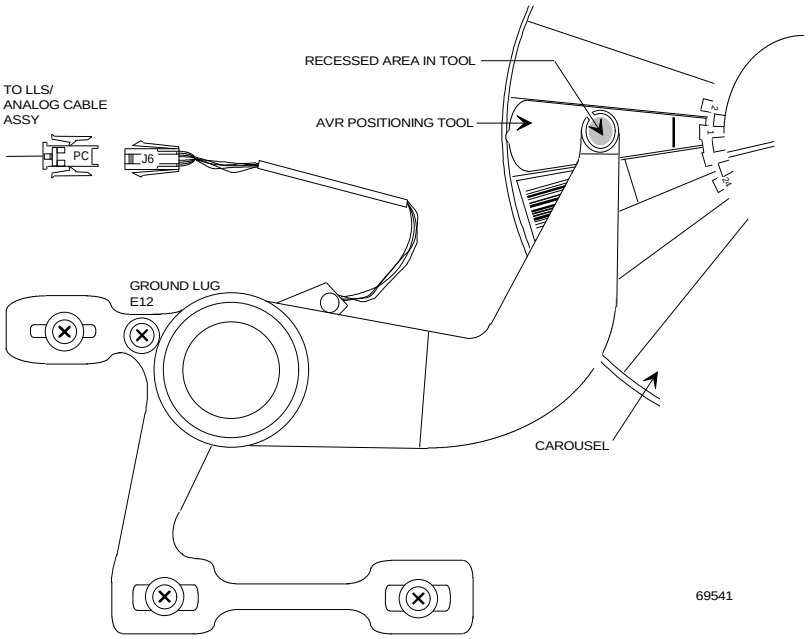


Figure ISA 69-005-13: AVR Positioning Tool

VP-65 AVR SENSOR CHECK

Time: 5 minutes
Purpose: To verify that the AVR sensor operates properly.

1. Place the AVR arm in the LOCKED (home) position.
2. Enter Dispense Hand Controls.
   - MONITOR
   - HND_CNTL
   - DISPENSE
3. Displayed AVR sensor status should be YYY.
4. Move AVR arm to UNLOCKED position. Displayed status should change to YYN.

If display does not indicate correct AVR arm position, refer to IP 87 for corrective actions.

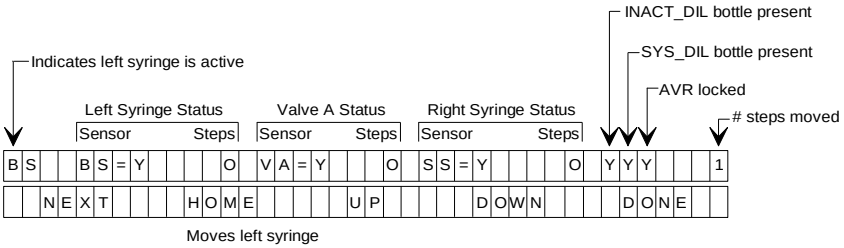


Figure ISA 69-005-14: Display

VP-15 BUFFER SENSOR CHECK

Time: 5 minutes
Purpose: To verify buffer and AVR sensors operate properly.

1. Enter Dispense Hand Controls.
   - MONITOR
   - HND_CNTL
   - DISPENSE
2. Check INACT_DIL sensor.
   a. Remove INACT_DIL bottle.
      YYY changes to NYY
   b. Replace INACT_DIL bottle.
      NYY changes to YYY
3. Check SYS_DIL sensor.
   a. Remove SYS_DIL bottle.
      YYY changes to YNY
   b. Replace SYS_DIL bottle.
      YNY changes to YYY
4. Check AVR sensor.
   a. With AVR in LOCKED position, status should be YYY.
   b. With AVR in UNLOCKED position, status should be YYN.

If display does not indicate correct AVR arm position, refer to IP 87 for corrective actions.

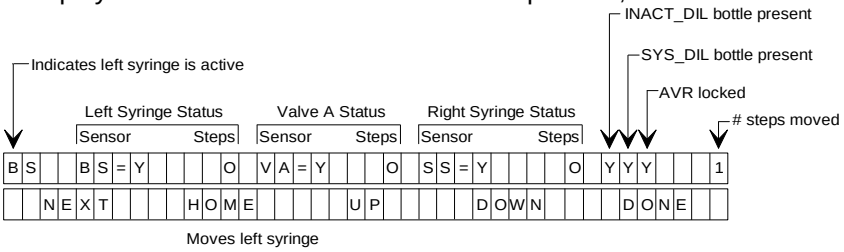


Figure ISA 69-005-15: Display

VP-47 MEIA PERFORMANCE PANEL RUN PROCEDURE

Time: 30 to 45 minutes
Purpose: To verify the amplified nucleic acid detection portion of the analyzer.

