ABBOTT ADD

INDEX
TECHNICAL SERVICE BULLETIN

PRODUCT: **ABBOTT PRISM® (82)**

DATE: **09-AUG-1999**

TSB #	IMPLEMENTATION	SUBJECT	EFFECTIVITY DATE
82-034	O - See TSB	Version 2.5 Software Upgrade	06-AUG-1999
82-033	**O - See TSB**	**Version 2.5 Software Upgrade - Japan Only**	**06-AUG-1999**
82-032	M - S/N 1152	Version 2.5 Software Upgrade CBER Site USA	15-JUL-1999
82-031	O - See TSB	Bar Code Scanner Read Enhancement	06-AUG-1999
82-029	I - See TSB	Version 2.1 Software Upgrade - Japan Only	17-FEB-1999
82-028	O - S/N 1160 & below	HBCore Hardware Upgrade (Channel 5)	17-FEB-1999
82-027	I - See TSB	Version 2.1 Software Upgrade	17-FEB-1999
82-026	I - See TSB	Version 2.1 Hardware Upgrade	17-FEB-1999
82-025	I - See TSB	Bar Code Reader Firmware Upgrade (Japan)	11-DEC-98
82-024	M - See TSB	Software Version 2.0 (Clinical)	N/A
82-023	M - See TSB	Hardware for Version 2.0 Software (Clinical)	N/A
82-022B	I - S/N 001 thru 1140	1.52 Software Upgrade	11-FEB-98
82-022A	I - S/N 001 thru 1146	1.52 Software Upgrade	OBSOLETE
82-022	I - S/N 001 thru 1146	1.52 Software Upgrade	OBSOLETE
82-021	I - S/N 001 thru 1146	1.51 Software Upgrade	COMPLETE
82-020A	I - S/N 001 thru 1140	Reagent Bottle Tubing ID Verification	11-FEB-98
82-020	I - S/N 001 thru 1146	Reagent Bottle Tubing ID Verification	OBSOLETE
82-019A	I - S/N 001 thru 1140	Bar code Reader Update	11-FEB-98
82-019	I - S/N 001 thru 1146	Bar code Reader Update	OBSOLETE
82-018A	I - S/N 001 thru 1140	Air Tip Wash/ Dispense Verify Update	11-FEB-98
82-018	I - S/N 001 thru 1146	Air Tip Wash/ Dispense Verify Update	OBSOLETE
82-017	O - S/N 001 & Above	1.5 Software Upgrade	COMPLETE
82-016	I - S/N 1109 & below	ABBOTT PRISM® Power Supply Extender Cable	25-SEP-96
82-015	O - See TSB	ABBOTT PRISM® (4) to (6) Channel Upgrade	15-OCT-96
82-014	F - S/N 1071 & below	Barcode Reader Cover	11-OCT-96
82-013	O - 1074 & below	ABBOTT PRISM® Stacker Door	02-AUG-96
82-012	I - S/N 1106 & below	Heater Controller EPROM Upgrade	COMPLETE
82-011	I - S/N 1049 & below	EFT (Electrical Fast Transients) Level 3 Upgrade	COMPLETE
82-010	O - 1050 & above	Tip Stripper Assembly	31-MAY-96
82-009	F - S/N 1057 & below	Bar Code Reader Motor Coupler	21-OCT-96
82-008	I - S/N 1049 & below	ABBOTT PRISM® Refrigerator Remote Sensor Retrofit Upgrade	COMPLETE
82-007	O - S/N 1049 & below	ABBOTT PRISM® Non-CFC Refrigerator and Cover Upgrade	23-MAY-96
82-006	I - S/N 1049 & below	ABBOTT PRISM® Tip Chute Assembly Upgrade	COMPLETE
82-005	I - S/N 001 & above	ABBOTT PRISM® 1.3 Software Upgrade	COMPLETE
82-004	I - S/N 1049 & below	ABBOTT PRISM® New Tray Loader with Firmware	COMPLETE
82-003	O - S/N 1049 & below	EMC (Emissions) Level 2 Upgrade	10-OCT-96
82-002	O - S/N 1049 & below	EMC (Susceptibility) Level 1 Upgrade / CE Mark Certified PRISM® CE Mark Upgrade Procedure and Modifications	10-OCT-96
82-001	I - S/N 1049 & below	ABBOTT PRISM® XY Axis Controller Firmware Upgrade	COMPLETE

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

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TECHNICAL SERVICE BULLETIN

SUBJECT:
Version 2.5 Software Upgrade

TSB#: **82-034**

ORIGINATOR: **Dan Armstrong**
APPROVED: **Dan Armstrong 06-AUG-1999**

PRODUCT:
ABBOTT PRISM® (82)
REF. ECN: 14049-004, 005

IMPLEMENTATION:	TSB Part/Kit #: **1-65750-01**	Upgrade Time: **4 hrs.**
○ **Mandatory**	TSB Part(s) Availibility: **16-JUL-1999**	VerificationTime: **4 hrs.**
○ **Next Service Call**	**TSB Tracking by Serial # required (MANDATORY TSB's ONLY)**	Total Mod. Time: **8 hrs.**
● **Optional**	○ YES	****NOTE** The instrument must be at TSB Level 82-027 prior to performing this TSB.**
Instruments Requiring Modification: **As Required**	● NO	

I. DISTRIBUTION:

World Wide except Japan

II. PURPOSE:

Update the instrument to version 2.5 software. Documents and procedures associated with 2.5 software will also be

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required for this installation. Changes associated with this version software are identified in ISA 82-031.

III. ADMINISTRATIVE NOTES:

This TSB must be performed after TSB 82-027. Make copies of the Checklist at the end of this TSB. Complete the checklist after upgrade, sign it and leave it with the customer. The password for **Abbott Access** in this version software is **INCREDULOUS** (all caps).

Customer Support Information:

1. **Initial Reactive** samples should be retested prior to software upgrade.
2. At the completion of this upgrade, the customer should run additional samples to duplicate actual routine testing. The testing protocol should be determined by the laboratory's Standard Operating Procedures. All test results must be consistent with expected results.
3. Leave all letters with the customer.
4. All test results will be deleted when the new version software is loaded. Therefore, have the customer print reports, copy reports to floppy and/or send data to the host as required based on their test result status.
5. On a four channel instrument, after installing software, you will get communication errors on the uninstalled channels until you configure them to "Not Used".

Upon completion of the upgrade:

1. Use the normal procedures for notification of the TSB.
2. Leave the check list and all associated documentation with the customer.
3. Make sure both you and the customer have signed the documents.
4. Remove all previous version software disks and dispose of them.

IV. SPECIAL TOOLS:

N/A

V. PARTS:

1-65750-01	Kit, Version 2.5 Software Upgrade		1
	Contains:		
	Disks, version 2.5 Software		1 set
	Resource Accounting File Conversion Tools Disk	1	
	Letter, Software		1
	Letter, Enhancement		1

REPLACED PARTS:

N/A

COMPATIBILITY:

Previous versions of software are not compatible.

VI. PROCEDURE:

MODIFICATION STEPS:

NOTE: Use of the current Field Service DT Manual and TSB's is required.

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A. Software Installation:

1. Pre-Software Load.
   a. Turn on all installed channels (set Channel 6 as maintenance)

   b. Print the current Run Controls Configuration.
   From the Main Menu:
   Instrument Preparation
   Manage Resources
   Run Controls
   Select a defined run control
   Print the Run Control Configuration screen (**F3**). Retain this printout for use later in this procedure.
   Repeat these steps for all defined Run Controls. Return to the Main Menu by pressing the **Esc** key.

   c. Print the current Audible Alarm Configuration.
   From the Main Menu:
   Maintenance
   Hardware Configuration
   Audible Alarm Configuration
   Print the Audible Alarm Configuration screen (**F3**). Retain this printout for use later in this procedure.
   Return to the Main Menu by pressing the **Esc** key.

   d. Print the current Host Interface Configuration.
   From the Main Menu:
   Maintenance
   Hardware Configuration
   Host Interface Configuration
   Print the Host Interface Configuration screen (**F3**). Retain this printout for use later in this procedure.
   Return to the Main Menu by pressing the **Esc** key.

   e. Print the current Bar Code Configuration.

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From the Main Menu:
Maintenance
Hardware Configuration
Bar Code Configuration
Print the Bar Code Configuration screen (**F3**). Retain this printout for use later in this procedure.
Return to the Main Menu by pressing the **Esc** key.

f. Print the current Batch Parameters.
From the Main Menu:
Maintenance
Software Configuration
Batch Parameters
Print the Batch Parameters Configuration screen (**F3**). Retain this printout for use later in this procedure.
Return to the Main Menu by pressing the **Enter** and then **Esc** key.

g. Print the current Print Report Configuration.
From the Main Menu:
Maintenance
Software Configuration
Print Report Configuration
Print the Print Report Configuration screen (**F3**). Retain this printout for use later in this procedure.
Return to the Main Menu by pressing the **Esc** key.

h. Print a listing of the current Users.
From the Main Menu:
Maintenance
User Configuration
List the Users
Print the Users List screen (**F3**). Retain this printout for use later in this procedure.

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Return to the Main Menu by pressing the **Esc** key.

i. Print a listing of the current gray zone settings **(if applicable)**.
From the Main Menu:
Maintenance
Software Configuration
Gray zone Configuration
Print the Gray zone Configuration screen (**F3**). Retain this printout for use later in this procedure.
Return to the Main Menu by pressing the **Esc** key.

j. Print Localization settings.
From the Main Menu:
Maintenance
Software Configuration
Localization
Print the Localization screen (**F3**). Retain this printout for use later in this procedure.
Return to the Main Menu by pressing the **Esc** key.

k. Purge all Channels.

l. Print tests available for current reagents.
From the Main Menu:
Instrument Preparation
Manage Resources
Go into the menu options (reagents, wash solutions, and purges) and print.

m. Print Kit Usage Information.
From the Main Menu:
Maintenance
Kit Usage Review

Go into the menu for each assay and print the Kit Utilization screen .

n. Set all channels to XFER_2S or XFER_3S

2. Software Installation Instructions.

Equipment Required:

Software Update diskettes
Resource Accounting File Conversion Tools Disk
Blank Formatted 3.5", 1.44 MB Floppy Diskette

a. Log on to ABBOTT PRISM® System with Abbott Access.

b. Make a backup copy of current instrument configuration.
- Use a blank, formatted diskette.
- Perform Configuration Backup
  From the Main Menu:
  Maintenance
  Software Configuration
  Configuration Backup/Restore
  Backup Configuration
  When requested, insert the blank formatted diskette and press **Enter**.
  Press **Enter** to continue.
- When backup is complete press **Enter**. Remove diskette.
- Label diskette as Configuration Backup, with date and ABBOTT PRISM® Serial Number. Retain for later use.
- Return to Main Menu (press **Esc** key 3 times).

c. Exit ABBOTT PRISM® Software.
From the Main Menu:
Engineering

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Exit Program

Press the **Y** key to confirm shutdown.

d. Backup Resource Accounting Data.

(1) Verify Date and Time.

At the DOS prompt type:

C:\date

Verify that the correct date is displayed. If it is not, enter the correct date. If the correct date is displayed press the enter key.

At the DOS prompt type:

C:\time

Verify that the correct time is displayed. If it is not, enter the correct time. If the correct time is displayed press the enter key.

(2) Insert the conversion tools disk into the floppy drive.

(3) At the DOS prompt, type:

A:\C12

Once the conversion is completed successfully you will get the message:

"RAC Backup: Success"

If a lockup occurs, reboot the instrument and repeat steps **c** and **d**.

If you get an error (other than "the wrong diskette") you will need to manually convert the Manage Resources as described in section B of this TSB.

(4) Remove the disk from the floppy drive.

e. Install the new software.

- Insert Disk 1 of the new software disk set.
- At the prompt:

C:\PRISM\VGA>_

Type in:

cd\

and press the enter key.

- At the prompt:

  C:

  Type in

  a:\install

  and press the enter key.
- Follow the screen prompts to complete loading the new version of software.

Note: Some prompts will refer to the new version software disk set as the backup.

3. Restore System configuration.

   a. When prompted, reboot ABBOTT PRISM® System Computer by pressing **CTRL**, **ALT**, **DEL** keys simultaneously. Computer boots up to ABBOTT PRISM® Logon Screen.

   b. Log on to ABBOTT PRISM® System with Abbott Access.
   Note: The Password is **INCREDULOUS** (all Caps)

   c. Place configuration backup diskette created earlier into floppy disk drive.

   d. Restore Configuration.
   From the Main Menu:
   Maintenance
   Software Configuration
   Configuration Backup/Restore
   Restore Configuration

   e. When restore is complete, press **Enter**. Remove floppy diskette from diskette drive and retain for future use. (Use only with this serial number instrument.)

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f. Return to Main Menu (press **Esc**).

g. Reboot ABBOTT PRISM® Computer.
Engineering
Exit Program
From DOS prompt press **CTRL**, **ALT**, and **DEL** keys simultaneously.

4. Restore Resource Accounting Data.

a. Exit ABBOTT PRISM® Software.

From the Main Menu:
Engineering
Exit Program
Press the **Y** key to confirm shutdown.

b. Insert the conversion tools disk into the floppy drive.

c. At the DOS prompt, type:
A:\C12
If you get an error (other than "the wrong diskette") you will need to manually convert the Manage Resources as described in section B of this TSB.

If the restore works correctly you will get the message:

RAC Restore SUCCESS

d. Remove the conversion tools disk from the floppy drive.

e. Reboot ABBOTT PRISM® Computer.
From DOS prompt press **CTRL**, **ALT**, and **DEL** keys simultaneously.

Note: Return conversion tools disk to:

N. A. Abunimeh
D-9GK/Bldg AP1A
100 Abbott Park Road
Abbott Park, IL, USA 60064

5. Restore System Configuration.

   a. Log on to ABBOTT PRISM® System with Abbott Access.
   Note: The Password for 2.5 is **INCREDULOUS** (all Caps).

   b. Configure the Mode Directive setting to US or ROW.
   From Main Menu:
   Maintenance
   Software Configuration
   Mode Directive
   Set to **US or ROW** - (Spacebar) to select
   (F10) to save

   Follow instructions on screen and shutdown
   Press **CTRL**, **ALT**, and **DEL** keys simultaneously when requested to reboot the system.

   c. Configure Assays.
   From Main Menu:
   Maintenance
   Assay Configuration (this may be site or country specific)
   Set access types for selected assays to customer, and set status to active for the selected assays. Save (F10) settings.

   Assign assays to channels as shown:

Channel 1	HTLV I/II	Channel 2	HCV
Channel 3	HIV 1/2	Channel 4	HBsAg

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Channel 5 HBc Channel 6 Not Used
(Spacebar) to select (F10) to save

d. Configure Channels to the same as before loading software.

e. Verify the tests available. Match the previous (before installing software) levels.

(1) Print tests available for current reagents.
From the Main Menu:
Instrument Preparation
Manage Resources
Go into the menu options (reagents, wash solutions, and purges) and print.

(2) Print Kit Usage Information.
From the Main Menu:
Maintenance
Kit Usage Review
Go into the menu for each assay and print out the Kit Utilization screen .

Compare the printouts before and after loading software. Verify that the numbers are close to the same (within 30). If there are any discrepancies complete section B, Reagent Tracking Worksheet and Table.

Refer to the printout obtained from the Pre-Software Load section (if applicable) for the following procedures. (see the Operations Manual for editing instructions).

f. Configure the Run Controls from the appropriate printout.

g. Configure the Host Interface from the appropriate printout.

h. Configure a maintenance level User. Check with the customer for name and password preference.

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i. Configure language, Keyboard, and Date Format from appropriate printout.
From Main Menu:
Maintenance
Software Configuration
Localization
(Spacebar) to select (F10) to shutdown and save. Press F10 again when prompted. Reboot the system (press Ctrl Alt, and Del keys simultaneously) when prompted.
Note: Save (F10) your settings even if you are leaving the settings at the default (English).

j. Configure the Bar Code configuration from the appropriate printout.

k. Configure the Print Reports from the appropriate printout.

l. Verify the Batch Parameters. Check previous printout for setting (default is

8.5 hrs.)

m. Verify Audible Alarm Configuration matches printout from step 1(edit if necessary).

n. Verify the correct serial number (located in the upper left corner of the screen). Enter the correct number if incorrect. If incorrect, perform the following procedure:
From Main Menu:
Maintenance
Software Configuration
Set Serial Number

- Reboot the system for the new number to take effect.

From the Main Menu:
Engineering
Exit Program
From DOS prompt press **CTRL**, **ALT**, and **DEL** keys

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simultaneously.

o. Verify the date and time (located in the upper right corner of the displayed screen). If correction is required, perform the following procedure:
From Main Menu:
Maintenance
Hardware Configuration
Set Time and Date

p. Verify Gray Zone settings match printout from step 1 (if applicable).

q. Reboot ABBOTT PRISM® Computer.

B. REAGENT TRACKING WORKSHEET AND TABLE

This worksheet will provide a method for supplying the customer with a method to track the tests available for reagent kits, wash solutions and purge solutions that were in progress when software was upgraded if the resource management backup does not work. The number next to New, represents the tests available for a new kit, wash or purge component. By subtracting the number of tests that remained for a reagent from the tests available for a new reagent, when the user reaches the number of tests on line 2.5 they have completed that reagent and **must** replace it.

1. For each assay:
On the 2.1 line, enter the number of Tests Available" (from the printouts made before loading software) for each of the following:
Reagent Kit
Wash solution
Purge Solution

2. Enter on the 2.5 line:
The difference between New (tests available for new kit) minus Vs. 2.1 (tests available). Note: These numbers are on the print screens that you printed before performing the software upgrade.

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3. Enter the 2.5 tests available number onto the “Reagent Tracking” table.
IMPORTANT: Instruct the customer that when any reagent, wash or purge component “Tests Available” decreases to the number on the “Reagent Tracking” table, there are zero (0) tests remaining. **REPLACE THE COMPONENT!**

Worksheet:

ASSAY	REAGENT KIT	TRANSFER WASH	CONJUGATE WASH	PROBE WASH	PURGE SOLUTION
HTLV	New 5976 Ver2.1 - _____ Ver2.5= _____	New 5080 Ver2.1- _____ Ver2.5= _____	New 5426 Ver2.1- _____ Ver2.5= _____	New 5404 Ver2.1- _____ Ver2.5= _____	New 39 Ver2.1- _____ Ver2.5= _____
HCV	New 6092 Ver2.1- _____ Ver2.5= _____	New 5110 Ver2.1- _____ Ver2.5= _____	New 5456 Ver2.1- _____ Ver2.5= _____	**XXXX**	New 44 Ver2.1- _____ Ver2.5= _____
HIV	New 6030 Ver2.1- _____ Ver2.5= _____	New 5116 Ver2.1- _____ Ver2.5= _____	New 5274 Ver2.1- _____ Ver2.5= _____	New 5329 Ver2.1- _____ Ver2.5= _____	New 39 Ver2.1- _____ Ver2.5= _____
HBsAg	New 6148 Ver2.1- _____ Ver2.5= _____	New 5162 Ver2.1- _____ Ver2.5= _____	New 5306 Ver2.1- _____ Ver2.5= _____	**XXXX**	New 55 Ver2.1- _____ Ver2.5= _____
HBc	New 6286 Ver2.1- _____ Ver2.5= _____	New 5208 Ver2.1- _____ Ver2.5= _____	New 5532 Ver2.1- _____ Ver2.5= _____	**XXXX**	New 55 Ver2.1- _____ Ver2.5= _____

"REAGENT TRACKING"

REPLACE REAGENT KIT, WASH SOLUTION OR PURGE SOLUTION WHEN THE NUMBER OF TESTS AVAILABLE REACHES THE VOLUME LISTED BELOW.

ASSAY	REAGENT KIT	TRANSFER WASH	CONJUGATE WASH	PROBE WASH	PURGE SOLUTION
HTLV					
HCV				XXXX	
HIV					
HBsAg				XXXX	
HBc				XXXX	

CHECKOUT:

1. Confirm XY settings are correct. Pick up and strip off ten sets of pipette tips. From the Main Menu:
   - Component Diagnostics

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- Sample Manager
- Tip Pick Up

Set for ten cycles, both axis.

2. Perform the Optics Validation Procedure on all channels on the instrument.
3. Perform the Channel Temperature Validation Procedure on all channels on the instrument.
4. Perform an Assay Calibration on identified channels.

MODIFICATION CONTROL STICKER UPDATE:

Using a permanent marker, mark through the number thirty four (34) on the TSB Modification Control Sticker.

ABBOTT PRISM® Version 2.5 Software Upgrade Checklist

While performing this TSB, mark off the items listed in the checklist after they are successfully performed. Attach all printouts from this upgrade.

Instrument S/N _____ Account Name _____

Date of Update _____ Account Address _____

Configuration:

# of tests remaining verified	Yes _____	No* _____
Mode Directive Configured	Yes _____	No* _____
Assays Configured	Yes _____	No* _____
Host Interface Configured	Yes _____	No* _____
Maintenance level user Configured (Customer chooses name and password).	Yes _____	No* _____
Localization Configured	Yes _____	No* _____
Bar Code Configured	Yes _____	No* _____
Print Reports Configured	Yes _____	No* _____
Batch Parameters Verified.	OK _____	
Audible Alarm Verified.	OK _____	
Serial Number Verified.	OK _____	

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Date and Time Verified.	OK _____	
Gray Zone Verified (if applicable)	OK _____	

Validation:

Successfully picked up and stripped 10 tips.	Yes _____	No* _____
Optics Validation passed.	Yes _____	No* _____
Channel Temperature Validation passed.	Yes _____	No* _____
Assays Performed with acceptable results on channels 1 - 5.	Yes _____	No* _____

* An explanation must be provided

Explanations:

_____

_____

_____

_____

Abbott Representative

Signature _____ Date _____

END OF DOCUMENT

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TECHNICAL SERVICE BULLETIN

SUBJECT:
Version 2.5 Software Upgrade - Japan only

TSB#: **82-033**

ORIGINATOR: **Dan Armstrong**
APPROVED: **Dan Armstrong 06-AUG-1999**

PRODUCT:
ABBOTT PRISM® (82)
REF. ECN: 14049-004, 005

IMPLEMENTATION:	TSB Part/Kit #: **1-65750-01**	Upgrade Time: **4.0 hrs.**
○ **Mandatory**	TSB Part(s) Availibility: **16-JUL-1999**	VerificationTime: **4.0 hrs.**
○ **Next Service Call**	**TSB Tracking by Serial # required (MANDATORY TSB's ONLY)**	Total Mod. Time: **8.0 hrs.**
● **Optional**	○ YES ● NO	****NOTE** The instrument must be at TSB Level 82-029 prior to performing this TSB.**
Instruments Requiring Modification: **As Required**		

I. DISTRIBUTION:

Japan Only

II. PURPOSE:

Update the instrument to version 2.5 software. Documents and procedures associated with 2.5 software will also be required for this installation. Changes associated with this version software are identified in ISA 82-031.

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

III. ADMINISTRATIVE NOTES:

This TSB must be performed after TSB 82-029. Make copies of the Checklist at the end of this TSB. Complete the checklist after upgrade, sign it and leave it with the customer. The password for **Abbott Access** in this version software is **INCREDULOUS** (all caps).

Customer Support Information:

1. **Initial Reactive** samples should be retested prior to software upgrade.
2. At the completion of this upgrade, the customer should run additional samples to duplicate actual routine testing. The testing protocol should be determined by the laboratory's Standard Operating Procedures. All test results must be consistent with expected results.
3. Leave all letters with the customer.
4. All test results will be deleted when the new version software is loaded. Therefore, have the customer print reports, copy reports to floppy and/or send data to the host as required based on their test result status.
5. On a four channel instrument, after installing software, you will get communication errors on the uninstalled channels until you configure them to "Not Used".

Upon completion of the upgrade:

1. Use the normal procedures for notification of the TSB.
2. Leave the check list and all associated documentation with the customer.
3. Make sure both you and the customer have signed the documents.
4. Remove all previous version software disks and dispose of them.

IV. SPECIAL TOOLS:

N/A

V. PARTS:

1-65750-01	Kit, Version 2.5 Software Upgrade		1
	Contains:		
	Disks, version 2.5 Software		1 set
	Resource Accounting File Conversion Tools Disk	1	
	Letter, Software		1
	Letter, Enhancement		1

REPLACED PARTS:

N/A

COMPATIBILITY:

Previous versions of software are not compatible.

VI. PROCEDURE:

MODIFICATION STEPS:

NOTE: Use of the current Field Service DT Manual and TSB's is required.

A. Software Installation:

1. Pre-Software Load.
   a. Turn on all installed channels (set Channel 6 as maintenance)

   b. Print the current Run Controls Configuration.
   From the Main Menu:
   Instrument Preparation
   Manage Resources
   Run Controls
   Select a defined run control
   Print the Run Control Configuration screen (**F3**). Retain this printout for use later in this procedure.
   Repeat these steps for all defined Run Controls. Return to the Main Menu by pressing the **Esc** key.

   c. Print the current Audible Alarm Configuration.
   From the Main Menu:
   Maintenance
   Hardware Configuration
   Audible Alarm Configuration
   Print the Audible Alarm Configuration screen (**F3**). Retain this printout for use later in this procedure.
   Return to the Main Menu by pressing the **Esc** key.

   d. Print the current Host Interface Configuration.
   From the Main Menu:
   Maintenance
   Hardware Configuration
   Host Interface Configuration
   Print the Host Interface Configuration screen (**F3**). Retain this printout for use later in this procedure.
   Return to the Main Menu by pressing the **Esc** key.

   e. Print the current Bar Code Configuration.
   From the Main Menu:

Maintenance
Hardware Configuration
Bar Code Configuration

Print the Bar Code Configuration screen (**F3**). Retain this printout for use later in this procedure.
Return to the Main Menu by pressing the **Esc** key.

f. Print the current Batch Parameters.
From the Main Menu:
Maintenance
Software Configuration
Batch Parameters
Print the Batch Parameters Configuration screen (**F3**). Retain this printout for use later in this procedure.
Return to the Main Menu by pressing the **Enter** and then **Esc** key.

g. Print the current Print Report Configuration.
From the Main Menu:
Maintenance
Software Configuration
Print Report Configuration
Print the Print Report Configuration screen (**F3**). Retain this printout for use later in this procedure.
Return to the Main Menu by pressing the **Esc** key.

h. Print a listing of the current Users.
From the Main Menu:
Maintenance
User Configuration
List the Users
Print the Users List screen (**F3**). Retain this printout for use later in this procedure.

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Return to the Main Menu by pressing the **Esc** key.

i. Print a listing of the current gray zone settings **(if applicable)**.
From the Main Menu:
Maintenance
Software Configuration
Gray zone Configuration
Print the Gray zone Configuration screen (**F3**). Retain this printout for use later in this procedure.
Return to the Main Menu by pressing the **Esc** key.

j. Print Localization settings.
From the Main Menu:
Maintenance
Software Configuration
Localization
Print the Localization screen (**F3**). Retain this printout for use later in this procedure.
Return to the Main Menu by pressing the **Esc** key.

k. Purge all Channels.

l. Print tests available for current reagents.
From the Main Menu:
Instrument Preparation
Manage Resources
Go into the menu options (reagents, wash solutions, and purges) and print.

m. Print Kit Usage Information.
From the Main Menu:
Maintenance
Kit Usage Review

Go into the menu for each assay and print the Kit Utilization screen .

n. Set all channels to XFER_2S or XFER_3S

2. Software Installation Instructions.

Equipment Required:

Software Update diskettes
Resource Accounting File Conversion Tools Disk
Blank Formatted 3.5", 1.44 MB Floppy Diskette

a. Log on to ABBOTT PRISM® System with Abbott Access.

b. Make a backup copy of current instrument configuration.
- Use a blank, formatted diskette.
- Perform Configuration Backup
  From the Main Menu:
  Maintenance
  Software Configuration
  Configuration Backup/Restore
  Backup Configuration
  When requested, insert the blank formatted diskette and press **Enter**.
  Press **Enter** to continue.
- When backup is complete press **Enter**. Remove diskette.
- Label diskette as Configuration Backup, with date and ABBOTT PRISM® Serial Number. Retain for later use.
- Return to Main Menu (press **Esc** key 3 times).

c. Exit ABBOTT PRISM® Software.
From the Main Menu:
Engineering

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

Exit Program

Press the **Y** key to confirm shutdown.

d. Backup Resource Accounting Data.

(1) Verify Date and Time.

At the DOS prompt type:

C:\date

Verify that the correct date is displayed. If it is not, enter the correct date. If the correct date is displayed press the enter key.

At the DOS prompt type:

C:\time

Verify that the correct time is displayed. If it is not, enter the correct time. If the correct time is displayed press the enter key.

(2) Insert the conversion tools disk into the floppy drive.

(3) At the DOS prompt, type:

A:\C12

Once the conversion is completed successfully you will get the message:

"RAC Backup: Success"

If a lockup occurs, reboot the instrument and repeat steps **c** and **d**.

If you get an error (other than "the wrong diskette") you will need to manually convert the Manage Resources as described in section B of this TSB.

(4) Remove the disk from the floppy drive.

e. Install the new software.

- Insert Disk 1 of the new software disk set.
- At the prompt:

C:\PRISM\VGA>_

Type in:

cd\

and press the enter key.

- At the prompt:

  C:

  Type in

  a:\install

  and press the enter key.
- Follow the screen prompts to complete loading the new version of software.

Note: Some prompts will refer to the new version software disk set as the backup.

3. Restore System configuration.

   a. When prompted, reboot ABBOTT PRISM® System Computer by pressing **CTRL**, **ALT**, **DEL** keys simultaneously. Computer boots up to ABBOTT PRISM® Logon Screen.

   b. Log on to ABBOTT PRISM® System with Abbott Access.
   Note: The Password is **INCREDULOUS** (all Caps)

   c. Place configuration backup diskette created earlier into floppy disk drive.

   d. Restore Configuration.
   From the Main Menu:
   Maintenance
   Software Configuration
   Configuration Backup/Restore
   Restore Configuration

   e. When restore is complete, press **Enter**. Remove floppy diskette from diskette drive and retain for future use. (Use only with this serial number instrument.)

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

f. Return to Main Menu (press **Esc**).

g. Reboot ABBOTT PRISM® Computer.
Engineering
Exit Program
From DOS prompt press **CTRL**, **ALT**, and **DEL** keys simultaneously.

4. Restore Resource Accounting Data.

a. Exit ABBOTT PRISM® Software.

From the Main Menu:
Engineering
Exit Program
Press the **Y** key to confirm shutdown.

b. Insert the conversion tools disk into the floppy drive.

c. At the DOS prompt, type:
A:\C12
If you get an error (other than "the wrong diskette") you will need to manually convert the Manage Resources as described in section B of this TSB.

If the restore works correctly you will get the message:

RAC Restore SUCCESS

d. Remove the conversion tools disk from the floppy drive.

e. Reboot ABBOTT PRISM® Computer.
From DOS prompt press **CTRL**, **ALT**, and **DEL** keys simultaneously.

Note: Return conversion tools disk to:

N. A. Abunimeh
D-9GK/Bldg AP1A
100 Abbott Park Road
Abbott Park, IL, USA 60064

5. Restore System Configuration.

   a. Log on to ABBOTT PRISM® System with Abbott Access.
   Note: The Password for 2.5 is **INCREDULOUS** (all Caps).

   b. Configure the Mode Directive setting to US or ROW.
   From Main Menu:
   Maintenance
   Software Configuration
   Mode Directive
   Set to **US or ROW** - (Spacebar) to select
   (F10) to save

   Follow instructions on screen and shutdown
   Press **CTRL**, **ALT**, and **DEL** keys simultaneously when requested to reboot the system.

   c. Configure Assays.
   From Main Menu:
   Maintenance
   Assay Configuration (this may be site or country specific)
   Set access types for selected assays to customer, and set status to active for the selected assays. Save (F10) settings.

   Assign assays to channels as shown:

Channel 1	AUSAB	Channel 2	HCV
Channel 3	HTLV I/II	Channel 4	HBsAg

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

Channel 5 HBcAb Channel 6 HBCore
(Spacebar) to select (F10) to save

d. Configure Channels to the same as before loading software.

e. Verify the tests available. Match the previous (before installing software) levels.

(1) Print tests available for current reagents.
From the Main Menu:
Instrument Preparation
Manage Resources
Go into the menu options (reagents, wash solutions, and purges) and print.

