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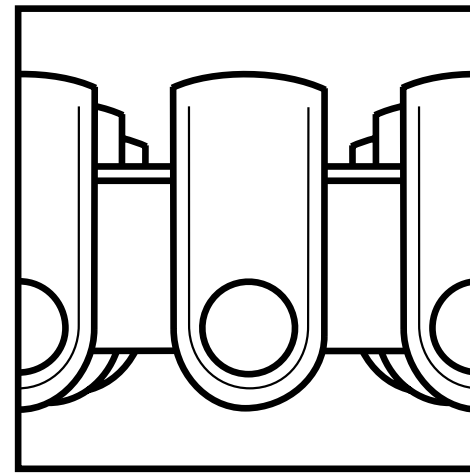

Parallel Processing Center (PPC™)

Operations Manual

List No. 1A05-57

Revision Number 69-0102/R16
(manual with binder)

Abbott Laboratories
Abbott Park, IL 60064
69-0104/R11

NOTES

Revision Status

Document Control Number(s)	Revision Date	Section(s) Revised	Pages Revised And Added
Originally Issued—42325-101	11/87	Not Applicable	Not Applicable
42325-102			Stickered version of Manual -103
42325-103	1/93		56, 60, 76, 117, 150, 157, 167, 168
42325-104			139, 150
83-5103/R5			All pages
83-6577/R6			All pages
83-7575/R7		Glossary Sections 1, 2, 3, 4, 5, 6 Index Cutoff Assay Protocol Point-to-Point Assay Protocol,	All pages in these sections
83-8835/R8		Not Released	
83-8840/R9		Cover Page Revision Status Table of Contents Sections 1, 2, 3, 4, 5, 6, 7 Index Thin Card Memory Cartridge customers only. (This revision does not apply to Memory Module customers.),	
66-0335/R10		Not Released	
66-1100/R11		Not Released	
66-1672/R12		Not Released	
66-4235/R13		Not Released	
66-4853/R14	9/95	Entire Manual	
66-9601/R15	6/97	Front Matter, Master Table of Contents, Section 9, Index	All pages in these sections
69-0102/R16	11/97	Entire Manual	All pages

Current Configuration of this Operations Manual

COMMANDER Parallel Processing Center (PPC) Operations Manual (List No. 1A05-45) (69-0102/R16)

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- 69-0114/R2 — Section 5. Special Operating Procedures
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- 69-0122/R7 — Appendix A: Cutoff Assay Protocol Reference Guide
- 69-0123/R7 — Appendix B: Point-to-Point Assay Protocol Reference Guide
- 69-0124/R7 — Appendix C: System Integration Guide
- 69-0125/R8 — Index

Revision Log

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1. Write the document control number in the first column. You will find the number in the footer of each section or tab. Make an entry for each section or tab you receive to be placed in the manual.
2. Write the revision date, also found in the footer, in the second column.
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NOTES

Foreword

The COMMANDER Parallel Processing Center (PPC) is designed to automate reagent dispensing, bead washing, in-the-well spectrophotometric readings and data reduction for specified Abbott assays. Congratulations on incorporating the PPC into your laboratory operation.

The PPC system is backed by dedicated professionals who excel in engineering, training, and technical information. For continuing service, we provide telephone technical assistance should you need help in diagnosing a problem. This service is available by calling Abbott Customer Support. Abbott Laboratories looks forward to serving you in any way possible.

Technical Customer Support

Technical customer support is provided to answer any questions you may have about the system, and to help with any serious or recurring error messages.

United States—Call the Customer Support Center (CSC) at 1-800-323-9100.

All other countries—Contact your Abbott Representative.

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NOTE: The length of the Warranty Period and the telephone number of the Customer Support Center (CSC) are only valid in the U.S.

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Refer to the left side of the instrument to identify safety agency approvals for your instrument.

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	**WARNING:**	2–5, 2–5, 2–8, 2–9, 5–5, 5–5, 5–6, 5–34, 9–5, 9–6, 9–20

Refer to *Section 7, Precautions and Limitations* and *Section 8, Hazards* for more details on the specific precautions and hazards.

NOTES

Special Modes Flow Charts

Special Modes allow the operator to perform basic data base and instrument set-up procedures. Special Modes are accessed by pressing **<#>** when **"INSERT TRAY"** is displayed. The operator is then prompted through a menu of special operating procedures.

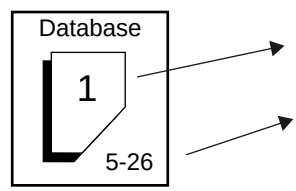
Flow Diagrams

The flow diagrams which follow summarize the Special Modes and the procedures performed by each mode. More detailed information and diagrams concerning each Special Mode are found on the page referenced in the lower right-hand corner of each box in the flow diagram.

These flow diagrams have been designed to provide the operator with a step-by-step approach to the completion of over 75 specific tasks, such as dispense system testing or port assignments.

Example

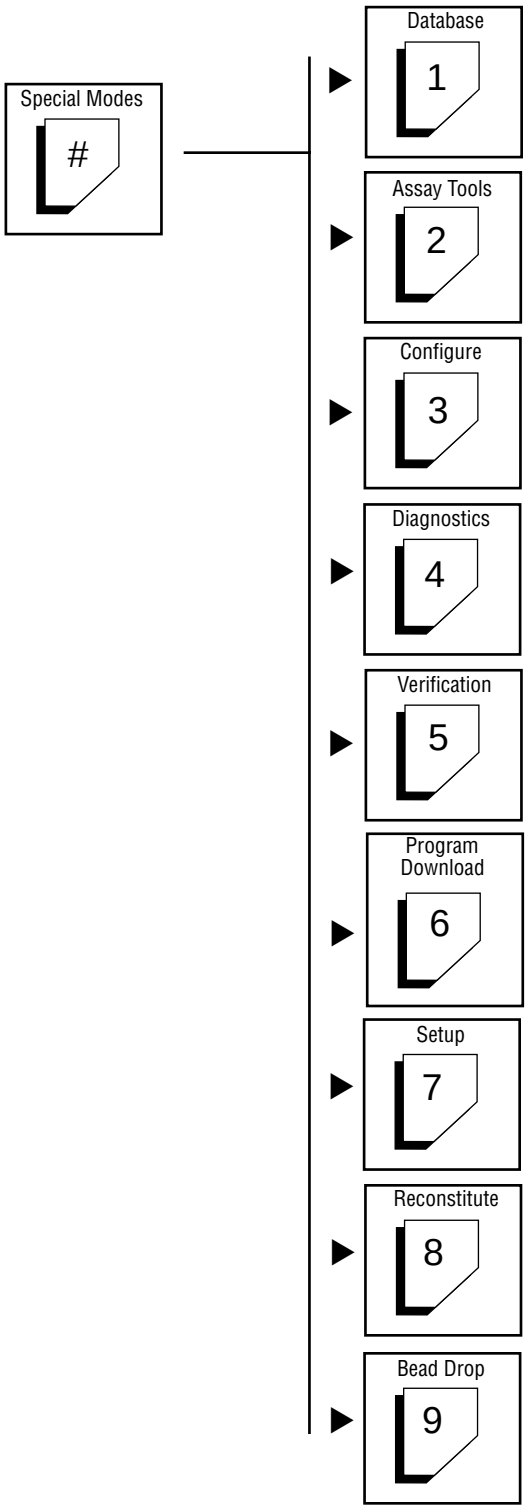
The following example will assist the operator in reading these flow diagrams:



Press **<1>** to access the database functions

Refer to page 5-26 for more detailed information on database functions.

The Special Modes Menu



- Database Functions
- Tray Tools
- Print Calibration Data

- Protocol Editing
- Assignment of Test Number to PPC Assay Protocol

- Connection to DMS or External BCR
- Connection to Pipettor
- Set Up Port Characteristics
- Set Internal Barcode

- System Tests

- Wash Verification
- Reader Verification

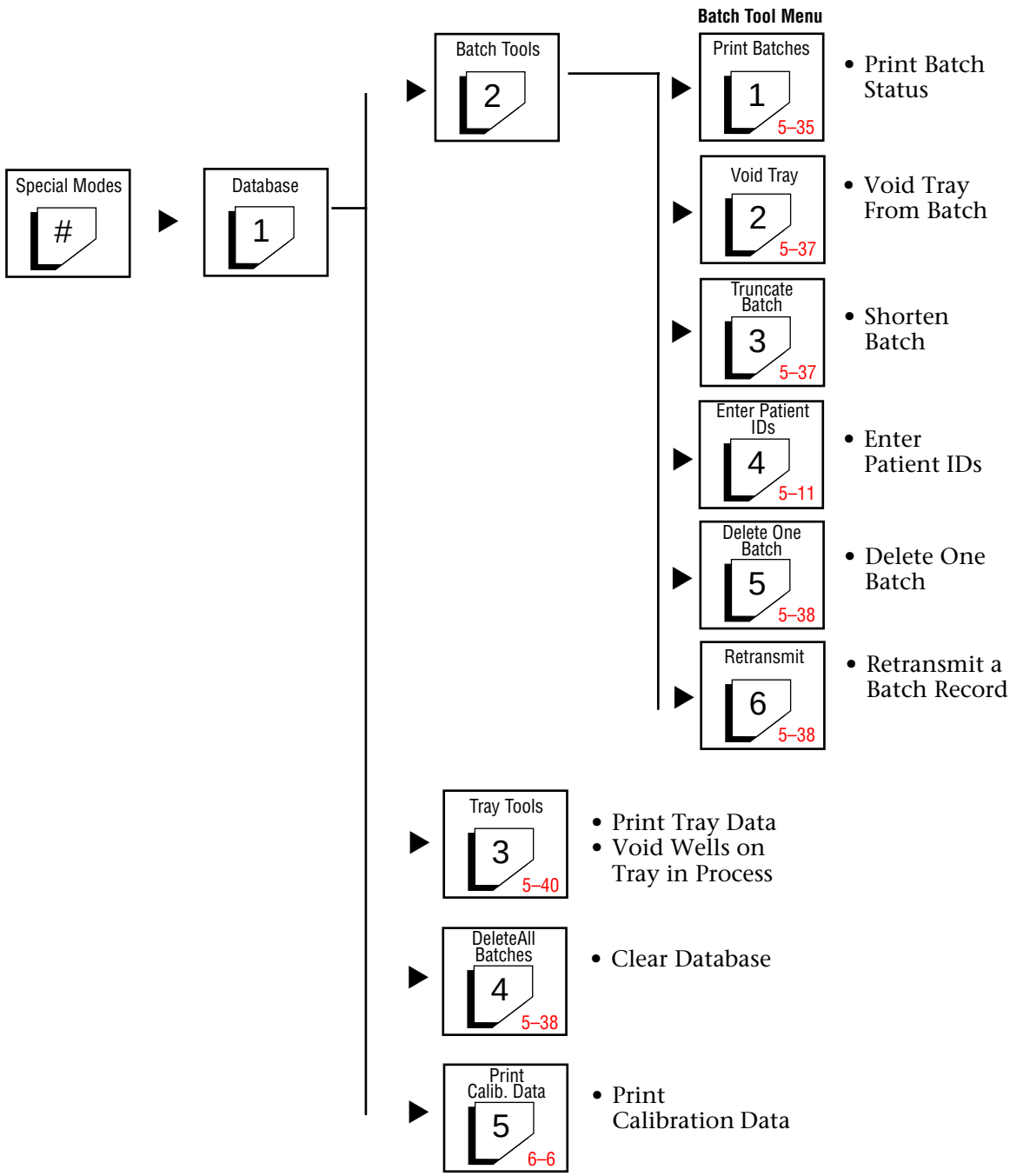
- For Abbott Use Only

- Reread (Disable/Enable)
- OPD Timing (Disable/Verify)
- TPC
- Sample ID Length
- Retransmit (Disable/Enable)
- Set Time and Date

- Performing the Reconstitute Procedure

- Performing the Bead Drop Procedure for
  - Blanks Tray
  - Control/Std/Sample
  - Calibration Tray

Database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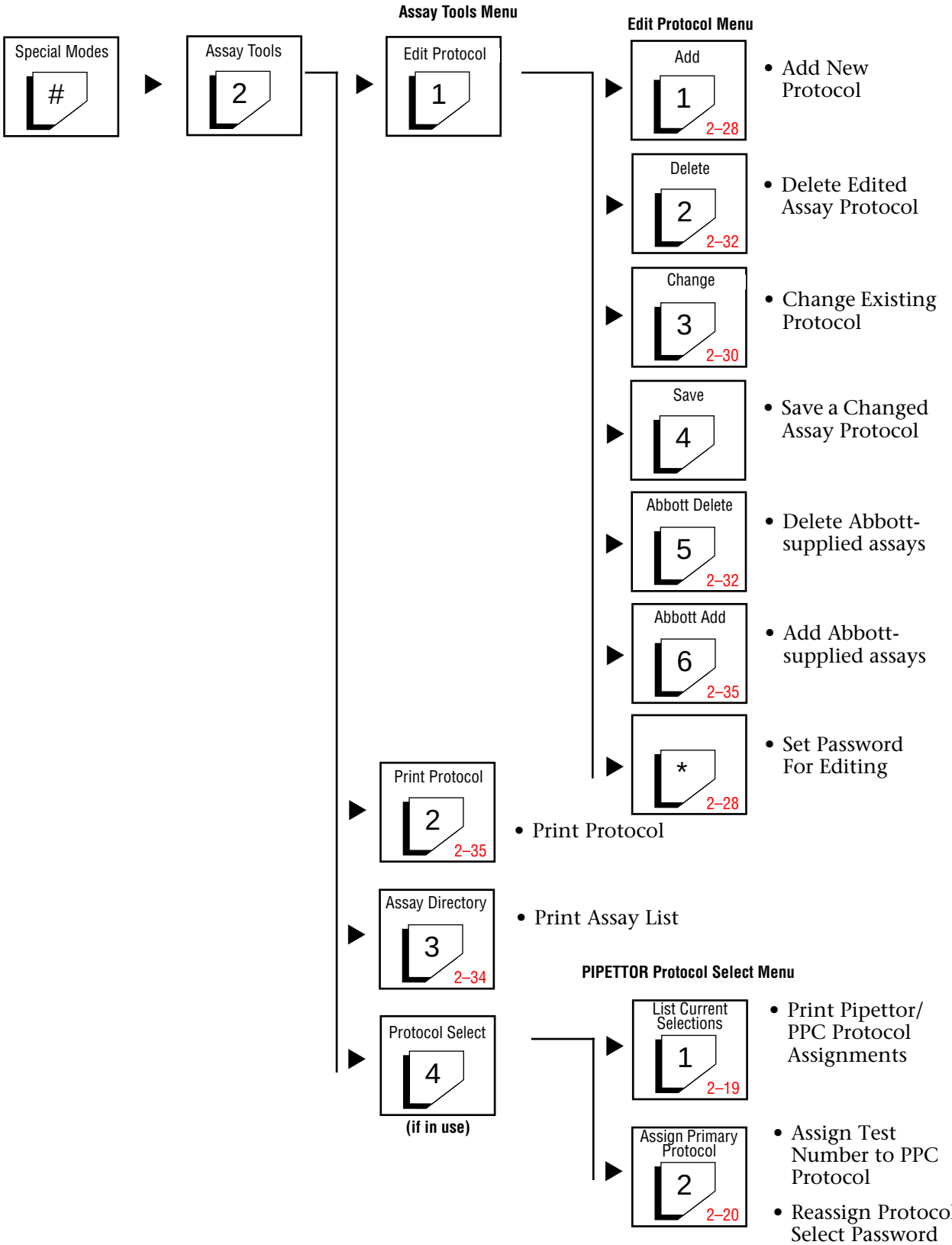
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• Reassign Protocol Select Password

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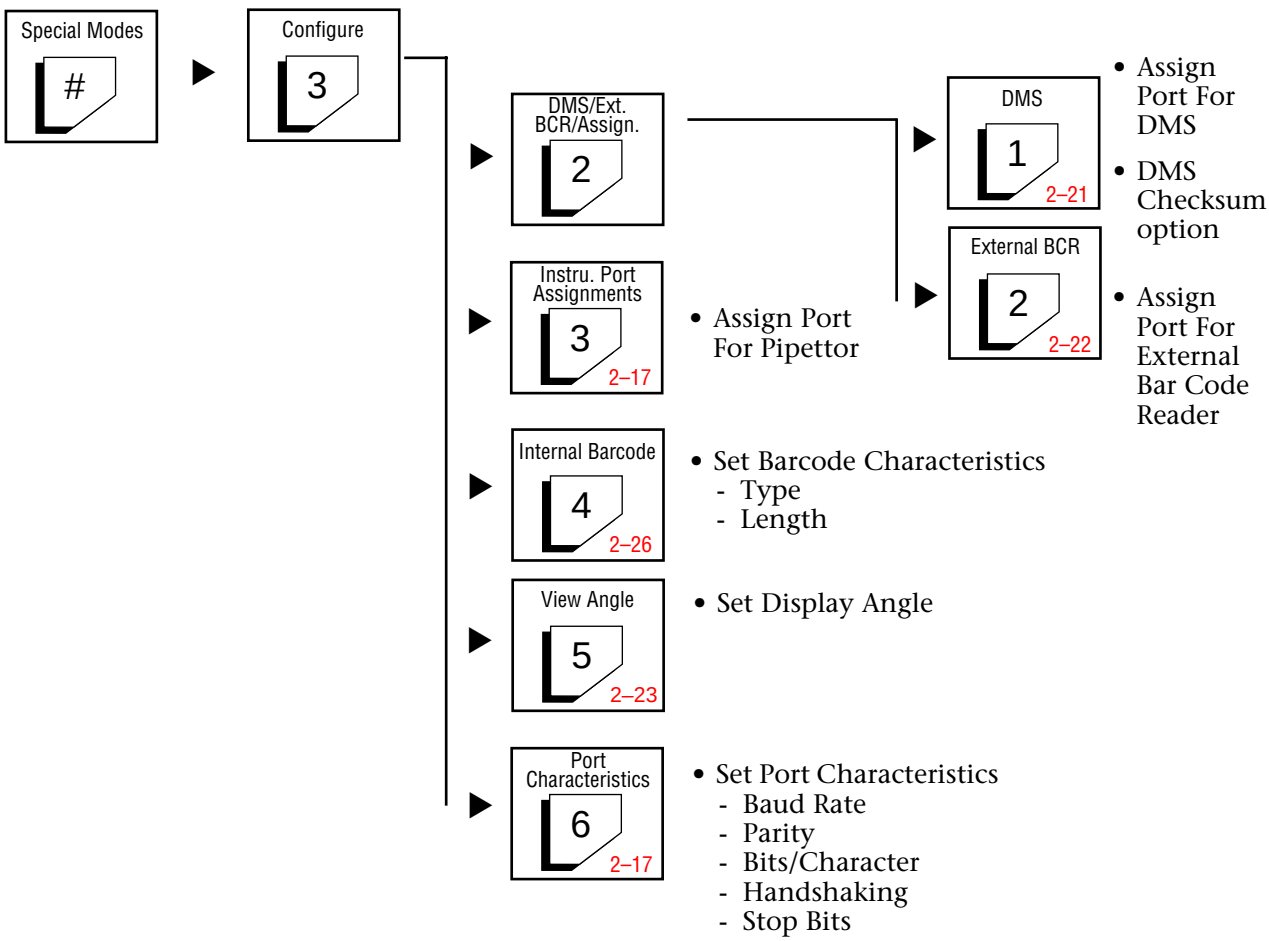
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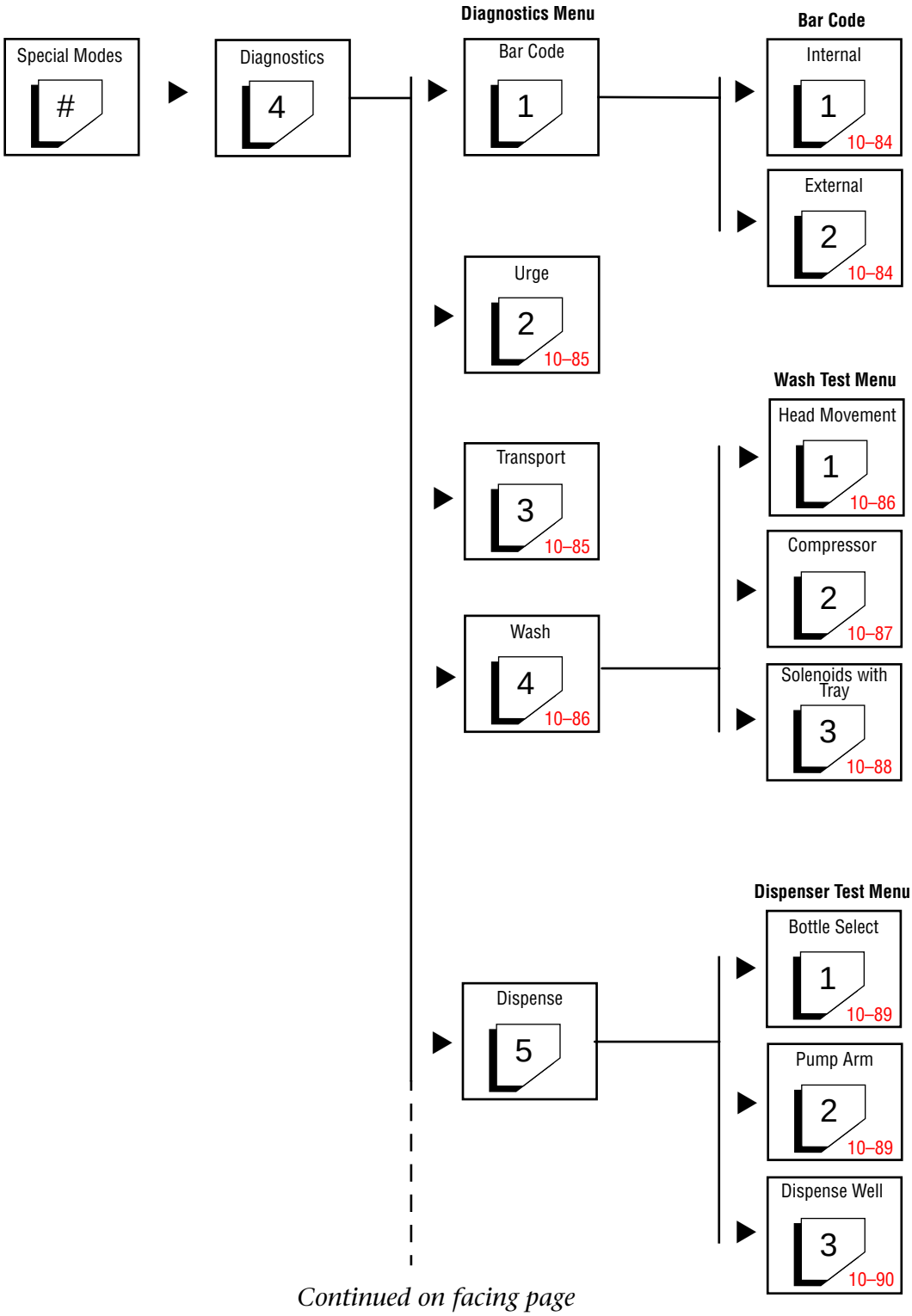

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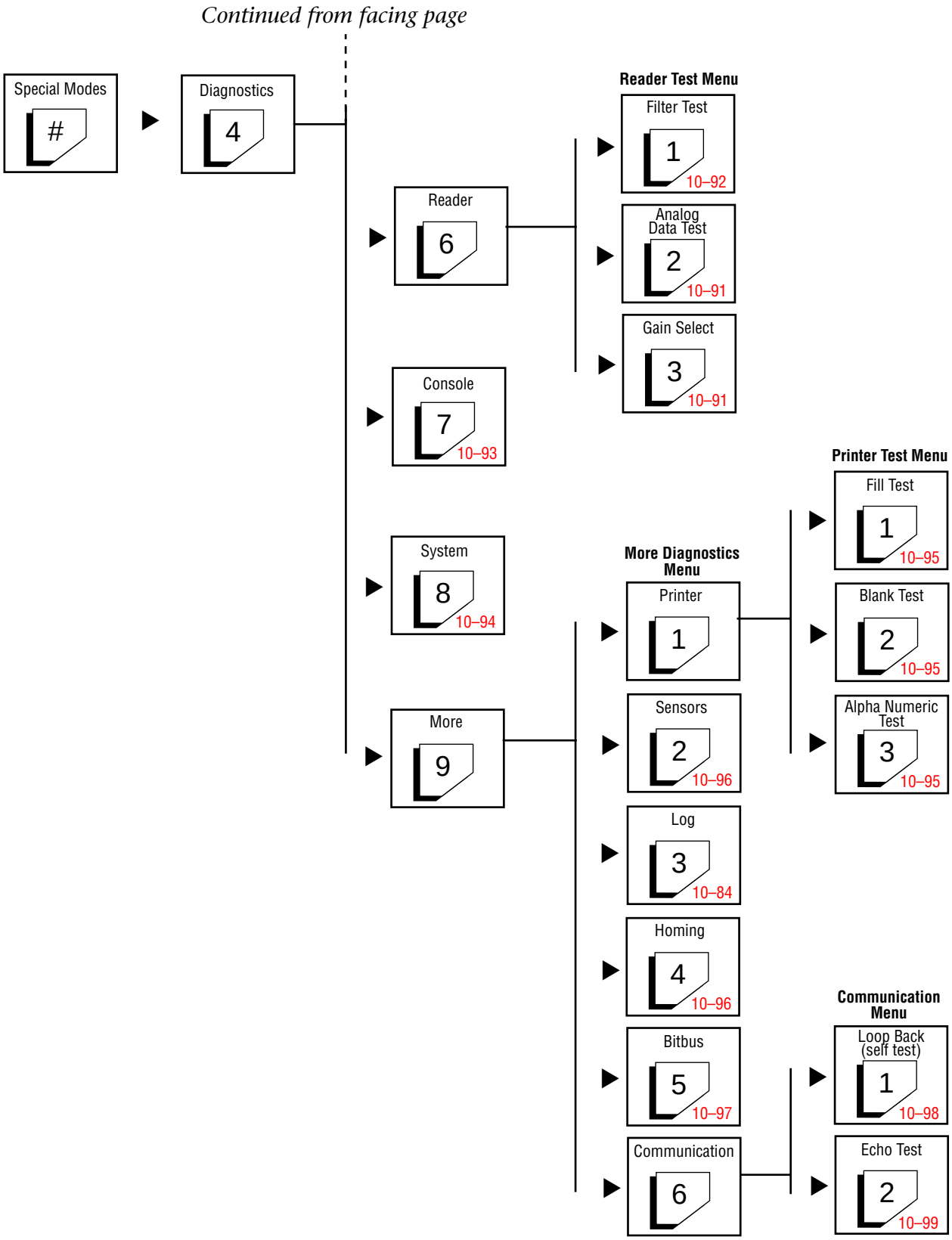
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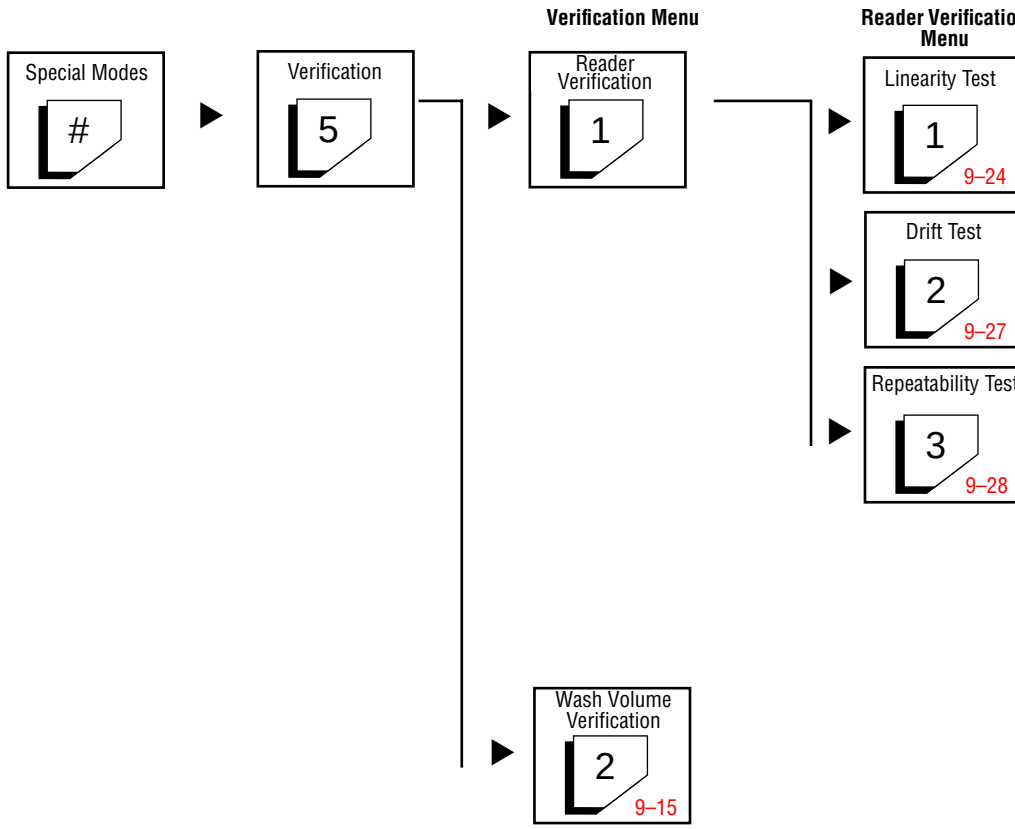
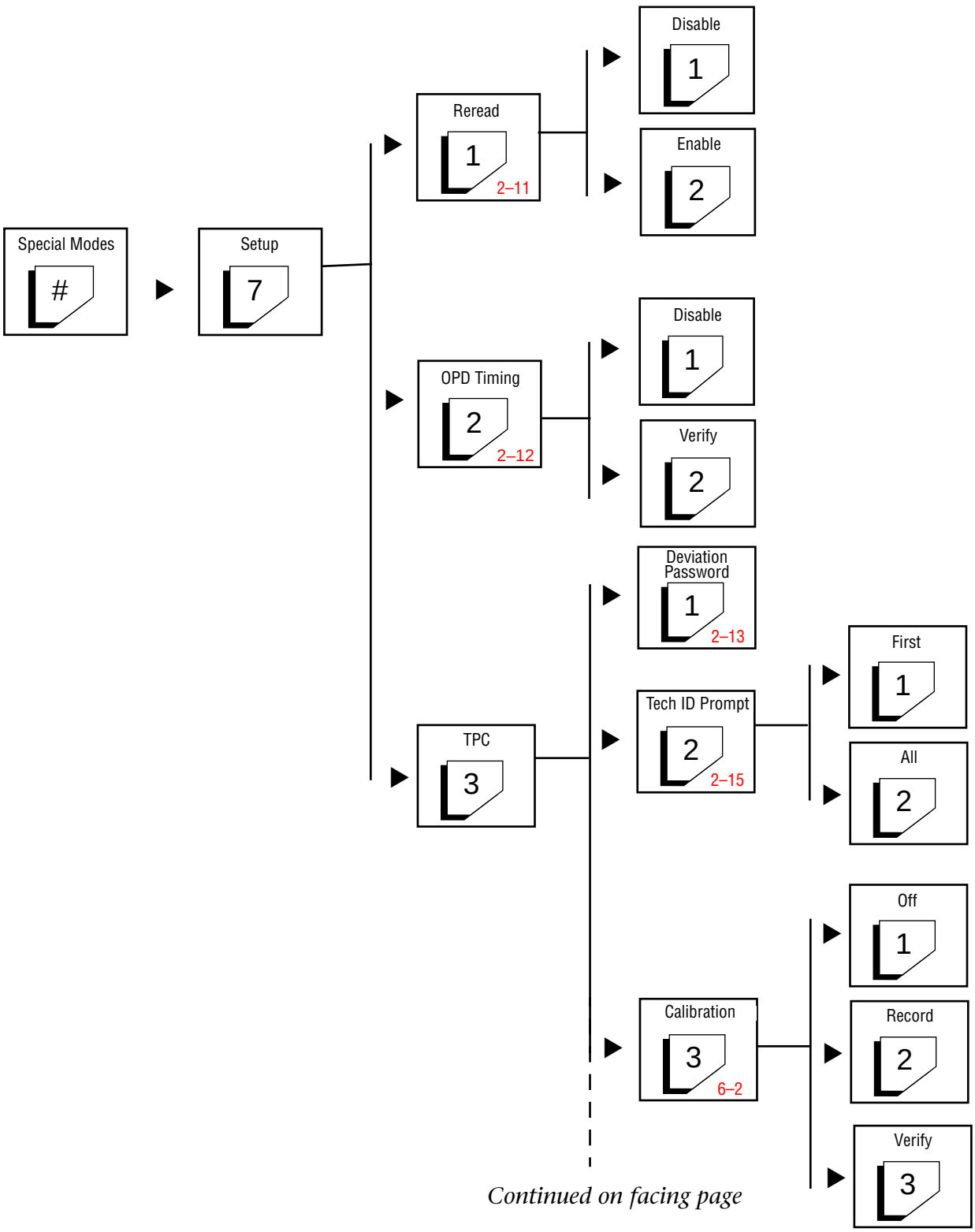


Setup



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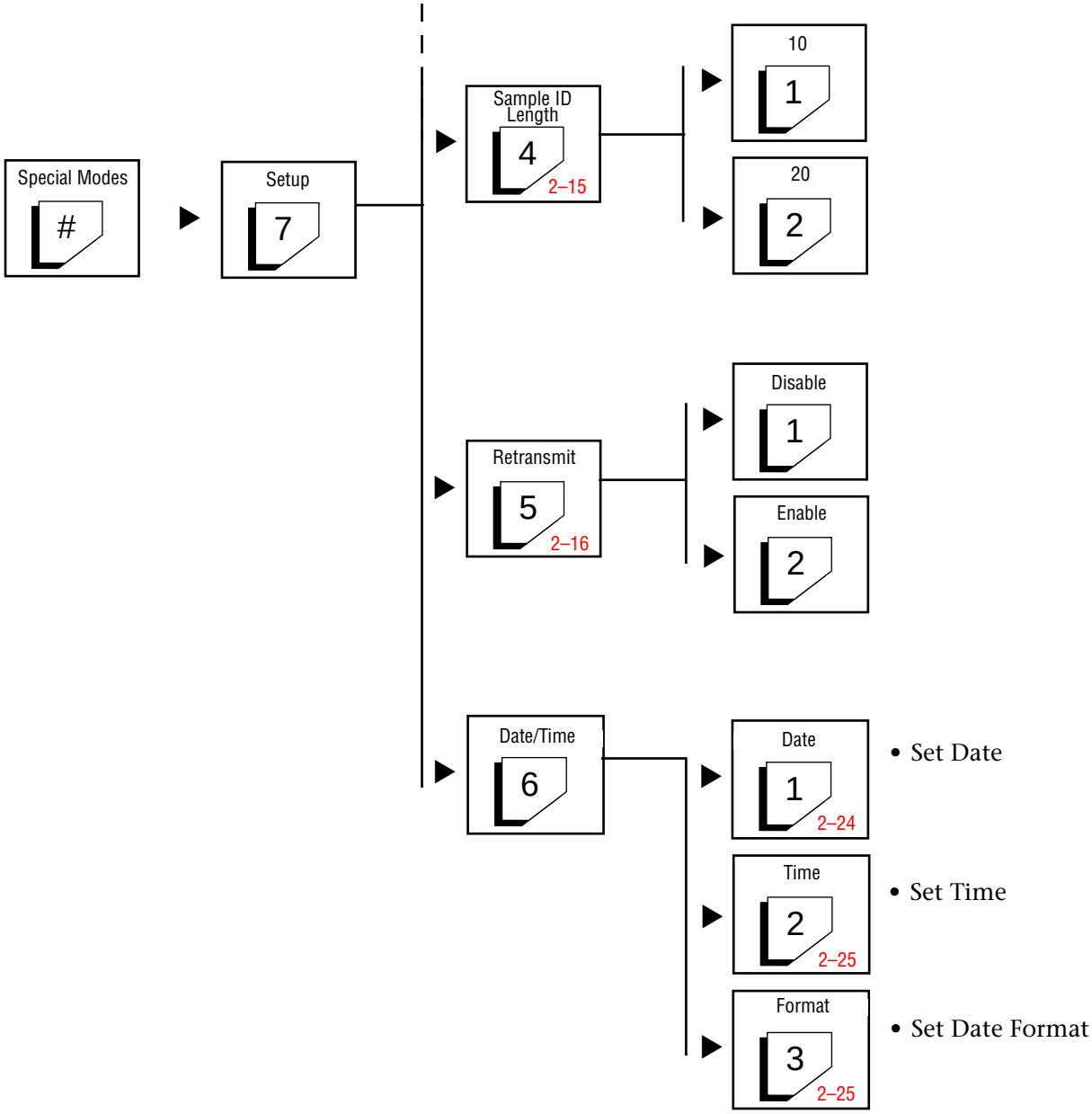
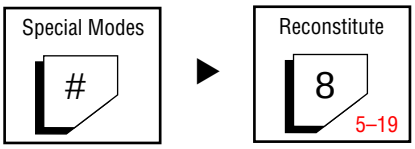


Reconstitution Procedure

TPC



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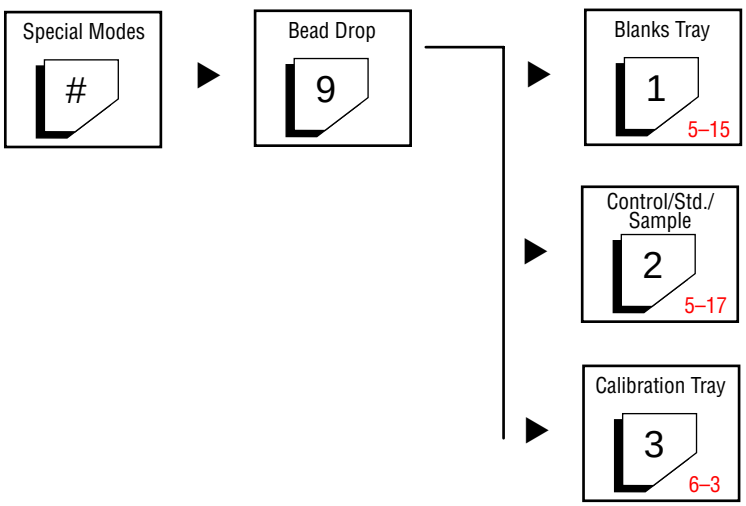
TPC



How To Use This Manual

Introduction

This section presents information on making the most productive use of the COMMANDER Parallel Processing Center (PPC) Operations Manual. The manual has been designed to provide guidance for new and experienced operators alike.

Manual Organization

The Manual is tabbed and divided into sections as listed in the Master Table of Contents. The Master Table of Contents also contains the flow charts which reference Special Modes operations. Accessed by pressing **<#>**, Special Modes allow the operator to perform basic data base and instrument set-up procedures.

Primary manual sections begin with a sectional table of contents and an introductory overview. Task-oriented information is presented in step-by-step format. Sections include:

- **Use and Function**—A complete description of the system, its components, features, and benefits, including a detailed description of PPC processing.
- **Installation Procedures and Special Requirements**—Installation of the PPC including:
  - Unpacking
  - Setting voltage
  - Setting up the wash & waste cart
  - Software installation
  - Powering up
  - Configuration
  - Post-installation procedures
- **Principles of Operation**—A detailed description of the read function, optical density and timing checks and Total Processing Control (TPC™).
- **Performance Characteristics and Specifications**—The general physical, electrical, data communications, reader, and processing specifications of the PPC system.

- **Operating Instructions**—A step-by-step guide to daily operations of the PPC, including:
  - Pre-operating Procedures
  - Operating Procedures, including the Bead Drop and Reconstitution Procedures necessary for TPC™ operation.
  - Special Operating Procedures, including batch tools, tray tools, and detailed information on the PPC keypad.
- **Calibration**—A description of the procedures used to calibrate the PPC, including generating a printout of calibration data.
- **Operational Precautions and Limitations**—Conditions that can affect performance including environmental requirements, precautions and limitations for the system and its components.
- **Hazards**—Describes the possible electrical, mechanical and physical hazards you may encounter while using the PPC.
- **Service and Maintenance**—Details the care and upkeep of the PPC, including: decontamination, cleaning, adjustments, verification, and component replacement. Maintenance schedules and logs are also included.
- **Troubleshooting and Diagnostics**—Provides methods for identifying and responding to error codes and observed hardware and software problems.
- **Bibliography**—A reference section for regulations and technical documents to enhance your use of PPC.
- **Glossary**—Contains information on the technical terms, jargon, and abbreviations used throughout PPC operations.
- **Appendices**—Additional supporting material, including reference guides for cutoff assay protocols and point-to-point assay protocols.
- A comprehensive **Index**.
- **Supplemental Information**—Additional information useful for processing on the PPC.

Text Conventions

Descriptions and instructions in this manual are concise and well illustrated. Most procedures are explained using numbered steps. All of the information related to an activity is generally covered in one place to minimize referencing between sections. Illustrations appear where they are useful to the explanation.

Icons

Throughout the text, icons appear where the nature of the information warrants special attention:

NOTE: This icon is used to indicate important information, or information that represents an exception to conventional methods.

This icon is used to indicate performance and features pertaining to Total Processing Control (TPC™). For a further explanation of the principles of TPC, refer to *Section 3, Principles of Operation.*

CAUTION: The general CAUTION icon appears adjacent to explanations of conditions that could interfere with proper functioning of the system.

WARNING: The general WARNING icon identifies a physical, mechanical or procedural situation where the operator must be aware, alert and cautious to prevent physical injury.

This icon, when present on a label on the system hardware, refers the operator to the manual for information about the hazard.

WARNING: Potential Biohazard. The BIOHAZARD icon labels an activity or area where the operator may be exposed to infectious materials or substances.

Graphic Conventions

Step-by-step instructions involving keyboard sequences are provided throughout the manual using graphics that depict those sequences, as shown in Figure 1 below.

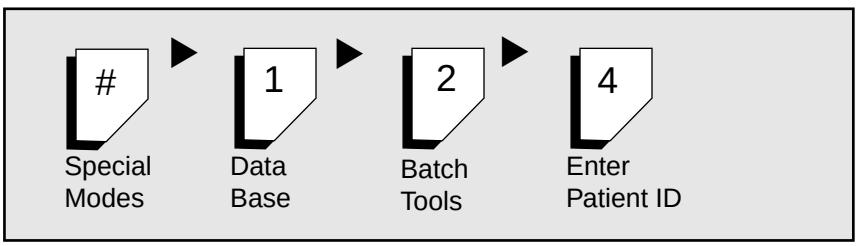


Figure 1. *Informational keyboard graphic. This example explains the keyboard sequence for database special mode entry.*

It is recommended that you read and understand this manual before beginning processing.

Use or Function

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Use or Function

Introduction

The Abbott COMMANDER Parallel Processing Center (PPC) is designed to automate reagent dispensing, bead washing, in-the-well spectrophotometric readings and data reduction for specified Abbott assays. In addition, Total Process Control (TPC™) capability makes it possible to monitor PPC activities.

The PPC is a semi-automated batch-oriented instrument which performs bead enzyme immunoassays. It can be operated as a "stand alone" instrument or interfaced through RS-232 ports with up to four sample preparation instruments such as the COMMANDER Flexible Pipetting Center (FPC™). One of those four ports can be set up to allow information transfer to an external computer. Port 4 can be configured for connection of an external bar code reader.

The primary components of the PPC are the Main Processing Center (Figures 1.1 and 1.2) and the Wash & Waste Cart (Figure 1.3).

NOTE: Your water canister may have a slightly different configuration than the canister shown in this manual.

Instrument Overview

Main Processing Center

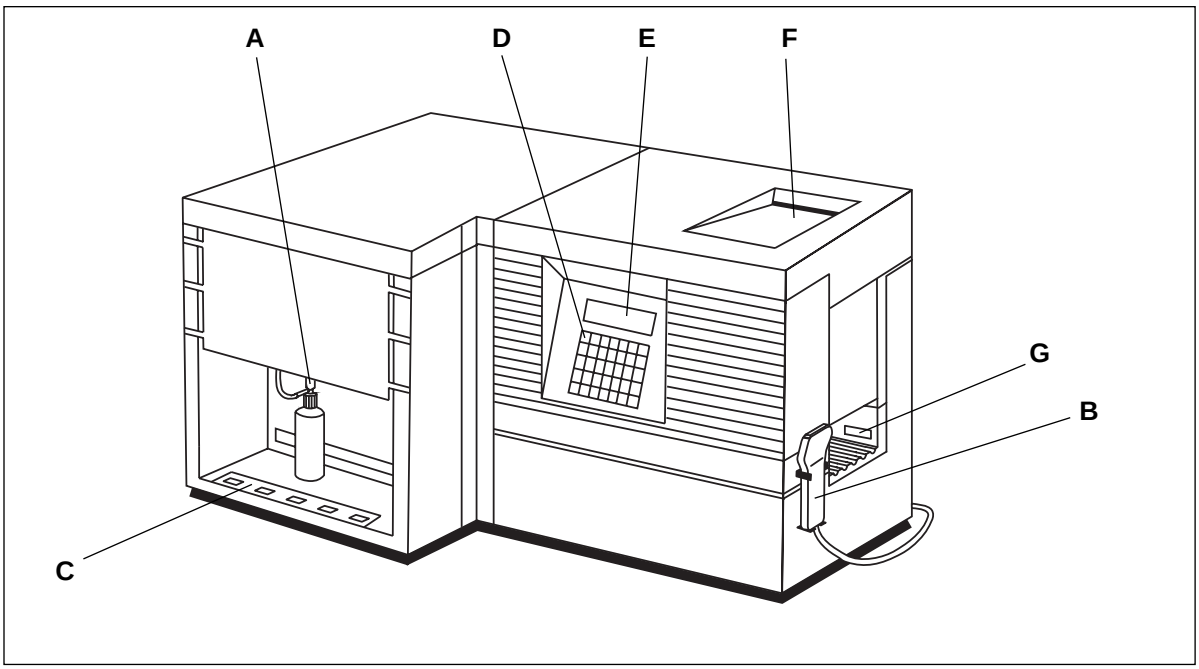

Figure 1.1

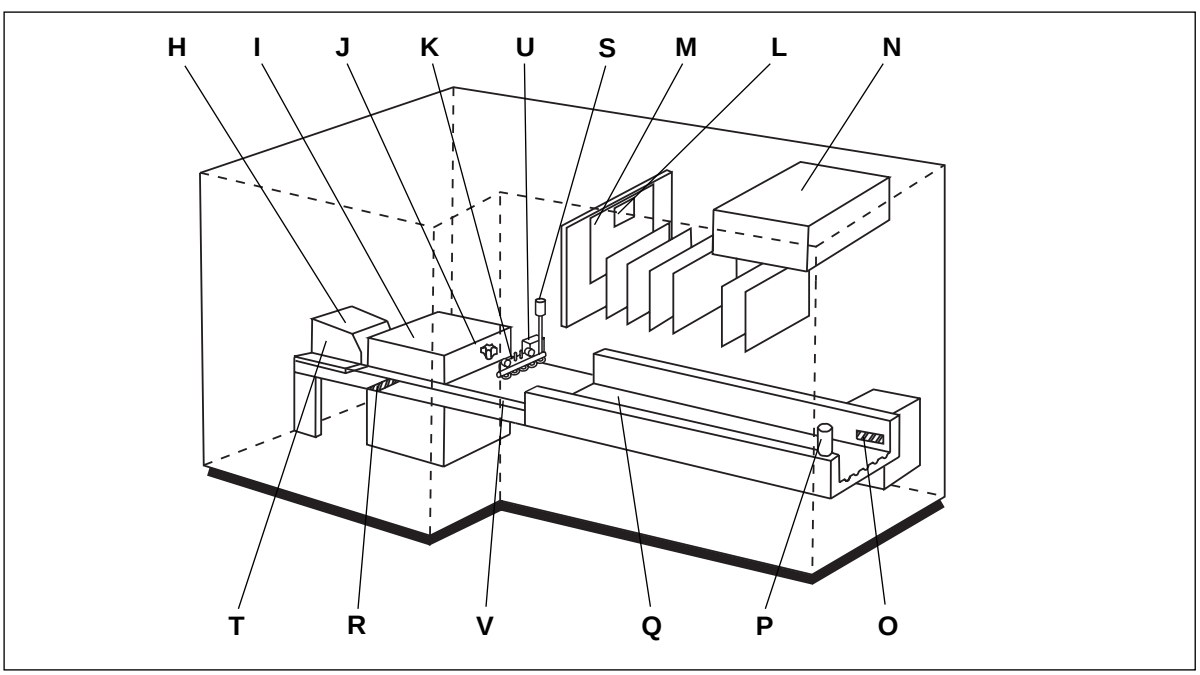

Figure 1.2

Wash & Waste Cart

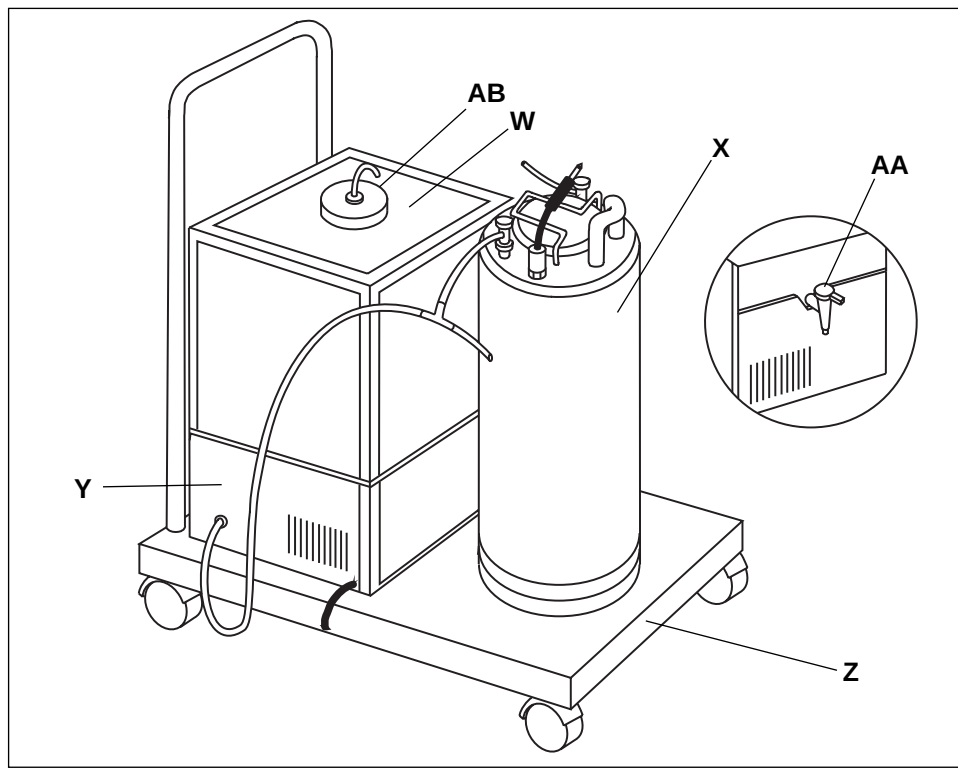

Figure 1.3

Main Processing Center

Exterior

- **A.** Component Station
- **B.** External Bar Code Reader in Holder (optional)
- **C.** Component Station Bar Code Label
- **D.** Keypad
- **E.** Display
- **F.** Printout Area
- **G.** Load Station

Interior

- **H.** Exit Station
- **I.** Optical Reader
- **J.** Dispense Tip Holder
- **K.** Wash Manifold
- **L.** Memory Cartridge Socket (Software)
- **M.** CPU Board and Memory Interface Board
- **N.** Printer
- **O.** Internal Bar Code Reader
- **P.** Entrance Solenoid
- **Q.** Web Switch
- **R.** Glass Liquid Barrier
- **S.** Wash Gate Solenoid
- **T.** Exit Switch
- **U.** Drip Cup
- **V.** Wash Station Switch

Wash & Waste Cart

- **W.** Waste Container
- **X.** Water Canister
- **Y.** Compressor
- **Z.** Cart
- **AA.** Waste Container Spigot (on other side of cart)
- **AB.** Waste Cap with Filter

PPC Control Center

Control Electronics

The PPC's self contained control electronics consist of three functional groups: the CPUs (Central Processing Units), sensors, and memory. The CPUs provide control of processing, display and printer function as well as conversion of spectrophotometer readings.

Sensors tell the CPU what is happening in the instrument at any given time, allowing proper operation of the processing stations.

Assay protocols, data reduction procedures and all process control and TPC™ information are stored in the memory.

Display

The PPC has a 4-line by 40 character LCD display. Instrument status information and operator prompts are shown on the display.

Keypad

Information requested during processing or for performance of some special operating procedures may be entered through the keypad (Figure 1.4) using either alphanumeric entry or dedicated special function keys.

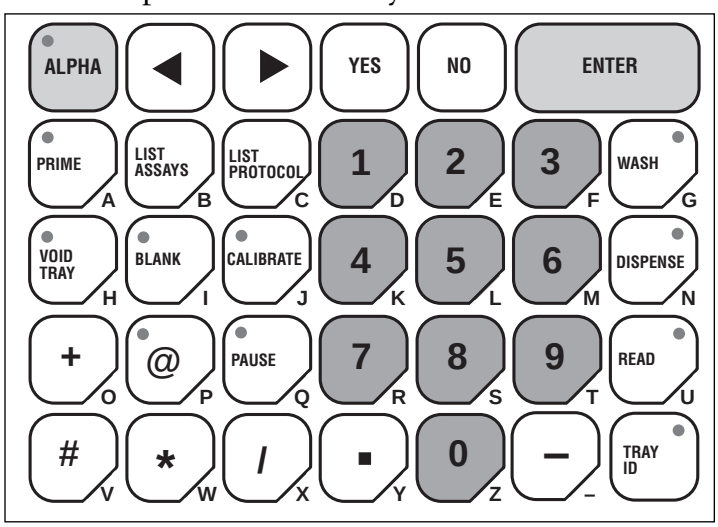

Figure 1.4

NOTE: When entering bar code data with the keypad, verify that the number shown on the display matches the entry you intend to make, then press <**Enter**>.

Printer

The PPC includes a forty-column thermal printer.

External Bar Code Reader

The PPC may include an external bar code reader, connected to Port 4, for entering data (*e.g.,* component lot number, component lot station) necessary for Total Process Control (TPC™), and adding Abbott-supplied assay protocols.

System Description

The PPC is designed to perform a discrete series of processing steps for Abbott bead enzyme immunoassays. The system tracks processing steps performed by PPC. As defined by the protocol, the system executes one or a combination of several tray processing functions on each tray that passes through the instrument. The major instrument functions include:

- Tray Transport function
- Wash function
- Dispense function
- Read function

Each of these functions are described in the following pages.

Tray Transport Function

The Tray Transport Function moves trays through the PPC (Figure 1.5). The system pulls a tray into the instrument and then moves the tray, row by row, through the instrument to accurately position it for precision washing, dispensing and reading. The PPC is designed to support the Abbott 20 well, 20 wide-well, 60 well, and 60 wide-well trays. When all functions are complete, the system moves the tray into the exit station.

The system is programmed to process the contents of the trays in sequential order, accommodating trays that include empty or voided wells.

Various switches along the path report the tray's position to the control software.

There are three stages used in the transport function. The stages, which include the load module, the main drive module and the exit module are described as follows.

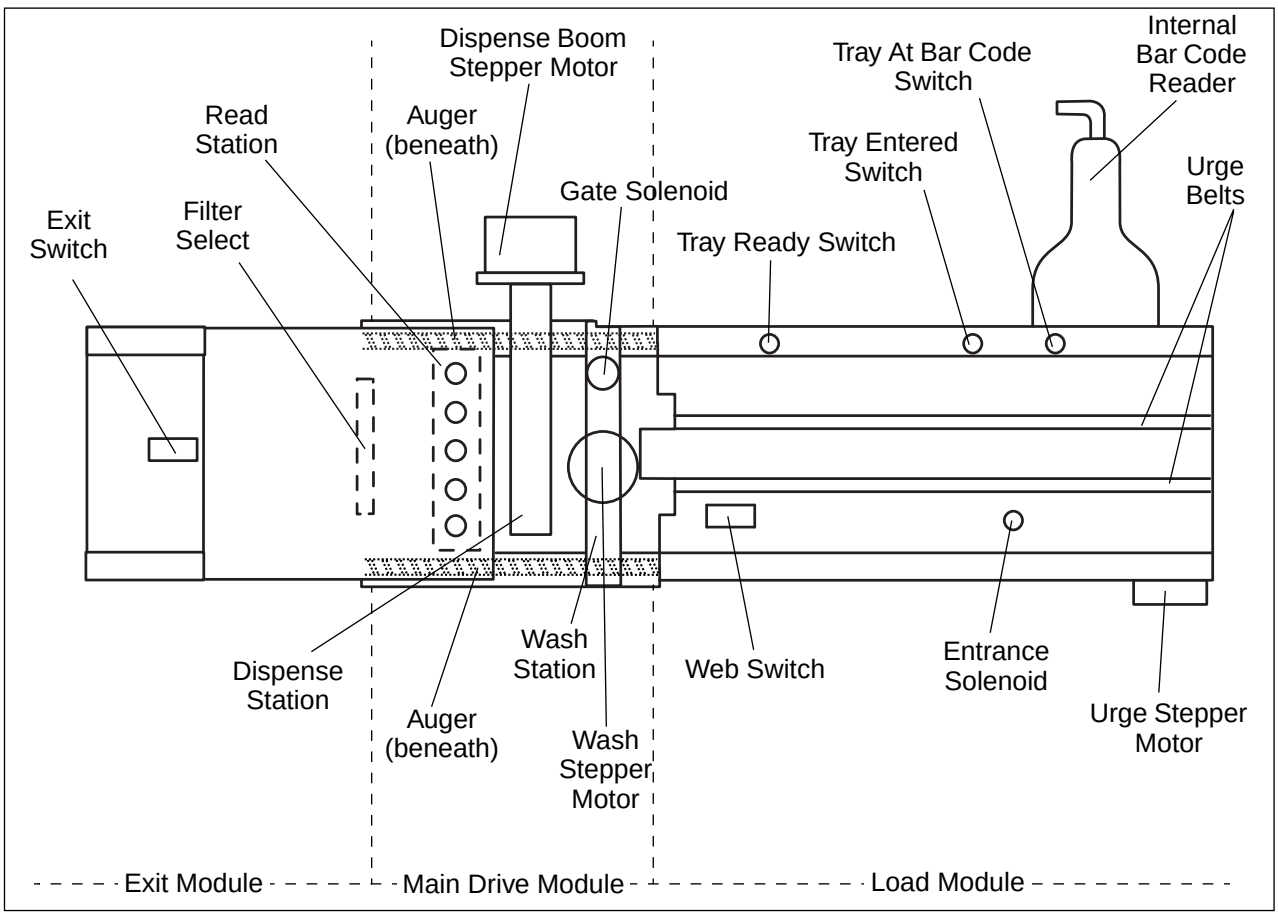

Figure 1.5

Load Module

The first stage of tray transport is the Load Module, which is comprised of several electro-mechanical devices.

The PPC Load Module (Figure 1.6) contains an internal bar code reader (**A**) that automatically reads tray labels (**B**) which are placed on trays. Refer to *Tray Barcoding* in *Section 5, Operating Instructions* for proper bar code label placement. Trays that are not bar coded may be manually identified through the keypad.

When a tray is placed into the Load Module, the "Tray at Bar Code Switch" is actuated. This signals the system to read the bar code label and also turns on the urge stepper motor, which drives the urge belts.

The Entrance Solenoid is not activated until the bar code has been read, or the tray ID has been entered manually via the keypad, and displayed prompts answered. After the tray is identified, it is pulled into the system by the Transport Module.

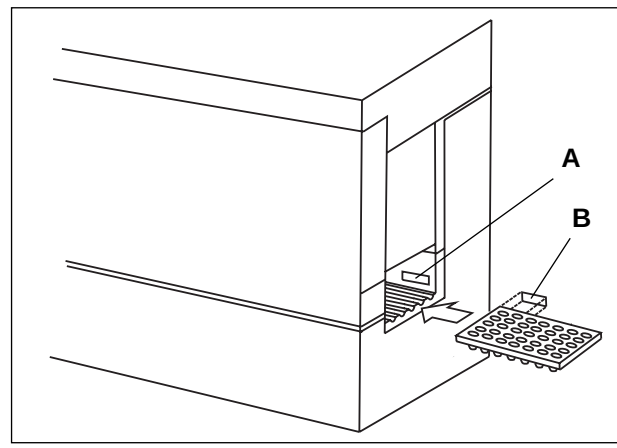

Figure 1.6

Two switches are used to sense tray position. The Tray Entered Switch senses the presence of a tray and deactivates the entrance solenoid. The Tray Ready Switch indicates that the tray is at the Main Drive Module.

The tray's initial position and size, 20 or 60 well, is determined by the web switch.

Main Drive Module

The second stage of tray transport is the main drive module. Its transport augers move the tray through the wash station, dispense station and read station.

The gate solenoid prevents tray entry until the augers are aligned properly and the previous tray is in a position to allow another tray to enter.

The transport augers move trays to precise locations within the transport system. The augers are mechanically designed so that three full turns move the tray one web. There is one web per tray well. This allows the transport system to position and advance the tray wells into exact position under the wash, dispense and read functions of the instrument. The software keeps track of the number of auger turns in order to know which well of the tray is at each station and when a tray is finished at each station.

Exit Module

The third stage of tray transport is the Exit Module. The Exit Station accepts one 60-well tray or two 20-well trays at a time after it has been processed through the main drive module. The Exit switch notifies the control center when a completed tray enters the Exit Station. The Exit Station accepts trays until it is full and then halts processing and beeps, notifying the operator to remove the completed trays in order to continue processing (Figure 1.7).

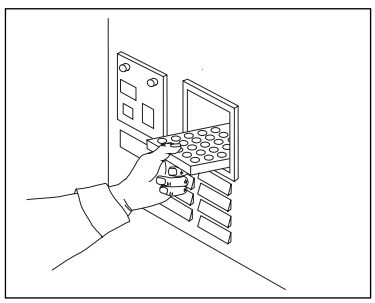

Figure 1.7

Subsequent trays will not exit the main drive module until the tray actuating the exit switch has been removed.

Wash Function

The Wash Function is accomplished by a wash station comprised of a wash system connected to the remote Wash & Waste Cart. The manifold washes one row of wells at a time. The manifold seals the row of wells (Figure 1.8), then delivers pressurized water through the water line (**A**) followed by compressed air through the air line (**B**). This forces the water out of the wells through the manifold's waste ports (**C**). The shape and angle of the jet nozzle forces water to hit the side of the well and spin the bead. The pressurized air flow follows the same pattern (Figure 1.9). When the wash is complete, the manifold is raised to allow the next row to move into position.

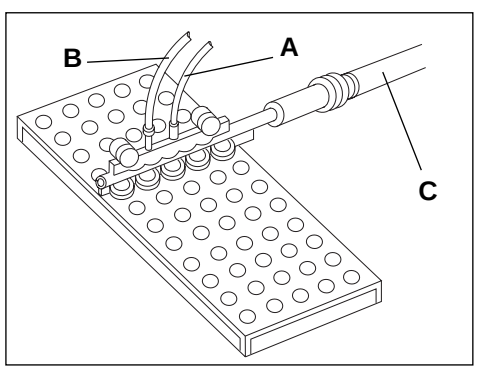

Figure 1.8

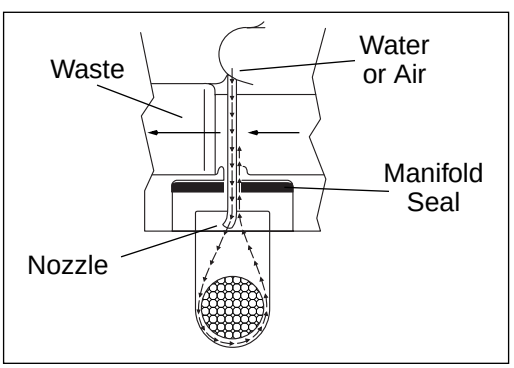

Figure 1.9

The Wash & Waste Cart houses a 20-liter, stainless steel pressurized wash water canister, a see-through waste container, and an air compressor. A COMMANDER Dual Compressor Module (CDCM) can be used in place of the air compressor housed in the compressor cart.

Various switches and sensors detect the position of the wash head, the level of the wash water, and the pressure of the wash air to the control software.

Wash System

The wash system is comprised of the following:

- Wash head stepper motor
- Water and air solenoids
- Water level and air pressure sensors
- Manifold assembly
- Compressor cart or CDCM

Wash Head Stepper Motor

The wash head stepper motor raises and lowers the wash head over a row of five tray wells.

Water and Air Solenoids

The flow of fluids through the wash station is controlled by two solenoids. The water solenoid opens the water valve causing water to flow from the pressurized water canister, through the wash head/bead well cavity and out to the waste container. The air solenoid opens the air valve causing pressurized air to flow through the wash manifold, forcing the remaining fluid from the reaction wells and out to the waste container (see Figure 1.10).

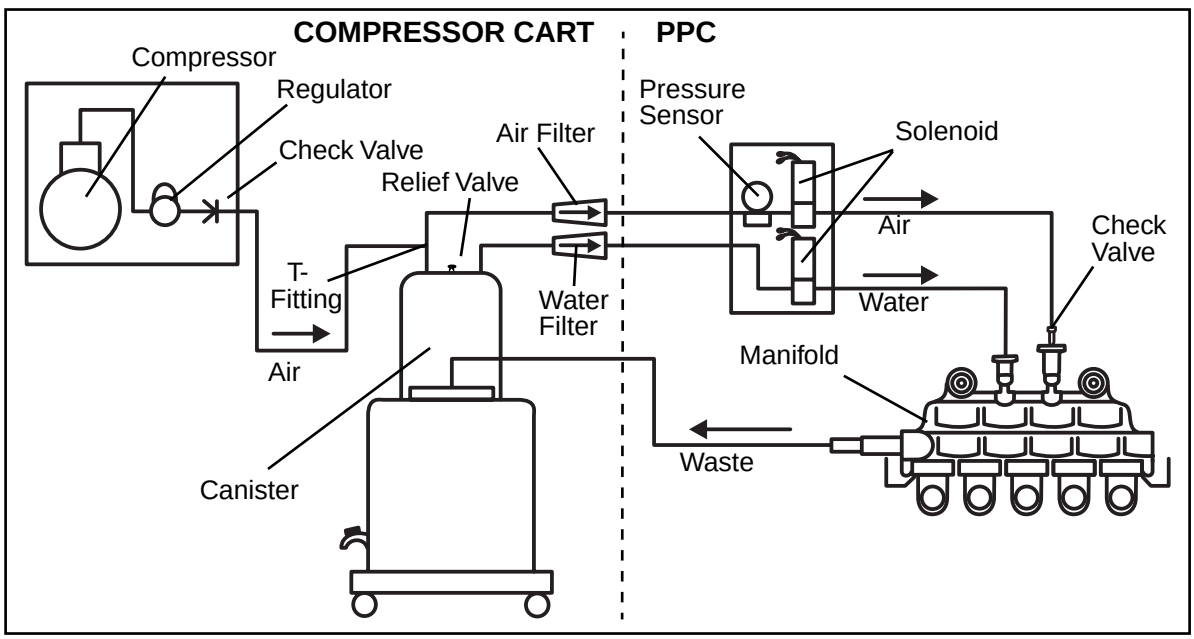

Figure 1.10

Water Level and Air Pressure Sensors

The system verifies the status of the wash water container before initiating the wash cycle. Two sensors are used to monitor its status. An air pressure sensor, located internally in the PPC, monitors to assure that system pressure has reached operating range. On some instruments, another sensor will shut off the compressor when maximum air pressure is reached. The wash cycle will not start or is halted if the pressure drops below the pressure setting (approximately 25 PSI). Water level of the water canister is monitored by a float-switch assembly mounted internally in the water tank. A low water warning will be displayed if the switch is not actuated. A wash in progress when low level has been sensed will continue without interruption. The water tank has an approximate 2 to 3 liter wash reserve to allow processing of approximately three 60-well trays of any wash type after the first low water warning.

Manifold Assembly

When the tray is properly positioned, the manifold seals on a row of five wells. Pressurized water is introduced into the manifold, where it is directed out the five nozzles into the five bead well/manifold cavities. As the water flows, washing each of the five beads, it is simultaneously forced out of the well/manifold cavities through exit ports. Immediately after the wash, pressurized air is forced through the same nozzles, blowing the residual water out the same exit ports to the waste container. A check valve is placed in the air inlet to prohibit water backup in the air line.

Compressor Cart or CDCM

The compressor cart (Figure 1.11) consists of a compressor (**A**), regulator, wash water canister (**B**) with level sensor (**C**), and a waste container (**D**). The cart itself is mounted on lockable wheels and includes a handle to allow for easy movement of the assembly. The PPC uses an air compressor to wash wells under pressure. The PPC controls the AC power to the compressor and is activated by software at the start of a wash operation. The compressor shuts off three to five minutes after the last wash operation. In some models, a switch turns the compressor on and off in response to air pressure.

The CDCM is an optional accessory that maintains the air pressure at all times. The CDCM is powered directly from an AC wall outlet, and can support two instruments.

Five connections link the Wash & Waste Cart to the Main Unit:

- 2 Electrical Connections:

  Water Canister Level Sensor (**C**)

  Compressor Power Cord (**E**)

- 3 Tubing Connections:

  Wash Water Line (**F**)

  Waste Water Line (**G**)

  Air Line (**H**)

The quick disconnects on water and waste lines have shut-offs to prevent water and waste from spilling into the lab environment.

NOTE: Your water canister may have a slightly different configuration than the canister shown in this manual.

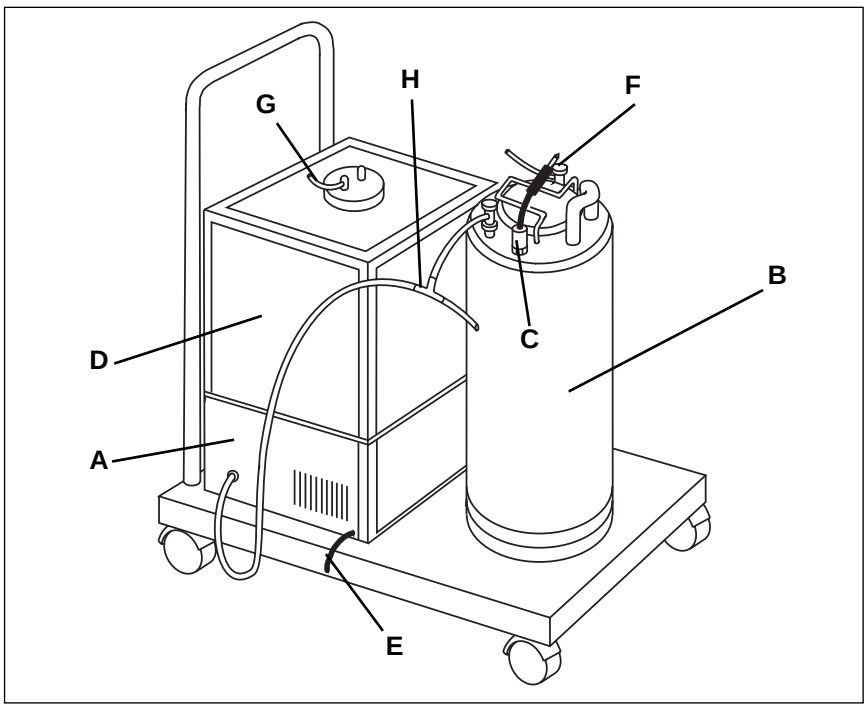

Figure 1.11

Compressor/Regulator System

A compressor maintains air pressure. It pressurizes the system to deliver air and water to the reaction well.

Water Canister

The 20 Liter stainless steel Water Canister has the capacity to hold enough pressurized wash water for approximately twenty 60-well trays depending on the wash type used for the assay. Low water level in the water canister is detected by a level sensor. The PPC first notifies the operator through the display and an audible double beep when wash water is running low but is full enough to complete the trays in the PPC (approximately 3 Liters). The warning display appears when low wash water is first sensed and reappears on every other row of wells that passes the wash station. The level sensor is a monitor only and will not disable the wash station.

Three outlets, located on top of the water canister (Figure 1.12), provide connections to:

- Compressed air (**A**)
- Wash water (**B**)
- The level sensor (**C**)

A relief valve (**D**), also on the top, allows manual release of pressure so that the container can be opened to add water (**E**).

NOTE: If using the CDCM, refer to the *COMMANDER® Dual Compressor Module Installation Guide* for instructions on servicing the water canister.

