

INDEX TECHNICAL SERVICE BULLETIN

PRODUCT:	DATE:
IMx® (60)	14-DEC-95

TSB#	IMPLEMENTATION	SUBJECT	EFFECTIVITY DATE
60-040A	N - 24848 & Below	Release of System Software Version 6.0	28-MAR-93
60-040	N - 24848 & Below	Release of System Software Version 6.0	OBSOLETE
60-039	N - 20706 through 24600	Refurbed FPIA Optics that do not meet VDE Certification	27-NOV-92
60-038	N - See TSB	Non-VDE Motor Driver PCB's Shipped in New Build IMx Instruments	15-JAN-93
60-037B	F - 23299 & Below	Improved FPIA Lamp Socket	03-AUG-93
60-037	F - 23299 & Below	Improved FPIA Lamp Socket	OBSOLETE
60-036	O - See TSB	FPIA Lamp Housing Gasket	14-DEC-95
60-035	N - See TSB	Using Non-VDE parts in VDE Certified IMx analyzers	15-MAY-92
60-034	O - See TSB	Release of VDE Certified IMx Analyzers	15-MAY-92
60-033	O - See TSB	Release of System Software Version 5.0	09-DEC-91
60-032	N - 16071 & Below	COM1/COM2 Port alignment	01-AUG-91
60-031	O - See TSB	IMx Continuous Waste System	23-MAY-91
60-030A	N - See TSB	PAL change to IMx Memory PCB	11-MAY-93
60-030	N - See TSB	PAL change to IMx Memory PCB	OBSOLETE
	I - See TSB	"SELECT" Boom Arm release	20-NOV-91
	N - See TSB	"SELECT" Boom Arm release	OBSOLETE
60-029		"SELECT" Boom Arm release	OBSOLETE
60-028		Release of Version 3.0 System Software	03-DEC-90
60-027B		New Diagnostic Chips for INTEL CPU Bd.	19-OCT-90
60-027A		New Diagnostic Chips for INTEL CPU Bd.	OBSOLETE
60-027		New Diagnostic Chips for INTEL CPU Bd.	OBSOLETE
60-026	N - See TSB	C12 on ASIC CPU/Memory PCB	27-MAR-90
60-025B		ASIC CPU/Memory Bd. Replacements	02-SEP-90
60-025A		ASIC CPU/Memory Bd. Replacements	OBSOLETE
60-025	O - See TSB	ASIC CPU/Memory Bd. Replacements	OBSOLETE

IMx® (60) Index		
60-024 F - 3700 & Below	Printer Cable/Paper Feed Switch Changes	29-SEP-89
60-023 F - 3479 & Below	New Sheet Metal Assembly	20-SEP-89
60-022 F - 8315 & Below	Release of System Software Module Version 2.0	OBSOLETE
60-021 F - 3000 & Below	Memory Bd. Incompatibility Problems	24-JUL-89
60-020B N -3181 & Below	New Air Heater/Fan Assemblies	12-DEC-91
60-020A N -3181 & Below	New Air Heater/Fan Assemblies	CANCELLED
60-020 N -3181 & Below	New Air Heater/Fan Assemblies	CANCELLED
60-019 N - 400 through 793	Card Cage Alignment	08-MAR-89
60-018 N - See TSB	PMT Socket Replacement	OBSOLETE
60-017 I - See TSB	Upgrade of Demo systems	OBSOLETE
60-016 I - 432 through 788	Air Fan Decal	OBSOLETE
60-015 F - All	Revision 1.07 System Software	OBSOLETE
60-014	CANCELLED	CANCELLED
60-013 N - All	MEIA Lamp P/S (04708-104)	29-NOV-88
60-012A N - 529 & Below	New CPU Power Diagnostic Chips	OBSOLETE
60-012 N - 529 & Below	New CPU Power Diagnostic Chips	OBSOLETE
60-011 N - 509 & Below	MEIA Lamp P/S Modification	OBSOLETE
60-010	CANCELLED	CANCELLED
60-009 N - 249 & Below	Main P/S Duct Modification	OBSOLETE
60-008 N - 249 & Below	Analog Bd. Level Sense Modification	OBSOLETE
60-007 N	Memory Map/Closed Loop CEI	OBSOLETE
60-006 F	Boom Arm Z-Boom Guide	OBSOLETE
60-005 F	Buffer Platform Switches	OBSOLETE
60-004 F	MEIA Optics Board Modification	OBSOLETE
60-003 F	Main Digital I/O Bd. Modification	OBSOLETE
60-002 N	Lamp Power Supply Modification	OBSOLETE
60-001 N	Memory Board Modification	OBSOLETE

PENDING - TSB index number has been reserved for a future TSB.

CANCELLED - TSB index number is cancelled.

INCORPORATED - TSB was incorporated into another document or manual.

OBSOLETE - TSB no longer applies.

COMPLETE - TSB implementation is complete.

END OF DOCUMENT



SUBJECT:

TECHNICAL SERVICE BULLETIN

TSB#: 60-040A

WorldWide Upgrade of IMx® System Software to revision 6.0			
ORIGINATOR: Louis Valich	PRODUCT: IMx® (60)		
APPROVED: Bob Schabel 4/27/93 (sign	nature on file)	REF. ECN: IMx - 2529	
IMPLEMENTATION:	TSB Part/Kit #: See TSB	Upgrade Time: 15 min.	
Immediate Next Service Call	TSB Effectivity/ Part(s) Availibility: 29-JAN-93	Validation Time: 4 Hours	
		Total Mod. Time: 4 Hrs. 15 min.	

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I. Distribution: Domestic and International

II. General

n/a

A. Purpose

Next Failure Optional

Instruments Requiring Modification:

This TSB is to inform the field that all IMx® Analyzers will be upgraded to a new software revision 6.0. Currently there are three revisions of software available. Revisions 2.0, 3.0 and 5.0 will be discontinued and all instruments above S/N 24,848 will be manufactured with revision 6.0.

Although this modification is mandatory, I have given this TSB an effectivity of NEXT SERVICE CALL. The entire instrument population should take about 9 - 10 months to upgrade. The IMx® Marketing organization has been in contact **Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.**

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

with the various IMx® Product managers in each country to ensure that all countries know approximately when they will start receiving upgrade kits. Each country is expected to complete their upgrades within approximately 6 - 9 months of their first software shipments.

Although classified as NEXT SERVICE CALL, this upgrade is designed to be customer installable. A decision regarding the level of FSE involvement in supporting this upgrade is Country specific. Direction will be provided within each Country organization. This TSB includes the Features of this upgrade and the Installation procedure the customers will receive. If the FSE installs this upgrade, use the installation procedure provided in this TSB. If you perform the software upgrade for the customer, please be sure to do the following:

IMPORTANT CHANGES ON PAGE 23 OF 24 AND NEW PAGE 24 ADDED. PLEASE REVIEW THESE PAGES BEFORE PERFORMING THIS MODIFICATION.

A. Purpose (continued):

- 1. Explain the two changes in maintenance procedures highlighted in step 13 of the Installation Instructions included in this TSB. These include the TEAH probe cleaning procedure as part of the daily maintenance and the order in which MEIA and SELECT temperature calibrations are performed.
- 2. Confirm that the TEAH Probe Cleaning Solution has been received, and is not expired.
- 3. Return the old software version following the appropriate instructions for your specific country.

B. Administrative notes:

United States FSEs only:

This TSB should be closed out in FieldWatch as follows:

$$SC = DL$$
 $TC = 40$ $RC = 88$

If you visit an account and find that the customer has installed the modification, DO NOT open a call and close it out with the above codes. Ask the customer if they have called the CSC to let them know that the upgrade was completed. If they haven't, Call the CSC and notifiy them that the customer has completed the mod and they will close a call out for you. They will insure that the hardware and software rev fields are updated.

C. Time Required: 4.25 Hours

D. Tools Required: Standard FSE Tool Kit

E. Parts:

United States:

Each FSE will be sent the following parts:

LN8384-06 System Module revision 6.0 LN8376-06 Operation Manual revision 6.0

International:

Each FSE should be sent an upgrade kit L/N 6A82-XX with the following parts included in it:

LN8384-06 System Module revision 6.0
LN8376-06 Operation Manual revision 6.0
LN4A31-01 Carousel ID Barcode Labels

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LN4A35-01 FPIA Carousel ID Holder

83-86581/R1 Installation & Benefits information

International service sites should forecast parts requirements through their normal channels.

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III. Procedure

A new feature not documented in the Features section is a new MONITOR menu key:

The MONITOR menu has a new function key, TESTS. This key will allow the user to access two functions:

TEST LEFT

Displays the number of tests remaining in a reagent pack on that IMx® System.

TOTAL

Allows a user to display the total number of MEIA or FPIA tests run on an IMx® System.

TOTAL has not been highlighted to the customer as it is intended primarily for FSE and/or CSC use. Features of this new function include:

- * Displays the total number of MEIA or FPIA tests run on that IMx from when v6.0 was initially installed.
- Displays the date when tracking begins.
- * Counts MEIA and FPIA tests separately to a 999,999 maximum for each assay type. IMx SELECT and Ion Capture assays are included in the MEIA count.
- * Resets the date and the count to 0 when a FAC_SET ALL is performed or the maximum count of 999,999 is reached.
- Counter is incremented each time the reagent pack count is decremented.

On the following pages is documentation to describe the Features of the Revision 6.0 software and the Installation procedure.

Features of IMx System Module Version 6.0 Software Enhancement

The IMx System Module Version 6.0 Software Enhancement has many features including the IMx SELECT™ option, which was introduced with IMx System Module Version 5.0. Using the IMx SELECT option, you can run specific assays, up to three at a time, on the same carousel. IMx SELECT offers two different pipetting methods: By-Assay and By-Panel. IMx SELECT By-Assay enables you to run different combinations of specific assays in a single run. IMx SELECT By-Panel enables you to run the same assays on all patient samples on the carousel. In addition, Version 6.0 of the IMx System Software continues to provide you with the capability to run IMx Assays in the standard format. The following pages detail the key features of IMx SELECT and other new IMx System Software features.

Refer to the IMx System Operation Manual (List No. 8376-06) for a more complete description of features. The manual page number is enclosed in parentheses following each subsection title.

IMX SELECT ASSAY PROCEDURES

IMx SELECT By-Assay Pipetting Method (5c-5)

- This pipetting method runs specified assays on specified patient samples.
- One, two or three assays can be run at one time.
- The patient sample must be pipetted into a separate reaction cell for each assay.
- Following the MODE 1 Calibrator, the control(s) can be interspersed among the patient samples within an assay group.
- Dilution protocols can be run when using the By-Assay pipetting method.
- The IMx System prints an individual test results tape for each assay at the end of the run. The IMx System does **not** print a Patient Summary.

IMx SELECT By-Panel Pipetting Method (5c-18)

- This pipetting method runs the same assays on all patient samples in that carousel.
- At least two assays must be run at one time.
- The patient sample is pipetted only once into a reaction cell within the first assay group. The IMx System will transfer appropriate amounts of the patient sample to the empty reaction cells to run each assay.
- Control(s) must be placed directly after the MODE 1 Calibrator, and before the patient samples within an assay group.
- Dilution protocols cannot be run when using the By-Panel pipetting method.
- Patient samples and controls must be run singly. Assay parameter XX.3 SAMPLE REP, can only be set to a value of 1 for each assay.
- The IMx System prints an individual test results tape for each assay, at the end of the run, as well as a Patient Summary. The Patient Summary is an additional printout, generated when using the By-Panel pipetting method, which groups assay results by patient. This printout is not transmitted through the IMx System RS-232 Interface.

Features of IMx System Module Version 6.0 Software Enhancement Loadlist Creation (MEIA: 5b-2, SELECT: 5c-3, FPIA: 5d-2)

- The loadlist is a special printout designed to assist in loading the IMx SELECT™ Carousel prior to running an assay(s). It identifies the placement of reagents, disposables, calibrators, controls and patient samples. The loadlist also specifies the volume required for calibrators, controls and patient samples.
- The creation of a loadlist is required prior to running a IMx SELECT Assay(s).
- The creation of a loadlist is optional for other IMx Assays.

IMx SELECT MUP Lot Identification (Loadlist: 5c-10, 5c-23; Test results: 5c-16, 5c-29)

 When entered via the numeric keypad, MUP LOT will appear on the loadlist after SERIAL #, and on the test results printout between RGNT LOT and SERIAL #.

IMx SELECT CALIBRATION AND TROUBLESHOOTING PROCEDURES IMx SELECT Reagent Pack Calibration (9d-17)

- A step, specific to IMx SELECT System, has been added to the Boom Calibration procedure. This step determines the horizontal positioning for the probe/electrode assembly for all reagent packs located in the IMx Select carousel. This additional location, CRSL_RGNT, is calibrated by centering the probe over the cross target at the center of the buffer pack cap in location A in the IMx SELECT Carousel.
- The CRSL RGNT location can also be checked during Boom Check (9a-6).

IMx SELECT Temperature Calibration (9d-25) and Check (9b-13)

- An IMx SELECT Temperature Calibration and Check will be required for running IMx SELECT Assays.
- When performing the IMx SELECT Temperature Calibration and Check, the IMx SELECT Carousel must be used.

IMx SELECT Level Sense Error Information (5c-4)

For a IMx SELECT Assay run, when a level sense error stops one of the assays, an error code will be displayed. This error
code indicates which assay(s) encountered the level sense error by the IMx SELECT Reagent pack location (A, B, C). The
operator must choose whether to press [STOP ASSAY] to discontinue the remaining assay(s), or press [EXIT] to allow the
other assays to continue.

IMx SELECT Buffer Run (10-4)

- Performing an IMx SELECT buffer run requires the generation of a loadlist.
- A buffer run loadlist requires the entry of the assay number, rather than the reagent bar code number which is used in the creation of an assay loadlist.
- A buffer run loadlist cannot be edited after the information is stored.

Features of IMx System Module Version 6.0 Software Enhancement

IMx SELECT™ ACCESSORIES

In order to utilize the IMx SELECT Option, an IMx SELECT Enhancement Kit is available as

List No. 7A34-01. To further enhance the IMx SELECT features, the use of the IMx Bar Code Scanner is advised. The IMx Bar Code Scanner must be ordered separately as List No. 3A81-01.

IMx SELECT Carousel (1-14)

• The IMx SELECT Carousel accommodates up to three assay reagent packs in the center of the carousel, thus allowing up to three specific IMx SELECT assays to be run at a time in the same carousel.

IMx Bar Code Scanner (1-7)

- The IMx Bar Code Scanner facilitates loadlist creation by reading both reagent pack bar code labels and patient sample tube bar code labels.
- Alphanumeric sample IDs can be entered during loadlist creation or while in MULTI_TASK.
- Assay activation can be simplified by using the IMx Bar Code Scanner to read reagent pack bar codes.
- The IMx Bar Code Scanner must be ordered separately (List No. 3A81-01).

IMx SELECT MUP Holder (1-16)

• For an IMx SELECT Assay run, the IMx SELECT MUP bottle is placed into the MUP holder, which is then placed in the reagent heater block.

IMx SELECT MUP Storage Rack (2-5)

 The MUP Storage Rack is a convenient rack for compact storage and inventory control of IMx SELECT MUP bottles in the refrigerator.

ADDITIONAL IMx SYSTEM SOFTWARE FEATURES

IMx Spooler (6a-6)

- A new IMx Software feature which gives the IMx System the ability to store up to 30K bytes of assay data until the LIS system is ready to receive it.
- The IMx System will have the ability to "spool" approximately 9 (IMx SELECT Assays) to 18 (standard IMx Assays) carousels of data until the LIS is available to receive it.
- The IMx Spooler will transmit data to the LIS system in ASTM low-level format, which will allow for error recovery of transmitted data.
- [SPOOLER] is a new function key under the ASSAY menu, which will display the percentage of space used in the spooler buffer for untransmitted data.

Features of IMx System Module Version 6.0 Software Enhancement

Dilution/Alternate Submenu (MEIA: 5b-17, SELECT: 5c-31)

- A Dilution/Alternate submenu will prompt for the number of reaction cells to be used for the Dilution/Alternate protocol, rather than the number of undiluted samples.
- This change in the Dilution/Alternate submenu prompt applies to both MEIA and IMx SELECT assays.
- For IMx SELECT, a Dilution/Alternate protocol can only be run using the By-Assay pipetting method.

Test Left (6a-24)

- [TEST_LEFT] is a function key under the MONITOR menu, which allows the operator to check the number of tests remaining in a reagent pack on that IMx System.
- If the IMx System has never read the bar code on the reagent pack being checked, ??? will appear in the display window.
- IMx SELECT Reagent packs can only be checked using the IMx Bar Code Scanner. Other IMx Reagent packs can be checked by using the bar code reader on the boom or the IMx Bar Code Scanner.
- TESTS LEFT information also appears on the loadlist for each reagent pack being used in that assay run.

Status (6a-40)

- As in previous system software versions, when MULTI_TASK is displayed, pressing the [STATUS] key displays the status of the assay currently being performed.
- Pressing the [STATUS] key for IMx SELECT Assays will display the approximate amount of time remaining (hours and minutes) until the run is completed.

Sample Identification (6a-17)

Sample IDs can be entered before an assay run begins through the creation of a loadlist. The operator has the choice of
entering sample IDs during loadlist creation or through the MULTI_TASK menu.

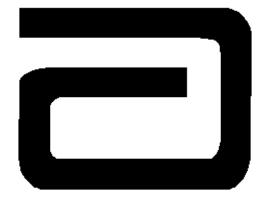
SYSTEM SOFTWARE MODULE VERSION 6.0 INSTALLATION INSTRUCTIONS

STOP!

Do not install System Software Module Version 6.0 before printing out System Files 1, 2, 3, 4, 37, and 38 from your current System Software.

Prior to beginning this software upgrade, verify that you have received the separate shipment containing one bottle of IMx Probe Cleaning Solution.

Refer to the following installation instructions.



ABBOTT LABORATORIES ABBOTT PARK, IL 60064 U.S.A.

83-8129/R1

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IMx System Software Module Version 6.0

Overview

Enclosed is your IMx System Software Enhancement Kit Version 6.0. System Module Version 6.0 will continue to provide you with the capability to run fully automated assays and, if using the IMx SELECT™ Option, multiple assays (up to three at a time) on the same carousel.

System Module Version 6.0 incorporates a new feature into the IMx System. This new feature is a spooler that will provide IMx RS-232 Interface users the ability to store several carousels of data before transferring it to the host computer.

The IMx System Software Enhancement Kit Version 6.0 contains:

- 1. IMx System Software Module Version 6.0 (No. 8384-06)
- 2. IMx System Operation Manual (No. 8376-06)
- 3. Carousel ID Bar Code Labels (No. 4A31-01), 1 sheet of 50 for IMx SELECT, MEIA and FPIA Carousels
- 4. FPIA Carousel ID Holder (No. 4A35-01)
- 5. Envelope containing:
 - Installation Instructions for IMx System Software Module Version 6.0
 - Features of IMx System Software Module Version 6.0
 - Updated version of the IMx Bar Code Scanner User's Guide (Note: The IMx Bar Code Scanner, No. 3A81-01, is an optional accessory which must be ordered separately).
- Box, Form and Label for return of your current Version 2.0, Version 3.0 or Version 5.0 System Software Module (U.S. Customers only).

Required Materials Being Shipped Separately:

7. IMx Probe Cleaning Solution (No. 1A71), 1 bottle; additional bottles must be ordered separately.

To install the IMx System Software Module Version 6.0 in your IMx Instrument system, you must perform all of the procedures listed in the installation instructions step by step. Detailed descriptions of each of these procedures are provided on the following pages. It is extremely important that these procedures are completed in the order given. Please allow approximately 3-5 hours for completion of the installation.

NOTE: All system files listed in these installation instructions (including those referring only to FPIA or MEIA technology) must be printed from your current system software and the parameters edited into System Software V6.0 once it has been installed.

Prior to installing the IMx System Software Module Version 6.0 in your IMx Instrument system, verify that all of the components were shipped in your IMx System Software Enhancement Kit Version 6.0. Check the packing slip inside the shipping carton.

Due to the increasing number of assays requiring the probe cleaning procedure, it is now part of Daily Maintenance.

Please advise your laboratory personnel of these key items concerning the conversion to Version 6.0 System Software. If you have any questions concerning the Enhancement Kit or the new IMx Software, please contact your IMx Customer Support Center.

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There are parameters within your current system files that are unique to your IMx System. These parameters must be printed from your current system files and edited into the new system files once System Software Version 6.0 has been installed. Detailed below (Steps 1-14) are instructions for printing out and editing these parameters.

Perform each step, in the order listed, beginning with Step 1. As you complete each step, check the box to the left.

1. DO NOT REMOVE YOUR PRESENT SYSTEM MODULE VERSION 2.0, 3.0 OR 5.0 UNTIL THE FOLLOWING SYSTEM FILES ARE PRINTED. Print System Files 1, 2, 3, 4, 37, and 38. Set these printouts aside for later reference in this Installation Procedure.