(2) Print Kit Usage Information.
From the Main Menu:
Maintenance
Kit Usage Review
Go into the menu for each assay and print out the Kit Utilization screen .

Compare the printouts before and after loading software. Verify that the numbers are close to the same (within 30). If there are any discrepancies complete section B, Reagent Tracking Worksheet and Table.

Refer to the printout obtained from the Pre-Software Load section (if applicable) for the following procedures. (see the Operations Manual for editing instructions).

f. Configure the Run Controls from the appropriate printout.

g. Configure the Host Interface from the appropriate printout.

h. Configure a maintenance level User. Check with the customer for name and password preference.

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

i. Configure language, Keyboard, and Date Format from appropriate printout.
From Main Menu:
Maintenance
Software Configuration
Localization
(Spacebar) to select (F10) to shutdown and save. Press F10 again when prompted. Reboot the system (press Ctrl Alt, and Del keys simultaneously) when prompted.
Note: Save (F10) your settings even if you are leaving the settings at the default (English).

j. Configure the Bar Code configuration from the appropriate printout.

k. Configure the Print Reports from the appropriate printout.

l. Verify the Batch Parameters. Check previous printout for setting (default is

8.5 hrs.)

m. Verify Audible Alarm Configuration matches printout from step 1(edit if necessary).

n. Verify the correct serial number (located in the upper left corner of the screen). Enter the correct number if incorrect. If incorrect, perform the following procedure:
From Main Menu:
Maintenance
Software Configuration
Set Serial Number

- Reboot the system for the new number to take effect.

From the Main Menu:
Engineering
Exit Program
From DOS prompt press **CTRL**, **ALT**, and **DEL** keys

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

simultaneously.

o. Verify the date and time (located in the upper right corner of the displayed screen). If correction is required, perform the following procedure:
From Main Menu:
Maintenance
Hardware Configuration
Set Time and Date

p. Verify Gray Zone settings match printout from step 1 (if applicable).

q. Reboot ABBOTT PRISM® Computer.

B. REAGENT TRACKING WORKSHEET AND TABLE

This worksheet will provide a method for supplying the customer with a method to track the tests available for reagent kits, wash solutions and purge solutions that were in progress when software was upgraded if the resource management backup does not work. The number next to New, represents the tests available for a new kit, wash or purge component. By subtracting the number of tests that remained for a reagent from the tests available for a new reagent, when the user reaches the number of tests on line 2.5 they have completed that reagent and **must** replace it.

1. For each assay:
On the 2.1 line, enter the number of Tests Available" (from the printouts made before loading software) for each of the following:
Reagent Kit
Wash solution
Purge Solution

2. Enter on the 2.5 line:
The difference between New (tests available for new kit) minus Vs. 2.1 (tests available). Note: These numbers are on the print screens that you printed before performing the software upgrade.

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

3. Enter the 2.5 tests available number onto the “Reagent Tracking” table.
IMPORTANT: Instruct the customer that when any reagent, wash or purge component “Tests Available” decreases to the number on the “Reagent Tracking” table, there are zero (0) tests remaining. **REPLACE THE COMPONENT!**

Worksheet:

ASSAY	REAGENT KIT	TRANSFER WASH	CONJUGATE WASH	PROBE WASH	PURGE SOLUTION
HTLV	New 5976 Ver2.1 - _____ Ver2.5= _____	New 5080 Ver2.1- _____ Ver2.5= _____	New 5426 Ver2.1- _____ Ver2.5= _____	New 5404 Ver2.1- _____ Ver2.5= _____	New 39 Ver2.1- _____ Ver2.5= _____
HCV	New 6092 Ver2.1- _____ Ver2.5= _____	New 5110 Ver2.1- _____ Ver2.5= _____	New 5456 Ver2.1- _____ Ver2.5= _____	**XXXX**	New 44 Ver2.1- _____ Ver2.5= _____
HIV	New 6030 Ver2.1- _____ Ver2.5= _____	New 5116 Ver2.1- _____ Ver2.5= _____	New 5274 Ver2.1- _____ Ver2.5= _____	New 5329 Ver2.1- _____ Ver2.5= _____	New 39 Ver2.1- _____ Ver2.5= _____
HBsAg	New 6148 Ver2.1- _____ Ver2.5= _____	New 5162 Ver2.1- _____ Ver2.5= _____	New 5306 Ver2.1- _____ Ver2.5= _____	**XXXX**	New 55 Ver2.1- _____ Ver2.5= _____
HBc	New 6286 Ver2.1- _____ Ver2.5= _____	New 5208 Ver2.1- _____ Ver2.5= _____	New 5532 Ver2.1- _____ Ver2.5= _____	**XXXX**	New 55 Ver2.1- _____ Ver2.5= _____

"REAGENT TRACKING"

REPLACE REAGENT KIT, WASH SOLUTION OR PURGE SOLUTION WHEN THE NUMBER OF TESTS AVAILABLE REACHES THE VOLUME LISTED BELOW.

ASSAY	REAGENT KIT	TRANSFER WASH	CONJUGATE WASH	PROBE WASH	PURGE SOLUTION
HTLV					
HCV				XXXX	
HIV					
HBsAg				XXXX	
HBc				XXXX	

CHECKOUT:

1. Confirm XY settings are correct. Pick up and strip off ten sets of pipette tips. From the Main Menu:
   - Component Diagnostics

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

- Sample Manager
- Tip Pick Up

Set for ten cycles, both axis.

2. Perform the Optics Validation Procedure on all channels on the instrument.
3. Perform the Channel Temperature Validation Procedure on all channels on the instrument.
4. Perform an Assay Calibration on identified channels.

MODIFICATION CONTROL STICKER UPDATE:

Using a permanent marker, mark through the number thirty three (33) on the TSB Modification Control Sticker.

ABBOTT PRISM® Version 2.5 Software Upgrade Checklist

While performing this TSB, mark off the items listed in the checklist after they are successfully performed. Attach all printouts from this upgrade.

Instrument S/N _____ Account Name _____

Date of Update _____ Account Address _____

Configuration:

# of tests remaining verified	Yes _____	No* _____
Mode Directive Configured	Yes _____	No* _____
Assays Configured	Yes _____	No* _____
Host Interface Configured	Yes _____	No* _____
Maintenance level user Configured (Customer chooses name and password).	Yes _____	No* _____
Localization Configured	Yes _____	No* _____
Bar Code Configured	Yes _____	No* _____
Print Reports Configured	Yes _____	No* _____
Batch Parameters Verified.	OK _____	
Audible Alarm Verified.	OK _____	
Serial Number Verified.	OK _____	

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Date and Time Verified. OK _____

Gray Zone Verified (if applicable) OK _____

Validation:

Successfully picked up and stripped 10 tips.	Yes _____	No* _____
Optics Validation passed.	Yes _____	No* _____
Channel Temperature Validation passed.	Yes _____	No* _____
Assays Performed with acceptable results on channels 1 - 5.	Yes _____	No* _____

* An explanation must be provided

Explanations:

_____

_____

_____

_____

Abbott Representative

Signature _____ Date _____

END OF DOCUMENT

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

ABBOTT ADD

TECHNICAL SERVICE BULLETIN

SUBJECT:
Version 2.5 Software Upgrade CBER Site USA

TSB#: **82-032**

ORIGINATOR: **Dan Armstrong**
APPROVED: **Dan Armstrong 15-JUL-1999**

PRODUCT:
ABBOTT PRISM® (82)
REF. ECN: 14049-004 , 005

IMPLEMENTATION: ● **Mandatory** ○ **Next Service Call** ○ **Optional** Instruments Requiring Modification: **1152**	TSB Part/Kit #: **N/A** TSB Part(s) Availibility: **12-JUL-1999** **TSB Tracking by Serial # required (MANDATORY TSB's ONLY)** ● YES ○ NO	Upgrade Time: **2.0 hrs** VerificationTime: **2.0 hrs** Total Mod. Time: **4.0 hrs** ****NOTE** The instrument must be at TSB Level 82-024 prior to performing this TSB.**

I. DISTRIBUTION:

US - CBER Site - Instrument Serial Number 1152

II. PURPOSE:

Update the instrument to version 2.5 software. Documents and procedures associated with 2.5 software will also be required for this installation. Changes associated with this version software will be identified in ISA 82-031.

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

III. ADMINISTRATIVE NOTES:

Make copies of the Checklist at the end of this TSB. Complete the checklist after upgrade, sign it and leave it and any associated printouts with the customer. The password for **Abbott Access** in this version software is **INCREDULOUS** (all caps).

Customer Support Information:

1. **Initial Reactive** samples should be retested prior to software upgrade.
2. At the completion of this upgrade, the customer should run additional samples to duplicate actual routine testing. The testing protocol should be determined by the laboratory's Standard Operating Procedures. All test results must be consistent with expected results.
3. Leave all letters (if applicable) with the customer.
4. All test results will be deleted when the new version software is loaded. Therefore, have the customer print reports, copy reports to floppy and/or send data to the host as required based on their test result status.

Upon completion of the upgrade:

1. Use the normal procedures for notification of the TSB.
2. Leave the check list and all associated documentation with the customer.
3. Make sure both you and the customer sign the documents.
4. Remove all previous version software disks (if applicable) and dispose of them.

IV. SPECIAL TOOLS:

N/A

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

V. PARTS:

52430-185	Disks, Version 2.5 Software	1
LN 1G40-12	Operations Manual Version 2.5	1

REPLACED PARTS:

N/A

COMPATIBILITY:

N/A

VI. PROCEDURE:

MODIFICATION STEPS:

NOTE: Use of the current Field Service DT Manual and TSB's is required.

A. Software Installation:

1. Pre-Software Load.
   a. Turn on all installed channels (set Channel 6 as maintenance)

b. Print the current Run Controls Configuration.
From the Main Menu:
Instrument Preparation
Manage Resources
Run Controls
Select a defined run control
Print the Run Control Configuration screen (**F3**). Retain this printout for use later in this procedure.
Repeat these steps for all defined Run Controls. Return to the Main Menu by pressing the **Esc** key.

c. Print the current Audible Alarm Configuration.
From the Main Menu:
Maintenance
Hardware Configuration
Audible Alarm Configuration
Print the Audible Alarm Configuration screen (**F3**). Retain this printout for use later in this procedure.
Return to the Main Menu by pressing the **Esc** key.

d. Print the current Bar Code Configuration.
From the Main Menu:
Maintenance
Hardware Configuration
Bar Code Configuration
Print the Bar Code Configuration screen (**F3**). Retain this printout for use later in this procedure.
Return to the Main Menu by pressing the **Esc** key.

e. Print the current Batch Parameters.
From the Main Menu:
Maintenance
Software Configuration

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

Batch Parameters
Print the Batch Parameters Configuration screen (**F3**). Retain this printout for use later in this procedure.
Return to the Main Menu by pressing the **Enter** and then **Esc** key.

f. Print the current Print Report Configuration.
From the Main Menu:
Maintenance
Software Configuration
Print Report Configuration
Print the Print Report Configuration screen (**F3**). Retain this printout for use later in this procedure.
Return to the Main Menu by pressing the **Esc** key.

g. Print a listing of the current Users.
From the Main Menu:
Maintenance
User Configuration
List the Users
Print the Users List screen (**F3**). Retain this printout for use later in this procedure.
Return to the Main Menu by pressing the **Esc** key.

h. Print Localization settings.
From the Main Menu:
Maintenance
Software Configuration
Localization
Print the Localization screen (**F3**). Retain this printout for use later in this procedure.
Return to the Main Menu by pressing the **Esc** key.

i. Purge all Channels.

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

j. Set all channels to XFER_2S or XFER_3S

2. Software Installation Instructions.

Equipment Required:
Software Update diskettes
Blank Formatted 3.5", 1.44 MB Floppy Diskette

a. Log on to ABBOTT PRISM® System with Abbott Access.

b. Make a backup copy of current instrument configuration.
- Use a blank, formatted diskette.
- Perform Configuration Backup
  From the Main Menu:
  Maintenance
  Software Configuration
  Configuration Backup/Restore
  Backup Configuration
  When requested, insert the blank formatted diskette and press **Enter**.
  Press **Enter** to continue.
- When backup is complete press **Enter**. Remove diskette.
- Label diskette as Configuration Backup, with date and ABBOTT PRISM® Serial Number. Retain for later use.
- Return to Main Menu (press **Esc** key 3 times).

c. Exit ABBOTT PRISM® Software.
From the Main Menu:
Engineering
Exit Program
Press the **Y** key to confirm shutdown.

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

d. Install the new software.
   - Insert Disk 1 of the new software disk set.
   - At the prompt:
     C:\PRISM\VGA>_
     Type in: cd\
     and press the enter key.
   - At the prompt:
     C:
     Type in a:\install
     and press the enter key.
   - Follow the screen prompts to complete loading the new version of software.

   Note: Some prompts will refer to the new version software disk set as the backup.

3. Restore System configuration.

   a. When prompted, reboot ABBOTT PRISM® System Computer by pressing **CTRL**, **ALT**, **DEL** keys simultaneously. Computer boots up to ABBOTT PRISM® Logon Screen.

   b. Log on to ABBOTT PRISM® System with Abbott Access.
   Note: The Password is **INCREDULOUS** (all Caps)

   c. Place configuration backup diskette created earlier into floppy disk drive.

   d. Restore Configuration.
   From the Main Menu:
   Maintenance
   Software Configuration
   Configuration Backup/Restore
   Restore Configuration

   e. When restore is complete, press **Enter**. Remove floppy diskette from diskette drive and retain for

future use. (Use only with this serial number instrument.)

f. Return to Main Menu (press **Esc**).

g. Reboot ABBOTT PRISM® Computer.
Engineering
Exit Program
From DOS prompt press **CTRL**, **ALT**, and **DEL** keys simultaneously.

4. Restore System Configuration.

a. Log on to ABBOTT PRISM® System with Abbott Access.
Note: The Password for 2.5 is **INCREDULOUS** (all Caps).

b. Configure the Mode Directive.
From Main Menu:
Maintenance
Software Configuration
Mode Directive
Set to **US** - (Spacebar) to select
(F10) to save

Follow instructions on screen and shutdown
Press **CTRL**, **ALT**, and **DEL** keys simultaneously when requested to reboot the system.

c. Configure Assays.

From Main Menu:
Maintenance
Assay Configuration (this may be site or country specific)
Set access types for selected assays to **customer**, and set status to active for the selected

assays. Save (F10) settings.

Assign assays to channels as shown:

Channel 1	HTLV-I/II	Channel 2	HCV
Channel 3	HIV I/II	Channel 4	HBsAg
Channel 5	HBc	Channel 6	N/A

(Spacebar) to select (F10) to save

d. Configure Channels to the same as before loading software.

e. Configure the Run Controls from the appropriate printout.

f. Configure the Host Interface from the appropriate printout.

g. Configure a maintenance level User. Check with the customer for name and password preference.

h. Configure language, Keyboard, and Date Format from appropriate printout.
From Main Menu:
Maintenance
Software Configuration
Localization
(Spacebar) to select (F10) to shutdown and save. Press F10 again when prompted. Reboot the system (press Ctrl Alt, and Del keys simultaneously) when prompted.
Note: Save (F10) your settings even if you are leaving the settings at the default (English).

i. Configure the Bar Code configuration from the appropriate printout.

j. Configure the Print Reports from the appropriate printout.

k. Verify the Batch Parameters. Check previous printout for setting (default is 8.5 hrs.)

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

l. Verify Audible Alarm Configuration matches printout from step 1 (edit if necessary).

m. Verify the correct serial number (located in the upper left corner of the screen). Enter the correct number if incorrect. If incorrect, perform the following procedure:
From Main Menu:
Maintenance
Software Configuration
Set Serial Number

- Reboot the system for the new number to take effect.

From the Main Menu:
Engineering
Exit Program
From DOS prompt press **CTRL**, **ALT**, and **DEL** keys simultaneously.

n. Verify the date and time (located in the upper right corner of the displayed screen). If correction is required, perform the following procedure:
From Main Menu:
Maintenance
Hardware Configuration
Set Time and Date

p. Reboot ABBOTT PRISM® Computer.

CHECKOUT:

1. Confirm XY settings are correct. Pick up and strip off ten sets of pipette tips.
From the Main Menu:

- Component Diagnostics
- Sample Manager
- Tip Pick Up

Set for ten cycles, both axis.

2. Perform the Optics Validation Procedure on all channels on the instrument.
3. Perform the Channel Temperature Validation Procedure on all channels on the instrument.
4. Load all Assay Reagents and perform an Assay Calibration on identified channels.
5. Remove previous version Operations Manual from customer site**.** Record part number of Ops manual _____on this TSB.

MODIFICATION CONTROL STICKER UPDATE:

Using a permanent marker, mark through the number thirty two (32) on the TSB Modification Control Sticker.

ABBOTT PRISM® Version 2.5 Software Upgrade Checklist

While performing this TSB, mark off the items listed in the checklist after they are successfully performed. Attach all printouts associated with this upgrade to the checklist.

Instrument S/N _____ Account Name _____

Date of Update _____ Account Address _____

Configuration:

Mode Directive Configured	Yes _____	No* _____
Assays Configured	Yes _____	No* _____
Maintenance level user Configured		
(Customer chooses name and password)	Yes _____	No* _____
Localization Configured	Yes _____	No* _____
Bar Code Configured	Yes _____	No* _____
Print Reports Configured	Yes _____	No* _____
Batch Parameters Verified.	OK _____	
Audible Alarm Verified.	OK _____	
Serial Number Verified.	OK _____	
Date and Time Verified.	OK _____	

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

Validation:

Successfully picked up and stripped 10 tips.	Yes _____	No* _____
Optics Validation passed.	Yes _____	No* _____
Channel Temperature Validation passed.	Yes _____	No* _____
Assays Performed with acceptable results on channels 1 - 5.	Yes _____	No* _____

* An explanation must be provided

Explanations:

_____

_____

_____

_____

Abbott Representative:

Signature _____ Date _____

Customer:

Signature _____ Date _____

END OF DOCUMENT

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

ABBOTT ADD

TECHNICAL SERVICE BULLETIN

SUBJECT:
Bar Code Scanner Read Enhancement

TSB#: **82-031**

ORIGINATOR: **Dan Armstrong**
APPROVED: **Dan Armstrong 06-AUG-1999**

PRODUCT:
ABBOTT PRISM® (82)
REF. ECN: 14029-001

IMPLEMENTATION: ○ **Mandatory** ○ **Next Service Call** ● **Optional** Instruments Requiring Modification: **As needed. See Administrative Notes.**	TSB Part/Kit #: **N/A** TSB Part(s) Availability: **07-JUL-1999** **TSB Tracking by Serial # required (MANDATORY TSB's ONLY)** ○ YES ● NO	Upgrade Time: **1.0 hrs.** VerificationTime: **0.5 hrs** Total Mod. Time: **1.5 hrs** ****NOTE** The instrument must be at TSB Level 82-029 prior to performing this TSB.**

I. DISTRIBUTION:

World Wide

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

II. PURPOSE:

An optional Bar Code Reader firmware with a reading redundancy of three (3) versus the standard two (2) has been made available. This optional firmware may reduce the possibility of misreads when a customer site fails to meet the minimum Sample Bar Code Label Guidelines described in the ABBOTT PRISM® Operations Manual. The use of this optional firmware may require the operator to insert the sample racks at a slower speed to compensate for a possible increase in No Read results due to the increased reading redundancy.

III. ADMINISTRATIVE NOTES:

This TSB is to be incorporated only as needed. Notification of it's incorporation should be communicated to ACS or WWCS. To obtain this firmware, please contact a Prism Specialist with ACS or a CSE with WWCS.

IV. SPECIAL TOOLS:

N / A

V. PARTS:

55970-103C Firmware, Bar Code Reader Board

REPLACED PARTS:
Dispose of per site requirements for contaminated material.

COMPATIBILITY:
N /A

VI. PROCEDURE:

MODIFICATION STEPS:

Note : Use of current field service DT manual is required.

1. Perform system power off (VP-1).
2. Remove the sample access front cover (PL-Covers).
3. Disconnect J3 and J6 from the bar code reader control board so that its cover may be removed.
4. Loosen the two large screws at the top and then remove the cover. Carefully remove EPROM U9 from the bar code reader controller board. Install the new EPROM.
5. Change the last three digits of the bar code reader controller board part number to -108.
6. Replace the bar code reader control board cover.
7. Replace the sample access cover
8. Perform system start up (VP-2).

CHECKOUT:

1. Perform bar code verification procedure (VP-29).

MODIFICATION CONTROL STICKER UPDATE:

1. Using a permanent marker, mark through the number thirty-one (31) on the TSB Modification Control Sticker.

END OF DOCUMENT

ABBOTT ADD

TECHNICAL SERVICE BULLETIN

SUBJECT:
Version 2.1 Software Upgrade - Japan Only

TSB#: **82-029**

ORIGINATOR: **Mark D. Redman**
APPROVED: **Dan Armstrong 2/11/1999**

PRODUCT:
ABBOTT PRISM® (82)

REF. ECN: **14619-010**

IMPLEMENTATION: ● **Immediate** ○ **Next Service Call** ○ **Next Failure** ○ **Optional** Instruments Requiring Modification: **See List in Administrative Notes**	TSB Part/Kit #: **1-65679-01** TSB Effectivity/ Part(s) Availibility: **17-FEB-1999** **TSB Tracking by Serial # required (IMMEDIATE TSB's ONLY)** ● YES ○ NO	Upgrade Time: **4** Validation Time: **4** Total Mod. Time: **8** ****NOTE** The instrument must be at TSB Level 82-022B prior to performing this TSB.**

I. DISTRIBUTION:

Japan only

II. PURPOSE:

Update the instrument to version 2.1 software. All documents and procedures associated with 2.1 software will also be required for this version installation.

III. ADMINISTRATIVE NOTES:

This TSB must be performed in conjunction with TSB 82-026. Make copies of the Checklist at the end of this TSB. Complete the checklist after upgrade, sign it and leave it with the customer. The password for Abbott Access in this version software is INCREDULOUS (all caps).

Following instruments will require this upgrade: SN 1056, 1074, 1121, 1148, 1061, 1119, 1139 along with any instruments arriving prior to instruments manufactured with Version 2.1.

Customer Support Information:

1. Initial Reactive samples should be re-tested prior to software upgrade.
2. At the completion of this upgrade, the customer should run additional samples to duplicate actual routine testing. The testing protocol should be determined by the laboratory's Standard Operating Procedures. All test results must be consistent with expected results.
3. Leave all letters with the customer.
4. Leave the new Operations Manual (6A36-97) with the customer.
5. All test results will be deleted when the new version software is loaded. Therefore, have the customer print reports, copy reports to floppy and/or send data to the host as required based on their test result status.
6. On a four channel instrument, after installing software, you will get communication errors on the un-installed channels until you configure them to Not Used.

Upon completion of the upgrade:

1. Use the normal procedures for notification of the TSB.

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

2. Leave the check list and all associated documentation with the customer.
3. Make sure both you and the customer have signed the documents.
4. Remove all previous version software disks and dispose of them.
5. **The completion date of this TSB is the end of 2nd Quarter 1999.**

IV. SPECIAL TOOLS:

N/A

V. PARTS:

1-65679-01 Kit, Version 2.1 Software Upgrade		1
	Contains:	
	Disks, version 2.1 Software	1 set
	Resource Accounting File Conversion Tools Disk	1
	Letter, Software	1
	Letter, Enhancement	1
	Letter, Run Control	1
	Bar Code Labels, Tubing ID	1 set
	Bar Code Label Holders, Tubing	39
	Bar Code Labels, Purge Bottle	1 set
	Adapter, Run Control	10
	Rack, Run Control	1

These items are required for the upgrade but are not included in this kit. They will need to be ordered separately.

6A36-32	Rack, HBsAg Confirmatory Preparation	1
6A36-33	Template, HBsAg Confirmatory	2
6A36-97	Manual, Operations	1
6A36-49	Manual, Host Interface Specification	1

REPLACED PARTS:

Remove and dispose of parts following the lab procedures for disposal of biohazardous components.

COMPATIBILITY:

NOTE: Prior to loading a new or different reagent on a channel, the channel must be cleaned. Use the “Clean Backup Channel” procedure, in the operations manual (6A36-97) for these cleaning instructions. Modify the channel number in the procedure to identify the channel being cleaned. When the procedure is complete change the channel configuration to the proper assay.

New purge bottle labels are not compatible with any previous versions of software. Once new software is installed, Host Interface errors may occur unless host has been configured for this version of software.

VI. PROCEDURE:

MODIFICATION STEPS:

NOTE: Use of the current Field Service DT Manual and TSB’s is required.

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

A. Software Installation:

1. Pre-Software Load.
   a. Turn on all installed channels (set Channel 6 as maintenance)

   b. Print the current Run Controls Configuration.
   From the Main Menu:
   Instrument Preparation
   Manage Resources
   Run Controls
   Select a defined run control
   Print the Run Control Configuration screen (F3). Retain this printout for use later in this procedure.
   Repeat these steps for all defined Run Controls. Return to the Main Menu by pressing the Esc key.

   c. Print the current Audible Alarm Configuration.
   From the Main Menu:
   Maintenance
   Hardware Configuration
   Audible Alarm Configuration
   Print the Audible Alarm Configuration screen (F3). Retain this printout for use later in this procedure.
   Return to the Main Menu by pressing the Esc key.

   d. Print the current Host Interface Configuration.
   From the Main Menu:
   Maintenance
   Hardware Configuration
   Host Interface Configuration
   Print the Host Interface Configuration screen (F3). Retain this printout for use later in this procedure.
   Return to the Main Menu by pressing the Esc key.

   e. Print the current Bar Code Configuration.
   From the Main Menu:
   Maintenance
   Hardware Configuration
   Bar Code Configuration
   Print the Bar Code Configuration screen (F3). Retain this printout for use later in this procedure.
   Return to the Main Menu by pressing the Esc key.

   f. Print the current Batch Parameters.
   From the Main Menu:
   Maintenance
   Software Configuration
   Batch Parameters
   Print the Batch Parameters Configuration screen (F3). Retain this printout for use later in this procedure.
   Return to the Main Menu by pressing the Enter and then Esc key.

   g. Print the current Print Report Configuration.
   From the Main Menu:
   Maintenance
   Software Configuration
   Print Report Configuration
   Print the Print Report Configuration screen (F3). Retain this printout for use later in this procedure.
   Return to the Main Menu by pressing the Esc key.

   h. Print a listing of the current Users.
   From the Main Menu:

Maintenance
User Configuration
List the Users
Print the Users List screen (F3). Retain this printout for use later in this procedure.
Return to the Main Menu by pressing the Esc key.

i. Print a listing of the current gray zone settings (if applicable).
From the Main Menu:
Maintenance
Software Configuration
Gray zone Configuration
Print the Gray zone Configuration screen (F3). Retain this printout for use later in this procedure.
Return to the Main Menu by pressing the Esc key.

j. Print Localization settings.
From the Main Menu:
Maintenance
Software Configuration
Localization
Print the Localization screen (F3). Retain this printout for use later in this procedure.
Return to the Main Menu by pressing the Esc key.

k. Purge all Channels.

l. Print tests available for current reagents.
From the Main Menu:
Instrument Preparation
Manage Resources
Go into the menu options (reagents, wash solutions, and purges) and print.

m. Print Kit Usage Information.
From the Main Menu:
Maintenance
Kit Usage Review
Go into the menu for each assay and print the Kit Utilization screen .

n. Set all channels to XFER_2S or XFER_3S

2. Load Software

Equipment Required:
Software Update diskettes
Resource Accounting File Conversion Tools Disk
Blank Formatted 3.5", 1.44 MB Floppy Diskette

a. Log on to ABBOTT PRISM® System with Abbott Access.

b. Make a backup copy of current instrument configuration.
- Use a blank, formatted diskette.
- Perform Configuration Backup
From the Main Menu:
Maintenance
Software Configuration
Configuration Backup/Restore
Backup Configuration
When requested, insert the blank formatted diskette and press Enter.
Press Enter to continue.
- When backup is complete press Enter. Remove diskette.
  - Label diskette as Configuration Backup, with date and ABBOTT PRISM® Serial Number. Retain for later use.
- Return to Main Menu (press Esc key 3 times).

c. Exit ABBOTT PRISM® Software.

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

From the Main Menu:
Engineering
Exit Program
Press the Y key to confirm shutdown.

d. Backup Resource Accounting Data.

(1) Verify Date and Time.

At the DOS prompt type:
C:\date
Verify that the correct date is displayed. If it is not, enter the correct date. If the correct date is displayed press the enter key.

At the DOS prompt type:
C:\time
Verify that the correct time is displayed. If it is not, enter the correct time. If the correct time is displayed press the enter key.

(2) Insert the conversion tools disk into the floppy drive.

(3) At the DOS prompt, type:
A:\C12
Once the conversion is completed successfully you will get the message:
"RAC Backup: Success"
If a lockup occurs, reboot the instrument and repeat steps c and d.

If you get an error (other than "the wrong diskette") you will need to manually convert the Manage Resources as described in section B of this TSB.

(4) Remove the disk from the floppy drive.

e. Install the new software.

- Insert Disk 1 of the new software disk set.
- At the prompt:
  C:\PRISM\VGA>_
  Type in:
  cd\
  and press the enter key.
- At the prompt:
  C:
  Type in:
  a:\install
  and press the enter key.
- Follow the screen prompts to complete loading the new version of software.

Note: Some prompts will refer to the new version software disk set as the backup.

3. Restore System configuration.

a. When prompted, reboot ABBOTT PRISM® System Computer by pressing CTRL, ALT, DEL keys simultaneously. Computer boots up to ABBOTT PRISM® Logon Screen.

b. Log on to ABBOTT PRISM® System with Abbott Access.
Note: The Password is INCREDULOUS (all Caps)

c. Place configuration backup diskette created earlier into floppy disk drive.

d. Restore Configuration.
From the Main Menu:
Maintenance
Software Configuration
Configuration Backup/Restore

Restore Configuration

e. When restore is complete, press Enter. Remove floppy diskette from diskette drive and retain for future use. (Use only with this serial number instrument.)

f. Return to Main Menu (press Esc).

g. Reboot ABBOTT PRISM® Computer.
Engineering
Exit Program
From DOS prompt press CTRL, ALT, and DEL keys simultaneously.

4. Restore Resource Accounting Data.

a. Exit ABBOTT PRISM® Software.

From the Main Menu:
Engineering
Exit Program
Press the Y key to confirm shutdown.

b. Insert the conversion tools disk into the floppy drive.

c. At the DOS prompt, type:
A:\C12
If you get an error (other than "the wrong diskette") you will need to manually convert the Manage Resources as described in section B of this TSB.

If the restore works correctly you will get the message:

ARC Restore SUCCESS

d. Remove the conversion tools disk from the floppy drive.

e. Reboot ABBOTT PRISM® Computer.
From DOS prompt press CTRL, ALT, and DEL keys simultaneously.

Note: Return conversion tools disk to:

N. A. Abunimeh
D-9GK/Bldg AP1A
100 Abbott Park Road
Abbott Park, IL, USA 60064

5. Restore System Configuration.

a. Log on to ABBOTT PRISM® System with Abbott Access.
Note: The Password for 2.1 is INCREDULOUS (all Caps).

b. Configure the Mode Directive setting to US or ROW.
From Main Menu:
Maintenance
Software Configuration
Mode Directive
Set to US or ROW - (Spacebar) to select
(F10) to save

Follow instructions on screen and shutdown
Press CTRL, ALT, and DEL keys simultaneously when requested to reboot the system.

c. Configure Assays.
From Main Menu:
Maintenance
Assay Configuration (this may be site or country specific)
Set access types for selected assays to customer, and set status to active for the selected assays. Save (F10) settings.

Assign assays to channels as shown:

Channel 1	AUSAB	Channel 2	HCV
Channel 3	HTLV I/II	Channel 4	HBsAg
Channel 5	HBcAb	Channel 6	HBCore

(Spacebar) to select (F10) to save

d. Configure Channels to the same as before loading software.

e. Put new purge bottle labels on the purge bottles.

f. Put new tubing label holders and labels on the tubing in the ambient bay and refrigerator.

g. Verify the tests available. Match the previous (before installing software) levels.

(1) Print tests available for current reagents.
From the Main Menu:
Instrument Preparation
Manage Resources
Go into the menu options (reagents, wash solutions, and purges) and print.

(2) Print Kit Usage Information.
From the Main Menu:
Maintenance
Kit Usage Review
Go into the menu for each assay and print out the Kit Utilization screen .