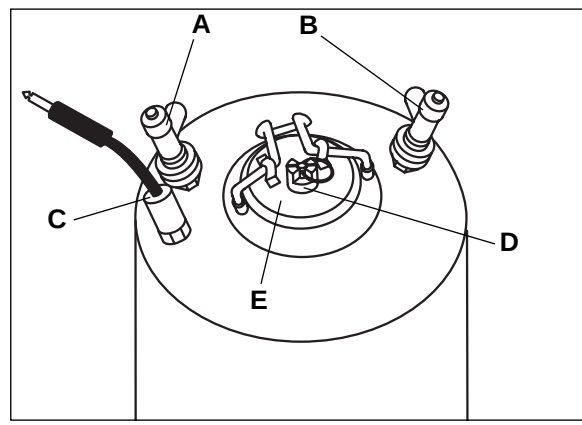

Figure 1.12

NOTE: Your water canister may have a slightly different configuration than the canister shown in this manual.

Waste Container

The 20 Liter Waste Container holds the waste from ten to fourteen 60-well trays plus bleach. The Waste Container connects to the system with a quick disconnect waste hose.

WARNING: Potential Biohazard. Consider all waste from assays run on the PPC as potentially infectious. Wear gloves, lab coats, and follow other biosafety practices as specified in the OSHA Bloodborne Pathogens Regulation 29 CFR 1910.1030 or other equivalent biosafety procedures. Dispose of biohazardous waste in accordance with local, state and federal regulations.

Dispense Function

Reagents are dispensed from dispensers loaded in any of five component stations located on the front of the instrument and identified with bar code labels (Figures 1.13), three for conjugate and one each for OPD and acid. (Station 1 is located closest to the left). Dispensers are pumped by the component actuator (**A**) which automatically positions itself over the component station to be used. Dispenser lines and tips are fed from the component station to the dispense tip holder located over the tray track inside the instrument.

Dispenser selection is accomplished as a preliminary step prior to dispensing. The dispense select stepper motor moves the dispense pump assembly to the appropriate bottle location. The dispense pump stepper motor drives the actuator and dispenser plunger its full travel length as determined by software, resulting in reagent dispense. The PPC dispenses reagent per the component station specified in the assay protocol. If the reagent dispenser is not loaded into the correct component station, reagent dispense will not occur and no error messages will be generated.

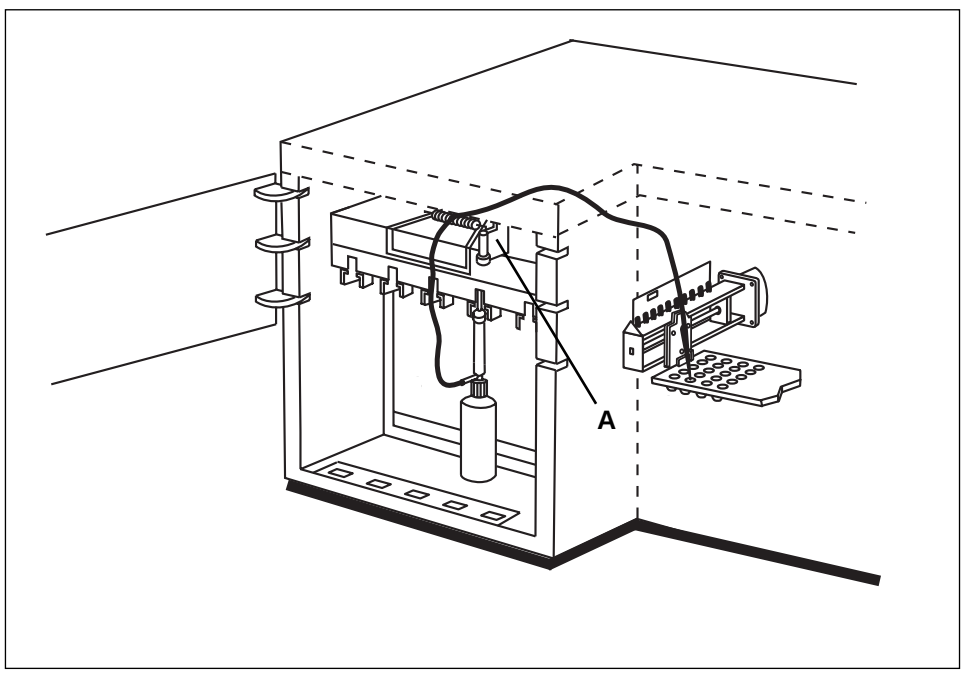

Figure 1.13

The dispense tip holder will hold dispenser tips for up to five reagents, each angled to dispense into the same well. The five tips are clustered together and angled in to point to the center of a bead well. As the dispense tip holder moves across a tray, the dispense boom automatically positions the five tips for sequential dispensing into one well at a time, as required. When a dispense operation is complete, the dispense tip holder homes itself over the drip cup.

Specific dispense rates for each dispenser size have been programmed into the PPC to optimize each dispense operation and prevent splashing. Each component station is backlit when its reagent is to be dispensed to assist the operator with correct dispenser loading.

When the dispense tip holder is properly positioned, the dispense actuator is activated, dispensing the reagent into the well.

The dispense tip holder is then moved to the next well. See Figure 1.14 for the order of dispense.

When all five of the wells have been dispensed, the transport system moves the tray so that the next row of wells in a tray is under the dispense boom. After all the appropriate wells in a tray have been dispensed, the tray is moved out of the dispense station and the dispense tip holder returns to the home position.

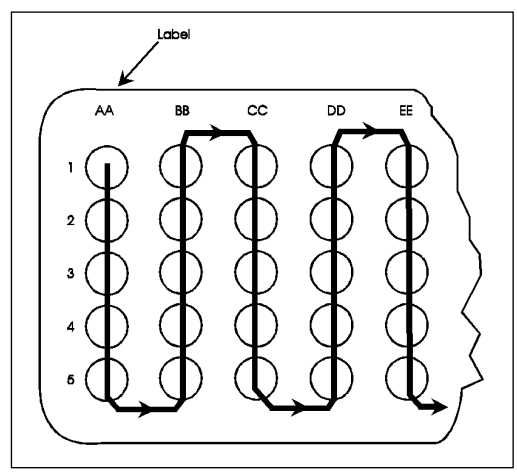

Figure 1.14

Read Function

The PPC reader (figure 1.15) is a dual wavelength analyzer that measures differential absorbances of liquid reactions and converts these readings into analytical values. An algorithm computes the absorbance of each reaction based on the light band with which it was read. Optical readings are taken on each reaction well at two wavelengths, 600 nanometers (nm) and 460 nm. A peak reading is taken at 460 nm and 600 nm is used as the sideband. Absorbance readings are determined from the difference between the two values to eliminate discrepancies that could occur due to optical interferences, variations, or sample turbidity. Measurements are read from –0.029 to 2.200 absorbance units, depending on the assay.

The light source is a tungsten halogen lamp which is focused through a rotating filter wheel. Peak band and side band readings are taken on an entire row of wells simultaneously.

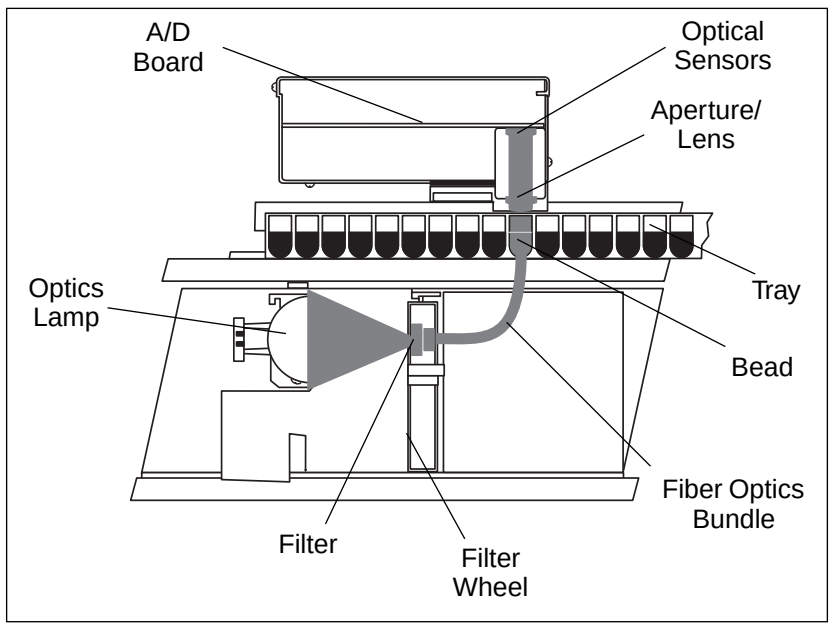

Figure 1.15

The Read Station

The Read Station consists of a lamp, interference filters, a fiber optic bundle with the output subdivided into five separate bundles, and five photocells with lenses.

Light from the lamp is focused through the interference filters onto the fiber optics bundle. The filter wheel containing the interference filters spins to move the appropriate filter into the light path.

The fiber optics divides the light source into five strands. The light is directed through the liquid glass barrier, then through the bottom of the tray, illuminating the bead.

Light collected by five lenses from a row of five wells is read by the five photocells. Light detected by the photocells is converted into absorbance values.

When a row has been read, the Transport function moves the tray so that the next row of wells is under the Read station. After all the rows in a tray have been read, the tray is moved out of the Read station and into the exit module.

The lamp supplies the optical system with the appropriate light for measurement of reaction well absorbance difference. Lamps must be purchased from Abbott. Substitutes may not produce optimal results. The lamp burns constantly. Lamp life expectancy is approximately 2,000 hours (3 months). Noise may be heard when the reader is inactive because the filter wheel spins periodically.

Lens, Optical Sensors and Analog/Digital Read Board

The lens focuses the light beam from the reaction well onto the optical sensors. The optical sensors collect the light and supply the Analog/Digital (A/D) Read Board with the analog data collected from the light intensities of each reaction well. The A/D Read Board converts the analog data to digital data used for the absorbance difference calculation.

- It is acceptable to have negative absorbance values on the final printout. For example, the bead is read in one orientation on the substrate step; it shifts and is read in a different orientation on the final read. The result may be negative due to MINOR bead variation.
- Extreme negative absorbance (less than lower instrument limit) is flagged as an *ERROR.

Memory

The flash memory interface is a hardware and software configuration designed to provide greater flexibility in software upgrades. Upgrades are completed via download from a Memory Card to programmable EEPROMS. After downloading, the memory card may be removed from the instrument and processing occurs using the program information, assay protocols, and data reduction procedures stored in the EEPROMS.

NOTES

Section 2

Installation Procedures and Special Requirements

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Section Overview

This section provides instructions for unpacking, installing and setting up the COMMANDER Parallel Processing Center (PPC) and the Wash and Waste Cart.

NOTES

Installation

Introduction

The following instructions are appropriate for installation or relocation of the instrument. Before unpacking, inspect the carton for damage.

Unpacking

If the carton is damaged, notify Abbott and the shipper immediately.

CAUTION: Do not open immediately upon arrival. To avoid damage to Parallel Processor Optics, boxed instrument must be allowed to remain at room temperature for four hours before opening.

Before removing the PPC from the shipping carton, a location for the instrument should be identified. Refer to *Section 4, Performance Characteristics and Specifications* for information regarding the environmental and electrical requirements.

CAUTION: Allow adequate space above the instrument so both lids can be fully opened. This will allow for safe access to the instrument.

At least two people will be needed to remove the PPC from its shipping carton. Proper precautions should be taken while lifting heavy materials.

1. Place the carton on the floor where the instrument can be removed easily.
2. Wear safety glasses and safety gloves. Carefully cut the strapping with suitable snips and open the top of the box.
3. Remove the accessory carton.
4. Lift the outside box off the carton base.
5. Remove the divider from the instrument if not already removed with the outside box.
6. With at least one person at each end, bend at the knees and place hands under instrument base plate. Lift the instrument onto a strong, level surface.

Next, remove the Wash & Waste Cart from its carton.

1. Open the top of the carton.
2. Remove the wash, waste and air hoses.
3. Remove the protective foam divider.
4. Lift out the water canister and waste container separately.
5. Lift the compressor cart and attached cord out of the carton and set near the instrument.

Setting the Voltage

Refer to the left side of the instrument to determine whether the CE Mark label is present.

Instruments With CE Mark Label

1. Make sure the power cord is not connected.
2. Using a flat blade screwdriver or equivalent, unlock the Fuse Drawer and pull straight out to remove from the Power Module. (Figure 2.1)
3. Be sure the instrument's fuses (**A**) are correct for the voltage selected. (Figure 2.2) Fuses are as follows:

Supply Voltage	Fuse Type and Rating
100/120	F250V 10A, 5x20mm (Qty 2)
220/240	F250V 5A, 5x20mm (Qty 2)

4. Remove the Voltage Selector Insert (**B**). (Figure 2.3)
5. Rotate the Voltage Selector Insert so that the desired voltage will be displayed in the window of the Fuse Drawer.

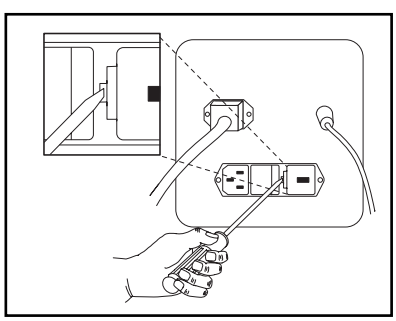


Figure 2.1

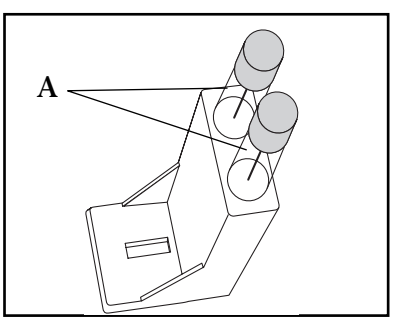


Figure 2.2

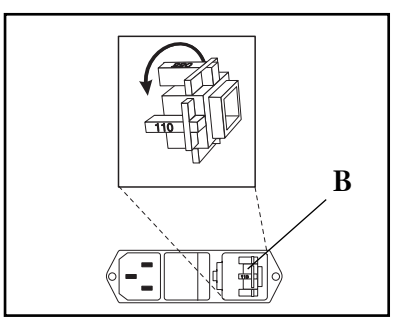


Figure 2.3

6. Reinsert the Voltage Selector Insert.
7. Reinsert the Fuse Drawer.
8. Verify that the desired voltage is displayed in the window of the fuse drawer.
9. If changing the preset voltage, obtain the proper power cord for the new voltage from your Abbott Representative.

WARNING: Verify that the compressor cart is rated for use at the voltage supplying the system, and verify that the system voltage selector indicates the proper supply voltage before connecting.

Instruments Without CE Mark Label

1. Make sure the power cord is not connected.
2. Using a flat blade screwdriver, move the power selection indicator (**A**) located on the power panel on the left side of the instrument to 90-132 VAC or 198-264 VAC, as appropriate for your power supply. (Figure 2.4)

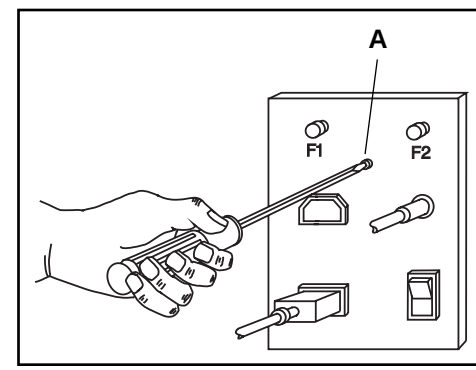


Figure 2.4

3. If changing the preset voltage, obtain the proper power cord for the new voltage setting from your Abbott representative.
4. Be sure the instrument's fuses are correct for the voltage selected and are inserted in the correct position. See "Fuse Replacement" in *Section 9, Service and Maintenance*. Fuses are as follows:

Supply Voltage	Fuse
90-132V	One 10-Amp Fuse in position F1
198-264V	Two 5-Amp Fuses: one in position F1, one in position F2

WARNING: Verify that the compressor cart is rated for use at the voltage supplying the system, and verify that the system voltage selector indicates the proper supply voltage before connecting.

Setting Up the Wash & Waste Cart

NOTE: Your water canister and power panel may have a slightly different configuration than shown in this manual.

NOTE: CDCM is approved for use with the COMMANDER Parallel Processing Center. (See the Parts List in *Section 9, Service and Maintenance*.) Refer to your CDCM Installation Guide for installation instructions.

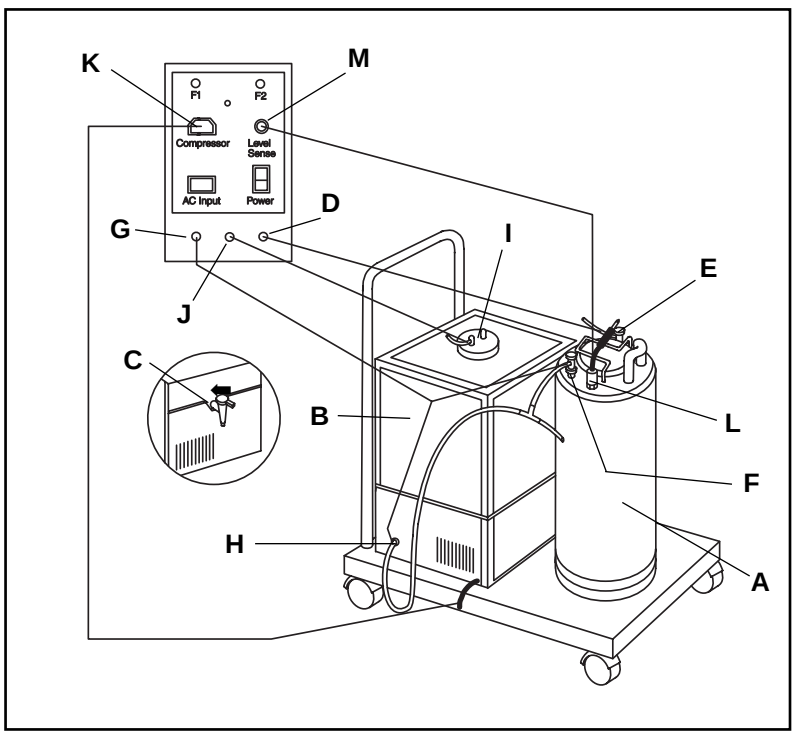


Figure 2.5

After removing the wash and waste cart (Figure 2.5) from its carton:

1. Place the water canister (**A**) in position on the cart.
2. Attach the spigot (stored inside the waste container for shipping) to the waste container.
3. Place the waste container (**B**) on the cart with the spigot aligned with notch in base (**C**).
4. Fill the water canister. Refer to *Section 5, Operating Instructions.*

5. Connect the water canister to the PPC using the tubing with black connectors as follows (Figure 2.5):

   - Connect the black quick disconnect to the connection labeled “WATER” on the left side of the PPC (**D**).
   - Connect the other end of the tubing to the connection labeled “WATER” on the water canister (**E**). Raise the ring around the bottom of the connector as you press it into the water connection (Figure 2.6).

   NOTE: Both connectors must be fully engaged to provide proper wash. PPC will not sense the connections.

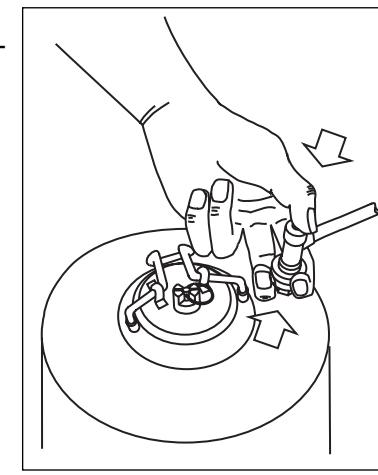


Figure 2.6

6. Connect air compressor to the water canister and PPC using the tubing with white connectors as follows (Figure 2.5):

   - Connect the gray connector on the short piece of tubing attached to the “T” assembly onto the water canister connection labeled “AIR” (**F**). Raise the ring around the bottom of the connector as you press it onto the air connection (Figure 2.6).
   - Connect the quick disconnect on the longer length of tubing to the connection labeled “AIR” on the left side of the PPC (**G**).
   - Connect the quick disconnect on the shorter length of tubing to the base of the compressor on the wash cart (**H**).

   NOTE: When connecting hoses, listen for a “snap” of the connections. This signifies a solid connection.

7. Connect the waste container to the PPC using the tubing with the yellow connectors as follows (Figure 2.5):
   - Connect one quick disconnect (with right angle) to the yellow connector on the tubing attached to the waste container lid (**I**).
   - Connect the other quick disconnect to the yellow connection labeled “WASTE” on the left side of the PPC (**J**).

   WARNING: Potential Biohazard. Both connectors on the waste line must be fully engaged to avoid splashing, leakage, or backup of waste through the system.

8. Connect the compressor power cable to the power outlet labeled “COMPRESSOR” on the left side of the PPC (**K**).

   WARNING: Verify that the Compressor Cart is rated for use at the voltage supplying the system and verify that the system Voltage Selector indicates the proper supply voltage before connecting.

9. Connect the water level sense cable to the water canister and PPC as follows (Figure 2.5):
   - Connect the cable to the plug on the water canister labeled “LEVEL SENSE” (**L**).
   - Plug the metal connector on the cable outlet labeled “LEVEL SENSE” on the left side of the PPC station (**M**). Make sure it is completely and firmly inserted.

Software Installation

If installing the PPC for the first time, software must be downloaded from the memory card. Software download may only be performed by an Abbott Representative. For additional information, refer to the *COMMANDER® Parallel Processing Center (PPC) Installation and Validation Protocols*.

Powering Up

WARNING: Be sure that the AC power module is set for the proper voltage before plugging the instrument into the AC power line.

CAUTION: Ensure proper grounding by using the grounded power supply cord provided and connecting to a properly grounded outlet.

NOTE: It is recommended that the PPC be left on at all times.

1. With the instrument set for its proper voltage and placed in its final lab location, plug the power line cord into the AC power module on the left side of the instrument and then into the power outlet.
2. Press the power switch to ON. The first time the PPC is powered up, the screen prompts for entry of the serial number.

```
PPC Serial Number
SN: _____________

Enter PPC Serial Number
```

3. Type the instrument's seven-character *(i.e.,* 0001234 or 1234-96) serial number and press <**Enter**>. The screen requests confirmation.

```
PPC Serial Number
SN: _____________

Confirm Data Please
```

4. Re-enter the serial number and press <**Enter**>.

NOTE: If the serial number does not match, you will be returned to Step #3.

NOTE: The system also requests entry and confirmation of its serial number at power up whenever the number has been deleted from its database.

The system progresses through a series of self-diagnostic tests, which will take approximately one minute to complete. When the tests are successfully completed, the screen displays the welcome screen. The system will also print a welcome message.

```
**********************************************

            Welcome to the ABBOTT
         PARALLEL PROCESSING CENTER
      mm/dd/yy hh:mm:ss V:x.xx SN:sssssss
     Copyright XXXX by ABBOTT LABORATORIES

**********************************************
```

Version x.xx denotes software version, SSSSSSS denotes instrument serial number

NOTE: When powering up the PPC, verify that all trays have been cleared before inserting any new trays.

When the PPC has finished initializing, the display prompts:

```
                INSERT TRAY —>

 Date: MM/DD/YY                Time: hh:mm:ss
```

Configuring the PPC

NOTE: A password must be selected during the first use of the Setup option. The password must contain four characters (alphanumerics, *, /, ., -, [, and space are allowed). This password will be required on subsequent attempts to use the Setup mode. It should be recorded and retained in a safe place.

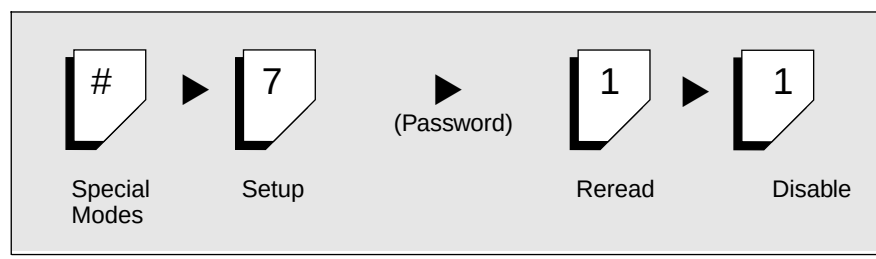
The Reread Function

Determine whether you want the PPC to be enabled to reread a processed batch. The operator must assure that rereads are completed within two hours of acid addition. Reread batches must meet all other manufacturer's criteria for validity.

NOTE: When Reread is selected, the time stamp in the batch header is the time when the original batch was archived. Prior to configuring the PPC for reread, proper procedures should ensure that reread data is not interpreted as duplicate test results. It is recommended that the retransmit function be used to resend batch data to an LIS.

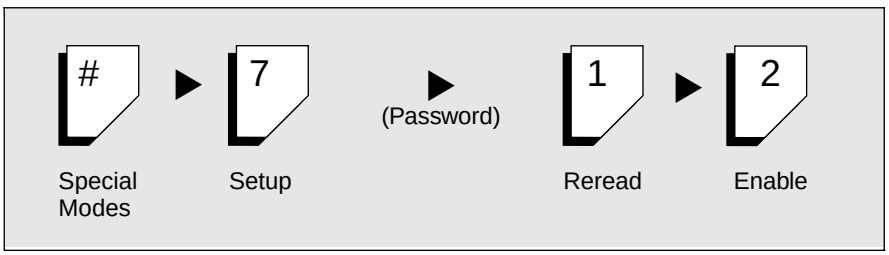
Key in the following to specify the reread function.

To Disable



Disables the Reread option. Pressing the **<Read>** key will result in display of error 3.4.7 Reread Disabled.

To Enable

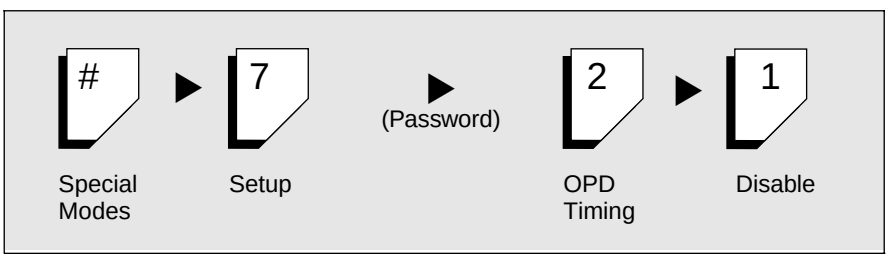


Allows rereading of trays for which archived data exists. This is the default mode.

OPD Timing

Determine whether you want the PPC to compare OPD Incubation Time with assay protocol minimum and maximum limits. The option may be changed during batch processing, but whichever option was in effect at the beginning of the batch will remain in effect for that batch. Archived batches will retain original option. Key in one of the following to specify OPD Timing.

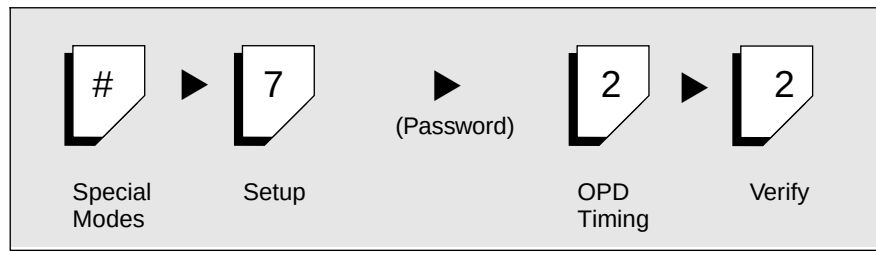
To Disable



OPD Incubation Time will NOT be compared to assay protocol minimum and maximum limits. An advisory message will be printed stating when the first row of OPD was dispensed. This is the Default mode.

```
****************************************
TRAY#                          78963
ASSAY # 3    NAME: AUSZYME MC A
SN: sssssss
Next Step:
Dispense 300 uL 1N SULFURIC Sta.#5/Read
First Row OPD Dispensed At: 14:10:59
****************************************
```

To Enable (verify)



OPD Incubation Time will be compared to assay protocol minimum and maximum limits. An advisory message will be printed for the first tray.

```
****************************************
TRAY#       36908
ASSAY # 1       NAME: CORZYME A
SN: sssssss
Next Step:
Dispense 300 uL 1N SULFURIC Sta.#5/Read
Insert Tray After: 14:50:50
            OPERATOR NOTE
          OPD Timing in effect.
    Allow time to load needed reagents
        prior to tray processing.
  ****************************************

            For Subsequent Trays
****************************************
TRAY#       89532
ASSAY # 1       NAME: CORZYME A
SN: sssssss
Next Step:
Dispense 300 uL 1N SULFURIC Sta.#5/Read
Insert Tray After: 14:54:50
****************************************
```

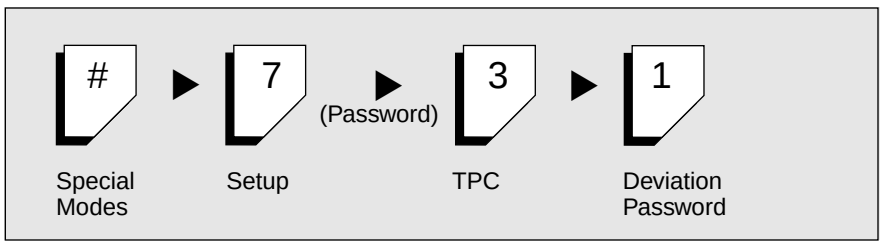
TPC™ Functions

Determine the TPC functionality that is appropriate for your laboratory procedures and key in the following as necessary.

Defining/Changing Deviation Password

A Deviation Password enables the PPC operator to continue processing after a TPC error (*e.g.,* use of an expired component) when TPC Mode is Verify, or, in some cases, Record. Key in the following to define or change the Deviation Password:

CAUTION: If no Deviation Password is defined, override of TPC Deviation cannot occur. The operator will be returned to the previous screen to correct the entry, or may press <#> to exit. If the operator exits the processing of the batch, the batch must be manually voided.



If entering the first Deviation Password, the PPC displays: "ENTER NEW PASSWORD".

1. Enter a four-character password using alphanumerics or the characters * / . - [{space}, or press <#> to return to the TPC™ menu.
2. The PPC displays the new password and requests confirmation: "CORRECT? (YES/NO)".
3. Select <YES> to store the new password. The screen returns to the PPC menu.

If changing an existing Deviation Password, the PPC displays "ENTER PASSWORD".

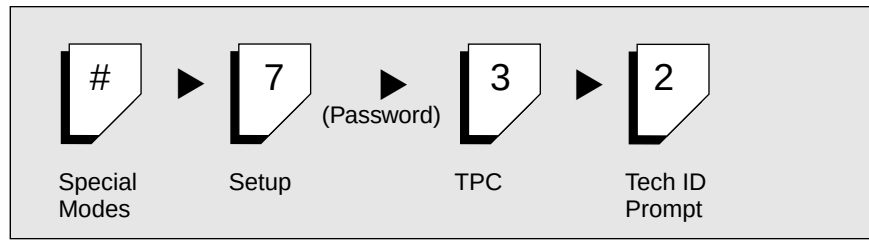
1. Enter the existing password. The screen displays "ENTER NEW PASSWORD".
2. Enter a new 4-character password or press <#> to retain the existing password and return to the TPC menu.
3. The PPC displays the new password and requests confirmation: "CORRECT? (YES/NO)".
4. Select <YES> to store the new password. The screen returns to the PPC menu.

NOTE: If the TPC deviation password is changed, it will be effective immediately, even on batches in process (*i.e.,* which have been identified with a tray ID and have not been physically removed from the instrument) on the PPC.

Anytime a deviation password is used and accepted, adherence to the manufacturer's recommended operating procedures for that assay did not occur.

Specifying A Tech ID Prompt

Determines whether the PPC prompts for a Tech ID during PPC operation when TPC™ is set to Record or Verify mode. (In TPC Off mode, the status of the Technician Identification parameter in an assay protocol takes priority.) The default is "FIRST PASS". Key in the following to make a change:



The PPC displays the current setting and two options: "FIRST PASS" and "ALL PASSES".

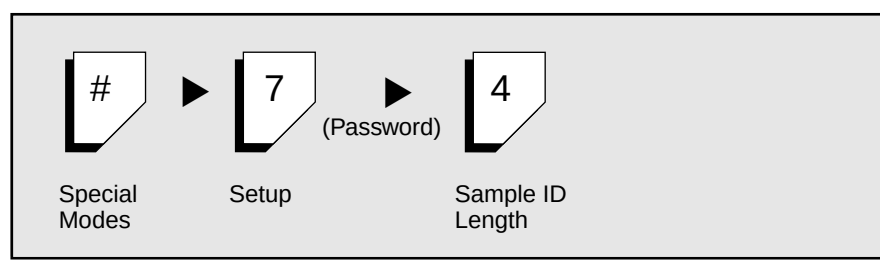
- Press <1> to set the PPC to prompt for the Tech ID at the beginning of the first pass of a batch.
- Press <2> to set the PPC to prompt for the Tech ID at the beginning of all passes.
- Press <#> to return to the TPC menu.

NOTE: When TPC Mode is Off, Tech ID may be 1 to 3 characters in length.

When TPC Mode is Record or Verify, Tech ID may be 1 to 6 characters in length.

Maximum Sample ID Length

Sets the PPC for the maximum number of characters to be allowed in a sample ID. Key in the following:



The PPC displays the current setting (default is "10") and two options: "10" and "20".

- Press <1> to select 10 as the maximum length. (Range = 0-10 characters)
- Press <2> to select 20 as the maximum length. (Range = 0-20 characters)
- Press <#> to return to the Setup menu.

NOTE: When setting PPC sample ID lengths to 20 characters, make sure that the LIS is compatible with sample IDs of up to 20 characters.

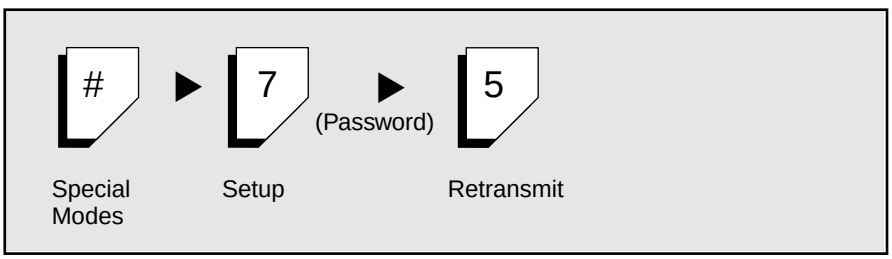
NOTE: The sample ID length limit for a batch is the limit that was configured on the PPC at the time the batch was created. Changes to the sample ID length limit will not affect pre-existing batches.

Retransmit

Allows the PPC to reprint and retransmit the entire batch report for an Allowed Batch to an LIS. The use of the Retransmit feature is recommended for loss of data transmission to a host computer, printer jams, or power loss.

NOTE: Prior to configuring the PPC for retransmit, proper procedures should ensure that the retransmitted data is not interpreted as duplicate test results.

Key in the following:



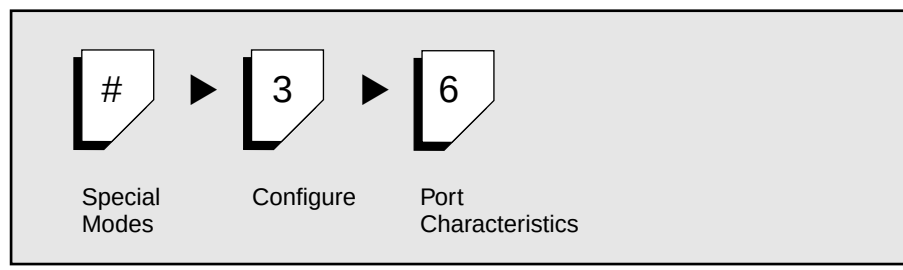
The PPC displays the current setting (the default is “DISABLE”) and two options: “DISABLE” and “ENABLE”.

- Press <1> to disable the retransmit function.
- Press <2> to enable the retransmit function.
- Press <#> to return to the Setup menu.

Port Characteristics

The PPC port characteristics, including baud rate, parity, bits/character, handshaking and stop bits can be manually set to allow communication between the PPC and connected instruments. All port characteristics between the PPC and the connected device must match.

Port Characteristics must be set for each port to be used with other devices (*e.g.,* FPC™, DMS, etc.).



Display prompts operator to input a series of values for port characteristics.

NOTE: When the communications PPC port is configured for data output only (*i.e.,* data output to LIS or printer), the baud rate may be set up to 19,200 baud.

When the PPC communications port is configured for data output and input (*i.e.,* with FPC for sample ID collection or auto-configuration), the baud rate must be limited to 4800 baud.

Connecting Pipettor Systems

The COMMANDER Flexible Pipetting Center (FPC) or other compatible instrument systems (PIP) may be connected to the PPC for transfer of sample ID information.

NOTE: Do not perform this procedure while a batch is in progress.

1. Determine which PPC port will be used. If using Port 4 with the pipettor, set the mechanical switch located on the back panel to **4** (see Figure 2.8). This inactivates the round Port 4 connection.

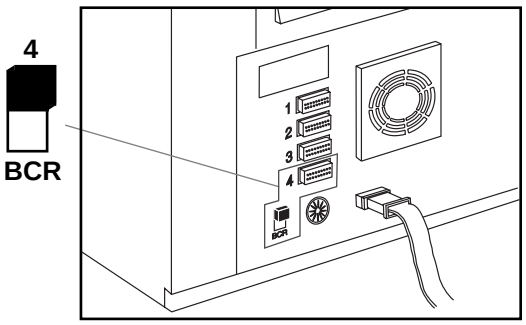
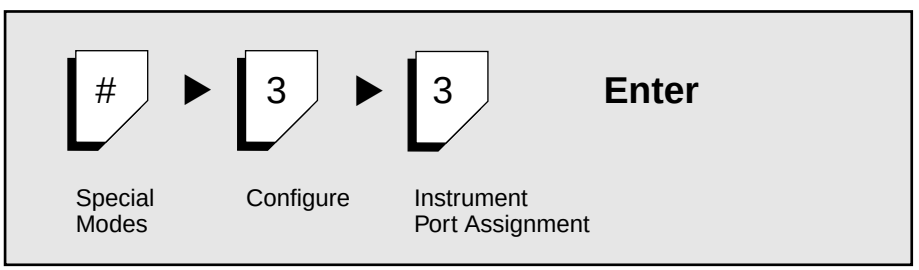


Figure 2.8

2. Set the characteristics on the intended PPC/Pipettor port to match the Pipettor (See *Port Characteristics* elsewhere in this section.) Maximum baud rate is 4800.

3. Connect the pipettor to the appropriate PPC port.

4. Key in the following to allow PPC to automatically set port assignments:



PPC automatically checks each port, determines which identifiable instrument is connected to each and lists the assignments for each port as they are determined. If a DMS port has been previously assigned, the DMS port assignment will be displayed. If an external bar code reader is connected, the PPC may beep during instrument port assignment.

NOTE: A non-FPC pipettor system may identify itself as “FPC” or “PIP”.

Upon exiting, a message is displayed, informing you to USE/NOT USE the Protocol Select feature. If the Protocol Select feature is in use, assign the test number(s) to the PPC assay protocol(s).

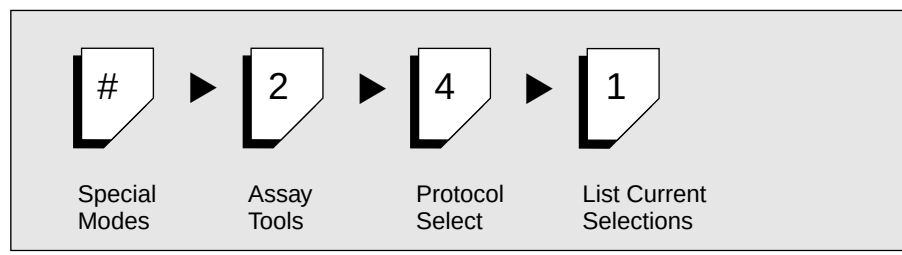
Protocol Select

This feature is to be used only if directed by the PPC when performing the instrument port assignment, or upon entering an edit session. If the PPC is connected to a compatible pipettor system, only one test number may be assigned to one single PPC assay. The test number is used to identify an assay on a non-FPC™. This one-to-one correlation between the PPC assay protocol and the test number allows automatic assay protocol linkage from the pipettor to the PPC for each tray processed from the pipettor. It is the laboratory's responsibility to assure assay protocol assignments are correct. **Incorrect assignments will result in trays being processed by the PPC with the wrong PPC assay protocol.**

NOTE: If this feature is selected but is not in effect, error 6.3.1.1 will be generated.

Printing Pipettor/PPC Protocol Assignments

Key in the following to generate a printout of Pipettor and PPC Protocol assignments:



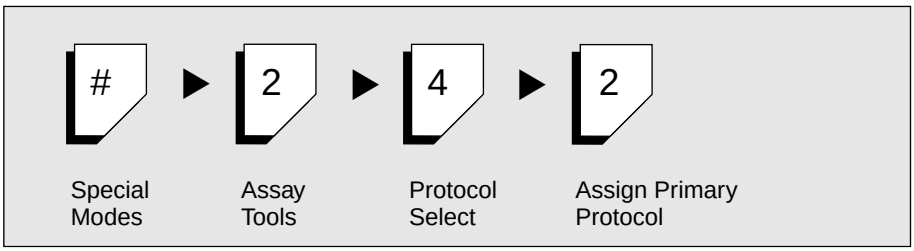
Pipettor/PPC protocol assignments are printed.

```
              SAMPLE PRINTOUT
*************************************
           Pipettor/PPC Protocol
Test #: 51          PPC Protocol #: 5
Test #: 57          PPC Protocol #: 7
           Pipettor/PPC Protocol Complete
*************************************
```

NOTE: The pipettor protocol should be checked to ensure that blanks are not included in trays prepared for the PPC. The pipettor protocol may require editing to delete the blank locations.

Assigning a Test Number to a PPC Protocol

Key the following to assign the test number:

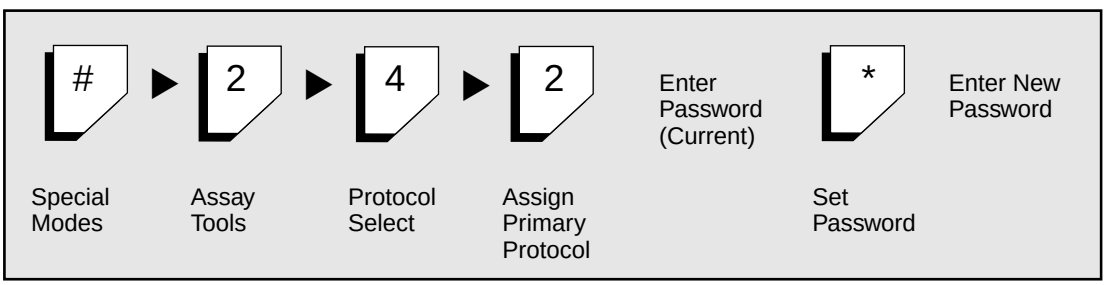


The display first asks for the Password, then asks for test number and the corresponding PPC assay number. The PPC will automatically print the assay protocol assignments when you exit. Review and verify that all assay protocol assignments are correct. You may choose to retain this printout for your records.

NOTE: Assay assignment must be consistent with the PPC Assay Protocol number and the Test number entered in the PPC Assay Protocol.

Reassigning Protocol Select Password

Key in the following to reassign the Protocol Select password:



The display asks for new password.

This procedure requires the setting of a four-character, alpha/numeric password to control protocol selection. After the password is entered in the procedure, no subsequent protocol selections can occur without first entering the operator assigned password at the proceeding step.

NOTE: Save the password in a secure place for future additions or changes.

Connecting An Abbott DMS System or Data Collection Device

The Abbott DMS™ (Data Management System) or an LIS data collection device may be connected to the PPC for data transfer and communication. The DMS-configured port is the port through which the RS-232 data output of the PPC is routed.

A DMS port may be assigned to an open port or a port that is already configured as an FPC. (See System Integration Guide.) If the DMS port is assigned to an already configured FPC port, all RS-232 data output is routed through the combined instrument/DMS port. The combined port assignment is identified with a "*".

1. Determine which port will be used. If using Port 4 with the data collection device, set the mechanical switch located on back panel to **4**. This inactivates the round Port 4 connection (Figure 2.9).

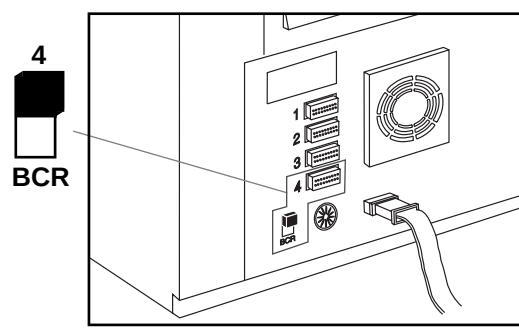


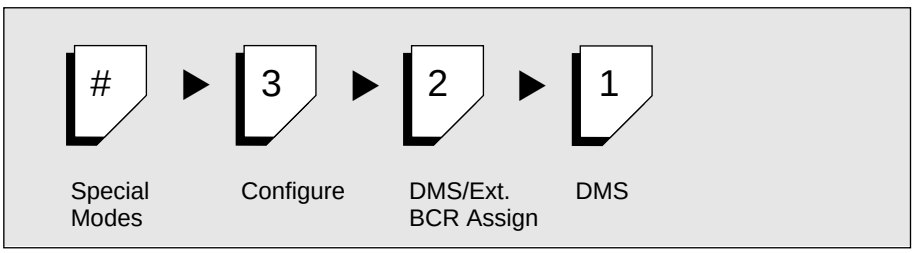
Figure 2.9

2. Set the characteristics of the intended instrument/DMS port to match the data collection device. (See *Port Characteristics* elsewhere in this section.)

3. Connect the data collection device to the intended instrument/DMS port.

4. Select DMS Checksum option. This feature adds an additional check for proper data transmission. (When this feature in enabled, the data collection device must be configured for checksums.) For information regarding the checksum algorithm, refer to *COMMANDER® Parallel Processing Center (PPC) RS-232 Interface Specification.*

5. Key in the following to set DMS port assignments:



The display asks for the number of the port to which DMS has been connected and also asks for checksum option (ON or OFF). The default is ON.

Connecting an External Bar Code Reader (optional)

The external bar code reader (BCR) can be used to input component lot numbers, information entered during the Reconstitution Procedure, tray IDs entered during the Bead Drop Procedure, Tech IDs, and adding Abbott-supplied assay protocols.

1. Affix the bar code reader holder and clips to the right side of the PPC instrument or other convenient location.
2. Connect the external bar code reader to the round version of Port 4 (Figure 2.10). Feed the bar code reader cable through the clips and place the bar code reader in the holder.
3. Set the mechanical switch located on the back panel to **BCR** (Figure 2.10). This inactivates the rectangular Port 4 connection.

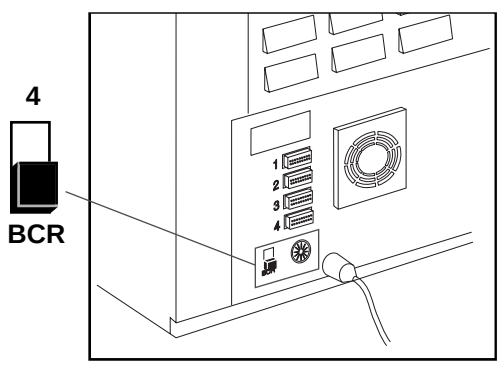
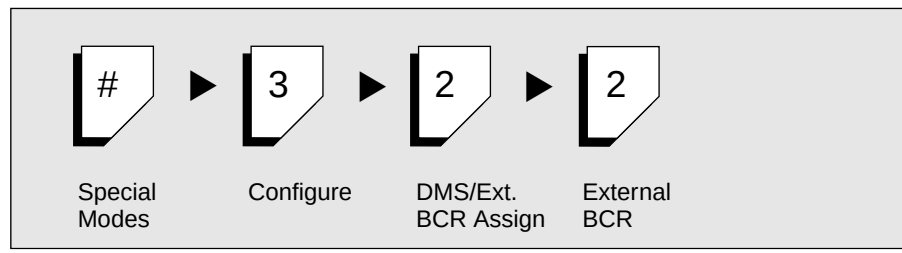


Figure 2.10

4. Key in the following to set the external bar code reader port assignment:



5. Select <2> to configure the External BCR.

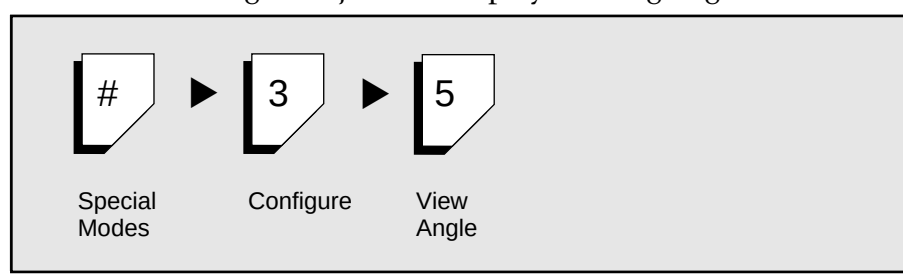
6. Select **Port #4** to assign the External BCR. The port characteristics are automatically assigned.

7. Press <#> to return to the Configure menu.

NOTE: The External BCR cannot overwrite the assignment of other instruments. For example, if Port 4 had been previously assigned as a DMS port, you must first disable the port by selecting **Port Ø** at the DMS Port Assignment display, then proceed with the External BCR assignment above.

Adjusting the Display Angle

The PPC's display may be adjusted to improve viewing. Key in the following to adjust the display viewing angle:



Move the cursor to the right or left on the display until the display reads clearly.

Setting Date And Time

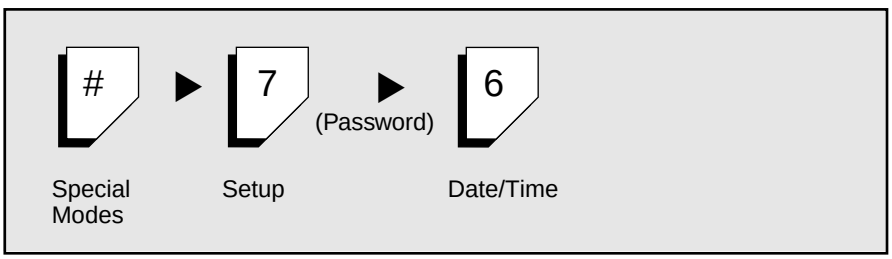
The PPC's date and time clock is backed up by battery and need only be set at installation, after software download, monthly thereafter, and at seasonal time changes.

NOTE: PPC software displays "00" for the year "2000".

Date Setting Procedure

Verify that there are no active batches on the PPC by printing the batch listing and verifying that all batches are archived. Complete or delete any batches that are in process prior to setting the clock.

Press the following keystrokes:

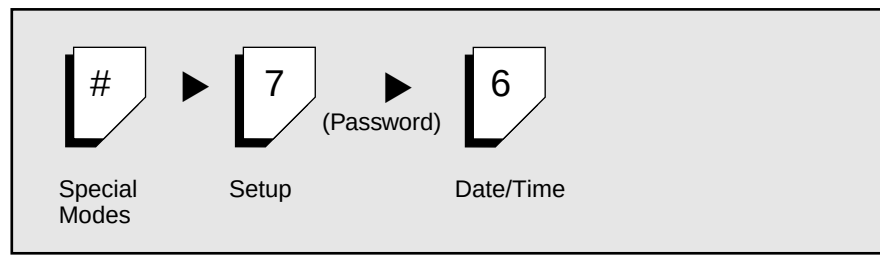


1. Select the Date menu from the PPC display.
2. At the `Month`: display, type the number of the current month and press **<Enter>**.
3. At the `Day`: display, type the number of the current day and press **<Enter>**.
4. At the `Year`: display, type the number of the current year and press **<Enter>**.
5. Press <#> to exit from the Special Modes function.

Date Format Setting Procedure

American (Month/Day/Year), European (Day/Month/Year) or Japanese (Year/Month/Day) date formats may be selected.

Press the following keystrokes:



1. Select the Format menu from the PPC display.
2. Select the desired date format from the three selections presented.

   `1. MM/DD/YY  2. DD/MM/YY  3. YY/MM/DD`

   Where:

   DD = two digits referring to day (*i.e.,* 01, 05, 30)

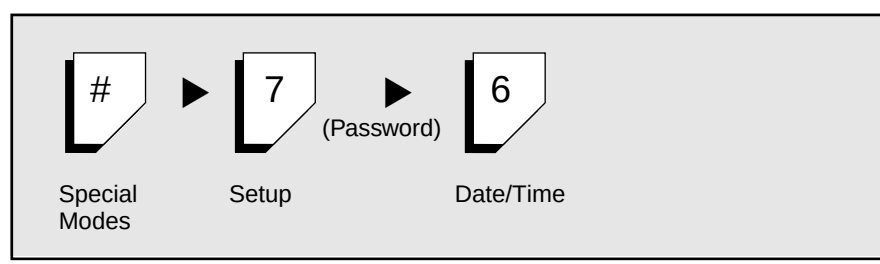
   MM = two digits referring to month (*i.e.,* May = 05, October = 10)

   YY = two digits referring to year (*i.e.,* 1997 = 97, 2000 = 00)
3. Press <#> to exit from the Special Modes function.

Clock Setting Procedure

Verify that there are no active batches on the PPC by printing the batch listing and verifying that all batches are archived. Complete or delete any batches that are in process prior to setting the clock.

Press the following keystrokes:



If Using the NIST Clock

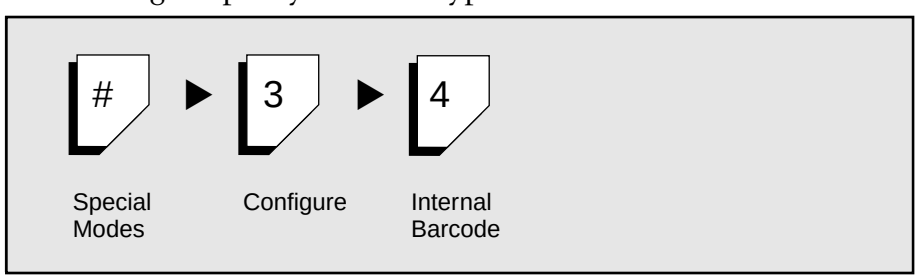
1. Select the `Time` menu from the PPC display.
2. At the `HOUR:` display, type the current hour using a 24-hour format and press **<Enter>**.
3. Call the NIST clock at (303) 499-7111. The NIST clock provides the Coordinated Universal time. Depending on what time it is when you call, a series of clicks will be heard. Continue waiting until the actual time is announced.
4. At the `MINUTE:` display, type the minute one minute ahead of the time provided in the announcement. Continue listening to the announcement until another minute elapses. **DO NOT PRESS <ENTER> YET**. Once the time is announced, there will be a 2-3 second pause, followed by a tone. At the sound of the tone, press **<Enter>** on the PPC keyboard.
5. Press <#> to exit from the Special Modes function.

If Using a NIST-traceable Clock

1. Select the `Time` menu from the PPC display.
2. At the `HOUR:` display, type the current hour using a 24-hour format and press **<Enter>**.
3. At the `MINUTE:` display, type the next whole minute as compared to the NIST-traceable clock (*e.g.,* if the NIST-traceable clock reads 12:00:14, set the PPC time to 12:01). **DO NOT PRESS <ENTER> YET.** When the NIST-traceable clock reads the next whole minute (12:01:00 in the example above), press **<Enter>** on the PPC keyboard.
4. Press <#> to exit from the Special Modes function.

Setting Internal Bar Code Length and Types

The PPC may be configured to accept Codabar, Code 39, Interleaved 2 of 5 or Code 128 tray bar code labels. Key in the following to specify bar code type:



The display prompts for the minimum character length and type of bar code.

- Default setting: 5 characters (Codabar)
- Maximum setting: 10 characters. Minimum setting: 1 character.
- Codabar characters "$" and ":" cannot be entered manually.
- Not all Code 128 characters can be entered manually due to keypad limitations.

Editing Protocols

New assay protocols may be created using existing Abbott protocols as a template, changing specific parameters and assigning new assay numbers. Abbott-supplied assay protocols cannot be edited and saved under the original assay protocol number. A user-edited version of the Abbott-supplied assay protocol can be created and stored under an unassigned assay protocol number. Whenever a user-edited assay protocol is created, either the list number or the procedure must be changed to create a unique list number/procedure combination for that protocol. The list number and procedure of the original Abbott-supplied assay protocol cannot be used for user-edited assay protocols.

When connected to an FPC™ pipettor version 2.5 or greater, the TPC mode of PPC assay processing is dictated by the FPC assay protocol. An edit to the PPC assay protocol to set the desired TPC mode is not required. When operating the PPC with a PIP-configured pipettor or in stand alone mode, the TPC mode of PPC assay processing is dictated by the TPC mode of the PPC assay protocol. If you wish to change the TPC mode of PPC assay processing, a user-edited assay protocol will be required.

The Assay Protocol Reference Guides explain each line of the assay protocols. Refer to the *Appendices* section of this manual.

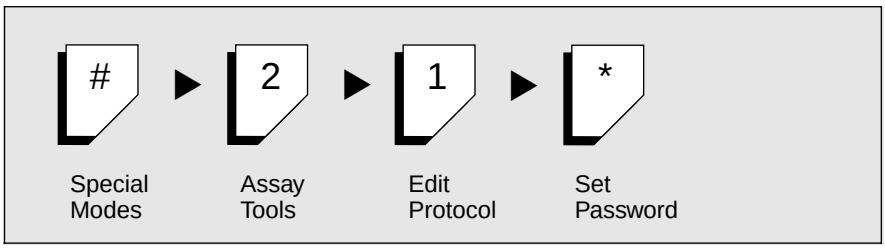
Up to 99 assay protocols may be actively stored in the PPC memory. You may edit protocols until the number of unassigned assays in the assay directory is zero.

NOTE: When you delete an assay, whether an Abbott assay or an edited assay, the location is not reclaimed from memory. Refer to "Unassigned Assay Locations" on the Assay Directory printout (see example of this printout on page 2–34) to find out how many locations remain.

CAUTION: Downloading new software will result in a loss of all edited protocols, batch/tray data and system configuration data. Prior to a software download, record this information.

Set Password for Editing

Key in the following if you require password entry for editing:



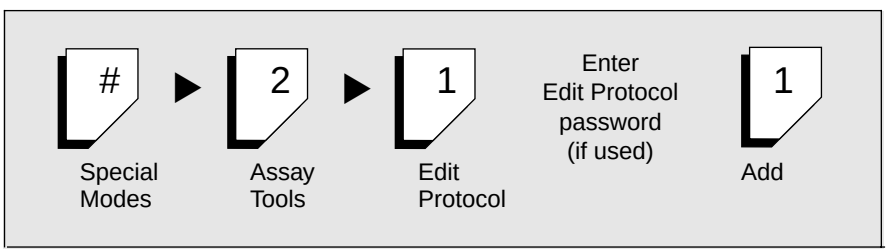
The display asks for new password.

This procedure allows the setting of a four-character, alpha/numeric password to control protocol editing. After the password is entered, no subsequent protocol editing can occur without first entering the appropriate password at the preceding step.

NOTE: Save this password in a secure place for future additions or changes.

Add A New Protocol

Key in the following to add an edited assay based on an Abbott protocol:



The display asks for the Abbott assay to be used as a template for the new assay and then presents the protocol on the screen. Edit the parameters desired.

- See the appropriate Assay Protocol Reference Guide for further explanation of each line of the protocol.
- Upon entering an edit session, the display informs you whether to use or not use the Protocol Select feature.

- The combined Assay List Number and Assay Procedure must be unique for each assay protocol. If an assay is added, a new assay list number and/or assay procedure must be entered.

TPC **NOTE:** When editing an assay for TPC processing, edit the procedure code to create a unique Assay List Number/Assay Procedure Code combination.

1. Print the assay directory and check listing for all unassigned assay numbers.

2. Edit the desired assay protocol. You can jump to any line you wish to edit by pressing <**Tray ID**>. After pressing <**Tray ID**>, key in the 2-digit line number and press <**Enter**>, or press <#> to exit or <*> to abort the editing session.

   When you press <#> to exit the edit session, the system will jump to any line in which an inconsistency has been introduced during the edit (*e.g.,* duplicate bottle locations). Correct the inconsistency and exit again. This procedure will repeat until all inconsistencies have been resolved.

3. Key the new assay protocol number and press <**Enter**> to save the assay protocol.

4. Check assay directory. Verify that the new assay appeared in its appropriate slot with an "E" to the right of the name.

5. Print and verify all assay protocol parameter lines match the reagent package insert prior to use. You may choose to retain the printed and verified protocol for your records.

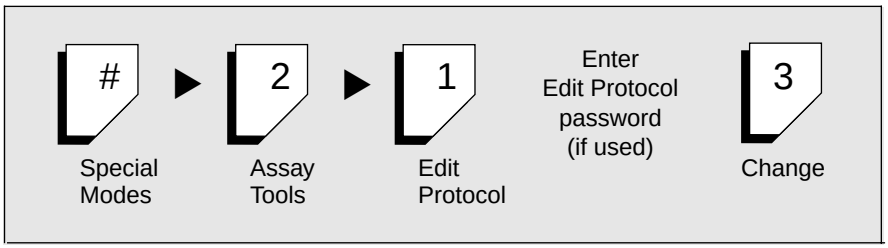
   NOTE: An operator-edited assay protocol may be used if the edited lines are consistent with the reagent package insert specifications and are supported by documentation at the time of edit. It is the laboratory's responsibility to verify edited assay protocols.

6. If the Protocol Select feature is in use, modify the Protocol Select test number assay protocol assignments, as appropriate, to reflect the new assay protocol. Verify assignments.

   NOTE: Each test number can be assigned (correlated) to only one PPC protocol number at a time.

Changing an Edited Protocol

Key in the following to change a protocol that has been edited by your laboratory:



NOTE: Any archived data for an assay will be deleted when the assay's protocol is changed. An assay protocol cannot be changed if it is associated with trays in process.

An operator-edited assay protocol may be used if the edited lines are consistent with the reagent package insert specifications and are supported by documentation at the time of edit. It is the laboratory's responsibility to verify edited assay protocols.

The display asks for the assay protocol to be modified. (This must be an operator-added protocol).

- See the appropriate Assay Protocol Reference Guide for further explanation of each line in the protocol.
- Upon entering an edit session, the display informs you whether to use or not use the Protocol Select feature.
- The combined Assay List Number and Assay Procedure must be unique for each assay protocol. If an assay is modified, a new assay list number and/or assay procedure must be entered.

TPC **NOTE:** When editing an assay for TPC processing, edit the procedure code to create a unique Assay List Number/Assay Procedure Code combination.

1. Edit the desired assay protocol. When editing, you can jump to any line by pressing <**Tray ID**>. After pressing <**Tray ID**>, key in the 2-digit line number and press <**Enter**>, or press <#> to exit or <*> to abort the editing session.

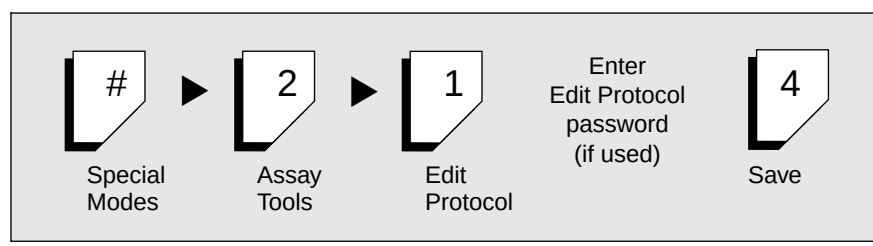
When you press <#> to exit the edit session, the system will jump to any line in which an inconsistency has been introduced during the edit (*e.g.,* duplicate bottle locations). Correct the inconsistency and exit again. This procedure will repeat until all inconsistencies have been resolved. The PPC will prompt "SAVE? YES/NO" to save or review the changed protocol.

- Press **<No>** to review the changed protocol before saving it.
- Press **<Yes>** to save the protocol immediately.

2. When No is selected, the changed assay will appear at the top of the assay list, flagged with an "R" to the right of the name. The original assay protocol from which the "R" protocol was created will remain in its proper position in the Assay Directory. This "R" assay should be used for edit confirmation only. When the "R" protocol is saved, it is flagged with an "E" and it will overwrite the original assay protocol from which it was created. If the original protocol is desired instead of the "R" version, delete the "R" version instead of saving it.
3. If the Protocol Select feature is in use, verify correct assay protocol number and test number assignment.
4. List the assay directory to verify saving the assay.

Save A Changed Assay Protocol

Key in the following to save a changed assay protocol:



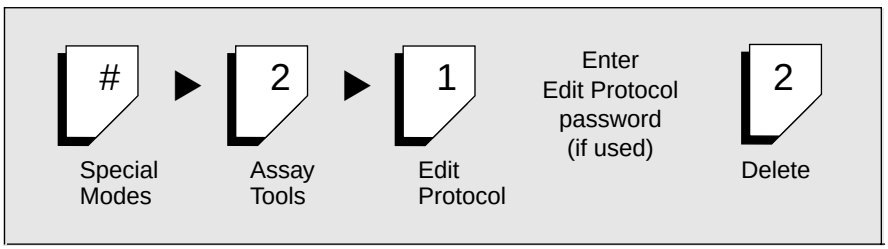
The display asks for the assay number to be saved. The original assay is deleted when the changed assay is saved.

The save process takes several seconds. When the protocol has been saved:

1. Check the assay directory. The changed assay no longer appears at the top of the assay list flagged with an "R". It moves to its appropriate slot flagged with an "E".
2. If the Protocol Select feature is in use, verify correct assay protocol number and test number assignment.

Delete An Edited Assay Protocol

Key in the following to delete a changed assay protocol:

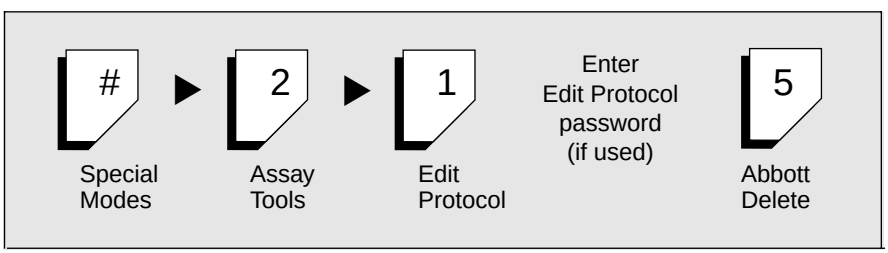


The display asks for the assay number to be deleted. When the assay has been deleted, check assay directory. The assay disappears from the directory when deleted.

Delete An Abbott-Supplied Assay Protocol

Use the following instructions to delete an Abbott-Supplied assay protocol. For information on the Abbott Delete password or assay codes necessary to perform this procedure, contact the Abbott Customer Support Center.

Key in the following:



CAUTION: Once an Abbott-supplied assay has been successfully deleted, it cannot be re-enabled on that instrument. To restore the original list of assays, the software must be downloaded from the memory card by an Abbott representative.

The display asks for a password.

```
Abbott Delete

Enter Password: ____
Enter Password or <#> to Exit
```

1. Type the Abbott-defined password and press **<Enter>**. The screen asks for the unique code of the assay you wish to delete.

```
                Abbott Delete

                Enter Code: __
          Enter Code or <#> to Exit
```

2. Type the assay-specific code and press **<Enter>**. The screen requests confirmation of the delete.

```
                Abbott Delete
     Assay Number: xx
      Assay Name: yyyyyyyyyyyyyyyyyyyy
    Sure you want to delete? (YES/NO)
```

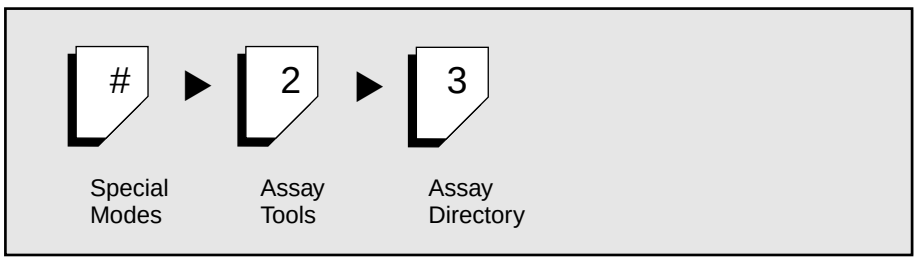
3. Press the **<YES>** key. The system deletes the assay and prints a Delete Verification Report, as shown in the example below, as hard-copy verification of the activity.

```
****************************************
         Delete Verification Report

      Assay Number: xx
        Assay Name: xyyyyyyyyyyyyyyyyyyy

  Date: __/__/__  __:__:__ SN: zzzzzzz
****************************************
```

Printing The Assay Directory

The assay name, assay number, and List Number/Procedure of every assay protocol in active storage on the PPC is listed in the assay directory. The assay directory may be obtained through the **<List Assay>** special function key or under **Assay Directory** in the Special Modes.

Key in the following to print the assay directory:



The assay directory prints out.

```
                SAMPLE PRINTOUT
*************************************
             Assay Directory
         PPC Software Version X.XX
               SN: sssssss

     Unassigned Assay Locations: 24
No.     Assay Name           LIST#-Proc
 91     CORZYME A             9977-1A   R
 01     CORZYME A             9977-A    A
 02     CORZYME B             9977-B    A
 03     AUSZYME MC A          1980-A    A
 04     AUSZYME MC B          1980-B    A
 05     AUSZYME MC C          1980-C    A
 06     AUSZYME MC D          1980-D    A
 87     CORZYME A 1 UNK REPS  9977-A1   E

*************************************
```

R = Changed assay in RAM memory, not yet saved to permanent memory. A temporary assay that should not be used for assay processing, only for testing prior to saving.

A = Abbott supplied protocol.

E = Edited assay.

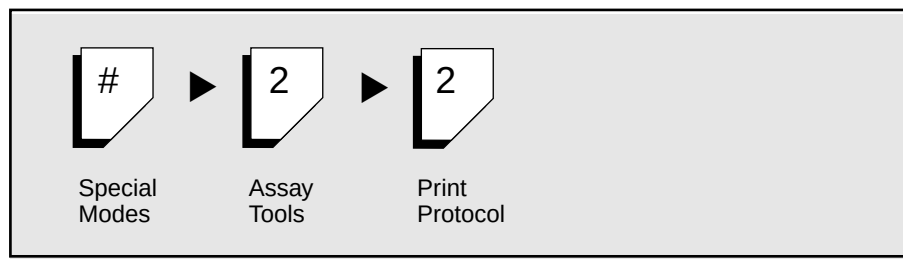
X.XX = Software version number

Printing an Assay Protocol

The assay protocol for any actively stored assay may be printed for review. It may be obtained through the **<List Protocol>** key or **Print Protocol** in the Special Modes.

Parameters listed in the assay protocol are explained in the Assay Protocol Reference Guides found in the *Appendices* of this manual.

Key in the following to print a protocol while in the Special Modes function of PPC:



The display prompts for the PPC assay number of the protocol to be printed.

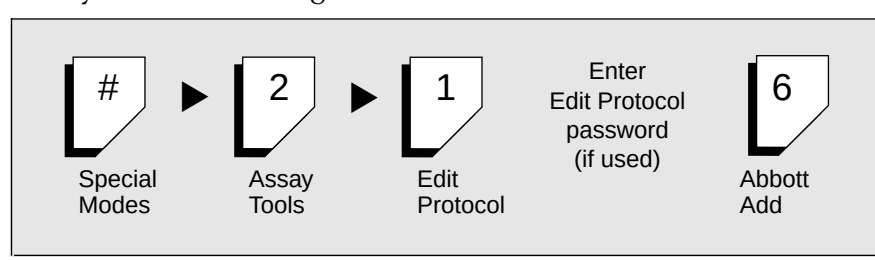
NOTE: Laboratories desiring a printed assay protocol for the assay being processed may print the assay protocol just prior to inserting the first tray of the batch for the final pass.

Adding an Abbott-Supplied Assay Protocol

This feature allows for the addition of new or modified assay protocols using the external bar code reader. The instructions that follow are valid only with assay protocols supplied by Abbott Laboratories.

CAUTION: User-created assay protocols must be added using the Edit Protocol function.

Key in the following:



The display asks for the first line of the assay protocol to be entered.

```
                Assay Upload

          Data: _____________________

            Enter Line 1 OR <#> to Exit
```

1. Use the External bar code reader to enter the assay protocol. The screen displays the protocol line information. If there are no errors, the Line number updates for the next line of information to be entered. Continue to scan each line of information until all lines of the protocol are added.

