ABBOTT ADD	INDEX INSTRUMENT SERVICE ADVISORY

PRODUCT: **IMx® (60)**	DATE: **07-JUL-98**

ISA #	SUBJECT	EFFECTIVITY DATE
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60-156	Incorrect Orientation of Buffer Platform Switches	03-MAR-97
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60-132	IMx Boom Diagnostics for Use on Laptop Computers (Phase 1)	OBSOLETE
60-131	PENDING	PENDING

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60-127	Release of Thyroid V2.0 Assay Module	15-NOV-93
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60-121	Release of IMx Tumor Markers V7.0 Assay Module	30-JUN-93
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60-118	CANCELLED	CANCELLED
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60-103	Release of Hepatitis Assay Module Version 4.01	21-JUL-92
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60-096B	Main Power Supply Fan Replacements	02-DEC-93
60-095	Release of Reproductive Endocrinology Assay Module Version 6.0	25-JUN-92
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60-093	Dispense System Contamination	27-FEB-92
60-092	MEIA Temp Check	05-FEB-92
60-091	Release of Select Tumor Markers Assay Module Version 1.0	05-FEB-92
60-090	Z-Boom Motors Rusting	05-FEB-92
60-089	IMx Air Deflector	05-FEB-92
60-088	CANCELLED	CANCELLED
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60-085	Bar Code Reader Set Screw, Thermopile Screws & Boom Shroud	11-FEB-92
60-084	Release of Hepatitis Assay Module Version 3.03	26-NOV-91
60-083	IMx Select Bar Code Scanner Reconfiguration	09-DEC-91
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60-081	Ferritin Assay Parameter Changes	14-OCT-91
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60-079	New Lubrication for the Boom Assembly	21-AUG-91
60-078	Air Fan and Gasket Assembly	28-JUN-91
60-077	Wash Station Screw Kit Addition	28-JUN-91
60-076	R-Boom/Z-Boom Positioning and Repeatability	15-MAY-91
60-075	Identifying Defective MEIA Carousels	23-APR-91
60-074A	IMx Card Cage Fan	23-OCT-91
60-073	Reaction Cells for New IMx Assays	OBSOLETE
60-072	Typical IMx Assay Times	28-JUN-91
60-071	Stepper Motors	11-FEB-91
60-070	Code 70 Remote Temperature Low During HBsAg Assay	11-FEB-91
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60-068	Release of Theophylline/B12 Assay Module	28-FEB-91
60-067	Z-Boom Flag Added to FSE Spare Parts Kit	21-DEC-90
60-066	Release of Congenital Diagnostics Assay Module Version 3.00	30-NOV-90
60-065	Release of Tumor Markers Assay Module Version 5.01	26-NOV-90
60-064B	Procedure for IMx Instrument Returns	12-MAY-93
60-063	MEIA Carousel Calibration Errors	03-DEC-90
60-062	Release of IMx System Temperature Probe Adapter	01-OCT-90
60-061	Release of Hepatitis Assay Module Version 2.03	01-OCT-90
60-060	Release of Thyroid Assay Module Version 1.08	18-SEP-90
60-059	Release of Reproductive Endocrinology Version 4.00 Assay Module	OBSOLETE
60-058	Tumor Markers Assay Module Version 4.01	OBSOLETE
60-057	(R=) Specification Change for the MEIA Optics	16-JUN-90
60-056	Addition of Blank Cells to the Spare Parts Kits	15-JUN-90
60-055	Release of Version 2.0 IMx FSE Service Manual	12-JUN-90
60-054	CANCELLED	CANCELLED
60-053	IMx FSE Service Manual Supplement	08-JUN-90
60-052	Buffer Management with Version 2.0 Software	06-JUN-90
60-051	RS-232 Connections and Version 2.0 Software	02-APR-90
60-050	Release of Reproductive Endocrinology Version 3.04 Assay Module	OBSOLETE
60-049	Release of Tumor Markers Version 3.01 Assay Module	OBSOLETE
60-048	CANCELLED	CANCELLED
60-047	Lubrication of the Boom Guide Shafts	INCORPORATED
60-046	Voltage Selector Switch on Main Power Supplies	12-MAR-90
60-045	Troubleshooting MEIA Lamp and Lamp P/S Problems	08-MAR-90
60-044	T4 Curve Instability, Precision and Reproducibility Problems	05-JAN-90
60-043	Memory Board/Bar Code Cable Change	28-NOV-89
60-042	Release of the -106 Motor Driver PCB	28-NOV-89
60-041	Boom Lubrication Procedure	INCORPORATED
60-040	Congenital Diagnostics Assay Module Version 2.0	OBSOLETE
60-039	Reproductive/Endocrinology Assay Module Version 2.0	CANCELLED
60-038	Minimum Buffer Volumes Required for Assay Runs	OBSOLETE
60-037	IgE Assay Parameter Change	OBSOLETE

60-036	Release of Hepatitis Assay Module Version 1.0	OBSOLETE
60-035	FPIA Temperature Calibration Failures	08-SEP-89
60-034B	Protocol for Factory Sets/Checksum Errors	08-APR-92
60-033	Intermittent Heater Error Messages	INCORPORATED
60-032	Reproductive Endocrinology Assay Module Version 1	OBSOLETE
60-031	Release of New Syringe Retainer Nuts	19-APR-89
60-030	Tumor Markers Assay Module Version 2.03	OBSOLETE
60-029	Congenital Diagnostics Assay Module	OBSOLETE
60-028	Card Cage Alignment	INCORPORATED
60-027	Deletion of Temperature/Humidity Bracket Assembly	08-MAR-89
60-026	Cancellation of TSB 60-010	15-FEB-89
60-025	Hanging, Clinging Drop Update	INCORPORATED
60-024	Motor Driver Bd. and Z-Boom Step Loss	INCORPORATED
60-023	Matching Pump Covers with Pump assemblies	15-FEB-89
60-022	Return of System Software/MEIA Lamp P/S	OBSOLETE
60-021	Proper Alignment of the Reagent Heat Block	INCORPORATED
60-020	Use of the Door Override Function	17-DEC-88
60-019	Dispense Check Parameter Change	INCORPORATED
60-018	IMx Total T3 Parameter Change	OBSOLETE
60-017	Hanging, Flinging and Clinging Drops	INCORPORATED
60-016	Editing Parameters Using SUPERUSER	CANCELLED
60-015	Probe/Electrode Assembly	OBSOLETE
60-014	Pump Valve Extender	OBSOLETE
60-013	Peaking MEIA Lamp	INCORPORATED
60-012	Keyed Lamp and Lamp Housing	INCORPORATED
60-011	hTSH, T3 and Ferritin Assay Parameters	OBSOLETE
60-010	Door Sensor Metallic Tape	19-OCT-88
60-009	Use of ADx Fan Filter in IMx	OBSOLETE
60-008	Blank Cells and MEIA Photo Std's Problem	OBSOLETE
60-007	Adjustable Reagent Heat Block	INCORPORATED
60-006	Carousel Load Error and Carousel Bar Code Label	OBSOLETE
60-005	New Thumbscrew for MEIA Lamp Fixture	CANCELLED
60-004	Probe Abrasion Procedure	INCORPORATED
60-003	VDE Ground Cable and PMT High Voltage P/S	17-OCT-88
60-002	Wire Routing (Air Heater, Carousel Motor, Fan)	INCORPORATED
60-001	Fan Filter Guard	17-OCT-88

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

ABBOTT ADD	**INSTRUMENT SERVICE ADVISORY**

SUBJECT: **IMx® Service Manual**	ISA#: **60-158**
ORIGINATOR: **Eric Tormos**	PRODUCT: **IMx® (60)**
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 IMx® 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 Procedures

1. Verify proper TSB level.
2. Obtain printout of System Parameters 1, 2, 3, 4, 37, and 38.
   - System
   - Files
   - 1

- Print

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.
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 assay of customer's choice with controls.
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
3.		Clean Air Heater and Thermistor with compressed air. a. Remove Boom Shroud Assembly (RR2.3). b. Remove Air Duct Cover (RR23.6). c. Clean dust for heater coils and thermistor with compressed air.
4.		Inspect instrument and assessories 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 an assay of the customer's choice with controls.
11.		Obtain printout of System Parameters 1, 2, 3, 4, 37 and 38.

END OF DOCUMENT

ABBOTT ADD	**INSTRUMENT SERVICE ADVISORY**

SUBJECT: **Release of X SYSTEMS® Pump Belt Tensioning Aid** **C/N: 3-47725-01**	ISA#: **60-157**
ORIGINATOR: **Kyle Hranitzky**	PRODUCT: **IMx® (60)**
APPROVED: **Bob Schabel**	EFFECTIVITY DATE: **19-JAN-98**

Distribution:

International and USA

PURPOSE:

This ISA will serve as a guideline for the replacement and correct tension setting of timing belts (P/N: 44528-101) used on the X SYSTEMS® Pump Assembly using the X SYSTEMS® Pump Belt Tensioning Aid (C/N: 3-47725-01).

Precautions: When working with any pump assembly, follow these precautions:

a. If the pump assembly is placed down with the syringe arms in contact with the supporting surface, you must use some means of support or cushion.
b. Do not attempt to replace the rack bearings or remove the bearing support blocks.
c. Do not attempt to adjust the rack gear preload.

PROTOCOL:

1. Removal of Pump Assembly and Timing Belts

a. Remove the X SYSTEMS® Pump Assembly using procedure described in RR-5.1 in the IMx® service manual.
b. Remove both timing belts from the pump assembly by carefully cutting the belts. If a knife or scissors is not available, the belts can be removed by loosening the two mounting bolts used to secure each stepper motor to the pump frame. This will release the tension on the belts.

2. Replacement of the Timing Belts

a. If the stepper motor mounting bolts were not loosened:
   1) Place the pump on the work surface with the syringe drives facing away from you and the small timing pulley to the left of the larger timing pulley.
   2) Place one end of the timing belt over the small timing belt pulley.
   3) Place the other end of the belt around the top half of the large pulley and rotate the large pulley clockwise. The timing belt should slip into place.
   4) If the belt does not slip into place proceed to step b.
b. If the stepper motor mounting bolts were loosened:
   1) Place the timing belt over both pulleys.

3. Belt Tension Measurement and Adjustment

a. Check the tension on each timing belt with the face of the pump facing away from you and the small timing pulley to the left of the larger timing pulley.
b. Place the side of the belt tension adjustment aid flush along the length of the timing belt with the handle fitting between the two walls of the small pulley (see Figure 1).
c. While holding the tension adjustment aid in place with one hand, depress the spring-loaded plunger so that the shaft pushes against the belt. Push the plunger until the belt deflects to its farthest point.
d. Measure the deflection of the belt against the graduated scale. The bottom of the belt, where it intersects with the scale, should align with the 4th mark down (4.0 +/- 0.5 marks) from the top of

the tool. This setting is equivalent to 4.0 +/- 0.5 mm belt deflection (see Figure 2).

e. Increase or decrease belt tension as needed by loosening the stepper motor mounting bolts.
   1) Increase the belt tension by pulling on the motor housing with gloved fingers to increase the distance between the small pulley and the large pulley. Tighten the bolts and remeasure the belt tension. Repeat as needed.
   2) Reduce the belt tension by decreasing the distance between the small and large pulley. Tighten the bolts and remeasure the belt tension. Repeat as needed.

4. Alternative Method for Increasing Belt Tension

Precaution: Because the walls of the small pulleys are sonic welded onto the pulley shaft, there is a slight risk that when using this method the pulley wall may snap off. Exercise caution when using this method.

a. With the pump assembly in the same orientation as above and with the motor housing mounting bolts loosened slightly, place the tool between the small and large pulleys, with the walls of each pulley sliding into the groove on each side of the tool. The grooves are not symmetrically cut, so the plunger of the tool should be to the right (see Figures 3 and 4).
b. Slowly push the belt tensioning aid inward increasing the distance between the small and large pulleys.
c. When adequate belt tension (as determined by trial and error) is obtained, tighten the bolts and remove the aid.
NOTE: There is some play in the shaft so that when the aid is removed there will be some relaxation of belt tension. Repeated use will tell you how much you will need to compensate for this ease of belt tension.
d. Measure the deflection of the belt as described above and ensure that the deflection of the belt is at the 4th mark (+/- 0.5 mark) (see Figure 2).

5. Installation of Pump Assembly and Verification

a. Install the X SYSTEMS® Pump Assembly using procedures in RR-5.1 in the IMx® service manual.
b. Perform the verification procedures as listed in RR-5.1 (IMx® service manual). Be sure to very carefully perform a successful Dispense Check (VP-13, IMx® service manual) and to very accurately assess the controls of a customer's assay.

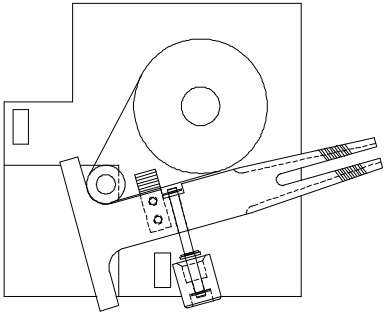


Figure 1

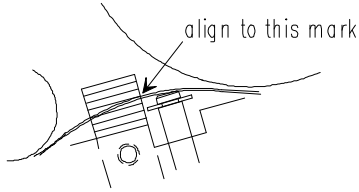


Figure 2

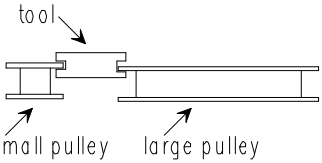


Figure 3 (side view)

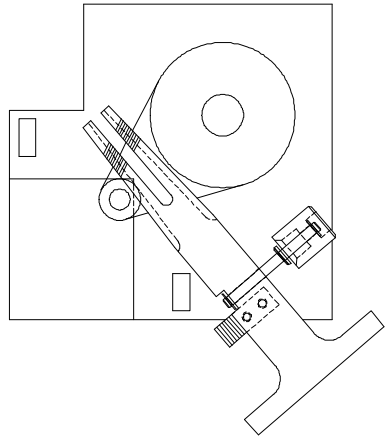


Figure 4

ABBOTT ADD	**INSTRUMENT SERVICE ADVISORY**

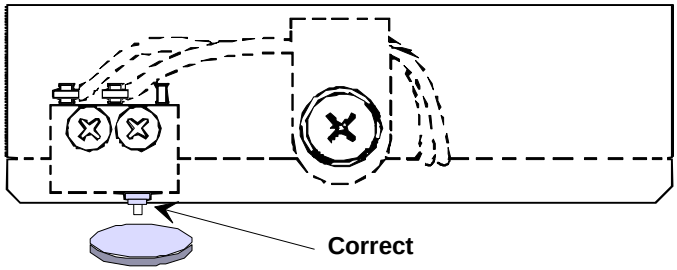
SUBJECT: **Incorrect Orientation of Buffer Platform Switches**	ISA#: **60-156**
ORIGINATOR: **Gary Tompkins**	PRODUCT: **IMx® (60)**
APPROVED: **Bob Schabel 3/March/97**	EFFECTIVITY DATE: **03-MAR-97**

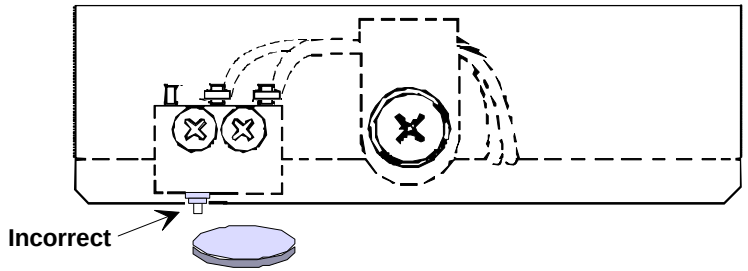
This ISA informs the Field of the incorrect orientation of buffer platform switches on IMx® Analyzers and Buffer Platform assemblies shipped in the last six months, approximately June 1996 through mid January 1997. Affected S/Ns for new analyzers begin at approximately 32300. Since refurb S/Ns are nonsequential and numerous, they are not listed in this ISA.

On these analyzers (New, LN 8389-01, LN 8389-86 and Refurb, LN 8389-59) and spare parts assemblies, the switches on Buffer Platform #1 (left), 3-41796-01, and Buffer Platform #2 (right), 3-41796-02, may have been improperly installed (rotated 180 degrees out of position). In this position, the button on the switch may not properly contact the appropriate raised spot on the baseplate. This can cause intermittent or faulty operation and lead to ERR CODE 48, Buffer Insufficient/Empty 1/2.

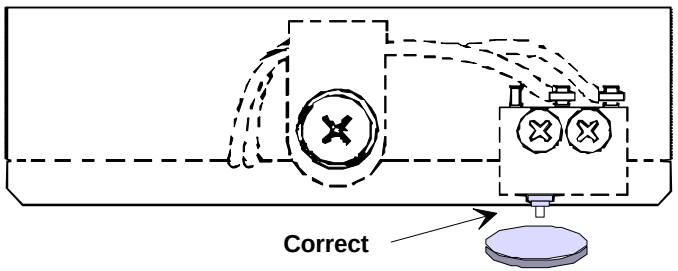
When servicing any IMx® Analyzer (especially those shipped in the time frame noted above), verify whether or not the buffer platform switches are installed properly. If not, remove and reinstall them in the correct position as shown in the diagram below. It will be necessary to remove the platforms to access the switches as they are secured by small screws and nuts. Once rework is complete, perform the Buffer Sensor Check, VP-15 in the IMx Service Manual.

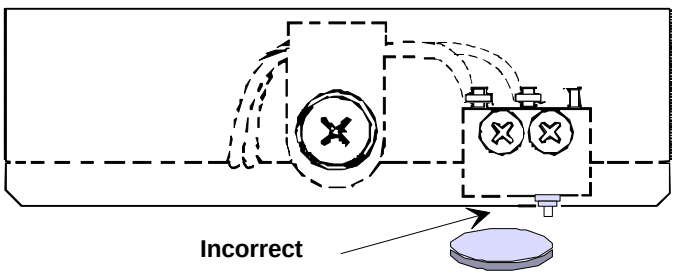
Please note that this problem may likely be found in kit/stock/depot parts if you have ordered the catalog numbers (noted above) within the last six months. Check your kit/stock/depot parts and rework as necessary.





Buffer Platform #1 (Left)





Buffer Platform #2 (Right)

END OF DOCUMENT

ABBOTT ADD

INSTRUMENT SERVICE ADVISORY

SUBJECT: **Release of IMx SELECT® STD Assay Module Version 2.0**	ISA#: **60-154**
ORIGINATOR: **Gary Tompkins**	PRODUCT: **IMx® (60)**
APPROVED: **Mike Manion for Mark Slater 17-APR-96**	EFFECTIVITY DATE: **17-APR-96**

Purpose

This ISA announces the release of the IMx SELECT STD (Sexually Transmitted Disease) Assay Module Version 2.0.

Assay # and Name	List Number	Revision	Protocol/Parameter Changes
14 Chlamydia	2206	4	None

Assay Calibration

Assay Calibration will be required when changing from IMx SELECT Assay Module V1.0 to V2.0. If a customer attempts to use V1.0 of IMx SELECT STD Assay Module after installing V2.0, the error CODE 104 ASSAY REVISIONS MISMATCH will be displayed.

Reagent Barcode Changes

To ensure all customers perform the IMx SELECT STD Assay Module Upgrade, the reagent bar code number for IMx SELECT Chlamydia has been changed. The IMx SELECT Chlamydia reagent packs that require the use of the IMx SELECT STD Assay Module V2.0 will be highlighted by a **blue card** included in the kit. The Version 2 Assay Module must be used with these IMx SELECT Chlamydia reagent kits that contain the blue card.

CODE 29 REAGENT PACK NOT ON MODULE will appear if the operator attempts to use the old IMx SELECT Chlamydia reagent kit with the new Version 2 module. Only reagent kits with the blue card included may be used with the Version 2 module.

Flagged Results Change

The % Blocking result printout is modified in the IMx SELECT STD Assay Module V2.0. On the % Blocking results tape, under the % BLK Column, asterisks ****** will no longer appear when the S/N is equal to 1.0. The new Assay Module V2.0 blocking results will print 0% Blocking in place of the asterisks. This result is interpreted the same as the asterisks. The Blocking Reagent results are considered inconclusive as noted in the package insert.

Memory Allocation System Error Correction

The System Error ec-0002 has been corrected in this Version 2.0 of the IMx SELECT STD Assay Module. Please refer to ISA 60-136 for details on this error.

IMx® Chlamydia Assay Clinical Utility

The IMx SELECT Chlamydia assay is used for the qualitative detection of the chlamydia antigen from female endocervical and male urethal swabs. The IMx SELECT Chlamydia Blocking Reagent is used for the verification of the chlamydia antigen in IMx SELECT Chlamydia reactive specimens.

Assay Parameters

There are no unique parameters for IMx SELECT Chlamydia. However, the following assay parameters can not be edited:

1	Decimal	
	3	Sample Rep
	60	Print Option

Since Parameter 3 can not be edited, the user who wishes to run duplicate samples must calculate the average S/N manually for patient samples.

Instrument Notes

The IMx SELECT STD Assay Module Version 2.0 can only be used with the IMx System Software Version 6.0 or higher. Additionally, the IMx SELECT Boom Assembly must be installed on the instrument (refer to TSB 60-029B).

If the IMx SELECT STD Assay Module Version 1.0 is installed with a lower version of System Software (i.e. 2.0, 3.0 or 5.0), the error code **134 INCOMPATIBLE SYSTEM/ ASSAY MODULES** is displayed. To return to the IMx Main Menu: turn the IMx® system power OFF, remove the IMx SELECT STD Assay Module, install another appropriate module, and turn the power back ON.

System Messages and Error Codes

The following systems messages are specific to the IMx SELECT Chlamydia assay:

"ID MISMATCH OR ID MISSING"

This message will be generated in the % Blocking Results section of the printout when using the Blocking Reagent, if the ID's for the unblocked and blocked samples do not match or if the ID's were not entered. The % Blocking Results will not be printed on the test results tape for that specimen.

"MULTIPLE CRSL RGNT PACKS NOT APPLICABLE"

This message will be generated at the end of a run if a BY PANEL or BY ASSAY Loadlist is created using the carousel reagent pack locations A and B and/or C with multiple
IMx SELECT Chlamydia reagent packs on the same carousel. IMx SELECT Chlamydia can be run using only one (1) reagent pack in location A in the IMx SELECT carousel.

"CODE 140 CHECK DATA"
This error code may also appear in the % Blocking Results section of the printout when using the Blocking Reagent, if test results were not determined due to a level sense error on 1 of the 2 results needed to process a sample being verified with the Blocking Reagent.

Other Error Message
CODE 29 REAGENT PACK NOT ON MODULE will appear if the operator attempts to use the old IMx SELECT Chlamydia reagent kit with the new Version 2.0 module. IMx SELECT Chlamydia reagent kits that are labeled with the blue sticker must be used with the Version 2.0 Assay Module.

RS-232 Interface Changes

There are no changes to the RS-232 output on this module from the IMx SELECT Chlamydia Version 1.0 module.

The IMx SELECT Chlamydia assay with Blocking Reagent test results format is different than the format of other IMx® system assays. The IMx SELECT Chlamydia with Blocking Reagent RS-232 output contains additional sections which include Blocked Samples and
% Blocking Results. This new format requires the modification of the interface software to accept IMx SELECT Chlamydia assay results.

The customer will be notified of these changes by a green warning sticker placed over the opening of the cushioned bag of assay module and letter. The sticker states: IMPORTANT RS-232 INFORMATION ENCLOSED. The letter enclosed with the assay module directs the customer to contact their customer support center for information regarding the changes to the RS-232 interface specifications. The letter printed on green paper states the following:

ATTENTION: IMx SELECT Chlamydia Assay Users

Caution: The IMx SELECT Chlamydia assay utilizes a unique format for reporting results. If your IMx® system is interfaced to a laboratory computer, new interface software must be developed in order to capture IMx SELECT Chlamydia results through the Abbott IMx RS-232 Interface. A description of the output changes is available through the IMx Customer Support Center (CSC) for customers in the U.S.A. and through the local Abbott Customer Service Department for customers outside the U.S.A.

Please refer to the description of the output changes, entitled "RS-232 Output Information for IMx SELECT Chlamydia" for further information.

END OF DOCUMENT

ABBOTT ADD	**INSTRUMENT SERVICE ADVISORY**

SUBJECT: **Updates on IMx® Assay Modules**	ISA#: **60-153**
ORIGINATOR: **Lou Valich / Gary Tompkins**	PRODUCT: **IMx® (60)**
APPROVED: **Mark Slater 12/7/95**	EFFECTIVITY DATE: **07-DEC-95**

PURPOSE:
ISA 60-153 summarizes IMx Assay Modules in the Field, and those soon to be released. This ISA supersedes ISA 60-069B. Please remove ISA 60-069B from your manual.

TUMOR MARKERS VERSION 2.03

1	AFP	2257	Revision 3
9	B2-M	2201	Revision 3
10	BCM	2202	Revision 2
13	CEA	2205	Revision 3
57	SCC	2249	Revision 3
65	AFP	2271	Revision 2

TUMOR MARKERS VERSION 3.01

1	AFP	2257	Revision 3
9	B2-M	2201	Revision 3
10	BCM	2202/3A43	Revision 3
13	CEA	2205	Revision 3
66	CEA	2272	Revision 2
76	CEA	3A33	Revision 2
57	SCC	2249	Revision 4
65	AFP	2271	Revision 2

TUMOR MARKERS VERSION 4.01

1	AFP	2257	Revision 3
9	B2-M	2201	Revision 3
10	BCM	2202/3A43	Revision 4
11	CA 19-9	2203	Revision 1
12	CA 125	2204	Revision 1
13	CEA	2205	Revision 3
57	SCC	2249	Revision 4
65	AFP	2271	Revision 2
66	CEA	2272	Revision 3
76	CEA	3A33	Revision 2

TUMOR MARKERS VERSION 5.01

1	AFP	2257	Revision 3
9	B2-M	2201	Revision 3
10	BCM	2202/3A43	Revision 5
11	CA 19-9	2203/2A79	Revision 2
12	CA 125	2204/4A63	Revision 2
13	CEA	2205	Revision 3
53	PSA	2245/4A60	Revision 1
57	SCC	2249	Revision 4
65	AFP	2271	Revision 2
66	CEA	2272	Revision 4
76	CEA	3A33	Revision 3

TUMOR MAKERS VERSION 6.01

1	AFP	2257	Revision 3
9	B2-M	2201	Revision 3
11	CA 19-9	2203/2A79	Revision 2
12	CA 125	2204/4A63	Revision 2
13	CEA	2205	Revision 3
49	PAP	2241	Revision 1
53	PSA	2245	Revision 1
57	SCC	2249	Revision 4
65	AFP	2271	Revision 2
66	CEA	2272	Revision 5
76	CEA	3A33	Revision 4
118	AFP	2271	Revision 1

TUMOR MARKERS VERSION 7.0

1	AFP	2257	Revision 3
9	B2-M	2201	Revision 4
11	CA 19-9	2203/2A79	Revision 2
12	CA 125	2204/4A63	Revision 2
13	CEA	2205	Revision 3
24	CA 125	7A89	Revision 1
49	PAP	2241	Revision 1
53	PSA	2245	Revision 2
57	SCC	2249	Revision 5
65	AFP	2271	Revision 2
76	CEA	3A33	Revision 4
118	AFP	2271	Revision 1
125	AFP	9A21	Revision 1

TUMOR MARKERS VERSION 8.0

1	AFP	2257	Revision 3
9	B2-M	2201	Revision 5
11	CA 19-9	2203/2A79	Revision 2
12	CA 125	2204/4A63	Revision 3
13	CEA	2205	Revision 3
24	CA 125	7A89	Revision 1
25	CA 19-9	5B09	Revision 2
49	PAP	2241	Revision 1
53	PSA	2245	Revision 2
57	SCC	2249	Revision 5
76	CEA	3A33	Revision 4
117	CA 15-3	6A75	Revision 1
118	AFP	2271	Revision 1

REPRODUCTIVE ENDOCRINOLOGY VER 1.01

31	FSH	2223	Revision 1
47	LH	2239	Revision 1

REPRODUCTIVE ENDOCRINOLOGY VER 2.01

15	CK-MB	2207	Revision 2
31	FSH	2223	Revision 3
37	hCG	2230	Revision 3
47	LH	2239	Revision 1
70	β-hCG	1A06	Revision 2

REPRODUCTIVE ENDOCRINOLOGY VERS 3.04

15	CK-MB	2207	Revision 2
31	FSH	2223	Revision 3
37	hCG	2230	Revision 3
47	LH	2239	Revision 1
69	Prolactin	2244	Revision 1
70	β-hCG	1A06	Revision 3
82	hCG	3A63	Revision 3

REPRODUCTIVE ENDOCRINOLOGY VERS 4.00

15	CK-MB	2207	Revision 2
31	FSH	2223	Revision 3
37	hCG	2230	Revision 3
47	LH	2239	Revision 1
69	Prolactin	2244	Revision 1
70	β-hCG	1A06	Revision 3
82	hCG	3A63	Revision 4

REPRODUCTIVE ENDOCRINOLOGY VERS 5.02

15	CK-MB	2207	Revision 2
31	FSH	2223	Revision 3
47	LH	2239	Revision 1
69	Prolactin	2244	Revision 2
70	β-hCG	1A06	Revision 4
82	hCG	3A63	Revision 4
107	hCG	3A63	Revision 2

REPRODUCTIVE ENDOCRINOLOGY VERS 6.00

15	CK-MB	2207	Revision 2
23	Estradiol	2215	Revision 1
31	FSH	2223	Revision 3
47	LH	2239	Revision 1
50	Progesterone	2242	Revision 1
69	Prolactin	2244	Revision 2
70	β-hCG	1A06	Revision 4
107	hCG	3A63	Revision 3

REPRODUCTIVE ENDOCRINOLOGY VERS 7.0

15	CK-MB	2207	Revision 2
23	ESTRADIOL	2215	Revision 2
31	FSH	2223	Revision 3
47	LH	2239	Revision 1
50	Progesterone	2242	Revision 1
69	Prolactin	2244	Revision 2
70	β-hCG	1A06	Revision 4
107	hCG	3A63	Revision 3

* International Use Only

REPRODUCTIVE ENDOCRINOLOGY VERS 8.0

15	CK-MB	2207	Revision 2
23	Estradiol	2215	Revision 2
31	FSH	2223	Revision 3
47	LH	2239	Revision 1
50	Progesterone	2242	Revision 1
69	Prolactin	2244	Revision 2
70	β-hCG	1A06	Revision 4
107	hCG	3A63	Revision 3
120	STAT CK-MB	7A28	Revision 1