Press [SYSTEM] [FILES]

[XX] (file number)

[PRINT]

2. Prepare for software module removal by turning your IMx System power switch OFF. Wait 10 seconds and then open the software module door located on the top, right side of your system. Remove the System Module from the left module port.

NOTE: Your Version 2.0, 3.0 or 5.0 System Module must be returned to Abbott Laboratories.

U.S. Customers Only: Place the Version 2.0, 3.0 or 5.0 System Module in the box provided and complete the return form. Enclose the completed form with the module and return to Abbott Laboratories using the postage-paid mailing label provided.

Customers outside of U.S.: Your Abbott Laboratories area representative will provide you with specific instructions for the return of your module.

If you have any questions, contact your IMx Customer Support Center.

- 3. After you have printed System Files 1, 2, 3, 4, 37, and 38 from your current system software, install your new System Module Version 6.0 by plugging the module into the left module port. Press the module firmly into place.
- 4. Turn your IMx System power switch ON. When the System Module is properly installed, your system performs an internal

power-up routine. After this routine is completed, the Main Menu will appear in the display window.

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- 5. Refer to the printout for System File 1: CONFIGURATION from your current System Module (refer to Step 1). Please note your current system version by referring to parameter 1.1 SYSTEM REV which is printed in the format X.0X; for example, 3.0X. The first two digits identify the System Software Version. Other digits are used for internal control.
 - If you are currently using System Module Version 2.0, proceed to Step 5a
 - If you are currently using System Module Version 3.0 or 5.0, proceed to Step 5b.
 - If you are currently using an RS-232 interface, Step 5c must also be performed.
 - a. If you are currently using System Module Version 2.0, circle the printed values corresponding to the parameters listed below:
 - 1.3 SERIAL NUMBER
 - 1.5 DATE FORMAT
 - 1.17 LINE FEEDS

If you are currently using System Module Version 2.0, and wish to use the Carousel ID feature present in Versions 3.0, 5.0 and 6.0, System File 1.19 should be set to "1" (default).

Proceed to Steps 5c-5f.

- b. If you are currently using System Module Version 3.0 or 5.0, circle the printed values corresponding to the parameters listed below:
 - 1.3 SERIAL NUMBER
 - 1.5 DATE FORMAT
 - 1.17 LINE FEEDS
 - 1.19 CRSL ID 1 = ON (optional)

Proceed to Steps 5c-5f.

- c. If your laboratory is currently using the RS-232 Interface, the following parameters in System File 1 must also be circled:
 - 1.10 COM2 BAUD
 - 1.11 COM2 CHR LEN
 - 1.12 COM2 STOP BIT

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1.13	COM2 PARITY
1.10	CONZ PARTIT

^{1.18} HOST INTERFACE

1.29 XOFF TIMEOUT

- 5. (Cont.)
 - d. To edit the circled values into your new System Module Version 6.0:

```
Press [SYSTEM]
[FILES]
[1.3]
[DISPLAY]
Using the numeric keypad, enter the circled value for parameter 1.3.
[STORE]
[EXIT]
[EXIT]
```

- e. Repeat for parameters 1.5, 1.17, and 1.19 (optional). If the RS-232 Interface is being used, repeat for parameters 1.10, 1.11, 1.12, 1.13, and 1.29. For parameter 1.18, HOST INTERFACE, you must choose one of two options:
 - 1) The password "2215" must be entered to enable the Computer Interface and transmit data to the LIS.
 - 2) The password "5713" must be entered to enable the IMx Spooler to store assay data and transmit data to the LIS.
- f. To confirm that the circled values have been edited correctly, print System File 1 and check against your circled file printout.

```
Press [SYSTEM]
[FILES]
[1]
[PRINT]
```

6. Refer to the printout for System File 2: SYSTEM PARAMS from your current System Module (refer to Step 1). Circle the printed value corresponding to the parameter listed below:

2.9 WASTE TOT VOL

To edit this circled value into your new System Module Version 6.0:

```
Press [SYSTEM]
[FILES]
[2.9]
[DISPLAY]
Using the numeric keypad, enter the circled value for parameter 2.9.
[STORE]
[EXIT]
[EXIT]
```

Edit only this one parameter in this file. Editing other parameters in this file may interfere with system operation.

To confirm that the circled values have been edited correctly, print System File 2 and check against your circled file printout.

```
Press [SYSTEM]
[FILES]
[2]
[PRINT]
```

- 7. Refer to the printout for System File 3: FPIA CAROUSEL from your current System Module (refer to Step 1).
 - If you are currently using System Module Version 2.0 or 3.0, proceed to Step 7a.
 - If you are currently using System Module Version 5.0, proceed to Step 7b.

NOTE: You must be sure to edit all of the parameters listed below even if you are running MEIA or IMx SELECTä Assays only.

- 7. (Cont.)
 - a. If you are currently using System Module Version 2.0 or 3.0, circle the printed values corresponding to the parameters listed below:
 - 3.11 PIPET1 OFFSET
 - 3.13 READ OFFSET
 - 3.14 DETECT OFFSET
 - 3.17 LOCK POS
 - 3.18 UNLOCK POS

Locate parameter 3.17 LOCK POS. Subtract 693 from the value printed for this parameter. Record and circle the difference on your printout, and label this value as parameter 3.21 DOT LOC. Please note that parameter 3.21 (DOT LOC) is not seen in System Module Version 2.0 or 3.0, but is present in System Module Version 6.0.

For example, if parameter 3.17 is 783, the new calculated value to be edited into parameter 3.21 is 783 - 693 = 90.

Proceed to Steps 7c - 7e.

- b. If you are currently using System Module Version 5.0, circle the printed values corresponding to the parameters listed below:
 - 3.11 PIPET1 OFFSET
 - 3.13 READOFFSET 3.14 DETECT OFFSET
 - 3.17 LOCKPOS
 - 3.18 UNLOCKPOS
 - 3.21 DOT LOC

Proceed to Steps 7c - 7e.

c. To edit the circled values into your new System Module Version 6.0:

```
Press [SYSTEM]
[FILES]
[3.11]

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```

[DISPLAY]

Using the numeric keypad, enter the circled value for parameter 3.11.

[STORE]

[EXIT] [EXIT]

- 7. (Cont.)
 - d. Repeat for parameters 3.13, 3.14, 3.17, 3.18, and 3.21. Edit only these six parameters in this file. Editing other parameters in this file may interfere with system operation.
 - e. To confirm that the circled values have been edited correctly, print System File 3 and check against your circled file printout.

```
Press [SYSTEM]
[FILES]
[3]
[PRINT]
```

- 8. Refer to the printout for System File 4: MEIA CAROUSEL from your current System Module (refer to Step 1).
 - If you are currently using System Module Version 2.0 or 3.0, proceed to Step 8a.
 - If you are currently using System Module Version 5.0, proceed to Step 8d.

NOTE: You must be sure to edit all of the parameters listed below even if you are running FPIA assays only.

- a. If you are currently using System Module Version 2.0 or 3.0, circle the printed values corresponding to the parameters listed below:
 - 4.17 LOCK POS
 - 4.18 UNLOCK POS
- b. Locate parameter 4.17 LOCK POS. Subtract 536 from the value printed for this parameter.

Record and circle the difference on your printout, and label this value as parameter 4.21 DOT LOC. Please note that parameter 4.21 (DOT LOC) is not seen in System Module Version 2.0 or 3.0, but is present in System Module Version 6.0.

For example, if parameter 4.17 is 623, the new calculated value to be edited into parameter 4.21 is 623 - 536 = 87.

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- 8. (Cont.)
 - c. Subtract 17 from the original value printed for parameter 4.17 (LOCK POS). Record and circle the difference on your printout and label this value as parameter 4.22 FLAG LOC. Please note that parameter 4.22 (FLAG LOC) is not seen in System Module Version 2.0 or 3.0, but is present in System Module Version 6.0.

For example, if parameter 4.17 is 623, the new calculated value to be edited into parameter 4.22 is 623 - 17 = 606.

Proceed to Steps 8e - 8g.

- d. If you are currently using System Module Version 5.0, circle the printed values corresponding to the parameters listed below:
 - 4.17 LOCKPOS
 - 4.18 UNLOCKPOS
 - 4.21 DOTLOC
 - 4.22 FLAGLOC

Proceed to Steps 8e - 8g.

e. To edit the circled values into your new System Module Version 6.0:

```
Press [SYSTEM]
[FILES]
[4.17]
[DISPLAY]
Using the numeric keypad, enter the circled value for parameter 4.17.
[STORE]
[EXIT]
[EXIT]
```

- f. Repeat for parameters 4.18, 4.21, and 4.22. Edit only these four parameters in this file. Editing other parameters in this file may interfere with system operation.
- g. To confirm that the circled values have been edited correctly, print System File 4 and check against your circled file printout.

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Press [SYSTEM] [FILES]

[4] [PRINT]

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

- 9. Refer to the printout for System File 37: TEMPERATURE from your current System Module (refer to Step 1).
 - If you are currently using System Module Version 2.0 or Version 3.0, proceed to Step 9a.
 - If you are currently using System Module Version 5.0, proceed to Step 9b.
 - a. If you are currently using System Module Version 2.0 or 3.0, circle the printed values corresponding to the parameters listed below:
 - 37.1 FPIA SETPT
 - 37.2 FPIA AMB CRTN
 - 37.12 AMB OFF TIME
 - 37.16 MEIA AIR SET
 - 37.18 MEIA PID DEV
 - 37.20 MEIA INCTIME
 - 37.21 MEIA CAL TIME
 - 37.26 PID GAIN
 - 37.27 PID INTEGRAL
 - 37.29 PID BIAS

Proceed to Steps 9c - 9e.

- b. If you are currently using System Module Version 5.0, circle the printed values corresponding to the parameters listed below:
 - 37.1 FPIA SETPT
 - 37.2 FPIA AMB CRTN
 - 37.12 AMB OFF TIME
 - 37.15 MB AIR SET
 - 37.16 MEIA AIR SET
 - 37.18 MEIA PID DEV
 - 37.20 MEIA INCTIME
 - 37.21 MEIA CAL TIME
 - 37.26 PID GAIN
 - 37.27 PID INTEGRAL
 - 37.29 PID BIAS

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

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

- 9. (Cont.)
 - c. To edit the circled values into your new System Module Version 6.0:

```
Press [SYSTEM]
[FILES]
[37.1]
[DISPLAY]
Using the numeric keypad, enter the circled value for parameter 37.1.
[STORE]
[EXIT]
[EXIT]
```

d. If you are currently using System Module Version 2.0 or 3.0, repeat for parameters 37.2, 37.12, 37.16, 37.18, 37.20, 37.21, 37.26, 37.27, and 37.29. Edit only these parameters in this file.

If you are currently using System Module Version 5.0, this must also be repeated for parameters 37.2, 37.12, 37.15, 37.16, 37.18, 37.20, 37.21, 37.26, 37.27, and 37.29. Editing other parameters in this file may interfere with system operation.

e. To confirm that the circled values have been edited correctly, print System File 37 and check against your circled file printout.

```
Press [SYSTEM]
[FILES]
[37]
[PRINT]
```

10. Refer to the printout for System File 38: PHOTO PARAMETERS from your current System Module (refer to Step 1). Circle the printed values corresponding to the parameters listed below:

38.12 MEIA STD M 38.25 MEIA LMP REF#

10. (Cont.)

To edit the circled values into your new System Module Version 6.0:

```
Press [SYSTEM]
[FILES]
[38.12]
[DISPLAY]
Using the numeric keypad, enter the circled value for parameter 38.12.
[STORE]
[EXIT]
[EXIT]
```

Repeat for parameter 38.25. **Edit only these two parameters in this file.** Editing other parameters in this file may interfere with system operation.

To confirm that the circled values have been edited correctly, print System File 38 and check against your circled file printout.

Press [SYSTEM] [FILES] [38] [PRINT]

11. To store the newly edited parameters, turn your IMx System power **OFF**, wait 10 seconds then turn the power **ON** again. This procedure will reinitialize the parameters in memory.

Installation Procedure

12. If you are using the Carousel ID option, label each IMx SELECT™ MEIA or FPIA Carousel with a Carousel ID Bar Code Label.

To install a Carousel ID Bar Code Label on each MEIA or IMx SELECT Carousel:

a. Peel the desired red carousel bar code label from the sheet of Carousel ID Bar Code Labels (No. 4A31-01) included in this enhancement kit.

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b. Carefully affix the label onto the raised frame area of the MEIA or IMx SELECT Carousel. Ensure that the label is flat and smooth.

12. (Cont.)

To install a Carousel ID Bar Code Label on an FPIA Carousel:

- a. Spread the sides of the FPIA Carousel ID Holder (No. 4A35-01, included in this enhancement kit) and slide it onto the FPIA Carousel into the blank space between carousel positions 1 and 20.
- b. Push the carousel ID holder until it clicks into position aligned with the raised frame area.
- c. Peel the desired carousel bar code label from the sheet of Carousel ID Bar Code Labels (No. 4A31-01, included in this enhancement kit).
- d. Carefully affix the bar code label onto the carousel ID holder. Ensure that the label is flat and smooth.

NOTE: If a number or bar code label is already present on a carousel, remove it completely before installing another carousel ID bar code label. To remove the label, loosen one corner of the label and pull up. Excess label adhesive should be removed from the carousel with 95% ethanol. **Do not** use other solvents.

Installation Procedure

13. To complete the installation of your IMx System Software Module Version 6.0, perform all of the System Calibration and System Check procedures shown below.

NOTE: To ensure temperature equilibration, your IMx system must be powered up for at least 45 minutes prior to beginning System Calibration and System Check procedures. Turning the power off for 10 seconds in Step 11 does not affect the temperature equilibration.

Perform each procedure in the order listed. As you complete each procedure, check the box to the left. Refer to your Version 6.0 IMx System Operation Manual for a detailed description of the subsections highlighted below.

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Perform Steps 1 through 10 below. If you are only running FPIA Assays, perform Steps 1, 3, 4, 5, 9, and 10 below.

<u>PROCEDURE</u>	MANUAL SUBSECTION	
Step 1 Perform Diluent Buffer Replacement Procedure	Component Replacement	
☐ Step 2 Perform an MEIA Carousel Calibration	As Required Maintenance	
☐ Step 3 Perform a Boom Calibration.	As Required Maintenance	
If you are running FPIA Assays, be sure to include the FPIA	sample cartridge portion of the procedure.	
If you are running IMx SELECT™ Assays, be sure to perform	m the IMx SELECT portion of the Boom Cal procedure.	
☐ Step 4 Perform Daily Maintenance.	Daily Maintenance	
NOTE: Performing the TEAH probe cleaning procedure is now part of Daily Maintenance.		
☐ Step 5 Perform a Dispense System Check.	Monthly Maintenance	
☐ Step 6 Perform a IMx SELECT Temperature Calibration, only if you are running IMx SELECT Assays.	As Required Maintenance	
NOTE: If you are performing both an MEIA and a IMx SELECT Temperature Calibration on the same day, you must do the IMx SELECT Temperature Calibration first.		
☐ Step 7 Perform an MEIA Temperature Calibration.	As Required Maintenance	

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As Required Maintenance

13. (Cont.)

		PROCEDURE	MANUAL SUBSECTION
□ s	tep 9	Perform an FPIA Temperature Calibration, only if you are running FPIA Assays.	As Required Maintenance
□ s	tep 10	Perform an FPIA Photo Calibration, only if you are running FPIA Assays.	As Required Maintenance
	When all required calibrations and checks have been completed:		
	Print System Files 1, 2, 3, 4, 37, and 38.		
		the copies of the system file printouts in the inside reference.	e pocket of your Version 6.0 IMx System Operation Manual for
□ 1·	14. You are now ready to run assays once the specific IMx SELECT™ or IMx Assay Module is installed. When each IMx SELECT, MEIA or FPIA assay is run for the first time using IMx System software Module Version 6.0, run all levels of controls on the carousel. Check that each control is within its specified control range. If any control is outside its specified range, recalibrate the assay. Refer to the assay package insert for assay-specific information.		
IV.	Completion of TSB		
	Mark o	ff # 40 on the TSB sticker.	
_			

Hand the Customer the Features section of the TSB Modification Kit and explain to them the changes that have occurred with this upgrade. Carefully explain the changes made to the Dilution protocol as specified in the letter you received from the CSC Office. The dilution protocol can be found in the Operator's manual in Section 5b-17 for MEIA and 5c-31 for IMx SELECT. Failure to inform the Customer may cause them to receive incorrect results from the Dilution protocol. See attached letter sent out to all FSE's on 4/12/93 on next page. A customer letter with the same information was sent the week of 4/12/93 to all USA customers. Each geographical area is responsible for distributing this customer letter to all IMx® Customers.

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When closing out the call in FieldWatch, write in the comments section: "Customer given 'Features' of Rev. 6.0 and Dil/Alt changes discussed."

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ABBOTT LABORATORIES
DIAGNOSTICS DIVISION
INTEROFFICE CORRESPONDENCE
X-SYSTEMS CUSTOMER SUPPORT CENTER

FROM: Kevin Comstock DEPT: 9034 EXT. 7669

DATE: 4/11/93 M.S. 2-29

TO: All Field Service Engineers

cc: Bernadette Brand 36T AP34

Joe Coffey 2LB AP6C 5 Stephanie Douglas 926 AP6C Cindy Hofen 2-29 Hal Hopkins 9BA AP1A

RE: Important Revision 5.0/6.0 Information for all Field Service Engineers

This is an important reminder that the IMx System procedures, as described in the IMx System Operation manual, must be followed to ensure accurate and reliable performance from IMx instruments.

Beginning with IMx System Software Ver. 5.0, a change was made to the Dilution/Alternate (DIL/ALT) protocol. The Dil/ALT protocol now prompts for the total number of reaction cells to be used for the Dil/ALT protocol, rather than the number of undiluted positions. A <u>change</u> to the keystrokes has also occurred on Dil/ALT protocol. To properly initiate a Dil/ALT run, the following keystrokes must be used:

Assay

XX (Assay Number)

Other

Dil-ALT

Protocol # (1-5)

Store

#Rxn cells to use Dil-ALT

Store

Run

The customer must press Store and Run to properly initiate a Dil/ALT run. Failure to perform the above steps, as written,

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will cause incorrect dilution of samples and incorrect results.

After upgrading a customer to Rev. 6.0 please proactively give the "Features" of the upgrade, found in the installation instructions envelope, to the customer and highlight the changes that have occurred with Dil/Alt protocol as well as the other changes.

When a call in FieldWatch is entered to document the upgrade, the following statement must be included, "Customer given "Features" of Rev. 6.0 and Dil/Alt changes discussed."

TSB #40 will be re-written to include the added procedure of giving the "Features" to the customer and discussing the changes to the Dil/Alt protocol.

Customers that have upgraded to Rev 6.0 software prior to April 9th will be contacted by CSC to discuss the features of the new software.

A separate customer letter will be mailed to all U.S. customers highlighting the correct procedure for the Dil/Alt protocol for Ver. 5.0 or Ver. 6.0 IMx system software.

END OF DOCUMENT



ABBOTT ADD

TECHNICAL SERVICE BULLETIN

SUBJECT: Release of System Software Version 6.0		TSB#: 60-040
ORIGINATOR:		PRODUCT: IMx® (60)
APPROVED:		REF. ECN:
IMPLEMENTATION: Immediate Next Service Call Next Failure Optional Instruments Requiring Modification: n/a	TSB Part/Kit #: TSB Effectivity/ Part(s) Availibility: OBSOLETE	Upgrade Time: Validation Time: Total Mod. Time:
NOTE The instrument must be at TS n/a	B Level <u>n/a</u> prior to performing this TS	В.



TECHNICAL SERVICE BULLETIN

Refurbed FPIA Optics that do not meet	VDE Certification	15B#: 60-039
ORIGINATOR: Louis Valich		PRODUCT: IMx® (60)
APPROVED: Bob Schabel - 1/15/93 (si	gnature on file)	REF. ECN: N/A
IMPLEMENTATION: Immediate Next Service Call Next Failure Optional	TSB Part/Kit #: <u>M/A</u> TSB Effectivity/ Part(s) Availibility: <u>27-NOV-92</u>	Upgrade Time: 15 min. Validation Time: 65 min. Total Mod. Time: 1 hr. 20 min.
Instruments Requiring Modification: S/N 20706 thru 24600		

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I. Distribution: Domestic and International

II. General

A. Purpose

THIS TSB ONLY AFFECTS S/N 20706 AND ABOVE THAT HAVE HAD A REFURBED FPIA OPTICS INSTALLED.

This TSB is to inform the field that since releasing VDE Certified IMx® analyzers, refurbished FPIA Optics assemblies (3-31008-02) have not been meeting VDE Certification. All new build FPIA Optics meet VDE Certification. The PMT connector on the refurbed optics has not had heat shrink tubing or clear tubing placed over the violet and black high voltage wires. This does not meet VDE standards. See Figure 1 for reference.

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In the United States and the areas of the world where VDE is not required, FSE's must remove the VDE sticker from the back of all VDE Certified instruments which have had refurbed FPIA Optics installed. See illustration of VDE label below.

In Europe, any refurbed optics not having the clear tubing or heat shrink tubing that was put in a VDE Certified instrument must be removed and have a VDE Certified optics installed. A decision has been made to have all FSE's and stock locations in Europe send back all FPIA optics assemblies (c/n 3-31008-02) that do not meet VDE Certification back through the normal parts return protocol and we will send VDE Certified optics to replace them. This will allow Europe to stock only VDE optics and makes it less likely that a VDE instrument will be decertified.



A. Purpose (Continued)

All VDE parts will have a small VDE label attached to the outer shipping box. In addition, a small VDE label will be affixed to the part. This will allow FSE's to visually see that the part is VDE approved. There are some parts such as the Liquid Heater and FPIA Optics that have not had a Catalog number change so there is no way to know if the part is VDE approved or not. This VDE sticker will let the FSE be able to tell the difference.

B. Administrative notes:

United States FSE's only:

This TSB should be closed out in FieldWatch as follows:

SC = 03 TC = 39 RC = 93

C. Time Required: 15 minutes

D. Tools Required: Standard FSE Tool Kit

E. Parts:

United States and Non-European International sites:

Not Applicable

International:

Europe only: European FSE spare parts kits and depot stock locations should be cleared of non-VDE FPIA optics (

3-31008-02). Physically inspect all -02 Optics per Figure 1. If no tubing or Heat Shrink is present, then

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

these optics should be returned via your normal parts return channels. All returned optics should have a returned goods tag attached with the following statement in the remarks section:

"Returned per TSB 60-039 - non-VDE FPIA Optics"

European service sites should forecast parts required to replace all FSE kits and depot locations through their normal channel.

III. Procedure

Print out System Files 1, 2, 3, 4, 37 and 38. This is for precautionary reasons, just in case you cause a FAC_SET while performing this TSB.

Turn power off to the instrument.

Remove the System and Assay software modules.

Remove the Enclosure assembly.

Remove the black Electronics Cover sitting over the FPIA Optics assembly.

Verify that the PMT connector wires (violet and black) have a clear tubing or black heat shrink tubing covering them (See Figure 1 for reference). If they do not, perform the following:

III. Procedure (Continued)

Non-European sites - Reinstall the Electronic Cover, Enclosure assembly, System and Assay Modules and power up the instrument. Remove the VDE sticker attached to the back of the Enclosure assembly (see illustration on page 1 of this TSB to identify the VDE sticker). Perform the Total Service Call protocol as defined by your Field Service Organization. Mark off # 39 on the TSB sticker. This TSB is completed.

European sites - Replace the FPIA Optics assembly with one that has the clear tubing or heat shrink applied to the pmt wiring. Attach a returned goods tag to the optics and fill it out completely. In the remarks section put: "Replaced per TSB 60-039 non-VDE FPIA Optics"

Reinstall the Electronics Cover, Enclosure assembly, System and Assay Software Modules and power up the instrument. Send back all non-VDE FPIA Optics via the normal return parts protocol.

IV. Checkout procedure

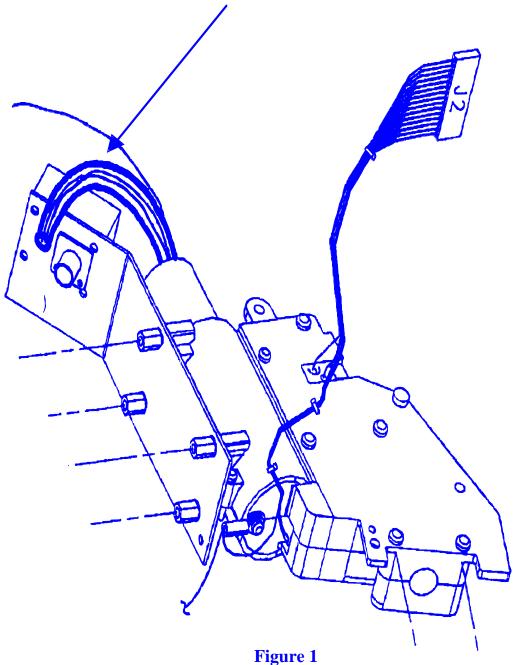
If the FPIA Optics has been replaced, perform the following:

FPIA Carousel Calibration FPIA Temperature Calibration FPIA Photo Calibration Total Service Call Protocol

V. Completion of TSB

Mark off # 39 on the TSB sticker.

Clear tubing or black heatshrink must enclose the violet and black high voltage wires to conform to VDE requirements.



FPIA Optics assembly showing VDE configured PMT high voltage wire shielding

END OF DOCUMENT



Louis Valich

TECHNICAL SERVICE BULLETIN

IMx® (60)

SUBJECT:	TSB#: 60-038
Non-VDE Motor Driver PCB's shipped in new Build IMx® instruments	
ORIGINATOR:	PRODUCT:

APPROVED: Bob Schabel - 1/15/93 (signature on file) REF. ECN: N/A

IMPLEMENTATION:	TSB Part/Kit #: 3-04915-02	Upgrade Time: 15 min.
Immediate	TSB Effectivity/	Validation Time: 15 min.
Next Service Call	Part(s) Availibility: <u>N/A</u>	validation Time. <u>10 mm.</u>
Next Failure		Total Mod. Time: 30 min.
Optional		
Instruments Requiring Modification: S/N See list attached with this TSB		

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Below is the list of IMx® Serial Numbers that may have the Non-VDE certified Motor Dr. PCB's installed. I have also included the country that they were shipped to:

23769 USA	23770 USA	23771 USA	23772 USA	23774 USA	23777 USA
23779 USA	23780 USA	23781 USA	23782 USA	23783 USA	23784 USA
23785 USA	23786 USA	23787 USA	23788 USA	23789 USA	23790 USA
23791 USA	23792 USA	23793 USA	23794 USA	23795 USA	23796 USA
23797 USA	23798 USA	23799 USA	23800 USA	23801 USA	23802 USA
23803 USA	23804 USA	23805 USA	23806 USA	23807 USA	23808 USA
23809 USA	23810 USA	23811 USA	23812 USA	23813 USA	23814 USA

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^{**}NOTE** The instrument must be at TSB Level $\ \underline{34}$ prior to performing this TSB.

23815 USA	23817 USA	23818 USA	23819 USA	23820 USA	23821 USA
23822 USA	23823 USA	23824 USA	23825 USA	23826 USA	23827 USA
23828 USA	23829 USA	23830 USA	23831 USA	23832 USA	23833 USA
23834 USA	23835 USA	23836 USA	23837 USA	23838 USA	23841 USA
23842 USA	23845 USA	23848 USA	23849 USA	23850 USA	23852 USA
23853 USA	23856 USA	23857 USA	23859 USA	23860 USA	23861 USA
23862 USA	23864 USA	23868 USA	23871 USA	23872 USA	23873 USA
23875 USA	23879 USA	23880 USA	23881 USA	23884 USA	

23773 DOMINICAN REPUBLIC

23775 CANADA

23778 CANADA

23776 BRAZIL

. Distribution: Domestic and International

II. General

A. Purpose

This TSB is to inform the field that several Motor Driver PCB's that do not meet VDE configuration have been installed in new instruments. These PCB's were inadvertently upgraded and marked as -110 PCB's. Due to the etch spacing, they do not meet VDE requirements. A list of instrument serial numbers is provided that may contain one of these PCB's. There were 14 of these boards upgraded. The factory caught 6 of them and removed them from instruments. That leaves 8 PCB's unaccounted for.

A diagram, Figure 1, shows the artwork placement of the VDE certified PCB's. Artwork in any other location means that the PCB is not VDE certified. Figure 2 shows a non-VDE PCB artwork placement. Both figures reference the Solder side of the PCB.

None of these instruments were shipped to Europe. The majority of them were shipped to the United States with one to the Dominican Republic, one to Brazil and two to Canada.

We would like to have these PCB's removed from the instrument and replaced with a Motor Driver PCB from your parts kits. Tag these PCB's with a returned goods tag and put in the remarks section:

"REPLACED PER TSB 60-038, Non-VDE certified Motor Driver PCB".

We want these PCB's removed and returned because they have been marked incorrectly and we want to be assured that when they come back in house, we can identify them easily and correctly mark them.

B. Administrative notes:

United States FSE's only:

This TSB should be closed out in FieldWatch as follows:

$$SC = 03$$
 $TC = 38RC = 93$

C. Time Required: 30 minutes

D. Tools Required: Standard FSE Tool Kit

E. Parts:

United States: Use 3-04915-01 from spare parts kit

International: Europe - N/A

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Outside of Europe - use 3-04915-01 or 3-04915-02 from spare parts kit

All Motor Driver PCB's replaced should be sent back through your normal parts return protocol. Tag the PCB's with a returned goods tag stating in the Remarks section "Replaced per TSB 60-038, Non-VDE certified Motor Driver PCB".

III. Procedure

Print out System Files 1, 2, 3, 4, 37, and 38. This is a precautionary step so that if you generate a FAC_SET, you can recover quickly.

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

III. Procedure (Cont.)

Power the IMx® analyzer off.

Remove the Assay and System Modules.

Remove the Enclosure Assembly.

Note: Remember to follow proper grounding procedures to prevent static discharge and possible damage to the circuit boards. Handle the circuit boards as little as possible and the the boards in the anti static bag until ready to install into the instrument.

From the rear of the instrument, locate the two 60 pin black cables that enter the top of the I/O PCB from the Motor Driver PCB and the Analog PCB. Disconnect the cables from the Motor Driver and Analog PCB's.

Locate the two captive post screws that hold the cardcage in place and unscrew them from the baseplate.

Pull the cardcage back enough to expose the two cables that enter the I/O PCB from the Display/Keypad assembly and disconnect them from the I/O PCB.

Allow the cardcage to lean back the full length of the restraining cable to provide access to the connectors at the bottom of the Motor Driver PCB.

Remove all cables from the Motor Driver PCB and remove the PCB from the instrument.

Look at the solder side of the Motor Driver PCB and locate the artwork printing, referencing Figure 1 for the correct location and Figure 2 for non-VDE configuration.

If the artwork is in the same location as Figure 1, you can reinstall that Motor Driver PCB.

If the artwork is in the same location as Figure 2, replace the Motor Driver PCB with the one from your parts kit. If you installed a 3-04915-01 into the instrument, you will need to remove the VDE sticker from the rear of the Enclosure (see illustration below). If you installed a 3-04915-02 into the instrument, the VDE sticker can remain on the Enclosure.



VDE label located on 3-04915-02 Motor Driver PCB.



VDE Sticker located on rear of instrument.

NOTE: A -01 MOTOR DRIVER PCB WILL NOT HAVE THE CIRCULAR VDE LABEL AFFIXED TO THE PCB.

Reconnect all cabling back up to the Motor Driver PCB. Reconnect all cabling back up to the cardcage assembly.

Lift the cardcage back to it's upright position and secure in place with the two captive post screws.

Reinstall the Enclosure assembly, insuring that all four corners are latched properly.

Reinstall the System and Assay Modules, insuring that they are seated properly.

Power the instrument back on. It will go through its power on diagnostics and then come up to the READY menu.

IV. Checkout procedure

Get into the Temperature Hand Controls by pressing MONITOR/HND_CTRL/TEMP. The display looks like this:

BUFFER TEMP 35.0.C 2.493V ON NEXT HEAT_OFF HEAT_ON EXIT

Observe that the voltage displayed is not at 0.0V or 5.0V. The 0.0V indicates that the thermistor cable is shorted. The 5.0V indicates that the thermistor cable is open. If either is showing, you will have to check the cabling going to the Motor Driver PCB.

Press NEXT and scroll through all the heaters and verify the voltages. We are only interested in the BUFFER TEMP, AIR TEMP, OPTICS TEMP, REMOTE TEMP and REAGENT BLOCK. Disregard all of the other temperatures since they are not used.

Perform the Total Service Call procedure. Insure that the Dispense Check and both MEIA Temperature check and FPIA temperature checks pass.

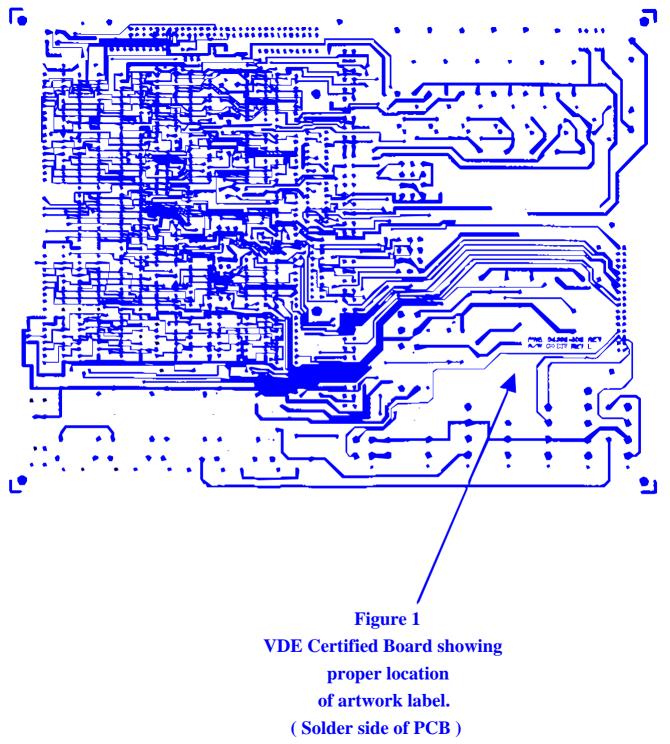
V. Completion of TSB

Mark off # 38 on the TSB sticker.

Send a confirmation on all Motor Driver PCB's replaced due to this TSB to the IMx CSE group in Irving, Texas. This can be done by phone (if in the USA, 1-800-527-1869, enter 85 for IMx CSE group), by FAX (for international sites 214-518-7781), or by mail to the following address:

Abbott Laboratories P.O. Box 152020 Irving, Texas 75015-2020 Attn: IMx CSE Group M.S. 2-26

It is important that the CSE group track all of these boards replaced.



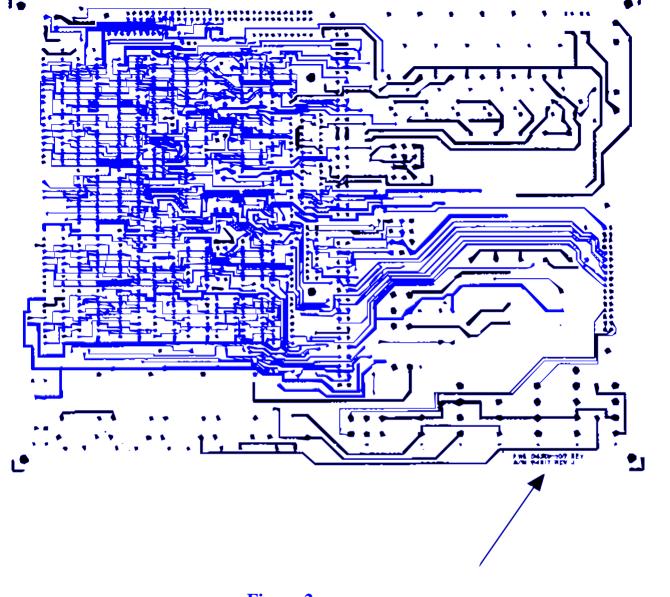


Figure 2
Non-VDE configuration
showing the placement of
the artwork label in the lower
right corner.

(Solder side of PCB)



TECHNICAL SERVICE BULLETIN

SUBJECT: Improved FPIA Lamp Socket		TSB#: 60-037B	
ORIGINATOR: Gary Tomkins		PRODUCT: IMx® (60)	
APPROVED: Bob Schabel - 8/3/93		REF. ECN: IMx-2449	
IMPLEMENTATION:	TSB Part/Kit #: 3-31053-01	Upgrade Time: 6 min.	_

Immediate Next Service Call Next Failure Optional	TSB Effectivity/ Part(s) Availibility: 01-FEB-93	Validation Time: <u>60 min.</u> Total Mod. Time: <u>66 min.</u>
Instruments Requiring Modification: S/N 23299 & Below, Next Failure		

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

TDx and IMx are registered trademarks of Abbott Laboratories.

I. Distribution: Worldwide

II. General:

A. Purpose:

A strain relief has been added to the lamp socket connector to relieve stress on the wires when the lamp is being changed. This will reduce wire fatigue and help prevent lamp out errors.

 \longrightarrow

This TSB supersedes TSB 60-037A. The revision contains additional information under Section B. Administrative Notes.

B. Administrative Notes:

U.S.A. FSEs ONLY:

This TSB should be closed out in FieldWatch as follows:

SC=03

TC=37

RC=93

6 minutes

C. Time Required:

Modification time:

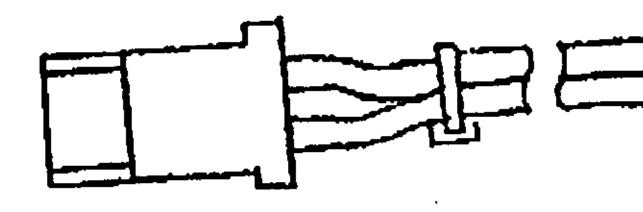
Validation time: 60

60 minutes (Photo Check)

D. Tools Required: Standard FSE Tool Kit

E. Part(s) Required for Modification:

1 each - Assembly, Lamp Socket C/N 3-31053-01 (C/N = Catalog Number)



RETAINING WIRE

U.S.A.:

The new Lamp Socket Assembly will replace the old one in the X SYSTEMS™ Common Parts Kit. Three (3) each of the C/N 3-31053-01 will be sent to each FSE through the TDx® Program for performing this TSB. Refer to TDx TSB 09-037B.

International:

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

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

Japan and Pacific Rim: The cut-in S/N for AKL manufactured IMx® Analyzers is S/N K1461.

III. Procedure:

After repairs of the current service call are made:

- 1. Print System files 1, 2, 3, 4, 37, and 38.
- 2. Turn IMx System power OFF.
- 3. Remove the Electronics Cover.
- 4. Remove FPIA Lamp Housing Cover and lamp.

NOTE: USE CAUTION AS LAMP MAY BE HOT!

- 5. Disconnect old Lamp Socket Assembly (cable).
- 6. Connect new, improved Lamp Socket Assembly (3-31053-01).
- 7. Reinstall lamp and Lamp Housing Cover.
- 8. Install Electronics Cover.
- 9. Turn instrument power ON.
- 10. Proceed to the FPIA Optics menu in hand controls and verify that R= is 50K +/- SK.
- 11. Perform FPIA Photo Check.

When the modification is complete, remember to mark off number 37 on the TSB sticker.

END OF DOCUMENT



ABBOTT ADD

TECHNICAL SERVICE BULLETIN

SUBJECT: Improved FPIA Lamp Socket Assembly		TSB#: 60-037
ORIGINATOR:		PRODUCT: IMx® (60)
APPROVED:		REF. ECN:
IMPLEMENTATION: Immediate Next Service Call Next Failure Optional	TSB Part/Kit #: TSB Effectivity/ Part(s) Availibility: OBSOLETE	Upgrade Time: Validation Time: Total Mod. Time:
Instruments Requiring Modification: n/a		



ABBOTT ADD

TECHNICAL SERVICE BULLETIN

SUBJECT: TSB#: 60-036

FPIA Lamp Housing Gasket

ORIGINATOR: Gary Tompkins
APPROVED: Mark Slater 12/14/95

PRODUCT: IMx® (60)
REF. ECO:

Trademark: IMx is a registered trademark of Abbott Laboratories.

IMPLEMENTATION:

Immediate

Next Service Call

Next Failure

Optional

Instruments Requiring
Modification:

S/N 21449 and below

TSB Part/Kit #:

TSB Effectivity/
Part(s) Availability: 14-DEC-95

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

Upgrade Time: 0.5 Hrs.

Validation Time: 1.5 Hrs.

Total Mod. Time: 2.0 Hrs.

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

I. DISTRIBUTION:

Worldwide

II. PURPOSE:

To reduce dust collection in the Lamp Housing aperture area.

III. ADMINISTRATIVE NOTES:

DOMESTIC: When the modification is done, the service order should be closed out as TSB 60-036 completed and the

call coded as:

SC (03) MODIFICATION

TC (36) TSB 36

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

RC (93) TSB INSTALLED

INTERNATIONAL: The International Service Managers will set up the protocol to follow for this TSB.

IV. SPECIAL TOOLS:

Standard FSE Tool Kit

V. PARTS:

REPLACED PARTS:

N/A

COMPATIBILITY:

N/A

VI. PROCEDURE:

MODIFICATION STEPS:

NOTE: Due to variations in the thickness of the lenses and gaskets, it may be difficult to perform the modification. It may be necessary to replace the entire FPIA Lamp Housing assembly (3-31054-01) which already has the gaskets installed.

- 1. Turn the IMx® Analyzer OFF.
- 2. Open the Access Door and remove the Electronics Shroud Cover.
- 3. Remove the FPIA Lamp Housing Cover, Lamp (assure that it is not HOT) and Lamp Socket Assembly.
- 4. Remove the four screws which secure the Lamp Housing to the baseplate and remove the Lamp Housing.
- 5. Remove the lens retainer on the bottom of the Lamp Housing and carefully remove the two lenses being sure to note their orientation.
- 6. Clean the two lenses with lens paper.
- 7. Reinstall the two lenses and one or two gaskets (3-45875-01) as required to create an airtight fit between the body of the Lamp Housing and the Heat Reflector Lens. (See Figure 1.) If the lenses cannot be reinstalled with at least one gasket in place because it is too tight, try other gasket and lens combinations using service kit parts. If still unable to find a set that fits, order and replace the entire Lamp Housing Assembly, 3-31054-01, which will have the gasket and lenses already installed.
- 8. Replace the Lamp Filter Retainer and reinstall the Lamp Housing, Lamp Socket Assembly, Lamp and Electronics Shroud Cover.

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

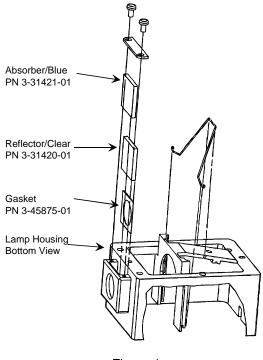


Figure 1

CHECKOUT:

1. Turn system power ON. Turn the FPIA Lamp on using the following procedure:

Press MONITOR

HND_CTRL

FPIA

PROCEED (if carousel was not in place)

LAMP (to turn the lamp ON)

- 2. Using a DVM, verify the presence of 7.5 +/- 1.0 VDC across the Lamp Socket connector.
- 3. Perform a Photo Check. (If the Photo Check fails, perform a Photo Calibration.)