   If an error occurs, the line number is displayed. Repeat the line, and continue.

   NOTE: If the bar code reader is unable to read the code, it can be entered using the keypad. Enter the information exactly as it appears below the bar code and press **<Enter>**.

2. The PPC prints the protocol after all information has been successfully entered and the screen displays:

```
            Assay Upload Complete

          Save Assay PROTOCOL?  (YES/NO)
```

3. Verify the assay protocol is correct using the information provided by Abbott Laboratories.

   - If correct, press the **<YES>** key. The assay protocol is saved and the PPC returns to the Edit Protocol menu screen.
   - If the assay protocol does not correspond to the information provided by Abbott Laboratories with the bar codes, press the **<NO>** key to cancel the operation. The PPC returns to the Edit Protocol menu screen. Attempt to enter the protocol again.
   - If the Abbott-supplied protocol cannot be successfully entered, contact the Customer Support Center (CSC) or your Abbott representative.

Post-Installation Procedures

The following procedures must be performed after the installation and configuration of the PPC.

Software Installation and Validation Protocols

If a software download was performed during PPC installation, complete the Software Installation and Validation Protocols. Refer to the *COMMANDER® Parallel Processing Center (PPC) Installation and Validation Protocols*.

Verifying Optical Reader Operation

Perform the Linearity, Repeatability and Drift tests. Refer to *Section 9, Service and Maintenance*.

Manual Wash Procedure

Perform a Manual Wash Procedure (Type 01) on a 60-well tray to purge air from the system by pressing the **<Wash>** key. Refer to *Section 5, Operating Instructions*.

NOTE: Use of the **<Wash>** key to prime the wash system requires a valid calibration. If a valid calibration does not exist, the Wash Volume Verification test should be used to prime the wash system prior to performing calibration.

Verifying Wash Volume

Verify wash volume after hooking up the Wash & Waste Cart, prior to running the first assay on the PPC. Refer to *Section 9, Service and Maintenance*.

Calibration

Refer to recommended calibration intervals in *Section 9, Service and Maintenance* and specific instructions in *Section 6, Calibration*.

External Bar Code Reader

If an external bar code reader has been installed and configured, perform the external BCR reading test. Refer to *Section 10, Troubleshooting and Diagnostics*.

Relocation Procedures

The following procedures must be performed when the PPC is relocated within your facility.

NOTE: A software download is not required. However, if one was performed, complete the Software Installation and Validation Protocols. Refer to the *COMMANDER® Parallel Processing Center (PPC) Installation and Validation Protocols*.

Verifying Optical Reader Operation

Perform the Linearity, Repeatability and Drift tests. Refer to *Section 9, Service and Maintenance*.

Manual Wash Procedure

Perform a Manual Wash Procedure (Type 01) on a 60-well tray to purge air from the system by pressing the **<Wash>** key. Refer to *Section 5, Operating Instructions*.

NOTE: Use of the **<Wash>** key to prime the wash system requires a valid calibration. If a valid calibration does not exist, the Wash Volume Verification test should be used to prime the wash system prior to performing calibration.

Verifying Wash Volume

Verify wash volume after hooking up the Wash & Waste Cart, prior to running the first assay on the PPC. Refer to *Section 9, Service and Maintenance*.

Calibration

Refer to recommended calibration intervals in *Section 9, Service and Maintenance* and specific instructions in *Section 6, Calibration*.

Principles of Operation

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Principles of Operation

Introduction

The COMMANDER Parallel Processing Center (PPC) is a semi-automated instrument for processing enzyme immunoassays. Processing is accomplished as a bar coded tray or batch of trays passes through the instrument. Each pass may include washing, dispensing and/or reading steps.

Control and direction for the PPC comes from an on-board microprocessor which also provides data reduction capability. It is capable of self diagnostics and other operating options.

Sample dispensing into the 20 or 60 well trays may be performed manually or through the use of an automated pipetting device, such as the COMMANDER Flexible Pipetting Center (FPC™).

Trays are identified in the load station, either by reading a bar code label on the tray or by manual keypad entry. After a tray is identified, the PPC's control center determines which assay steps are required during the current pass of the tray. If the PPC requires more information about the tray or further operator action, it prompts the operator via the instrument display. When all information is received and the PPC has determined which assay steps are to be performed, the tray moves into the transport module.

The PPC transport module then moves trays through the wash, dispense or read stations. When the processing is complete, the tray moves into the exit station where it is removed by the operator.

This process is repeated until the final read step is completed. Results are then calculated by the control center, matched with sample identification numbers, printed and transmitted to a data collection system if one is connected.

NOTE: The PPC does not accommodate assays requiring more than four processing steps. If additional processing steps are required, they must be performed manually, or by using special function keys on the PPC.

Read Function

The PPC reader is a dual wavelength analyzer that measures differential absorbances of reactions and converts these readings into analytical values. An algorithm computes the absorbances of each reaction based on the light band with which it was read. Optical readings are taken on each reaction well at two wavelengths. A peak reading is taken at 460 nm and a sideband reading at 600 nm.

- For assays which require blanks, the PPC must first calculate the blanks reading using the following calculation:

  $$BLANKS = BLANKS_{(acid)} - BLANKS_{(OPD)}$$

  The final results are calculated:

  $$RESULTS = NON\text{-}BLANK\ WELL_{(acid)} - NON\text{-}BLANK\ WELL_{(OPD)} - BLANKS$$

- For assays which do not require blanks, final results are calculated using:

  $$RESULTS = WELL_{(acid)} - WELL_{(OPD)}$$

Optical Density and Timing Checks

The following Optical Density (OD) and timing checks may be performed on optical readings taken by the PPC.

- Maximum OPD Dispense-Read Time
- Initial Read Check
- Blanks Check—Minimum and Maximum Limits
- Blanks Check—Standard Deviation and Minimum Number

Maximum OPD Dispense – Read Time

The elapsed time from OPD dispense to the first read ($READ_{OPD}$) is monitored by the PPC. The time specified in the assay protocol for Maximum OPD Dispense-Read Time (in seconds) must not be exceeded. Wells which exceed this limit will be flagged VOID, and error code 3.3.7.3 will be printed. No OPD Dispense-Read timing checks will be made if N/A is specified in the assay protocol for this parameter.

NOTE: Error code 3.3.7.3 is printed only after the tray containing the error is removed. To prevent the inclusion of error messages of a previous batch in the output for the subsequent batch, care must be taken to not start processing a batch until all trays of the previous batch have been removed.

Initial Read Check

During batch processing, after the OPD has been dispensed, each well is read. The calibration mean for each column (CALn) is subtracted from the reading of each well ($READ_{OPD}$) in that column. To pass this check the result must be greater than or equal to an internal limit.

$$READ_{OPD} - CAL_n \geq \text{internal limit}$$

If the result is less than the internal limit, then that well is flagged VOID, and error code 3.3.7.1 is printed.

NOTE: Error code 3.3.7.1 is printed only after the tray containing the error is removed. To prevent the inclusion of error messages of a previous batch in the output for the subsequent batch, care must be taken to not start processing a batch until all trays of the previous batch have been removed.

Blanks Check – Minimum and Maximum Limits

For assays requiring blanks, blank wells may be subjected to additional checks. Each blank well is read and compared to the calibration mean for the appropriate column. If the final pass reading ($READ_{acid}$) of a blank well minus the calibration mean (CAL_n) is not in the range specified by the Blank Check Minimum and Maximum Difference, then that blank will be flagged OPD-REJ.

NOTE: The $READ_{acid}$ is the final pass reading, not the resultant absorbance difference between the OPD read and the Acid read.

To pass this check:

$$READ_{acid} - CALn \geq \text{Blank Check Min. Diff.}$$

and

$$READ_{acid} - CAL_n \leq \text{Blank Check Max. Diff.}$$

No checks will be made on either or both limits if the parameters are specified as N/A.

Since this comparison is made before the final OD calculation, it is possible that some Blanks may be flagged OPD-REJ even though the final ODs for all Blanks appear to be similar.

Blanks Check – Standard Deviation and Minimum Number

For assays requiring blanks, if both the initial read ($READ_{OPD}$) and final read ($READ_{acid}$) for a blank well are accepted, then the final OD for each blank (OD_{blank}) well is calculated:

$$OD_{blank} = READ_{acid} - READ_{OPD}$$

The mean and standard deviation for the ODs of the blank wells are computed.

The standard deviation must be 0.009 or less for the Blanks to be accepted. If the standard deviation exceeds 0.009, then the value farthest from the mean will be discarded and a new mean and standard deviation will be calculated. In the case of two values equidistant from the mean, both values will be discarded, and the run will be terminated with an “End of Batch” message and no filled samples will be processed. A minimum number of four valid blanks is required for batch processing.

Total Process Control (TPC™)

Total Process Control (TPC) allows the PPC to automatically track and document assay processing information, resulting in a more comprehensive degree of record keeping and reporting of the assay process.

TPC also provides electronic input of information that was previously entered manually, resulting in greater accuracy and fewer errors as well as a higher degree of automation and operator convenience.

TPC capability is available on FPC™ version 2.5 or higher with TPC software installed.

TPC™ can be configured for three levels of involvement on a per-assay basis:

- **Verify**—records operator activities in the PPC database and intervenes when invalid activities are attempted (*e.g.,* use of an invalid conjugate lot number). If override capability is enabled, the operator can enter a valid TPC deviation password for processing to continue. The final batch results will then be flagged with an appropriate deviation code. Use of the Verify mode can only occur with an FPC™ pipettor, version 2.5 or greater. The Verify mode is enabled by the assay protocol on the FPC, regardless of the TPC mode on the PPC assay protocol.

  The PPC/FPC verifies the following:

  - Tray is reserved (locked) for use by the PPC.
  - Component type does not already exist in this tray.
  - Lot number belongs to the correct component type.
  - Master lot is not expired.
  - Component is a non-expired reagent in the Component Library.
  - Component matches the master lot in use.

- **Record**—records operator activities in the PPC database.

  Use of the Record mode occurs with the use of a Record mode assay protocol on a TPC-capable pipettor (FPC), or as dictated by the PPC assay protocol when communicating to another pipetting device, or when operating in stand alone mode.

- **Off**—disables all TPC activity for the assay. Use of the Off mode occurs with the use of an Off mode assay protocol on an FPC pipettor, version 2.5 or greater, or as dictated by the PPC assay protocol when communicating to another pipetting device, or when operating in stand alone mode.

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Section 4

Performance Characteristics and Specifications

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Performance Characteristics and Specifications

Physical Dimensions

Main Processor

20.5″ H x 37″ W x 21.5″ D (52 cm x 94 cm x 54.6 cm).

Weight: 140 lbs (63.6 kg).

Wash & Waste Cart

24″ L x 16″ W x 28″ H (61.0 cm x 40.6 cm x 71.1 cm).

Weight: 38 lbs (18 kg).

Environmental Requirements for Instrument Operation

For Indoor Use

Temperature

15 to 30° C

Humidity

15% to 85% RH at 25° C (non-condensing)

Electrical Safety Parameters

NOTE: These parameters have no bearing on instrument performance.

Installation Category (Overvoltage Category)

II – Transient power line spikes that can be expected in the non-specific environment of a typical office or laboratory, where the instrument is connected by a cord to a power supply.

Pollution Degree

2 – A non-specific environment described as typical office or laboratory.

Altitude

Up to 2,000 m (6,600 ft.)

Electrical Requirements

Line Voltage (selectable)

100 V 50 Hz

120 V 60 Hz

220 V 50 Hz

240 V 50 Hz

Voltage Extremes Accepted

100/120/220/240 VAC ± 10%

50/60 Hz

Power

700 VA

Fuses

Refer to left side of instrument to determine if CE Mark label is present.

Instrument with CE Mark label

Supply Voltage	Fuse Type and Rating
100/120	F250V 10A, 5x20mm (Qty 2)
220/240	F250V 5A, 5x20mm (Qty 2)

Instrument without CE Mark label

Supply Voltage	Fuse
90-132V	One 10-Amp Fuse in position F1
198-264V	Two 5-Amp Fuses: one in position F1, one in position F2

Data Communications

External data communications is handled via four RS-232 ports. Parity is selectable (odd, even, or none). Either 5, 6, 7 or 8 bits/character may be selected. Baud rates are also selectable at 110, 150, 300, 600, 1200, 2400, 4800, 9600, 19200.

RS-232C serial port pin number assignment is as follows:

Signal	Connector Pin Number
TxD (Out)	3
RxD (In)	2
RTS (Out)	5
CTS (In)	4
Signal GND	7
+12V (Thru 1K resistor)	6

NOTE: When the communications PPC port is configured for data output only (*i.e.,* data output to LIS or printer), the baud rate may be set up to 19,200 baud.

When the PPC communications port is configured for data output and input (*i.e.,* with FPC for sample ID collection or auto-configuration), the baud rate must be limited to 4800 baud.

Reader

Principle

Dual Wavelength Spectrophotometry

Wavelength Selection

460 and 600 nm. Dichromatic Filters

Absorbance Range

0.000–2.200 determined by applications software

Repeatability

Better than 0.0025A Standard Deviation or 0.5% CV, whichever is greater

Linearity

0–1.5A: Better than 0.005A or 2% deviation from straight line fit, whichever is greater, and

0–2.2A: 3.5% Full Scale or less

Drift

Within ±0.005A over 1 hour period

Light Source

Tungsten-Halogen Lamp

Bar Code Labels

Bar Code labels recognized by the PPC are in the following formats:

- Codabar
- Code 39
- Code 128
- Interleaved 2 of 5

For the system to decode the correct information from the bar code, the label must meet the following specifications.

- All labels must have a minimum line density of six characters per inch and a maximum line density of ten characters per inch.
- All labels must be a maximum of 2 3/8" in length.
- Labels must display both eye-readable and bar code information.
- Labels can use any start/stop characters unless otherwise specified.
- The end of the label must have a minimum of a 1/8" quiet zone.
- Length of character reads for the internal and external bar code readers are as follows:
  - Tech ID . . . . . 1-3 or 1-6
  - Tray ID 1-10
  - Master Lot Number 1-10
  - Component Lot Number 1-10
  - Diagnostic Bar Code Reading Test 1-20

Bar Code Label Characteristic Specifications

Space Reflectance (white space between bars):	45% minimum
Bar Reflectance (dark reflectance of black bars):	2% minimum to 25% maximum
Print Contrast Signal (PCS):	50% minimum

$$\left(PCS = \frac{\text{Light Space Reflectance} - \text{Dark Bar Reflectance}}{\text{Light Reflectance}} \right)$$

This can be verified by label checking equipment.

Processing

Washing

14 ± 3 mL of wash water per well, followed by 1.5 seconds of pressurized air at approximately 25 PSI, with the Verification Test.

Dispensing

Volume determined by dispenser used. Sizes available: 50 µL, 100 µL, 175 µL, 200 µL, 300 µL.

Throughput

The approximate times for washing, dispensing and reading a 60-well tray—from tray gating to exit—are provided for the following wash types:

Wash Type 00..... 4 minutes
Wash Type 01..... 3 minutes
Wash Type 02..... 4 minutes
Wash Type 03..... 4 minutes
Wash Type 04..... 4 minutes
Wash Type 05..... 3 minutes
Wash Type 06..... 4 minutes

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Operating Instructions

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Pre-Operating Procedures

Introduction

This section explains the procedures which prepare the PPC for operation.

These procedures include:

- Wash and Waste Cart Preparation
- Tray Bar Coding
- Pipetting Samples

Wash and Waste Cart Preparation

The water canister and waste container volumes should be checked and emptied or filled as appropriate prior to processing a batch. Do not fill the water canister during a processing pass which requires a wash. Waste should be checked periodically during processing between passes to avoid overfilling.

WARNING: Potential Biohazard. Waste is biohazardous and should be treated in accordance with standard lab practices.

Always fill the water canister and empty drip cup when waste is emptied. The water canister level sensor is a back-up signal only.

NOTE: Your water canister may have a slightly different configuration than the canister shown in this manual.

Empty Waste Container

1. Disconnect waste line at container (**A**) and remove container from cart (Figure 5.1).

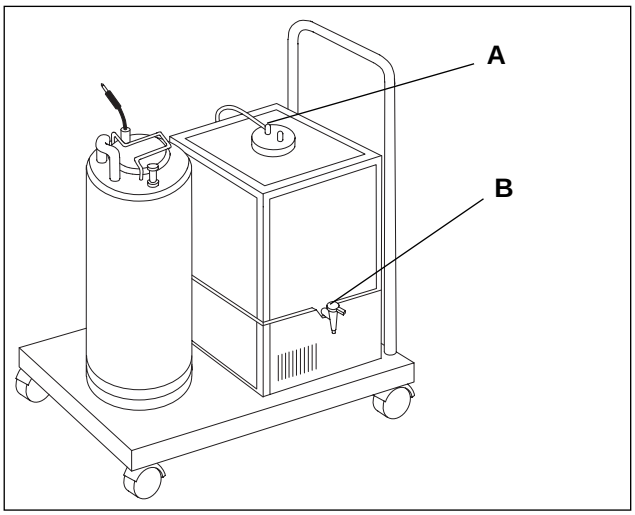


Figure 5.1

2. Open the spigot (**B**) to drain waste.
3. Close spigot and return empty waste container to cart.
4. Check the waste container cap for filter integrity, cracks and loose fittings. Replace cap if necessary.
5. Verify that waste cap is secure.
6. Reconnect waste line.

WARNING: Potential Biohazard. Waste is biohazardous and should be treated in accordance with standard lab practices.

When reconnecting waste line, listen for "snap" of connectors that will signify a solid connection of the hoses.

Anti-Foaming Agents

Several compounds have been identified which may be used to eliminate excessive foam build-up in the waste container during batch processing. These compounds, listed below, will substantially reduce foaming when used as prescribed in this process. These Anti-Foaming Agents, if used as described below are compatible with bleach.

Approved Anti-Foaming Agents

Anti-Foam 1510-US (Dow Corning Corp., Midland, Mich.)

Anti-Foam A Emulsion (Sigma Chemical Co., St. Louis, Mo.)

Catalog No. A5758

Anti-Foam C Emulsion (Sigma Chemical Co., St. Louis, Mo.)

Catalog No. A8011

It remains the responsibility of the operator to ensure that the waste container is not over-filled. Over-filling the waste container will result in the wetting of the waste container cap which will affect the performance of the wash system. If the waste container cap becomes wet, replace it to prevent filter blockage due to crystallization.

WARNING: Potential Biohazard. The waste container contains biohazardous material. Please exercise appropriate precautions in the handling of the waste container and cap.

1. Disconnect waste line at waste cap connector.
2. Remove waste container cap.
3. Add 1.0 to 2.0 mL of Anti-Foam to the waste container. (Use only from those listed above as APPROVED.)
4. Re-attach the waste container cap and reconnect the waste line. (When re-connecting the waste line, listen for “snap” of connectors that will signify a solid connection of the hoses.)
5. Proceed with batch processing.

NOTE: Due to the variation of regulations concerning waste water, check to make sure that disposal of these anti-foaming agents in your area is in compliance with all local, state and federal regulations.

Empty Drip Cup

The drip cup under the dispense tip traveler home position should be emptied when the waste container is emptied.

WARNING: Potential Biohazard. Waste should be treated as biohazardous in accordance with standard lab practices.

1. Press **<*>** key; dispense traveler will move to center of transport.
2. Twist knurled knob (**A**) (Figure 5.2).
3. Lift up drip cup, being careful not to spill (Figure 5.3).
4. Empty cup into waste container.
5. Rinse and replace drip cup and secure knurled knob.
6. Press **<*>** key; dispense traveler will return to "home" position.

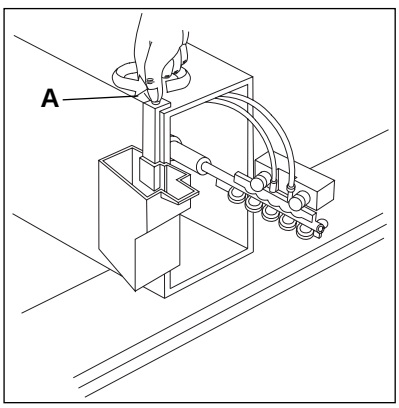


Figure 5.2

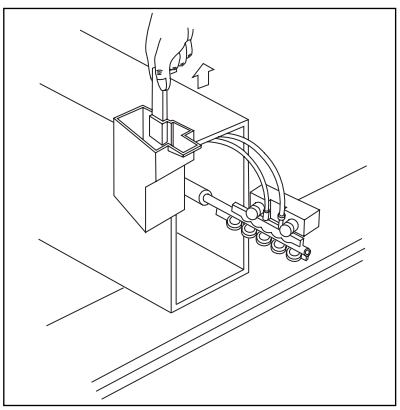


Figure 5.3

Fill the Water Canister

1. Check position of relief valve (A) (Figure 5.4). If valve is closed (Figure 5.5), pull and twist pressure relief valve one quarter turn (Figure 5.6). Listen for an audible hiss.

   WARNING: Water canister is pressurized – use appropriate caution.

   Do not unscrew pressure relief valve from the water canister lid (A) (Figure 5.4).

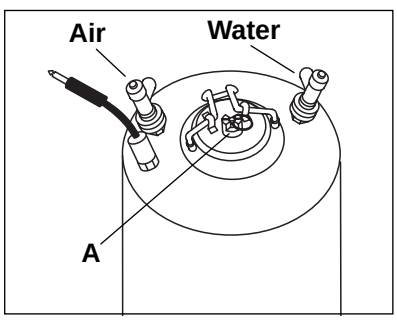


Figure 5.4

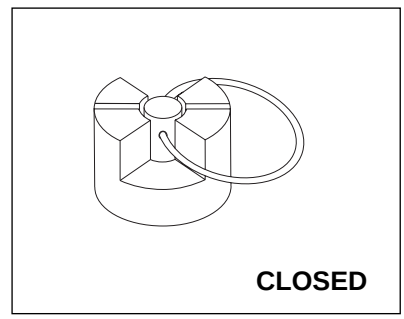


Figure 5.5

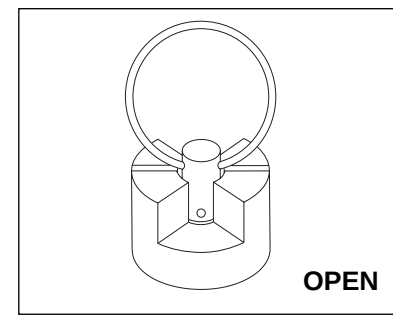


Figure 5.6

NOTE: Your water canister may have a slightly different configuration than the canister shown in this manual.

2. After releasing pressure, release and remove Water Canister lid (Figure 5.7).

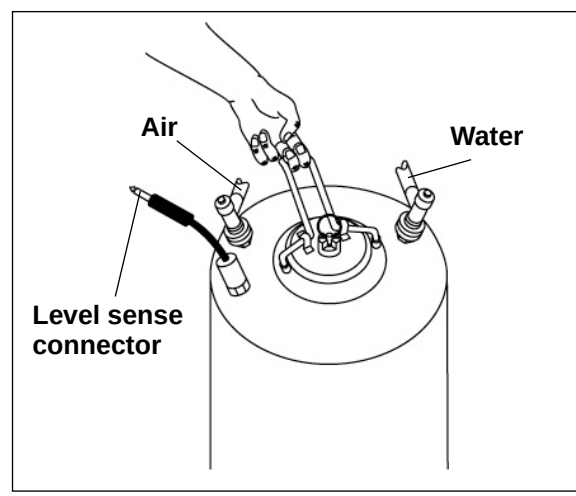


Figure 5.7

WARNING: Use proper precautions when lifting a filled water canister.

3. Fill to approximately **3 inches** below the top with deionized or distilled water and replace and lock lid.

   CAUTION: Overfilling the canister will affect wash performance.

   If disconnected, reconnect air, water and waste lines, level sense connector, and power cord.

   WARNING: When connecting hoses, listen for a "snap" of the connectors. Connectors must be fully engaged to avoid splashing, leakage, or backwash of waste through the system.

4. Close canister lid securely and verify that relief valve is closed.

Check the Tubing

Verify that all tubing is properly connected to both the cart and the instrument. Check tubing for leaks, cracks and discoloration.

Prime the Wash System

Purge air from the wash system by performing a Manual Wash Procedure (Type 01) on a 60-well tray. For more information, refer to *Section 9, Service and Maintenance.*

NOTE: Use of the <**Wash**> key to prime the wash system requires a valid calibration. If a valid calibration does not exist, the Wash Volume Verification test should be used to prime the wash system prior to performing calibration.

Exit the Station

Ensure that the PPC exit station is clear of trays.

Tray Bar Coding

Trays should have Bar Code labels applied prior to processing on the PPC. Trays prepared on a PIPETTOR should already be bar code labeled. Unique tray bar code IDs are recommended.

Place bar code label on the outside of tray in the frosted area provided. The bar code label is slightly longer than the frosted area. The bar code label should be placed even with the leading edge of the frosted area (edge near well A1). On trays without a frosted locator area, make sure the label is placed on the Column 1 side of the tray with the bar code beginning at well A1 (Figure 5.8).

NOTE: Bar code labels must be applied no higher or lower than the frosted area of the tray to ensure proper operation of the PPC.

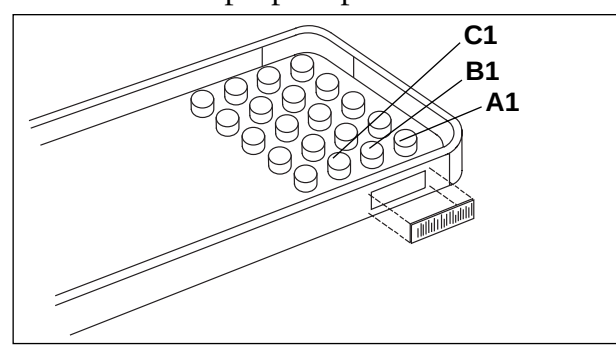


Figure 5.8

Pipetting Samples

Pipette samples into the tray vertically (*i.e.,* A1 through A5, B1 through B5, etc.). This includes singlets as well as replicates of samples.

NOTE: The PPC reads samples in the vertical sequence.

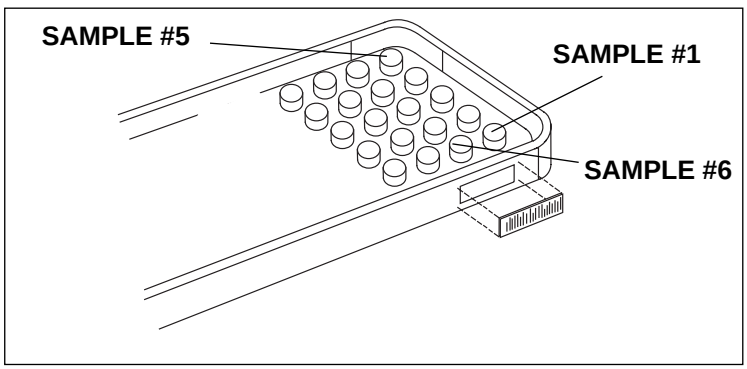


Figure 5.9

Operating Procedures

Introduction

The Operating Procedures section describes routine assay processing.

The PPC guides the operator through these steps with display prompts as trays are inserted.

Display prompts may vary, depending on the instruments and reagents used with the PPC.

Tray Entry

When the first tray of a batch is inserted into the PPC, the instrument reads the tray bar code and identifies the tray.

NOTE: If you are performing an assay for which use of a water bath incubation is approved, carefully wipe or blot the bottom of the tray dry before inserting it into the PPC.

The PPC then asks a series of questions to complete the information required to run the batch.

The batch set-up is complete when all required information has been received and a status screen displays the assay name, tray ID number, correct dispense volume and the tray position in the batch. The PPC will prompt with the next tray ID. Only insert the tray at the correct incubation interval.

In subsequent passes, the Status Screen will request operator input only when the first tray of a batch is inserted and identified by the instrument. Other trays in the batch must be reinserted in their original order and will be processed automatically.

NOTE: Unless otherwise specified within the reagent package insert, a maximum batch size of eight (8) trays is recommended for assay processing. Nine (9) and ten (10) tray batch sizes may be difficult to process within reagent package insert incubation specifications due to instrument communications and processing functions.

Reagent Blanking

Reagent blanking is required for some assays to correct for reagent coloration. During the conjugate incubation step, prepare a blanks tray using a separate tray. If operating in a TPC™ Verify or Record mode, perform the Bead Drop procedure described elsewhere in this section. Place one reagent blanking bead into each of five wells, A1 through A5. At the beginning of the OPD dispense pass, press the **<Blank>** key and insert the blanks tray, followed immediately by the first assay tray. At the beginning of the acid dispense pass, insert the blanks tray as the first tray of the batch.

NOTE: Use ONLY COMMANDER Reagent Blanking Beads (pink) in the PPC blanks tray. Accessory Blanking Beads (blue) may affect assay results. For more information, refer to the Parts List in *Section 9, Service and Maintenance*.

Assay Timing

An assay must be processed within the time limits indicated in the specific assay package insert. It is recommended that when processing a batch with multiple trays, the operator allow a time interval between trays during bead addition to avoid potential over/under incubation.

Depending on the wash type used, allow the following approximate times between trays. Refer to the assay protocol to determine which wash types are used from the assay. Use the longest wash type time to establish the time interval.

Wash Type 00..... 3 minutes
Wash Type 01..... 2 minutes
Wash Type 02..... 3 minutes
Wash Type 03..... 3 minutes
Wash Type 04..... 3 minutes
Wash Type 05..... 2 minutes
Wash Type 06..... 3 minutes

OPD Timing

OPD timing checks are made by the PPC. Two options are available – “Verified” and “Disabled”.

The option may be changed during batch processing, but whichever option was in effect at the beginning of the batch will remain in effect for that batch. Archived batches will retain original option.

Verified: this option monitors the time elapsed between the start of OPD dispense and the start of acid dispense for each row of a tray.

When set to “Verified”, early tray insertion is not allowed. The PPC will not accept trays which have been incubated for a shorter time than specified by protocol parameter Min. Elapsed Time 3. For rows which have been incubated longer than the time specified by protocol parameter Max. Elapsed Time 3, the results are flagged OPD TIME. Interpretation of results will not be provided for such wells.

If N/A is specified by Min. Elapsed Time 3, the minimum OPD incubation time check will not be performed; trays will be accepted when entered. If N/A is specified by Max. Elapsed Time 3, the maximum OPD incubation time check will not be performed; the OPD TIME flagging will not be available.

Disabled: this option identifies the start time at which OPD is dispensed in the first row of each tray.

In the “Disabled” option (default) the elapsed time from OPD dispense to the acid dispense is determined for the first row of each tray. Acid dispense in subsequent rows of each tray occurs only when the elapsed time is equal to or greater than the elapsed time for the first row of that tray.

Sample ID Entry

Sample IDs can range from 0 to 10 characters or 0 to 20 characters in length. Refer to *Section 2, Installation Procedures and Special Requirements* for instructions to specify which size sample ID your lab is using. Sample identification may be automatically downloaded to the PPC from the Pipettor, or entered manually when the PPC is operating Stand Alone.

If included in an assay protocol, the PPC will automatically prompt for sample IDs at the beginning of the OPD dispense pass. Sample IDs may also be entered using the option Enter Patient ID in the Database Special Mode.

Manual Entry

The display asks for the first well to be identified by one series of IDs and the first and last number of the series of IDs to be assigned. The display will repeat the questions, allowing the next series of IDs to be entered. This will continue until all wells have been identified.

NOTE: All Sample IDs entered must have the same number of digits (*i.e.,* if Sample IDs range from 1-100, then enter 001, . . . , . . . , 100).

The source of the Sample ID is identified to the right of the printed Sample ID by one of the following:

M = Manually entered ID at the PPC

E = Edited ID at the PPC

Pipettor originated IDs:

m = Non-bar code-entered ID (*i.e.,* keyboard entry or sequential entry) or Quality Control

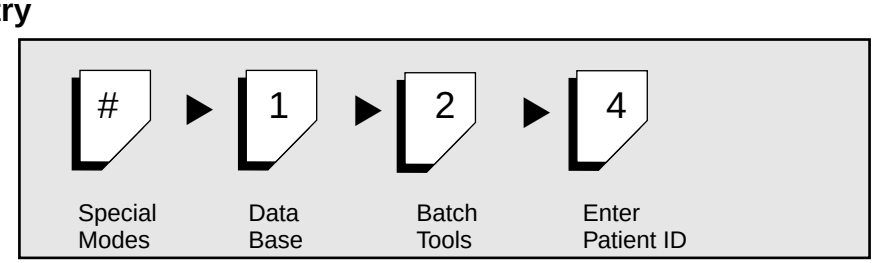
b = Bar code-entered ID

Source identifiers that are not added by the PPC are defined by the connected system. For example, the "b" and "m" are communicated by the FPC along with the sample ID. Other connected systems may append identifiers with unique meanings.

NOTE: ********** – indicates a Sample ID was received from a pipettor that was greater than the PPC Sample ID setting of 10.

1. Key in the tray/first well location (*i.e.,* 1 B1). Press **<Enter>**.
2. Key in the first ID number of the series associated with these wells. Press **<Enter>**.
3. Key in the last ID number associated with this series. Press **<Enter>**. The PPC will automatically compute and display the last well of this series.
4. Repeat for the next wells and their corresponding series of ID numbers.
5. Press <#> to exit.

Database Special Mode Entry



Display asks for tray number and first well of patient samples, and then asks for sample IDs. The tray must have completed the first pass at the time of the request.

When exiting the sample ID entry screen while the printer is not busy, the display asks if a printout of the entered sample IDs is desired. If yes, a printout will be provided.

"Tray Tickets"

As each tray completes a processing pass, a "tray ticket" is printed.

The following is an example of a "tray ticket" printed upon completion of the pass preceding the OPD pass.

```
****************************************
TRAY #                                78963

ASSAY # 3    NAME: AUSZYME MC A
SN: sssssss
Next Step:
Wash/Dispense 300 uL          OPD Sta.#4

****************************************
```

The following is an example of a "tray ticket" printed upon the completion of the OPD pass, with the OPD timing set to the "Disabled".

```
****************************************
TRAY #                                78963

ASSAY # 3    NAME: AUSZYME MC A
SN: sssssss
Next Step:
Dispense 300 uL 1N SULFURIC Sta.# 5/Read
First Row OPD Dispensed At: 14:10:59

No Bead Registered For This Tray

****************************************
```

NOTE: The time stamp printed during the OPD pass corresponds to the time at which the OPD was dispensed in the first row of the tray.

The following is an example of a “tray ticket” printed upon the completion of the OPD pass, with the OPD timing set to “Verified”.

```
****************************************
TRAY #                              78963

ASSAY # 65    NAME: SAMPLE
SN: sssssss
Next Step:
Dispense 300 uL 1N SULFURIC Sta.# 5/Read
Insert Tray After: 14:50:50
OPERATOR NOTE
OPD Timing in effect.
Allow time to load needed reagents
prior to tray processing

****************************************
```

The ticket may be torn off and kept with its tray to help the operator keep track of processing steps.

The Bead Drop Procedure

TPC

The Bead Drop Procedure allows for the registration of bead lot data necessary when TPC™ mode is Record or Verify for each tray in a batch. Performing this procedure is recommended for Blanks trays, Control/Standards/Sample trays and Calibration trays with a TPC mode of Record; and is mandatory with a TPC mode of Verify.

NOTE: When processing in TPC Verify mode, at completion of the OPD pass (for control/sample trays), the tray ticket will indicate if a Bead Drop Procedure has not been performed. To avoid generating a Deviation 06 error, the Bead Drop Procedure must be registered on the PPC which is processing the batch.

If the Bead Drop Procedure is performed on a different PPC, a Deviation 06 error will be generated. This error will only appear on the PPC Batch Report.

- With Controls, Standards and Sample trays, the PPC requests tray ID and bead lot number. As processing continues in the session, the operator is prompted only for the tray IDs, the bead lot number is automatically entered for the rest of the batch.

- With Blanks trays, the system is checked during processing to see if information has already been saved for the tray (*i.e.*, in the Bead Drop "Store"). The operator is prompted for the tray ID and bead lot number for each tray. The system can keep up to 10 Blanks trays in storage.
- With Calibration trays, the Bead Drop Procedure must be performed on each instrument. Only the latest Calibration Bead Drop Procedure data is stored in the system (last tray for which a Calibration Bead Drop Procedure was performed). The operator is prompted both for tray ID and the bead lot number for each tray. (For more information on performing the Bead Drop Procedure for calibration trays, refer to *Section 6, Calibration*.)

NOTE: The Bead Drop Procedure can be performed on Controls/Standards/Samples Trays on *any* PPC in the cluster which is attached to the pipettor that pipetted the tray. However, all processing passes must occur on a single PPC within the cluster utilized for the Bead Drop Procedure. When the Bead Drop Procedure is performed on blanks trays and the calibration tray, the procedure must be performed on the *same* PPC which will process the tray.

Subsequent Bead Drop Procedures performed on the same tray ID in Record Mode will overwrite existing bead data until the tray is archived.

With Blanks Trays

TPC

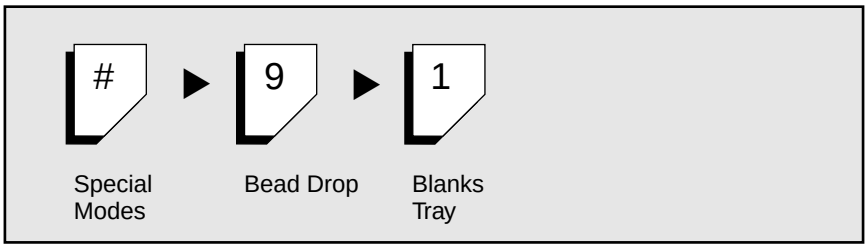
NOTE: Use ONLY COMMANDER Reagent Blanking Beads in the PPC blanks tray. Accessory Blanking Beads may affect assay results. For more information, refer to the Parts List in *Section 9, Service and Maintenance*.

Perform the Bead Drop Procedure with Blanks Trays when using the PPC in the following TPC™ mode:

- TPC Mode = Record (R) or Verify (V)
  Pipettor = FPC

NOTE: The Bead Drop Procedure cannot be used on a Blanks Tray when connected to a compatible (non-FPC) pipettor, or when operating in Stand Alone mode.

To register bead lot data, key in the following to perform the procedure:



The Blank Tray Bead "Store" saves the blank tray ID in the PPC until it is deleted or the tray is processed.

- Press <**1**> to add the blanks tray.
- Press <**2**> to print the tray list.
- Press <**3**> to delete the blanks tray.

The component type will be set to BLANKS BEAD (BKBD).

1. Scan a tray ID using the external bar code reader, or enter it with the keyboard.

2. After a valid tray ID is entered, scan or key the blank bead lot number from the bottle. Verify manually entered data and press <**Enter**>.

   NOTE: If you enter an invalid blank bead lot number, the display may request a deviation password before allowing you to proceed.

3. Continue to enter tray IDs or press <#> to exit.

```
                SAMPLE PRINTOUT

*************************************
      Blanks Tray Bead Drop Store

Date: 04/14/95 Time: 10:30:07 SN:sssssss

TRAY ID     TYPE      LOT#          DEV.
-------     ----    ---------       ----
11111       BKBD    12345M100

*************************************
```

With Controls, Standards and Sample Trays

TPC

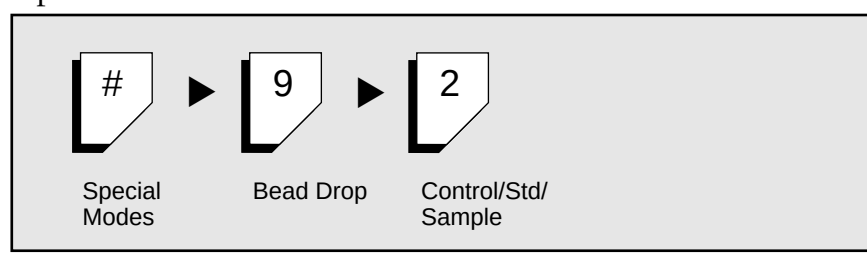
Perform the Bead Drop Procedure with Controls, Standards and Sample Trays when using the PPC in the following TPC™ modes:

- TPC Mode = Record (R) or Verify (V)
  Pipettor = FPC

When operating in the following TPC mode, the Bead Drop Procedure cannot be performed before the first pass on the PPC.

- TPC Mode = Record (R)
  Pipettor = compatible (non-FPC) or none (stand alone)

To register bead lot data, key in the following to perform the procedure:



The component type will be set to BEAD.

1. Scan a tray ID using the external bar code reader, or enter it with the keyboard.

2. After a valid tray ID is entered, scan or key the bead lot number. Verify manually entered data and press <**Enter**>.

   NOTE: If you enter an invalid bead lot number, the display may request a deviation password before allowing you to proceed.

3. Continue to enter tray IDs or press <#> to exit.

The Reconstitution Procedure

TPC

The Reconstitution Procedure provides the lot number and expiration data necessary for tracking the reagents which are reconstituted when the TPC™ Mode is Record or Verify, and can be used only with FPC™ pipettor, version 2.5 or greater. Performing this procedure is recommended with a TPC Mode of Record; and is mandatory with a TPC Mode of Verify.

When the Reconstitution Procedure is performed, the PPC requests the lot numbers of the two reagents to be combined, and of the resultant new mixture. For each physical mixture of reagent components, the resultant new mixture lot number must be unique (even if the lot numbers of the reagent components are the same).

The PPC and all connected FPCs verify that the mixture status is valid, and calculate the resultant new mixture expiration date and time. Non-OPD resultant mixtures will expire at midnight (23:59:59) on the calculated expiration day. OPD reagent will expire 60-minutes from validation of the components. PPC displays the new mixture's lot number and expiration date and time. After the components are physically mixed together, the PPC updates the component libraries of all connected FPCs. The resultant new mixture's lot number may not be reassigned until deleted from the component libraries of all connected FPCs.

For laboratories that wish to use a resultant new mixture on multiple PPC/FPC clusters, the Reconstitution Procedure must be performed on all PPC/FPC clusters so that the resultant new mixture will be recorded in all of the FPC component libraries. When performing the Reconstitution Procedure on multiple PPC/FPC clusters, the procedure must be performed on the same day to assure expiration date calculation consistency. Once an expiration date is calculated for a new mixture or other reagents, it cannot be changed.

The use of OPD mixtures on multiple PPC/FPC clusters is not recommended because of timing limitations and expiration calculation.

Performing the Reconstitution Procedure

Key in the following to perform the procedure:

Allows the PPC operator to verify the reconstitution of reagents used on the PPC (used only with TPC™-capable pipettors when TPC Mode is Verify or Record).

Abbott tray ID bar code labels are recommended for use as the new mixture lot number. Assure that all new mixture lot numbers are unique.

1. Affix the new mixture lot number label vertically on the mixture bottle in a position that will not compromise the reading of the label.
2. Scan or key the two component lot numbers to be mixed.
3. Scan or key the new mixture lot number.
4. After the reconstituted reagent has been validated between instruments, record the expiration time or date on the mixture bottle and press **<Yes>** to continue. If using the bottle of one of the original components, deface the original bar code label. If **<No>** is selected, the procedure is aborted.
5. Physically mix the components and press **<Enter>**.

NOTE: Expiration date/time is calculated during the validation of components. For optimum reagent usage, mixing of components should occur in a timely fashion when directed by the display. Calculation of expiration is according to the earliest instrument time as determined by all connected FPC™ instruments and the PPC.

Reagent Loading

Reagents and their dedicated dispensers should be loaded onto the PPC for assay processing. When in TPC™ Record or Verify mode, the PPC will prompt the operator for reagent loading and placement verification. Between uses on the PPC, each dispenser should be detached, cleaned, and stored in accordance with the dispenser package insert.

NOTE: Consult reagent package insert for time limitations for reagents.

NOTE: The OPD component expiration timing checks are made at the beginning and end of the OPD pass for the batch.

1. Be sure to use the dispenser with the larger dispense tip (Figure 5.10). For more information, refer to the Parts List in *Section 9, Service and Maintenance*.

2. Attach dispenser to the correct reagent bottle.

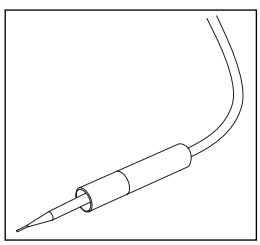


Figure 5.10

3. For the OPD dispense pass, the PPC primes the dispenser nine times into the drip cup before dispensing into the tray. This is to remove any oxidized OPD from the dispenser line. This priming is performed if it has been more than five minutes since the last OPD dispense.

4. For non-OPD dispensing passes, prime the dispenser by pressing the tip of outlet tube into dispenser recirculation port. Depress and release plunger button, ensuring that all lines are free of air bubbles prior to dispensing reagents. Remove the outlet tube from recirculation port. The dispenser is primed and ready for installation on the PPC (Figure 5.11).

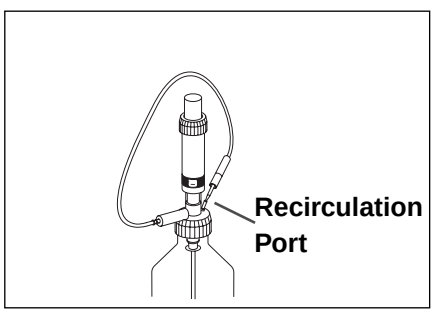


Figure 5.11

NOTE: For optimal reagent performance, follow the cleaning procedure specified in the Tri-Continent package insert.

5. Verify that the dispenser contains sufficient fluid level to complete the pass(s).

6. Open the pump compartment door (Figure 5.12) and load reagent bottle and dispenser in the correct component station (1 to 5 from left to right) with tubing connection facing out. Dispenser top should snap into position.

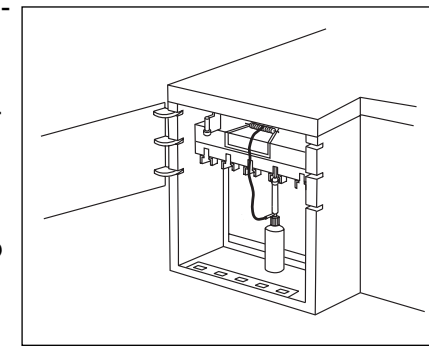


Figure 5.12

NOTE: For assays utilizing 50 µL volumes, be sure the dispenser is set to the 50 µL mark prior to installation on the PPC.

7. Feed tubing up into the tubing guide (Figure 5.13).

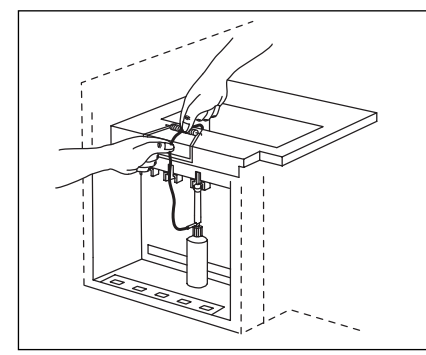


Figure 5.13

8. Insert dispense tip onto the tip holder until fully inserted (Figure 5.14).

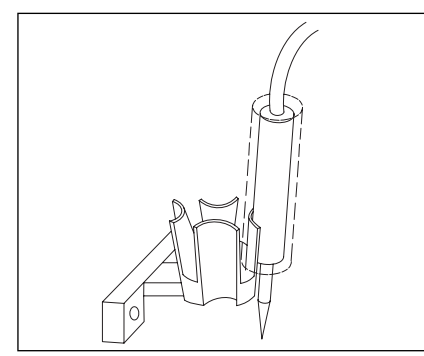


Figure 5.14

Correct reagent position may be checked when the Status screen is displayed and the component station is backlit at the beginning of each processing pass. Each component station is labeled with a bar code ID. When processing an assay with a TPC™ mode of Record or Verify, you can use the external bar code reader, when prompted, to read the station label.

Proper Tray Insertion

Trays must be inserted so that the bar code on the tray (**B**) aligns with the bar code reader window (**A**) (Figure 5.15). When properly inserted, the back end of a tray remains outside the load station and is pulled in as processing begins. **Do Not Force Trays Into Load Station.** Refer to assay timing for a suggested time interval between insertion of trays.

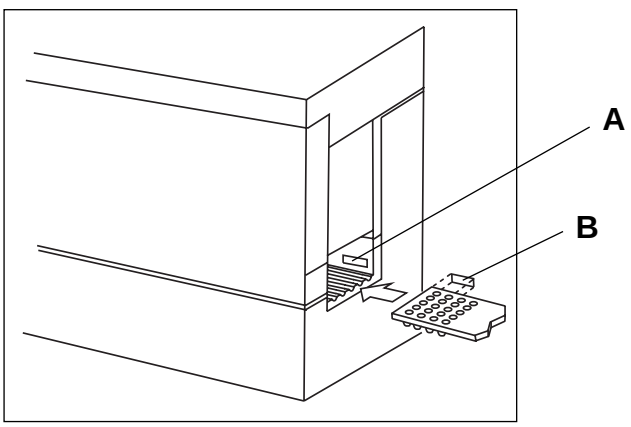


Figure 5.15

NOTE: A tray may be pulled into the PPC without being recognized if:

- The tray is placed end-to-end with the preceding tray. Allow the preceding tray to be pulled in before placing a tray on the entrance chute. The operator must cycle power to move an unrecognized tray to the exit.
- An error message is displayed which instructs the operator to remove the tray and the operator removes and reinserts the tray prior to the Insert Tray message being displayed. **The operator should allow the Insert Tray message to be displayed prior to re-inserting the tray.**

NOTES

Routine PPC Operations

TPC™ Mode = Record or Verify
Pipettor = FPC

Use these instructions for routine PPC operations when TPC Mode is Record or Verify and PPC is attached to an FPC™.

First Pass

PPC is ready to begin a processing pass when the display reads **"INSERT TRAY →"**

1. Perform the Reconstitution Procedure as necessary for mixtures to be used in running the assay.
2. If specified by the assay package insert, perform the Bead Drop Procedure for the controls, standards and/or sample tray(s), and dispense beads into the tray(s).
3. Insert first tray of batch.
4. Begin scanning or keying information requested on display. Verify manually entered data and press **<Enter>** if correct. Information requested can include:

   TRAY ID
   TECH ID
   COMPONENT LOT NUMBER

   NOTE: If you enter an invalid component lot number, the display may request a deviation password or allow you to correct the entry before proceeding.

   COMPONENT STATION
5. Place the component bottle in the correct position and scan or key the component station bar code label.
6. Continue scanning or keying as requested:

   # OF TRAYS IN BATCH
   "READY? (YES/NO)"
7. Verify dispenser volume, fluid level, and wash water and waste volume are sufficient to complete the batch pass.
8. Press **<Yes>** to begin processing.
9. Insert remaining trays in batch. (See *Assay Timing* elsewhere in this section.)
10. Remove trays from the exit as they are completed.
11. Continue processing as directed in the reagent package insert.

Subsequent Passes

Subsequent Passes Without A Blanks Tray	Subsequent Pass Requiring First Pass of Blanks Tray
• Perform the Reconstitution Procedure as necessary for mixtures (*i.e.,* OPD) to be used in running the assay. • If specified by the assay package insert, perform the Bead Drop Procedure for controls, standards and/or sample tray(s), and dispense beads into the tray(s). • The PPC will prompt for the next tray ID with the display "**INSERT TRAY →**". Only insert the tray at the correct incubation interval.	
1. Re-insert first tray of batch. (Before the OPD dispense pass of the assay, sample IDs may be requested, and OPD will be primed.)	**1a.** Perform the Bead Drop Procedure for the blanks tray, and dispense beads into the tray. **1b.** Press **<Blank>** key. **1c.** Insert blanks tray. **1d.** Re-insert first tray of batch. (Before the OPD dispense pass of the assay, sample IDs may be requested, and OPD will be primed.)
2. Begin scanning or keying information requested on display. Verify manually entered data and press **<Enter>** if correct. **NOTE:** If you enter an invalid component lot number, the display may request a deviation password or allow you to correct the entry before proceeding.	
3. Place the component bottle in the correct position and scan or key the component station bar code label.	
4. Verify dispenser volume, fluid level, and wash water and waste volume are sufficient to complete the batch pass.	
5. Continue scanning or keying information requested on display.	
6. Press **<Yes>** to begin processing.	
7. Re-insert remaining trays in batch. (Display will specify the ID number of trays to be inserted next.)	
8. Remove trays from the exit as they are completed. (If this was an OPD dispense pass, protect trays from light. Abbott Tray Covers are available for this purpose. For more information, refer to the Parts List in *Section 9, Service and Maintenance.)*	**8.** Remove trays from the exit as they are completed. The blanks tray becomes the first tray of the batch from this point on. There is no need to press the **<Blank>** key on subsequent passes. Protect trays from light. Abbott Tray Covers are available for this purpose. For more information, refer to the Parts List in *Section 9, Service and Maintenance.*
9. Continue processing as directed in the reagent package insert.	
• When all trays in a batch have completed a pass through the instrument, PPC is ready to process other batches. • If the PPC malfunctions and the batch cannot be completed, some assays in progress may be completed by an approved manual method (Quantum™ II). (CALL THE CUSTOMER SUPPORT CENTER TO DETERMINE IF THE ASSAY YOU ARE PERFORMING MAY BE COMPLETED MANUALLY.) When this occurs, it is the operator's responsibility to ensure that all assay parameters are within the stated limits of the reagent package insert.	

TPC™ Mode = Record
Pipettor = Compatible (non-FPC)

Use these instructions for routine PPC operations when TPC Mode is Record and PPC is attached to a compatible (non-FPC) pipettor.

First Pass

PPC is ready to begin a processing pass when the display reads **"INSERT TRAY →"**

1. If specified by the assay package insert, dispense beads into controls, standards and/or sample tray(s).

   NOTE: The Bead Drop Procedure cannot be performed prior to the first processing pass on the PPC.

2. Insert first tray of batch.
3. Begin scanning or keying information requested on display. Verify manually entered data and press **<Enter>** if correct. Information requested can include:

   TRAY ID
   TECH ID
   COMPONENT LOT NUMBER
   COMPONENT STATION

4. Place the component bottle in the correct position and scan or key the component station bar code label.
5. Continue keying or scanning as requested:

   # OF TRAYS IN BATCH
   "READY? (YES/NO)"

6. Verify dispenser volume, fluid level, and wash water and waste volume are sufficient to complete the batch pass.
7. Press **<Yes>** to begin processing.
8. Insert remaining trays in batch. (See *Assay Timing* elsewhere in this section.)
9. Remove trays from the exit as they are completed.
10. Continue processing as directed in the reagent package insert.

Subsequent Passes

Subsequent Passes Without A Blanks Tray	Subsequent Pass Requiring First Pass of Blanks Tray
• If specified by the assay package insert, perform the Bead Drop Procedure for controls, standards, and/or sample tray(s), and dispense beads into the tray(s). • The PPC will prompt for the next tray ID with the display "**INSERT TRAY →**". Only insert the tray at the correct incubation interval.	
1. Re-insert first tray of batch. (Before the OPD dispense pass of the assay, sample IDs may be requested, and OPD will be primed.)	**1a.** Dispense beads into the blanks tray. **1b.** Press **<Blank>** key. **1c.** Insert blanks tray. **1d.** Re-insert first tray of batch. (Before the OPD dispense pass of the assay, sample IDs may be requested, and OPD will be primed.)
2. Begin scanning or keying information requested on display. Verify manually entered data and press **<Enter>** if correct.	
3. Place the component bottle in the correct position and scan or key the component station bar code label.	
4. Verify dispenser volume, fluid level, and wash water and waste volume are sufficient bo complete the batch pass.	
5. Continue scanning or keying information requested on display.	
6. Press **<Yes>** to begin processing.	
7. Re-insert remaining trays in batch. (Display will specify the ID number of trays to be inserted next.)	
8. Remove trays from the exit as they are completed. (If this was an OPD dispense pass, protect trays from light. Abbott Tray Covers are available for this purpose. For more information, refer to the Parts List in *Section 9, Service and Maintenance.)*	**8.** Remove trays from the exit as they are completed. The blanks tray becomes the first tray of the batch from this point on. There is no need to press the **<Blank>** key on subsequent passes. Protect trays from light. Abbott Tray Covers are available for this purpose. For more information, refer to the Parts List in *Section 9, Service and Maintenance.*
9. Continue processing as directed in the reagent package insert.	

- When all trays in a batch have completed a pass through the instrument, PPC is ready to process other batches.
- If the PPC malfunctions and the batch cannot be completed, some assays in progress may be completed by an approved manual method (Quantum™ II). (CALL THE CUSTOMER SUPPORT CENTER TO DETERMINE IF THE ASSAY YOU ARE PERFORMING MAY BE COMPLETED MANUALLY.) When this occurs, it is the operator's responsibility to ensure that all assay parameters are within the stated limits of the reagent package insert.

TPC™ Mode = Off
Pipettor = Any

Use these instructions for routine PPC operations when TPC Mode is Off and the PPC is connected to any pipettor.

First Pass

PPC is ready to begin a processing pass when the display reads **"INSERT TRAY →"**

1. If specified by the assay package insert, place beads in the controls, standards and/or sample trays.
2. Insert first tray of batch.
3. Begin keying information requested on display. Verify manually entered data and press **<Enter>** if correct. Information requested can include:

   TRAY ID
   TECH ID
   # OF TRAYS IN BATCH
   MASTER LOT?
   "READY? (YES/NO)"
4. Verify reagent position, dispenser volume, fluid level, and wash water and waste volume are sufficient to complete the batch pass.
5. Press **<Yes>** to begin processing.
6. Insert remaining trays in batch. (See *Assay Timing* elsewhere in this section.)
7. Remove trays from the exit as they are completed.
8. Continue processing as directed in the reagent package insert.

Subsequent Passes

Subsequent Passes Without A Blanks Tray	Subsequent Pass Requiring First Pass of Blanks Tray
• If specified by the assay package insert, dispense beads into controls, standards and/or sample tray(s). • The PPC will prompt for the next tray ID with the display "**INSERT TRAY →**". Only insert the tray at the correct incubation interval.	
1. Re-insert first tray of batch. (Before the OPD dispense pass of the assay, sample IDs may be requested and OPD will be primed.)	**1a.** Dispense beads into blanks tray. **1b.** Press <**Blank**> key. **1c.** Insert blanks tray. **1d.** Re-insert first tray of batch. (Before the OPD dispense pass of the assay, sample IDs may be requested and OPD will be primed.)
2. Key information requested on display. Verify data and press <**Enter**> if correct.	**2.** Key information requested on display. Verify data and press <**Enter**> if correct.
3. Place the component bottle in the correct position.	
4. Verify dispenser volume, fluid level, and wash water and waste volume are sufficient to complete the batch pass.	
5. Continue keying information requested on display.	
6. Press <**Yes**> to begin processing.	
7. Re-insert remaining trays in batch. (Display will specify the ID number of trays to be inserted next.)	
8. Remove trays from the exit as they are completed. (If this was an OPD dispense pass, protect trays from light. Abbott Tray Covers are available for this purpose. For more information, refer to the Parts List in *Section 9, Service and Maintenance.)*	**8.** Remove trays from the exit as they are completed. The blanks tray becomes the first tray of the batch from this point on. There is no need to press the <**Blank**> key on subsequent passes. Protect trays from light. Abbott Tray Covers are available for this purpose. For more information, refer to the Parts List in *Section 9, Service and Maintenance.*
9. Continue processing as directed in the reagent package insert.	

- When all trays in a batch have completed a pass through the instrument, PPC is ready to process other batches.
- If the PPC malfunctions and the batch cannot be completed, some assays in progress may be completed by an approved manual method (Quantum™ II). (CALL THE CUSTOMER SUPPORT CENTER TO DETERMINE IF THE ASSAY YOU ARE PERFORMING MAY BE COMPLETED MANUALLY.) When this occurs, it is the operator's responsibility to ensure that all assay parameters are within the stated limits of the reagent package insert.

TPC™ Mode = Record
Pipettor = None

TPC

Use these instructions for routine PPC operations when TPC Mode is Record and PPC is in Stand Alone operation, not connected to a pipettor.

First Pass

PPC is ready to begin a processing pass when the display reads **"INSERT TRAY →"**

1. If specified by the assay package insert, dispense beads in controls, standards and/or sample tray(s).

   NOTE: The Bead Drop Procedure cannot be performed prior to the first processing pass on the PPC.

2. Insert first tray of batch.
3. Begin scanning or keying information requested on display. Verify manually entered data and press **<Enter>** if correct. Information requested can include:

   TRAY ID
   ASSAY #
   TECH ID
   COMPONENT LOT NUMBER
   COMPONENT STATION
   # OF TRAYS IN BATCH
   MASTER LOT
   VOID, NO SAMPLE OR EMPTY WELLS
   LAST FILLED WELL
   PRINT-OUT OF WELL STATUS
   CHANGES TO WELL STATUS
   "READY? (YES/NO)"
4. Verify reagent position, dispenser volume, fluid level, and wash water volume are sufficient to complete the batch pass.
5. Press **<Yes>** to begin processing.
6. Insert remaining trays in batch. (See *Assay Timing* elsewhere in this section.)
7. Remove trays from the exit as they are completed.
8. Continue processing as directed in the reagent package insert.

Subsequent Passes

Subsequent Passes Without A Blanks Tray	Subsequent Pass Requiring First Pass of Blanks Tray
• If specified by the assay package insert, perform the Bead Drop Procedure for controls, standards and/or sample tray(s), and dispense beads into the tray(s). • The PPC will prompt for the next tray ID with the display "**INSERT TRAY →**". Only insert the tray at the correct incubation interval.	
1. Re-insert first tray of batch. (Before the OPD dispense pass of the assay, sample IDs may be requested, and OPD will be primed.)	**1a.** Dispense beads into the blanks tray. **1b.** Press **<Blank>** key. **1c.** Insert blanks tray. **1d.** Re-insert first tray of batch. (Before the OPD dispense pass of the assay, sample IDs may be requested, and OPD will be primed.)
2. Begin scanning or keying information requested on display. Verify manually entered data and press **<Enter>** if correct.	
3. Place the component bottle in the correct position and scan or key the component station bar code label.	
4. Verify dispenser volume, fluid level, and wash water and waste volume are sufficient to complete the batch pass.	
5. Continue scanning or keying information requested on display.	
6. Press **<Yes>** to begin processing.	
7. Re-insert remaining trays in batch. (Display will specify the ID number of trays to be inserted next.)	
8. Remove trays from the exit as they are completed. (If this was an OPD dispense pass, protect trays from light. Abbott Tray Covers are available for this purpose. For more information, refer to the Parts List in *Section 9, Service and Maintenance.)*	**8.** Remove trays from the exit as they are completed. The blanks tray becomes the first tray of the batch from this point on. There is no need to press the **<Blank>** key on subsequent passes. Protect trays from light. Abbott Tray Covers are available for this purpose. For more information, refer to the Parts List in *Section 9, Service and Maintenance.*
9. Continue processing as directed in the reagent package insert.	

- When all trays in a batch have completed a pass through the instrument, PPC is ready to process other batches.
- If the PPC malfunctions and the batch cannot be completed, some assays in progress may be completed by an approved manual method (Quantum™ II). (CALL THE CUSTOMER SUPPORT CENTER TO DETERMINE IF THE ASSAY YOU ARE PERFORMING MAY BE COMPLETED MANUALLY.) When this occurs, it is the operator's responsibility to ensure that all assay parameters are within the stated limits of the reagent package insert.

TPC™ Mode = Off
Pipettor = None

Use these instructions for routine PPC operations when TPC Mode is Off and PPC is in Stand Alone operation, not connected to a pipettor.

First Pass

PPC is ready to begin a processing pass when the display reads **"INSERT TRAY →"**

1. If specified by the assay package insert, dispense beads in controls, standard and/or sample tray(s).
2. Insert first tray of batch.
3. Begin keying information requested on display. Verify manually entered data and press **<Enter>** if correct. Information requested can include:

   TRAY ID
   ASSAY #
   TECH ID
   # OF TRAYS IN BATCH
   MASTER LOT
   VOID, NO SAMPLE OR EMPTY WELLS
   LAST FILLED WELL
   PRINT-OUT OF WELL STATUS
   CHANGES TO WELL STATUS
   "READY? (YES/NO)"
4. Verify reagent position, dispenser volume, fluid level, and wash water volume.
5. Press **<Yes>** to begin processing.
6. Insert remaining trays in batch. (See *Assay Timing* elsewhere in this section.)
7. Remove trays from the exit as they are completed.
8. Continue processing as directed in the reagent package insert.

Subsequent Passes

Subsequent Passes Without A Blanks Tray	Pass Requiring First Pass of Blanks Tray
• If specified by the assay package insert, dispense beads in controls, standards, and sample tray(s). • The PPC will prompt for the next tray ID with the display "**INSERT TRAY →**". Only insert the tray at the correct incubation interval.	
1. Re-insert first tray of batch. (Before the OPD dispense pass of the assay, sample IDs may be requested, and OPD will be primed.)	**1a.** Dispense beads in blanks tray. **1b.** Press **<Blank>** key. **1c.** Insert blanks tray. **1d.** Re-insert first tray of batch. (Before the OPD dispense pass of the assay, sample IDs may be requested.)
2. Begin keying information requested on display. Verify manually entered data and press **<Enter>** if correct.	
3. Place the component bottle in the correct position.	
4. Verify dispenser volume, fluid level, and wash water and waste volume is sufficient to complete the batch pass.	
5. Continue keying information requested on display.	
6. Press **<Yes>** to begin processing.	
7. Re-insert remaining trays in batch. (Display will specify the ID number of trays to be inserted next.)	
8. Remove trays from the exit as they are completed. (If this was an OPD dispense pass, protect trays from light. Abbott Tray Covers are available for this purpose. For more information, refer to the Parts List in *Section 9, Service and Maintenance.)*	**8.** Remove trays from the exit as they are completed. The blanks tray becomes the first tray of the batch from this point on. There is no need to press the **<Blank>** key on subsequent passes. Protect trays from light. Abbott Tray Covers are available for this purpose. For more information, refer to the Parts List in *Section 9, Service and Maintenance.*
9. Continue processing as directed in the reagent package insert.	

- When all trays in a batch have completed a pass through the instrument, PPC is ready to process other batches.
- If the PPC malfunctions and the batch cannot be completed, some assays in progress may be completed by an approved manual method (Quantum™ II). (CALL THE CUSTOMER SUPPORT CENTER TO DETERMINE IF THE ASSAY YOU ARE PERFORMING MAY BE COMPLETED MANUALLY.) When this occurs, it is the operator's responsibility to ensure that all assay parameters are within the stated limits of the reagent package insert.

Post Operating Procedures

1. Remove reagent dispensers from instrument.
2. Remove dispensers from reagent bottles. Clean and store as directed in dispenser insert.
3. Store reagents as directed in the assay package insert.
4. Open pressure relief valve on water canister to de-pressurize the system (Figure 5.16 and 5.17).

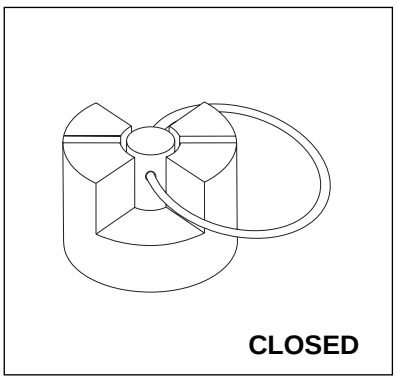


Figure 5.16

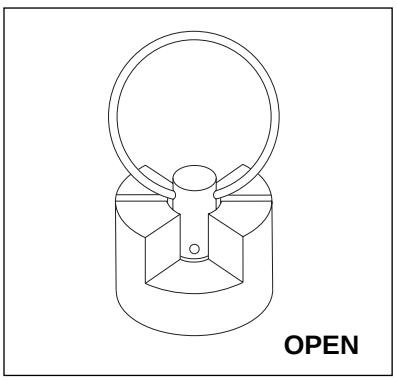


Figure 5.17

WARNING: Do not unscrew pressure relief valve from the water canister lid.

5. For laboratories which interface the PPC to a Data Collection Device, compare the PPC BATCH INFO results tape to the computer-generated report for verification of data transfer.

Special Operating Procedures

Introduction

This section describes the special operating procedures that are not performed as part of routine processing. These procedures are accessed through Special Modes and Special Function keys.

Batch Tools

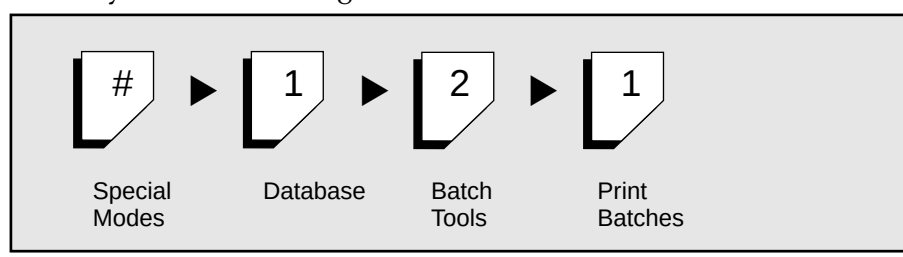
Assay numbers, tray identification and processing status of the most recent 10 batches or forty trays (whichever comes first) are tracked by the PPC.

The following tasks can be performed under Batch Tools:

- Print a Batch Status List
- Void Tray from a Batch
- Shorten Batch
- Delete One Batch
- Delete All Batches
- Retransmit a Batch Record

Print A Batch Status List

Key in the following:

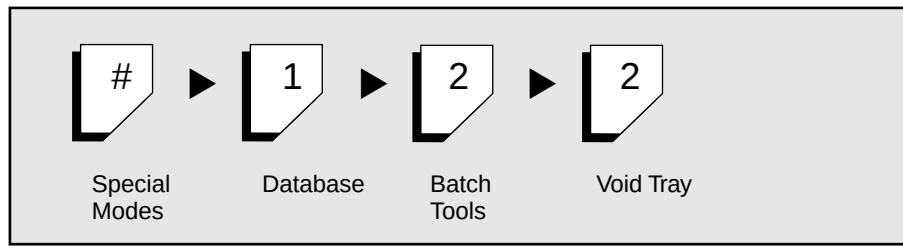


Assay name and ID number and processing status of each tray in a batch tracked by the PPC will print out. Date and time shown on the printout correspond to the date and time of printing.

```
                SAMPLE PRINTOUT

*************************************
              Batch Listings
           Number of Batches = 3
Date: 08/27/87 Time: 12:34:14 SN:sssssss
*************************************
               Assay Number = 1
             Number of Trays = 1
Tray:      123  Status:   ARCHIVED BLANK
Tray:    12345  Status:          ARCHIVED

*************************************
               Assay Number = 2
             Number of Trays = 5
Tray:      101  Status:   ARCHIVED BLANK
Tray:    11223  Status:          ARCHIVED
Tray:    11224  Status:          ARCHIVED
Tray:    11225  Status:          ARCHIVED
Tray:    11226  Status:          ARCHIVED
Tray:    11227  Status:          ARCHIVED

*************************************
               Assay Number = 3
             Number of Trays = 6
Tray:      221  Status:   ARCHIVED BLANK
Tray:     2221  Status:          ARCHIVED
Tray:     2222  Status:          ARCHIVED
Tray:     2223  Status:          ARCHIVED
Tray:     2224  Status:          ARCHIVED
Tray:     2225  Status:          ARCHIVED
Tray:     2226  Status:          ARCHIVED
```

Void Tray From Batch

Key in the following:



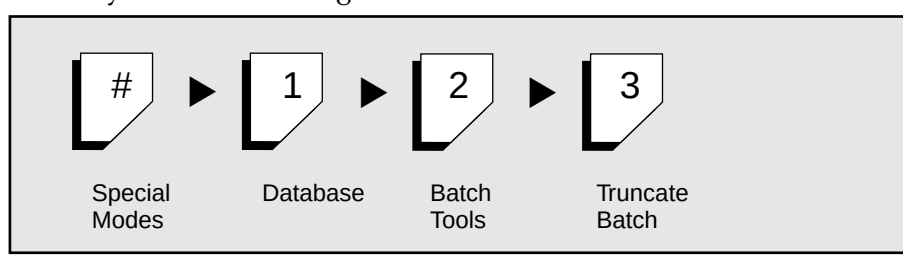
Display asks for ID of tray to be voided and will void it when the operator responds. If the first tray of the batch is voided, the entire batch will be void.

NOTE: The tray cannot be in the PPC at the time of request.

Shorten Batch

A batch may be shortened during the first processing pass if there are fewer trays to be processed than the number entered when the batch was set up. To eliminate the last trays, press the following key sequence after inserting the tray that will become the new last tray of the batch.