Compare the printouts before and after loading software. Verify that the numbers are close to the same (within 30). If there are any discrepancies complete section B, Reagent Tracking Worksheet and Table.

Refer to the printout obtained from the Pre-Software Load section (if applicable) for the following procedures. (see the Operations Manual for editing instructions).

h. Configure the Run Controls from the appropriate printout.

i. Configure the Host Interface from the appropriate printout.

j. Configure a maintenance level User. Check with the customer for name and password preference.

k. Configure language, Keyboard, and Date Format from appropriate printout.

From Main Menu:
Maintenance
Software Configuration
Localization
(Spacebar) to select (F10) to shutdown and save. Press F10 again when prompted. Reboot the system (press Ctrl Alt, and Del keys simultaneously) when prompted.
Note: Save (F10) your settings even if you are leaving the settings at the default (English).

l. Configure the Bar Code configuration from the appropriate printout.

Note: I 2 of 5 is now available.

m. Configure the Print Reports from the appropriate printout.

n. Verify the Batch Parameters are set to 8.5 hrs.

o Verify Audible Alarm Configuration matches printout from step 1.

p. Verify the correct serial number (located in the upper left corner of the screen). Enter the correct number if incorrect. If incorrect, perform the following procedure:

From Main Menu:
Maintenance
Software Configuration

Set Serial Number

Reboot the system for the new number to take effect.

From the Main Menu:
Engineering
Exit Program
From DOS prompt press CTRL, ALT, and DEL keys simultaneously.

q. Verify the date and time (located in the upper right corner of the displayed screen). If correction is required, perform the following procedure:

From Main Menu:
Maintenance
Hardware Configuration
Set Time and Date

r. Verify Gray Zone settings match printout from step 1.

s. Reboot ABBOTT PRISM® Computer.

B. REAGENT TRACKING WORKSHEET AND TABLE

This worksheet will provide a method for supplying the customer with a method to track the tests available for reagent kits, wash solutions and purge solutions that were in progress when software was upgraded if the resource management backup does not work. The number next to New, represents the tests available for a new kit, wash or purge component. By subtracting the number of tests that remained for a reagent from the tests available for a new reagent, when the user reaches the number of tests on line 2.1 they have completed that reagent and must replace it.

1. For each assay:
   On the 1.52 line, enter the number of “Tests Available” (from the printouts made before loading software) for each of the following:
   Reagent Kit
   Wash solution
   Purge Solution

2. Enter on the 2.1 line:
   The difference between New (tests available for new kit) minus Vs. 1.52 (tests available).
   Note: These numbers are on the print screens that you printed before performing the software upgrade.

3. Enter the 2.1 tests available number onto the "Reagent Tracking” table.
   IMPORTANT: Instruct the customer that when any reagent, wash or purge component “ Tests Available” decreases to the number on the “Reagent Tracking” table, there are zero (0) tests remaining. **REPLACE THE COMPONENT!**

Worksheet:

ASSAY	REAGENT KIT	TRANSFER WASH	CONJUGATE WASH	PROBE WASH	PURGE SOLUTION
HTLV	New 5976 Ver1.52 - _____ Ver2.1 = _____	New 5080 Ver1.52 - _____ Ver2.1 = _____	New 5426 Ver1.52 - _____ Ver2.1 = _____	New 5404 Ver1.52 - _____ Ver2.1 = _____	New 39 Ver1.52 - _____ Ver2.1 = _____
HCV	New 6092 Ver1.52 - _____ Ver2.1 = _____	New 5110 Ver1.52 - _____ Ver2.1 = _____	New 5456 Ver1.52 - _____ Ver2.1 = _____	**XXXX**	New 44 Ver1.52 - _____ Ver2.1 = _____
HIV	New 6030 Ver1.52 - _____ Ver2.1 = _____	New 5116 Ver1.52 - _____ Ver2.1 = _____	New 5274 Ver1.52 - _____ Ver2.1 = _____	New 5328 Ver1.52 - _____ Ver2.1 = _____	New 39 Ver1.52 - _____ Ver2.1 = _____
HBsAg	New 6148 Ver1.52 - _____ Ver2.1 = _____	New 5162 Ver1.52 - _____ Ver2.1 = _____	New 5306 Ver1.52 - _____ Ver2.1 = _____	**XXXX**	New 55 Ver1.52 - _____ Ver2.1 = _____
HBc	New 6286 Ver1.52 - _____ Ver2.1 = _____	New 5208 Ver1.52 - _____ Ver2.1 = _____	New 5532 Ver1.52 - _____ Ver2.1 = _____	**XXXX**	New 55 Ver1.52 - _____ Ver2.1 = _____

"REAGENT TRACKING"

REPLACE REAGENT KIT, WASH SOLUTION OR PURGE SOLUTION WHEN THE NUMBER OF TESTS AVAILABLE REACHES THE VOLUME LISTED BELOW.

ASSAY	REAGENT KIT	TRANSFER WASH	CONJUGATE WASH	PROBE WASH	PURGE SOLUTION
HTLV					
HCV				**XXXX**	
HIV					
HBsAg				**XXXX**	
HBc				**XXXX**	

CHECKOUT:

1. Go back to TSB 82-026 to perform verifications / validations.
2. Confirm XY settings are correct. Pick up and strip off ten sets of pipette tips.
   From the Main Menu:
   Component Diagnostics
   Sample Manager
   Tip Pick Up
   Set for ten cycles, both axis.
3. Perform the Optics Validation Procedure on all channels on the instrument.
4. Perform the Channel Temperature Validation Procedure on all channels on the

instrument.

5. Perform a Clinical Assay Calibration on identified channels.

MODIFICATION CONTROL STICKER UPDATE:

Using a permanent marker, mark through the number twenty nine (29) on the TSB Modification Control Sticker.

ABBOTT PRISM® Version 2.1 Software Upgrade Checklist

While performing this TSB, mark off the items listed in the checklist after they are successfully performed. Attach all printouts from this upgrade.

Instrument S/N _____ Account Name _____

Date of Update _____ Account Address _____

Configuration:

# of tests remaining verified	Yes _____	No* _____
Mode Directive Configured	Yes _____	No* _____
Assays Configured	Yes _____	No* _____
Host Interface Configured	Yes _____	No* _____
Maintenance level user Configured (Customer chooses name and password).	Yes _____	No* _____
Localization Configured	Yes _____	No* _____
Bar Code Configured	Yes _____	No* _____
Print Reports Configured	Yes _____	No* _____
Batch Parameters Verified.	OK _____	
Audible Alarm Verified.	OK _____	
Serial Number Verified.	OK _____	
Date and Time Verified.	OK _____	
Gray Zone Verified	OK _____	
Put new purge bottle labels on purge bottles	Yes _____	No* _____
Replaced tubing label tags with the new tubing label tags and labels	Yes _____	No* _____

Validation:

Successfully picked up and stripped 10 tips.	Yes _____	No* _____
Optics Validation passed.	Yes _____	No* _____
Channel Temperature Validation passed.	Yes _____	No* _____
Assays Performed with acceptable results on channels 1 - 5.	Yes _____	No* _____

* An explanation must be provided

Explanations:

_____

_____

_____

_____

Abbott Representative

Signature _____ Date _____

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

END OF DOCUMENT

ABBOTT ADD

TECHNICAL SERVICE BULLETIN

SUBJECT:
HBCore Hardware Upgrade (Channel 5)

TSB#: **82-028**

ORIGINATOR: **Mark D. Redman**
APPROVED: **Dan Armstrong 2/11/1999**

PRODUCT:
ABBOTT PRISM® (82)

REF. ECO: **14619-009**

Trademark: Abbott Prism® is a registered trademark of Abbott Laboratories

IMPLEMENTATION:	TSB Part/Kit #: **1-65681-01**	Upgrade Time: **3 hours**
○ Immediate ○ Next Service Call ○ Next Failure ● Optional	TSB Effectivity/ Part(s) Availability: **17-FEB-1999**	Validation Time: **4 hours**
Instruments Requiring Modification: **1163 and below as required**	**TSB Tracking by Serial # required (IMMEDIATE TSB's ONLY)** ○ YES ● NO	Total Mod. Time: **7 hours** ****NOTE** The instrument must be at TSB Level 82-027 prior to performing this TSB.**

I. DISTRIBUTION:

Worldwide

II. PURPOSE:

Update Channel 5 configuration for HBCore Assay.

III. ADMINISTRATIVE NOTES:

Retrofit budget only covers existing HBc customers.

IV. SPECIAL TOOLS:

Volume Validation tool 6A36-81.

V. PARTS:

1-65681-01 Kit, Version 2.1 Hardware Upgrade
Contains:

Pump, Reagent	1
Plug, Refrigerator Tubing	1
Dispenser, Microparticle/Specimen Diluent Station with Sensor and Tubing	1
Tubing, Channel 5 Air Tip Wash	1 set
Tubing, Bottle to Purge Valve (labeled 52SR)	1
Tubing, Purge Valve to Bottle (labeled 52S)	1
Spare Connector Ferrules, Nuts, and seals	1 set

REPLACED PARTS:

Remove and dispose of parts following the lab procedures for disposal of biohazardous

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

components.

COMPATIBILITY:

VI. PROCEDURE:

MODIFICATION STEPS:

1. Install new pump (RR-D1) to channel 5, “D” position.
2. Replace the microparticle station with a new quad head microparticle station with tubing attached. (RR-C2.2/3).
3. Locate the tubing plug in the refrigerator with no hole for tubing. This will be located above the Channel 5, first bottle position. Replace the plug with the tubing plug with a single hole from the kit.
4. Install tubing:

   Note: The Channel 5 Purge Valve, ports H and G, have plugs. Remove them before performing the following steps.

   a.) Reagent Bottle to Purge Valve port H (see RR-D2) (tubing is labeled 52SR).

   b.) Purge Valve port G (see RR-D2) to Pump D inlet port (see RR-D1) (tubing is labeled 52S).

   c.) Pump D port A (see RR-D1) to Dispenser A (tubing is labeled 52SA).

   d.) Pump D port B (see RR-D1) to Dispenser B (tubing is labeled 52SB).

5. Remove all of the Channel 5 dispenser tubing and replace with tubing supplied with replacement dispenser.

CHECKOUT:

1. Perform Volume Validation on the new pump D (cysteine) in Channel 5.
2. Perform an HBCore Assay Calibration.

MODIFICATION CONTROL STICKER UPDATE:

Using a permanent marker, mark through the number twenty (28) on the TSB Modification Control Sticker.

END OF DOCUMENT

ABBOTT ADD

TECHNICAL SERVICE BULLETIN

SUBJECT:
Version 2.1 Software Upgrade

TSB#: **82-027**

ORIGINATOR: **Mark D. Redman**
APPROVED: **Dan Armstrong 2/11/1999**

PRODUCT:
ABBOTT PRISM® (82)

REF. ECO: **14619-010**

IMPLEMENTATION:	TSB Part/Kit #: **1-65679-01**	Upgrade Time: **4 hours**
(●) **Immediate** ( ) **Next Service Call** ( ) **Next Failure** ( ) **Optional**	TSB Effectivity/ Part(s) Availability: **17-FEB-1999**	Validation Time: **4 hours**
Instruments Requiring Modification: **001 through 1157, 1159 through 1163**	**TSB Tracking by Serial # required (IMMEDIATE TSB's ONLY)** (●) YES ( ) NO	Total Mod. Time: **8 hours** ****NOTE** The instrument must be at TSB Level 82-026 prior to performing this TSB.**

I. DISTRIBUTION:

Worldwide except Japan

II. PURPOSE:

Update the instrument to version 2.1 software. All documents and procedures associated with 2.1 software will also be required for this version installation.

III. ADMINISTRATIVE NOTES:

This TSB must be performed in conjunction with TSB 82-026. Make copies of the Checklist at the end of this TSB. Complete the checklist after upgrade, sign it and leave it with the customer. The password for **Abbott Access** in this version software is **INCREDULOUS** (all caps).

Customer Support Information:

1. **Initial Reactive** samples should be retested prior to software upgrade.
2. At the completion of this upgrade, the customer should run additional samples to duplicate actual routine testing. The testing protocol should be determined by the laboratory's Standard Operating Procedures. All test results must be consistent with expected results.
3. Leave all letters with the customer.
4. Leave the new Operations Manual (6A36-97) with the customer.
5. All test results will be deleted when the new version software is loaded. Therefore, have the customer print reports, copy reports to floppy and/or send data to the host as required based on their test result status.
6. On a four channel instrument, after installing software, you will get communication errors on the uninstalled channels until you configure them to "Not Used".

Upon completion of the upgrade:

1. Use the normal procedures for notification of the TSB.
2. Leave the check list and all associated documentation with the customer.

3. Make sure both you and the customer have signed the documents.
4. Remove all version 1.52 software disks and dispose of them.
5. **The completion date of this TSB is the end of 2nd Quarter 1999.**

IV. SPECIAL TOOLS:

N/A

V. PARTS:

1-65679-01 Kit, Version 2.1 Software Upgrade	1
Contains:	
Disks, version 2.1 Software	1 set
Resource Accounting File Conversion Tools Disk	1
Letter, Software	1
Letter, Enhancement	1
Letter, Run Control	1
Bar Code Labels, Tubing ID	1 set
Bar Code Label Holders, Tubing	39
Bar Code Labels, Purge Bottle	1 set
Adapter, Run Control	10
Rack, Run Control	1

These items are required for the upgrade but are not included in this kit. They will need to be ordered separately.

6A36-32	Rack, HBsAg Confirmatory Preparation	1
6A36-33	Template, HBsAg Confirmatory	2
6A36-97	Manual, Operations	1
6A36-49	Manual, Host Interface Specification	1

REPLACED PARTS:

Remove and dispose of parts following the lab procedures for disposal of biohazardous components.

COMPATIBILITY:

New purge bottle labels are not compatible with any previous versions of software. **Once new software is installed, Host Interface errors may occur unless host has been configured for this version of software.**

VI. PROCEDURE:

MODIFICATION STEPS:

NOTE: Use of the current Field Service DT Manual and TSB's is required.

A. Software Installation:

1. Pre-Software Load.
   a. Turn on all installed channels (set Channel 6 as maintenance)
   b. Print the current Run Controls Configuration.
      From the Main Menu:
      Instrument Preparation
      Manage Resources
      Run Controls
      Select a defined run control
      Print the Run Control Configuration screen (**F3**). Retain this printout for use later in this

procedure.
Repeat these steps for all defined Run Controls. Return to the Main Menu by pressing the **Esc** key.

c. Print the current Audible Alarm Configuration.
From the Main Menu:
Maintenance
Hardware Configuration
Audible Alarm Configuration
Print the Audible Alarm Configuration screen (**F3**). Retain this printout for use later in this procedure.
Return to the Main Menu by pressing the **Esc** key.

d. Print the current Host Interface Configuration.
From the Main Menu:
Maintenance
Hardware Configuration
Host Interface Configuration
Print the Host Interface Configuration screen (**F3**). Retain this printout for use later in this procedure.
Return to the Main Menu by pressing the **Esc** key.

e. Print the current Bar Code Configuration.
From the Main Menu:
Maintenance
Hardware Configuration
Bar Code Configuration
Print the Bar Code Configuration screen (**F3**). Retain this printout for use later in this procedure.
Return to the Main Menu by pressing the **Esc** key.

f. Print the current Batch Parameters.
From the Main Menu:
Maintenance
Software Configuration
Batch Parameters
Print the Batch Parameters Configuration screen (**F3**). Retain this printout for use later in this procedure.
Return to the Main Menu by pressing the **Enter** and then **Esc** key.

g. Print the current Print Report Configuration.
From the Main Menu:
Maintenance
Software Configuration
Print Report Configuration
Print the Print Report Configuration screen (**F3**). Retain this printout for use later in this procedure.
Return to the Main Menu by pressing the **Esc** key.

h. Print a listing of the current Users.
From the Main Menu:
Maintenance
User Configuration
List the Users
Print the Users List screen (**F3**). Retain this printout for use later in this procedure.
Return to the Main Menu by pressing the **Esc** key.

i. Print a listing of the current gray zone settings (if applicable).
From the Main Menu:
Maintenance
Software Configuration
Gray zone Configuration
Print the Gray zone Configuration screen (**F3**). Retain this printout for use later in this

procedure.
Return to the Main Menu by pressing the **Esc** key.

j. Print Localization settings.
From the Main Menu:
Maintenance
Software Configuration
Localization
Print the Localization screen (**F3**). Retain this printout for use later in this procedure.
Return to the Main Menu by pressing the **Esc** key.

k. Purge all Channels.

l. Print tests available for current reagents.
From the Main Menu:
Instrument Preparation
Manage Resources
Go into the menu options (reagents, wash solutions, and purges) and print.

m. Print Kit Usage Information.
From the Main Menu:
Maintenance
Kit Usage Review
Go into the menu for each assay and print the Kit Utilization screen .

n. Set all channels to XFER_2S or XFER_3S

2. Load Software

Equipment Required:
Software Update diskettes
Resource Accounting File Conversion Tools Disk
Blank Formatted 3.5", 1.44 MB Floppy Diskette

a. Log on to ABBOTT PRISM® System with Abbott Access.

b. Make a backup copy of current instrument configuration.
- Use a blank, formatted diskette.
- Perform Configuration Backup
From the Main Menu:
Maintenance
Software Configuration
Configuration Backup/Restore
Backup Configuration
When requested, insert the blank formatted diskette and press **Enter**.
Press **Enter** to continue.
- When backup is complete press **Enter**. Remove diskette.
- Label diskette as Configuration Backup, with date and ABBOTT PRISM® Serial Number. Retain for later use.
- Return to Main Menu (press **Esc** key 3 times).

c. Exit ABBOTT PRISM® Software.
From the Main Menu:
Engineering
Exit Program
Press the **Y** key to confirm shutdown.

d. Backup Resource Accounting Data.
(1) Verify Date and Time.

At the DOS prompt type:
C:\date
Verify that the correct date is displayed. If it is not, enter the correct date. If the correct date is displayed press the enter key.

At the DOS prompt type:

C:\time

Verify that the correct time is displayed. If it is not, enter the correct time. If the correct time is displayed press the enter key.

(2) Insert the conversion tools disk into the floppy drive.

(3) At the DOS prompt, type:

A:\C12

Once the conversion is completed successfully you will get the message:

"RAC Backup: Success"

If a lockup occurs, reboot the instrument and repeat steps **c** and **d**.

If you get an error (other than "the wrong diskette") you will need to manually convert the Manage Resources as described in section B of this TSB.

(4) Remove the disk from the floppy drive.

e. Install the new software.

- Insert Disk 1 of the new software disk set.
- At the prompt:

C:\PRISM\VGA>_

Type in:

cd\

and press the enter key.

- At the prompt:

C:

Type in

a:\install

and press the enter key.

- Follow the screen prompts to complete loading the new version of software.

Note: Some prompts will refer to the new version software disk set as the backup.

3. Restore System configuration.

a. When prompted, reboot ABBOTT PRISM® System Computer by pressing **CTRL**, **ALT**, **DEL** keys simultaneously. Computer boots up to ABBOTT PRISM® Logon Screen.

b. Log on to ABBOTT PRISM® System with Abbott Access.
Note: The Password is **INCREDULOUS** (all Caps)

c. Place configuration backup diskette created earlier into floppy disk drive.

d. Restore Configuration.
From the Main Menu:
Maintenance
Software Configuration
Configuration Backup/Restore
Restore Configuration

e. When restore is complete, press **Enter**. Remove floppy diskette from diskette drive and retain for future use. (Use only with this serial number instrument.)

f. Return to Main Menu (press **Esc**).

g. Reboot ABBOTT PRISM® Computer.
Engineering
Exit Program
From DOS prompt press **CTRL**, **ALT**, and **DEL** keys simultaneously.

4. Restore Resource Accounting Data.

a. Exit ABBOTT PRISM® Software.

From the Main Menu:
Engineering
Exit Program

Press the **Y** key to confirm shutdown.

b. Insert the conversion tools disk into the floppy drive.

c. At the DOS prompt, type:
A:\C12
If you get an error (other than "the wrong diskette") you will need to manually convert the Manage Resources as described in section B of this TSB.

If the restore works correctly you will get the message:

RAC Restore SUCCESS

d. Remove the conversion tools disk from the floppy drive.

e. Reboot ABBOTT PRISM® Computer.
From DOS prompt press **CTRL**, **ALT**, and **DEL** keys simultaneously.

Note: Return conversion tools disk to:

N. A. Abunimeh
D-9GK/Bldg AP1A
100 Abbott Park Road
Abbott Park, IL, USA 60064

5. Restore System Configuration.

a. Log on to ABBOTT PRISM® System with Abbott Access.
Note: The Password for 2.1 is **INCREDULOUS** (all Caps).

b. Configure the Mode Directive setting to US or ROW.
From Main Menu:
Maintenance
Software Configuration
Mode Directive
Set to **US or ROW** - (Spacebar) to select
(F10) to save

Follow instructions on screen and shutdown
Press **CTRL**, **ALT**, and **DEL** keys simultaneously when requested to reboot the system.

c. Configure Assays.
From Main Menu:
Maintenance
Assay Configuration (this may be site or country specific)
Set access types for selected assays to customer, and set status to active for the selected assays. Save (F10) settings.

Assign assays to channels as shown:

Channel 1	HTLV-I/II	Channel 2	HCV
Channel 3	HIV I/II	Channel 4	HBsAg
Channel 5	HBc	Channel 6	N/A

(Spacebar) to select (F10) to save

d. Configure Channels to the same as before loading software.

e. Put new purge bottle labels on the purge bottles.

f. Put new tubing label holders and labels on the tubing in the ambient bay and refrigerator.

g. Verify the tests available. Match the previous (before installing software) levels.
(1) Print tests available for current reagents.
From the Main Menu:
Instrument Preparation
Manage Resources

Go into the menu options (reagents, wash solutions, and purges) and print.

(2) Print Kit Usage Information.
From the Main Menu:
Maintenance
Kit Usage Review
Go into the menu for each assay and print out the Kit Utilization screen .

Compare the printouts before and after loading software. Verify that the numbers are close to the same (within 30). If there are any discrepancies complete section B, Reagent Tracking Worksheet and Table.

Refer to the printout obtained from the Pre-Software Load section (if applicable) for the following procedures. (see the Operations Manual for editing instructions).

h. Configure the Run Controls from the appropriate printout.

i. Configure the Host Interface from the appropriate printout.

j. Configure a maintenance level User. Check with the customer for name and password preference.

k. Configure language, Keyboard, and Date Format from appropriate printout.
From Main Menu:
Maintenance
Software Configuration
Localization
(Spacebar) to select (F10) to shutdown and save. Press F10 again when prompted. Reboot the system (press Ctrl Alt, and Del keys simultaneously) when prompted.
Note: Save (F10) your settings even if you are leaving the settings at the default (English).

l. Configure the Bar Code configuration from the appropriate printout.

Note: I 2 of 5 is now available.

m. Configure the Print Reports from the appropriate printout.

n. Verify the Batch Parameters are set to 8.5 hrs.

o Verify Audible Alarm Configuration matches printout from step 1.

p. Verify the correct serial number (located in the upper left corner of the screen). Enter the correct number if incorrect. If incorrect, perform the following procedure:
From Main Menu:
Maintenance
Software Configuration
Set Serial Number

- Reboot the system for the new number to take effect.

From the Main Menu:
Engineering
Exit Program
From DOS prompt press **CTRL**, **ALT**, and **DEL** keys simultaneously.

q. Verify the date and time (located in the upper right corner of the displayed screen). If correction is required, perform the following procedure:
From Main Menu:
Maintenance
Hardware Configuration
Set Time and Date

r. Verify Gray Zone settings match printout from step 1.

s. Reboot ABBOTT PRISM® Computer.

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

B. REAGENT TRACKING WORKSHEET AND TABLE

This worksheet will provide a method for supplying the customer with a method to track the tests available for reagent kits, wash solutions and purge solutions that were in progress when software was upgraded if the resource management backup does not work. The number next to New, represents the tests available for a new kit, wash or purge component. By subtracting the number of tests that remained for a reagent from the tests available for a new reagent, when the user reaches the number of tests on line 2.1 they have completed that reagent and **must** replace it.

1. For each assay:
   On the 1.52 line, enter the number of "Tests Available" (from the printouts made before loading software) for each of the following:
   Reagent Kit
   Wash solution
   Purge Solution
2. Enter on the 2.1 line:
   The difference between New (tests available for new kit) minus Vs.1.52 (tests available). Note: These numbers are on the print screens that you printed before performing the software upgrade.
3. Enter the 2.1 tests available number onto the "Reagent Tracking" table.
   IMPORTANT: Instruct the customer that when any reagent, wash or purge component " Tests Available" decreases to the number on the "Reagent Tracking" table, there are zero (0) tests remaining. **REPLACE THE COMPONENT!**

Worksheet:

ASSAY	REAGENT KIT	TRANSFER WASH	CONJUGATE WASH	PROBE WASH	PURGE SOLUTION
HTLV	New 5976 Ver1.52 - _____ Ver2.1= _____	New 5080 Ver1.52- _____ Ver2.1= _____	New 5426 Ver1.52- _____ Ver2.1= _____	New 5404 Ver1.52- _____ Ver2.1= _____	New 39 Ver1.52- _____ Ver2.1= _____
HCV	New 6092 Ver1.52- _____ Ver2.1= _____	New 5110 Ver1.52- _____ Ver2.1= _____	New 5456 Ver1.52- _____ Ver2.1= _____	**XXXX**	New 44 Ver1.52- _____ Ver2.1= _____
HIV	New 6030 Ver1.52- _____ Ver2.1= _____	New 5116 Ver1.52- _____ Ver2.1= _____	New 5274 Ver1.52- _____ Ver2.1= _____	New 5329 Ver1.52- _____ Ver2.1= _____	New 39 Ver1.52- _____ Ver2.1= _____
HBsAg	New 6148 Ver1.52- _____ Ver2.1= _____	New 5162 Ver1.52- _____ Ver2.1= _____	New 5306 Ver1.52- _____ Ver2.1= _____	**XXXX**	New 55 Ver1.52- _____ Ver2.1= _____
HBc	New 6286 Ver1.52- _____ Ver2.1= _____	New 5208 Ver1.52- _____ Ver2.1= _____	New 5532 Ver1.52- _____ Ver2.1= _____	**XXXX**	New 55 Ver1.52- _____ Ver2.1= _____

"REAGENT TRACKING"

REPLACE REAGENT KIT, WASH SOLUTION OR PURGE SOLUTION WHEN THE NUMBER OF TESTS AVAILABLE REACHES THE VOLUME LISTED BELOW.

ASSAY	REAGENT KIT	TRANSFER WASH	CONJUGATE WASH	PROBE WASH	PURGE SOLUTION

HTLV					
HCV				**XXXX**	
HIV					
HBsAg				**XXXX**	
HBc				**XXXX**	

CHECKOUT:

1. Go back to TSB 82-026 to perform verifications / validations.
2. Confirm XY settings are correct. Pick up and strip off ten sets of pipette tips.
   From the Main Menu:
   - Component Diagnostics
   - Sample Manager
   - Tip Pick Up

   Set for ten cycles, both axis.
2. Perform the Optics Validation Procedure on all channels on the instrument.
3. Perform the Channel Temperature Validation Procedure on all channels on the instrument.
4. Perform a Clinical Assay Calibration on identified channels.

MODIFICATION CONTROL STICKER UPDATE:

Using a permanent marker, mark through the number twenty seven (27) on the TSB Modification Control Sticker.

ABBOTT PRISM® Version 2.1 Software Upgrade Checklist

While performing this TSB, mark off the items listed in the checklist after they are successfully performed. Attach all printouts from this upgrade.

Instrument S/N _____ Account Name _____

Date of Update _____ Account Address _____

Configuration:

# of tests remaining verified	Yes _____	No* _____
Mode Directive Configured	Yes _____	No* _____
Assays Configured	Yes _____	No* _____
Host Interface Configured	Yes _____	No* _____
Maintenance level user Configured (Customer chooses name and password).	Yes _____	No* _____
Localization Configured	Yes _____	No* _____
Bar Code Configured	Yes _____	No* _____
Print Reports Configured	Yes _____	No* _____
Batch Parameters Verified.	OK _____	
Audible Alarm Verified.	OK _____	
Serial Number Verified.	OK _____	
Date and Time Verified.	OK _____	
Gray Zone Verified	OK _____	
Put new purge bottle labels on purge bottles	Yes _____	No* _____
Replaced tubing label tags with the new tubing label tags and labels	Yes _____	No* _____

Validation:

Successfully picked up and stripped 10 tips.	Yes _____	No* _____
Optics Validation passed.	Yes _____	No* _____
Channel Temperature Validation passed.	Yes _____	No* _____
Assays Performed with acceptable results on channels 1 - 5.	Yes _____	No* _____

* An explanation must be provided

Explanations:

_____

_____

_____

_____

Abbott Representative

Signature _____ Date _____

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

ABBOTT ADD

TECHNICAL SERVICE BULLETIN

SUBJECT:
Version 2.1 Hardware Upgrade

TSB#: **82-026**

ORIGINATOR: **Mark D. Redman**
APPROVED: **Dan Armstrong 2/15/1999**

PRODUCT:
ABBOTT PRISM® (82)

REF. ECO: **14619-003 & 009**

IMPLEMENTATION:	TSB Part/Kit #: **1-65680-01 and 1-65689-01**	Upgrade Time: **4 hours**
● Immediate ○ Next Service Call ○ Next Failure ○ Optional	TSB Effectivity/ Part(s) Availability: **17-FEB-1999**	Validation Time: **6 hours**
Instruments Requiring Modification: **001 through 1157, 1159 through 1163**	**TSB Tracking by Serial # required (IMMEDIATE TSB's ONLY)** ● YES ○ NO	Total Mod. Time: **10 hours** ****NOTE** The instrument must be at TSB Level 82-022B prior to performing this TSB.**

I. DISTRIBUTION:

Worldwide

II. PURPOSE:

Update the instrument with the required hardware required for the Version 2.1 software. Inspect all Transfer Syringes and Transfer Nozzles for foreign material and or blockage.

III. ADMINISTRATIVE NOTES:

NOTE: Follow the Validation instructions (in the checkout section) included in this TSB only after Software Version 2.1 (TSB 82-027) has been installed (complete the assay run portion of TSB 82-027 validation after completing this TSB).

1. Use the normal procedures for notification of the TSB.
2. Complete the Checklist at the end of this TSB and leave a copy with all associated printouts at the site.
3. Reagents and wash solutions for Channels 2 and 6 must be removed prior to this upgrade. Store them in the appropriate locations per their requirements. Bottles containing purge solution will be required during the validation of the ceramic purge valve installations.
4. The completion date of this TSB is the end of 2nd Quarter 1999.

IV. SPECIAL TOOLS:

Volume Validation tool 6A36-81.

V. PARTS:

1-65689-01 Firmware, BCR Board
1-65680-01 Kit, Version 2.1 Hardware Upgrade
Contains:
Purge Valve, Ceramic 2

Bracket, Ceramic Purge Valve Mounting	2
Screw, 10-32, 0.375"	2
Tools, Purge Valve	1
Holder, Activator Bottle	1
Label, Activator Bottle	1
Tray, Activator Bottle	1
Tubing, 0.045"ID (Labeled 62S) 19"	1
Plugs, Purge Valve	4

REPLACED PARTS:

Remove and dispose of parts following the lab procedures for disposal of biohazardous components.

COMPATIBILITY:

The old style purge valve is no longer compatible for use in channel 6 once the instrument is upgraded to 2.1 version of software using TSB 82-027 (WW) or 82-029 (Japan only).

NOTE: Use of the current Field Service DT Manual and TSB's is required.

VI. PROCEDURE:

INSPECTION STEPS: Perform Inspection on all instrument channels.

NOTE: Use of the current Field Service DT Manual is required.