1. Verify correct Assay Module installed for desired assay.
2. Change Assay Modules (if necessary).
   a. Shutdown analyzer.
      - UTILITY
      - SHUTDOWN
      - START
   b. Install correct Assay Module.

c. Verify printout matches Module.

3. Edit Protocol Default to Assay Number being performed.
   - ASSAY
   - ASSAY_FILES
   - PROTOCOL
   - Enter new parameter (111)
   - STORE
   - EXIT
4. Perform MEIA Performance Panel Run
   a. Load the Carousel.
      (1) Insert 3 Reaction Cells.
      (2) Lock Carousel.
      (3) Dispense 5 drops of Level 1 into amplification vial into reaction cell #1, dispense 5 drops of Level 2 into position 2, dispense 5 drops of Level 3 into position 3.
   b. Load Carousel into analyzer. Lock Amplification Vial Retainer.
   c. Mix and load Reagents (mix until particles are suspended).
   d. Open Reagent Caps (sequence 1, 2, 3, 4).
   e. Press RUN.

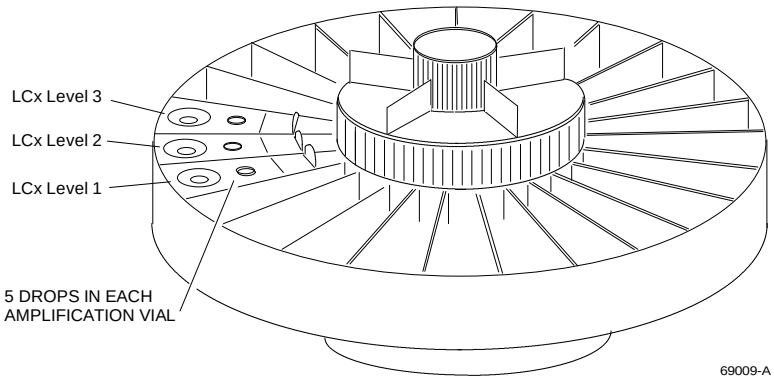


Figure ISA 69-005-16: MEIA Performance Panel Run Procedure

Preventive Maintenance/Total Service Call

6.1 PM/TOTAL SERVICE CALL PROCEDURE

1. Perform VP-60: Decontamination Procedure.
2. Verify proper TSB level.
3. Obtain printout of System Parameters 1, 2, 4, 37, and 38. (Press SYSTEM, FILES, 1 PRINT.) Repeat for each file, store with system.
4. Verify correct serial number in Parameter 1.3 (see printout).
5. Verify MEIA Lamp Ref. parameter 38.25 1 (see printout).
   NOTE: If parameters 1.3 and 38.25 are 1, a Factory Set has occurred. Perform VP-53.
6. Check Maintenance Log for possible problems. Verify customer is performing daily, weekly, and monthly maintenance.
7. Check Power Supply voltages (VP-1).
8. Clean Air Heater and Thermistor with compressed air.
   a. Remove left VDE Cover (PL 10.2).
   b. Remove Reagent Shroud Assembly (RR 2.3).
   c. Remove Amplification Vial Retainer (RR 2.11).
   d. Raise Display (RR 8.1.1)
   e. Remove Protective Wire Cover (RR 2.7).
   f. Remove Air Duct Cover (RR 2.6).
   g. Clean dust from heater coils and thermistor with compressed air.
9. Clean instrument base and covers.
   a. Wipe analyzer base and covers with 95% ethanol or methanol.
   b. Reinstall Air Duct Cover (RR 2.6).
   c. Reinstall Amplification Vial Retainer (RR 2.11).
   d. Reinstall Reagent Shroud Assembly (RR 2.3).
   e. Install left VDE Cover (PL 10.2).
   f. Install Protective Wire Cover (RR 2.7).

g. Reposition and secure Display Assembly (RR 8.1.1).

10. Clean MEIA Lens.
    a. Clean lens with 95% ethanol or methanol and a lint-free tissue.
    b. Dry with lint-free tissue.
11. Inspect Accessories for wear and leakage. Prime both diluents 5 times, watching for leaks in tubing or multivalve block.
12. *PM ONLY* Replace Multivalve Block, Probe Assembly, Syringes, and Lamp.
    a. RR 5.3
    b. RR 3.5
    c. RR 5.12
    d. RR 4.11
13. Perform MEIA Carousel Calibrations (VP-30).
14. Realign Amplification Vial Retainer (VP-64).
15. Perform Boom Assembly Checks and Calibrations (VP-7).
16. Verify Bar Code Operation (VP-4).
17. Perform Dispense Check (VP-13).
18. Perform diagnostic board tests.
    a. Printer Test (VP-41)
    b. Keyboard Test (VP-42)
    c. Display Test (VP-43)
    d. RS-232 Comm. Port Test (VP-44)
19. Perform MEIA Lamp Adjustment Check (VP-22).
20. Perform MEIA Photodiode Check (VP-25).
21. Perform MEIA PMT Check (VP-24).
22. Perform MEIA Temperature Check (VP-28).
23. Verify Matrix Counting Operation (VP-31).
24. Perform MEIA Performance Panel Run Procedure (VP-47).