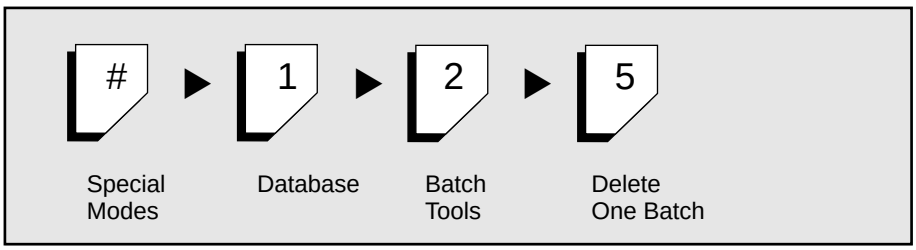
Key in the following:



Instrument returns to Insert Tray screen.

Delete One Batch

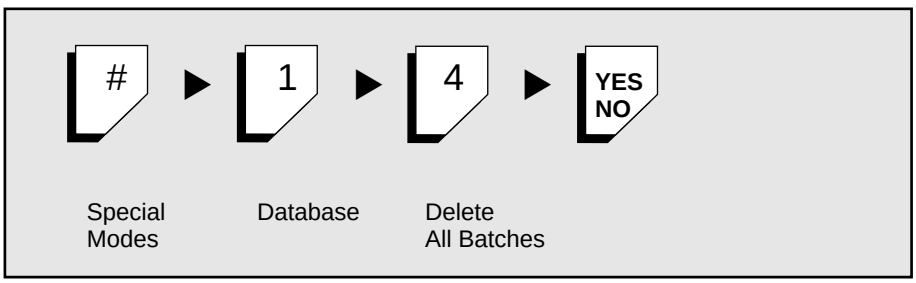
Key in the following:



Display asks for a Tray ID from any tray in a batch which is to be deleted. Once a batch has been deleted, it is not available for reread or retransmission.

Delete All Batches

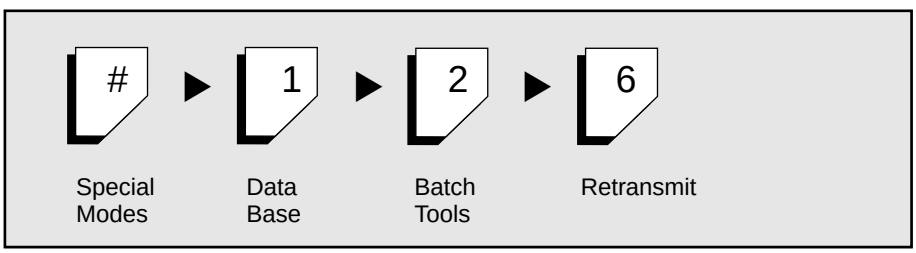
Key in the following:



PPC deletes all batches from Database. Once a batch has been deleted, it is not available for reread or retransmission.

Retransmit A Batch Record

Key in the following:



NOTE: Prior to selecting retransmit, proper procedures should ensure that the retransmitted data is not interpreted as duplicate results.

The PPC retransmits and reprints the original RS-232 Batch Info data output for an Allowed Batch. An Allowed Batch is a batch that has completed the final pass, is archived, and has not had any well status changes since being read. The PPC database can store a maximum of 10 batches or 40 trays for retransmission at a time.

A retransmitted batch is identified by a Retransmit header. For further information, refer to the *COMMANDER® Parallel Processing Center (PPC) RS-232 Interface Specification.*

The use of the retransmit feature is recommended for loss of data transmission to a host computer, printer jams or power loss.

1. To transmit all trays in the batch, key in the Tray ID of any tray in the batch to be retransmitted, followed by **<Enter>**. Press **<Enter>** alone to select all batches in the database.
2. Results specified are printed and retransmitted.

NOTE: Any processing error messages, except mechanical errors that occurred during the final read pass, will be included in the retransmission. The date and time reflect the date and time of the original transmission.

If OPD Time is enabled and some rows have been flagged with **OPD TIME**, the timing information at the end of the tray report will not be included in the retransmit data and printout. Tray status may also be updated to ARCHIVED or VOIDED as appropriate.

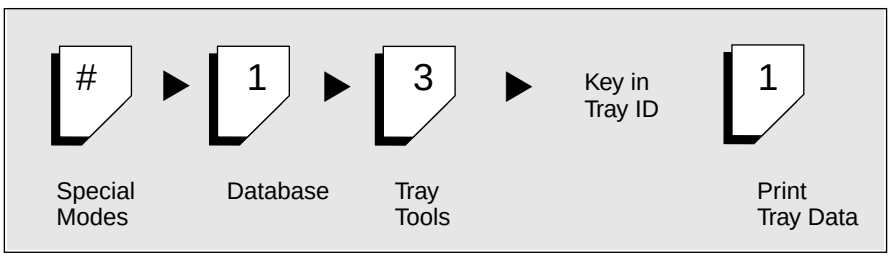
Tray Tools

Tray Tools allows a well to be voided after processing has begun. The following tasks can be performed under Tray Tools:

- Print Tray Data
- Void a Well on a Tray in Process

Print Tray Data

Key in the following:



PPC prints data for each well in a Tray. This includes status of the well, sample IDs and read values from the OPD pass. For control wells, the component label identified by the FPC may be printed in the tray map. The control well's component label will not be printed on the final batch report.

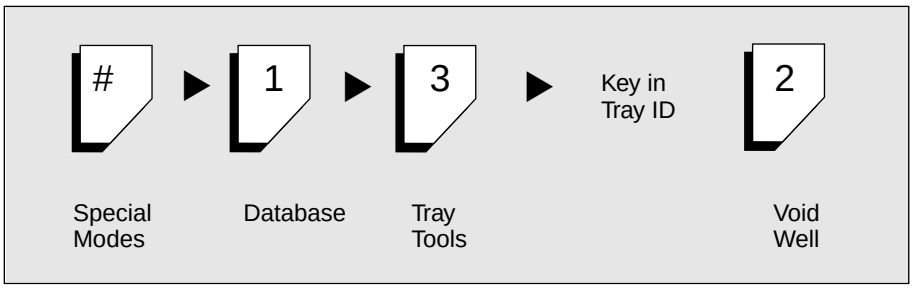
Date and time in the header correspond to the data and time of printing. "Time Last Step Started" corresponds to the time the tray was gated for the previous pass. TPC™ information is printed in TPC Mode of Record or Verify. If "OPD Time" is enabled, the printout shows Elapsed Time, which represents the time from the beginning of OPD dispense to the time of the beginning of the acid dispense.

```
                SAMPLE PRINTOUT
*************************************
Tray:    100000 Status:    INCUBATE 3
Date: 04/29/87 Time: 15:00:03 SN:sssssss
Batch Number                        5
Assay #: 3   Name:  AUSZYME MC A
LIST #-PROCEDURE:    1980A
Tray Id Source (M/B):               M
Tray Size                          20
Controls                            Y
Time Last Step Started        09:58:34
OPD Time = Disabled
[Elapsed Time]
Sample ID Length = 10
TPC Mode: RECORD
TPC Information:
ML                        12345M200M
CNJ1                      22297M200B
OPD                         1234567M
NCN1                      32112M200B
PCN1                      33000M200B
BEAD                      44000M200B

 Well Status:
      5      4      3      2      1
   +------+------+------+------+------+
  A|FILLED|FILLED|FILLED|FILLED|FILLED|A
   |      |      |      |      |      |
   |Posit |Posit |Negat |Negat |Negat |
   |ive 1m|ive 1m|ive 1m|ive 1m|ive 1m|
   | 0.017| 0.022| 0.018| 0.025| 0.034|
   +------+------+------+------+------+
  B|FILLED|FILLED|FILLED|FILLED|FILLED|B
   |      |      |      |      |      |
   |      |      |      |      |      |
   |10005b|10004b|10003b|10002b|10001b|
   | 0.022| 0.034| 0.017| 0.023| 0.026|
   +------+------+------+------+------+
  C|FILLED|FILLED|FILLED|FILLED|FILLED|C
   |      |      |      |      |      |
   |      |      |      |      |      |
   |10010b|10009b|10008b|10007b|10006b|
   | 0.021| 0.015| 0.023| 0.047| 0.024|
   +------+------+------+------+------+
  D|FILLED|FILLED|FILLED|FILLED|FILLED|D
   |      |      |      |      |      |
   |      |      |      |      |      |
   |10015b|10014b|10013b|10012b|10011b|
   | 0.021| 0.015| 0.012| 0.017| 0.029|
   +------+------+------+------+------+
*************************************
```

NOTE: The values printed at the bottom of each well are read values from the OPD pass. These are NOT final read values.

Void a Well on a Tray in Process

Key in the following:



Display asks for wells to be voided. The tray cannot be in the PPC at the time of the request.

The PPC Keypad

Information requested during processing or for performance of some special operating procedures is entered through the keypad (Figure 5.18) using either alphanumeric entry or dedicated special function keys.

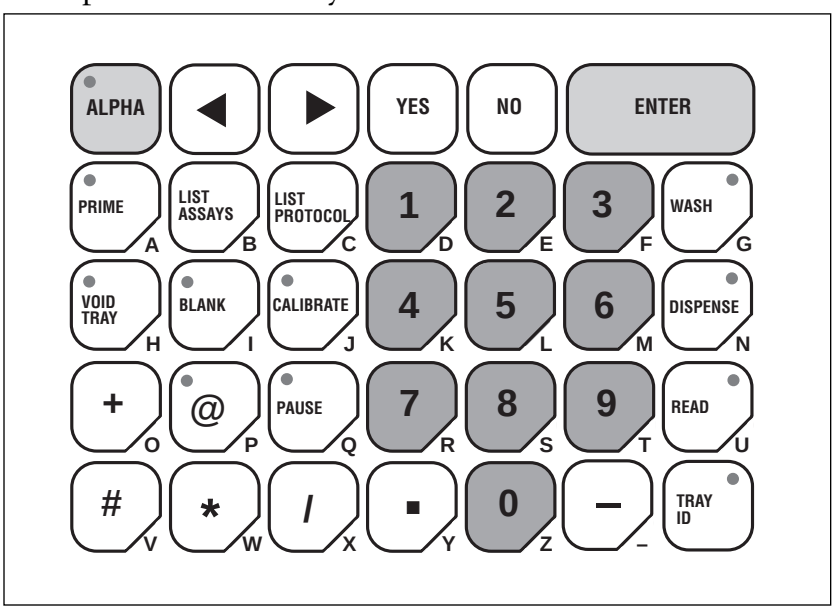


Figure 5.18

LEDs on some special function keys illuminate when the function is selected. Use of the special function keys are described below.

- **<Alpha>** key allows you to make alphabetic entries by pressing keys secondarily labeled with alpha characters. When in alpha mode, an LED on the key is lit. The PPC will automatically shift into alpha mode at certain processing steps.

- **<◀>** **<▶>** Keys are used to backspace the cursor, deleting a character, and to advance the cursor forward.

- **<Yes>** or **<No>** keys, when pressed in response to instrument prompts, proceed to the next question in the sequence. The keys are also used to scroll through the lines of an assay protocol for editing.

- **<Enter>** key is used at the end of some sequences to finalize the procedure.

- **<Prime>** key may be used in the manual mode to prime dispensers before dispensing, ensuring that all lines are free of air bubbles prior to dispensing reagents.

  When this key is pressed, the display prompts for the position and volume of the dispenser to be primed then automatically dispenses nine times into the drip cup.

  NOTE: Excessive priming may cause shortages of reagents. The dispensers should be primed manually before loading on the PPC.

- **<List Assay>** key prints the current active assays, their corresponding assay code numbers, their list number – procedure, serial number, and the software version number.

  The assay directory may also be printed while in the Assay Tools Special Mode.

- **<List Protocol>** key is pressed to print a list of parameters for a specific assay protocol. This listing includes the software version number and serial number.

  When this key is pressed, the display will ask for the number of the assay protocol to be printed.

  An assay protocol printout may also be requested in the Assay Tools Special Mode.

- **<Wash>** key is used to perform the Manual Wash Procedure, a manual stand-alone wash that is not part of a PPC assay protocol. This wash function may also be used to prime the wash system after refilling the water canister.

  When this key is pressed, the display prompts for type of wash and well locations to be washed, then prompts to insert tray.

  Many different wash types are available; use only Wash Type 1 for manual stand-alone wash procedures.

  CAUTION: If the system power is lost when washing a tray while using the PPC as a stand alone wash instrument, that tray must be voided and discarded. The integrity of the wash cannot be assured if the power is lost.

- **<Void Tray>** key voids a tray from a batch in process. The instrument responds with prompts for the ID of the tray to be voided.

  These trays are noted as Void on the Batch Listing. Voided trays will not be accepted into the PPC as part of their former batches.

  – Voiding a standards, controls, or blanks tray will result in voiding the entire batch.

  – Trays may also be voided in Database Special Mode.

- **<Blank>** key identifies the next tray to be entered as a blanks tray. The blanks tray is used for the reagent blanking pass in routine cutoff assay processing.

  Any formerly unidentified tray inserted after the BLANK key is pressed will be identified as a blanks tray and will be drawn into the PPC. Display then prompts to insert first tray of batch.

- **<Calibrate>** key is used to initiate instrument calibration. When this key is pressed, the instrument responds with a prompt to insert calibration tray. (Refer to *Section 6, Calibration* for more information.)

- **<Dispense>** key is used to perform a manual dispense function that is not included in a PPC assay protocol. When this key is pressed, the display asks for pump volume, pump location, number of trays to be dispensed, well locations to be dispensed and single vs. double dispense. Display then asks the operator to insert tray.

The manual dispense process may be truncated by pressing the <**Dispense**> key any time during the manual process.

CAUTION: If the system power is lost when dispensing while using the PPC as a stand alone dispense instrument, that tray must be voided and discarded. The integrity of the dispense cannot be assured if the power is lost.

NOTE: When using the manual dispense mode, carefully inspect each tray of the batch for proper reagent addition.

- <+> key is not functional at this time.
- <@> key is not functional at this time.
- <**Pause**> key, when pressed, temporarily halts PPC processing functions after completing the current row in process. If used during routine batch processing, <**Pause**> should be used with care to avoid interrupting assay timing. The <**Pause**> key should be pressed again to continue processing.
- <**Read**> key is used — if the Reread option is enabled — to allow a processed batch to be reread and results to be printed. Only a batch that has been fully processed and is still archived on the PPC can be reread. Reread batches must meet all other manufacturer's labeling criteria for validity.

  When this key is pressed, the display asks the operator to re-insert trays in sequence.

  CAUTION: Immediately prior to rereading a batch, reread the blanks tray (if applicable to the assay being processed) associated with that batch. **Failure to reread the blanks tray associated with a batch may affect assay results.**

  Abbott recommends that the operator manually note, on the original tape, reasons for a reread.

  The LIS may overwrite original data and duplicate results may be transmitted. Therefore, operators must ensure that their laboratory procedures adequately address reconciliation of the original and reread tapes. If available, retain all tapes when it is necessary to reread on the PPC.

It is recommended that the retransmit function be used to resend batch data to an LIS.

Elapsed time between initial and rereads cannot exceed two hours.

- <#> key is used to enter and exit Special Modes.
- <*> key is used to move the dispense tip holder away from the drip cup when the drip cup is to be removed. When this key is pressed, the dispense tip holder moves from its home position to the number three well position to provide easy access to remove and replace the drip cup. Pressing the <*> key a second time returns the dispense tip holder to its home position.

  The <*> key is also used in Special Modes to set passwords for assay protocol editing and to abort certain assay protocol editing procedures.
- </> key is used during assay protocol editing to insert "not applicable" (N/A) for parameters which permit N/A as a value.
- <•> <–> keys are used in the **EDIT** Mode.
- <**Tray ID**> key allows the user to reread a tray bar code label in the load station that was not recognized initially.

  Before pressing the key, adjust the tray in load station. The internal bar code reader will flash and display will move on to the next screen when the bar code is properly read.

  During editing, press <**Tray ID**> followed by the line number to go to a specific line number.
- <**Number**> keys are used in making menu and assay selections, in identifying trays and samples, and in the edit mode.

Calibration

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NOTES

Calibration

The calibration feature establishes internal references which are used when running assays. These internal references are used during the Initial Read check and for Blank Checking if specified by the assay protocol. They are not used in final results calculation.

An instrument calibration uses a 60-well tray, which contains Reagent Blanking beads in wells A1 through F5. The tray processing includes bead washing and dispensing of PPC Optical Reference Solution into each of the wells containing beads. Each of the wells (A1-F5) is read. For each column (column 1, for example, includes wells A1, B1, C1, D1, E1 and F1) a mean and a standard deviation are calculated.

If the standard deviation for a column is 0.007 or less, then the column mean is stored as a reference. If the standard deviation is larger than 0.007, then the value farthest from the mean is discarded, the well is flagged REJECT, and a new mean and standard deviation are calculated. In the case of two values equidistant from the mean, the more positive value will be discarded. No more than two values may be rejected. Each column must have an accepted mean stored as an internal reference before running of assays is allowed.

Required Materials

60-well Reaction Tray. (Be sure that the tray bottom is free of scratches or marks.)

Reagent Blanking Beads

NOTE: Use only COMMANDER Reagent Blanking Beads (pink) in the PPC blanks tray. Accessory Blanking Beads (blue) may affect assay results. For more information, refer to the Parts List in *Section 9, Service and Maintenance*.

PPC Optical Reference Solution (ORSN)

Dedicated 300 µL Dispenser (Refer to the Parts List in *Section 9, Service and Maintenance*.)

Storage Requirements

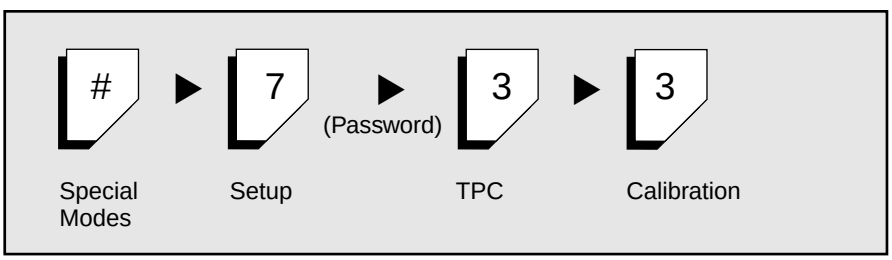
PPC Optical Reference Solution (ORSN) must be stored at 2 to 8° C.

ORSN must be brought to room temperature (15 to 30° C) for use and returned to storage conditions indicated above immediately after use. (Do not expose ORSN to strong light during storage.)

TPC™ Mode For Calibration

The TPC mode for calibration should be set whenever you download software, prior to initial calibration, and subsequently thereafter if your laboratory desires to change the mode. This function requires an FPC™ pipettor, version 2.5 or greater.

To set the TPC Mode for calibration, key in the following:



The PPC displays the current setting (default is OFF) and three options: OFF, RECORD and VERIFY.

- Press <**1**> to set TPC Mode for Calibration to Off, prompting for no component information prior to performing an instrument calibration.
- Press <**2**> to set TPC Mode for Calibration to Record, prompting for component information prior to performing an instrument calibration without checking for component validity.
- Press <**3**> to set TPC Mode for Calibration to Verify, prompting for component information prior to performing an instrument calibration and check for component validity.
- Press <**#**> to return to the TPC menu.

Pre-Calibration Procedures

Perform the following Pre-Operating Procedures before performing Calibration. For instructions, refer to *Section 5, Operating Procedures*.

- Wash & Waste Cart Preparation
- Tray Bar Coding

Procedure

1. Aliquot approximately 15 to 20 mL of PPC Optical Reference Solution (ORSN) into a dark glass or plastic dispenser bottle. (Amount may vary depending upon type of bottle and priming technique.)

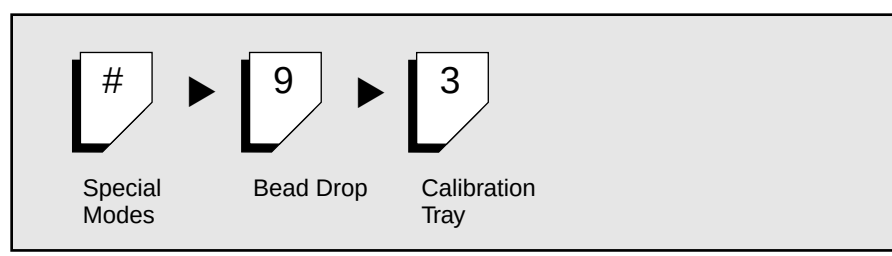
   CAUTION: Do not perform Calibration while batches are in process. Calibration will delete all batches and data.

2. Install the dispenser on the dispenser bottle.

3. Manually prime the dispenser.

4. Dispense reagent blanking beads in the trays as follows:

   - **OFF:** If TPC™ Mode for Calibration is Off, dispense Reagent Blanking beads into the first thirty wells of a 60-well tray (wells A1 through F5). Proceed directly to Step 5.
   - **RECORD** or **VERIFY:** If TPC Mode for Calibration is Record or Verify, perform the Bead Drop Procedure for the calibration trays. Key in the following to perform the procedure:



   The component type will be set to BLANKS BEAD (BKBD).

   a. Scan a tray ID using the external bar code reader (or enter it with the keypad).

b. After a valid tray ID is entered, key or scan the lot number of the reagent blanking beads **from the bottle**. For manually entered information, verify that the number shown on the display matches the reagent blanking bead lot number, then press **<Enter>**.

NOTE: If you enter an invalid reagent blanking bead lot number, the display may request a deviation password before allowing you to proceed.

c. Press <#> to exit.

Dispense reagent blanking beads into the first thirty wells of a 60-well tray (wells A1-F5).

5. Press the **<Calibrate>** key.

6. Insert Calibration tray into the PPC. The screen displays:

   All Batches Will be Deleted (Y/N)

   NOTE: Once a Calibration is initiated, a passing Calibration must be completed before processing will be allowed.

7. Select **Yes**. Then:

   - **OFF:** If TPC™ Mode for Calibration is Off, place the bottle of PPC ORSN in Component Station Three. Proceed directly to Step 8.
   - **RECORD** or **VERIFY:** If TPC Mode for Calibration is Record or Verify:

     a. Scan or key your Tech ID.

     b. Scan or key the ORSN lot number.

     NOTE: If you enter an invalid ORSN lot number, PPC may request a deviation password before allowing you to continue.

     c. Install bottle containing the PPC ORSN at Component Station Three, and scan or key the Component Station.

8. The screen displays:

   Ready? (Y/N)

9. Select **Yes**. The PPC performs the calibration. Values from passing calibrations are stored for internal reference.

Select **No** to abort the calibration procedure and transport the tray to the exit.

Post-Calibration Procedures

Dispose of the remainder of the aliquoted ORSN. Do not return remainder of aliquot to original container. Dispose of the ORSN in accordance with local, state and federal regulations.

Clean and store the dispenser according to the dispenser package insert.

Results

The PPC will print the status of the calibration, the mean for each column and the standard deviation for each column, as shown in the example below.

```
****************************************
 TPC Mode: VERIFY

TPC INFORMATION:
================

TYPE  EXPIRATION       LOT#       DEV.
----  -----------   -----------   ----
BKBD  04/05/96      1234567890
ORSN  04/05/96      2345678901

PPC SERIAL NUMBER sssssss
PPC VERSION NUMBER x.xx
TECH ID: 123456

****************************************
          Calibration PASSED

  Date: 08/20/95          Time: 12:59:29
****************************************
      Col 5  Col 4  Col 3  Col 2  Col 1
Mean:-0.074 -0.084 -0.075 -0.077 -0.081
Std.  0.003  0.002  0.002  0.003  0.003
```

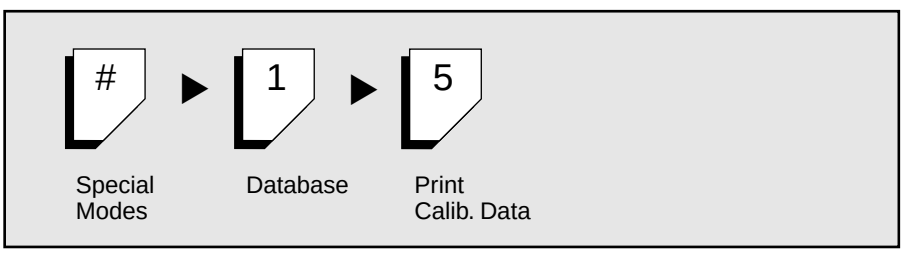
NOTE: If TPC™ Mode is Off, the TPC information section is not included on the printout.

If the calibration fails:

1. Check trays for scratches or marks.
2. Repeat Calibration.
3. If Calibration fails, replace the lamp.
4. Repeat Calibration.
   - If Calibration passes, perform the Linearity and Drift tests.
   - If Calibration fails, contact the Abbott Customer Support Center.

Printing Calibration Data

Key in the following to print calibration data:



The printer prints data from the last passing calibration.

Section 7

Operational Precautions and Limitations

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NOTES

Operational Precautions and Limitations

General

- All covers should be closed and in place when running assays.
- Proper maintenance of the PPC should be followed as described in *Section 9, Service and Maintenance.*
- Turn off power and unplug unit before working inside the instrument.
- Use of Diagnostics causes the System to reset. Data on trays in process (*i.e.,* which have been identified with a tray ID and have not been physically removed from the instrument) will be lost.

Emergency Stop

To stop PPC Operation in case of emergency:

- Turn off power on main instrument.
- Lift pressure relief valve ring on water canister.
- Unplug the PPC.

Dispense System

- Maintain and prime dispensers as described in dispenser package insert.
- Use only those dispensers itemized in the parts list. Refer to the parts list in *Section 9, Service and Maintenance*.

Reader

- Do not operate the PPC in direct sunlight or under high intensity lighting.
- Reader Verification causes the system to reset. Data on trays in process that have not been physically removed from the PPC will be lost.

External Bar Code Reader

- Do not use the external bar code reader in direct sunlight or under high intensity lighting.
- Avoid contact with the material being scanned.

Wash System

- Do not fill the water canister during a processing pass which requires a wash.
- Purge air from the wash system prior to use and after every wash changeout. Perform a Manual Wash Procedure (Type 01) on one 60-well tray.
- Release pressure on the water canister prior to opening.
- When connecting hoses, listen for a “snap” of the connections. This signifies a solid connection.

WARNING: Potential Biohazard. Both connectors on the waste line must be fully engaged to avoid splashing, leakage, or backup of waste through the system.

Trays

- Be sure that the upper edge of bar code label does not extend above frosted area.
- Do not force trays into load station. When properly inserted, the back end of a 60-well tray remains outside the load station and is pulled in as processing begins.
- Make sure tray bottoms and bar code labels are dry and clean before processing in the PPC.

Calibration

- A calibration must be performed before assays may be run. Refer to *Section 6, Calibration*.
- Do not perform calibration while batches are in process. Calibration will delete all batches and data.
- Once a calibration is initiated, a passing calibration must be completed before processing will be allowed.

Assay Timing

- An assay must be processed within the time limits indicated in the specific assay package insert.
- It is recommended that when processing a batch with multiple trays, the operator allow a time interval between the trays upon bead addition to avoid potential over/under incubation. For more information, refer to Assay Timing in *Section 5, Operating Procedures*.

Reagent Kit Blanking Beads

Make sure to use only COMMANDER Reagent Blanking Beads (pink) (List No. 6208-42) for reagent blanking and calibration. Do not use “Accessory Blanking Beads” (blue) (List No. 5577-30).

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Hazards

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Hazards 8-1

NOTES

Hazards

While operating the PPC, good operator safety practices should be followed. Take appropriate precautions to avoid electrical shock and other hazards. The operator should wear protective clothing, safety glasses and gloves.

There should be no smoking or eating near the instrument or where specimens or kit reagents are being handled.

WARNING: Potential Biohazard. Consider all waste from assays run on the PPC as potentially infectious. Wear gloves, lab coats, and follow other biosafety practices as specified in the OSHA Bloodborne Pathogens Regulation 29 CFR 1910.1030 or other equivalent biosafety procedures. Dispose of biohazardous waste in accordance with local, state and federal regulations.

When cleaning or decontaminating the PPC, follow biosafety practices as specified in the OSHA Bloodborne Pathogens Regulation 29 CFR 1910.1030 or other applicable biosafety requirements.

Disconnect system from power supply by turning off and removing power cord before cleaning, servicing, or performing maintenance.

Keep fingers and hands away from moving parts and out of the path of moving trays.

When opening covers make sure they are stable and securely open and will not fall closed.

When closing covers be careful not to pinch hands or fingers.

The PPC is a heavy instrument. Use proper precautions and lifting techniques while moving or transporting.

NOTES

Service and Maintenance

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Section Overview

Introduction

This section describes routine maintenance and servicing procedures that should be followed for use with the COMMANDER Parallel Processing Center.

General

If your laboratory is using the Abbott Preventive Maintenance Tracking System (PMTS®), verify that the PMTS/PPC template has been updated per the maintenance procedures outlined in this section.

Maintenance Schedule

	Daily (day of use)	Weekly	Monthly	Every 6 Months	Annually	As Required
Transport System Wipe down track.		●				After spills
Change urge belts				●		
Wash System *External Tubing and Connections* Check air, water and waste tubing for cracks or discoloration.	●					
Check for leaks at all connections along water and waste lines. Look for evidence of leaks inside instrument.	●					
Change air and water filters.						●
Change air, water or waste tubing.						●
Water Canisters and Waste Containers Check waste container for leaks and cracks.	●					
Check waste container cap for filter integrity. Look for cracks and loose fittings.	●					
Fill water canister and empty waste container and drip cup. Refer to *Section 5, Operating Procedures.*	●					
Prime wash system using the Manual Wash Procedure. Refer to instructions on page 9–15.	●					After filling water canister
Perform a Wash Volume Verification Procedure. Refer to instructions on page 9–15.		●				After changing tubing, filters, manifold, air line check valve, and wash gaskets
Empty water canister and allow to air dry.		●				
Clean water canister.						Quarterly
Replace wash manifold.					●	
Replace air line check valve.						●
Replace gaskets in wash manifold.					●	Or after 125,000 wash cycles (see page 9–14)

	Daily (day of use)	Weekly	Monthly	Every 6 Months	Annually	As Required
Dispense System Change dispenser backlights.						●
Clean and store Tri-Continent dispenser and outlet tube after each use. Refer to instructions on page 9–17.	●					
Check Tri-Continent dispensing tips and tip adapters. Refer to instructions on page 9–18.	●					Clean if dirty
Clean Tri-Continent dispensing tips and tip adapters. Refer to instructions on page 9–18.		●				
Replace Component Station Label						●
Optical Read System Clean the reader window in transport track.						When reader verification fails
Verify Linearity. Refer to instructions on page 9–24.			●			After lamp change
Verify Drift. Refer to instructions on page 9–27.			●			After lamp change
Verify Repeatability. Refer to instructions on page 9–28.						When reader problem is suspected
Change lamp.						Quarterly
Printer Replace paper.						●
Fuses Replace fuse.						●
Fan Filter Clean Fan Filter.				●		
Calibration Perform Calibration procedure. Refer to *Section 6, Calibration.*			●			After lamp change • After cleaning reader window (when reader verification test has failed)
External Bar Code Reader Replace reader.						●
Date and Time Perform clock setting procedure.			●			

Decontamination Procedure

WARNING: Potential Biohazard. The PPC should be decontaminated prior to service, relocation, shipment, or spills. Due to the sensitive nature of the assays, disinfectant solutions cannot be flushed through the wash head. However thorough flushing of the wash head with DISTILLED or DEIONIZED water will minimize the possibility of infectious organisms being present and thus minimize the potential for personal exposure. Wear gloves, lab covering, and protective eyeware when carrying out these procedures.

- Perform a Manual Wash Procedure (Type 01) on two 60-well trays using DISTILLED or DEIONIZED water.
- Wipe the surface of the instrument with a detergent to remove any soilings. Then wipe the unit down with a tuberculocidal disinfectant such as 10% chlorine bleach solution. Be sure not to flush the instrument or allow seals or tubing to come in contact with the chlorine bleach solution.
- Clean up spills of potentially infectious materials in accordance with established biosafety practices. A generally accepted procedure for cleaning such spills is to absorb the spill with toweling or other absorbent material, saturate a disposable towel with a 10% bleach solution, and disinfect the spill area. Let stand for 30 minutes and wipe dry. Use a disposable towel saturated with distilled/deionized water to rinse the spill area. Wipe the area dry.

NOTE: Do not increase the concentration of the chlorine solution in order to reduce decontamination time.

Transport System Maintenance

The transport track should be wiped down once a week with a soft cloth or swab dampened with isopropyl alcohol. Spills should be cleaned immediately.

WARNING: Turn off instrument and unplug power cord before opening instrument.

To access the track for cleaning:

1. Lift right hand side of top (Figure 9.1).
2. Lower the keypad face of the instrument (**A**) to loosen locking knobs inside (**B**) (Figure 9.2).

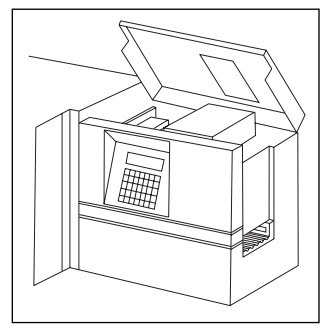


Figure 9.1

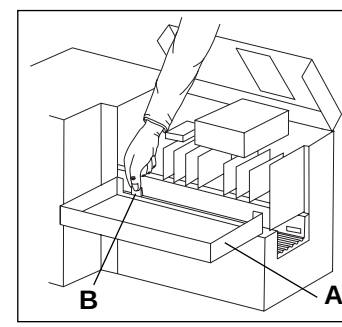


Figure 9.2

3. Move the display face back into place and tilt back right half of instrument (Figure 9.3).

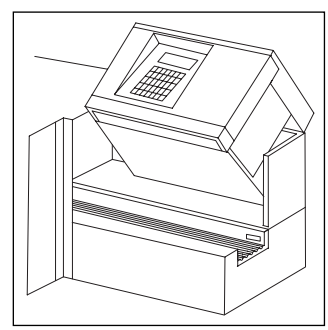


Figure 9.3

4. Wipe down all accessible areas of the track and urge belts.

CAUTION: Be careful not to bend or damage switches when wiping.

5. Return right side of instrument to normal position and tighten locking knobs behind the keypad when finished.

Load/Urge Belt Replacement

Use the following procedure to replace urge belts. This procedure is divided into three operations: removing the slide assembly, installing new urge belts, and replacing the slide assembly.

Removing the Slide Assembly

WARNING: Power off the PPC analyzer and unplug from the power source.

1. Lift right hand side of top (Figure 9.4).
2. Lower the keypad face of the instrument (**A**) to loosen locking knobs inside (**B**) (Figure 9.5).

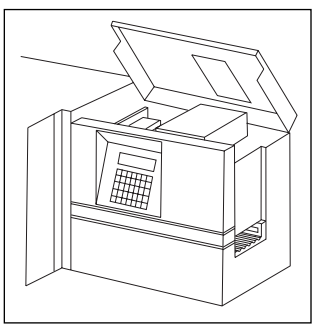


Figure 9.4

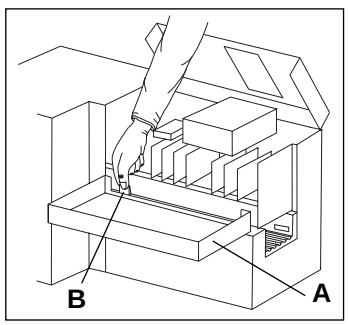


Figure 9.5

3. Move the display face back into place and tilt back right half of instrument (Figure 9.6).

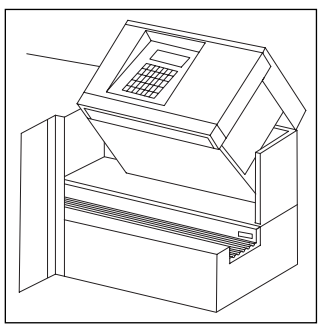


Figure 9.6

4. Remove the four mounting screws that attach the load urge belt slide assembly (Figure 9.7).

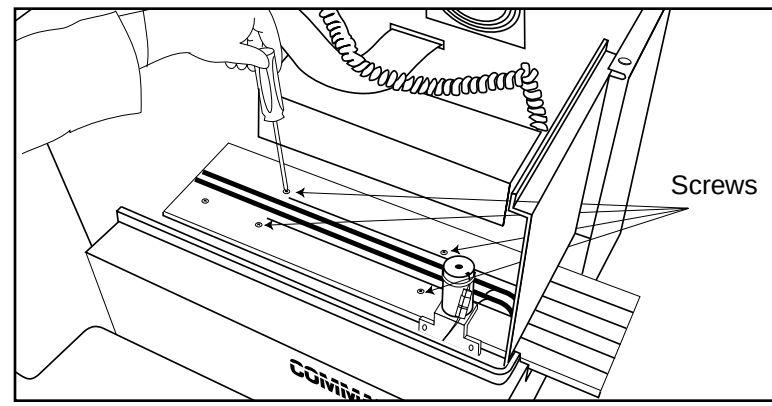


Figure 9.7

CAUTION: Be careful when performing the following step (5). Damage to the web switch sensor wire will require replacement by an Abbott Field Service Representative.

5. Grip one or both urge belts with your left hand and gently lift the right end of the slide assembly. Stop when you can see the web switch sensor wires at the left end of the slide assembly.

6. Using your right hand, carefully grasp the two sensor wires and free them from the restraining clip. This clip is affixed to the underside of the load module. Though out of view, the clip is easy to locate (Figure 9.8).

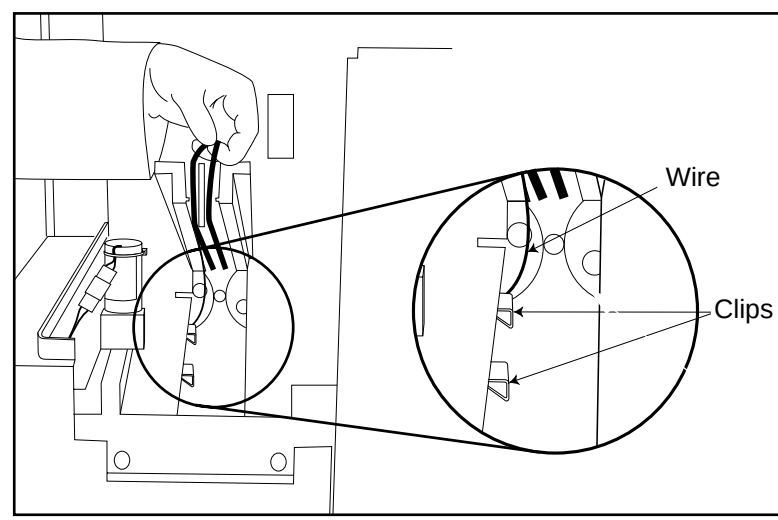


Figure 9.8

7. Place the slide assembly gently on an adjacent surface. Using both hands, disconnect the sensor connector.

Installing New Urge Belts

1. Roll the belts off the pulleys and remove them from the slide assembly (Figure 9.9).
2. Place the belt on the small pulley first.
3. Then roll the belt into position on the larger pulley.
4. Repeat Steps 2 and 3 to install the second belt.

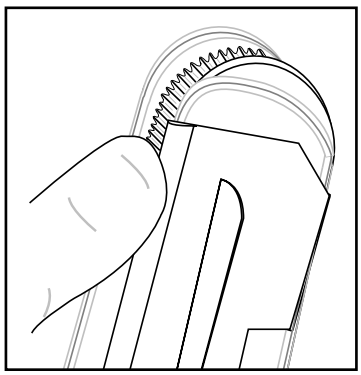


Figure 9.9

CAUTION: Make sure belts are seated in pulley grooves. Rotate by hand and visually verify proper seating.

Replacing the Slide Assembly

1. Gently position the slide assembly near its mounting position as in Step 7 of *Removing the Slide Assembly* above.
2. Use both hands to reconnect the sensor connector (Figure 9.10).

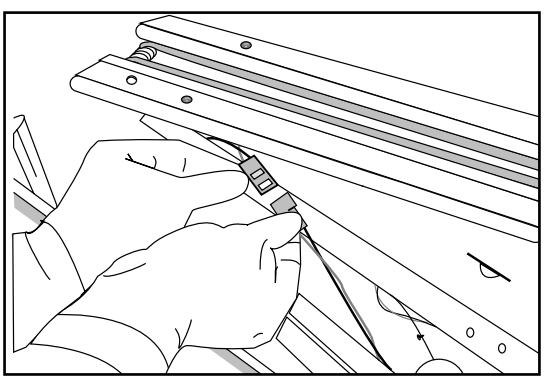


Figure 9.10

3. Replace the slide assembly first into the left side while keeping the right side elevated.
4. Place the sensor wires into the restraining clip as originally located in Step 6 of *Removing the Slide Assembly* above.
5. Grip the slide assembly by the urge belts and gently lower the right end of the slide assembly into position.

6. Locate and fasten the four mounting screws.
7. Close the right side of the analyzer and tighten the locking knobs behind the keypad.
8. Reconnect the power cord and power on the analyzer.
9. Perform a Manual Wash Procedure (Type 01) on a 60-well tray.
10. Verify that trays move through the PPC as expected.

Wash System Maintenance

Tubing and Connections

Check the tubing and its connecting ends daily (each day of use) for leaks, cracks and discoloration.

Replace damaged or deteriorated external tubing with replacement parts which may be ordered through Abbott Customer Service. See the parts list in this section for List Numbers.

To replace external tubing:

1. Turn off the power switch.
2. Lift the metal pressure relief ring to release all air pressure in the water canister.
3. Disconnect and remove tubing.
4. Connect replacement tubing.
5. Turn on the power switch.
6. Perform a Manual Wash Procedure (Type 01) on a 60-well tray.
7. Perform the Wash Volume Verification Procedure.

Filter Change

Change filters when Wash Volume Verification fails (below 11 mL) and no other restrictions or causes for failure are found.

To change filters:

1. Turn off the power switch.
2. Lift the metal pressure relief ring to release all air pressure in the water canister.
3. Cut the tubing close at both ends of the filter and discard it. (Some water spillage is unavoidable.)
4. Insert the new filter in the cut ends of the tubing. Use ties supplied to clamp the connections.

   NOTE: The arrow markings on the filter must point in the direction of flow toward the PPC.
5. Turn on the power switch.
6. Perform a Manual Wash Procedure (Type 01) on a 60-well tray.
7. Perform the Wash Volume Verification Procedure.

Water Canister and Waste Container

- Check the water canister and waste container daily (each day of use) for leaks and replace if necessary.
- Daily (each day of use) and each time the waste container is emptied, check the waste container cap for filter integrity, cracks, and loose fittings. Replace the waste cap if necessary.

  NOTE: The waste cap filter must remain dry, to ensure proper ventilation. If the waste container cap becomes wet, replace it to prevent filter blockage due to crystallization.
- Daily (each day of use) and as needed while processing, empty the waste container and the drip cup and add DISTILLED/DEIONIZED water to the water canister. Refer to *Section 5, Operating Instructions* for information.

- Perform a Manual Wash Procedure (Type 01) on a 60-well tray to purge air from the wash system daily, and after filling the water canister and before proceeding with normal operations or volume verification. Refer to instructions elsewhere in this section.
- Perform a Wash Volume Verification Procedure weekly as directed elsewhere in this section. Completely empty the water canister weekly and allow it to air dry for a minimum of twelve hours.

NOTE: Do not allow water to flood the level sense connector when emptying the canister.

Water Canister Cleaning

Clean the water canister quarterly, or more frequently if needed, to prevent system performance problems caused by particulate matter in air and water lines and to minimize possible bacterial growth.

The following procedure should be used for cleaning the water canister.

CAUTION: Be sure not to flush the instrument or allow wash gaskets or tubing to come in contact with the cleaning solutions.

1. Heat 2 liters of DISTILLED/DEIONIZED water to 40°-50°C (104°-122°F).
2. Add approximately 30 grams (approximately 2 level tablespoons) of Terg-A-Zyme® powder to the heated DISTILLED/DEIONIZED water. Swirl or stir until all powder is dissolved.
3. Add Terg-A-Zyme solution to water canister.
4. Swirl detergent around interior of water canister for approximately 2 minutes. Then pour out.
5. Rinse water canister thoroughly with DISTILLED/DEIONIZED water. Fill and pour out 5 times.
6. Fill water canister with DISTILLED/DEIONIZED water, reconnect the PPC system and perform a Manual Wash Procedure (Type 01) on three 60-well trays. DO NOT attempt to clean water canister with other cleaners without Abbott approval.

Wash Manifold Replacement

Change the wash manifold annually:

1. Turn off instrument.
2. Lift the metal pressure relief ring to release air pressure in the water canister.
3. Lift left hand side of the PPC lid. Do not remove clear plastic interior cover.
4. Remove the two thumbscrews that hold the manifold in place (Figure 9.11).
5. Twist and pull to disconnect air line (**A**) (Figure 9.12).

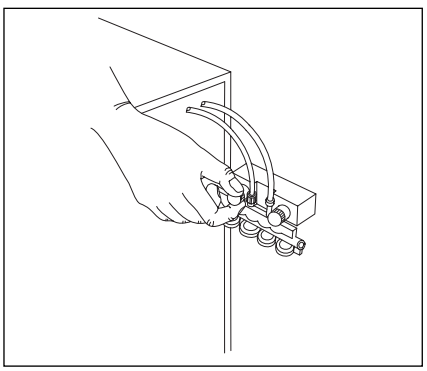


Figure 9.11

NOTE: Do not remove the air line check valve or the water line luer lock fitting from the tubing.

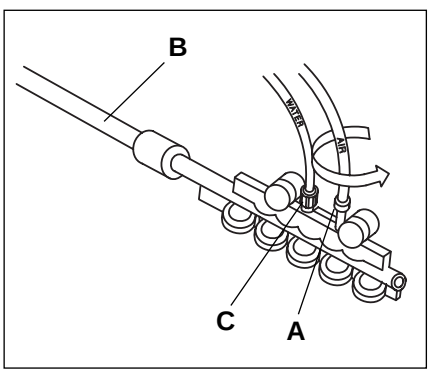


Figure 9.12

6. Disconnect (**B**) the waste hose from the waste outlet (Figure 9.12).

   Do not allow the waste hose to fall back into the instrument.
7. Turn the entire manifold to disconnect the water line (**C**) (Figure 9.12).
8. To install the new manifold, first reconnect the water line. Twist the manifold so that the luer lock fitting is tight. After tightening the luer lock fitting, the waste outlet on the manifold should be facing the waste hose.

9. Connect the waste outlet on the manifold to the waste hose on the instrument. There should be a distinctive “snap” as the quick disconnects lock together.

10. Reconnect the air line to the manifold ensuring that the air line check valve is securely inserted into the manifold.

11. Secure the manifold in place with the two thumbscrews.

12. Turn on the instrument.

13. Perform a Manual Wash Procedure (Type 01) on a 60-well tray.

14. Perform the Wash Volume Verification Procedure. Refer to instructions elsewhere in this section.

Air Line Check Valve Replacement

The air line check valve (**A**) (Figure 9.12) may be replaced without removing wash manifold.

1. Turn off the instrument.

2. Lift the metal pressure relief ring to release air pressure in the water canister.

3. Twist and pull check valve to disconnect air line from wash manifold.

4. Cut air line tubing immediately above the end of the check valve inserted in the tubing (**A**) (Figure 9.13). If tubing is too short, call the Abbott Customer Support Center.

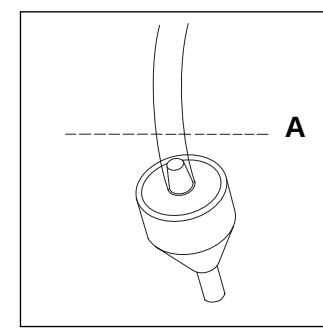


Figure 9.13

5. Insert narrower end (A) (Figure 9.14) of new check valve into tubing, pressing tubing over end of valve as far as possible.

6. Insert exposed end of check valve onto wash manifold to reconnect air line.

7. Turn on the instrument.

8. Perform a Manual Wash Procedure (Type 01) on a 60-well tray.

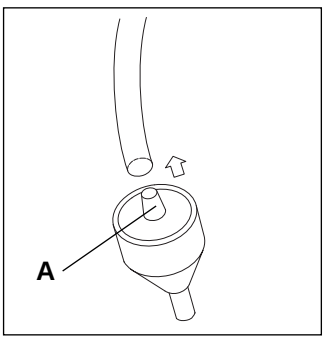


Figure 9.14

9. Perform the Wash Volume Verification Procedure. Refer to instructions elsewhere in this section.

Manifold Gaskets

Change the rubber manifold gaskets annually or after every 125,000 cycles.

One wash cycle = when the wash head goes up and down one time.

1. Disconnect manifold as described in Wash Manifold Replacement elsewhere in this section.

2. Carefully remove existing gaskets with non-metallic tweezers. (Figure 9.15).

CAUTION: Do not use metallic tweezers. They may damage the wash gasket or deposit metallic particles.

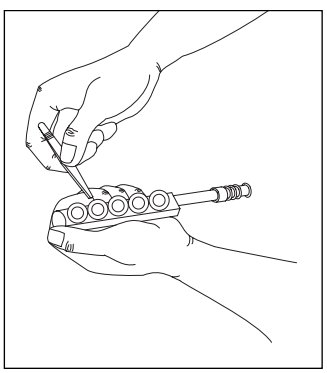


Figure 9.15

3. Install new gaskets such that the cone side faces into the wash head. Make sure the opening has cleared the metal cannula (to prevent accidentally damaging the cannula), then work the gasket into the manifold until it fits into the groove. Make sure the fitted gaskets are smooth and not distorted. Otherwise, they are not properly seated.

4. Reconnect the wash manifold as described in Wash Manifold Replacement elsewhere in this section.

5. Turn the power on.
6. Perform a Manual Wash Procedure (Type 01) on a 60-well tray.
7. Perform the Wash Volume Verification Procedure. Refer to instructions elsewhere in this section.

Manual Wash Procedure

The Manual Wash Procedure (Type 01) is performed daily, as a means of priming the PPC, and as a step in many other maintenance procedures.

One or more 60-well trays are required for the procedure. Be sure the tray(s) used is not worn by over use, or water droplets may appear on the surface. For best results, use a new tray.

1. Press the **<Wash>** key.
2. Select Wash Type **01**.
3. Select **<Yes>** to wash all wells.
4. Insert the tray into the PPC.

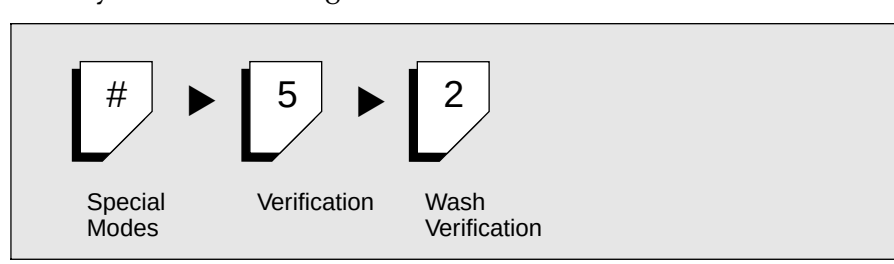
Wash Volume Verification Procedure

The Wash Volume Verification Procedure is performed to ensure that each of the wash channels is performing within expected ranges and that the wash system is neither restricted nor leaking.

Two rows of wells are washed in Verification — the first to make sure the system is purged of air, the second to allow the volume to be verified.

- Verify wash volume weekly.
- Use the wash volume verification tray (Figure 9.16).

Key in the following:



Display asks the operator to insert wash tray.

Water level for all wells should be between the two lines marked on the wash volume verification tray.

Water level falling outside of the lines marked indicates problem with wash system. Consult *Section 10, Troubleshooting and Diagnostics*.

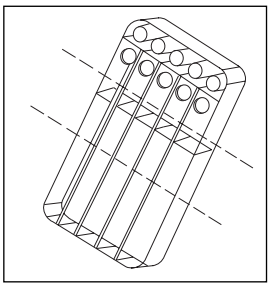


Figure 9.16

Dispense System Maintenance

Dispenser Backlights

Change burned out component station backlights. Wear safety glasses when changing the backlights.

1. Turn off power.
2. Flex front bulb window out of position (Figure 9.17).

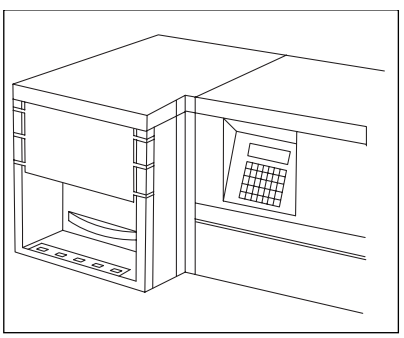


Figure 9.17

3. Use the fuse puller (Figure 9.18) included in the parts kit to grasp the bulb.

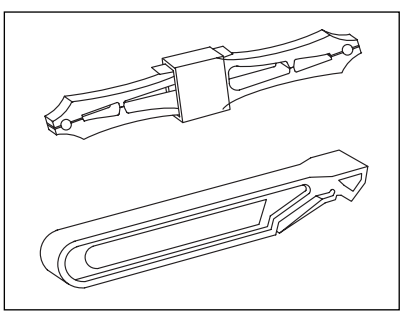


Figure 9.18

4. Pull bulb out of its position and twist to remove through opening (Figure 9.19).
5. Use fuse puller to push new bulb into position.
6. Replace front bulb window.
7. Turn power on.

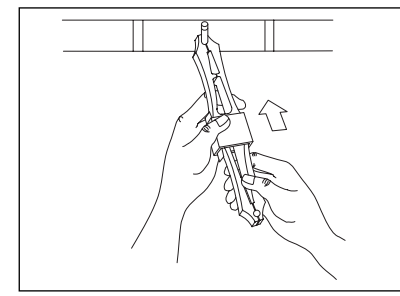


Figure 9.19

8. Perform the Dispense Bottle Select diagnostic and ensure that the dispenser backlights are lit. For more information, refer to *Section 10, Troubleshooting and Diagnostics*.

Tri-Continent STAT MATIC I® Dispenser Maintenance

Satisfactory performance of Tri-Continent STAT MATIC Dispensers requires a strict but simple cleaning practice. When using with a PPC, the following maintenance procedures are recommended to optimize performance. For complete operation and maintenance procedures, refer to the package insert that accompanied the dispenser.

Dispenser and Outlet Tube Cleaning and Storage

Clean and store dispenser and outlet tube immediately after each use. Dedicate a container to dispenser for this purpose.

1. Remove dispenser from reagent bottle.
2. Fill cleaning and storage container with clean deionized or distilled water.
3. Insert outlet tube tip into dispenser recirculation port. Recirculate sufficient water from container through port to eliminate residual reagent from priming of dispenser. Remove tube tip from port.
4. Change water in container.
5. Dispense water from container until dispenser and outlet tube are flushed thoroughly. Dispense — do not recirculate — water.
6. With dispenser for reagent other than OPD, store dispenser so that internal components are kept wet.

   With Dispenser for OPD, perform additional Steps 7 through 10.

7. From a separate container, dispense 1 Normal H_2SO_4 or HCl acid solution until OPD dispenser and outlet tube are flushed thoroughly.
8. Change water in cleaning and storage container.
9. Dispense water from container until OPD dispenser and outlet tube are flushed thoroughly.
10. Store OPD dispenser so that internal components are kept wet.

Outlet Tube Dispensing Tip and Tip Adapter Cleaning

Check condition of outlet tube dispensing tip and tip adapter daily and clean them if they appear dirty. At a minimum, clean tip and tip adapter at end of each week.

1. Remove outlet tube from dispenser.
2. Pull and twist tip adapter to separate front and back halves of adapter (Figure 9.20).

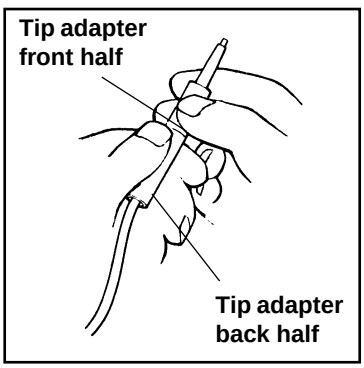


Figure 9.20

3. Slide dispensing tip from tip adapter (Figure 9.21).
4. **Thoroughly wash outside of tip and inside of tip adapter with 1 Normal H_2SO_4 or HCl acid solution.**
5. Rinse tip and tip adapter with distilled or deionized water.
6. Insert dispensing tip into back half of tip adapter. Slide front half of adapter over tip. Press and twist adapter halves together to completely close adapter.

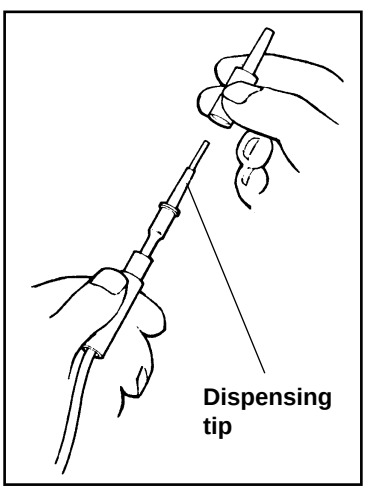


Figure 9.21

7. Attach outlet tube to dispenser.

Optical Read System

Reader Window

The reader window may be cleaned when necessary.

1. Turn power off and disconnect the power cord.
2. Lift left side of the PPC lid.
3. Remove exit port as described in the lamp change procedure. Refer to instructions elsewhere in this section.
4. Use a swab or lint free soft cloth and isopropyl alcohol and reach hand in through the exit port to clean the window (**A**) (Figure 9.22).

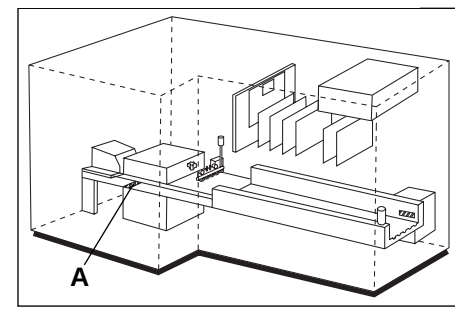


Figure 9.22

5. Replace the exit port as described in the Lamp Change procedure.
6. Reconnect the power cord and turn the power on.
7. Perform calibration. Refer to *Section 6, Calibration.*

Lamp

Change the lamp quarterly or more frequently if needed. The need for lamp change may be indicated either by an error code or failed verification tests. Steps 1 through 4 below are common for both lamp mounting configurations.

NOTE: There are two lamp mounting configurations. Follow the procedure specific to your instrument configuration.

To change the lamp:

1. Turn off power and disconnect power cord.
2. Open left side of the PPC lid and remove clear plastic interior cover (Figure 9.23).

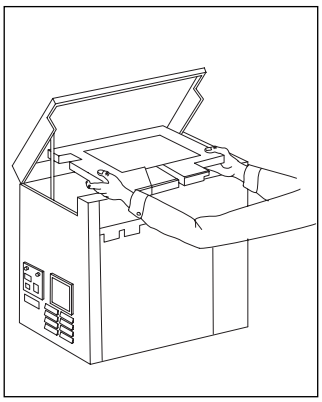


Figure 9.23

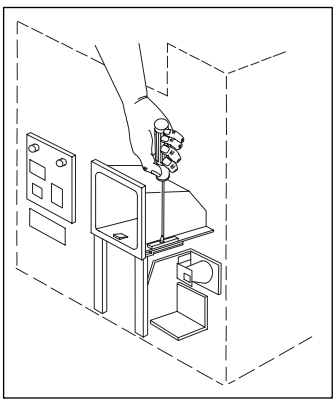


Figure 9.24

3. Use 9/64" Allen head screwdriver included in parts kit to reach inside and loosen the screw on each side of the exit port one-half turn (Figure 9.24).
4. Slide the exit port out of the PPC, being careful not to damage the exit switch (Figure 9.25).

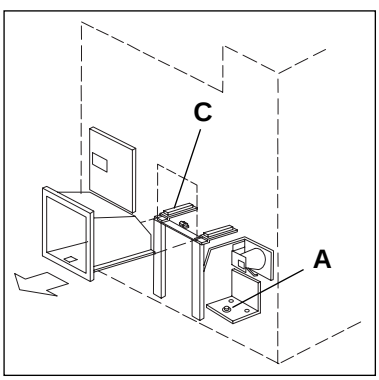


Figure 9.25

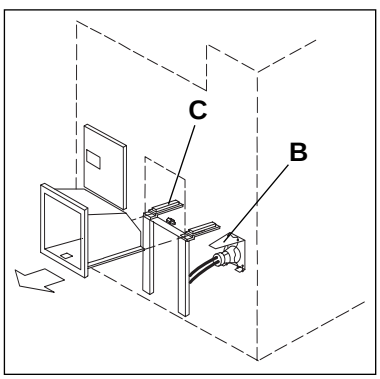


Figure 9.26

Follow Steps 5 through 11 if the instrument has the base plate mounted lamp bracket (**A**) as shown in Figure 9.25. Follow Steps 12 through 18 if the lamp is mounted on the transport support bracket (**B**) as shown in Figure 9.26.

WARNING: Lamp may be hot.

5. Reach in through exit hole (**C**) (being careful not to damage exit switch). Lift the lamp bracket off its two seating pins while pushing on the bottom to spring the bracket forward off its mount (Figure 9.27).

6. Reaching from the top opening, lift the lamp fitting for better access.

7. Pull the lamp release lever (**D**) down and slide lamp (**E**) out of fitting (Figure 9.28).

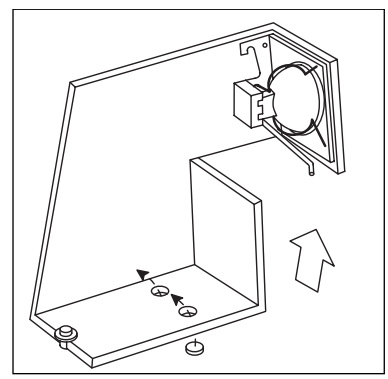


Figure 9.27

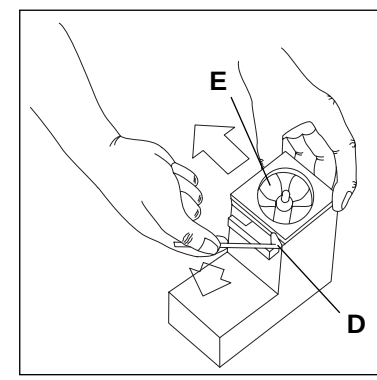


Figure 9.28

8. Move the lamp release lever back into position.

9. Slide the new lamp in under the two guiding wires (**F**), fitting the two connecting pins into their slots (Figure 9.29). Make sure lamp face opening is lined up with bracket opening (Figure 9.30). Use only Abbott-supplied lamps. Substitutes may not produce optimal results. For more information, refer to the *Parts List* elsewhere in this section.

CAUTION: Do not touch glass lens on new lamp. Touching lens may shorten lamp life.

10. Push the lamp fitting back under its springloaded bracket, seating it on the two seating pins.

11. Replace exit port. Ensure that the exit switch is in position, in the slot in the base of the exit port and is free to move. Proceed to Step 18.

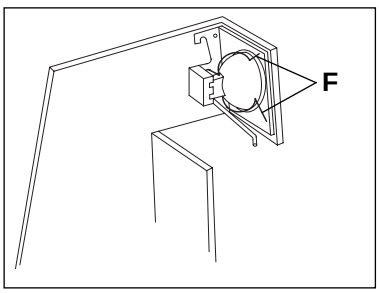


Figure 9.29

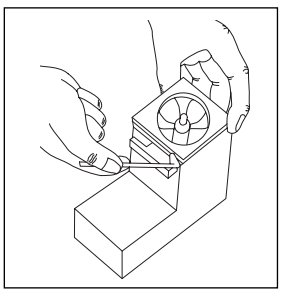


Figure 9.30

12. Using care not to damage the exit switch, reach through the exit hole to remove the lamp (**G**). Pull the lamp, then slip it down and free from the guiding wires (**H**) (Figure 9.31).

13. Disconnect the plug (**I**) on the lamp cable assembly (Figure 9.32).

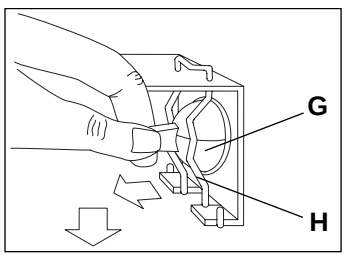


Figure 9.31

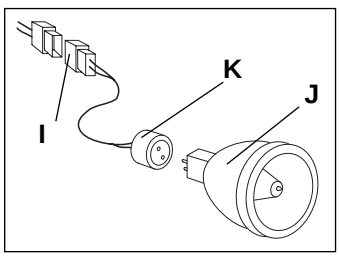


Figure 9.32

14. Replace the lamp (**J**), plugging it into the socket (**K**) (Figure 9.32). Do not touch the glass lens on the new lamp.

15. Reconnect the plug (**I**) on the lamp cable assembly (Figure 9.32).

16. Reinsert the lamp in the guiding wires by sliding the lamp up from below. Ensure that the lamp is fully seated in its support bracket.

17. Replace the exit port. Ensure that the exit switch is in position in the slot in the base of the exit port and is free to move.

18. Replace plastic interior cover, close PPC lid and power up.

19. After changing the lamp, perform Reader Verification (Linearity and Drift) and Calibration prior to running assays.

Reader Verification

Linearity, Drift and Repeatability Tests are run periodically to verify spectrophotometer accuracy.

- The **Linearity Test** determines the difference between the measured absorbance values of the Standards Tray and the predicted absorbance value calculated by the instrument.
- The **Reader Drift Test** verifies that the spectrophotometer takes consistent readings over time.
- The **Repeatability Test** verifies that the read system is performing consistently.

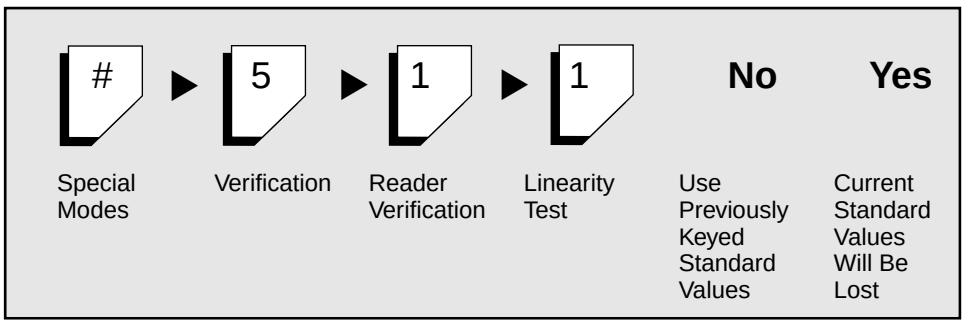
CAUTION: Reader verification causes the system to reset. Data on trays in process (*i.e.,* which have been identified with a tray ID and have not been physically removed from the instrument) will be lost.

All three tests use the Standards Tray. Before using the Standards Tray for the first time or after a software download, the factory specified concentrations for each well must be entered into the PPC. The concentrations are listed in the storage case for the Standards Tray. The operator will have the opportunity to enter/re-enter this information, when necessary, at the beginning of the linearity test.

The Standards Tray serial number should be used as the Standards Tray ID.

NOTE: To maintain the integrity of the Standards Tray, it should be stored in the closed storage case provided. When not is use, the tray should be promptly returned to the closed storage case.

Entering New Standards Tray Concentration Values



Display asks the operator to insert tray and then to enter the Standards Tray concentration values as listed in the tray storage case.

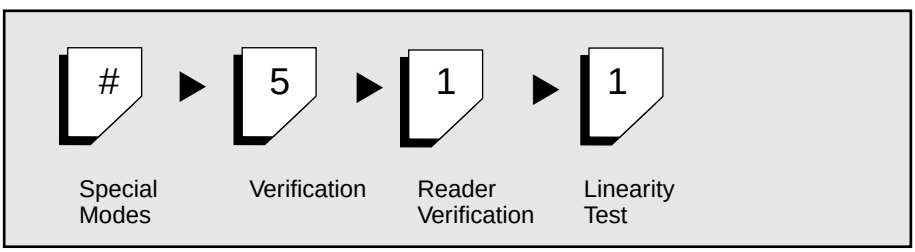
Enter the concentration value for the tray location requested on the display.

When the last value is entered (Well D5) the tray will be gated and the linearity test will be performed.

NOTE: Pressing the <#> key before the test is finished will abort the test, returning the display to the Reader Verification menu.

Linearity Test

Perform the Linearity Test monthly and after lamp change. The test takes approximately 5 minutes.



Display prompts to insert Standards Tray. The Linearity Test screen will remain on display until printout is complete.

```
              SAMPLE PRINTOUT
**************************************
Date: mm/dd/yy   hh:mm:ss   SN: sssssss

           Reader Column # 1
--------------------------------------
STD #       0       1       2       3
Conc.    0.00    21.85   44.70   104.6
Loc.     A1      B1      C1      D1
Actual   0.000   0.437   0.893   2.092
Predic   0.000   0.436   0.893   2.092
Diff.    0.000   0.001   0.000   0.000
% Diff.          0.2%    0.0%    0.0%
        Column # 1      PASSED
--------------------------------------

[READER COLUMN #2 THROUGH #5 FOLLOW]
```

Key:

STD # = Standard Number.
Conc. = Concentration of the Standard.
Loc. = Well Location
Actual = Measured Absorbance
Predic = Predicted Absorbance from linear regression Conc. vs. Actual.
Diff = Actual Absorbance – Predicted Absorbance

$$\textbf{\% Diff} = \frac{\text{DIFFERENCE}}{\text{PREDICTED ABSORBANCE}} \times 100$$

NOTE: Pressing the <#> key before the test is finished will abort the test, returning the display to the Reader Verification menu.

Linearity verification calculates the difference between actual and predicted absorbance values as a percent difference.

$$\frac{\text{DIFFERENCE}}{\text{PREDICTED ABSORBANCE}} \times 100 = \% \text{ Diff}$$

To pass Linearity, the percent difference for STD #0, 1 and 2 must be less than or equal to 2% or .005A, whichever is greater, and the percent difference for STD #3 (with a linear regression of STD #0, 1, 2 and 3) must be less than or equal to 3.5% full scale.

NOTE: If the %Diff is 10.0 or greater, the percent sign will not appear on the printout.

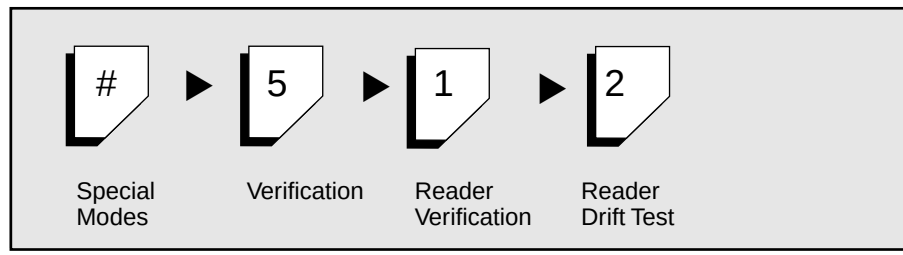
If Linearity verification fails:

1. Make sure that the concentration values that appear on the printout match the actual values of the Standards Tray. If values do not match, enter correct values and re-run linearity.
2. Clean the optical reader window and transport surface.
3. Clean the bottom surface of Standards Tray with a mild detergent solution and soft cloth.
4. Repeat the Linearity Test.
5. If test passes, perform Calibration. (Refer to *Section 6, Calibration.*)
6. If test fails again, change the lamp.
7. Repeat the Linearity Test.
8. If the test passes, perform Drift Test and Calibration. (Refer to *Section 6, Calibration.*)
9. If test fails again, replace Standards Tray and repeat the Linearity Test.
   - If test fails, call Abbott Customer Support Center.
   - If test passes, perform the Drift Test and Calibration. (Refer to *Section 6, Calibration.*)

NOTE: Upon completion of test, promptly return the Standards Tray to its closed storage case.

Reader Drift Test

Perform the Reader Drift Test monthly and after lamp change. The test takes 1 hour.



Display prompts to insert Standards Tray and informs of current start and end times for the test. Drift Test screen should remain displayed until test is complete.

```
                SAMPLE PRINTOUT
*************************************
Date: mm/dd/yy   hh:mm:ss   SN: sssssss

          Drift Test in Progress
-------------------------------------
A1          A2          A3          A4          A5
0.102     0.101     0.102     0.102     0.102
0.102     0.101     0.102     0.102     0.101
0.102     0.101     0.101     0.101     0.101
0.102     0.101     0.101     0.101     0.101
0.101     0.101     0.101     0.101     0.101
0.101     0.101     0.101     0.101     0.101
0.101     0.101     0.101     0.102     0.101

Drift for column A1 = 0.001 TEST PASSED
Drift for column A2 = 0.000 TEST PASSED
Drift for column A3 = 0.001 TEST PASSED
Drift for column A4 = 0.001 TEST PASSED
Drift for column A5 = 0.001 TEST PASSED
Drift Test Completed Time: 11:53:29
```

NOTE: Pressing the **<#>** key before the test is finished will abort the test, returning the display to the Reader Verification menu.

