

PRODUCT:
ABBOTT PRISM® (82)

DATE:
09-AUG-1999

ISA#	SUBJECT	EFFECTIVITY DATE
82-033	Installation Checklist for USO	04-AUG-1999
82-032	Transfer Efficiency Validation Troubleshooting Information	21-JUL-1999
82-031	Version 2.5 Software	16-JUL-1999
82-030	Batch File Number Backup / Restore Utility	30-JUN-1999
82-029	Purge Valve Leak Test Procedure	16-AUG-1999
82-028	Preventative Maintenance Procedure	16-AUG-1999
82-027	Release of Okidata® Okipage 20 Page Printer	24-MAY-1999
82-026	Inspection Procedure for Transfer Syringe and Dispenser	25-MAR-1999
82-025	Version 2.1 Software	17-FEB-1999
82-024	Reagent Pump Cleaning	24-FEB-1999
82-023	Pipettor Assembly - New R&R's and Catalog Numbers	07-JUL-98
82-022	Non-conformance Issues with Dispense Nozzles	23-JUN-98
82-021	Mode Switch Assembly Information	23-JUN-98
82-020	Assembling Reagent Dispense Nozzles	11-MAY-98
82-019	Leaking Purge Valve Contaminating Purge Solution	29-APR-98
82-018	Activator Cap O-Ring Lubrication Procedure	31-JUL-98
82-017	Power Supply Grounding Check	12-JAN-1999
82-016	1.51 Version of Software	13-JAN-98
82-015	1.5 Service Manual	05-DEC-97
82-014	1.5 Version of Software	INCORP.
82-013	Dispenser Nozzle Inspections	22-AUG-97
82-012	Release of ABBOTT PRISM® Reference Manual	17-FEB-97
82-011	ABBOTT PRISM® Version 1.3 Changes	INCORP.
82-010	Release of Unlubricated Transfer Syringe	18-DEC-96
82-009	Release of ABBOTT PRISM® Service Manual 2.0	OBSOLETE
82-008	Tray Ready Sensor	09-SEP-96
82-007	Pipetting and Barcode errors	24-JUN-96
82-006	1.2 Software/Hardware Changes	INCORP.
82-005	Installation Procedure Update (Incorp. in Service Manual 2.0)	
82-004	Volume Validation Procedure (VP-51) Updated (Incorp. in Service Manual 2.0)	INCORP.
82-003	Release of Service Manual (Incorp. in Service Manual 2.0)	INCORP.
82-002	Procedure Updates to Version 1.1 Software	INCORP.
82-001	(Incorp. in Service Manual 2.0) New Error Codes for Version 1.1 Software (Incorp. in Service Manual 2.0)	INCORP.

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

CANCELLED - ISA index number is cancelled.

INCORPORATED - ISA was incorporated into another document or manual.

OBSOLETE - ISA no longer applies. ISA is complete.



SUBJECT: Installation Checklist for USO	ISA#: 82-033
ORIGINATOR: John Buckland	PRODUCT: ABBOTT PRISM® (82)
APPROVED: Dan Armstrong 05-AUG-1999	EFFECTIVITY DATE: 04-AUG-1999

ABBOTT PRISM® is a registered trademark of Abbott Laboratories.

I. Distribution:

United States - (USO-United States Organization)

II. Purpose:

This document includes the ABBOTT PRISM® Installation Checklist to be used during the installation of the instrument. This ISA will be updated as each assay is approved.

III. Description:

The attached checklist (USO Install Checklist.pdf) must be used for installs in the United States. The checklist follows the installation procedure from the Field Service Manual, (Compact Disk catalog number 2-83276-02). The checklist must be completed, signed and left with the customer.

END OF DOCUMENT

Complete this checklist after each successful procedure. Use the Abbott PRISM® System Service Manual Installation section for a more detailed description of each procedure. This checklist and associated instrument printouts must be left with the account as a record of the installation validation

Description				Description									
	Unpack all boxes. Remove all packing materials and tie wraps used for packing / shipping. S/M pages 7-7, 7-9				Perform Refrigerator Temperature Verification (VP-33): Record Temperature reading. S/M page 5-68								
	Verify all ins	stallation compo	nents arrive	d S/M page	e 7-7			Refrigerator Temperature (2-8°C) =					
	Install Reag	jent Bar Code I	Reader and	Holder. S/N	И page 3-45	item #25		Perform Sample Manager Position Verification (VP-27). S/M page 5-60					
	Install Optics Cover Filters. S/M Page 3-43 item #4					Perform Z Axis Up Sensor Alignment (VP-31). S/M page 5-66							
	Install Pipette Tip Waste Container. S/M Page 3-45 Item #11. Unpack 2nd tip chute,tip container and brush. For customer						Perform Channel Temperature Validation (VP-34).						
	Install Moni	tor/ Keyboard A	rms and Pla	tform. S/M	page 7-10			Attach printouts. S/M page 5-70 Perform Dark Count Verification (VP-23). Attach					
	Install Moni	tor and Keyboai	d and route	cabling. S/I	M page 7-1	1		printouts. S/M page 5-53					
	Install Option	s Assemblies (RR-F2). S/	M pages 7-	13, 4-169			Perform Optics PNF Generation Verification					
		gerator Thermo r 5. Give calibr		•				(VP-17). Attach printouts. S/M page 5-31 Perform Transfer Efficiency (VP-32). Attach					
		rge Solution for						printouts. S	3/M page5-67				
		identification la all Assay Identi							olume Validation uent and Cystie				oparticle d
		Waste Sensor	and Mountin	g Bracket	S/M page		СН#	1	2	3	4	5	6
		y operation of s		-			uР						
	Install Wast	te Cart Ramp a	nd Tray Wa	ste Contain	ers. S/M pa	age 3-29	SDB / Cyst.						
	Level the In	strument (VP-2	0). S/m pag	je 5-37			Cyst.	Perform Sa	ımple Manager	Volume Val	dation (VP-	21) on any (configured
		ste Cart Caster S/M page 7-16	Height. Be :	sure to tight	en lock nut	s after		channel. At	ttach printouts		i-38		Johnston
	Measure and record AC Source Voltage: S/M Page 7-16				Z1	\/orification	<u> </u>	2	oon of and of				
		Voltage (168-2)		0 1 1 0 1					orm Bar Code Reader Verification (VP-29) Do a Print screen at end of cation. Attach printout. S/M page 5-64				
	Connect UPS (RR-E6). Measure UPS Output: S/M page 7-16 UPS Output Voltage (223 -237 VAC) =				Backup current configuration to a disk. S/M page 7-21. Place back up diskette in holder for storage.								
	Set the Power Supply Voltage Select Switch				Configure Assays : First Run								
	Install the System Power Cable (RR-H1). Verify cord is not plugged in before attaching to Prism. S/M page 4-190					1941071001	ayo. Thours		annels				
	Turn on all Power Supply Switches. Measure and						1	2	3	4	5	6	
	Record Volt	tages below (VF	P-25): S/M p	age 5-56					Maintenance	Not used	Not used	Not used	HCV
		d Lead Connec (23.18 - 25.62)		D (P RTN):				1101 0 0 0 0	- Indiritorialis	1101 4004	110t dood	riot doca	110 0
	With Ground Lead Connected to P GND (P RTN): 24V Power (23.18 - 25.62 VDC)= 30V Power (29.18 - 31.62 VDC)= 5V Power (4.9 - 5.5 VDC)= With Ground Lead Connected to D GND (D RTN):												
					Verify environmental requirements are met before assay calibration. Load reagents using Resource Management and Perform Assay calibrations on all channels. (Reference Operations Manual) Attach printouts. S/M page 7-6								
		al (11.4 - 12.6 \					Configure Assays : Second Run						
	-12V Digital (-12.6 to -11.4 VDC)= 5V Digital 1 (5.0 - 5.8 VDC)=						Channels						
		(4.85 - 5.75 VI		in the state of		.i		1	2	3	4	5	6
	with stand	Printer Stand an	u Power Str	ıp. mstructi	ons molude	u		Not Used	HCV	Not used	Not used	Not used	Maintenance
	l	Configure Printe e to parallel port		. ,		3		Perform Cl O/M page 5	ean Backup Ch 5-104	annel Proce	dure(see O	perations M	anual)
	l	em (RR-E7) S	/M page 4-1	64. Connec	ct to Serial F	Port #2 on				urce Manac	ement and	Perform Ass	sav calibration
	back of Prism. Phone #			Load reagents using Resource Management and Perform Assay calibration on channel 3. (Reference Operations Manual) Attach printouts. S/M page									
	Prime all ch S/M page 7	annels 3 times -19	use Fluidics	Maintenan	ce function			7-6 Perform Da	aily / Weekly Ma	intenance.	Record com	pletion on M	1aintenance
Ch#	1	2	3	4	5	6			pages 9-3, 9-15				
		1110 4					ACCOL	ınt ivame i	and Address:				
	Verify Shroud Lift Assembly mechanical movement. S/M page 7-19												
	Verify UPS can correctly power the system when disconnected from the AC power source. S/M page 7-20			Instrument S/N:									
	Perform Refrigerator Stirrer Verification (VP-26). S/M page 5-59			FSR II) #	Signature:							
			Date										

(July 30, 1999)



SUBJECT:	ISA#:
Transfer Efficiency Validation Troubleshooting Information	82-032
ORIGINATOR: Dan Armstrong	PRODUCT: ABBOTT PRISM® (82)
APPROVED:	EFFECTIVITY DATE:
Dan Armstrong 06-AUG-1999	21-JUL-1999

ABBOTT PRISM® is a registered trademark of Abbott Laboratories.

I. Distribution:

Worldwide.

II. Purpose:

To provide to the Worldwide Field Support Organizations a copy of a Product Information letter (PDF) released from ADD Quality referencing troubleshooting information for Transfer Efficiency Validation. The letter will be distributed to all Worldwide customers for insertion into the Operations manual. This procedure may be used by customers and Field Support personnel.

III. Description:

The attached letter (PI 1013-1999) describes a cleaning procedure of the conjugate and transfer wash fluidics tubing if Transfer Efficiency Validation fails. The procedure requires the Transfer Efficiency Wash solution to be left in the tubing for 4 to 24 hours. This procedure has shown Transfer Efficiency Validation will fail less often.

END OF DOCUMENT



Abbott Diagnostic Division

Quality Systems

Abbott Laboratories 100 Abbott Park Road Abbott Park North, IL 60064

Product Information Issue Date: 21 July 1999

Product

- List No. 6A58-05 ABBOTT PRISM® Transfer Efficiency Kit
- List No. 6A58-02 ABBOTT PRISM® Transfer Efficiency Wash Kit

Reason

This Product Information is being issued by Abbott Diagnostics Division to inform you of troubleshooting information for the Transfer Efficiency Validation procedure.

Current Status

Abbott Diagnostics has determined that residual wash solution from the ABBOTT PRISM® assays may interfere with the Transfer Efficiency Validation procedure by impacting the percent transfer efficiency and/or percent CV.

Cleaning the wash fluidics with Transfer Efficiency Wash for a minimum of 4 hours followed by a double prime prior to performing the Transfer Efficiency Validation has been shown to decrease the need for repeat Transfer Efficiency testing.

Action

Clean Wash Fluidics Procedure:

Step	Action	Comment
1	If assay reagents have not been purged from	See ABBOTT PRISM®
	the channel(s) to be tested, perform Purge	Operations Manual, Section 5:
	Reagent Fluidics System procedure.	Operating Instructions,
	Or	Subsection: Purge Reagent
	If Transfer Efficiency Validation has just been	Fluidics System.
	performed and does not pass, go to step 8.	
2	From the Main Menu, select:	
	Instrument Preparation	
	Channel Configuration	
3	TAB to select channel(s).	
4	SPACEBAR to select:	
	• XFER_2S if two-step assay channel	
	XFER_3S if three-step assay channel	
	or	
	Not Used for channels not being tested.	
5	• ENTER to save.	
	• ESC to Main Menu.	
6	Disconnect and remove the bottles of transfer	
	wash and conjugate wash from the channel(s)	
	to be tested.	
	Replace with bottles of Transfer Efficiency	
	Wash.	