REPRODUCTIVE ENDOCRINOLOGY VERS 9.0

23	Estradiol	2215	Revision 2
31	FSH	2223	Revision 3
47	LH	2239	Revision 1
50	Progesterone	2242	Revision 1
69	Prolactin	2244	Revision 2
70	β-hCG	1A06	Revision 4
107	hCG	3A63	Revision 3
120	STAT CK-MB	7A28	Revision 2

HEPATITIS VERSION 1.05*

3	CORE	2259	Revision 1
4	CORE-M	2260	Revision 1
7	HAVAB-M	2263	Revision 1
36	HBsAg	2228	Revision 2
74	HBsAg CONF	2228	Revision 2
75	CORE (%INH)	2259	Revision 1

HEPATITIS VERSION 2.03**

3	CORE	2259	Revision 1
4	CORE-M	2260	Revision 2
6	AUSAB	2262	Revision 1
7	HAVAB-M	2263	Revision 2
34	HAVAB	2226	Revision 1
36	HBsAg	2228	Revision 3
74	HBsAg CONF	2228	Revision 3
75	CORE (%INH)	2259	Revision 1

HEPATITIS VERSION 3.03**

3	CORE	2259	Revision 1
4	CORE-M	2260	Revision 2
5	ANTI-HBe	2261	Revision 2
6	AUSAB	2262	Revision 1
7	HAVAB-M	2263	Revision 2
34	HAVAB	2226	Revision 2
35	HBe	2227	Revision 2
36	HBsAg	2228	Revision 4
74	HBsAg CONF	2228	Revision 4
75	CORE (%INH)	2259	Revision 1
105	ANTI-HBe %I	2261	Revision 2
111	HAVAB %INH	2226	Revision 1

HEPATITIS VERSION 4.0**

3	CORE	2259	Revision 1
4	CORE-M	2260	Revision 2
5	ANTI-HBe	2261	Revision 2

HEPATITIS VERSION 4.0 (continued)**

6	AUSAB	2262	Revision 1
7	HAVAB-M	2263	Revision 2
34	HAVAB	2226	Revision 2
35	HBe	2227	Revision 3
36	HBsAg	2228	Revision 5
74	HBsAg CONF	2228	Revision 5
75	CORE (%INH)	2259	Revision 1
105	ANTI-HBe %I	2261	Revision 2
111	HAVAB %INH	2226	Revision 1

HEPATITIS VERSION 6.0**

3	CORE	2259	Revision 2
4	CORE-M	2260	Revision 3
5	ANTI-HBe	2261	Revision 3
6	AUSAB	2262	Revision 2
7	HAVAB-M	2263	Revision 3
34	HAVAB	2226	Revision 3
35	HBe	2227	Revision 4
36	HBsAg	2228	Revision 6
39	HIV-1/HIV-2	2231	Revision 1
74	HBsAg CONF	2228	Revision 6
75	CORE (%INH)	2259	Revision 2
83	HCV	3A99	Revision 1
88	HBe 2	4B14	Revision 1
89	Anti HBe 2	4B16	Revision 1
90	Anti HBe 2 % I	4B16	Revision 1
105	ANTI-HBe %I	2261	Revision 3
110	HCV CONF	3A99	Revision 1
111	HAVAB %INH	2226	Revision 1

** Assay names will not appear in the file directory until the assay is activated

HEPATITIS VERSION 7.0**

3	CORE	2259	Revision 2
4	CORE-M	2260	Revision 3
5	ANTI-HBe	2261	Revision 3
6	AUSAB	2262	Revision 2
7	HAVAB-M	2263	Revision 3
34	HAVAB	2226	Revision 3
35	HBe	2227	Revision 4
36	HBsAg	2228	Revision 6
39	HIV-1/HIV-2	2231	Revision 1
51	HIV PLUS	8B32	Revision 1
74	HBsAg CONF	2228	Revision 6
75	CORE (%INH)	2259	Revision 2
83	HCV	3A99	Revision 1
88	HBe 2	4B14	Revision 1
89	Anti HBe 2	4B16	Revision 1
90	Anti HBe 2 % I	4B16	Revision 1
105	ANTI-HBe %I	2261	Revision 3
110	HCV CONF	3A99	Revision 1
111	HAVAB %INH	2226	Revision 2

HORMONE ASSAYS VERSION 1.02

27	FERRITIN	2219	Revision 2
37	hCG	2230	Revision 1
58	T3	2250	Revision 1
59	T4	2251	Revision 1
60	T-UPTAKE	2252	Revision 1
64	hTSH	2256	Revision 1

THYROID ASSAYS VERSION 1.08

8	B12	2200	Revision 2
27	FERRITIN	2219	Revision 5
29	FREE T3	2221	Revision 4
30	FREE T4	2222	Revision 5
58	T3	2250	Revision 4
59	T4	2251	Revision 1
60	T-UPTAKE	2252	Revision 3
64	hTSH	2256	Revision 5
80	ULTRA hTSH	3A62	Revision 3
81	T4	2A82	Revision 1

THYROID ASSAYS VERSION 2.0

29	FREE T3	2221	Revision 4
30	FREE T4	2222	Revision 6
58	T3	2250	Revision 4
60	T-UPTAKE	2252	Revision 3
80	ULTRA hTSH	3A62	Revision 3
81	T4	2A82	Revision 1

THYROID ASSAYS VERSION 3.0

29	FREE T3	2221	Revision 4
30	FREE T4	2222	Revision 6
40	FREE T3	7B18	Revision 2
45	TOTAL T3	8B13	Revision 1
48	ULTRA hTSH II	4B01	Revision 1
58	T3	2250	Revision 4
60	T-UPTAKE	2252	Revision 3
80	ULTRA hTSH	3A62	Revision 3
81	T4	2A82	Revision 2

** Assay names will not appear in the file directory until the assay is activated

CONGENITAL DIAGNOSTICS Version 1.06

41	IgE	2233	Revision 3
55	RUBELLA-G	2247	Revision 3
56	RUBELLA-M	2248	Revision 2
62	TOXO-G	2254	Revision 3
63	TOXO-M	2255	Revision 2

CONGENITAL DIAGNOSTICS Version 2.01

16	CMV-G	2208	Revision 1
17	CMV-M	2209	Revision 1
55	RUBELLA-G	2247	Revision 3
56	RUBELLA-M	2248	Revision 3
62	TOXO-G	2254	Revision 3
63	TOXO-M	2255	Revision 3
41	IgE	2233	Revision 4

CONGENITAL DIAGNOSTICS Version 3.00

16	CMV-G	2208	Revision 2
17	CMV-M	2209	Revision 1
41	IgE	2233	Revision 5
55	RUBELLA-G	2247	Revision 3
56	RUBELLA-M	2248	Revision 3
62	TOXO-G	2254	Revision 3
63	TOXO-M	2255	Revision 3

CONGENITAL DIAGNOSTICS Version 4.0

16	CMV-G	2208	Revision 3
17	CMV-M	2209	Revision 1
41	IgE	2233	Revision 6
55	RUBELLA-G	2247	Revision 4
62	TOXO-G	2254	Revision 4
63	TOXO-M	2255	Revision 3
122	RUBELLA-M	7A24	Revision 1
124	TOXO-M	7A82	Revision 2

CONGENITAL DIAGNOSTICS Version 5.0

16	CMV-G	2208	Revision 3
17	CMV-M	2209	Revision 1
20	CMV-M	2209	Revision 1
41	IgE	2233	Revision 6
55	RUBELLA-G	2247	Revision 4
62	TOXO-G	2254	Revision 4
63	TOXO-M	2255	Revision 3
122	RUBELLA-M	7A24	Revision 1
124	TOXO-M	7A82	Revision 2
126	TOXO-A**	9A46	Revision 1

CONGENITAL DIAGNOSTICS Version 6.0

16	CMV-G	2208	Revision 3
20	CMV-M	2209	Revision 1
32	RUBELLA-G**	1B05	Revision 1
41	TOTAL IgE	2233	Revision 6
46	TOXO-G**	4B45	Revision 1
55	RUBELLA-G	2247	Revision 4
62	TOXO-G	2254	Revision 4
63	TOXO-M	2255	Revision 3
122	RUBELLA-M	7A24	Revision 1
124	TOXO-M	7A82	Revision 2
126	TOXO-A**	9A46	Revision 2

THEOPHYLLINE/B12 VERSION 1.01

72	THEO	1A81	Revision 1
104	B12	2200	Revision 3

TDM/TRANSPLANT VERSION 1.0

108	TACROLIMUS	6A19/7A19	Revision 2

TDM/TRANSPLANT VERSION 2.0

72	THEO	1A81	Revision 2
108	TACROLIMUS	6A19/7A19	Revision 2

TDM/TRANSPLANT VERSION 3.0

21	DIGOXIN	2213	Revision 1
72	THEO	1A81	Revision 2
108	Tacrolimus	6A19/7A19	Revision 2
109	Tacrolimus II (IUO)**	8A45	Revision 1
112	Tacrolimus II**	3C10	Revision 1

METABOLIC VERSION 1.0

27	FERRITIN	2219	Revision 6
44	INSULIN	2A10	Revision 1
104	B12	2200	Revision 4

METABOLIC VERSION 2.1

27	FERRITIN	2219	Revision 6
44	INSULIN	2A10	Revision 2
79	%GHb (GHb)	1A86	Revision 2
116	%GHb (Hb)	1A86	Revision 2
104	B12	2200	Revision 4

METABOLIC VERSION 3.0

27	FERRITIN	2219	Revision 6
28	FOLATE	2220	Revision 1
44	INSULIN	2A10	Revision 3
79	%GHb (GHb)	1A86	Revision 2
116	%GHb (Hb)	1A86	Revision 2
104	B12	2200	Revision 4

SELECT FERTILITY VERSION 1.04

26	FSH	2223	Revision 2
42	LH	2239	Revision 1
43	PROLACTIN	2244	Revision 2

SELECT TUMOR MARKERS VERSION 1.0*

18	AFP	2257	Revision 1
19	CA 19-9	2203	Revision 1
22	CEA	3A33	Revision 1

SELECT TUMOR MARKERS VERSION 2.0*

18	AFP	2257	Revision 1
19	CA 19-9	2203	Revision 1
22	CEA	3A33	Revision 1
91	CA 19-9	5B09	Revision 1

SELECT STD VERSION 1.0*

14	CHLAMYDIA	2206	Revision 3

***** International Use Only

NOTE: The above information refers to assay module availability only and is not indicative of reagent availability. Assay modules may contain software protocols for assay reagent systems which are not currently available. Also, some assays on the modules may be available FOR INVESTIGATIONAL USE ONLY, as specified in the assay package insert.

ASSAY PARAMETERS: Many of the assay modules require the editing of assay parameters before performing assays. Assay package inserts from current reagent packs have the most up to date assay parameters. When verifying and editing assay parameters, ensure that the Assay Number and the List Number at the top of the assay parameter list, printed from the assay module, match the Assay Number and List Number in the IMx reagent pack assay package insert.

ASSAY MODULE LIST NUMBERS (All of these modules are compatible with System Software Version 6.0 or higher only):

CONGENITAL DIAGNOSTICS VERSION 6.00	1A74-06
HEPATITIS VERSION 7.0	3A30-07
REPRODUCTIVE ENDOCRINOLOGY VERSION 9.0	1A94-09
THYROID VERSION 3.0	3A38-03
TUMORS MARKERS VERSION 8.0	8385-08
METABOLIC VERSION 3.0	6A22-03
TDM/TRANSPLANT VERSION 3.0	4B05-03

SELECT Assay Module List Numbers (Compatible with Systems Software Version 6.0 or higher unless noted.):

SELECT FERTILITY VERSION 1.0	4A05-01**
SELECT TUMOR MARKERS VERSION 2.0	4A06-02*
SELECT STD VERSION 1.0	1B04-01*

*** International use only.**
****Compatible with System Software Version 5.0 or higher.**

END OF DOCUMENT

ABBOTT ADD	INSTRUMENT SERVICE ADVISORY

SUBJECT: **IMx® Keypad Redesign to reduce Electro-Static discharge**	ISA#: **60-152**
ORIGINATOR: **Louis Valich**	PRODUCT: **IMx® (60)**
APPROVED: **Mark Slater 11/30/95**	EFFECTIVITY DATE: **30-NOV-95**

I. DISTRIBUTION:

International and USA

II. PURPOSE:

This ISA explains the new style of keypad used in the top half of the touchpad assembly (3-04531-02). The new keypad and attaching hardware reduces the instruments susceptibility to static discharge. The keypad is now available as a separate part with the mounting hardware (3-47312-02). The main differences in the keypad are that it is now plastic and has a grounding strap to be attached under the upper left screw, and three insulated screws (see illustration on page 3 of this ISA for location). This change was introduced to resolve potential issues related with FACTORY SET and/or CHECKSUM ERROR due to electro-static discharge.

III. PARTS:

Catalog Number	Description
3-04531-02	Touchpad Assembly (Display, grounded Keypad, shell enclosure)
3-04531-01	Touchpad Assembly (now discontinued and obsolete)
3-47312-02	Keypad, grounded

United States:

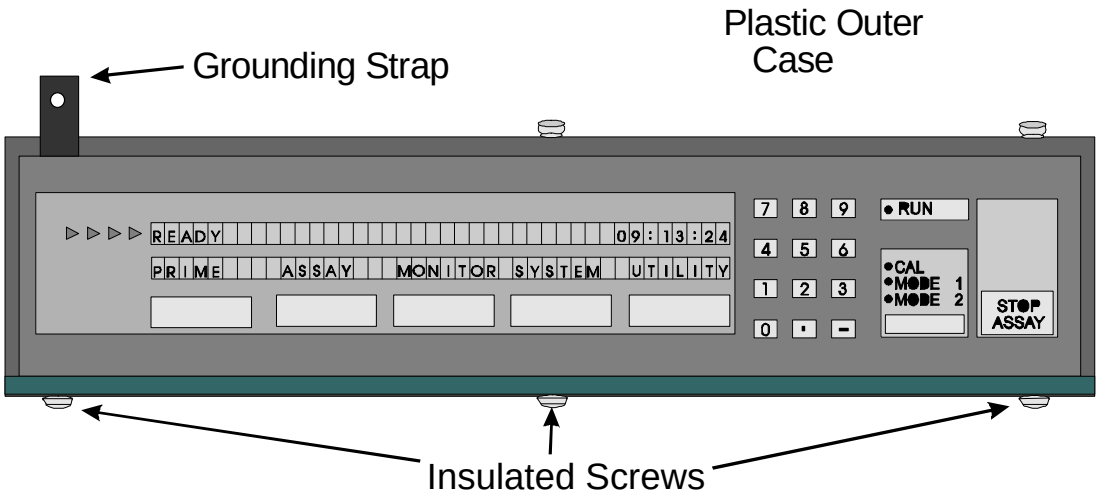
Once you use up your 3-04531-01 Touchpad in your parts kits, it will be replaced automatically with the 3-47312-02 Keypad. The 3-04531-02 Touchpad will not be stocked in your parts kits. The 3-04531-01 Touchpad will no longer be available.

Other Areas of the World:
When your FSE parts kits and Depot stock are depleted, they should be replaced with either the new 3-04531-02 Touchpad or the 3-47312-02 Keypad. Any of the 3-04531-01 Touchpads that are currently on order will be upgraded to the 3-04531-02 Touchpad. You can forecast your requirements for the above two parts through your normal channels.

IV. PROCEDURE:

Whenever you suspect that a FAC_SET or CHECKSUM error has occurred because of static discharge, insure that you install the 3-47312-02 Keypad or the 3-04531-02 Touchpad. It is more cost effective to replace the Keypad rather than the entire Touchpad assembly. When installing the keypad onto the base of the touchpad (piece where the display is mounted to), insure that the ground strap is fastened under the upper left hand screw of the touchpad. Use the three (3) insulated screws on the bottom of the Keypad since these will be exposed to external electro static sources. more than the top of the Keypad. See illustration on page 4 of this ISA.

If you are having a problem with the display portion of the Touchpad assembly, you will need to replace the Touchpad assembly (3-04531-02) rather than just the Keypad (3-47312-02).



END OF DOCUMENT

ABBOTT ADD	INSTRUMENT SERVICE ADVISORY

SUBJECT: **Release of CE Mark Certified IMx® Instruments**	ISA#: **60-151**
ORIGINATOR: **Louis Valich**	PRODUCT: **IMx® (60)**
APPROVED: **Bob Schabel 31-OCT-95**	EFFECTIVITY DATE: **31-OCT-95**

I. DISTRIBUTION:

Domestic and International

II. PURPOSE:

This ISA informs the Field Service Organizations Worldwide of the release of CE Mark Certified IMx® Instruments. The size code for the IMx instrument will reflect CE Mark status by changing to -86, therefore, the new build CE Mark IMx Instrument will have a list number of 8389-86. A new build non-CE Mark IMx instrument will remain as list number of 8389-01. The refurbed non-CE Mark IMx instrument will remain as 8389-59. There will not be any refurbished CE Mark IMx Instruments. The serial number of CE Marked IMx instruments will begin at 70,001. A recap of the different size codes for the IMx Analyzer follows:

8389-01	Non-CE Mark new build IMx Analyzer
8389-59	Non-CE Mark refurbished IMx Analyzer
8389-86	CE Mark new build IMx Analyzer

The CE Marking is a European Union (EU) conformity mark that is placed on product to indicate conformance to the CE Marking Directives that are applicable to that product. The EU represents a majority of the nations in Europe, that have joined together to remove internal barriers to goods, capital, services and people within their boundaries. Countries outside the EU, (i.e. USA, Japan, Etc.) are not currently affected by these CE Mark Directives. The European Directives specify essential requirements regarding product safety and quality. The EMC Directive defines essential requirements of electrical

and electronic apparatus with regard to emissions of, or susceptibility to, electro-magnetic disturbances. The Low Voltage Directive defines the requirements necessary to insure that electrical equipment placed on the European Market does not endanger the safety of persons, domestic animals, or property installed, maintained and used in applications for which it was made. Without this CE Marking displayed on the IMx instrument, we would not be able to sell new IMx Instruments in Europe after 01-JAN-96 in those countries requiring CE Mark.

This ISA is for parts information only. It gives the part numbers necessary to service the CE Mark IMx instruments. Procedures for upgrading an IMx instrument may be provided in a TSB at a later date, should Abbott management decide to upgrade IMx instruments in the future.

III. PARTS:

See Table 1

CE Mark parts for the IMx instrument are not one-for-one compatible with non-CE Mark parts. Service CE Mark IMx instruments with CE Mark certified parts only. Service non-CE Mark IMx instruments with non-CE Mark certified parts only.

United States:

No parts are required for the United States. The USA will not be servicing CE Mark instruments since none will be shipped in the USA.

International:

European Countries that require CE Mark should insure FSR Spare Parts Kits are stocked with IMx CE Mark Certified parts to facilitate servicing of CE Mark Certified IMx instruments. Service sites should forecast parts requirements through their normal channels. See Table 1 for the list of parts required for CE Mark.

Countries that do not require CE Mark should not stock FSR Spare Parts Kits with IMx CE Mark Certified parts. CE Mark IMx instruments should not be shipped to countries not requiring them.

Table 1
IMx instrument parts affected by CE Mark

Part Description	Part Number	Catalog Number	QTY Req'd
Card Cage (Cover was modified to accommodate new cable grounding bar)	47009-101	3-47009-01	1
Main Power Supply (Filtering added)	47230-101	3-47230-01	1
ASIC Motor Driver PCB (reduced emissions)	47405-101	3-47405-01	1

Printer Assy, Fujitsu with wire (Reduced emissions and adds ground wire)	47227-102	3-47227-01	1
CPU to Printer Cable Assembly with Ferrite (Shortened length of cable to reduce noise and ferrite added)	47225-101	3-47225-01	1
RS-232 Bracket/Cable Assembly (Shortened length of cable to reduce noise)	47224-101	3-47224-01	1
Ferrite (To be attached to COM1 of RS-232 Bracket/cable)	14108-062	N/A	1
Digital I/O to Analog Cable (New cable with improved shield and grounding scheme)	47221-101	3-47221-01	1
Digital I/O to Motor Driver Cable (New cable with improved shield and grounding scheme)	47220-101	3-47220-01	1
ASIC CPU PCB (New layout & adds power for bar code scanner at the RS-232 outputs)	47615-101	3-47615-01	1
ASIC Digital I/O PCB (Removes capacitor C36)	47635-101	3-47635-01	1
MEIA Optics Assy (Switch pmt & photodiode connectors around on PCB & add ferrite to pmt cable and photodiode cable)	47228-101	3-47228-01	1
MEIA Lamp Power Supply Cable with Ferrite (Add ferrite to MEIA Lamp P/S cable)	79229-101	3-79229-01	1
FPIA Optics Assembly with Ferrite (Add ferrite to FPIA Optics cable)	47639-101	3-47639-01	1
Carousel Motor Assembly with Ferrite (Add ferrite to carousel motor cable)	47641-101	3-47641-01	1
Keypad Assembly for the Touchpad (More robust anti-static prevention)	47312-103	3-47312-02	1
Bar Code Scanner (Removes external power supply and uses power from the ASIC CPU and added shielding to the cable)	LN 3C26-01	N/A	1 (only if customer has scanner)

A CE Mark designator will be attached to the rear of the IMx Enclosure assembly. The CE Mark label will look like the illustration below:

END OF DOCUMENT

ABBOTT ADD	INSTRUMENT SERVICE ADVISORY

SUBJECT: **Release of IMx SELECT® Tumor Markers Assay Module Ver. 2.0**	ISA#: **60-150**
ORIGINATOR: **Michael A. Mowen**	PRODUCT: **IMx® (60)**
APPROVED: **Bob Schabel 01-NOV-95**	EFFECTIVITY DATE: **01-NOV-95**

I. DISTRIBUTION:

International and USA

II. PURPOSE:

This ISA informs the Field Service Organizations of a new release of the *IMx SELECT Tumor Markers Assay Module, Version 2.0, List No. 4A06-02. The primary reason for the new module is that new Assay #91 CA 19-9, has been added to the IMx SELECT Tumor Markers Assay Module Version 2.0 from version 1.0

All the assays on this module are the same as the assays found on the current IMx® Tumor Markers assay module V8.0, only the Assay Numbers and size codes (-70 for SELECT) for the reagent pack list numbers are different

*INTERNATIONAL RELEASE ONLY

IMx SELECT Tumor Markers Assay Module V2.0 includes the following assays:

Assay Name and Number	List Number	Revision Number	Parameter Changes
18 AFP	2257-70	1	No
19 CA 19-9	2203-70	1	No

22 CEA	3A33-70	1	No
91 CA 19-9	5B09-70	1	New Assay

NO assay activation required for any of the assays on this module.

New Assays

IMx SELECT CA 19-9: List Number 5B09-70
Assay Number 91

For additional information on new assay refer to IMx® CA 19-9 (LN 5B09) assay package insert.

System Software Compatibility

The IMx SELECT Tumor Markers Assay Module Version 2.0 can only be used with IMx System Software Version 6.0 or higher.

Parameter Changes

There are no parameter changes to any assays on this assay module.

Protocol Changes

There are no protocol changes to any assays on this assay module.

Assay Calibration

The new IMx SELECT CA 19-9 assay, List Number 5B09-70, will require IMx SELECT assay calibration when installing the IMx SELECT Tumor Markers Assay Module V2.0. The IMx SELECT CA 19-9 LN 5B09 assay will replace the current IMx SELECT CA 19-9 LN 2203 assay. LN 5B09 reagents, calibrators and controls **CAN NOT** be used interchangeably with LN 2203 reagents, calibrators, and controls.

System Messages/Error Codes:

No new System Messages/Error Codes introduced on this assay module

END OF DOCUMENT

ABBOTT ADD	INSTRUMENT SERVICE ADVISORY

SUBJECT: **Protocol for IMx® Factory Sets/Checksum Errors**	ISA#: **60-149**
ORIGINATOR: **Louis Valich**	PRODUCT: **IMx® (60)**
APPROVED: **Bob Schabel 07-13-95**	EFFECTIVITY DATE: **13-JUL-95**

ISA 60-149 supersedes ISA 60-034, ISA 60-34A, and ISA 60-034B!
Please discard them immediately!

I. PURPOSE:

The purpose of this ISA is to update the CHECKSUM/FACTORY RESET protocol to address the release of System Software version 6.0. This ISA describes the differences between these two types of errors and the corrective action required to resume operation after these errors occur.

Checksum Errors

Error 100 (Directory Checksum Error) and Error 101 (File Checksum Error) are "mini factory sets." They cause an individual file(s) or directory to be reloaded with factory set values. If the error occurs while attending the instrument, open the printer door and press the paper advance button to see the specific error printed on the tape. The System Log also lists the error.

To print the Instrument System Log Report PRESS: UTILITY, OTHER, OTHER, SYS_LOG

There are three types of files that can be reset. These are System, Assay and Protocol files. If the file that has been reloaded is **1.XXX, an system file** was reloaded. The number after the decimal indicates the particular system file reloaded. The name of the reloaded file will also appear on the printout next to the file number. For example: "File 1.038 Photo Parameters.....Loaded." If the file that has been reloaded is **2.XXX, an assay file** was reloaded. If the file that has been

reloaded is **3.XXX, a protocol file** was reloaded.

System Files

After determining what file was reloaded, follow the chart below to re-edit the parameters in that file.

File No.	File Name	Action To Take:
1	Configuration	Re-edit: 1.3 Serial Number 1.5 Date Format 1.17 Line Feeds 1.19 CRSL ID 1=ON (optional)
		If connected to a host computer system the following parameters must be edited to match the specifications of the HOST. 1.10 COM2 BAUD 1.11 COM2 CHR LEN 1.12 COM2 STOP BIT 1.13 COM2 PARITY 1.18 HOST INTERFACE (PASSWORD to ENABLE INTERFACE=2215 or 5713 to use Spooler) 1.29 XOFF TIMEOUT Perform an ASSAY MODULE SHUTDOWN procedure to activate these parameters if you have edited them. Press UTILITY, SHUTDOWN, START, remove assay module and reinstall it again.
2	System Params	Empty waste container to avoid overflow Reset: 2.3 Current Buffer 2 (MEIA)* 2.6 Current Buffer 1 (FPIA)* 2.9 WASTE TOT VOL** *Set volume to match level of buffer bottles now in use! **Set Volume to 0 if continuous waste option is installed!

3	FPIA Carousel	Perform FPIA Carousel Calibration* Perform Boom Calibration *Customers are unable to perform the FPIA Carousel Calibration; the FSE can perform this procedure. If the customer can perform Boom Calibration and the probe can clear the reagent bottle opening and the probe is centered over the probe positioning cartridge target during the FPIA BOOM Check, then they can proceed with returning the instrument to operational status without performing the FPIA Carousel Calibration.
4	MEIA Carousel	Perform FPIA Carousel Calibration Perform MEIA Carousel Calibration
5 thru 36	Boom Location Files	Perform Boom Calibration

File No.	**File Name**	**Action To Take:**

37	Temperature	Review ISA 60-092. Review TSB 60-020B/ edit parameters if necessary; **File # Parameter Old heater fan New Heater Fan** 37.2 FPIA AMB CRTN -0.5 -0.25 37.12 AMB OFF TIME 240 90 37.18 MEIA PID DEV 0.0 0.5 37.21 MEIA CAL TIME 420 600 37.26 PID GAIN 32.0000 64.0000 37.27 PID INTEGRAL 0.0250 0.0500 37.29 PID BIAS 120.0 116.0 Perform Temperature Calibrations in this order: 1. SELECT Temperature Calibration (OPTIONAL) 2. MEIA Temperature Calibration 3. FPIA Temperature Calibration
38	Photo Parameters	Edit parameters below: 38.11 MEIA STD B to 0. 38.12 MEIA STD M to M value on optical stds. 38.25 MEIA LMP REF to R= value in MEIA OPTICS HAND CONTROLS-Lamp should be ON and stable (approx. 2 min.). Perform MEIA Carousel Calibration Perform MEIA Photo Calibration

COMPLETE THE IMx® TOTAL SERVICE CALL PROCEDURE!

Assay Files

If the file reloaded is 2.XXX, an assay file has been reloaded. The number after the decimal is the assay number that has been reloaded. Get a list from the customer of which assays have been calibrated. Then do as follows:

Press: UTILITY, OTHER, OTHER, FILEMGT, NOVRAM, ASSAYS.

All assays that have been loaded into NOVRAM will list a date next to the name on the printout. Assays with a date of 11/11/11 have no calibration curve in memory. Determine if any of the assays that the customer has been using have the 11/11/11 date. If so, they must be recalibrated.

Check revision levels of assay modules for assays run by the customer. Ensure the customer is using the most current revisions of assay modules, edit if necessary.

Edit reference ranges, print options and T-Uptake file, if necessary.

Activate Hepatitis assays if necessary. To do this perform the following:

Install the Hepatitis assay module by performing the ASSAY SHUTDOWN procedure.
Install a reagent pack of the assay to be activated. (Open the vial caps before inserting into the reagent heater block.)
Press ASSAY
Enter assay number example 4 for CORE M
OTHER
OTHER
ACTIVATE (When the bar code reader reads the reagent pack bar code label, activation is complete.)
Repeat for other hepatitis assays that need activation.

Protocol Files

Normally, no action is required when a protocol file is reloaded. If you want to reload a protocol file you can perform the following:

Press UTILITY
OTHER
OTHER
FILEMGT
PROTOCOL
BWD or FWD (to the protocol you want to reload)
RELOAD

Factory Sets

Except for the FPIA Carousel Calibration, the CSC group normally instructs the customer in the Factory Set Recovery Protocol. A Field Service call is then opened to request that the FPIA Carousel Calibration be performed and card cage/enclosure alignment examined per VP-2/VP-3 in the IMx Service Manual.

Error 218 SPECIAL OPERATION, that is present in the System Log along with Error 102, INITIALIZE DATABASE, indicates that the instrument memory of the reagent bar code numbers has been reset. The instrument will then recognize all reagent packs as new i.e. having 100 tests left. The customer should be instructed to manually monitor any reagent packs used previously on the instrument.