After the final reading has been completed, the PPC calculates the difference between the absorbance of each group of readings and compares each group to specifications.

The difference for each group should be less than or equal to 0.005 to pass the Drift Test.

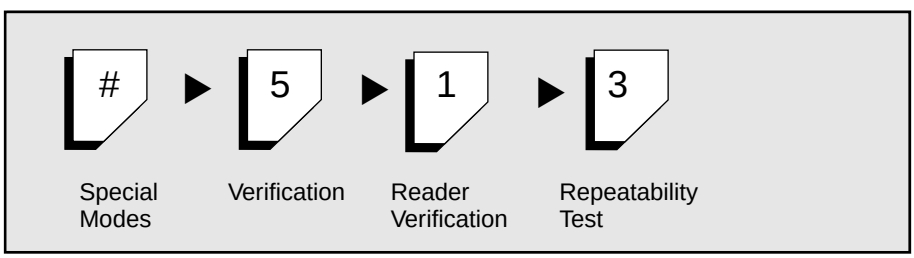
If the Reader Drift Test fails:

1. Clean the optical reader window and transport surface. (Refer to *Section 9, Service and Maintenance*.)
2. Clean the bottom surface of Standards Tray with a mild detergent solution and soft cloth.
3. Repeat the Reader Drift Test.
4. If the test passes, perform Calibration. (Refer to *Section 6, Calibration*.)
5. If test fails again, change the lamp (refer to *Section 9, Service and Maintenance*) and repeat the Drift Test.
   - If the test passes, run the Linearity Test and perform Calibration. (Refer to *Section 6, Calibration*.)
   - If the test fails, call Abbott Customer Support Center.

NOTE: Upon completion of test, promptly return the Standards Tray to its closed storage case.

Repeatability Test

Perform the Repeatability Test when a reader problem is suspected. Use the Standards Tray. The test takes approximately 15 minutes.



Display prompts to insert tray 20 times.

The following printout is generated as the test progresses:

```
                SAMPLE PRINTOUT
*************************************
 Date: mm/dd/yy   hh:mm:ss   SN: sssssss

   Repeatability Test In Progress
-------------------------------------
    A1     A2      A3     A4     A5
 1  0.069  0.058  0.059  0.079  0.062
 2  0.070  0.058  0.059  0.080  0.062
 3  0.070  0.058  0.059  0.080  0.063
 4  0.070  0.058  0.059  0.080  0.063
 5  0.070  0.059  0.059  0.080  0.063
 6  0.070  0.059  0.059  0.080  0.063
 7  0.070  0.059  0.059  0.080  0.063
 8  0.068  0.058  0.058  0.079  0.063
 9  0.070  0.059  0.059  0.080  0.063
10  0.070  0.059  0.059  0.080  0.063
11  0.070  0.060  0.059  0.080  0.063
12  0.070  0.060  0.060  0.081  0.063
13  0.070  0.060  0.059  0.081  0.065
14  0.070  0.060  0.060  0.081  0.063
15  0.071  0.061  0.060  0.081  0.064
16  0.071  0.061  0.060  0.081  0.064
17  0.071  0.061  0.060  0.081  0.065
18  0.071  0.061  0.060  0.081  0.064
19  0.071  0.061  0.060  0.081  0.064
20  0.071  0.061  0.060  0.081  0.064

    Mean   Std.Dev.  %CV   PASS/FAIL
A1 = 0.070  0.001   1.0%   PASSED
A2 = 0.059  0.001   1.9%   PASSED
A3 = 0.059  0.001   1.0%   PASSED
A4 = 0.080  0.001   0.9%   PASSED
A5 = 0.063  0.001   1.4%   PASSED
-------------------------------------
*************************************
```

NOTE: The Std. Dev. for the repeatability test is printed as follows:

<9.9 = x.xxxxxx
>9.9 = xx.xxxxx
>99.9 = xxx.xxxx
>999.9 = xxxx.xxx

The standard deviation of each well reading must be less than or equal to 0.0025 or the percent coefficient of variation must be less than or equal to 0.5%. If any of the absorbances are printed as "*ERROR", the mean and standard deviation for that column will print as "*ERROR". The %CV will print as "**.*" and the column will "FAIL". If a Repeatability Test fails:

1. Clean the optical reader window and transport surface.
2. Clean the bottom surface of the Standards Tray with a mild detergent solution and soft cloth.
3. Repeat the Repeatability Test.
4. If the test passes, perform Calibration. (Refer to *Section 6, Calibration*).
5. If test fails, replace lamp.
6. Repeat Repeatability Test.
7. If the test passes, perform Linearity Test, Drift Test and Calibration. (Refer to *Section 6, Calibration*).
8. If test fails, replace Standards Tray.
9. Repeat Repeatability Test.
   - If test fails, call Abbott Customer Support Center.
   - If test passes, perform Linearity Test, Drift Test and Calibration. (Refer to *Section 6, Calibration*.)

NOTE: Upon completion of test, promptly return the Standards Tray to its closed storage case.

Calibration

Calibration, described in *Section 6, Calibration*, should be performed monthly, after lamp change, and after cleaning reader window.

Setting Date and Time

The PPC instrument's date and time clock is backed up by battery and needs only be set at installation, monthly thereafter, and at seasonal time changes.

Fuses

Fuse Replacement

Refer to the left side of the instrument to determine if a CE Mark label is present.

Instruments With CE Mark Label

If fuses need to be replaced, be sure to match fuse size to power setting. Fuses are as follows:

Supply Voltage	Fuse Type and Rating
100/120	F250V 10A, 5x20mm (Qty 2)
220/240	F250V 5A, 5x20mm (Qty 2)

1. Turn the PPC power off and disconnect power.
2. Using a flat blade screwdriver or equivalent, unlock the Fuse Drawer and pull straight out to remove from the Power Module. (Figure 9.33)

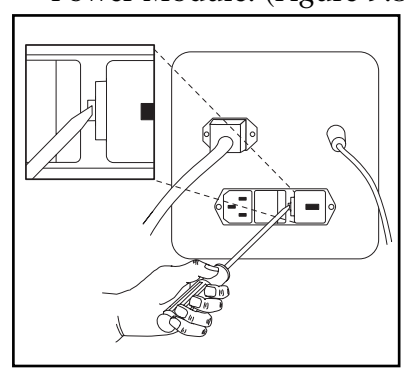


Figure 9.33

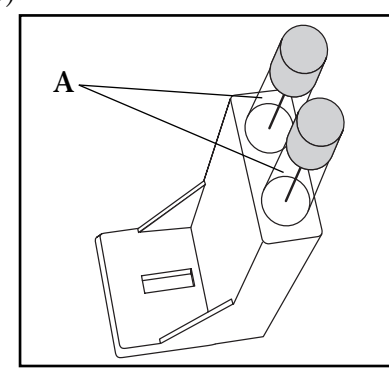


Figure 9.34

3. Remove fuse (A) and note amperage. (Figure 9.34)
4. Replace with a new fuse of the same type and equal amperage.
5. Reinsert the Fuse Drawer.
6. Push fuse cover back into place firmly and turn clockwise to secure.
7. Reconnect the AC power and turn on the PPC.
8. After initialization, verify that the PPC display reads “Insert Tray -->”.

Instruments Without CE Mark Label

If fuses need to be replaced, be sure to match fuse size to power setting. Fuses are as follows:

Supply Voltage	Fuse
90-132V	One 10-Amp Fuse in position F1
198-264V	Two 5-Amp Fuses: one in position F1, one in position F2

1. Turn the PPC power off and disconnect power.
2. Turn fuse cover (**A**) counter clockwise approximately 1/4 turn (Figure 9.35).
3. Pull fuse cover and fuse from socket.
4. Remove fuse and note amperage.
5. Replace with a new fuse of the same type and equal amperage.

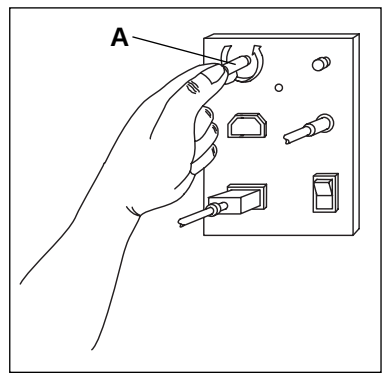


Figure 9.35

6. Push fuse cover back into place firmly and turn clockwise to secure.
7. Reconnect the AC power and turn on the PPC.
8. After initialization, verify that the PPC display reads “Insert Tray -->”.

Fan/Fan Filter

This procedure should be performed every six months or as required.

1. Disconnect the AC power to the PPC.
2. Lift the right side of the PPC (Figure 9.36).

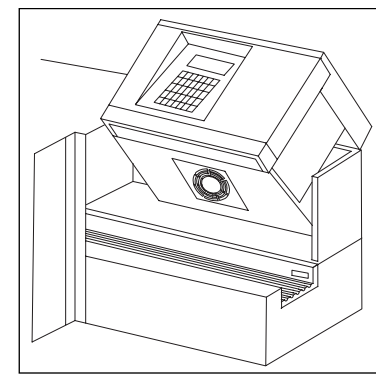


Figure 9.36

NOTE: All PPC instruments do not have fan filters under the card cage. If you see the blades of the fan through the fan guard (with the power turned off), your PPC is not equipped with a fan filter.

For PPC instruments that have a fan filter

1. Unsnap the filter and filter holder from the fan.
2. Rinse/clean the filter and filter holder under running tap water.
3. Blot dry the filter and filter holder.
4. Re-install the filter and filter holder.
5. After the filter has been cleaned, lower the right side of the PPC and connect the AC power.

For PPC instruments that do not have a fan filter

1. With a damp cloth, wipe the fan housing and fan guard to remove the accumulated dust.
2. After fan housing and fan guard have been cleaned, lower right side of PPC and connect AC power.

Printer

Printer Replacement

1. Turn off the PPC power.
2. Open right side of the PPC lid.
3. Lower the keypad face of the instrument.
4. Unscrew and remove the retaining bracket if in place.
5. Slide printer forward, out of position (Figure 9.37).
6. Slide new printer into place.
7. Replace the retaining bracket if necessary.
8. Return right side of instrument to normal position.

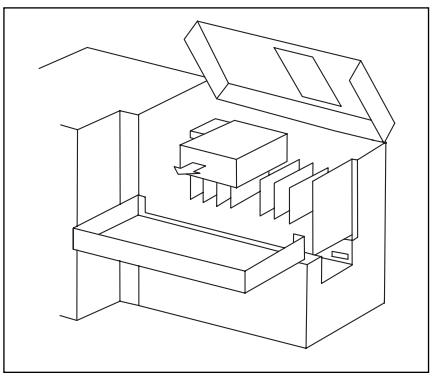


Figure 9.37

9. Turn on the PPC power.
10. Perform Printer Diagnostics. Refer to *Section 10, Troubleshooting and Diagnostics.*

Paper

Printer paper may be replaced as needed.

1. Press left side of paper roll holder (**A**) out to remove roll (Figure 9.38).
2. Move bail lever (**B**) towards front of instrument into load position (Figure 9.38).

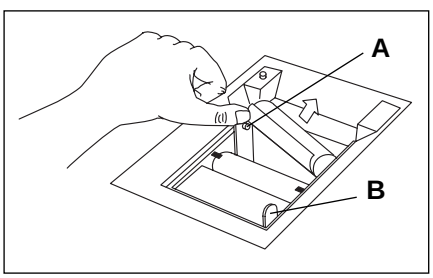


Figure 9.38

3. Pull any remaining paper out of paper feed.

4. Install new roll with paper feeding off the bottom.

NOTE: Only one side of the paper is heat sensitive. If it is put in wrong, it will not print.

Replace paper with the right side lid down. **Do not lift the lid to replace the paper.**

Allow an upper margin of paper before returning bail lever. If data is in queue for printing, printer will start upon return of the bail lever.

Some printers may not include guides. If the guides are present, it is important that the paper be fed under them.

5. Feed paper under guides (**C**), if present, and into slot (**D**) (Figure 9.39).

6. Return bail lever to original run position.

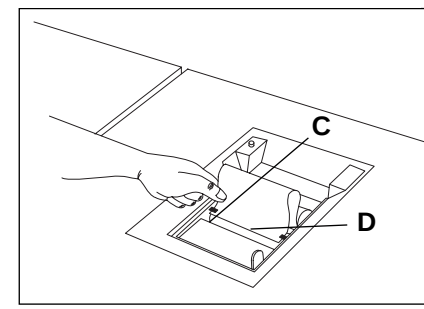


Figure 9.39

7. Press paper feed button (**E**) to feed paper (Figure 9.40).

8. Make sure new paper is held under knippers (**F**) (Figure 9.40).

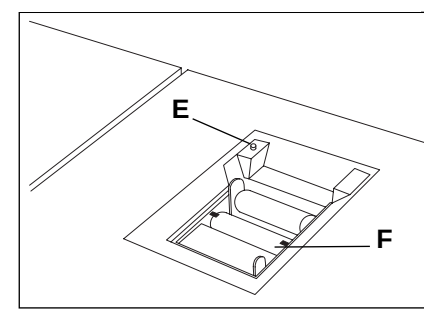


Figure 9.40

NOTE: Print-out information will not be lost due to the printer running out of paper or being taken off line. Printing will resume once printer paper is refilled and printer is put back on line.

External BCR Replacement

The External BCR may be replaced as needed.

1. Power off the PPC and disconnect the power cord.
2. Disconnect the external BCR from the round port.
3. Connect the replacement BCR. Feed the bar code reader cable through the clips and place the bar code reader in the holder.
4. Reconnect the PPC to the power supply and power on the PPC.
5. Perform the external BCR reading test. Refer to *Section 10, Troubleshooting and Diagnostics*.

Component Station Label Replacement

The component station label may be replaced as necessary.

1. Remove existing component station label.
2. Affix the component station label to the reagent shelf (flat surface) so that bar code 1 is below reagent dispenser 1, and bar code 5 is below reagent dispenser 5.

Parts

The following is a list of parts to be used with the ABBOTT COMMANDER Parallel Processing Center. All parts listed here may be ordered as spare parts.

Main Unit

Item	List No.
PPC with Power Cord (with CE Mark label)	6208-86
PPC Operations Manual	1A05-57
PPC Maintenance Log	6208-93
Commander Dispenser (50 µL)	6208-32
Commander Dispenser (100 µL)	6208-33
Commander Dispenser (150 µL)	6208-84
Commander Dispenser (175 µL)	6208-34
Commander Dispenser (200 µL)	6208-35
Commander Dispenser (300 µL)	6208-36
Tri-Continent OPD Diluent Dispenser 5 mL	7186-11
Outlet Tube Assembly	6208-31
Standards Tray	6208-52
Wash Volume Verification Tray	6258-20
Printer	6208-60
Printer Paper (six rolls)	6208-61
Pkg. Tray Bar Code Labels	6262-07

Item	List No.
User Replaceable Parts: Lamp Wash Manifold Urge Belts Pkg. of Dispenser Lights Bulb Puller Pkg. Spare 5-Amp Fuses Pkg. Spare 10-Amp Fuses 9/64" Allendriver Loop Back Connector Component Station Label Bar Code Reader and Holder Bar Code Reader Holder only	 6208-75 6208-58 6208-65 6208-70 6208-71 6208-40 6208-41 6208-74 6208-72 1A05-51 8A50-08 8A50-09
Pkg. Reagent Blanking Beads	6208-42
Multi-Bead Dispenser (for dispensing 20 beads at one time from a 500 bead bottle)	6155-01
Single Bead Dispenser	6155-20
PPC Optical Reference Solution	1B07-01
OPD Tray Cover (20-well)	6208-38
OPD Tray Cover (60-well)	6208-39
Abbott COMMANDER Parallel Processing Center Validation Record User's Guide	8A50-60
Abbott COMMANDER PPC Validation Record	8A50-61
Abbott COMMANDER PPC RS232 Output Specification	1A05-56

Wash and Waste Cart

Item	List No.
Wash Cart (without CE Mark label)	6208-11 for 100-115 Volt 6208-12 for 230 Volt (no longer available)
Wash Cart (with CE Mark label)	6208-87 for 100-115 Volt 6208-88 for 230 Volt
Wash Cart (refurbished, without CE Mark label)	6208-27 for 100-115 Volt (no longer available)
Wash Cart (refurbished, with CE Mark label)	6208-68 for 100-115 Volt
CDCM (COMMANDER Dual Compressor Module, without CE Mark label)	6208-45 for 100-115 Volt 6208-46 for 230 Volt (no longer available)
CDCM (COMMANDER Dual Compressor Module, with CE Mark label)	6208-67 for 100-115 Volt 6208-92 for 230 Volt (no longer available)
Filters (2)	6208-26
Manifold Gaskets	6208-57
Water Canister	6208-20
Waste Water Container	6208-21
Waste Cap	6208-22
Waste Spigot	6208-19
Water/Waste and Air Tubing	6208-23
Water Level Sense Cable	6208-24
Check Valve	6258-22

NOTES

COMMANDER Parallel Processing Center
Maintenance Log (Page 1 of 2)

Month_____ Year_____ Serial No._____

			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Daily (day of use)	Start-Up	Fill water canister																															
		Empty decontaminated waste.																															
		Empty PPC drip cup.																															
		Prime wash system. (Wash a 60-well tray.)																															
		Check air, water and waste hoses for cracks or discoloration.																															
		Check for leaks at all connections along water and waste lines. Look for evidence of leaks inside instrument.																															
		Check waste container for leaks and cracks.																															
		Check waste container cap for filter integrity. Look for cracks and loose fittings.																															
	Each Use	Clean and store Tri-Continent Dispensers and outlet tubes.																															
	Shut Down	Release air pressure on water canister.																															
		Check all Tri-Continent Outlet Tube Dispensing Tips.																															
Weekly		Empty water canister and allow to air dry.																															
		Wipe down track.																															
		Verify wash volume.																															
		Clean all Tri-Continent Outlet Tube Dispensing Tips.																															

NOTES

COMMANDER Parallel Processing Center
Maintenance Log (Page 2 of 2)

Month_____ Year_____ Serial No._____

		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Monthly	Verify linearity																															
	Verify drift																															
	Calibrate																															
	Perform clock setting procedure																															
Every 6 Months	Replace Urge Belt																															
	Clean Fan Filter																															
Annually	Replace wash manifold																															
	Replace gaskets in wash manifold (annually or after 125,000 wash cycles)																															
As Required	Change air and water filters																															
	Change air, water or waste tubing																															
	Clean water canister																															
	Replace air line check valve																															
	Change dispenser backlights																															
	Clean reader window in transport track																															
	Verify repeatability																															
	Change lamp																															
	Replace printer																															
	Replace fuse																															
	Replace component station label																															
	Replace external bar code reader																															

Reviewed by:_____ Date:_____

NOTES

Section 10

Troubleshooting and Diagnostics

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NOTES

Troubleshooting

Introduction

The Troubleshooting section provides a quick reference to observed problems, error messages and deviation codes that may appear on the PPC. It explains the probable cause of the problem and describes the actions that may be taken by the operator to correct the problems.

Alternate corrective measures are identified by letter and are listed in the order in which they should be tried. Multiple steps within any one corrective action are numbered.

In some cases, the error message or deviation code on the screen acts only to advise the operator either that controls or standards have not processed correctly or that he or she has attempted to perform a step incorrectly and will not be allowed to continue until the mistake is corrected. The comment “Advisory” appears in the corrective action column for these errors.

Some of the corrective actions described require the operator to turn the PPC off, wait 30 seconds and then turn the PPC back on to proceed with processing. Under these circumstances, the PPC may void rows being washed, dispensed into or read at the time the power is turned off, but will maintain all other processing data.

NOTE: Some error messages include an advisory “Press <ENTER> To Continue.” This should not be interpreted as the next action; it is the action required after the corrective action has been accomplished.

NOTE: Deviation codes apply primarily to operation in the TPC™ Verify Mode.

CAUTION: If power is cycled twice during a processing pass for a tray (the tray has entered the PPC but not yet exited), the tray may be voided. If the voided tray is a blanks, controls or standards tray, the batch will be VOIDED.

CAUTION: Some of the following corrective actions may require opening the PPC. To assure accuracy in reading, all covers should be closed and in place when running assays.

CAUTION: If the PPC is operating in conjunction with an Abbott DMS™ and power to the PPC is interrupted during a PPC read process, data to the DMS will be lost. Use the following procedure immediately after power recovery to restore data to the DMS:

- Complete the read process on the PPC.
- Abort the currently active batch on the DMS.
- Reactivate the batch on the DMS.
- Retransmit the batch on the PPC.

Technical Customer Support

Technical customer support is provided to answer any questions you may have about the system, and to help with any serious or recurring error messages.

United States—Call the Customer Support Center (CSC) at 1-800-323-9100.

All other countries—Contact your Abbott Representative.

Observed Problems

DISPLAY

Improper or no display.

Probable Cause(s)	Corrective Action(s)
Disconnected power cord.	Connect power cord.
Power switch "OFF."	Turn power switch "ON."
Blown fuse.	Replace fuse. Refer to *Section 9, Service and Maintenance*.
Improper voltage setting.	Set voltage according to local power requirements.
Electronic problems.	Call Abbott Customer Support Center (CSC).

Display reads: DATA IS INVALID RE-ENTER

Probable Cause(s)	Corrective Action(s)
An invalid keyboard entry was made.	Check for valid entry and re-enter.

Display reads: TRAY # XXXXXX HAS BEEN REMOVED

Probable Cause(s)	Corrective Action(s)
A tray already identified by the PPC was removed from the entrance.	Advisory message no action required.

DISPENSE

Reagent dispense misses wells or hits sides and/or tops of wells

Probable Cause(s)	Corrective Action(s)
Dispense tip not fully inserted on tip traveler.	Check tip insertion on traveler.
Damaged or broken dispense tip.	Check tip and straighten or replace it.
Tray did not line up properly when inserted.	Call Abbott Customer Support Center (CSC).
Dispense traveler sensor out of alignment.	Call Abbott Customer Support Center (CSC).

Reagent dispense splashes or sprays

Probable Cause(s)	Corrective Action(s)
Dispense tip not fully inserted on tip traveler	Check tip insertion on traveler.
Damaged or broken dispense tip.	Check tip and straighten or replace it.
Dispense tip needs cleaning.	Clean dispense tip.
Volume of dispenser is incorrect for volume to be dispensed.	Check that proper volume dispenser is installed for desired volume.
Dispenser is improperly inserted in component station.	Check dispenser insertion in component station to make sure that dispenser has been pushed fully into position.
Instrument mechanical malfunction.	Call Abbott Customer Support Center (CSC).

Leaking dispense tip or dispenser

Probable Cause(s)	Corrective Action(s)
Leaking connections on dispenser inlet or outlet tubing.	Check and secure all dispenser tubing and fittings.
Dispenser needs cleaning.	Clean dispenser.
Dispenser is not fully primed.	Prime dispenser.

Reagent volume dispensed is insufficient or inconsistent

Probable Cause(s)	Corrective Action(s)
Dispenser is not primed.	Prime dispenser.
Insufficient volume of reagent in dispenser bottle.	Install new reagent bottle on dispenser.
Incorrect dispenser size.	Replace dispenser with dispenser of correct size.
Kinked or blocked dispenser tubing.	Eliminate obstruction or replace tubing.
Leaky connection between dispenser and outlet tubing.	Check tubing connection.
Kinked or blocked inlet tube.	Eliminate obstruction or replace tube.
Incomplete return strokes by dispenser plunger.	Clean the dispenser and plunger as directed in the dispenser package insert.
Mechanical failure with dispensing mechanism.	Call Abbott Customer Support Center (CSC).

Dispense actuator does not strike the dispenser plunger near the center of the plunger.

Probable Cause(s)	Corrective Action(s)
Dispenser is improperly inserted in dispenser station.	Check dispenser insertion to make sure that dispenser has been pushed fully into position.
Dispense actuator assembly is misaligned.	Call Abbott Customer Support Center (CSC).
Check for the presence of the retaining button on the dispenser holder.	If missing, call Abbott Customer Support Center (CSC).

Dispense actuator does not clear top of dispenser plunger on upstroke or fully compress dispenser plunger on downstroke.

Probable Cause(s)	Corrective Action(s)
Dispenser improperly inserted in dispense station.	Check dispenser insertion to make sure that dispenser has been pushed fully into position.
Dispenser size is incorrect for volume of reagent to be dispensed.	Install dispenser of appropriate size.
Dispense actuator assembly is misaligned.	Call Abbott Customer Support Center (CSC).

No reagent dispensed.

Probable Cause(s)	Corrective Action(s)
Dispenser not installed in correct dispenser station.	Move dispenser to correct dispenser station and continue processing as directed below.
Reagent bottle is empty.	Refer to the Reagent Package Insert. If appropriate, replace reagent bottle on dispenser and continue processing as directed below.
Inlet tube on dispenser is not connected.	Connect inlet tube and continue processing as directed below.
Dispenser not primed.	Prime dispenser and continue processing as directed below.
	To Continue Processing: Void missed wells and continue run.

INTERNAL BAR CODE READER

PPC does not recognize trays

Probable Cause(s)	Corrective Action(s)
The Bar Code Switch is not activating.	Clean the Bar Code Switch with isopropyl alcohol and reinsert the tray. ⚠ **CAUTION:** Be careful not to bend or damage switch when wiping.
The Tray Entered Switch was already activated.	Clean the Tray Entered Switch with isopropyl alcohol and reinsert the tray. ⚠ **CAUTION:** Be careful not to bend or damage switch when wiping.
Internal bar code reader failure or switch failure.	Call Abbott Customer Support Center (CSC).

PORT 4 COMMUNICATIONS

Connected device not communicating

Probable Cause(s)	Corrective Action(s)
Connected device not assigned to Port 4.	Assign the device to Port 4.
Mechanical switch set incorrectly.	A. Turn power off. B. To activate external bar code reader, set mechanical switch to “BCR”. To activate rectangular port, set mechanical switch to “4”. C. Turn power on.

PRINTER

Final printout contains additional/incorrect characters

Probable Cause(s)	Corrective Action(s)
Defective printer.	A. Verify that the data is correct in FPC (if connected) B. Verify that the data is correct in the LIS computer (if connected). C. Replace the printer (Refer to *Printer Replacement* in *Section 9, Service and Maintenance*.) or Call Abbott Customer Support Center (CSC).

READ

Negative absorbance values

Probable Cause(s)	Corrective Action(s)
It is acceptable to have negative absorbance values on the final printout. For example, the bead is read in one orientation on the substrate step; it shifts and is read in a different orientation on the final read. The result may be negative due to MINOR bead variation. For more information, refer to the Reagent Package Insert	None — acceptable instrument performance.

Linearity test fails

Probable Cause(s)

- Incorrect values stored for Standards Tray.
- Optical reader window on transport track is not clean.
- Failed lamp.
- Worn Standards Tray.
- Equipment malfunction.

Corrective Action(s)

Refer to *Section 9, Service and Maintenance* for the complete listing of actions to be taken when this test fails.

Drift test fails

Probable Cause(s)

- Optical reader window on transport track is not clean.
- Failed lamp.
- Equipment malfunction.

Corrective Action(s)

Refer to *Section 9, Service and Maintenance* for the complete listing of actions to be taken when this test fails.

Repeatability test fails

Probable Cause(s)

- Optical reader window on transport is not clean.
- Failed lamp.
- Worn Standards Tray.
- Equipment malfunction.

Corrective Action(s)

Refer to *Section 9, Service and Maintenance* for the complete listing of actions to be taken when this test fails.

O.D. printed as *ERROR

Probable Cause(s)

- Lamp failure.
- Reader failure.
- Transport jam.
- Color in Blanks Tray.

Corrective Action(s)

- Replace Lamp if *ERROR continues to occur.
- If problem persists, call Abbott Customer Support Center (CSC).
- Reassay samples from the entire row.

CAUTION: The results of other samples in the row are questionable. Reassay all samples in the row and resolve per your laboratory standard operating procedure.

Batch Aborted with Batch Abort message

Probable Cause(s)	Corrective Action(s)
• A mechanical failure occurred after the last tray of the batch started the final pass. • The last tray of the batch was voided after the preceding tray has completed processing.	Results prior to Batch Abort message are valid. The Batch Abort message is followed by the End of Batch message.

WASH

Water on tray

Probable Cause(s)	Corrective Action(s)
Loose or misaligned wash manifold.	Check manifold mounting.
Manifold gaskets improperly seated in wash manifold.	Seat gaskets properly in manifold. Refer to *Section 9, Service and Maintenance*.
Disconnected waste line.	Make sure that waste line is properly connected.
Waste container full or waste cap wet.	Empty waste container or replace waste cap.
Leak in manifold.	Replace manifold. Refer to *Section 9, Service and Maintenance*.
Loose water line on manifold.	Re-install manifold and tighten water line.
Manifold travel insufficient to properly seal top of wells.	Call Abbott Customer Support Center (CSC).

Water in Air Tubing

Probable Cause(s)	Corrective Action(s)
Water canister overfilled. **NOTE:** Ignore moisture that has formed as a result of condensation due to differences in air and water temperature.	Fill canister to approximately 3 inches below the top.

Wet Wells (excessive residual water)

Probable Cause(s)	Corrective Action(s)
Disconnected or kinked air, water, or waste line tubing.	Make sure that all tubing connections are properly connected.
Leak in manifold.	Replace manifold. Refer to *Section 9, Service and Maintenance*.
Manifold gaskets improperly seated in wash manifold.	Seat gaskets properly in manifold. Refer to *Section 9, Service and Maintenance*.
Plugged or damaged wash tip inside manifold.	A. Perform wash water volume verification. B. If verification fails, replace manifold. Refer to *Section 9, Service and Maintenance*.

Wash water volume verification test failure

Probable Cause(s)	Corrective Action(s)
Blocked water line filter.	Replace water line filter. Refer to *Section 9, Service and Maintenance*.
Crimped or leaking tubing.	Replaced crimped or leaking tubing.
Water lines not fully primed at beginning of verification.	Rerun test.
Incorrectly connected wash or waste tubing.	Check all tubing connections.
Plugged or damaged tip in manifold.	Replace manifold. Refer to *Section 9, Service and Maintenance*.
Improperly pressurized lines.	Call Abbott Customer Support Center (CSC).

Error Codes

0.1.0.0 RAM test failure. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Component failure.	Call Abbott Customer Support Center (CSC).

0.2.0.0 No Valid Program. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Failed download or corrupted memory.	Call Abbott Customer Support Center (CSC).

0.2.0.3 Program Checksum Error. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Program memory fault.	Call Abbott Customer Support Center (CSC).

0.2.0.4 Programming Code Corrupted. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Program code copy in RAM is corrupted.	A. Turn power off, wait 30 seconds then turn power on. B. If error persists call Abbott Customer Support Center (CSC).

1.1.1 Bitbus fault. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Component failure or hardware reset error.	A. Turn power off, wait 30 seconds, then turn power back on. B. If problem persists, record error number and status number and call Abbott Customer Support Center (CSC).

1.1.2 Transport motor CONTROLLER FAULT. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Component failure or hardware reset error.	A. Turn power off, wait 30 seconds, then turn back on B. If problem persists, call Abbott Customer Support Center (CSC).

1.1.3 Web switch did not close. Check for tray jam. Press <ENTER> to continue.

Probable Cause(s)	Corrective Action(s)
No web switch signal after gating.	A. 1. Lift right half of instrument exposing urge mechanism on transport track. 2. Pull tray back and allow it to advance to the transport gate solenoid. 3. Press **<Enter>** to continue. B. 1. If error message reappears, turn power switch off, wait 30 seconds, then turn back on to clear tray from transport track. 2. Check tray for properly placed bar code label. 3. Depress the web switch and verify that LED #106 lights up, indicating that the switch is operative. If LED #106 is not lit up when web switch is depressed, contact Abbott Customer Support Center (CSC) to replace defective web switch. 4. Clean the load module and transport mechanism. 5. Replace Urge Belts. **NOTE:** Do not try to adjust tray if error screen is not present. C. If problem persists, call Abbott Customer Support Center (CSC).

1.1.4 Incompatible Transport Hardware – transport hardware must be changed. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Transport hardware is incompatible with software.	Call Abbott Customer Support (CSC).

1.1.5 Transport motor Time Out.

followed by the message:
Attempt to Clear Jam:
Press right and left arrow keys
to move tray.
When tray is free, Press <#> to EXIT
Followed by the message:
Turn power off, wait 30 seconds.
Turn power back on.
Processing may then be continued.

Probable Cause(s)	Corrective Action(s)
Tray jammed in transport track or defective wash switch.	A. Advisory message is displayed. Follow instructions on next screen. B. If tray is properly positioned under wash manifold, check that LED #103 is lit. If LED #103 is not lit with tray in proper position, call Abbott Customer Support Center (CSC) to replace defective wash switch. C. Check for obstruction in transport mechanism. D. 1. Loosen tray by depressing "<" or ">". 2. Press "<" to move tray into Exit Station. 3. Check tray for broken webs or side rails before reinserting into instrument. E. Turn power off, wait 30 seconds, then turn power back on. F. If tray cannot be loosened, and problem continues, turn power off and call Abbott Customer Support Center (CSC).

1.1.6 Remove tray from exit. Press <ENTER> to advance tray.

Probable Cause(s)	Corrective Action(s)
Completed tray in Exit Station blocking other completed trays.	Remove tray from exit. If it is still held by the transport, press **<Enter>** to advance tray one web. Message disappears when tray is removed.

1.1.7 Web switch is not open. Check for tray jam. Press <ENTER> to continue.

Probable Cause(s)	Corrective Action(s)
Web switch closed prior to gating.	A. 1. Lift right half of instrument exposing urge mechanism on transport track. 2. Pull tray back and allow it to advance to the transport gate solenoid. 3. Check that LED #106 is off and then press <Enter> to continue. If LED #106 is still off, turn power switch off, wait 30 seconds, then turn back on to clear tray from transport track. B. 1. If error message reappears, turn power switch off, wait 30 seconds, then turn back on to clear tray from transport track. 2. Check tray for properly placed bar code label. 3. Depress the web switch and verify that LED #106 lights up, indicating that the switch is operative. If LED #106 is not lit up when web switch is depressed, contact Abbott Customer Support Center (CSC) to replace defective web switch. 4. Clean the load module and transport mechanism. 5. Replace Urge Belts. **NOTE:** Do not try to adjust tray if error screen is not present. C. If problem persists, call Abbott Customer Support Center (CSC).

1.1.8 Tray exit switch defective. Press <ENTER> to continue.

Probable Cause(s)	Corrective Action(s)
Tray removed from instrument exit prior to recycling power after a transport motor time out error.	Advisory message.
Faulty exit switch.	Press **<Enter>** to continue processing. Call Abbott Customer Support Center (CSC) for switch replacement.

1.1.9 Wash switch is defective. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Defective switch.	Check for obstruction and remove.
Obstruction causing switch to be closed when it should not be.	If no obstruction, call Abbott Customer Support Center (CSC).

1.1.10 Tray not gated. Wash switch defective or tray jam. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Defective switch.	Check for obstruction and remove.
Tray jam.	Check for damaged tray.
Damaged tray.	If neither of the above, call Abbott Customer Support Center (CSC).
Slow tray movement	Replace Urge Belts.

1.2.1 Bitbus fault. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Component failure or hardware reset error.	A. Turn power off, wait 30 seconds, then turn power back on. B. If problem persists, record error number and status number and call Abbott Customer Support Center (CSC).

1.2.2 Wash head motor controller fault. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Component failure or hardware reset error.	A. Turn power off, wait 30 seconds, then turn power back on. B. If problem persists, record error number and status number and call Abbott Customer Support Center (CSC).

1.2.3 Check air lines Low air pressure

Probable Cause(s)	Corrective Action(s)
Air pressure is insufficient for wash step.	A. Make sure compressor is plugged into instrument and is running. B. Make sure all tubing is properly connected and not kinked. C. Check all tubing and connections for leaks. D. Make sure lid is fully sealed on wash water container. E. Make sure that pressure relief valve on wash container is closed and fully threaded into lid. F. Check for blockage at air line filter and replace if necessary. G. If pressure has not built up in 4 minutes, turn power switch off, wait 30 seconds, then turn back on to turn compressor back on. H. If system fails to pressurize sufficiently to perform a wash cycle, call Abbott Customer Support Center (CSC).

1.2.3.1 Check waste line for complete connection. Press <ENTER> to continue.

Probable Cause(s)	Corrective Action(s)
Waste line not fully connected.	A. Verify that all waste line connections are complete. Then press **<Enter>** to continue. B. If problem persists, call Abbott Customer Support Center (CSC).

1.2.4 Check for low water level.

Probable Cause(s)	Corrective Action(s)
Less than 3 Liters of water remain in wash container.	A. Check water level in wash container. Fill with distilled or deionized water and empty or change waste container. **NOTE:** Signal will repeat every two rows. The signal is a warning only and will not disable the wash system. B. If water level is above the 3 Liter level in the wash container, make sure the level sense cable is properly connected at both the container and instrument. C. If signal continues when container is full, processing may continue if water level is checked manually. If problem persists, call Abbott Customer Support Center (CSC).
Defective level sense cable	Verify functionality by using another cable.
Defective water canister	Verify functionality by using another water canister. **NOTE:** When air drying the canister, be sure the level sense cable is not damaged.

1.2.5 Wash head motor time out. Press <ENTER> to continue.

Probable Cause(s)	Corrective Action(s)
Wash head motor jammed.	A. Check tray position. If there is no obvious misalignment or obstruction of the wash head, press **<Enter>** to continue. B. If tray is not properly positioned, turn power switch off, wait 30 seconds, then turn back on to purge the tray. C. If problem persists, call Abbott Customer Support Center (CSC).

1.2.6 Check tray and wash head. Press <ENTER> to continue.

Probable Cause(s)	Corrective Action(s)
Wash head not down when about to start a wash cycle.	A. Press **<Enter>** to continue. B. If problem persists, call Abbott Customer Support Center (CSC).

1.2.7 Wash head sensor is defective. Press <ENTER> to continue.

Probable Cause(s)	Corrective Action(s)
Wash head sensor or motor malfunction.	A. Press **<Enter>** to continue. B. If problem persists, call Abbott Customer Support Center (CSC).

1.2.8 Wash switch is defective. Press <ENTER> to continue.

Probable Cause(s)	Corrective Action(s)
Damaged tray.	A. Press **<Enter>** to continue. B. Check for damaged tray (a piece of the tray may be missing). If tray is not damaged, call Abbott Customer Support Center (CSC).
Defective switch.	A. Press **<Enter>** to continue. B. Call Abbott Customer Support Center (CSC).

1.3.1 Bitbus fault. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Component failure or hardware reset error.	A. Turn power off, wait 30 seconds, then turn power back on. B. If problem persists, call Abbott Customer Support Center (CSC).

1.3.2 Dispense boom motor time out. Press <ENTER> to continue.

Probable Cause(s)	Corrective Action(s)
Dispense boom motor jammed (Motor that drives dispense tip holder.)	A. Check dispense boom mechanism for obstructions and press **<Enter>** to continue. B. Turn power off, wait 30 seconds, then turn power back on. C. If problem persists, call Abbott Customer Support Center (CSC).

1.3.3 Pump motor time out. Press <ENTER> to continue.

Probable Cause(s)	Corrective Action(s)
Dispense pump motor jammed.	A. Check dispense pump mechanism for obstructions and make sure dispenser is properly seated. Press **<Enter>** to continue. B. Turn power off, wait 30 seconds, then turn power back on. C. If problem persists, call Abbott Customer Support Center (CSC).

1.3.4 Bottle select motor time out. Press <ENTER> to continue.

Probable Cause(s)	Corrective Action(s)
Motor jammed on dispense station selector.	A. Check the dispense pump station selector mechanism for obstructions and press **<Enter>** to continue. B. Turn power off, wait 30 seconds, then turn power back on. C. If problem persists, call Abbott Customer Support Center (CSC).

1.3.5.1 Dispense boom motor fault. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Component failure or hardware reset error.	A. Turn power off, wait 30 seconds, then turn back on B. If problem persists, call Abbott Customer Support Center (CSC).

1.3.6.1 Pump motor fault. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Component failure or hardware reset error.	A. Turn power off, wait 30 seconds, then turn back on B. If problem persists, call Abbott Customer Support Center (CSC).

1.3.7.1 Bottle select motor fault. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Component failure or hardware reset error.	A. Turn power off, wait 30 seconds, then turn back on B. If problem persists, call Abbott Customer Support Center (CSC).

1.3.11.1 Pump sensor is defective. Press <ENTER> to continue.

Probable Cause(s)	Corrective Action(s)
Component failure or hardware reset error.	A. Press **<Enter>** to continue. B. If error message reappears, turn power switch off, wait 30 seconds, then turn power back on. C. If problem persists, call Abbott Customer Support Center (CSC).

1.3.12.1 Well select sensor is defective. Press <ENTER> to continue.

Probable Cause(s)	Corrective Action(s)
Component failure or hardware reset error.	A. Press **<Enter>** to continue. B. If error message reappears, turn power switch off, wait 30 seconds, then turn power back on. C. If problem persists, call Abbott Customer Support Center (CSC).

1.3.13.1 Bottle select sensor is defective. Press <ENTER> to continue.

Probable Cause(s)	Corrective Action(s)
Component failure or hardware reset error.	A. Press **<Enter>** to continue. B. If error message reappears, turn power switch off, wait 30 seconds, then turn power back on. C. If problem persists, call Abbott Customer Support Center (CSC).

1.4.1 Bitbus fault. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Component failure or hardware reset error.	A. Turn power off, wait 30 seconds, then turn power back on. B. If problem persists, call Abbott Customer Support Center (CSC).

1.4.2 Filter select motor controller fault. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Component failure or hardware reset error.	A. Turn power off, wait 30 seconds, then turn power back on. B. If problem persists, call Abbott Customer Support Center (CSC).

1.4.3 Filter select motor time out. Press <ENTER> to continue.

Probable Cause(s)	Corrective Action(s)
Filter select motor jam.	A. Press **<Enter>** to continue. B. Turn power off, wait 30 seconds, then turn power back on. C. If problem persists, call Abbott Customer Support Center (CSC).

1.4.4 Read function fault. CANNOT CONTINUE
1.4.5 Check read head Limit 1. CANNOT CONTINUE
1.4.6 Check read head Limit 2. CANNOT CONTINUE
1.4.7 Check read head Limit 3. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Component failure or hardware reset error.	A. Turn power switch off, wait 30 seconds, then turn power back on. B. If problem persists, call Abbott Customer Support Center (CSC).

1.4.8 Check reader lamp or sensors. Press <ENTER> to continue.

Probable Cause(s)	Corrective Action(s)
Component failure, hardware reset error, or loss of lamp intensity.	A. Press **<Enter>** to continue. B. Replace lamp. Refer to *Section 9, Service and Maintenance*. C. If problem persists, call Abbott Customer Support Center (CSC).

1.4.9 Check read head Limit 4. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Component failure or hardware reset error.	A. Turn power switch off, wait 30 seconds, then turn back on. B. If problem persists, call Abbott Customer Support Center (CSC).

1.4.10 Filter Select Home Sensor Failure. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
A 1.4.8 error (Check reader lamp or sensors) was not responded to.	A. Replace lamp. Refer to *Section 9, Service and Maintenance*. B. If problem persists, call Abbott Customer Support Center (CSC).
Filter home sense circuit failure.	A. Turn power off, wait 30 seconds, then turn power back on. B. If problem persists, and call Abbott Customer Support Center (CSC).

1.5.1 Bitbus fault. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Component failure or hardware reset error.	A. Turn power off, wait 30 seconds, then turn power back on. B. If problem persists, and call Abbott Customer Support Center (CSC).

1.5.2 Bitbus fault. PRESS <ENTER> TO CONTINUE

Probable Cause(s)	Corrective Action(s)
Component failure or hardware reset error.	A. Press **<Enter>**. B. Turn power off, wait 30 seconds, then turn power back on. C. If problem persists, and call Abbott Customer Support Center (CSC).

1.5.3 Tray was Locked in Without Being Gated. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
The PPC has incorrectly allowed a tray to be pulled into the urge mechanism without identifying the tray number.	A. Turn power switch off, wait 30 seconds, then turn power back on to flush the tray. B. Do not insert trays end-to-end. (Refer to *Section 5, Operating Instructions* for proper tray insertion.)
Tray cannot be accepted because the operator removed and re-inserted the tray prior to when the **INSERT TRAY** message was displayed.	A. Turn power switch off, wait 30 seconds, then turn power back on to flush the tray. B. Allow the **INSERT TRAY** message to appear before inserting the tray.

1.6.1 Bitbus fault. Press <ENTER> to continue.

Probable Cause(s)	Corrective Action(s)
Component failure or hardware reset error.	A. Press **<Enter>** to continue. B. Turn power off, wait 30 seconds, then turn power back on. C. If problem persists, call Abbott Customer Support Center (CSC).

1.6.2 Printer out of paper or OFF LINE

Probable Cause(s)	Corrective Action(s)
Printer is out of paper or is off line.	A. Check paper and replace if necessary. Refer to *Section 9, Service and Maintenance.* B. Check position of bail lever on printer. C. Turn power switch off and replace printer as directed in *Section 9, Service and Maintenance.* D. If problem persists, call Abbott Customer Support Center (CSC).

1.7.1 Bitbus Fault. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Component failure or hardware reset error.	A. Turn power off, wait 30 seconds, then turn power back on. B. If problem persists, call Abbott Customer Support Center (CSC).

1.7.2 Bottle light fault. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Component failure.	A. Turn power switch off, wait 30 seconds, then turn back on. B. If problem persists, call Abbott Customer Support Center (CSC).

1.7.3 Invalid Prime Pump Size. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Pump prime size is not a defined value (50, 100, 150, 175, 200 or 300).	Turn power switch off, wait 30 seconds, then turn back on.

1.7.4 Prime Bottle Location Invalid. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
The Prime bottle location is greater than 5.	Turn power switch off, wait 30 seconds, then turn back on.

1.7.5 Process Checksum Failure. PRESS <ENTER> TO CONTINUE

Probable Cause(s)	Corrective Action(s)
The tray data has been corrupted and detected at power up.	Press **<Enter>** to void the tray, and the tray ID will be displayed and printed. PPC will complete power-up, and display the Insert Tray screen.

2.1.1.1 Tray database error. CANNOT CONTINUE
2.1.1.2 Tray database error-not found. CANNOT CONTINUE
2.1.1.3 Tray database error-not open. CANNOT CONTINUE
2.1.1.4 Tray database error-write. CANNOT CONTINUE
2.1.1.5 Tray database error-read. CANNOT CONTINUE
2.1.1.6 Batch database error-read. CANNOT CONTINUE
2.1.1.7 Batch database error-write. CANNOT CONTINUE
2.1.1.8 Batch database error. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Database error.	A. Turn power switch off, wait 30 seconds, then turn back on. B. If problem persists, call Abbott Customer Support Center (CSC).

2.1.1.9 Assay not found. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Could not locate assay.	A. Turn power switch off, wait 30 seconds, then turn back on. B. If problem persists, call Abbott Customer Support Center (CSC).

2.1.1.10 Assay database error-read. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Could not find an assay.	A. Turn power switch off, wait 30 seconds, then turn back on. B. If problem persists, call Abbott Customer Support Center (CSC).

2.1.1.11 Unexpected row was read.

Probable Cause(s)	Corrective Action(s)
Row read by reader not expected.	Printed results are correct.

2.1.1.12 Internal error-bad command to DRT. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Illegal data reduction command received.	A. Turn power switch off, wait 30 seconds, then turn back on. B. If problem persists, call Abbott Customer Support Center (CSC).

2.1.1.13 Internal error-bad task ID to DRT. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Unrecognized internal communication.	A. Turn power switch off, wait 30 seconds, then turn back on. B. If problem persists, call Abbott Customer Support Center (CSC).

2.1.1.14 Internal error-bad well class. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Could not classify well.	A. Turn power switch off, wait 30 seconds, then turn back on. B. If problem persists, call Abbott Customer Support Center (CSC).

2.1.1.15 Internal error-no request to DRT for tray XXXXXXXXXX. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Abort command sent before tray was received.	Advisory message.

2.1.1.16 Internal error-bad reduction type. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Data reduction error detected.	A. Turn power switch off, wait 30 seconds, then turn back on. B. If problem persists, call Abbott Customer Support Center (CSC).

2.1.1.17 Reduction started on new tray.

Probable Cause(s)	Corrective Action(s)
Last row voided before tray complete.	Advisory message.

2.1.1.18 No cutoff calculated yet-No flagging will be done.

Probable Cause(s)	Corrective Action(s)
No cutoff calculated yet for tray. Unknown wells were read when expecting control wells.	Advisory message.

2.1.1.19 Incomplete standards-No concentrations will be calculated.

Probable Cause(s)	Corrective Action(s)
Void or no sample executed on standards used for data reduction.	Advisory message.

2.1.1.20 No blank value-no further calculations possible.

Probable Cause(s)	Corrective Action(s)
Blanks were voided. If a blank well is flagged with *ERROR, the PPC displays this error and the batch is lost.	Advisory message.

2.1.1.22 Assay # is defective - subsequent calculations may be invalid. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Illegal values seen in assay.	A. Turn power switch off, wait 30 seconds, then turn back on. B. If problem persists, call Abbott Customer Support Center (CSC).

2.1.1.25 Blanks have failed OPD timing checks - No further calculations possible

Probable Cause(s)	Corrective Action(s)
Wells in the Blanks tray exceed the specified maximum incubation time limit.	Advisory message.

2.1.1.26 Controls have failed OPD timing checks - No flagging will be done.

Probable Cause(s)	Corrective Action(s)
Too many Control wells exceed the specified maximum incubation time limit.	Advisory message.

2.1.1.28 No negative controls found. No flagging will be done.

Probable Cause(s)	Corrective Action(s)
Started processing positive controls before the negative controls were found.	Advisory message.

2.1.1.29 Internal error-well status/bit map conflict. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Database error.	A. Turn power switch off, wait 30 seconds, then turn back on. B. If problem persists, call Abbott Customer Support Center (CSC).

2.1.1.30 Internal error-no status on well

Probable Cause(s)	Corrective Action(s)
Pipettor taken off line right after gating tray.	A. Advisory message. Verify communication between the PPC and the connected pipettor. B. If problem persists, call Abbott Customer Support Center (CSC).

2.1.1.32 Controls or standards cannot fit into one tray. Please void this batch.

Probable Cause(s)	Corrective Action(s)
Controls/standards not on one tray.	Advisory. Enter Batch Tools in the Database Special Mode to void the batch.

2.1.1.33 Controls have failed validity check(s). No flagging will be done.

Probable Cause(s)	Corrective Action(s)
Controls failed validity checks.	Advisory message.

2.1.1.34 Insufficient controls to do cutoff. No flagging will be done.

Probable Cause(s)	Corrective Action(s)
Total number of valid controls is less than the minimum number of replicates specified for the assay.	Advisory message.

2.1.1.35 Too many aberrant values in controls. No flagging will be done.

Probable Cause(s)	Corrective Action(s)
Greater than 1 aberrant per control type is not allowed.	Advisory message.

2.1.1.36 Negative control out of range. No flagging will be done.

Probable Cause(s)	Corrective Action(s)
Negative mean value is greater than the maximum or less than the minimum acceptable value.	Advisory message.

2.1.1.37 Positive control out of range. No flagging will be done.

Probable Cause(s)	Corrective Action(s)
Positive mean value is greater than the maximum or less than the minimum acceptable value.	Advisory message.

2.1.1.38 (POS-NEG) difference test failed. No flagging will be done.

Probable Cause(s)	Corrective Action(s)
Positive mean (P) minus negative mean (N) test failed. **NOTE:** (P–N) is equivalent to –(N–P). Refer to the *Cutoff Assay Protocol Reference Guide* in the *Appendices*.	Advisory message.

2.1.1.39 Standards are not monotonic. No concentrations will be calculated.

Probable Cause(s)	Corrective Action(s)
Replicates of standards did not continuously increase or decrease.	Advisory message.

2.1.1.40 Selected standard failed the mean test. No concentrations will be calculated.

Probable Cause(s)	Corrective Action(s)
Value of selected standard less than minimum or greater than maximum acceptable value.	Advisory message.

2.1.1.41 STD A - STD B difference test failed. No concentrations will be calculated.

Probable Cause(s)	Corrective Action(s)
Standard A minus Standard B less than minimum or greater than maximum acceptable values.	Advisory message.

2.1.1.42 STD A /STD B first ratio test failed. No concentrations will be calculated.

Probable Cause(s)	Corrective Action(s)
Standard A divided by Standard B less than minimum or greater than maximum acceptable values.	Advisory message.

2.1.1.43 STD C /STD D second ratio test failed. No concentrations will be calculated.

Probable Cause(s)	Corrective Action(s)
Standard C divided by Standard D less than minimum or greater than maximum acceptable values.	Advisory message.

2.1.1.45 Internal error-undefined. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Undefined error code.	A. Turn power switch off, wait 30 seconds, then turn back on. B. If problem persists, call Abbott Customer Support Center (CSC).

2.1.1.46 Absorbance of a control exceeded 2.200.

Probable Cause(s)	Corrective Action(s)
A control used in sample calculations has exceeded instrument limit of 2.200 O.D.	Advisory message.

2.1.1.47 Absorbance of a standard exceeded 2.200. No concentrations will be calculated.

Probable Cause(s)	Corrective Action(s)
No standard may exceed instrument limit of 2.200 O.D.	Advisory message.

2.1.1.50 Absorbance of standard out of instrument range. No concentrations will be calculated.

Probable Cause(s)	Corrective Action(s)
The absorbance of a standard exceeds the upper or lower instrument range	Advisory message.

2.1.1.51 No Control or Standards tray exists. Flagging concentrations will not be done.

Probable Cause(s)	Corrective Action(s)
Attempt to process a batch without a standards or controls tray.	A. Remove tray and insert standards or controls tray. B. Reprocess batch.

2.1.1.52 Standard below minimum absorbance. No concentrations will be calculated.

Probable Cause(s)	Corrective Action(s)
Standard below acceptable minimum absorbance.	A. Check for tray jam. B. Reprocess batch.

2.1.1.53 Sample below Minimum Sample Absorbance.

Probable Cause(s)	Corrective Action(s)
Sample below acceptable minimum absorbance.	A. Check for tray jam. B. Reprocess samples.

2.1.1.54 Absorbance of control out of instrument range. No flagging will be done.

Probable Cause(s)	Corrective Action(s)
The absorbance of a control may not exceed the upper or lower instrument range.	Advisory message.

2.1.1.56 Positive-2 control difference test failed. No flagging will be done.

Probable Cause(s)	Corrective Action(s)
Positive-2 control mean minus negative control mean test failed.	Advisory message.

2.1.1.57 Insufficient positive-2 controls. No flagging will be done.

Probable Cause(s)	Corrective Action(s)
The number of valid positive-2 control replicates is less than the Min. PC2 Replicates requirement.	Advisory message.

2.1.1.58 Invalid Positive-2 Controls – PC2 Mean is not Reactive No flagging will be done

Probable Cause(s)	Corrective Action(s)
The Positive-2 Control mean is not Reactive	Advisory message.

2.1.1.60 Positive-3 Control Difference test failed – No flagging will be done

Probable Cause(s)	Corrective Action(s)
Positive-3 control mean minus negative control mean test failed.	Advisory message.

2.1.1.61 Insufficient Positive-3 controls No flagging will be done

Probable Cause(s)	Corrective Action(s)
The number of valid Positive-3 control replicates is less than the Min. PC3 Replicates Requirement.	Advisory message.

2.1.2.1 CALIBRATION ABORTED! Insufficient Wells Press <ENTER> to continue.

Probable Cause(s)	Corrective Action(s)
Too many wells in the Calibration tray were VOIDed or REJECTed.	A. Re-run Calibration. B. If problem persists, call Abbott Customer Support Center (CSC).

2.1.2.2 Calibration checksum failure. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
The calibration tray data has been corrupted.	A. Turn power off, wait 30 seconds, then turn power back on. Run a new calibration tray and resume processing. B. If problem persists, call Abbott Customer Support Center (CSC).

3.?.?.? Assay interpreter error: xxxx. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Unknown error code generated.	A. Turn power off, wait 30 seconds, then turn back on. B. If problem persists, call Abbott Customer Support Center (CSC).

3.1.1 INTERNAL SYSTEM ERROR: Database write error. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Attempt to update the tray or batch database failed.	A. Turn power switch off, wait 30 seconds, then turn power back on. Continue processing. B. If problem persists, call Abbott Customer Support Center (CSC).

3.1.2 INTERNAL SYSTEM ERROR: Tray database error. CANNOT CONTINUE
3.1.3 INTERNAL SYSTEM ERROR: Batch database error. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Database error.	A. Turn power switch off, wait 30 seconds, then turn power back on. Continue processing. B. If problem persists, call Abbott Customer Support Center (CSC).

3.1.4 INTERNAL SYSTEM ERROR: Cannot find assay. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Attempt to find an assay in the database failed.	A. Turn power switch off, wait 30 seconds, then turn power back on. Continue processing. B. If problem persists, call Abbott Customer Support Center (CSC).

3.1.5 INTERNAL SYSTEM ERROR: Assay Data Corrupted. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
PPC memory is corrupted. Unable to continue.	Call Abbott Customer Support Center (CSC).

3.1.6 INTERNAL SYSTEM ERROR: Processing Duration Invalid. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
The PPC clock time at the end of the OPD pass is earlier than the start time of the OPD pass.	Turn power switch off, wait 30 seconds, then turn power back on.

3.2.1 INTERNAL SYSTEM ERROR: Tray database error. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
A tray ID reported to have finished processing by the instrument and could not be successfully found from the database.	A. Turn power switch off, wait 30 seconds, then turn power back on. Continue processing. B. If problem persists, call Abbott Customer Support Center (CSC).

3.2.1.1 No TPC capable instruments connected. Press <ENTER> To Continue

Probable Cause(s)	Corrective Action(s)
No TPC™ instruments are connected and there is no way to validate TPC information.	A. Remove the tray. B. Verify communication to connected instruments.

3.2.1.4 Invalid tray type from Pipettor. Tray ID: wwwwwwwwww. Press <ENTER> To Continue

Probable Cause(s)	Corrective Action(s)
Tray ID entered does not belong to a valid (20 or 60 well) tray.	A. Remove the tray. B. Use a 20-well or 60-well tray.

3.2.1.8 Illegal Operation – [Type] data exists. Tray ID: wwwwwwwwww. Press <ENTER> To Continue

Probable Cause(s)	Corrective Action(s)
Component data for this pass currently exists for the identified tray.	Remove the tray. This tray cannot be processed in the TPC™ Verify mode.

3.2.1.9 Lot Number not found – xxxxxxxxxx. Press <ENTER> To Continue.

Probable Cause(s)	Corrective Action(s)
Component lot number entered was not found in the database of the pipettor which contained the tray.	• Correct and re-enter a valid lot number. or • If a deviation password has been defined, acknowledge the deviation with a valid password and continue processing. **DEV 03** will be documented on the final results.

3.2.1.10 Illegal Operation – Invalid component type. Press <ENTER> To Continue.

Probable Cause(s)	Corrective Action(s)
Lot number entered is not the proper component type as defined in the assay protocol for this pass.	A. Enter a valid component lot number. B. Review edited protocols on both PPC and FPC™ to resolve inconsistent protocols. Refer to the *COMMANDER FPC™ Operations Manual* for additional information.
External run controls are identified incorrectly in the FPC assay protocol.	External run control types should be identified as QC## (with ## replaced by alphanumerics). Refer to the *COMMANDER FPC™ Operations Manual* for additional information.

3.2.1.11 Illegal Operation – List # mismatch. Press <ENTER> To Continue.

Probable Cause(s)	Corrective Action(s)
List number of the component does not match the list number of the tray master lot.	Enter a valid lot number.

3.2.1.12 [Type] Lot Expired – xxxxxxxxxx. Press <ENTER> To Continue

Probable Cause(s)	Corrective Action(s)
The master lot or component lot number entered has expired.	For all passes except OPD: • Correct and re-enter a valid lot number. or • If a deviation password has been defined, acknowledge the deviation with a valid password and continue processing. **DEV 01** will be documented on the final results. For OPD pass: • If a deviation password has been defined, **DEV 01** will automatically be documented on the final results. • If a deviation password has not been defined, the batch will be automatically voided.

3.2.1.13 Master Lot mismatch. Press <ENTER> To Continue

Probable Cause(s)	Corrective Action(s)
The master lot of a tray does not match the master lot of the batch.	A. Remove the tray. B. Verify that the master lot of the tray matches the master lot of the controls tray.
The master lot of the component lot number entered does not match the master lot of the tray.	• Correct and re-enter a valid lot number. or • If a deviation password has been defined, acknowledge the deviation with a valid password and continue processing. **DEV 04** or **DEV 05** (if the component is expired) will be documented on the final results.

3.2.1.14 Registration of component used failed. Press <ENTER> To Continue

Probable Cause(s)	Corrective Action(s)
The PPC's attempt to record the component used information in the TPC™ Pipettor's database has failed.	Continue processing. No action is required. This is an advisory message.

3.2.1.21 Tray in use. Press <Enter> To Continue

Probable Cause(s)	Corrective Action(s)
Inserted tray has been locked by another instrument and therefore cannot be accessed.	A. Remove the tray. B. Process tray on original PPC.

3.2.1.22 List #/Procedure from Pipettor is inconsistent with current assay. Press <ENTER> To Continue

Probable Cause(s)	Corrective Action(s)
Inserted tray's associated assay list number and procedure do not match the current batch.	Remove the tray.

3.2.1.23 TPC mode mismatch. Press <ENTER> To Continue

Probable Cause(s)	Corrective Action(s)
TPC™ mode of a tray does not match the TPC mode of the batch.	Remove the tray.

3.2.1.24 Illegal Operation – Invalid component dispense station. Press <ENTER> To Continue

Probable Cause(s)	Corrective Action(s)
The dispense station entered is not the proper component station for this pass.	Enter the correct component station number.

3.2.1.25 Tray found on wrong Pipettor. Press <ENTER> To Continue

Probable Cause(s)	Corrective Action(s)
The Pipettor that supplied tray information on a subsequent pass was not the same as the Pipettor that supplied tray information on the first pass.	Remove and void the tray.

3.2.1.26 Illegal Operation – No Bead Drop. Press <ENTER> To Continue

Probable Cause(s)	Corrective Action(s)
No Bead Drop Procedure was performed for the Calibration tray.	A. Remove the tray. B. Perform the Bead Drop Procedure on the Calibration tray.

3.2.1.27 Unable to verify component. Press <ENTER> To Continue

Probable Cause(s)	Corrective Action(s)
No Pipettor has information on the requested tray.	Press <**Enter**> to continue processing. A code **NV** will be documented on final results.

3.2.1.28 No Bead Drop registered. Press <ENTER> To Continue

Probable Cause(s)	Corrective Action(s)
No Bead component lot number is associated with the requested tray.	For all passes except Acid pass: • If a deviation password has been defined, acknowledge the deviation with a valid password and continue processing. **DEV 06** will be documented on the final results. For Acid pass: • **DEV 06** will automatically be documented on the final results.

3.2.1.29 INTERNAL SYSTEM ERROR: External barcode reader status fault. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
External bar code reader task reported a fault status of not configured.	Turn power switch off, wait 30 seconds, then turn power back on.

3.2.1.30 Illegal Operation – Master Lot not found:xxxxxxxxxx. Press <ENTER> To Continue

Probable Cause(s)	Corrective Action(s)
Tray's Master Lot cannot be found on the pipettor.	A. Remove the tray. B. Insert correct tray or Insert tray and enter correct tray ID.

3.2.1.31 Calibration Aborted! Invalid Calibration Tray ID. Remove This Tray.

Probable Cause(s)	Corrective Action(s)
The Calibration tray ID does not match the Calibration Bead Drop Procedure tray ID.	Remove the tray. Repeat Calibration with tray ID entered in the Calibration Bead Drop Procedure.

3.2.2 INTERNAL SYSTEM ERROR: Machine control command status fault. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Machine control reported status for an unknown command.	A. Turn power switch off, wait 30 seconds, then turn power back on. Continue processing. B. If problem persists, call Abbott Customer Support Center (CSC).

3.2.3 INTERNAL SYSTEM ERROR: Tray ID Lost. Rejecting Tray. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Internal system error.	A. Advisory. B. If problem persists, call Abbott Customer Support Center (CSC).

3.2.4 INTERNAL SYSTEM ERROR: Tray database error. CANNOT CONTINUE
3.2.5 INTERNAL SYSTEM ERROR: Tray database error. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Tray database error.	A. Turn power switch off, wait 30 seconds, then turn power back on. Continue processing. B. If problem persists, call Abbott Customer Support Center (CSC).

3.2.6 INTERNAL SYSTEM ERROR: Batch database error. CANNOT CONTINUE
3.2.7 INTERNAL SYSTEM ERROR: Batch database error. CANNOT CONTINUE
3.2.8 INTERNAL SYSTEM ERROR: Batch database error. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Batch data is corrupted for the current tray. Data will be lost.	A. Turn power switch off, wait 30 seconds, then turn power back on. Continue processing. B. If problem persists, call Abbott Customer Support Center (CSC).

3.2.9 INTERNAL SYSTEM ERROR: Tray database error. CANNOT CONTINUE
3.2.10 INTERNAL SYSTEM ERROR: Tray database error. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Tray has stored status which is corrupted in the database. The tray information is lost.	A. Turn power switch off, wait 30 seconds, then turn power back on. Continue processing. B. If problem persists, call Abbott Customer Support Center (CSC).

3.2.11 Bad Pipettor Test Number…Cannot find assay

Probable Cause(s)	Corrective Action(s)
Test number sent by the pipettor has not been assigned to an assay number in the PPC.	Remove tray. Assign test number to appropriate PPC assay in Protocol Select. Refer to *Section 5, Operating Instructions*.

3.2.12 This tray may not be inserted. Remove this tray.

Probable Cause(s)	Corrective Action(s)
A. A blanks tray is already in the instrument. B. A blanks tray is inserted while "Blanks tray is waiting for first tray of batch" displays. C. A blanks tray has already been identified for this batch. D. Trying to process a voided tray.	Remove blanks or improper tray and load proper tray.

3.2.13 This tray has the wrong mode. Remove this tray.

Probable Cause(s)	Corrective Action(s)
Stand alone and Pipettor trays may have been intermixed.	Remove tray. Intermixing of Stand alone, and Pipettor trays within the same batch is not allowed. Set up a new batch.
Tray deleted from pipettor database.	Remove tray. Manually void tray on PPC.

3.2.14 Test number from the Pipettor is inconsistent with the current assay.

Probable Cause(s)	Corrective Action(s)
Test # for non-controls tray does not select the same PPC assay as did the controls tray. Remove tray.	Enter correct tray for batch being processed. Trays of different assays cannot be in same batch.

3.2.15 Unknown Assay List Number/Assay Procedure. Cannot Find Assay. Remove This Tray.

Probable Cause(s)	Corrective Action(s)
The Assay List Number/Assay Procedure sent from the pipettor for this tray does not match any on the PPC	A. Remove the tray. B. Identify the cause for the discrepancy and correct.

3.2.16 Improper number of unknown replicates. Remove this tray.

Probable Cause(s)	Corrective Action(s)
Pipettor indicates that the number of unknown reps for a sample tray is not the same as that for the controls tray of the batch.	Insert correct trays. Complete first pass with trays having the same number of unknown replicates.

3.2.17 Tray is not in readable state. Remove this tray.

Probable Cause(s)	Corrective Action(s)
A tray which is Not Archived, or has been Voided on the PPC has been inserted for rereading.	Remove tray and check tray's status on the PPC. Refer to *Section 5, Operating Instructions*. The PPC will not reread a voided or non-archived tray.

3.2.18 Controls/standards must be in the first tray of the batch.

Probable Cause(s)	Corrective Action(s)
The Pipettor indicates that there are controls or standards in a tray which is not first of batch.	The tray cannot be run as part of the batch. a. Remove tray. b. Truncate the PPC batch and run the second controls tray and any trays following it as a separate batch.

3.2.19 Improper location controls/standards

Probable Cause(s)	Corrective Action(s)
The controls/standards location transmitted by a connected pipettor are invalid	Remove tray. Select correct pipetting protocol, or edit to agree with the PPC protocol.

3.2.20 Improper number of controls/standards. Remove this tray.

Probable Cause(s)	Corrective Action(s)
The Pipettor indicates to the PPC that any of the following conditions exist: A. The number of standards in a point to point assay controls tray is less than 2 or greater than 8. B. The number of replicates of controls in a cutoff assay controls tray is less than 1 or greater than 10. C. The number of positive controls in a cutoff assay controls tray was less than 1 or greater than 6 or the number of negative controls was greater than 6. D. If communicating with a TPC-compatible pipettor, the number of positive controls in a cutoff assay controls tray was less than 1 or greater than 10, or the number of negative controls was greater than 10.	Remove tray. Select correct pipetting protocol. Controls and standards are only allowed in the first tray.

3.2.21 Too many standards in this tray.

Probable Cause(s)	Corrective Action(s)
The Pipettor indicates that the (#STDS x #STD REPS) is greater than the tray size for a point to point assay controls tray.	Remove tray. Select correct pipetting protocol or edit to agree with the PPC protocol.

3.2.22 Invalid tray status from PIPETTOR.

Probable Cause(s)	Corrective Action(s)
The PIPETTOR reported invalid tray status.	Remove tray and check tray status from instrument of origin. A Valid Status on the FPC is “Active” or “Archived”. • If the status on the FPC™ is “Void”, manually void the tray on the PPC. • If the status on the FPC is “Busy”, wait for the tray status to be updated on the FPC.

3.2.23 The batch associated with the tray is not in an archived state. Please remove this tray.

Probable Cause(s)	Corrective Action(s)
Batch still in process.	Advisory.

3.2.24 Tray was locked in without being gated. Stuck entrance solenoid? CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Entrance solenoid stuck open (retracted).	A. Check solenoid for proper position. B. If problem persists, call Abbott Customer Support Center (CSC).

3.2.25 Multiple Matches of Assay List Number/Assay Procedure. Cannot Find Assay. Remove This Tray.

Probable Cause(s)	Corrective Action(s)
A tray exists on an attached pipettor and the Assay List Number/Assay Procedure matches multiple protocols on the PPC.	A. Remove the tray. B. Correct the edited assay’s List #/Procedure.

3.3.1 Size of tray does not match previously stored size.

Probable Cause(s)	Corrective Action(s)
On first pass, the PPC "measures" the tray to be a different size than that indicated by the pipettor.	A. If on first pass, verify tray size defined in the FPC™ assay protocol. B. Check tray for broken or worn webs, etc. C. Use bar code labels on trays to minimize mixing trays in the processing of assays.
On second, third, or fourth pass, the PPC "measures" the tray to be a different size than "measured" on first pass.	A. Verify the correct tray has been inserted. B. Check tray for broken or worn webs, etc. C. Use bar code labels on trays to minimize mixing trays in the processing of assays.
Tray has broken or worn webs, etc.	Call Abbott Customer Support Center (CSC).
	If no discernible problems exist, call Abbott Customer Support Center (CSC).

3.3.3 Tray XXXXXXX has been rejected. It will be voided. Press <ENTER> To Continue

Probable Cause(s)	Corrective Action(s)
Processing of tray failed.	A. Press **<Enter>** to continue. Tray will be voided. B. If problem persists, call Abbott Customer Support Center (CSC).

3.3.4 Tray XXXXXXX has been rejected. The batch will be voided. Press <ENTER> To Continue

Probable Cause(s)	Corrective Action(s)
Processing of controls or blanks tray failed.	A. Press **<Enter>** to continue. Tray will be voided. B. If problem persists, call Abbott Customer Support Center (CSC).

3.3.7 Wells XX-XX will be voided. TRAY XXXXXXX

Probable Cause(s)	Corrective Action(s)
Power down or mechanism failure occurred after processing had begun on the tray named.	Advisory message. No action is required. Any wells with questionable status will be voided.

3.3.7.1 INVALID READINGS IN TRAY XXXXXXXXXX WELLS VOIDED.

Probable Cause(s)	Corrective Action(s)
Well(s) failed check against calibration value during the OPD pass and was VOIDed.	A. Advisory message. B. If problem persists, repeat Calibration. (Refer to *Section 6, Calibration*.) C. If problem persists, change lamp. (Refer to *Section 9, Service and Maintenance*.) D. If problem persists, call Abbott Customer Support Center (CSC).