Continued on next page

Product Information, Continued

Step	Action	Comment
7	Perform Prime Reagent Fluidics System procedure on channel(s) to be tested.	See ABBOTT PRISM® Operations Manual, Section 5: Operating Instructions, Subsection: Prime Reagent Fluidics System.
8	Allow the Transfer Efficiency Wash to remain in the fluidics for 4-24 hours before proceeding with step 9.	
9	Perform Prime Reagent Fluidics System procedure on channel(s) to be tested.	See ABBOTT PRISM® Operations Manual, Section 5: Operating Instructions, Subsection: Prime Reagent Fluidics System.
10	Note that two primes are required after Transfer Efficiency Wash remains in the fluidics for 4-24 hours (step 8). The prime step (3.08) in the Transfer Efficiency Validation procedure must be performed.	See ABBOTT PRISM® Operations Manual, Section 6: Instrument Calibration Procedures, Subsection: Transfer Efficiency Validation.
	Perform the Transfer Efficiency Validation procedure.	

For reference, place this communication in your ABBOTT PRISM® Operations Manual, Section 6, Transfer Efficiency Validation.

Contacts

If you have any questions regarding this information, please...

- Contact your local Abbott Diagnostics Technical Support Organization.
 (In the US, contact the Customer Support Center at 1-800-323-9100)
- Please refer to: PI 1013-1999



SUBJECT: Version 2.5 Software	ISA#: 82-031
ORIGINATOR: Dan Armstrong	PRODUCT: ABBOTT PRISM® (82)
APPROVED: Dan Armstrong	EFFECTIVITY DATE: 16-JUL-1999

ABBOTT PRISM® is a registered trademark of Abbott Laboratories. Abbott DMS[™] is a trademark of Abbott Laboratories

I. Distribution:

Worldwide.

II. Purpose:

This document describes the changes incorporated into Version 2.5 Software.

III. Description:

- In this update the screen messages which appear to the operator upon selecting the
 option to exit Sample Processing, have been re-ordered to minimize the possibility of
 unintentionally exiting Sample Processing prior to loading a Release Control.
- The capability of interfacing the ABBOTT PRISM Instrument to the US Marketed ABBOTT DMS[™] via instrument interface (serial port 1) is in this version. Configuration screens allow for this option.
- Version 2.1 Operations Manual (LN 6A36-97) may continue to be used while operating the instrument with Version 2.5 Software.

4. New Error Code added:

24-212 Log: Simple Format Port Failure

Alarm: Simple Format Port Failure

Window:

Audio: Urgent Alarm

Possible Cause(s)	Corrective Action - Operations Manual
Hardware error occurred during the configuration of	Immediately contact Abbott Laboratories
the simple format host interface port.	Diagnostics Division Customer Support
	Representative.
	Corrective Action - Field Service Manual
	Verify Parameters between DMS and instrument
	are correct.
	Check cable connections at DMS and instrument.
	Replace interface port assembly.
	Replace cable between DMS and instrument.

END OF DOCUMENT



SUBJECT: Batch File Number Backup / Restore Utility	ISA#: 82-030
ORIGINATOR: Dan Armstrong	PRODUCT: ABBOTT PRISM® (82)
APPROVED: Dan Armstrong 06-AUG-1999	EFFECTIVITY DATE: 30 -JUN- 1999

ABBOTT PRISM® is a registered trademark of Abbott Laboratories.

I. Distribution:

This ISA has been created for the following location. Centre de Transfusion Sanguine de Liege, Belgium, Instrument Serial Number 1041.

II. Purpose:

This utility disk will backup and restore the instrument Batch File number to allow Prism batch data to be accepted by the site Host Computer.

III. Description:

This ISA is to be completed during the upgrade of the instrument to Version 2.1 Software. Follow instructions in TSB 82-027.

BATCH NUMBER - BACKUP UTILITY

After Modification Step 2.c but before 2.d perform the following:

- (1) Insert the Batch Number Backup / Restore Utility Disk into the floppy drive
- (2) At the DOS prompt, type:

A:\BKPBATCH

- (3) Remove the disk from the floppy drive. Set it aside to be used after Version 2.1 Software has been successfully installed.
- (4) Continue with Step2.d of 2.1 Modification

BATCH NUMBER - RESTORE UTILITY

After Modification Step 4.d but before 4.e perform the following:

- (1) Insert the Batch Number Backup / Restore Utility Disk into the floppy drive
- (2) At the DOS prompt, type:

A:\RESBATCH

- (3) Remove the disk from the floppy drive.
- (4) Continue with Step 4.e of 2.1 Modification.

VERIFICATION

Verification of operation will be performed after next batch record is sent to the host computer. Support personnel will provide to the customer documentation which indicates acceptable operation of this change.

End of Document



SUBJECT: Purge Valve Leak Test Procedure	ISA#: 82-029
ORIGINATOR: Scott Hamblin	PRODUCT: ABBOTT PRISM® (82)
APPROVED: Dan Armstrong 04-AUG-1999	EFFECTIVITY DATE: 16-AUG-1999

ABBOTT PRISM® is a registered trademark of Abbott Laboratories.

I. Distribution

Worldwide

II. Purpose

This document describes the recommended procedure for testing the plastic type Purge Valve (1-52527-01) for leaks. This test is important to ensure the correct function of the fluidics system and to prevent contamination of the purge solution as described in ISA 82 -019 *Leaking purge valve contaminating purge* solution.

This procedure is not intended to be used for testing the new 'ceramic disc' style Purge Valves (1-55942-01).

III. Description

This test is performed using the Leak Test Fittings (1-65766-01) and Transfer syringe (6A36-30). A wristwatch or another method of timing a 2 minute interval will be needed also. With the purge valve in the off state the syringe is connected to the purge valve purge inlet port using a short length of tubing. A vacuum is applied to the purge valve inlet port by pulling the syringe plunger out. A metal retainer is supplied to lock the plunger in that position. A small amount of purge solution will then be drawn into the syringe. If the syringe is held upside-down then any air leaking into the valve will bubble up through the solution. Counting the bubbles will indicate if the valve is leaking.

During a 2 minute period a small number of bubbles is expected from a normal valve. Approximately 4 bubbles is typical of a normally operating valve but as the valve wears the bubble counts may increase.

A bubble count of greater than **19 bubbles** in a two minute period indicates that the valve should be replaced.

IV. Parts

Transfer syringe Leak test tool fittings 6A36-30

1-65766-01

Note: The leak test tool fittings kit includes the tubing, plunger retainer, unions and plug.

Transfer syringe

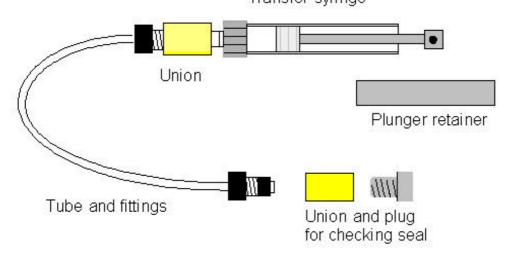


Figure 1. Purge valve leak test tool

V. Procedure

- 1. Perform a purge on all channels to be tested.
- 2. Assemble the Leak Test Tool by connecting the syringe, union and tubing as shown in Figure 1.
- 3. Check that the tool does not leak by drawing a small amount of liquid into the tubing and then sealing the end with the second union and plug. Pull back the plunger and lock it in the out position with the plunger retainer. Watch the system for at least two minutes to make sure that no bubbles are leaking into the tool. Any bubbles indicate a leak in the tubing or connections that must be corrected before using the tool.
- 4. After checking the tool remove the union and plug.
- 5. Prime the test tool by placing the free end of the tubing into the purge bottle and drawing up the solution with the syringe. Pulling slowly should help prevent bubbles from forming. Now expel the purge solution and any air in the system by pushing the plunger in.
- 6. Once all of the air has been removed from the tool the syringe plunger should remain pushed all the way in.
- 7. Disconnect the purge bottle tubing from the purge valve and connect the leak test tool to the purge valve purge inlet port. This may require you to remove the wash solution bottles and rack.
- 8. Pull the syringe plunger until you can lock it in the out position using the plunger retainer. Most of the liquid in the tubing will be drawn into the syringe and some small bubbles may be formed. After a few seconds the small bubbles should disperse or attach themselves to the side of the syringe wall. They will not interfere with the test and should not be counted. Flicking the side of the syringe with your finger should help remove them.
- 9. Hold the tool so that the syringe plunger is pointing upwards (the tool is vertical) and begin timing.
- 10. Watch closely for air bubbles moving through the tubing, entering the syringe and bubbling up through the liquid. Count any bubbles that enter the syringe for exactly 2 minutes.

- 11. If the number of bubbles counted is greater than 19 then the purge valve should be replaced and the purge solution discarded. Refer to the Service Manual (RR D 2.2 Purge Valve assembly) for further information.
- 12. Reconnect the purge valve inlet line to the purge bottle tubing.
- 13. Purge the system.

END OF DOCUMENT



SUBJECT: Preventative Maintenance Procedure	ISA#: 82-028
ORIGINATOR: Scott Hamblin	PRODUCT: ABBOTT PRISM® (82)
APPROVED: Dan Armstrong 04-AUG-1999	EFFECTIVITY DATE: 16-AUG-1999

ABBOTT PRISM® is a registered trademark of Abbott Laboratories.

I. DISTRIBUTION:

Worldwide

II. PURPOSE:

This procedure replaces the existing Preventative Maintenance (P.M.) procedure in the Service Manual. It incorporates the inspection of all reagent and transfer wash nozzles to be performed at each PM. Two recommended protocols are defined.

- 1. 90 Day P.M. procedure
- 2. Additional yearly P.M. procedures

This document contains checklists to document the P.M. when completed. Each item on the checklist is explained in detail in the attached list of recommended maintenance guidelines. The purpose of the guidelines is to suggest effective maintenance techniques and is not intended to be the required methods.

Additional procedures may be included in the P.M. as needed.

III. DESCRIPTION:

Carefully read the attached maintenance guidelines and keep them with you for reference as needed. US Letter and A4 size checklist forms are provided for you to use when performing the P.M. As each item is completed successfully you should place a check mark (tick) in the column immediately to the right. When all items are marked with a tick the P.M. is complete and should be signed by you and the customer. A copy of this checklist should be left at the customer site along with any other required documentation (including printouts from instrument validations, verifications and calibrations).

The P.M. is very comprehensive and may take longer than 8 hours to complete. If the P.M. is to be performed over a number of days and the customer plans to use the instrument in between them

then it is important that all appropriate verifications and validations are completed each day. **This** includes an assay calibration for all active channels.

If the P.M is to be performed over two days or by two people the protocol can be split in two. Table 1 shows an example of how this may be done. One group of maintenance items (A) requires removal of the rack plate while the other does not.

Table 1. Splitting the P.M into two groups of maintenance items.

Maintenance list A	Maintenance list B
Transfer syringes	Clean or replace all air filters
Transfer Dispensers & channel	Optics & O-rings
Reagent dispensers and DV optics	Optics shroud gaskets (yearly)
Microparticles tube (yearly)	Reagent pumps
XY teach	Purge valves
Rack loader	XY gantry belts
U.P.S	Flex cable
Activator cap	Z-axis drive and tip-on cables
Inspect customer logs	Probe tips
Replace compressor filters (yearly)	Refrigerator
	Lubricate lift Shroud
	Optics PNF generation
	Channel drive belts

Maintenance Guidelines

The following material should be regarded as reference material for performing the P.M. The maintenance items are not intended to be performed in the order presented.

Inspect the customer maintenance logs

Before starting the P.M. you should ensure that the customer is performing the required maintenance on the instrument. Inspect customer maintenance log and check results for the following;

- 1. Optics Validation (should be performed monthly)
- 2. Channel temperature Validation (should be performed monthly)
- 3. Refrigerator temperature Verification (should be performed each day)

Shutdown and power off

Follow VP -1 System power off

Remove the front and rear covers

Refer to the Service Manual PL - Covers.

Clean air filters

The instructions for removing and washing the filters can be found in the Service Manual verification procedures;

VP - 40 Optics cover filter cleaning

- VP 41 Refrigerator filter cleaning
- VP 43 Card cage fan filter cleaning
- VP 44 System power supply inlet filter cleaning

Replace compressor filters (Yearly)

The six air tip wash compressors are mounted on a plate that sits under the tip waste bin. The compressor air inlets are fitted with a small plastic filter that should be replaced once per year.