Error 102 Initialize Database, indicates that a complete Factory Set has occurred. All SYSTEM and ASSAY files have been reset/reloaded to factory values. All system and assay calibrations will need to be performed and several parameters must be edited. The procedure listed below must be followed:

File No.	File Name	Action To Take:
1	Configuration	Re-edit: 1.3 Serial Number 1.5 Date Format 1.17 Line Feeds
		If connected to a host Computer system the following parameters must be edited to match the specifications of the HOST. 1.10 COM2 BAUD 1.11 COM2 CHR LEN 1.12 COM2 STOP BIT 1.13 COM2 PARITY 1.18 HOST INTERFACE (PASSWORD to ENABLE INTERFACE=2215 or 5713 to use Spooler) 1.29 XOFF TIMEOUT Perform an ASSAY MODULE SHUTDOWN procedure to activate these parameters if you have edited them. Press UTILITY, SHUTDOWN, START, remove assay module and reinstall it again.
2	System Params	Empty waste container to avoid overflow Reset: 2.3 Current Buffer 2 (MEIA)* 2.6 Current Buffer 1 (FPIA)* *Set volume to match level of buffer bottles now in use!

<table>
<tr>
<td>37</td>
<td>Temperature</td>
<td>Review ISA 60-092/ edit parameters if necessary.
Review TSB 60-020B/ edit parameters if necessary;
<table>
<tr><th>File #</th><th>Parameter</th><th>Old heater fan</th><th>New Heater Fan</th></tr>
<tr><td>37.2</td><td>FPIA AMB CRTN</td><td>-0.5</td><td>-0.25</td></tr>
<tr><td>37.12</td><td>AMB OFF TIME</td><td>240</td><td>90</td></tr>
<tr><td>37.18</td><td>MEIA PID DEV</td><td>0.0</td><td>0.5</td></tr>
<tr><td>37.21</td><td>MEIA CAL TIME</td><td>420</td><td>600</td></tr>
<tr><td>37.26</td><td>PID GAIN</td><td>32.0000</td><td>64.0000</td></tr>
<tr><td>37.27</td><td>PID INTEGRAL</td><td>0.0250</td><td>0.0500</td></tr>
<tr><td>37.29</td><td>PID BIAS</td><td>120.0</td><td>116.0</td></tr>
</table>
</td>
</tr>
<tr>
<td>38</td>
<td>Photo Parameters</td>
<td>Edit parameters below :
<table>
<tr><td>38.11</td><td>MEIA STD B</td><td>to 0.</td></tr>
<tr><td>38.12</td><td>MEIA STD M</td><td>to M value on optical stds.</td></tr>
<tr><td>38.25</td><td>MEIA LMP REF</td><td>to R= value in MEIA OPTICS HAND CONTROLS-Lamp should be ON and stable (approx. 10 min.).</td></tr>
</table>
</td>
</tr>
</table>

Perform the following instrument calibrations in order:

FPIA CAROUSEL CALIBRATION*
MEIA CAROUSEL CALIBRATION
BOOM CALIBRATION
SELECT TEMPERATURE CALIBRATION
MEIA TEMPERATURE CALIBRATION
MEIA PHOTO CALIBRATION
FPIA TEMPERATURE CALIBRATION
FPIA PHOTO CALIBRATION

Assay Files

Press: UTILITY, OTHER, OTHER, FILEMGT, NOVRAM, ASSAYS.

All assays that have been loaded into NOVRAM will list a date next to the name on the printout. Assays with a date of 11/11/11 have no calibration curve in memory. Determine if any assays that the customer has been using have the 11/11/11 date. If so, they must be recalibrated.

Check revision levels of assay modules for assays run by the customer. Ensure customer is using the most current revisions of assay parameters, edit if necessary.

Edit reference ranges, print options and T-Uptake file, if necessary.

Activate Hepatitis assays if necessary. To do this perform the following:

Install the Hepatitis assay module by performing the ASSAY SHUTDOWN procedure.
Install a reagent pack for the assay to be activated. (Open the vial caps before inserting into the reagent heater block.)

Press	ASSAY	
enter	assay number	example; 4 for CORE M
	OTHER	
	OTHER	
	ACTIVATE	(When the bar code reader reads the reagent pack bar code label, activation is complete)

Repeat for other hepatitis assays that need activation.

COMPLETE THE IMx TOTAL SERVICE CALL PROCEDURE!

END OF DOCUMENT

ABBOTT ADD	INSTRUMENT SERVICE ADVISORY

SUBJECT: **Release of IMx® TDM/Transplant Assay Module V3.0**	ISA#: **60-148**
ORIGINATOR: **Louis Valich**	PRODUCT: **IMx® (60)**
APPROVED: **Bob Schabel 08/02/95**	EFFECTIVITY DATE: **02-AUG-95**

I. PURPOSE:

This ISA informs the Field Service Organizations of the release of the IMx® TDM/Transplant Module Version 3.0, List Number 4B05-03. The assays available on this module are listed below:

Assay # and Name		List Number	Revision	Parameter/Protocol Changes
21	Digoxin	2213	1	New Assay
72	Theophylline	1A81	3	YES
108	Tacrolimus	6A19/7A19	2	NO
109* (IUO)	Tacrolimus II	8A45	1	New Assay
112*	Tacrolimus II	3C10	1	New Assay

* Resides on the assay module as a hidden assay. Assay name will not appear in the file directory until the assay is activated. Some assays are not available worldwide.

New Assay information

IMx Digoxin (List Number 2213 with an Assay Number 21):
Digoxin is a drug that is widely prescribed for the treatment of congestive heart failure and for some types of cardiac arrhythmia's. The IMx Digoxin Assay is a Microparticle Enzyme Immunoassay (MEIA) used for the quantitative detection of digoxin levels in human serum and plasma.

General information:

1. The IMx® Digoxin assay will not require sample pretreatment.
2. The IMx Digoxin assay does not require Assay Activation.
3. The IMx Digoxin assay utilizes a competitive two-step format.
4. The IMx Digoxin assay correlates well with the TDx/TDxFLx Digoxin II assay.

IMx Tacrolimus II (Tacro II) (List Number 3C10 with an Assay Number 112):
The IMx Tacrolimus Assay is a Microparticle Enzyme Immunoassay (MEIA), used for the quantitative determination of tacrolimus levels in whole blood samples. Tacrolimus is an immunosuppressant drug administered for the treatment of rejection following transplantation.

IMx Tacrolimus II (Tacro II/IUO) (List Number 8A45 with an Assay Number 109):
Identical to IMx Tacrolimus II (List Number 3C10, Assay Number 112). Labeled for INVESTIGATIONAL USE ONLY on IMx printouts.

General Information:

1. The IMx Tacrolimus II Assay has increased sensitivity compared to the Tacrolimus (LN 6A19/7A19) assay.
2. The IMx Tacrolimus II Assay requires a manual pretreatment step of all whole blood samples, MODE 1 Calibrator, Calibrators, and Controls. If a specimen requires a dilution, it must be diluted prior to the pretreatment step. Refer to the DILUTION INFORMATION section in the assay package insert.
3. The IMx Tacrolimus II Assay utilizes a one step protocol which improves the assay precision with the increased sensitivity.
4. Tacrolimus II Assay # 109 and 112, both are new assays that reside on the module as hidden assays. Assay names will not appear in the file directory until the assay is activated.
5. The Tacrolimus Assay (List Numbers 6A19/7A19) Calibrators and Controls can **not** be used with the Tacrolimus II assays (List Numbers 8A45/3C10).

System Messages/Error Codes:
There are no new System Messages/Error Codes on this assay module.

Assay Calibration:
The following assays will require calibration when changing from a previous version of the IMx TDM/Transplant Assay Module to Version 3.0:

If changing from:

V1.0 to 3.0 Calibrate the following assays:	V2.0 to V3.0 Calibrate the following assays:
21 Digoxin	21 Digoxin
72 Theophylline	72 Theophylline
109 Tacrolimus II/IUO	*109 Tacrolimus II/IUO*
112 Tacrolimus II	*112 Tacrolimus II*

*Assays are hidden and must be activated prior to use for the first time.

Protocol Changes:

The IMx® Theophylline protocol was revised to include assay status information to the IMx user when in the Multitask Menu. IMx Theophylline on the TDM/Transplant Version 2.0 Assay Module (List Number 4B05-02) does not accurately display the assay status when accessed in the Multitask Menu.

END OF DOCUMENT

ABBOTT ADD	INSTRUMENT SERVICE ADVISORY

SUBJECT: **Release of IMx® Folate Assay**	ISA#: **60-147**
ORIGINATOR: **Michael A. Mowen**	PRODUCT: **IMx® (60)**
APPROVED: **Bob Schabel 11/August/95**	EFFECTIVITY DATE: **11-AUG-95**

I. PURPOSE:

To inform the field of the Folate assay release, and the unique features of the reagents and operating procedures.

Sample/Reagents/controls: **(See figure one for loading instructions. See figure two for storage conditions.)**

Bottle one is shipped separate from the pack (in absorbent pouch) and must be installed into the pack. This is done because the solution in vial one is **CORROSIVE** Potassium Hydroxide.

The Medium Control is separate from the Low and High Controls, because it contains the compound 5-mTHF, which is not as stable as the compound PGA that is found in the Low and High control. The Medium Control must be included on each run.

IMx Folate RBC Lysis reagent is used to prepare whole blood samples to be run on the IMx. The reagent needs to be reconstituted before usage.

IMx Folate Denaturant is used during the run for processing Folate samples. **(See figure one for loading instructions.)**

20% chloride bleach solution (1.0% sodium hypochlorite) is used at successful completion of run to decontaminate probe automatically. If the run is interrupted before completion, then a manual probe decontamination procedure must be performed. (Reference protocol for manual decontamination). The Bleach solution is made by the site. **(See figure one for loading instructions.)**

The procedure for preparing whole blood samples requires 90 ±5 minutes to complete, and samples must be run within 30 minutes of completion.

Sample dilutions are not recommended above a ratio of 1:4

Loading/running Folate assay:

The predilution well of the first Ion Capture cell must be filled with IMx Folate Denaturant. **(See figure one for loading instructions.)**

The predilution well of the second Ion Capture cell must be filled with 20% chloride bleach solution. **(See figure one for loading instructions.)**

At the end of each assay run, the probe must be cleaned to remove invisible build up on outside of probe assembly.

If a run is aborted for any reason, a manual probe decontamination procedure must be performed, and then the probe must be cleaned to remove invisible build up on outside of probe assembly.

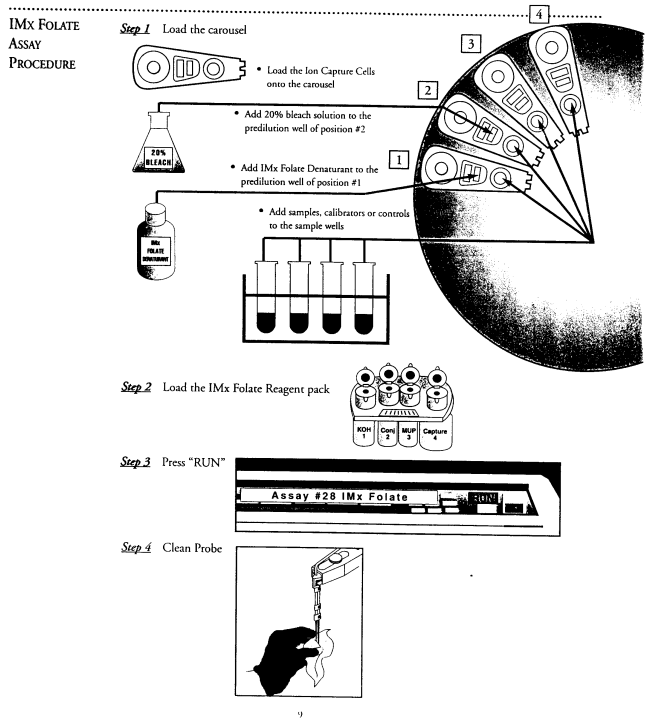

IMx Folate Assay Procedure
Step 1 Load the carousel
• Load the Ion Capture Cells onto the carousel
• Add 20% bleach solution to the predilution well of position #2
• Add IMx Folate Denaturant to the predilution well of position #1
• Add samples, calibrators or controls to the sample wells
20% BLEACH
IMx FOLATE DENATURANT
1
2
3
4
Step 2 Load the IMx Folate Reagent pack
KOH 1
Conj 2
MUP 3
Capture 4
Step 3 Press "RUN"
Assay #28 IMx Folate
RUN
Step 4 Clean Probe

Figure 1

	List Numbers	Storage Conditions (Once received in lab)
IMx FOLATE Reagent pack and Ion Capture Reaction Cells	2220-88	2-8°C – Reagents 15-30°C – Ion Capture Reaction Cells
Calibrators	2220-01	-10°C or colder
Low and High Controls	2220-10	2°-8°C
Medium Control	2220-11	-10°C or colder, or 2-8°C after thawing (stable up to 7 days)
MODE 1 Calibrator	2220-40	2°-8°C
Denaturant	2220-35	2°-8°C
RBC Lysis Reagent	2220-60	15°-30°C unreconstituted, or 2°-8°C reconstituted (stable up to 7 days)
Specimen Diluent	2220-50	2°-8°C

Figure 2
END OF DOCUMENT

ABBOTT ADD	**INSTRUMENT SERVICE ADVISORY**

SUBJECT: **Release of IMx® Hepatitis Assay Module Version 7.0**	ISA#: **60-146**
ORIGINATOR: **Michael A. Mowen**	PRODUCT: **IMx® (60)**
APPROVED: **Bob Schabel 17-OCT-95**	EFFECTIVITY DATE: **17-OCT-95**

I. PURPOSE:

This ISA informs the Field Service Organizations of the release of a new Hepatitis Assay Module, Version 7.0, List No. 3A30-07.

IMx® Hepatitis Assay Module Version 7.0 includes the following assays:

Assay Name and Number	List Number	Revision Number	Print Option	Parameter Changes
3 CORE*	2259	2	11	NO
4 CORE-M	2260	3	12	NO
5 ANTI-HBe*	2261	3	11	NO
6 AUSAB*	2262	2	13	NO
7 HAVAB-M	2263	3	12	NO
34 HAVAB	2226	3	11	NO
35 HBe*	2227	4	12	NO
36 HBsAg*	2228	6	10	NO
39 HIV-1/HIV-2*	2231	1	14	NO
51 HIV PLUS*	8B32	1	14	NEW ASSAY

74 HBsAg CONF*	2228	6	10	NO
75 CORE (%ıNH) *	2259	2	10	NO
83 HCV*	3A99	1	14	NO
88 HBe 2*	4B14	1	12	NO
89 AntiHBe2*	4B16	1	11	NO
90 AntiHBe2%ı*	4B16	1	10	NO
105 ANTI-HBe %ı*	2261	3	10	NO
110 HCV CONF*	3A99	1	10	NO
111 HAVAB %ıNH	2226	2	10	NO

*** -- International Use Only**

NOTE: This Assay Module may contain software protocols for assay reagent systems which are not currently available.

New Assays

The only new assay on this module is IMx® HIV PLUS Assay #51, which is available Rest of the World only. The new assay and assays # 39 (HIV-1/HIV-2) and #83 (HCV) utilize the Print Option 14. After activation of IMx HIV PLUS, assay calibration is required.

System Software Compatibility

The IMx Hepatitis Assay Module Version 7.0 can only be used with IMx System Software Version 6.0 or higher. If the IMx Hepatitis Assay Module Version 7.0 is installed with IMx System Software Versions 2.0, 3.0 or 5.0 the message "134 INCOMPATIBLE SYSTEM/ASSAY MODULES" is displayed. To return the IMx System to the Main Menu: turn the IMx OFF, remove the IMx Hepatitis Assay Module and turn the IMx power switch back to ON.

Assay Activation and Calibration

All assays on the IMx Hepatitis Assay Module V7.0 will require *activation* prior to being performed for the first time on each instrument. After activation of each assay, assay calibration is required.

The customer must continue to use the V7.0 Assay Module once it is has been installed. If the customer attempts to use an earlier version (i.e., V3.0 or V4.0 or V6.0) the error code 104 REVISION MISMATCH will be displayed.

To ensure that all customers perform Assay #4 CORE-M, Assay #7 HAVAB-M, Assay #34 CORE, Assay #36 HBsAg, Assay #74 HBsAg CONF and Assay #111 HAVAB %INH on the Hepatitis Assay Module V7.0 or the IMx Hepatitis Assay Module V6.0, **the barcode on the reagent packs will be changed the second quarter of 1995**. This change will be invisible to the customer unless a customer uses a reagent pack with a changed barcode number on an earlier version of an IMx Hepatitis Assay Module, then the error code 29 REAGENT PACK NOT ON MODULE will be displayed.

RS-232 Interface Changes(International use only at this time)

The Required Controls Feature changes the RS-232 output format of the IMx HBsAg Confirmatory Assay and the IMx HCV Confirmatory Assay. The IMx International Customers will be notified of these changes by the following statement in the IMx Hepatitis Assay Module V6.0 enclosure: ***NOTE: After installation of this assay module, a change in the RS-232 output specification is required. Check your assay specific package insert. A description of the RS-232 output changes is available through your local Abbott Customer Service Department.***

Attached is the description of the output changes, entitled "RS-232 Output Information For IMx Required Controls (Hepatitis)", which is referred to in the assay module enclosure. The attachment contains an example of an IMx HBsAg (U.S.A. Licensed Assay-pending) and IMx HBsAg Confirmatory assay printout.

Customers will be notified of these changes by a green warning sticker placed over the opening of the cushioned bag, and by a letter. The sticker states: IMPORTANT IMx RS-232 INTERFACE INFORMATION ENCLOSED. The letter, enclosed in the assay module cushion bag, directs the customer to contact CSC for information regarding the changes to the IMx RS-232 interface specifications.

RS-232 OUTPUT INFORMATION FOR IMx REQUIRED CONTROLS (HEPATITIS)

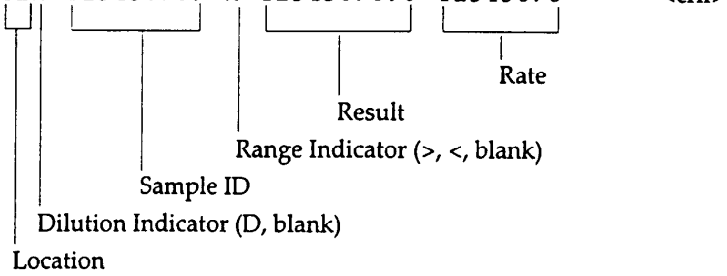
This output information should be used with the IMx RS-232 Interface Manual Revision 6 (List No. 83-8663/R6).

The IMx assay #74 HBsAg CONF is the first IMx assay to utilize a "Required Controls" feature. The software assumes that control(s) are being tested, immediately following the calibrator(s) for that run. The required control(s) must pass the assay-specific control ranges, as specified by the assay parameters. MEIA Qualitative Results follow the required control results.

For Required Controls:

Four different logical records are used to present Required Control results. The first record is the header showing CONTROLS. The second record shows the LOC, ID, RESULT UNIT and RATE labels. The RESULT UNIT label is transmitted as the 8 character field and its field content varies based on the unit selected. The third record is a separator record consisting of 35 dashes. All other records, following the separator record, are data records, consisting of Location, Dilution Indicator, Sample ID*, Range Indicator, Result (in the units shown in the header record), and Rate. The Dilution Indicator field will be "D" if the sample was diluted; otherwise it will be blank. The layout of these records is as shown below:

CONTROLS<crlf>
<crlf>
LOC^^^^ID^^^^^^^^^12345678^^^^^RATE <crlf>
---------- <crlf>
12x^123456789^x^1234567890^12345678^^^^^ <crlf>



*The Sample ID field for a Required Control can be one of the following ID names:

POSITIVE^ for a positive control
NEGATIVE^ for a negative control
Pos+RGT A for positive control & Reagent A

The Required Controls are compared against their assay-specific ranges as defined by the appropriate assay parameters. Each Required Control must pass its respective range check. If a Required Control fails the range check, it will be followed immediately by this error message:

CODE^146^CONTROL^OUT^OF^RANGE<crlf>

and, asterisks (**********) will print in the Results column for all samples.

For MEIA Qualitative Confirmatory Results:

Five different logical records are used to present the NEUTRALIZATION RESULTS. The first record is the header showing NEUTRALIZATION RESULTS, followed by a separator record consisting of 22 dashes. The next three records are data records, consisting of location pairs separated by a comma, Sample ID, Result in the units shown in the header record, and Note (POS or blank).:

```
^^^^^^^^^NEUTRALIZATION RESULTS
^^^^^^^^^----------------------

^^LOC^^^^^ID^^^^^^^^^^^^%NEUT^^^^NOTE
-----------------------------------
12,12^^123456789^^^1234567890^^^^1234
```

After all the location pairs have been transmitted, the following informational message is sent:
POS^>OR =^^^^^50.00^^%NEUT^AND
^^^^SAMPLE^+^RGT^B^IS^REACTIVE

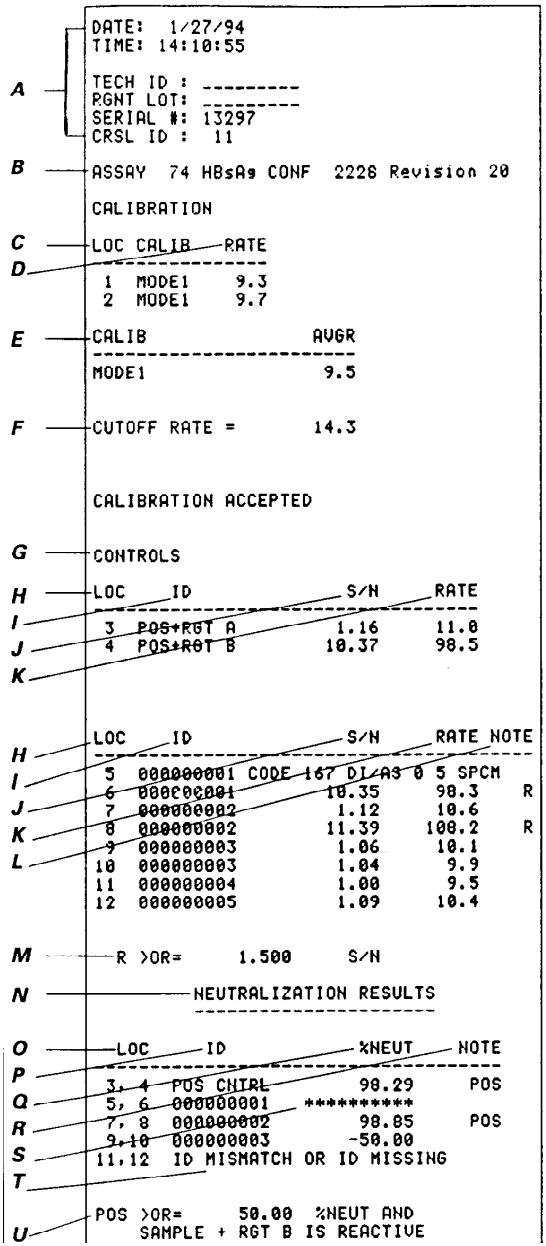
The portion of the message, "^^^^^50.00" is actually a floating point number with a total field width of 10, including the decimal point and 2 places to the right of the decimal. Prior to implementation of the Required Controls feature, the first line of the message consisted only of a character string containing the string constant "POS^>OR =^50.00^%NEUT^AND".

The Sample ID name for the Required Control, in the NEUTRALIZATION RESULTS section of the IMx results output, is POS CNTRL.

The % NEUT result for the Required Control (POS CNTRL) is compared against an assay-specific range defined by the assay parameters. If the POS CNTRL does not pass its range check it will be followed immediately by this error message:

CODE^146^CONTROL^OUT^OF^RANGE<crlf>
and asterisks (**********) will print, for all samples, in the Results column, and the % NEUT column.

MEIA Confirmatory with Required Controls



An example of an MEIA Confirmatory Calibration test results tape for a qualitative assay is shown:

A. Date of MEIA Calibration run
Time of MEIA Calibration run
Tech ID (Optional)
Reagent lot number (optional)
Serial number of your system
Carousel ID (optional)

B. Assay number, file name, list and revision numbers

C. Position of calibrators in MEIA carousel

D. Rates for the calibrators

E. Average Rate (AVGR) for the replicated calibrators (CALIB)

F. Cutoff Rate is calculated from the MODE 1 Calibrator rate on the carousel

G. Required Controls section header

H. Positions of the Required Controls or the unknown test samples on the MEIA carousel

I. Required Control ID or unknown test sample ID

J. Unit of measurement with unit results listed below

K. RATE, an intermediate value

L. Flags in the NOTE column

M. Range that determines flagged results in the NOTE column

N. Neutralization Results section header

O. Paired positions of the Required Controls or the unknown test samples

P. Paired IDs of the Required Controls or the unknown test samples

Q. % Neutralization, an intermediate result

R. Final results in the NOTE column are POS or blank

S. Asterisks in the concentration column resulting from the error CODE 167 DI/AS 05 SPCM

T. 25 character message indicating the paired IDs do not match or the IDs were missing

U. Range that determines results in the NOTE column

END OF DOCUMENT

ABBOTT ADD	INSTRUMENT SERVICE ADVISORY

SUBJECT: **IMx® Diagnostic Software Version 3.0.0**	ISA#: **60-145**
ORIGINATOR: **Louis Valich**	PRODUCT: **IMx® (60)**
APPROVED: **Bob Schabel 8-MAY-95**	EFFECTIVITY DATE: **25-APR-95**

I. DISTRIBUTION:

USA and International

NOTE: THIS ISA SUPERSEDES ISA's 60-132 AND 60-137. PLEASE DISCARD THESE AND PUT THIS ISA IN YOUR MANUAL.

II. PARTS:

USA FSR's will automatically receive:

1 ea. C/N 3-47508-03 IMx Diagnostic Software (Phase 3)

International Service Sites should order/forecast parts via their regular spare parts channels.

III. PURPOSE:

To inform the World Wide Field Service Organizations of the release of Phase 3 IMx® Diagnostic Software. These diagnostic tests allow the FSE/FSR to perform R-Boom, Z-Boom, LLS, Bar Code, Boom Life, RS-232, CV calculations, MEIA Optics, and Analog PCB by connecting a computer via a cable to the IMx analyzer. 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.

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

IV. WHEN TO USE:

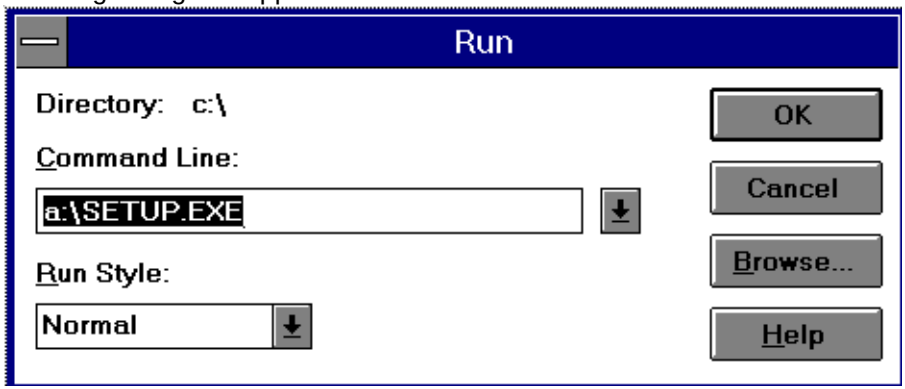
It is recommended that you use these diagnostics on IMx® analyzer service calls that involve R-Boom and Z-Boom problems, MEIA Optics, Temperature, Bar Code, LLS errors, RS-232 problems, and Analog Bd. problems.

V. SYSTEM SETUP:

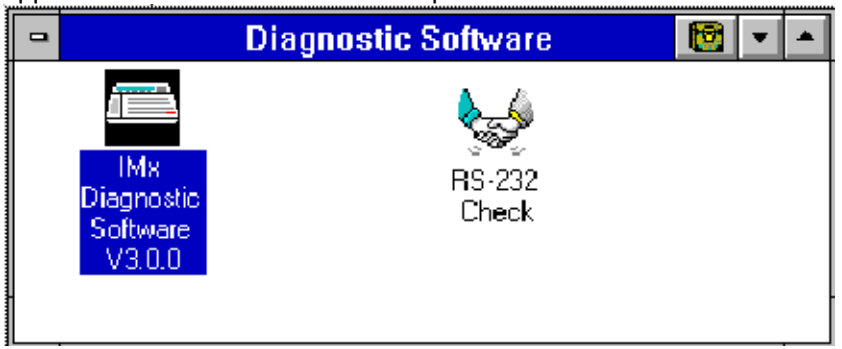
The System setup includes both software and hardware. Software is defined as the laptop diagnostics program supplied to you on a 1.44 Meg floppy disk. Hardware is defined as the serial cable that has to be connected from the COM2 port of the GRiD® laptop Computer to the COM1 port of the IMx System. On computers other than the GRiD, COM1 through COM4 may be used. This software will run in the Windows™ environment only.

VI. 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. The following dialog box appears:



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 (see below). All tests, including the RS-232 can be run out of the IMx Diagnostic Software V3.0.0 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 installation is not installed properly, the following message will appear:

IMx 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 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:

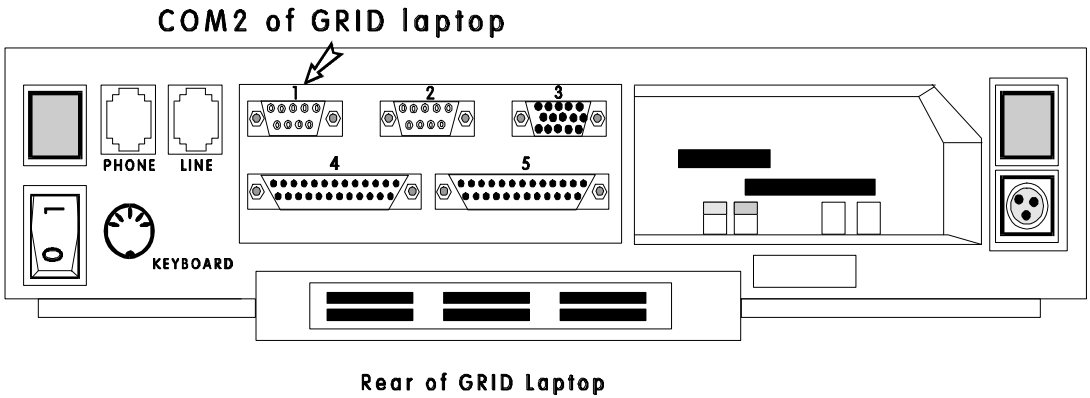
If the application will not execute, due to missing or corrupted file(s), re-install the application as described above. If still unsuccessful, contact the X SYSTEMS® CSE group to report it. We will see that you get another copy of the software to install.