- 4. Complete the Total Service Call (including running assay controls.)

MODIFICATION CONTROL STICKER UPDATE:

1. Mark off TSB 36 on the mod control sticker.

END OF DOCUMENT

END OF DOCUMENT

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



SUBJECT:

TECHNICAL SERVICE BULLETIN

TSB#: 60-035

Using Non-VDE Parts in VDE Certified in	IIX'S	
ORIGINATOR: Lou Valich	PRODUCT: IMx® (60)	
APPROVED: Lou Valich (signature on f	ile)	REF. ECN: IMx-2287
IMPLEMENTATION: Immediate Next Service Call Next Failure Optional	TSB Part/Kit #: See Table 1 TSB Effectivity/ Part(s) Availibility: 15-MAY-92	Upgrade Time: 0 Validation Time: 0 Total Mod. Time: 0
Instruments Requiring Modification: S/N 20706 & above have mod installed.		

With the release of TSB 60-034, VDE Certified IMx's, it was imperative that a plan be developed for servicing these IMx's in the United States. It is too costly to throw away all non-VDE parts and use only certified ones. Since VDE is an European International organization, it was determined that only European International Service sites will be issued VDE Certified parts.

The United States and the rest of the world will continue servicing these IMx's with non-VDE parts. When a non-VDE part (See Table 1 for a list of all VDE Certified Parts) is installed in a VDE Certified IMx (S/N 20706 and above) the FSE must remove the VDE sticker affixed to the back of the IMx. See Figure 1 for label. They must also mark off number 35 on the TSB sticker. At this point, the IMx can not be recertified and will have to remain a non-VDE Certified IMx.

^{**}NOTE** The instrument must be at TSB Level 34 prior to performing this TSB.

In Europe, if a non-VDE part is installed in a VDE Certified IMx, the VDE sticker must be removed and number 35 marked off on the TSB sticker. Since the VDE label can only be affixed at the manufacturing site, these IMx's will have to remain non-VDE Certified. Therefore, it is imperative that when servicing VDE Certified IMx's, use only VDE Certified parts.

There will be two Enclosure Assemblies. The 3-04389-01 is for use on all non-VDE Certified IMx's. The 3-04389-02 is for use on VDE Certified IMx's. The only difference is that the -02 Enclosure has the VDE sticker affixed to it. If the Enclosure requiresreplacement, you will have to note what type of IMx you are working on and order the appropriate one.

It is important to Abbott that whenever possible, especially in Europe, service non-VDE IMx's with non-VDE parts.

When servicing VDE Certified IMx's, use only those parts listed in Table 1 under VDE Catalog Number and/or New Part Number. Many of the parts listed in Table 1 under Non-VDE are the same as VDE parts. An example would be the MEIA Lamp Power Supply. The only difference is that the VDE part has sticker p/n 45821-101 applied to it. The same goes for the PMT High Voltage Power Supply. To make these two parts comply with VDE, just add the sticker (45821-101) to them. The only difference in the Enclosure assembly is the VDE sticker applied to the -02 Enclosure assembly.

Some of the VDE Certified parts have been in use for some time. These include the Card Cage assembly and the Air Fan & Gasket.

A brief description of what was modified to the parts to make them conform to VDE is included in Table 1. This may help you recognize the physical differences easier. All VDE parts will be packaged with a sticker that has VDE on it. The outside box, the wrapper for the part and the part itself will be marked with this sticker. This will make it easier for you to determine just from looking at the packing material if you have a VDE or Non-VDE part.

Table 1 IMx Field Service Parts affected by VDE

Non-VDE Catalog Number and/or Old Part Number	VDE Catalog Number and/or New Part Number	Description of what was modified to conform to VDE Certification
3-41606-01	3-41606-01	Liquid Heater & Bracket (heat shrink added to wires going into connector)
3-31358-02	3-31358-02	Air Fan & Gasket (same one used for TSB60- 20B)
3-04760-01	3-04760-01	Card Cage (new cable for fan ass'y; has been implemented for some time)
3-04956-01	3-04956-02	Main Power Supply (add fuse for neutral line)
3-04915-01	3-04915-02	Motor Driver PCB (etching spacing)
3-04875-01	3-04875-01	Ground Cable (new crimp contacts)
04507-105	04507-106	Sheet Metal Subassembly (add mounting holes for right cover; move hole for interconnect tubing higher to facilitate easier changing of tubing)
N/A	45802-101***	VDE Cover, right (protect customer from HV P/S terminals and Lamp P/S)
N/A	45803-101***	VDE Cover, left (protect customer from 115 vac on reagent heater)
3-04389-01	3-04389-02	Enclosure Assembly (with VDE Label attached)
3-31009-01	3-31009-01	PMT HV Power Supply (with CAUTION Label p/n 45821-101 applied)
3-04708-01	3-04708-01	MEIA Lamp Power Supply (with CAUTION Label p/n 45821-101 applied)

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

* * * new parts required for VDE Certification



Figure 1
VDE Certification Label

END OF DOCUMENT



SUBJECT:

ABBOTT ADD

TECHNICAL SERVICE BULLETIN

TSB#: 60-034

Release of VDE Certified livix Affaiyzers		
ORIGINATOR: Lou Valich		PRODUCT: IMx® (60)
APPROVED: Louis Valich (signature or	n file)	REF. ECN: IMx - 2287
IMPLEMENTATION: Immediate Next Service Call Next Failure Optional	TSB Part/Kit #: See Table 1 TSB Effectivity/ Part(s) Availibility: 18-MAY-92	Upgrade Time: 0.0 HRS Validation Time: 0.0 HRS Total Mod. Time:
Instruments Requiring Modification: S/N 20706 & above have mod installed		
NOTE The instrument must be at TS	B Level 20706 prior to performing this	TSB

This TSB is an informational TSB only. No modification to the IMx is necessary since IMx's below S/N 20706 will not be upgraded to meet VDE Certification.

- I. Distribution: Domestic and International FSE's
- II. General

A. Purpose

This TSB is to inform the FSE that Abbott Diagnostics is releasing a VDE Certified IMx Analyzer. VDE is a safety organization for the European Community, somewhat like UL is for the United States. **This certification will affect how International Service sites service the IMx in Europe.** This will not affect how FSE's in the rest of the world repair IMx's.

All new build IMx's above S/N <u>20706</u> will be VDE certified. This entails changes required by VDE as listed in Table 1. A brief description of changes is included. A VDE label will be affixed to the back of the IMx denoting certification. See Figure 1 for label.

Refurbished IMx instruments <u>will not</u> be reconfigured to VDE specifications. This may change in the future. An assumption being made is that all IMx's currently at customer sites, R&D labs and Sales Demos will not be required to update to VDE Certification.

VDE Certification required TSB status, rather than an ISA, since we want the ability to track these instruments for MTBSC reasons and to have International sites be able to recognize the serial number effectivity of these instruments.

B: Parts Required: See Table 1 on Page 3.

United States:

United States FSE Spare Parts Kits will not be upgraded with IMx VDE Certified parts unless VDE Certified parts are the only ones available.

International:

International FSE Spare Parts Kits should be upgraded with VDE Certified parts to facilitate servicing of VDE Certified IMx instruments. Service sites should forecast parts requirements through their normal channels.

Non-VDE IMx instruments can be serviced with either VDE Certified parts or Non-VDE parts. Whenever possible, FSE's WorldWide should continue to repair Non-VDE IMx instruments with Non-VDE parts.

III. Procedure

All VDE Certified parts will be labelled with a small sticker with the word VDE on the outside of the packing box, on the inside on the wrapping, and on the part itself.

There will be no program to upgrade current Customer/Sales/R&D Non-VDE IMx's to VDE Certification levels. VDE requires that their sticker be installed only at the manufacturing facility that it has approved.

The Enclosure Assembly now has two part numbers. The 3-04389-01 is for all non-VDE IMx's. The 3-04389-02 is for VDE Certified IMx's. The only difference is that the -02 has the VDE sticker. Be careful of what Enclosure you order.

The only difference between VDE Certified PMT High Voltage Power Supply and MEIA Lamp Power Supply is the sticker applied to the outside to warn of danger. See Table 1 on page 3 for the part number of the sticker.

You will note that some of the Non-VDE parts have the same part number as the VDECertified parts. That is because we have been using these parts for some time in anticipation of VDE Certification.

IMPORTANT NOTE:

If you put non-VDE parts in a VDE Certified IMx, you will need to remove the VDE sticker on the back of the IMx. At this point the IMx is no longer VDE Certified and can not be upgraded again. This is because VDE requires that their sticker be installed only at the manufacturing facility that it has approved.

Table 1
IMx Field Service Parts affected by VDE

Non-VDE Catalog Number and/or Old Part Number	VDE Catalog Number and/or New Part Number	Description of what was modified to conform to VDE Certification
3-41606-01	3-41606-01	Liquid Heater & Bracket (heat shrink added to wires going into connector)
3-31358-02	3-31358-02	Air Fan & Gasket (same one used for TSB60-20B)
3-04760-01	3-04760-01	Card Cage (new cable for fan ass'y; has been implemented for some time)
3-04956-01	3-04956-02	Main Power Supply (add fuse for neutral line)
3-04915-01	3-04915-02	Motor Driver PCB (etching spacing)
3-04875-01	3-04875-01	Ground Cable (new crimp contacts)
04507-105	04507-106	Sheet Metal Subassembly (add mounting holes for right cover; move hole for interconnect tubing higher to facilitate easier changing of tubing)
N/A	45802-101***	VDE Cover, right (protect customer from HV P/S terminals and Lamp P/S)
N/A	45803-101***	VDE Cover, left (protect customer from 115 vac on reagent heater)
3-04389-01	3-04389-02	Enclosure Assembly (with VDE Label attached)
3-31009-01	3-31009-01	PMT HV Power Supply (with CAUTION Label p/n 45821-101 applied)

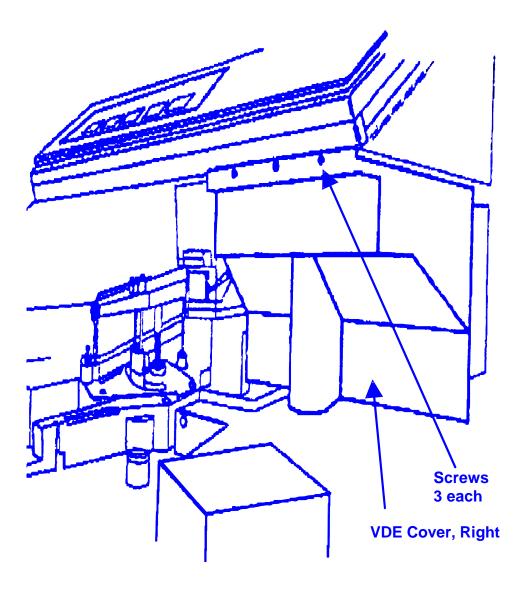
^{**}Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.**

3-04708-01	3-04708-01	MEIA Lamp Power Supply (with CAUTION Label p/n 45821-101 applied)
		p/1143021-101 applied)

* * * new parts required for VDE Certification



Figure 1 VDE Certification Label



Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

END OF DOCUMENT



SUBJECT:

TECHNICAL SERVICE BULLETIN

TSB#: 60-033

Release of IMx System Software Version	5.0	
ORIGINATOR: Fred Schwartz		PRODUCT: IMx® (60)
APPROVED: Lou Valich (signature on f	ile)	REF. ECN: IMx-2219
IMPLEMENTATION: Immediate Next Service Call Next Failure Optional Instruments Requiring Modification:	TSB Part/Kit #: TSB Effectivity/ Part(s) Availibility: 03-DEC-91	Upgrade Time: n/a Validation Time: n/a Total Mod. Time: n/a
Customer purchased option		

I. Distribution: International and Domestic FSEs

II. General

A. Purpose

The purpose of this TSB is to notify the field of the release of IMx System Software Version 5.0. The IMx Version 5.0 System Software will provide the ability to run specific assays up to three at a time, on the same carousel . The option provided to run specific assays on the same carousel is called IMx SELECT.

NOTE: AN INDEX OF THE CONTENTS OF THIS TSB IS ON PAGES 39 & 40.

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

NOTE:

In order to use the IMx System Software Version 5.0 these TSBs will need to be completed :

*TSB 60-020B New Air Heater/Fan Combination
TSB 60-029B "SELECT" Boom arm release
TSB 60-030 PAL change to IMx Memory PCB
TSB 60-032 COM1/COM2 Port Alignment

*REQUIRED ONLY IF PARTS ARE AVAILABLE

B. Administrative Notes

Domestic FSEs Only:

This TSB should be closed out in FieldWatch as the following:

SC=03 TC=33 RC=93

C. Time Required: 4-5 hours

D. Tools Required: Standard FSE Tool Kit

E. Parts:

Domestic:

Each FSE will receive:

IMx System Operation Manual (LN 8376-05)

IMx System Module Version 5.0 (LN 8384-05)

International:

The FSEs should receive the new IMx System Operation Manual and the IMx System Module Version 5.0. Send forecast requirements to Field Service Logistics in Dallas, Attn: Mark Cooney, M.S. 3-1, ext. 6254.

F. Enhancements:

The IMx System Module Version 5.0 Software Enhancement has many new features including the IMx SELECT option. The following pages detail the key features of IMx SELECT and other new IMx System SoftwareVersion 5.0 features.

Refer to the IMx System Operation Manual (List No. 8376-05) for a more complete description of features.

The Operation Manual page number is enclosed in parenthesis following each subsection title.

IMX SELECT ASSAY PROCEDURES

SELECT By-Assay Pipetting Method (5-63)

This pipetting method runs specified assays on specified patient samples.

The patient sample must be pipetted into a separate reaction cell for each assay.

Following the MODE 1 Calibrator the control(s) can be interspersed among the patient samples within an assay group.

The IMx prints an individual test results tape for each assay. The IMx does not print a Patient Summary.

One, two, or three assays can be run at one time.

A dilution protocol can be run when using the By-Assay pipetting method.

IMX SELECT ASSAY PROCEDURES

SELECT By-Panel Pipetting Method (5-76)

This pipetting method runs the same assays on all patient samples in that carousel.

The patient sample is pipetted only once into a reaction cell within the first assay group. The IMx will transfer appropriate amounts of the patient sample to the empty reaction cells to run each assay. The required sample volume is printed on the loadlist printout.

Control(s) must be placed directly after the MODE 1 Calibrator, and before the patient samples within an assay group.

The IMx prints an individual test results tape for each assay, as well as a Patient Summary. The Patient Summary is an additional printout generated when using the By-Panel pipetting method which groups assay results by patient. This printout is not transmitted through the IMx Unidirectional RS232 Interface.

At least two assays must be run at one time.

A dilution protocol cannot be run when using the By-Panel pipetting method.

Patient samples and controls must be run singly. Assay parameter XX.3 SAMPLE REP. can only be set to a value of 1 for each assay.

Loadlist Creation (MEIA: 5-28, SELECT: 5-61, FPIA: 5-102)

The loadlist is a special printout designed to assist in loading the SELECT carousel prior to running an assay(s). It

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

identifies the placement of reagents, disposables, calibrators, controls and patient samples. The loadlist also specifies the volume required for calibrators, controls and patient samples.

The creation of a loadlist is required prior to running SELECT assay(s).

The creation of a loadlist is optional for MEIA and FPIA assays.

SELECT MUP Lot Identification (Loadlist: 5-68, Test results: 5-74)

When entered via the numeric keypad, the value for MUP LOT I.D. will appear on the loadlist after SERIAL #, and on the test results printout between RGNT LOT and SERIAL #.

IMX SELECT CALIBRATION AND TROUBLESHOOTING PROCEDURES

New SELECT Reagent Pack Calibration (9-62)

A new step, specific to SELECT, has been added to the Boom Calibration procedure. The additional step determines the horizontal positioning for the probe/electrode assembly for all reagent packs located in the SELECT carousel. This additional location, CRSL_RGNT, is calibrated by centering the probe over the cross target at the center of the buffer pack cap in location A in the SELECT carousel. The vertical limit is set by the LLS portion of Boom Cal.

The CRSL_RGNT location can also be checked during Boom Check (9-9) .

IMX SELECT CALIBRATION AND TROUBLESHOOTING PROCEDURES

New SELECT Temperature Calibration (9-70) and Check (9-20)

A new SELECT Temperature Calibration and Check will be required for running SELECT assays.

When performing the SELECT Temperature Calibration or Check, the SELECT carousel must be used.

The SELECT Temperature Calibration must be performed prior to the MEIA Temperature Calibration to ensure that the instrument temperature achieved for the SELECT Temperature Calibration is not biased by warming that can occur during the MEIA Temperature Calibration.

SELECT Level Sense Error Information (5-62)

For a SELECT assay run, when a level sense error stops one of the assays, an error code will be displayed that indicates which assay(s) encountered the level sense error by the SELECT reagent pack location (A, B, C). The operator must choose whether to press [STOP ASSAY] to discontinue the remaining assay(s), or press [EXIT] to exit from the error while the other assays continue to run.

SELECT Buffer Run (10-4)

Performing a SELECT buffer run requires the generation of a loadlist.

A buffer run loadlist requires the entry of the assay number, rather than the reagent bar code number which is used in the creation of an assay loadlist.

A buffer run loadlist cannot be edited after the information is stored.

IMX SELECT ACCESSORIES

SELECT Carousel (1-14)

The new IMx SELECT Carousel accommodates up to three assay reagent packs in the center of the carousel, thus allowing up to three specific SELECT assays to be run at a time in the same carousel.

IMx Bar Code Scanner (1-7)

The IMx Bar Code Scanner facilitates loadlist creation by reading both reagent pack bar code labels and patient sample tube bar code labels.

Alphanumeric sample IDs can be entered during loadlist creation or while in MULTI TASK.

Assay activation can be simplified by using the Bar Code Scanner to read reagent pack bar codes.

The Bar Code Scanner must be ordered separately.

The list number for the Bar Code Scanner is: (LN 3A81-10)

NOTE: SELECT Hepatitis assays will require activation via the IMx Bar Code Scanner

IMX SELECT ACCESSORIES

SELECT MUP Holder (1-15)

For a SELECT assay run, the SELECT MUP bottle is placed into the MUP holder, which is then placed in the reagent heater block.

SELECT MUP Storage Rack (2-6)

The MUP Storage Rack is a convenient rack for compact storage and inventory control of SELECT MUP bottles in the refrigerator.

OTHER NEW IMX SYSTEM SOFTWARE FEATURES

Boom Calibration Level Sense Range

The Level Sense portion of Boom Calibration will now fail if the average value is outside the range of 258 to 272.

Dilution/Alternate submenu (MEIA: 5-44, SELECT: 5-89)

A new Dilution/Alternate submenu will prompt for the number of reaction cells to be used for the Dilution/Alternate protocol, rather than the number of undiluted samples.

This change in the Dilution/Alternate submenu prompts applies to both MEIA and SELECT assays.

For SELECT, a Dilution/Alternate protocol can only be run using the By-Assay pipetting method.

Test Left (6-25)

TEST_LEFT is a new function key under the MONITOR menu, which allows the operator to check the number of tests remaining in a reagent pack on that IMx.

If the IMx has never read the bar code on the reagent pack being checked, ??? will appear in the display window.

MEIA and FPIA regent packs can be checked by using the bar code reader on the boom or the IMx Bar Code Scanner. SELECT reagent packs can only be checked using the IMx Bar Code Scanner.

TESTS_LEFT information also appears on the loadlist for each reagent pack being used in that MEIA, SELECT, or FPIA assay run.

Status (6-41)

As in previous system software versions, when MULTI_TASK is displayed, pressing the STATUS key displays the status of the MEIA or FPIA assay currently being performed.

Pressing the STATUS key for SELECT assays will display the approximate amount of time remaining (hours and minutes) until the run is completed.

Sample Identification (6-18)

Sample IDs can now be entered before an MEIA or FPIA assay run begins through the creation of a loadlist. The operator has the choice of entering sample IDs during loadlist creation or through the MULTI_TASK menu.

III. Procedure

This procedure outlines the hardware, software, and initialization of the IMx system to operate with IMx System Software Version 5.0

IMx System Module Version 5.0 Software Enhancement Kit

The IMx System Module Version 5.0 Software Enhancement Kit contains:

- 1. IMx System Module Version 5.0 (LN 8384-05)
- 2. IMx SELECT Carousels, (2) (LN 3A82-01)
- 3. Carousel ID Bar Code Labels, 1 sheet of 50 for SELECT, MEIA, and FPIA carousels (LN 4A31-01)
- 4. IMx SELECT Buffer packs (3) (LN 4A85-01)
- 5. IMx SELECT MUP Holder with MUP Bar Code Label (LN 4A68-01)
- 6. IMx System Operation Manual (LN 8376-05)
- 7. Installation Instructions for IMx System Module Version 5.0 Software.
- 8. Envelope/Label and Form for return of Version 2.0 or Version 3.0 System Software Module (U.S. Customers only).
- 9. MUP Storage Rack (LN 3A84-01)

The following must be ordered separately:

10. IMx Bar Code Scanner (LN 3A81)

Installation Procedure

Perform each step, in the order listed, beginning with Step 1.

1. DO NOT REMOVE YOUR PRESENT SYSTEM MODULE VERSION 2.0 OR 3.0 UNTIL THE FOLLOWING SYSTEM FILES ARE PRINTED. Print System Files 1, 3, 4, 37 and 38.

Set these printouts aside for later reference in this Installation Procedure.

Press SYSTEM

FILES

XX (file number)

PRINT

INSTALLATION PROCEDURE

2. Prepare for software module removal by turning the IMx System power switch OFF. Open the software module door located on the top, right side of the system. Remove the System Module from the left module port.

NOTE:

The Version 2.0 or Version 3.0 System Module must be returned to Abbott Laboratories.

U.S. Customers Only:

Place the Version 2.0 or Version 3.0 System Module in the envelope provided and complete the return form. Enclose the completed form with the module and return to Abbott Laboratories using the postage-paid mailing label provided.

Customers Outside U.S.:

Your Abbott Laboratories area representative will provide you with specific instructions for the return of the module. If you

have any questions, contact the IMx Customer Support Center.

- 3. Install the new System Module Version 5.0 by plugging the module into the left module port. Press the module firmly into place.
- 4. Turn the IMx System power switch ON. When the System Module is properly installed, the system performs an internal power-up routine. After this routine is completed, the Main Menu will appear in the display window.
- 5. Refer to the printout for System File 1: CONFIGURATION from the current System Module (refer to step 1). Circle the printed values corresponding to the parameters listed below:
 - 1.3 SERIAL NUMBER
 - 1.5 DATE FORMAT
 - 1.17 LINE FEEDS

If you are currently using System Module Version 3.0, the following parameter in System File 1 must also be circled:

1.19 CRSL ID = ON (optional)

If your laboratory is currently using the RS232 Unidirectional Interface, the following parameters in System File 1 must be circled:

- 1.10 COM2 BAUD
- 1.11 COM2 CHR LEN
- 1.12 COM2 STOP BIT
- 1.13 COM2 PARITY
- 1.18 HOST INTERFACE
- 1.29 XOFF TIMEOUT

To edit the circled values into your new System Module Version 5.0:

Press SYSTEM

FILES

1.3

DISPLAY

Using the numeric keypad, enter the circled value for parameter 1.3

Press STORE

EXIT

EXIT

Repeat for parameters 1.5, 1.17, and 1.19 (optional).

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

INSTALLATION PROCEDURE

5. (continued)

If the RS232 Unidirectional Interface is being used, this must also be repeated for parameters 1.10, 1.11, 1.12, 1.13, 1.18, and 1.29. For parameter 1.18, which enables the host interface, the password "2215" must be entered after pressing DISPLAY. To store the parameters edited for the RS232 unidirectional Interface in System File 1 (1.10, 1.11, 1.12, 1.13, 1.18, and 1.29), turn the IMx System power OFF, wait 10 seconds and turn the power ON again. This procedure will reinitialize the parameters in memory. Edit only these parameters in this file. Editing other parameters in this file may interfere with system operation.

To confirm that the circled values have been edited correctly, print System File 1 and check against your circled file printout.

Press SYSTEM FILES 1 PRINT

After you have confirmed that the file has been edited correctly, retain the System Module Version 5.0 printout of System File 1: CONFIGURATION in the inside pocket of the IMx System Operation Manual for future reference.

Please note that the System Software Version, parameter 1.1 SYSTEM REV is printed in the format 5.0X. The first two digits identify the System Software Version (5.0). The other digit are used for internal control.

6. Refer to the printout for System File 3: FPIA CAROUSEL from the current System Module (refer to step 1).

Circle the printed values corresponding to the parameters listed below:

- 3.11 PIPET1 OFFSET
- 3.13 READ OFFSET
- 3.14 DETECT OFFSET
- 3.17 LOCK POS
- 3.18 UNLOCK POS

Locate parameter 3.17 LOCK POS. Subtract 693 from the value printed for this parameter.

Record and circle the difference on the printout, and label this value as parameter 3.21 DOT LOC. Please note that parameter 3.21 (DOT LOC) is not seen in the current System Module, but is present in System Module Version 5.0.

For example, if parameter 3.17 is 783, the new calculated value to be edited into parameter 3.21 is 783 - 693 = 90.

To edit the circled values into the new System Module Version 5.0:

Press SYSTEM FILES 3.11 DISPLAY

INSTALLATION PROCEDURES

6. (continued)

Using the numeric keypad, enter the circled value for parameter 3.11

Press STORE EXIT

EXIT

EXII

Repeat for parameters 3.13, 3.14, 3.17, 3.18, and 3.21. Edit only these six parameters in this file. Editing other parameters in this file may interfere with system operation.

To confirm that the circled values have been edited correctly, print System File 3 and check against your circled file printout.

Press SYSTEM

FILES

3

PRINT

After you have confirmed that the file has been edited correctly, retain the System Module Version 5.0 printout of System File 3: FPIA CAROUSEL in the inside pocket of the IMx System Operation Manual for future reference.

7. Refer to the printout for System File 4: MEIA CAROUSEL from your current System Module (refer to step 1).

Circle the printed values corresponding to the parameters listed below:

4.17 LOCK POS

4.18 UNLOCK POS

Locate parameter 4.17 LOCK POS. Subtract 536 from the value printed for this parameter.

Record and circle the difference on your printout, and label this value as parameter 4.21 DOT LOC. Please note that parameter 4.21(DOT LOC) is not seen in the current System Module, but is present in System Module Version 5.0.

For example, if parameter 4.17 is 623, the new calculated value to be edited into parameter 4.21 is 623-536 = 87.

Subtract 17 from the <u>original</u> value printed for parameter 4.17(LOCK POS). Record and circle the difference on your printout and label this value as parameter 4.22 FLAG LOC.

Please note that parameter 4.22 (FLAG LOC) is not seen in your current System Module, but is present in System Module Version 5.0.

For example, if parameter 4.17 is 623, the new calculated value to be edited into parameter 4.22 is 623-17 = 606.

To edit the circled values into your new System Module Version 5.0:

Press SYSTEM FILES

4.17

DISPLAY

INSTALLATION PROCEDURE

7. (continued)

Using the numeric keypad, enter the circled value for parameter 4.17

Press STORE

EXIT

EXIT

Repeat for parameters 4.18, 4.21, and 4.22. Edit only these four parameters in this file. Editing other parameters in this file may interfere with system operation.

To confirm that the circled values have been edited correctly, print System File 4 and check against your circled printout.

Press SYSTEM

FILES

4

PRINT

After you have confirmed that the file has been edited correctly, retain the System Module Version 5.0 printout of System File 4: MEIA CAROUSEL in the inside pocket of the IMx System Operation Manual for future reference.

8. Refer to the printout for System File 37: TEMPERATURE from the current System Module(refer to step 1). Circle the printed values corresponding to the parameters listed below:

```
37.1 FPIA SETPT
37.2 FPIA AMB CRTN
37.12 AMB OFF TIME
37.16 MEIA AIR SET
37.18 MEIA PID DEV
37.21 MEIA CAL TIME
37.26 PID GAIN
37.27 PID INTEGRAL
37.29 PID BIAS
```

To edit the circled values into the new System Module Version 5.0:

Press SYSTEM FILES 37.1 DISPLAY

Using the numeric keypad, enter the circled value for parameter 37.1

Press STORE EXIT EXIT

Repeat for parameters 37.2, 37.12, 37.16, 37.18, 37.21, 37.26, 37.27, and 37.29. Edit only these nine parameters in this file. Editing other parameters in this file may interfere with system operation.

INSTALLATION PROCEDURE

8. (continued)

To confirm that the circled values have been edited correctly, print System File 37 and Check against your circled file printout.

Press SYSTEM FILES 37 PRINT

After you have confirmed that the file has been edited correctly, retain the System Module Version 5.0 printout of System File 37: TEMPERATURE in the inside pocket of the IMx System Operation Manual for future reference.

9. Refer to the printout for System File 38: PHOTO PARAMETERS from the current System Module (refer to step 1). Circle
Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

the printed values corresponding to the parameters listed below:

38.12 MEIA STD M 38.25 MEIA LMP REF#

To edit the circled values into your new System Module Version 5.0:

Press SYSTEM

FILES 38.12 DISPLAY

Using the numeric keypad, enter the circled value for parameter 38.12

Press STORE

EXIT

EXIT

Repeat for parameter 38.25. Edit only these two parameters in this file. Editing other parameters in this file may interfere with system operation.

To confirm that the circled values have been edited correctly, print System File 38 and check against the circled file printout.

Press SYSTEM

FILES

38

PRINT

After you have confirmed that the file has been edited correctly, retain the System Module Version 5.0 printout of System File 38: PHOTO PARAMETERS in the inside pocket of the IMx System Operation Manual for future reference.

- 10. If you are using the Carousel ID option, label each IMx SELECT Carousel with a different Carousel ID Bar Code Label.
- 11. To complete the installation of the IMx System Module Version 5.0 Software, perform all of the System Calibration and System Check procedures shown below in the order that they are listed:
 - 1.) Diluent Buffer Replacement
 - 2.) MEIA Carousel Calibration

INSTALLATION PROCEDURE

11. (continued)

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

- 3.) Boom Calibration (using the SELECT Carousel)
- 4.) Daily Maintenance (using the SELECT Carousel)
- 5.) SELECT Temperature Calibration (using the SELECT Carousel)
- 6.) MEIA Temperature Calibration (using the MEIA Carousel)
- 7.) MEIA Photo Calibration
- 8.) Dispense Check

If FPIA assays are run:

- 9.) FPIA Boom Calibration
- 10.) FPIA Temperature Calibration
- 11.) FPIA Photo Calibration
- 12. The IMx System Module Version 5.0 Software installation is now complete. You may proceed to the next section to install the IMx Bar Code Scanner if desired. Otherwise you are now ready to run assays once the specific IMx SELECT or IMx AssayModule is installed. IMx SELECT assays will require calibration. When each MEIA or FPIA assay is run for the first time using IMx System Module Version 5.0 Software, run all levels of controls on the carousel. Check that each control is within its specified control range. If any control is outside its specified range, recalibrate the assay. Refer to the assay package insert for assay-specific information.

To view the next section of this TSB click once on the button Continue to Section 2

IMx Bar Code Scanner Installation and Operation OVERVIEW

The IMx Bar Code Scanner is designed for use with the IMx System Software Version 5.0 (and higher), and provides fast and easy reading of bar codes on IMx reagent packs and/or patient sample tubes.

The IMx Bar Code Scanner Kit includes:

- 1. IMx Bar Code Scanner with magnet: (LN 3A81)
- 2. IMx Bar Code Scanner User's Guide

Imx Bar Code Scanner Installation and Operation OVERVIEW (continued)

The IMx Bar Code Scanner has been set up to read the following bar code symbologies:

- 1. Interleaved 2 of 5
- 2. Code 39
- 3. Codabar
- 4. Code 128

The IMx reagent packs have 10 character Interleaved 2 of 5 bar code labels. Most sample tube bar code labels will be Code 39 or Codabar symbologies. If your sample tube bar code labels are not one of the above symbologies, please contact the IMx Customer Support Center.

INSTALLATION PROCEDURE

To install the IMx Bar Code Scanner, you must perform the following procedures:

- 1. Verify that all of the components were shipped in the IMx Bar Code Scanner Kit. Check the packing slip inside the shipping carton.
- 2. Turn the IMx power OFF before connecting the IMx Bar Code Scanner.
- 3. Plug the IMx Bar Code Scanner cable with the 25 pin connector into the COM 1 port (the port nearest the ON/OFF switch) on the back of the IMx System (see Figure 1 on page 14). Use the thumbscrews on the connector to the IMx. Hand tighten the thumbscrews; do not use any tools.

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

- 4. Plug the IMx Bar Code Scanner power supply into a grounded, 3 lead AC wall outlet (100V Japan, 110V U.S,. and 220V Europe).
- 5. Turn the IMx power ON and wait for the Ready Menu to appear. Two beeps will sound when the IMx Bar Code Scanner is initially powered up.
- 6. You can test the operation of the IMx Bar Code Scanner by reading IMx reagent packs while the IMx is in the bar code section of the Hand Controls Menu.

Press MONITOR HND_CTRL OTHER BARCODE WAND

A bar code label may then be scanned. Successful reads are displayed on the front panel of the IMx display.

Please note that there are no beeps indicating a successful read when testing the IMx Bar Code Scanner operation in hand controls.

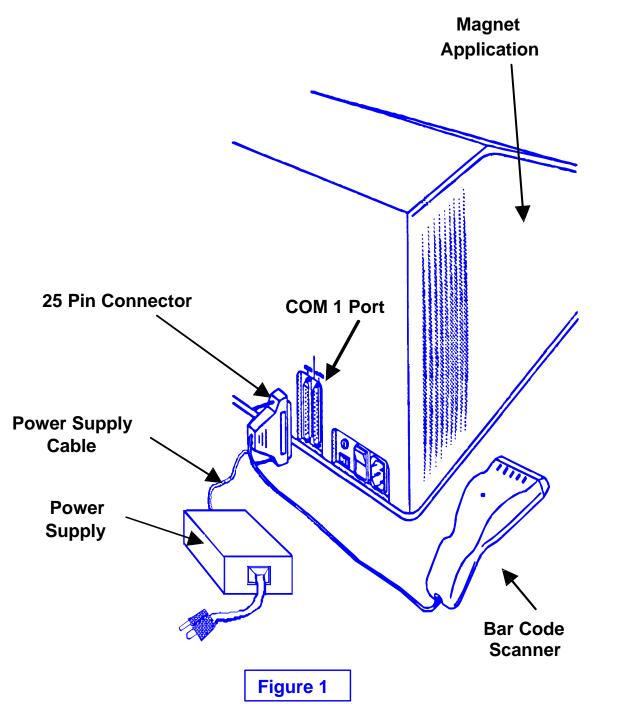
IMx Bar Code Scanner Installation and Operation INSTALLATION PROCEDURE (continued)

7. The IMx Bar Code Scanner is equipped with a magnet to hold it when not in use. The magnet attaches to either the left or right side of the IMx System (see Figure 1, page 14) with tape. To attach the magnet, remove the label on the back of the magnet to expose the tape. Place the tape side of the magnet in the desired location and press the magnet firmly against the side of the IMx.

Note:

Please choose desired location carefully, as removal/reattachment may be difficult.

NOTE: In the following examples, you may have to scroll down to view the contents in its entirety.



IMx Bar Code Scanner Installation and Operation

OPERATION

There are two techniques that can be used when reading IMx reagent pack or patient sample tube bar codes; with either technique, a successful read will be indicated by a beep from the IMx. If operating in hand controls, no beep will be heard.

- 1. Hold the IMx Bar Code Scanner within 1/4 inch of the bar code label and center it over the bar code. Sweep the IMx Bar Code Scanner over the bar code in the direction of the bars (see Figure 2). Repeat this procedure until a successful read is indicated.
- 2. Hold the IMx Bar Code Scanner 1 to 2 inches away from the bar code and move the scanner towards the bar code label until a successful read is indicated.

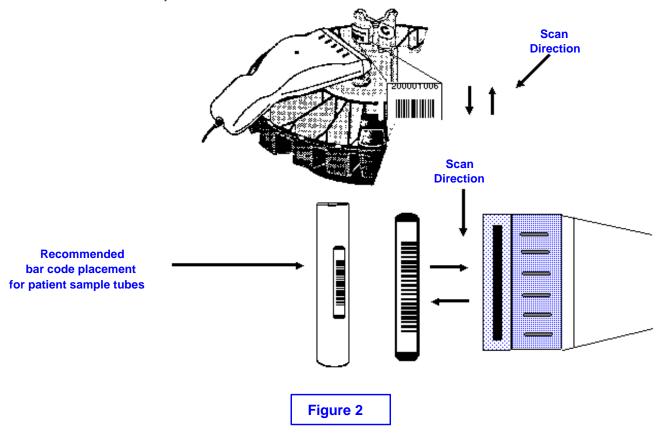
The IMx Bar Code Scanner will enter a standby mode ten seconds after the last read. Dim LEDs at the reader head indicate that the IMx Bar Code Scanner is in standby. Once the scanner is brought back into position over a bar code, it will exit the standby mode and turn ON.

DISCONNECTING THE IMX BAR CODE SCANNER

- 1. Turn the IMx power OFF.
- 2. Unplug the IMx Bar Code Scanner power supply.
- 3. Loosen the thumbscrews on the 25 pin connector and unplug the connector from the COM 1 port on the back of the IMx.

APPLICATION OF BAR CODE LABELS

To ensure fast and easy reads of bar code labels by the IMx Bar Code Scanner, it is recommended that bar code labels be flat and straight when applied down the length of patient sample tubes. It is not recommended that bar code labels be wrapped around sample tubes. See Figure 2 for recommended bar code label placement for patient sample tubes.



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

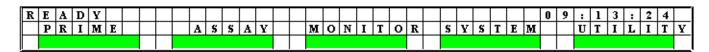
EXAMPLES

This section demonstrates some of the new menus and keystroke sequences that are unique to the SELECT features of IMx System Software Version 5.0. Each screen has the required instructions below it: following those instructions will bring the next screen to the display.

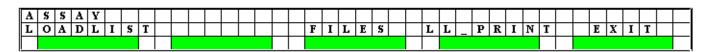
IMx SELECT Single Assay Calibration

From the READY Menu:

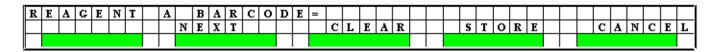
NOTE: In the following examples, you may have to scroll to the right to view the contents in its entirety.



Press ASSAY



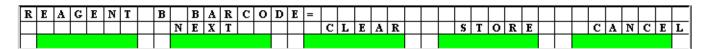
Press LOADLIST



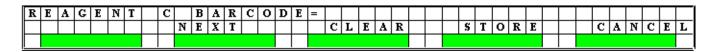
Enter the reagent bar code located in position A in the SELECT Carousel with the numeric keypad or Bar Code Scanner.

R	E	Α	Ţ	G	E	N	T		A		В	A	R	С	C) [)]	E	=	2	0	0	0	0	2	2	0	0		П									
	K	S	Ţ	P						N	E	X	T	Т	Т		Τ			С	L	E	Α	R				S	T	0	R	E		С	A	N	С	E	L
								Г	Т								Т	П								Г													

If the bar code number is entered through the numeric keypad: Press **STORE** If the Bar Code Scanner is used, **"BKSP"** will not appear on the screen and this step will not be necessary; the next screen will come up automatically.



Press **NEXT**



Press **NEXT**

EXAMPLES IMx SELECT Single Assay Calibration (continued)



Enter the number of samples (controls and patients) from the numeric keypad.



Press the run selection key until the Cal light is illuminated

A	:	F		S	Н			T					:	#	N	0	N	C	1	A	L		R	x	С	L	s	=	3							С	A	L
D	Ι	L	Ι		A	L	T		С	U	R	V	E		2			C	1	L	E	A	R				S	T	0	R	E		С	A	N	С	E	L
								Т								П																						Г

Press Store

E	N	٧Ţ	T	E	I	3	Ι	D	s	Τ	T	0	r		Ι	F	F	Ι	N	I	S	Н	E	D	,	P	R	E	S	S	П	D	0	N	E	П	П	\Box	
	Т	Т			Τ	Т			Г		Τ		Ι	D					D	0	N	E				С	A	N	С	E	L							\Box	
Г									П																Г														

You may now enter patient sample, tech, control, and lot IDs by entering the ID Menu or PressDONE

Press DONE



Pressing done will generate a loadlist from the printer to aid in loading the carousel. The screen returns to the READY menu; Patient sample, control, tech, and lot IDs can be entered via the MULTI_TASK menu once the assay has begun or prior to initiating the run through the loadlist menu.

R	E	A	I)	Y		Τ			Τ						Т	Τ																0	9	:	1	3	:	2	4	
	P	R]		М	E	Τ	П		Τ	П	A	S	S	A	Y	T	П	M	0	N	Ι	T	О	R		S	Y	S	T	E	M			U	T	I	L	Ι	T	$ \mathbf{Y} $
									Г									П								П								П							

After preparing the carousel and loading the reagents, place the carousel in the instrument. Place the MUP in the Mup holder, open the cap and place the MUP holder in the reagent heater block.

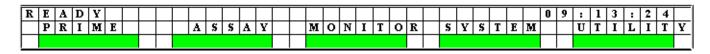
Press the RUN key to begin the assay calibration.

NOTE: THE CAL RUN SELECTION LIGHT WILL NOT BE ILLUMINATED DURING SELECT ASSAY RUNS

EXAMPLES

IMx SELECT Assay

run using BY_ASSAY Method



Press **ASSAY**



Press **LOADLIST**

R	E	Α	G	E	N	T	П	A		В	Α	R	С	0	D	E	=																	
							П		N	E	X	T						C	L	E	A	R		S	T	R	E		С	A	Ν	С	E	L
Г							Г	Т																										-I

Enter the reagent barcode located in position A in the SELECT carousel with the numeric keypad or Bar Code Scanner

R	E	A	G	E	N	1	T	A		В	A	R	С	0	D	E	=	2	0	0	0	0	2	2	0	0											
В	K	S	P			\perp			N	E	X	T						С	L	E	A	R				S	T	0	R	E		С	A	N	С	E	L

If the bar code

number is entered through the numeric keypad:

Press STORE

If the Bar Code Scanner is used, "**BKSP**" will not appear on the screen and this step will not be necessary; the next screen will come up automatically.

R	E	A	G	E	N	T	В		В	A	R	C	0	D	E	=																		
								Ν	E	X	T						С	L	E	A	R		S	T	0	R	E		С	A	Ν	U	E	L

Enter the reagent barcode located in position B in the SELECT carousel with the numeric keypad or Bar Code Scanner

R	E	A	G	E	N	T	В		В	A	R	C	0	D	E	=	2	0	4	0	0	0	3	3	0											
В	K	S	P					Ν	E	X	T						С	L	E	A	R				S	T	0	R	E		С	A	Ν	C	E	L

_lf the bar code

number is entered through the numeric keypad:

Press **STORE**

If the Bar Code Scanner is used, **"BKSP"** will not appear on the screen and this step will not be necessary; the next screen will come up automatically.

EXAMPLES

IMx SELECT Assay Run using BY_ASSAY Method (continued)

R	E	A	G	E	N	T	С		В	A	R	С	0	D	E	=																		
								N	E	X	T						С	L	E	A	R		S	T	0	R	E		C	A	N	С	E	L

Enter the reagent barcode located in positon C in the SELECT carousel with the numeric keypad or the Bar Code Scanner.

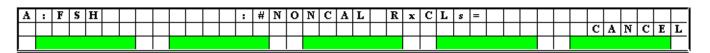
R	E	Α	G	I	εT	N	T		Tc	Т		В	Α	R	С	О	D	E	=	2	12	To	ıT	0	3	3	0	0	1	Г	П	П	Г				Г	Г		$\overline{}$
10	-	S	P	✝¯	7		_	Г	┿	ı	-	F	X	T	一	一	†	╀	T	Ċ	Ī	F		Ā	R	_	<u> </u>	<u> </u>	S	T	О	R	E		С	A	N	С	E	L
								Г	Τ									Г																						Г

= If the bar code

number is entered through the numeric keypad:

Press STORE

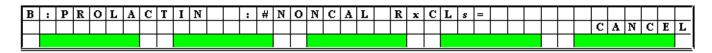
If the Bar Code Scanner is used, "**BKSP**" will not appear on the screen and this step will not be necessary; the next screen will come up automatically.



Enter the number of samples (controls and patients) from the numeric keypad.



Press STORE



Enter the number of samples (controls and patients) from the numeric keypad.

В	<u>:</u>	P	1	R	0	L	Α	С	T	I		N			:	N	0	N	С	A	L	Τ		R	x	С	L	s	=	3					С	1		M	1	
D	Ι	L	⊥.		A	L	T			(: [U	R	V	E		2			C	L]	E	A	R				S	T	0	R	E		\mathbf{c}	A	N	C	E	L
匚																																								

Press STORE

EXAMPLES IMx SELECT Assay Run using BY_ASSAY Method (continued)

С	:	I	Ĺ	н				Т			:	#	N	О	N	С	A	L	R	x	С	L	s	=									
		Γ						\perp																				С	A	Ν	С	E	L
							Τ							Τ																			

Enter the number of samples (controls and patients) from the numeric keypad.

С	:	L	I	I										:	N	C)	N	C	A	L		R	,	c	С	L	s	=	3			Т	Π	C	1		M	1	\Box
D	I	L	Τ.	П	A	L	T		C	Ţ	J	R	\mathbf{v}	E		2				С	L	E	A	. I	3				S	T	О	R	E		С	Α	N	С	E	L
								Г									Т																	Τ						

Press **STORE**

S	E	L	E	С	T			P	Ι	P	E	T	T	I	N	G	S	T	Y	L	E														
В	Y	_	A	S	S	A	ī	Y										В	Y		P	A	N	E	L					С	A	N	C	E	L
Г								\neg																Г											

Press BY ASSAY

See page 2 of TSB 60-033 or Section 5-63, IMx System Operation Manual (LN 8376-05) for more information.

E	N	T]	E	R	Ι	Ι	ग	s	0	г		Ι	F	F	Ι	N	I	S	Н	E	D	,	P	R	E	S	S		D	0	N	E			
			Г				Г	Т			Ι	D					D	0	N	E				С	A	N	С	E	L							
Г							Г	Т																												

You may now enter patient sample, control, tech, and lot IDs by entering the ID Menu or Press DONE Press **DONE**

P	R	I	N	T	I	N	G																			
																					C	A	N	С	E	L

Pressing done will generate a loadlist from the printer to aid in loading the carousel. The screen returns to the READY menu; Control and sample IDs can be entered via the MULTI_TASK menu once the assay has begun or prior to initiating the run through the loadlist menu.

R	E	A	. [D	Y																							П		0	9	:	1	3	:	2	4	
	P	R	Т	Ι	M	I	E	Г	Т		A	S	S	A	Y		M	0	N	Ι	T	0	R	S	Y	S	T	E	M			U	T	Ι	L	Ι	T	Y
								Г	Т							П																						

After preparing the carouseland loading the reagents, place the carousel in the instrument. Place the MUP into the MUP Holder, open the cap, and place the MUP Holder in the reagent heater block.

Press the **RUN** key to begin the assay run.

NOTE: THE RUN SELECTION LIGHTS WILL NOT BE ILLUMINATED DURING SELECT ASSAY RUNS

EXAMPLES IMx SELECT Assay

run using BY_PANEL Pipetting Method

From the READY

Menu:

R	E	A	D	ī	Y			Π	Т	Τ	П						П	П	Π	Π	Τ	Τ							Π	Π	0	9	:	1	3	:	2	4	
	P	R	I	7	M	E		Г		Ţ	A	S	S	A	Y		M	0	N	Ι	T	О	R		S	Y	S	T	E	M			U	T	Ι	L	Ι	T	$ \mathbf{Y} $
\Box								Г								П								П								П							\Box

Press ASSAY



Press LOADLIST



Enter the reagent barcode located in position A in the SELECT carousel with the numeric keypad or Bar Code Scanner

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

R	E	A	ιŢ	G	E	N	T	A		В	A	R	C	0	D	E	=	2	0	0	0	0	2	2	0	0											
В	K	S	Т	P					N	E	X	T						C	L	E	A	R				S	T	0	R	E		С	Α	N	С	E	L
Г								Т																													

If the bar code number is entered through the numeric keypad:

Press STORE

If the Bar Code Scanner is used, **"BKSP"** will not appear on the screen and this step will not be necessary; the next screen will come up automatically

R	E	Α	G	E	N	T	1	В		В	A	R	T	C	0	D	E	=	Т	Τ	Т							Π	Π	Т							
				П	П	Т	Т		N	E	X	T	Т	П				П	C	I	4	E	A	R		S	T	О	R	E		С	A	N	С	E	L

Enter the reagent barcode located in position B in the SELECT carousel with the numeric keypad or Bar Code Scanner

R	E	A	G	E	N	T	В		В	A	R	С	0	D	E	=	2	0	4	0	0	0	3	3	0											
В	K	S	P					N	E	X	T						С	L	E	A	R				S	T	0	R	E		С	A	Ν	С	E	L

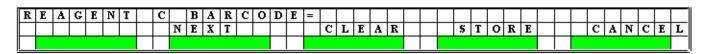
If the bar code number is entered through the numeric keypad:

Press STORE

If the Bar Code Scanner is used, **"BKSP"** will not appear on the screen and this step will not be necessary; the next screen will come up automatically

EXAMPLES IMx SELECT Assay

run using BY_PANEL Pipetting Method (continued)



Enter the reagent barcode located in position C in the SELECT carousel with the numeric keypad or Bar Code Scanner

R	E	A	G	E]	N	T	С		Ţ	В	A	R	С	0	D	E	=	2	2	1	ij	0	3	3	0	0	1											
					Τ				N	T	E	X	T						C	L	· E		A	R				S	T	0	R	E		C	A	N	С	E	L

If the bar code number is entered through the numeric keypad:

Press STORE

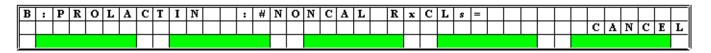
If the Bar Code Scanner is used, "BKSP" will not appear on the screen and this step will not be necessary; the next screen will come up automatically



Enter the number of samples (controls and patients) from the numeric keypad.



Press STORE



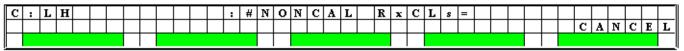
Enter the number of samples (controls and patients) from the numeric keypad.



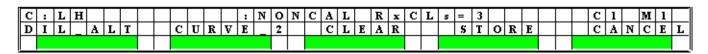
Press STORE

EXAMPLES IMx SELECT Assay

run using BY_PANEL Pipetting Method (continued)



Enter the number of samples (controls and patients) from the numeric keypad.

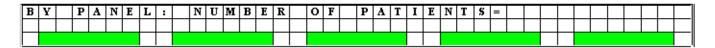


Press STORE



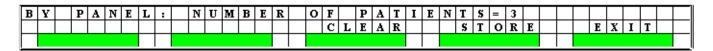
Press BY PANEL

See page 3 of TSB 60-033 or Section 5-76, IMx System Operation Manual (LN 8376-05) for more information.



Enter the number of patients to be tested in BY_PANEL Pipetting mode from the numeric keypad.

NOTE: DO NOT INCLUDE CONTROLS IN THIS NUMBER.



Press STORE

E	N	T	E	R	Ι	D	s	0	г		I	F	F	Ι	N	Ι	S	Н	E	D	,	P	R	E	S	S	П	D	0	N	E		П	П	
									Ι	D					D	0	Ν	E				С	A	N	С	E	L								

You may now enter patient sample, tech, and lot IDs by entering the ID Menu or Press DONE Press DONE

EXAMPLES
IMx SELECT Assay

run using BY_PANEL Pipetting Method (continued)

P	R	Ι	N	T	Ι	N	G																			
																					С	A	N	C	E	L

Pressing done will generate a loadlist from the printer to aid in loading the carousel. The screen returns to the READY menu; control, patient sample, tech, and lot IDs can be entered via the MULTI_TASK menu once the assay has begun or prior to initiating the run through the loadlist menu.

R	E	Ţ.	A	D	Ī	Y		Τ		Τ			Τ	T				Τ	Τ	T			П	Π	Т	Τ	T	П				П	Τ	Τ	0	9	<u> </u>	1	3	T	:	2	4	
	P	Т	R	Ι]	ΨI	E	Ι		Γ		A	5	Π	S	A	Y		Ι		M	0	N	Ι	T	T)]	R	S	Y	S	T	E		[U	T	I	I	Ĺ.	Ι	T	Y
										Γ								Г	Τ									\Box								Т								

After preparing the carousel and loading the reagents, place the carousel in the instrument. Place the MUP into the MUP holder, open the cap, and place the MUP Holder in the reagent heater block.

Press the **RUN** key to begin the assay run.

NOTE: THE RUN SELECTION LIGHTS WILL NOT BE ILLUMINATED DURING SELECT ASSAY RUNS

IMx SELECT Buffer

Run

To perform an IMx

OTHER

OTHER

SELECT Buffer Run:

From the READY

menu:

Press

UTILITY

OTHER

SERVICE

OTHER

BUF_RUN

This screen will appear:

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

R	E	A	G	E	N	T	Α		A	S	S	A	Y	N	U	M	В	E	R	=											\Box
								N	E	X	T															С	A	N	C	E	L
														Γ																	

At this screen, enter the assay number of the SELECT assay chosen for position A in the SELECT carousel using the numeric keypad.

NOTE: ASSAY NUMBERS FOR SELECT ASSAYS ARE CHANGED FROM MEIA BATCH ASSAYS.

R	E	A	7	ž	E	N	T	A	1	A	S	S	A	Y	N	U	1	1	В	E	R	=	2	6												
В	K	S	I	<u>ग</u>					Ι	\Box							T	7	L	E	A	R			S	T	0	R	E		С	A	N	С	E	L
								Γ							Τ																					

Press STORE

EXAMPLES
IMx SELECT Buffer

Run (continued)

R	E	A	G	E	N	T	В		A	S	S	A	Y	N	U	М	В	E	R	=											
								N	E	X	T															С	A	N	С	E	L
							П																		П						

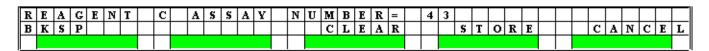
At this screen, enter the assay number of the SELECT assay chosen for position B in the SELECT carousel using the numeric keypad.

R	E	A	(;	E	N	T	В	A	. 5		S	A	Y	N	U	M	E	3	E	R	=	4	2					Т							
В	K	S	I	T					П	Т	Т	П					C	I	4	E	A	R			S	T	0	R	E	П	С	A	N	C	E	L
															П															Т						Г

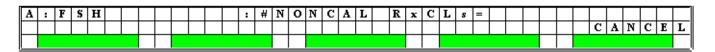
Press STORE

R	: []	E	A	G	E	N	T	Τ	T	,		A	S	S	Α	Y	N	U	M	В	E	R	=												7
	\perp]	N	E	X	T															С	A	Ν	С	E	L	

At this screen, enter the assay number of the SELECT assay chosen for position C in the SELECT carousel using the numeric keypad.



Press STORE



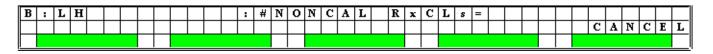
Enter the number of samples (controls and patients) from the numeric keypad.



Press STORE

EXAMPLES
IMx SELECT Buffer

Run (continued)



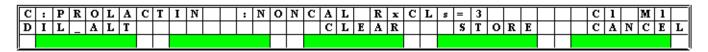
Enter the number of samples (controls and patients) from the numeric keypad.



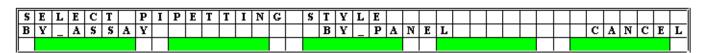
Press STORE

С	:	P	R	C	I	 A	C	T	Ι	N	ī	:	#	N	0	N	С	Α	L	R	x	С	L	s	=									
																													\mathbf{c}	A	N	C	E	L

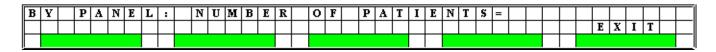
Enter the number of samples (controls and patients) from the numeric keypad.



Press STORE



Press BY_ASSAY or BY_PANEL



Enter the number of patients to be tested in BY_PANEL Pipetting mode from the numeric keypad.

NOTE: DO NOT INCLUDE CONTROLS IN THIS NUMBER.

EXAMPLES IMx SELECT Buffer

Run (continued)

В	Y	Τ		P	A	N	E	L	T :		Ν	U	M	В	E	R	0	F		P	A	T	Ι	E	N	T	S	=	3							
		Т	Т						Г									С	L	E	A	R				S	T	0	R	E		E	X	Ι	T	
								Г	Т																											

This next screen will appear at this point in the BY_PANEL sequence or immediately after choosing the BY_ASSAY pipetting style.

P	R	E	S	S	R	U	N	T	О	В	E	G	Ι	N	П	В	U	F	F	E	R	R	U	N								\Box
P	R	Ι	N	T																							С	A	Ν	С	E	L
																																Г

You may press print to obtain a copy of the loadlist to aid in loading the carousel. When finished:

Press the RUN key to initiate the buffer run.

EXAMPLES
IMx SELECT BOOM

CALIBRATION

The IMx SELECT Boom Calibration will require the training of the location of the opening of the SELECT reagent vials. The operator will be prompted after completing the MEIA Carousel and Cartridge portion of the Boom Calibration with the following screen:

Ι	N	S	Ī	E	R	T	В	τ	ī [F	F	E	R	P	A	С	K		I	N		С	R	S	L	R	G	N	T	L	0	С		A		$\overline{}$
	N	E	7	ĸ	T				Τ									S	T	A	R	T									E	X	Ι	T		
								Т																												

Press START

After pressing start, the instrument will home and align to begin the calibration for the SELECT Carousel reagent location. The calibration for the reagent location will establish carousel position and R-Boom location only. The Z-Aspirate limit will be determined by an offset calculated from the level sense portion of Boom Cal; therefore, it is not necessary to touch the target on the cap of the reagent vial. It is only required to ensure that the probe is centered over the target on the cap on the reagent vial.

The IMx SELECT Boom Calibration Level Sense portion is changed:

The level sense values must be within the range 258 to 272 steps or the error "INVALID LEVELS" will be generated.

EXAMPLES

IMx SELECT BOOM

CALIBRATION (continued)

The following screen

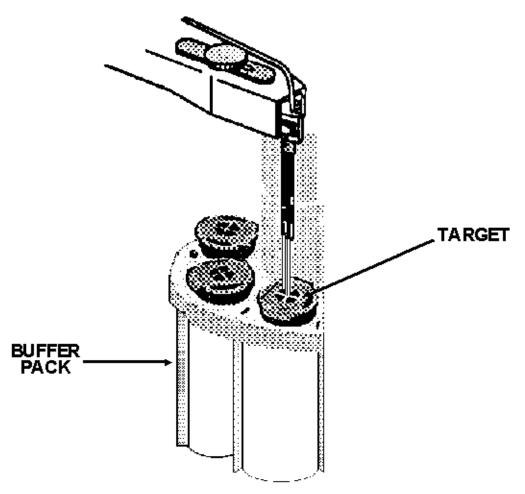
will display:

C	E	N	T	E	R	: [Т	P	R	0	В	E	Τ	To	V	E	F	ा	П	С	A	P	П	Т	П	Τ	T	ग	1	6	3	6	Т	П	T		П	Π	R	2	8	6	
V	E	R	Ι	F	Y		\Box			В	0	О	M			Т		Т		С	W							T	C	С	W					E	X	Ι	T			Т	
																	Т									Т																	\parallel

Adjust the boom and carousel as necessary, using Figure 3 as guide.

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

NOTE: The diagram shows the reagent pack removed from the carousel to provide a better illustration of proper calibration.

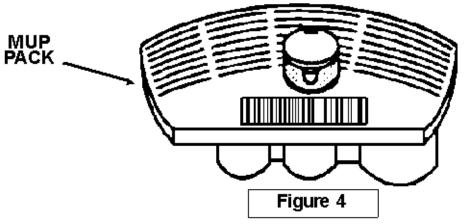


Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

EXAMPLES

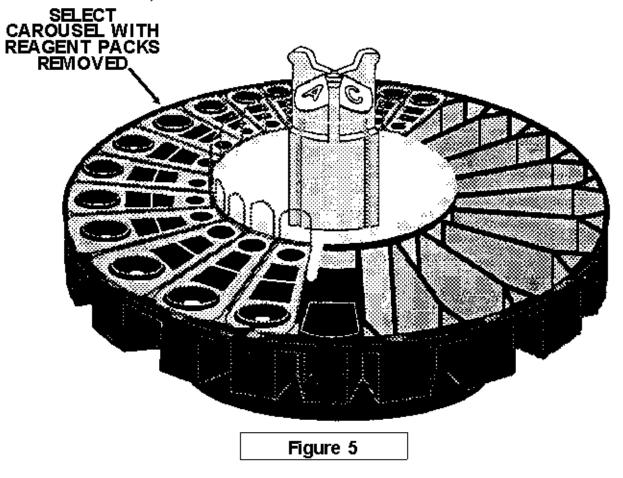
ACCESSORIES

In addition to the buffer pack displayed on page 28, Figure 3, other new accessories are the MUP Holder and the SELECT carousel. The MUP Holder will properly position the MUP vial in the reagent heater block. The MUP Holder will be placed in the reagent heater block during SELECT assay runs. See Figure 4



NOTE: In the following example, you may have to scroll to the right or down to view the contents in its entirety.

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



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

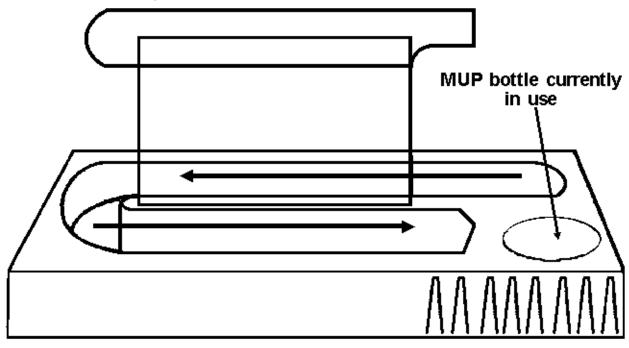
EXAMPLES ACCESSORIES

The IMx SELECT 4-Methylumbelliferyl Phosphate Reagent (MUP), included with each IMx SELECT Reagent Pack, is a separate component which may be used interchangeably for all SELECT assays.

The MUP Storage Rack (LN 3A84-01), provided as part of the IMx System Module Version 5.0 Software Enhancement Kit, is designed to facilitate refrigerated storage and inventory control of the IMx SELECT MUP reagent.

The MUP Storage Rack consists of two parts, the base and the clear plastic guide, which must be assembled (see Figure 6). The IMx SELECT MUP bottles should be loaded into the storage rack in a first in, first out order according to expiration dates and moved around the track in the direction of the arrows (see Figure 6). The MUP bottle that is currently in use may be stored in the separate position in the Storage Rack as shown. Arranging the MUP in this fashion will assure that the IMx SELECT MUP inventory is controlled and used most efficiently.

NOTE: In the following example, you may have to scroll to the right or down to view the contents in its entirety.



TROUBLESHOOTING IMx BAR CODE SCANNER

Problem: The IMx Bar Code Scanner will not read reagent pack and /or patient sample tube bar codes.

1. Look into the reading end of the IMx Bar Code Scanner. The red LEDs should be visible, although very dim.

If the LEDs are not visible, verify that the 25 pin connector of the IMx Bar Code Scanner is firmly plugged into the COM 1 port. Check the power supply connection at the wall outlet and at the power supply housing. If those connections appear good, follow the cable that runs from the IMx Bar Code Scanner power supply to the 25 pin connector. Verify this connection by pushing the power cable into the 25 pin connector.

If the LEDs are visible, turn the IMx power OFF. Unplug the IMx Bar Code Scanner from the wall outlet, wait 10 seconds, then plug the scanner back in, and turn the IMx power ON.

- 2. If reagent packs read and sample tubes don't, determine whether the sample tube bar code is the proper type. If not, reprogram the scanner per ISA 60-083.
- 3. Check to see if the bar code label is damaged or dirty.
- 4. Verify that the System File 1 Parameters, stored in the IMx, are correct. The correct values for System File 1 parameters are listed below:

1.6 COM1 BAUD 1200

1.7 COM1 CHR LEN 8

1.8 COM1 STOP BIT 1

1.9 COM1 PARITY 0

If the values for these parameters are not correct, use the numeric keypad to edit the parameters.

Press SYSTEM FILES 1.6 DISPLAY

Using the numeric keypad, enter the value listed above for this particular file number

STORE EXIT EXIT

Repeat for parameters 1.7, 1.8, and 1.9. Edit only these four parameter values for the IMx Bar Code Scanner. Editing other parameters in this file may interfere with system operation.

5. If the problem is not resolved, contact IMx CSE.

Problem: The IMx Bar Code Scanner appears to be turned off.

1. The IMx Bar Code Scanner is probably in standby mode. Holding the IMx Bar Code Scanner in the read position over a bar code should bring it out of the standby mode. If it does not exit the standby mode within a few seconds, try moving the IMx Bar Code Scanner to a slightly different position over the bar code label.

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TROUBLESHOOTING IMX BAR CODE SCANNER

Problem: The IMx Bar Code Scanner appears to be turned off (continued).

- 2. Look into the reading end of the IMx Bar Code Scanner. The red LEDs should be visible, although very dim. If they are not visible, verify that the 25 pin connector of the IMx Bar Code Scanner is firmly plugged into the COM 1 port. Check the power supply connection at the wall outlet. If that connection appears good, follow the cable that runs from the IMx Bar Code Scanner power supply to the 25 pin connector. Verify this connection by pushing the power cable into the 25 pin connector. The IMx Bar Code Scanner will power up if there was a problem with that connection.
- 3. If the problem is not resolved, contact IMx CSE.

Problem: The IMx Bar Code Scanner goes into a continuous alarm mode.

- 1. Turn the IMx power OFF.
- 2. Unplug the IMx Bar Code Scanner from the wall outlet, wait 10 seconds then plug the scanner back in.
- 3. Turn the IMx power ON.
- 4. If the problem is not resolved, contact IMx CSE.

NEW ERROR CODES

49 DAMAGED CAROUSEL (displayed)

Probable Cause

Carousel is damaged and cannot be properly recognized.

Corrective Action

1. Use a different carousel of the same type for the procedure.

58 INVALID MUP PACK (displayed)

Probable Cause

MEIA reagent pack placed in reagent heater block for a SELECT run. Incorrect MUP bar code entered manually during SELECT run.

Corrective Action

1. Ensure MUP pack is placed in reagent heater block during SELECT run.

2. Manually re-enter bar code from MUP pack.

83 DIL/ALT NOT ALLOWED IN BY_PANEL (displayed)

Probable Cause

Dil/Alt Protocol selected for assay A, B, and /or C during SELECT loadlist creation and By_Panel pipetting mode was selected.

Corrective Action

1. To perform a SELECT Assay run with Dilution or Alternate Protocol, you must choose By_Assay not By_Panel.

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TROUBLESHOOTING NEW ERROR CODES

85 INVALID NUMBER OF RxCLs/SmpCt (displayed)

Probable Cause

During Assay Loadlist Creation:

Sum total of reaction cells for all SELECT assays on the carousel is greater than 24.

Inappropriate number entered for #Noncal RxCLs compared to the stored valuefor assay parameter XX.3 SAMPLE REP.

0 is entered for #Noncal RxCLs for a MODE 2 run.

Number entered for number of patients is outside of the appropriate range (greater than 12) when choosing BY_PANEL pipetting mode.

Number entered for # of samples is greater than number of Noncal RxCLs for any assay.

Number entered for # of Dil/Alt samples is greater than number of Noncal RxCLs for any assay.

Corrective Action

- 1. Re-enter number of Noncal RxCLs so total is 24 or less.
- 2. Enter number of Noncal RxCLs so that it is divisible by number stored in SAMPLE REP.
- 3. Re-enter SAMPLE REP in assay parameter file.
- 4. For MODE 2 run, you must have at least one Noncal RxCL: Enter 1.
- 5. Enter appropriate number of patients which correlates to RxCL number and that is within range, or re-enter number of Noncal RxCLs for each assay.

86 DUPLICATE REAGENT PACKS (displayed)

Probable Cause

During loadlist creation for SELECT assays, you entered exactly the same bar code for two or three assays.

Corrective Action

Enter a different bar code for assay(s) where a duplicate bar code was entered.

87 ABORT TOLERANCE EXCEEDED (displayed)

Probable Cause

During a SELECT assay, assay timing is outside allowable limits

Corrective Action

- 1. Press EXIT to return the display window to the Main Menu.
- 2. Contact IMx CSE

88 INCOMPATIBLE ASSAY (displayed)

Probable Cause

SELECT assay is not compatible with another assay chosen in the loadlist.

Corrective Action

1. During loadlist creation, enter bar codes for only those assays that can be run together.

TROUBLESHOOTING NEW ERROR CODES (continued)

89 LOADLIST BAR CODE MISMATCH

Probable Cause

Reagent pack bar code read during an FPIA or MEIA assay run does not match the that in the loadlist.

Corrective Action

1. Replace the reagent pack to match the one entered in the loadlist or reenter the bar code in the loadlist to match the reagent pack.

92 REAGENT PACK B MISSING (displayed)

Probable Cause

During SELECT loadlist creation, a bar code for reagent packs A and C was entered, but not for B.

Corrective Action

1. Enter bar code for reagent pack B.

93 INVALID VALUE PRTCL DFLT FILE(L) (displayed)

Probable Cause

Protocol Default file was edited for an assay(s) in the loadlist after loadlist creation.

NOTE: L corresponds to the reagent pack Location designator in a SELECT assay, A, B or C.

Corrective Action

- 1. Edit protocol default file back to original value to match loadlist.
- 2. Edit loadlist to match current protocol default file.

94 INVALID # OF SAMPLE REP IN FILE (displayed)

Probable Cause

Parameter XX.3 SAMPLE REP has been set to a value other than 1 for one or more assays, and By_Panel was selected during loadlist creation. This error will only be obtained during loadlist creation.

Corrective Action

1. You may edit assay parameter XX.3 by doing the following:

Press EDIT

Press the key labeled "ONE" on the left side of the screen.

Press STORE

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The value 1 will be stored for SAMPLE REP for that assay.

2. You may press EXIT and select By_Assay in which you can run sample reps at more than 1.

TROUBLESHOOTING NEW ERROR CODES (continued)

95 LOADLIST NEEDED FOR SELECT RUN (displayed)

Probable Cause

RUN was pressed for a SELECT assay without having created a loadlist.

Corrective Action

Create a loadlist for a SELECT run.

96 BAR CODE ERROR: MUP ID= (displayed)

Probable Cause

An assay run was initiated without MUP in the reagent heater block. The bar code reader is obstructed, misaligned or dirty. The bar code label on the MUP is dirty or positioned incorrectly.

Corrective Action

- 1. Place or reseat the MUP and MUP holder in the reagent heater block, and press REPEAT to reread the bar code label.
- 2. Press STOP ASSAY and EXIT to return the display window to the Main Menu.
- Clean the bar code reader.
- 4. Clean the bar code label on the MUP with a damp lint-free tissue and dry.
- 5. Use another MUP holder to verify the problem still occurs.
- 6. If not corrected, adjust the bar code reader.

183 NO DATA AVAILABLE (printed)

Probable Cause

Specimen concentration or calibrator rate could not be determined due to level sense error that aborted the run.

Corrective Action

Repeat the assay ensuring that there is adequate reagent or calibrator. (See error message displayed on top of the printout to determine where the error occured.)

SEE FIGURE 7 BELOW...