Note: Refer to RR - D5 *Air tip wash filter* for instructions on how to replace the filters. Filter part number 1-52719-01

Inspect the channel drive belts

It may be easier to see the belts if you remove the reaction trays from the destacker. With the power off the belt should rotate freely. At the tray loader end of the instrument rotate the channel belt and check for cracked or broken lugs. Look for cracks around the bond between the lug and the belt. With power reapplied the channel transport motor should hold the belt firmly. Try to move the belt back and forth. A small amount of backlash is normal. A slipping belt may be caused by a loose transport motor pulley.

XY gantry belts

There are four belts to be examined. The two timing belts are the long black toothed belts running the length and width of the gantry. The X and Y drive belts are much smaller and run from the X and Y motors to the metal pulleys that drive the gantry. The correct procedures for tensioning the X and Y timing belts can be found in the Service manual VP-9 and VP-10. With the power off move the sample manager by hand and listen carefully for squeaking and binding. When moving the sample manager observe how the X and Y drive belts move between the two pulleys. A stretched belt may exhibit a change in tension as it rotates and this can often be seen or felt by pushing on the belt. Sometimes a pinching or squeaking noise may be heard. Any belt suspected of being stretched should be replaced.

Note: The correct timing belt tensioning procedures must be used (VP - 9 & VP -10). An over-tightened belt may seriously damage the gantry.

Probe Tips

Look closely at the two metal probes that pick up the plastic pipette tips. A burred or scratched probe may cause a leaky seal when picking up tips leading to pressure sensing errors. Replace any damaged probe tips.

Z1 and Z2 axis drive cables

The plastic coated steel Z-axis drive cables may begin to split if damaged. The blue plastic coating on the cable begins to turn black and small strands of steel may protrude through the plastic coating. Clean the cable with a dampened cloth. Move the nozzle up and down and inspect it closely for signs of damage. If any of the steel is protruding through the plastic then the cable should be replaced. Check both Z1 and Z2 cables.

Note: Refer to ISA 82-023 *Pipettor assembly new R&R and catalogue numbers* for instructions on cable replacement. If the cables are found to be damaged then VP - 4 *Tip remover alignment* should be performed to ensure that the nozzles are not catching on the stripper assembly.

Z1 and Z2 axis Tip-on sensor cables

Both Z1 and Z2 sides of the sample manager have a tip-on sensor. The coiled black cables that connect the sensors to the Z-axis backplane are at the front of the sample manager. The cables move when the probe tip is extended and should be checked for signs of fatigue or damage. Replace any faulty cables.

Refer to RR A1.5 Z axis tip on sensor assembly for instructions on replacing the cable and sensor.

Inspect Optics O-rings

The optics assembly should fit snug into the lift shroud. The O-rings on the optics unit help achieve a secure (and light proof) seal. Insert the optics assembly and remove it to check that the O-rings are gripping a little and resisting movement. The O-rings should not be cracked or split. Replace the O-rings if the fit is loose due to worn O-rings.

Inspecting light pipes

Remove the optics from the lift shroud assembly and inspect the end of the light pipes for signs of build up or damage. Some spatter may be found here from the activator dispense. Clean them with a damp cloth and reinstall the optics. An Optics PNF generation will now be required and is included in both P.M. protocols.

Refer to VP -39 Optics light pipes cleaning for more information.

Check optics shroud gaskets (Yearly)

Disconnect the LVPS and remove the optics unit. Carefully pop the optics station and remove the entire lift shroud assembly. Inspect the optics shroud gaskets on the underside of the optics. They should have a clean furry appearance and not be crushed flat. Damaged gaskets may allow light to leak into the optics and elevate dark counts. Replace any damaged gaskets.

Refer to RR - F7 Shroud Gasket

Lubricate lift shroud bearings

The synthetic oil provided with the IMX spare parts kit is used to lubricate the lift shroud bearings. This prevents the lift shroud from binding which can cause the optics to not seal correctly with the reaction trays and sometimes cause shroud down errors.

Note: Synthetic lubricant part number 14237 - 015

Procedure

- 1. Remove the optics assembly using RR F2 Optics assembly.
- 2. Rotate the encoder wheel so that the lift block is in the down position.
- 3. Apply a thin coating of synthetic lubricant to the shaft around the top of the bearing.
- 4. Manually move the lift block up and down to work in the lubricant.
- 5. Reinstall the optics assembly using RR -F2 Optics Assembly

Optics PNF generation

Perform VP - 17 Optics PNF generation.

Inspect the Rack Loader

With the power off manually move the rack loader mechanism using the handle at the right. If any binding is evident the lead screw that drives it may be lubricated using synthetic lubricant. Apply a small amount and carefully work it in by moving the mechanism from left to right.

Reagent pumps

Disconnect and remove the reagent wash solutions and the bottle holder racks. Inspect each pump for signs of leaks and solid residue. A small amount of salt and coloured deposits is generally acceptable. It is often found on the Conjugate Wash pump. A small amount may be found around the pump heads. If any of the pumps shows signs of excessive leakage and is wet or dripping then the connections should be checked and pump may need to be replaced. If the pumps are not leaking then take a damp cloth and wipe away any residue.

Refer to RR - D1 Reagent pump assembly if pump replacement is required.

Check purge valves.

Ensure that the purge valve is not allowing air to leak into the fluidics system by performing a leak test procedure. A small leak may result in reagents back siphoning into the purge bottle. Check the purge solution for any evidence of microparticle contamination. Check all channels but look very closely at any channel running HCV.

Refer to ISA 82 - 029 *Purge valve leak test procedure* and ISA 82 - 019 *Leaking purge valve contaminating purge solution* for more information.

Inspect transfer syringes and dispensers

Check the transfer syringes for any signs of shearing plastic material from the tip. It looks like a clear 'gel' accumulating on the top of the syringe plunger. Inspect the transfer wash dispensers if any build-up is found. Solid residue on the bottom of the channel at the transfer station may indicate that the transfer wash dispenser is blocked and splashing liquid. Clean the deposits from the channel and check the transfer syringe and dispense nozzle for blockages.

Refer to ISA 82 - 026 Inspection procedure for transfer syringe and dispenser.

Inspect microparticles tubing (Yearly)

The tubing between the microparticles pump and dispense heads may collect a hard white residue on the inside of the reagent lines that is not removed by other routine cleaning procedures. It may also be found on the tubing between the pump inlet and the purge valve. If any of these tubes shows signs of excessive build up they should be replaced. Pay close attention to the HCV channel. Take care to use the correct tubing and cut it to the exact same length using the tube cutter tool.

Refer to RR - D9 Component to component tubing when replacing microparticles tubing.

Inspect reagent dispense nozzles and DV optics

To inspect the reagent dispensers the rack plate must be removed and each individual reagent dispense station unscrewed and carefully examined. Remove the rack plate and begin removing

the reagent dispense stations. Inspect each reagent nozzle for solid material occluding the nozzle or air tip wash system. Clean or replace any nozzles that are blocked or not centered. Using a clean damp cloth wipe away any spatter from the underside of the reagent dispense station and using a damp cotton bud (Q-tip) clean the DV optics.

Refer to RR - C2.2/3 Reagent dispenser and ISA 82 - 022 Non-conformance issues with dispense nozzles.

Perform XY teach for tip racks, sample dispense, stripper, sample racks and calibrators

The alignment procedures are in the Service Manual. Pay careful attention to VP - 4 *Tip remover alignment*. A badly aligned tip stripper may place excessive force on the Z-axis and damage the Z-axis cables. Ensure that VP - 8 *Sample dispense alignment* is set correctly. If the dispense position is set too close to the tray it may result in 4X-106 *High pressure during dispense detected* errors. Complete the following verification procedures.

- VP 3 Z-Reference alignment
- VP 4 Tip remover alignment
- VP 5 Tip rack alignment
- VP 6 Sample rack alignment
- VP 7 Calibrator rack alignment
- VP 8 Sample dispense alignment

Activator cap connection

Connect and disconnect the activator bottle to the tubing. If the activator cap is difficult to connect and disconnect then treat the cap O-rings with Activator cap lubricant by performing ISA 82 -018 Activator cap O-ring lubrication procedure.

Warning: ONLY use the approved lubricant contained within the Activator lube kit. Other lubricants must not be used. Activator cap lubrication kit part number 1-14205-01

Check the refrigerator

Ensure that the system refrigerator is functioning normally. Inspect the door seals and tubing seals to make sure they fit correctly and that no large air leaks are present. Check the temperature by either performing VP - 33 *Refrigerator temperature verification* or (if an external refrigerator monitor is used) inspecting customer records.

Reminder: The System Power Supply waits 10 minutes after power on before switching on the refrigerator. This delay helps prevent damage to the refrigerator's compressor.

Calibrate all channels in routine use

The FSR should verify that the instrument calibrates and runs a successful release control for all channels in routine use before the P.M. can be considered completed. The assay calibration may be performed by the FSR or customer depending on site requirements.

END OF DOCUMENT

Site name Address			ABBOTT	PRISM SI	ERVICE Power Behind Our Promise.
Software version	Serial number				
	. 1	01/	The College of the Co		rision 1.1 April 26 1999
Inspect customer maintenance	e logs	OK	The following alignmen	ts were performed	ОК
Refrigerator temperature verification			XY teach on all positions		
Channel temperature validation					
Optics validation			The following components have been lubricated with approved		
		lubricants			
Prepare the instrument					
		Lift shroud bearings			
Purge all channels			Activator cap connection		
Shutdown and power off			•		_
if necessary		•	Uninterruptable Power Su Optics PNF on all active of	channels	
Card cage fan filters			Check refrigerator temperature		
System Power Supply inlet filters			Calibrate all active chann	els	
Refrigerator filter					
Optics cover filters			As each of the maintenance items are completed sucessfully place a tick (check mark) in the column to the right of the item on this checklist. The PM is complete when all items are checked (except		k mark) in the column
Transfer syringes					
Transfer station dispensers			for yearly items not required).	Sign when completed.	
Reagent dispensers			Disease sign and date wi	an completed	
Optics light pipes		Please sign and date w	nen completed		
Optics O-Rings Channel drive belts					
XY gantry timing belts			Customer		
Gantry flex cables			Customer		
Z1 and Z2 axis drive cables					
Z1 and Z2 Tip on sensor cables			Abbott representative		
Optics shroud gaskets		Yearly	<u>- 1.0.000.10p.000.100.10</u>		
Replace compressor filters		Yearly			
Probe Tips					
Microparticle Tubing		Yearly			
Reagent pumps		,			
Purge valves		ABBOTT PRISM® Prevei	itative Maintenance Checklist		

This P.M. should be performed <u>approximately</u> every 90 days by your Abbott representative. It is not intended to state that the P.M. must be performed exactly at that date. **The checklist is not a list of instructions and should be used in conjuction with the Preventative Maintenance guidelines contained within Abbott Instrument Service Advisory (ISA 82-028) and the Abbott Prism Service Manual.** Additional procedures may be performed as a part of this PM if needed. Note: ABBOTT PRISM® is a registered trademark of Abbott Laboratories.



SUBJECT: Release of Okidata® Okipage 20 Page Printer	ISA#: 82-027
ORIGINATOR: John Buckland	PRODUCT: ABBOTT PRISM® (82)
APPROVED: Dan Armstrong 24-MAY-1999	EFFECTIVITY DATE: 24-MAY-1999

ABBOTT PRISM® is a registered trademark of Abbott Laboratories. Okidata® is a registered trademark of Okidata.

I. Distribution:

Worldwide

II. Purpose:

The purpose of this ISA is to inform the service organization of the ABBOTT PRISM'S ® new approved page printer, which will be taking the place of the present matrix printer, both on new instruments and field replacements. The print speed is 20 pages per minute in simplex mode. The Ram is 4 MB standard, expandable to 68MB. The interface is parallel IEEE 1284 compliant, bi-directional port. The new Printer will not be used for field replacements until the current inventory of the matrix printers is depleted. Follow the below instructions to order and configure the new Okipage 20 printer.

III. Parts:

New printer part numbers:

1) Okidata® Okipage 20 printer 110 volt	6A36-13
2) Okidata® Okipage 20 printer 220 volt	6A36-14
3) 10 foot IEEE 1284 bi-directional cable	6A36-15

Note:

The current printer, Okidata® printer 220 volt, part number 6A36-53 is available until current inventory is gone.