1. Remove any reagents which are present from the refrigerator (using manage resources) and store per package instructions.
2. Perform System Power Off (VP-1)
3. Remove Sample Access Front and Back Covers(PL-Covers).
4. Remove the Rack Plate Assembly.
5. Visually inspect all the Transfer Syringes. If any foreign matter is observed in the syringe barrel or attached to the plunger, replace the Transfer Syringe.
6. Perform System Start-up (VP-2)
7. Remove the Drain Time Sensor Assembly (see RR C2.5) by the Transfer Station Mounting Screws (standoff's). Visually inspect the Transfer Dispensers for any blockage. If blockage is present, then replace the Transfer Dispenser(s).
8. If the dispensers are visually clean, then check the spray pattern of the dispenser.
   a. Exchange the Transfer Solution with a bottle of Purge Solution for the following check.
   b. Check the Spray Pattern check of Transfer Dispensers:
      - COMPONENT DIAGNOSTICS
      - CHANNELS
      - TRANSFER TESTS
      - CYCLE TRANSFER (will require a reaction tray to be loaded)

      Hold the dispenser assembly over a Prime/Purge tray and visually inspect the pattern of each stream. There should be a defined separation between the streams. If not, then replace the dispenser(s).
9. If Transfer components require replacement, perform necessary system verifications per the current Field Service DT Manual. Replace the Transfer Wash solution on the channel under test.
10. Replace Rack Plate Assembly (per RR -B1.11).

MODIFICATION STEPS:

NOTE: Use of the current Field Service DT Manual and TSB's are required.

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

1. Remove any reagents which are present from the refrigerator (using manage resources) and store per package instructions.
2. Perform System Power Off (VP-1)
3. Remove Rear Electronics Bay Cover (PL-Covers).
4. Replace old Activator Bottle Holder (2 screws) with the new Activator Bottle Holder, Tray, (3 screws) and label.
5. Replace Channel 2 Purge Valve with Ceramic Purge Valve.
   a. Remove old purge valve (RR-D2).
   b. Remove purge valve mounting standoffs. It will be necessary to start unscrewing with a wrench. Once the stand off starts to move oil the threads with super lube. Finish unscrewing the posts by hand because it is very easy to break the standoffs when unscrewing. A kit (Purge Valve Tools, 1-14207-01) is provided if you do break the stand off. The kit contains a drill bit, a tap and a tap handle.
   c. Install new purge valve mounting bracket (2 screws) and ceramic purge valve.

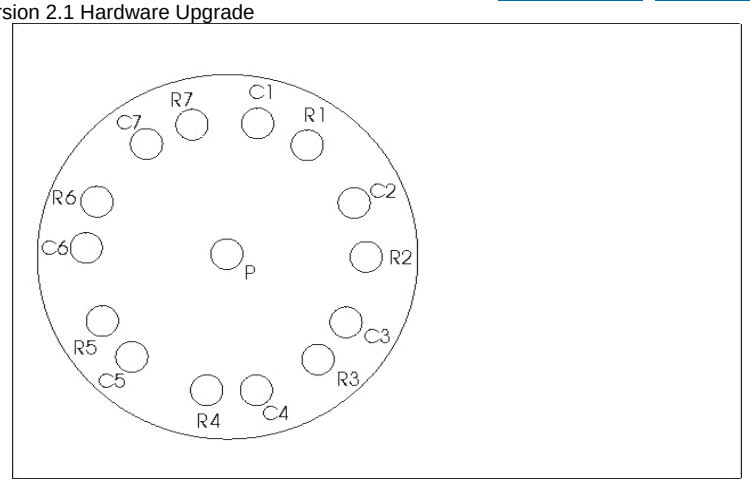
      Note: The tubing connections to the Purge Valve will be made during the checkout portion of this TSB.
6. Replace Channel 6 Purge Valve with Ceramic Purge Valve.
   a. Remove old purge valve (RR-D2).
   b. Remove purge valve mounting standoffs. It will be necessary to start unscrewing with a wrench. Once the stand off starts to move oil the threads with super lube. Finish unscrewing the posts by hand because it is very easy to break the standoffs when unscrewing. A kit (Purge Valve Tools, 1-14207-01) is provided if you do break the stand off.
   c. Install new purge valve mounting bracket (2 screws) and ceramic purge valve.

   d. Retube pump in E position of channel 5 so that it connects to the ceramic purge valve in channel 6 instead of directly to the reagent bottle.
      (1) Disconnect the tubing labeled 62R (Bottle tubing from refrigerator) from the pump in the E position of Channel 5. Cut off 12 inches (30.48 cm) from this tubing. It should be 73 inches (185.42 cm) in length after removing this section. Install connector (see RR-D9) and new label (62SR) onto the end of the tubing.
      (2) Take the new piece of tubing (labeled 62S) and connect from pump, inlet port, in position E to Purge Valve C1.

      Note: The tubing connections to the Purge Valve will be made during the checkout portion of this TSB.
7. Replace Bar Code Reader Firmware (in Japan, reference TSB 82-025).
   a. Remove the Bar Code Reader Controller Cover. On the Bar Code Reader Bd., replace the EPROM in U9 with the new EPROM. Change the last three digits of the Board part number to -107. Replace the Cover. Change the last three digits of the part number on the Bar Code Reader Controller Assembly to -107.
   b. Perform System Start Up (VP-2).
   c. Install the Bar Code Reader Controller Cover and Sample Access Front Cover.

CHECKOUT:

1. Install software version 2.1 using TSB 82-027 (WW) or 82-029 (Japan only). Once software has been installed, configured, and validated return to this checkout procedure (complete the checkout of TSB 82-027 (WW) or TSB 82-029 (Japan only) after completing this TSB).
2. Connect channel 2 purge valve tubing and validate connections. To properly validate each reagent, connect tubing to the new purge valve one reagent/wash solution bottle at a time.



Purge Pos	Tubing from (Tubing Label)	Purge Pos	Tubing from (Tubing Label)
C1	Specimen Diluent Pump(22S)	C5	Conjugate Pump (25C)
R1	Specimen Diluent Bottle (22SR)	R5	Conjugate Bottle (25CR)
C2	Conjugate Wash Pump (28CW)	C6	u-particles Pump (21M)
R2	Conjugate Wash Bottle (28CWR)	R6	u-particles Bottle (21MR)
C3	Plug	C7	Plug
R3	Plug	R7	Plug
C4	Transfer Wash Pump (24T)	P	Purge Bottle (2PG)
R4	Transfer Wash Bottle (24TR)		

a. Connect Tubing plugs to Channel 2 Purge Valve, connectors C3, R3, C7, and R7.

b. Connect the microparticle reagent tubing to the purge valve.

21M to C6

21MR to R6

Connect a bottle containing purge solution to the microparticle reagent tube in the refrigerator. Using Pump Test in Component Diagnostics, cycle the pump 99 times to prime it (ignore errors while priming). Cycle the pump an additional 15 times and check for errors. If errors are present, troubleshoot accordingly (reference service manual). If no errors, then continue.

c. Connect the specimen diluent reagent tubing to the purge valve.

22S to C1

22SR to R1

Connect a bottle containing purge solution to the specimen diluent reagent tube in the refrigerator. Using Pump Test in Component Diagnostics, cycle the pump 99 times to prime it (ignore errors while priming). Cycle the pump an additional 15 times and check for errors. If errors are present, troubleshoot accordingly (reference service manual). If no errors, then continue.

d. Connect the transfer wash reagent tubing to the purge valve.

24T to C4

24TR to R4

Connect a bottle containing purge solution to the transfer wash tube in the refrigerator. Using Transfer Syringe Test in Component Diagnostics, perform Cycle Transfer. Visually confirm the syringe aspirates liquid and dispenses fluid into the reaction tray. If errors are present, troubleshoot accordingly (reference service manual). If no errors, then continue.

e. Connect the conjugate reagent tubing to the purge valve.

25C to C5

25CR to R5

Connect a bottle containing purge solution to the conjugate reagent tube in the refrigerator. Using Pump Test in Component Diagnostics, cycle the pump 99 times to prime it (ignore errors while priming). Cycle the pump an additional 15 times and check for errors. If errors are present, troubleshoot accordingly (reference service manual). If no errors, then continue.

f. Connect the conjugate wash tubing to the purge valve.

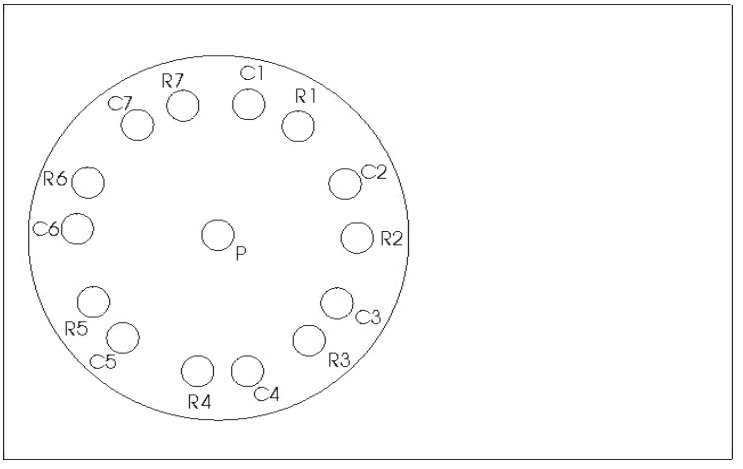
28CW to C2

28CWR to R2

Connect a bottle containing purge solution to the conjugate wash tube in the refrigerator. Using Pump Test in Component Diagnostics, cycle the pump 99 times to prime it (ignore errors while priming). Cycle the pump an additional 15 times and check for errors. If errors are present, troubleshoot accordingly (reference service manual). If no errors, then continue.

g. Connect the purge bottle tubing to the new purge valve. Reload reagents and purge solution for channel 2. Perform a system purge for channel 2. Visually check the LED's located on the Channel 2 Dispense Verify Board during purge for proper operation.

3. Connect channel 6 purge valve tubing and validate connections. To properly validate each reagent, connect tubing to the new purge valve one reagent/wash solution bottle at a time.



Purge Pos	Tubing from (Tubing Label)	Purge Pos	Tubing from (Tubing Label)
C1	Specimen Diluent Pump(62S)	C5	Conjugate Pump (67C)
R1	Specimen Diluent Bottle (62SR)	R5	Conjugate Bottle (67CR)
C2	Conjugate Wash Pump (68CW)	C6	u-particles Pump (61M)
R2	Conjugate Wash Bottle (68CWR)	R6	u-particles Bottle (61MR)
C3	Probe Pump (65C)	C7	Probe Wash Pump (66PW)
R3	Probe Bottle (65CR)	R7	Probe Wash Bottle (66PWR)
C4	Transfer Wash Pump (64T)	P	Purge Bottle (6PG)
R4	Transfer Wash Bottle (64TR)		

a. Connect the microparticle reagent tubing to the purge valve.

61M to C6

61MR to R6

Connect a bottle containing purge solution to the microparticle reagent tube in the refrigerator. Using Pump Test in Component Diagnostics, cycle the pump 99 times to prime it (ignore errors while priming). Cycle the pump an additional 15 times and check for errors. If errors are present, troubleshoot accordingly (reference service manual). If no errors, then continue.

b. Connect the specimen diluent reagent tubing to the purge valve.

62S to C1

62SR to R1

Connect a bottle containing purge solution to the specimen diluent reagent tube in the refrigerator. Using Pump Test in Component Diagnostics, cycle the pump 99 times to prime it (ignore errors while priming). Cycle the pump an additional 15 times and check for errors. If errors are present, troubleshoot accordingly (reference service manual). If no errors, then continue.

c. Connect the transfer wash tubing to the purge valve.

64T to C4

64TR to R4

Connect a bottle containing purge solution to the transfer wash tube in the refrigerator. Using Transfer Syringe Test in Component Diagnostics, perform Cycle Transfer. Visually confirm the syringe aspirates liquid and dispenses fluid into the reaction tray. If errors are present, troubleshoot accordingly (reference service manual). If no errors, then continue.

d. Connect the conjugate/probe reagent tubing to the purge valve.

65C to C3

65CR to R3

Connect a bottle containing purge solution to the conjugate/probe reagent tube in the refrigerator. Using Pump Test in Component Diagnostics, cycle the pump 99 times to prime it (ignore errors while priming). Cycle the pump an additional 15 times and check for errors. If errors are present, troubleshoot accordingly (reference service manual). If no errors, then continue.

e. Connect the probe wash tubing to the purge valve.

66PW to C7

66PWR to R7

Perform Dispense Volume Validation (VP-21) to validate these connections.

f. Connect the conjugate reagent tubing to the purge valve.

67C to C5

67CR to R5

Connect a bottle containing purge solution to the conjugate tube in the refrigerator. Using Pump Test in Component Diagnostics, cycle the pump 99 times to prime it (ignore errors while priming). Cycle the pump an additional 15 times and check for errors. If errors are present, troubleshoot accordingly (reference service manual). If no errors, then continue.

g. Connect the conjugate wash tubing to the purge valve.

68CW to C2

68CWR to R2

Prior to checking this pump, change the channel configuration to a two step assay (HCV, HIV I/II). This will activate the DV sensor for this dispenser. Connect a bottle containing purge solution to the conjugate wash tube in the refrigerator. Using Pump Test in Component Diagnostics, cycle the pump 99 times to prime it (ignore errors while priming). Cycle the pump an additional 15 times and check for errors. If errors are present, troubleshoot accordingly (reference service manual). If no errors, then continue.

h. Connect the purge bottle tubing to the new purge valve. Reload reagents and purge solution for channel 6. Perform a system purge for channel 6. Visually check the LED's located on the Channel 6 Dispense Verify Board during purge for proper operation.

4. Perform Bar Code Reader Verification (VP-29).
5. Replace all Covers removed in previous steps.
6. Complete the Version 2.1 Hardware Upgrade Checklist.

MODIFICATION CONTROL STICKER UPDATE:

Using a permanent marker, mark through the number twenty six (26) on the TSB Modification Control Sticker.

ABBOTT PRISM® Version 2.1 Hardware Upgrade Checklist

While performing this TSB, mark off the items listed in the checklist after they are successfully performed. Attach all printouts from this upgrade.

Instrument S/N _____ Account Name _____

Date of Update _____ Account Address _____

Configuration:

Replaced Activator Bottle Holder and label.	Yes _____	No* _____
Replaced Channel 2 Purge Valve with new style ceramic purge valve.	Yes _____	No* _____
Replaced Channel 6 Purge Valve with new style ceramic purge valve.	Yes _____	No* _____
Replaced Bar Code Reader Firmware	Yes _____	No* _____

System Checkout:

TO BE PERFORMED AFTER 2.1 SOFTWARE INSTALLATION

All Channel 2 pump connections (except Activator) validated.	Yes _____	No* _____
All Channel 6 pump connections (except Activator) validated.	Yes _____	No* _____
Perform Bar Code Reader Verification (VP-29)	Yes _____	No* _____

Complete validation portion of TSB 82-027 (WW) or 82-029 (Japan only).

* An explanation must be provided

Explanations:

_____

_____

_____

_____

Abbott Representative

Signature _____ Date _____

END OF DOCUMENT

ABBOTT ADD

TECHNICAL SERVICE BULLETIN

SUBJECT:
Bar Code Reader Firmware Upgrade (Japan)

TSB#: **82-025**

ORIGINATOR: **Mark D. Redman**
APPROVED: **Dan Armstrong 2/11/1999**

PRODUCT:
ABBOTT PRISM® (82)

REF. ECO: **14958-002**

IMPLEMENTATION: ● **Immediate** ○ **Next Service Call** ○ **Next Failure** ○ **Optional** Instruments Requiring Modification: **See list in Administrative Notes.**	TSB Part/Kit #: **1-65689-01** TSB Effectivity/ Part(s) Availability: **11-DEC-98** **TSB Tracking by Serial # required (IMMEDIATE TSB's ONLY)** ● YES ○ NO	Upgrade Time: **1 hours** Validation Time: **0.5 hours** Total Mod. Time: **1.5 hours** ****NOTE** The instrument must be at TSB Level 82-022B prior to performing this TSB.**

I. DISTRIBUTION:

Japan only

II. PURPOSE:

This document provides instructions on how to update firmware in the bar code reader control board. The purpose of the upgrade is to enable the Prism to read bar codes that will be used by the Japanese Red Cross. These barcodes have a check digit of zero and can not be read using existing firmware.

III. ADMINISTRATIVE NOTES:

1. Use the normal procedures for notification of the TSB.
2. Upgrade Current or new spares of Bar Code Reader Board in addition to the listed instruments.

SN 1056	**SN 1074**	**SN 1121**	**SN 1148**
SN 1061	**SN 1119**	**SN 1139**	

3. Any new instruments arriving without the next TSB installed (TSBs 82-026 and 82-027) will require this TSB.
4. For additional parts contact the Abbott Prism® WWCS CSE Department.
5. The completion date of this TSB is the end of 2nd Quarter 1999.

IV. SPECIAL TOOLS:

N/A

V. PARTS:

1-65689-01 Firmware, Bar Code Reader Board

REPLACED PARTS:

Dispose of per site requirements for contaminated material.

COMPATIBILITY:

VI. PROCEDURE:

MODIFICATION STEPS:

Note : Use of current field service DT manual is required.

1. Perform system power off (VP-1).
2. Remove the sample access front cover (PL-Covers).
3. Disconnect J3 and J6 from the bar code reader control board so that its cover may be removed.
4. Loosen the two large screws at the top and then remove the cover. Carefully remove EPROM U9 from the bar code reader controller board. Install the new EPROM.
5. Change the last three digits of the bar code reader controller board part number to -107.
6. Replace the bar code reader control board cover.
7. Change the last three digits of the part number on the bar code reader controller assembly to -107.
8. Replace the sample access cover
9. Perform system start up (VP-2).
10. Perform bar code reader verification (VP-29)

CHECKOUT:

1. Perform bar code verification procedure (VP-29).

MODIFICATION CONTROL STICKER UPDATE:

1. Using a permanent marker, mark through the number twenty-five (25) on the TSB Modification Control Sticker.

END OF DOCUMENT

ABBOTT ADD

TECHNICAL SERVICE BULLETIN

SUBJECT:
Software Version 2.0 (Clinical)

TSB#: **82-024**

ORIGINATOR: **Mark D. Redman**
APPROVED: **Bob Schabel (6/23/98)**

PRODUCT:
ABBOTT PRISM® (82)

REF. ECN: **12551-001**

IMPLEMENTATION:	TSB Part/Kit #: **N/A**	Upgrade Time: **8.0 hrs.**
● Immediate ○ Next Service Call ○ Next Failure ○ Optional	TSB Effectivity/ Part(s) Availability: **N/A**	Validation Time: **6.0 hrs.**
Instruments Requiring Modification: See Administrative Notes below	**TSB Tracking by Serial # required (IMMEDIATE TSB's ONLY)** ● YES ○ NO	Total Mod. Time: **14.0 hrs** ****NOTE** The instrument must be at TSB Level 23 prior to performing this TSB.**

I. DISTRIBUTION:

Limited to Clinical / Evaluation Sites, in-house installed Systems including but not limited to R & D (Systems & Software), FSR training and Prism Engineering, etc.

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

II. PURPOSE:

Update the instrument to 2.0 software. All documents and procedures associated with 2.0 software will also be required for this version installation.

III. ADMINISTRATIVE NOTES:

NOTE: The following instruments require Immediate modification under this TSB: Clinical / Evaluation Sites, in-house installed Systems including but not limited to R & D (Systems & Software), FSR training and Prism Engineering, etc.

Make copies of the Checklist at the end of this TSB. Complete the checklist after upgrade, sign it and leave it with instrument. **Abbott Access** for this version software is **PLUTOCHARON** (all caps). Confirm a Clinical Operations Manual (June 1998) is at the site. Upon completion of the upgrade:

1. There will be an exception to the normal notification of this TSB. The Prism CSE organization will be the primary service and logistics organization for Clinicals in the USA. *Upgrade Completion for USA Clinical instruments is prior to Clinical start date.* Other clinicals or evaluations outside of the USA will be supported or monitored by Area Operations in Delkenheim or the Prism CSE organization.

2. Complete the Checklist and leave a copy with all associated printouts at the site.

IV. SPECIAL TOOLS:

N/A

V. PARTS:

Kit, Software Version 2.0 contains:

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

	Software Diskettes	1 set
52200-168	Bar Code Labels, Tubing ID	1 set
51302-101	Bar Code Tubing Label Holder	39
	Purge Bottle Labels	1 set

Accessories:

55706-102	Confirmatory Template	2
55710-102	Confirmatory Prep Rack	1
55953-101	Insert, Control Bottle	12
52314-101	Holder, Control Bottle Insert	1

REPLACED PARTS:
Remove and dispose of parts following the lab procedures for disposal of biohazardous components.

COMPATIBILITY:
Once labels have been added, previous version software is not compatible.

VI. PROCEDURE:

NOTE: Use of the current Field Service DT Manual and TSB's is required.

Software Installation:

1. Pre-Software Load
   a. Print a listing of the current Users.
      From the Main Menu:
      - Maintenance
      - User Configuration

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

- List the Users

Print the Users List screen (**F3**). Retain this printout for use later in this procedure. Return to the Main Menu by pressing the **Esc** key.

2. Load Software

Equipment Required:

- Software Update diskettes
- Blank Formatted 3.5", 1.44 MB Floppy Diskette

a. Log on to ABBOTT PRISM® System with Abbott Access.

b. Make a backup copy of current configuration.

- Use a blank, formatted diskette.
- Perform Configuration Backup

  From the Main Menu:

  - Maintenance
  - Software Configuration
  - Configuration Backup/Restore
  - Backup

  When requested, insert the blank formatted diskette and press **Enter**. Press **Enter** to continue.
- When backup is complete press **Enter**. Remove diskette.
- Label diskette as Configuration Backup, with date and ABBOTT PRISM® Serial Number. Retain for later use.
- Return to Main Menu (press **Esc** key 3 times).

c. Exit ABBOTT PRISM® Software.

From the Main Menu:

- Engineering
- Exit Program

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

Press the **Y** key to confirm shutdown.

d. Install the new software.
   - Insert Disk 1 of the new software disk set.
   - At the prompt:
     C:\PRISM\VGA>_
     Type in:
     cd\
     and press the enter key.
   - At the prompt:
     C:
     Type in
     a:\install
     and press the enter key.
   - Follow the screen prompts to complete loading the new version of software.

   Note: Some prompts will refer to the new version software disk set as the backup.

3. Restore System configuration.
   a. As prompted, reboot ABBOTT PRISM® System Computer by pressing **CTRL**, **ALT**, **DEL** keys simultaneously. Computer boots up to ABBOTT PRISM® Logon Screen.
   b. Log on to ABBOTT PRISM® System with Abbott Access.
      Note: The Password for 2.0 is PLUTOCHARON (all Caps)
   c. Place configuration backup diskette created earlier into floppy disk drive.
   d. Restore Configuration.
      From the Main Menu:
      - Maintenance
      - Software Configuration
      - Configuration Backup/Restore

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

- Restore Configuration

e. When restore is complete, press **Enter**. Remove floppy diskette from diskette drive and retain for future use. (Use only with this serial number instrument.)
f. Return to Main Menu (press **Esc**).
g. Reboot ABBOTT PRISM® Computer.
From the Main Menu:
- Engineering
- Exit Program

From DOS prompt press **CTRL**, **ALT**, and **DEL** keys simultaneously.

4. Configuration
Refer to the printout obtained from the Pre-Software Load section for the following procedures. (see the Operations Manual for editing instructions).
a. Configure the Mode Directive setting to US.
From Main Menu:
- Maintenance
- Software Configuration
- Mode Directive
Set to **US** - (Spacebar) to select
(F10) to save

Follow instructions on screen and shutdown
Press **CTRL**, **ALT**, and **DEL** keys simultaneously when requested to reboot the system.

b. Configure Assays.
From Main Menu:
- Maintenance
- Assay Configuration

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

Select assays and set access levels for selected assays to customer and save (F10).
Assign assays to channels as shown

Channel 1	HTLV-I/II	Channel 2	HCV
Channel 3	HIV-O PLUS	Channel 4	HBsAg
Channel 5	HBcore	Channel 6	N/A

(Spacebar) to select (F10) to save

c. Configure the Run Controls (Abbott and Customer). For the clinical testing set up at least one release control on all assays.
d. Configure the Host Interface:
From Main Menu:
- Maintenance
- Hardware Configuration
- Host Interface Configuration

Parameters to be set as follows:

Mode:	Enabled
Baud rate:	9600
Parity:	None
Data Bits:	8
Stop Bits:	1
Retest Mode:	Abbott Prism
Host Wait:	10 seconds

(Spacebar) to select (F10) to save
e. Configure a maintenance level User. Check with the customer for name and password preference.
f. Configure language, Keyboard, and Date Format to native language as requested by the customer.

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

From Main Menu:

- Maintenance
- Software Configuration
- Localization

(Spacebar) to select (F10) to save

Note: Save (F10) your settings even if you are leaving the settings at the default (English).

g. Verify the Audible Alarm.

h. Verify the Bar Code configurations .

i. Verify the Batch Parameters are set to 8.5 hrs.

j. Configure the Print Reports:

From Main Menu:

- Maintenance
- Software Configuration
- Print Report Configuration

Enable the following reports

Calibration Report	Y
Group Report	Y
Assay Report	Y
Sample Report	Y
Resource Report	Y
Group Retest Report	Y
Sample Retest Report	Y
Confirmatory Report	Y

Site Name: Enter the appropriate site information

(Spacebar) to select (F10) to save

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

k. Verify the correct serial number (located in the upper left corner of the screen). Enter the correct number if incorrect. If incorrect, perform the following procedure:
From Main Menu:
- Maintenance
- Software Configuration
- Set Serial Number

l. Verify the correct date and time (located in the upper right corner of the displayed screen). Enter the correct date and time if incorrect. If incorrect, perform the following procedure:
From Main Menu:
- Maintenance
- Hardware Configuration
- Set Time and Date

m. Reboot ABBOTT PRISM® Computer.
From the Main Menu:
- Engineering
- Exit Program

From DOS prompt press **CTRL**, **ALT**, and **DEL** keys simultaneously.

5. Put new purge bottle labels on the purge bottles.
Note: This step is not necessary if you have already performed TSB 82-023.

6. Put new tubing label holders and labels on the tubing in the reagent bay and refrigerator.
Note: This step is not necessary if you have already performed TSB 82-023.

MODIFICATION STEPS:

CHECKOUT:

1. Confirm XY settings are correct. Pick up and strip off ten sets of pipette tips.
   From the Main Menu:
   - Component Diagnostics
   - Sample Manager
   - Tip Pick Up

   Set for ten cycles, both axis.
2. Perform the Optics Validation Procedure on all channels on the instrument.
3. Perform the Channel Temperature Validation Procedure on all channels on the instrument.
4. Perform an Assay Calibration on channels 1 - 5.
5. ABBOTT PRISM® Version 2.0 Software Upgrade Checklist is attached and printed below.


82-024At.doc

MODIFICATION CONTROL STICKER UPDATE:
None.

ABBOTT PRISM® Version 2.0 Software Upgrade Checklist

While performing this TSB, mark off the items listed in the checklist after they are successfully performed. Attach all printouts from this upgrade.

Instrument S/N _____ Account Name _____

Date of Update _____ Account Address _____

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

Configuration:

Run Controls Configured.	Yes _____	No* _____
Host Interface Configured	Yes _____	No* _____
Language, Keyboard, and Date Format (Localization) Configured.	Yes _____	No* _____
Maintenance level user Configured (Customer chooses name and password).	Yes _____	No* _____
Batch Size Verified.	OK _____	
Print Reports Configured.	OK _____	
Serial Number Verified.	OK _____	
Date and Time Verified.	OK _____	
Put new purge bottle labels on purge bottles	Yes _____	No* _____
Replaced tubing label tags with the new tubing label tags and labels	Yes _____	No* _____

Validation:

Successfully picked up and stripped 10 tips.	Yes _____	No* _____
Optics Validation passed.	Yes _____	No* _____

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

Channel Temperature Validation passed. Yes _____ No* _____

Assays Performed with acceptable results

on channel 1 - 5. Yes _____ No* _____

* An explanation must be provided

Explanations:

_____

_____

_____

_____

Abbott Representative

Signature _____ Date _____

END OF DOCUMENT

ABBOTT ADD

TECHNICAL SERVICE BULLETIN

SUBJECT:
Hardware for Version 2.0 Software (Clinical)

TSB#: **82-023**

ORIGINATOR: **Mark D. Redman**
APPROVED: **Bob Schabel 6/23/98**

PRODUCT:
ABBOTT PRISM® (82)

REF. ECN: **Deviation DT-428**

IMPLEMENTATION:	TSB Part/Kit #: **N/A**	Upgrade Time: **8.0 hrs.**
● **Immediate** ○ **Next Service Call** ○ **Next Failure** ○ **Optional**	TSB Effectivity/ Part(s) Availability: **N/A**	Validation Time: **6.0 hrs.**
Instruments Requiring Modification: See Administrative Notes below	**TSB Tracking by Serial # required (IMMEDIATE TSB's ONLY)** ● YES ○ NO	Total Mod. Time: **14.0 hrs** ****NOTE** The instrument must be at TSB Level 22 prior to performing this TSB.**

I. DISTRIBUTION:

Limited to Clinical / Evaluation Sites, in-house installed Systems including but not limited to R & D (Systems & Software), FSR training and Prism Engineering, etc.

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

II. PURPOSE:

Update the instrument with the required hardware to perform the System Clinical.

III. ADMINISTRATIVE NOTES:

NOTE: The following instruments require Immediate modification under this TSB: Clinical / Evaluation Sites, in-house installed Systems including but not limited to R & D (Systems & Software), FSR training and Prism Engineering, etc.

NOTE: After completing this TSB it will be necessary to perform TSB 82-024 (2.0 Software Upgrade).

1. There will be an exception to the normal notification of this TSB. The Prism CSE organization will be the primary service and logistics organization for Clinicals in the USA. *Upgrade Completion for USA Clinical instruments is prior to Clinical start date.* Other clinicals or evaluations outside of the USA will be supported or monitored by Area Operations in Delkenheim or the Prism CSE organization.

2. Complete the Checklist and leave a copy with all associated printouts at the site.

IV. SPECIAL TOOLS:

Volume Validation tool 6A36-81.

V. PARTS:

Kit, 2.0 Hardware update which contains:

52248-101	Holder, Activator Bottle	1
38378-101	Label, Activator Bottle Holder	1
14494-306	Screw, 10-32 X3/8, Activator Bottle Holder	3

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

	Assy, Purge Valve	1
55942-101	Mounting Bracket, Purge Valve	1
14494-306	Screw, 10-32 X3/8, PV Mounting Bracket	2
N/A	Tubing, Chn 6 PV to Pump (labeled 62S) Length=19", .045 ID, Nat	1
52534-108	Pump, Chn 5	1
50051-101	Refrigerator Plug	1
N/A	Tubing, Chn 5 Bottle to PV (52SR) Length=63", .045 ID, Nat	1
N/A	Tubing, Chn 5 PV to Pump (52S) Length=17", .045 ID, Nat	1
N/A	Tubing, Pump to Dispenser A (52SA) Length=62", .031 ID, Nat	1
N/A	Tubing, Pump to Dispenser B (52SB) Length=62", .031 ID, Nat	1
14370-132	Tubing, Tip Wash	4 ft.
14603-168	"Y" fittings, spares	3
50514-101	Ferrule, Connector, spares	4
50515-101	Nut, Connector, spares	4
50517-101	Seal, Connector, spares	4

REPLACED PARTS:
Remove and dispose of parts following the lab procedures for disposal of biohazardous components.

COMPATIBILITY:
Once Valve and labels have been added previous versions of Software are not compatible.

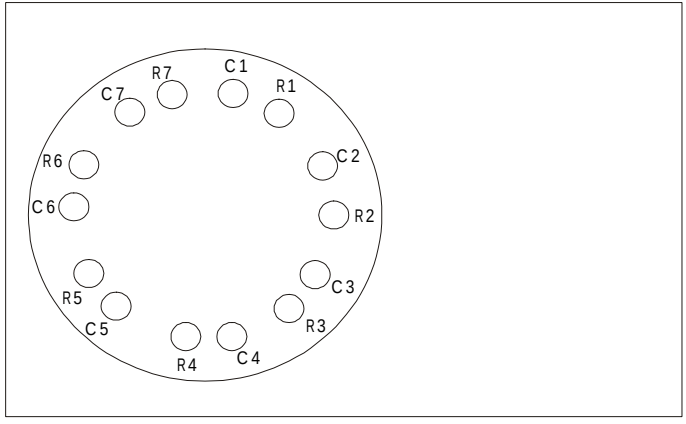
Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

VI. PROCEDURE:

NOTE: Use of the current Field Service DT Manual and TSB's is required.

Hardware Modification.