6.2 PM/TOTAL SERVICE CALL REPORT

TC PM PROCEDURE

___ ___ Perform VP-60: Decontamination Procedure.

___ ___ Print Parameters 1, 2, 4, 38 and System Log.

___ ___ Check Modification Status for proper TSB level (TSB Modification Index).

___ ___ Verify Serial Number is correct in Parameter 1.3

___ ___ Verify MEIA Lamp Ref. Parameter 38.25 is not set to "1".

___ ___ Check Maintenance Log for possible problems.

___ ___ Clean Air Heater and Thermistor with compressed air.

___ ___ Clean MEIA Optical Lens.

___ ___ Clean analyzer Base and Cover.

___ ___ Inspect Accessories for wear and leakage.

___ Replace Valve Block, Probe, Syringes and Lamp (RR 5.3, RR 3.5, RR 5.12, RR 4.11).

___ ___ MEIA Carousel Calibration (VP-30).

___ ___ Boom Assembly Check (VP-7).

___ ___ Amplification Vial Retainer Alignment (VP-64).

___ ___ Boom Cal as required (VP-8).

___ ___ Verify Bar Code Operation (VP-4).

___ ___ Dispense Check (VP-13).

___ ___ Check Power Supply voltages (VP-1).

___ ___ Diagnostic Board Test (VP-41, VP-42, VP-43, VP-44).

___ ___ MEIA Photodiode Check (VP-25).

___ ___ MEIA PMT Check (VP-24).

___ ___ Temperature Verification (VP-28).

___ ___ Verify Matrix Counting Operation (VP-31).

___ ___ MEIA Performance Panel Run Procedure (VP-47).

END OF DOCUMENT

ABBOTT ADD	INSTRUMENT SERVICE ADVISORY

SUBJECT: **LCx® Analyzer Service Manual and Field Service PreTraining Guide**	ISA#: **69-004**
ORIGINATOR: **Kyle Hranitzky**	PRODUCT: **LCx® Probe System (69)**
APPROVED: **Bob Schabel 11/8/95**	EFFECTIVITY DATE: **08-NOV-95**

I. DISTRIBUTION:
International and USA

II. PURPOSE:
To announce availability of the new LCx® Analyzer Service Manual and Field Service PreTraining Guide.

III. PARTS ISSUES:
LCx® Analyzer Service Manual: **Catalog number: 3-47277-01**
This catalog number includes the binder, tabs, and text.
This is the first service manual for the LCx® Analyzer; this manual replaces no previous service manuals.
Order this manual through usual procedures.

LCx® Analyzer Field Service PreTraining Guide: **Catalog number: 3-47292-01**

END OF DOCUMENT

ABBOTT ADD	INSTRUMENT SERVICE ADVISORY

SUBJECT: **Release of LCx® Assay Software Module 1 Version 2.0**	ISA#: **69-003**
ORIGINATOR: **Kyle Hranitzky**	PRODUCT: **LCx® Probe System (69)**
APPROVED: **Bob Schabel 11/7/95**	EFFECTIVITY DATE: **16-NOV-95**

I. DISTRIBUTION:

International and USA

II. PURPOSE:

This ISA is to inform the field of the release of the LCx Assay Module 1 Version 2.0 (List No. 06A23-02).

The LCx Assay Module 1 Version 2.0 contains the following assays:

Assay Number and Name	List Number	Revision	Parameter Changes from V1.0	New Reagent Bar Code
11 Chlamydia LCR	7A91	15	Yes	Yes
12 GC LCR*	8A48	13	New Assay	-
111 PRFM	6A20	12	No	-

* Resides on the Assay Module as a hidden assay requiring Assay Activation.