IV. Configuration Instructions:

Follow **Chapter 1** of Okidata's® Okipage 20 Printer User's Guide for **initial set up** of printer.

After initial set up, the printer must be configured to emulate IBM PPR III XL.

- 1) Press the **on-line** button to place the printer off-line.
- 2) Press Menu 1 / Menu 2 button to enter the Level 1 Menu.
- 3) The word **Personality** should be displayed press **Enter** to select the category.
- 4) Press the right arrow key to display selections.
- 5) Stop when you see IBM PPR III XL
- 6) Press **Enter** to select as the default setting. An * will appear to indicate the new default setting.
- 7) Press **on-line** to put the printer back on-line.
- 8) Verify that you can print by doing a print screen from the ABBOTT PRISM®.



Okipage 20 Printer

END OF DOCUMENT



SUBJECT: Inspection Procedure for Transfer Syringe and Dispenser	ISA#: 82-026
ORIGINATOR: Scott Hamblin	PRODUCT: ABBOTT PRISM® (82)
APPROVED: Dan Armstrong 3/25/1999	EFFECTIVITY DATE: 25-MAR-1999

ABBOTT PRISM® is a registered trademark of Abbott Laboratories.

I. Purpose

This document informs the service organization of the need to inspect the transfer reagent fluidics system when performing preventative maintenance. A number of instruments in the field have been identifed as having a 'clear gel like' material inside the transfer syringes. The material clings to the top of the transfer syringe piston and often traps small bubbles. Investigations have shown this material to be a very thin film of 'plastic' which has gradually sheared from the transfer syringe tip as it rubs against the syringe barrel.

It is important to ensure that the film is removed (if present) and that it has not dislodged and blocked the transfer dispense station nozzles. Detailed instructions on how to perform this procedure are provided.

This procedure should be included in the Preventative Maintenance protocol performed every 90 days.

II. Description

- 1. Remove the front and rear cover and rack plate assembly (PL Covers and RR B1.11)
- Carefully inspect each of the transfer syringes for any evidence of the film. It looks like a
 translucent gel sitting on top of the syringe piston tip. It sometimes traps small bubbles in the
 syringe. Important: If any of the syringes appear to contain the film it must be
 completely removed by completing the following steps;
 - 1. If any of the channels to be inspected are primed with reagent then purge them.
 - 2. Disconnect the purge bottle tubing from all channels to be inspected. Perform another purge to fill the tubing and syinges with air.
 - 3. Remove the syringe and disassemble it. Wash the two components (piston and barrell) in clean purge solution. Carefully rub the syringe piston tip with a clean lint free tissue to remove any solid material clinging to it. Rinse the piston and reassemble the syringe. Before re-installing the syringe fill it with purge solution and ensure that no film remains. Reinstall the transfer syringe (RR B2.1).
 - 4. Remove the entire transfer station from the channel by loosening the two large standoffs that secure it (See RR C2.5 Figure 4 -47) Note: <u>Do not loosen the screws that set the position of the transfer wash dispensers.</u> If the dispenser position is changed then re-alignment (VP 18) and the Transfer Efficiency test (VP 32) are required.
 - 5. Visually inspect the nozzles for corrosion, blockage or any other damage. Replace any blocked or damaged transfer dispensers (RR C2.6)

- 6. Test the ability of the transfer dispenser to correctly deliver three streams of liquid (see figure 1) by completing the following steps;
 - Hold the transfer station above a prime & purge tray or tissue to catch any dispensed liquid.
 - Select COMPONENT DIAGNOSTICS/CHANNELS/TRANSFER SYRINGE/CYCLE TRANSFER
 - The software will ask you to load a prime & purge tray (but it is not used to catch the liquid)
- 7. Watch the liquid streams as they are dispensed into the tray you are holding. It is important to verify the following;
 - All three dispensers squirt liquid (none are blocked)
 - All of the streams are straight.
 - The streams do not spray or splash.
- 8. Replace the transfer dispenser if it does not meet these requirements (RR C2.6) and repeat steps 6 8 to verify the new dispenser dispenses correctly.
- 9. Reinstall the transfer station.
- 3. Replace the rack plate assembly (RR B1.11)
- 4. Reconnect all purge bottle tubing and purge all channels.
- 5. Replace the front and rear cover (PL Covers)

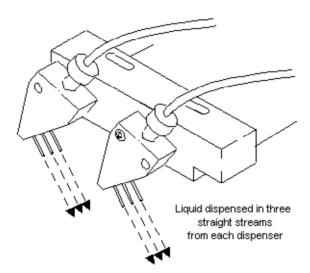


Figure 1. Transfer wash dispensed correctly in three straight streams

Note: The transfer station hardware, DT sensor and cables are not shown here for clarity. It is not required to dissassemble the transfer station to this level to inspect the dispensers.



SUBJECT:	ISA#:
Version 2.1 Software	82-025
ORIGINATOR: Scott Hamblin and Mark D. Redman	PRODUCT: ABBOTT PRISM® (82)
APPROVED:	EFFECTIVITY DATE:
Dan Armstrong 2/16/1999	17-FEB-1999

ABBOTT PRISM® is a registered trademark of Abbott Laboratories.

I. Distribution:

Worldwide.

II. Purpose:

This document describes the changes to hardware and software when upgrading Prism from version 1.52 to 2.1.

III. Description:

A. Hardware.

Upgrading the prism from version 1.52 to software version 2.1 will also require changes to hardware. There will be some minor rerouting additions of reagent and air tip wash tubing. The major changes are outlined below.

1. New style purge valves on backup and HCV channel.

To allow for flexible channel assignment a new type of purge valve is required on the backup channel. With the exception of activator all of the reagents used on channel six will be connected to the new valve. The new valve is a ceramic shear valve type and expected to resist wearing better than the existing design. All tubing connections are easily accessible on the front of the valve.

The existing purge valve will be removed from the HCV channel and replaced with a new style valve. The improved resistance to wear is expected to eliminate any potential problems with microparticles contaminating the purge as described in Prism ISA 82-019.

2. Activator bottle holder.

A new style activator bottle holder will be added. It ensures that the bottle is held vertical with smaller volumes.

3. New bar code labels for reagent tubing connections.

The pending release of new assays for Prism requires the existing color scheme matching each of the reagents with a channel will be removed in 2.1 software. New reagent tubing labels are provided for the reagent tubes. The new labels are printed in black.

4. Control bottle inserts.

Abbott run controls will be available in bottles that may be loaded directly onto the instrument for pipetting. This enhancement eliminates wasted dead volume when utilizing sample cups. The bottles are similar to individual calibrator bottles and are loaded into a sample rack using control bottle inserts.

5. New bar code reader firmware.

New firmware in the bar code reader controller board supports a Codabar checksum algorithm to be used in Japan.

B. Software.

In this update several screen and report formatting problems were corrected as well as some translations when operating in languages other than English. Also several software deficiencies (13 in total) were identified and corrected that may have caused lock ups and AIM codes to be generated. The major changes made to the way in which the instrument operates are detailed below.

1. Support for new assays.

Software version 2.1 has the capability to accommodate up to 20 new assays. At this time the following assays are planned for worldwide release.

HIV O PLUS HBCore HBsAg confirmatory

There are also two new assays planned for release in Japan only.

AUSAB HBcAb

Note: The HBCore assay requires an extra reagent pump and quad head dispenser to be added to channel 5. The new reagent (Cysteine) will be dispensed at station 1 in a similar manner to the specimen diluent on the HCV channel. These parts are not provided as a part of the upgrade but available as a separate upgrade kit.

2. Flexible channel configuration.

A two step channel may be configured to run any of the two step assays available. A three step may run any three step assay. In the future when more assays are available, this enhancement will be necessary. During this upgrade the Abbott representative will configure each channel on the Prism to run a specific assay The assays will be configured exactly as they are with the current version 1.52 software. The exception to this will be with the instruments in Japan.

3. Expanded the maximum CV on volume validation to 10%.

Investigations into the volume validation procedure have shown the CV percentage for calibration, confirmation and validation could be safely widened. The specification has been widened from 3% to 10% and should greatly improve the performance of the procedure.

4. Support for US requirements.

During the upgrade the Abbott representative can set a 'mode directive' forcing the instrument to operate in one of two modes. This removes the requirement to create two separate versions of Prism software and effectively supports the specific requirements of the United States (U.S) market. The differences between U.S and rest of world (ROW) are:

Change	United States mode	Rest of world mode
Must use Abbott positive release control material to release results	Yes	No
Must include all successful calibrator results in calculation of cutoff	Yes	No
Gray zone supported	No	Yes
Use US made reagents only	Yes	No

5. Rescheduling of failed release controls.

If a system error occurs while processing a release control the channel will not immediately be taken off line. It is important to note that any errors caused by the release control running out of specification will still cause the channel to be shut down. This feature will reduce the number of unnecessary forced shutdowns caused by such things as empty control bottles. In this case an alarm is generated and the user may reload a fresh bottle of release control.

6. Simpler XY teach procedure

When setting the sample rack pipetting positions it is no longer necessary to teach every sample rack. Software version 2.1 will calculate all of the sample rack positions using the first and the tenth rack teach points. Editing the teach parameters (such as the Z-step) is no

7. Widening of raw optics count limits for all assays.

To allow for the calculation of larger sample to cutoff ratio's the upper count limits have been raised for non-competitive assays. For competitive assays (such as HBc) the same feature is achieved by lowering the minimum count rate. For reference the count limits for the new HBcore assay are shown also.

Assay	Old count limit	New count limit
HTLV 1/2	1,000,000	2,000,000
HBsAg	600,000	2,000,000
HCV	200,000	2,000,000
HBc	250	120
HBcore	250	120

8. Allowing the '&' character in sample ID.

The ampersand character (&) may now be used as a part of the SID. It had been disallowed in version 1.52 because it may have interfered with the ASTM host communications. Prism version 2.1 overcomes this problem by choosing not to use the ampersand as a field delimiter in communications with the host.

The remaining three delimiter characters, caret ^, vertical line | and forward slash / can not be used in the sample ID.

9. Changes that (may) impact the host interface.

- a. The names of any new assays may need to be configured at the host.
- b. Release control may now be US type and labeled A01...Axx
- c. Subchannel data will now be grouped together.
- d. Ampersand (&) character may be used in SID
- e. During data reduction all values will be calculated to three decimal places.

10. Support for Interleave 2 of 5 (I 2 of 5) bar codes

The ability to read sample bar codes using the I 2 of 5 symbology has been added.

11. Prompts and reminders.

Additional warnings and reminders have been added.

- Reminder to install tip chute.
- Warning when priming a channel set to maintenance
- Remove calibrator rack reminder (audible alarm)

12. Updated virus scan software.

The McAffe virus scan software and data file have been updated. The Scan program is now version 3.2.0 and the virus data file is version 3109 dated 15 September 1998.

13. Grayzone samples are added to the retest report

Any sample results falling within the greyzone will now be added to the sample retest report. It is important to note however that retest management will not automatically reschedule those samples for further testing. Any subsequent tests must be assigned manually when the sample is reloaded.

14. Changes to siphon prime algorithm

After a period of inactivity in sample processing the instrument dispenses reagent into one or more well pairs to ensure that the system is fully primed. This process is known as a 'siphon prime.' Any air detected by the DV system during the siphon prime will not result in subsequent samples being flagged with a DV error.

15. Renaming of supplemental calibrator to assay control

The supplemental calibrator used in three step assay calibration has been renamed to a positive assay control. This change reflects the fact that the positive assay control is not used to calculate the sample to cutoff ratio. During the calibration process the positive and negative calibrators are used to calculate the S/CO ratio. Then the positive assay control is

run to verify the assay will successfully detect the positive material in that control.

16. DV system monitors pumps during diagnostics

When running pump diagnostics (dual port pump test) the DV system will monitor fluid dispense and produce AIM codes when a dispense problem is detected.

17. Event log and history log changes

The contents of the event log will be copied to the history log at the end of each batch. Any messages that have not yet been copied to the history log will not be erased when the event log is cleared.

18. New Error Codes added:

02-209 Data Reduction detected an Assay Control failure.

Log: none Alarm: none Window: none Audio: none

This error code is used for sample status only.