1. Replace old Activator Bottle Holder (2 screws) with the new Activator Bottle Holder (3 screws) and label.
2. Replace Channel 6 Purge Valve with new style purge valve.
   a. Remove old purge valve (RR-D2).
   b. Remove purge valve mounting standoffs. It will be necessary to start with a wrench. Once the stand off starts to move oil the threads with super lube. Finish unscrewing the posts by hand.
   c. Install new purge valve (2 screws).
   d. Reattach tubing to new purge valve as shown.



Purge Pos		Tubing From (Tubing Label)	Purge Pos	Tubing From (Tubing Label)
C1	*	Specimen Diluent Pump (52S)	C5	Conjugate Pump (67C)
R1	*	Specimen Diluent Bottle (52SR)	R5	Conjugate Bottle (67CR)
C2		Conjugate Wash Pump (68CW)	C6	u-particles Pump (61M)
R2		Conjugate Wash Bottle (68CWR)	R6	u-particles Bottle (61MR)
C3		Probe Pump (65C)	C7	Probe Wash Pump (66PW)
R3		Probe Bottle (65CR)	R7	Probe Wash Bottle (66PWR)
C4		Transfer Wash Pump (64T)	P	Purge Bottle (6PG)
R4		Transfer Wash Bottle (64TR)		

* These two connections will be made in step e.

e. Retube pump in E position of channel 5 so that it goes through new purge valve in channel 6 instead of directly to the reagent bottle.

1.) Cut off 12 inches from the Bottle to Pump Tubing at the Pump end of the tubing. It should be 73 inches long after cutting. Install connector (see RR-D9) and new label onto the end of the tubing. Connect to the Purge Valve R1.

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

2.) Take the new piece of tubing (labeled 62S) and connect from pump, inlet port, in position E to Purge Valve C1.

3. Add new reagent to channel 5.
   a. Install new pump (RR-D1) to channel 5, “D” position.
   b. Replace the microparticle station with a new quad head microparticle station (RR-C2.2/3).
   c. Locate the tubing plug in the refrigerator with no hole for tubing. This will be located above the Channel 5, first bottle position. Replace the plug with a tubing plug with a single hole for tubing in it.
   d. Install tubing:
      1.) Reagent Bottle to Purge Valve port H (see RR-D2) (tubing is labeled 52SR).
      2.) Purge Valve port G (see RR-D2) to Pump D inlet port (see RR-D1) (tubing is labeled 52S).
      3.) Pump D port A (see RR-D1) to Dispenser A (tubing is labeled 52SA).
      4.) Pump D port B (see RR-D1) to Dispenser B (tubing is labeled 52SB).
   e. Modify the Tip Wash tubing on channel 5 so that it is the same as channel 2.

MODIFICATION STEPS:

CHECKOUT:

1. Perform a Dispense Volume Validation (VP-21) for the 7 pumps in Channel 6 that go through the purge valve (all pumps except activator). Acceptance criteria is based on 2.0 software criteria. Retain printout to attach to checklist.
2. Perform Dispense Volume Validation (VP-21) on Channel 5 microparticle and Cystine pumps. Acceptance criteria is based on 2.0 software criteria. Retain printout to attach to checklist.
3. ABBOTT PRISM® Version 2.0 Hardware Upgrade Checklist is attached here. 82-023At.doc and

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

printed below.

MODIFICATION CONTROL STICKER UPDATE:
None.

ABBOTT PRISM® Version 2.0 Hardware Upgrade Checklist

While performing this TSB, mark off the items listed in the checklist after they are successfully performed. Attach all printouts from this upgrade.

Instrument S/N _____ Account Name _____

Date of Update _____ Account Address _____

Configuration:

Replaced Activator Bottle Holder.	Yes _____	No* _____
Replaced Channel 6 Purge Valve with new style purge valve.	Yes _____	No* _____
Added new reagent fluidics to channel 5.	Yes _____	No* _____

System Checkout:

TO BE PERFORMED AFTER 2.0 SOFTWARE INSTALLATION

All Channel 6 pumps (except Activator) validated (include printout).	Yes _____	No* _____
Channel 5 microparticle and Cystine Pumps validated (include printout).	Yes _____	No* _____
Complete validation portion of TSB 82-024.		

* An explanation must be provided

Explanations:

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

_____

_____

_____

_____

Abbott Representative

Signature _____ Date _____

END OF DOCUMENT

ABBOTT ADD

TECHNICAL SERVICE BULLETIN

SUBJECT:
1.52 Software Upgrade

TSB#: **82-022B**

ORIGINATOR: **Mark D. Redman**
APPROVED: **Jack Hall**

PRODUCT:
ABBOTT PRISM® (82)

REF. ECN: **12524-001, Deviation DT-426**

IMPLEMENTATION:	TSB Part/Kit #: **1-52430-02**	Upgrade Time: **8.0 Hr.**
● **Immediate** ○ **Next Service Call** ○ **Next Failure** ○ **Optional**	TSB Effectivity/ Part(s) Availability: **01-DEC-97**	Validation Time: **6.0 Hrs.**
Instruments Requiring Modification: S/N 001 through 1140	**TSB Tracking by Serial # required (IMMEDIATE TSB's ONLY)** ● YES ○ NO	Total Mod. Time: **14 Hrs.** ****NOTE** The instrument must be at TSB Level 016 prior to performing this TSB.**

I. DISTRIBUTION:

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

Worldwide.

II. PURPOSE:

NOTE: The only change to this TSB from the previous version is that the instruments requiring modification has been changed to S/N 001 through 1140.

Update the instrument to 1.52 software. All documents and procedures associated with 1.51 software will also be required for this version installation. If the instrument has previously been upgraded with hardware and software for Version 1.51, then only this TSB will be required.

III. ADMINISTRATIVE NOTES:

Make copies of the Checklist at the end of this TSB. Complete the checklist after upgrade, sign it and leave it with the customer. **Abbott Access** for this version software is **PLUTOCHARON** (all caps).

Customer Support Information:

1. Initial Reactive samples not retested prior to this upgrade need to be run before the installation of this version of software.
2. At the completion of this software/hardware upgrade TSB, the customer should run additional samples to duplicate actual routine testing. The testing protocol should be determined by the laboratory Standard Operating Procedures. All test results must be consistent with expected results.
3. If partially used reagent kits, wash solutions or purge solutions are installed on the instrument after the upgrade, the customer will need to manually track usage of these resources as before the upgrade. This is because the system will recognize the used reagents as full kits after the upgrade.

When new reagent kits, wash solutions and purge solutions are installed, the system will accurately monitor the resources.

4. Leave the Customer letter and new assay package inserts with the customer.
5. Leave the new Operations Manual with the customer.
6. All test results will be deleted when the new version software is loaded. Therefore, have the customer print reports, copy reports to floppy and/or send data to the host as required based on their test result status.
7. On a four channel instrument you will get communication errors on the uninstalled channels until you configure them to Not Used.
8. If customer is utilizing Abbott BBS™ you will need to update the software version number on the Abbott BBS™ as described in ISA 27-007.

   Countries using the German language: If customer is utilizing Abbott BBS™ refer to TSB 27-006 for driver change requirements and changes to the Host interface.

Upon completion of the upgrade:

1. Use the normal procedures for notification of the TSB.
2. Leave the check list and Reagent Tracking Table with all associated documentation with the customer.
3. Make sure both you and the customer have signed the document/s.

IV. SPECIAL TOOLS:

The new version Volume Validation Tool (6A36-88 for 220 VAC, 6A36-81 for 120 VAC) is also required for the site. You are not required to utilize the tool during this upgrade.

V. PARTS:

Worldwide:Operations Manual LN will be related to the language used.

Customer Support Information letter (in TSB Kit)

1-52430-02 Kit, Software Version 1.52

REPLACED PARTS:

Remove and destroy previous versions of software

COMPATIBILITY:

Old version Volume Validation Tools are not compatible.

VI. PROCEDURE:

Use of the current Field Service DT Manual and ISA's is required. TSB 82-018, 019, and 020 are required to be completed for this software to operate correctly. If the instrument has been previously upgraded to Version 1.51, then TSB's 018, 019, 020 will not to be installed again.

A. Software Installation

1. Pre-Software Load

   a. Print the current Run Controls Configuration.

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

From the Main Menu:

- Instrument Preparation
- Manage Resources
- Run Controls
- Select a defined run control

Print the run control configuration screen (**F3**). Retain this printout for use later in this procedure.

Repeat these steps for all defined Run Controls. Return to the Main Menu by pressing the **Esc** key.

b. Print the current Audible Alarm Configuration.

From the Main Menu:

- Maintenance
- Hardware Configuration
- Audible Alarm

Print the audible alarm configuration screen (**F3**). Retain this printout for use later

in this procedure.

Return to the Main Menu by pressing the **Esc** key.

c. Print the current Host Interface Configuration.

From the Main Menu:

- Maintenance
- Hardware Configuration
- Host Interface Configuration

Print the Host Interface Configuration screen (**F3**). Retain this printout for use later in this procedure.

Return to the Main Menu by pressing the **Esc** key.

d. Print the current Bar Code Configuration.

From the Main Menu:

- Maintenance
- Hardware Configuration
- Bar Code Configuration

Print the Bar Code Configuration screen (**F3**). Retain this printout for use later in

this procedure.

Return to the Main Menu by pressing the **Esc** key.

e. Print the current Batch Parameters.

From the Main Menu:

- Maintenance
- Software Configuration
- Batch Parameters Configuration

Print the Batch Parameters Configuration screen (**F3**). Retain this printout for use later in this procedure.

Return to the Main Menu by pressing the **Esc** key.

f. Print the current Print Report Configuration.

From the Main Menu:

- Maintenance
- Software Configuration
- Print Report Configuration

Print the Print Report Configuration screen (**F3**). Retain this printout for use later

in this procedure.

Return to the Main Menu by pressing the **Esc** key.

g. Print a listing of the current Users.

From the Main Menu:

- Maintenance
- User Configuration
- List the Users

Print the Users List screen (**F3**). Retain this printout for use later in this procedure.

Return to the Main Menu by pressing the **Esc** key.

h. Print a listing of the current gray zone settings.

From the Main Menu:

- Maintenance
- Software Configuration
- Gray zone Configuration

Print the Gray zone Configuration screen (**F3**). Retain this printout for use later in

this procedure.

Return to the Main Menu by pressing the **Esc** key.

i. Print out tests available for current reagents.

From the Main Menu:

- Instrument Preparation
- Manage Resources

Go into the menu options (reagents, wash solutions, and purges) and print and record the tests remaining for all assays in the Reagent Tracking Worksheet (Section C of this TSB) in the table. Follow the worksheet instructions and complete the Reagent Tracking Table.

j. Print out Kit Usage Information.

From the Main Menu:

- Maintenance
- Kit Usage Review

Go into the menu for each assay and print out the Kit Utilization screen .

2. Load Software

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

Equipment Required:

- Software Update diskettes
- Blank Formatted 3.5", 1.44 Mb Floppy Diskette

a. Log on to ABBOTT PRISM® System with Abbott Access.

b. Make a backup copy of current configuration.

- Use a blank, formatted diskette.
- Perform Configuration Backup

From the Main Menu:

- Maintenance
- Software Configuration
- Configuration Backup/Restore
- Backup

When requested, insert the blank formatted diskette and press **Enter**.

Press **Enter** to continue.

- When backup is complete press **Enter**. Remove diskette.
- Label diskette as Configuration Backup, with date and ABBOTT PRISM® Serial Number. Retain for later use.
- Return to Main Menu (press **Esc** key 3 times).

c. Exit ABBOTT PRISM® Software.

From the Main Menu:

- Engineering
- Exit Program

Press the **Y** key to confirm shutdown.

d. Install the new software.

- Insert Disk 1 of the new software disk set.
- At the prompt:

C:\PRISM\VGA>_

Type in:

cd\

and press the enter key.

- At the prompt:

  C:

Type in

  a:\install

and press the enter key.

- Follow the screen prompts to complete loading the new version of software.

Note: Some prompts will refer to the new version software disk set as the backup.

3. Restore System configuration.

   a. As prompted, reboot ABBOTT PRISM® System Computer by pressing **CTRL**, **ALT**, and **DEL** keys simultaneously. Computer boots up to ABBOTT PRISM® Logon Screen.

   b. Log on to ABBOTT PRISM® System with Abbott Access.

Note: The Password for 1.52 is PLUTOCHARON (all Caps)

   c. Place configuration backup diskette created earlier into floppy disk drive.

   d. Restore Configuration.

From the Main Menu:

- Maintenance
- Software Configuration
- Configuration Backup/Restore
- Restore Configuration

e. When restore is complete, press **Enter**. Remove floppy diskette from diskette drive and retain for future use. (Use only with this serial number instrument.)

f. Return to Main Menu (press **Esc**).

g. Reboot ABBOTT PRISM® Computer.

From the Main Menu:

- Engineering

- Exit Program

From DOS prompt press **CTRL**, **ALT**, and **DEL** keys simultaneously.

4. Configuration

Refer to the printouts obtained from the Pre-Software Load section for the following procedures. (see the Operations Manual for editing instructions).

NOTE: In the new software, all dates are defaulted to US Format of MM/DD/YYYY. You will

set to local format in step eleven (11).

a. Configure the Run Controls from the appropriate printout.

b. Configure the Host Interface from the appropriate printout.

c. Configure a maintenance level User. Check with the customer for name and password preference.

d. Configure language, Keyboard, and Date Format to native language as requested by the customer.

From Main Menu:

- Maintenance

- Software Configuration
- Localization

(Spacebar) to select (F10) to save

Note: Save (F10) your settings even if you are leaving the settings at the default (English).

Configure the printer to the same language.

On the printer:

– Hold down the SHIFT key and press the SEL/MENU key

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

– Press the GROUP key until you get to Symbol Sets option.

– Press the ITEM key until you get to the Language Set option.

– Press the SET key until you get the correct language.

e. Verify the Audible Alarm from the appropriate printout.

f. Verify the Bar Code configurations from the appropriate printout.

g. Check with the customer and verify the Batch Parameters per the customers requirements.

h. Verify the Print Report from the appropriate printout.

I. Verify Gray zone from the appropriate printout.

j. Verify the correct serial number (located in the upper left corner of the screen). Enter the correct number if incorrect. If incorrect, perform the following procedure:

From Main Menu:

- Maintenance
- Software Configuration
- Set Serial Number

k. Verify the correct date and time (located in the upper right corner of the displayed screen).

Enter the correct date and time if incorrect. If incorrect, perform the following

procedure:

From Main Menu:

- Maintenance
- Hardware Configuration
- Set Time and Date

l. Reboot ABBOTT PRISM® Computer.

From the Main Menu:

- Engineering
- Exit Program

From DOS prompt press **CTRL**, **ALT**, and **DEL** keys simultaneously.

B. SYSTEM CHECKOUT:

1. Confirm XY settings are correct. Pick up and strip off ten sets of pipette tips.

From the Main Menu:

- Component Diagnostics
- Sample Manager
- Tip Pick Up

Set for ten cycles, both axes.

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

2. Verify that all of the Air Tip Wash Compressors turn on and off, and that there are no errors.
3. Perform the Optics Validation Procedure on all channels on the instrument.
4. Perform the Channel Temperature Validation Procedure on all channels on the instrument.
5. **This step is not required if TSB 82-018 was previously performed.** Verify that each of the new dispensers and mode switch (that you installed in TSB 82-018) work correctly.

    a. Perform System Start-up (VP-2).
    b. Remove the Electronics Bay Cover.
    c. Check out Channel 1 Conjugate Dispense DVS. It will be easier to perform the following steps if you have the monitor moved to the back of the instrument so that you can easily work on it and monitor the Dispense verify boards.

    From the Main Menu
    - Component Diagnostics
    - Channels
    - Pump Tests and Utilities
    - Dual Port Pump Test
    - Enter channel number(1-6): (Select 1)
    - Enter the position number of the pump to be tested: (Select 63)
    - Select the pump to test: (Select 1)
    - Enter number of dispenses: (Enter 15)
    - Do you want a disposable moved to the correct position (Y/[N]): (Select Y)

      Load a prime/purge tray when requested and press enter. While

the pump is dispensing monitor the two bottom LED's on the Channel 1 Dispense Verify Board and verify that they both flash.

- Do you want to repeat this test: (Select No)

d. Check out Channel 3 Conjugate Dispense DVS. Use the same procedure as in step c for channel 3.

e. Check out Channel 6, 3 step Conjugate Dispense DVS.

- Configure channel 6 as a three step assay.
- Check out using same procedure as in step c for channel 6

f. Check out Channel 6, 2 step Conjugate Wash DVS.

- Configure Channel 6 as a two step assay.
- Check out using same procedure as in step c for channel 6, specimen diluent pump.

6. Perform an Assay Calibration with Release control on each channel. The most time efficient way to perform the assays is as follows. Run the backup channel first, then perform the Clean Backup Channel procedure. Channel 6 can be going through the idle time with cleaning solution in the lines as the other channels are being run.

NOTE: Set up the backup channel as a 3- step assay. Backup channel will need to be run by itself.

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

When backup assay is complete:

- Perform Clean Backup Channel procedure
- Reload 3-step assay reagents on original channel.
- Now run the assays on the other channels. When complete, perform Purge.

C. REAGENT TRACKING WORKSHEET AND TABLE

This worksheet will provide a method for supplying the customer with a method to track the tests available for reagent kits, wash solutions and purge solutions that were in progress when software was upgraded. The number next to New, represents the tests available for a new kit, wash or purge component. By subtracting the number of tests that remained for a reagent from the tests available for a new reagent, when the user reaches the number of tests on line 1.52 they have completed that reagent and **must** replace it.

1. For each assay:
   - On the 1.3 line, enter the number of “Tests Available” for each of the following:

     Reagent Kit

     Wash solution

     Purge Solution

2. Enter on the 1.52 line:

   The difference between New (tests available for new kit) minus Vs.1.3 (tests available).

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

Note: These numbers are on the print screens that you printed before performing the software upgrade.

3. Enter the 1.52 tests available number onto the “Reagent Tracking” table.

IMPORTANT: Instruct the customer that when any reagent, wash or purge component “ Tests Available” decreases to the number on the “Reagent Tracking” table, there are zero (0) tests remaining. **REPLACE THE COMPONENT!**

Worksheet:

ASSAY	REAGENT KIT	TRANSFER WASH	CONJUGATE WASH	PROBE WASH	PURGE SOLUTION
HTLV	New 5970 Ver1.3 _____ Ver1.52 _____	New 4982 Ver1.3 - _____ Ver1.52 = _____	New 5304 Ver1.3 - _____ Ver1.52 = _____	New 5282 Vs1.3 - _____ Vs1.52 = _____	New 37 Vs1.3 _____ Vs1.52 _____

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

HCV	New 6088 Ver1.3 _____ Ver1.52 _____	New 5010 Ver1.3 - _____ Ver1.52 = _____	New 5336 Vs1.3 - _____ Vs1.52 = _____	**XXXX**	New 44 Vs1.3 _____ Vs1.52 _____
HIV	New 6026 Ver1.3 _____ Ver1.52 _____	New 5018 Ver1.3 - _____ Ver1.52 = _____	New 5150 Vs1.3 - _____ Vs1.52 = _____	New 5206 Vs1.3 - _____ Vs1.52 = _____	New 38 Vs1.3 _____ Vs1.52 _____
HBsAg	New 6146 Ver1.3 _____ Ver1.52 _____	New 5064 Vs1.3 - _____ Vs1.52 = _____	New 5184 Vs1.3 - _____ Vs1.52 = _____	**XXXX**	New 56 Vs1.3 _____ Vs1.52 _____
HBc	New 6280 Ver1.3____ Ver1.52=_____	New 5110 Vs1.3 - _____ Vs1.52 = _____	New 5414 Vs1.3 - _____ Vs1.52 = _____	**XXXX**	New 57 Vs1.3 _____ Vs1.52 _____

“REAGENT TRACKING”

REPLACE REAGENT KIT, WASH SOLUTION OR PURGE SOLUTION WHEN THE NUMBER OF TESTS AVAILABLE REACHES THE VOLUME LISTED BELOW.

ASSAY	REAGENT KIT	TRANSFER WASH	CONJUGATE WASH	PROBE WASH	PURGE SOLUTION
HTLV					

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

HCV				**XXXX**	
HIV					
HBsAg				**XXXX**	
HBc				**XXXX**	

MODIFICATION STEPS:
See Procedure Above

CHECKOUT:
See Procedure Above

MODIFICATION CONTROL STICKER UPDATE:

1. Using a permanent marker, mark through the number twenty two (22) on the TSB Modification Control Sticker.

ABBOTT PRISM® Version 1.52 Upgrade Checklist

While performing this TSB, mark off the items listed in the check list after they are successfully performed. Attach all printouts from this upgrade.

Instrument S/N _____ Account Name _____

Date of Update _____ Account Address _____

Configuration:

Run Controls Configured.	Yes _____ No* _____
Host Interface Configured.	Yes _____ No* _____
Language, Keyboard, and Date Format (Localization) Configured.	Yes _____ No* _____
Maintenance level user Configured (Customer chooses name and password).	Yes _____ No* _____
Batch Size Verified.	OK _____
Print Reports Verified.	OK _____
Audible Alarm Verified.	OK _____
Gray zone Verified.	OK _____
Bar Code Configuration Verified.	OK _____

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

Serial Number Verified. OK _____

Date and Time Verified. OK _____

Validation:

Successfully picked up and stripped 10 tips. Yes _____ No* _____

Verified Air Tip Wash Compressor Operation Yes _____ No* _____

Optics Validation passed. Yes _____ No* _____

Channel Temperature Validation passed. Yes _____ No* _____

New Conjugate Station DV Sensors installed in TSB 82-018 passed. Yes _____ No* _____

Assays Performed with acceptable results. Yes _____ No* _____

* An explanation must be provided

Customer Support Information:

Customer has been given Customer letter with new assay package inserts. Yes_____No*_____

Customer has been given Operations Manual and

old version manual has been destroyed Yes_____No*_____

Customer has been given Software Marketing Letter

Yes_____No*_____

Customer has been given Software Quality Letter

Yes_____No*_____

Customer has been given Sample Bar Code Label Guidelines Letter

Yes_____No*_____

At the completion of the Validation Protocol, additional samples should be run to duplicate your actual routine testing environment. The testing protocol should be determined by your laboratory Standard Operating Procedures. All test results must be consistent with expected results.

* An explanation must be provided

Explanations:

_____

_____

_____

_____

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

Abbott Representative

Signature _____ Date _____

Laboratory Representative

Signature _____ Date _____

END OF DOCUMENT

ABBOTT ADD	TECHNICAL SERVICE BULLETIN

SUBJECT:
1.51 Software Upgrade

TSB#: **82-021**

ORIGINATOR: **Mark D. Redman**
APPROVED: **Bob Schabel**

PRODUCT:

REF. ECO:

IMPLEMENTATION:	TSB Part/Kit #: **1-52430-01**	Upgrade Time: **8.0 Hr.**
● **Immediate** ○ **Next Service Call** ○ **Next Failure** ○ **Optional**	TSB Effectivity/ Part(s) Availability: **09-NOV-97**	Validation Time: **6.0 Hrs.**
Instruments Requiring Modification: S/N 001 through 1146	**TSB Tracking by Serial # required (IMMEDIATE TSB's ONLY)** ● YES ○ NO	Total Mod. Time: **14 Hrs.** ****NOTE** The instrument must be at TSB Level 016 prior to performing this TSB.**

This TSB is complete.

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

I. DISTRIBUTION:

II. PURPOSE:

III. ADMINISTRATIVE NOTES:

IV. SPECIAL TOOLS:

V. PARTS:

REPLACED PARTS:

COMPATIBILITY:

VI. PROCEDURE:

MODIFICATION STEPS:

CHECKOUT:

MODIFICATION CONTROL STICKER UPDATE:

END OF DOCUMENT

ABBOTT ADD

TECHNICAL SERVICE BULLETIN

SUBJECT:
Reagent Bottle Tubing ID Verification

TSB#: **82-020A**

ORIGINATOR: **Mark D. Redman**
APPROVED: **Jack Hall**

PRODUCT:
ABBOTT PRISM® (82)

REF. ECN: **Deviation DT-426**

IMPLEMENTATION: ● **Immediate** ○ **Next Service Call** ○ **Next Failure** ○ **Optional** Instruments Requiring Modification: S/N 001 through 1140	TSB Part/Kit #: **N/A** TSB Effectivity/ Part(s) Availability: **09-NOV-97** **TSB Tracking by Serial # required (IMMEDIATE TSB's ONLY)** ● YES ○ NO	Upgrade Time: **3.0 Hr.** Validation Time: **0 Hrs** Total Mod. Time: **3 Hrs** ****NOTE** The instrument must be at TSB Level 016 prior to performing this TSB.**

I. DISTRIBUTION:

Worldwide

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

II. PURPOSE:

NOTE: The only change to this TSB from the previous version is that the instruments requiring modification has been changed to S/N 001 through 1140.

To verify that the instrument has the correct inside diameter (ID) tubing from the purge valves to the reagent bottle.

III. ADMINISTRATIVE NOTES:

Upon completion of the upgrade:

1. Use the normal procedures for notification of the TSB.
2. After completing this TSB perform TSB 82-021 or TSB 82-022.

IV. SPECIAL TOOLS:

N/A

V. PARTS:

Worldwide:

N/A

REPLACED PARTS:
Dispose of per site requirements for contaminated material.

COMPATIBILITY:
N/A

VI. PROCEDURE:

Use of the current Field Service DT Manual and ISA's is required.

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

A. Preparation

Note: To perform Section B of this TSB you will need to be logged on under Abbott access.

1. Configure channels 1 through 5 to assays and channel 6 to Maintenance.

2. Load Line Cleaner for all refrigerator component tubing locations. (If Line Cleaner is not available for channel 6, load bottles of Purge Solution at all four tubing locations). Verify that all channels have either a wash solution or a bottle of Purge Solution at all wash locations in the Ambient Bay.

3. Perform Fluidics Maintenance "Prime All Pumps And Syringe" for all channels. (Note the time)

B. Tubing Size Verification

1. To verify tubing size for Channel 1 and 3:

   a. Go to Channel Diagnostics Menu.

   From the Main Menu:
   - Component Diagnostics
   - Channels

   b. Check the tubing for Channel 1 Microparticle pump.

   - Pump Tests and Utilities
   - Dual Port Pump Test
   - Enter the channel number (1-6): (Select Channel Number)

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

- Enter the position number of the pump to be tested: (Select position)
- Enter the pump to test: (Select Pump)
- Enter the number of dispenses: (Enter 1)
  Unscrew the bottle from the cap and stem assembly. DO NOT disconnect the tubing from the cap and stem assembly.
- Do you want a disposable moved to the correct position? (Y/[N]): (Select Y)
  Load a prime/purge tray when requested and press Enter.
- Do you want to repeat this test? (Y/[N]): (Select Y)
  Screw the bottle back onto the cap and stem assembly.
- Enter the pump to test: (Select Pump)
- Enter the number of dispenses: (Enter 5)
- Do you want a disposable moved to the correct position? (Y/[N]): (Select N)
  After the instrument has dispensed, use a flashlight to highlight the air segment. If the air segment is partially hidden by the label, you can tell the instrument to dispense one more cycle to move the air segment beyond the label. Using the pin from the Transfer Station Alignment Tool (the pin you drop into the hole to align the station) measure the air segment. The air segment should be at least one pin length but less than two pin lengths or 6.35 cm (2.5”) to 12.7 cm (5.0”). If the air segment is not the correct length, replace the tubing from the purge valve to the bottle with .045 inch ID tubing. If the air segment is extremely fragmented and you can not determine the length of the air segment repeat step 1b again.
  Note: If the tubing you are evaluating is in the refrigerator, it may be necessary to carefully pull any available tubing slack through the plug at the top of the refrigerator to see the entire air segment. The Microparticle tubing may also require removal of the plug to maximize the view able length.

- Do you want to repeat this test? (Y/[N]): (Select N)

c. Check the tubing for Channel 1 Probe pump.

Perform step 1b for Probe pump on Channel 1.

d. Check the tubing for Channel 1 Probe Wash pump.

Perform step 1b for Probe Wash pump on Channel 1.

e. Check the tubing for Channel 1 Conjugate Wash pump.

Perform step 1b for Conjugate Wash pump on Channel 1.

f. Repeat steps 1b through 1e for Channel 3.

2. To verify tubing size for Channel 2, 4, and 5.

a. Go to Channel Diagnostics Menu.

From the Main Menu:
- Component Diagnostics
- Channels

b. Check the tubing for Channel 2 Specimen Diluent pump.

Perform step 1b for Specimen Diluent pump on Channel 2.

c. Check the tubing for Channel 2 Microparticle pump.

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

Perform step 1b for Microparticle pump on Channel 2.

d. Check the tubing for Channel 2 Conjugate Wash pump.

Perform step 1b for Conjugate Wash pump on Channel 2.

e. Repeat steps 2c and 2d for Channel 4 and 5.

3. To verify tubing size for Channel 6.

a. Go to Channel Diagnostics Menu.

From the Main Menu:
- Component Diagnostics
- Channels

b. Check the tubing for Channel 6 Specimen Diluent pump.
Perform step 1b for Specimen Diluent pump on Channel 6.

c. Check the tubing for Channel 6 Microparticle pump.

Perform step 1b for Microparticle pump on Channel 6.

d. Check the tubing for Channel 6 Probe Wash pump.

Perform step 1b for Probe Wash pump on Channel 6.

e. Check the tubing for Channel 6 Conjugate Wash pump.

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

Perform step 1b for Conjugate Wash pump on Channel 6.

C. Completion

1. Wait until it has been at least 2 hours since you performed Fluidics Maintenance in section A step 3 of this TSB.

2. Verify that there is a Purge Bottle with Purge Solution at the Channel 6 Purge location and Channel 6 Specimen Diluent location. Purge All Channels.

3. Replace the Line Cleaner with Purge Solution. Perform Fluidics Maintenance “Prime All Rare Reagent Pumps Only” two times.

MODIFICATION STEPS:

CHECKOUT:

MODIFICATION CONTROL STICKER UPDATE:
1. Using a permanent marker, mark through the number twenty (20) on the TSB Modification Control Sticker.

END OF DOCUMENT

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

ABBOTT ADD

TECHNICAL SERVICE BULLETIN

SUBJECT:
Bar Code Reader Update

TSB#: **82-019A**

ORIGINATOR: **Mark D. Redman**
APPROVED: **Jack Hall**

PRODUCT:
ABBOTT PRISM® (82)

REF. ECN: **12334-022, Deviation DT-426**

IMPLEMENTATION:	TSB Part/Kit #: **1-51644-01 & 1-55970-01**	Upgrade Time: **1.0 Hrs.**
● **Immediate** ○ **Next Service Call** ○ **Next Failure** ○ **Optional**	TSB Effectivity/ Part(s) Availability: **09-NOV-97**	Validation Time: **0.5 Hrs.**
Instruments Requiring Modification: S/N 001 through 1140	**TSB Tracking by Serial # required (IMMEDIATE TSB's ONLY)** ● YES ○ NO	Total Mod. Time: **1.5 Hrs.** ****NOTE** The instrument must be at TSB Level 016 prior to performing this TSB.**

I. DISTRIBUTION:

Worldwide.

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

II. PURPOSE:

NOTE: The only change to this TSB from the previous version is that the instruments requiring modification has been changed to S/N 001 through 1140.

Update the instrument with additional hardware to improve the Bar Code Reader function of the instrument by replacing:

Bar Code Reader Assy Mounting Bracket
Bar Code Reader Scanner and Tube Sensor Mounting Bracket

The new brackets will allow the Bar Code Reader to be mounted further from the tube. This improves the capability of the instrument to read Bar Codes.

The firmware in the Bar Code Reader Controller Assy is replaced with new firmware to allow the instrument to read two new check digit configurations for Codabar labels:

JRC
MOD 11-2

III. ADMINISTRATIVE NOTES:

It is required that TSB 82-021 or TSB 82-022 be completed for the hardware installed in this TSB to operate correctly. You must also complete the checkout in TSB 82-021 or TSB 82-022 after completing this TSB.

Upon completion of the upgrade:

1. Use the normal procedures for notification of the TSB.
2. After completion of this TSB, perform TSB 82-021 or TSB 82-022.

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

IV. SPECIAL TOOLS:

N/A

V. PARTS:

Worldwide:

1-51644-01	Kit, Bar Code Reader Brackets
1-55970-01	Kit, Bar Code Reader Firmware
1-55143-01	PCB, Bar Code Reader

If you have this board in your inventory, it will need to be upgraded. You will need to order 1-55970-01 Kit, Bar Code Reader Firmware.