RUNNING THE APPLICATION:

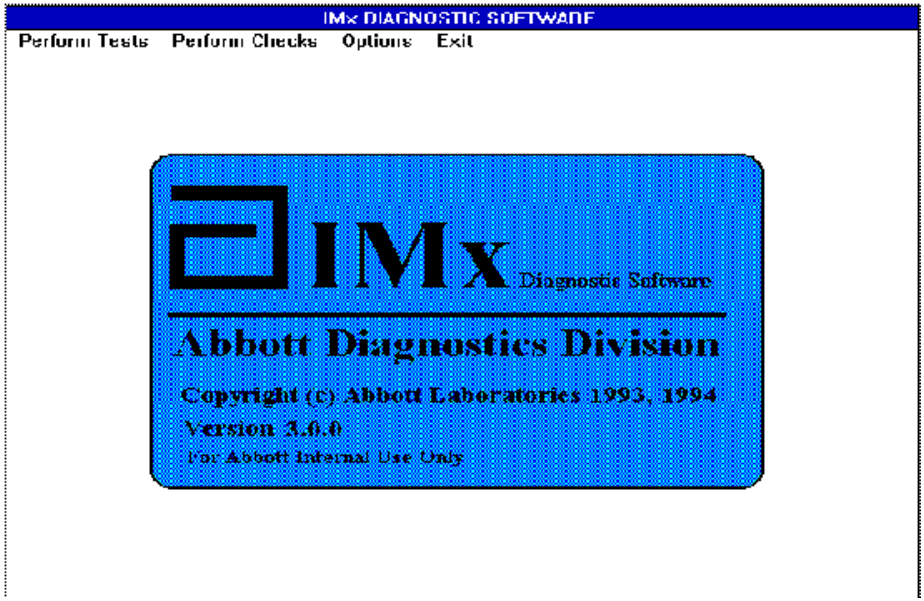
NOTE: Disable your screen saver before running these diagnostics. If you are level sensing and the screen saver activates, it could show incorrect LLS numbers.

NOTE: Before running the Laptop Diagnostics program, connect the A/T to Modem cable to the COM2 port of the GRiD® laptop Computer (see illustration below) and the COM1 port of the IMx System (RS 232 connection closest to the Main power On/Off switch). Turn the power switch of the IMx analyzer to the ON position.

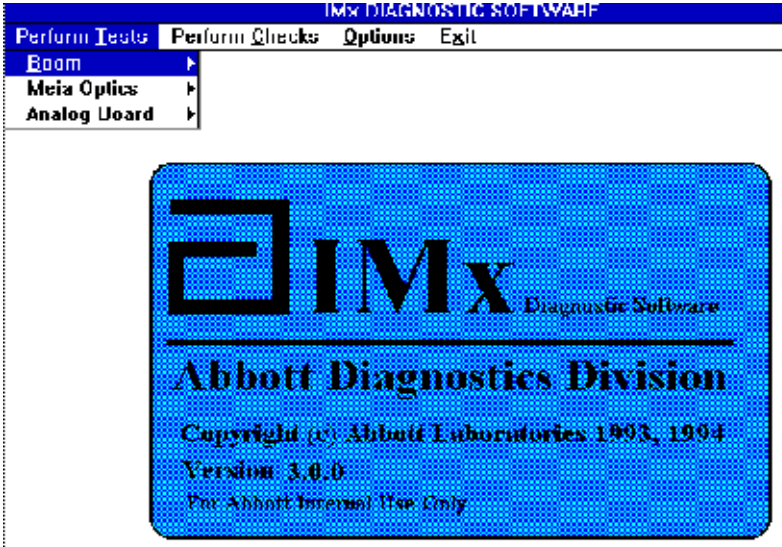
COM2 port is labelled as "1" above the connection on the back of the GRID laptop



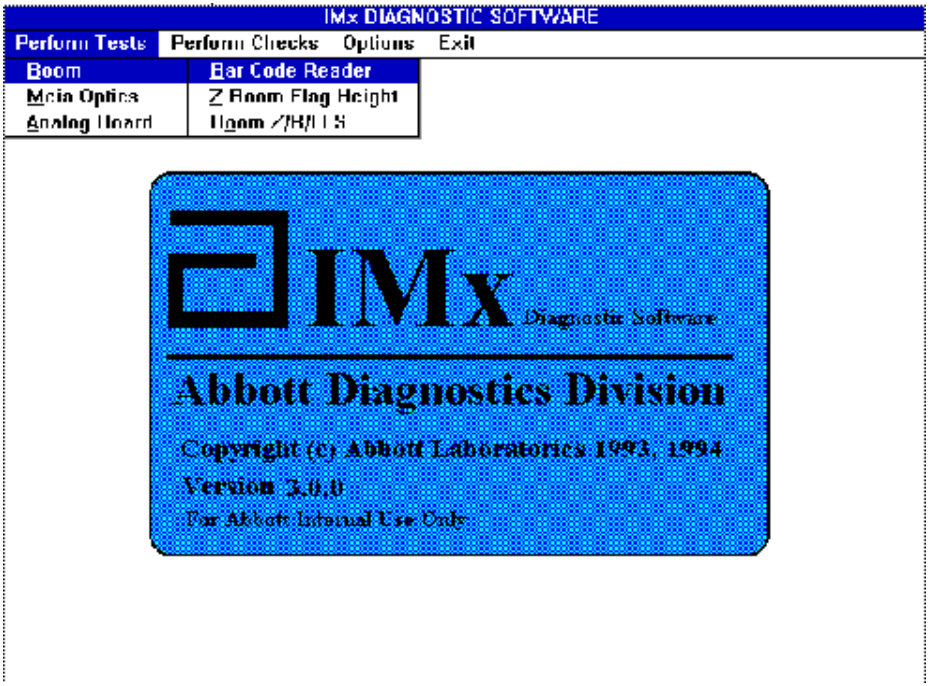
Using the mouse on your GRiD® computer, double click the mouse on the IMx® Diagnostic Software ICON just created. The following screen will appear:



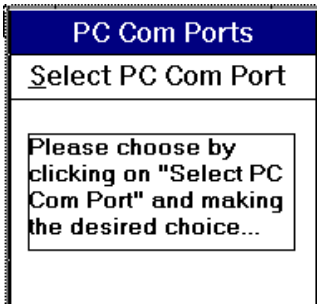
Four options are available for you to choose. These are to **1) Perform Tests** (gives pass/fail results), **2) Perform Checks** which the FSE/FSR determines pass/fail, **3) Options** which allows calculation of Coefficient of Variation for assay test results, and **4) Exit** which terminates the program. For reasons of explanation, select Perform Tests by moving the mouse pointer until it is on Perform Tests and click the left button. The following screen appears:


IMx DIAGNOSTIC SOFTWARE
Perform Tests
Perform Checks
Options
Exit
Boom
Meia Optics
Analog Board
IMx Diagnostic Software
Abbott Diagnostics Division
Copyright (c) Abbott Laboratories 1993, 1994
Version 3.0.0
For Abbott Internal Use Only

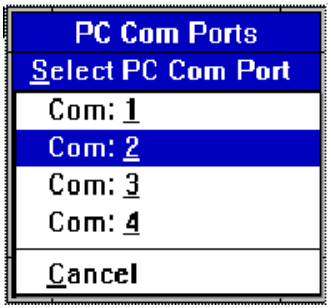
Select the Boom item with the mouse from the menu , the following dialog box will appear:



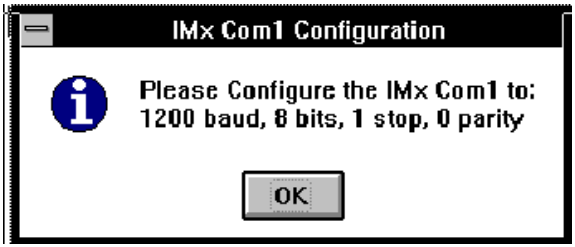
Select Bar Code Reader from the menu and the following screen appears:



Select the PC Com Port and the following screen appears:



Use the mouse and choose the appropriate communication port. On the GRiD laptop, choose Com: 2.



Verify that the IMx COM 1 port is setup to 1200 baud, 8 bits, 1 stop and 0 parity as follows:

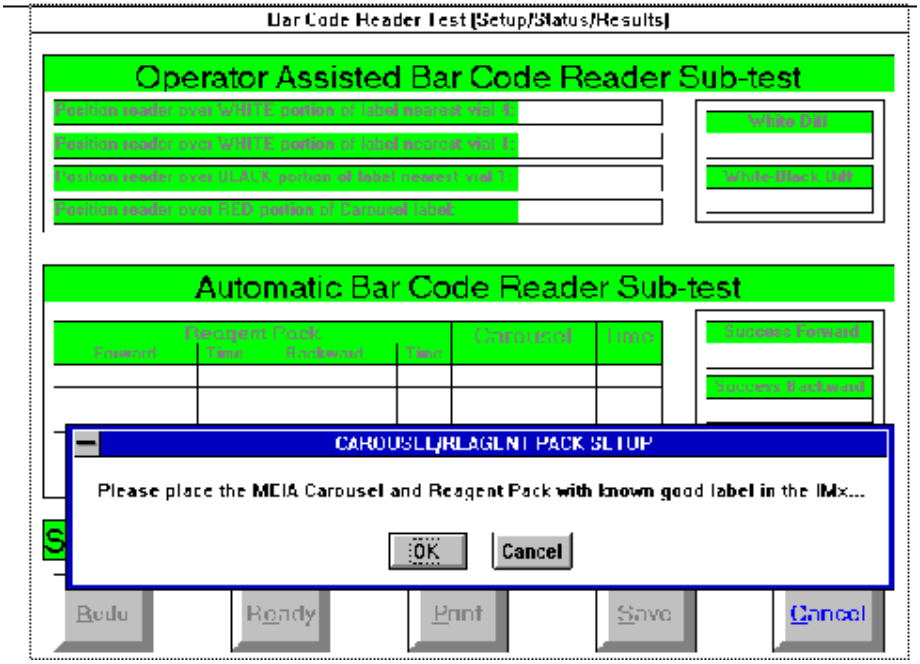
NOTE: ***REMEMBER TO RE-EDIT ORIGINAL PARAMETERS BACK WHEN DIAGNOSTIC TESTING IS COMPLETED***

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

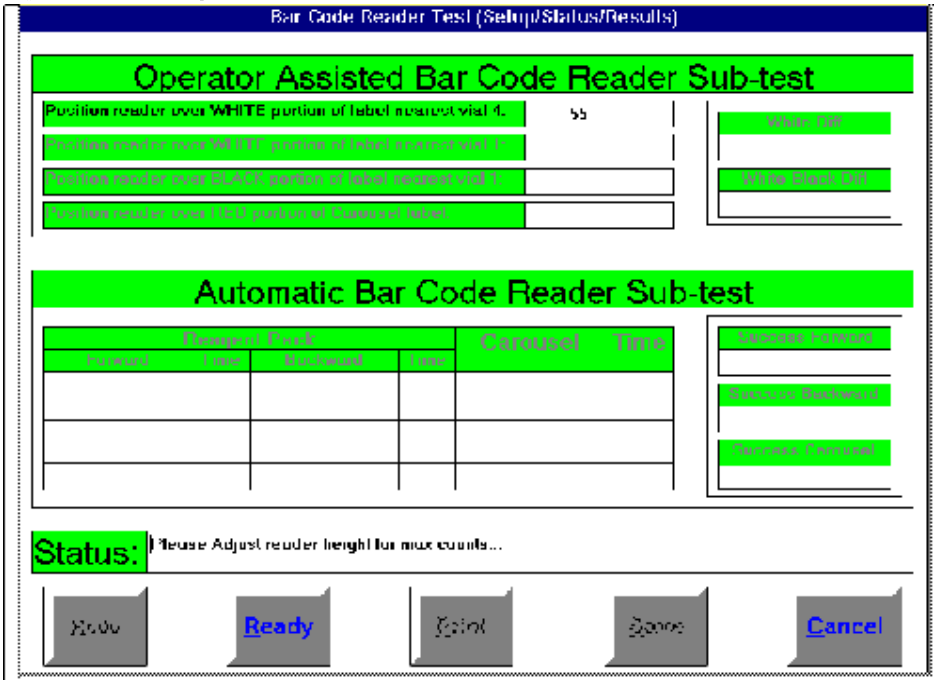
If any system files were edited, perform the Assay Module Shutdown procedure to activate these values as follows:

Press UTILITY
SHUTDOWN
START
When "130 READY TO CHANGE MODULES" appears, lift the assay module from its connector and reseat it. The IMx 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 IMx analyzer and the following window will be displayed:



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. The screen changes to below:



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.

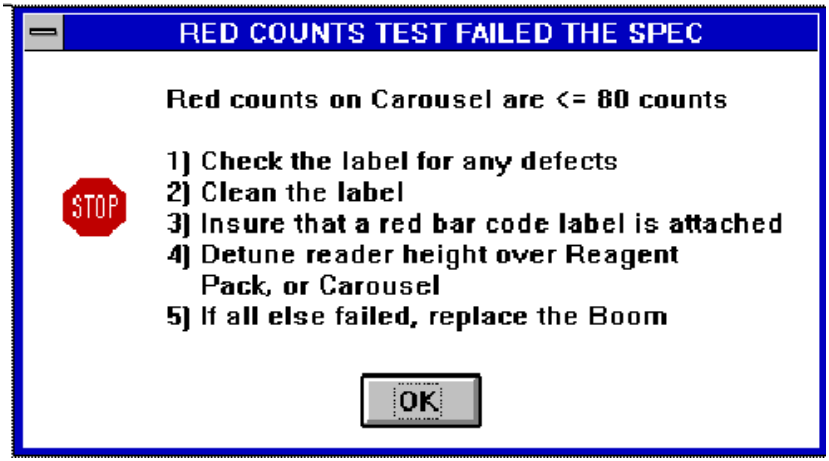
.

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 IMx Service Manual. These suggestions are made only to facilitate the troubleshooting process. Always refer to the IMx Service Manual when in doubt. A typical troubleshooting message box appears below:



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.

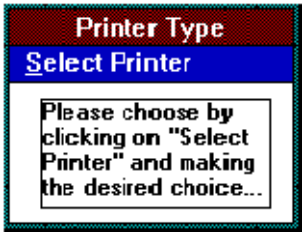
If carousel reader time is > 2.5 seconds:

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

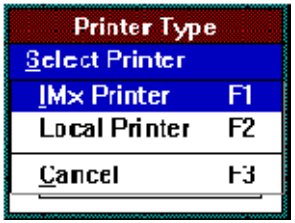
Printing out test results:

You can print out the results of the Bar Code test by choosing the Print button on the bottom of the display. The software allows two methods of printing. The first is to use the IMx printer. Doing so will print only the results and specifications, and no graphics. It can take up to a minute or more to print out using the IMx printer. The other 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.

After selecting the print button on the display with the mouse, the following screen appears:



Choose Select Printer and the following screen appears:

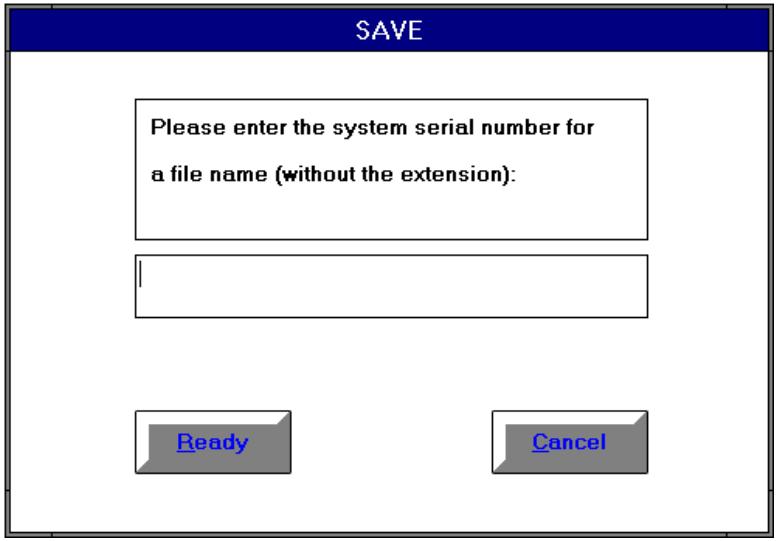


Select IMx Printer to print directly to the IMx printer. Select Local printer to print to the printer connected to your computer. Local printer will print the exact screen above. IMx printer will print the following:

BAR CODE READER TEST
Date=3/22/94 Date test was performed
TIME=13:29:54 Time test was performed
WHT LFT= 152 White reading on reagent pack near vial #4
WHT RT= 144 White reading on reagent pack near vial #1
BLK= 68 Black reading on reagent pack near vial #1
CRSL= 96 Carousel reading on red portion of label
W/W DIFF= 8 White (left) - White (right) reading on reagent pack
W/B DIFF= 76 White - black reading on reagent pack
SUCC FWD= 5 OF 5 Successful forward readings on reagent pack
SUCC BKWD= 5 OF 5 Successful backward readings on reagent pack
SUCC CRSL= 5 OF 5 Successful carousel readings
STATUS=PASSED Status either passed or failed
SPEC: Specifications of test follow below
W/W DIFF <=10 Max White (left) - White (right) reading on reagent pack
B/W DIFF>30 Min White - black reading on reagent pack
WHT>80 Min White readings on reagent pack
CRSL>30 Min Red reading on carousel
BCR TIME: Time it takes to read bar code labels
REAG<2.2 Max Time it should take to read reagent pack label
CRSL<=2.5 Max Time it should take to read carousel label

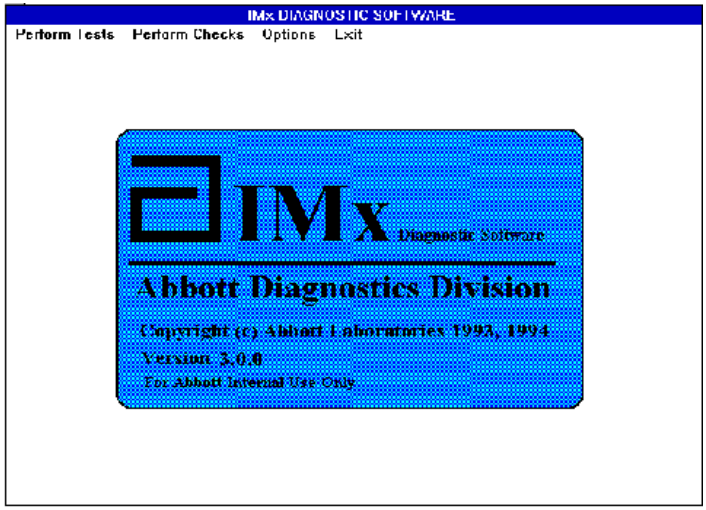
Saving Test results:

You can also save the test results by using the Save button. When you select save the following screen appears:



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.

To rerun the bar code test you can select the Redo button. Select the Cancel button to put you back to the following screen:

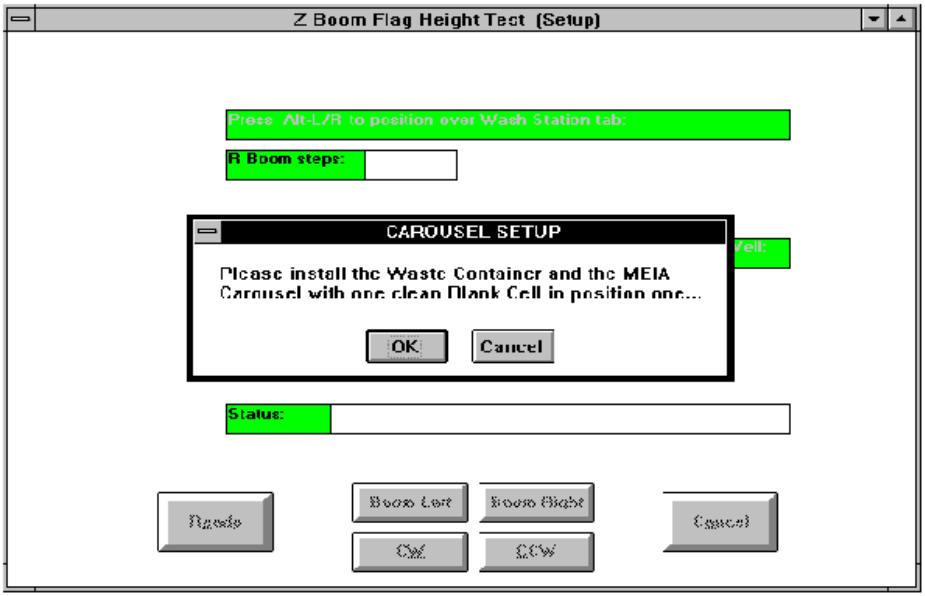


The two remaining items under Perform Tests / Boom are:

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).
Boom Z/R/LLS 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.

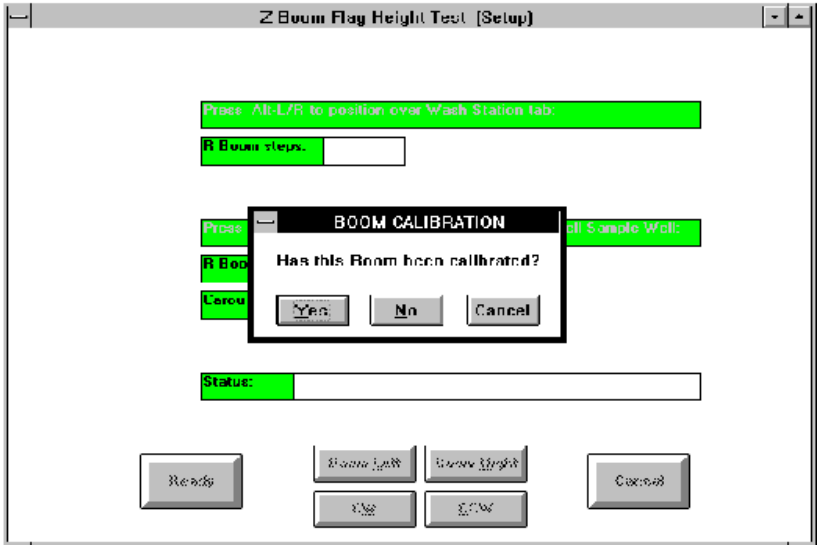
Select the Z Boom Flag Height test.

The test begins by homing the Z and R Boom motors of the Boom assembly. A dialog box appears with instructions to install the waste container and a MEIA carousel with one clean blank cell in position number one.

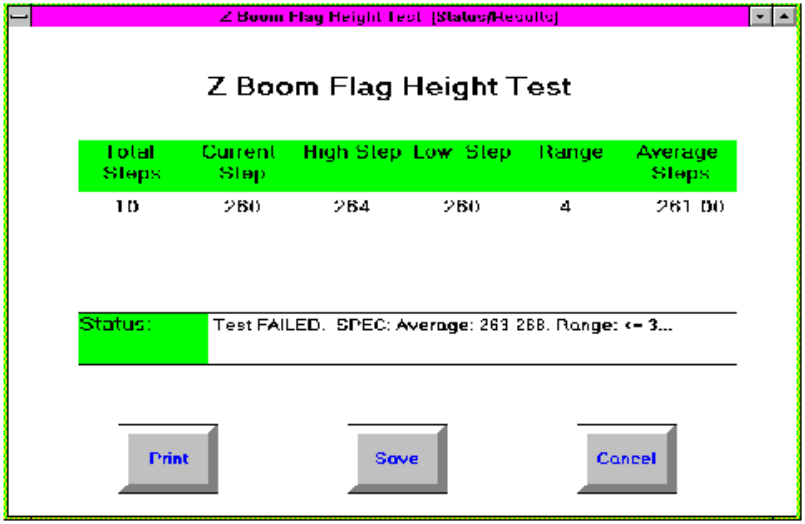


Click on the OK button to proceed to the next step.

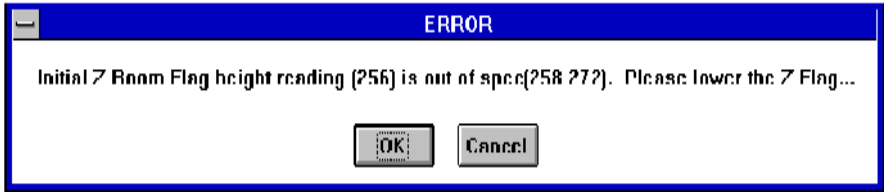
The following dialog box will appear:



If you answer Yes to this prompt, the software will use the existing boom calibration settings. Always answer Yes to this question *unless* you have just replaced the Boom or a FAC_SET has occurred. If you answer No, the program will prompt you to adjust the probe positioning over the wash station and the four reagent pack bottles. After adjusting the probe, click on Ready to advance to the next probe positioning step. Upon completion of the Z Boom Flag Height Test, the following display will provide the test results and a pass/fail status.

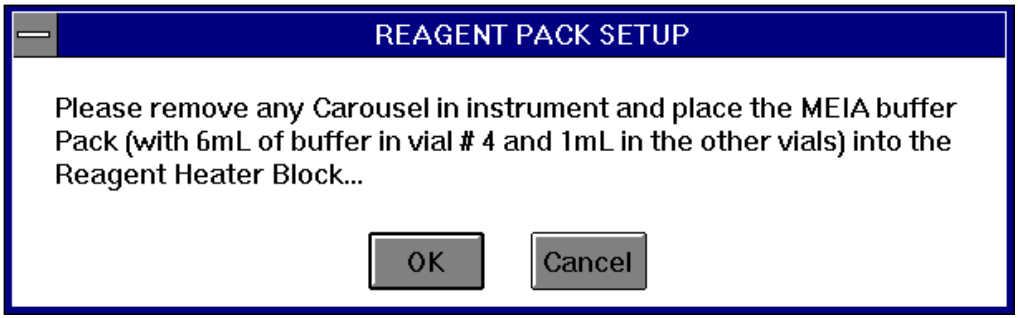


If a failure occurs, a message box will come up offering suggestions as to where to begin troubleshooting. This is not meant to replace the IMx Service Manual. These suggestions are made only to facilitate the troubleshooting process. Always refer to the IMx Service Manual when in doubt. A typical troubleshooting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

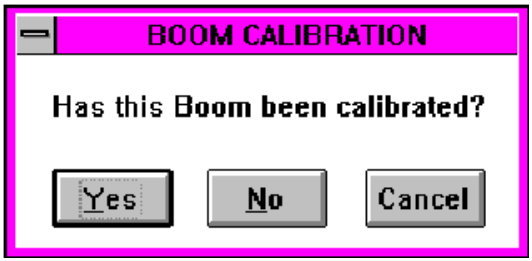


Two failure modes are possible, first is the Z-Flag height. The IMx System allows levels of 258 to 272 to pass. For the FSR, acceptable levels for the Z-Flag are 263 to 267 (we want to insure that the flag is set near the mid point of 265). A Z-Flag height outside of this range requires adjustment. If 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/electrode assembly or a bad Boom.

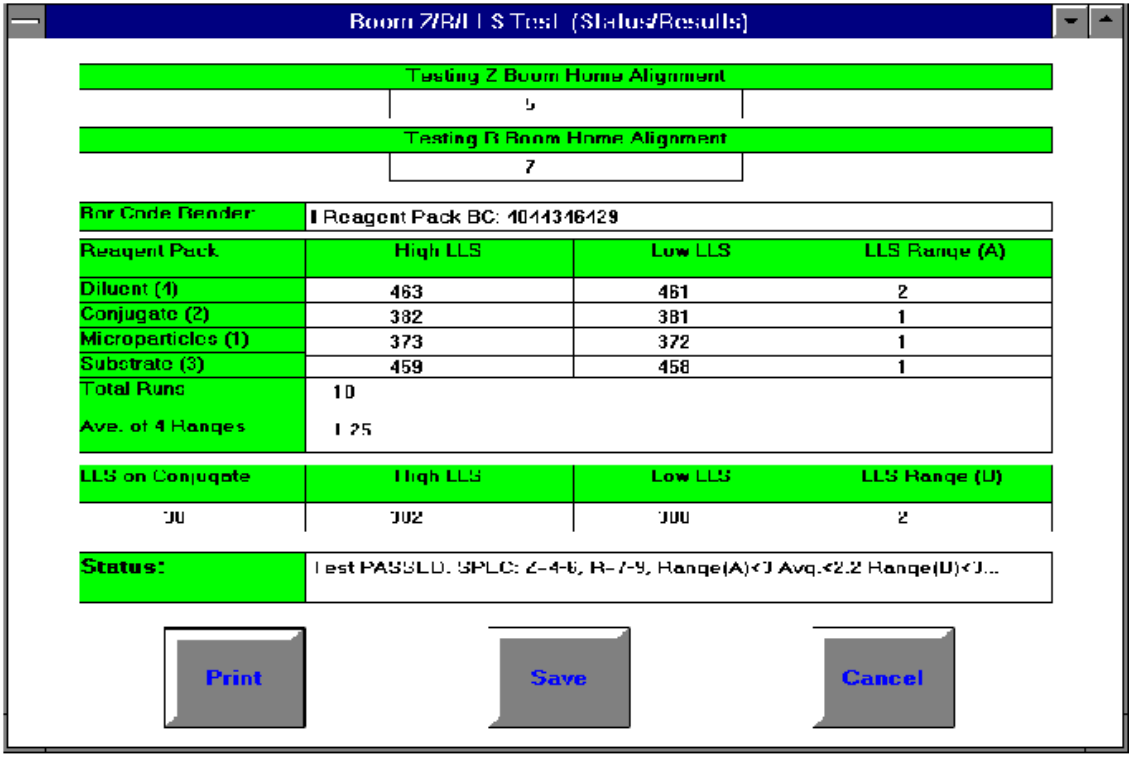
The other available test is the Boom Z/R/LLS Test. To start this test, select the Perform Tests, Boom, then the Boom Z/R/LLS item. The following dialog box will be displayed:



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. The following dialog box will be displayed:



If you answer YES to this question, the software will use the boom settings presently stored in the various system files. Always answer YES to this question *unless* you have just replaced the Boom or a FAC_SET has occurred. If you answer No, the program will prompt you to adjust the probe positioning over the wash station and the four reagent pack bottles. After adjusting the probe, click on Ready to advance to the next probe positioning step. Upon completion of the test, the following screen will be displayed:



♦ 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.

♦ The bar code is read and displayed for bar code operation test. If no bar code is present, the test will continue but a message will be displayed about the bar code failure.