02-400 Negative Control with Reagent A Bad Status, or Negative Control with Reagent B Bad Status, or Positive Control with Reagent A Bad Status, or Positive Control with Reagent B Bad Status

> Log: none Alarm: none Window: none Audio: none

This error code is used for diagnostic pair status of confirmatory report.

02-401 Negative Control with Reagent A >= Confirmatory Cutoff or Negative Control with Reagent B >= Confirmatory Cutoff or Positive Control with Reagent B < Confirmatory Cutoff

Log: none Alarm: none Window: none Audio: none

This error code is used for diagnostic pair status of confirmatory report.

02-402 Positive Control % Neutralization < 50%

Log: none Alarm: none Window: none Audio: none

This error code is used for diagnostic pair status of confirmatory report.

02-403 Sample NEAT with Reagent A Bad Status, or Sample NEAT with Reagent B Bad Status, or Sample Dilute with Reagent A Bad Status, or Sample Dilute with Reagent B Bad Status

Log: none Alarm: none Window: none Audio: none This error code is used for diagnostic pair status of confirmatory report.

02-404 Sample NEAT with Reagent B < Confirmatory Cutoff Sample Dilute with Reagent B < Confirmatory Cutoff

Log: none Alarm: none Window: none Audio: none

This error code is used for diagnostic pair status of confirmatory report.

02-504 A channel or channels needs to be installed to enter the selected function.

Log: none Alarm: none

Window: No channels are installed.

Audio: none

04-532 Negative volume calculated during Volume Validation testing.

Log: Negative volume calculated during Volume Validation testing.

Alarm: none Window: none Audio: none

06-550 HBsAg Confirmatory Rack has tube(s) in improper position(s).

Log: none Alarm: none

Window: HBsAg Confirmatory Rack can not have tube(s) at position(s):

Audio: none

06-551 HBsAg Confirmatory Rack contains tube(s) with invalid ID(s). Pilot tubes, sample dilution tubes, and control id's are checked.

Log: none Alarm: none

Window: HBsAg Confirmatory Rack has invalid ID(s) at position(s):

Audio: none

06-552 HBsAg Confirmatory Rack is missing required tube(s).

Log: none Alarm: none

Window: HBsAg Confirmatory Rack has tube(s) missing at position(s):

Audio: none

06-553 There are no Sample Groups (pilot tubes and dilution tubes) in the HbsAg Confirmatory Rack.

Log: none Alarm: none

Window: HBsAg Confirmatory Rack does not have a Sample Group.

Audio: none

06-554 The tube(s) in the HBsAg Confirmatory Rack are in the wrong order.

Log: none Alarm: none

Window: HBsAg Confirmatory Rack has improper grouping at position(s):

Audio: none

06-555 The Abbott Run Control for HBsAg Confirmatory is invalid because it is not defined or it has expired.

Log: none Alarm: none

Window: An Abbott Run Control for HBsAg Confirmatory is invalid.

Audio: none

50-210 The channel state(s) are not successfully primed or purged.

Log: Channels Not Primed/Purged: %s

Alarm: None Window: None Audio: None

%s will be replaced by the channel number(s)

50-410 The channel state(s) are successfully primed.

Log: Primed Channels: %s

Alarm: None Window: None Audio: None

%s will be replaced by the channel number(s)

50-510 The channel state(s) are successfully purged.

Log: Purged Channels: %s

Alarm: None Window: None Audio: None

%s will be replaced by the channel number(s)

51-512 The user attempted to define an Abbott run control which is not valid.

Log: none Alarm: none

Window: No active assays for this control.

Audio: none

51-519 There are no active assays. Assays can be activated in the Assay Configuration utility

Log: none Alarm: none

Window: No active assays available.

Audio: none

52-511 The list number is not valid or incorrect regulatory format or incorrect list number

Log: none Alarm: none

Window: List number not approved.

Audio: Error Tone

This message will be displayed on the bar code prompt line

52-570 A work load has been modified.

Log: Work Load Modified

Alarm: none Window: none Audio: none



SUBJECT: Reagent Pump Cleaning	ISA#: 82-024
ORIGINATOR: Mark D. Redman	PRODUCT: ABBOTT PRISM® (82)
APPROVED: Dan Armstrong 2/23/1999	EFFECTIVITY DATE: 24-FEB-1999

ABBOTT PRISM® is a registered trademark of Abbott Laboratories.

I. Distribution

Worldwide

II. Purpose

Inform the field of a cleaning procedure for reagent pumps. This procedure addresses external as well as internal cleaning of the pumps. This cleaning procedure addresses two concerns with the pumps.

- 1. Material buildup on the outside of the pump. A pump that operates within specification but has external seepage should be externally cleaned only (see step 5). Seepage is not indicative of a problem with the pump.
- 2. Pumps that do not move smoothly and/or generating errors.Performing the cleaning procedure in this ISA may preclude having to replace the pump.

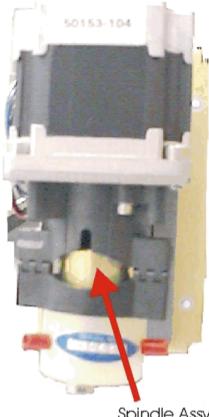
III. Description

This procedure will require the use of the Fluidics Test Tool. The part number for the tool is: Fluidics Test Tool 1-65644-01

- 1. Perform a purge of all reagent pumps on the channel requiring a cleaning procedure.
- 2. Open the Front Ambient Reagent Bay Doors.
- Identify the pump(s) generating messages. Unload Reagents using manage resources.
 Disconnect the appropriate reagent/wash bottle(s) connected to the pump(s) and load purge solution bottles(s) instead. Use towels to capture excess fluid.
- Remove the appropriate wash bottle rack and then try to manually rotate the spindle in the pump.

If you can NOT manually move the spindle replace the pump (RR-D1).

If you can manually move the spindle continue with this procedure.



- Spindle Assy
- 5. If needed, clean off all crystallization buildup from the outside of the pump using a wipe dampened with warm water.
- Remove the inlet tubing. When looking at the pump, this is the tubing on the right side of the pump (see RR-D1 figure).
- Fill the Fluidics Test Tool with 99% isopropyl alcohol. Do not use other types of alcohol. If you do not have access to 99% alcohol, you can use Line Cleaner instead. Connect the Fluidics Test Tool to the inlet port of the pump.

Inject the 99% alcohol (or Line Cleaner) into the pump using the Fluidics Test Tool (that you connected to the pump) while priming the pump (using the following procedure to prime).

Note: While priming the pump, apply pressure to the syringe plunger (of the Fluidics Test Tool).

To prime all pumps except Activator:

- Main Menu.
- Component Diagnostics.
- Channels.
- Pumps.
- Dual Port Pump.
- Select channel number: __ (and press Enter).
- Select the position number of the pump to be tested: ___ (and press Enter).
- Select the pump number to test:___ (and press Enter).
- Enter number of dispenses:___ (type 99 and press Enter).
- Move a disposable to the position: (Y/[N]): (type Y and press Enter). Load prime/purge tray when requested and press Enter.

Repeat? (Y/[N]): ___ (Repeat a second time).

To prime affected Activator Pump (for Activator Pump, use Activator Line Treatment fluid), from the Main Menu select:

- Instrument Preparation.
- Fluidics Maintenance.

Use the Spacebar to select "Prime All Activator Pumps Only".

Press Enter.

Toggle off all channels except the one with the pump to be tested. Press Enter twice. Load Prime/Purge tray when prompted. Press Enter.

Press Enter to continue.

Repeat the above steps to prime the activator pump a second time.

Note: It may be necessary to repeat this step (step 9) until the pump rotates smoothly.

- 8. Once the pump is working disconnect the Fluidics Test Tool.
- 9. Reconnect the inlet tubing to the Pump.
- 10. Prime the channel three times using Fluidics Maintenance, Prime all Pumps and Syringe. On the reagent, transfer and wash pumps use purge fluid. Use Activator Line Treatment fluid for the Activator Pump.
- 11. Reload reagents on the channel using manage resources.
- 12. Clean out your Leak test tool with water after you are done.



SUBJECT: Pippettor Assembly - New R&R's and Catalog Numbers	ISA#: 82-023
ORIGINATOR: Mark D. Redman	PRODUCT: ABBOTT PRISM® (82)
APPROVED: Bob Schabel 7/27/98	EFFECTIVITY DATE: 27-JUL-98

ABBOTT PRISM® is a registered trademark of Abbott Laboratories.

I. Distribution

Worldwide

II. Purpose

Availability of Pipettor (Z Axis) Assembly parts and their R&R procedures. With the addition of these catalog numbers, the majority of parts required for pipettor repairs are available. Depot inventories can be adjusted to include these parts rather than the entire Pipettor (Z Axis) Assembly.

III. Description

The Z1/Z2 Axis motors and Drive cables of the Pipettor Assembly are now available. The availability of these parts should reduce the need to replace the Z Axis Assembly due to motor and drive cable failures.

1-50217-01 Z Axis Cabling Kit

includes:

- 2 Z Axis Drive Cables
- 2 Drive Cable Tensioning Springs
- 2 Z Axis Drive Cable Mounting Nut
- 1 Cable Installation Hook
- 1 Capstan Clamp
- 1-50222-01 Z1 Axis Motor (Silver Capstan)
- 1-50223-01 Z2 Axis Motor (Yellow Capstan)

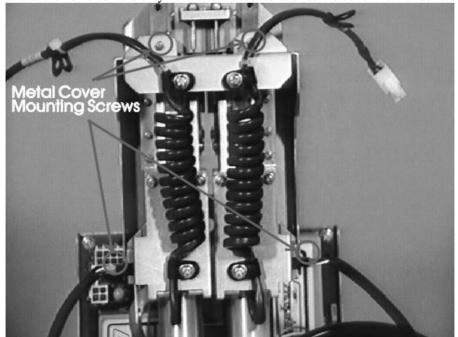
Note: The Z1 Axis is closest to the rear of the instrument. The Z2 Axis is closest to the front of the instrument.

Section A describes the procedure for replacing the Z Axis Drive Cables and section B describes the procedure for replacing the Z Axis Motors.

A. Z1/Z2 Axis Drive Cables

Removal

- 1. It is recommended that you replace both Z1 and Z2 Axis Drive Cables when perform this procedure. It will be easier to perform this procedure if you do them one at a time so that you will have the other Z Axis Drive Cable to look at for reference.
- 2. Perform System Power Off (VP-1).
- 3. Remove Z Axis Assembly from the instrument (RR-A1).
- 4. Remove the metal cover located immediately above the top of Z1 and Z2 Axis plungers (4 mounting screws and four screws attaching the Z1/Z2 Tip Sensor cables to the cover). The two mounting screws at the home sensors only need to be loosened to slide the cover from under them.



5. Remove the cable to be replaced from the Z Axis by removing the nut securing the top of the Z Axis Drive Cable and disconnecting the bottom from the spring. Discard the old Z Axis Drive Cable, spring and nut.

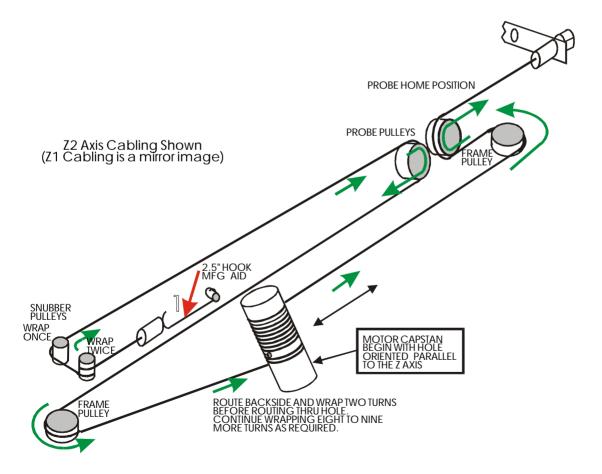
Replacement

- 1. On the side you are installing the new cable, using cable ties, tie the plunger assembly in the Home (up) position.
- 2. Install the new cable using the Cable Installation Hook to hold the end in place on the spring post projection. Route the cable as shown.

Note: To determine whether to wrap wire 8 or 9 turns around the capstan, first wrap 8 turns then determine if the remaining wire is sufficient to reach the frame. If it is too long then go back to the capstan and wrap one additional time.