```
DATE: 8/21/91
TIME: 6:44:48
TECH ID :
RGNT LOT:
MUP LOT :
SERIAL #:
             1
CRSL ID: 40
CURVE : 1
CAL DATE: 8/02/91
CAL TIME: 15:22:05
ASSAY 26 FSH
                   2223 Revision 2
107 CALIBRATOR LEVEL SENSE ERROR SPCM
MODE 1 CALIBRATOR
LOC mIU/mL RATE FACTOR
 1
     C CODE 183 NO DATA AVAILABLE
```

FIGURE 7

SELECT FERTITLITY MODULE VERSION 1.0

These assays will be included on the SELECT Fertility Assay Module Version 1.0:

#26 FSH #42 LH #43 Prolactin

These assays are the same assays found on the current Reproductive Endocrinology Assay Module Version 4.0 although the protocols have been changed so the assays can be run in the SELECT mode.

The following are the new features of the SELECT Fertility Assay Module Version 1.0

- 1. Loadlist Creation: A loadlist must be created prior to running assays on the IMx SELECT Fertility Assay Module.
- 2. New Assay Parameters: the following parameters are visible and editable in SUPERUSER only:
- Parameter 63 ASY PRIORITY Determines the order in which the assay will be scheduled by the scheduler.
- Parameter 64 BTWN VIAL R1 The rinse type which is used between reagent vial level sensing.
- Parameter 66 SAMPLE VOLUME The minimal volume of sample required for an assay.
- Parameter 82 DELAY BLOCK The block number to which the reagent dispense delay will apply.
- Parameter 86 MN/DL/NT/D&N The protocol type to which the reagent dispense delay will apply.
- 3. New Assay Module Parameters: 7 assay module parameters will be hardcoded with default values that are module specific. These parameters are invisible to the customer and include the following:

Post Rinse Time (POTM) Between block time delay in seconds which must be triggered to execute the post block rinse.

Pre Rinse Time (PRTM) Between block time delay in seconds which must be exceeded before the pre-warm rinse is executed.

Post Rinse Type (POTP) The post block rinse type to be executed.

Pre Rinse Type (PRTP) The pre-warm rinse type to be executed.

Window Option (WOPT) Specifies which calculation is used to determine initial incubation times for those blocks which have incubation windows.

Reagent % Adjustment (PCNT) Percentage by which the software will adjust the calculated reagent volumes.

Abort Tolerance (ABTM) The number of seconds difference between the scheduled and actual incubation times which will cause the assay to abort.

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SELECT FERTITLITY MODULE VERSION 1.0

4. Changes to the Assay Printout: Assay reports will be printed out consecutively for each assay on a SELECT run. If a SELECT run is in the By-Panel format, an additional printout (patient summary) will be generated immediately following the assay printouts which reports assay results on a patient basis. (see Figure 8).

If one or more IMx SELECT assays have aborted due to a fatal level sense error, a printout will be generated for each of those assays with the fatal level sense error. This printout will include the fatal level sense error that caused the assay to abort and each disposable location will be identified with: CODE 183 NO DATA AVAILABLE (see Figure 9)

A new line of information will be added to the header of each assay printout. The new line, "MUP LOT:" will appear on the printouts between "RGNT LOT:" and "SERIAL #:". The addition of this information will help assist in trouble shooting any problems that may occur in using generic MUP with different IMx SELECT reagents (see Figures 9 &10).

NOTE: Scroll down to view graphic examples.

--- PATIENT SUNMARY ---