All current LCx customers that have the LCx Assay Module 1 Version 1.0 should receive the LCx Assay Module 1 Version 2.0 Upgrade Kit (List No. 6A23-60). This kit contains the following:

1-LCx Assay Module Version 2.0 (List No. 6A23-02)
1-LCx Assay Module I Information Sheet (Commodity #66-6120/R2)
1-LCx Assay Module 1 Version 2.0 Customer Letter (Commodity #66-6219/R1)
This is a mandatory upgrade for all current LCx customers. The customer needs to retain the customer letter with their LCx Analyzer Operations Manual until the LCx Analyzer is upgraded for the AVR (Amplification Vial Retainer) modification.
It is very important that the current LCx *Chlamydia trachomatis* assay kits containing the Positive Control are run with the LCx Assay Module 1 Version 1.0. Once the new version (LCx Assay Module 1 Version 2.0) is installed, the current LCx *Chlamydia trachomatis* kits can not be used. The new reagent bar code on the LCx *Chlamydia trachomatis* kits are only compatible with the new version.
The kits containing the new bar codes will be highlighted by a pink sticker on the kit.

New Assay

The new assay on this module is Assay #12 GC LCR, LCx *Neisseria gonorrhoeae*, which requires assay activation to be visible. This assay can only be performed on the LCx Assay Module 1 Version 2.0. The LCx *Neisseria gonorrhoeae* Assay uses LCR (Ligase Chain Reaction) amplification technology in the LCx Probe System for the direct, qualitative detection of a specific target nucleic acid sequence in the Opa gene of *Neisseria gonorrhoeae* in swab specimens from the endocervix and the male urethra or in urine from males and females as an aid in the diagnosis of primary N. *gonorrhoeae* local genital tract infection.

Changes from LCx Assay Module 1 Version 1.0 to Version 2.0

1. The LCx Assay Module 1 Version 2.0 will flag the specimens above the cutoff S/CO rate ≥ 1.0

as POS in the NOTE column on the assay results tape. Previously the specimens that were above the assay cutoff as ≥ 1.0.

2. The Positive Control is no longer required on each carousel, only the Negative Control and Calibrator are required. If desired, an optional specimen processing control may be run. Please refer to the Quality Control Procedures Section in the LCx assay-specific package insert.
3. The reagent pack bar code has been changed for Assay #11 Chlamydia LCR. The new assay kits without the Positive Control will be highlighted by a pink sticker instructing the user that the kit is for use with LCx Assay Module 1 Version 2.0.

LCx Assay Carousel Setup

The LCx assays (Assay #11 Chlamydia LCR and Assay #12 GC LCR) on the LCx Assay Module 1 Version 2.0 utilize the following carousel setup:

Carousel Position	Sample
1-2	Negative Control
3-4	Calibrator
5-24	Specimens

Assay #111-PRFM-MEIA Performance Panel

The MEIA Performance Panel can be performed with either the Assay #11 Chlamydia LCR or Assay #12 GC LCR for troubleshooting the detection portion of the LCR Probe System. The Protocol Default file for the Chlamydia LCR or GC LCR assay must be edited to 111 to perform the panel. After completion of the MEIA Performance Panel, the Protocol Default file must be edited back from 111 to 11 for Chlamydia LCR or 12 for GC LCR.

System Messages and Error Codes

CODE 31 INVALID ASSAY

This message will appear if the operator attempts to perform the LCx *Neisseria gonorrhoeae* Assay before completing the Assay Activation. The operator should perform the Assay Activation procedure. Refer to the LCx Analyzer Operations Manual, Section 5 for instructions.

CODE 29 REAGENT PACK NOT ON MODULE

This message will appear if the operator attempts to use the LCx *Chlamydia trachomatis* reagent kit which contains the Positive Control with the new LCx Assay Module 1 Version 2.0. LCx *Chlamydia trachomatis* reagent kits without the Positive Control (labelled with the pink sticker) must be used with the LCx Assay Module 1 Version 2.0.

CODE 36 CAROUSEL LOAD ERROR

This message will appear if the operator performed the MEIA Performance Panel and did not edit the Protocol Default file back from 111 to 11 for Chlamydia LCR or 12 for GC LCR.

END OF DOCUMENT

ABBOTT ADD	INSTRUMENT SERVICE ADVISORY

SUBJECT: **MEIA Performance Panel Ranges**	ISA#: **69-002**
ORIGINATOR: **Bill Simpson / Gary Tompkins**	PRODUCT: **LCx® Probe System (69)**
APPROVED: **Mark Slater 6/7/96**	EFFECTIVITY DATE: **07-JUN-96**

I. DISTRIBUTION:
International and USA

II. PURPOSE:
This ISA gives the Field the values needed to verify instrument performance when running the MEIA Performance Panel (6A20-01). This information may not be distributed directly to LCx® Probe System customers.

The MEIA Performance Panel specified ranges are as follows:

Level	**Rate**
Level 1	0.0 - 40.0
Level 2	greater than or equal to 130
Level 3	greater than or equal to 900

These ranges are not lot specific to any Performance Panel or LCx Detection Reagent Pack, but are inclusive of all reagent lots.

END OF DOCUMENT