After routing the cable around the capstan, use the Capstan Clamp to hold the Capstan in place while finishing the cable routing.

- 3. Secure the opposite end of the cable to the frame using the new nut. Tighten the nut snug so that the cable is held taught, but not tensioned. Remove the Capstan Clamp. Tension the cable by replacing the Cable Installation Hook with the new spring.
- 4. Move the plunger up and down several times and verify that the capstan windings are tracking properly
- 5. Repeat the process on the other Z Axis Drive Cable.
- 6. Install the metal cover (4 mounting screws and four screws attaching the Z1/Z2 Tip Sensor cables to the cover).
- 7. Install the Z Axis Assembly.



Verification

- 1. Perform System Start-up (VP-2).
- 2. Perform Z Reference Alignment (VP-3).
- 3. Perform Tip Remover Alignment (VP-4).
- 4. Perform Tip Rack Alignment (VP-5).

- 5. Perform Sample Rack Alignment (VP-6).
- 6. Perform Calibrator Rack Alignment (VP-7).
- 7. Perform Sample Dispense Alignment (VP-8).
- 8. Perform Dispense Volume Validation (VP-21) for the Sample Dispense.
- 9. Install Sample Access Rear Cover.

B. Z Axis Motor

Removal

- 1. Perform System Power Off (VP-1).
- 2. Remove the Z Axis Assembly (RR-A1).
- 3. Remove the Z1/Z2 Axis Drive Cable for the motor you are replacing (see this ISA).
- 4. Remove the two Sample Syringe Pump Assemblies (RR-A1.7). This is to allow you to access two of the screws on the motor.
- 5. Remove the Z1/Z2 Axis Motor Assembly (4 screws).

Replacement

- 1. Install the new Z1/Z2 Axis Motor Assembly (4 screws).
- 2. Install the two Sample Syringe Pump Assemblies (RR-A1.7).
- 3. Install the Z1/Z2 Axis Drive Cable for the motor you are replaced (see this ISA).
- 4. Install the Z Axis Assembly (RR-A1).

Verification

- 1. Perform System Start-up (VP-2).
- 2. Perform Z Reference Alignment (VP-3).
- 3. Perform Tip Remover Alignment (VP-4).
- 4. Perform Tip Rack Alignment (VP-5).
- 5. Perform Sample Rack Alignment (VP-6).
- 6. Perform Calibrator Rack Alignment (VP-7).
- 7. Perform Sample Dispense Alignment (VP-8).
- 8. Perform Dispense Volume Validation (VP-21) for Sample Dispense.
- 9 Install Sample Access Rear Cover (PL-Covers).

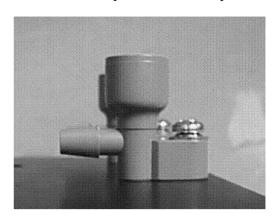
End of Document

ISA #82-022 ESC to exit

Nozzle body not seated flush with plate



Nozzle body seated correctly





SUBJECT: Non-conformance Issues with Dispense Nozzles	ISA#: 82-022
ORIGINATOR: Mark Redman	PRODUCT: ABBOTT PRISM® (82)
APPROVED: Bob Schabel (6/23/98)	EFFECTIVITY DATE: 23-JUN-98

Abbott Prism® is a registered trademark of Abbott Laboratories.

I. Distribution Worldwide

Purpose II.

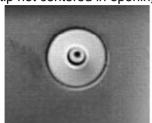
To inform the field that during failure analysis of a dispense assembly by factory personnel several non-conformances were observed.

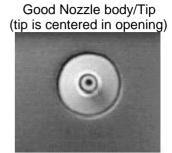
III. Description

.)

A. The first was that the white tip that extends through the end of the nozzle body was not centered properly in the opening. This may cause the tip wash to function incorrectly, or may cause Dispense Verification Errors. The tip should be centered with an equal amount of space on all sides of the tip. (See below.)

Bad Nozzle body/Tip (tip not centered in opening)





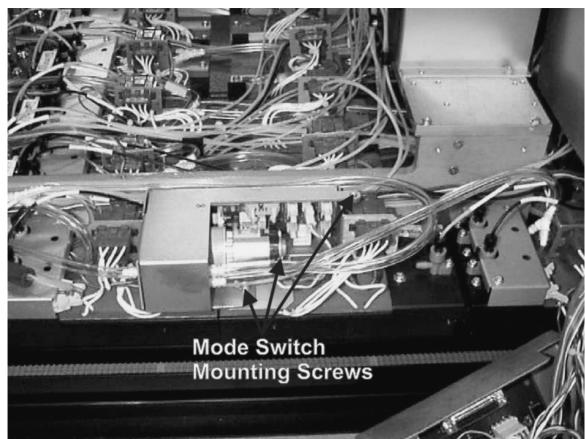
If you find that the nozzle is not centered, replace the nozzle assembly with a new one. You can not adjust the centering of the nozzle.

B. The second non-conformance was with the nozzle body not being seated flush with the dispense plate. This may result in Dispense Verification Errors. If you find that the nozzle body does not seat flush with the plate, replace the nozzle assembly with a new one. (See



The Field Service Engineer should inspect each new dispense station for these points before installing on a Prism. The Field Service Engineer should also inspect each nozzle they assemble for tip alignment and nozzles for flushness when they install them on a dispense assembly. All bad parts should be replaced and properly disposed of.

ISA 82-021 ESC to exit





SUBJECT: Mode Switch Assembly Information	ISA#: 82-021
ORIGINATOR: Mark D. Redman	PRODUCT: ABBOTT PRISM® (82)
APPROVED: Bob Schabel (6/23/98)	EFFECTIVITY DATE: 23-JUN-98

Abbott Prism® is a registered trademark of Abbott Laboratories.

I. Distribution

Worldwide

II. Purpose

Inform the field of the function, replacement, and verification of the New Mode Switch Assembly. The new Mode Switch Assembly is available as:

Mode Switch Assembly

1-55951-01

III. Description

Theory of Operation

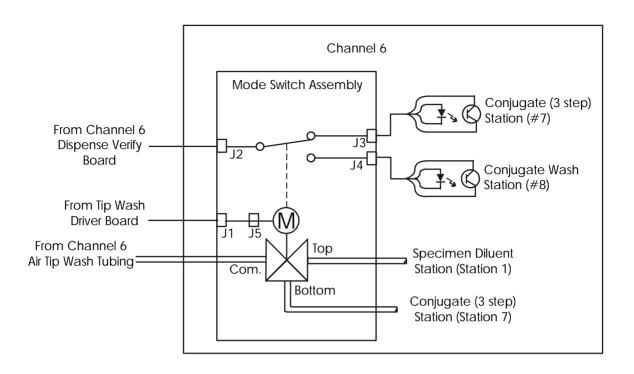
The Mode Switch Assembly was added to the instrument in the 1.52 Update. It allows the system to set the Back Up Channel Air Tip Wash and DVS for a 2 step or 3 step assay. The position (2 or 3 step) of the Mode Switch is controlled from the Air Tip Wash Driver Board. When the Mode Switch Assy changes position it does two things.

The Mode Switch redirects the Air Tip Wash:

- For 2 step assay operation the Air Tip Wash is provided to the Specimen Diluent Dispense Station (Station 1).
- For 3 step assay operation the Air Tip Wash is provided to the Conjugate Dispense Station (Station 7).

The Mode Switch selects between the output of two Dispense Verify Sensors:

- For 2 step assay operation the Dispense Verify information is provided from the Conjugate Wash Dispense Station (Station 8) to the Dispense Verify Board.
- For 3 step assay operation the Dispense Verify information is provided from the Conjugate Dispense Station (Station 7) to the Dispense Verify Board.



Removal

- 1. Perform System Power Off (VP-1).
- 2. Remove Tray Loader and Sample Access Front Covers (PL-COVERS).
- 3. Remove Rack Plate Assy (RR-B1.11).

Note: When removing Rack Plate Assy it is not necessary to remove the Bar Code Reader Assy to complete this procedure.

- 4. Remove the cable shield (loosen 2 screws) located in front of Channel 6.
- 5. Remove the 2 screws mounting the Bar Code Reader Controller Assy to the Transfer Syringe Assy Mounting Bracket. Set the screws aside.
- 6. Disconnect the 3 Air Tip Wash tubing connections from the Mode Switch.
- 7. Disconnect cables from Mode Switch Assy J1, J2, J3, and J4.
- 8. Remove the Mode Switch Assy (3 screws). (See attached ...)

Replacement

- 1. Install Mode Switch Assy (3 screws).
- 2. Connect the following cables:

55804 J1 51116 J2 55805-101 J3 55805-102 J4

3. Connect 3 Air Tip Wash tubing connections to the Mode Switch as follows:

Mode Switch Connection	Tubing Source
Common Connector	From Source Tubing (Labeled COM).
Top Connection	Specimen Diluent Dispenser Tubing (Labeled TOP).
Bottom Connection	Conjugate Wash Dispenser (Labeled BOT).

Note: Verify the cable from Heater Cover at Station 5 does not interfere with the free movement of the tubing connected to the common port (COM).

- 4. Replace The Bar Code Reader Controller Assy. (2 screws).
- 5. Replace the Cable Shield (tighten 2 screws).

Verification

- 1. Perform System Start-Up (VP-2).
- 2. Verify the Mode Switch operates correctly.
 - a) Configure Channel 6 as Maintenance.
 - b) Switch the Mode Switch to the 2-step position:
 - Component Diagnostics
 - Channels
 - DV/TW
 - Set DV/TW Switch to 2 step
 The Mode Switch should move to the TOP position without errors.
 - c) Switch the Mode Switch to the 3-step position.
 - Set DV/TW Switch to 3 step
 The Mode Switch should move to the BOT (bottom) position without errors.
- 3. Replace the Rack Plate Assy (RR B1.11).
- 4. Install all removed covers.

Note: Run a 2-step and a 3-step assay on Channel 6 when performing a Total Service Call.



SUBJECT: Assembling Reagent Dispense Nozzles	ISA#: 82-020
ORIGINATOR: Mark Redman	PRODUCT: ABBOTT PRISM® (82)
APPROVED: Bob Schabel 05/11/98	EFFECTIVITY DATE: 11-MAY-98

Abbott Prism® is a registered trademark of Abbott Laboratories.

I. Distribution

Worldwide

II. Purpose

To inform the field how to assemble the Reagent Dispense Nozzles.

III. Description

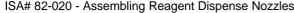
The Reagent Dispense Nozzles are available under two kit catalog part numbers. These are:

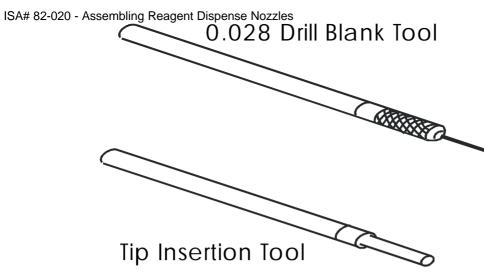
	<u>1-50592-01 Kit</u>	<u>1-50592-02 Kit</u>
Screws 6-32 x 9/16ths	12	72
Nozzle Seals	12	72
Nozzle Body	12	72
Nozzle Tip	12	72
Assembly Tool Set	N/A	1

The Reagent Dispense Nozzles must be assembled from the parts in the kits. Only the 1-50592-02 kit comes with the tools required to assemble the Reagent Dispense Nozzles. When doing nozzle inspections it is preferable to order the 1-50592-02. 1-50592-01 is a refill kit for the -02 kit.

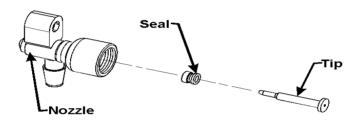
To assemble the nozzles:

1. Verify that the 0.028 Drill Blank Tool can be inserted into the Nozzle Tip. If not, throw away the tip and try another.





2. Assemble the Nozzle by inserting the seal into the nozzle as shown. Next, insert the Tip as shown.



3. Seat the Nozzle Tip and Seal into the Nozzle Body using the Tip Insertion Tool.



SUBJECT: Leaking Purge Valve Contaminating Purge Solution	ISA#: 82-019
ORIGINATOR: Scott Hamblin	PRODUCT: ABBOTT PRISM® (82)
APPROVED: Bob Schabel (04/28/98)	EFFECTIVITY DATE: 29-APR-98

Abbott Prism® is a registered trademark of Abbott Laboratories.