```
DATE: 6/05/91
TIME: 12:42:38
TECH ID : _____
SERIAL #: 52
CRSL ID : 48
ASSAY
   LH
                     mill/mL
   FSH
                     mill/ml
LOC
     ASSAY
          RESULT RATÉ HÔTE
   PATIENT # 1 ID=000000111
2 LH
                6.09
                       62.8
6 FSH
                       65.0
   PRIJENT # 2 ID=000000222
3 LH
7 FSH
                 6.60
                       66.7
                4.67
                       72.5
   PATIENT # 3 ID=000000333
                5.89
 4 LH
                       61.3
8 FSH
                4.36
                       68.3
```

```
DATE: 8/21/91
TIME: 6:44:48
TECH ID : _____
RGNT LOT: _____
MUP LOT :
SERTAL #:
CRSL ID :
         40
CURVE
CAL DATE: 8/02/91
CAL TIME: 15:22:05
                   2223 Revision 2
RSSAV 26 F3H
107 CALIBRATOR LEVEL SENSE ERROR SPON
MODE 1 CALIBRATOR
LOC
      mIU∠mL
                RATE FACTOR
     C CODE 183 NO DATA AVAILABLE
LOC
      ΙD
                   m/IU/mL
                             RATE NOTE
    LILLEL CODE 183 NO DATA AVAILABLE
    LLLLLL CODE 183 NO DATE AVAILABLE
    _____ CODE 183 NO DATA AVAILABLE
TESTS USED TO DATE :
```

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```
--- IMX SELECT LOADLIST ---
BY RSSPY
```

```
DATE: 8/05/91
TIME: 6:38:36
TECH 10 :
SERIAL #:
          52
MUF LOT :
4818080100381138181111
      ASSAY
                  BERCODE
                           LEFT
                 200401144
    26 FSH
                 200405046
$200f$2:0303:13:03:03000ffffffffct2:0000;
          MODE CURVE DILVALT
            ΜL
FSH
            ΜI
LOU.
        10
                    ASSAY
    :50
         MODE 1
    :50
    .50
    :50
    :50
         NODE 5
    150
    150
    1.59
```

FERTILITY ASSAY

MODULE VERSION 1.0

- 5. Reagent, Waste, and Buffer Management During the assay prologue, after the schedule is determined, the software will calculate the necessary volume management (reagents, buffer, and waste) for that particular SELECT run.
- 6. New Rinse Philosophy for SELECT Assays: SELECT assay protocols will contain a new CLI command that will define which rinse should be executed dependent on the assay block that was performed prior to the current block. This approach will safeguard against unknown analyte carryover.
- 7. Rinse Types: The rinse table listing the defined rinses for the new CLI rinse command resides on the assay module.
- 8. Scheduling of Assay Runs: After a loadlist has been created for a SELECT run, scheduling of the assays will be accomplished via a scheduling algorithm.
- 9. Assay Grouping: Different groups of assays may reside on the same assay module, but only those assays defined within the same group are allowed to be performed together on the same SELECT run. LH, FSH, and Prolactin are in the same assay group.
- 10. Parameter 105 DATA REDUC: If this parameter is set to 0, an assay report will be generated in which each disposable location is identified with NO DATA AVAILABLE.
- 11. Parameter 60 PRINT OPTION: For all assays on the module, this parameter will have a default value of 0 with option 1 (Low, High) allowed as an alternate.
- 12. Alternate Result Unit: For Prolactin, assay parameter 12, RESULT UNIT, will have a default unit of 1(ng/mL) and an alternate result unit of 29 (mIU/L) with a conversion factor of 24.
- 13. Compatibility with System Software Modules: The Fertility Assay Module will not be compatible with system software versions lower than v5.0.

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END OF DOCUMENT



SUBJECT:

TECHNICAL SERVICE BULLETIN

TSB#: 60-032

COM1/COM2 Port Alignment		
ORIGINATOR: Louis Valich		PRODUCT: IMx® (60)
APPROVED: Lou Valich (signature on f	file)	REF. ECN: n/a
IMPLEMENTATION: Immediate Next Service Call Next Failure Optional Instruments Requiring Modification:	TSB Part/Kit #: TSB Effectivity/ Part(s) Availibility: 01-AUG-91	Upgrade Time: n/a Validation Time: n/a Total Mod. Time: n/a
NOTE The instrument must be at TS	Blavel n/a prior to porforming this T	Tep.
NOTE THE INSTITUTION THUST BE AT 13	D Level <u>liva</u> prior to performing this i	JD.

I. Distribution: International and Domestic FSE's

II. General

A. Purpose

When Revision 5.0 Software is released, the customer will be using a Bar Code Scanner to aid in patient sample/reagent identification. The Bar Code Scanner will be plugged into the COM1 port (the port nearest the ON/OFF switch) via a 25 pin connector. It has been found that the Com1/Com2 ports at the rear of the IMx may not align properly, which will prevent the bar code scanner from being attached. This TSB is being issued to correct this problem.

B. Administrative Notes Domestic FSE's only:

This TSB should be closed out in Fieldwatch as follows:

C. Time Required: Approximately 25 minutes

D. Tools Required: Standard FSE Tool Kit

RS-232 LoopBack Plug

E. Parts:

No parts required

Domestic:

No parts required

International:

No parts required

III. Procedure:

Locate the Com1 and Com2 ports at the rear of the IMx. See Figure 1. Using the loopback plug that comes in your Tool Kit, connect the plug into each port. Insure that the plug is centered Top-to-Bottom on both connectors. Since the loopback plug is smaller than the Bar Code Scanner connector, this procedure requires centering of the loopback plug.

If the connectors are centered properly, this TSB is complete. Mark off number 32 on the TSB sticker. Remove the Loopback plug.

If alignment is required perform the following:

- 1. Note the direction and distance to move the Com1/Com2 port to center it properly. This is required because you will need to remove the Enclosure Assembly in order to make the adjustment.
- 2. Power down the instrument and unplug the power cord. Remove the Assay and System Modules. Locate and remove the phillips screw on the front left corner of the baseplate (this screw is not present on instruments S/N 2250 and below). Unlock the sliding latches on all four corners of the instrument by sliding the latch towards the inside of the instrument. Lift straight up on the Enclosure Assembly to remove it from the baseplate. Gently place the enclosure on a FLAT, LEVEL SURFACE.
- 3. Locate the two screws mounting the RS-232 bracket to the cardcage assembly. See Figure 2. Loosen the two screws and adjust the bracket as noted in step 1 above.
- 4. Reinstall the Enclosure Assembly and latch it into place. Repeat procedure to insure correct alignment.

- 5. When the connectors are centered properly, this TSB is complete.
- 6. Reinstall the System and Assay Modules.
- 7. Plug the power cord into the rear of the instrument and power the system on.
- 8. Monitor the display as the system goes through the power-up diagnostics and verify that the system boots properly. During power-up diagnostics "System Diagnostics Version 2.30" will appear in the display. "System Diagnostics Version 2.30" will also be printed on the power-up header.
- 9. Check off number 32 on the TSB sticker (located on the buffer access door, the module access door, the back of the instrument, or the right front of the baseplate assembly).

NOTE: Scroll down to view graphic examples.