♦ 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 IMx printer or an external printer connected to your computer.

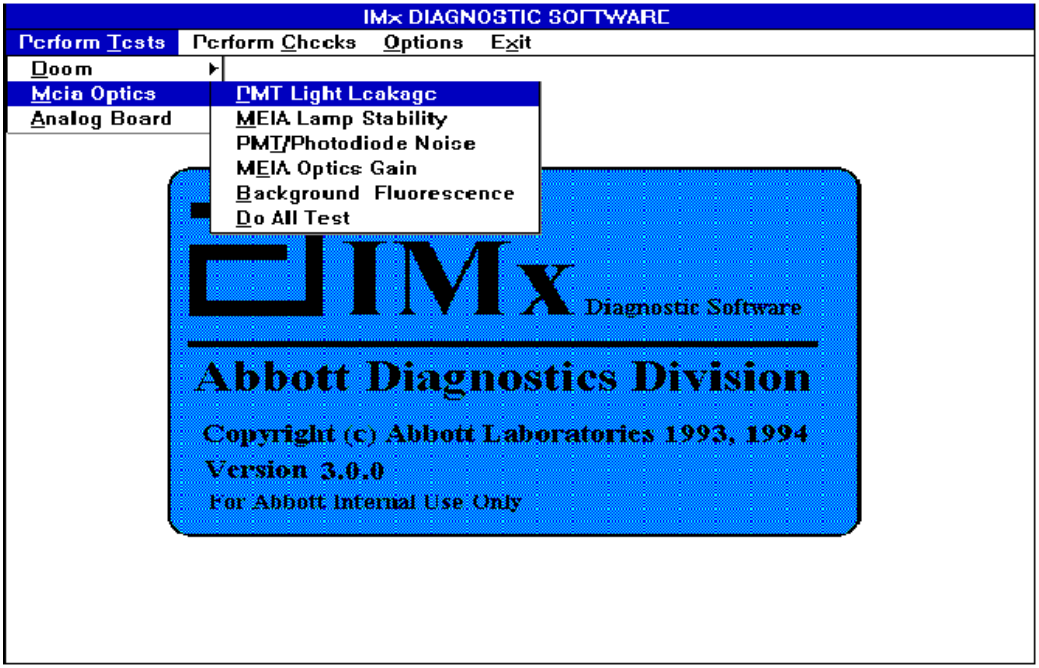
Save: Saves the data as an ASCII file. You will be prompted to name the file as the instrument serial number, include the -96 for refurbished instruments. As you save files from the different tests, keep in mind that the files are appended to the last file saved. If you run the Z Boom Height test three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

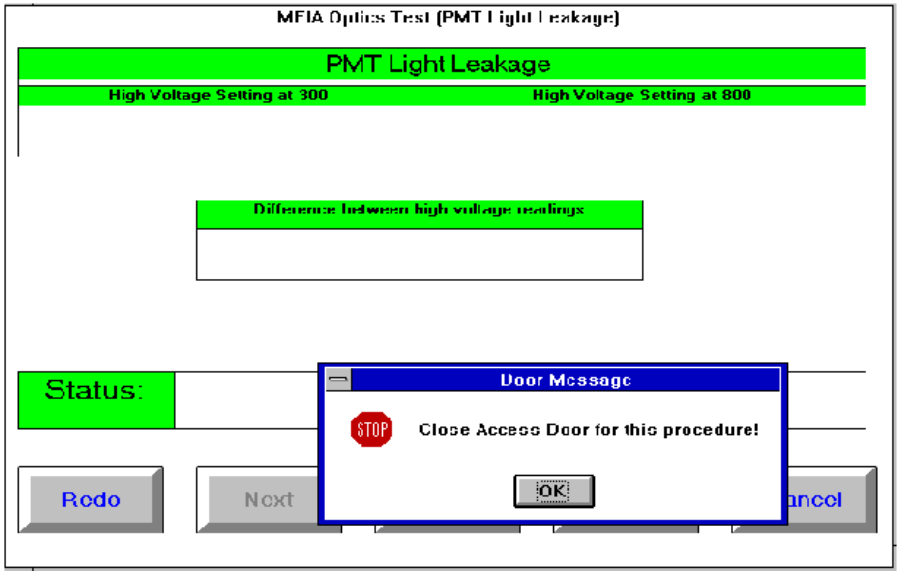
Printouts of the failed tests should be attached to the defective part and sent back to Dallas. The information on the printout can be helpful to the personnel who troubleshoot the part.

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.

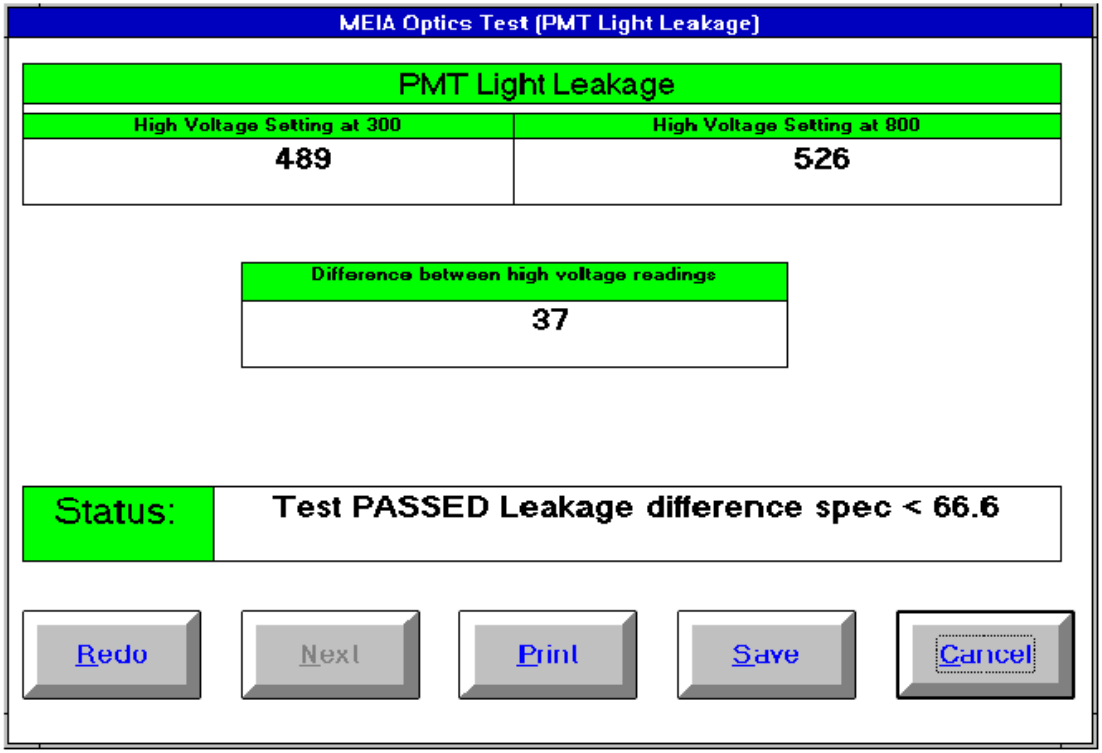
Press Cancel to get back to the main Diagnostic menu and select Perform Tests/MEIA Optics. The following screen appears:



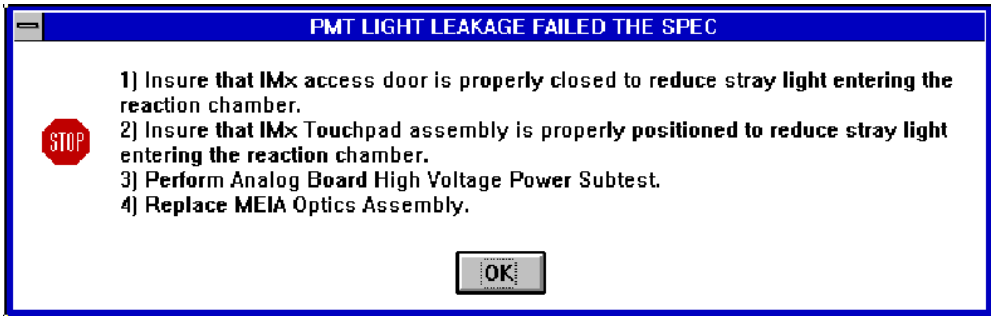
Select PMT Light Leakage and the following is displayed:



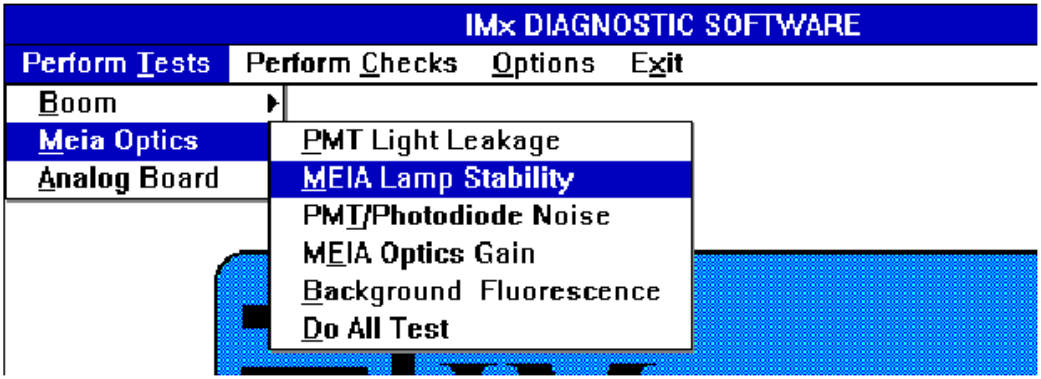
Close the access door and select OK. The test proceeds to completion. The status bar shows either passed or failed and the specification that the test was compared against. A typical screen follows:



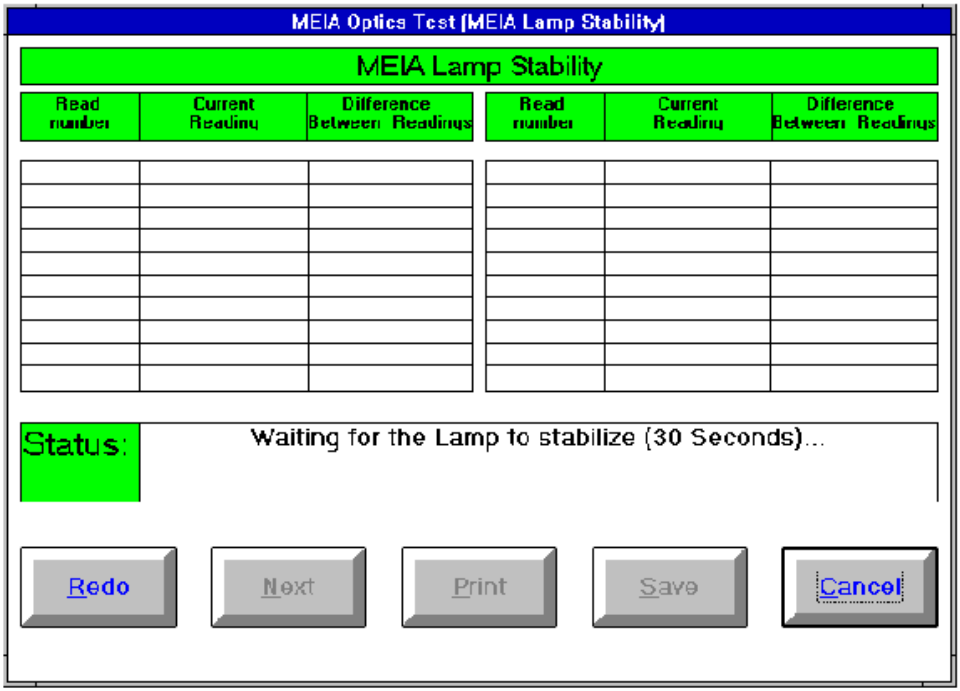
If the test fails, a message box will come up offering suggestions as to where to begin troubleshooting. This is not meant to replace the IMx Service Manual. These suggestions are made only to facilitate the troubleshooting process. Always refer to the IMx Service Manual when in doubt. A typical troubleshooting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



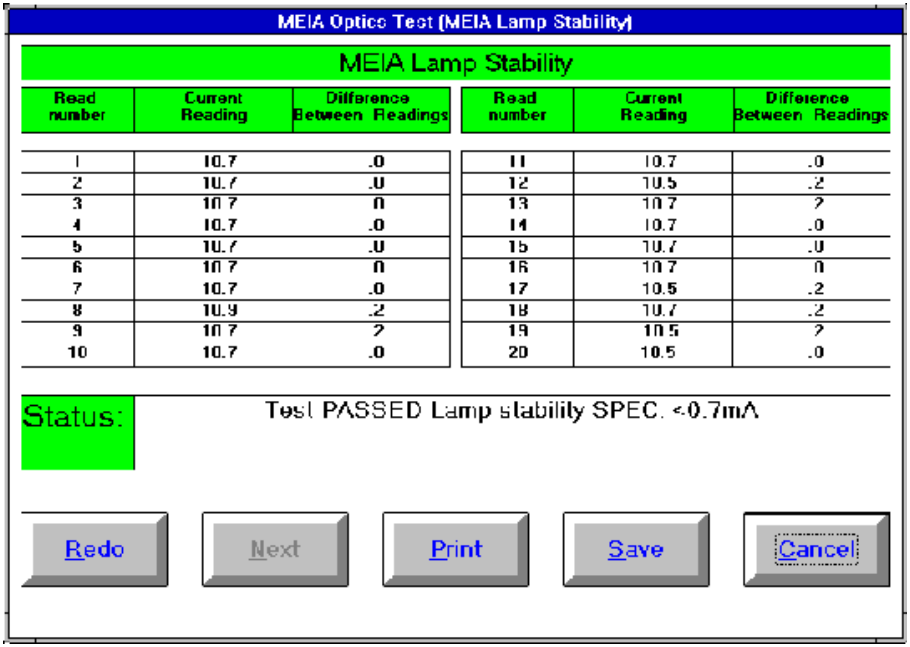
Select the CANCEL button to get back to the main menu. Select Perform Tests then MEIA Optics and the following screen appears:



Select MEIA Lamp Stability and the following screen is displayed:

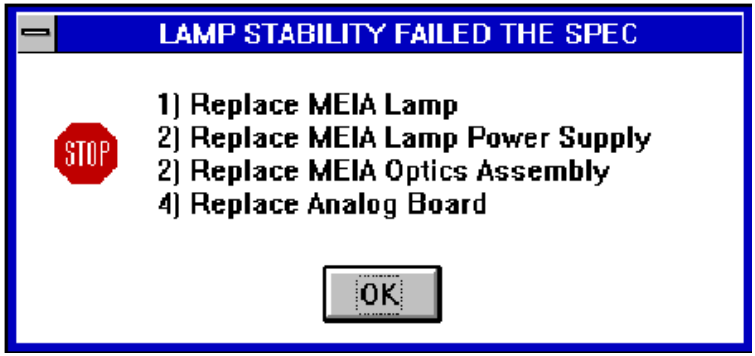


After the lamp stabilizes, the test proceeds by taking 20 reads of the MEIA lamp current and compares the difference from the previous reading. The screen below shows a typical test result:

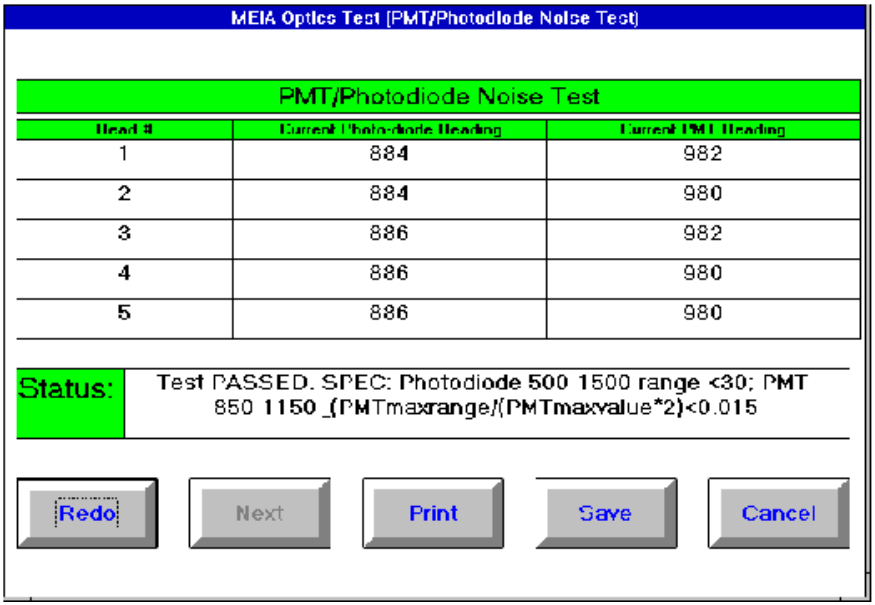


Read number	Current Reading	Difference Between Readings	Read number	Current Reading	Difference Between Readings
1	10.7	.0	11	10.7	.0
2	10.7	.0	12	10.5	.2
3	10.7	0	13	10.7	?
4	10.7	.0	14	10.7	.0
5	10.7	.0	15	10.7	.0
6	10.7	0	16	10.7	0
7	10.7	.0	17	10.5	.2
8	10.9	.2	18	10.7	.2
9	10.7	?	19	10.5	?
10	10.7	.0	20	10.5	.0

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 IMx Service Manual. These suggestions are made only to facilitate the troubleshooting process. Always refer to the IMx Service Manual when in doubt. A typical troubleshooting message box appears below:



Press CANCEL to return to the main menu. 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. The following screen appears when the test has completed:

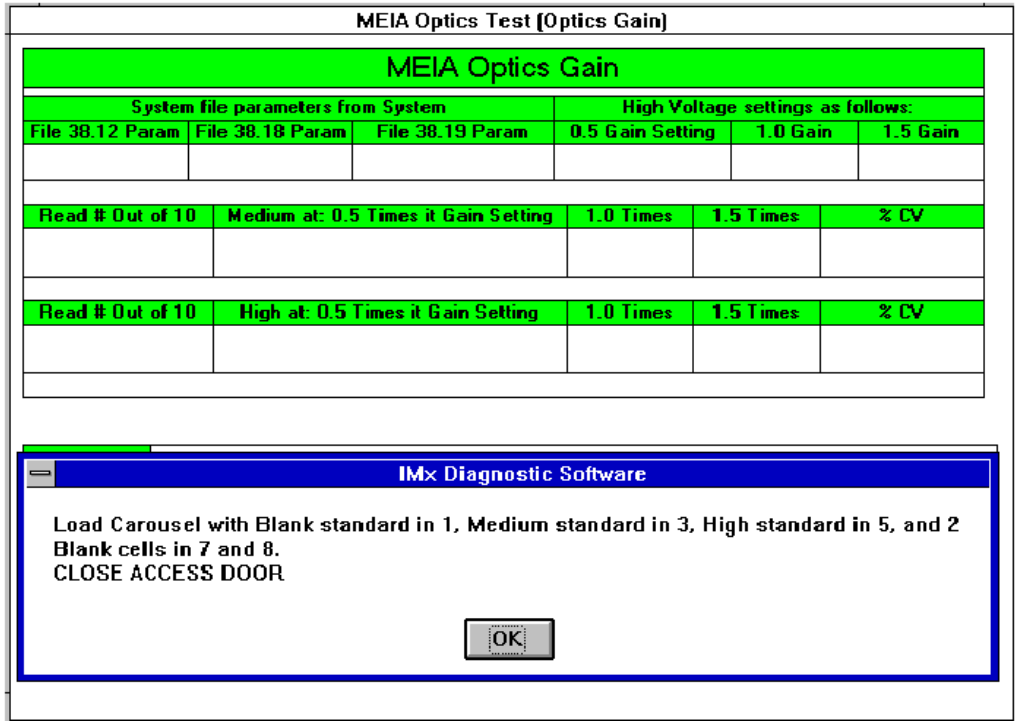


This test verifies that the readings are within a specific range and does another calculation based off of the PMT readings.

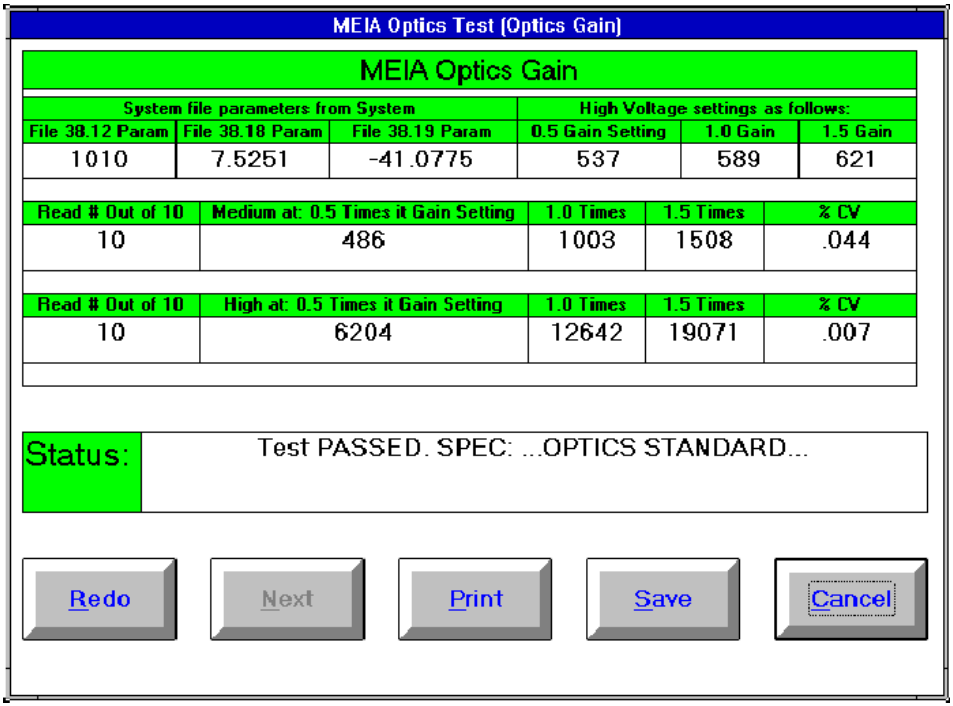
If the test fails, a message box will come up offering suggestions as to where to begin troubleshooting. This is not meant to replace the IMx Service Manual. These suggestions are made only to facilitate the troubleshooting process. Always refer to the IMx Service Manual when in doubt. A typical troubleshooting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

Press the CANCEL button to get back to the main menu.

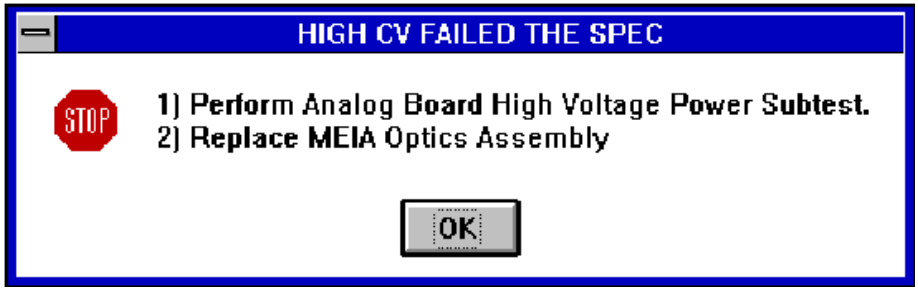
Select Perform Tests, MEIA Optics, MEIA Optics Gain and the following screen appears:



Insure the carousel is loaded properly and installed in the IMx and close the access door. The test proceeds to completion and the following screen appears:

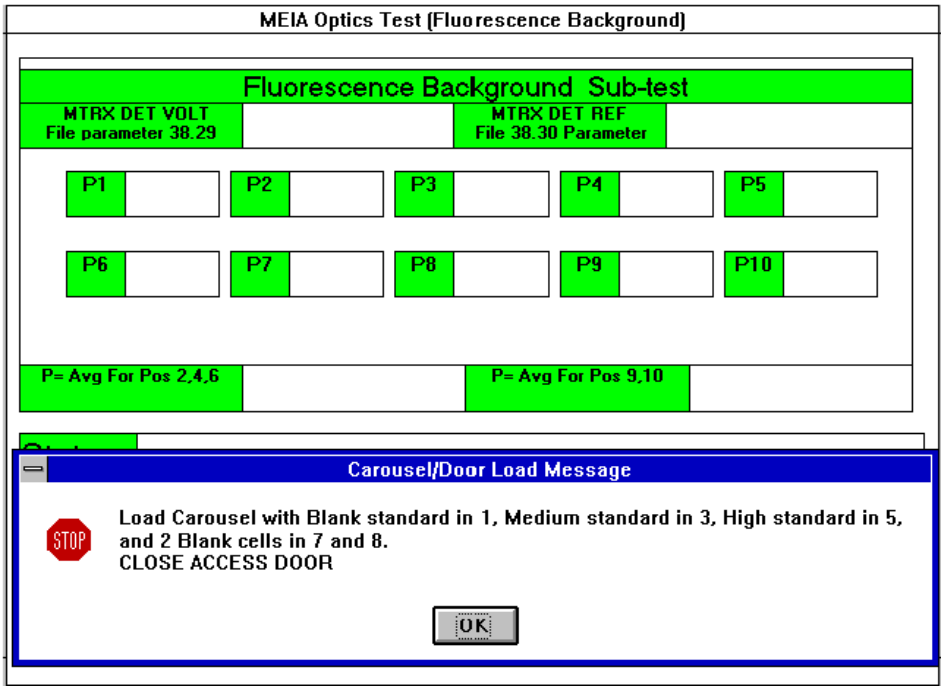


If the test fails, a message box will come up offering suggestions as to where to begin troubleshooting. This is not meant to replace the IMx Service Manual. These suggestions are made only to facilitate the troubleshooting process. Always refer to the IMx Service Manual when in doubt. A typical troubleshooting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



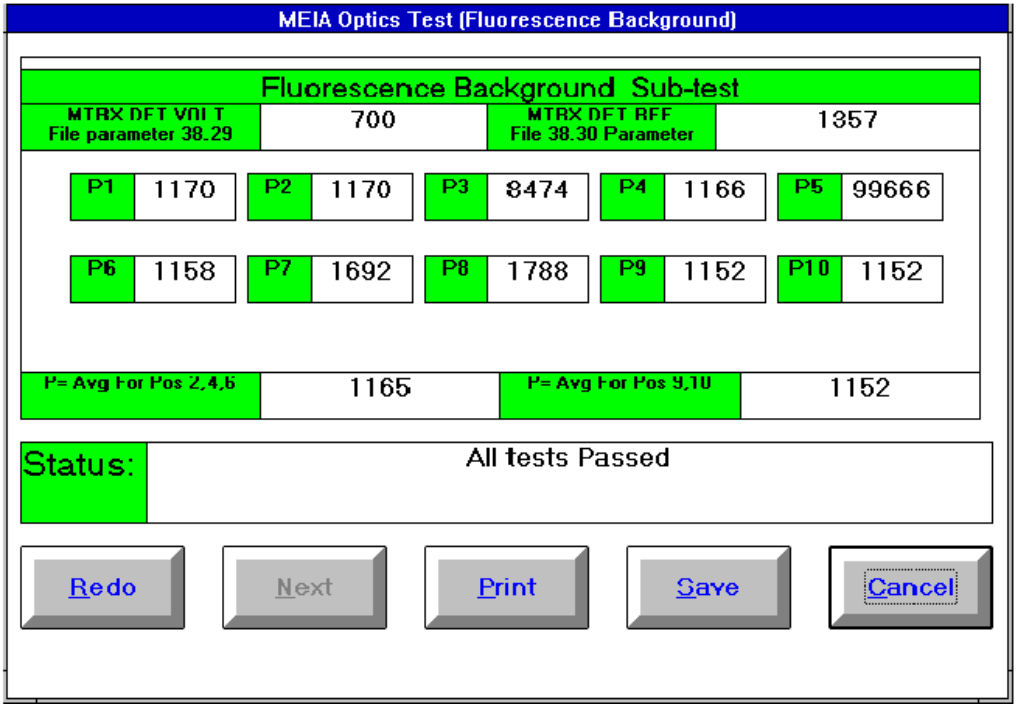
Press CANCEL to return to main menu. Select Perform Tests, MEIA Optics, Fluorescence Background and the following screen

appears:

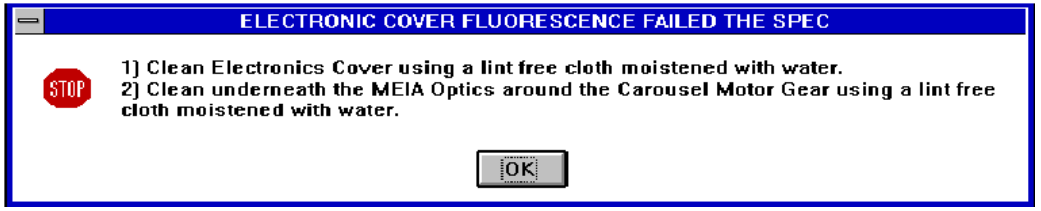


Load the carousel up correctly and install in the IMx. Close the Access door and select OK. A message box comes up asking you if you have 1 or 2 white disks on your MEIA Optical standards. Answer NO if you have only 1 white disk. Answer Yes if you have 2 white disks.