I. Distribution

Worldwide

II. Purpose

A number of Prism instruments in the field have been found to be contaminating the purge solution with microparticles. When contaminated, the purge bottles may contain a layer of white sediment at the bottom. The contaminated purge solution may also appear milky when shaken. Discoloration can also be seen in the transfer syringe during purging.

The contamination can be caused by a faulty purge valve leaking between the microparticle inlet

port and the purge inlet port. The leak allows rare reagent to slowly flow back through the valve and accumulate in the purge bottle over a period of days or weeks. **Under normal conditions the purge valve should not allow reagents to pass back into the purge bottle**. If an instrument is found to have contaminated purge then the following procedure should be performed.

III. Description

- 1. Verify that each of the reagent lines are connected to the correct port on the purge valve. Refer to the Prism service manual removal and replacement procedure section RR-D2, tables 4-6 and 4-7 for information on the correct connection of reagent lines to the valve.
- 2. Refer to removal and replacement procedure RR-D5 in the Prism service manual to replace the faulty purge valve. Before beginning any of the validation procedures in RR-D5 the contaminated purge bottle should be discarded or carefully cleaned using distilled water and rinsed with purge solution before refilling. Reload clean purge solution, perform a purge on that channel and then continue with the procedure.
- 3. Prime the channel and perform an assay calibration. Verify that all controls and channel functions are normal.



SUBJECT: Activator Cap O-Ring Lubrication Procedure	ISA#: 82-018
ORIGINATOR: Mark D. Redman	PRODUCT: ABBOTT PRISM® (82)
APPROVED: Bob Schabel 07/31/98	EFFECTIVITY DATE: 31-JUL-98

Abbott Prism® is a registered trademark of Abbott Laboratories.

I. Distribution

Worldwide

II. Purpose

To inform the field of a procedure to lubricate the Activator Cap and the part number for the Activator Cap O-Ring Lubrication Kit.

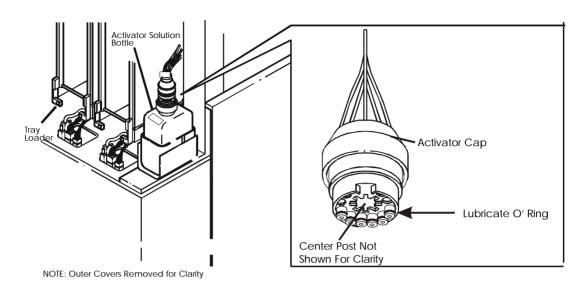
III. Description

As the Activator Caps age the o-rings in them can become dry. This can make it very difficult to correctly connect the cap to the Activator Bottle. Lubricating the o-rings in the Activator Cap can resolve this problem.

This procedure describes the lubrication procedure for the Activator Cap O-Rings. These o-rings are in the half of the Activator Cap that is connected to the tubing that goes to the Activator Pumps, **not** the half that is screwed onto the Activator Bottle. To lubricate the o-rings you will need the Activator Cap Lube Kit (CN 1-14205-01). This Kit contains 5 packages of lubricant and one package of urethane cleaning swabs.

- 1. Open the Tray Loader Door and disconnect the Activator Cap and tubing from the Activator Bottle.
- 2. Clean each O'ring of the Activator Cap with a dry clean swab.
- 3. Squeeze a drop of lubricant onto a piece of plastic bag (you may use the bag the kit comes in).
- 4. Touch a new, clean swab to the drop of lubricant and turn the swab so that there is a **thin** film of lubricant evenly distributed on the swab.

5. Using the swab, lubricate the o-ring on each of the individual tubing connectors in the Activator Cap (See drawing).Do not get any lubricant on any part of the connector except the o-ring.If you do get excess lubricant on the connector, wipe off the excess with a clean swab.



END OF DOCUMENT



SUBJECT: Power Supply Grounding Check	ISA#: 82-017				
ORIGINATOR: Scott Hamblin	PRODUCT: ABBOTT PRISM® (82)				
APPROVED: Dan Armstrong 1/12/1999	EFFECTIVITY DATE: 12-JAN-1999				

Abbott Prism® is a registered trademark of Abbott Laboratories.

I. PURPOSE

This document provides test procedures and reference material to help detect a short circuit in the Abbott Prism® electrical system and locate the cause. Power supply subsystem diagrams are included for all power supply outputs +30 VDC, 24 VAC, +24VP, +12 VD, -12VD, +5VP, +5VD1 and +5VD2.

II. OVERVIEW

The Abbott Prism® electrical system is protected from internal failures by overload devices such as fuses and circuit breakers. In some cases however it is possible for an electrical short to occur (perhaps due to a pinched wire or component failure) and the amount of current flowing through the short may not be enough to trip the overload device. Under these circumstances the electrical fault may go undetected but still interfere with the operation of other sensitive circuits like the bitbus system.

The following test procedures will require a multi-meter to measure resistance. It is important that the user has a good understanding of how to use the multi-meter and interpret the readings. All checks should be performed in the sequence shown. Steps 2 through 4 require the heater controller and barcode reader connectors to be removed or those test procedures will produce false low readings and fail.

III. SYSTEM PREPARATION

Before beginning ensure to complete the following system preparation.

- If system is powered up, power down the system.
- Turn UPS OFF on the front of the unit and turn it OFF at the rear. Un-plug from the wall socket.
- Remove the cable and power entry connector at the Abbott Prism® system power supply
- Ensure that all system power supply circuit breakers and switches are turned ON.
- Set your multi-meter to measure a resistance greater than 100 K (Ohms).

1. Check for electrical short between the chassis and power ground

- Connect the black lead to the chassis ground strap braid at the base of the power supply.
- Connect the red lead to the system power supply test point labelled "PGND".
- The resistance should be greater than 10K Ohms. A short to chassis will typically result in less than 100 Ohms.
- If you do find a short you will need to refer to the wiring diagrams in the reference manual.
 Begin by unplugging connectors from the system power supply until the resistance increases to greater than 10K Ohms. When it does take note of the connector and refer to the manual.
 Once you have determined what components the connector powers you may plug it back in

and continue to work your way unplugging connectors and components until you locate the short.

2. Check for electrical short between the chassis and digital ground

- Follow the removal and replacement procedure RR B2.4 (steps 1...4) to expose the barcode reader control board but do not remove the board. Disconnect P2 (cable 55140) and P4 (cable 50037) from the barcode reader board. These connectors are on the left of the board when standing in front of the instrument.
- Follow the removal and replacement procedure RR J1 (steps 1...3) to expose the rear of the heater controller but do not remove it. Disconnect P2 (cable 51443) from the heater controller. This is the large silver connector at the rear.
- Connect the black test lead on the chassis ground strap at the base of the power supply.
- Connect the red test lead to the system power supply test point labelled "DGND".
- The resistance should be greater than 10K Ohms. A short to chassis will typically result in 0-100 Ohms.
- To find the short you will need to refer to the wiring diagrams in the reference manual. Begin by unplugging connectors from the system power supply until the resistance increases to greater than 10K Ohms. When it does take note of the connector and refer to the manual. Once you have determined what components the connector powers you may plug it back in and continue to work your way unplugging connectors and components until you locate the short.

3. Check for electrical short between the digital ground and power ground

- Connect the black test lead to the system power supply test point labelled "PGND".
- Connect the red test lead to the system power supply test point labelled "DGND".
- The resistance should be greater than 10K Ohms. A short between them will typically result in 0-100 Ohms.

4. Check for electrical short between power supply voltage and chassis

- Place the black test lead on the chassis ground strap at the base of the power supply.
- Use the red test lead to measure the resistance at the system power supply test points 24VPWR, 30VPWR, 5VPWR, +12VDIG, -12VDIG, 5VD1, AND 5VD2. The resistance should be greater than 500K Ohms. An external short to chassis will typically result in a 9K to 15K Ohm measurement.
- If you see a low reading at any test point refer to the power supply subsystem diagram for that voltage. To find the cable or subassembly causing the short you may remove connectors one by one while monitoring the resistance at the power supply test points until the resistance increases to an acceptable level. Once the faulty subassembly is found replace the connectors and continue to monitor the resistance. Careful and systematic examination of cables, removal of connectors and components in that subassembly will help you locate the short.

Power supply block diagrams

The following PDF files contain diagrams that show the electrical path of each individual system voltage through the instrument. A more complete diagram showing all voltages may be found in the Abbott Prism® reference manual.

















5vd2.pdf +5vp.pdf -12vd.pdf 24vAC.pdf 24vp.pdf 30vDC.pdf 5vd1.pdf +12vD.pdf



SUBJECT: 1.51 Version of Software	ISA#: 82-016				
ORIGINATOR: Mark D. Redman	PRODUCT: ABBOTT PRISM® (82)				
APPROVED: Bob Schabel	EFFECTIVITY DATE: 13-JAN-98				

Abbott Prism is a registered trademark of Abbott Laboratories.

I. Distribution: Worldwide

II. Purpose:

To inform the field of the changes to PRISM hardware and software for the 1.51 Version of software.

III. Description:

Listed below are the changes:

A. Hardware Changes

Pressure Activated Switches

Pressure activated switches have been added to the new Air Tip Wash Driver Board to monitor the pressure in the Air Tip Wash Tubes. The switches are connected to the Air Tip Wash Tubes with a "Y" connector.

Air Tip Wash Pressure Filter

A Pressure Filter was added to the Air Tip Wash Tubing to remove the pulsating from the air flow.

3. Add Conjugate Station Dispense Verify Sensors

Dispense Verify Sensors have been added to the 3 step channels (1, 3, & 6), conjugate dispensers.

Add Mode Switch.

This switch allows the system to set the Air Tip Wash and DVS for a 2 step or 3 step assay depending on Channel 6 configuration.

One tube of the Air Tip Wash is switched so that it goes to either the Specimen Diluent or the 3 step Conjugate Dispenser:

- For 2 step assay operation the Air Tip Wash is provided to the Specimen Diluent Dispense Station (station 1).
- For 3 step assay operation the Air Tip Wash is provided to the Conjugate Dispense Station (Station 7).

One Dispense Verify cable is switched so that it goes to either the Conjugate Wash Station or 3 step Conjugate Station:

- For 2 step assay operation the Dispense Verify control is provided to the Conjugate Wash Dispense Station (Station 8).
- For 3 step assay operation the Dispense Verify control is provided to the Conjugate Dispense Station (Station 7).
- 5. Add Drip Shield to the Air Tip Wash Driver Board.

 Add Hardware and Firmware to improve the Bar Code Reader function

The new firmware in the Bar Code Reader Controller Assy will support French 11-2 and JRC checksum (barcodes).

B. Software Changes

- 1. Software Control for the functions listed under hardware changes.
- 2. New Error Codes added for Air Tip Wash Pressure Monitoring:

3X-700 Error occurs when the air tip wash compressor is commanded to be on. The Pressure Activated Switch indicated the compressor was off.

Log: Channel X Tip Wash Failed to Turn On Alarm: Channel X Tip Wash Failed to Turn On

Window:none

Audio: Urgent Alarm

Possible Causes: Channel X Air Tip Wash Compressor

Air Tip Wash Driver Board Leak in Air Tip Wash Tubing

System PIB

3X-701 Error occurs when the air tip wash compressor is commanded to be off. The Pressure Activated Switch the compressor was on.

Log: Channel X Tip Wash Failed to Turn Off Alarm: Channel X Tip Wash Failed to Turn Off

Window:none

Audio: Urgent Alarm

Possible Causes: Channel X Air Tip Wash Compressor

Air Tip Wash Driver Board

System PIB

36-710 Error Occurs when the Dispense Verify/Tip Wash configuration on Channel 6 is commanded to switch between the 2 step and 3 step configurations.

Log: Channel 6 DV/TW Configuration Switch Failed

Alarm: Channel 6 Failed

Window:none

Audio: Urgent Alarm

Possible Causes: Mode Switch Assembly

Air Tip Wash Driver Board

System PIB



SUBJECT: 1.5 Service Manual	ISA#: 82-015
ORIGINATOR: Mark D. Redman	PRODUCT: ABBOTT PRISM® (82)
APPROVED: Bob Schabel	EFFECTIVITY DATE: 05-DEC-97

Abbott Prism ® is a registered trademark of Abbott Laboratories.