1 Sample Bar Code Label Guidelines Letter

REPLACED PARTS:

Dispose of per site requirements for contaminated material.

COMPATIBILITY:

1-55143-01 is no longer compatible. The catalog number has changed to a -02 version.

REPLACED PARTS:

COMPATIBILITY:

VI. PROCEDURE:

Use of the current Field Service DT Manual and ISA's is required.

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

1. Remove the Sample Access Front Cover(PL-Covers).

2. Perform System Power Off (VP-1).

3. Remove the Bar Code Reader Assy. (RR - B1.5). It will be necessary to remove the Bar Code Reader Sensor Mounting Bracket (two screws), with the Scanner and Tube Sensor attached, to gain access to the Bar Code Reader Assy Mounting Screws.

4. Remove the Bar Code Reader Tube Sensor (2 screws) and Scanner (2 screws) from the Bar Code Reader Sensor Mounting Bracket.

5. Remove the Bar Code Sensor Interface Board (2 screws).

6. Install the Bar Code Reader Tube Sensor (2 screws) and Scanner (2 screws) onto the new Bar Code Reader Sensor Mounting Bracket.

7. Install Bar Code Sensor Interface Board (2 screws) onto the new Bar Code Reader Assy. Mounting Bracket.

8. Install Bar Code Reader Assy. (2 screws). Attach the shroud to the Bar Code Reader Assembly (2 screws).

9. Install the Bar Code Reader Sensor Mounting Bracket (two screws) with the Scanner and Tube Sensor attached onto the new Bar Code Reader Assy Mounting Bracket.

10. Connect the cables to the Bar Code Sensor Interface as shown.

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

J1	Cable from Bar Code Reader Controller Assy
J2	Bar Code Reader Scanner Cable
J3	Bar Code Reader Tube Sensor
J4	Rack Position Sensor
J5	Empty

11. Remove the Bar Code Reader Controller Cover. On the Bar Code Reader Bd., replace the EPROM in U9 with the new EPROM. Change the last three digits of the Board part number to -106. Replace the Cover. Change the last three digits of the part number on the Bar Code Reader Controller Assembly to -106.

12. Perform System Start Up (VP-2).

13. Perform Bar Code Reader Verification (VP-29)

14. Install the Bar Code Reader Controller Cover and Sample Access Front Cover.

MODIFICATION STEPS:

CHECKOUT:

MODIFICATION CONTROL STICKER UPDATE:

1. Using a permanent marker, mark through the number nineteen (19) on the TSB Modification Control Sticker.

END OF DOCUMENT

ABBOTT ADD

TECHNICAL SERVICE BULLETIN

SUBJECT:
Air Tip Wash/ Dispense Verify Update

TSB#: **82-018A**

ORIGINATOR: **Mark D. Redman**
APPROVED: **Jack Hall**

PRODUCT:
ABBOTT PRISM® (82)

REF. ECN: **12334-022,Deviation DT-426**

IMPLEMENTATION:	TSB Part/Kit #: **1-55959-01**	Upgrade Time: **3.0 Hrs.**
● **Immediate** ○ **Next Service Call** ○ **Next Failure** ○ **Optional**	TSB Effectivity/ Part(s) Availability: **07-NOV-97**	Validation Time: **0.5 Hrs.**
	TSB Tracking by Serial # required (IMMEDIATE TSB's ONLY)	Total Mod. Time: **3.5 Hrs**
Instruments Requiring Modification: S/N 001 through 1140	● YES ○ NO	****NOTE** The instrument must be at TSB Level 016 prior to performing this TSB.**

I. DISTRIBUTION:

Worldwide

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

II. PURPOSE:

NOTE: The only change to this TSB from the previous version is that the instruments requiring modification has been changed to S/N 001 through 1140.

Update the instrument with additional hardware to improve the Air Tip Wash function of the instrument and add the Dispense Verification function onto Channels 1,3, and 6 Conjugate Dispensers.

III. ADMINISTRATIVE NOTES:

It is required that TSB 82-021 (1.51 Software Update) or TSB 82-022 (1.52 Software Update) be completed for the hardware installed in this TSB to operate correctly. You must also complete the checkout in TSB 82-021 or TSB 82-022 after completing this TSB.

Upon completion of the upgrade:

1. Use the normal procedures for notification of the TSB.
2. After completing this TSB perform TSB 82-021 or TSB 82-022.

IV. SPECIAL TOOLS:

N/A

V. PARTS:

Worldwide:

1-55959-01 Kit, TSB 82-018 (See VMI included with TSB kit for a list of parts)

REPLACED PARTS:

Dispose of per site requirements for contaminated material.

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

REPLACED PARTS:

COMPATIBILITY:

VI. PROCEDURE:

Use of the current Field Service DT Manual and ISA's is required.

A. Preparation

1. Remove the Tray Loader Cover (PL-Covers).

2. Remove the Sample Access Front and Rear Covers (PL-Covers), Heater Controller Cover (PL-Covers), and the Rack Plate Assembly (RR-B1.11). Also remove the Cable Shield (loosen the 2 screws) located in front of Channel 6.

3. Locate the gray cable guide behind and to the left of the Heater Controller. Break off the top two fingers in front and back, and cut off 2 inches (5.08 cm) of the gray cable guide cover.

4. Install Filter Assy. With long portion routed over the top of the cable guide (where you just cut off) and the top of the refrigerator. Route the short portion along the back side (the side towards the back of the instrument) of the cable guide (see picture in VMI page 11).

5. Open the Tip Waste door, remove the Tip waste container and lift the hinged Tip Waste Container Plate to gain access to the Tip Wash Plate Assemblies. One by one, cut the air tip wash supply lines from the channels to the necessary length to connect to the filter tubing that was just installed across the top of the refrigerator. Tag both sides of the cut tubing with identical letters (A, B, C, D, E, or F) matching the piece of filter tubing you are going to

connect to. Connect the cut piece of tubing that comes through the base plate to the filter tubing (see picture in VMI page 12).

B. **Compressor Plate Rework**

1. Remove the compressor plate with the air tip wash supply lines attached. While removing plate disconnect the power and control cables.

2. Remove the tie wraps, if present, which bundle the cables from the compressors. Disconnect the Compressor Cables from the Tip Wash Driver Board.

3. Remove the Tip Wash Pump Driver Board (6 screws and 6 connectors).

4. Remove the 6 standoffs that the board was mounted to.

5. Connect the compressor cables to the new Tip Wash Pump Driver Board. It is written on the board where to connect each compressors cable. See RR-D3 for Compressor locations.

6. Remove the drip shield from the Tip Wash Driver Board Assy. Install the Tip Wash Pump Driver Board (6 screws) to the compressor plate. Tie-wrap the cables between the compressors and the controller (it is not necessary to install the center screw that goes under the board).

7. Cut each of the tubes from the compressors at the point where it will meet the tubing from the switch. The length will vary depending what is needed to properly route the tubing. You will need to route the tubing so that the tubing is not bent and that it does not stick up above the top of the compressors. Install the piece of tubing from the compressor to the Y connector of the tubing that goes to the switch on the Pump driver board as shown in figure 1. The other half of the tubing that you cut (the tubing with the letter label on the other end) goes to the "Y" connector as shown in figure 1.

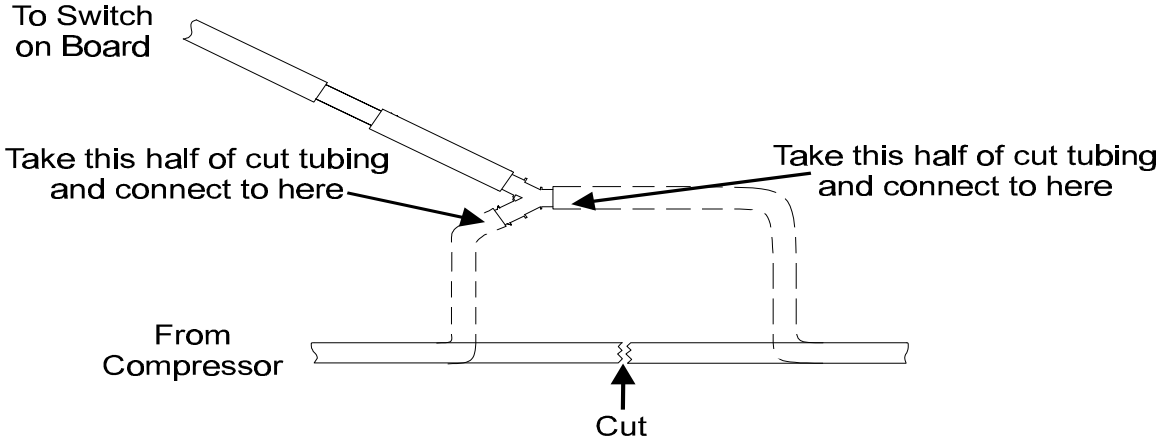


Figure 1

8. Install the drip shield onto the Tip Wash Driver Board Assy.

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

9. Place the Compressor Plate aside. You will install it in a later step.

C. Dispenser Installation

1. Remove the Bar Code Reader Controller Cover. Remove the 2 screws holding the Bar Code Reader Controller Assembly housing to the Transfer Syringe Assembly Mounting Bracket and swing the housing aside. Move the Z-Axis assembly toward the tray loader end of the instrument.

2. Remove the four screws (2 flat head screws from the front and two pan head from the back) which hold the sample plate supports to the horizontal bracket under the Transfer Syringe Assembly. Remove the two screws which hold the front end of the Transfer Syringe Assembly Mounting Plate to the Rack Plate Supports. Move the Transfer Syringe Assembly toward the tray loader end of the instrument to get access to the Channels 1 and 3 conjugate dispensers. Note: You may have to disconnect cables from the syringe pump assemblies.

   Warning: Be sure that the Transfer Syringe Assembly is resting on a stable location. If the assembly falls over it is possible that all 6 Transfer Syringes will break and the cables could be pulled apart.

3. Disconnect the reagent tubing and air tip wash tubing from the conjugate dispense brackets on channels 1, 3, and 6. Replace the Conjugate Dispense Station (2 screws) on Channels 1, 3, and 6 with the new stations that have Dispense Verify sensors.

Chn 1	55108-105
Chn 3	55108-305
Chn 6	55108-605

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

Reconnect the Reagent and Air Tip Wash Tubing to the dispensers (do not reconnect air tip wash on channel 6 as you will remove it again in a later step).

4. Remove the dispense verification dummy loads from the Dispense Verify Cable connector, P2, on channels 1 and 3 and connect P2 to the new sensors. Connect the new cable 55805-101 P2 to the new Conjugate Dispense Station Sensor on Channel 6.

5. Reinstall the Transfer Syringe Pump Assembly (6 screws).

D. Mode Switch Assembly Installation on channel 6

All of the following steps in this section are performed on Channel 6 unless otherwise specified.

1. Remove the Air Tip Wash source tubing (should be labeled 6TW) for Channel 6 from where it connects to the first “Y” connector. Remove the rest of the Air Tip Wash tubing from channel 6.

2. Disconnect the heater cables and remove the heater cover connectors from their supports on the covers at the Probe Dispense Heater Cover (Station 5) and Probe Wash Dispense Heater Cover (Station 6). Remove the two supports (1 screw each). Note the orientation of the connectors in the bracket then remove the two connectors from the supports. Discard the supports (retain the screw). Disconnect the two ground wires that go to Station 5 and Station 6 Heater Covers (1 screw each).

3. Remove the mounting bracket (55819-101) from the Mode Switch Assembly (2 caphead and 1 countersunk screws). Install the heater cover connectors (2 for each heater Cover) in the Mode Switch Assembly Mounting Bracket in the same orientation as noted in step 2.

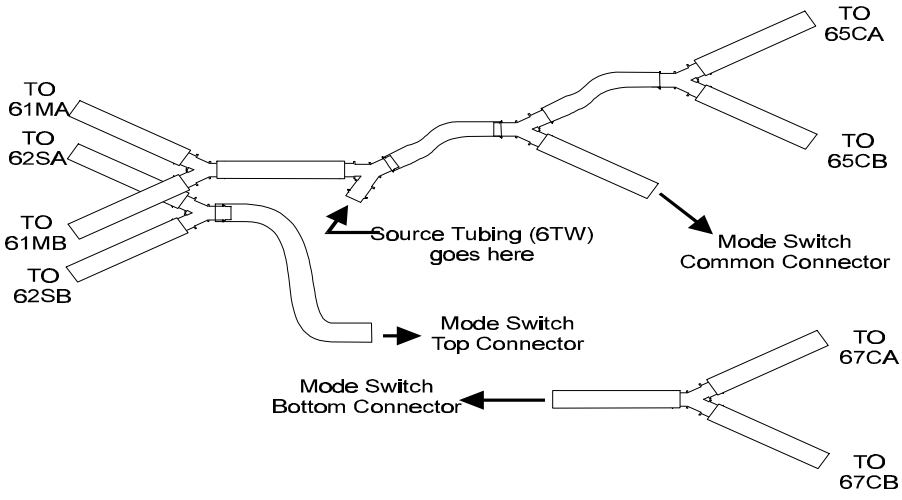
Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

4. Install the Mode Switch Assembly Mounting Bracket on channel 6 with the heater ground wires on the screws closest to the front of the instrument. The ground wires should be dressed so that they go towards the end of the channel (see VMI page 13).

5. Install the Mode Switch Assembly (see VMI page 14).

6. Disconnect the dispense verification cable connector P2 from the Conjugate Wash Dispense Station (Station 8) on channel six and connect it to the Mode Switch Assembly at J2. You may have to move the ferrite back a little to dress the cable across the motor.

7. Connect P2 from the new cable 55805-102 to the Conjugate Wash Dispense Station (Station 8) Sensor on channel 6 and connect the other end to J4 of the Mode Switch Assembly.
8. Connect the new cable 55805-101 P3 to J3 on the Mode Switch. Connect the other end of the cable (P2) to Station 7 Dispenser.
9. Connect the three air tip wash tubing assemblies included in the Channel 6 Tubing kit (55075-603) as shown in the figure below. Dress the tubing as shown in the picture in the VMI, page 14.



10. Dress the heater cover cables at station 5 so that the Mode Switch common tubing connector can move freely.

11. Connect the control cable 55804-101 to J1 on the Mode Switch Assembly. Route the cable down through the baseplate (beside the tip wash tubing) behind the Tip Waste Container Plate. This cable will be connected to the Tip Wash Driver Board in a later step. Dress the cable with cable ties.

E. Hardware Update Completion and Checkout

1. Install the Compressor Plate out far enough to access all of the compressor filters. With the

plate in this position, dress the tubes from the compressor assembly under the refrigerator (using spiral wrap (14370-207) to the lower end of the filter assembly. One by one, cut these tubes to length and connect to the corresponding filter end (A to A, B to B etc.).

2. Connect the Power Cable (P2) to J2 and the Control Cable (P1) to J1 on the Board. Connect the Mode Switch Cable (55804-101) P10 to J10 on the board.

3. Use the diagnostics to check that each of the compressors turns on and that the right compressor is operating (feel the input of the compressor filter). Disconnect the source tubing at the point where it connects to each channel and verify that you have air flow at the channel. Reconnect the tubing after checking.

4. Replace the compressor assembly in the instrument.
5. Dress the tubing away from the fans.

6. You will check out the new Dispense Verify Stations in TSB 82-021.

7. Replace the cable shield at the front of the instrument.

8. Replace the Bar Code Reader Controller.

9. Replace the Rack Plate and covers.

MODIFICATION STEPS:

CHECKOUT:

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

MODIFICATION CONTROL STICKER UPDATE:

1. Using a permanent marker, mark through the number eighteen (18) on the TSB Modification Control Sticker.

END OF DOCUMENT

ABBOTT ADD

TECHNICAL SERVICE BULLETIN

SUBJECT:
ABBOTT PRISM® Power Supply Extender Cable

TSB#: **82-016**

ORIGINATOR: **Dan Armstrong**
APPROVED: **Bob Schabel 25/September/96**

PRODUCT:
ABBOTT PRISM® (82)

REF. ECN: **12214-004**

IMPLEMENTATION: ● **Immediate** ○ **Next Service Call** ○ **Next Failure** ○ **Optional** Instruments Requiring Modification: **S/N 001 to 1109**	TSB Part/Kit #: **1-55716-01** TSB Effectivity/ Part(s) Availability: **25-SEP-96** **TSB Tracking by Serial # required (IMMEDIATE TSB's ONLY)** ● YES ○ NO	Upgrade Time: **0.5 Hrs.** Validation Time: **0.5 Hrs.** Total Mod. Time: **1.0 Hrs.** ****NOTE** The instrument must be at TSB Level 001 prior to performing this TSB.**

I. DISTRIBUTION:

Worldwide

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

II. PURPOSE:

To eliminate excessive AC noise on the Digital 2, 5 VDC power line being generated by a ground loop within the power supply. The elimination of the ground loop is accomplished by shorting the Digital 2, 5 VDC sense return to the 5 VDC return at the connector of the power supply. On instruments currently in the field, an extender cable will be added to cable 50401-103 and attached to J10 of the power supply. New build instruments starting at Serial number 1110 will have the cable modified to eliminate the noise caused by the ground loop.

III. ADMINISTRATIVE NOTES:

Upon completion of the upgrade, use the normal procedures for notification of the TSB.

IV. SPECIAL TOOLS:

N/A

V. PARTS:

Worldwide: 1-55716-01 TSB 82-016 Power Supply Extender Cable

REPLACED PARTS:
N/A

COMPATIBILITY:
N/A

VI. PROCEDURE:

MODIFICATION STEPS:
Use of Field Service D.T. Manual is required.

1. Perform System Power Off (VP-1).
2. Remove the following cover (PL - COVERS) Electronics Bay.

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

3. Remove the cable (50401-103) plugged into J10 of the power supply (see VP-25 for location of cable).
4. Cut the cable identifier cable tie on the cable.
5. Install the extender cable onto the cable (50401-103).
6. Plug the other end of the extender cable into J10 of the power supply.
7. Write the cable part number on the new identifier cable tie and reposition the cable.
8. Add the new cable ties to provide support for the cable.

CHECKOUT:
Use of Field Service D.T. Manual is required.

1. Perform System Start-up VP-2.
2. Perform System Power Supply Voltage Check VP-25.
3. Replace electronics bay cover.

MODIFICATION CONTROL STICKER UPDATE:
Mark off TSB 16 on the Modification Control Sticker.

END OF DOCUMENT

ABBOTT ADD

TECHNICAL SERVICE BULLETIN

SUBJECT:
ABBOTT PRISM® (4) to (6) Channel Upgrade

TSB#: **82-015**

ORIGINATOR: **John Buckland**
APPROVED: **Bob Schabel 15/OCTOBER/1996**

PRODUCT:
ABBOTT PRISM® (82)

REF. ECN: **10296-0661**

IMPLEMENTATION:	TSB Part/Kit #: **LN 6A36-03**	Upgrade Time: **3.0 Hrs.**
○ Immediate ○ Next Service Call ○ Next Failure ● Optional	TSB Effectivity/ Part(s) Availability: **15-OCT-96**	Validation Time: **9.0 Hrs.**
Instruments Requiring Modification: **Any (4) Channel instrument which a customer wishes to make into a (6) Channel instrument.**	**TSB Tracking by Serial # required (IMMEDIATE TSB's ONLY)** ○ YES ● NO	Total Mod. Time: **12.0 Hrs.** ****NOTE** The instrument must be at TSB Level n/a prior to performing this TSB.**

I. DISTRIBUTION:

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

Worldwide

II. PURPOSE:

To notify the field of how to upgrade from a (4) channel PRISM® to a (6) channel PRISM.

III. ADMINISTRATIVE NOTES:

PRISM configuration will change with this upgrade.

IV. SPECIAL TOOLS:

There are no special tools, just use the FSR PRISM Alignment Tools.

V. PARTS:

DOMESTIC AND INTERNATIONAL:
LN 6A36-03 Upgrade kit for PRISM (4) to (6) channels.

Kit includes following parts:

Part Number:		**Quantity:**
51434-101	Transfer Pump Assy	2
14332-305	Cable Clamp, 3/16	2
14494-109	Screw, 6-32x9/16	4
14494-108	Screw, 6-32x1/2	4
55086-104	Lift/Shroud Assy	2
52534-108	FMI Pump 50UL	10
55050-109	PMT Channel Reader	2
55015-102	Low Volt. Power Supply	2
50635-101	PRISM Heater Drvr	2
52600-101	Tray Loader Assy	2
14435-192	Screw, 10-32x1/2	4
55065-104	Channel Step Cont/ Drvr	2

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

55410-113	Parallel Interface Assy	2
51050-109	Dispense Verif. Bd	2
50316-107	Channel Exit Chute	2
14494-306	Screw, 10-32x3/8	2
10890-021	Washer, Flat (M)	2
51348-102	Bracket, Waste Chute	2
14481-581	Screw, 8-32x3/8	2
50290-103	Bottle Rack	2

REPLACED PARTS:
Scrap

COMPATIBILITY:
N/A

VI. PROCEDURE:

MODIFICATION STEPS:
Use "The ABBOTT PRISM SERVICE MANUAL". Do all Replacement Procedures before doing the Verification Procedures listed in CHECKOUT.

	Part Number:	Description:	Removal/Replacement Procedure:	
1.	51434-101	Transfer Pump Assy	RR - B.6	The four Screws needed are in the kit.
2.	55086-104	Lift/Shroud Assy	RR - F.4	
3.	52534-108	FMI Pump 50UL	RR - D.1	
4.	55050-109	PMT Channel Reader	RR - F.2	
5.	55015-102	Low Volt. Power Supply	RR - F.8	
6.	50635-101	PRISM Heater Drvr	RR - J.5	
7.	52600-101	Tray Loader Assy	RR - K.1	The two screws needed are in the kit.
8.	55065-104	Channel Step Cont/Drvr	RR - H2.1/2/3/4	
9.	55410-113	Parallel Interface Assy	RR - H2.1/2/3/4	
10.	51050-109	Dispense Verif. Bd	RR - H2.1/2/3/4	
11.	50316-107	Channel Exit Chute	RR - F.3	The needed screw and washer is in the kit. Also the needed bracket and screw is in kit.
	50290-103	Bottle Rack -	Place in Ambient Reagent Bay in front of proper channel.	

CHECKOUT:

1. Using the PRISM Service Manual perform the following Verification Procedures:

Procedure	Description	Verification For
1. Verification Procedure	System Start-up	
2. RR-F.4	Verification Step 2	Lift/Shroud Assy
3. RR-F.3	Verification Step 1	Channel Exit Chute
4. Verification Procedure	Optics PNF Gen.	Lift/Shroud Assy, PMT Channel Reader
5. Verification Procedure	Reagent Prime	Transfer Pump Assy

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

6. RR-B.6	Verification Step 3	Transfer Pump Assy
7. Verification Procedure	Dark Count Verif.	Lift/Shroud Assy, PMT Channel Reader, Low Voltage Power Supply
8. Verification Procedure	Tray Loader Verif.	Tray Loader Assembly
9. Verification Procedure	Optics Validation	PMT Channel Reader, Low Voltage Power Supply
10. Verification Procedure	Transfer Efficiency	Transfer Pump Assy
11. Verification Procedure	Temperature Valid.	PRISM Heater Driver
12. Verification Procedure	Volume Validation	FMI Pump 50 uL

2. If reagents are available, do an Assay run on channel 1 and channel 5.

MODIFICATION CONTROL STICKER UPDATE:

1. Using a Permanent Marker, Mark through number fifteen (15) on the TSB Modification Control Sticker.

END OF DOCUMENT

ABBOTT ADD

TECHNICAL SERVICE BULLETIN

SUBJECT:
Barcode Reader Cover

TSB#: **82-014**

ORIGINATOR: **Mark Yaeger**
APPROVED: **Bob Schabel 11-OCT-96**

PRODUCT:
ABBOTT PRISM® (82)

REF. ECN: **10294-044/047**

IMPLEMENTATION: ○ Immediate ○ Next Service Call ● Next Failure ○ Optional Instruments Requiring Modification: **S/N 1071 and below**	TSB Part/Kit #: **1-52654-01** TSB Effectivity/ Part(s) Availability: **11-OCT-96** **TSB Tracking by Serial # required (IMMEDIATE TSB's ONLY)** ○ YES ● NO	Upgrade Time: **0.5 Hrs.** Validation Time: **0.25 Hrs.** Total Mod. Time: **0.75 Hrs.** ****NOTE** The instrument must be at TSB Level n/a prior to performing this TSB.**

I. DISTRIBUTION:

International

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

II. PURPOSE:
PRISM® analyzer serial numbers 1071 and lower might have a plastic Barcode Reader Cover which could crack along its seams. A new aluminium cover has been released to remedy that problem.

III. ADMINISTRATIVE NOTES:
N/A

IV. SPECIAL TOOLS:
N/A

V. PARTS:
International: 1-52654-01 Barcode Reader Cover

REPLACED PARTS:
Dispose of replaced parts per site requirements for contaminated material.

COMPATIBILITY:
There is not a compatibility issue, either assembly will function. If there is not a problem with the existing Barcode Reader Cover, then there is no need to replace it.

VI. PROCEDURE:
Use of the Field Service D.T. Manual is required.

MODIFICATION STEPS:
Removal:

1. Perform system power off.
2. Remove Sample Access Front Cover.

   See Figure 1 for the following 3 steps.
3. Remove Bar Code Assembly Top Cover (6 screws).

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

4. Remove the 2 screws on top of the Bar Code Reader Cover.
5. Remove the Bar Code Reader Cover, and dispose of properly.

Replacement:

1. Install new Bar Code Reader Cover (2 screws).
2. Install Bar Code Assembly Top Cover (6 screws).
3. Install Sample Access Front Cover.
4. Perform System Start-up.

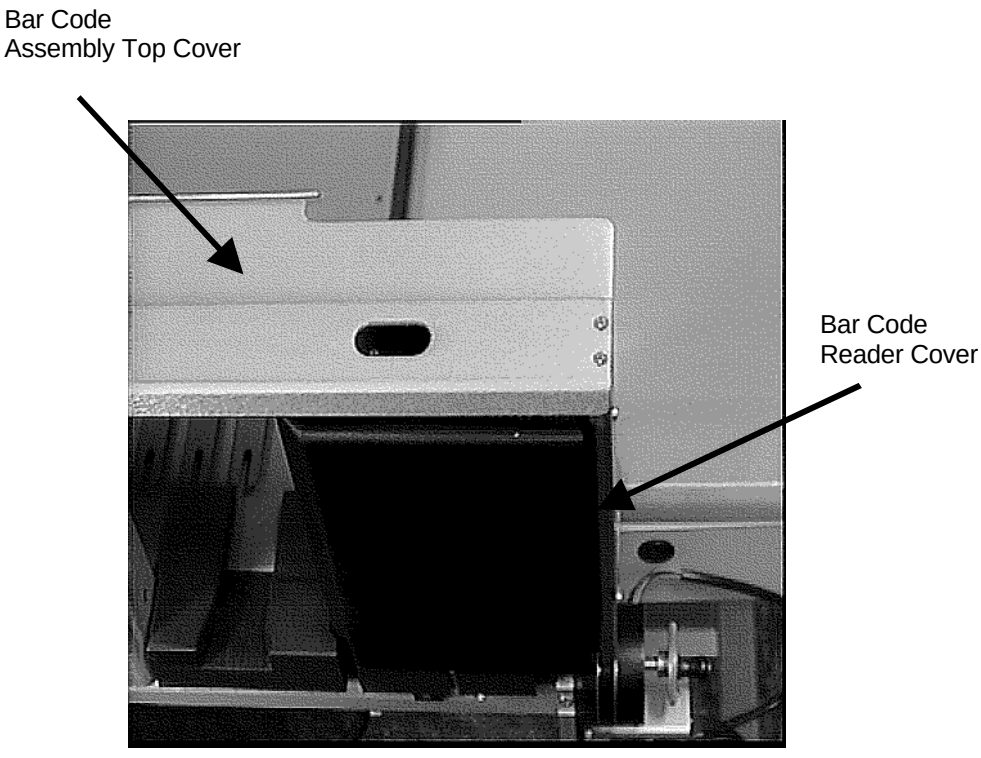


Figure 1

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

CHECKOUT:

1. Perform Bar Code Reader Verification. If test fails, troubleshoot accordingly.

MODIFICATION CONTROL STICKER UPDATE:
Mark off TSB 14 on the Modification Control sticker.

END OF DOCUMENT

ABBOTT ADD

TECHNICAL SERVICE BULLETIN

SUBJECT:
ABBOTT PRISM® Stacker Door

TSB#: **82-013**

ORIGINATOR: **Dan Armstrong**
APPROVED: **Bob Schabel 2/August/96**

PRODUCT:
ABBOTT PRISM® (82)

REF. ECN: **11752-003**

IMPLEMENTATION:	TSB Part/Kit #: **1-50048-01**	Upgrade Time: **0.5 Hrs.**
○ Immediate ○ Next Service Call ○ Next Failure ● Optional	TSB Effectivity/ Part(s) Availability: **02-AUG-96**	Validation Time: **0.0 Hrs.**
Instruments Requiring Modification: **S/N 1074 & below**	**TSB Tracking by Serial # required (IMMEDIATE TSB's ONLY)** ○ YES ● NO	Total Mod. Time: **0.5 Hrs.** ****NOTE** The instrument must be at TSB Level 001 prior to performing this TSB.**

I. DISTRIBUTION:

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

Worldwide

II. PURPOSE:

To correct an alignment problem with the tray loader doors. When closed the bottom or top may collapse in toward the tray loaders. If this is the case then this TSB needs to be performed on the instrument.

III. ADMINISTRATIVE NOTES:

N/A

IV. SPECIAL TOOLS:

N/A

V. PARTS:

DOMESTIC: Same as World Wide.

WORLDWIDE: 1-50048-01 TSB 82-013 Tray Loader right side door with instructions.

REPLACED PARTS:
Dispose of per site requirements for contaminated material.

COMPATIBILITY:
N/A

VI. PROCEDURE:

Copies of the Video Manufacturing instructions will be included with this upgrade.

MODIFICATION STEPS:
Removal:

1. Remove the right side door from the tray loader cover assembly.
2. Remove the hardware from this door assembly.

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

3. Dispose of the component per the site requirements for contaminated material.

Replacement: Use the assembly instructions which are included in the parts package.

1. Assemble the new right side door as shown in the instructions. Loctite is optional for the assembly.
2. Attach the hardware removed from the old door.

CHECKOUT:

1. Verify door assembly does not collapse in towards the tray loaders.

MODIFICATION CONTROL STICKER UPDATE:
Mark off TSB 13 on the Modification Control Sticker.

END OF DOCUMENT

ABBOTT ADD

TECHNICAL SERVICE BULLETIN

SUBJECT:
Heater Controller EPROM Upgrade

TSB#: **82-012**

ORIGINATOR: **Mark Redman**
APPROVED: **Bob Schabel 29/OCT/96**

PRODUCT:
ABBOTT PRISM® (82)

REF. ECO:

IMPLEMENTATION:
- (●) **Immediate**
- ( ) **Next Service Call**
- ( ) **Next Failure**
- ( ) **Optional**

Instruments Requiring Modification:
S/N 1106 and below

TSB Part/Kit #: **1-50645-01**

TSB Effectivity/
Part(s) Availability: **29-OCT-96**

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

- (●) YES
- ( ) NO

Upgrade Time: **0.5 Hrs.**

Validation Time: **1.0 Hrs.**

Total Mod. Time: **1.5 Hrs.**

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

This TSB is complete.

I. DISTRIBUTION:

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

II. PURPOSE:

III. ADMINISTRATIVE NOTES:

IV. SPECIAL TOOLS:

V. PARTS:

REPLACED PARTS:

COMPATIBILITY:
N/A

VI. PROCEDURE:

MODIFICATION STEPS:

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

CHECKOUT:

MODIFICATION CONTROL STICKER UPDATE:

END OF DOCUMENT

ABBOTT ADD

TECHNICAL SERVICE BULLETIN

SUBJECT:
EFT (Electrical Fast Transients) Level 3 Upgrade

TSB#: **82-011**

ORIGINATOR: **Dan Armstrong**
APPROVED: **Bob Schabel 26/July/96**

PRODUCT:
ABBOTT PRISM® (82)

REF. ECO:

IMPLEMENTATION: ● **Immediate** ○ **Next Service Call** ○ **Next Failure** ○ **Optional** Instruments Requiring Modification: **S/N 1049 & below**	TSB Part/Kit #: **1-55664-01** TSB Effectivity/ Part(s) Availability: **25-JUL-96** **TSB Tracking by Serial # required (IMMEDIATE TSB's ONLY)** ● YES ○ NO	Upgrade Time: **1.0 Hrs.** Validation Time: **2.0 Hrs.** Total Mod. Time: **3.0 Hrs.** ****NOTE** The instrument must be at TSB Level 001 prior to performing this TSB.**

I. DISTRIBUTION:

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

Worldwide

II. PURPOSE:

To provide radiated electrical fast transients protection for the instrument.