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. We then make suggestions based off of these readings. A typical test result is below:



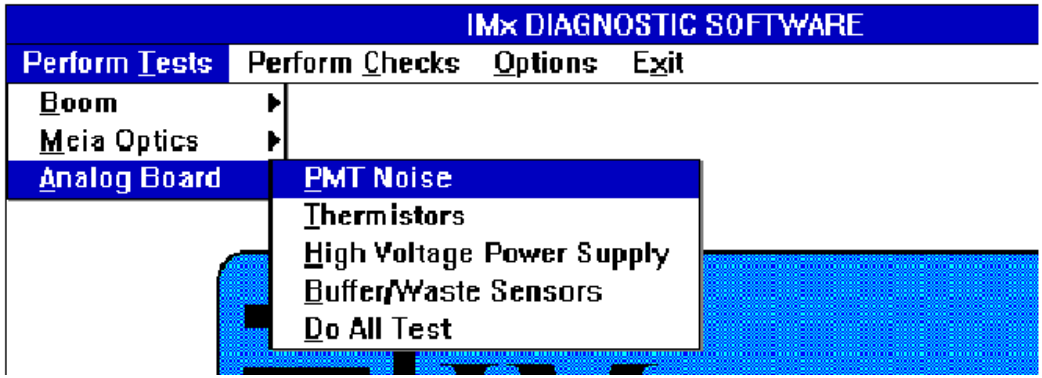
This test checks to see that no fluorescence occurs under the MEIA Optics assembly. Cleaning of the Electronic Cover or the MEIA Optics or the Carousel usually resolves the failures. If the test fails, a message box will come up offering suggestions as to where to begin troubleshooting. This is not meant to replace the IMx Service Manual. These suggestions are made only to facilitate the troubleshooting process. Always refer to the IMx Service Manual when in doubt. A typical troubleshooting message box appears below:



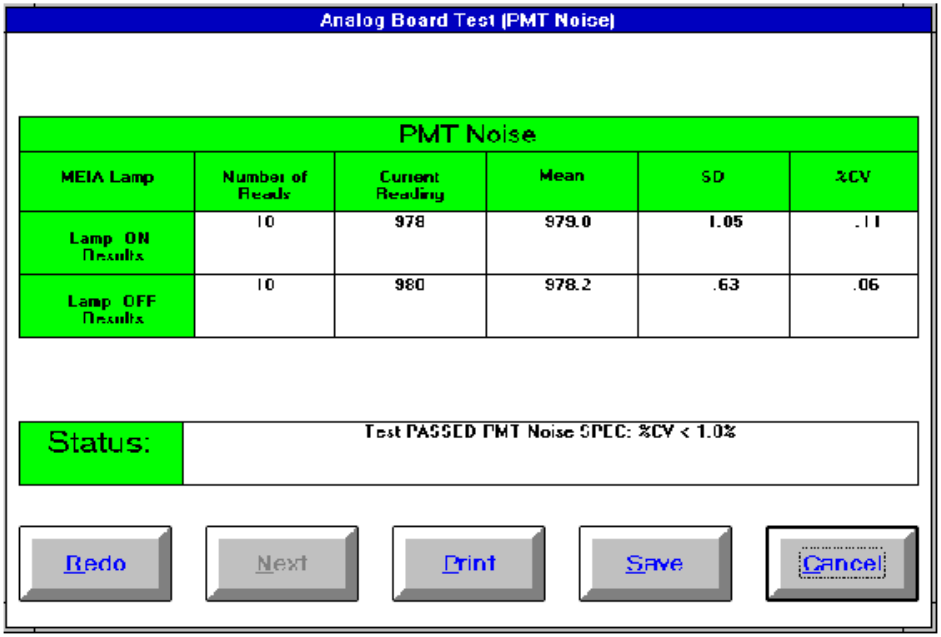
Select CANCEL and return to the main menu. The last function under Perform Tests, MEIA Optics is the Do All Test. This runs all the MEIA Optics subtests in the order they appear in the main menu list. It does not keep rerunning the same test over and over again. The Do All Test will continue on until 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.

The last test under Perform Tests is the Analog Board test. Select Perform Tests and Analog Board and the following screen appears:



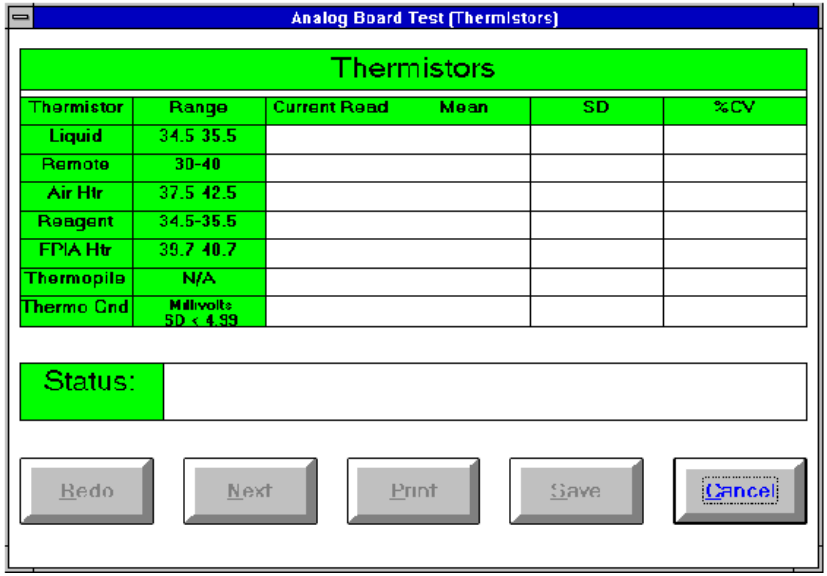
There are four subtests under Analog Board: PMT Noise, Thermistors, High Voltage Power Supply and Buffer/Waste Sensors. The Do All Test would perform these four tests in the order they appear in the menu. Select PMT Noise and the following screen appears when the test has completed:



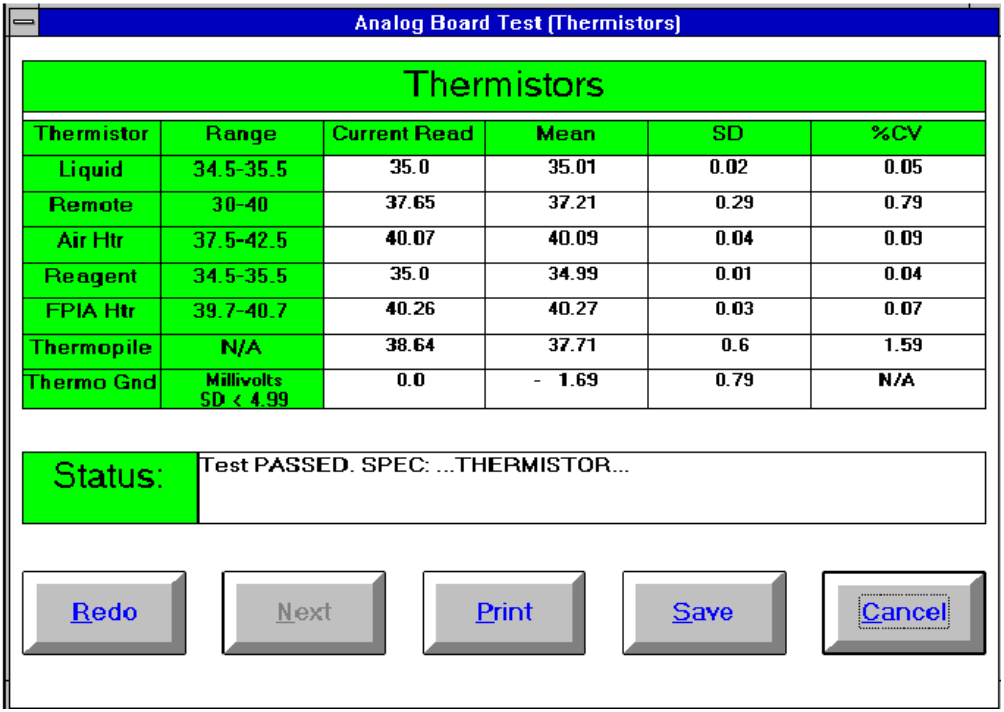
The PMT Noise test takes 10 readings of the PMT when the High Voltage is set at 300 Volts. It takes 10 readings with the lamp off and with the lamp on. Calculations are then performed for the mean, Standard Deviation, and the %CV of each of the 10 readings. The test will insure that individual reads 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 IMx Service Manual. These suggestions are made only to facilitate the troubleshooting process. Always refer to the IMx Service Manual when in doubt.

Select CANCEL to return to the main menu. Select Perform Tests, Analog Board, then Thermistors and the following screen appears:



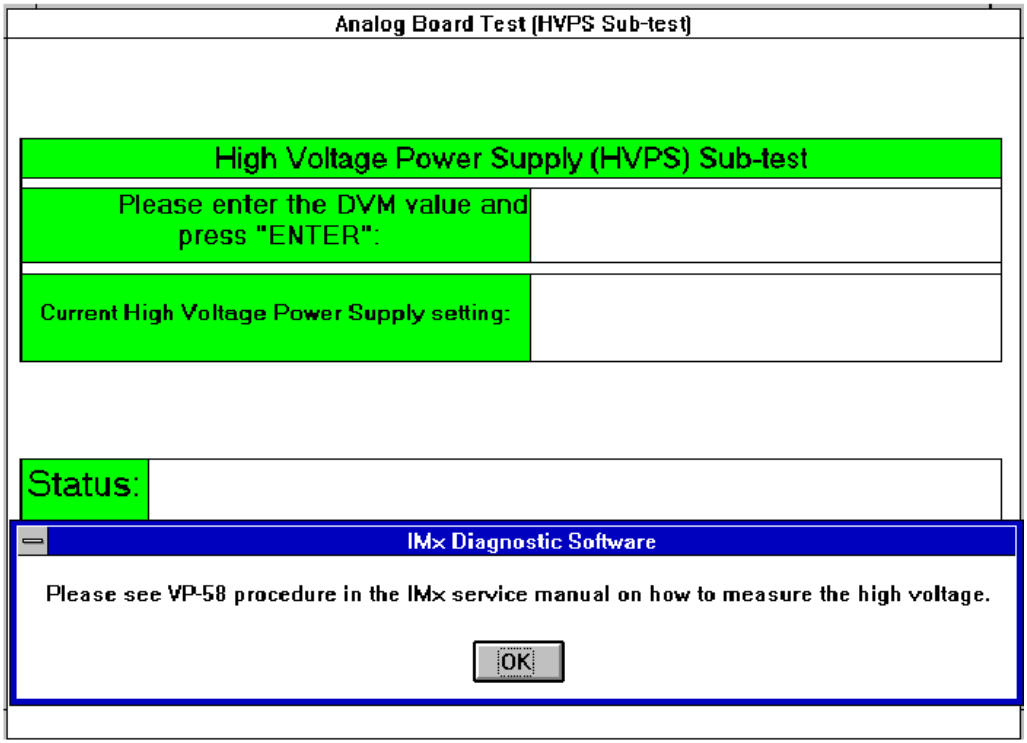
After waiting for 90 seconds for the FPIA Optics temperature to stabilize, temperature readings are taken for the Liquid heater, Remote thermistor, Air Heater, Reagent Heater, and FPIA Optics Heater. Readings are also taken for the Thermopile and Thermopile ground. These last two readings are in milivolts. No specification is set for these last two readings. Use Remote Thermistor and the Air Thermistor Ranges as typical values only. Failure of these two requires further diagnostics and check out. A typical test result screen is as follows:



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. The SD of the Analog Ground is verified to be less than 5.

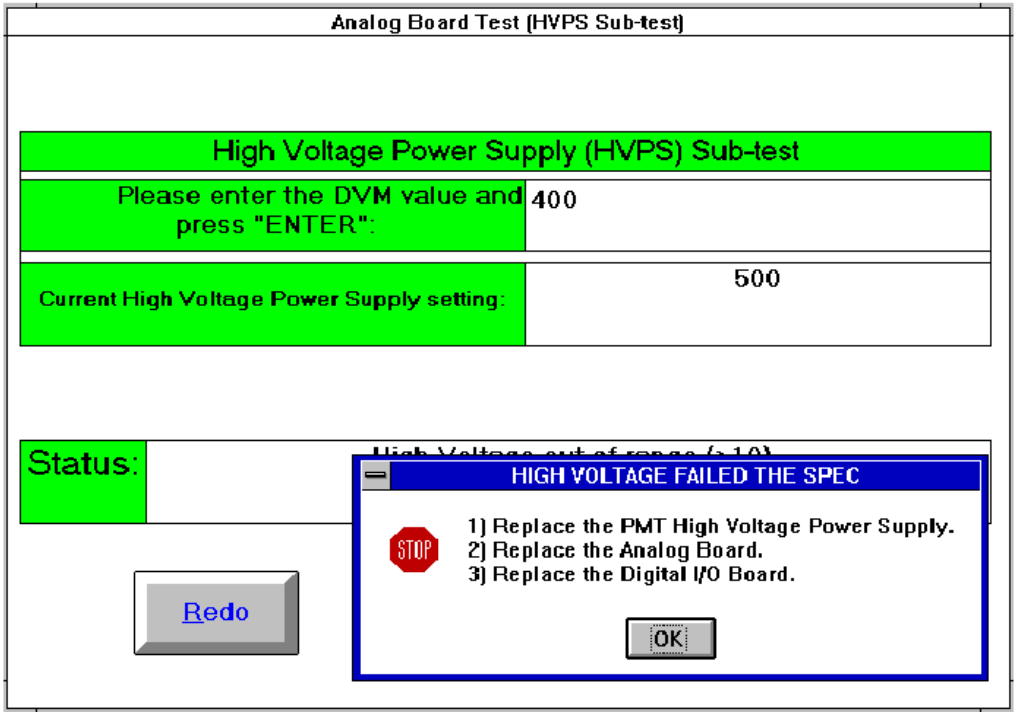
If the test fails, a message box will come up offering suggestions as to where to begin troubleshooting. This is not meant to replace the IMx Service Manual. These suggestions are made only to facilitate the troubleshooting process. Always refer to the IMx Service Manual when in doubt.

Select the CANCEL button to return to the main menu. Select Perform Tests, Analog Board, and then High Voltage Power Supply. The following screen appears:

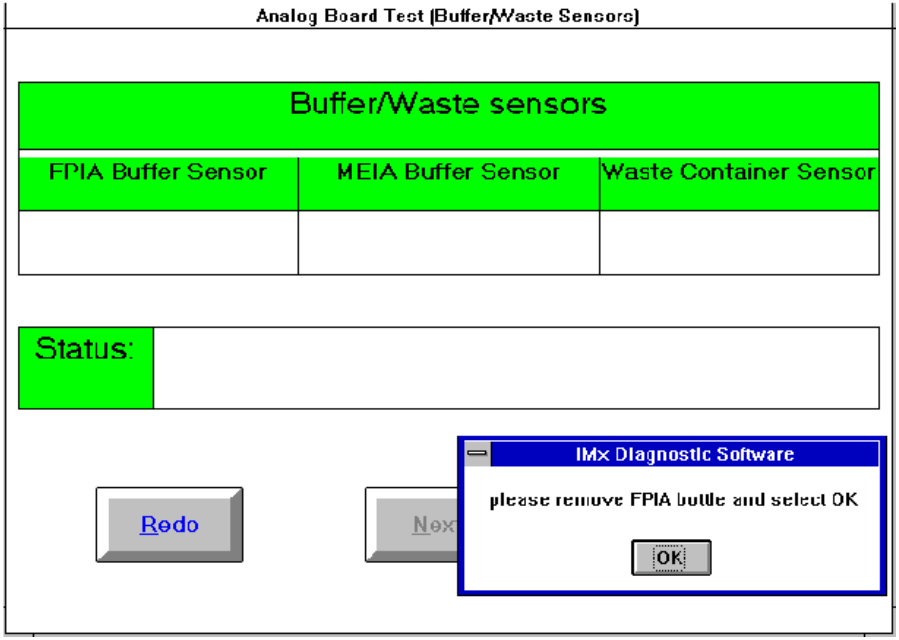


The message box tells you to go to VP-58 in the IMx Service Manual to see how to measure the High Voltage. After completing the review of the VP, select OK. The test will ask you to measure the high voltage at the cable and have you input the voltage that you measure. ONLY ENTER IN THE NUMERICAL VALUE. 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.

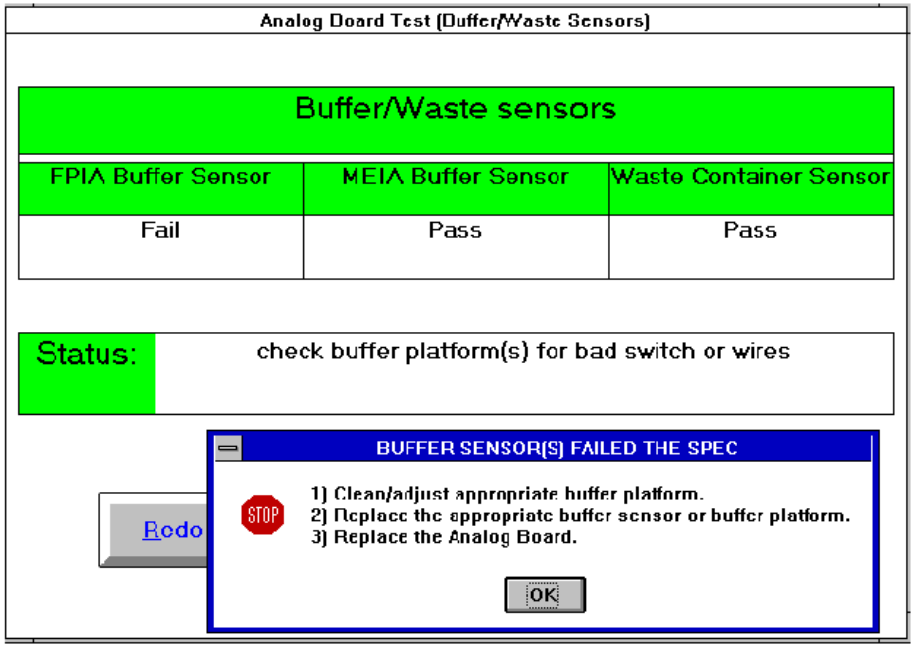
If the test fails, a message box will come up offering suggestions as to where to begin troubleshooting. This is not meant to replace the IMx Service Manual. These suggestions are made only to facilitate the troubleshooting process. Always refer to the IMx Service Manual when in doubt. A typical screen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



Select CANCEL to return to the main menu. Select Perform Tests, Analog Board and then Buffer/Waste Sensors and the following screen appears:

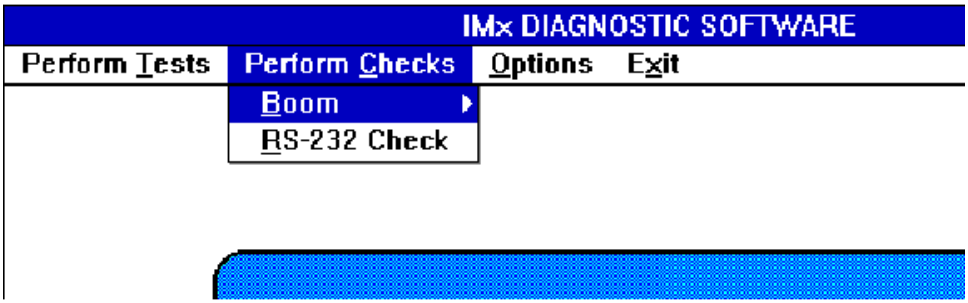


Follow the instructions given such as "please remove FPIA bottle and select OK." If the buffer switch is working properly, PASS will be displayed for that sensor. If it fails, FAILED appears. If the test fails, a message box will come up offering suggestions as to where to begin troubleshooting. This is not meant to replace the IMx Service Manual. These suggestions are made only to facilitate the troubleshooting process. Always refer to the IMx Service Manual when in doubt. A typical screen follows:

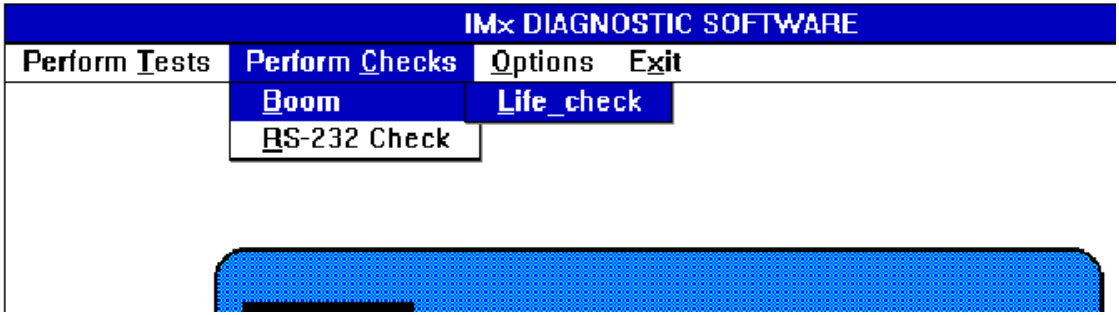


Select CANCEL to return to the main menu.

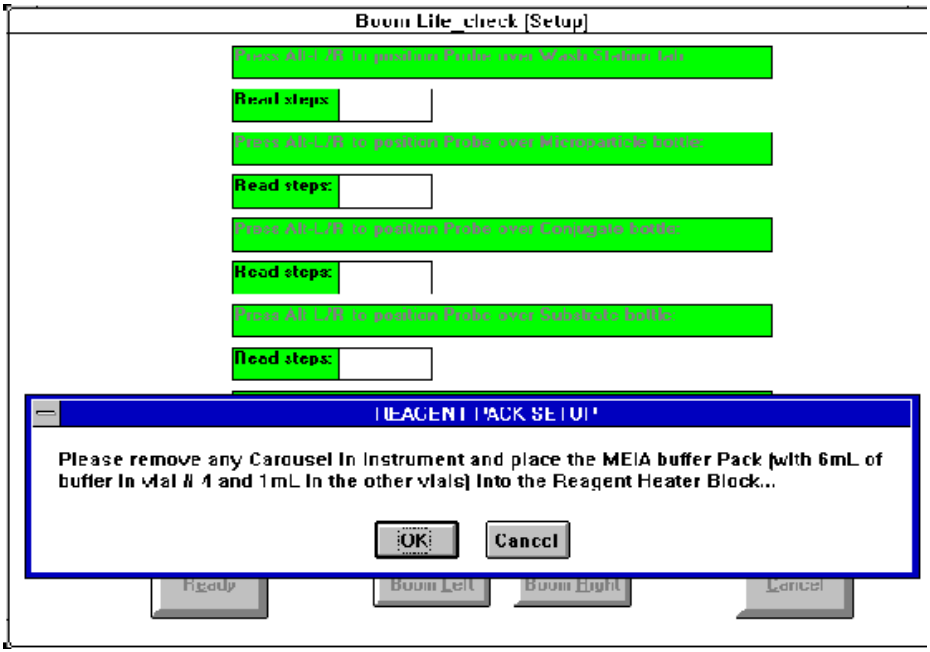
Press Cancel to get back to the main Diagnostic menu and select Perform Checks. The following screen appears:



Select the Boom option and the following screen appears:



Select Life Check and the following screen appears:



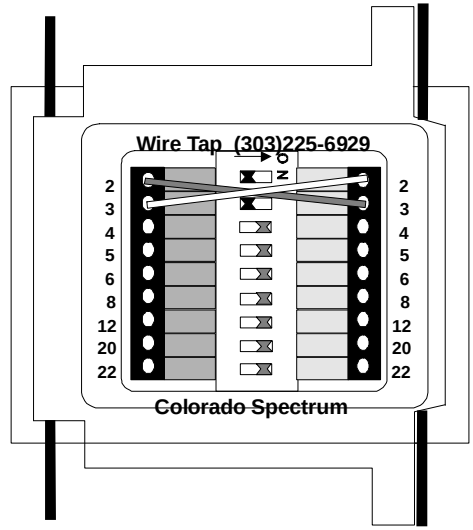
Follow the instructions and press OK when finished. The Life Check begins by reading the bar code on the buffer pack (if present). If no bar code is present, an error will be recorded and the test will continue on. Level sensing will take place in the buffer pack. The Life Check is set up to run continuously 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. Possibly 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.

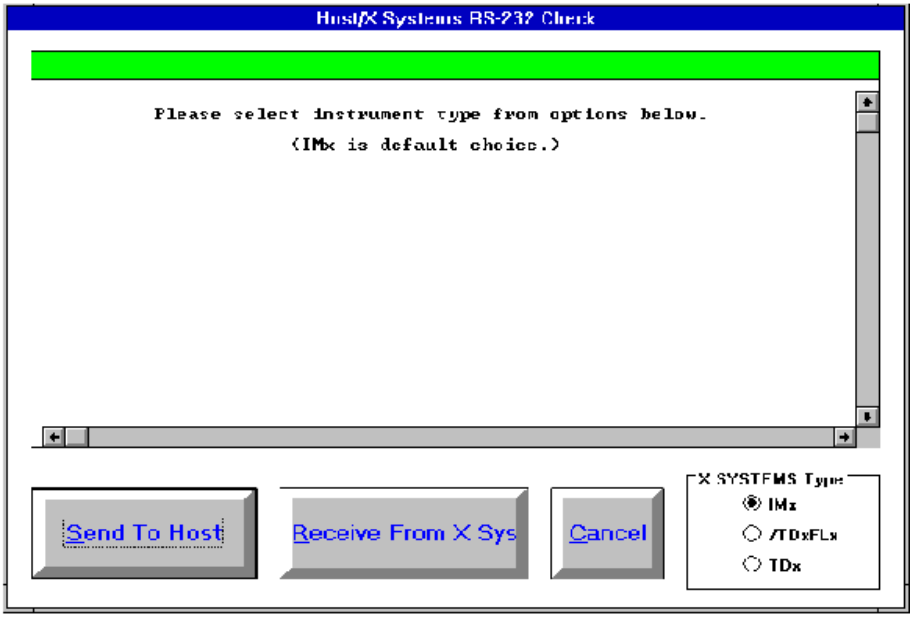
Performing the RS-232 check:

NOTE: Depending on the instrument you will be trying to check out, 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. See illustration below.



Wire Tap Breakout Connector
P/N 14207-034

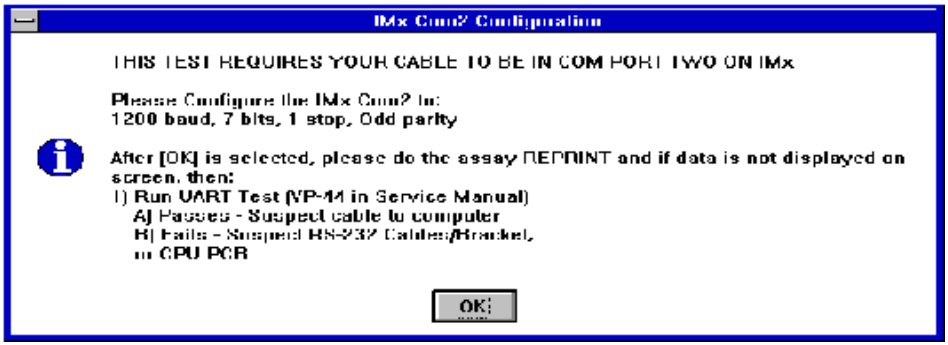
Insure the AT to Modem cable is connected to COM2 on the IMx Analyzer. From the main menu, select Perform Checks, then RS-232 check, then select PC COM Port, then select COM2 if running the GRiD Laptop computer or select the appropriate Com port for the computer you are using. The following screen appears:



This test allows you to check out the RS-232 operation for the IMx, TDx and /TDxFLx instruments. Select IMx.

The three options available are "Send to Host", "Receive from IMx" and "Cancel". Cancel will quit the check and take you back to the main menu. Receive from IMx 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 IMx". The following screen appears:



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***

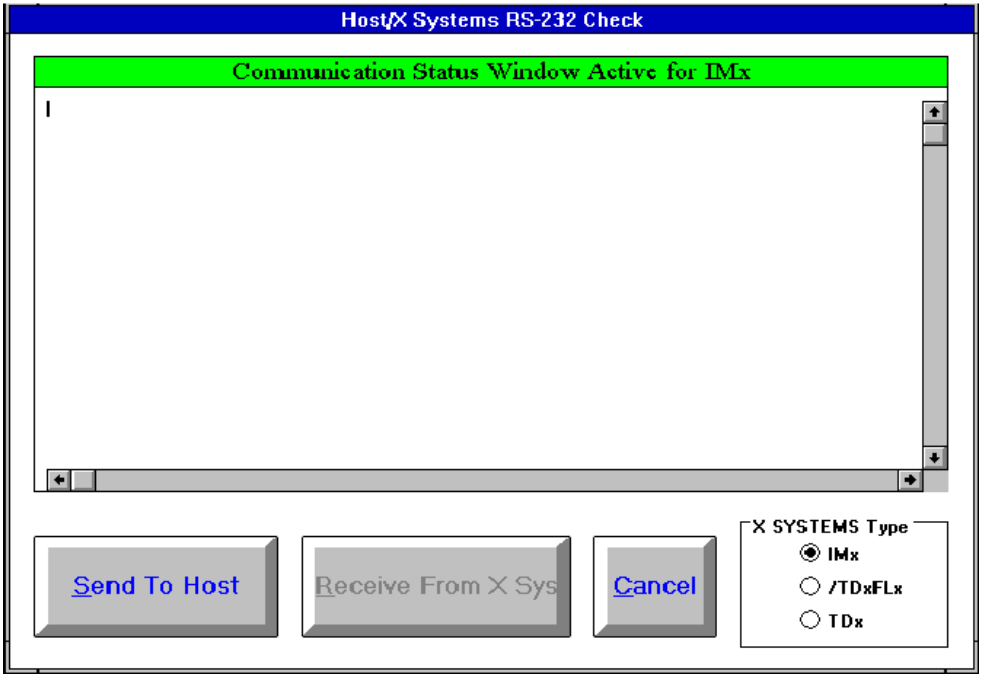
Press SYSTEM
FILES
1.10
DISPLAY to show COM2 baud
(If necessary, press 1200 using the IMx keypad then STORE)
FWD to display COM2 chr len
(If necessary, press 7 using the IMx keypad then STORE)
FWD to display COM2 stop bit
(If necessary, press 1 using the IMx keypad then STORE)
FWD to display COM2 parity
0 = none
1 = Odd
2 = Even
(If necessary, press 1 using the IMx keypad then STORE)
EXIT
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:

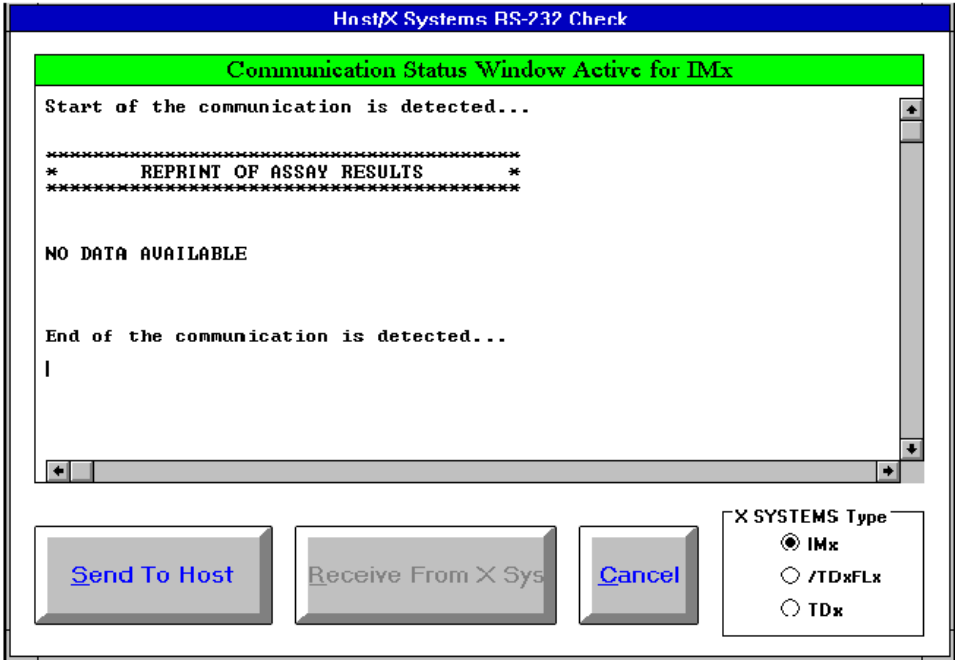
Press UTILITY
SHUTDOWN
START

When "130 READY TO CHANGE MODULES" appears, lift the assay module from it's connector and reseat it. The IMx System will re-boot and return to the READY menu.