I. PURPOSE:

To inform all Worldwide Service organisations of an PRISM updated service manual.

II. DESCRIPTION OF CHANGES:

The PRISM Service manual was updated to include changes resulting from the release of 1.5 Software.

III. ADMINISTRATIVE NOTES:

An update is also available for people with older versions of the manual. The update includes all the

pages of the manual, but does not include the binder and tabs. To update your old manual remove the old pages and insert the new set of pages.

The new PRISM Service Manual can be ordered by Catalog Part Number: 1-51428-04

The updated pages of the PRISM Service Manual can be ordered by Catalog Part Number: 1-55766-01

It will be up to the individual country's to forecast and order manuals through normal parts channel.



SUBJECT: Dispenser Nozzle Inspections	ISA#: 82-013
ORIGINATOR: John Buckland	PRODUCT: ABBOTT PRISM® (82)
APPROVED: Bob Schabel	EFFECTIVITY DATE: 22-AUG-97

ABBOTT PRISM is a registered trademark of Abbott Laboratories.

I. DISTRIBUTION:

Worldwide

II. PURPOSE

This ISA informs the World Wide Customer Support Organizations of the <u>requirement</u> to inspect the Abbott Prism instruments' dispensers for accumulation of foreign material. <u>All instruments</u> must be inspected.

III. DESCRIPTION

All Prism instruments must have the Microparticle, Specimen Diluent, Conjugate, and Probe dispenser nozzles inspected every 60 to 75 days. This inspection is required due to the possible accumulation of dried material on or around the nozzle tips. A Preventive Maintenance check is considered an inspection. If dried material is observed on or in any nozzles, they <u>must</u> be replaced, <u>not cleaned</u>. When you replace the nozzle's, care must be taken not to over tighten the mounting screws. Hairline Cracks in the nozzle body could result from over tightening. The nozzles removed from the instrument should be returned to Abbott Diagnostics 1921 Hurd Dr., Irving, Texas 75038, Attention: Dan Armstrong, Mail Station 2-19.

A monitoring program has been developed by Quality and each country will be advised of when the inspections are due. Dallas CSE and Delkenheim ACS will monitor for compliance. It is mandatory to complete either the Nozzle inspection forms or the PM form for all dispenser nozzles the same day the inspection is completed. After the forms are completed, send the form electronically as an attachment in Lotus Notes to Dan W. Armstrong in Dallas or to Delkenheim ACS. If you can not use Lotus Notes, send a Hard copy to Dan Armstrong at the above address or to Delkenheim ACS. The country will then be notified of the next inspection date. The inspection must continue until a software and hardware TSB is released providing automatic monitoring of additional dispensers. The current plan is to release these improvements by the end of October 1997.

Two nozzle inspection forms and a PM checklist have been included with this ISA. Both of these are available in the Abbott Prism® Discussion Data Base.

Rare Reagent Dispense Nozzle Inspection / or Replacement Check list

CUSTOMER:	
ADDRESS:	
FSR:	 PRISM Serial Number:

Channel	1		2		3		•	4	ţ	5	6	ò
Sub Channel	Α	В	Α	В	Α	В	Α	В	Α	В	Α	В
No Build up												
Build up on outside of Nozzle												
Build up at base of Nozzle												
Partial Obstruction of inside of Nozzle												
Obstruction of Nozzle												
Replaced Nozzle												
Nozzle returned to Dan Armstrong												
Last Inspection date												

Conjugate

Please check the appropriate areas below

Channel	1		2		3		4	4	5	j	6	
Sub Channel	Α	В	Α	В	Α	В	Α	В	Α	В	Α	В
No Build up												
Build up on outside of Nozzle												
Build up at base of Nozzle												
Partial Obstruction of inside of Nozzle												
Obstruction of Nozzle												
Replaced Nozzle												
Nozzle returned to Dan Armstrong												
Last Inspection date												

Rare Reagent Dispense Nozzle Inspection / or Replacement Check list

CUSTOMER:	
ADDRESS:	
FSR:	 PRISM Serial Number:

Probe:

Please check the appropriate areas below:

Channel	•	1		2	(ô
Sub Channel	Α	В	Α	В	Α	В
No Build up						
Build up on outside of Nozzle						
Build up at base of Nozzle						
Partial Obstruction of inside of Nozzle						
Obstruction of Nozzle						
Replaced Nozzle						
Nozzle returned to Dan Armstrong						
Last Inspection date						

Specimen Diluent

Please check the appropriate areas below:

Channel	2	2	6		
Sub Channel	Α	В	Α	В	
No Build up					
Build up on outside of Nozzle					
Build up at base of Nozzle					
Partial Obstruction of inside of Nozzle					
Obstruction of Nozzle					
Replaced Nozzle					
Nozzle returned to Dan Armstrong					
Last Inspection date					

PREVENTIVE MAINTENANCE CHECKLIST

CUSTOMER:		
ADDRESS:		
FSR:	CUSTOMER SIGNATURE:	SERIAL NUMBER:
	DATE:	SOFTWARE REVISION:

PROCEDURES

INTERVAL

1	WEAR	VISUAL INSPECTION	MEASURE	TE ST	CLEAN	REPLA CE	3 MONTH S	6 MONTH S	12 MONT HS
	Drive Mechanisms	Inspect for any wear associated with operation.							

Maintenance Record review	Х				1		
UPS Power Fail Test (RR-E6)			Х			√	
Verify Power Supply (VP-25)		Х					1
Check Printer Operation	Х				✓		

(1) Raise and lower the lift shroud mechanism manually and check for binding.

Lubricate using Super Lube 14237-015. Instructions: Apply a bead of oil to the top of the bearing keeper which is on the lift block assembly. For further information review the instructions in prism Discussion Data base.

End of Document



SUBJECT: Release of ABBOTT PRISM® Reference Manual	ISA#: 82-012
ORIGINATOR: Mark Redman	PRODUCT: ABBOTT PRISM® (82)
APPROVED: Bob Schabel 17/Feb/97	EFFECTIVITY DATE: 17-FEB-97

PRISM is a registered trademark of Abbott Laboratories.

I. DISTRIBUTION:

Worldwide

II. PURPOSE:

To inform the field of the release of the Reference Manual.

III. DESCRIPTION:

The reference Manual is now in stock and can be ordered. This manual contains system descriptions, schematics, cable diagrams, and block diagrams. The catalog part number for this manual is:

ABBOTT PRISM® Reference Manual 1-55568-01

The ABBOTT PRISM Reference Manual will not be automatically shipped to all ABBOTT PRISM trained FSEs/FSRs worldwide. It will be up to the individual countries to forecast and order manuals through normal parts channels.



SUBJECT: Release of Unlubricated Transfer Syringe	ISA#: 82-010
ORIGINATOR: Mark Redman	PRODUCT: ABBOTT PRISM® (82)
APPROVED: Bob Schabel 18/DEC/96	EFFECTIVITY DATE: 18-DEC-96

PRISM is a registered trademark of Abbott Laboratories.

I. DISTRIBUTION:

Worldwide

II. PURPOSE:

Inform the field of the availability of an Unlubricated Transfer Syringe.

III. DESCRIPTION:

The new unlubricated syringe is available and should be used for any replacement. This syringe is to replace the old transfer syringe in your kit. When you receive the unlubricated syringe destroy the old version syringe in your kit and verify the depot kit has the correct part. Lubricant in the syringe has been shown to cause HCV calibration failures. Please be sure to destroy any lubricated syringes that you may have in your kit so that they cannot be put on a PRISM in the future. You can identify the new syringe by the part number on the syringe packaging. The new syringe will have part number 51294-102 label on the end of the box. The old syringe part number is 51294-101. To order new syringe the list number is:

Unlubricated Transfer Syringe.......6A36-30

The ABBOTT PRISM® Unlubricated Transfer Syringe <u>will not</u> be automatically shipped to all ABBOTT PRISM® trained FSEs/FSRs Worldwide. <u>It will be up to the individual countries to forecast and order through logistics</u>.

NOTE: All instruments with serial number 1083 and above have been equipped with unlubricated syringes during manufacture.



SUBJECT: Tray Ready Sensor	ISA#: 82-008
ORIGINATOR: John Buckland	PRODUCT: ABBOTT PRISM® (82)
APPROVED: Bob Schabel 9/Sept/96	EFFECTIVITY DATE: 09-SEP-96

ABBOTT PRISM is a registered trademark of Abbott Laboratories.

I. DISTRIBUTION:

Worldwide

II. PURPOSE

This ISA informs the World Wide Customer Support Organizations of a way to reduce frequency of 3x-804 messages caused by stray light when channel is out of trays.

ABBOTT PRISM® instruments S/N 1096 and below are the only instruments affected.

III. DESCRIPTION

Engineering has discovered that the tray ready sensor, Part # 1-52306-01, is affected by stray light. The orientation of the sensor can reduce its sensitivity to stray light. Manufacturing is reversing the orientation of all sensors on new instruments. When replacing a tray ready sensor in the Field, on the above serial number instruments, rotate the tray ready sensor, with support bracket attached, 180 degrees so that the long side of the plastic support bracket is next to the channel.



SUBJECT: Pipetting and Barcode errors	ISA#: 82-007		
ORIGINATOR: Dan Armstrong	PRODUCT: ABBOTT PRISM® (82)		
APPROVED: Bob Schabel 24/JUN/96	EFFECTIVITY DATE: 24-JUN-96		

PRISM is a registered trademark of Abbott Laboratories.

I. DISTRIBUTION

Worldwide

II. PURPOSE

Inform the World Wide Customer Support Organizations of possible causes of pipetting, pressure, and/or barcode errors.

III. DESCRIPTION

Errors such as 4X-101 through 4X-108 could be attributed to the use of unapproved sample

tubes. Procedures such as artificially raising the tube in the rack can result in these errors. Inserting smaller tubes into larger ones and using tubes with serum separator filters should not be done.

As stated in the ABBOTT PRISM Operations Manual, **Section 7**: *Operational Precautions and Limitations*, **Subsection**: *Specimen Collection*, *Preparation*, *and Storage*, the following tubes may be used to insure there is sufficient sample present for the aspirate algorithm.

7 mL (13 x 100 mm) 10 mL (16 x 100 mm) Abbott-designed sample cup = 13 x 99 mm

No other sample tubes should be used with ABBOTT PRISM® analyzers.

Diameter and height requirements

The minimum internal diameter requirement is a height/volume ratio restriction which ensures that the pipette tip stays below the surface during aspiration. If the internal diameter of the sample tube is too small, a pipetting error can result. The most probable error is 4X-103, 4X-105, or 4X-108.

If the outer diameter is too small or the height is too short, the barcode reader may have difficulty reading the sample barcode.

If the outer diameter is too large, the sample tube may get stuck in the sample rack.

The following failure conditions may be caused by a sample tube which is too tall, a sample tube with an elongated bottom skirt, or a sample tube which is artificially raised in the sample rack.

Top of the sample tube is too high

The top of the tube may crash into the top of the rack plate guard and break the sample tube during sample rack insertion.

Pipette tips may hit the top of the tube, fall off, and result in one of the following pipetting errors: 4X-102, 4X-105, or 4X-108.

The barcode reader may have difficulty reading the sample barcode.

Sample surface is too high

The pipettor may begin level sensing when it is already under the sample surface. The pipettor will dive to the bottom of the tube searching for the surface, and the sample may spill over the

sides of the tube. When the surface cannot be detected, error 4X-102 will result.

Sample surface is too high and the bottom of the tube is too high

The pipettor may begin level sensing when it is already under the sample surface. The pipettor will dive to the bottom of the tube searching for the surface. The pipette tip may bend as it crashes into the bottom of the tube. One of the following pipetting errors will result: 4X-101, 4X-102, 4X-104, or 4X-107. In addition, the bent tip could result in a jam at the tip chute.

Shape Requirements for the Bottom of the Sample Tube

If the bottom of the sample tube is a narrow cone, the height/volume ratio may not be sufficient and result in one of the following pipetting errors: 4X-103, 4X-105, or 4X-108.

Another possibility is that the pipette tip may touch the side of the cone when aspirating and a 4X-104 or 4X-107 error may result.

IV. EQUIPMENT REQUIRED

N/A

V. PROCEDURE

N/A