III. ADMINISTRATIVE NOTES:

Upon completion of the upgrade, the ABBOTT PRISM® Program via Transfusion Diagnostic Customer Service Engineering must receive information back for each instrument. This information is to include the serial number of the ABBOTT PRISM® instrument and the date the upgrade was performed. This information can be sent via fax (214-518-7365), E-mail, or Notes to the attention of Dan Armstrong.

International: Installation of TSB 82-011 will be decided by each area and should be done preferably at the same time as the software version 1.3 upgrade.

IV. SPECIAL TOOLS:

N/A

V. PARTS:

REPLACED PARTS:
Dispose of per site requirements for contaminated material.

COMPATIBILITY:
NONE

VI. PROCEDURE:

MODIFICATION STEPS:
Copies of the Video Manufacturing instructions will be included with the EFT Level 3 upgrade.

Use of Field Service D.T. Manual is required.

Removal and Replacement:

1. Perform System Power Off (VP-1).
2. Remove the following covers (PL - COVERS) , Sample Access Rear, Computer, and Optics.
3. Move the Z axis assembly to the rear of the instrument to gain access to the cable mentioned in the instructions on page 7.
4. Follow the instructions on page 7.
5. Follow the instructions on page 8 associated with the digi box. Discard the one removed from the instrument.
6. Page 9 describes the positioning of the cables associated with the computer assembly. These cables must be oriented as the picture indicates.
7. Page 9 also indicates the addition of the ferrite to cable 51144. If this has already been done on a previous TSB, ignore this step, if it has not been done, then do it now.
8. Follow instructions on page 10 of the replacement of cable 50828 with a new cable marked as

50828-103.

9. Replace the covers removed in step 2 of this procedure.

CHECKOUT:
Use of Field Service D.T. Manual is required.

1. Perform System Start-up VP-2.
2. Perform VP-30 Optics Validation
3. Perform VP-51 Volume Validation for Sample Volume
4. Perform Assay run.

MODIFICATION CONTROL STICKER UPDATE:
Mark off TSB 11 on the Modification Control Sticker.

END OF DOCUMENT

ABBOTT ADD

TECHNICAL SERVICE BULLETIN

SUBJECT:
Tip Stripper Assembly

TSB#: **82-010**

ORIGINATOR: **Mark Yaeger**
APPROVED: **Bob Schabel 1/AUG/96**

PRODUCT:
ABBOTT PRISM® (82)

REF. ECN: **10298-023, 024**

IMPLEMENTATION: ○ **Immediate** ○ **Next Service Call** ○ **Next Failure** ● **Optional** Instruments Requiring Modification: **S/N 1050 & above**	TSB Part/Kit #: **1-50563-01** TSB Effectivity/ Part(s) Availability: **31-MAY-96** **TSB Tracking by Serial # required (IMMEDIATE TSB's ONLY)** ○ YES ● NO	Upgrade Time: **1.0 Hr.** Validation Time: **0.5 Hr.** Total Mod. Time: **1.5 Hrs.** ****NOTE** The instrument must be at TSB Level 01 prior to performing this TSB.**

I. DISTRIBUTION:

International

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

II. PURPOSE:
Instruments from serial number 1050 and higher may have a tip stripper assembly which has been damaged by the Pipettor Probes. This assembly will need to be replaced with the one in this kit.

III. ADMINISTRATIVE NOTES:
N/A

IV. SPECIAL TOOLS:
N/A

V. PARTS:
DOMESTIC:
Same as International but only training instruments in Dallas and AQA instruments in Abbott Park are included.

INTERNATIONAL:
This is optional. The kits will be available for any further problems which may occur with this assembly.

REPLACED PARTS:
Dispose of replaced parts per site requirements for contaminated material.

COMPATIBILITY:
There is not a compatibility issue, either assembly will function. If there is not a problem with existing tip stripper, then there is no need to replace it.

VI. PROCEDURE:

MODIFICATION STEPS:
Use of the Field Service D.T. Manual is required.

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

Removal:

1. Perform System Power off (VP-1).
2. Remove the Sample Access Front Cover (PL-Covers).
3. The tip stripper is held onto the plate with 2 hex head counter sink screws. Remove the screws in order to remove the tip/grip stripper. DO NOT REUSE THESE SCREWS. Replacements are included in the kit.
4. Dispose of the old tip/grip stripper after performing proper decontamination procedures.

Replacement:

1. Assemble the new tip/grip stripper.
   - Remove the 2 inch screw, 2 nylon washers, black tip gripper, and nut from the kit.
   - Place 1 nylon washer on the 2 inch screw. Insert the screw through the vertical center hole of the black tip gripper. The head of the screw and washer should be on the wide side of the tip gripper. Place the second washer on the screw. There should be a washer on the top and bottom of the assembly. See Fig. 1.
   - Put the nut on the screw. Using a screwdriver and a wrench, tighten until the nut is against the tip gripper. Do not over tighten (the screw should still turn).
   - Remove the gold colored mounting bracket from the kit. Lay the black, tip gripper onto the mounting bracket. The center screw hole of the mounting bracket should be at the bottom of the assembly by the nut. See Fig. 2.
   - Screw the 2 inch screw into the mounting bracket (DO NOT TIGHTEN).
   - Remove both 6/32 x 3/8 inch screws with captive washers from the kit. Screw them into

the outside holes of the assembly (DO NOT TIGHTEN).

- Remove two of the 10/32 x 3/8 inch hex head counter sink screws from the kit (there might be 2 EXTRA 10/32 x 3/8 inch screws remaining).

2. Install the replacement assembly to the existing plate.
3. Perform System start-up (VP-2).
4. Perform Z Reference Alignment (VP-3). **NOTE: See next step before exiting this alignment.**
5. Subtract 1905 from the Z1 position value shown on the monitor.
   (i.e. Z1 position value - 1905). **Record this value.**
6. Start Tip Remover Alignment (VP-4).
7. Press "C" to enter "Configure Teach" screen.
8. Enter the value from step 5 into Remover Z-Drop.
9. Save the changes before escaping from Configure Teach.
10. Continue with the Tip Remover Alignment procedure. Move the pipetter away from the tip stripper, and drop the probes.
11. Move the pipetter in until it almost touches the tip stripper
    (**Do Not Raise** or **Lower** Z1or Z2).
12. Manually set the tip stripper Z height. This is done by turning the 2 inch screw clockwise or counter clockwise until the top of the tip stripper is .06 - .12 in
    (1.5 - 3.0 mm) below the bottom of the gold portion of the tip stripper. See Fig. 3.
13. Continue by centering the probes in the slots of the tip gripper.

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

14. Save changes before exiting.
15. Move pipetter away from home. This can be done by de-activating the safety interlock switch (remove the sample access rear cover (PL-Covers), and leave the pin out). Tighten the set screws on the outside portion of the tip gripper assembly. Install the sample access rear cover.

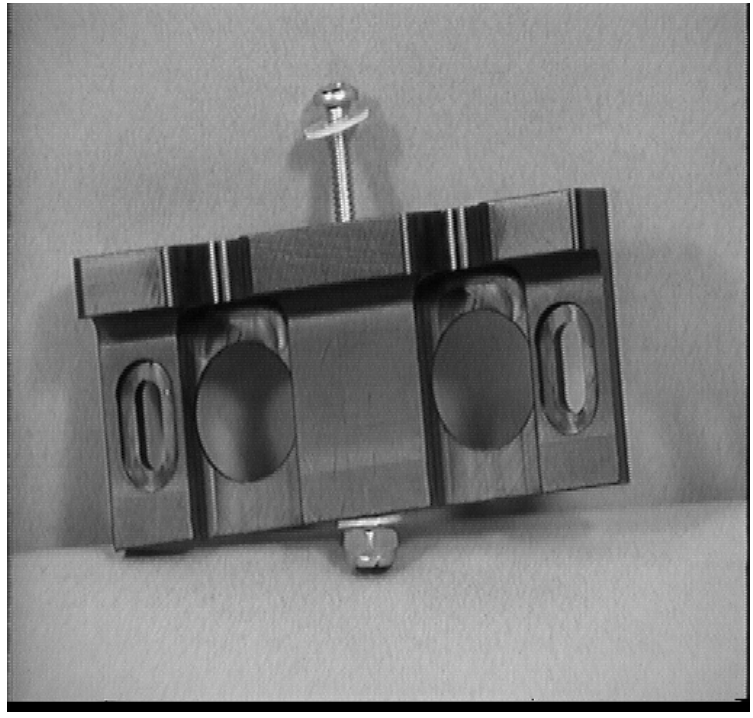


Fig. 1

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

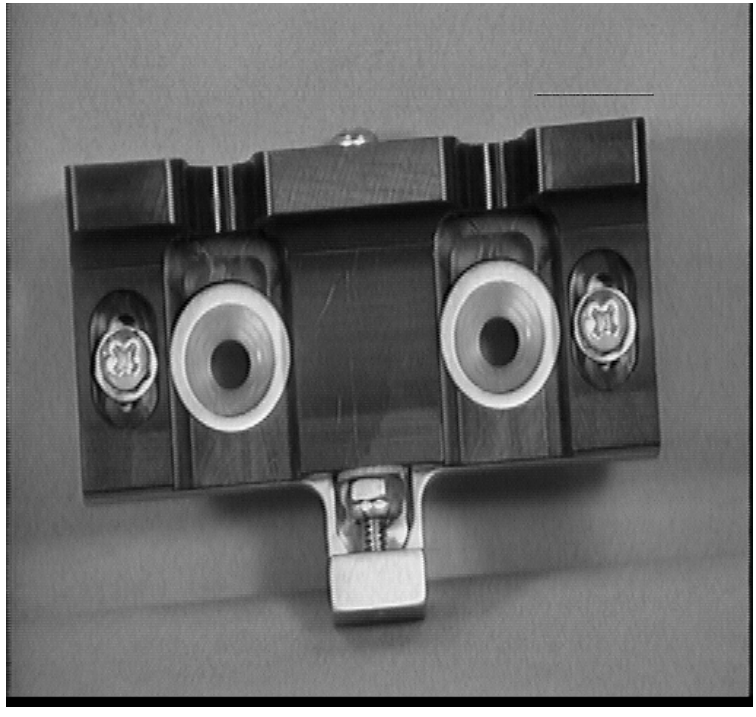


Fig. 2

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

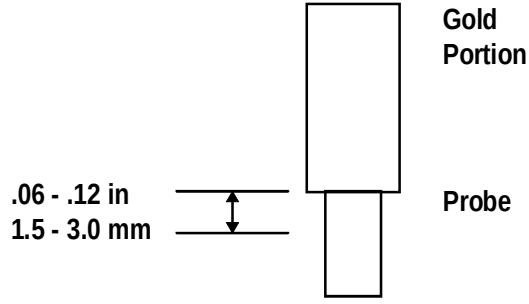


Fig. 3

CHECKOUT:

1. Perform Z-axis Home to home the pipetter.

   * Component Diagnostics
   * XY Table
   * Positive Home

   After pipetter homes press ESC

2. Perform several Tip Pickups to verify tips are stripped off properly.

   * Sample Manager (Note: remember to place a full tip rack in the PRISM)
   * Tip Pickup

MODIFICATION CONTROL STICKER UPDATE:
Mark off TSB 10 on the Modification Control sticker.

END OF DOCUMENT

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

ABBOTT ADD

TECHNICAL SERVICE BULLETIN

SUBJECT:
Bar Code Reader Motor Coupler

TSB#: **82-009**

ORIGINATOR: **Mark Yaeger**
APPROVED: **Bob Schabel 14/NOV/96**

PRODUCT:
ABBOTT PRISM® (82)

REF. ECN: **10294-043/046**

IMPLEMENTATION:	TSB Part/Kit #: **1-51070-01**	Upgrade Time: **1.75 Hrs.**
○ Immediate ○ Next Service Call ● Next Failure ○ Optional	TSB Effectivity/ Part(s) Availability: **21-OCT-96**	Validation Time: **0.75 Hrs.**
Instruments Requiring Modification: **S/N 1057 and below**	**TSB Tracking by Serial # required (IMMEDIATE TSB's ONLY)** ○ YES ● NO	Total Mod. Time: **2.5 Hrs.** ****NOTE** The instrument must be at TSB Level n/a prior to performing this TSB.**

I. DISTRIBUTION:

Worldwide

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

II. PURPOSE:

PRISM® analyzer serial numbers 1057 and below have a Bar Code Reader Drive Gear which may not be horizontal. If the gear is not horizontal, it may put added pressure on the motor coupler, and may cause the coupler to crack. This situation can be resolved by replacing the old parts with the ones in this kit.

III. ADMINISTRATIVE NOTES:

N/A

IV. SPECIAL TOOLS:

N/A

V. PARTS:

1-51070-01 Kit, Motor Coupler Upgrade

REPLACED PARTS:
Dispose of replaced parts per site requirements for contaminated material.

COMPATIBILITY:
There is not a compatibility issue, either assembly will function. If there is not a problem with the existing Bar Code Reader coupler, then there is no need to replace it.

VI. PROCEDURE:

Use of the Field Service D.T. Manual is required.

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

MODIFICATION STEPS:
Removal:

1. Remove Bar Code Reader Assy, and Rack Plate Assy. (NOTE: When removing Bar Code Reader Assy, it may be helpful to remove the top guard, and to move the scanner to access the back mounting screw).
2. Place Rack Plate Assy on a flat surface, motor side up.
3. Remove Rack Position Motor Assy.
   (NOTE: Do **NOT** remove motor handle)

See Figure 1 for the following 3 steps:

4. Loosen the coupler set screw on the gear drive side. Discard old coupler.
5. Remove 2 screws from short side of L-bracket. (Place screwdriver through motor bracket to access screws).
6. The remaining 2 screws holding the L-bracket in place can be accessed from the top of the rack plate assy. Discard old L-bracket.

Replacement:

1. Install the replacement L-bracket, 2 (8-32 X 3/4) screws from top and 2 (8-32 X 1/2) screws underneath - **DO NOT TIGHTEN SCREWS**.
2. Place coupler on gear drive.
3. Replace motor. Insure that the motor is flush against the mounting bracket, and that the screws are tight.
4. Position the coupler so that 1 pair of set screws are centered on the **FLAT PORTION** of the

motor shaft and the gear drive shaft. Also, center coupler over the two shafts.

5. Tighten the 2 set screws on the flat portion of the shafts. Tighten the remaining 2 set screws.
6. Tighten the 2 screws on the long portion (top) of the L-bracket.
7. Tighten the 2 screws on the short portion (underneath) of the L-bracket.
8. Manually move the rack loader (using the motor handle) to position 1 and back to home. If the motor binds, stop turning the handle, loosen 1 pair of screws on the L-bracket, and then tighten them again. The L-bracket may be bending the gear drive; thus, causing the binding. Loosening and then tightening the 2 pairs of screws on the L-bracket should align it.
9. Replace the Rack Plate Assy.
10. Replace the Barcode Reader Assy, as mentioned in step above.

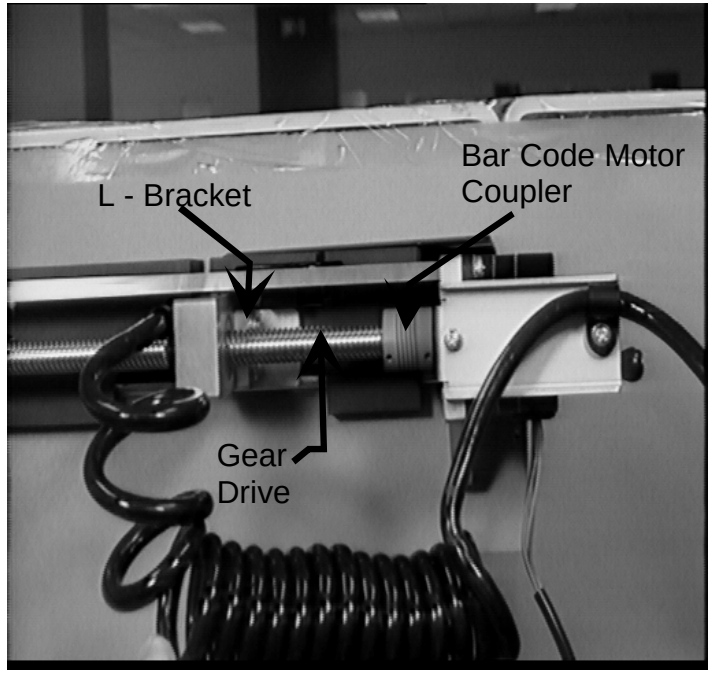


Figure 1

CHECKOUT:

1. Perform verifications as stated in verification section of Rack Plate Assy Removal and Replacement.

(If verifications fail troubleshoot accordingly.)

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

MODIFICATION CONTROL STICKER UPDATE:
Mark off TSB 9 on the Modification Control sticker.

END OF DOCUMENT

ABBOTT
ADD

TECHNICAL SERVICE BULLETIN

SUBJECT:
ABBOTT PRISM® Refrigerator Remote Sensor Retrofit Upgrade

TSB#: **82-008**

ORIGINATOR: **John Buckland**
APPROVED: **Bob Schabel 23/May/96**

PRODUCT:
ABBOTT PRISM® (82)

REF. ECN: **11117-001**

IMPLEMENTATION:
- (●) **Immediate**
- ( ) **Next Service Call**
- ( ) **Next Failure**
- ( ) **Optional**

Instruments Requiring Modification:
S/N 1049 & Below

TSB Part/Kit #: **1-55645-01**

TSB Effectivity/
Part(s) Availibility: **23-MAY-96**

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

- ( ) YES
- (●) NO

Upgrade Time: **1.0 Hr.**

Validation Time: **1.5 Hrs.**

Total Mod. Time: **2.5 Hrs.**

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

This document is Complete.

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

END OF DOCUMENT

ABBOTT ADD

TECHNICAL SERVICE BULLETIN

SUBJECT:
ABBOTT PRISM® Non-CFC Refrigerator and Cover Upgrade

TSB#: **82-007**

ORIGINATOR: **John Buckland**
APPROVED: **Bob Schabel 23/MAY/96**

PRODUCT:
ABBOTT PRISM® (82)

REF. ECO:

IMPLEMENTATION: ○ **Immediate** ○ **Next Service Call** ○ **Next Failure** ● **Optional** Instruments Requiring Modification: **S/N 1049 & below**	TSB Part/Kit #: **1-51688-01** TSB Effectivity/ Part(s) Availability: **23-MAY-96** **TSB Tracking by Serial # required (IMMEDIATE TSB's ONLY)** ○ YES ● NO	Upgrade Time: **1.0 Hr.** Validation Time: **2.0 Hrs.** Total Mod. Time: **3.0 Hrs.** ****NOTE** The instrument must be at TSB Level n/a prior to performing this TSB.**

I. DISTRIBUTION:

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

International

II. PURPOSE:
To notify the field of the need to upgrade to the CFC free refrigerator with appropriate covers if R-12 refrigerator needs replacing.

III. ADMINISTRATIVE NOTES:
N/A

IV. SPECIAL TOOLS:
N/A

V. PARTS:

REPLACED PARTS:
Properly Scrap the R-12 refrigerator and refrigerator cover which was removed.

COMPATIBILITY:
There is not a compatibility problem. Either the R-12 or the CFC free refrigerator will work properly. There is no need to change out the R-12 refrigerator unless it fails.

VI. PROCEDURE:

MODIFICATION STEPS:
Removal

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

1. Perform (RR-L1).

Replacement

1. Install the new CFC-Refrigerator using the instructions provided in the retrofit kit.
2. Install the new covers using the instructions provided in the retrofit kit.

CHECKOUT:

1. Perform System Start-up (VP-2)
2. Perform Refrigerator Stirrer Verification (VP-26)
3. Run an Assay
4. Follow up with customer the next day to make sure refrigerator temperature is o.k.

MODIFICATION CONTROL STICKER UPDATE:

1. Using a permanent marker, mark through the number seven (7) on the TSB Modification Control label.

END OF DOCUMENT
END OF DOCUMENT

ABBOTT ADD

TECHNICAL SERVICE BULLETIN

SUBJECT:
ABBOTT PRISM® Tip Chute Assembly Upgrade

TSB#: **82-006**

ORIGINATOR: **Dan Armstrong**
APPROVED: **Bob Schabel 26/July/96**

PRODUCT:

REF. ECO:

IMPLEMENTATION: ● **Immediate** ○ **Next Service Call** ○ **Next Failure** ○ **Optional** Instruments Requiring Modification: **S/N 1049 & below**	TSB Part/Kit #: **1-55619-01** TSB Effectivity/ Part(s) Availability: **25-JUL-96** **TSB Tracking by Serial # required (IMMEDIATE TSB's ONLY)** ● YES ○ NO	Upgrade Time: **0.75 Hrs.** Validation Time: **0.75 Hrs.** Total Mod. Time: **1.5 Hrs.** ****NOTE** The instrument must be at TSB Level 001 prior to performing this TSB.**

I. DISTRIBUTION:

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

Worldwide

II. PURPOSE:

To upgrade the new version Tip Chute Assembly on the ABBOTT PRISM® instrument. This TSB may be performed with other TSB's but it is documented as if this is the only procedure being performed.

III. ADMINISTRATIVE NOTES:

Upon completion of the upgrade, the ABBOTT PRISM® Program via Transfusion Diagnostic Customer Service Engineering must receive information back for each instrument. This information is to include the serial number of the ABBOTT PRISM® instrument and the date the upgrade was performed. This information can be sent via fax (214-518-7365), E-mail, or Notes to the attention of Dan Armstrong.

International: Installation of TSB 82-006 will be decided by each area and should be done preferably at the same time as the software version 1.3 upgrade.

IV. SPECIAL TOOLS:

N/A

V. PARTS:

REPLACED PARTS:
Dispose of per site requirements for contaminated material.

COMPATIBILITY:
Previous version Tip Chute no longer functional.

VI. PROCEDURE:

MODIFICATION STEPS:
Copies of the Video Manufacturing instructions will be included in the Tip Chute Assembly upgrade.

Use of Field Service D.T. Manual is required.

Removal:

1. Perform System Power Off (VP-1).
2. Remove the following covers (PL - COVERS) Tray loader, Sample Access Front, Electronics Bay, and Heater Controller.
3. Remove the Tray loader assembly for Channel 6. This will provide needed access to the upright where the Tip Stripper is attached.
4. Open the Pipette Tip Waste door, and remove the Tip Waste can, leaving the door open.
5. Move the Pipettor assembly to provide access to the mounting screws holding the Tip Stripper in place.
6. Remove the sensor assembly for the lower portion of the old version Tip Chute.

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

7. Unplug the sensor cable. It is connected to the Miscellaneous Sensor Board.
8. Dispose of the components (tip waste canister, upper and lower tip chute, lower tip chute sensor assembly, and the miscellaneous hardware) per the site requirements for contaminated material.

Replacement: Use the assembly instructions which are included in the parts package.

1. Assemble new Tip Stripper Assembly as shown. Loctite is optional for the assembly.
2. Attach new tube guide assembly and bracket to frame. When attaching the tube guide, make sure it is flush against the heater cover on channel 6. Attach the sensor cable connector to the Miscellaneous board J-2.
3. Insert tubes into guide and slide into the plate. The tube unit should lock into the plate.
4. Remove the nut on the Sample Access Cover Assembly and install the acorn nut on the cover assembly.
5. Install the new Tip Stripper guard onto the Rack Plate Assembly.
6. Replace Tray Loader Assembly removed previously.

CHECKOUT:
Use of Field Service D.T. Manual is required.

1. Perform System Start-up VP-2.
2. Perform Tray Loader Verification VP-24.
3. Use Diagnostics, XY Gantry Flag status to verify Tip Chute sensor operation.

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

4. Perform Z Reference Alignment (VP-3). **NOTE: See next step before exiting this alignment.**
    a. Subtract 1905 from the Z1 position value shown on the monitor, **Write this value down.**
5. Perform Tip Remover Alignment VP-4.
    a. Press "C" to enter "Configure Teach" screen.
    b. Enter the value from Step 4 above you recorded into "Remover Z-Drop".
    c. Save the changes before escaping from "Configure Teach".
    d. Continue with Tip Remover Alignment. Move the pipettor away from the tip stripper, and drop the probes.
    e. Move the pipettor in until it almost touches the tip **stripper (DO NOT RAISE OR LOWER Z1 OR Z2)**.
6. Manually set the tip stripper Z height.
    a. Turn the 2 inch screw clockwise or counterclock wise to set the top of the stripper below the bottom of the gold portion of the pipettor plunger (1.5 - 3.0 mm). TSB 82-010 has this procedure also if you need more information.
    b. Continue by centering the probes in the slots of the gripper.
    c. Save changes before exiting the procedure.
    d. Tighten the set screws on the outside portion of the tip gripper assembly.
7. Perform several Tip Pickups using Sample Manager menu in Component Diagnostics. Verify tips are being stripped off properly.
8. Replace all covers and install the new Tip Waste container.

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

MODIFICATION CONTROL STICKER UPDATE:
Mark off TSB 6 on the Modification Control Sticker.

END OF DOCUMENT

ABBOTT ADD

TECHNICAL SERVICE BULLETIN

SUBJECT:
ABBOTT PRISM® 1.3 Software Upgrade

TSB#: **82-005**

ORIGINATOR: **Dan Armstrong**
APPROVED: **Bob Schabel 3/DEC/96**

PRODUCT:
ABBOTT PRISM® (82)

REF. ECO:

IMPLEMENTATION:
- (●) **Immediate**
- ( ) **Next Service Call**
- ( ) **Next Failure**
- ( ) **Optional**

Instruments Requiring Modification:
S/N 001 and Above

TSB Part/Kit #: **1-55585-02**

TSB Effectivity/
Part(s) Availability: **03-DEC-96**

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

- (●) YES
- ( ) NO

Upgrade Time: **0.5 Hr.**

Validation Time: **6.0 Hrs.**

Total Mod. Time: **6.5 Hrs.**

****NOTE**** **The instrument must be at TSB Level 004 prior to performing this TSB.**

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

I. DISTRIBUTION:

Worldwide

II. PURPOSE:

New version of instrument operating software. Instrument Service Advisory 82-011 will provide a summary of features contained in the new version of software.

III. ADMINISTRATIVE NOTES:

Make copies of the Checklist at the end of this TSB. Complete the checklist after upgrade, sign it and leave it with the customer.

Once this upgrade is installed, host communications will not operate unless the host interface is using the information contained in the Host interface specification manual LN 6A36-68. If the site is utilizing Euro-BBS™ with the Dawning interface there are no issues with communication. If the site is using Euro-BBS with any other interface, there may be communication problems once 1.3 is installed.

Customer Support Information:

1. Initial Reactive samples not retested prior to this upgrade need to be run before the installation of this version of software.
2. At the completion of this software upgrade TSB, the customer should run additional samples to duplicate actual routine testing. The testing protocol should be determined by the laboratory Standard Operating Procedures. All test results must be consistent with expected results.
3. If partially used reagent kits, wash solutions or purge solutions are installed on the instrument after the upgrade, the customer will need to manually track usage of these resources as

before the upgrade. This is because the system will recognize the used reagents as full kits after the upgrade.
When new reagent kits, wash solutions and purge solutions are installed, the system will accurately monitor the resources.

4. Leave the Customer letter and new assay package inserts with the customer.
5. Leave the new Operations Manual (LN 6A36-67). If possible, remove the old version Operations Manual and destroy it. If the customer has notes in the manual, please have them transfer the notes to the new version and then destroy the old manual.
6. All test results will be deleted when the new version software is loaded. Therefore, have the customer print reports, copy reports to floppy and/or send data to the host as required based on their test result status.

Upon completion of the upgrade:

1. Use the normal procedures for notification of the TSB.
2. Leave the check list with all associated documentation at the customer site.
3. Make sure both you and the customer have signed the document/s.

IV. SPECIAL TOOLS:

The new version tape drive unit (C/N 1-55611-02) is required to load this version of Software.

The new version Volume Validation Tool (LN 6A36-88 for 220 VAC) is also required for the site. You are not required to utilize the tool during this upgrade.

V. PARTS:

REPLACED PARTS:
N/A

COMPATIBILITY:
Old version Volume Validation Tools are not compatible.

Previous versions of the tape drive units are not compatible with this new version software.

VI. PROCEDURE:

MODIFICATION STEPS:
Use of the new Field Service D.T. Manual (1-51428-03) or ISA is required.

Pre-Software Load

1. Print the current Run Controls Configuration.

   From the Main Menu:

   - Instrument Preparation
   - Manage Resources
   - Run Controls
   - Select a defined run control

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Print the run control configuration screen (**F3**). Retain this printout for use later in this procedure.

Repeat these steps for all defined Run Controls. Return to the Main Menu by pressing the **Esc** key.

2. Print the current Audible Alarm Configuration.

   From the Main Menu:

   - Maintenance
   - Hardware Configuration
   - Audible Alarm

   Print the audible alarm configuration screen (**F3**). Retain this printout for use later in this procedure.

   Return to the Main Menu by pressing the **Esc** key.

3. Print the current Host Interface Configuration.

   From the Main Menu:

   - Maintenance
   - Hardware Configuration
   - Host Interface Configuration

   Print the Host Interface Configuration screen (**F3**). Retain this printout for use later in this procedure.

   Return to the Main Menu by pressing the **Esc** key.

4. Print the current Bar Code Configuration.

   From the Main Menu:

   - Maintenance
   - Hardware Configuration
   - Bar Code Configuration

   Print the Bar Code Configuration screen (**F3**). Retain this printout for use later in this procedure.

   Return to the Main Menu by pressing the **Esc** key.

5. Print the current Batch Parameters.

   From the Main Menu:

   - Maintenance
   - Software Configuration
   - Batch Parameters Configuration

   Print the Batch Parameters Configuration screen (**F3**). Retain this printout for use later in this procedure.

   Return to the Main Menu by pressing the **Esc** key.

6. Print the current Print Report Configuration.

   From the Main Menu:

   - Maintenance
   - Software Configuration

- Print Report Configuration

Print the Print Report Configuration screen (**F3**). Retain this printout for use later in this procedure.

Return to the Main Menu by pressing the **Esc** key.

7. Print a listing of the current Users.

From the Main Menu:

- Maintenance
- User Configuration
- List Users

Print the Users List screen (**F3**). Retain this printout for use later in this procedure.

Return to the Main Menu by pressing the **Esc** key.

Load Software

Equipment Required:

- Colorado® Trakker 350 Megabyte External Tape Drive (with cables and installation diskette)
- Software Update Tape
- Blank Formatted 3.5", 1.44 Mb Floppy Diskette

1. Log on to ABBOTT PRISM® System with Abbott Access.
2. Make a backup copy of current configuration.
   a. Use a blank, formatted diskette.

b. Perform Configuration Backup

From the Main Menu:

- Maintenance
- Software Configuration
- Configuration Backup/Restore
- Backup

When requested, insert diskette and press **Enter**.

Press **Enter** to continue.

c. When backup is complete press **Enter**. Remove diskette.

d. Label diskette as Configuration Backup, with date and ABBOTT PRISM® Serial Number. Retain for later use.

e. Return to Main Menu (press **Esc** key 3 times).

Note: Only the information listed below is backed up using Version 1.2

- Instrument Serial Number
- Sample Manager Teach Positions
- Bar Code Configuration
- Reader PNF Values

3. Exit ABBOTT PRISM® Software.

From the Main Menu:

- Engineering
- Exit Program

Press the **Y** key to confirm shutdown.

4. Delete the old version of software.

   a. Delete files.

   Type **CD** and press **Enter**.
   Type **deltree *.*** and press **Enter**.