3.3.7.2. INSUFFICIENT BLANKS WELLS BLANKS TRAY XXXXXXXXXX VOIDED

Probable Cause(s)	Corrective Action(s)
Too many blank wells failed check against calibration value during the OPD pass. The blanks tray was VOIDed.	A. Verify procedure for preparing OPD reagent. B. Perform Calibration. (Refer to *Section 6, Calibration*.) C. If problem persists, call Abbott Customer Support Center (CSC).

3.3.7.3 Wells Y1-Y5 will be VOIDed Tray XXXXXXXXXX Wells exceeded OPD Dispense-Read time

Probable Cause(s)	Corrective Action(s)
Row was delayed too long between dispense and read on the OPD pass. The row was VOIDed.	Advisory message.

3.3.8 Do you want to continue processing those trays still in the PPC? (YES/NO)

Probable Cause(s)	Corrective Action(s)
The PPC lost power while one or more trays were in process, but tray status is known and they can be recovered.	A. Advisory message. Input **<Yes>** or **<No>**. B. When continuing to process, review the assay results and reconcile, per your lab's SOPs, any duplicate results that may have been generated for the tray that was in the process of being read.

3.3.9 This tray is active and may not be voided.

Probable Cause(s)	Corrective Action(s)
Attempting to void a tray in the instrument.	Wait to void until tray is out of the instrument.

3.3.10 Voiding this tray will cause the batch containing it to be voided. Do you wish to void tray? (YES/NO)

Probable Cause(s)	Corrective Action(s)
Attempting to void a controls tray or the blanks tray of a batch.	Advisory message. Input <Yes> or <No>.

3.3.11 Wrong step for blanks tray. Remove this tray.

Probable Cause(s)	Corrective Action(s)
Blanks tray inserted in the middle of a batch.	Advisory message. Remove blanks tray and wait until the start of its batch.

3.3.12 Wrong step for blanks tray: blanks tray will not be processed. Remove this tray.

Probable Cause(s)	Corrective Action(s)
A sample tray is inserted for a non-blanking processing pass after a blanks tray has already been inserted and is locked in waiting for the first tray of a batch on its blanking pass.	Advisory message. Blanks tray will be purged without processing.

3.3.13 Wrong blanks tray, Insert tray XXXXXXX. Remove this tray.

Probable Cause(s)	Corrective Action(s)
A blanks tray belonging to a different batch than the current one is inserted.	Advisory message. Remove tray and insert correct blanks trays.

3.3.14 Not all trays in this batch have completed the previous step. Remove this tray.

Probable Cause(s)	Corrective Action(s)
A sample tray is inserted before part of the batch to which it belongs has completed the previous processing step.	Advisory message.

3.3.15 Blanks tray not yet processed. Remove this tray.

Probable Cause(s)	Corrective Action(s)
Blanks tray has not yet gone through necessary steps preceding the final read step of the inserted sample tray.	Advisory message.

3.3.16 Blanks tray not yet processed. Remove this tray.

Probable Cause(s)	Corrective Action(s)
The first tray of a batch on its blanking pass was inserted without inserting a blanks tray first.	Advisory message. Insert blanks tray then continue processing.

3.3.17 Trays out of sequence. Insert tray XXXXXXX. Remove this tray.

Probable Cause(s)	Corrective Action(s)
A tray was inserted in different sequence than originally inserted.	Advisory message. Make sure trays are inserted in the same order as first pass.

3.3.19 This tray is NOT a blanks tray. Remove this tray.

Probable Cause(s)	Corrective Action(s)
A previously identified sample tray was inserted after pressing the BLANK key.	Advisory message.

3.3.20 This tray does NOT belong to the current batch. Remove this tray.

Probable Cause(s)	Corrective Action(s)
A tray was inserted with trays from a different batch.	Advisory message.

3.3.21 No blanks wells allowed in a sample tray. Remove this tray.

Probable Cause(s)	Corrective Action(s)
The Pipettor indicates there are blanks in a sample tray that should not have blanks.	Advisory message.

3.3.22 Tray XXXXXXXXXX too early. Remove this tray.

Probable Cause(s)	Corrective Action(s)
Tray inserted for final pass before minimum OPD incubation time has elapsed	Remove tray and incubate OPD per Package Insert.

3.3.24 Tray or batch data is no longer stored in the database. Remove this tray.

Probable Cause(s)	Corrective Action(s)
Attempting to reread a tray which is not in the database.	Advisory message.

3.3.25 Cannot find assay. Remove this tray.

Probable Cause(s)	Corrective Action(s)
Unsuccessful attempt to find the assay associated with the archived tray inserted for reread.	Advisory message.

3.3.26 This batch will be truncated to contain only those trays inserted previously.

Probable Cause(s)	Corrective Action(s)
A communication link failure occurred and NO was pressed.	Advisory message.

3.3.27 No more blanks trays allowed for this batch. Remove this tray.

Probable Cause(s)	Corrective Action(s)
Attempting to add more than one blanks tray to the batch.	Advisory message.

3.3.28 Specified batch size will not fit in the database. Remove this tray.

Probable Cause(s)	Corrective Action(s)
When starting a batch, the number of trays in batch entered will not fit in the database (too many trays in batch).	Advisory message. Remove unneeded trays from the database (40 trays maximum allowed). Refer to *Section 5, Operating Instructions.*

3.3.29 Batch may not be truncated with tray at entrance.

Probable Cause(s)	Corrective Action(s)
Attempting to truncate batch while a tray is on the entrance switch.	Advisory message.

3.3.30 There is no active batch to be truncated.

Probable Cause(s)	Corrective Action(s)
Attempting to truncate batch which is not in the process of being run.	Advisory message.

3.3.31 Pipettor communications link failure. Tray XXXXXXXXXX may not be archived.

Probable Cause(s)	Corrective Action(s)
The PPC attempted to archive a tray on the Pipettor, but got a communications failure or found that the tray no longer exists in the Pipettor database.	A. Check status of the Pipettor. Make sure the software application is running. B. Check communication cables. C. Manually archive tray on the Pipettor. D. Check tray status on the Pipettor.

3.3.32 Batch may not be truncated since all trays have been inserted.

Probable Cause(s)	Corrective Action(s)
Attempting to truncate batch during second, third, or fourth pass.	Advisory message.

3.3.34 Tray voiding not allowed during reprocessing.

Probable Cause(s)	Corrective Action(s)
Attempting to void a tray during reprocessing after power up.	Advisory message.

3.3.35 Control/standard wells voided. Do you wish to continue processing (YES/NO)?

Probable Cause(s)	Corrective Action(s)
A row containing controls or standards was voided by the PPC.	Requires operator input of **<Yes>** or **<No>**. **<Yes>** continues batch processing, **<No>** halts processing and voids the batch.

3.3.36 Tray contains no active wells. Tray voided: XXXXXXX

Probable Cause(s)	Corrective Action(s)
All wells of the tray are either empty and/or void.	Advisory message.

3.4.1 INTERNAL SYSTEM ERROR: Communication status fault. Press <Enter> to Continue

Probable Cause(s)	Corrective Action(s)
Unrecognized internal communication.	A. If the tray is at the entrance, remove and reinsert after pressing **<Enter>**. B. If problem persists, call Abbott Customer Support Center (CSC).

3.4.2 INTERNAL SYSTEM ERROR: Task ID fault. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Unrecognized internal communication.	A. Turn power switch off, wait 30 seconds, then turn back on. B. If problem persists, call Abbott Customer Support Center (CSC).

3.4.3 INTERNAL SYSTEM ERROR: Assay interpreter send message error. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Internal communication backlog.	A. Turn power switch off, wait 30 seconds, then turn back on. B. If problem persists, call Abbott Customer Support Center (CSC).

3.4.4 Pipettor Communications link failure Do you wish to retry? (YES/NO)

Probable Cause(s)	Corrective Action(s)
A communication link failure occurred while the PPC was accessing assay data from a pipettor.	A. Check status of instruments and cable between instruments. B. Retry communications link.

3.4.5 Space not available for new tray. Remove this tray.

Probable Cause(s)	Corrective Action(s)
Attempting to add a tray to the database failed because the database is full.	Advisory message. Remove unneeded trays from the database. Refer to *Section 5, Operating Instructions*.

3.4.6 Space not available for new batch. Remove this tray.

Probable Cause(s)	Corrective Action(s)
Attempting to add a batch to the database failed because the database is full.	Advisory message. Remove unneeded trays from the database. Refer to *Section 5, Operating Instructions*.

3.4.7 Reread Disabled

Probable Cause(s)	Corrective Action(s)
Attempted to reread a tray while Reread function is disabled.	Remove tray. Enable Reread function if it is required.

3.5.1 CALIBRATION ABORTED! Error during Processing Press <ENTER> to continue.

Probable Cause(s)	Corrective Action(s)
Mechanical error or power failure during Calibration tray processing.	Correct error and restart processing of the Calibration tray.

3.5.2 CALIBRATION ABORTED! Incorrect tray size Press <ENTER> to continue.

Probable Cause(s)	Corrective Action(s)
Wrong size tray was inserted for calibration processing.	Restart calibration processing with the proper size tray.

3.5.3 Instrument not calibrated Calibrate before processing Assays. Remove this tray.

Probable Cause(s)	Corrective Action(s)
Attempting to process trays before completing a successful calibration.	Perform a successful calibration.

3.5.5 Calibration checksum failure. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
The calibration data has been corrupted.	A. Turn power off, wait 30 seconds, then turn power back on. Run a new Calibration tray and resume processing. B. If problem persists, call Abbott Customer Support Center (CSC).

5.1.1 Multiple Communicating Types Found. Disconnect Differing Instruments. Press <ENTER> to Continue

Probable Cause(s)	Corrective Action(s)
Instruments using different communications protocols or TPC™ and non-TPC instruments were connected simultaneously to the PPC.	A. Press **<Enter>**. The display returns to the Instrument Configuration screen. B. Check status of instruments for proper communications mode.

5.1.2 Communications Link Failure. Port: n, n, n, n. Press <ENTER> to Continue

Probable Cause(s)	Corrective Action(s)
A transmission or expected reception could not be completed and will be retried at each available port until connected.	A. Check status of instruments for proper communications mode. B. Check communications cables are properly connected. C. Check that instrument power is on. D. If necessary, configure the PPC to eliminate the failed port.

5.1.3 Multiple Responses from Pipettors. Duplicate Tray ID: xxxxxxxxxx. Press <ENTER> to Continue

Probable Cause(s)	Corrective Action(s)
Tray ID is not unique, as more than one connected instrument has information on the tray.	Remove tray and delete the invalid tray number(s) on all but one connected instrument.

5.1.4 Hardware Communications Failure. Port: n. Press <ENTER> to Continue

Probable Cause(s)	Corrective Action(s)
Hardware failure was detected during auto-configuration.	A. Press **<Enter>**. The display returns to the Instrument Configuration screen and retry. B. If problem persists, call Abbott Customer Support Center (CSC).

5.1.5 Instrument NOT Supported. Disconnect Unsupported Instruments. Press <ENTER> to Continue

Probable Cause(s)	Corrective Action(s)
A non-FPC or non-compatible instrument was encountered during auto-configuration.	Disconnect instrument.

5.1.6 Invalid Message Format. Press <ENTER> to Continue

Probable Cause(s)	Corrective Action(s)
An invalid message format or field size too large has been detected per the TPC™ communications protocol.	A. Verify proper function of connected instrument. B. If problem persists, call Abbott Customer Support Center (CSC).

5.1.7 Incorrect Communications Response. Press <ENTER> to Continue

Probable Cause(s)	Corrective Action(s)
An invalid message type was detected per the TPC communications protocol.	A. Verify proper function of connected instrument. B. If problem persists, call Abbott Customer Support Center (CSC).

5.1.8 INTERNAL SYSTEM ERROR. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
The communications structure has been corrupted.	A. Turn off power, wait 30 seconds, then turn power back on. B. If problem persists, call Abbott Customer Support Center (CSC).

6.1.2.1 Internal database error-invalid. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Error during database exchange.	A. Record error # and status #. B. Turn power switch off, wait 30 seconds, then turn back on. C. If problem persists, call Abbott Customer Support Center (CSC).
When using an edited protocol and processing in TPC Verify or Record mode, more than 12 tray components or 12 batch components were registered.	PPC does not support more than 12 tray or batch components. A. Re-edit the assay protocol on both the FPC™ and PPC to limit tray components and batch components to 12 each. B. Reprocess the samples.

6.1.2.5 Cannot print-does not exist.

Probable Cause(s)	Corrective Action(s)
Attempting to print a protocol for an assay not on the system.	Advisory message.

6.1.2.6 Invalid ID-does not exist.

Probable Cause(s)	Corrective Action(s)
The tray to be manipulated in the Tray Tools Mode is not in the database.	Advisory message.

6.1.2.7 Cannot void-in use

Probable Cause(s)	Corrective Action(s)
Attempt to void wells while tray was in process.	Advisory message.

6.1.2.8 Invalid assay number-does not exist.

Probable Cause(s)	Corrective Action(s)
Tray tools assay assigned to tray not found.	Select valid assay #.

6.1.2.9 Printer in use-cannot print.

Probable Cause(s)	Corrective Action(s)
Printer busy.	Advisory message.

6.1.3 Can not void-four blanks required. Press <ENTER> to continue.

Probable Cause(s)	Corrective Action(s)
Attempting to void a blank well required for processing.	Advisory message.

6.1.3.1 Cannot void-well not filled.

Probable Cause(s)	Corrective Action(s)
Attempting to void an empty well.	Advisory message.

6.1.3.2 Well already voided.

Probable Cause(s)	Corrective Action(s)
Attempting to void a well that's already been voided.	Advisory message.

6.1.4.1 Invalid entry.

Probable Cause(s)	Corrective Action(s)
Keying in ID numbers, entry out of range.	Check valid range of entry.

6.1.4.2 Illegal operation-tray in process.

Probable Cause(s)	Corrective Action(s)
Attempting to perform reader verification while a tray is being processed.	Advisory message.

6.1.4.5 No Calibration Data.

Probable Cause(s)	Corrective Action(s)
Calibration printout requested before calibrating instrument.	Advisory message.

6.1.4.6 Calibration checksum failure. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
The calibration data has been corrupted.	A. Turn power off, wait 30 seconds, then turn power back on. Run a new Calibration tray and resume processing. B. If problem persists, call Abbott Customer Support Center (CSC).

6.1.5.1 Cannot enter patient IDs until all trays finish the first step.

Probable Cause(s)	Corrective Action(s)
Manually entering patient IDs before first pass of batch is complete.	Advisory message.

6.1.6.3 Cannot Delete Open Batch

Probable Cause(s)	Corrective Action(s)
Attempting to delete an active batch.	Advisory message.

6.1.6.4 Cannot Download.

Probable Cause(s)	Corrective Action(s)
Attempt to perform program download when not allowed.	Advisory message.

6.1.7.1 Retransmit Disabled

Probable Cause(s)	Corrective Action(s)
A Retransmit has been attempted and the Retransmit Option is disabled.	Enable the Retransmit option. Refer to *Section 2, Installation Procedures and Special Requirements*.

6.1.7.2 Illegal Operation – Batch In Process. Press <Enter> to Continue

Probable Cause(s)	Corrective Action(s)
A Retransmit has been attempted and a batch is currently being processed, either with trays in the instrument or the instrument is waiting for the rest of the batch to be inserted.	A. Press **<Enter>**. The screen returns to the Batch Tools menu. B. Reselect Retransmit after completing final pass of the batch.

6.1.7.3 Illegal Operation – Batch Not Completed. Press <Enter> to Continue

Probable Cause(s)	Corrective Action(s)
A Retransmit has been attempted and a valid tray ID has been entered whose batch is currently being processed and is not yet archived.	A. Press **<Enter>**. The display returns to the Batch Tools menu. B. Reselect Retransmit after completing final pass of the batch.

6.1.7.4 Illegal Operation – Batch Void. Press <Enter> to Continue

Probable Cause(s)	Corrective Action(s)
A Retransmit has been attempted and a valid tray ID has been entered whose batch is void (all trays in the batch are voided.)	A. Press **<Enter>**. The display returns to the Batch Tools menu. B. Voided batch cannot be retransmitted.

6.1.7.5 Illegal Operation – Batch Modified. Press <Enter> to Continue

Probable Cause(s)	Corrective Action(s)
A Retransmit has been attempted and a valid tray ID has been entered whose batch has had a status change since the last read.	A. Press **<Enter>**. The display returns to the Batch Tools menu. B. Modified Batch cannot be retransmitted.

6.1.8.1 Cannot Assign Barcode Reader Port. Port 4 Not Available. Press <ENTER> to continue.

Probable Cause(s)	Corrective Action(s)
The External BCR option was selected while another instrument was configured to Port 4.	A. Press **<Enter>**. The display returns to the DMS/Ext. BCR screen. B. Select DMS and Port Ø. C. Reselect Ext. BCR and Port 4. D. Set mechanical switch to BCR.

6.2.1.1 No TPC capable instruments connected. Press <ENTER> To Continue

Probable Cause(s)	Corrective Action(s)
There is no place to store TPC component information because an FPC™ pipettor, version 2.5 or greater, is not connected.	Connect an FPC pipettor, version 2.5 or greater.

6.2.1.2 Illegal Operation – Lot number exists: wwwwwwwwww. Press <ENTER> To Continue

Probable Cause(s)	Corrective Action(s)
You have attempted the Reconstitution Procedure and the resultant mixture lot number entered already exists on a connected FPC pipettor, version 2.5 or greater.	Enter unique resultant mixture lot number.

6.2.1.3 Tray not found. Tray ID: wwwwwwwwww. Press <ENTER> To Continue

Probable Cause(s)	Corrective Action(s)
Tray ID entered was not found on any Pipettor.	• Enter correct tray ID. or • Verify communication to connected instruments.

6.2.1.4 Invalid tray type from Pipettor. Tray ID: wwwwwwwwww. Press <ENTER> To Continue

Probable Cause(s)	Corrective Action(s)
Tray ID entered does not belong to a valid (20 or 60 well) tray.	Enter correct tray ID. A 20-well or 60-well tray must be used.

6.2.1.5 Invalid tray status from Pipettor. Tray ID: wwwwwwwwww. Press <ENTER> To Continue

Probable Cause(s)	Corrective Action(s)
Tray ID entered was NOT available (Busy or Void).	A. Enter correct tray ID. B. Tray ID must have a status of Active or Archived. C. Tray must not currently be processed on another PPC.

6.2.1.6 Illegal Operation – TPC mode OFF. Tray ID: wwwwwwwwww. Press <ENTER> To Continue

Probable Cause(s)	Corrective Action(s)
TPC™ mode of the tray ID entered is OFF.	Information entered in the Bead Drop Procedure can only be used in Record or Verify modes.

6.2.1.7 Warning – Master Lot expired. Do you wish to continue (YES/NO)

Probable Cause(s)	Corrective Action(s)
The master lot of the tray has expired.	Confirm that you are using the correct lot number. • Press YES to continue the operation. • Press NO to return to enter a new tray ID.

6.2.1.8 Illegal Operation – [Type] data exists. Tray ID: wwwwwwwwww. Press <ENTER> To Continue

Probable Cause(s)	Corrective Action(s)
Bead data currently exists for the tray ID entered.	Enter correct tray ID.
Component [TYPE] data currently exists for the tray ID entered.	Void the affected tray.

6.2.1.9 Lot Number not found – xxxxxxxxxx. Press <ENTER> To Continue

Probable Cause(s)	Corrective Action(s)
The lot number entered was not found on any TPC™-capable instrument.	• Enter correct lot number. **NOTE:** Non Master Lot component data must be registered on all FPC™ systems within a cluster. or • If a deviation password has been defined, acknowledge the deviation with a valid password and continue processing. **DEV 03** will be documented on the final results.

6.2.1.10 Illegal Operation – Invalid component type. Press <ENTER> To Continue

Probable Cause(s)	Corrective Action(s)
The component type entered was not Bead for Controls/Standards/Sample trays, or Blank Bead for Blanks or Calibrate trays.	Enter valid lot number.

6.2.1.11 Illegal Operation – List # mismatch. Press <ENTER> To Continue

Probable Cause(s)	Corrective Action(s)
The list number of the component does not match the list number of the tray master lot.	Enter valid lot number.

6.2.1.12 [Type] Lot Expired – xxxxxxxxxx. Press <ENTER> To Continue

Probable Cause(s)	Corrective Action(s)
The master lot or component lot number entered has expired.	• Correct and re-enter a valid lot number. or • If a deviation password has been defined, acknowledge the deviation with a valid password and continue processing. **DEV 01** will be documented on the final results.

6.2.1.13 Master Lot mismatch. Press <ENTER> To Continue

Probable Cause(s)	Corrective Action(s)
The master lot of the component lot number entered does not match the master lot of the tray.	• Correct and re-enter a valid lot number. or • If a deviation password has been defined, acknowledge the deviation with a valid password and continue processing. **DEV 04** or **DEV 05** (if the component is expired) will be documented on the final results.

6.2.1.14 Registration of component used failed. Press <ENTER> To Continue

Probable Cause(s)	Corrective Action(s)
The PPC instrument's attempt to record the component used information for the Bead Drop Procedure in the TPC™ Pipettor's database failed.	• Verify communications with connected instruments. • Re-enter component lot number.

6.2.1.15 Unable to validate. Press <ENTER> To Continue

Probable Cause(s)

- The PPC was unable to communicate with a TPC™ Pipettor during the Bead Drop Procedure.
- The Bead Drop Procedure was performed on a Blanks Tray when the PPC was connected to a compatible (non-FPC™) pipettor or when operating in Stand Alone mode.

Corrective Action(s)

For Control/Standard/Sample trays:

- Verify communications with connected instruments.
- Re-enter component lot number.

For Blanks tray:

- Status code NV may be applied to the Blanks Bead on the final results.

6.2.1.16 Illegal Operation – Invalid mixture. Press <ENTER> To Continue

Probable Cause(s)

Connected FPC instruments were unable to validate the requested information during the Reconstitution Procedure.

Corrective Action(s)

- Verify that both constituent lot numbers exist on FPC and can be combined.
- Re-enter constituent lot numbers.

6.2.1.17 Warning – Master Lot mismatch. Do you wish to continue (YES/NO)

Probable Cause(s)

The constituent components entered were found in different master lots.

Corrective Action(s)

A. Press YES to continue processing. When using a resultant mixture, PPC will warn that a deviation will occur.

B. Press NO to return to enter a valid lot number.

6.2.1.18 Warning – Mixture expired. Do you wish to continue (YES/NO)

Probable Cause(s)

The resultant component entered has expired.

Corrective Action(s)

A. Press YES to continue processing. When using a resultant mixture, PPC will warn that a deviation will occur.

B. Press NO to return to enter a valid lot number.

6.2.1.19 Warning – Mixture not registered. Press <ENTER> To Continue

Probable Cause(s)

An FPC could not be accessed to register the resultant mixture.

Corrective Action(s)

Reconstitution is complete. PPC will document **Dev 03** on final results.

6.2.1.20 Warning – Mixture registration failed. Port n. Press <ENTER> To Continue

Probable Cause(s)	Corrective Action(s)
An FPC™ found the constituent components comprising a resultant mixture in its database but could not register the resultant mixture.	Reconstitution is complete. PPC may document **Dev 03** on final results.

6.2.1.21 Blanks bead drop store full. Press <ENTER> To Continue

Probable Cause(s)	Corrective Action(s)
The PPC was unable to add another record to the Blanks tray Bead Drop store.	Delete appropriate Blanks trays from Bead Drop store.

6.2.1.22 This tray is NOT a Blanks tray. Press <ENTER> To Continue

Probable Cause(s)	Corrective Action(s)
The tray ID of the Blanks tray was found in the tray database to be a Control/ Standard/Sample type tray.	Process tray as a Control/Standard/Sample type tray. Enter Blanks tray ID.

6.2.1.29 INTERNAL SYSTEM ERROR External Barcode Reader Status Fault. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
External bar code reader task reports a fault status of not configured.	A. Turn power off, wait 30 seconds, then turn power back on. B. If problem persists, call Abbott Customer Support Center (CSC).

6.2.1.30 Illegal Operation – Master Lot not found:xxxxxxxxxx. Press <ENTER> To Continue

Probable Cause(s)	Corrective Action(s)
Tray's Master Lot cannot be found on the pipettor.	• Enter correct tray ID. or • If a deviation password has been defined, acknowledge the deviation with a valid password and continue processing. **DEV 02** will be documented on the final results.

6.3.1.1 Protocol Select option not available in current communication mode

Probable Cause(s)	Corrective Action(s)
An attempt was made to use the Protocol Select option when the option was not available.	Advisory message.

7.1 Barcode error-Character count wrong

Probable Cause(s)	Corrective Action(s)
Insufficient number of characters read on bar code label.	Reconfigure bar code length to correct number of characters.

7.2 Barcode error-Illegal Barcode Type.

Probable Cause(s)	Corrective Action(s)
Bar code label not Codabar, Code 39, Code 128, or Interleaved 2 of 5.	Bar code type must be Codabar, Code 39, Code 128, or Interleaved 2 of 5. Check PPC configuration.

7.3 Barcode error-Illegal Task ID. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Based on the requesting Task ID, the external or internal bar code reader was unable to decode where to send incoming data.	A. Turn power off, wait 30 seconds, then turn back on B. If problem persists, call Abbott Customer Support Center (CSC).

7.4 Barcode error-Bitbus User Error. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
The external bar code reader was unable to create a user ID.	A. Turn power off, wait 30 seconds, then turn power back on. B. If problem persists, call Abbott Customer Support Center (CSC).

7.5 Barcode error-Bitbus Connection Error. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
The external bar code reader was unable to create a bitbus connection.	A. Turn power off, wait 30 seconds, then turn power back on. B. If problem persists, call Abbott Customer Support Center (CSC).

7.6 External Barcode Not Configured

Probable Cause(s)	Corrective Action(s)
The external bar code reader is not configured and a read request was made.	Configure the external bar code reader.

8.1.1.1 Printer in use-cannot print.

Probable Cause(s)	Corrective Action(s)
Attempt to print further information while printer is in use.	Advisory message.

8.1.1.2 Current assay must first be saved or deleted.

Probable Cause(s)	Corrective Action(s)
Attempting to edit an assay protocol before saving a previously changed assay protocol.	Advisory message.

8.1.1.3 Assay not found.

Probable Cause(s)	Corrective Action(s)
Invalid assay number specified for editing.	Advisory message.

8.1.1.4 Assay Not-Editable. Number must be non-Abbott Use LIST ASSAY key.

Probable Cause(s)	Corrective Action(s)
Assay number must be non-Abbott.	Advisory message.

8.1.1.5 No new assay locations available.

Probable Cause(s)	Corrective Action(s)
Attempt to add or change assay with full memory.	Advisory message.

8.1.1.6 This assay is in use. It cannot be edited now.

Probable Cause(s)	Corrective Action(s)
Attempted to edit an assay protocol currently in use for a batch in progress.	Advisory message.

8.1.1.7 Invalid entry.

Probable Cause(s)	Corrective Action(s)
Keyed in data out of range.	Advisory message. Check valid data range.

8.1.1.8 Fatal assay database error. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Database error.	A. Turn power switch off, wait 30 seconds, then turn back on. B. If problem persists, call Abbott Customer Support Center (CSC).

8.1.1.9 Assay consistency error-duplicate bottle positions.

Probable Cause(s)	Corrective Action(s)
When editing, the same dispense station was used twice in the same assay.	Re-edit to avoid using the same dispense station.

8.1.1.10 Assay consistency error-OPD & quench dispense required.

Probable Cause(s)	Corrective Action(s)
You have edited an assay protocol which does not contain OPD or acid.	Re-edit to include OPD and acid.

8.1.1.11 Assay consistency error-elapsed times mismatch.

Probable Cause(s)	Corrective Action(s)
Assay protocol has been edited with minimum incubation time greater than maximum incubation time.	Re-edit to correct timings.

8.1.1.12 Assay consistency error-controls not adjacent

Probable Cause(s)	Corrective Action(s)
All control wells must be contiguous and non-overlapping.	Re-edit control well position.

8.1.1.13 Assay consistency error-standards concentration mismatch.

Probable Cause(s)	Corrective Action(s)
Edited standard concentrations are not continuously increasing or decreasing.	Re-edit standard concentrations.

8.1.1.14 Negative Control MIN Absorbance is larger than the MAX Absorbance.

Probable Cause(s)	Corrective Action(s)
Assay protocol edited with negative control minimum absorbance greater than the maximum absorbance.	Re-edit to correct absorbances.

8.1.1.15 Positive Control MIN Absorbance is larger than the MAX Absorbance.

Probable Cause(s)	Corrective Action(s)
Assay protocol edited with positive control minimum absorbance greater than the maximum absorbance.	Re-edit to correct absorbances.

8.1.1.16 Positive Negative MIN Difference larger than the MAX Difference.

Probable Cause(s)	Corrective Action(s)
Assay protocol edited with positive control–negative control (P–N) minimum difference greater than the maximum difference.	Re-edit (P–N) control difference.

8.1.1.18 Standard Number inconsistent with the number of Standards.

Probable Cause(s)	Corrective Action(s)
The standard chosen for minimum and maximum mean absorbance check is not within the Number of Standards.	Re-edit Standard Number so it is within the Number of Standards.

8.1.1.19 Difference Standard A inconsistent with number of Standards.

Probable Cause(s)	Corrective Action(s)
Assay protocol edited, with the difference Standard A inconsistent with the number of standards.	Re-edit the difference Standard A to be consistent.

8.1.1.20 Difference Standard B inconsistent with number of Standards.

Probable Cause(s)	Corrective Action(s)
Assay protocol edited with the difference Standard B inconsistent with the number of standards.	Re-edit the difference Standard B to be consistent.

8.1.1.21 Ratio 1 Standard A inconsistent with number of Standards.

Probable Cause(s)	Corrective Action(s)
Assay protocol edited with the Ratio 1 Standard A inconsistent with the number of standards.	Re-edit Ratio 1 to be consistent with the Number of Standards.

8.1.1.22 Ratio 1 Standard B inconsistent with number of Standards.

Probable Cause(s)	Corrective Action(s)
Assay protocol edited with the Ratio 1 Standard B inconsistent with the number of standards.	Re-edit Ratio 1 to be consistent with the Number of Standards.

8.1.1.23 Ratio 2 Standard C inconsistent with number of Standards.

Probable Cause(s)	Corrective Action(s)
Assay protocol edited with the Ratio 2 Standard C inconsistent with the number of standards.	Re-edit Ratio 2 to be consistent with the Number of Standards.

8.1.1.24 Ratio 2 Standard D inconsistent with number of Standards.

Probable Cause(s)	Corrective Action(s)
Assay protocol edited with the Ratio 2 Standard D inconsistent with the number of standards.	Re-edit Ratio 2 to be consistent with the Number of Standards.

8.1.1.25 Mean Absorbance MIN larger than the MAX mean absorbance.

Probable Cause(s)	Corrective Action(s)
Assay protocol edited with mean absorbance minimum greater than maximum mean absorbance.	Re-edit mean absorbance value.

8.1.1.26 Absorbance MIN larger than the MAX absorbance.

Probable Cause(s)	Corrective Action(s)
Assay protocol edited with absorbance minimum greater than maximum absorbance.	Re-edit absorbance min and max.

8.1.1.27 Ratio-1 MIN larger than the MAX Ratio-1.

Probable Cause(s)	Corrective Action(s)
Assay protocol edited with Ratio 1 minimum greater than maximum Ratio 1.	Re-edit Ratio 1 min and max.

8.1.1.28 Ratio-2 MIN larger than the MAX Ratio-2.

Probable Cause(s)	Corrective Action(s)
Assay protocol edited with Ratio 2 minimum greater than maximum Ratio 2.	Re-edit Ratio 2 min and max.

8.1.1.31 Illegal operation-tray in process. Press <ENTER> to continue.

Probable Cause(s)	Corrective Action(s)
Attempting to save an edited assay while trays are in process.	Press **<Enter>** to continue. Wait until processing is complete to save edited assay.

8.1.1.32 Assay data corrupted. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Software checksums failed.	A. Turn power switch off, wait 30 seconds, then turn back on. B. If problem persists, call Abbott Customer Support Center (CSC).

8.1.1.33 PC2 MIN. absorbance is larger than the MAX. absorbance.

Probable Cause(s)	Corrective Action(s)
Assay protocol edited with positive-2 control minimum absorbance greater than the maximum absorbance.	Re-edit positive control min and max absorbance.

8.1.1.34 PC2 MIN difference is larger than the MAX difference.

Probable Cause(s)	Corrective Action(s)
Assay protocol edited with positive-2 control minimum difference greater than the maximum difference.	Re-edit positive-2 control min and max difference.

8.1.1.35 Blank Check MIN. Difference is larger than the MAX. Difference. Press <ENTER> to continue.

Probable Cause(s)	Corrective Action(s)
Assay protocol edited with Blank Check minimum difference greater than the maximum difference.	Re-edit Blank Check min and max difference.

8.1.1.36 Assay List Number/Assay Procedure Combination Not Unique. Press <ENTER> to Continue

Probable Cause(s)	Corrective Action(s)
Attempt to save an edited assay protocol Assay List Number/Assay Procedure is not unique.	Enter a unique Assay List Number/Assay Procedure.

8.1.1.37 Incorrect Password. Press <ENTER> to Return to Edit

Probable Cause(s)	Corrective Action(s)
During an Abbott Delete procedure, the password entered does not match.	Press **<Enter>** to return to the Edit Protocol Menu screen, then re-enter the correct password.

8.1.1.38 Incorrect Code. Press <ENTER> to Return to Edit

Probable Cause(s)	Corrective Action(s)
During an Abbott Delete procedure, the assay-specific code entered is incorrect.	Press **<Enter>** to return to the Edit Protocol Menu screen, then re-enter the correct code.

8.1.1.39 This Assay is in use. Press <ENTER> to Return to Edit

Probable Cause(s)	Corrective Action(s)
During an Abbott Delete procedure, the assay-specific code entered matches an assay currently in use.	Press **<Enter>** to return to the Edit Protocol Menu screen. To delete this assay, repeat the Abbott Delete procedure when the assay has been completed.

8.1.1.42 Assay Upload Failure: nnnn Press <ENTER> to Continue

Probable Cause(s)	Corrective Action(s)
The PPC has failed to add an Abbott-supplied assay protocol you have attempted to upload via the keyboard or bar code reader.	Press **<Enter>** to return to the Edit Protocol Menu screen and try again. If the error persists, record the status number and call Abbott Customer Support Center (CSC).

8.1.1.43 No New Assay Locations Available Press <ENTER> to Continue

Probable Cause(s)	Corrective Action(s)
The assay memory of the PPC, which has a location capacity for 99 assays, is full. **NOTE:** This can occur even if you have deleted assays because, though deleted assays are removed from the menu, their location is not released.	Press **<Enter>** to return to the Edit Protocol Menu screen. Assay locations are released from memory when software is reloaded. Call Abbott Customer Support Center (CSC) for assistance. **NOTE:** Since this procedure will delete any edited assays your lab has created, be sure to print out those assay protocols so you can re-enter them when software reloading is complete.

8.1.1.44 Assay nn exists Press <ENTER> to Continue

Probable Cause(s)	Corrective Action(s)
The assay number of the assay you are trying to upload is already in use by the system.	A. Press **<Enter>** to return to the Edit Protocol Menu screen. B. Print the assay directory to find out which assay is occupying the location. • If an edited assay, re-edit the assay to change its assay number, then continue with uploading. • If a duplicate of the assay being uploaded, do not continue uploading.

8.1.2 Assay save was unsuccessful. Do you wish to retry? (Yes/No)

Probable Cause(s)	Corrective Action(s)
• Defective memory • Hardware problem	A. Select NO if you do not wish to retry. B. Select YES to retry. C. If problem persists, call Abbott Customer Support Center (CSC).

8.1.2.1 Assay number reserved for future use.

Probable Cause(s)	Corrective Action(s)
Assay number is reserved for future use.	Assign different assay number to user assay.

9.1.1.1 Tray database error. Press <ENTER> To Continue

Probable Cause(s)	Corrective Action(s)
Tray database error.	A. Press **<Enter>** to continue. B. Turn power switch off, wait 30 seconds, then turn back on. C. If problem persists, call Abbott Customer Support Center (CSC).

9.1.1.2 Tray database error - Not Found. Press <ENTER> to continue.

Probable Cause(s)	Corrective Action(s)
Tray ID not found in database.	A. Advisory message. B. If problem persists, call Abbott Customer Support Center (CSC).

9.1.1.4 Tray database error-write. Press <ENTER> To Continue

Probable Cause(s)	Corrective Action(s)
Bad status from database when updating tray well status.	A. Press **<Enter>** to continue. B. Turn power switch off, wait 30 seconds, then turn back on. C. If problem persists, call Abbott Customer Support Center (CSC).

9.1.1.5 Tray database error-read. Press <ENTER> To Continue

Probable Cause(s)	Corrective Action(s)
Unsuccessful attempt to read a tray.	A. Press **<Enter>** to continue. B. Turn power switch off, wait 30 seconds, then turn back on. C. If problem persists, call Abbott Customer Support Center (CSC).

9.1.1.6 Batch data base error-read. Press <ENTER> To Continue

Probable Cause(s)	Corrective Action(s)
Unsuccessful attempt to read a batch.	A. Press **<Enter>** to continue. B. Turn power switch off, wait 30 seconds, then turn back on. C. If problem persists, call Abbott Customer Support Center (CSC).

9.1.1.10 Assay database error-read. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Unsuccessful attempt to read an assay.	A. Turn power switch off, wait 30 seconds, then turn back on. B. If problem persists, call Abbott Customer Support Center (CSC).

9.1.1.11 Internal error-bad command to PAT IDS. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Patient IDs read; invalid command in communication.	A. Turn power switch off, wait 30 seconds, then turn back on. B. If problem persists, call Abbott Customer Support Center (CSC).

9.1.1.12 Internal error-bad task ID to PAT IDS. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Invalid task ID in command message.	A. Turn power switch off, wait 30 seconds, then turn back on. B. If problem persists, call Abbott Customer Support Center (CSC).

9.1.1.13 Can't get sample IDs on Tray XXXXXXX Check Pipettor connections or modes.

Probable Cause(s)	Corrective Action(s)
External communication error.	Check the Pipettor communication cables.

9.1.1.15 ID database full-no IDs will be available for this tray.

Probable Cause(s)	Corrective Action(s)
Database limit is 40 trays.	A. Advisory message. After a short pause, tray will continue processing without sample IDs. B. Turn power switch off, wait 30 seconds, then turn back on. C. If problem persists, call Abbott Customer Support Center (CSC).

9.1.1.16 PIPETTOR response for unexpected tray.

Probable Cause(s)	Corrective Action(s)
Wrong tray ID from external message.	Advisory message.

9.1.1.17 PIPETTOR sample ID collection was terminated.

Probable Cause(s)	Corrective Action(s)
Tray was removed from database.	Advisory message.

9.1.1.18 WARNING: Entered ID(s) will overwrite existing ID(s) starting with well xxxx. Do you want to continue (Yes/No)?

Probable Cause(s)	Corrective Action(s)
Manually entering ID over existing ID.	**Yes** = Advisory message. **No** = Manually enter correct location for sample ID.

9.1.1.20 Controls or standards cannot fit into one tray. Please void this batch.

Probable Cause(s)	Corrective Action(s)
Too many controls/standards for one tray.	Advisory message.

9.1.1.21 Internal error-state table. Press <ENTER> To Continue

Probable Cause(s)	Corrective Action(s)
Software error.	1. Press **<Enter>** to continue. 2. Let trays in process finish. 3. Turn power off, wait 30 seconds, then turn back on. 4. If problem persists, call Abbott Customer Support Center (CSC).

9.1.1.22 Internal error - action table. Press <ENTER> To Continue

Probable Cause(s)	Corrective Action(s)
Internal systems error.	1. Press **<Enter>** to continue. 2. Let trays in process finish. 3. Turn power off, wait 30 seconds, then turn back on. 4. If problem persists, call Abbott Customer Support Center (CSC).

9.1.1.23 Sample IDs may only be assigned to sample wells.

Probable Cause(s)	Corrective Action(s)
Attempt to assign ID a standard or control.	Advisory message.

9.1.1.24 Non-numeric parts of starting ID and ending ID do not match.

Probable Cause(s)	Corrective Action(s)
Manual ID entry invalid.	Advisory message. Re-enter valid data.

9.1.1.25 Starting ID must be numerically smaller than ending ID

Probable Cause(s)	Corrective Action(s)
Manual ID entry invalid.	Advisory message. Re-enter valid data.

9.1.1.26 Internal error-not ready for keyboard input

Probable Cause(s)	Corrective Action(s)
Invalid entry.	1. Let trays in process finish. 2. Turn power off, wait 30 seconds, then turn back on. 3. If problem persists, call Abbott Customer Support Center (CSC).

9.1.1.27 The last part of the sample ID is not numeric

Probable Cause(s)	Corrective Action(s)
Manual ID entry invalid.	Advisory message. Re-enter valid data.

9.1.1.28 Tray number too big

Probable Cause(s)	Corrective Action(s)
Tray number entered larger than number of trays in batch.	Advisory message. Re-enter valid data.

9.1.1.29 The well location specified is illegal for this size tray

Probable Cause(s)	Corrective Action(s)
The well location specified is improper for size of tray.	Advisory message. Re-enter valid data.

9.1.1.30 The well location specified is not a replicate boundary

Probable Cause(s)	Corrective Action(s)
Attempt to change Sample ID at a well position other than at the first replicate of a sample. Attempt to ID an empty well.	Advisory message. Re-enter valid data.

9.1.1.31 Cannot collect sample IDS or well statuses for this PIPETTOR tray. Do you want to retry? (Yes/No)

Probable Cause(s)	Corrective Action(s)
Tray OPD dispense pass, communications error.	• Select YES to attempt to recollect sample IDs • Select NO to continue processing without sample IDs.

9.1.1.32 Patient ID Checksum Failure Tray XXXXXXXXXX

Probable Cause(s)	Corrective Action(s)
Patient IDs lost for this tray. The IDs will be recollected on the OPD dispense pass, if necessary.	Advisory message. Instrument will collect IDs on the OPD dispense pass.

9.1.1.33 Pipettor Sample ID Length Incompatible. Tray xxxxxxxxxx

Probable Cause(s)	Corrective Action(s)
PPC is in 10 character mode and has attempted to collect a row of sample IDs with IDs greater than 10 characters.	A. Select Sample ID Length at the Setup menu and set to 20. B. If a sample ID greater than 10 characters was received and the PPC was set to 10 characters, the sample IDs for the entire row will be converted to "*"s.

9.1.1.34 Internal error-undefined. Press <ENTER> To Continue

Probable Cause(s)	Corrective Action(s)
Invalid error code passed to error handler.	1. Press **<Enter>** to continue. 2. Let trays in process finish. 3. Turn power off, wait 30 seconds, then turn back on. 4. If problem persists, call Abbott Customer Support Center (CSC).

10.1 Data Error slope Aborting. Press <ENTER> to continue.
10.2 Data Error intercept Aborting. Press <ENTER> to continue.

Probable Cause(s)	Corrective Action(s)
Data reduction error.	A. Press **<Enter>** to continue. B. Check for valid and clean standards tray. C. Check standards tray values entered in instrument. D. Rerun the test. E. If problem persists, call Abbott Customer Support Center (CSC).

10.3 External BCR Port is Not Assigned

Probable Cause(s)	Corrective Action(s)
The EXT. BARCODE option was selected, in Diagnostics, while Port 4 was not configured to an External BCR.	Select DMS/Ext. BCR Assign from the Configuration menu, then assign Port 4 to External BCR. Set mechanical switch to BCR.

11.2.1 810 Create Bitbus User error. CANNOT CONTINUE
11.2.2 810 Delete User error. CANNOT CONTINUE
11.2.3 810 Set Device error. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Bitbus controller error.	Call Abbott Customer Support Center (CSC).

11.2.4 810 Device Table Error Status: XXXX. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Bad bitbus cable or all bitbus boards are not communicating.	A. Turn power off, wait 30 seconds, then turn back on. B. If problem persists, call Abbott Customer Support Center (CSC).

11.2.5 810 Delete user error. CANNOT CONTINUE
11.2.6 810 Create Connection error. CANNOT CONTINUE
11.3.1 Create Connection Error to SIO. Status: XXXX. CANNOT CONTINUE
11.3.2 SIO reset error. CANNOT CONTINUE
11.3.3 SIO Config Port A error. CANNOT CONTINUE
11.3.4 SIO Config Port B error. CANNOT CONTINUE
11.3.5 SIO Config Port C error. CANNOT CONTINUE
11.3.6 SIO Config Port D error. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Bitbus controller error.	A. Turn power off, wait 30 seconds, then turn back on. B. If problem persists, call Abbott Customer Support Center (CSC).

11.4.1 Stepper reset error. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
One of the stepper controller boards is not responding properly to commands.	A. Turn power off, wait 30 seconds, then turn back on B. If problem persists, call Abbott Customer Support Center (CSC).

11.5.1 Create Connection Error to Stepper Board. Status: XXXX. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
One of the two stepper controller boards is unable to communicate.	A. Turn power off, wait 30 seconds, then turn back on. B. If problem persists, call Abbott Customer Support Center (CSC).

11.5.2 Stepper reset error. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
One of the stepper controller boards is not responding properly to commands.	A. Turn power off, wait 30 seconds, then turn back on B. If problem persists, call Abbott Customer Support Center (CSC).

11.6.1 Create Connection Error to DIO. Status: XXXX. CANNOT CONTINUE
11.6.2 DIO reset error. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Digital I/O board is unable to communicate.	A. Turn power off, wait 30 seconds, then turn back on. B. If problem persists, call Abbott Customer Support Center (CSC).

12.1.1 Internal Status Checksum Failure. All Assay Data Destroyed. Press <ENTER> to continue.

or

Internal Status Checksum Failure. All Assay Data Destroyed. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Internal Status corrupted.	A. Press **<Enter>** to continue. All assay data is destroyed. Reset all user configurable parameters as needed. B. If problem persists or in TPC™ mode, call Abbott Customer Support Center (CSC). or A. Cannot continue. All assay data is destroyed. Turn power off, wait 30 seconds, then turn back on. Reset all user-configurable parameters as needed. B. If problem persists or in TPC mode, call Abbott Customer Support Center (CSC).

12.1.2 Program Checksum Error. CANNOT CONTINUE

Probable Cause(s)	Corrective Action(s)
Software corrupted Hardware failure	Call Abbott Customer Support Center (CSC).

TPC™ Codes and Flags

The codes and flags that may be printed in the DEV column of the PPC Result Printout are listed below.

Code/Flag	Condition	Explanation
01	Expired Master Lot or Component Lot	For reconstituted mixtures, the expiration time is calculated at the time the new mixture lot number is validated between all connected FPC™ instruments and the PPC. The earliest instrument time is used to establish the expiration time as shown on the PPC. • For non-OPD passes, the expiration is checked at the beginning of the pass for the batch. • For OPD pass, the expiration is checked at the beginning and end of the pass for the batch. • For non-OPD component types, the expiration date is printed. • For the OPD component type, the expiration date and time is printed. • All expirations are checked to the second. • For component types with expirations in terms of days, the expiration time is 23:59:59 on the date of expiration. • For component types with expirations in terms of hours, the expiration time is to the hh:mm:ss, even though the expiration in the printout may only include hh:mm. For all other reagents and master lots, the expiration dates are listed on the assay kit card and the individual components. These dates are entered via the FPC.
02	Unknown Master Lot	The Master Lot number cannot be located in the FPC component library.
03	Unknown Component Lot	The component lot number cannot be located in the FPC component library.
04	Invalid Component (wrong Master Lot)	The Master Lot of the component lot number does not match the Master Lot of the tray.
05	Expired Master Lot or Component Lot *and* Invalid Component (wrong Master Lot)	Combination of 01 and 04 (see above)

Code/Flag	Condition	Explanation
06	No Bead lot number recorded	• The bead lot number cannot be located in the FPC™ component library. • The Bead Drop Procedure may not have been performed. • The Bead Drop Procedure was performed after the OPD pass on a PPC not processing the batch.
NV	Unable to verify component (communication failure)	This is a flag that is applied when an instrument error occurs. If the problem is resolved before the final results are printed, this flag will not be printed.

Deviation Code 01 documentation on the final results and tray maps will occur as follows:

1. For all processing passes, if an expired component or master lot is detected at the beginning of a processing pass, the operator will be prompted for the deviation password. At this point, the operator has three options:

   a. The operator may enter the password if one has been defined and continue processing which will result in the deviation code being documented on the final results and tray maps.

   b. The operator may press the <#> key to return to the previous screen to correct the entry/deviation condition.

   c. The operator may press the <#> key and remove the tray to return to the Insert Tray screen and discontinue batch processing. If the operator chooses to discontinue batch processing, the operator must manually void the batch in the PPC database.

2. For the OPD processing pass, if an expired component (OPD) is detected at the end of the last tray of the batch, the deviation code will be documented on the final results and tray maps as follows:

   a. If a deviation password has been previously assigned, the code 01 will automatically be documented on the final results and tray maps. An error message is displayed and printed to advise the operator of the deviation condition. The code 01 will be sent to a connected pipettor only for the last tray of the batch.

b. If a deviation password has not been previously assigned, the batch will be automatically voided at this point, and no further processing can occur. An error message is displayed and printed to advise the operator of the deviation condition.

NOTE: The OPD dispense pass is the only pass for which component expiration is verified at both the beginning and the end of the processing pass.

Deviation Codes 02-05 documentation on the final results and tray maps will occur for all processing passes, if a deviation condition is detected at the beginning of a processing pass.

The operator will be prompted for the deviation password. At this point, the operator has three options:

1. The operator may enter the password if one has been defined and continue processing which will result in the deviation code being documented on the final results and tray maps.
2. The operator may press the <#> key to return to the previous screen to correct the entry/deviation condition.
3. The operator may press the <#> key and remove the tray to return to the Insert Tray screen and discontinue batch processing. If the operator chooses to discontinue batch processing, the operator must manually void the batch in the PPC database.

Deviation Code 06 documentation on the final results and tray maps will occur as follows:

1. For the blanks tray at the beginning of the OPD dispense pass, if no blanks beads are associated with the blanks tray (no Bead Drop Procedure performed for that tray), the operator has three options:
   a. The operator may enter the password if one has been defined and continue processing which will result in the deviation code being documented on the final results and tray maps.
   b. The operator may press the <#> key and remove the tray to return to the Insert Tray screen. The Bead Drop Procedure for the Blanks tray can then be performed to correct the entry/deviation condition.

c. The operator may press the <#> key and remove the tray to return to the Insert Tray screen and discontinue batch processing. If the operator chooses to discontinue batch processing, the operator must manually void the batch in the PPC database.

NOTE: When processing in TPC™ Verify or Record mode, at completion of the OPD pass (for control/sample trays), the tray ticket will indicate if a Bead Drop Procedure has not been performed. To avoid generating a Deviation 06 error, the Bead Drop Procedure must be registered on the PPC which is processing the batch.

If the Bead Drop Procedure is performed on a different PPC, a Deviation 06 error will be generated. This error will only appear on the PPC Batch Report.

2. For all trays at the beginning of the Acid pass, if no beads are associated with the trays (no Bead Drop Procedure performed for the trays), a bead component with a deviation code 06 is automatically assigned. This bead component is documented on the final results and tray maps.

NOTE: If a deviation code is associated with the processing of an assay, it may indicate that adherence to the manufacturer's recommended operating procedures for that assay did not occur. Codes 06 and NV may occur in cases of communications failure. Verify whether a communications failure has occurred when interpreting these codes.

Diagnostics

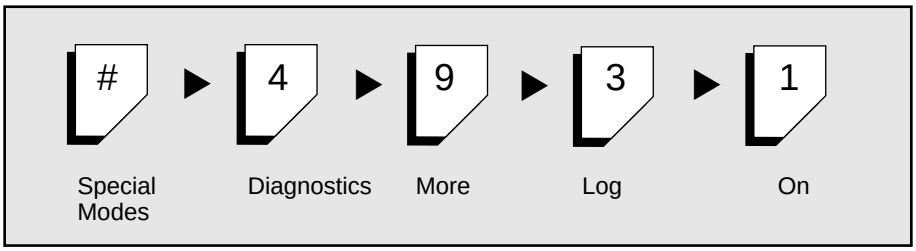
Introduction

Diagnostics may be used to check specific functions or areas of the system in response to an error code as indicated in the Troubleshooting section of this manual, as directed by the Customer Support Center in response to an instrument problem, or as part of routine maintenance checks or service as performed by an Abbott representative.

CAUTION: Use of Diagnostics causes the System to reset. Data on trays in process (*i.e.,* which have been identified with a tray ID and have not been physically removed from the instrument) will be lost.

Log Results Of Diagnostics Tests

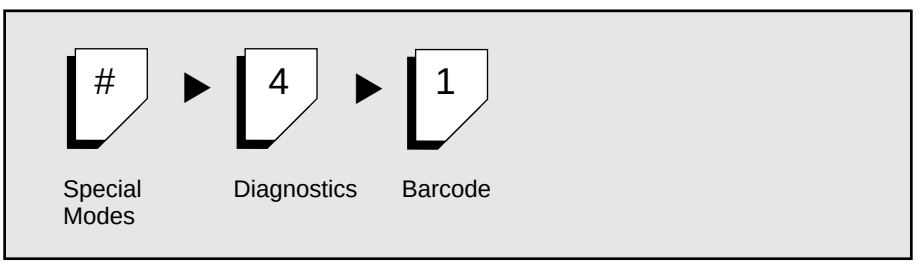
The Log mode of Diagnostics may be switched on to print the results of diagnostics.



Most diagnostics will be printed as they are performed.

Test Bar Code Reading

The Bar Code Test checks the functionality of the internal and optional external bar code reader(s).



Display asks whether you want to test the internal or external (optional) bar code reader.

- Select <**1**> to test the internal bar code reader.
- Select <**2**> to test the external bar code reader.

NOTE: Port 4 must be configured for the external BCR and mechanical switch must be in BCR position.

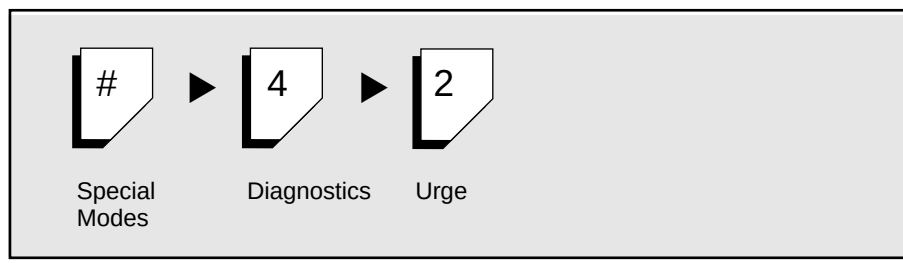
- Select <**#**> to return to the diagnostics menu.

Read a bar code as directed.

If there are no errors, the label information is displayed but not printed.

Urge Test

The Urge Test checks switches along the path of the urge belts (the conveyer belts used to pull a tray into the PPC). It also moves a tray into the PPC to test the transport system or in combination with the Transport Test for Wash, Dispense or Reader Tests.



Display asks the operator to insert tray and press **<Enter>** to move tray into the PPC.

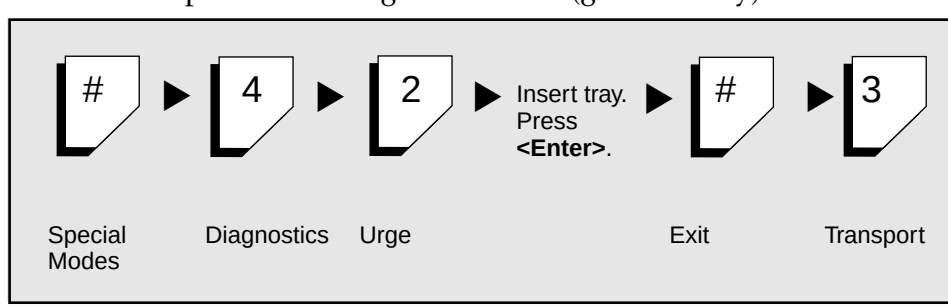
Test is complete when display asks for the number of webs (1 web = 1 row) to advance the tray.

Advance the tray the appropriate number of webs to transport it to the exit, then remove.

Transport Function Test

The Transport Test checks the switches and movement of the transport system. It is also used in conjunction with the Urge Test to move a tray into the system for Wash, Dispense or Reader Tests.

- An Urge Test must be run before a Transport Test to move a tray into the system.
- Follow prompts through the Urge Test to allow the tray to pass the wash gate solenoid (gate the tray).



Display asks for number of webs (1 web = 1 row) to advance the tray. The tray can be advanced from 1 to 9 webs at a time. Move tray 16 webs (16 rows) to exit for a 20 well tray, 24 webs (24 rows) for a 60 well tray.

If Log is switched “on”, a printout is printed.

```
                SAMPLE PRINTOUT
*************************************
TRANSPORT TEST
TRANSPORT HOME SWITCH          HOME
TRAY READY SWITCH              OFF
WEB SWITCH                     OFF
WASH STATION SWITCH            ON
WASH STATION SWITCH            OFF
EXIT SWITCH                    ON
EXIT SWITCH                    OFF
*************************************
```

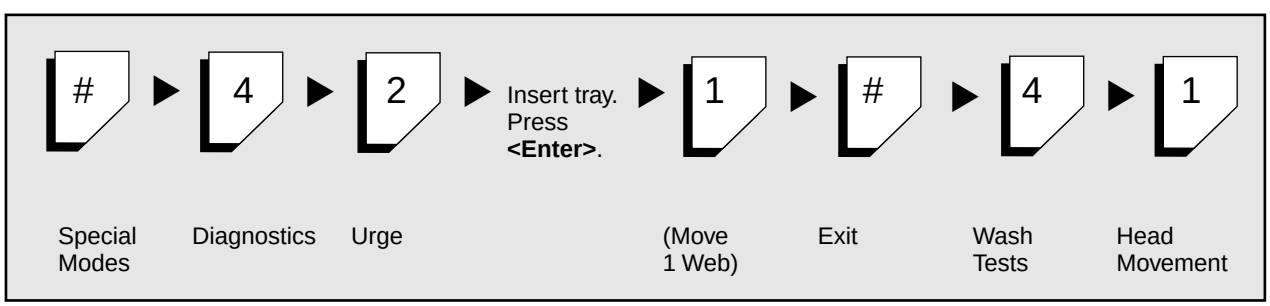
Wash Head

The Wash Tests check the wash manifold function. Run an Urge Test to gate the tray and move the tray 1 web (1 web = 1 row) in preparation for the Wash Test.

- Wash Head Movement
- Test Compressor
- Test Wash Solenoid

CAUTION: Be sure to insert a tray prior to performing Wash Tests to prevent wash water from flooding instrument.

Wash Head Movement



Operator presses **<Enter>** to move wash head through 3 positions which are displayed simultaneously on the screen.

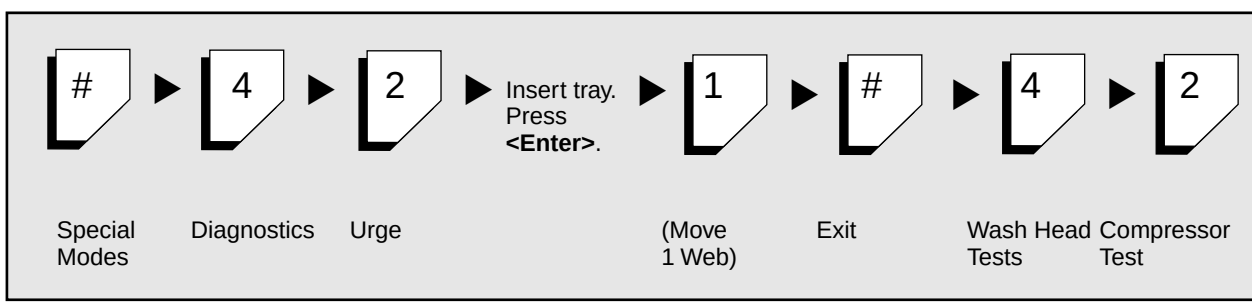
If Log is switched “on”, a printout is printed.

```
                SAMPLE PRINTOUT
*************************************
WASH HEAD TEST
WASH HEAD                   READY
WASH HEAD                   DOWN
WASH HEAD                   READY
WASH HEAD                   HOME
WASH HEAD                   READY
WASH HEAD                   DOWN
WASH HEAD                   READY
WASH HEAD                   HOME
*************************************
```

After completing the test, press <#> to exit. At the Diagnostics menu, select the Transport Function to advance the tray to the exit.

Test Compressor

This procedure is for testing Wash Carts (List Nos. 6208-11 and 6208-12). It is not for use with the CDCM (List Nos. 6208-45 and 6208-46).

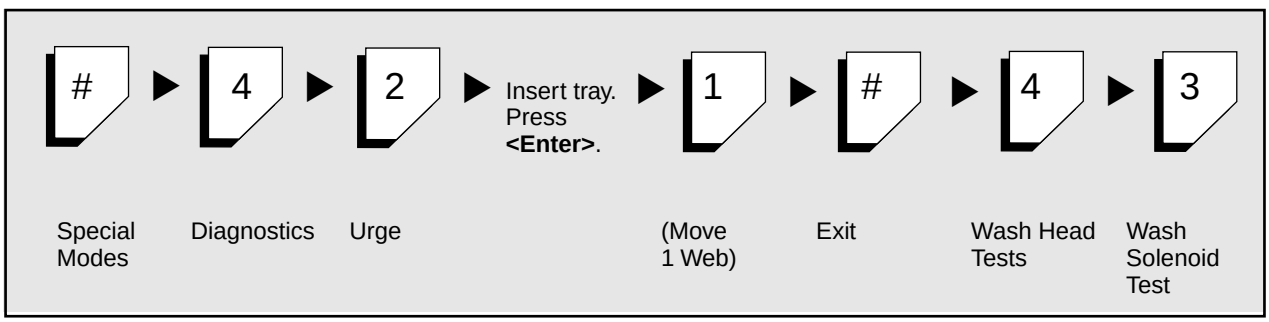


Display asks the operator to turn compressor on and off. Listen to determine if compressor has been switched on and off.

If Log is switched “on”, a printout is printed.

```
                SAMPLE PRINTOUT
*************************************
COMPRESSOR TEST
COMPRESSOR                  OFF
COMPRESSOR                  ON
COMPRESSOR                  OFF
*************************************
```

Wash Solenoid Test



Options of 1) Air Test, or 2) Water Test are displayed. Either air or water, depending on the option selected, will run for 5 seconds.

```
****************************************
WASH SOLENOID TEST
AIR PRESSURE SWITCH          NORMAL
WATER LEVEL SWITCH           NORMAL
WASTE PRESSURE SWITCH        NORMAL
AIR PRESSURE SWITCH          NORMAL
WATER LEVEL SWITCH           NORMAL
WASTE PRESSURE SWITCH        NORMAL
AIR PRESSURE SWITCH          NORMAL
****************************************
```

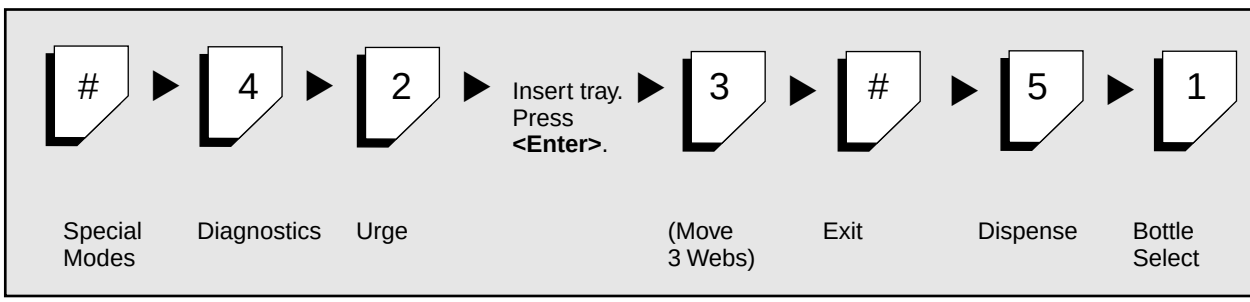
Dispense

The Dispense Tests are used to check the accuracy of the dispense head positioning. Run an Urge Test to gate the tray and move the tray 3 webs (3 webs = 3 rows) in preparation for the Dispense Tests. After completing the test, press <#> to exit. At the Diagnostics menu, select the Transport function to advance the tray to the exit.

- Bottle Selection
- Pump Arm Movement
- Position for Dispensing into Wells

NOTE: A Dispense Test should be run without dispense bottles installed. If dispense bottles are used, be sure to insert a tray to prevent contamination of the instrument with dispense solution.

Bottle Selection Test

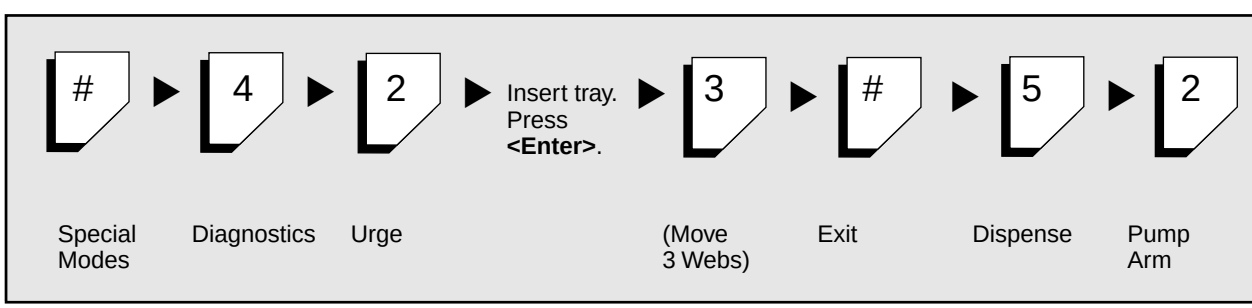


The operator is prompted to press **<Enter>**, moving the dispense pump arm to each available bottle station.

If Log is switched "on", a printout is printed.

```
                SAMPLE PRINTOUT
****************************************
BOTTLE SELECT TEST
BOTTLE SELECTED                  1
BOTTLE SELECTED                  2
BOTTLE SELECTED                  3
BOTTLE SELECTED                  4
BOTTLE SELECTED                  5
BOTTLE SELECTED                  4
BOTTLE SELECTED                  3
BOTTLE SELECTED                  2
BOTTLE SELECTED                  1
****************************************
```

Pump Arm Movement Test

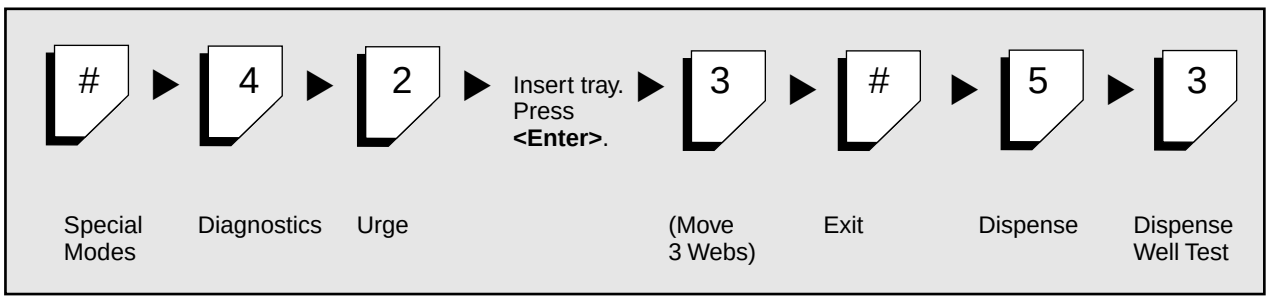


The operator is prompted to remove any reagent bottles and then press **<Enter>** to cycle the pump arm through its three working positions.

If Log is switched “on”, a printout is printed.

```
                SAMPLE PRINTOUT
****************************************
PUMP ARM TEST
PUMP ARM                    HOME
PUMP ARM                    READY
PUMP ARM                    DOWN
****************************************
```

Position for Dispensing Into Wells Test



The operator is prompted to move the dispense tip to each well in a row by pressing **<Enter>**.

If Log is switched “on”, a printout is printed.

```
                SAMPLE PRINTOUT
****************************************
DISPENSE WELL TEST
WELL SELECTED                    1
WELL SELECTED                    2
WELL SELECTED                    3
WELL SELECTED                    4
WELL SELECTED                    5
WELL SELECTED                    4
WELL SELECTED                    3
****************************************
```

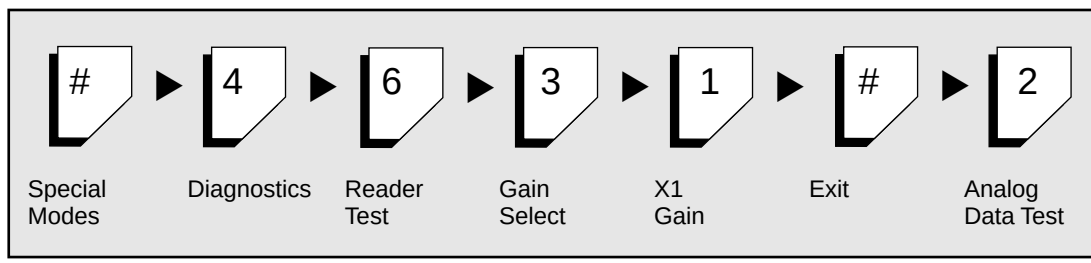
Reader

The Reader Test allows the operator to run:

- Reader And Gain Test
- Lamp Intensity Check
- Reader Output Observation

Reader and Gain Test

1. First, test the reader electronics under gain of X1.

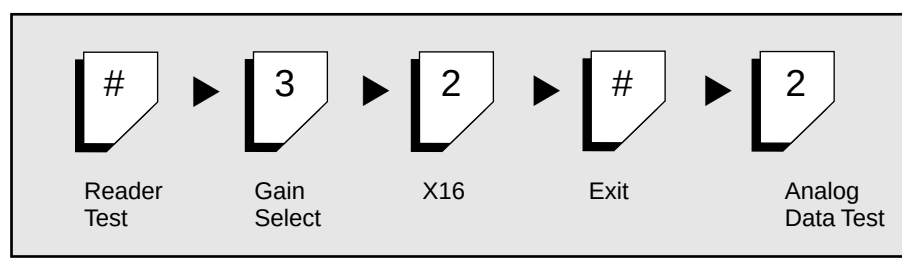


2. Press **<Enter>** to cycle the reader electronics through readings on wells 5-1 and on the "references" 1-3. Readings will be displayed one at a time, as in the example shown:

```
REF 3                                    40
NO FILTER
<ENTER> TO CONTINUE OR, <#> TO EXIT
```

3. Record all values as they appear on the screen and calculate the value of A:

   A = (Ref 2 – Ref 3)



4. Press **<Enter>** to cycle through readings on wells 5-1 and on the "references" 1-3. These readings will also be displayed one at a time:

```
REF 3                                  32798
NO FILTER
<ENTER> TO CONTINUE OR, <#> TO EXIT
```

5. Record each value as it appears on the screen and calculate the value of B:

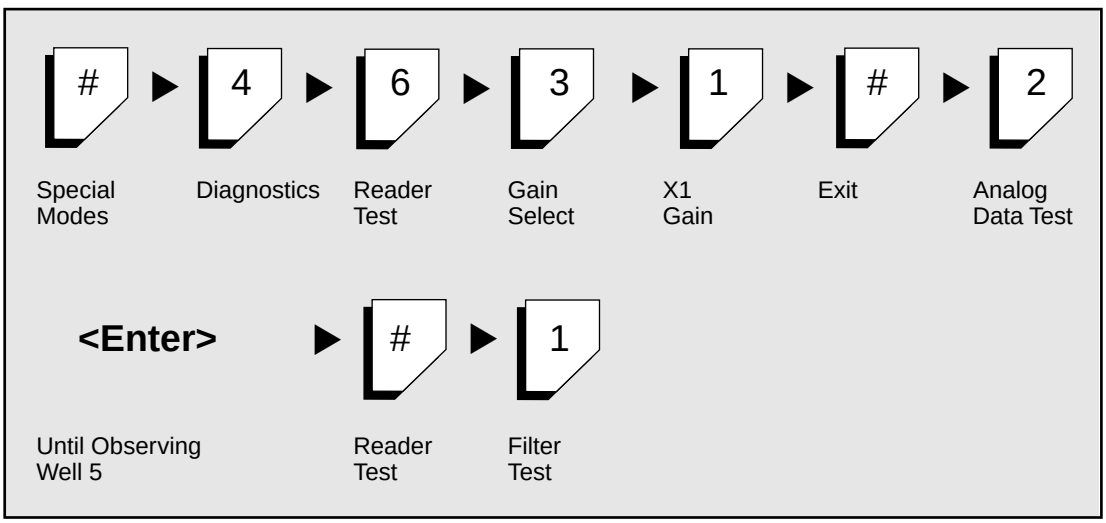
   B = (Ref 2 – Ref 3)

6. Divide B above by A above. Resulting values must be:

   B/A = 16.00 ± 0.15

This checks the gain of the dual range read system.