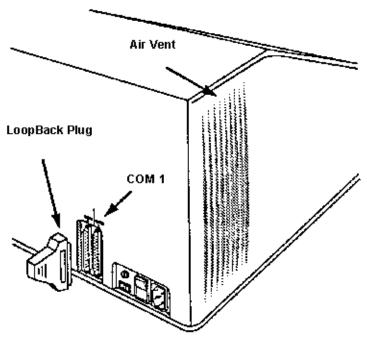


Figure 1

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

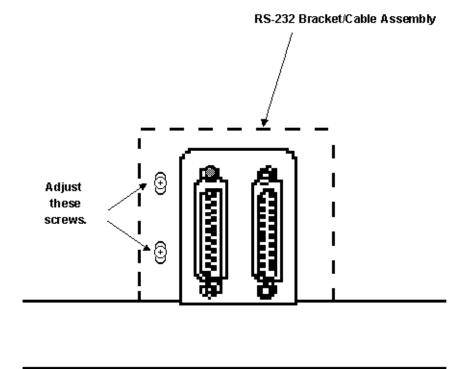


Figure 2

END OF DOCUMENT

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SUBJECT:

TECHNICAL SERVICE BULLETIN

TSB#: 60-031

IMx Continuous Waste System		
ORIGINATOR: Louis Valich		PRODUCT: IMx® (60)
APPROVED: Louis Valich (signature or	n file)	REF. ECN: IMx-1929
IMPLEMENTATION: Immediate Next Service Call Next Failure Optional	TSB Part/Kit #: TSB Effectivity/ Part(s) Availibility: 23-MAY-91	Upgrade Time: n/a Validation Time: n/a Total Mod. Time: n/a
Instruments Requiring Modification: Customer Selected Option		

Distribution: International and Domestic FSE's

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

II. General

A. Purpose

This modification will provide the customer with a convenient alternative to the standard IMx waste collection and removal. It will eliminate frequent emptying of the IMx waste container by allowing large volumes of waste to be collected in an external waste bottle. The external waste bottle will be connected to the IMx by a waste tubing that is routed through an opening on the front panel of the IMx system. This tubing is attached to a modified internal IMx waste container. The Continuous Waste System is implemented by editing one System File parameter on the IMx.

B. Administrative Notes

Domestic FSE's only:

This TSB should be closed out in Fieldwatch as follows:

- C. Time Required: Approximately 30 minutes
- D. Tools Required: Standard FSE Tool Kit

E. Parts:

IMx Continuous Waste Kit (LN 3A40-01) provides the following: (See Diagram 1 on page three of installation procedure.)

IMx Continuous Waste Container with drain tubing and clamp

White Elbow Connector with Nut

Waste Tubing with Black and Yellow Connectors (30 inch clear tygon tubing)

Items required but not provided:

IMx Front Panel with Button cover and Serial Number Label (P/N 45716-101). (See Diagram 2 on page three of installation procedure.)

Waste Bottle with vented cap (LN 6208-21) (High-density polyethylene rectangular 15 liter carboy with spigot)

Scissors

Domestic:

1. No parts will be added to the Field Service parts kit.

International:

1. No parts will be added to the Field Service parts kit.

III. Procedure:

To install the IMx Continuous Waste System, follow the instructions provided with this TSB. These are the same instructions given to the customer at the time of purchase. These instructions provide the following information:

- 1) Hardware requirements
- 2) Installation procedure

- 3) Edit software parameter to activate continous waste
- 3) Maintenance
- 4) Troubleshooting

The IMx Front Panel with button cover and Serial Number Label is not a customer installed item. Regulatory requires that Abbott personnel remove this item and install the new panel and serial number. Transcription of the serial number onto the new front panel is crucial. IMx S/N's below 3024 will need this Front Panel.

Since this is an optional TSB, if you are required to go in and install the Front Panel with Button and new Serial Number Label, you will need to bill the customer at the normal billing rates for travel and labor. In order to avoid this extra billing to the customer, the CSC will attempt to have a TMR install these items.

To remove the old Front Panel assembly, remove the five screws attaching the Front Panel to the IMx base and remove the Front Panel. Install the new Front Panel with Button hole and Serial Number Label (45716-101) and secure with the five screws just removed. Transcribe the Serial Number EXACTLY from the old front panel to the new Serial Number Label, with black endurable ink. Deface the old Front Panel by marking an "X" over the serial number.

Domestic FSE's and TMR's should send the old front panels back to Dallas for proper handling. Use the following address:

Abbott Laboratories 1825 Walnut Hill Lane LC-5 Irving, Texas 75038 Attn: "X"-Systems Field Service

International Service sites should follow the procedure set up with the local TSO organization.

Follow the installation procedure to complete the installation of the Continuous Waste Kit.

Mark off number 31 on the TSB sticker.

END OF DOCUMENT



Next Service Call

SUBJECT:

TECHNICAL SERVICE BULLETIN

TSR#- 60-030A

PAL change to IMx® Memory PCB					
	ORIGINATOR: Louis Valich/Chris Rodolfo		PRODUCT: IMx® (60)		
APPROVED: Ron Elston - 5/11/93 (signature on file)		ature on file)	REF. ECN: 1870		
	IMPLEMENTATION:	TSB Part/Kit #: n/a	Upgrade Time: 25 min.		
	Immediate	TSB Effectivity/	Validation Time:		

Next Failure
Optional

Instruments Requiring Modification:
S/N 6503 & Below and 6782 thru
8272

Part(s) Availibility: 20-APR-93

IMx is a registered trademark of Abbott Laboratories.

Distribution: International and Domestic FSE's

II. General

A. Purpose

This TSB is being updated to reflect changes in the PAL chip availability. The existing PAL chip (P/N 04880-103) is no longer available from the vendor. A replacement chip has been selected and tested by engineering (P/N 04880-104). Any PAL chips still in FSE stock are good and should be used before ordering the new chip.

The purpose of this modification is to expand the assay module memory address space, which will be required for future **Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.**

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

enhancements of the IMx® . A PAL (Programmable Array Logic chip) will need to be changed on the Memory PCB located in the card cage.

Only instruments with Intel CPU boards and a separate Memory Board are affected

B. Administrative Notes

Domestic FSE's only:

This TSB should be closed out in Fieldwatch as follows:

SC =03

TC =30

RC =93

C. Tools Required: Standard FSE Tool Kit

D. Parts:

1 each programmed PAL P/N 04880-104 (Designated U25 on newer boards and E15 on older version boards.)

The 04880-103 chips were shipped per the IRL. The -104 chips should only be ordered if additional chips are needed.

III. Procedure:

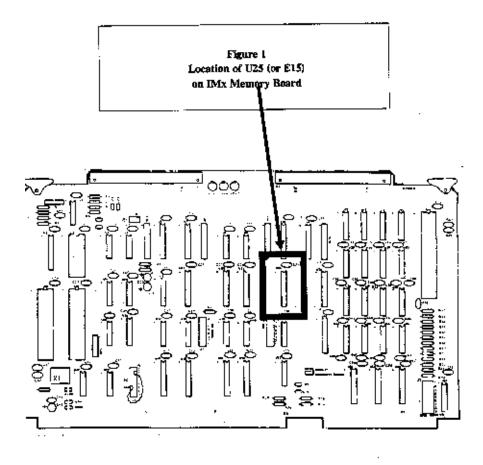
- 1. Power down the instrument and unplug the power cord.
- 2. Remove the Assay and System modules
- 3. Locate and remove the Phillips screw on the front left corner of the baseplate (this screw is not present on instruments S/N 2250 and below). Unlock the sliding latches on all four comers of the instrument by sliding the latch towards the inside of the instrument. Lift straight up on the enclosure assembly to remove it from the baseplate. Gently place the enclosure on a FLAT, LEVEL SURFACE.
- 4. Use proper anti-static precautions. Always ground yourself to the Main Power Supply chassis before handling any printed circuit board.
- 5. Disconnect the cables that are attached to the printed circuit boards through the card cage top plate. Pay particular attention to the orientation of the two wire cable that connects to the Memory Board through the card cage top plate: wrongly oriented, this cable can damage the Analog Board quickly! Remove the two thumbscrews that hold the shield bar and motor driver cable onto the card cage top plate. Slip the cable out from under the shield bar. Unlatch the clips holding the card cage top plate (some units will have four thumbscrews rather than latches) and remove the top plate.

NOTE: Instruments with an ASIC board do not require this modification.

- 6. Locate the Memory PCB: this will be the board farthest to the rear of the 3 boards housed within the card cage. Lift up, simultaneously, on the Memory board's ejector clips to loosen the board. Once loosened, pull up on the outside comers of the Memory board to remove it from the card cage.
- 7. Lay the Memory Board component side up; remove and replace U25 on the newer version boards or E15 on the older version boards. See Figure 1 for the location of this chip on the Memory Board. After installing the chip, check that all leads are in the sockets and not bent underneath them. Verify that the chip is fully seated in it's socket.
- 8. Reinstall the Memory PCB back into the card cage. Put the top cover of the card cage back on.
- 9. Reinstall all cables in their respective connectors.
- 10. Reinstall the Enclosure assembly and latch it into place.
- 11. Reinstall the System and Assay modules.
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- 12. Plug the power cord into the rear of the instrument and power the system on.
- 13. Monitor the display as the system goes through the power-up diagnostics and verify that the system boots properly. During power-up diagnostics "System Diagnostics Version 2.30" will appear in the display. "System Diagnostics Version 2.30" will also be printed on the power-up header.
- 14. Check off number 30 on the TSB sticker (located on the buffer access door, the module access door, the back of the instrument, or the right front of the base plate assembly).
- 15. Discard the old PALs.

NOTE: Scroll down to view graphic example.



COMPONENT SIDE

END OF DOCUMENT

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TECHNICAL SERVICE BULLETIN

SUBJECT: ASIC CPU/M emory Board Replacements	TSB#: 60-025B	
ORIGINATOR: Louis Valich	PRODUCT: IMx® (60)	
APPROVED: Fred Schwartz (signature	on file)	REF. ECN: 1-330
IMPLEMENTATION: Immediate Next Service Call Next Failure Optional	TSB Part/Kit #: TSB Effectivity/ Part(s) Availibility: 02-SEP-90	Upgrade Time: Validation Time: Total Mod. Time:
Instruments Requiring Modification: Serial numbers 6503 and below and 6782 to 8272.		
NOTE The instrument must be at TS	l B Level <u>n/a</u> prior to performing this TS	<u> </u> B.

I. Distribution: International and Domestic FSE's

II. General

A. Purpose

THIS TSB SUPERSEDES TSBs 60 025 and 60 025A EFFECTIVE IMMEDIATELY

The purpose of this TSB is to notify the field of a change to the CPU printed circuit board. We are implementing a newly designed chip set to replace the Intel CPU Board and the Memory Board. This new design is called the ASIC CPU Board. ASIC stands for Application Specific Integrated Circuits. This new technology affords us an excellent opportunity to reduce the cost of the IMx System.

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The ASIC CPU Board is a drop-in replacement for the existing Intel 286t10A-F CPU/IMx Memory Board combination. The ASIC Board will maintain complete mechanical compatibility with the current IMx system with the following exceptions: The Printer port and serial port cables will change from edge mount to board mount connectors (cable lengths will also change).

B. AdministrativeNotes Domestic FSE's only:

If this TSB is used to upgrade a current "Intel" system, it should be closed out in FieldWatch as follows:

SC=03 TC=25 RC=93

C. Time Required: 30 minutes for upgrade; 2 hours for checkout

D. Tools Required: Standard FSE Tool Kit

E. Parts:

<u>Part</u>	Part Number	Quantity
ASIC CPU Board	3-44410-01	1
Printer Cable	3-44620-01	1
RS-232 Cable assembly	3-44617-01	1
Switch, Paper Feed *	3-04855-01	1
* S/N 3700 and lower		

There will be a limited supply of ASIC CPU Boards during the initial launch. In December, approximately 300 IMx Systems will be manufactured with the ASIC CPU. There will be an inventory of 100 ASIC CPU Boards to be used for Field Service and other support functions. No other ASIC Boards will be built or used in manufacturing until February, 1990.

An ASIC Board should only be replaced in an IMx System that already has an ASIC Board. If a Memory Board or Intel CPU Board goes bad, replace with a Memory or Intel CPU Board.

Special Note

The only condition that would allow you to update a Memory/Intel CPU combination would be If checksum or factory set errors have occurred more than once and cannot be resolved by normal troubleshooting methods. Again, this is the only condition to update an IMx. It is mandatory to call an IMx TSS when installing an ASIC CPU board to give the instrument S/N for tracking purposes.

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Domestic:

Due to the limited availability of the ASIC Board, Federal Express the part to the account, per normal priority shipping procedures.

International:

The Field Service Kits should contain the new Printer Cable and RS-232 Cable/Bracket assembly. Again, due to the availability of the ASIC CPU, limited quantities are available. Send forecast requirements to Field Service Parts Logistics in Dallas.

III. Procedure

Enter superuser by doing the following:

Press "."

Enter the 4 digit date code from the superuser card.

Press ".". The display should say Ready (super)

Print out System files 1,2,3,4,37,38. Doing this will cut down on the checkout time when this modification is completed.

Power the IMx Analyzer off.

Remove the Assay and System Modules.

Remove the Enclosure Assembly.

NOTE: Remember to tollow proper grounding procedures (ground yourself) to prevent static discharge and possible damage to the circuit boards. Handle the circuit boards as little as possible and leave the ASIC CPU board in the anti static bag until ready to install into the IMx System.

Remove the printer cable going from the CPU Board to the printer interface or Printer Driver Board.

Disconnect the paper feed switch connector from the printer cable, if that is the type of cabling installed.

Remove the I/O to Analog Bd 60 pin cabling at the card cage.

Remove the I/O to Motor Driver Bd 60 pin cabling at the card cage.

Remove the RS-232 cable from the CPU Board and remove the other end of the cable (bracket assembly) from the base of **Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.**

Remove the Barcode Reader cable from the Memory Board.

Pull the top cover off the card cage.

Remove the Memory Board and the Intel CPU Board.

Before installing the new ASIC CPU board, remove all four NOVRAMs (U53,U54, U86, U87). Refer to Figure 2 for location. Set the NOVRAMs aside.

Next, remove NOVRAM U53 from the Intel CPU board and install it in the U53 socket on the ASIC CPU board. Refer to Figure 1 for location of NOVRAMs on the Intel CPU board. Note Novram orientation in Figure 4.

Repeat for the remaining three NOVRAMs.

Then install the 4 NOVRAMs that were removed from the ASIC CPU board into the empty NOVRAM sockets on the Intel CPU board. Install the new ASIC CPU Board in the slot where the Memory Board normally . goes.

Connect the new RS-232 Cable and bracket assembly to the IMx base where the old one attached. Fold the cables so that the routing will travel up the right side of the card cage and along the top of the boards in the cage. Connect the cable ends to the appropriate connectors on the ASIC CPU Board. Route the cabling neatly since the cardcage top cover will be placed over these cables. Refer to Figure 3 for cable routing.

Connect the new printer cable to the Printer Driver board (for S/N 3700 and below, change paper feed switch per TSB-024) and route the other end carefully up the right side of the card cage and connect to the CPU Board. Again, be careful about dressing the cable neatly since the card cage cover will go over it.

Connect the Barcode Reader cable to the CPU Board. Install the card cage top cover.

Connect the cabling from the Motor Driver and Analog Boards to the I/O Board in the card cage.

Reinstall the Enclosure assembly and software modules, insuring that the connectors on the ASIC CPU Board are centered in the openings of the Enclosure Assembly. Make sure to latch the Enclosure to the Base assembly.

Get into superuser as you did earlier in this procedure. Print out System files

Using the System files that you printed out earlier, verify that the new System file printouts match the original printouts.

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Perform a Boom Check and both MEIA and FPIA Temperature Checks and Photo Checks. Perform a Dispense Check.

Run an FPIA and MEIA Assay to verify overall functionality of the IMx.

Mark off number 25 on the TSB sticker located either on the backside of the Buffer Door or the rear of the IMx Enclosure.

Domestic FSE's should send the Intel CPU and Memory Boards back to Dallas through the normal parts return procedure. Be sure to tag all parts with a Returned Goods Tag indicating " replaced per TSB 60-025 " and the "reason for replacement".

International FSE's should send the Intel CPU and Memory boards back to their local Abbott depot for return to the United States. All parts should be tagged as to "reason for replacement" and "Replaced for TSB 60-025".

To view the previous section of this TSB click once on the button Return to Section 1

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

To view the previous section of this TSB click once on the button Return to Section 1

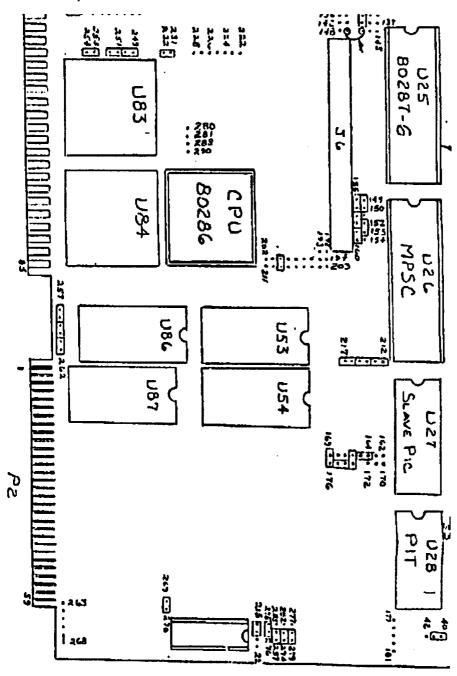


Figure 1
Intel CPU Board Layout

Figure 1 Intel CPU Board Layout

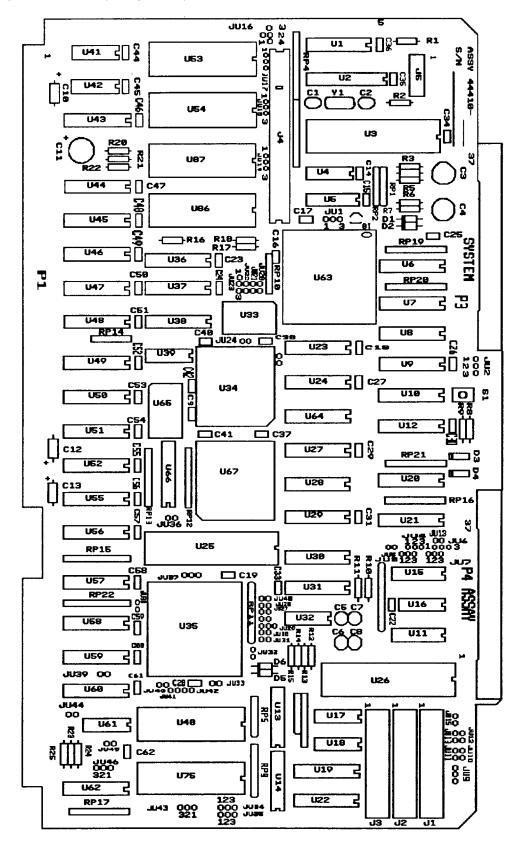
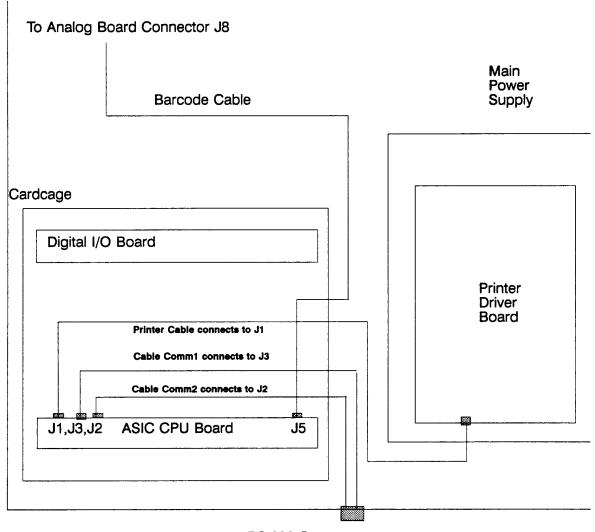


Figure 2
ASIC CPU Board Layout



RS-232 Connectors

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All Cables are run

through the right side of the cardcage underneath the removable top cover.

Figure 3
ASIC CPU Cable Routing

To view the previous section of this TSB click once on the button Return to Section 4

The ASIC CPU/MEMORY Board has four 32 pin sockets on board that the NOVRAM (U53, U54, U86, and U87) are placed in. The NOVRAM are 28 pin devices that are oriented as shown in the diagram below (Figure 4).

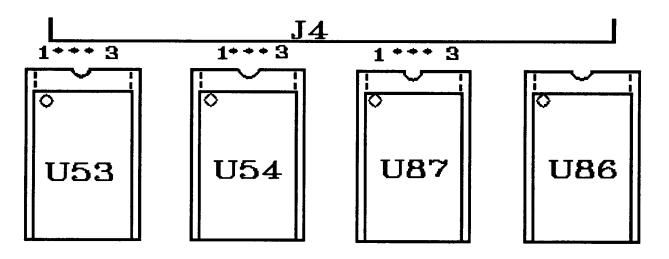


Figure 4
Novram orientation on ASIC CPU/MEMORY Board

END OF DOCUMENT

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