Select OK to continue on. The following screen appears:



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, then the following should appear on your screen:



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 Systems. 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 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

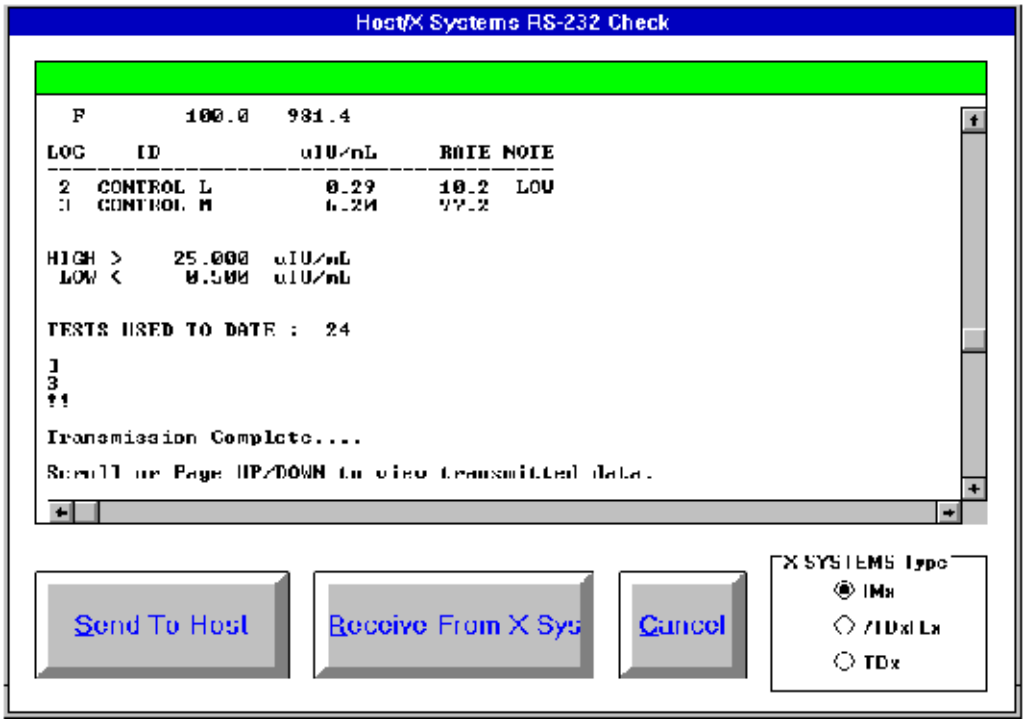
position. Connect 9 pin female connector to correct DATATRAC port. You will need to verify with the customer which port is set up for IMx Analyzer. All hardware connections have been made. Now set up the DATATRAC™ System to accept our results.

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:



SEE THE FULL TEXT OF WHAT WAS SENT TO THE HOST ON THE NEXT PAGE.

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
!!

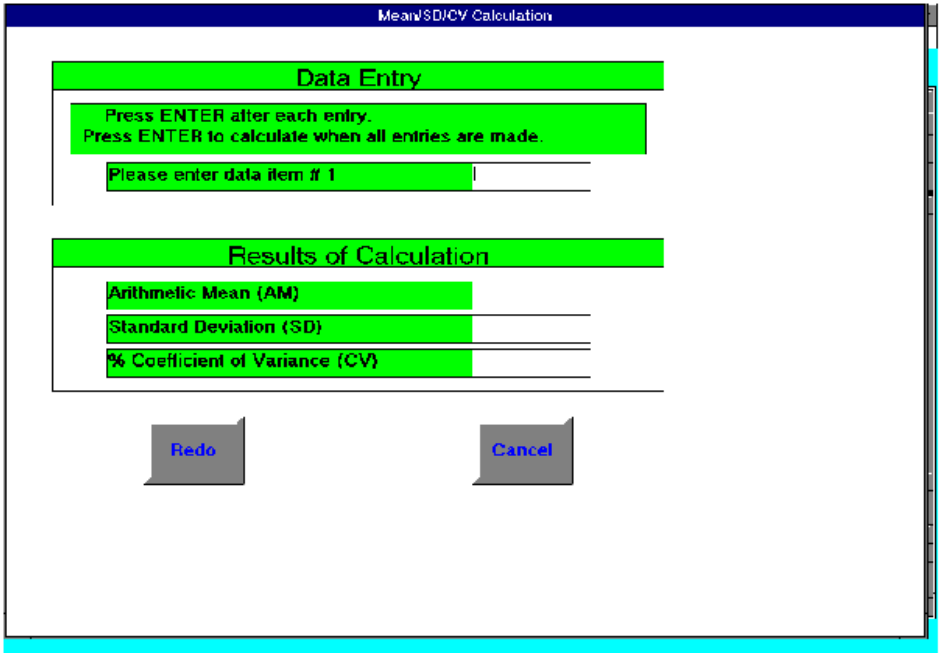
Transmission Complete....

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***

The last menu item to use is located under Options. This is 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. When you select options and then AM/SD/%CV CALC the following screen is displayed:



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.

To exit the IMx Diagnostics, select Exit. Then select Confirm Exit.

Viewing files that were saved during running of the IMx Diagnostic Software:

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

Click once on "File" menu item.
Click once on "Open" menu item.
Type "*.60".
Click once on "OK".
Change to directory that the files are stored (usually c:\DIAGSW\IMX 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 changes?"

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 as referenced on page 27.

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 IMx Analyzer.

J. IMx 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_____
Revision: _____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 state, 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

Proposed 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 consequences: ___

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

Description of proposed diagnosis / corrective action: _____

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

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

Affected modules: _____

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

SOFTWARE PROBLEM / CHANGE REPORT

Report # _____ Title: _____
___Problem or ___Change _____

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

DESCRIPTION Reported by: _____ Date: _____
Unit Serial Number(s): _____
Equipment configuration and usage (e.g., system state, 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

Proposed 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 consequences: ____

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

Description of proposed diagnosis / 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: **Release of IMx Congenital Assay Module Version 6.0**	ISA#: **60-144**
ORIGINATOR: **Gary Tompkins**	PRODUCT: **IMx® (60)**
APPROVED: **Bob Schabel 12-14-94**	EFFECTIVITY DATE: **14-DEC-94**

I. PURPOSE:

This ISA informs the Field of the release of a new Congenital Diagnostics Assay Module, Version 6.0 (List No. 1A74-06).

Congenital Diagnostics Assay Module Version 6.0 contains the following assays:

Assay Name and Number	List Number	Revision Number	Parameter Changes
16 CMV-G	2208	3	No
20 CMV-M	2209	1	No
32* RUBELLA-G	1B05	1	New Assay
41 TOTAL IgE	2233	6	No
46* TOXO-G	4B45	1	New Assay
55 RUBELLA-G	2247	4	No

62	TOXO-G	2254	4	No
63	TOXO-M	2255	3	No
122	RUBELLA-M	7A24	1	No
124	TOXO-M	7A82	2	No
126*	TOXO-A	9A46	2	No

*** Resides on the assay module as a hidden assay. Assay name will not appear in the file directory until the assay is activated. Some of the assays are not available worldwide.**

System Software Compatibility

The IMx® Congenital Diagnostics Assay Module Version 6.0 is compatible only with IMx System Software Version 6.0 or higher.

Protocol Changes

There are no protocol changes to any assays on this module.

Parameter Changes

There are not parameter changes to any assays on this module.

New Assays

IMx RUBELLA IgG (RUBELLA-G) List Number 1B05
Assay Number 32

Clinical Utility:

The IMx RUBELLA-G assay is a Microparticle Enzyme Immunoassay (MEIA) for the quantitative measurement of IgG antibodies to rubella virus in serum and plasma (Heparin, EDTA, Sodium Citrate) to aid in determination of immune status.

General Information:

The new IMx RUBELLA-G assay (LN 1B05) offers the following benefits over the currently marketed RUBELLA-G assay (LN 2247):

1. More precisely correlates with WHO standard.
2. Reagents are reformulated to reduce non-specific binding and to improve specificity.
3. Microparticles have been optimized to resolve resuspension issues.
4. Assay protocol optimized to eliminate curve span and other calibration related errors.
5. Equivocal range added to allow detection of low levels of antibody present in the patient sample, but below the NCCLS recommended level of 10 IU/mL for indication of immune status.
6. The Positive Control has been lowered closer to "cut-off" due to NCCLS guidelines and customer requests.

IMx TOXO IgG List Number 4B45
Assay Number 46

Clinical Utility:

The IMx TOXO-G assay is a MEIA for the quantitative measurement of IgG antibodies to *Toxoplasma gondii* in serum and plasma (Heparin, EDTA, Sodium Citrate) to aid in the determination of immune status.

General Information:

The new IMx TOXO-G assay (LN 4B45) offers the following benefits over the currently marketed IMx TOXO-G assay (LN 2254).

1. Improved specificity and improved sensitivity.
2. Modifications/changes made to TOXO-G include recalibration, reagent formulation, and assay protocol optimization.

System Messages/Error Codes

There are no new System Messages/Error Codes on this assay module.

Assay Calibration

The following assays will require calibration when changing from a previous version of the IMx Congenital Diagnostics Assay Module to Version 6.0:

If changing from:

V. 1.06 to 6.0	V. 2.01 to 6.0	V. 3.00 to 6.0	V. 4.0 to 6.0	V. 5.0 to 6.0
16 CMV-G	16 CMV-G	16 CMV-G		

20 CMV-M	20 CMV-M	20 CMV-M	20 CMV-M	
32 RUBELLA-G*	32 RUBELLA-G*	32 RUBELLA-G*	32 RUBELLA-G*	32 RUBELLA-G*
41 TOTAL IgE	41 TOTAL IgE	41 TOTAL IgE		
46 TOXO-G*	46 TOXO-G*	46 TOXO-G*	46 TOXO-G*	46 TOXO-G*
55 RUBELLA-G	55 RUBELLA-G	55 RUBELLA-G		
62 TOXO-G	62 TOXO-G	62 TOXO-G		
63 TOXO-M	63 TOXO-M	63 TOXO-M		
122 RUBELLA-M				
124 TOXO-M				
126 TOXO-A*	126 TOXO-A*	126 TOXO-A*	126 TOXO-A*	126 TOXO-A*

* Assays are hidden and must be activated prior to use for the first time.

END OF DOCUMENT

ABBOTT ADD	INSTRUMENT SERVICE ADVISORY

SUBJECT: **Release of IMx Metabolic Assay Module Version 3.0**	ISA#: **60-143**
ORIGINATOR: **Gary Tompkins**	PRODUCT: **IMx® (60)**
APPROVED: **Bob Schabel 01-27-95**	EFFECTIVITY DATE: **27-JAN-95**

Purpose: This ISA informs the Field of the release of a new Metabolic Assay Module, Version 3.0 (List No. 6A22-03).

Metabolic Assay Module Version 3.0 contains the following assays:

Assay Name and Number	List Number	Revision Number	Parameter Changes	Distribution Area
27 Ferritin	2219	6	No	Worldwide
28 Folate	2220	1	New Assay	Worldwide
44 Insulin	2A10	3	Yes	Worldwide
79 & 116 Glycated Hemoglobin	1A86	3	Yes	Worldwide
104 B12	2200	4	No	Worldwide

System Software Compatibility
The IMx Metabolic Assay Module Version 3.0 is compatible only with IMx System Software Version 6.0 or higher. If the IMx Metabolic Assay Module Version 3.0 is installed with IMx System Software Versions 2.0, 3.0 or 5.0 the message "134 INCOMPATIBLE SYSTEM/ ASSAY MODULES" is displayed.

Protocol Changes
There are no protocol changes to any assays on this module.

Mandatory Upgrades
IMx Metabolic Assay Module Version 3.0 is a mandatory upgrade for all IMx Glycated Hemoglobin customers. To allow the customers to deplete their current reagent inventory and yet to assure the implementation of the upgrade, a new reagent bar code number, compatible only with IMx Metabolic Assay Module Version 3.0 or higher, will be used on the future Glycated Hemoglobin reagent shipments.

Error Handling
This assay module has been corrected for the System Error ec=0002 which will occur on an IMx® instrument run frequently without powering down or removing the assay module. Please refer to IMx ISA # 60-136 for further information.

Parameter Changes

IMx Insulin:

List No. 2A10
Assay No. 44

Assay Parameter 44.12, RESULT UNIT:
Default Option: 30 (µU/mL)
Alternate Option: 13 (µIU/mL)

Added a new alternate RESULT UNIT option: 44.12, option 27 (pmol/L)

Insulin values expressed as µU/mL or as µIU/mL can be converted to pmol/L as follows:

pmol/L = 7.175 x µU/mL
and
pmol/L = 7.175 x µIU/mL

Assay parameters 41-46 changed to the following:

44.41	MIN CHECK 1	0.167
44.42	MAX CHECK 1	0.511
44.43	MIN CHECK 2	0.271

44.44	MAX CHECK 2	0.513
44.45	MIN CHECK 3	0.275
44.46	MAX CHECK 3	0.530

IMx Glycated Hemoglobin:

List No. 1A86
Assay No. 79 % GHb (GHb) & 116 % GHb (Hb)

Assay parameter 1, DECIMAL, changed to be NOT EDITABLE by the customer. The number of digits remain unchanged, default value being 2.

New Assays

IMx Folate: List No. 2220
Assay No. 28

IMx Folate assay is visible, requiring no assay activation.

Clinical Background:
Folate assays are used in assessing folate status in individuals suspected of being deficient in this nutrient. Folate deficiency may result in numerous metabolic alterations, including abnormal cell division. The first stage of folate deficiency is assessed by measuring serum folate levels. The second stage of folate deficiency is tissue depletion, which can be assessed by RBC folate levels. Thus, the diagnostic purpose of a folate assay is to reliably discriminate folate deficiency from non-deficiency.

General Information:
IMx® Folate assay is based on Ion Capture technology. IMx Folate Reagent Pack including Potassium Hydroxide and Ion Capture reaction cells are packaged as a set which must be calibrated and used together.

The Potassium Hydroxide in the IMx Folate REAGENT PACK is corrosive and should be handled with caution.

The IMx Folate Potassium Hydroxide bottle is shipped in an absorbent pouch. Prior to using the IMx Folate Reagent Pack, the Potassium Hydroxide bottle must be removed from the absorbent pouch and inserted into the empty location (position 1) of the reagent pack. Once inserted, the Potassium Hydroxide remains in the IMx Folate Reagent Pack.

Additional Maintenance Procedure for Folate:
An invisible residue will build up on the outside of the probe/electrode assembly during IMx Folate assay use. This residue must be removed at the completion of each assay by performing a probe/electrode assembly washing and wiping procedure at the completion of each IMx Folate assay. Refer to the IMx System Operation Manual, Section 9, for details on the probe wipe procedure. The IMx Folate assay protocol incorporates a probe decontamination procedure after all assay steps are completed. Additional probe decontamination procedures are not necessary following successful completion of an IMx Folate assay. The bleach (1% sodium hypochlorite), needed for decontamination, is dispensed into the predilution well of Ion

Capture reaction cell number 2 (by the operator prior to initiating the assay run). IMx Folate assay also requires Denaturant to be dispensed into predilution well of Ion Capture reaction cell number 1.

IMx Folate Calibrators, MODE 1 Calibrator, Low and High Controls and Medium Control are shipped on dry ice.

The reagents and other components require storage conditions as follows:

Storage at 2-8º C:	Reagent Pack Denaturant MODE 1 Calibrator Low and High Controls Specimen Diluent RBC Lysis Reagent (**after** reconstitution) Medium Control (**after** thawing)
Storage at 15-30º C	Ion Capture Reaction Cells RBC Lysis Reagent (**before** reconstitution)
Storage at -10º C or colder	Calibrators Medium Control (**before** thawing)

System Messages/Error Codes

IMx Glycated Hemoglobin — List No. 1A86
Assay No. 79 - % GHb (GHb) & 116 - % GHb (Hb)

Added the following message: <3.61
This message will be printed under the header % A1c in the summary section of the test results tape if the calculated value of %A1c is less than 3.61.

For a specimen with glycated hemoglobin concentration of less than 3.61%GHb, the standardized %A1c will not be quantitated by the IMx analyzer. The IMx analyzer will print <3.61 rather than a standardized %A1c value. Please refer to the discussion of hemolytic anemias, in the LIMITATIONS OF THE PROCEDURE section of a Glycated Hb package insert, for discussion of samples which have low %GHb results. If the RESULT FORM (assay parameters 79.64 and 116.64) has been set to "2", a %GHb result will not print. The customer should refer to the NOTE in the IMx GLYCATED HEMOGLOBIN ASSAY PARAMETERS section for instructions on how to edit the RESULT FORM to report %GHb (edit parameter to "1") or report both %GHb and %A1c (edit parameter to "3"). Once the parameter has been edited, rerun the patient sample in question to obtain a %GHb result.

RS-232 Data Output Format Information:

IMx Glycated Hemoglobin: List Number 1A86
Assay Number 79 %GHb (GHb) and 116 %GHb (Hb)

The RS-232 data output format of the IMx Glycated Hemoglobin assay is different from the format of other IMx assays. With the implementation of the IMx Metabolic Assay Module Version 3.0, an additional modification was made to the %A1c result field.

For further information, please refer to the IMx RS-232 Interface Manual, List Number 3A58-01 and to the letter, commodity number 66-4074/R1.

Assay Calibration

Please refer to the IMx Metabolic V3.0 RS-232 Output Information for modification to IMx® Glycated Hemoglobin Enclosure for assays that require calibration when installing this module.

END OF DOCUMENT

ABBOTT ADD	INSTRUMENT SERVICE ADVISORY

SUBJECT: **Release of IMx Thyroid Assay Module Version 3.0**	ISA#: **60-142**
ORIGINATOR: **Louis Valich**	PRODUCT: **IMx® (60)**
APPROVED: **Bob Schabel 10/11/94**	EFFECTIVITY DATE: **11-OCT-94**

This ISA informs the Field of the release of the IMx Thyroid Assay Module version 3.0. Specific assay changes are delineated below.

Assays on Thyroid Assay Module v3.0:

ASSAY NUMBER	ASSAY NAME	LIST NUMBER	PARAMETER CHANGES
29	FREE T3	2221	NO
30	FREE T4	2222	UPGRADED FROM IMx THYROID ASSAY MODULE V1.0
40	FREE T3	7B18	NEW ASSAY
45	TOTAL T3	8B13	NEW ASSAY
48	ULTRA hTSH II	4B01	NEW ASSAY
58	T3	2250	NO

60	T-UPTAKE	2252	NO
80	ULTRA hTSH	3A62	NO
81	T4	2A82	UPGRADED FROM IMx THYROID ASSAY MODULE V2.0

Assay Calibrations Required when changing from:

V.1.0 to V.3.0	V2.0 to V3.0
#30 FREE T4	
#40 FREE T3	#40 FREE T3
#45 TOTAL T3	#45 TOTAL T3
#48 ULTRA hTSH II	#48 ULTRA hTSH II
#81 T4	#81 T4

Specific assay changes:

The Assay #81 T4 protocol was changed in the IMx® Thyroid Assay Module V3.0 to improve Boom and syringe homing movements. Assay #30 FREE T4 parameters (MIN CHECK) were changed in the IMx Thyroid Assay Module V2.0.

If a customer attempts to use the IMx Thyroid Assay Module V1.0 after installing V3.0, in order to run Assay #81 T4, the error CODE 104 ASSAY REVISIONS MISMATCH will be displayed. The customer must re-install the IMx Thyroid Assay Module V3.0.

If a customer attempts to use the IMx Thyroid Assay Module V2.0 after installing V3.0, in order to run Assay #30 FREE T4 or Assay #81 T4, the error CODE 104 ASSAY REVISIONS MISMATCH will be displayed. The customer must re-install the IMx Thyroid Assay Module V3.0.

New Assays:
There are three new assays on the IMx Thyroid Assay Module V3.0, all of which have been designed to improve assay performance. These assays include Assay #40 FREE T3 (List No. 7B18), Assay #45 TOTAL T3 (List No. 8B13) and Assay #48 ULTRA hTSH II (List No. 4B01). These three new assays will require calibration when changing from a previous version of the assay module.

NOTE: Although Assay #40 FREE T3 is a new assay on the module, the assay revision number is 2 for traceability to revisions made during development to the assay prior to release to the field.

IMx System Compatibility:
IMx Thyroid Assay Module V3.0 is only compatible with IMx System Software V6

END OF DOCUMENT

ABBOTT ADD	INSTRUMENT SERVICE ADVISORY

SUBJECT: **Release of IMx TDM/TRANSPLANT Assay Module Ver. 2.0**	ISA#: **60-141**
ORIGINATOR: **Gary Tompkins**	PRODUCT: **IMx® (60)**
APPROVED: **Bob Schabel 10/11/94**	EFFECTIVITY DATE: **11-OCT-94**

I. Purpose:

This ISA informs the Field Service Organizations of a new release of the IMx TDM/TRANSPLANT Assay Module, Version 2.0, List No. 4B05-02.

TDM/TRANSPLANT V2.0 Assay Module includes the following assays:

Assay Name and Number	List Number	Revision Number	Parameter Changes
72 THEO	1A81	2	Yes
108 TACRO	6A19/7A19	2	No

New Assays

There are no new assays introduced on this module.

Theophylline has been transferred from the IMx Theophylline/B12 Assay Module V1.0 to this module. However, the IMx Theophylline assay can be performed on either of these modules.

System Software Compatibility

The IMx TDM/TRANSPLANT Assay Module Version 2.0 can only be used with IMx System Software Version 6.0 or higher.

Parameter Changes

The assay parameter for THEO, 72.108 MODE has changes from 1 to 2.

Assay Calibration

Assay 72 THEO has a parameter change and therefore will require recalibration when changing from the IMx THEO/B12 Assay Module V1.0 to the IMx TDM/TRANSPLANT V2.0. Refer to the IMx TDM/TRANSPLANT Assay Module V2.0 Enclosure for information directing the customer to recalibrate the Theophylline.

Other

The Memory Allocation System Error ERR ec=0002 has been corrected in the IMx TDM/TRANSPLANT Assay Module V2.0. Please refer to IMx® ISA 60-136 for further information regarding this error.

END OF DOCUMENT

ABBOTT ADD	INSTRUMENT SERVICE ADVISORY

SUBJECT: **IMx® Hepatitis Plus Assay Module Version 1.0 Release**	ISA#: **60-135**
ORIGINATOR: **Louis Valich**	PRODUCT: **IMx® (60)**
APPROVED: **Mark Slater 2/7/96**	EFFECTIVITY DATE: **07-FEB-96**

This ISA is to inform the field of the release of the IMx® Hepatitis Plus Assay Module version 1.0 (List No. 4B22-01).

NOTE: This assay module is intended for customers requiring the use of a U.S.A. licensed IMx HBsAg and HBsAg Confirmatory assays.

The IMx Hepatitis Plus Assay Module version 1.0 contains the following assays:

ASSAY # AND NAME	LIST NUMBER	REVISION	CHANGE TO PARAMETERS	PRINT OPTION
74 HBsAg Conf	2228	20	yes	10
121 HBsAg	2228	2	yes	10

System Software Compatibility:
The IMx Hepatitis Plus Assay Module version 1.0 can only be used with IMx System Software Version 6.0 or higher. If the IMx Hepatitis Plus Assay Module Version 1.0 is installed with IMx System Software Versions 2.0, 3.0, or 5.0 the message "134 INCOMPATIBLE SYSTEM/ASSAY MODULES" is displayed. To return the IMx System to the Main Menu: Turn the IMx System off, remove the IMx Hepatitis Plus Assay Module and turn the IMx power switch back to on.

Required Control Feature:
The IMx Hepatitis Plus Assay Module version 1.0 utilizes a "Required Control" feature. The software assumes that the controls

are being tested immediately following the calibrators for that run. The required controls must pass the assay specific control ranges, as specified by the assay parameters.

Assay Activation:
The IMx HBsAg and IMx HBsAg Confirmatory assays on this module do not require assay activation.

RS-232 Interface Changes:
The IMx HBsAg and HBsAg Confirmatory assay test results format is different from the format of other IMx assays. The IMx customer will be notified of these changes by a green warning sticker placed over the opening of the cushioned bag, and by a letter. The sticker states: IMPORTANT IMx RS-232 INFORMATION ENCLOSED. The letter, enclosed in the assay module cushion bag, directs the customer to contact CSC for information regarding the changes to the RS-232 interface specifications. This letter written on green paper, states the following:

ATTENTION: CUSTOMERS USING THE IMx HEPATITIS PLUS ASSAY MODULE

The IMx Hepatitis Plus Assay Module version 1.0 contains Assay #121 HBsAg and #74 HBsAg Confirmatory. This module must be used by those customers requiring U.S.A. licensed IMx HBsAg and HBsAg Confirmatory assays. Customers performing assay #121 IMx HBsAg and #74 HBsAg Confirmatory , using the IMx Hepatitis Plus Assay Module version 1.0, must run the required controls on every carousel. These assays utilize a unique format for reporting results due to the fact that the validity of the controls is verified by the software. If your IMx is interfaced to a laboratory computer, new interface software must be developed in order to capture results through the IMx RS-232 interface. A description of the output changes is available through the IMx Customer Support Center (CSC), for customers in the U.S.A. and through the local Abbott Customer Service Department for Customers outside the U.S.A.

Attached is the description of the output changes, entitled "RS-232 Output Information For IMx Required Controls (Hepatitis Plus)", which was referred to in the letter to the customer. The attachment contains an example of an IMx HBsAg and IMx HBsAg Confirmatory assay printout.

IMx HBsAg
The IMx Hepatitis Plus Assay Module version 1.0 utilizes the "Required Control" feature for the IMx HBsAg assay and assumes that samples on the carousel are loaded as follows:

Carousel Position	For Calibration

Carousel Position	For Mode 1 Assay

1	Mode 1	1	Mode 1
2	Mode 1	2	Positive Control
3	Positive Control	3	Negative Control
4	Negative	4-24	Specimens
5-24	Control Specimens		

The Required Controls are located on the printout under the header CONTROLS with the ID names as POSITIVE and NEGATIVE. The POSITIVE and NEGATIVE controls must pass assay parameters 21 MIN CTRL 1, 22 MAX CTRL 1, and 23 MIN CTRL 2, 24 MAX CTRL 2, respectively.

Assay Parameters - #121 HBsAg

	Parameters	Parameter Value	Comments
1	DECIMAL	2	Non-editable
3	SAMPLE REP	1	Non-editable. If user is performing duplicate samples the average must be calculated manually.
4	CAL REP	2	Editable 2 to 5
21	MIN CNTRL 1	7.00	Minimum value for the Positive Control range
22	MAX CNTRL 1	63.00	Maximum value for the Positive Control range
23	MIN CNTRL 2	0.75	Minimum value for the Negative Control range
24	MAX CNTRL 2	1.30	Maximum value for the Negative Control range
25	MIN CNTRL 3	-9999.00	Default value, parameter not in use.
26	MAX CNTRL 3	9999.00	Default value, parameter not in use.
60	PRINT OPTION	10	Non-editable

Messages and Error Codes for HBsAg

Code 146 CONTROL OUT OF RANGE

This message will appear below the required control POSITIVE if it fails the assay specific ranges defined by the assay parameters 121.21 and 121.22, MIN CNTRL 1 and MAX CNTRL 1, respectively. This message will also be generated if the required control NEGATIVE fails parameter 121.23 and 121.24, , MIN CNTRL 2 and MAX CNTRL 2. Asterisks (**********) will be printed for all samples in the Results column.

On an assay calibration, asterisks (**********) will appear in the S/N column for all samples, if the average rate of at least two replicates of the MODE 1 Calibrator could not be determined because of an error on one or more of the replicates. The error code 172 CALIBRATION NOT ACCEPTED will also be printed.

IMx HBsAg Confirmatory

The IMx Hepatitis Plus Assay Module version 1.0 utilizes the "Required Control" feature and assumes that samples on the carousel are loaded as follows:

Position	HBsAg Confirmatory

1	Mode 1
2	Mode 1
3	Positive Control plus Reagent A
4	Positive Control plus Reagent B
5	Specimen 1 plus Reagent A
6	Specimen 1 plus Reagent B
7	Specimen 2 plus Reagent A
8	Specimen 2 plus Reagent B
9-24	Additional Specimens

The Required Controls are located on the printout under the header CONTROLS with the ID names, POS+RGT A and POS+RGT B. In addition, under the header NEUTRALIZATION RESULTS, where sample positions are paired, (i.e., 3,4 and 5,6 etc.,) the ID name for the paired Positive Controls plus reagent A and B is POS CNTRL.

The POS + Rgt B control must be within the ranges as specified by assay parameters, 74.21 MIN CTRL 1 and 74.22 MAX CTRL 1. The combined result of the paired controls POS + RGT A and POS + RGT B, must be above the range as specified by assay parameter 74.23
MIN CTRL 2.

Assay Parameters-Assay #74 IMx HBsAg Confirmatory

	Parameters	Parameter Value	Comments
1	DECIMAL	2	Non-editable
3	SAMPLE REP	1	Non-editable. If user is performing duplicate samples the average must be calculated manually.
4	CAL REP	2	Editable 2 to 5
2	MIN CNTRL 1	7.00	Minimum value for the Positive Control plus Reagent B range
1	MAX CNTRL 1	63.00	Maximum value for the Positive Control plus Reagent B range
2	MIN CNTRL 2	50.00	Minimum value for the Positive Control % Neutralization
2	MAX CNTRL 2	9999.00	Default value, parameter not in use.
2	MIN CNTRL 3	-9999.00	Default value, parameter not in use.
3	MAX CNTRL 3	9999.00	Default value, parameter not in use.
2	PRINT OPTION	10	Non-editable
4			
2			
5			
2			
6			
6			
0			

Loadlist Creation
A loadlist cannot be created for the IMx HBsAg Confirmatory Assay #74.