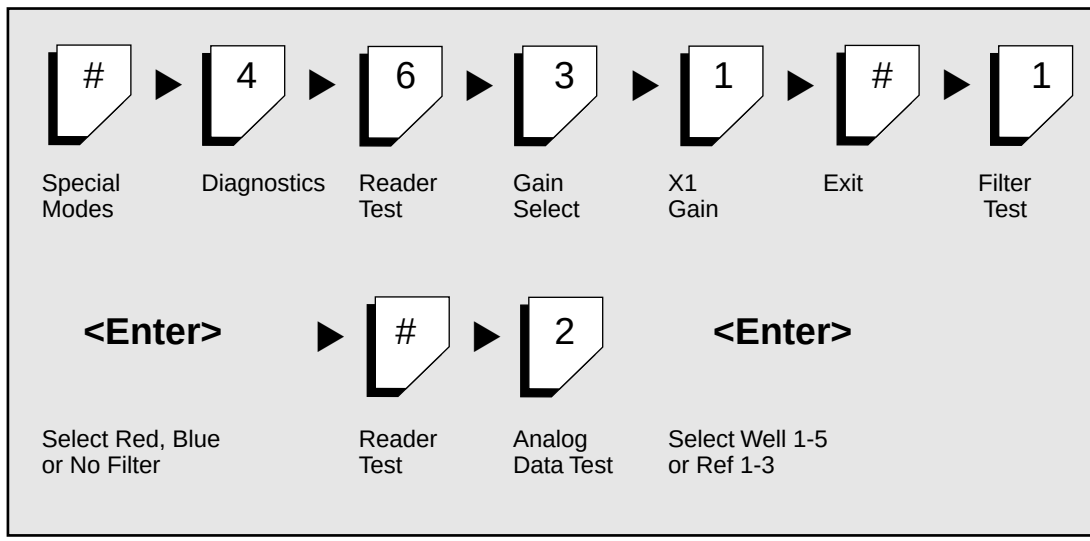
Lamp Intensity Check



Press **<Enter>** to cycle through displays of intensity values for red, blue, and no filters. The values for both the red and blue filters should be greater than 600. If readings are lower than 600, replace lamp.

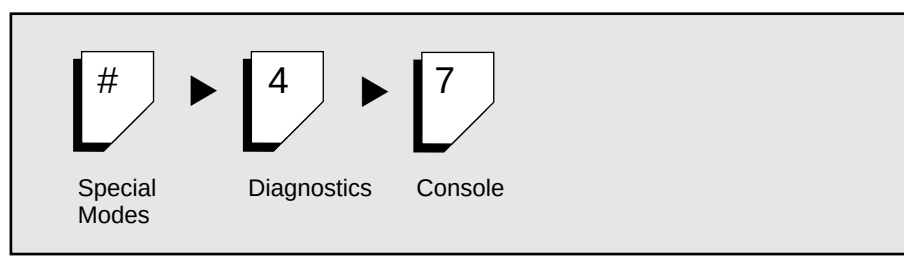
Observation of Reader Output

The output for each filter and well position can be observed as follows:



Console Test

The Console Test allows a check of keypad and display functions.

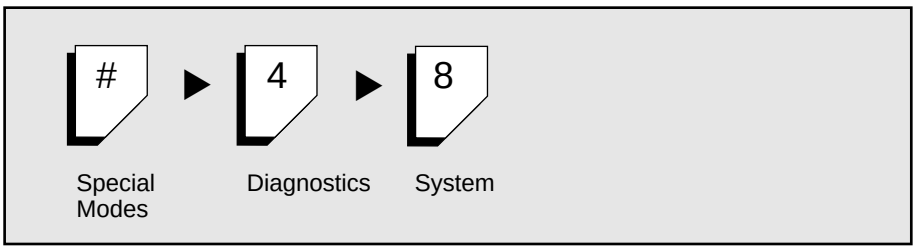


The system will automatically cycle through display filling and blanking, LED and keypad tests. The keypad LEDs will continue to light until the operator presses **<Enter>** to continue or **<#>** to exit. If **<Enter>** is pressed the display prompts to press each key. The key pressed will be displayed when pressed and functioning correctly.

NOTE: The lower right corner of the filled display will always remain blank.

System Test

The System Test cycles continuously through all operational functions.



Remove all trays and disconnect air and water as directed. Press <**Enter**>. System will continuously cycle through all operational functions until # is pressed. The number of cycles completed is displayed.

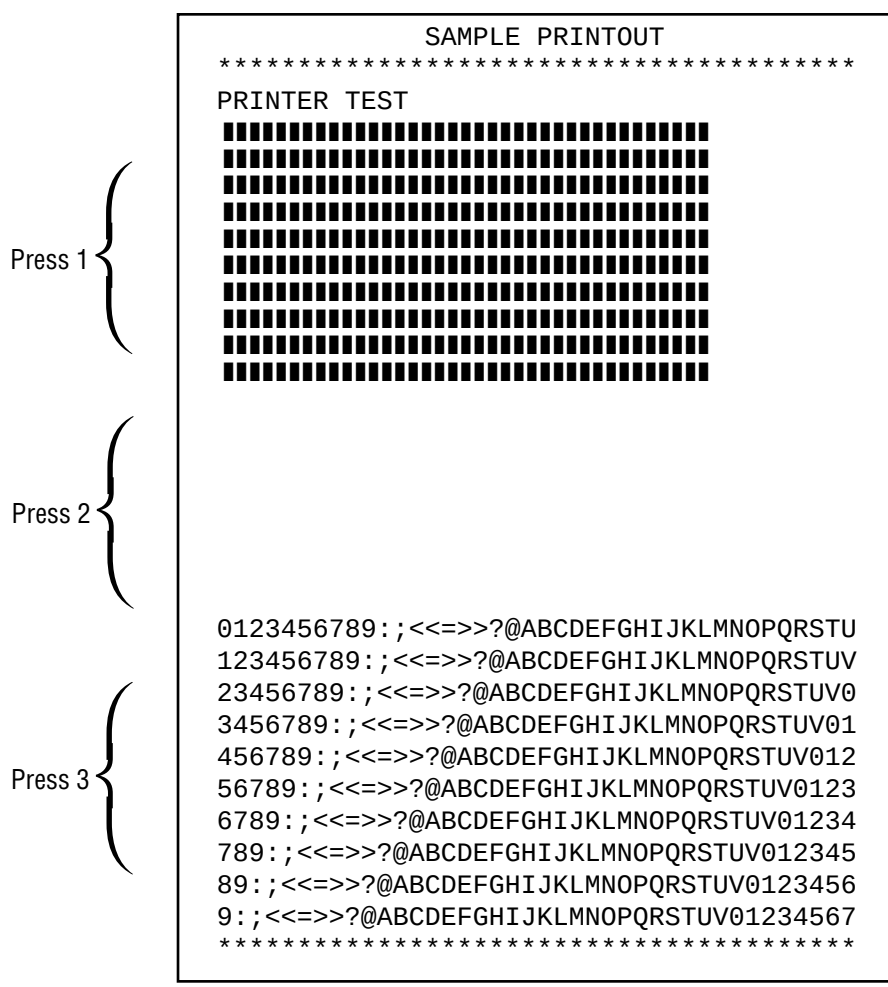
Printer

The Printer Test may be used to determine if all print heads are functioning correctly.

Press <**1**>to print several rows of solid squares. (Fill Test)

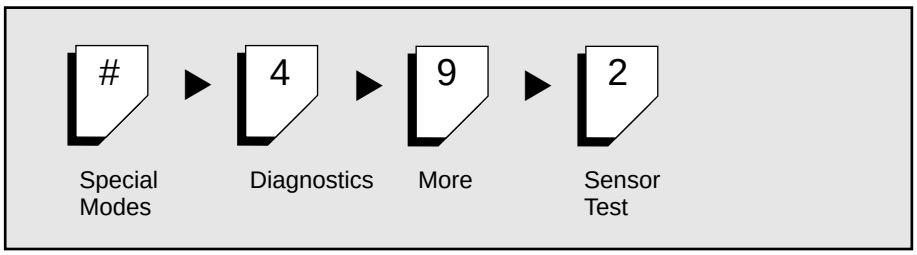
Press <**2**>to advance printer without printing. (Blank Test)

Press <**3**>to print several rows of alpha-numeric characters. (Alpha/Numeric Test)



Sensor Test

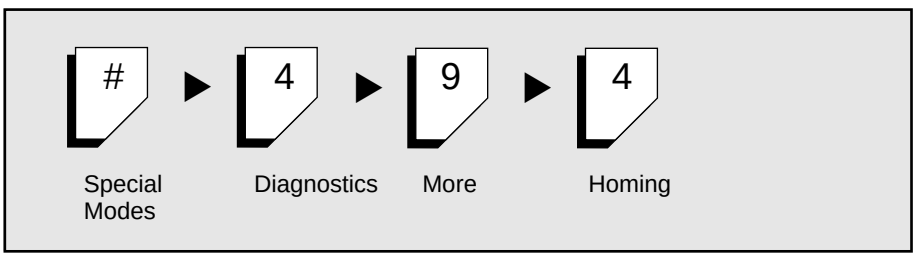
The Sensor Test may be used to assure proper functioning of all sensors.



A summary of all sensors in the system will be printed if the logging capability is turned on.

Homing Test

The Homing Test checks to make sure that the stepper motors move into the correct position when they are sent to the "home" position.



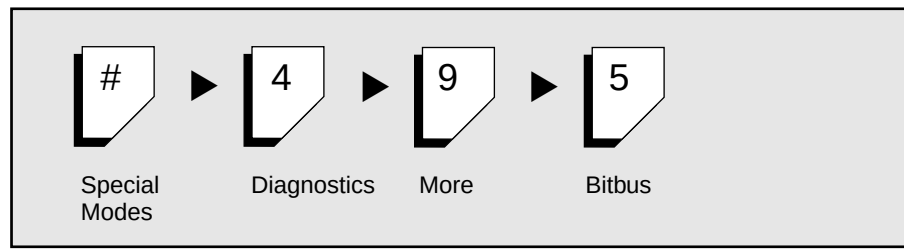
System prompts operator to remove all trays and press **<Enter>** to begin automatic cycling of all stepper motors that can be homed. The test will automatically cycle continuously until <#> is pressed.

If Log is switched "on", a printout is printed.

```
              SAMPLE PRINTOUT
****************************************
HOME TEST
TRANSPORT                PASSED
PUMP ARM                 PASSED
BOTTLE SELECT            PASSED
DISPENSE WELL            PASSED
WASH HEAD                PASSED
READER FILTER            PASSED
****************************************
```

Bitbus Test

The Bitbus Test checks each circuit board in the PPC.



The system will check communications to and from each board and will display the board's name and pass or fail status. The test will automatically cycle continuously until # is pressed.

If Log is switched "on", a printout is printed.

```
              SAMPLE PRINTOUT
*****************************************
BITBUS TEST
STEPPER 1 BOARD            PASSED
STEPPER 2 BOARD            PASSED
COMMUNICATIONS BOARD       PASSED
DIGITAL BOARD              PASSED
*****************************************
```

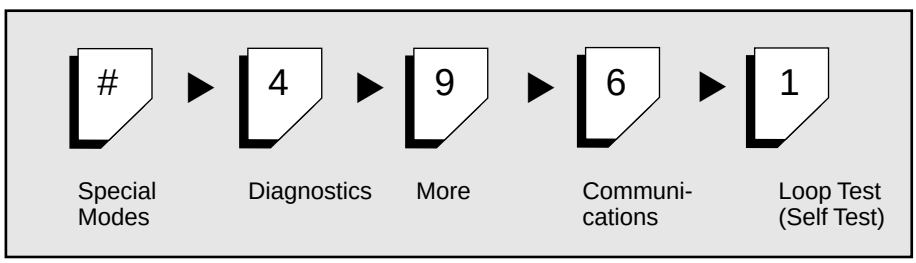
Communication Tests

- The Loop Back Test allows the system to test itself to determine if PPC is transmitting or receiving communications.
- The Echo Test checks the system's ability to communicate with other instruments. It is used with instruments that are capable of sending a signal to the PPC and receiving it back. This checks the sending and receiving capabilities of both instruments and ensures that both instruments' communication parameters are compatible.

Loop Back or Self Test

The Self Test requires a loop back connector which must be plugged into the channel (channel = port) to be tested before the test begins.

If running LoopBack test on the PPC in conjunction with another instrument set to Echo Test, the loop back connector is not used. Instead, the instrument set to Echo Test should remain cabled to the PPC and will function as the loop back connector.



Display instructs operator to insert loop connector and then select the channel to be tested.

Insert loop connector. See Figure 10.1 for port locations.

The display shows the channel number and passed or failed result of the test.

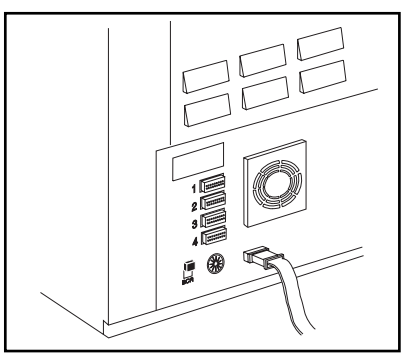
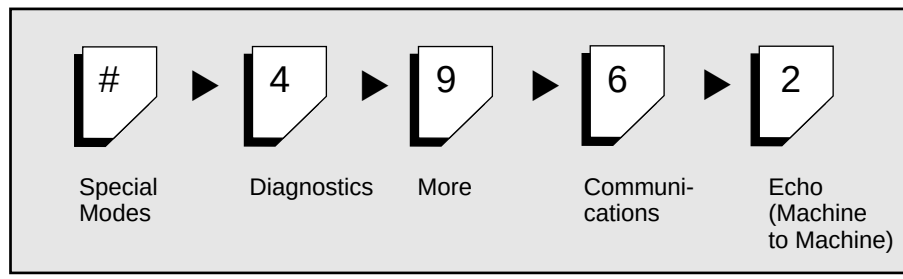


Figure 10.1

Echo Test or Machine-to-Machine

The Echo Test requires that the PPC be connected to a pipettor and the PPC is set for Echo testing. Results are determined on the remote instrument.



Display prompts operator to select a channel (channel = port) connected to a pipettor or DMS and run a Loop Back test on the instrument connected to that channel. Diagnostic messages appear on the display of the connected instrument.

NOTES

Bibliography

COMMANDER® Parallel Processing Center (PPC) RS-232 Interface Specification. Software Version 9.0/9.1. Abbott Laboratories, Abbott Park, IL.

COMMANDER® Parallel Processing Center (PPC) Installation and Validation Protocols, Software Version 9.00/9.10. Abbott Laboratories, Abbott Park, IL.

COMMANDER® Dual Compressor Module Installation Guide. Abbott Laboratories, Abbott Park, IL.

OSHA Regulation 29 CFR Part 1910.1030. Occupational Exposure to Bloodborne Pathogens, Final Rule. Federal Register, Vol. 56, No. 235, December 6, 1991.

NOTES

Glossary

Active Tray

A tray is "Active" from the time it is inserted into the PPC for the first processing pass, to the point at which it is finally read, including time between processing passes. (same as In Process Tray)

Archived Tray

The status of a tray changes to Archived from In Process after the final read is completed. Up to 40 trays or 10 batches can be archived or stored after results are calculated and printed. The oldest archived batches are deleted as new batches are stored on a first-in, first-out basis.

Assay

A PPC Assay is an assay, such as AUSZYME® MONOCLONAL, CORZYME®, etc.

Assay Protocol

The Assay Protocol is the listing of parameters for running the assay on the PPC. It defines assay processing on the PPC.

Batch

A batch is a group of trays (recommend 8, maximum 10) run under the same assay protocol using a common set of controls or standards. When an operator sets up a batch, the PPC will ask for the number of trays to be run within that group.

Bead Drop Procedure

A procedure for associating the tray ID and bead lot number to be used by the PPC in that tray, necessary when processing an assay with a TPC™ Mode of Record or Verify.

Blanks Tray

A Blanks tray is a standard reaction tray with COMMANDER Reagent Blanking Beads inserted in the proper wells. It is used to correct for reagent coloration.

Checksum

A numerical verification of accurate data transmission.

Controls

Controls are reference materials that are run to verify that an assay is within acceptable limits. In a cutoff assay, controls are used to calculate the cutoff values. The controls are dispensed into the first tray of Cutoff assay.

Database

The PPC Database contains information about tray status, and edited assay protocols. It may contain up to 10 batches/40 trays (combined total of In-Process, Archived or Voided) and protocols for up to 99 assays.

Empty Well

An Empty Well is a tray location which has nothing in it and requires that no patient ID be assigned to it. The PPC skips these wells during processing.

FPC	COMMANDER Flexible Pipetting Center
In Process Tray	A tray is “In Process” from the time it is inserted into the PPC for the first processing pass, to the point at which it is finally read, including time between processing passes. (same as Active Tray)
Locked	To avoid multiple PPCs from accessing the same tray on the FPC™, a tray is automatically locked by the first PPC to read the tray well map. Locked maps are automatically unlocked upon completion of processing on the PPC.
No Sample Well	A No Sample Well is a tray location that is reserved for a sample that was identified but not actually processed.
OD Only	“OD ONLY” is a message printed adjacent to the sample results when certain error conditions occur. It indicates that no interpretation of results will be printed for that sample.
PIP	A non-FPC pipettor system that is compatible for use with PPC.
PPC	COMMANDER Parallel Processing Center
Processing Pass	A Processing Pass begins when the first tray is inserted into the PPC, and ends when the last tray is removed from the instrument at the completion of a processing step.
RAM Memory	RAM is **R**andom **A**ccess **M**emory which is temporary information storage for the PPC system. RAM may contain data, tray status, and assay protocols that are being edited.
Reagent Blanking	Reagent Blanking is an optical reading that is taken to correct for reagent coloration prior to calculating results.
Reconstitution Procedure	A procedure for entering the lot number and expiration data to be used by the PPC in tracking reagents which are reconstituted, necessary when processing an assay with a TPC™ Mode of Record or Verify. Can be used only with TPC-capable pipettors.
Stand Alone Mode	The PPC is in stand alone mode when not communicating sample IDs with an FPC or generic pipettor.

Standards — Standards are reagents of known concentrations, run to set the curve of values against which unknowns may be run in a quantitative assay. The standards are dispensed into the first tray of a Point-to-Point assay.

Standards Tray — The Standards Tray is filled with solid materials of known optical densities, which are used to verify proper reader operation.

Status Screen — A Status Screen appears at the beginning of each processing pass after the first tray of the batch has been identified. The screen presents assay information for operator verification before each processing step.

"Tray Ticket" — A "Tray Ticket" indicates the next processing step and is printed as each tray completes a processing pass.

Unlocked — To avoid multiple PPCs from accessing the same tray on the FPC™, a tray is automatically locked by the first PPC to read the tray well map. When the tray has finished processing the final pass, the PPC will unlock the tray on the FPC.

Void Well — A Void Well is a tray location which contains a sample, control, or standard that is invalid.

NOTES

Appendix A
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Appendix A

NOTES

Appendix A
Cutoff Assay Protocol Reference Guide

Introduction

The COMMANDER® Parallel Processing Center (PPC) automatically performs the data reduction calculations for Cutoff Assays. The assay protocol parameters and values are included in the specific assay protocols.

Assay protocol parameters can be viewed by printing a copy of the assay protocol. This may be done by using the LIST PROTOCOL special function key. The Data Reduction parameters appear in Lines 46 through 89. Refer to the Sample Printouts elsewhere in this section.

A cutoff assay compares the absorbance reading for a patient sample to a calculated cutoff value. The cutoff value is calculated from negative and/or positive controls run with each batch.

Editing Protocols

Some assay protocol values can be adjusted by following the editing procedures explained in *Editing Protocols* in *Section 2, Installation Procedures and Special Requirements*.

Although Abbott-supplied assay protocols are non-editable, they may be changed and stored under a different assay number without changing or deleting the original Abbott assay.

NOTE: An operator-edited assay protocol may be used if the edited protocol parameters are consistent with the reagent package insert specifications and are supported by documentation at the time of edit.

Whenever a user-edited assay protocol is created, either the list number or the procedure must be changed to create a unique list number/procedure combination for that protocol. The list number and procedure of the original Abbott-supplied assay protocol cannot be used for user-edited assay protocols.

When connected to an FPC™ pipettor, version 2.5 or greater, the TPC™ mode of PPC assay processing is dictated by the FPC assay protocol. The operator must assure that the list number/ procedure code combination on the PPC and FPC are identical. An edit to the PPC assay protocol to set the desired TPC mode is not required. When operating the PPC with a non TPC-capable pipettor, or in Stand Alone Mode, the TPC mode of PPC assay processing is dictated by the TPC mode of the PPC assay protocol. If you wish to change the TPC mode of PPC assay processing, a user-edited assay protocol will be required.

Cutoff Assay Checks

Assay Control Checks

Assay control checks are made automatically as assay processing takes place. These checks are applicable to each control type (Negative, Positive, Positive-2, and Positive-3) in an assay. Controls (Neg, Pos, Pos-2, Pos-3) must be in the first tray of a batch.

The following checks are defined by parameters that are entered in an assay protocol. The list below includes checks that may be included in a protocol and the order in which they are performed. If a check fails, the PPC either prints a flag or error message. Once an error is encountered which invalidates the run, no further control errors will be generated. When an error message is printed, only absorbance values (optical density or O.D.) for sample results are reported. No interpretations will be given.

NOTE: Absorbance values greater than 2.200 that are not rejected by other validity checks are treated as 2.200 in subsequent calculations. The printed results are preceded by a “>”.

The possible checks, flags, and error messages include:

1. The absorbance of each negative control must be between the minimum and maximum instrument limits (-0.029, 4.400). If they are not, the control will be REJECTED and only the O.D. will be given for samples. The printed error message is: “ABSORBANCE OF CONTROL OUT OF INSTRUMENT RANGE”.

2. The absorbance of each negative control must be between the minimum and maximum acceptable values set in Lines 50 and 51 of the protocol. If they are not, the control will not be used for further calculation and will be flagged "REJECT".
3. If the absorbance of a negative control is >2.200, only the O.D. values will be given for samples. The printed error message is: "ABSORBANCE OF A CONTROL EXCEEDED 2.200".
4. The absorbance of each positive control must be between the minimum and maximum instrument limits (-0.029 and 4.400). If they are not, the control will be REJECTED and only O.D. values will be given for samples. The printed error message is: "ABSORBANCE OF CONTROL OUT OF INSTRUMENT RANGE".
5. The absorbance of each positive control must be between the minimum and maximum acceptable values set in Lines 57 and 58 of the protocol. If they are not, the control will not be used for further calculation and will be flagged "REJECT".
6. If the assay includes positive controls in the cutoff calculation and the absorbance of a positive control is >2.200, the error message is: "ABSORBANCE OF A CONTROL EXCEEDED 2.200". Only O.D. values will be given for samples.
7. The aberrant range is calculated for negative controls. Line 52 of the Assay Protocol defines the aberrant value. See *Control Aberrant Range Calculation* elsewhere in this section.
8. Negative control values are labeled aberrant according to the data reduction option defined in Line 87 of the assay protocol. See *Aberrant Value Handling* elsewhere in this section.
9. The aberrant range is calculated for positive controls. Line 59 of the assay protocol defines the aberrant value. See *Control Aberrant Range Calculation* elsewhere in this section.
10. Positive control values are labeled aberrant according to the data reduction option defined in Line 87 of the assay protocol. See *Aberrant Value Handling* elsewhere in this section.

11. For data reduction option (Line 87) values of 0, 2, 4 and 6, the minimum negative control reps is specified in the assay protocol. For data reduction option values of 1, 3, 5 and 7, the minimum negative control reps equals the negative control reps times 0.75. If the remaining valid negative control reps are less than the minimum negative control reps, the error message is: "INSUFFICIENT CONTROLS TO DO CUTOFF". Only O.D. values will be given for samples.
12. The minimum positive control reps is calculated based on data reduction options as explained above. If the remaining positive control reps are less than the minimum positive control reps, the error message is: "INSUFFICIENT CONTROL TO DO CUTOFF". Only O.D. values will be given for samples.
13. For negative or positive controls, if the remaining reps minus the reps which failed OPD timing are less than the minimum control reps, the error message is: "CONTROLS HAVE FAILED OPD TIMING CHECKS". Only O.D. values will be given for samples.
14. The control difference is within the minimum and the maximum limits established in Lines 74 and 75.

    CONTROL DIFFERENCE = $(PC\bar{x} - NC\bar{x})$

    If the algebraic control difference is greater than the maximum control difference or less than the minimum control difference, the error message "(POS-NEG) DIFFERENCE TEST FAILED" is printed and only optical density values are given for samples.

NOTE: The calculation of the $(PC\bar{x} - NC\bar{x})$ value is algebraic. A negative minimum difference and/or maximum difference is possible. For example, if the:

MINIMUM DIFFERENCE = -2.00

MAXIMUM DIFFERENCE = -1.250

A value of -0.900 for $(PC\bar{x} - NC\bar{x})$ is greater than the maximum difference and the difference test fails.

NOTE: P-N is equivalent to -(N-P).

15. If a Positive-2 control is defined by an assay, the absorbance of a Positive-2 control must be between -0.029 and 4.400. If it is not, the control will be REJECTED and only O.D. values will be given for samples. The error message is: "ABSORBANCE OF CONTROL OUT OF INSTRUMENT RANGE".

16. If a Positive-2 control is defined by an assay, the absorbance of each Positive-2 control must be between the minimum and maximum acceptable values defined in Lines 64 and 65 of the protocol. If the absorbance is not in the range, the Positive-2 control will not be used in the calculation of the Positive-2 control average and will be flagged "REJECT".

17. If a Positive-2 control is defined by an assay, the aberrant range is calculated for Positive-2 controls. Line 66 of the assay protocol defines the aberrant value. See *Control Aberrant Range Calculation* elsewhere in this section.

18. If a Positive-2 control is defined by an assay, values are labeled as aberrant according to the data reduction option defined in Line 87 of the assay protocol. See *Aberrant Value Handling* elsewhere in this section.

19. If a Positive-2 control is defined by an assay, the minimum Positive-2 control reps is calculated based on data reduction options, as explained above. If the remaining replicates is less than the required minimum (*i.e.,* Positive-2 reps is less than minimum Positive-2 reps), only O.D. values will be given for samples. The printed error message is: "INSUFFICIENT POSITIVE-2 CONTROLS".

20. If a Positive-2 control is defined by an assay and an OPD timing error occurs during processing, the minimum Positive-2 reps criteria must still be met. If it is not (*i.e.,* the remaining Positive-2 reps minus the Positive-2 reps which failed OPD timing are less than the minimum Positive-2 reps), only O.D. values will be given for samples. The printed error message is, "CONTROLS HAVE FAILED OPD TIMING CHECKS".

21. If a positive-2 control is defined by an assay, the difference between the mean of the positive-2 control absorbances and the mean of the negative control absorbances is within the minimum and maximum limits defined in Lines 76 and 77.

The positive-2 control represents an additional positive control. The positive-2 control difference check is:

$$\text{CONTROL DIFFERENCE} = (PC2\bar{x} - NC\bar{x})$$

If the **algebraic** control difference is greater than the maximum positive-2 control difference or less than the minimum positive-2 control difference, the error message "POSITIVE-2 CONTROL DIFFERENCE TEST FAILED" is printed and only optical density values are printed for samples.

NOTE: The calculation of $(PC2\bar{x} - NC\bar{x})$ value is **algebraic**. A negative minimum difference and/or maximum difference is possible. For example, if the:

MINIMUM DIFFERENCE = -2.00

MAXIMUM DIFFERENCE = -1.250

A value of -0.900 for $(PC2\bar{x} - NC\bar{x})$ is greater than the maximum difference and the difference test fails.

NOTE: PC2–N is equivalent to –(N–PC2).

22. If a Positive-2 control is defined by the assay and the Data Reduction Option is 4, 5, 6 or 7, the Positive-2 mean must be REACTIVE when compared to the cutoff. If it is not, only O.D. values will be given for samples. The printed error message is: "INVALID POSITIVE-2 CONTROLS - PC2 MEAN IS NOT REACTIVE".

23. If a Positive-3 control is defined by an assay, the O.D. of a Positive-3 control must be between -0.029 and 4.400. If it is not, the control will be REJECTED and only O.D. values will be given for samples. The error message is: "ABSORBANCE OF CONTROL OUT OF INSTRUMENT RANGE".

24. If a Positive-3 control is defined by an assay, the absorbance of each Positive-3 control must be between the minimum and maximum acceptable values defined in Lines 71 and 72 of the assay protocol. If the absorbance is not in the range, the Positive-3 control will not be used in the calculation of the Positive-3 control average and will be flagged "REJECT".

25. If a Positive-3 control is defined by an assay, the aberrant range is calculated for Positive-3 controls. Line 73 of the assay protocol defines the aberrant value. See *Control Aberrant Range Calculation* elsewhere in this section.

26. If a Positive-3 is defined by an assay, values are labeled as aberrant according to the data reduction option defined in Line 87 of the assay protocol. See *Aberrant Value Handling* elsewhere in this section.

27. If a Positive-3 control is defined by an assay, the minimum Positive-3 control reps is calculated based on the Data Reduction Option, as explained above. If remaining Positive-3 reps are less than the minimum Positive-3 reps, only O.D. values will be given for samples. The printed error message is, “INSUFFICIENT POSITIVE-3 CONTROLS”.

28. If a Positive-3 control is defined by an assay and an OPD timing error occurs during processing, the minimum Positive-3 reps criteria must still be met. If it is not (*i.e.,* the remaining Positive-3 reps minus the Positive-3 reps which failed OPD timing are less than the minimum Positive-3 reps), only O.D. values will be given for samples. The printed error message is: “CONTROLS HAVE FAILED OPD TIMING CHECKS”.

29. If a Positive-3 control is defined by an assay, the difference between the mean of the Positive-3 control absorbances and the mean of the negative control absorbances must be within the minimum and maximum limits defined in Lines 78 and 79.

    The Positive-3 control represents an additional positive control. The Positive-3 control difference check is,

    $$\text{CONTROL DIFFERENCE} = (PC3\bar{x} - NC\bar{x})$$

    If the **algebraic** control difference is greater than the maximum Positive-3 control difference or less than the minimum Positive-3 control difference, the error message “POSITIVE-3 CONTROL DIFFERENCE TEST FAILED” is printed and only optical density values are printed for samples.

NOTE: The calculation of ($PC3\bar{x} - NC\bar{x}$) value is **algebraic**. A negative minimum difference and/or maximum difference is possible. For example, if the:

MINIMUM DIFFERENCE = -2.00

MAXIMUM DIFFERENCE = -1.250

A value of -0.900 for ($PC3\bar{x} - NC\bar{x}$) is greater than the maximum difference and the difference test fails.

NOTE: PC3–N is equivalent to –(N–PC3).

30. After all of the above control checks have been made:

    a. In the case of more than one control replicate, the PPC automatically calculates and prints an average O.D. and %CV. The calculations are as follows:

    – An Average, or Mean ($\bar{x}$) = $\frac{\Sigma_i (O.D)_i}{n}$

    where

    n = number of replicates

    $(O.D.)_i$ = an absorbance reading for the i^{th} replicate sample

    – % Coefficient of Variation (%CV) = $\left(\frac{SD}{\bar{x}}\right)$ x 100

    where

    Standard Deviation (SD) = $\sqrt{\frac{[(n)(\Sigma x^2)] - (\Sigma x)^2}{(n)(n-1)}}$

    b. If only one valid control replicate remains, the average is set to that replicate's OD and the %CV is zero.

31. The following equation is used to calculate the cutoff:

$$\text{CUTOFF VALUE} = (A)\ \overline{NC_x} + (B)\ \overline{PC_x} + C$$

where

A = NEGATIVE CONTROL FACTOR (Line 80)

$\overline{NC_x}$ = MEAN OF NEGATIVE CONTROL ABSORBANCES

B = POSITIVE CONTROL FACTOR (Line 81)

$\overline{PC_x}$ = MEAN OF POSITIVE CONTROL ABSORBANCES

C = CUTOFF OFFSET (Line 82)

NOTE: Positive-2 or Positive-3 control factors are not included in the Cutoff Value equation.

Control Aberrant Range Calculation

a. If $\overline{Control_x}$ is greater than or equal to 0.020:

Each control replicate must be within the range defined by the control aberrant percentage of the mean to be accepted.

For example:

$$\overline{Control_x} \pm \frac{(\text{Control ABERRANT \%})\ (\overline{Control_x})}{100}$$

where

$\overline{Control_x}$ = Mean of Control Absorbances

CONTROL ABERRANT (%) = The value set in the appropriate line of the assay protocol.

b. If $\overline{Control_x}$ is less than 0.020:

Each control replicate must be no more than 0.010 units from the mean to be accepted.

$$\overline{Control_x} \pm 0.010$$

NOTE: This calculation is specific for PPC processing only. When using manual methods, refer to the reagent package insert or appropriate manual instrument specifications.

Aberrant Value Handling

Data Reduction Option 0

All control replicates outside the aberrant range are flagged aberrant.

If more than one control replicate is aberrant, the error message “TOO MANY ABERRANT VALUES” is printed and sample interpretation is not provided (OD ONLY!). If only one control is aberrant, a new mean and aberrant range are calculated for those remaining.

Data Reduction Option 1

All control replicates outside the aberrant range are flagged aberrant.

If more than one control replicate is aberrant, the error message “TOO MANY ABERRANT VALUES” is printed and sample interpretation is not provided (OD ONLY!). If only one control is aberrant, a new mean and aberrant range are calculated for those remaining.

At least 75% of the control replicates must remain after aberrant checks are performed. If less than 75% of the control replicates remain, sample interpretation is not provided (OD ONLY!).

Data Reduction Option 2

If any replicates are outside the aberrant range, the single control replicate farthest from the mean is flagged aberrant. If two values are outside the aberrant range and equidistant from the mean, both replicates are flagged aberrant.

A new mean and aberrant range is calculated and the remaining control replicates are checked for aberrant values.

If more than one control replicate is aberrant, the error message, “TOO MANY ABERRANT VALUES” is printed and sample interpretation is not provided (OD ONLY!).

Data Reduction Option 3

If any replicates are outside the aberrant range, the single control replicate farthest from the mean is flagged aberrant. If two values are outside the aberrant range and equidistant from the mean, both replicates are flagged aberrant.

A new mean and aberrant range is calculated and the remaining control replicates are checked for aberrant values.

If more than one control replicate is aberrant, the error message “TOO MANY ABERRANT VALUES” is printed and sample interpretation is not provided (OD ONLY!).

At least 75% of the control replicates must remain after aberrant checks are performed. If less than 75% of the control replicates remain, sample interpretation is not provided (OD ONLY!).

Data Reduction Option 4

All control replicates outside the aberrant range are flagged aberrant.

If more than one control replicate is aberrant, the error message “TOO MANY ABERRANT VALUES” is printed and sample interpretation is not provided (OD ONLY!). If only one control is aberrant, a new mean and aberrant range are calculated for those remaining.

In addition to the aberrant checks, the Positive-2 control must be reactive. If the Positive-2 control is not reactive, sample interpretation is not provided (OD ONLY!).

Data Reduction Option 5

All control replicates outside the aberrant range are flagged aberrant.

If more than one control replicate is aberrant, the error message “TOO MANY ABERRANT VALUES” is printed and sample interpretation is not provided (OD ONLY!). If only one control is aberrant, a new mean and aberrant range are calculated for those remaining.

At least 75% of the control replicates must remain after aberrant checks are performed. If less than 75% of the control replicates remain, sample interpretation is not provided (OD ONLY!).

In addition to aberrant checks, a check is made to assure the Positive-2 control is reactive. If the Positive-2 control is not reactive, sample interpretation is not provided (OD ONLY!).

Data Reduction Option 6

If any replicates are outside the aberrant range, the single control replicate farthest from the mean is flagged aberrant. If two values are outside the aberrant range and equidistant from the mean, both replicates are flagged aberrant.

A new mean and aberrant range is calculated and the remaining control replicates are checked for aberrant values.

If more than one control replicate is aberrant, the error message, “TOO MANY ABERRANT VALUES” is printed and sample interpretation is not provided (OD ONLY!).

In addition to aberrant checks, a check is made to assure the Positive-2 control is reactive. If the Positive-2 control is not reactive, sample interpretation is not provided (OD ONLY!).

Data Reduction Option 7

If any replicates are outside the aberrant range, the single control replicate farthest from the mean is flagged aberrant. If two values are outside the aberrant range and equidistant from the mean, both replicates are flagged aberrant.

A new mean and aberrant range is calculated and the remaining control replicates are checked for aberrant values.

If more than one control replicate is aberrant, the error message, “TOO MANY ABERRANT VALUES” is printed and sample interpretation is not provided (OD ONLY!).

At least 75% of the control replicates must remain after aberrant checks are performed. If less than 75% of the control replicates remain, sample interpretation is not provided (OD ONLY!).

In addition to aberrant checks, a check is made to assure the Positive-2 control is reactive. If the Positive-2 control is not reactive, sample interpretation is not provided (OD ONLY!).

Assay Protocol Values

The following is a line by line description of the parameters listed in the assay protocol.

General Information

Line 1

Assay Number: Used to identify the assay protocol to be utilized by the PPC.

Line 2

Assay Name: Provides a descriptive identification of an assay protocol for operator use.

Line 3

Reminder: A 20 character Reminder Message may be entered to be displayed at the beginning of the first pass. This message will become part of the following:

"HAVE YOU ^^^^^^^^^^^^^^^^^^^^?(YES/NO)"

"^" represents each of the 20 characters that may be defined. When a reminder message is entered, the operator is required to enter YES for the processing to continue. If NO is entered, the operator will be prompted to remove the tray.

If no message is entered, the question will not be asked and the operator entry will not be required.

Line 4

Test Number: The test number is used to identify an assay on a compatible pipettor system (non-FPC™). Pipettor test number and PPC assay protocols must be linked to allow automatic transfer of data when using a compatible pipettor system (non-FPC). (See Protocol Select in *Section 2, Installation and Special Requirements*.)

Line 5 & 6

Assay List Number, Assay Procedure: The Abbott product number supplied on an assay kit and the assay procedure code. The procedure code may be identified in assay package insert which identifies specific processing parameters for the different procedures and/or calculations, or it may be an identifier unique to specific procedures for common Assay List Numbers. The Assay List Number and Assay Procedure specified in the assay protocol is a unique identifier to link the assay protocols on the FPC™ and PPC.

Line 7

TPC™ Mode: The level of Total Process Control (TPC) to be used in processing the assay: Record or Off. The default for new assays is Off.

Use of the Verify mode can only occur with an FPC™ pipettor, version 2.5 or greater. The Verify mode is dictated by the assay protocol on the FPC, regardless of the TPC™ mode in the PPC assay protocol.

Line 8

Blanking: Identifies the type of Blanking to be used (*i.e.*, OPD, ACID, NONE [no blanks tray]).

Line 9

Data Reduction: Indicates the type of data reduction used to calculate results (*i.e.,* cutoff or point-to-point).

Line 10

Well Status Flag: A "Y" on this line will cause display to prompt for void, no sample or empty wells when in Stand Alone Mode.

Line 11

Multiple Trays: Allows the operator to select either single or multiple tray batch processing. "Y" on this line will cause the display to prompt for the number of trays in a batch.

Line 12

Technician Identification: Allows printouts to be identified with technician initials. "Y" on this line causes the display to prompt for tech ID. Applies only to assays with TPC mode of OFF.

Line 13

Master Lot: Allows a printout to be identified with master lot number. "Y" on this line causes display to prompt for master lot number. Applies only to assays with TPC mode of OFF.

Line 14

Sample IDs: Allows Stand Alone PPC to print results with sample ID. "Y" on this line causes PPC to prompt for sample IDs and identify results with IDs.

Line 15

Number of Blanks: Used to indicate the number of reagent blank wells to be processed with each batch.

Line 16

Unknown Replicates: Used to indicate the number of sample replicates to be run.

Processing Functions

Line 17

Wash 1: A number on this line specifies the type of wash function that will be performed on the first pass of a batch (0 = no wash).

Line 18

Component 1 Volume (uL): Indicates the volume in µL (microliters) of the reagent to be dispensed on the first pass. If no dispense occurs, volume = 0.

Line 19

Component 1 Name: Provides a descriptive identification of the reagent to be dispensed on the first pass.

Line 20

Component 1 Type: A 4-character abbreviation of the component name as it appears on the results printout.

If creating an assay protocol that will be pipetted with an FPC™, the parameters of the created component type must exactly match those of the FPC. Do not use ML, UNKN, BEAD, or BKBD as component types in any edited assay protocol because proper assay processing cannot be assured.

Line 21

Component 1 Station: Indicates the dispenser station, identified on the PPC with a bar code label for use in TPC™, in which reagent for the first pass should be placed. The location will be displayed on the status screen at the beginning of a processing pass and the bottle will be backlit.

Line 22

Incubation Temperature 1 (ºC): Indicates the approximate temperature (in degrees C) for incubation occurring between the first and second pass. Room temperature is designated by 25. Refer to the reagent package insert for specific incubation temperature requirements.

Line 23 & 24

Minimum Elapsed Time 1 (minutes), Maximum Elapsed Time 1 (minutes): Set to zero. Currently the PPC does not time passes prior to OPD timing.

Line 25

Wash 2: A number on this line specifies the type of wash function that will be performed on the second pass of a batch (0 = no wash).

Line 26

Component 2 Volume (uL): Indicates the volume in µL (microliters) of the reagent to be dispensed on the second pass. If no dispense occurs, volume = 0.

Line 27

Component 2 Name: Provides a descriptive identification of the reagent to be dispensed on the second pass.

Line 28

Component 2 Type: A 4-character abbreviation of the component name as it appears on the results printout.

If creating an assay protocol that will be pipetted with an FPC™, the parameters of the created component type must exactly match those of the FPC. Do not use ML, UNKN, BEAD, or BKBD as component types in any edited assay protocol because proper assay processing cannot be assured.

Line 29

Component 2 Station: Indicates the dispenser station, identified on the PPC with a bar code label for use in TPC™, in which reagent for the second pass should be placed. The location will be displayed on the status screen at the beginning of a processing pass and the bottle will be backlit.

Line 30

Incubation Temperature 2 (ºC): Indicates the approximate temperature (in degrees C) for incubation occurring between the second and OPD pass. Room temperature is designated by 25. Refer to the reagent package insert for specific incubation temperature requirements.

Line 31 & 32

Minimum Elapsed Time 2 (minutes), Maximum Elapsed Time 2 (minutes): Set to zero. Currently the PPC does not time passes prior to OPD timing.

Line 33

Wash 3: A number on this line specifies the type of wash function that will be performed on the OPD pass of a batch (0 = no wash).

Line 34

Component 3 Volume (uL): Indicates the volume in µL (microliters) of the reagent to be dispensed on the OPD pass. If no dispense occurs, volume = 0.

Line 35

Component 3 Name: Provides a descriptive identification of the reagent to be dispensed on the OPD pass.

Line 36

Component 3 Type: A 4-character abbreviation of the component name as it appears on the results printout.

If creating an assay protocol that will be pipetted with an FPC™, the parameters of the created component type must exactly match those of the FPC. Do not use ML, UNKN, BEAD, or BKBD as component types in any edited assay protocol because proper assay processing cannot be assured.

Line 37

Component 3 Station: Indicates the dispenser station, identified on the PPC with a bar code label for use in TPC™, in which reagent for the OPD pass should be placed. The location will be displayed on the status screen at the beginning of a processing pass and the bottle will be backlit.

Line 38

Incubation Temperature 3 (ºC): Indicates the approximate temperature (in degrees C) for incubation occurring between the OPD and acid pass. Room temperature is designated by 25. Refer to the reagent package insert for specific incubation temperature requirements.

Line 39

Minimum Elapsed Time 3 (minutes): Minimum OPD incubation time. An N/A on this line means no check is to be made.

Line 40

Maximum Elapsed Time 3 (minutes): Maximum OPD incubation time. An N/A on this line means no check is to be made.

Line 41

Maximum OPD Dispense-Read Time (sec): Maximum allowable time (in seconds) from OPD dispense to OPD read. An N/A on this line means no check is to be made.

Line 42

Component 4 Volume (uL): Indicates the volume in µL (microliters) of the reagent to be dispensed on the acid pass. If no dispense occurs, volume = 0.

Line 43

Component 4 Name: Provides a descriptive identification of the reagent to be dispensed on the acid pass.

Line 44

Component 4 Type: A 4-character abbreviation of the component name as it appears on the results printout.

If creating an assay protocol that will be pipetted with an FPC™, the parameters of the created component type must exactly match those of the FPC. Do not use ML, UNKN, BEAD, or BKBD as component types in any edited assay protocol because proper assay processing cannot be assured.

Line 45

Component 4 Station: Indicates the dispenser station, identified on the PPC with a bar code label for use in TPC™, in which reagent for the acid pass should be placed. The location will be displayed on the status screen at the beginning of a processing pass and the bottle will be backlit.

Controls

Line 46

Component 5 Type: A 4-character abbreviation of the component name as it appears on the results printout, typically the negative control associated with the component described on Lines 47-52.

If creating an assay protocol that will be pipetted with an FPC™, the parameters of the created component type must exactly match those of the FPC. Do not use ML, UNKN, BEAD, or BKBD as component types in any edited assay protocol because proper assay processing cannot be assured.

Line 47

Negative Replicates: Indicates the number of negative control replicates to be used.

Line 48

Min. Neg. Cntl. Replicates: Determines minimum number of negative controls with which assay results will be calculated.

Line 49

Negative Location: Indicates the first well for placement of negative controls. Replicates must follow sequentially (*i.e.,* A1, A2, A3…).

Line 50 & 51

Negative Minimum Absorbance, Maximum Absorbance: Indicates lowest and highest acceptable absorbance reading for each negative control replicate. An “N/A” on these lines means no check is to be made.

Each negative control value must be equal to or below the maximum and equal to or above the minimum values. If not, the control will not be used for further calculation and will be flagged "REJECT" on the printout.

Line 52

Negative Aberrant: This percentage value is used to determine a range around the negative control mean. Values outside this range will be flagged as "aberrant" on the result printout. An "N/A" on this line means no check is to be made.

Line 53

Component 6 Type: A 4-character abbreviation of the component name as it appears on the results printout, typically the positive control associated with the component described on Lines 54-59.

If creating an assay protocol that will be pipetted with an FPC™, the parameters of the created component type must exactly match those of the FPC. Do not use ML, UNKN, BEAD, or BKBD as component types in any edited assay protocol because proper assay processing cannot be assured.

Line 54

Positive Replicates: Indicates the number of replicates of positive controls to be used.

Line 55

Min. Pos. Control Replicates: Determines minimum number of positive controls with which assay results will be calculated.

Line 56

Positive Location: Indicates the first well for placement of positive controls. Replicates must follow sequentially (*i.e.,* A4, A5…). Positive controls must immediately follow negative controls.

Line 57 & 58

Positive Minimum Absorbance, Maximum Absorbance: Indicates lowest and highest acceptable absorbance reading for each positive control. An "N/A" on this line means no check is to be made.

Each positive control value must be equal to or below the maximum and equal to or above the minimum values. If not, the control will not be used for further calculation and will be flagged “REJECT” on the printout.

Line 59

Positive Aberrant: This percentage value is used to determine a range around the positive control mean. Values outside this range will be flagged as “aberrant” on the result printout. An “N/A” on this line means no check is to be made.

Line 60

Component 7 Type: A 4-character abbreviation of the component name as it appears on the results printout, typically none or positive control-2 (PCN2); associates with Lines 61-66.

If creating an assay protocol that will be pipetted with an FPC™, the parameters of the created component type must exactly match those of the FPC. Do not use ML, UNKN, BEAD, or BKBD as component types in any edited assay protocol because proper assay processing cannot be assured.

Line 61

PC2 Replicates: Indicates the number of Positive-2 control replicates to be used. A “0” on this line indicates no Positive-2 control is defined by the assay.

Line 62

Minimum PC2 Replicates: Determines minimum number of Positive-2 controls with which assay results will be calculated. A zero on this line indicates there is no minimum number of Positive-2 control replicates required.

Line 63

PC2 Location: Indicates the first well for placement of Positive-2 controls. Replicates must follow sequentially (*i.e.,* B1,B2 …). An “N/A” on this line indicates no Positive-2 control location has been defined. Positive-2 controls must immediately follow positive controls.

Line 64 & 65

PC2 Minimum Absorbance, Maximum Absorbance: Indicates lowest and highest acceptable absorbance reading for each Positive-2 control. An "N/A" on these lines indicates no checks are to be made.

Each Positive-2 control value must be equal to or below the maximum and equal to or above the minimum values. If not, the control will not be used for further calculation and will be flagged "REJECT" on the printout.

Line 66

PC2 Aberrant (%): This percentage value is used to determine a range around the Positive-2 control mean. Values outside this range will be flagged as "aberrant" on the result printout. An "N/A" on this line means no check is to be made.

Line 67

Component 8 Type: A 4-character abbreviation of the component name as it appears on the results printout, typically none or Positive-3 control (PCN3); associates with Lines 68-73.

If creating an assay protocol that will be pipetted with an FPC™, the parameters of the created component type must exactly match those of the FPC. Do not use ML, UNKN, BEAD, or BKBD as component types in any edited assay protocol because proper assay processing cannot be assured.

Line 68

PC3 Replicates: Indicates the number of Positive-3 control replicates to be used. A "0" on this line indicates no Positive-3 control is defined by the assay.

Line 69

Minimum PC3 Replicates: Determines minimum number of Positive-3 controls with which assay results will be calculated. A zero on this line indicates there is no minimum number of Positive-3 control replicates required.

Line 70

PC3 Location: Indicates the first well for placement of Positive-3 controls. Replicates must follow sequentially (*i.e.,* B3,B4 …). An "N/A" on this line indicates no Positive-3 control location has been defined. Positive-3 controls must immediately follow positive controls.

Line 71 & 72

PC3 Minimum Absorbance, Maximum Absorbance: Indicates lowest and highest acceptable absorbance reading for each Positive-3 control. An "N/A" on these lines indicates no checks are to be made.

Each Positive-3 control value must be equal to or below the maximum and equal to or above the minimum values. If not, the control will not be used for further calculation and will be flagged "REJECT" on the printout.

Line 73

PC3 Aberrant (%): This percentage value is used to determine a range around the Positive-3 control mean. Values outside this range will be flagged as "aberrant" on the result printout. An "N/A" on this line means no check is to be made.

Line 74 & 75

Minimum Control Difference, Maximum Control Difference (P-N): These values are used to check the algebraic difference between the Positive Control Mean and the Negative Control Mean. An "N/A" on these lines means no check is to be made.

Line 76 & 77

Minimum PC2 Difference, Maximum PC2 Difference: These values are used to check the algebraic difference between the Positive-2 control mean and negative control mean. An "N/A" on these lines means no check is to be made.

Line 78 & 79

Minimum PC3 Difference, Maximum PC3 Difference: These values are used to check the algebraic difference between the Positive-3 control mean and negative control mean. An "N/A" on these lines means no check is to be made.

Cutoff Calculation

Line 80, 81, 82

Negative Control Factor, Positive Control Factor, Cutoff Offset: These values are used to calculate the cutoff value against which patient sample absorbances are compared.

Line 83 & 84

Reactive Gray Zone (%) & Negative Gray Zone (%): These values are percentages above and below the cutoff value which may be used to set a range in which results are of borderline reactivity. The cutoff value is included in the reactive gray zone. A zero (0) entry means there is no Gray Zone flagging.

Flags

Line 85

Reactive Distinction: This line indicates whether the Reactive result is above or below the cutoff. "A" indicates results greater than or equal to the cutoff value are reactive. "B" indicates results less than or equal to the cutoff value are reactive.

Line 86

Minimum Sample Reactivity Absorbance: This is an editable value for the minimum allowable sample reactivity absorbance.

If absorbance values greater than the cutoff are reactive (Sandwich assays), then absorbance values less than the Minimum Sample Reactivity Absorbance will be flagged as "LOW".

If absorbance values less than the cutoff are reactive (Competitive assays), then absorbance values greater than the Minimum Sample Reactivity Absorbance will be flagged as "LOW".

Line 87

Data Reduction Option: This option determines the method of aberrant routine calculation. See "Aberrant Value Handling" elsewhere in this section. **Do not edit this line unless specifically authorized by Abbott Laboratories.**

Line 88

Blank Check Min. Diff.: The minimum value allowed for the arithmetic difference of the acid pass read minus the internal calibration value for each column.

Line 89

Blank Check Max. Diff.: The maximum value allowed for the arithmetic difference of the acid pass read minus the internal calibration value for each column.

Examples of Printouts

The bold letters identifying the explanations below are keyed to the printout examples that follow.

A. NOTES Column Message Flags: The flags that may be printed in the NOTES column of the PPC Result Printout are listed below.

- . . . — Indicates a non-reactive or negative result. Refer to the reagent package insert for interpretation.
- **EMPTY —** Tray well does not have a sample pipetted into it by an automated pipettor or the well location was designated as "empty" when running the PPC in the Stand Alone Mode.
- **REACTIVE —** Absorbances of samples are compared to the cutoff value to determine if they fall above or below the Cutoff. Sample results that meet the criteria defined in the assay protocol being run, are flagged as "REACTIVE" in the NOTES column. Refer to the reagent package insert for the appropriate action.
- **NO SAMPLE —** Samples that have been designated as NO SAMPLE, possibly because of insufficient sample volume to conduct an assay, and you want to maintain sample ID sequence until after reading the batch results.
- **VOID —** This indicates that something has occurred during processing, possibly caused by the pipettor, that has invalidated the sample results.
- **GRAY ZONE (*) —** Sample results that meet the Reactive and Negative Gray Zone (%) criteria defined in the assay protocol being run, are flagged with an "*" in the NOTES column. The "*" may be printed with "..." or with the "REACTIVE" flag or the "LOW" flag. The asterisk will only be printed with the "LOW" flag if the "MIN SAMPLE REACT ABS" is defined within the gray zone region. Refer to the package insert for the appropriate action.
- **E*R*R*O*R —** This indicates an Invalid Reading. The sample result is either outside the instrument range or there has been a reader error. This flag will always have an absorbance of *ERROR printed with it. This flag supersedes the "...", "REACTIVE" and "LOW" flags.

CAUTION: A sample with an OD of "*ERROR" should alert the operator to inspect the results of the entire row. The results of other samples in the row are questionable. **Reassay all samples in the row and resolve per your laboratory standard operating procedure.**

- **LOW —** This indicates the sample reactivity violates the Minimum Sample Reactivity Absorbance value defined in the assay protocol.

  If absorbance values greater than the cutoff are reactive, then absorbance values less than the Minimum Sample Reactivity Absorbance will be flagged as "LOW".

  If absorbance values less than the cutoff are reactive, then absorbance values greater than the Minimum Sample Reactivity Absorbance will be flagged as "LOW".

- **OPD-REJ —** This indicates a blank which did not meet limits tests for maximum or minimum.
- **OPD TIME —** OPD incubation time too long. Exceeds maximum OPD time (Line 41). Refer to the reagent package insert for the appropriate action.
- **OD ONLY! —** The OD ONLY! message occurs under certain conditions and indicates that no interpretation of results will be printed for that sample. The sample absorbance value printed is accurate.

NOTE: In a Cutoff assay using multiple (2 or more) replicates of unknown samples, if a replicate has one of the flags: "NOSAMPLE", "VOID", "LOW", "OPDTIME", or "E*R*R*O*R", the PPC will not print the "AVERAGE" line for that replicate set.

B. ABSORB DIFF Column Message Flags/Data: The information that may be printed in the ABSORB DIFF column of the PPC Result Printout are listed below.

- **OD VALUE**: The numeric value is the Optical Density that relates to the respective sample. The OD may be flagged as > 2.200 to indicate that the absorbance of the sample is beyond the reading capability of the instrument.

- ***ERROR**: This message will be printed when the OD is not valid. When the OD is not a numeric value, the sample should be reassayed. For more information, refer to *Section 10, Troubleshooting and Diagnostics*.

The ABSORB DIFF Column should be reviewed as well as the NOTES column when making a determination of sample status.

CAUTION: A sample with an OD of "*ERROR" should alert the operator to inspect the results of the entire row. The results of other samples in the row are questionable. **Reassay all samples in the row and resolve per your laboratory standard operating procedure.**

C. **SAMPLE IDENTIFICATION**: Sample IDs are printed in the I.D.# Column of the PPC Result Printout. A sample ID can be configured for a maximum of either 10 or 20 characters.

The sample IDs may either be entered manually or transferred from an automated pipettor. The source of the sample ID will be identified on the PPC Result Printout by the following characters to the right of the sample ID:

M = Manually entered ID at the PPC

E = Edited ID at the PPC

Pipettor originated IDs:

m = Non-bar code-entered ID (*i.e.,* keyboard entry or sequential entry)

b = Bar code-entered ID

Source identifiers that are not added by the PPC are defined by the connected system. For example, the "b" and "m" are communicated by the FPC along with the sample ID. Other connected systems may append identifiers with unique meanings.

D. **TRAY IDENTIFICATION**: Tray ID's are printed in the header of the PPC Results Printout. The tray ID may either be entered manually or by bar code reader when the tray is entered into the PPC. The source of the sample ID will be identified on the PPC Result Printout by adding the B or M to the right of the Tray ID.

M = Manually entered Tray ID on the PPC

B = Bar Code entered Tray ID on the PPC

E. **ERROR MESSAGES**: Error Messages are printed on the PPC Results Printout as a flag to the operator of possible conditions that may affect the validity of the results.

F. **POSITIVE-NEGATIVE CALCULATION**: A P-N Calculation is always performed and printed provided the positive and negative control groups are valid. This is true even if no P-N checks are specified in the assay protocol.

G. **TPC™ Information**

TPC information for the batch is printed in the BATCH INFO portion of the tape.

TPC information that is tray-specific is printed within the Tray Identification portion of the tape.

The source of the component lot number entry is identified by adding **M** or a **B** to the right of the lot #. Source of entry for components that are combined to create resultant mixtures are not identified.

M = manual entry (This includes lot numbers that are displayed and acknowledged using the keypad in such procedures as the Bead Drop Procedure.)

B = bar coded entry

The codes that may be printed in the DEV column of the PPC Result Printout are listed below.

Code/Flag	Condition	Explanation
01	Expired Master Lot or Component Lot	For reconstituted mixtures, the expiration time is calculated at the time the new mixture lot number is validated between all connected FPC™ instruments and the PPC. The earliest instrument time is used to establish the expiration time as shown on the PPC. • For non-OPD passes, the expiration is checked at the beginning of the pass for the batch. • For OPD pass, the expiration is checked at the beginning and end of the pass for the batch. • For non-OPD component types, the expiration date is printed. • For the OPD component type, the expiration date and time is printed. • All expirations are checked to the second. • For component types with expirations in terms of days, the expiration time is 23:59:59 on the date of expiration. • For component types with expirations in terms of hours, the expiration time is to the hh:mm:ss, even though the expiration in the printout may only include hh:mm. For all other reagents and master lots, the expiration dates are listed on the assay kit card and the individual components. These dates are entered via the FPC.
02	Unknown Master Lot	The Master Lot number cannot be located in the FPC component library.
03	Unknown Component Lot	The component lot number cannot be located in the FPC component library.
04	Invalid Component (wrong Master Lot)	The Master Lot of the component lot number does not match the Master Lot of the tray.
05	Expired Master Lot or Component Lot *and* Invalid Component (wrong Master Lot)	Combination of 01 and 04 (see above)

Code/Flag	Condition	Explanation
06	No Bead lot number recorded	• The bead lot number cannot be located in the FPC™ component library. • The Bead Drop Procedure may not have been performed. • The Bead Drop Procedure was performed after the OPD pass on a PPC not processing the batch
NV	Unable to verify component (communication failure)	This is a flag that is applied when an instrument error occurs. If the problem is resolved before the final results are printed, this flag will not be printed.

H. POSITIVE-2 CONTROL: A Positive-2 control group is a second Positive Control group. The following applies to an assay that defines a Positive-2 control:

- With a TPC™-capable pipettor (FPC Version 2.5 or greater), the Positive-2 controls (pipetted as the component type specified in the assay protocol) must immediately follow the Positive Controls.
- With Stand Alone Mode, the Positive-2 controls must immediately follow the Positive Controls.
- With a pipettor other than FPC Version 2.5 or greater:
  - The Positive-2 controls must be pipetted as Quality Controls. Refer to the pipettor manual for pipetting Quality Control.
  - The Positive-2 controls (pipetted as Quality Controls) must immediately follow the Positive Controls.
  - All pipetted Quality Controls will be interpreted as Positive-2 controls by the PPC.

I. POSITIVE-3 CONTROL: A Positive-3 control group is a third Positive Control group. The following applies to an assay that defines a Positive-3 control:

- With a TPC-capable pipettor (FPC Version 2.5 or greater), the Positive-3 controls (pipetted as the component type specified in the assay protocol) must immediately follow the Positive-2 controls.

- With Stand Alone Mode, the Positive-3 controls must immediately follow the Positive-2 controls.
- With a pipettor other than FPC™ Version 2.5 or greater, Positive-3 controls are not supported.

J. %CV Printing:

- When the mean is equal to 0.0, the %CV cannot be calculated. It is flagged with a series of asterisks (******). Absorbance values printed for the wells are valid.
- It will also not be printed if the calculated %CV is greater than 999.99. In these cases, it is flagged with a series of asterisks (******).
- The CV will print as a series of asterisks (******) if the absorbance values are greater than 2.200 and less than 4.400.

K. Header Time Stamps: The time stamp printed in both the BATCH INFO header and on the REREAD reflects the time at which the batch was created in the database

L. Tray Time Stamps: The time stamps printed on the tray final results reflect the time stamp at which row A was positioned in the read station. This time may be correlated to the time at which row F was in the dispensing station; however, it does not indicate the time of dispense of any particular well in row F.

M. Footer Time Stamps: The time printed on the Batch Report Footer corresponds to the completion of the last row for the last tray of the batch.

Sample Assay Protocol Printout Pos-2 and Pos-3 Controls Defined TPC™ = Off

```
****************************************
     PPC Software Version   n.nn
          SN:sssssss

01 Assay Number                     09
02 Assay Name      Sample
03 Reminder      ROTATED TRAYS
04 Test Number                      90
05 Assay List Number              1111
06 Assay Procedure
07 TPC Mode                          0
08 Blanking                        OPD
09 Data Reduction               CUTOFF
10 Well Status Flag                  Y
11 Multiple Trays                    Y
12 Technician Identification         Y
13 Master Lot                        Y
14 Sample IDs                        Y
15 Number of Blanks                 05
16 Unknown Replicates               01
17 Wash 1                           01
18 Component 1 Volume (uL)         200
19 Component 1 Name           HIV CONJ
20 Component 1 Type               RCJ1
21 Component 1 Station               2
22 Incubation Temperature 1 (°C)    40
23 Min Elapsed Time 1 (minutes)      0
24 Max Elapsed Time 1 (minutes)      0
25 Wash 2                           00
26 Component 2 Volume (uL)           0
27 Component 2 Name
28 Component 2 Type               NONE
29 Component 2 Station               1
30 Incubation Temperature 2 (°C)     0
31 Min Elapsed Time 2 (minutes)      0
32 Max Elapsed Time 2 (minutes)      0
33 Wash 3                           02
34 Component 3 Volume (uL)         300
35 Component 3 Name                OPD
36 Component 3 Type                OPD
37 Component 3 Station               4
38 Incubation Temperature 3 (°C)    25
39 Min Elapsed Time 3 (minutes)     28
40 Max Elapsed Time 3 (minutes)     32
41 Max OPD Disp-Read Time (sec)    120
42 Component 4 Volume (uL)         300
43 Component 4 Name         1N SULFURIC
44 Component 4 Type               ACID
45 Component 4 Station               5
46 Component 5 Type               NCN1
47 Negative Replicates              03
48 Min. Neg. Cntl. Replicates       02
49 Negative Location                A1
50 Neg. Min. Absorbance         -0.010
51 Neg. Max. Absorbance          0.100
52 Negative Aberrant (%):         71.0
53 Component 6 Type               PCN1
54 Positive Replicates              02
55 Min. Pos. Cntl. Replicates       02
56 Positive Location                A4
57 Pos. Min. Absorbance          0.140
58 Pos. Max. Absorbance          1.600
59 Positive Aberrant (%):         20.0
60 Component 7 Type               PCN2
61 PC2 Replicates                   02
62 Min. PC2 Replicates              02
63 PC2 Location                     B1
64 PC2 Min. Absorbance           0.140
65 PC2 Max. Absorbance           1.600
66 PC2 Aberrant (%):              20.0
67 Component 8 Type               PCN3
68 PC3 Replicates                   02
69 Min. PC3 Replicates              02
70 PC3 Location                     B3
71 PC3 Min. Absorbance           0.140
72 PC3 Max. Absorbance           1.600
73 PC3 Aberrant (%):              20.0
74 Min. Cntl. Diff. (P-N):       0.150
75 Max. Cntl. Diff. (P-N):         N/A
76 Min. PC2 Diff.                0.150
77 Max. PC2 Diff.                  N/A
78 Min. PC3 Diff.                0.150
79 Max. PC3 Diff.                  N/A
80 Negative Control Factor       1.000
81 Positive Control Factor       0.000
82 Cutoff Offset                 0.100
83 Reactive Gray Zone (%):         0.0
84 Negative Gray Zone (%):         0.0
85 Reactive Distinction              A
86 Min Sample React Abs         -0.015
87 Data Reduction Option            01
88 Blank Check Min. Diff.          N/A
89 Blank Check Max. Diff.          N/A
****************************************
```

Sample Results Printout Pos-2 and Pos-3 Controls Defined, TPC™ = Off

```
+---------------------------------------+
|          BATCH    INFO                |   (K)
+---------------------------------------+
ASSAY # 09   NAME: SAMPLE
TECH ID: RST  LOT # 0000000000  TEST #21
DATE: 01/11/97      TIME:18:05:21
PPC SERIAL NUMBER sssssss
+---------------------------------------+
| CUTOFF=( 1.000)NCX+( 0.000)PCX+ 0.100|
+---------------------------------------+
       TRAY ID      SIZE    STATUS
        49999M       20     BLANKS
        50000M       20     CONTROLS
(D)
+---------------------------------------+
|  TRAY#                    49999M      |
|  DATE: 01/11/97     TIME: 17:05:04    |   (L)
+---------------------------------------+

              WELL ABSORB
 I.D.#        LOC.  DIFF             NOTES
BLANK          A1   0.001
BLANK          A2   0.000
BLANK          A3  -0.001
BLANK          A4  -0.001
BLANK          A5  -0.002
     AVERAGE =     -0.001
(D)
+---------------------------------------+
|  TRAY#                    50000M      |
|  DATE: 01/11/97 (B) TIME: 17:05:44    |   (L)
+---------------------------------------+

              WELL ABSORB
 I.D.#        LOC.  DIFF     %CV     NOTES
-----------------------------------------
              CONTROLS                    (A)
-----------------------------------------
NEGATIVE CONTROL
               A1   0.048
               A2   0.051
               A3   0.026
     AVERAGE =      0.042   32.8
POSITIVE CONTROL
               A4   1.255
               A5   1.176
               B1   1.065
     AVERAGE =      1.165   8.2

POSITIVE - NEGATIVE =   1.123    (F)
CUTOFF VALUE =    0.142

(H) POSITIVE-2 CONTROL
               B1   0.931
               B2   1.099
     AVERAGE =      1.015   11.7

POSITIVE-2 - NEGATIVE =   0.973  (F)

(I) POSITIVE-3 CONTROL
               B3   1.113
               B4   0.987
     AVERAGE =      1.050   8.5

POSITIVE-3 - NEGATIVE =   1.008  (F)
-----------------------------------------

-----------------------------------------
(C)             SAMPLES
-----------------------------------------
  0000100M B2                   VOID
  0000101M B3    0.376          REACTIVE
  0000102M B4   -0.017          LOW
  0000103M B5    0.083            ...
  0000104M C1    1.082          REACTIVE
  0000105M C2   *ERROR          E*R*R*O*R
  0000106M C3                   NO SAMPLE
  0000107M C4    0.084            ...
  0000108M C5    0.127            ...
  0000109M D1                   NO SAMPLE
  0000110M D2    0.474          REACTIVE
           D3                   EMPTY
  0000111M D4 >  2.200          REACTIVE
  0000112M D5    0.768          REACTIVE
+---------------------------------------+
|     END   OF   BATCH                  |
|  DATE: 01/11/97      TIME: 17:05:57   |   (M)
+---------------------------------------+
```

Sample Results Printout With Invalid Controls TPC™ = Off

```
+---------------------------------------+
|          BATCH    INFO                |
+---------------------------------------+
ASSAY # 09   NAME: SAMPLE
TECH ID: RST  LOT # 0000000000  TEST #21
DATE: 01/11/97      TIME:18:05:21          (K)
PPC SERIAL NUMBER sssssss
+---------------------------------------+
| CUTOFF=( 1.000)NCX+( 0.000)PCX+ 0.100|
+---------------------------------------+
       TRAY ID      SIZE    STATUS
        68000M       20     BLANKS
        68007M       20     CONTROLS
(D)
+---------------------------------------+
|  TRAY#                    68000M      |
|  DATE: 01/11/97     TIME: 18:10:36    |   (L)
+---------------------------------------+

              WELL ABSORB
 I.D.#        LOC.  DIFF             NOTES
BLANK          A1   0.001
BLANK          A2   0.000
BLANK          A3   0.001
BLANK          A4   0.000
BLANK          A5  -0.001
     AVERAGE =      0.000
(D)
+---------------------------------------+
|  TRAY#                    68007M      |
|  DATE: 01/11/97 (B) TIME: 18:11:18    |   (L)
+---------------------------------------+

              WELL ABSORB
 I.D.#        LOC.  DIFF     %CV     NOTES
-----------------------------------------
              CONTROLS                    (A)
-----------------------------------------
NEGATIVE CONTROL
               A1   0.001
               A2   0.050
               A3   0.087
     AVERAGE =      0.046   93.8
       RANGE =  0.043 TO  0.049
               A1   0.001           ABERRANT
               A2   0.087           ABERRANT
POSITIVE CONTROL
               A4   1.060
               A5   1.342
               B1   0.125           REJECT
     AVERAGE =      1.201   16.6
(H) POSITIVE-2 CONTROL
               B1   0.931
               B2   1.099
     AVERAGE =      1.015   11.7
(I) POSITIVE-3 CONTROL
               B3   1.113
               B4   0.987
     AVERAGE =      1.050   8.5
-----------------------------------------
#########################################
 Date: 01/11/97  18:11:23   SN:sssssss    (E)
ERROR 2.1.1.35
 Too many Aberrant values in Controls -
 No flagging will be done.
#########################################
(C)             SAMPLES
-----------------------------------------
   014000M B2    1.360          OD ONLY!
   014001M B3    1.928          OD ONLY!
   014002M B4                   VOID
   014003M B5                   VOID
   014004M C1    0.022          OD ONLY!
   014005M C2    2.021          OD ONLY!
   014006M C3    0.405          OD ONLY!
   014007M C4    2.083          OD ONLY!
   014008M C5    0.284          OD ONLY!
   014009M D2    0.127          OD ONLY!
   014011M D4    0.015          OD ONLY!
   014012M D5    0.218          OD ONLY!
+---------------------------------------+
|     END   OF   BATCH                  |
|  DATE: 01/11/97      TIME: 18:11:31   |   (M)
+---------------------------------------+
```

Circled letters in Sample Results Printouts refer to the text on preceding pages.