   NOTE: DOS prompts confirmation for each file and subdirectory in root directory. Do not delete the following files (Press N to not delete each file when DOS asks if you want to delete the file):

   - DOS (Directory)
   - MSDOS.SYS (Hidden system file)
   - IO.SYS (Hidden system file)
   - COMMAND.COM (Hidden system file)

   Press **Y**, when prompted, to delete files other than those listed above.

   b. Verify correct files were deleted.

   Type **Dir /a** and press **Enter**.
   The screen displays the directories and files listed above.

   c. Press the **CTRL**, **ALT**, and **DEL** keys simultaneously to reboot the Computer.

5. Connect Tape Drive to the Parallel Printer Port of the ABBOTT PRISM® System Computer.

Install the tape drive backup software.

a. Insert the Tape Backup for DOS installation diskette into the floppy drive.

b. To verify you are at the root directory, type **CD** and press **Enter**.

c. Type **a**: and press **Enter**.

d. Type **install** and press **Enter**.

e. When the "Install Destination" Screen is displayed, verify the following parameters are set:

Install software on Hard Disk Drive: C:

Install software in Directory: \CBD

Select OK.

f. The next screen asks if you want to install the Backup Scheduler. Leave the check box empty and select OK.

g. When the Boot Drive Selection Screen is displayed, verify that C: is selected and select OK.

h. The next screen indicates the installation was OK.

i. Select OK and remove the installation diskette.

j. Reboot per display.

Restore software.

Load Version 1.3 software from tape.

a. Insert update software tape into Tape Drive.

b. Start tape backup program.

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

Type **CD\CBD** and press **Enter**.

Type **TAPE** and press **Enter**.

The tape backup/restore program Main Menu is displayed.

c. Verify the tape backup software is correctly configured.

Press the **ALT** and **O** keys simultaneously.
Select Software Setups.

Set the options in the Software Setups Menu as shown below:

[ ] Auto format

[ ] Auto compare

[X] Overwrite existing files during restore

[X] Reset file archive attribute

[X] Concurrent mode

[X] Append volume to tape

Software data compression type: OPTIMIZE TIME

File sort type: NAME

Select OK when all entries have been made.

- Main Menu
- Restore
- Selective

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

If more than one volume displays, select the most recent date, then select OK.

Select the "Tag/Untag All" option. Verify the screen displays the following information:

Files tagged = 272 Kbytes tagged = 11,205

Select OK to continue.

Accept default value for drive letter to RESTORE TO and name of ERROR LOG FILE, then select OK.

Select OK when warned that overwrite of the disk is enabled.

Tape software begins to restore. A status of loading displays at bottom of screen.

Exit tape software by pressing the **Esc** key 3 times and then select Exit.

Remove tape from Tape Drive.

Disconnect Tape Drive from ABBOTT PRISM® Computer Parallel Port and reconnect Printer.

Restore System configuration.

a. Reboot ABBOTT PRISM® System Computer by pressing **CTRL**, **ALT**, and **DEL** keys simultaneously. Computer boots up to ABBOTT PRISM® Logon Screen.

b. Log on to ABBOTT PRISM® System with Abbott Access.

c. Place configuration backup diskette created earlier into floppy disk drive.

d. Restore Configuration.

From the Main Menu:

- Maintenance
- Software Configuration
- Configuration Backup/Restore
- Restore

e. When restore is complete, press **Enter**. Remove floppy diskette from diskette drive and retain for future use. (Use only with this serial number instrument.)

f. Return to Main Menu (press **Esc**).

Reboot ABBOTT PRISM® Computer.

a. From the Main Menu:

- Engineering
- Exit Program

b. From DOS prompt press **CTRL**, **ALT**, and **DEL** keys simultaneously.

Configuration

Refer to the printouts obtained from the Pre-Software Load section for the following procedures. (see the Operations Manual for editing instructions).

1. Configure the Run Controls from the appropriate printout.
2. Configure the Audible Alarm from the appropriate printout.
3. Verify the Host Interface from the appropriate printout.
4. Verify the Bar Code configurations from the appropriate printout.

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

5. Check with the customer and configure the Batch Parameters per the customers requirements.

   Notes: 1) Inform the customer the batch time can be set in 10 minute intervals to a maximum of 8.5 hours (default) with this software version (1.3).

   2) This software provides Gray Zone and the customer will need to set this based on their requirements.

6. Configure the Print Report from the appropriate printout.

   Note: ***Inform the customer there are three new files available for automatic printing, Group Retest, Sample Retest, and Kit Utilization. (See the Operations manual for definitions)***

1. Add a maintenance level User. Check with the customer for name and password preference.
2. Verify the correct serial number (located in the upper left corner of the screen). Enter the correct number if incorrect. If incorrect, perform the following procedure:

   From Main Menu:

   - Maintenance
   - Software Configuration
   - Set Serial Number

   Enter the correct serial number

3. Verify the correct date and time (located in the upper right corner of the displayed screen). Enter the correct date and time if incorrect. If incorrect, perform the following procedure:

   From Main Menu:

- Maintenance
- Hardware Configuration
- Set date and time

CHECKOUT:

1. Confirm XY settings are correct. Pick up and strip off ten sets of pipette tips.

   From the Main Menu:

   - Component Diagnostics
   - Sample Handler
   - Tip Pick Up

   Set for ten cycles, both axes.

2. Perform the Optics Validation Procedure on all channels on the instrument.
3. Perform the Channel Temperature Validation Procedure on all channels on the instrument.
4. Perform an Assay Calibration with Release control on each channel. The most time efficient way to perform the assays is as follows. Run the backup channel first, then perform the Clean Backup Channel procedure. Channel 6 can be going through the idle time with cleaning solution in the lines as the other channels are being run.

   NOTE: Set up the backup channel as a 3- step assay. Backup channel will need to be run by itself.

When backup assay is complete:

Perform Clean Backup Channel procedure

Reload 3-step assay reagents on original channel.

Now run the assays on the other channels. When complete, perform Purge.

MODIFICATION CONTROL STICKER UPDATE:
Mark off TSB 5 on the Modification Control Sticker.

ABBOTT PRISM® Version 1.3 Upgrade Checklist

While performing this TSB, mark off the items listed in the check list after they are successfully performed. Attach all printouts from this upgrade.

Instrument S/N _____ Account Name _____

Date of Update _____ Account Address _____

Preparation:

TSB 004 performed

(S/N 1049 and below) Yes _____ No* _____ NA _____

TSB 012 performed

(S/N 1106 and below) Yes _____ No* _____ NA _____

Software Loading:

Files Tagged = 272 OK _____

Kbytes tagged = 11,205 OK _____

* An explanation must be provided

Configuration:

Run Controls Configured. Yes _____ No* _____

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

Batch Size Configured. Yes _____ No* _____

Print Reports Configured. Yes _____ No* _____

Audible Alarm Configured. Yes _____ No* _____

Maintenance level user added
(Customer chooses name and password). Yes _____ No* _____

Bar Code Configuration verified. OK _____

Serial Number Verified. OK _____

Date and Time Verified. OK _____

Host Interface Verified OK _____

Validation:

Successfully picked up and stripped 10 tips. Yes _____ No* _____

Optics Validation passed. Yes _____ No* _____

Channel Temperature Validation passed. Yes _____ No* _____

Assays Performed with acceptable results. Yes _____ No* _____

* An explanation must be provided

Customer Support Information:

Customer has been given Customer letter with new assay package inserts Yes_____No*_____

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

Customer has been given Operations Manual and
old version manual has been destroyed Yes_____No*_____

At the completion of the Validation Protocol, additional samples should be run to duplicate your actual routine testing environment. The testing protocol should be determined by your laboratory Standard Operating Procedures. All test results must be consistent with expected results.

* An explanation must be provided

Explanations:

_____

_____

_____

_____

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

Abbott Representative

Signature _____ Date _____

Laboratory Representative

Signature _____ Date _____

END OF DOCUMENT

ABBOTT ADD

TECHNICAL SERVICE BULLETIN

SUBJECT:
ABBOTT PRISM® New Tray Loader with Firmware

TSB#: **82-004**

ORIGINATOR: **Dan Armstrong**
APPROVED: **Bob Schabel 26/NOV/96**

PRODUCT:
ABBOTT PRISM® (82)

REF. ECO:

IMPLEMENTATION: ● **Immediate** ○ **Next Service Call** ○ **Next Failure** ○ **Optional** Instruments Requiring Modification: **S/N 1049 and below**	TSB Part/Kit #: **See Section V** TSB Effectivity/ Part(s) Availability: **29-OCT-96** **TSB Tracking by Serial # required (IMMEDIATE TSB's ONLY)** ● YES ○ NO	Upgrade Time: **1.0 Hrs.** Validation Time: **0.5 Hrs.** Total Mod. Time: **1.5 Hrs.** ****NOTE** The instrument must be at TSB Level 001 prior to performing this TSB.**

I. DISTRIBUTION:

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

Worldwide

II. PURPOSE:

The tray loaders are of a new design. Instruments being upgraded to software version 1.3 and higher requires the new style tray loaders/destackers be installed. A new latch assembly is required for the tray loader cover doors.

New version firmware in the PIBs (Parallel Interface Boards) is required for the operation of the new tray loaders.

III. ADMINISTRATIVE NOTES:

Upon completion of the upgrade, use the normal procedures for notification of the TSB.

IV. SPECIAL TOOLS:

N/A

V. PARTS:

REPLACED PARTS:
Dispose of as per site decontamination procedures.

COMPATIBILITY:
1-51000-01 Old version tray loaders are not compatible.

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

When all instruments in your country will be upgraded, these old tray loaders could be discarded.

50920-111 PIBs (L/N 6A36-24, non-CE version) once modified are not downward compatible.

VI. PROCEDURE:

MODIFICATION STEPS:
Use of Field Service D.T. Manual is required.

1. Perform System Power Off.
2. Remove the following covers (PL - COVERS) Tray loader and electronics bay.
3. Remove the old tray loader assemblies. Use the removal procedure in the field service manual.

   CAUTION: ELECTROSTATIC DISCHARGE AREA, PLEASE PERFORM THE NEXT REMOVAL / INSTALLATION STEPS WITH PROPER ANTI-STATIC MEASURES.
4. Remove the Parallel Interface Boards, one at a time.
5. Remove the old version firmware from U- 7 location and install the replacement firmware, visually confirming all pins are seated properly into the socket.
6. Remark the dash number of the board to a -111 using a marker or pen. Install the board back into the card cage.
7. Continue steps 4, 5, and 6 until all PIBs have been updated.
8. Install the new tray loaders per the replacement procedure in the field service manual.
9. Remove the old magnetic catch mechanism from the tray loader cover assembly. Install the

replacement.

CHECKOUT:
Use of Field Service D.T. Manual is required.

1. Perform System Start-up.
2. Perform Tray loader verification from the field service manual.
3. Replace tray loader and electronics bay covers.
4. Verify tray loader door assembly closes and opens properly.

MODIFICATION CONTROL STICKER UPDATE:
Mark off TSB 4 on the Modification Control Sticker.

END OF DOCUMENT

ABBOTT ADD

TECHNICAL SERVICE BULLETIN

SUBJECT:
EMC (Emissions) Level 2 Upgrade

TSB#: **82-003**

ORIGINATOR: **Dan Armstrong**
APPROVED: **Bob Schabel 10-OCT-96**

PRODUCT:
ABBOTT PRISM® (82)

REF. ECN: **10821-131**

Trademark: PRISM is a registered trademark of Abbott Laboratories.

IMPLEMENTATION: ○ **Immediate** ○ **Next Service Call** ○ **Next Failure** ● **Optional** Instruments Requiring Modification: **S/N 1049 and below**	TSB Part/Kit #: **1-55607-01, -02** TSB Effectivity/ Part(s) Availability: **10-OCT-96** **TSB Tracking by Serial # required (IMMEDIATE TSB's ONLY)** ○ YES ● NO	Upgrade Time: **31.0 Hrs.** Validation Time: **28.5 Hrs.** Total Mod. Time: **59.5 Hrs** ****NOTE** The instrument must be at TSB Level 002 prior to performing this TSB.**

I. DISTRIBUTION:

Worldwide

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

II. PURPOSE:

This Technical Service Bulletin (TSB) is to inform the Worldwide Service Organizations of the release of a CE Mark Certified PRISM® instrument configuration. This configuration for newly manufactured instruments is mandatory for countries in the European Community (EC) only, but may also be marketed in countries not being members of the European Community. This TSB also provides modification instructions to the affected European service organizations on the steps needed to upgrade current non-CE Mark PRISM® instruments to the CE Mark configuration.

The "Communauté Européenne" (CE) Mark is a label placed on a product to indicate conformance to one of the European Community (EC) directives. In this case the CE Mark is related to the emissions of, or susceptibility to, electro-magnetic disturbances, specified in the Electro Magnetic Compatibility (EMC) directive and Low Voltage directive.

All PRISM® instruments shipped from Dallas Manufacturing, to either CE or Non-CE Mark countries will be the CE/UL Version only under the List Number: 6A36-04 (6 channels) and, 6A36-05 (4 channels). The -04 and -05 indicates the CE Mark configuration.

III. ADMINISTRATIVE NOTES:

This is an optional TSB.

Definition: Countries, that are complying to European Community directives are specified as CE Mark countries in this document. Countries, that are not complying with European Community directives are specified as non-CE Mark countries in this document.

Non-CE Mark countries (i.e., USA, Japan, Thailand, Australia, etc...) will not be affected by this TSB.

Instruments currently in customer accounts in CE Mark countries will be modified at the Country Manager's discretion, or upon specific customer's request.

Manufacturing will support CE Mark instruments and service parts. CE Mark service parts are approved for use on Non-CE Mark instruments due to obsolescence of some replacement parts.

Service organizations in the EC will be responsible for forecasting/ordering CE Mark modification kits and spare parts through normal channels.

Instruments Requiring Modification: (within the CE Mark countries).

Instruments that receive complete reconditioning (complete disassembly and upgrading), defined as Level III Servicing, must be upgraded to the CE Mark configuration. See 2nd Hand Equipment for Seed Account information.

Definitions related to CE Mark Countries: (Effective 01/01/96)

New Equipment: Equipment not previously operated by an end user (customer) within the CE Mark countries as of 01/01/96.

2nd Hand Equipment: Equipment previously operated by an end user (customer) within the CE Mark countries as of 01/01/96 and has not been remanufactured. The Seed instruments are included in this definition. Upon completion of the upgrade, to keep accurate the site specific declaration of conformity and the individual technical construction file for each instrument, you must inform Area Customer Service (Hannes Bauer and Eric Ragazzoli) by E-mail or fax (+49 6122 58 1521 or +49 6122 58 1315). This information must include the instrument serial number, its location and the date when the upgrade was performed.

Remanufactured Equipment: Instruments that receive complete reconditioning; like new condition (complete disassembly and upgrading), defined as Level III Servicing.

Repaired Equipment: Equipment that has been serviced with replacement of damaged/worn parts with equivalent parts; activity performed at a customer site or Abbott designated facility. Repair includes;

1. Performing Mandatory TSB's
2. Cleaning and decontaminating operator accessible areas

3. Making repairs if needed
4. Confirming instrument operation
5. Checking or assessing physical appearance (i.e. condition of covers, etc..)

Note: Repair does not include remanufacturing (complete disassembly and upgrade).

New Placements: (CE Mark Countries)

Effective 01/01/96 Abbott PRISM® Instruments shipped from Manufacturing will be of the CE Mark configuration. The TSB modification sticker located in the instrument will have 02 and 03 marked.

Servicing: activities as of 01/01/96

1. Instruments installed or modified after 01/01/96 and identified with the CE Mark label must be serviced with CE approved parts.
2. Instruments in customer accounts prior to 01/01/96, considered 2nd hand instruments, may be serviced with both type of parts.

NOTE 1: Field update/modification may be performed at the customers request and the country manager's discretion.

NOTE 2: As this TSB is Optional, no credit will be issued for Labor & Travel expenses or for Parts used to perform upgrade.

New Placements: (Non-CE Mark countries)

Effective 01/01/96 Abbott PRISM® Instruments shipped from Manufacturing will be of the CE Mark configuration. The TSB modification sticker located in the instrument will have 02 and 03 marked.

Servicing: No impact to current service practices.

IV. SPECIAL TOOLS:

Standard FSR/FSE tool kit.

V. PARTS:

Please inventory the kit prior to performing any changes.

DOMESTIC: Same as International but only training instruments in Dallas and possibly Engineering instruments in Abbott Park will require the upgrade.

INTERNATIONAL:

QTY	PART NUMBER	DESCRIPTION
1	1-55607-01	EMC Level 2 kit for a 4 channel which includes instructions
1	1-55607-02	EMC Level 2 kit for a 6 channel which includes instructions

Refrigerator -02 is not required for this upgrade. If the original one is operational do not upgrade it.

SERVICE KIT IMPACT:
Once this upgrade is complete, only CE mark components may be used for repairs.

REPLACED PARTS:
Dispose of per site requirements for contaminated material.

COMPATIBILITY:
New components are downward compatible. Only CE marked components may be used on these instruments. Components include PIB's, multiple cables, and reagent pump assemblies.

VI. PROCEDURE:

Prior to this upgrade, the instrument should be run as per the customer operations. Any corrective action should be performed prior to this upgrade.

This upgrade will require multiple ferrites. Spares have been included. The bill of material identifies the number of spares you will have after the upgrade.

Use of Field Service D.T. Manual is required for certain procedures in this TSB.

MODIFICATION STEPS:

1. Perform System Power Off (VP-1).
2. Remove the following covers (PL - COVERS) , Sample Access Front and Rear, Optics, tray loader, heater controller, rear cover for access to the power supply.
3. Follow the instructions included in the upgrade kit.
4. All pumps will require the driver PCB to be changed. Instructions are included in the package for this. Ensure ESD protection when replacing these PCBs.
5. Upgrade will require the replacement of all 7 parallel interface boards. If possible return old version boards.
6. When installing ferrites take care not to drop them. They will break if dropped or hit.

CHECKOUT:

Use of Field Service D.T. Manual is required.

1. Replace all covers previously removed.
2. Perform System Start-up VP-2.
3. Perform VP-51 Volume Validation for all pumps.

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

4. Perform Optics validation.
5. Perform Assay run.

MODIFICATION CONTROL STICKER UPDATE:
Mark off TSB 03 on the Modification Control Sticker.

END OF DOCUMENT

ABBOTT ADD

TECHNICAL SERVICE BULLETIN

SUBJECT:
EMC (Susceptibility) Level 1 Upgrade / CE Mark Certified PRISM®
CE Mark Upgrade Procedure and Modifications

TSB#: **82-002**

ORIGINATOR: **Dan Armstrong**
APPROVED: **Bob Schabel 10-OCT-96**

PRODUCT:
ABBOTT PRISM® (82)

REF. ECN: **10821-131**

IMPLEMENTATION:	TSB Part/Kit #: **1-55607-03**	Upgrade Time: **8.0 Hrs.**
○ Immediate ○ Next Service Call ○ Next Failure ● Optional	TSB Effectivity/ Part(s) Availability: **10-OCT-96**	Validation Time: **6.5 Hrs.**
Instruments Requiring Modification: **S/N 1049 and below**	**TSB Tracking by Serial # required (IMMEDIATE TSB's ONLY)** ○ YES ● NO	Total Mod. Time: **14.5 Hrs.** ****NOTE** The instrument must be at TSB Level 001 prior to performing this TSB.**

I. DISTRIBUTION:

Worldwide

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

II. PURPOSE:

This Technical Service Bulletin (TSB) is to inform the Worldwide Service Organizations of the release of a CE Mark Certified PRISM® instrument configuration. This configuration for newly manufactured instruments is mandatory for countries in the European Community (EC) only, but may also be marketed in countries not being members of the European Community. This TSB also provides modification instructions to the affected European service organizations on the steps needed to upgrade current non-CE Mark PRISM® instruments to the CE Mark configuration.

The "Communauté Européenne" (CE) Mark is a label placed on a product to indicate conformance to one of the European Community (EC) directives. In this case the CE Mark is related to the emissions of, or susceptibility to, electro-magnetic disturbances, specified in the Electro Magnetic Compatibility (EMC) directive and Low Voltage directive.

All PRISM® instruments shipped from Dallas Manufacturing, to either CE or Non-CE Mark countries will be the CE/UL Version only under the List Number: 6A36-04 (6 channels) and 6A36-05 (4 channels). The -04 and -05 indicates the CE Mark configuration.

III. ADMINISTRATIVE NOTES:

This is an optional TSB.

Definition: Countries, that are complying to European Community directives are specified as CE Mark countries in this document. Countries, that are not complying with European Community directives are specified as non-CE Mark countries in this document.

Non-CE Mark countries (i.e., USA, Japan, Thailand, Australia, etc...) will not be affected by this TSB.

Instruments currently in customer accounts in CE Mark countries will be modified at the Country Manager's discretion, or upon specific customer's request.

Manufacturing will support CE Mark instruments and service parts. CE Mark service parts are approved for use on Non-CE Mark instruments due to obsolescence of some replacement parts.

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

Service organizations in the EC will be responsible for forecasting/ordering CE Mark modification kits and spare parts through normal channels.

Instruments Requiring Modification: (within the CE Mark countries).

Instruments that receive complete reconditioning (complete disassembly and upgrading), defined as Level III Servicing, must be upgraded to the CE Mark configuration. See 2nd Hand Equipment for Seed Account information.

Definitions related to CE Mark Countries: (Effective 01/01/96)

New Equipment: Equipment not previously operated by an end user (customer) within the CE Mark countries as of 01/01/96.

2nd Hand Equipment: Equipment previously operated by an end user (customer) within the CE Mark countries as of 01/01/96 and has not been remanufactured. The Seed instruments are included in this definition. Upon completion of the upgrade, to keep accurate the site specific declaration of conformity and the individual technical construction file for each instrument, you must inform Area Customer Service (Hannes Bauer and Eric Ragazzoli) by E-mail or fax (+49 6122 58 1521 or +49 6122 58 1315). This information must include the instrument serial number, its location and the date when the upgrade was performed.

Remanufactured Equipment: Instruments that receive complete reconditioning; like new condition (complete disassembly and upgrading), defined as Level III Servicing.

Repaired Equipment: Equipment that has been serviced with replacement of damaged/worn parts with equivalent parts; activity performed at a customer site or Abbott designated facility. Repair includes;

1. Performing Mandatory TSB's
2. Cleaning and decontaminating operator accessible areas

3. Making repairs if needed
4. Confirming instrument operation
5. Checking or assessing physical appearance (i.e. condition of covers, etc..)

   Note: Repair does not include remanufacturing (complete disassembly and upgrade).

New Placements: (CE Mark Countries)

Effective 01/01/96 Abbott PRISM® Instruments shipped from Manufacturing will be of the CE Mark configuration. The TSB modification sticker located in the instrument will have 02 and 03 marked.

Servicing: activities as of 01/01/96

1. Instruments installed or modified after 01/01/96 and identified with the CE Mark label must be serviced with CE approved parts.
2. Instruments in customer accounts prior to 01/01/96, considered 2nd hand instruments, may be serviced with both type of parts.

   NOTE 1: Field update/modification may be performed at the customers request and the country manager's discretion.

   NOTE 2: As this TSB is Optional, no credit will be issued for Labor & Travel expenses or for Parts used to perform upgrade.

New Placements: (Non-CE Mark countries)

Effective 01/01/96 Abbott PRISM® Instruments shipped from Manufacturing will be of the CE Mark configuration. The TSB modification sticker located in the instrument will have 02 and 03 marked.

Servicing: No impact to current service practices.

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

IV. SPECIAL TOOLS:

Standard FSR/FSE tool kit

V. PARTS:

DOMESTIC: Same as International but only training instruments in Dallas and possibly Engineering instruments in Abbott Park will require the upgrade.

INTERNATIONAL:

QTY	PART NUMBER	DESCRIPTION
1	1-55607-03	EMC Level 1 kit including instructions
4	1-51106-02	Dispenser Assembly
4	1-51107-02	Dispenser Assembly
6	1-51108-02	Dispenser Assembly
2	1-51109-02	Dispenser Assembly

SERVICE KIT IMPACT:
DV Dispenser Assemblies must now be the -02 version for any repairs on an instrument with this incorporated TSB.

REPLACED PARTS:
Dispose of per site requirements for contaminated material.

COMPATIBILITY:
New components are downward compatible. The -01 version Dispenser Assembly is not upward compatible on CE marked instruments.

VI. PROCEDURE:

Use of Field Service D.T. Manual is required for certain procedures in this TSB (i.e. covers and dispensers).

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

MODIFICATION STEPS:
Removal and Replacement:

1. Perform System Power Off (VP-1).
2. Remove the following covers (PL - COVERS), Sample Access Rear, Computer, and Optics.
3. Remove the Rack plate assembly (RR - B.13)
4. Refer to page 12 for location of cable 51116 and remove it from the instrument. Install the new cable per pages 12 and 13.
5. Channel DV dispensers will be changed to the -02 versions. Transfer stations will remain. Remove the Dispense Verify Sensor Assemblies from each channel. Replace the Dispense Verify sensor Assemblies using pages 14, 15, and 16 for reference.
6. Remove and replace the cable from the Z axis power supply to the Level sense Assembly. Refer to Page 17 of the instructions for the location of this cable.
7. Remove the Serial interface box from the computer mounting bracket and replace it with the new version per page 18 of the instructions.
8. Remove the Bit bus cable from the CPU and install the replacement cable. Refer to page 20 of the instructions for reference.
9. Install the ferrite on the Temperature remote sensor cable. Refer to page 19 for location. This item has 2 shipped only 1 will be used.
10. Using the color page after page 20 install the replacement cable for the serial interface box to the computer. Use this page to route all the cables in the computer mount assembly as shown. **It is very important to have the cabling in this figure 8 pattern.**
11. Remove the cable for Bit bus from the PMT's to the CPU. Replace it using page 21 as

reference.

CHECKOUT:
Use of Field Service D.T. Manual is required.

1. Replace the Rack plate assembly and all covers previously removed.
2. Perform System Start-up VP-2.
3. Perform VP-51 Volume Validation for all dispensers.
4. Perform Assay run.

MODIFICATION CONTROL STICKER UPDATE:
Mark off TSB 02 on the Modification Control Sticker.

END OF DOCUMENT

ABBOTT ADD	TECHNICAL SERVICE BULLETIN

SUBJECT:
ABBOTT PRISM® XY Axis Controller Firmware Upgrade

TSB#: **82-001**

ORIGINATOR: **Tom Jacobson**
APPROVED: **John Buckland 11-8-95**

PRODUCT:

REF. ECO:

IMPLEMENTATION: ● **Immediate** ○ **Next Service Call** ○ **Next Failure** ○ **Optional** Instruments Requiring Modification: **S/N 1049 & below**	TSB Part/Kit #: **1-55602-01** TSB Effectivity/ Part(s) Availability: **08-NOV-95** **TSB Tracking by Serial # required (IMMEDIATE TSB's ONLY)** ○ YES ● NO	Upgrade Time: **0.50 Hrs.** Validation Time: **0.50 Hrs.** Total Mod. Time: **1.0 Hrs.** ****NOTE** The instrument must be at TSB Level n/a prior to performing this TSB.**

I. DISTRIBUTION:

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

International

II. PURPOSE:

To notify the field of the need to upgrade the XY Axis Controller Firmware on the ABBOTT PRISM® instrument.

III. ADMINISTRATIVE NOTES:

Upon completion of the upgrade, the ABBOTT PRISM® Program must receive information back for each instrument. This information is to include the serial number of the ABBOTT PRISM® instrument and the date the upgrade was performed. The replaced Controller I.C. must be returned to Dallas for Investigation. A return shipper will be provided in order to facilitate the immediate return of replaced parts.

IV. SPECIAL TOOLS:

N/A

V. PARTS:

REPLACED PARTS:
None

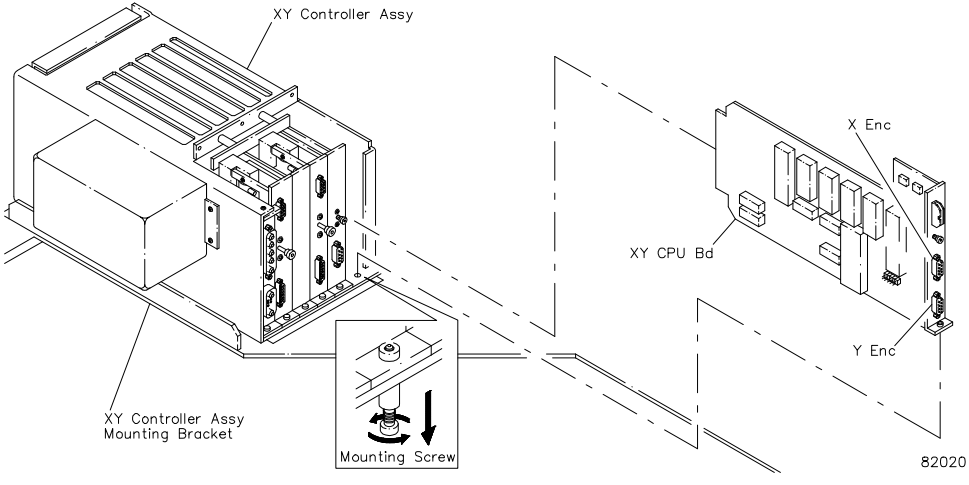
COMPATIBILITY:
N/A

VI. PROCEDURE:

Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

MODIFICATION STEPS:
Removal

1. Perform System Power Off (VP-1).
2. Remove Top Cover (PL - COVERS).
3. Disconnect 2 cables from XY Axis Controller CPU Board.
4. Remove screw securing board to XY Axis Controller Assy.
5. Remove XY Axis Controller CPU Board (1 captive screw).
6. Locate IC U15 on the XY Axis Controller CPU Board.
7. Using anti-static precautions, remove U15 from the XY Axis Controller CPU Board and replace it with the updated version.



Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.

Replacement

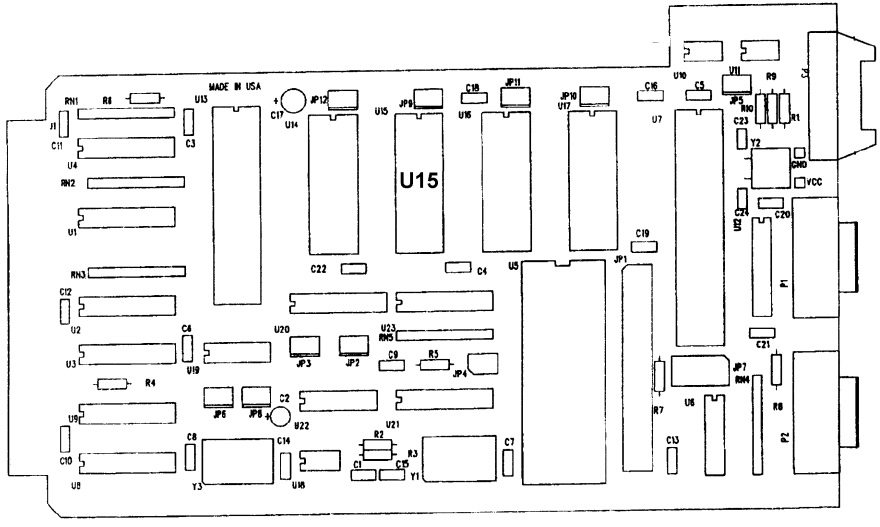
1. Insert XY Axis Controller CPU Board into the XY Axis Controller Assy.
   NOTE: Verify board is fully seated.
2. Connect 2 cables to XY Axis Controller CPU Board.
3. Secure XY Axis Controller CPU Board to XY Axis Controller Assy (1 captive screw).
4. On top side of Magnon Controller locate manufacturer's serial number and Rev. level of XY Axis Controller assembly.
5. On this sticker locate the Revision letter or Revision letter and date, depending on the sticker type.
6. With a permanent marker, mark through the Revision letter and date (if applicable).
7. Adhere new Rev. F level sticker below manufacturer's sticker.

CHECKOUT:

1. Perform System Start-up (VP-2).
2. Perform Sample Manager Position Verification (VP-27).
3. Run assay.

UPGRADING OF KIT BOARDS

1. Locate U15 on the XY Axis Controller CPU Board (1-55126-01).
2. If U15 has a part number other than 21247 it must be replaced.
3. Using anti-static precautions, remove U15 from the XY Axis Controller CPU Board and replace it with the updated version.



MODIFICATION CONTROL STICKER UPDATE:
Mark off TSB 001 on the Modification Control Sticker.

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Potential Biohazard & Voltage Hazard. Observe Proper Safety Precautions.