Required ID's
Identical ID's must be entered for every sample pair that contain Reagent A and Reagent B during MULTI-TASK. In those positions that are reserved for the Required Controls, the software will override any IDs entered manually and the IDs POS+RGT A and POS+RGT B will be printed. A system message ID MISMATCH OR ID MISSING will be printed for every sample pair for which IDs were not entered, or were not identical.

Messages and Error Codes for HBsAg Confirmatory

ID MISMATCH OR ID MISSING

This message will be printed for every sample pair for which IDs were not entered, or were not identical.

Code 146 CONTROLS OUT OF RANGE

This message will appear below the POS+RGT B, if it is outside the ranges as specified by assay parameters 74.21 and 74.22, MIN CNTRL 1 and MAX CNTRL 1, respectively. This message will also be generated if the Required Control pair of POS CNTRL under the

% **Neutralization** section of the printout is below the range as specified by assay parameter 74.23, MIN CNTRL 2. Asterisks (**********) will be printed for all samples in the Results column.

Asterisks (**********) may appear in the Neutralization Results section of the printout if S/N results were not determined due to a liquid level sense error or a read error on one of the two samples required to calculate a % Neutralization result. The NOTE flags will not be determined for that sample.

On an assay calibration, asterisks (**********) will appear in the S/N column for all samples, if the average rate of at least two replicates of the MODE 1 Calibrator could not be determined because of an error on one or more of the replicates. The error code 172 CALIBRATION NOT ACCEPTED will also be printed.

RS-232 OUTPUT INFORMATION FOR IMx REQUIRED CONTROLS (HEPATITIS Plus)

This output information should be used with the IMx RS-232 Interface Manual Revision 6 (List No. 3A58-01).

The IMx assay #74 HBsAg CONF and the IMx assay #121 HBsAg are the first IMx assays to utilize a "Required Controls" feature. The software assumes that control(s) are being tested immediately following the calibrators for that run. The required control(s) must pass the assay specific control ranges, as specified by the assay parameters. MEIA Qualitative results follow the Required Control results.

For Required Controls:

Four different logical records are used to present Required Control results. The first record is the header showing CONTROLS. The second record shows the LOC, ID, RESULT UNIT and RATE labels. The RESULT UNIT label is transmitted as the 8 character field and it field content varies based on the unit selected. The third record is a separator record consisting of 35 dashes. All other records, following the separator record, are data records, consisting of Location, Dilution Indicator, Sample ID*, Range Indicator, Result (in the units shown in the header record), and Rate. The Dilution Indicator field will be "D" if the sample was diluted: otherwise it will be blank. The layout of these records is as shown below:

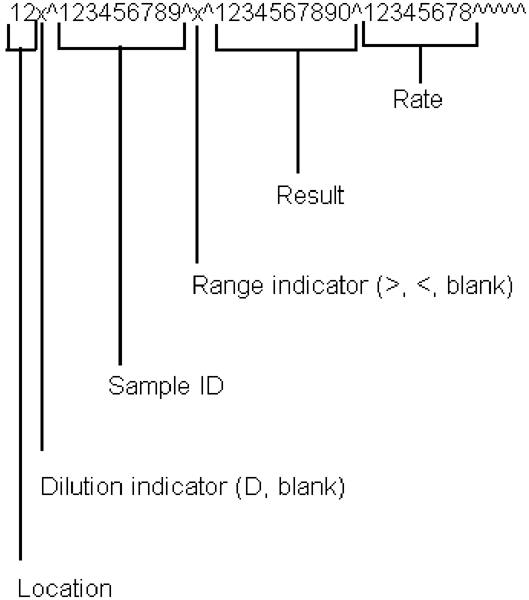
```
CONTROLS<crlf>

<crlf>

LOC ^^^^ ID ^^^^^^^^ 12345678 ^^^^ RATE <crlf>

- - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - <crlf>

12x^123456789^x^1234567890^12345678^^^^ <crlf>
```



The sample ID field for a Required Control can be one of the following ID names:

POSITIVE^	for a positive control
NEGATIVE^	for a negative control
Pos+RGT A	for positive control + Reagent A
Pos+RGT B	for positive control + Reagent B

The Required Controls are compared against their assay specific ranges as defined by the appropriate assay parameters. Each Required Control must pass its respective range check. If a Required Control fails the range check, it will be followed immediately by this error message:

CODE^146^CONTROL^OUT^OF^RANGE<crlf>
and asterisks (**********) will print, for all samples, in the Results column.

For MEIA Qualitative Confirmatory Results:

Five different logical records are used to present the NEUTRALIZATION RESULTS. The first record is the header showing NEUTRALIZATION RESULTS, followed by a separator record consisting of 22 dashes. The next three records are data records, consisting of location pairs separated by a comma, Sample ID, Result in the units shown in the header record, and Note (POS or blank):

```
^^^^^^^^NEUTRALIZATION RESULTS
^^^^^^^^----------------------
^^LOC^^^^^ID^^^^^^^^^^^^%NEUT^^^^NOTE
------------------------------------------------------------
12,12^^123456789^^^1234567890^^^^1234
```

After all the location pairs have been transmitted, the following informational message is sent:

```
POS^>OR=^^^^^50.00^^%NEUT^AND
^^^^SAMPLE^+^RGT^B^IS^REACTIVE
```

The portion of the message, "^^^^^50.00" is actually a floating point number with a total field width of 10, including the decimal point and 2 places to the right of the decimal. Prior to implementation of the Required Controls feature, the first line of the message consisted only of a character string containing the string constant "POS^>OR=^50.00^%NEUT^AND".

The Sample ID name for the Required Control is POS CNTRL.

The % NEUT result for the Required Control (POS CNTRL) is compared against an assay-specific range defined by the assay parameters. If the POS CNTRL does not pass its range check it will be followed immediately by this error message:

```
CODE^146^CONTROL^OUT^OF^RANGE<crlf>
```

and asterisks (**********) will print, for all samples, in the Results column, and the %NEUT column.

END OF DOCUMENT

ABBOTT ADD	**INSTRUMENT SERVICE ADVISORY**

SUBJECT: **Main Power Supply Fan Replacements**	ISA#: **60-096B**
ORIGINATOR: **J. Carlat/A. Ruvalcaba/L. Valich/G. Tompkins**	PRODUCT: **IMx® (60)**
APPROVED: **Bob Schabel 2/Dec/93**	EFFECTIVITY DATE: **02-DEC-93**

Purpose of Revision:

➔ *This revision makes minor corrections to the two wiring diagrams added in the previous revision and adds the 04956-101 version of the ZYTEC® power supply into the text of the ISA. Continue to use this ISA when replacing fans until it is incorporated into the new IMx® DT Service Manual.*

The following is a procedure for replacing IMx ZYTEC® Power Supply fans in the field. The procedure is separated at steps 10 and 11, based upon the dash level of the part number of the power supply. The part numbers of the two replacement fans used are:

115 VAC fan	14106-033	
24 VDC fan	3-47414-01	replaces 14106-032 (when depleted)

PARTS:

Domestic:

When stock of the old 24VDC fan (14106-032) is depleted, the new fan (3-47414-01) will be automatically shipped in it's place. Future IMx® Kit Lists will reflect the part number change.

International:

Continue to use the 14106-032 fan until stock is depleted. Forecast parts requirements to

your responsible service logistics organization.

Procedure for Replacing Fans in P/N 04956-101, -102, -103 and -105 ZYTEC Power Supplies

1. **BEFORE STARTING REPAIRS, PRINT OUT THE FOLLOWING SYSTEM FILES:**

   File 1 - CONFIGURATION
   File 2 - SYSTEM PARAMS
   File 3 - FPIA CAROUSEL
   File 4 - MEIA CAROUSEL
   File 37 - TEMPERATURE
   File 38 - PHOTO PARAMETERS

   This will save valuable time if a FAC_SET occurs since you only have to edit the above files to match the printout then perform a Boom Calibration to set files 5 through 36. Copies of these printouts should be left with the customer so that they can resolve FAC_SET problems more quickly.

2. **TURN POWER OFF:**

   Ensure that the READY menu is displayed.

   WARNING: Do not turn system power off while the instrument is performing Power-Up Diagnostics, as this may result in a Checksum or FAC_SET error.

   Press the power switch at the back of the instrument to the OFF position. Remove the power cord.

3. **REMOVE SYSTEM AND ASSAY MODULES:**

   Open the software module access door. Pull up on the Assay module cartridge in the slot on the right and the System module cartridge in the slot on the left and remove them.

4. **REMOVE ENCLOSURE ASSEMBLY:**

   Release the latch guides on the four corners of the IMx® System and slide the latches toward the inside of the base.

   NOTE: There may be a safety screw on the left front corner which must be removed to allow the latch to slide. Remove this screw and unlatch the Enclosure Assembly.

   Carefully lift the Enclosure Assembly straight up and off the instrument. Place the Enclosure in a secure area.

5. PROPER ANTI-STATIC PRECAUTIONS:

When handling system PCBs, proper anti-static procedures must be observed.

Always ground yourself to the instrument chassis by touching the Main Power Supply or Cardcage with your hand prior to handling PCB's. This will discharge static electricity and prevent board damage.

6. REMOVE CARDCAGE CABLES:

Remove all cabling attached to the cardcage including:

Display to I/O cable
Keypad to I/O cable
Analog to I/O cable
Motor Driver to I/O cable
CPU to Printer cable
Barcode reader cable
RS-232 cables

7. SWING CARDCAGE BACK TO ACCESS POWER SUPPLY CABLES:

Unscrew the two long cardcage hold down screws. Tilt the cardcage back until the cardcage restraining wire becomes taught. This will allow access to the Main Power Supply connectors.

8. REMOVE PRINTER ASSEMBLY:

Remove the four screws mounting the printer stand to the top of the power supply. Disconnect the paper advance switch from the ribbon cable. Disconnect the printer from the printer driver PCB by removing all cabling going to the driver PCB. Lift the printer, tub and stand off the power supply. Remove the four screws mounting the driver PCB to the top of the printer and remove the PCB.

9. REMOVE MAIN POWER SUPPLY:

Remove all cabling attached at the Main Power Supply including:

Display cable	Printer cable
Motor Dr/Analog cable	120VAC cable
Cardcage cable	Fan cable

Ground cable (located behind pump assembly)

10. REPLACING FAN (24 VDC) in POWER SUPPLY P/Ns 04956-103 and -105:

Remove the existing fan baffle by removing and saving the four screws and nuts. The fan baffle will be reinstalled.

Remove and save the eight screws from the front panel of the power supply (see Figure 1). The front panel has the part number labels and power switch.

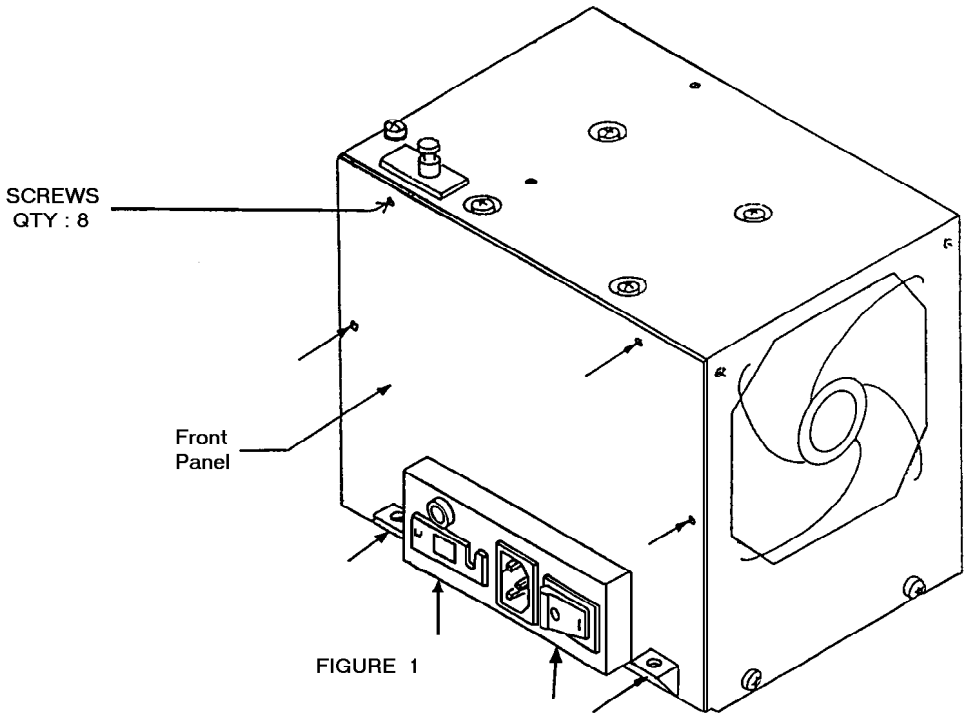


FIGURE 1

Remove and save the four screws from the opposite side of the supply (see Figure 2).

Remove and save the two top screws next to the interlock switch (see Figure 2).

Lift the top panel and disconnect the fan cable from connector P13 of the PCB inside the power supply.

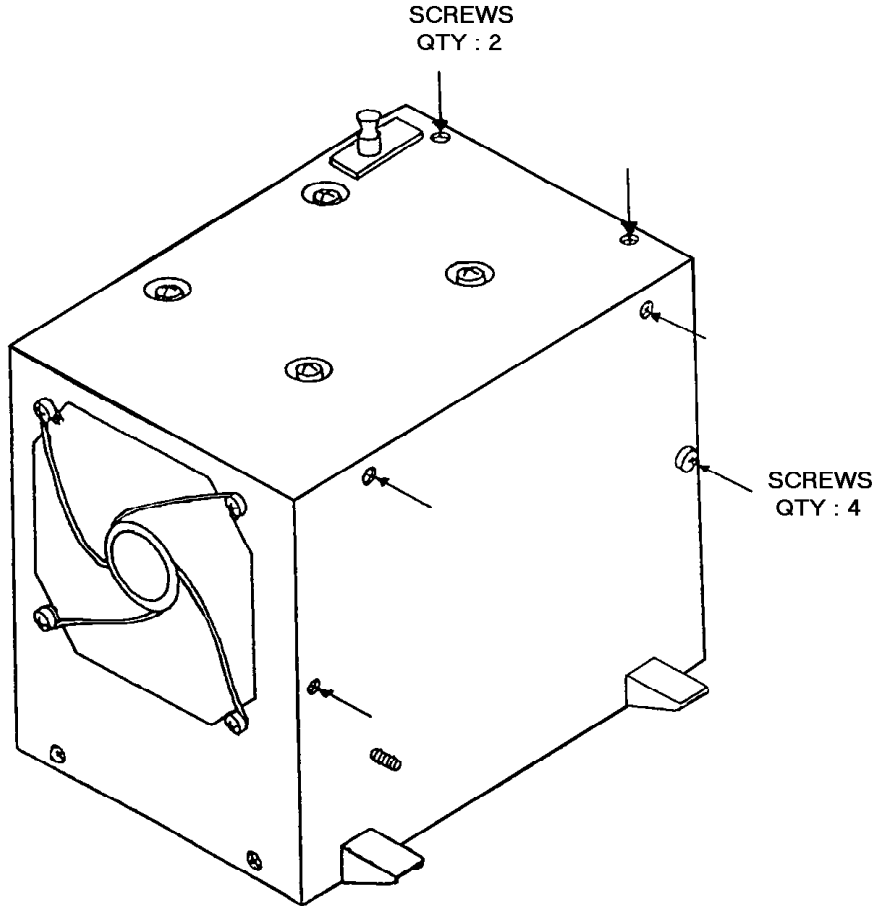


FIGURE 2

Remove and save the four screws, washers, and nuts which are holding the fan and finger guard in position (see Figure 3). Note: be careful not to drop the nuts and star washers.

Remove and scrap the old fan.

Orient the new fan such that the airflow moves from the inside of the supply to the outside (see Figure 3). The fan cable should be located in the top right corner of the fan.

Reinstall the finger guard and new fan per Figure 3 using the existing screws, flat washers, star washers, and nuts.

Plug the fan connector into P13 of the PCB on the right side of the power supply.

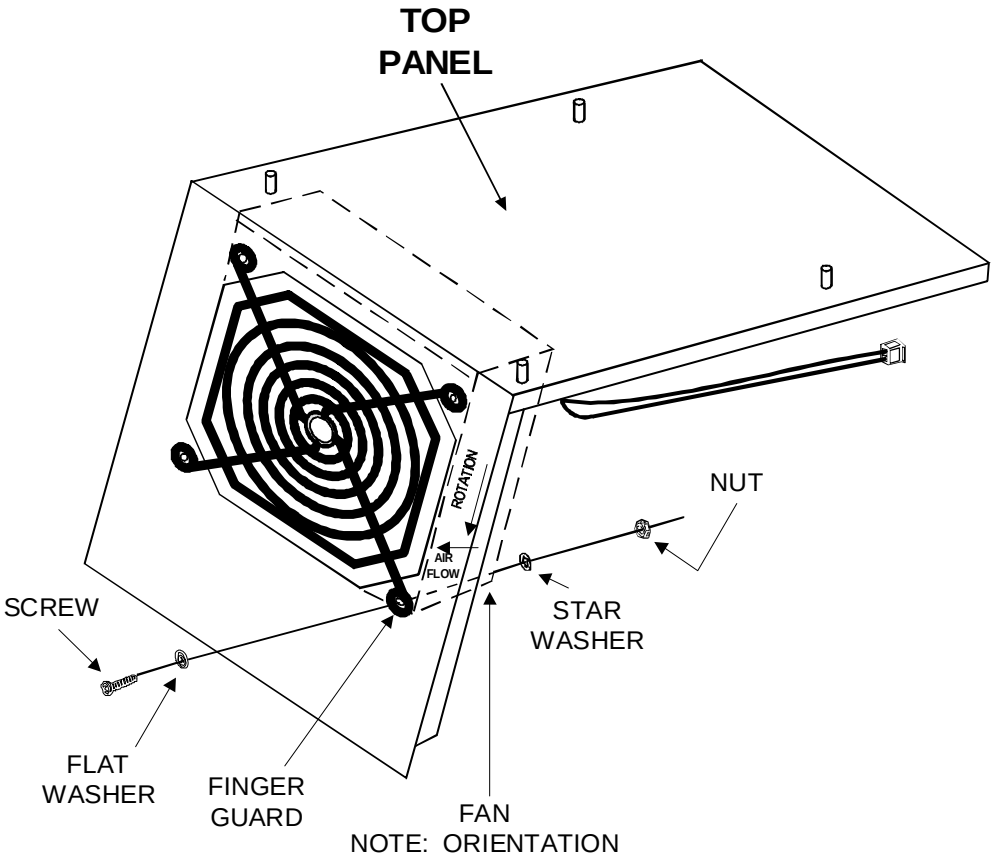


FIGURE 3

Align all sides of the supply and install the hardware to fasten the supply together.

Reinstall the fan baffle using the existing hardware.

Reinstall the power supply into the IMx® System.

Proceed to Step 12 of this procedure.

11. REPLACING FAN (115 VAC) in POWER SUPPLY P/N 049560-101 and -102:

Remove the existing fan baffle by removing and saving the four screws and nuts.

Remove and save the eight screws from the front panel of the power supply (see Figure 1). The front panel has the part number labels and power switch.

Remove and save the four screws from the opposite side of the supply (see Figure 2).

Remove and save the two top screws next to the interlock switch (see Figure 2).

Lower the side panel and disconnect the fan wires at the fan.

Remove and save the four screws, washers, and nuts which are holding the fan and finger guard in position (see Figure 3). Note: be careful not to drop the nuts and star washers.

Remove and scrap the old fan.

Orient the new fan such that the airflow moves from the inside of the supply to the out side (see Figure 3). The fan connector should be located at the top left corner of the supply.

Reinstall the finger guard and fan per Figure 3 using the existing screws, flat washers, star washers, and nuts.

Plug the fan wires into the fan connector located at the lower left corner of the fan.

Align all sides of the supply and install the hardware to fasten the supply together.

Reinstall the fan baffle using the existing hardware.

Reinstall the power supply into the IMx® System. Proceed to Step 12.

12. Reinstall the Printer Assembly to the power supply:

Reinstall the printer driver PCB to the power supply using the four screws removed earlier.

Install the printer, tub and stand to the power supply.

13. Reconnect the following cables to the power supply:

Display cable	Printer cable
Motor Dr/Analog cable	120VAC cable
Cardcage cable	Ground cable (located behind pump assembly)
Fan cable	

14. REINSTALL CABLING TO THE CARDCAGE:

WITH INTEL CPU PCB:

Install the barcode cable to the Memory PCB. Install the Keypad and Display cables to the I/O board. Connect the Analog to I/O cable and the Motor Driver to I/O cable. Install the CPU to Printer cable. Install the RS-232 cables.

WITH ASIC CPU PCB:

Install the Barcode Cable to the CPU PCB. Install the Keypad and Display cables to the I/O board. Connect the Analog to I/O cable and the Motor Driver to I/O cable. Install the CPU to Printer Cable and the RS-232 Cables.

15. SWING CARDCAGE UPRIGHT:

Lift the cardcage to its upright position and secure with the two long cardcage hold down screws to the base plate.

16. TO INSTALL THE ENCLOSURE ASSEMBLY:

Lift the Enclosure by its sides, keeping it as level as possible, and position it above the instrument. Gently lower the Enclosure and set it in place.

If the cardcage alignment is correct, the Memory Module connectors on the Memory or ASIC CPU PCB will be centered in the Enclosure software port openings. You should not have to move the connectors to align them in the port openings. Align the cardcage as required.

Latch the four corners of the Enclosure to the Base Plate with the latch slides.

WARNING: Failure to latch the Enclosure securely may result in poor connections between the software modules and the Memory or ASIC CPU PCB. This could result in FACTORY RESETS and/or CHECKSUM errors.

The Memory or CPU PCB connectors should be even or protrude slightly above the Enclosure software port openings. If they do not, align the cardcage as needed.

17. INSTALL THE SYSTEM & ASSAY MODULES:

Open the software access door and insert the System module in the left hand port openingand the Assay module in the right hand port opening. Each module connector has a curved end which functions as a keying element. Insert the module into the Memory or ASIC CPU connector with the curved end to the right. A very slight pressure may be felt when the two connectors are properly seated.

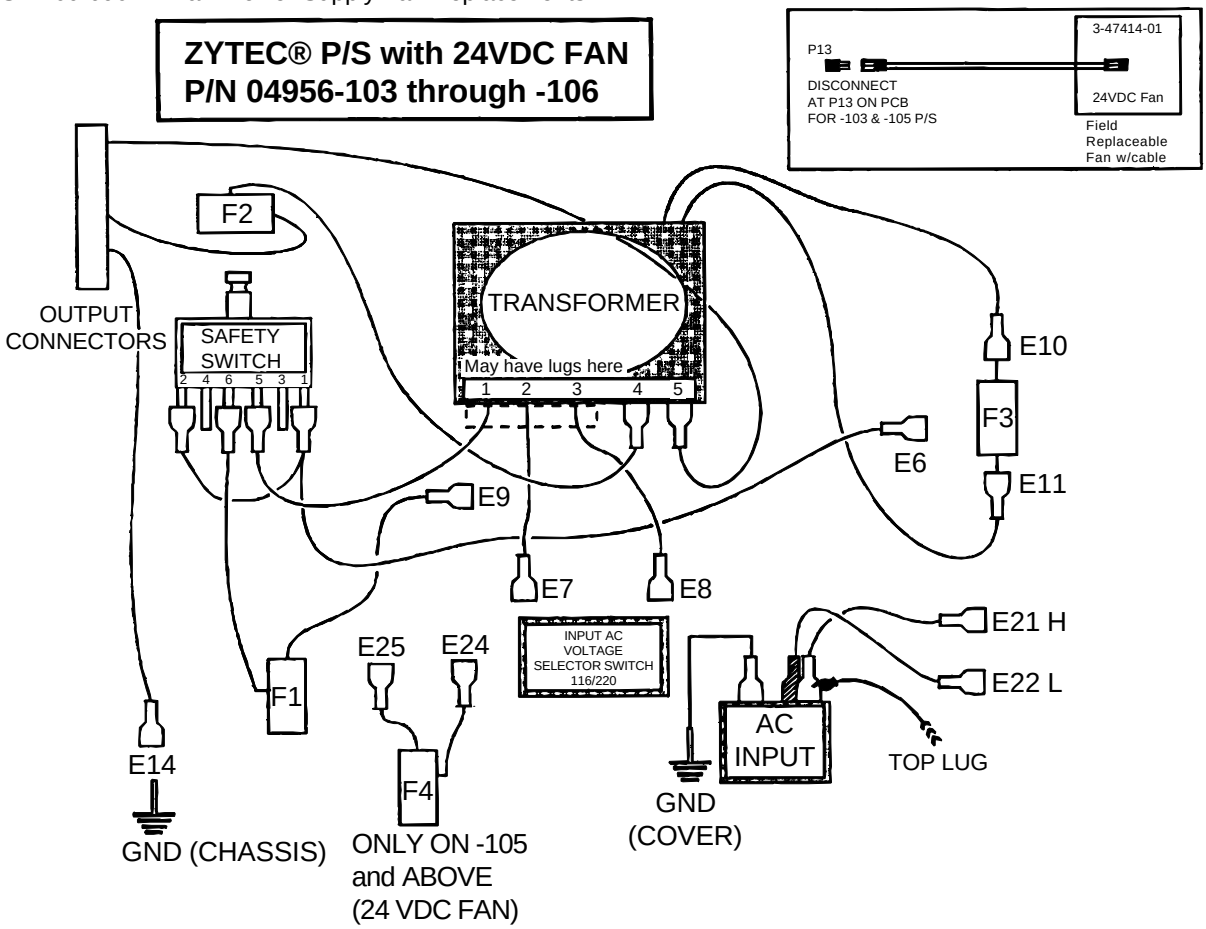
18. RESTORE INSTRUMENT POWER:

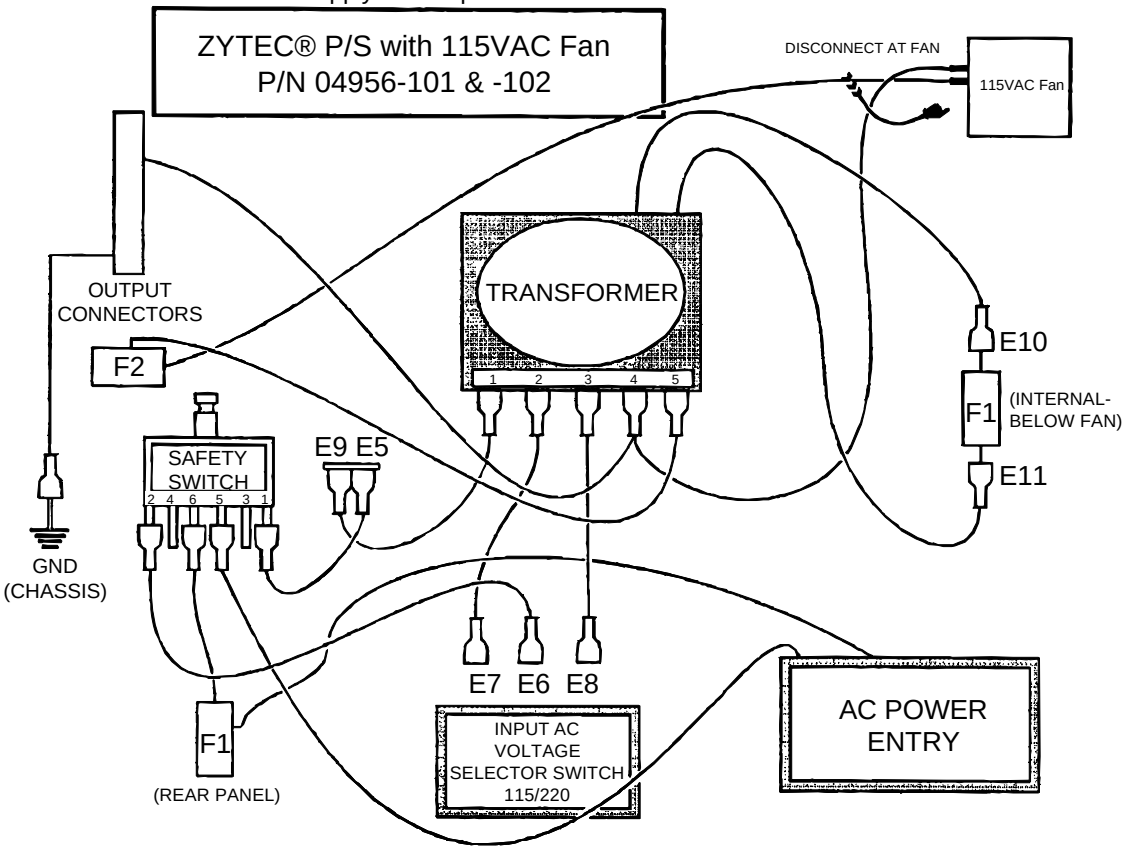
Plug the power cord into the wall outlet. Plug the other end of the power cord into the IMx® System power entry module at the back of the instrument. Turn the power switch at the back of the instrument to the ON position.

The instrument will perform a power-up diagnostic routine and display the READY menu.

19. INSTRUMENT CHECK-OUT:

Perform Total Service Call to verify instrument operation.


ZYTEC® P/S with 24VDC FAN
P/N 04956-103 through -106
P13
DISCONNECT
AT P13 ON PCB
FOR -103 & -105 P/S
3-47414-01
24VDC Fan
Field
Replaceable
Fan w/cable
F2
OUTPUT
CONNECTORS
SAFETY
SWITCH
2 4 6 5 3 1
TRANSFORMER
May have lugs here
1 2 3 4 5
E10
F3
E11
E6
E9
E7
E8
INPUT AC
VOLTAGE
SELECTOR SWITCH
116/220
E21 H
E22 L
AC
INPUT
TOP LUG
E25
E24
F1
F4
E14
GND (CHASSIS)
ONLY ON -105
and ABOVE
(24 VDC FAN)
GND
(COVER)



END OF DOCUMENT