Sample Assay Protocol Printout with Positive-2 Control Defined, TPC™ = Off

```
****************************************
        PPC Software Version   n.nn
              SN:sssssss

01 Assay Number                      66
02 Assay Name        Sample
03 Reminder        ROTATED TRAYS
04 Test Number                       71
05 Assay List Number               3A77
06 Assay Procedure
07 TPC Mode                           0
08 Blanking                         OPD
09 Data Reduction                CUTOFF
10 Well Status Flag                   Y
11 Multiple Trays                     Y
12 Technician Identification          Y
13 Master Lot                         Y
14 Sample IDs                         Y
15 Number of Blanks                  05
16 Unknown Replicates                01
17 Wash 1                            01
18 Component 1 Volume (uL)          200
19 Component 1 Name            HIV CONJ
20 Component 1 Type                RCJ1
21 Component 1 Station                2
22 Incubation Temperature 1 (°C)     40
23 Min Elapsed Time 1 (minutes)       0
24 Max Elapsed Time 1 (minutes)       0
25 Wash 2                            00
26 Component 2 Volume (uL)            0
27 Component 2 Name
28 Component 2 Type                NONE
29 Component 2 Station                1
30 Incubation Temperature 2 (°C)      0
31 Min Elapsed Time 2 (minutes)       0
32 Max Elapsed Time 2 (minutes)       0
33 Wash 3                            02
34 Component 3 Volume (uL)          300
35 Component 3 Name                 OPD
36 Component 3 Type                 OPD
37 Component 3 Station                4
38 Incubation Temperature 3 (°C)     25
39 Min Elapsed Time 3 (minutes)      28
40 Max Elapsed Time 3 (minutes)      32
41 Max OPD Disp-Read Time (sec)      90
42 Component 4 Volume (uL)          300
43 Component 4 Name          1N SULFURIC
44 Component 4 Type                ACID
45 Component 4 Station                5
46 Component 5 Type                NCN1
47 Negative Replicates               03
48 Min. Neg. Cntl. Replicates        02
49 Negative Location                 A1
50 Neg. Min. Absorbance          -0.010
51 Neg. Max. Absorbance           0.100
52 Negative Aberrant (%):          50.0
53 Component 6 Type                PCN1
54 Positive Replicates               02
55 Min. Pos. Cntl. Replicates        02
56 Positive Location                 A4
57 Pos. Min. Absorbance           0.500
58 Pos. Max. Absorbance             N/A
59 Positive Aberrant (%):          20.0
60 Component 7 Type                PCN2
61 PC2 Replicates                    02
62 Min. PC2 Replicates               02
63 PC2 Location                      B1
64 PC2 Min. Absorbance            0.350
65 PC2 Max. Absorbance              N/A
66 PC2 Aberrant (%):               50.0
67 Component 8 Type                 N/A
68 PC3 Replicates                   N/A
69 Min. PC3 Replicates              N/A
70 PC3 Location                     N/A
71 PC3 Min. Absorbance              N/A
72 PC3 Max. Absorbance              N/A
73 PC3 Aberrant (%):                N/A
74 Min. Cntl. Diff. (P-N):          N/A
75 Max. Cntl. Diff. (P-N):          N/A
76 Min. PC2 Diff.                   N/A
77 Max. PC2 Diff.                   N/A
78 Min. PC3 Diff.                   N/A
79 Max. PC3 Diff.                   N/A
80 Negative Control Factor        1.000
81 Positive Control Factor        0.000
82 Cutoff Offset                  0.100
83 Reactive Gray Zone (%):          0.0
84 Negative Gray Zone (%):          0.0
85 Reactive Distinction               A
86 Min Sample React Abs          -0.015
87 Data Reduction Option             00
88 Blank Check Min. Diff.           N/A
89 Blank Check Max. Diff.           N/A
****************************************
```

Circled letters in Sample Results Printouts refer to the text on preceding pages.

Sample Results Printout with Positive-2 Control Defined, TPC™ = Off

```
+--------------------------------------+
|        BATCH      INFO               |
+--------------------------------------+
ASSAY # 66    NAME: SAMPLE
TECH ID: RST   LOT # 0000000000   TEST #71
DATE: 01/17/97       TIME:12:03:04
PPC SERIAL NUMBER sssssss                     (K)
+--------------------------------------+
| CUTOFF=( 1.000)NCX+( 0.000)PCX+ 0.100|
+--------------------------------------+
      TRAY ID        SIZE     STATUS
    -----------      ----    --------
     2147111M         20     BLANKS           (L)
     2147000M         20     CONTROLS
(D)
+--------------------------------------+
| TRAY#           2147111M             |
| DATE: 01/17/97        TIME: 12:08:20 |
+--------------------------------------+

                WELL  ABSORB
  I.D.#         LOC.   DIFF          NOTES
=========== == =======            =========
BLANK           A1    0.001
BLANK           A2   -0.001
BLANK           A3    0.000
BLANK           A4    0.001
BLANK           A5    0.000
              -------  -------  -------  ---------
     AVERAGE =        0.000

+--------------------------------------+
(D) TRAY#           2147000M
 DATE: 01/17/97        TIME: 12:09:11    (L)
+                                    (B)
                WELL  ABSORB
  I.D.#         LOC.   DIFF    %CV    NOTES
=========== == ======= ======= =========
----------------------------------------
              CONTROLS                   (A)
----------------------------------------
NEGATIVE CONTROL
----------------
                 A1    0.044
                 A2    0.043
                 A3    0.031
          -------  -------  -------  ---------
     AVERAGE =        0.039    18.4
POSITIVE CONTROL
----------------
                 A4    1.370
                 A5    1.079
          -------  -------  -------  ---------
     AVERAGE =        1.225    16.8
(F)
POSITIVE - NEGATIVE =         1.186
CUTOFF VALUE =    0.139

POSITIVE-2 CONTROL
------------------
(H)              B1    1.116
                 B2    0.915
          -------  -------  -------  ---------
     AVERAGE =        1.016    14.0

POSITIVE-2 - NEGATIVE =    0.977
----------------------------------------

----------------------------------------
(C)           SAMPLES
----------------------------------------
  111111M B3    *ERROR             E*R*R*O*R
----------------------------------------
  111112M B4    -0.023             LOW
----------------------------------------
  111113M B5     0.138             ...     *
----------------------------------------
  111114M C1     1.099             REACTIVE
----------------------------------------
  111115M C2    *ERROR             E*R*R*O*R
----------------------------------------
  111116M C3                       VOID
----------------------------------------
  111117M C4     0.094             ...
----------------------------------------
  111118M C5     0.154             REACTIVE*
----------------------------------------
  111119M D1                       NO SAMPLE
----------------------------------------
  111120M D2     0.496             REACTIVE
----------------------------------------
  111121M D3     0.130             ...     *
          D4                       EMPTY
----------------------------------------
  111122M D5     0.643             REACTIVE
+--------------------------------------+
|     END   OF   BATCH                 |
|  DATE: 01/17/97       TIME: 12:09:24 |
+--------------------------------------+   (M)
```

Sample Results Printout with Positive-2 Control Defined and Invalid Controls, TPC™ = Off

```
+--------------------------------------+
|        BATCH      INFO               |
+--------------------------------------+
ASSAY # 66    NAME: SAMPLE
TECH ID: KLM   LOT # 0000000000   TEST #71   (K)
DATE: 01/16/97       TIME:12:08:44
PPC SERIAL NUMBER sssssss
+--------------------------------------+
| CUTOFF=( 1.000)NCX+( 0.000)PCX+ 0.100|
+--------------------------------------+
      TRAY ID        SIZE     STATUS
    -----------      ----    --------
(D)  8765000M         20     BLANKS
     8765432M         20     CONTROLS
+--------------------------------------+
| TRAY#           8765000M             |
| DATE: 01/16/97        TIME: 12:15:23 (L)
+--------------------------------------+

                WELL  ABSORB
  I.D.#         LOC.   DIFF          NOTES
=========== == =======            =========
BLANK           A1    0.001
BLANK           A2    0.001
BLANK           A3    0.000
BLANK           A4    0.000
BLANK           A5   -0.001
              -------  -------  -------  ---------
(D)  AVERAGE =        0.000
                                            (L)
+--------------------------------------+
| TRAY#       (B) 765432M
| DATE: 01/16/97        TIME: 12:16 (A)
+--------------------------------------+
                WELL  ABSORB
  I.D.#         LOC.   DIFF    %CV    NOTES
=========== == ======= ======= =========
----------------------------------------
              CONTROLS
----------------------------------------
NEGATIVE CONTROL
----------------
                 A1    0.078
                 A2    0.101             REJECT
                 A3    0.089
          -------  -------  -------  ---------
     AVERAGE =        0.084    9.3
POSITIVE CONTROL
----------------
                 A4    0.861
                 A5    1.200
(F)       -------  -------  -------  ---------
     AVERAGE =        1.031    23.3

POSITIVE - NEGATIVE =         0.947
CUTOFF VALUE =    0.184

(H)ITIVE-2 CONTROL
------------------
                 B1    0.266             REJECT
                 B2    1.178
          -------  -------  -------  ---------
     AVERAGE =        1.178    0.0

########################################
Date: 01/16/97   12:16:17   SN: sssssss      (E)
ERROR 2.1.1.57
Insufficient Positive-2 Controls -
No flagging will be done.
########################################
(C)
              SAMPLES
----------------------------------------
  21008M B3     0.525             OD ONLY!
----------------------------------------
  21009M B4     0.040             OD ONLY!
----------------------------------------
  21010M B5     0.858             OD ONLY!
----------------------------------------
  21011M C1                       VOID
----------------------------------------
  21012M C2     1.349             OD ONLY!
----------------------------------------
  21013M C3     0.393             OD ONLY!
----------------------------------------
  21014M C4     1.980             OD ONLY!
----------------------------------------
  21015M C5     0.237             OD ONLY!
----------------------------------------
  21016M D1     0.284             OD ONLY!
         D2                       EMPTY
----------------------------------------
  21017M D3     0.697             OD ONLY!
----------------------------------------
  21018M D4     0.110             OD ONLY!
----------------------------------------
  21019M D5                       NO SAMPLE
+--------------------------------------+
|     END   OF   BATCH                 |
|  DATE: 01/16/97       TIME: 12:16 (M)
+--------------------------------------+
```

Sample Results Printout with OPD Timing Set to "Verified", OPD Time Exceeded, TPC™ = Off

```
+----------------------------------------+
|          BATCH    INFO                 |
+----------------------------------------+
ASSAY # 65    NAME: SAMPLE
TECH ID: DKR  LOT # 0000000000  TEST #51
DATE: 09/14/97       TIME: 13:21:43
PPC SERIAL NUMBER sssssss                  (K)
OPD Timing = Verified
Minimum Time =  28   Maximum Time =  32
+----------------------------------------+
| CUTOFF=( 1.000)NCX+( 0.000)PCX+ 0.050  |
+----------------------------------------+
      TRAY ID        SIZE     STATUS
    -----------      ----     --------
        222479M       20      BLANKS
        222478M       20      CONTROLS

+----------------------------------------+
|  TRAY#              222479M            |
|  DATE: 09/14/97     TIME: 13:55:05     |
+----------------------------------------+

              WELL  ABSORB
 I.D.#        LOC.   DIFF             NOTES
===========  ==   =======          =========
BLANK         A1   -0.005
BLANK         A2   -0.003
BLANK         A3   -0.020
BLANK         A4   -0.006
BLANK         A5   -0.001
    -------     ------- ------- ---------
    AVERAGE =   -0.007
                                           (L)
+----------------------------------------+
|  TRAY#              222478M            |
|  DATE: 09/14/97     TIME: 13:59:39     |
+----------------------------------------+

              WELL  ABSORB
 I.D.#        LOC.   DIFF    %CV     NOTES
=========== == ======= ======= =========
-----------------------------------------
             CONTROLS
-----------------------------------------
NEGATIVE CONTROL
----------------
              A1    0.005
              A2    0.003
              A3    0.001
    -------     ------- ------- ---------
    AVERAGE =       0.003   66.7
POSITIVE CONTROL
----------------
              A4    0.242
              A5    0.181
    -------     ------- ------- ---------
    AVERAGE =       0.212   20.4

POSITIVE - NEGATIVE =   0.209
CUTOFF VALUE =   0.053
-----------------------------------------

-----------------------------------------
              SAMPLES
-----------------------------------------
              B1    0.004          ...
-----------------------------------------
              B2    0.005          ...
-----------------------------------------
              B3    0.083          REACTIVE
-----------------------------------------
              B4    0.003          ...
-----------------------------------------
              B5    0.043          ...
-----------------------------------------
              C1    0.008          ...
-----------------------------------------
              C2    0.004          ...
-----------------------------------------
              C3    0.013          ...
-----------------------------------------
              C4    0.197          REACTIVE
-----------------------------------------
              C5    0.007          ...
-----------------------------------------
              D1   -0.003          OPD TIME
-----------------------------------------
              D2    0.006          OPD TIME
-----------------------------------------
              D3    0.010          OPD TIME
-----------------------------------------
              D4    0.006          OPD TIME
-----------------------------------------
              D5    0.002          OPD TIME
-----------------------------------------
Row D incubation time=34  Exceeds limit
+----------------------------------------+
|       END   OF   BATCH                 |
|  DATE: 09/14/97       TIME: 14:00:0    (M)
+----------------------------------------+
```

Circled letters in Sample Results Printouts refer to the text on preceding pages.

Sample Assay Protocol Printout, TPC™ = Verify

```
*****************************************
         PPC Software Version  n.nn
               SN:ssssss
 01 Assay Number                      17
 02 Assay Name      Sample
 03 Reminder      ROTATED TRAYS
 04 Test Number                       71
 05 Assay List Number               3A77
 06 Assay Procedure
 07 TPC Mode                           0
 08 Blanking                         OPD
 09 Data Reduction                CUTOFF
 10 Well Status Flag                   Y
 11 Multiple Trays                     Y
 12 Technician Identification          Y
 13 Master Lot                         Y
 14 Sample IDs                         Y
 15 Number of Blanks                  05
 16 Unknown Replicates                01
 17 Wash 1                            01
 18 Component 1 Volume (uL)          200
 19 Component 1 Name            HIV CONJ
 20 Component 1 Type                RCJ1
 21 Component 1 Station                2
 22 Incubation Temperature 1 (°C)     40
 23 Min Elapsed Time 1 (minutes)       0
 24 Max Elapsed Time 1 (minutes)       0
 25 Wash 2                            00
 26 Component 2 Volume (uL)            0
 27 Component 2 Name
 28 Component 2 Type                NONE
 29 Component 2 Station                1
 30 Incubation Temperature 2 (°C)      0
 31 Min Elapsed Time 2 (minutes)       0
 32 Max Elapsed Time 2 (minutes)       0
 33 Wash 3                            01
 34 Component 3 Volume (uL)          300
 35 Component 3 Name                 OPD
 36 Component 3 Type                 OPD
 37 Component 3 Station                4
 38 Incubation Temperature 3 (°C)     25
 39 Min Elapsed Time 3 (minutes)      28
 40 Max Elapsed Time 3 (minutes)      32
 41 Max OPD Disp-Read Time (sec)      90
 42 Component 4 Volume (uL)          300
 43 Component 4 Name         1N SULFURIC
 44 Component 4 Type                ACID
 45 Component 4 Station                5
 46 Component 5 Type                NCN1
 47 Negative Replicates               03
 48 Min. Neg. Cntl. Replicates        02
 49 Negative Location                 A1
 50 Neg. Min. Absorbance          -0.010
 51 Neg. Max. Absorbance           0.100
 52 Negative Aberrant (%):          50.0
 53 Component 6 Type                PCN1
 54 Positive Replicates               02
 55 Min. Pos. Cntl. Replicates        02
 56 Positive Location                 A4
 57 Pos. Min. Absorbance           0.500
 58 Pos. Max. Absorbance             N/A
 59 Positive Aberrant (%):          50.0
 60 Component 7 Type                PCN2
 61 PC2 Replicates                    02
 62 Min. PC2 Replicates               02
 63 PC2 Location                      B1
 64 PC2 Min. Absorbance            0.350
 65 PC2 Max. Absorbance              N/A
 66 PC2 Aberrant (%):               50.0
 67 Component 8 Type                 N/A
 68 PC3 Replicates                   N/A
 69 Min. PC3 Replicates              N/A
 70 PC3 Location                     N/A
 71 PC3 Min. Absorbance              N/A
 72 PC3 Max. Absorbance              N/A
 73 PC3 Aberrant (%):                N/A
 74 Min. Cntl. Diff. (P-N):          N/A
 75 Max. Cntl. Diff. (P-N):          N/A
 76 Min. PC2 Diff.                   N/A
 77 Max. PC2 Diff.                   N/A
 78 Min. PC3 Diff.                   N/A
 79 Max. PC3 Diff.                   N/A
 80 Negative Control Factor        1.000
 81 Positive Control Factor        0.000
 82 Cutoff Offset                  0.100
 83 Reactive Gray Zone (%):          0.0
 84 Negative Gray Zone (%):          0.0
 85 Reactive Distinction               A
 86 Min Sample React Abs          -0.015
 87 Data Reduction Option             00
 88 Blank Check Min. Diff.           N/A
 89 Blank Check Max. Diff.           N/A
*****************************************
```

Sample Results Printout TPC™ = Verify

```
+---------------------------------------+
|        BATCH    INFO                  |
+---------------------------------------+
ASSAY # 17    NAME: SAMPLE
LIST #-PROCEDURE:       3A77-
TECH ID 1: 123456
TECH ID 2:
TECH ID OPD: 123456
TECH ID ACID: 654321
TPC MODE = VERIFY
PPC SERIAL NUMBER 0001485
PPC VERSION NUMBER  7R00
DATE: 08/04/95      TIME: 15:58:10        (K)
OPD Timing = Verified
Minimum Time =  28    Maximum Time =  32
Sample ID Size = 20
+---------------------------------------+
| CUTOFF=( 1.000)NCX+( 0.000)PCX+ 0.100|
+---------------------------------------+
       TRAY ID       SIZE     STATUS
     ----------      ----    --------
         77777M       20     BLANKS
       1721068M       20     CONTROLS

TPC INFORMATION:   (G)
================

TYPE  EXPIRATION            LOT#      DEV.
----  ----------         ----------   ----
ML    01/02/96            34567M100M
RCJ1  08/25/95             14774111M
CJC1  03/01/96            12345M207
CJD1  12/31/95             12344563
OPD   07/21/95-15:29:16     2530001M  *01*
BEAD  12/31/95             12344561M  *04*
ACID  12/12/96                01920M
(D) +-----------------------------------+
 TRAY#                   77777M
|TPC INFORMATION:   (G)                 |
|                                       |
|TYPE  EXPIRATION      LOT#         DEV.|
|----  ----------   ----------     ----|
|BKBD  12/12/96        01921M   (L)     |
|                                       |
|  DATE: 08/04/95          TIME: 16:47:00
+------------------- (B) ---------(A)---+
                WELL  ABSORB
  I.D.#         LOC.   DIFF          NOTES
===========     ==   =======     =========
BLANK           A1    0.000
BLANK           A2    0.000
BLANK           A3   -0.002
BLANK           A4   -0.001
BLANK           A5    0.000
          -------      -------  -------  ---------
     AVERAGE =        -0.001
(D) +-----------------------------------+
 TRAY#                 1721068M         |
|TPC INFORMATION:  (G)                  |
|                                       |
|TYPE  EXPIRATION       LOT#        DEV.|
|----  ----------                   ----|
|SPDL  10/02/96     45678M203M          |
|NCN1  05/01/96     76543M200M          |
|PCN1  01/03/96     34567M201M          |
|PCN2  04/04/96     87654M202M          |
|BEAD  12/31/95      12344561M     *04* |
|PIPETTOR SERIAL NUMBER        95N097   |
|PIPETTOR VERSION NUMBER     2.5        |
|PIPETTOR TECH ID: 123445        (L)    |
|                                       |
|  DATE: 08/04/95         TIME: 16:47:43|
+------------------- (B) ---------(A)---+
                WELL  ABSORB
  I.D.#         LOC.   DIFF     %CV     NOTES
===========     ==   =======  =======  =========
```

continued →

Sample Results Printout TPC™ = Verify

```
-------------------------------------------
               CONTROLS
-------------------------------------------
NEGATIVE CONTROL
----------------
                A1    0.080
                A2    0.057
                A3    0.053
          -------   -------  -------  ---------
     AVERAGE =        0.063   23.0
POSITIVE CONTROL
----------------
                A4    0.714
                A5    0.611
          -------   -------  -------  ---------
(F)  AVERAGE =        0.663   11.0
POSITIVE - NEGATIVE =      0.600
CUTOFF VALUE =    0.163

POSITIVE-2 CONTROL
------------------
                B1    0.513
                B2    0.929
          -------   -------  -------  ---------
     AVERAGE =        0.721   40.8

POSITIVE-2 - NEGATIVE =    0.658
-------------------------------------------

-------------------------------------------
               SAMPLES
-------------------------------------------
(C)    01625b B3    0.674           REACTIVE
-------------------------------------------
       01626m B4                    VOID
-------------------------------------------
       45646
5354134564m B5  > 2.200             REACTIVE
-------------------------------------------
 446654064
6464064654m C1    0.325             REACTIVE
-------------------------------------------
4654646546
5454546465m C2    1.047             REACTIVE
-------------------------------------------
4640654646
5464565789m C3  > 2.200             REACTIVE

            C4                      EMPTY
-------------------------------------------
6789798764
6465768434m C5    0.269             REACTIVE
-------------------------------------------
4646789467
4648616846m D1    0.755             REACTIVE
-------------------------------------------
  46467664
6486464654m D2    0.355             REACTIVE
-------------------------------------------
 464646654
8946384684m D3    1.169             REACTIVE
-------------------------------------------
4646465768
7648464065m D4    0.160             ...
-------------------------------------------
4657684630
6546789435m D5    0.099             ...
+------------------------------------------+
|    END   OF   BATCH                      |
|  DATE: 08/04/95         TIME: 16:48:12   |
+------------------------------------- (M)-+
```

Circled letters in Sample Results Printouts refer to the text on preceding pages.

NOTES

Appendix B

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Appendix B

NOTES

Appendix B
Point-to-Point Assay Protocol Reference Guide

Introduction

The COMMANDER® Parallel Processing Center (PPC) automatically performs the data reduction calculations for Point-to-Point Assays. The assay protocol parameters and values are included in the specific assay protocols.

Assay protocol parameters can be viewed by printing a copy of the assay protocol. This may be done by using the LIST PROTOCOL special function key. The Data Reduction parameters appear in Lines 46 through 82. Refer to the Sample Printouts elsewhere in this section.

The Point-to-Point data reduction is a procedure used to determine the concentration of a known substance in a patient sample. The concentration is calculated from a curve that is developed from the absorbances of a set of standards with known concentrations for each assay.

Editing Protocols

Some assay protocol values can be adjusted by following the editing procedures explained in *Editing Protocols* in *Section 2, Installation Procedures and Special Requirements*.

Although Abbott-supplied assay protocols are considered non-editable, they may be changed and stored under a different assay number without changing or deleting the original Abbott assay.

NOTE: An operator-edited assay protocol may be used if the edited protocol parameter values are consistent with the reagent package insert specifications and are supported by documentation at the time of edit.

Whenever a user-edited assay protocol is created, either the list number or the procedure must be changed to create a unique list number/procedure combination for that protocol. The list number and procedure of the original Abbott-supplied assay protocol cannot be used for user-edited assay protocols.

When connected to an FPC™ pipettor, version 2.5 or greater, the TPC™ mode of PPC assay processing is dictated by the FPC assay protocol. The operator must assure that the list number/ procedure code combination on the PPC and FPC are identical. An edit to the PPC assay protocol to set the desired TPC mode is not required. When operating the PPC with a non TPC-capable pipettor, or in Stand Alone Mode, the TPC mode of PPC assay processing is dictated by the TPC mode of the PPC assay protocol. If you wish to change the TPC mode of PPC assay processing, a user-edited assay protocol will be required.

Point-to-Point Assay Checks

The following checks are made automatically as assay processing takes place. If any one check fails, the PPC will print an error message indicating the failure and will print only absorbance values for patient samples.

1. All standards included in the assay protocol must be included in the first tray of a batch.
2. Standards must be monotonic (*i.e.,* the standards must be read in order of increasing concentrations, and the mean absorbance for each standard must have either a successively higher or lower absorbance than that of the preceding standard [an increasing or decreasing standard curve.])
3. There must be valid absorbances for all standards specified in the protocol. One absorbance value is allowed to be voided when standard replicates of two or more are specified. When a standard is voided and it is a single replicate, a valid standard curve cannot be constructed.

   In the case of more than one replicate, the PPC automatically calculates and prints an average OD and %CV. The calculations are as follows:

   a. An Average, or Mean (M) = $\frac{\Sigma_i (\text{O.D.})_i}{n}$

      where

      n = number of replicates

      $(\text{O.D.})_i$ = an absorbance reading for the i^{th} replicate sample

b. % Coefficient of Variation (%CV) = $\frac{SD}{M}$ x 100

where

Standard Deviation (SD) = $\sqrt{\frac{[(n)\ (\Sigma x^2)] - (\Sigma x)^2}{(n)\ (n-1)}}$

If only one valid control replicate remains, the average is set to that replicate's OD, and the %CV is zero.

4. The absorbance of each standard lies within the following range: –0.024 to 2.200.
5. The absorbance of each standard is less than the maximum instrument limit.

The following checks are defined by parameters entered in an assay protocol. If the following checks are included in a protocol, they must pass in the following order for sample results to be calculated. If any one check fails, the PPC will print a flag or an error message indicating the failure and will print only absorbance values for sample results.

1. The mean absorbance value of a reference standard named in Line 67 of the protocol must fall on or between the minimum and maximum acceptable absorbance values set in Lines 68 and 69.
2. The Absorbance Difference, calculated using Standards A and B (identified in Lines 70 and 71), must be equal to or between the minimum and maximum acceptable values named in Lines 72 and 73.

ABSORBANCE DIFFERENCE = STANDARD A ABSORBANCE – STANDARD B ABSORBANCE

3. Absorbance Ratio #1, calculated using Standards A and B named in Lines 74 and 75 of the protocol, must be equal to or between the minimum and maximum acceptable values named in Lines 76 and 77.

$$\text{ABSORBANCE RATIO} = \frac{\text{STANDARD A ABSORBANCE}}{\text{STANDARD B ABSORBANCE}}$$

4. Absorbance Ratio #2, calculated using Standards C and D named in Lines 78 and 79 and the same formula shown above, must be equal to or between the minimum and maximum acceptable values named in Lines 80 and 81.

Assay Protocol Values

The following is a line by line description of the parameters listed in the assay protocol.

General Information

Line 1

Assay Number: Used to identify the assay protocol to be utilized by the PPC.

Line 2

Assay Name: Provides a descriptive identification of an assay protocol for operator use.

Line 3

Reminder: A 20 character Reminder Message may be entered to be displayed at the beginning of the first pass. This message will be displayed during processing as:

"HAVE YOU ^^^^^^^^^^^^^^^^^^^^?(YES/NO)"

"^" represents each of the 20 characters that may be defined. When a reminder message is entered, the operator is required to enter YES for the processing to continue. If NO is entered, the operator will be prompted to remove the tray.

If no message is entered, the question will not be asked and the operator entry will not be required.

Line 4

Test Number: The test number is used to identify an assay on a compatible pipettor system (non-FPC™). Pipettor test number and PPC assay protocols must be linked to allow automatic transfer of data when using a compatible pipettor system (non-FPC). (See Protocol Select in *Section 2, Installation and Special Requirements*.)

Line 5 & 6

Assay List Number, Assay Procedure: The Abbott product number supplied on an assay kit and the assay procedure code. The procedure code may be identified in assay package insert which identifies specific processing parameters for the different procedures and/or calculations, or it may be an identifier unique to specific procedures for common Assay List Numbers. The Assay List Number and Assay Procedure specified in the assay protocol is a unique identifier to link the assay protocols on the FPC™ and PPC.

Line 7

TPC™ Mode: The level of Total Process Control (TPC™) to be used in processing the assay: Record or Off. The default for assays is Off.

Use of the Verify mode can only occur with an FPC™ pipettor, version 2.5 or greater. The Verify mode is dictated by the assay protocol on the FPC, regardless of the TPC mode in the PPC assay protocol.

Line 8

Blanking: Identifies the type of Blanking to be used (*i.e.*, OPD, ACID, NONE [no blanks tray]). Point-to-point assay protocols do not require blanking.

Line 9

Data Reduction: Indicates the type of data reduction used to calculate results (*i.e.,* cutoff or point-to-point).

Line 10

Well Status Flag: A "Y" on this line will cause display to prompt for void, no sample or empty wells when in the Stand Alone Mode.

Line 11

Multiple Trays: Allows the operator to select either single or multiple tray batch processing. "Y" on this line will cause the display to prompt for the number of trays in a batch.

Line 12

Technician Identification: Allows printouts to be identified with technician initials. “Y” on this line causes the display to prompt for tech ID. Applies only to assays with TPC™ mode of OFF.

Line 13

Master Lot: Allows printouts to be identified with master lot number. “Y” on this line causes display to prompt for master lot number. Applies only to assays with TPC mode of OFF.

Line 14

Sample IDs: Allows Stand Alone PPC to print results with sample IDs. “Y” on this line causes PPC to prompt for sample IDs and identify results with IDs.

Line 15

Number of Blanks: Used to indicate the number of reagent blank wells to be processed with each batch. Point-to-Point assay protocols do not require blanking.

Line 16

Unknown Replicates: Used to indicate the number of sample replicates to be run.

Processing Functions

Line 17

Wash 1: A number on this line specifies the type of wash function that will be performed on the first pass of a batch (0 = no wash).

Line 18

Component 1 Volume (uL): Indicates the volume in µL (microliters) of the reagent to be dispensed on the first pass. If no dispense occurs, volume = 0.

Line 19

Component 1 Name: Provides a descriptive identification of the reagent to be dispensed on the first pass.

Line 20

Component 1 Type: A 4-character abbreviation of the component name as it appears on the results printout.

If creating an assay protocol that will be pipetted with an FPC™, the parameters of the created component type must exactly match those of the FPC. Do not use ML, UNKN, BEAD, or BKBD as component types in any edited assay protocol because proper assay processing cannot be assured.

Line 21

Component 1 Station: Indicates the dispenser station, identified on the PPC with a bar code label for use in TPC™, in which the reagent for the first pass should be placed. The location will be displayed on the status screen at the beginning of a processing pass and the bottle will be backlit.

Line 22

Incubation Temperature 1 (ºC): Indicates the approximate temperature (in degrees C) for incubation occurring between the first and second pass. Room temperature is designated by 25. Refer to the reagent package insert for the specific incubation temperature requirement.

Line 23 & 24

Minimum Elapsed Time 1 (minutes), Maximum Elapsed Time 1 (minutes): Set to zero. Currently the PPC does not time passes prior to OPD timing.

Line 25

Wash 2: A number on this line specifies the type of wash function that will be performed on the second pass of a batch (0 = no wash).

Line 26

Component 2 Volume (uL): Indicates the volume in µL (microliters) of the reagent to be dispensed on the second pass. If no dispense occurs, volume = 0.

Line 27

Component 2 Name: Provides a descriptive identification of the reagent to be dispensed on the second pass.

Line 28

Component 2 Type: A 4-character abbreviation of the component name as it appears on the results printout.

If creating an assay protocol that will be pipetted with an FPC™, the parameters of the created component type must exactly match those of the FPC. Do not use ML, UNKN, BEAD, or BKBD as component types in any edited assay protocol because proper assay processing cannot be assured.

Line 29

Component 2 Station: Indicates the dispenser station, identified on the PPC with a bar code label for use in TPC™, in which reagent for the second pass should be placed. The location will be displayed on the status screen at the beginning of a processing pass and the bottle will be backlit.

Line 30

Incubation Temperature 2: Indicates the approximate temperature (in degrees C) for incubation occurring between the second and OPD pass. Room temperature is designated by 25. Refer to the reagent package insert for the specific incubation temperature requirement.

Line 31 & 32

Minimum Elapsed Time 2 (minutes), Maximum Elapsed Time 2 (minutes): Set to zero. Currently the PPC does not time passes prior to OPD timing.

Line 33

Wash 3: A number on this line specifies the type of wash function that will be performed on the OPD pass of a batch (0 = no wash).

Line 34

Component 3 Volume (uL): Indicates the volume in µL (microliters) of the reagent to be dispensed on the OPD pass. If no dispense occurs, volume = 0.

Line 35

Component 3 Name: Provides a descriptive identification of the reagent to be dispensed on the OPD pass.

Line 36

Component 3 Type: A 4-character abbreviation of the component name as it appears on the results printout.

If creating an assay protocol that will be pipetted with an FPC™, the parameters of the created component type must exactly match those of the FPC. Do not use ML, UNKN, BEAD, or BKBD as component types in any edited assay protocol because proper assay processing cannot be assured.

Line 37

Component 3 Station: Indicates the dispenser station, identified on the PPC with a bar code label for use in TPC™, in which reagent for the OPD pass should be placed. The location will be displayed on the status screen at the beginning of a processing pass and the bottle will be backlit.

Line 38

Incubation Temperature 3 (ºC): Indicates the approximate temperature (in degrees C) for incubation occurring between the OPD and acid pass. Room temperature is designated by 25. Refer to the reagent package insert for the specific incubation temperature requirement.

Line 39

Minimum Elapsed Time 3 (minutes): Minimum OPD incubation time. An N/A on this line means no check will be made.

Line 40

Maximum Elapsed Time 3 (minutes): Maximum OPD incubation time. An N/A on this line means no check will be made.

Line 41

Maximum OPD Dispense-Read Time (sec): Maximum allowable time (in seconds) from OPD dispense to OPD read. An N/A on this line means no check will be made.

Line 42

Component 4 Volume (uL): Indicates the volume in µL (microliters) of the reagent to be dispensed on the acid pass. If no dispense occurs, volume = 0.

Line 43

Component 4 Name: Provides a descriptive identification of the reagent to be dispensed on the acid pass.

Line 44

Component 4 Type: A 4-character abbreviation of the component name as it appears on the results printout.

If creating an assay protocol that will be pipetted with an FPC™, the parameters of the created component type must exactly match those of the FPC. Do not use ML, UNKN, BEAD, or BKBD as component types in any edited assay protocol because proper assay processing cannot be assured.

Line 45

Component 4 Station: Indicates the dispenser station, identified on the PPC with a bar code label for use in TPC™, in which reagent for the acid pass should be placed. The location will be displayed on the status screen at the beginning of a processing pass and the bottle will be backlit.

Standards

Line 46

Units: Determines the units in which results will be calculated and reported. These units are identified below:

Units	Key Selection
None	0
ng/mL	1
µg/mL	2
mg/mL	3
pg/mL	4
meq/L	5
meq/mL	6
mM	7
mIU/mL	8
IU/L	9
% ACT	10
fm/mL	11
IU/mL	12
µIU/mL	13
µg/dL	14
% SAT	15
Uptake	16
ng/dL	17
mIU/L	18
U/mL	19

Line 47

Unknown Dilution: Indicates the dilution factor by which concentration is multiplied to determine the original sample concentration.

Line 48

Number of Standards: Indicates the number of standards used to set the point-to-point curve against which results will be calculated.

Line 49

Standard Replicates: Indicates the number of replicates of each standard to be tested.

Line 50

Standard Location: Indicates the first well for standards placement. The subsequent standards must be placed sequentially in the first tray.

Line 51

Component 5 Type: A 4-character abbreviation of the component name as it appears on the results printout.

If creating an assay protocol that will be pipetted with an FPC™, the parameters of the created component type must exactly match those of the FPC. Do not use ML, UNKN, BEAD, or BKBD as component types in any edited assay protocol because proper assay processing cannot be assured.

Line 52

Std # 1 Concentration: Indicates the concentration of standard #1. N/A indicates an unused standard. Line 46 defines the concentration units.

Line 53

Component 6 Type: A 4-character abbreviation of the component name as it appears on the results printout.

If creating an assay protocol that will be pipetted with an FPC, the parameters of the created component type must exactly match those of the FPC. Do not use ML, UNKN, BEAD, or BKBD as component types in any edited assay protocol because proper assay processing cannot be assured.

Line 54

Std # 2 Concentration: Indicates the concentration of standard #2. N/A indicates an unused standard. Line 46 defines the concentration units.

Line 55

Component 7 Type: A 4-character abbreviation of the component name as it appears on the results printout.

If creating an assay protocol that will be pipetted with an FPC™, the parameters of the created component type must exactly match those of the FPC. Do not use ML, UNKN, BEAD, or BKBD as component types in any edited assay protocol because proper assay processing cannot be assured.

Line 56

Std # 3 Concentration: Indicates the concentration of standard #3. N/A indicates an unused standard. Line 46 defines the concentration units.

Line 57

Component 8 Type: A 4-character abbreviation of the component name as it appears on the results printout.

If creating an assay protocol that will be pipetted with an FPC, the parameters of the created component type must exactly match those of the FPC. Do not use ML, UNKN, BEAD, or BKBD as component types in any edited assay protocol because proper assay processing cannot be assured.

Line 58

Std # 4 Concentration: Indicates the concentration of standard #4. N/A indicates an unused standard. Line 46 defines the concentration units.

Line 59

Component 9 Type: A 4-character abbreviation of the component name as it appears on the results printout.

If creating an assay protocol that will be pipetted with an FPC, the parameters of the created component type must exactly match those of the FPC. Do not use ML, UNKN, BEAD, or BKBD as component types in any edited assay protocol because proper assay processing cannot be assured.

Line 60

Std # 5 Concentration: Indicates the concentration of standard #5. N/A indicates an unused standard. Line 46 defines the concentration units.

Line 61

Component 10 Type: A 4-character abbreviation of the component name as it appears on the results printout.

If creating an assay protocol that will be pipetted with an FPC™, the parameters of the created component type must exactly match those of the FPC. Do not use ML, UNKN, BEAD, or BKBD as component types in any edited assay protocol because proper assay processing cannot be assured.

Line 62

Std # 6 Concentration: Indicates the concentration of standard #6. N/A indicates an unused standard. Line 46 defines the concentration units.

Line 63

Component 11 Type: A 4-character abbreviation of the component name as it appears on the results printout.

If creating an assay protocol that will be pipetted with an FPC™, the parameters of the created component type must exactly match those of the FPC. Do not use ML, UNKN, BEAD, or BKBD as component types in any edited assay protocol because proper assay processing cannot be assured.

Line 64

Std # 7 Concentration: Indicates the concentration of standard #7. N/A indicates an unused standard. Line 46 defines the concentration units.

Line 65

Component 12 Type: A 4-character abbreviation of the component name as it appears on the results printout.

If creating an assay protocol that will be pipetted with an FPC, the parameters of the created component type must exactly match those of the FPC. Do not use ML, UNKN, BEAD, or BKBD as component types in any edited assay protocol because proper assay processing cannot be assured.

Line 66

Std # 8 Concentration: Indicates the concentration of standard #8. N/A indicates an unused standard. Line 46 defines the concentration units.

Line 67

Standard Number: Any single standard may be selected to be checked for minimum and/or maximum mean absorbance. An entry of zero means no standard is being checked.

Line 68 & 69

Minimum Mean Absorbance & Maximum Mean Absorbance: These values set the minimum and maximum acceptable mean absorbance values for the standard selected in Line 67. N/A on these lines means no check will be made.

Line 70 & 71

Difference Standard A & Difference Standard B: Used to select two standards for checking the absorbance difference (STD A – STD B). An entry of zero means no check. No difference is being checked.

Line 72 & 73

Minimum Absorbance Difference (A–B) & Maximum Absorbance Difference (A–B): These values set the minimum and maximum acceptable absorbance differences calculated from the two standards identified on Lines 70 and 71. N/A on these lines means no check will be made.

Line 74 & 75

Ratio 1 Standard A & Ratio 1 Standard B: Used to select two standards to check an absorbance ratio (STD A/STD B). An entry of zero means ratio 1 is not being checked.

Line 76 & 77

Minimum Ratio 1 & Maximum Ratio 1: Used to set the minimum and maximum acceptable values for the absorbance ratio of the standards selected in Lines 74 and 75 (STD A/STD B). N/A on these lines means no check will be made.

Line 78 & 79

Ratio 2 Standard C & Ratio 2 Standard D: Used to select another set of standards to check a second absorbance ratio (STD C/STD D). An entry of zero means no check.

Line 80 & 81

Minimum Ratio 2 (C/D) & Maximum Ratio 2 (C/D): Used to set the minimum and maximum acceptable values for the second absorbance ratio of the standards selected in Lines 78 and 79 (STD C/STD D). N/A entered on these lines means no check is to be made.

Line 82

Minimum Sample Absorbance: This value defines the minimum acceptable sample absorbance. If the Standard or Sample absorbance is less than this value, an appropriate error message will be displayed.

The following information can be referenced to the Sample Results Printout.

Examples of Printouts

The bold letters identifying the explanations below are keyed to the printout examples that follow.

Results Calculation

To calculate the Point-to-Point standard curve, the PPC "plots" the mean absorbances measured for each standard against its known concentration and then "constructs" a straight line between adjacent points. (No graph is printed.) The measured absorbances for the samples are then compared to the curve to determine the concentrations for each. Concentrations for samples requiring a dilution are multiplied by the dilution factor defined in Line 47 (*i.e.,* if a sample is diluted 1:2, the dilution factor is 2). If the samples are run in replicate, averages and %CVs of the absorbances and concentrations are printed for each set of replicates. The absorbances and concentrations are printed for each unknown, except as described below.

When the sample concentration is outside the range of the standard curve:

A. **ABOVE THE STANDARD CURVE:** The concentration value is set to the highest standard value multiplied by the dilution factor. The adjusted concentration is used in all subsequent calculations.

B. **BELOW THE STANDARD CURVE:** The concentration value is set to the lowest standard value multiplied by the dilution factor. The adjusted concentration is used in all subsequent calculations.

C. **SAMPLE FLAGGING:** An appropriate GREATER THAN (>) or LESS THAN (<) symbol is printed immediately preceding the adjusted concentration value.

D. **CONCENTRATION AVERAGE FLAGGING:** The appropriate GREATER THAN (>) or LESS THAN (<) symbol is printed immediately preceding the AVG concentration value, unless the flagged concentration value is 0.000. When the flagged sample concentration value is 0.000, the LESS THAN (<) symbol will not be printed for the average. A series of asterisks (******) will be printed for the AVG when individual sample results within a replicate series have both a GREATER THAN (>) and LESS THAN (<) symbol associated with them.

E. **% CV PRINTING:**

- The numeric CV will not be printed for the concentrations or absorbances when a GREATER THAN (>) or LESS THAN (<) sample concentration value is flagged. It will also not be printed if the calculated %CV is GREATER THAN (>) 999.99. In these cases, it is flagged with a series of asterisks (******).
- When the mean is equal to 0.0, the %CV cannot be calculated. This will be flagged with a series of asterisks (******). Absorbance values printed for the wells are valid.
- The CV will print as a series of asterisks (******) if the sample concentration is less than the minimum standard concentration or greater than the maximum standard concentration.

F. **CONCENTRATION:** The concentration value will not be printed under certain conditions. When the concentration is not printed, either the field will be left blank or an appropriate status message will be printed.

The status message that can be printed in the CONC. Column are as follows:

- **EMPTY —** Tray well does not have a sample pipetted into it by an automated pipettor or the well location was designated as "EMPTY" when running the PPC in the Stand Alone Mode.
- **NO SAMPLE —** Samples that have been designated as NO SAMPLE, possibly because of insufficient sample volume to conduct an assay, and you want to maintain sample ID sequence until after reading the batch results.
- **OPD TIME —** OPD incubation time too long. Exceeds maximum OPD time (line 41). Refer to the reagent package insert for the appropriate action.
- **VOID —** This indicates that something has occurred during processing, possibly caused by the pipettor, that has invalidated the sample results.
- **?STATUS —** This will be printed if a well has an invalid status.

G. When an absorbance value is below the Minimum Sample Absorbance as defined in Line 82 of the Assay Protocol, no concentration(s) will be printed. If the location is a Standard well, no concentrations will be printed for the samples. If the location is a sample well, no concentration will be printed for the sample (or any remaining samples of that replicate group if running replicates of 2 or more).

H. When the sample absorbance is printed as *ERROR, the reading is invalid. The sample absorbance is either outside the instrument range or there has been a reader error. When the absorbance is not a numeric value, the sample should be reassayed. For more information, refer to *Section 10, Troubleshooting and Diagnostics.*

CAUTION: A Sample with an OD of "*ERROR" should alert the operator to inspect the results of the entire row. The results of other samples in the row are questionable. **Reassay all samples in the row and resolve per your laboratory standard operating procedure.**

I. Error messages that occur within the Standards readings may cause concentration values to not be printed.

J. TPC™ Information

TPC information for the batch is printed in the BATCH INFO portion of the tape.

TPC information that is tray-specific is printed within the Tray Identification portion of the tape.

The source of the component lot number entry is identified by adding **M** or a **B** to the right of the lot #. Source of entry for components that are combined to create resultant mixtures are not identified.

M = manual entry (This includes lot numbers that are displayed and acknowledged using the keypad in such procedures as the Bead Drop Procedure.)

B = bar coded entry

The codes that may be printed in the DEV column of the PPC Result Printout are listed below.

Code/Flag	Condition	Explanation
01	Expired Master Lot or Component Lot	For reconstituted mixtures, the expiration time is calculated at the time the new mixture lot number is validated between all connected FPC™ instruments and the PPC. The earliest instrument time is used to establish the expiration time as shown on the PPC. • For non-OPD passes, the expiration is checked at the beginning of the pass for the batch. • For OPD pass, the expiration is checked at the beginning and end of the pass for the batch. • For non-OPD component types, the expiration date is printed. • For the OPD component type, the expiration date and time is printed. • All expirations are checked to the second. • For component types with expirations in terms of days, the expiration time is 23:59:59 on the date of expiration. • For component types with expirations in terms of hours, the expiration time is to the hh:mm:ss, even though the expiration in the printout may only include hh:mm. For all other reagents and master lots, the expiration dates are listed on the assay kit card and the individual components. These dates are entered via the FPC.

Code/Flag	Condition	Explanation
02	Unknown Master Lot	The Master Lot number cannot be located in the FPC™ component library.
03	Unknown Component Lot	The component lot number cannot be located in the FPC component library.
04	Invalid Component (wrong Master Lot)	The Master Lot of the component lot number does not match the Master Lot of the tray.
05	Expired Master Lot or Component Lot *and* Invalid Component (wrong Master Lot)	Combination of 01 and 04 (see above)
06	No Bead lot number recorded	• The bead lot number cannot be located in the FPC component library. • The Bead Drop Procedure may not have been performed. • The Bead Drop Procedure was performed after the OPD pass on a PPC not processing the batch.
NV	Unable to verify component (communication failure)	This is a flag that is applied when an instrument error occurs. If the problem is resolved before the final results are printed, this flag will not be printed.

K. **Header Time Stamps**: The time stamp printed in both the BATCH INFO header and on the REREAD reflects the time at which the batch was created in the database

L. **Tray Time Stamps:** The time stamps printed on the tray final results reflect the time stamp at which row A was positioned in the read station. This time may be correlated to the time at which row F was in the dispensing station; however, it does not indicate the time of dispense of any particular well in row F.

M. **Footer Time Stamps:** The time printed on the Batch Report Footer corresponds to the completion of the last row for the last tray of the batch.

Sample Assay Protocol Printout (TPC™ = Off)

```
****************************************
      PPC Software Version  n.nn
             SN:sssssss

01 Assay Number                   67
02 Assay Name  SAMPLE
03 Reminder
04 Test Number                    69
05 Assay List Number            2222
06 Assay Procedure
07 TPC Mode                        0
08 Blanking                     NONE
09 Data Reduction     POINT TO POINT
10 Well Status Flag                Y
11 Multiple Trays                  Y
12 Technician Identification       N
13 Master Lot                      N
14 Sample IDs                      N
15 Number of Blanks               00
16 Unknown Replicates             02
17 Wash 1                         01
18 Component 1 Volume (uL)       200
19 Component 1 Name         CONJ
20 Component 1 Type             CNJ1
21 Component 1 Station             2
22 Incubation Temperature 1 (°C) 45
23 Min Elapsed Time 1 (minutes)    0
24 Max Elapsed Time 1 (minutes)    0
25 Wash 2                         00
26 Component 2 Volume (uL)         0
27 Component 2 Name
28 Component 2 Type             NONE
29 Component 2 Station             1
30 Incubation Temperature 2 (°C)  0
31 Min Elapsed Time 2 (minutes)    0
32 Max Elapsed Time 2 (minutes)    0
33 Wash 3                         01
34 Component 3 Volume (uL)       300
35 Component 3 Name              OPD
36 Component 3 Type             OPD
37 Component 3 Station             4
38 Incubation Temperature 3 (°C) 25
39 Min Elapsed Time 3 (minutes)   29
40 Max Elapsed Time 3 (minutes)   31
41 Max OPD Disp-Read Time (sec)   90
42 Component 4 Volume (uL)       300
43 Component 4 Name      1N SULFURIC
44 Component 4 Type             ACID
45 Component 4 Station             5
46 Units                          01
47 Unknown Dilution            8.000
48 Number of Standards            07
49 Standard Replicates            02
50 Standard Location              A1
51 Component 5 Type             STD1
52 Std # 1 Concentration       0.000
53 Component 6 Type             STD2
54 Std # 2 Concentration       2.000
55 Component 7 Type             STD3
56 Std # 3 Concentration       5.000
57 Component 8 Type             STD4
58 Std # 4 Concentration      10.000
59 Component 9 Type             STD5
60 Std # 5 Concentration      20.000
61 Component 10  Type           STD6
62 Std # 6 Concentration      40.000
63 Component 11  Type           STD7
64 Std # 7 Concentration      60.000
65 Component 12  Type           NONE
66 Std # 8 Concentration        N/A
67 Standard Number                07
68 Min. Mean Absorbance        0.800
69 Max. Mean Absorbance        2.200
70 Difference Standard A          00
71 Difference Standard B          00
72 Min. Absorb Diff. (A-B):     N/A
73 Max. Absorb Diff. (A-B):     N/A
74 Ratio 1 Standard A             00
75 Ratio 1 Standard B             00
76 Min. Ratio 1  (A/B):         N/A
77 Max. Ratio 1  (A/B):         N/A
78 Ratio 2 Standard C             00
79 Ratio 2 Standard D             00
80 Min. Ratio 2  (C/D):         N/A
81 Max. Ratio 2  (C/D):         N/A
82 Min. Sample Absorbance       N/A
****************************************
```

Sample Results Printout (TPC™ = Off)

```
+--------------------------------------+
|           BATCH   INFO               |
+--------------------------------------+
ASSAY # 67   NAME: SAMPLE
TECH ID: RST  LOT # 0000000000  TEST #69
DATE: 01/17/97      TIME:12:03:04
PPC SERIAL NUMBER sssssss                  (K)
----------------------------------------
   9999999998      60    STANDARDS

----------------------------------------
| TRAY#  9999999990                    |
: DATE: 01/17/97      TIME: 01:21:52      (L)
+---------------------------------------

            WELL ABSORB          CONC.
 I.D.#      LOC.  DIFF    %CV    mIU/L
=========== == ======= ======= ========
----------------------------------------
             STANDARDS
----------------------------------------
STANDARD #1  - CONCENTRATION =  0.000
----------------------------------------
            A1    0.167
            A2                   EMPTY    (F)
            A3    0.173
            A4    0.162
   -------      ------- ------- --------
   AVERAGE =    0.167  3.3%
----------------------------------------
STANDARD #2  - CONCENTRATION =  4.000
----------------------------------------
            A5    1.059
            B1                   VOID     (F)
            B2    1.100
   -------      ------- ------- --------
   AVERAGE =    1.080  2.7%
----------------------------------------
STANDARD #3  - CONCENTRATION =  10.000
----------------------------------------
            B3    1.821
            B4    1.860
            B5    1.790
   -------      ------- ------- --------
   AVERAGE =    1.824  1.9%
----------------------------------------
             SAMPLES
     UNKNOWN DILUTION =  2.000
----------------------------------------
            C1    0.254            0.76
            C2    0.248            0.71
   -------      ------- ------- --------
   AVERAGE =    0.251  1.7%
CALCULATED CONC. =     5.1%        0.74
----------------------------------------  (B)
            C3    0.153          < 0.00
            C4    0.171            0.04
   -------      ------- ------- --------
   AVERAGE =    0.162  7.9%
CALCULATED CONC. =     ******      0.02
----------------------------------------
            C5    0.149          < 0.00
            D1    1.880          > 20.00  (D)
   -------      ------- ------- --------
   AVERAGE =    1.015  120.7%
CALCULATED CONC. =     ******     ******
----------------------------------------  (F)
            D2                  NO SAMPLE
            D3   -0.021
----------------------------------------  (H)
            D4  *ERROR
            D5    1.500
----------------------------------------  (A)
            E1 > 2.200           > 20.00
            E2 > 2.200           > 20.00
   -------      ------- ------- --------
   AVERAGE =  > 2.200  ******             (C)
CALCULATED CONC. =     ****** > 20.00
----------------------------------------  (E)
            E3   -0.024

████████████████████████████████████████
 Date: 01/17/97  01:23:18  SN:sssssss     (G)
ERROR 2.1.1.53
Sample below Minimum Sample Absorbance

████████████████████████████████████████
            E4    1.110
----------------------------------------
            E5    0.253            0.75
            F1    0.259            0.81
   -------      ------- ------- -------
   AVERAGE =    0.256  1.7%

                  §

            M4                  EMPTY
            M5                  EMPTY
+--------------------------------------+
|        END  OF  BATCH                |
| DATE: 01/17/97      TIME: 01:24:02   |
+--------------------------------------+
                                          (M)
```

Sample Results Printout with Reference Standards (TPC™ = Off)

```
+--------------------------------------+
|           BATCH   INFO               |
+--------------------------------------+
ASSAY # 67   NAME: SAMPLE
TECH ID: RST  LOT # 0000000000  TEST #69
DATE: 01/17/97      TIME:12:03:04
PPC SERIAL NUMBER sssssss
----------------------------------------  (K)
   9999999998      60    STANDARDS

----------------------------------------
| TRAY#  9999999990                    |
| DATE: 01/17/97      TIME: 00:04:52   |  (L)
+---------------------------------------

            WELL ABSORB          CONC.
 I.D.#      LOC.  DIFF    %CV    mIU/L
=========== == ======= ======= ========
----------------------------------------
             STANDARDS
----------------------------------------
STANDARD #1  - CONCENTRATION =  0.000
----------------------------------------
            A1    0.167
            A2    0.173
            A3    0.162
   -------      ------- ------- --------
   AVERAGE =    0.167  3.3%
----------------------------------------
STANDARD #2  - CONCENTRATION =  4.000
----------------------------------------
            A4    1.059
            A5    1.081
            B1    1.100
   -------      ------- ------- --------
   AVERAGE =    1.080  1.9%
----------------------------------------
STANDARD #3  - CONCENTRATION =  10.000
----------------------------------------
            B2    0.982
            B3    0.860
            B4    0.971
   -------      ------- ------- --------
   AVERAGE =    0.930  7.2%

████████████████████████████████████████
 Date: 01/17/97  00:04:52  SN:sssssss
ERROR 2.1.1.39                            (I)
Standards are not Monotonic -
No concentrations will be calculated.
████████████████████████████████████████
----------------------------------------
             SAMPLES
     UNKNOWN DILUTION =  2.000
----------------------------------------
            B5    0.254
            C1    0.248
   -------      ------- ------- --------
   AVERAGE =    0.251  1.7%
----------------------------------------
            C2    0.153
            C3    0.171
   -------      ------- ------- --------
   AVERAGE =    0.162  7.9%
----------------------------------------
            C4    0.149
            C5    1.880
   -------      ------- ------- --------
   AVERAGE =    1.015  120.7%
----------------------------------------
            D1    1.620
            D2    1.580
   -------      ------- ------- --------
   AVERAGE =    1.600  1.8%
----------------------------------------
            D3 > 2.200
            D4 > 2.200
   -------      ------- ------- --------
   AVERAGE =  > 2.200  ******
----------------------------------------
            D5    0.527
            E1                   EMPTY

                  §

            M4                   EMPTY
            M5                   EMPTY
+--------------------------------------+
|        END  OF  BATCH                |
| DATE: 01/17/97      TIME: 00:05:55   |
+--------------------------------------+
                                          (M)
```

Circled letters in Sample Results Printouts refer to the text on preceding pages.

Sample Result Printout (TPC™ = Verify)

```
*****************************************
      PPC Software Version  n.nn
            SN:sssssss
 01 Assay Number                      42
 02 Assay Name  SAMPLE
 03 Reminder
 04 Test Number                       70
 05 Assay List Number               2222
 06 Assay Procedure
 07 TPC Mode                           0
 08 Blanking                        NONE
 09 Data Reduction    POINT TO POINT
 10 Well Status Flag                   Y
 11 Multiple Trays                     Y
 12 Technician Identification          N
 13 Master Lot                         N
 14 Sample IDs                         N
 15 Number of Blanks                  00
 16 Unknown Replicates                02
 17 Wash 1                            00
 18 Component 1 Volume (uL)          200
 19 Component 1 Name                CONJ
 20 Component 1 Type                CNJ1
 21 Component 1 Station                1
 22 Incubation Temperature 1 (°C)     45
 23 Min Elapsed Time 1 (minutes)       0
 24 Max Elapsed Time 1 (minutes)       0
 25 Wash 2                            00
 26 Component 2 Volume (uL)            0
 27 Component 2 Name
 28 Component 2 Type                NONE
 29 Component 2 Station                1
 30 Incubation Temperature 2 (°C)      0
 31 Min Elapsed Time 2 (minutes)       0
 32 Max Elapsed Time 2 (minutes)       0
 33 Wash 3                            04
 34 Component 3 Volume (uL)          300
 35 Component 3 Name                  OPD
 36 Component 3 Type                  OPD
 37 Component 3 Station                4
 38 Incubation Temperature 3 (°C)     25
 39 Min Elapsed Time 3 (minutes)      29
 40 Max Elapsed Time 3 (minutes)      31
 41 Max OPD Disp-Read Time (sec)     120
 42 Component 4 Volume (uL)          300
 43 Component 4 Name      1N SULFURIC
 44 Component 4 Type                ACID
 45 Component 4 Station                5
 46 Units                             01
 47 Unknown Dilution               1.000
 48 Number of Standards               04
 49 Standard Replicates               02
 50 Standard Location                 A1
 51 Component 5 Type                STD1
 52 Std # 1 Concentration          0.000
 53 Component 6 Type                STD2
 54 Std # 2 Concentration          4.000
 55 Component 7 Type                STD3
 56 Std # 3 Concentration         30.000
 57 Component 8 Type                STD4
 58 Std # 4 Concentration         80.000
 59 Component 9 Type                NONE
 60 Std # 5 Concentration           N/A
 61 Component 10  Type              NONE
 62 Std # 6 Concentration           N/A
 63 Component 11  Type              NONE
 64 Std # 7 Concentration           N/A
 65 Component 12  Type              NONE
 66 Std # 8 Concentration           N/A
 67 Standard Number                   04
 68 Min. Mean Absorbance           0.800
 69 Max. Mean Absorbance           2.200
 70 Difference Standard A             00
 71 Difference Standard B             00
 72 Min. Absorb Diff. (A-B):        N/A
 73 Max. Absorb Diff. (A-B):        N/A
 74 Ratio 1 Standard A                00
 75 Ratio 1 Standard B                00
 76 Min. Ratio 1  (A/B):            N/A
 77 Max. Ratio 1  (A/B):            N/A
 78 Ratio 2 Standard C                00
 79 Ratio 2 Standard D                00
 80 Min. Ratio 2  (C/D):            N/A
 81 Max. Ratio 2  (C/D):            N/A
 82 Min. Sample Absorbance          N/A
*****************************************
```

Sample Results Printout With Reference Standards (TPC™ = Verify)

```
+-----------------------------------+
|          BATCH   INFO             |
+-----------------------------------+
ASSAY # 42   NAME: SAMPLE
LIST #-PROCEDURE:    2222
TECH ID 1: 123456
TECH ID 2:
TECH ID OPD: 654321
TECH ID ACID: 123456
TPC MODE = VERIFY
PPC SERIAL NUMBER 0001485
PPC VERSION NUMBER  7R00
DATE: 08/04/95     TIME: 17:27:02   (K)
Sample ID Size = 20
-------------------------------------
        100259M    20    STANDARDS

TPC INFORMATION:                 (J)
================

TYPE EXPIRATION            LOT#      DEV.
---- ----------        -----------   ----
ML   12/12/96           00000009M
CNJ1 12/12/96            1000004M
OPD  08/04/95-16:42:32   5554456M  *01*
OPDD 02/02/96           20000RU01
OPDT 07/05/96           10100M206
ACID 08/04/95            8885521M  *03*

+-----------------------------------+
|  TRAY#          100259M           |
|TPC INFORMATION:                   |
|                                (J)|
|TYPE EXPIRATION      LOT#      DEV.|
|---- ----------  -----------     ----|
|STD1 12/12/96       1000008M         |
|STD2 12/12/96       1000009M         |
|STD3 12/12/96       1000010M         |
|STD4 12/12/96       1000011M         |
|QCA  12/12/96       1000012M         |
|QCB  12/12/96       1000013M         |
|BEAD                         *06*   |
|PIPETTOR SERIAL NUMBER     95N097     |
|PIPETTOR VERSION NUMBER    2.5        |
|PIPETTOR TECH ID: 123456              |
|                                      |
|  DATE: 08/04/95      TIME: 17:45:02  |
+-----------------------------------+(L)

          WELL ABSORB              CONC.
 I.D.#    LOC.  DIFF    %CV        ng/mL
========== == ======= ======= ========
-----------------------------------------
              STANDARDS
-----------------------------------------
STANDARD #1  - CONCENTRATION =  0.000
-----------------------------------------
            A1   0.293
            A2   0.341
    ------- ------- ------- --------
    AVERAGE =    0.317  10.7%
-----------------------------------------
STANDARD #2  - CONCENTRATION =  4.000
-----------------------------------------
            A3   0.689
            A4   0.708
    ------- ------- ------- --------
    AVERAGE =    0.699  1.9%
-----------------------------------------
STANDARD #3  - CONCENTRATION =  30.000
-----------------------------------------
            A5   1.484
            B1   1.383
    ------- ------- ------- --------
    AVERAGE =    1.434  5.0%
-----------------------------------------
STANDARD #4  - CONCENTRATION =  80.000
-----------------------------------------
            B2   2.021
            B3   2.060
    ------- ------- ------- --------
    AVERAGE =    2.041  1.4%
-----------------------------------------
```

```
-----------------------------------------
              SAMPLES
-----------------------------------------

 Control Im B4   2.073          > 80.00

 Control Im B5   1.920            70.03
    ------- ------- ------- --------
    AVERAGE =    1.997  5.4%
CALCULATED CONC. =       ****** > 75.02
-----------------------------------------

Control IIm C1   0.970            13.59

Control IIm C2   0.671             3.71
    ------- ------- ------- --------
    AVERAGE =    0.821  25.8%
CALCULATED CONC. =       80.8%    8.65
-----------------------------------------

      01758b C3   1.048            16.35

      01758b C4   1.149            19.92
    ------- ------- ------- --------
    AVERAGE =    1.099  6.5%
CALCULATED CONC. =       13.9%    18.13
-----------------------------------------
 011111122
2221212100m C5 > 2.200          > 80.00
 011111122
2221212100m D1   2.056          > 80.00
    ------- ------- ------- --------
    AVERAGE =  > 2.128  ******
CALCULATED CONC. =       ****** > 80.00
-----------------------------------------
 022233322
3322332233m D2   0.146          < 0.00
 022233322
3322332233m D3   0.174          < 0.00
    ------- ------- ------- --------
    AVERAGE =    0.160  12.4%
CALCULATED CONC. =       ******   0.00
-----------------------------------------
2343223432
2343223432m D4   0.416            1.04
2343223432
2343223432m D5   0.487            1.78
    ------- ------- ------- --------
    AVERAGE =    0.452  11.1%
CALCULATED CONC. =       37.3%    1.41
+---------------------------------------+
|     END  OF  BATCH                    |
|  DATE: 08/04/95      TIME: 17:45:26   |
+---------------------------------------+
                                    (M)
```

Circled letters in Sample Results Printouts refer to the text on preceding pages.

Appendix C

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NOTES

Appendix C
System Integration Guide

Introduction

The following diagrams illustrate typical Abbott System configurations. When viewing the configurations, please note:

1. ALL Universal cables MUST be ordered separately (List Nos. 1A41-15, 50, 51). No Universal cable is provided with the FPC.
2. Each LIS cable identified is specific to your particular installation. It can be obtained through your Abbott sales representative.
3. One FPC™ computer can support up to two FPC pipettors.

The LIS baud rate is dependent on the type of LIS hardware used. Contact your Abbott representative for specific instructions if connected to an Abbott LIS.

See Configuration **D** and **E** for combined instrument and DMS port information.

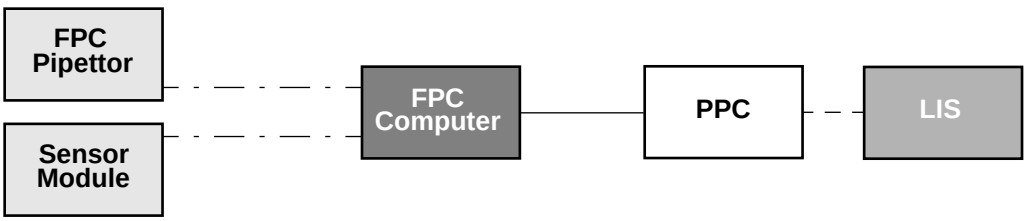
NOTE: At the time of cable installation, verify that the port characteristics of the two interfacing instruments are identical. The port characteristics to be adjusted are baud rate, parity, data bits, hand-shaking, and stop bits.

The following acronyms are used throughout this document.

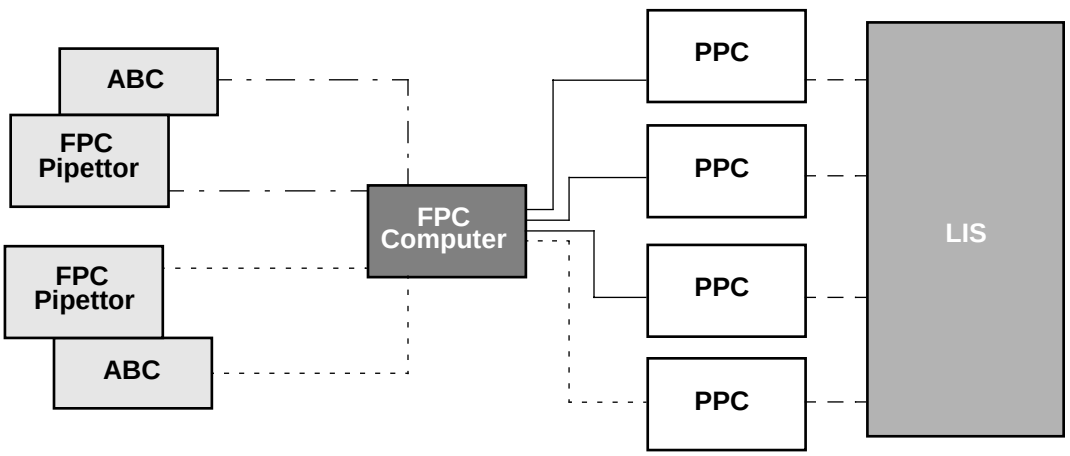
PPC	COMMANDER Parallel Processing Center
FPC	COMMANDER Flexible Pipetting Center
ABC	FPC Automatic Bar Code reader
LIS	Laboratory Information System. Refers to Abbott Data Management System (Abbott DMS™), Abbott Apheresis Results Tracking System (Abbott AARTS™), Euro-BBS™, or a laboratory's host computer system.
EXBCR	External Bar Code Reader

Configuration Examples

Configuration A



Configuration B



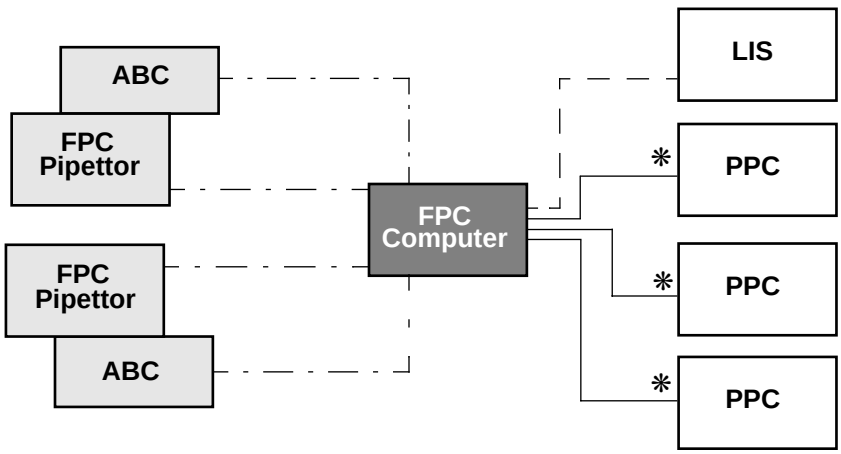
——————— Universal Cable (baud rate = 4800)

– – – – – – LIS cable

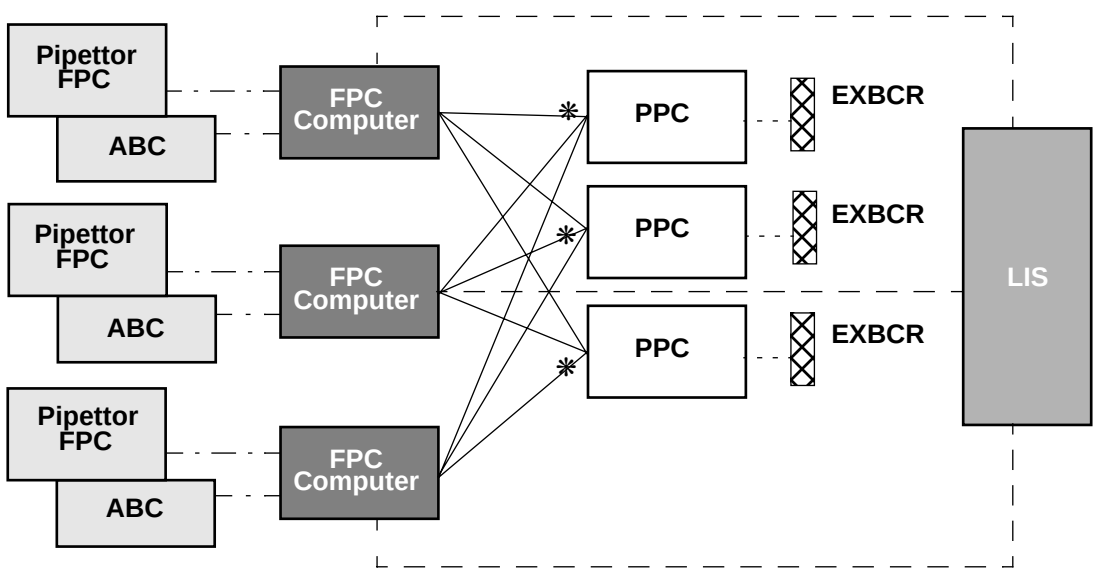
– – — – — – – Serial connector cable from the FPC computer

. . . . . Hardware shown in phantom lines illustrates full system configuration

Configuration C



Configuration D



———— Universal Cable (baud rate = 4800)

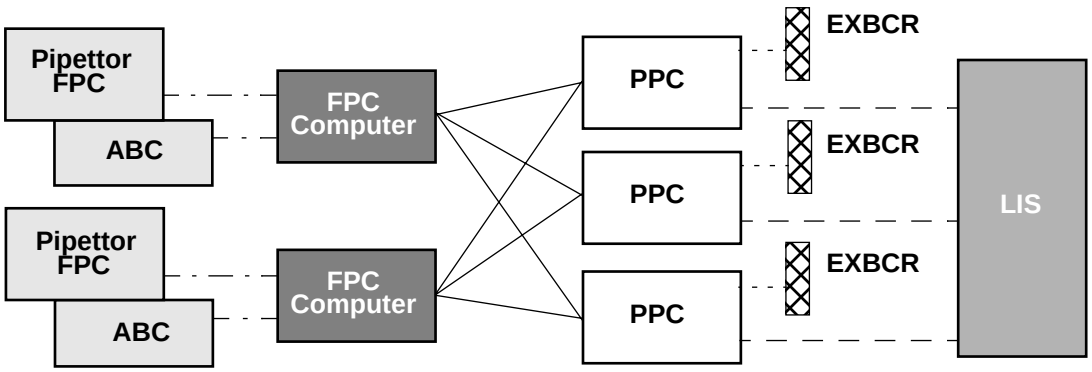
– – – – – – LIS Cable

– · — · — · – Serial connector cable from the FPC™ computer

· · · · · · · · · · · · Hardware shown in phantom lines illustrates full system configuration.

* PPC combined instrument/DMS port (All LIS data output is routed through the combined instrument/DMS port.)

Configuration E



———————— Universal Cable (baud rate = 4800)

– — — — — – LIS Cable

. . . . . External Bar Code Reader (EXBCR)

– - — - — - – Serial connector cable from the FPC computer

* PPC combined instrument/DMS port (All LIS data output is routed through the combined instrument/DMS port.)

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